

DEPARTMENT OF HEALTH

NOTICE OF FINAL RULEMAKING

The Interim Director of the Department of Health, pursuant to the authority set forth in Section 19(a)(3) of the District of Columbia Pharmacist and Pharmacy Regulation Act of 1980, effective September 16, 1980 (D.C. Law 3-98; D.C. Official Code § 47-2885.18(a)(3) (2005 Repl.)); Mayor's Order 98-48, dated April 15, 1998; Section 4902 of the Fiscal Year 2002 Budget Support Act of 2001, effective October 3, 2001 (D.C. Law 14-28; D.C. Official Code § 7-731 (2008 Repl.)); Section 15 of the District of Columbia Medical Device Manufacture and Distribution Licensure Act of 1990, effective June 13, 1990 (D.C. Law 8-137; D.C. Official Code § 48-714(a) (2005 Repl.)); and Mayor's Order 98-88, dated May 29, 1998, hereby gives notice of his intent to take final rulemaking action to adopt the following new Chapters 102 (Licensing of Medical Device Distributors and Manufacturers), 103 (Labeling of Medical Devices), 104 (Medical Device Reporting), 105 (Establishment, Registration, and Device Listing for Manufacturers and Initial Importers of Devices), 106 (Premarket Approval of Medical Devices), 107 (Quality System Regulation), and 108 (Radiological Health) of Subtitle B (Public Health and Medicine) of Title 22 (Health) of the District of Columbia Municipal Regulations (DCMR).

The purpose of the amendments is to bring the District regulations in line with the current requirements established under the Federal Food, Drug, and Cosmetic Act, approved June 25, 1938, 21 U.S.C. § 301, *et seq.* as amended; 21 Code of Federal Regulations (C.F.R.), part 801, Labeling, as amended; 21 C.F.R., part 803, Medical Device Reporting, as amended; 21 C.F.R., part 807, Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices, as amended; 21 C.F.R., part 814, Premarket Approval of Medical Devices, as amended; 21 C.F.R., part 820, Quality System Regulation, as amended; and 21 C.F.R., Subchapter J--Radiological Health, as amended.

These regulations were previously published in the *D.C. Register* on March 22, 2013 at 60 DCMR 004210. Only one set of comments were received – from Kaiser Permanente. Kaiser questioned the need of the Department of Health to draft regulations which are duplicative of the federal guidelines.

The Department notes that the Food & Drug Administration does not perform inspections. These regulations provide the Department with local jurisdiction over medical devices and enhance its ability to be proactive in ensuring the public health, safety, and environmental quality.

In addition, Kaiser questioned the definition in § 10499.1 for the term “ambulatory surgical facility.” Kaiser argues that the definition differs from that which appears in the D.C. Code. The Department has compared the definition it proposes with the definition in D.C. Official Code § 44-501(a)(8) and D.C. Official Code § 44-504(h). While the language in the proposed rules and the D.C. Official Code differ, both definitions appropriately define an “ambulatory surgical facility.” Thus, there is no need to adopt the language that appears in the D.C. Official Code.

Kaiser also suggested changing § 10413.1 which reads “The Department shall publish adverse events on its website.” to read “The Department shall publish adverse event codes on its website.” The language in the proposed regulations is correct – the Department will not publish “adverse events codes” but will publish a “narrative” of the adverse event. Thus, there is no need to reword that section.

Kaiser commented that the requirements in § 10912 “Treatment Use of an Investigational Device” would pose an undue on a healthcare provider because in addition to requiring approval from the federal government to use an investigational device, the provider would also require approval from the Department of Health. In response to Kaiser’s concerns, the Department will not impose any regulatory regimen that is more stringent than the federal government’s. If the federal government approves an investigational device, then the Department will accept that approval.

Finally, Section 10202.1, which would have exempted persons from licensure who engage in distribution from a place of business outside of the District, has been deleted. That language was inadvertently placed in the Notice of Proposed Rulemaking.

These final rules will become effective upon publication in the *D.C. Register*.

Subtitle B (Public Health and Medicine) of Title 22 (Health) of the DCMR is amended as follows:

Chapter 102 (Licensing of Medical Devices Distributors and Manufacturers) is added to read as follows:

CHAPTER 102 LICENSING OF MEDICAL DEVICE DISTRIBUTORS AND MANUFACTURERS

10200 GENERAL PROVISIONS

10200.1 These sections provide for the minimum licensing standards necessary to ensure the safety and efficacy of medical devices distributed by device distributors and manufacturers.

10201 APPLICABLE LAWS AND REGULATIONS

10201.1 The Department of Health (Department or DOH) adopts by reference the following laws and regulations:

- (a) Federal Food, Drug, and Cosmetic Act, approve June 25, 1938, 21 U.S.C. § 301, *et seq.* (“act”) as amended;
- (b) 21 Code of Federal Regulations (C.F.R.), part 801, Labeling, as amended;

- (c) 21 C.F.R., part 803, Medical Device Reporting, as amended;
- (d) 21 C.F.R., part 807, Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices, as amended;
- (e) 21 C.F.R., part 814, Premarket Approval of Medical Devices, as amended;
- (f) 21 C.F.R., part 820, Quality System Regulation, as amended; and
- (g) 21 C.F.R., Subchapter J--Radiological Health, as amended.

10201.2 Copies of these laws and regulations are indexed and filed at the Department, 899 North Capitol Street, N.E., Washington, D.C. 20002 and are available for inspection during normal working hours. Electronic copies of these laws and regulations are available online at www.hpla.doh.dc.gov.

10201.3 Nothing in these sections shall relieve any person of the responsibility for compliance with other applicable District of Columbia and federal laws and regulations.

10202 EXEMPTIONS

10202.1 A person is exempt from licensing under these sections if the person engages only in the following types of device distribution:

- (a) Intra-company sales; or
- (b) The sale, purchase, or trade of a distressed or reconditioned device by a salvage operator.

10202.2 An exemption from the licensing requirements under these sections does not constitute an exemption from other applicable provisions of federal and District of Columbia laws and regulations.

10203 LICENSURE REQUIREMENTS

10203.1 Except as provided by § 10202, a person may not engage in the distribution or manufacture of devices in the District of Columbia unless the person has a valid license from the Department of Health for each place of business.

10203.2 The license shall be displayed in an open public area at each place of business.

10203.3 Each person involved in the distribution or manufacture of devices in the District of Columbia on the effective date of these sections shall apply for a device

distributor or manufacturer license no later than sixty (60) days following the effective date of these regulations.

- 10203.4 Each person acquiring or establishing a place of business for the purpose of device distribution or manufacturing after the effective date of these sections shall apply to the Department for a license prior to beginning operation.
- 10203.5 If the device distributor or manufacturer operates more than one place of business, the device distributor or manufacturer shall obtain a license for each place of business.
- 10203.6 The Department may license a distributor or manufacturer of devices who meets the requirements of these sections and pays all fees.
- 10203.7 Licenses shall not be transferable from one (1) person to another or from one (1) place of business to another.
- 10203.8 Unless a license is amended pursuant to this section or revoked or suspended as provided in § 10207 (relating to Refusal, Cancellation, Suspension, or Revocation of a License), the license shall be valid for two (2) years.
- 10203.9 The license application as outlined in § 10204.2 of this chapter (relating to Licensing Procedures) and non-refundable licensing fees for each place of business shall be submitted to the department prior to the expiration date of the current license. A person who files a renewal application after the expiration date must pay an additional one hundred dollars (\$100) as a delinquency fee.
- 10203.10 A licensee who fails to submit a renewal application prior to the current license expiration date and continues operations may be subject to the enforcement and penalty provision in § 10210 (relating to Enforcement and Penalties), or the revocation and suspension provisions in § 10207.
- 10203.11 A renewal license shall only be issued when all past due fees and delinquency fees are paid.
- 10203.12 A license that is amended, including a change of name, ownership, or a notification of a change in the location of a licensed place of business, shall require submission of an application as outlined in § 10204 (relating to Licensing Procedures) and submission of fees.
- 10203.13 Not fewer than thirty (30) days in advance of the change, a licensee shall notify the Director or the Director's designee in writing of the licensee's intent to change the location of a licensed place of business. The notice shall include the address of the new location, and the name and residence address of the individual in charge of the business at the new location. Not more than ten (10) days after the completion of the change of location, the licensee shall notify the Director or the

Director's designee in writing to verify the change of location, the specific date of change, the new location, the address of the new location, and the name and residence address of the individual in charge of the business at the new address. Notice shall be deemed adequate if the licensee provides the intent and verification notices to the Director or the Director's designee by certified mail, return receipt requested, mailed to the Department, 899 North Capitol Street, N.E., Washington, D.C. 20002.

- 10203.14 If the United States Food and Drug Administration (FDA) or the Department determines, with respect to a product that is a combination of a drug and a device, that the primary mode of action of the product is as a device, a distributor or manufacturer of the product is subject to licensure as described in this section.

10204 LICENSING PROCEDURES

- 10204.1 License application forms may be obtained from the Department at 899 North Capitol Street, N.E., Washington, D.C., or online at www.hpla.doh.dc.gov.

- 10204.2 The application for licensure as a device distributor or manufacturer shall be signed and verified, and submitted on a license application form furnished by the Department.

- 10204.3 If the legal entity is a proprietorship, partnership, corporation, or association, the application shall contain the following:

- (a) The name and residence address of the applicant, and the date and place of incorporation (if applicable);
- (b) The name and address of the corporation's registered agent and corporation charter number, or if any other type of association;
- (c) The names of the principals of such association;
- (d) The name of the legal entity to be licensed, including the name under which the business is conducted;
- (e) The address of each place of business that is licensed;
- (f) If a proprietorship, the name and residence address of the proprietorship;
- (g) If a corporation, the date and place of incorporation and name and address of its registered agent in the state and corporation charter number; or
- (h) If any other type of association, the names of the principals of such association;

- (i) The name, residence address, and valid driver's license number of each individual in an actual administrative capacity which, in the case of proprietorship, shall be the managing proprietor; partnership, the managing partner; corporation, the officers and directors; or those in a managerial capacity in any other type of association; and
- (j) For each place of business, the residence address of the individual in charge;

10204.4 The renewal application for licensure as a device distributor or manufacturer shall be made on a license application form furnished by the Department.

10205 REPORT OF CHANGES

10205.1 The license holder shall notify the department in writing no later than ten (10) days after any change which would render the information contained in the application for the license, reported pursuant to § 10204 (relating to Licensing Procedures), no longer accurate. Failure to inform the department no later than ten (10) days after a change in the information required in the application for a license may result in a suspension or revocation of the license following a hearing.

10206 [RESERVED]

10207 REFUSAL, CANCELLATION, SUSPENSION, OR REVOCATION OF LICENSE

10207.1 The Director may refuse an application or may refuse to license an applicant, or, suspend or revoke a license, after providing the applicant or licensee with an opportunity for a hearing, if the applicant or licensee:

- (a) Has been convicted of a felony or misdemeanor that involves moral turpitude;
- (b) Is an association, partnership, or corporation whose managing officer has been convicted of a felony or misdemeanor that involves moral turpitude;
- (c) Has been convicted in a District of Columbia or federal court of the illegal use, sale, or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;
- (d) Is an association, partnership, or corporation whose managing officer has been convicted in the District of Columbia Superior Court or federal court of the illegal use, sale or transportation of intoxicating liquors, narcotic drugs, barbiturates, amphetamines, desoxyephedrine, their compounds or derivatives, or any other dangerous or habit-forming drugs;

- (e) Has violated any of the provisions of D.C. Official Code §§ 48-904.01, *et seq.* (2009 Repl.);
- (f) Has failed to pay a license fee or a renewal fee for a license; or
- (g) Has obtained or attempted to obtain a license by fraud or deception.

10207.2 The Director may refuse to license an applicant, or, suspend or revoke a license if the Director determines from evidence presented during a hearing that the applicant or licensee:

- (a) Has violated any provisions of the District of Columbia Official Code, §§ 22-901, *et seq.* concerning the counterfeiting of a drug or the sale or holding for sale of a counterfeit drug;
- (b) Has violated D.C. Official Code §§ 48-904.01, *et seq.*; or
- (c) Has violated any of these regulations, including being responsible for a significant discrepancy in the records that District law requires the applicant or licensee to maintain.

10207.3 The Department may, after providing opportunity for a hearing, refuse to license a distributor or manufacturer of devices, or may suspend or revoke a license for violations of the laws and regulations listed in § 10201.1 or for any of the reasons described in the Act.

10207.4 A license issued under this chapter shall be returned to the Department if the device distributor's or manufacturer's place of business:

- (a) Ceases business or otherwise ceases operation on a permanent basis;
- (b) Relocates; or
- (c) For a corporation, an ownership change is deemed to have occurred, as determined by a transfer of when five percent (5%) or more of the share of stock from one person to another.

10208 MINIMUM STANDARDS FOR LICENSURE

10208.1 All device distributors or manufacturers engaged in the design, manufacture, packaging, labeling, storage, installation, and servicing of devices shall comply with the minimum standards of this section.

10208.2 For the purpose of this section, the policies described in the FDA's Compliance Policy Guides as they apply to devices shall be the policies of the Department.

- 10208.3 All persons who operate as device distributors or manufacturers in the District of Columbia shall meet the applicable requirements in Chapter 105, titled “Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices.” Devices distributed by device distributors or manufacturers shall meet, if applicable, the premarket notification requirements of Chapter 105 of this subtitle or the premarket approval provisions of Chapter 106 of this subtitle, titled “Premarket Approval of Medical Devices.”
- 10208.4 Device distributors or manufacturers engaged in the design, manufacture, packaging, labeling, storage, installation, and servicing of finished devices shall be in compliance with the applicable requirements of Chapter 107 of this subtitle, entitled “Quality System Regulation.” The requirements in this section govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use.
- 10208.5 All manufacturing, assembling, packaging, packing, holding, testing, or labeling of devices by manufacturers shall take place in buildings and facilities described in §§ 10718 “Handling,” 10719 “Storage,” 10720 “Distribution,” and 10720 “Installation.”
- 10208.6 No manufacturing, assembling, packaging, packing, holding, testing, or labeling operations of devices by manufacturers or distributors shall be conducted in any personal residence.
- 10208.7 Any place of business used by a distributor to store, warehouse, hold, offer, transport, or display devices shall:
- (a) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
 - (b) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, and space;
 - (c) Have a quarantine area for storage of devices that are outdated, damaged, deteriorated, misbranded, or adulterated;
 - (d) Be maintained in a clean and order condition; and
 - (e) Be free from infestation by insects, rodents, birds, or vermin of any kind.
- 10208.8 All devices stored by distributors shall be held at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such devices.

- 10208.9 Devices distributed by device distributors or manufacturers shall meet the labeling requirements of Chapter 103 of this subtitle.
- 10208.10 Where District regulations conflict with device labeling or packaging exemptions adopted under the Federal Food, Drug, and Cosmetic Act, as amended, federal law or regulations shall preempt District regulations.
- 10208.11 Reconditioned devices shall comply with the provisions of this chapter.
- 10208.12 Device distributors or manufacturers shall meet the applicable medical device reporting requirements of Chapter 104 of this subtitle.
- 10208.13 Devices which emit electronic product radiation and are distributed by device distributors or manufacturers shall meet the applicable requirements of Chapter 108 entitled of this subtitle.
- 10208.14 A prescription device in the possession of a device distributor or manufacturer licensed under these sections of this subchapter shall be exempt from 21 U.S.C. § 352(f)(1) of the act, relating to labeling bearing adequate directions for use, providing it meets the requirements of §§ 10310 and § 10311 of this subtitle.
- 10208.15 Each device distributor or manufacturer who distributes prescription devices shall maintain a record for every prescription device, showing the identity and quantity received or manufactured and the disposition of each device.
- 10208.16 Each device distributor or manufacturer who delivers a prescription device to the ultimate user shall maintain a record of any prescription or other order lawfully issued by a practitioner in connection with the device.
- 10208.17 All types of contact lenses are medical devices which may be sold and dispensed only by an individual or a business authorized by law to dispense contact lenses.
- 10208.18 All types of contact lenses must be dispensed according to a prescription from the physician or optometrist who examined and fitted the contact lenses to the person's eyes.
- 10209 ADVERTISING**
- 10209.1 An advertisement of a device shall be deemed to be false if it is misleading in any particular.
- 10209.2 An advertisement of a device is false if the advertisement represents that the device affects:
- (a) Infectious and parasitic diseases;

- (b) Neoplasms;
- (c) Endocrine, nutritional, and metabolic diseases and immunity disorders;
- (d) Diseases of blood and blood-forming organs;
- (e) Mental disorders;
- (f) Diseases of the nervous system and sense organs;
- (g) Diseases of the circulatory system;
- (h) Diseases of the respiratory system;
- (i) Diseases of the digestive system;
- (j) Diseases of the genitourinary system;
- (k) Complications of pregnancy, childbirth, and the puerperium;
- (l) Diseases of the skin and subcutaneous tissue;
- (m) Diseases of the musculoskeletal system and connective tissue;
- (n) Congenital anomalies;
- (o) Certain conditions originating in the perinatal period;
- (p) Symptoms, signs, and ill-defined conditions; or
- (q) Injury and poisoning.

10209.3 Subsection 10209.2 shall not apply to an advertisement of a device if the advertisement does not violate the Act and is disseminated:

- (a) To the public for self-medication and is consistent with the FDA's labeling claims;
- (b) Only to members of the medical, dental, and veterinary professions and appears only in the scientific periodicals of those professions; or
- (c) Only for the purpose of public health education by a person not commercially interested, directly or indirectly, in the sale of the device.

10209.4 Nothing in this section shall be construed as establishing any official policy of the Department concerning self-medication for a disease, other than a disease listed

under § 10209.2, including any official policy that such self-medication is safe and effective.

10210 ENFORCEMENT AND PENALTIES

10210.1 To enforce the provisions of this chapter, the Department, an authorized agent, or a health authority may, on presenting appropriate credentials to the owner, operator, or agent in charge of a place of business:

- (a) Enter at reasonable times a place of business, including factory or warehouse, in which a device is manufactured, assembled, packed, or held for introduction into commerce or held after the introduction;
- (b) Enter a vehicle being used to transport or hold a device in commerce; or
- (c) Inspect at reasonable times, within reasonable limits, and in a reasonable manner, the place of business or vehicles and all equipment, finished and unfinished materials, containers, and labeling of any medical device and obtain samples.

10210.2 The inspection of a place of business, including a factory, warehouse, or consulting laboratory, in which a restricted device is manufactured, assembled, packed, or held for introduction into commerce extends to any place or thing, including a record, file, paper, process, control, or facility, in order to determine whether the device:

- (a) Is adulterated or misbranded;
- (b) May not be manufactured, introduced into commerce, sold or offered for sale under the Act; or
- (c) Is otherwise in violation of the Act.

10210.3 An inspection under § 10210.2 may not extend to:

- (a) Financial data;
- (b) Sales data other than shipment data;
- (c) Pricing data;
- (d) Personnel data other than data relating to the qualifications of technical and professional personnel performing functions under this chapter; or
- (e) Research data other than data:

- (1) Relating to devices; and
- (2) Subject to reporting and inspection under regulations issued under 21 U.S.C. §§ 360i or 360j of the act, as amended.

10210.4 An inspection under § 10210.2 shall be started and completed with reasonable promptness.

10210.5 An authorized agent or health authority who makes an inspection of a place of business, including a factory or warehouse, and obtains a sample during or on completion of the inspection and before leaving the place of business, shall give to the owner, operator, or the owner's or operator's agent a receipt describing the sample.

10210.6 A person who is required to maintain records under 21 U.S.C. §§ 360i or 360j or a person who is in charge of or has custody of those records shall, at the request of an authorized agent or health authority, permit the authorized agent or health authority at all reasonable times access to the records, and to copy and verify the records.

10210.7 A person who is subject to licensure shall, at the request of an authorized agent or health authority, permit the authorized agent or health authority at all reasonable times, access to all records, as well as to copy and verify all records showing:

- (a) The movement in commerce of any device;
- (b) The holding of any device after movement in commerce; and
- (c) The quantity, shipper, and consignee of any device.

10210.8 Records shall be maintained at the place of business or other location that is reasonably accessible for a period of at two (2) years following disposition of the device unless a greater period is required by laws and regulations adopted in § 10201 of this subtitle (relating to Applicable Laws and Regulations).

10210.9 If the Department of Health identifies an adulterated or misbranded device, the Department may take or seek enforcement actions including, but not limited to:

- (a) Detention;
- (b) Emergency order;
- (c) Recall;
- (d) Condemnation;

- (e) Destruction;
- (f) Injunction;
- (g) Civil penalties;
- (h) Criminal penalties; or
- (i) Administrative penalties.

Chapter 103 (LABELING OF MEDICAL DEVICES) is added to read as follows:

10300 MEDICAL DEVICES: NAME AND PLACE OF BUSINESS OF MANUFACTURER, OR DISTRIBUTOR

- 10300.1 The label of a device in package form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor.
- 10300.2 The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporation, only by the actual corporate name which may be preceded or followed by the name of the particular division of the corporation. Abbreviations for “Company” and “Incorporated” may be used, and “The” may be omitted. In the case of a proprietorship, partnership, or association, the name under which the business is conducted shall be used.
- 10300.3 Where a device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection the person has with the device such as “Manufactured for ...,” “Distributed by ...,” or any other wording that expresses the facts.
- 10300.4 The statement of the place of business shall include the street address, city, state, and zip code; however, the street address may be omitted if it is shown in a current city directory or telephone directory. The requirement for inclusion of the zip code shall apply only to consumer commodity labels developed or revised after the effective date of these regulations. In the case of non-consumer packages, the zip code shall appear on either the label or the labeling (including the invoice).
- 10300.5 If a person manufactures, packs, or distributes a device at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where the device was manufactured or packed or is to be distributed, unless the statement would be misleading.

10301 MEANING OF “INTENDED USES”

- 10301.1 The words “intended uses” or words of similar import in §§ 10302, 10312, and 10314 of this chapter refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons’ expressions or may be shown by the circumstances surrounding the distribution of the medical device.
- 10301.2 The objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of a medical device may change after it has been introduced into interstate commerce by its manufacturer.
- 10301.3 If, for example, a packer, distributor, or seller intends a medical device for different uses than those intended by the person from whom he received the devices, the packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses.
- 10301.4 If a manufacturer knows, or has knowledge of facts that would give him or her notice that a device introduced into interstate commerce by him or her is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with the other uses to which the medical device is to be put.

10302 RESERVED

10303 MEDICAL DEVICES: MISLEADING STATEMENTS

- 10303.1 Among representations in the labeling of a device which render the device misbranded is a false or misleading representation with respect to another device, drug, food, or cosmetic.

10304 MEDICAL DEVICES: PROMINENCE OF REQUIRED LABEL STATEMENTS

- 10304.1 A word, statement, or other information required by or under the authority of the Act to appear on the label may lack prominence and conspicuousness, for the following:
- (a) Such word, statement, or information fails to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;
 - (b) Such word, statement, or information fails to appear on two (2) or more parts or panels of the label, each of which has sufficient space therefore,

and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

- (c) The label fails to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;
- (d) The label space is insufficient for the prominent placing of such word, statement, or information, resulting from the use of label space for any other word, statement, design, or device that is not required by or under authority of the Act to appear on the label;
- (e) Label space is insufficient for the placing of such word, statement, or information, resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or
- (f) Type style in which such word, statement, or information appears is small, there is insufficient background contrast or obscuring designs or vignettes, or the label is crowded with other written, printed, or graphic matter.

10304.2 No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under 21 USC § 352(b) of the act, shall apply if such insufficiency is caused by:

- (a) The use of label space for any word, statement, design, or device which is not required by or under authority of the Act to appear on the label;
- (b) The use of label space to give greater conspicuousness to any word, statement, or other information than is required by 21 USC § 352(c); or
- (c) The use of label space for any representation in a foreign language.

10304.3 All words, statements, and other information required by or under authority of the Act to appear on the label or labeling shall appear thereon in the English language; provided, however, that in case of articles distributed solely in the Commonwealth of Puerto Rico or in a territory where the predominant language is one other than English, the predominant language may be substituted for English.

10304.4 If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act to appear on the label shall appear thereon in the foreign language.

10305 MEDICAL DEVICES: SPANISH LANGUAGE VERSION OF CERTAIN REQUIRED STATEMENTS

10305.1 If devices restricted to prescription use only are labeled solely in Spanish for distribution in the Commonwealth of Puerto Rico where Spanish is the predominant language, the labeling is authorized under §§ 10304.3 through 10304.4 of this chapter.

10306 PRINCIPAL DISPLAY PANEL

10306.1 The term “principal display panel” as it applies to over-the-counter devices in package form and as used in this part means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

10306.2 The principal display panel shall be large enough to accommodate all of the mandatory label information required to be placed thereon by this part with clarity and conspicuousness and without obscuring designs, vignettes, or crowding.

10306.3 Where packages bear alternate principal display panels, information required to be placed on the principal display panel shall be duplicated on each principal display panel. For the purpose of obtaining uniform type size in declaring the quantity of contents for all packages of substantially the same size, the term “area of the principal display panel” means the area of the side or surface that bears the principal display panel, which area shall be:

- (a) In the case of a rectangular package where one (1) entire side properly can be considered to be the principal display panel side, the product of the height times the width of that side;
- (b) In the case of a cylindrical or nearly cylindrical container, forty percent (40%) of the product of the height of the container times the circumference; and
- (c) In the case of any other shape of container, forty percent (40%) of the total surface of the container; provided however, that where the container presents an obvious “principal display panel” such as the top of a triangular or circular package, the area shall consist of the entire top surface.

10306.4 In determining the area of the principal display panel, exclude tops, bottoms, flanges at the tops and bottoms of cans, and shoulders and necks of bottles or jars. In the case of cylindrical or nearly cylindrical containers, information required by this part to appear on the principal display panel shall appear within that forty percent (40%) of the circumference which is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale.

10307 STATEMENT OF IDENTITY

- 10307.1 The principal display panel of an over-the-counter device in package form shall bear as one (1) of its principal features a statement of the identity of the commodity.
- 10307.2 The statement of identity shall be in terms of the common name of the device followed by an accurate statement of the principal intended action(s) of the device. The statement shall be placed in direct conjunction with the most prominent display of the name and shall employ terms descriptive of the principal intended action(s). The indications for use shall be included in the directions for use of the device, as required by 21 U.S.C. § 352(f)(1) and by the regulations in this section.
- 10307.3 The statement of identity shall be presented in bold face type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on the panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

10308 DECLARATION OF NET QUANTITY OF CONTENTS

- 10308.1 The label of an over-the-counter device in package form shall bear a declaration of the net quantity of contents. This shall be expressed in terms of weight, measure, numerical count, or a combination of numerical count and weight, measure, or size, provided that:
- (a) In the case of a firmly established general consumer usage and trade custom of declaring the quantity of a device in terms of linear measure or measure of area, the respective term may be used. The term shall be augmented when necessary for accuracy of information by a statement of the weight, measure, or size of the individual units or of the entire device; or
 - (b) If the declaration of contents for a device by numerical count does not give accurate information as to the quantity of the device in the package, it shall be augmented by such statement of weight, measure, or size of the individual units or of the total weight, measure, or size of the device as will give such information. For example, “one hundred (100) tongue depressors, adult size,” and “one (1) rectal syringe, adult size.” Whenever the Director determines for a specified packaged device that an existing practice of declaring net quantity of contents by weight, measure, numerical count, or a combination of these does not facilitate value comparisons by consumers, he or she shall, by regulation, designate the appropriate term or terms to be used for the medical device.

- 10308.2 Statements of weight of the contents shall be expressed in terms of avoirdupois pound and ounce. Statements of liquid measure of the contents shall be expressed in terms of the U.S. gallon of two hundred thirty-one cubic inches (231 cu. in.) and quart, pint, and fluid-ounce subdivisions thereof, and shall express the volume at sixty-eight degrees Fahrenheit (68 °F) (twenty degrees Celsius (20 °C)).
- 10308.3 The declaration may contain common or decimal fractions. A common fraction shall be in terms of halves, quarters, eighths, sixteenths, or thirty-seconds, except that if there exists a firmly established general consumer usage and trade custom of employing different common fractions in the net quantity declaration of a particular commodity, they may be employed. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two (2) places. A statement that includes small fractions of an ounce shall be deemed to permit smaller variations than one which does not include such fractions.
- 10308.4 The declaration shall be located on the principal display panel of the label, and with respect to packages bearing alternate principal panels it shall be duplicated on each principal display panel.
- 10308.5 The declaration shall appear as a distinct item on the principal display panel, and shall be separated from other printed label information appearing to the left or right of the declaration by a space at least equal to the height of the lettering used in the declaration. It shall not include any term qualifying a unit of weight, measure, or count, such as “giant pint” or “full quart,” that tends to exaggerate. It shall be placed on the principal display panel within the bottom thirty percent (30%) of the area of the label panel in lines generally parallel to the base on which the package rests as it is designed to be displayed, provided, that:
- (a) On packages having a principal display panel of five square inches (5 sq. in.) or less the requirement for placement within the bottom thirty percent (30%) of the area of the label panel shall not apply when the declaration of net quantity of contents meets the other requirements of this part;
 - (b) In the case of a device that is marketed with both outer and inner retail containers bearing the mandatory label information required by this part and the inner container is not intended to be sold separately, the net quantity of contents placement requirement of this section applicable to such inner container is waived; and
 - (c) The principal display panel of a device marketed on a display card to which the immediate container is affixed may be considered to be the display panel of the card, and the type size of the net quantity of contents statement is governed by the dimensions of the display card.

- 10308.6 The declaration shall accurately state the quantity of device in the package exclusive of wrappers and other material packed therewith.
- 10308.7 The declaration shall appear in conspicuous and easily legible bold face print or type in distinct contrast (by typography, layout, color, embossing, or molding) to other matter on the package; except that a declaration of net quantity blown, embossed, or molded on a glass or plastic surface is permissible when all label information is so formed on the surface.
- 10308.8 Requirements of conspicuousness and legibility shall include the specifications that:
- (a) The ratio of height to width of the letter shall not exceed a differential of three (3) units to one (1) unit, in other words, no more than three (3) times as high as it is wide;
 - (b) Letter heights pertain to upper case or capital letters. When upper and lower case or all lower case letters are used, it is the lower case letter “o” or its equivalent that shall meet the minimum standards; and
 - (c) When fractions are used, each component numeral shall meet one-half (1/2) the minimum height standards.
- 10308.9 The declaration shall be in letters and numerals in a type size established in relationship to the area of the principal display panel of the package and shall be uniform for all packages of substantially the same size by complying with the following type specifications:
- (a) Not less than one-sixteenth inch (1/16 in.) in height on packages the principal display panel of which has an area of five square inches (5 sq. in.) or less;
 - (b) Not less than one-eighth inch (1/8 in.) in height on packages the principal display panel of which has an area of more than five (5) but not more than twenty-five square inches (25 sq. in.);
 - (c) Not less than three-sixteenths inch (3/16 in.) in height on packages the principal display panel of which has an area of more than twenty-five (25) but not more than one hundred square inches (100 sq. in.); and
 - (d) Not less than one-quarter inch (1/4 in.) in height on packages the principal display panel of which has an area of more than one hundred square inches (100 sq. in.), except not less than one-half inch (1/2 in.) in height if the area is more than four hundred square inches (400 sq. in.).

- 10308.10 Where the declaration is blown, embossed, or molded on a glass or plastic surface rather than by printing, typing, or coloring, the lettering sizes specified in § 10308.9(a) - (d) shall be increased by one-sixteenth inch (1/16 in.).
- 10308.11 On packages containing less than four pounds (4 lbs.) or one gallon (1 gal.) and labeled in terms of weight or fluid measure, the declaration shall be expressed both in ounces, with identification by weight or by liquid measure and, if applicable (one pound (1 lb.) or one pint (1 pt.) or more) followed in parentheses by a declaration in pounds for weight units, with, with any remainder in terms of ounces or common or decimal fractions of the pound, or in the case of liquid measure, in the largest whole units (quarts, quarts and pints, or pints, as appropriate) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart. If the net weight of the package is less than one ounce (1 oz.) avoirdupois or the net fluid measure is less than one fluid ounce (1 fl. oz.), the declaration shall be in terms of common or decimal fractions of the respective ounce and not in terms of drams;
- 10308.12 Pursuant to § 10308.11, the declaration may appear in more than one line. The term “net weight” shall be used when stating the net quantity of contents in terms of weight. Use of the terms “net” or “net contents” in terms of fluid measure or numerical count is optional. It is sufficient to distinguish avoirdupois ounce from fluid ounce through association of terms: for example, “Net wt. six (6) oz.” or “six (6) oz. net wt.,” and “six (6) fl. oz.” or “net contents six (6) fl. oz.”
- 10308.13 On packages containing four pounds (4 lbs.) or one gallon (1 gal.) or more and labeled in terms of weight or fluid measure, the declaration shall be expressed in pounds for weight units with any remainder in terms of ounces or common or decimal fractions of the pound. In the case of fluid measure, it shall be expressed in the largest whole unit (such as gallons) followed by common or decimal fractions or a gallon or by the next smaller whole unit or units (quarts or quarts and pints), with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart.
- 10308.14 Pursuant to § 10308.13, examples are:
- (a) A declaration of one and one half pounds (1-1/2 lbs.) weight shall be expressed as “net wt. 24 oz. (1 lb. 8 oz.),” or “Net wt. 24 oz. (1-1/2 lb.)” or “Net wt. 24 oz. (1.5 lb.);”
 - (b) A declaration of three-fourths pound (3/4 lb.) avoirdupois weight shall be expressed as “Net wt. 12. oz.,”
 - (c) A declaration of one quart (1 qt.) liquid measure shall be expressed as “Net contents 32 fl. oz. (1 qt.).”

- (d) A declaration of one and three fourths quarts (1-3/4 qts.) liquid measure shall be expressed as “Net contents 56 fl. oz. (1 qt. 1.5 pt.),” but not in terms of quart and ounce such as “Net contents 56 fl. oz. (1 qt. 24 oz.);” or
- (e) A declaration of two and one half gallons (2-1/2 gals.) liquid measure shall be expressed as “Net contents 2 gal. 2 qt.,” “Net contents 2.5 gallons,” or “Net contents 2-1/2 gal.” but not as “2 gal. 4 pt.”

10308.15 Pursuant to § 10308.14, for quantities, the following abbreviations and none other may be employed. Periods and plural forms are optional:

gallon – gal.	liter – l
milliliter – ml	cubic centimeter – cc
quart – qt.	yard – yd.
pint – pt.	feet or foot – ft.
ounce – oz.	inch – in.
pound – lb.	meter – m
grain – gr.	centimeter – cm
kilogram – kg	millimeter – mm
gram – g	fluid – fl.
milligram – mg	square – sq.
microgram – mcg	weight – wt.

10308.16 On packages labeled in terms of linear measure, the declaration shall be expressed both in terms of inches and, if applicable (one foot (1 ft.)) or more, the largest whole units (yards, yards and feet, feet). The declaration in terms of the largest whole units shall be in parentheses following the declaration in terms of inches and any remainder shall be in terms of inches or common or decimal fractions of the foot or yard; if applicable, as in the case of adhesive tape, the initial declaration in linear inches shall be preceded by a statement of the width. Examples of linear measure are “86 inches (2yd, 1 ft. 2 in.),” “90 inches (2-1/2 yd.),” “30 inches (2.5 ft.),” and “3/4 inch by 36 in. (1 yd.).”

10308.17 On packages labeled in terms of area measure, the declaration shall be expressed both in terms of square inches and, if applicable one square foot (1 sq. ft.) or more, the largest whole square unit (square yards, square yards and square feet, square feet). The declaration in terms of the largest whole units shall be in parentheses following the declaration in terms of square inches and any remainder shall be in terms of square inches or common or decimal fractions of the square foot or square yard; for example, "158 sq. inches (1 sq. ft. 14 sq. in.)."

10308.18 Nothing in this section shall prohibit supplemental statements at locations other than the principal display panel(s) describing in non-deceptive terms the net quantity of contents, provided that such supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure, or count that tends to exaggerate the amount of the device contained in the package;

for example, "giant pint" or "full quart." Dual or combination declarations of net quantity of contents are not regarded as supplemental net quantity statements and shall be located on the principal display panel.

10308.19 A separate statement of net quantity of contents in terms of the metric system of weight or measure is not regarded as a supplemental statement and an accurate statement of the net quantity of contents in terms of the metric system of weight or measure may also appear on the principal display panel or on other panels.

10308.20 The declaration of net quantity of contents shall express an accurate statement of the quantity of contents of the package. Reasonable variations caused by loss or gain of moisture during the course of good distribution practice or by unavoidable deviations in good manufacturing practice will be recognized. Variations from stated quantity of contents shall not be unreasonably large.

10309 MEDICAL DEVICES: WARNING STATEMENTS FOR DEVICES CONTAINING OR MANUFACTURED WITH CHLOROFLUOROCARBONS AND OTHER CLASS I OZONE-DEPLETING SUBSTANCES

10309.1 All over-the-counter devices containing or manufactured with chlorofluorocarbons, halons, carbon tetrachloride, methyl chloride, or any other class I substance designated by the Environmental Protection Agency (EPA) shall carry one (1) of the following warnings:

(a) The EPA warning statement:

Warning: Contains [or Manufactured with, if applicable] [insert name of substance], a substance which harms public health and environment by destroying ozone in the upper atmosphere; or

(b) The alternative statement, which is as follows:

Warning: Contains [or Manufactured with, if applicable] [insert name of substance], a substance which harms public health and environment by destroying ozone in the upper atmosphere.

**CONSULT WITH YOUR PHYSICIAN, HEALTH PROFESSIONAL,
OR SUPPLIER IF YOU HAVE ANY QUESTION ABOUT THE USE
OF THIS PRODUCT.**

Note: The indented statement above is required by the Federal government's Clean Air Act for all products containing or manufactured with chlorofluorocarbons (CFCs) [or other class I substance, if applicable].

10309.2 The warning statement shall be clearly legible and conspicuous on the product, its immediate container, its outer packaging, or other labeling in accordance with the requirements and appear with such prominence and conspicuousness as to render it likely to be read and understood by consumers under normal conditions of purchase.

10310 PRESCRIPTION DEVICES

10310.1 A device which, because of any potential for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from 21 U.S.C. § 352(f)(1) if all the following conditions are met:

- (a) The device is:
 - (1) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or
 - (2) In the possession of a practitioner, such as a physician, dentist, or veterinarian, licensed by law to use or order the use of such device; and
 - (3) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his or her professional practice.
- (b) The label of the device, other than surgical instruments, bears:
 - (1) The statement "Caution: Federal law restricts this device to sale by or on the order of a -----", the blank to be filled with the word "physician," "dentist," or "veterinarian," or with the descriptive designation of any other practitioner licensed by the law of the state in which he practices to use or order the use of the device; and
 - (2) The method of its application or use;
- (c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented; provided, however, that such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other

information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefore, the Department will offer an opinion on a proposal to omit such information from the dispensing package under this provision;

- (d) Any labeling, as defined in 21 U.S.C. § 321(m) of the act, whether or not it is on or within a package from which the device is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the device, that furnishes or purports to furnish information for use of the device contains adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to employ the device can use the device safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented; and
- (e) All labeling, except labels and cartons, bearing information for use of the device also bears the date of the issuance or the date of the latest revision of such labeling.

10311 RETAIL EXEMPTION FOR PRESCRIPTION DEVICES

10311.1 A device subject to § 10310.1 shall be exempt at the time of delivery to the ultimate purchaser or user from 21 U.S.C. § 352(f)(1) if it is delivered by a licensed practitioner in the course of his or her professional practice or upon a prescription or other order lawfully issued in the course of his or her professional practice, with labeling bearing the name and address of such licensed practitioner and the directions for use and cautionary statements, if any, contained in such order.

10312 MEDICAL DEVICES HAVING COMMONLY KNOWN DIRECTIONS

10312.1 A device shall be exempt from 21 U.S.C. § 352(f)(1) insofar as adequate directions for common uses thereof are known to the ordinary individual.

10313 IN VITRO DIAGNOSTIC PRODUCTS

10313.1 A product intended for use in the diagnosis of disease and which is an in vitro diagnostic product shall be deemed to be in compliance with the requirements of this section if it meets the requirements of 21 C.F.R. § 809.10.

10314 DEVICES FOR PROCESSING, REPACKING, OR MANUFACTURING

10314.1 A device intended for processing, repacking, or use in the manufacture of another drug or device shall be exempt if its label bears the statement "Caution: For manufacturing, processing, or repacking."

10315 MEDICAL DEVICES FOR USE IN TEACHING, LAW ENFORCEMENT, RESEARCH, AND ANALYSIS

10315.1 A device subject to § 10310 of this chapter shall be exempt from 21 U.S.C. § 352(f)(1) if shipped or sold to, or in the possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or engaged in law enforcement, or in research not involving clinical use, or in chemical analysis, or physical testing, and is to be used only for such instruction, law enforcement, research, analysis, or testing.

10316 MEDICAL DEVICES: EXPIRATION OF EXEMPTIONS

10316.1 If a shipment or delivery, or any part thereof, of a device which is exempt under the regulations in this section is made to a person in whose possession the article is not exempt, or is made for any purpose other than those specified, such exemption shall expire, with respect to such shipment or delivery or part thereof, at the beginning of that shipment or delivery. The causing of an exemption to expire shall be considered an act which results in such device being misbranded unless it is disposed of under circumstances in which it ceases to be a drug or device.

10316.2 The exemptions conferred by §§ 10313 through 10315 of this chapter shall continue until the devices are used for the purposes for which they are exempted, or until they are relabeled to comply with 21 U.S.C. § 352(f)(1). If, however, the device is converted, or manufactured into a form limited to prescription dispensing, no exemption shall thereafter apply to the article unless the device is labeled as required by § 10310 of this chapter.

10317 OTHER EXEMPTIONS - MEDICAL DEVICES: PROCESSING, LABELING, OR REPACKING

10317.1 Except as provided by §§ 10317.2 and 10317.3, a shipment or other delivery of a device which is, in accordance with the practice of the trade, to be processed, labeled, or repacked, in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of 21 U.S.C. §§ 352(b) and (f) if:

- (a) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such device is to be processed, labeled, or repacked; or
- (b) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking,

as the case may be, of such device in such establishment as will ensure, if such specifications are followed, that such device will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until two (2) years after the final shipment or delivery of such device from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

- 10317.2 An exemption of a shipment or other delivery of a device under § 10317.1(a) shall not apply if, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, the device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed.
- 10317.3 An exemption of a shipment or other delivery of a device under § 10317.1(b) shall not apply with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by § 10317.1(b).
- 10317.4 An exemption of a shipment or other delivery of a device under § 10317.1(b) shall expire:
- (a) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the Act when so removed; or
 - (b) Upon refusal by the operator of the establishment where such device is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by § 10317.1(b).
- 10317.5 Because of common industry practice to manufacture or assemble, package, and fully label a device as sterile at one (1) establishment and then ship such device in interstate commerce to another establishment or to a contract sterilizer for sterilization, the Department of Health will initiate no regulatory action against the device as misbranded or adulterated when the non-sterile device is labeled sterile, provided all the following conditions are met:
- (a) There is in effect a written agreement which:
 - (1) Contains the names and post office addresses of the firms involved and is signed by the person authorizing such shipment and the operator or person in charge of the establishment receiving the devices for sterilization;

- (2) Provides instructions for maintaining proper records or otherwise accounting for the number of units in each shipment to ensure that the number of units shipped is the same as the number received and sterilized;
 - (3) Acknowledges that the device is non-sterile and is being shipped for further processing; and
 - (4) States in detail the sterilization process, the gaseous mixture or other media, the equipment, and the testing method or quality controls to be used by the contract sterilizer to assure that the device will be brought into full compliance; and
- (b) Each pallet, carton, or other designated unit is conspicuously marked to show its non-sterile nature when it is introduced into and is moving in interstate commerce, and while it is being held prior to sterilization. Following sterilization, and until such time as it is established that the device is sterile and can be released from quarantine, each pallet, carton, or other designated unit is conspicuously marked to show that it has not been released from quarantine (for example, "sterilized--awaiting test results" or an equivalent designation).

10318 SPECIAL REQUIREMENTS FOR SPECIFIC DEVICES - LABELING OF ARTICLES INTENDED FOR LAY USE IN THE REPAIRING OR REFITTING OF DENTURES

10318.1 The American Dental Association and leading dental authorities have advised the FDA of their concern regarding the safety of denture liners, repair kits, pads, cushions, and other articles marketed and labeled for lay use in repairing, refitting, or cushioning of ill-fitting, broken, or irritating dentures. It is the opinion of dental authorities and the FDA that to properly repair and properly refit dentures a person must have professional knowledge and specialized technical skill. Laymen cannot be expected to maintain the original vertical dimension of occlusion and the centric relation essential in the proper repairing or refitting of dentures. The continued wearing of improperly repaired or refitted dentures may cause acceleration of bone resorption, soft tissue hyperplasia, and other irreparable damage to the oral cavity. Such articles designed for lay use should be limited to emergency or temporary situations pending the services of a licensed dentist.

10318.2 The FDA and the Department therefore regard such articles as unsafe and misbranded under the Federal Food, Drug, and Cosmetic Act unless the labeling:

- (a) Limits directions for use for denture repair kits to emergency repairing pending unavoidable delay in obtaining professional reconstruction of the denture;

- (b) Limits directions for use for denture reliners, pads, and cushions to temporary refitting pending unavoidable delay in obtaining professional reconstruction of the denture;
- (c) Contains in a conspicuous manner the word "emergency" preceding and modifying each indication-for-use statement for denture repair kits and the word "temporary" preceding and modifying each indication-for-use statement for reliners, pads, and cushions; and
- (d) Includes a conspicuous warning statement to the effect:
 - (1) For denture repair kits: "Warning--For emergency repairs only. Long term use of home-repaired dentures may cause faster bone loss, continuing irritation, sores, and tumors. This kit is for emergency use only. See Dentist Without Delay;"
 - (2) For denture reliners, pads, and cushions: "Warning--For temporary use only. Long-term use of this product may lead to faster bone loss, continuing irritation, sores, and tumors. For Use Only Until a Dentist Can Be Seen."

10318.3 Adequate directions for use require full information of the temporary and emergency use recommended in order for the layman to understand the limitations of usefulness, the reasons therefore, and the importance of adhering to the warnings. Accordingly, the labeling should contain the following information:

- (a) For denture repair kits:
 - (1) Special training and tools are needed to repair dentures to fit properly. Home-repaired dentures may cause irritation to the gums and discomfort and tiredness while eating. Long term use may lead to more troubles, even permanent changes in bones, teeth, and gums, which may make it impossible to wear dentures in the future. For these reasons, dentures repaired with this kit should be used only in an emergency until a dentist can be seen. Dentures that don't fit properly cause irritation and injury to the gums and faster bone loss, which is permanent. Dentures that don't fit properly cause gum changes that may require surgery for correction. Continuing irritation and injury may lead to cancer in the mouth. You must see your dentist as soon as possible;
- (b) For denture reliners, pads, and cushions:
 - (1) Use of these preparations or devices may temporarily decrease the discomfort; however, their use will not make the denture fit

properly. Special training and tools are needed to repair a denture to fit properly. Dentures that do not fit properly cause irritation and injury to the gums and faster bone loss, which is permanent and may require a completely new denture. Changes in the gums caused by dentures that do not fit properly may require surgery for correction. Continuing irritation and injury may lead to cancer in the mouth. You must see your dentist as soon as possible;

- (2) If the denture relining or repairing material forms a permanent bond with the denture, a warning statement to the following effect should be included: "This reliner becomes fixed to the denture and a completely new denture may be required because of its use."

10318.4 Labeling claims exaggerating the usefulness or the safety of the material or failing to disclose all facts relevant to the claims of usefulness will be regarded as false and misleading under 21 U.S.C. §§ 321(n) and 352(a).

10318.5 Regulatory action may be initiated with respect to any article found within the jurisdiction of the Act contrary to the provisions of this policy statement after ninety (90) days following the date of publication of these rules in the *D.C. Register*.

10319 USE OF IMPACT-RESISTANT LENSES IN EYEGLASSES AND SUNGLASSES

10319.1 Examination of data available on the frequency of eye injuries resulting from the shattering of ordinary crown glass lenses indicates that the use of such lenses constitutes an avoidable hazard to the eye of the wearer.

10319.2 The consensus of the ophthalmic community is that the number of eye injuries would be substantially reduced by the use in eyeglasses and sunglasses of impact-resistant lenses.

10319.3 To protect the public more adequately from potential eye injury, eyeglasses and sunglasses must be fitted with impact-resistant lenses, except in those cases where the physician or optometrist finds that such lenses will not fulfill the visual requirements of the particular patient, directs in writing the use of other lenses, and gives written notification thereof to the patient.

10319.4 The physician or optometrist shall have the option of ordering glass lenses, plastic lenses, or laminated glass lenses made impact resistant by any method; however, all such lenses shall be capable of withstanding the impact test described in § 10319.7.

10319.5 Each finished impact-resistant glass lens for prescription use shall be individually tested for impact resistance and shall be capable of withstanding the impact test

described in § 10319.7. Raised multifocal lenses shall be impact resistant but need not be tested beyond initial design testing. Prism segment multifocal, slab-off prism, lenticular cataract, iseikonic, depressed segment one (1) piece multifocal, bioconcave, myodisc and minus lenticular, custom laminate, and cemented assembly lenses shall be impact resistant but need not be subjected to impact testing. To demonstrate that all other types of impact-resistant laminated glass lenses (such as lenses other than those described in the three (3) sentences of this paragraph), are capable of withstanding the impact test described in this regulation, the manufacturer of these lenses shall subject to an impact test a statistically significant sampling of lenses from each production batch, and the lenses so tested shall be representative of the finished forms as worn by the wearer, including finished forms that are of minimal lens thickness and have been subjected to any treatment used to impart impact resistance. All nonprescription lenses and plastic prescription lenses tested on the basis of statistical significance shall be tested in uncut-finished or finished form.

10319.6 For the purpose of this regulation, the impact test described in § 10319.7 shall be the "referee test," defined as "one which will be utilized to determine compliance with a regulation." The referee test provides the Department of Health with the means of examining a medical device for performance and does not inhibit the manufacturer from using equal or superior test methods. A lens manufacturer shall conduct tests of lenses using the impact test or any equal or superior test. Whatever test is used, the lenses shall be capable of withstanding the impact test if the Department of Health examines them for performance.

10319.7 In the impact test, a five-eighths inch (5/8 in.) steel ball weighing approximately 0.56 ounce is dropped from a height of fifty inches (50 in.) upon the horizontal upper surface of the lens. The ball shall strike within a five-eighths inch (5/8 in.) diameter circle located at the geometric center of the lens. The ball may be guided but not restricted in its fall by being dropped through a tube extending to within approximately four inches (4 in.) of the lens. To pass the test, the lens must not fracture; for the purpose of this section, a lens will be considered to have fractured if it cracks through its entire thickness, including a laminar layer, if any, and across a complete diameter into two (2) or more separate pieces, or if any lens material visible to the naked eyes becomes detached from the ocular surface. The test shall be conducted with the lens supported by a tube one inch (1 in.) inside diameter, one and one quarter inch (1-1/4 in.) outside diameter, and approximately one inch (1 in.) high affixed to a rigid iron or steel base plate. The total weight of the base plate and its rigidly attached fixtures shall be not less than twenty-seven pounds (27 lbs.). For lenses of small minimum diameter, a support tube having an outside diameter of less than one and one-fourth inches (1-1/4 in.) may be used. The support tube shall be made of rigid acrylic plastic, steel, or other suitable substance and shall have securely bonded on the top edge a one-eighth inch by one-eighth inch (1/8 in. x 1/8 in.) neoprene gasket having a hardness of 40 [+/-] 5, as determined by ASTM Method D 1415-88, Standard Test Method for Rubber Property -- International Hardness; a minimum tensile

strength of one thousand two hundred pounds (1,200 lbs.), as determined by ASTM Method D 412-98A, "Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers-Tension;" and a minimum ultimate elongation of four hundred percent (400 %), as determined by ASTM Method D 412-68. (Both methods are incorporated by reference and are from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428, or available for inspection at the Center for Devices and Radiological Health's Library, 9200 Corporate Blvd., Rockville, MD 20850, or at the Office of the Federal Register, 800 North Capitol St. NW., Suite 700, Washington, DC.) The diameter or contour of the lens support may be modified as necessary so that the one-eighth inch by one-eighth inch (1/8 in. x 1/8 in.) neoprene gasket supports the lens at its periphery.

- 10319.8 Copies of invoice(s), shipping document(s), and records of sale or distribution of all impact-resistant lenses, including finished eyeglasses and sunglasses, shall be kept and maintained for a period of three (3) years; however, the names and addresses of individuals purchasing nonprescription eyeglasses and sunglasses at the retail level need not be kept and maintained by the retailer. The records kept in compliance with this section shall be made available upon request at all reasonable hours to any officer or employee of the Department of Health and such officer or employee shall be permitted to inspect and copy such records, to make such inventories of stock as he or she deems necessary, and otherwise to check the correctness of such inventories.
- 10319.9 In addition, those persons conducting tests in accordance with §§ 10319.6 and 10319.7 shall maintain the results thereof and a description of the test method and of the test apparatus for a period of three (3) years. These records shall be made available upon request at any reasonable hour by any officer or employee acting on behalf of the Department. The persons conducting tests shall permit the officer or employee to inspect and copy the records, to make such inventories of stock as the officer or employee deems necessary, and otherwise to check the correctness of the inventories.
- 10319.10 For the purpose of this section, the term "manufacturer" includes an importer for resale. Such importer may have the tests conducted in the country of origin but must make the results thereof available, upon request, to the Department, as soon as practicable.
- 10319.11 All lenses shall be impact-resistant except when the physician or optometrist finds that impact-resistant lenses will not fulfill the visual requirements for a particular patient.
- 10319.12 This statement of policy shall not apply to contact lenses.
- 10320 MAXIMUM ACCEPTABLE LEVEL OF OZONE**

- 10320.1 Ozone is a toxic gas with no known useful medical application in specific, adjunctive, or preventive therapy. In order for ozone to be effective as a germicide, it must be present in a concentration far greater than that which can be safely tolerated by man and animals.
- 10320.2 Although undesirable physiological effects on the central nervous system, heart, and vision have been reported, the predominant physiological effect of ozone is primary irritation of the mucous membranes. Inhalation of ozone can cause sufficient irritation to the lungs, resulting in pulmonary edema. The onset of pulmonary edema is usually delayed for some hours after exposure. Thus, symptomatic response is not a reliable warning of exposure to toxic concentrations of ozone. Since olfactory fatigue develops readily, the odor of ozone is not a reliable index of atmospheric ozone concentration.
- 10320.3 A number of devices currently on the market generate ozone by design or as a byproduct. Since exposure to ozone above a certain concentration can be injurious to health, any such device will be considered adulterated or misbranded if it is used or intended for use under the following conditions:
- (a) In such a manner that it generates ozone at a level in excess of five hundredths (0.05) parts per million by volume of air circulating through the device or causes an accumulation of ozone in excess of five hundredths (0.05) parts per million by volume of air (when measured under standard conditions at twenty-five degrees Celsius (25 °C), seventy-seven degrees Fahrenheit (77 °F), and seven hundred sixty millimeters (760 mm.) of mercury in the atmosphere of enclosed space intended to be occupied by people for extended periods of time, e.g., houses, apartments, hospitals, and offices. This applies to any such device, whether portable or permanent or part of any system, which generates ozone by design or as an inadvertent or incidental product;
 - (b) To generate ozone and release it into the atmosphere in hospitals or other establishments occupied by the ill or infirm;
 - (c) To generate ozone and release it into the atmosphere and does not indicate in its labeling the maximum acceptable concentration of ozone which may be generated (not to exceed five-hundredths (0.05) parts per million by volume of air circulating through the device) as established herein and the smallest area in which such device can be used so as not to produce an ozone accumulation in excess of five-hundredths (0.05) parts per million;
 - (d) In any medical condition for which there is no proof of safety and effectiveness; or

- (f) To generate ozone at a level less than five-hundredths (0.05) parts per million by volume of air circulating through the device and it is labeled for use as a germicide or deodorizer.

10320.4 This section does not affect the present threshold limit value of one tenth (0.10) part per million (two tenths of a milligram per cubic meter (0.2 mg./m.³)) of ozone exposure for an eight (8)-hour-day exposure of industrial workers as the American Conference of Governmental Industrial Hygienists recommend.

10320.5 The method and apparatus specified in 40 C.F.R., part 50, or any other equally sensitive and accurate method, may be employed in measuring ozone pursuant to this section.

10321 CHLOROFLUOROCARBON PROPELLANTS

10321.1 The use of chlorofluorocarbon in devices as propellants in self-pressurized containers is generally prohibited except as provided in 21 C.F.R. § 2.125.

10322 HEARING AID DEVICES: PROFESSIONAL AND PATIENT LABELING

10322.1 Hearing aids shall be clearly and permanently marked with:

- (a) The name of the manufacturer or distributor, the model name or number, the serial number, and the year of manufacture; and
- (b) A "+" symbol to indicate the positive connection for battery insertion, unless it is physically impossible to insert the battery in the reversed position.

10322.2 All labeling information required by this section shall be included in a User Instructional Brochure that the manufacturer or distributor develops, shall accompany the hearing aid, and shall be provided to the prospective user by the dispenser of the hearing aid in accordance with 21 C.F.R. § 801.421(c). The User Instructional Brochure accompanying each hearing aid shall contain the following information and instructions for use, to the extent applicable to the particular requirements and characteristics of the hearing aid:

- (a) An illustration(s) of the hearing aid, indicating operating controls, user adjustments, and battery compartment;
- (b) Information on the function of all controls intended for user adjustment;
- (c) A description of any accessory that may accompany the hearing aid (for example, accessories for use with a television or telephone);
- (d) Specific instructions for:

- (1) Use of the hearing aid;
 - (2) Maintenance and care of the hearing aid, including the procedure to follow in washing the earmold, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time; and
 - (3) Replacing or recharging the batteries, including a generic designation of replacement batteries;
- (e) Information on how and where to obtain repair service, including at least one specific address where the user can go, or send the hearing aid to, to obtain such repair service;
 - (f) A description of commonly occurring avoidable conditions that could adversely affect or damage the hearing aid, such as dropping, immersing in liquid, or exposing the hearing aid to excessive heat;
 - (g) Identification of any known side effects associated with the use of hearing aid that may warrant consultation with a physician, e.g., skin irritation and accelerated accumulation of cerumen (ear wax);
 - (h) A statement that a hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions;
 - (i) A statement that in most cases infrequent use of a hearing aid does not permit a user to attain full benefit from it;
 - (j) A statement that the use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lip-reading;
 - (k) The warning statement required by § 10322.3;
 - (l) The notice for prospective hearing aid users required by § 10322.4; and
 - (m) The technical data required by § 10322.5, unless such data is provided in separate labeling accompanying the device.

10322.3 The User Instructional Brochure shall contain the following warning statement:

WARNING TO HEARING AID DISPENSERS

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing

a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information concerning the following conditions:

- (a) Visible congenital or traumatic deformity of the ear;
- (b) History of active drainage from the ear within the previous ninety (90) days;
- (c) History of sudden or rapidly progressive hearing loss within the previous ninety (90) days;
- (d) Acute or chronic dizziness;
- (e) Unilateral hearing loss of sudden or recent onset within the previous ninety (90) days;
- (f) Audiometric air-bone gap equal to or greater than fifteen decibels (15 dB) at five hundred hertz (500 Hz), one thousand hertz (1,000 Hz), and two thousand hertz (2,000 Hz);
- (g) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal; or
- (h) Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds one hundred thirty-two decibels (132 dB) because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than one hundred thirty-two decibels (132 dB).”

10322.4 The User Instructional Brochure shall contain the following notice:

IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists, or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

CHILDREN WITH HEARING LOSS

In addition to seeing a physician for a medical evaluation, a child with hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

10322.5 Technical data useful in selecting, fitting, and checking the performance of a hearing aid shall be provided in the User Instructional Brochure or in separate labeling that accompanies the device. The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the American National Standard "Specification of Hearing Aid Characteristics," ANSI S3.22-2003 (Revision of ANSI S3.22-19106) (includes April 2007 Erratum). At a minimum, the User Instructional Brochure or such other labeling shall include the appropriate values or information for the following technical data elements as these elements are defined or used in such standard:

- (a) Saturation output curve (SSPL 90 curve);
- (b) Frequency response curve;
- (c) Average saturation output (HF-Average SSPL 90);
- (d) Average full-on gain (HF-Average full-on gain);
- (e) Reference test gain;
- (f) Frequency range;
- (g) Total harmonic distortion;
- (h) Equivalent input noise;
- (i) Battery current drain;
- (j) Induction coil sensitivity (telephone coil aids only);
- (k) Input-output curve (automatic gain control aids only); or
- (l) Attack and release times (ACG aids only).

10322.6 If a hearing aid has been used or rebuilt, this fact shall be declared on the container in which the hearing aid is packaged and on a tag that is physically attached to the hearing aid. Such fact may also be stated in the User Instructional Brochure.

10322.7 A User Instructional Brochure may contain statements or illustrations in addition to those required by § 10322.2 if the additional statements:

- (a) Are not false or misleading in any particular (for example, diminishing the impact of the required statements); and
- (b) Are not prohibited by this chapter or by regulations.

10323 HEARING AIDE DEVICES: CONDITIONS FOR SALE

10323.1 Except as provided in § 10323.2, a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding six (6) months.

10323.2 If the prospective hearing aid user is eighteen (18) years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement of § 10323.1 of this section provided that the hearing aid dispenser:

- (a) Informs the prospective user that the exercise of the waiver is not in the user's best health interest;
- (b) Does not in any way actively encourage the prospective user to waive such a medical evaluation; and
- (c) Affords the prospective user the opportunity to sign the following statement:

“I have been advised by (Hearing aid dispenser's name) that the Department of Health has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish to have a medical evaluation before purchasing a hearing aid.”

10323.3 Before signing any statement under § 10323.2(c) of this section and before the sale of a hearing aid to a prospective user, the hearing aid dispenser shall:

- (a) Provide the prospective user a copy of the User Instructional Brochure for a hearing aid that has been, or may be, selected for the prospective user;

- (b) Review the content of the User Instructional Brochure with the prospective user orally, or in the predominate method of communication used during the sale; and
- (c) Afford the prospective user an opportunity to read the User Instructional Brochure.

10323.4 Upon request by an individual who is considering the purchase of a hearing aid, a dispenser shall, with respect to any hearing aid that he dispenses, provide a copy of the User Instructional Brochure for the hearing aid or the name and address of the manufacturer or distributor from whom a User Instructional Brochure for the hearing aid may be obtained.

10323.5 In addition to ensuring that a User Instructional Brochure accompanies each hearing aid, a manufacturer or distributor shall, with respect to any hearing aid that he manufactures or distributes:

- (a) Provide sufficient copies of the User Instructional Brochure to sellers for distribution to users and prospective users; and
- (b) Provide a copy of the User Instructional Brochure to any hearing aid professional, user, or prospective user who requests a copy in writing.

10323.6 The dispenser shall retain for three (3) years after the dispensing of a hearing aid a copy of any written statement required under § 10323.1 of this section from a physician or any written statement waiving a medical evaluation required under § 10323.2(c).

10323.7 Group auditory trainers, defined as a group amplification system, that a qualified school or institution purchases for the purpose of communicating with and educating individuals with hearing impairments, are exempt from the requirements in this section.

10324 USER LABELING FOR MENSTRUAL TAMPON

10324.1 This section applies to scented or scented deodorized menstrual tampons as identified in 21 C.F.R. § 884.5460 and unscented menstrual tampons as identified in 21 C.F.R. § 884.5470.

10324.2 Data show that Toxic Shock Syndrome (TSS), a rare but serious and sometimes fatal disease, is associated with the use of menstrual tampons. To protect the public and to minimize the serious adverse effects of TSS, menstrual tampons shall be labeled as set forth in §§ 10324.3 through 10324.5 of this section and tested for absorbency as set forth in § 10324.6.

10324.3 If the information specified in § 10324.4 is to be included as a package insert, the following alert statement shall appear prominently and legibly on the package label:

“ATTENTION: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information.”

10324.4 The labeling of menstrual tampons shall contain the following consumer information prominently and legibly, in such terms as to render the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use:

- (a) Warning signs of TSS (for example, sudden fever (usually one hundred two degrees Fahrenheit (102 °F)) or more) and vomiting, diarrhea, fainting or near fainting when standing up, dizziness, or a rash that looks like a sunburn);
- (b) What to do if these or other signs of TSS appear, including the need to remove the tampon at once and seek medical attention immediately;
- (c) The risk of TSS to all women using tampons during their menstrual period, especially the reported higher risks to women under thirty (30) years of age and teenage girls, the estimated incidence of TSS of one (1) to seventeen (17) per one hundred thousand (100,000) menstruating women and girls per year, and the risk of death from contracting TSS;
- (d) The advisability of using tampons with the minimum absorbency needed to control menstrual flow in order to reduce the risk of contracting TSS; and
- (e) The need to seek medical attention before resuming use of tampons if TSS warning signs have occurred in the past, or if women have any questions about TSS or tampon use.

10324.5 The statements required by § 10324.4 shall be prominently and legibly placed on the package label of menstrual tampons (unless the menstrual tampons are exempt).

10324.6 Menstrual tampon package labels shall bear one (1) of the following absorbency terms representing the absorbency of the production run, lot, or batch;

Ranges of absorbency in grams¹	Corresponding term of absorbency
6 and under	Junior absorbency
6 to 9	Regular absorbency
9 to 12	Super absorbency
12 to 15	Super plus absorbency
15 to 18	Ultra absorbency
Above 18	No term

- 10324.7 The package label shall include an explanation of the ranges of absorbency and a description of how consumers can use a range of absorbency, and its corresponding absorbency term, to make comparisons of absorbency of tampons to allow selection of the tampons with the minimum absorbency needed to control menstrual flow in order to reduce the risk of contracting TSS.
- 103324.8 A manufacturer shall measure the absorbency of individual tampons using the test method specified in § 10324.10 and calculate the mean absorbency of a production run, lot, or batch by rounding to the nearest one tenth of a gram (0.1 g).
- 10324.9 A manufacturer shall design and implement a sampling plan that includes collection of probability samples of adequate size to yield consistent tolerance intervals such that the probability is ninety percent (90%) that at least ninety percent (90%) of the absorbencies of individual tampons within a brand and type are within the range of absorbency stated on the package label.
- 10324.10 In the absorbency test, an unlubricated condom, with tensile strength between seventeen Mega Pascals (17 MPa) and thirty Mega Pascals (30 MPa), as measured according to the procedure in the American Society for Testing and Materials (ASTM) D 3492-97, "Standard Specification for Rubber Contraceptives (Male Condoms)"² for determining tensile strength is attached to the large end of a glass chamber (or a chamber made from hard transparent plastic) with a rubber band (see Figure 1) and pushed through the small end of the chamber using a smooth, finished rod. The condom is pulled through until all slack is removed. The tip of the condom is cut off and the remaining end of the condom is stretched

¹ These ranges are defined, respectively, as follows: Less than or equal to six grams (6 g); greater than six grams (6 g) up to and including nine grams (9 g); greater than nine grams (9 g) up to and including twelve grams (12 g); greater than twelve grams (12 g) up to and including fifteen grams (15 g); greater than fifteen grams (15 g) up to and including eighteen grams (18 g); and greater than eighteen grams (18 g).

² Copies of the standard are available from the American Society for Testing and Materials, 100 Barr Harbor Dr., West Conshohocken, PA 19428, or available for inspection at the Center for Devices and Radiological Health's Library, 9200 Corporate Blvd., Rockville, MD 20850, or at the Office of the Federal Register, 800 North Capitol St., NW., Suite 700, Washington, DC (20002).

over the end of the tube and secured with a rubber band. A pre-weighed (to the nearest one-tenth gram (0.1 g) tampon is placed within the condom membrane so that the center of gravity of the tampon is at the center of the chamber. An infusion needle fourteen gauge (14 ga.) is inserted through the septum created by the condom tip until it contacts the end of the tampon. The outer chamber is filled with water pumped from a temperature-controlled water bath to maintain the average temperature at twenty-seven, plus or minus one, degrees Celsius (27 ± 1 °C). The water returns to the water bath as shown in Figure 2. Syngyna fluid ten grams (10 g) sodium chloride, five tenths gram (0.5 g) Certified Reagent Acid Fuchsin, one thousand milliliters (1,000 ml) distilled water is then pumped through the infusion needle at a rate of fifty milliliters (50 ml) per hour. The test shall be terminated when the tampon is saturated and the first drop of fluid exits the apparatus. (The test result shall be discarded if fluid is detected in the folds of the condom before the tampon is saturated). The water is then drained and the tampon is removed and immediately weighed to the nearest one hundredths gram, (0.01 g). The absorbency of the tampon is determined by subtracting its dry weight from this value. The condom shall be replaced after ten (10) tests or at the end of the day during which the condom is used in testing, whichever occurs first.

FIG 1

FIG 2

- 10324.11 The FDA and the Department may permit the use of an absorbency test method different from the test method specified in this section if each of the following conditions is met:
- (a) The manufacturer presents evidence, in the form of a citizen petition submitted in accordance with the requirements of 21 C.F.R. § 10.30, demonstrating that the alternative test method will yield results that are equivalent to the results yielded by the test method specified in this section; and
 - (b) The FDA or the Department approves the method and has published notice of its approval of the alternative test method in the Federal Register.
- 10324.12 Any menstrual tampon intended to be dispensed by a vending machine is exempt from the requirements of this section.
- 10324.13 Any menstrual tampon that is not labeled as required by §§ 10324.3 through 10324.5 and that is initially introduced or initially delivered for introduction into commerce after March 1, 1990, is misbranded under 21 U.S.C. §§ 321(m) and, 352(a) and (f).

**10325 WARNING STATEMENTS FOR PRESCRIPTION AND RESTRICTED
DEVICE PRODUCTS CONTAINING OR MANUFACTURED WITH
CHLOROFLUOROCARBONS OR OTHER OZONE-DEPLETING
SUBSTANCES**

- 10325.1 All prescription and restricted device products containing or manufactured with chlorofluorocarbons, halons, carbon tetrachloride, methyl chloride, or any other class I substance designated by the Environmental Protection Agency (EPA) shall, except as provided in § 10325.3, bear the following warning statement:
- “Warning: Contains [or Manufactured with, if applicable] [insert name of substance], a substance which harms public health and the environment by destroying ozone in the upper atmosphere.”
- 10325.2 The warning statement shall be clearly legible and conspicuous on the product, its immediate container, its outer packaging, or other labeling in accordance with the requirements of 40 C.F.R. part 82 and appear with such prominence and conspicuousness as to render it likely to be read and understood by consumers under normal conditions of purchase.
- 10325.3 For prescription and restricted device products, the following alternative warning statement may be used:

“Note: The indented statement below is required by the District of Columbia for all products containing or manufactured with chlorofluorocarbons (CFCs) [or name of other class I substance, if applicable]:

This product contains [or is manufactured with, if applicable] [insert name of substance], a substance which harms the environment by destroying ozone in the upper atmosphere.

Your physician has determined that this product is likely to help your personal health. **USE THIS PRODUCT AS DIRECTED, UNLESS INSTRUCTED TO DO OTHERWISE BY YOUR PHYSICIAN.** If you have any questions about alternatives, consult your physician.”

10325.4 The warning statement shall be clearly legible and conspicuous on the product, its immediate container, its outer packaging, or other labeling and appear with such prominence and conspicuousness so that it is likely to be read and understood by consumers under normal conditions of purchase.

10325.5 If the warning statement in paragraph § 10325.3 is used, the following warning statement must be placed on the package labeling intended to be read by the physician (physician package insert) after the "How supplied" section, which describes special handling and storage conditions on the physician labeling:

“Note: The indented statement below is required by the District of Columbia for all products containing or manufactured with chlorofluorocarbons (CFCs) [or name of other class I substance, if applicable]:

Warning: Contains [or Manufactured with, if applicable] [insert name of substance], a substance which harms public health and environment by destroying ozone in the upper atmosphere.

A notice similar to the above WARNING has been placed in the information for the patient [or patient information leaflet, if applicable] of this product under Environmental Protection Agency (EPA) regulations. The patient's warning states that the patient should consult his or her physician if there are questions about alternatives.”

10325.6 This section does not replace or relieve a person from any requirements imposed under 40 C.F.R., part 82.

10326 USER LABELING FOR LATEX CONDOMS

10326.1 This section applies to the subset of condoms as identified in 21 C.F.R. § 884.5300, and condoms with spermicidal lubricant identified in 21 C.F.R. § 884.5310, whose products are formed from latex films.

- 10326.2 Data show that the material integrity of latex condoms degrades over time. To protect the public health and minimize the risk of device failure, latex condoms must bear an expiration date.
- 10326.3 The expiration date, as demonstrated by testing procedures required by §§ 10326.4 and 10326.8, must be displayed prominently and legibly on the primary packaging (such as individual package), and higher levels of packaging (such as boxes of condoms), in order to ensure visibility of the expiration date by consumers.
- 10326.4 Except as provided under § 10326.6, the expiration date must be supported by data demonstrating physical and mechanical integrity of the product after three (3) discrete and representative lots of the product have been subjected to each of the following conditions:
- (a) Storage of unpackaged bulk product for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the packaged product at seventy degrees Celsius (70 °C) (plus or minus two degrees Celsius (2 °C) for seven (7) days;
 - (b) Storage of unpackaged bulk product for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the packaged product at a selected temperature between forty degrees Celsius (40 °C) and fifty degrees (50 °C) (plus or minus two degrees Celsius (+/- 2 °C) for ninety (90) days; and
 - (c) Storage of unpackaged bulk product for the maximum amount of time the manufacturer allows the product to remain unpackaged, followed by storage of the packaged product at a monitored or controlled temperature between fifteen degrees Celsius (15° C) and thirty degrees Celsius (30° C) for the lifetime of the product (real time storage).
- 10326.5 If a product fails the physical and mechanical integrity tests commonly used by industry after the completion of the accelerated storage tests described in §§ 10326.4(a) and(b), the product expiration date must be demonstrated by real time storage conditions described in § 10326.4(c). If all of the products tested after storage at temperatures pass the manufacturer's physical and mechanical integrity tests, the manufacturer may label the product with an expiration date of up to five (5) years from the date of product packaging. If the extrapolated expiration date under §§ 10326.4(a) and(b) of this section is used, the labeled expiration date must be confirmed by physical and mechanical integrity tests performed at the end of the stated expiration period as described in section § 10326.4(c). If the data from tests following real time storage described in § 10326.4(c) of this section fail to confirm the extrapolated expiration date, the manufacturer must, at that time, re-label the product to reflect the actual shelf life.

- 10326.6 Products that already have established shelf life data based upon real time storage and testing and have such storage and testing data available for inspection are not required to confirm such data using accelerated and intermediate aging data described in §§10326.4(a) and (b). If, however, such real time expiration dates were based upon testing of products that were not first left unpackaged for the maximum amount of time as described in § 10326.4(c), the real time testing must be confirmed by testing products consistent with the requirements of § 10326.4(c). Until the confirmation testing in accordance with § 10326.4(c) is completed, the product may remain on the market labeled with the expiration date based upon previous real time testing.
- 10326.7 If a manufacturer uses testing data from one (1) product to support expiration on any variation of that product, the manufacturer must document and provide, upon request, an appropriate justification for the application of the testing data to the variation of the tested product.
- 10326.8 If a latex condom contains a spermicide, and the expiration date based on spermicidal stability testing is different from the expiration date based upon latex integrity testing, the product shall bear only the earlier expiration date.
- 10326.9 The time period upon which the expiration date is based shall start with the date of packaging.
- 10326.10 As provided in Chapter 107 of this subtitle, all testing data must be retained in each company's files, and shall be made available upon request for inspection by the FDA of the Department.
- 10326.11 Any latex condom not labeled with an expiration date as required by § 10326.3 and initially delivered for introduction into interstate commerce after the effective date of this regulation is misbranded under 21 U.S.C. §§ 321(n) and 352(a) and (f).

10327 USER LABELING FOR DEVICES THAT CONTAIN NATURAL RUBBER

- 10327.1 Data in the Medical Device Reporting System and the scientific literature indicate that some individuals are at risk of severe anaphylactic reactions to natural latex proteins. This labeling regulation is intended to minimize the risk to individuals sensitive to natural latex proteins and to protect the public health.
- 10327.2 This section applies to all devices composed of or containing, or having packaging or components that are composed of or contain, natural rubber that contacts humans.

- 10327.3 For purposes of this section, the term "natural rubber" includes natural rubber latex, dry natural rubber, and synthetic latex or synthetic rubber that contains natural rubber in its formulation.
- 10327.4 For purposes of this section, the term "natural rubber latex" means rubber that is produced by the natural rubber latex process that involves the use of natural latex in a concentrated colloidal suspension. Products are formed from natural rubber latex by dipping, extruding, or coating.
- 10327.5 For purposes of this section, the term "dry natural rubber" means rubber that is produced by the dry natural rubber process that involves the use of coagulated natural latex in the form of dried or milled sheets. Products are formed from dry natural rubber by compression molding, extrusion, or converting the sheets into a solution for dipping.
- 10327.6 For purposes of this section, the term "contacts humans" means that the natural rubber contained in a device is intended to contact or is likely to contact the user or patient. This includes contact when the device that contains natural rubber is connected to the patient by a liquid path or an enclosed gas path; or the device containing the natural rubber is fully or partially coated with a powder, and such powder may carry natural rubber proteins that may contaminate the environment of the user or patient.
- 10327.7 Devices containing natural rubber shall be labeled as set forth in §§ 10327.5 through 10327.9. Each required labeling statement shall be prominently and legibly displayed in accordance with 21 U.S.C. § 352(c).
- 10327.8 Devices containing natural rubber latex that contacts humans, as described in § 10327.2, shall bear the following statement in bold print on the device labeling:
- "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions."**
- This statement shall appear on all device labels, and other labeling, and shall appear on the principal display panel of the device packaging; the outside package, container, or wrapper; and the immediate device package, container, or wrapper.
- 10327.9 Devices containing dry natural rubber that contacts humans, as described in § 10327.2, shall bear the following statement in bold print on the device labeling:
- "This Product Contains Dry Natural Rubber."**
- This statement shall appear on all device labels, and other labeling, and shall appear on the principal display panel of the device packaging; the outside

package, container, or wrapper; and the immediate device package, container, or wrapper.

- 10327.10 Devices that have packaging containing natural rubber latex that contacts humans shall bear the following statement in bold print on the device labeling:

"Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions."

This statement shall appear on the packaging that contains the natural rubber, and the outside package, container, or wrapper.

- 10327.11 Devices that have packaging containing dry natural rubber that contacts as described in § 10327.2, shall bear the following statement in bold print on the device labeling:

"The Packaging of This Product Contains Dry Natural Rubber."

This statement shall appear on the packaging that contains the natural rubber and the outside package, container, or wrapper.

- 10237.12 Devices that contain natural rubber that contacts humans shall not contain the term "hypoallergenic" on their labeling.

- 10327.13 Any affected person may request an exemption or variance from the requirements of this section by submitting a citizen petition in accordance with 21 C.F.R. § 10.30.

- 10327.14 Any device subject to this section that is not labeled in accordance with §§ 10327.4 through 10327.8 and that is initially introduced or initially delivered for introduction into interstate commerce after the effective date of this regulation is misbranded under 21 U.S.C. §§ 321(n) and 352(a), (c), and (f).

10399 DEFINITIONS

- 10399.1 As used in this chapter, the following terms and phrases shall have the meanings ascribed:

Adequate directions for use - directions under which the layman can use a device safely and for the purposes for which it is intended. Directions for use may be inadequate because, among other reasons, of omission in whole or in part or incorrect specification of:

- (a) Statements of all conditions, purposes, or uses for which the device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic

advertising, and conditions, purposes, or uses for which the device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner;

- (b) Quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions;
- (c) Frequency of administration and application;
- (d) Duration of administration or application;
- (e) Time of administration or application, in relation to time of meals, time of onset of symptoms, or other factors;
- (f) Route or method of administration or application; and
- (g) Preparation for use (for example, adjustment of temperature or other manipulation or process).

Chlorofluorocarbon - means any fully halogenated chlorofluoroalkane.

Principal display panel – the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale, as it applies to over-the-counter devices in package form and as used in this chapter.

Propellant - means a liquefied or compressed gas that is used in whole or in part to expel from the same self-pressurized container or from a separate container a liquid or solid material different from the propellant, but the term does not include the use of a chlorofluorocarbon as an aerating agent for foamed or sprayed food products.

Chapter 104 (Medical Device Reporting) is added to read as follows:

CHAPTER 104 MEDICAL DEVICE REPORTING

10400 GENERAL

- 10400.1 This section establishes the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors. A device user facility shall report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports. A manufacturer or importer shall report

deaths and serious injuries that its device has or may have caused or contributed to, shall report certain device malfunctions, and shall establish and maintain adverse event files. A manufacturer shall also submit specified follow-up. These reports help the Department to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use. A medical device distributor shall maintain records (files) of incidents, but is not required to report these incidents.

10400.2 This part supplements and does not supersede other provisions of this chapter, including the provisions of Chapter 107.

10401 PUBLIC AVAILABILITY OF REPORTS

10401.1 The Department may disclose to the public any report, including any record of a telephone report, submitted under this part.

10401.2 Before the Department discloses a report to the public, the Department shall delete the following:

- (a) Any information that constitutes trade secret or confidential commercial or financial information under 21 C.F.R. § 20.61;
- (b) Any personal, medical, and similar information, including the serial number of implanted devices, which would constitute an invasion of personal privacy under 21 C.F.R. § 20.63. However, if a patient requests a report, the Department shall disclose to that patient all the information in the report concerning that patient; and
- (c) Any names and other identifying information of a third party that voluntarily submitted an adverse event report.

10401.3 The Department shall not disclose the identity of a device user facility that makes a report under this part except in connection with:

- (a) An action brought to enforce 21 U.S.C. § 331(q), including the failure of refusal to furnish material or information required by 21 U.S.C. § 360i;
- (b) A communication to a manufacturer of a device that is the subject of a report required to be submitted by a user facility under § 10415 of this chapter; or
- (c) A disclosure to employees of the Department of Health and Human Services, the Department of Justice, the District of Columbia Department of Health, or to the duly authorized committees and subcommittees of the Congress.

10402 GENERAL DESCRIPTION OF REPORTS REQUIRED FROM USER FACILITIES, IMPORTERS, AND MANUFACTURERS

10402.1 A device user facility must submit the following reports:

- (a) Reports of individual adverse events no later than ten (10) work days after the day that the facility becomes aware of a reportable event, which shall include:
 - (1) Reports of device-related deaths to the Department and to the manufacturer, if known; or
 - (2) Reports of device-related serious injuries to the manufacturers or, if the manufacturer is unknown, to the Department; and
- (b) Annual reports described in § 10417 to the Department.

10402.2 A device importer must submit the following reports:

- (a) Reports of individual adverse events no later than thirty (30) calendar days after the day that the importer becomes aware of a reportable event, which shall include:
 - (1) Reports of device-related deaths or serious injuries to the Department and to the manufacturer; or
 - (2) Reports of device-related malfunctions to the manufacturer.

10402.3 If you are a manufacturer must submit the following reports:

- (a) Reports of individual adverse events no later than thirty (30) days after the day that you become aware of a reportable death, serious injury, or malfunction;
- (b) Reports of individual adverse events no later than five (5) work days after the day that you become aware of:
 - (1) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health; or
 - (2) A reportable event for which we made a written request.

10402.4 Supplemental reports shall be filed if information is obtained that was not submitted as part of any initial report required by this section.

10403 RESERVED

10404 WHERE TO SUBMIT REPORTS

- 10404.1 You must submit any written report or additional information required under this part to the DC Department of Health, 899 North Capitol Street, N.E., 2nd Floor, Washington, D.C. 20002.
- 10404.2 You must specifically identify each report (for example, "User Facility Report," "Annual Report," "Importer Report," "Manufacturer Report," "10-Day Report").

10405 ENGLISH REPORTING REQUIREMENT

- 10405.1 All written or electronic equivalent reports must be in English.

10406 ELECTRONIC REPORTING

- 10406.1 You may electronically submit any report required by this part if you have our prior written consent. We may revoke this consent at anytime. Electronic report submissions include alternative reporting media (magnetic tape, and disc) and computer-to-computer communication.
- 10406.2 If your electronic report meets electronic reporting standards, guidance documents, or other medical device report (MDR) reporting procedures that we have developed, you may submit the report electronically without receiving our prior written consent.

10407 REQUESTS FOR ADDITIONAL INFORMATION

- 10407.1 The Department will notify you in writing if we require additional information and will tell you what information we need. The Department will require additional information if the Department determines that protection of the public health requires additional or clarifying information for medical device reports submitted to the Department and in cases when the additional information is beyond the scope of the Department's reporting forms or is not readily accessible to the Department.
- 10407.2 In any request under this section, the Department will state the reason or purpose for the information request, specify the due date for submitting the information, and clearly identify the reported event(s) related to our request. The Department shall confirm in writing any requests for additional information that it makes verbally.

10408 DISCLAIMERS

- 10408.1 A report or other information submitted by you, and the Department's release of report or information, is not necessarily an admission that the device, or you or your employees, caused or contributed to the reportable event. You do not have to

admit and may deny that the report or information submitted under this part constitutes an admission that the device, you, or your employees, caused or contributed to a reportable event.

10409 WRITTEN MEDICAL DEVICE REPORT PROCEDURES

10409.1 If you are a user facility, importer, or manufacturer, you must develop, maintain, and implement written MDR procedures for the following:

- (a) Internal systems that provide for:
 - (1) Timely and effective identification, communication, and evaluation of events that may be subject to Medical Device Report (MDR) requirements;
 - (2) A standardized review process or procedure for determining when an event meets the criteria for reporting under this part; and
 - (3) Timely transmission of complete medical device reports to manufacturers or to the Department, or to both if required; and
- (b) Documentation and recordkeeping requirements for:
 - (1) Information that was evaluated to determine if an event was reportable;
 - (2) All medical device reports and information submitted to manufacturers or the Department;
 - (3) Any information that was evaluated for the purpose of preparing the submission of annual reports; and
 - (4) Systems that ensure access to information that facilitates timely follow-up and inspection by the Department.

10410 FILES AND DISTRIBUTOR RECORDS

10410.1 A user facility, importer, or manufacturer shall establish and maintain MDR event files. The user shall clearly identify all MDR event files, and maintain them to facilitate timely access.

10410.2 For purposes of this section, "MDR event files" are written or electronic files maintained by user facilities, importers, and manufacturers. MDR event files may incorporate references to other information (e.g., medical records, patient files, and engineering reports), in lieu of copying and maintaining duplicates in this file. MDR event files must contain:

- (a) Information in your possession or references to information related to the adverse event, including all documentation of your deliberations and decision-making processes used to determine if a device-related death, serious injury, or malfunction was or was not reportable under this section; and
- (b) Copies of all MDR forms, as required by this section, and other information related to the event that you submitted to us and other entities such as an importer, distributor, or manufacturer.

10410.3 If you are a user facility, importer, or manufacturer, you must permit any authorized DOH employee, at all reasonable times, to access, copy, and verify the records required by this section.

10410.4 A user facility shall retain an MDR event file relating to an adverse event for a period of two (2) years from the date of the event. If you are a manufacturer or importer, you must retain an MDR event file relating to an adverse event for a period of two (2) years from the date of the event or a period of time equivalent to the expected life of the device, whichever is greater. If the device is no longer distributed, you still must maintain MDR event files for the time periods described in this section.

10410.5 If you are a device distributor, you must establish and maintain device complaint records (files). Your records must contain any incident information, including any written, electronic, or oral communication, either received or generated by you, that alleges deficiencies related to the identity (e.g., labeling), quality, durability, reliability, safety, effectiveness, or performance of a device. You must also maintain information about your evaluation of the allegations, if any, in the incident record. You must clearly identify the records as device incident records and file these records by device name. You may maintain these records in written or electronic format. You must back up any file maintained in electronic format.

10410.6 A device distributor shall retain copies of the required device incident records for a period of two (2) years from the date of inclusion of the record in the file or for a period of time equivalent to the expected life of the device, whichever is greater. Copies of these records shall be maintained even if a device is no longer distributed.

10410.7 A device distributor shall maintain the device complaint files established under this section at the principal business establishment. A manufacturer shall maintain the file at the same location where a complaint file is maintained under Chapter 107. Any authorized DOH employee shall, at all reasonable times, have access to copy or verify the records required by this section.

10410.8 A manufacturer shall maintain MDR event files as part of your complaint file, under Chapter 107, if you prominently identify these records as MDR reportable events. We will not consider your submitted MDR report to comply with this part unless you evaluate an event in accordance with the quality system requirements described in Chapter 107. You must document and maintain in your MDR event files an explanation of why you did not submit or could not obtain any information required by this part, as well as the results of your evaluation of each event.

10411 EXEMPTIONS, VARIANCES, AND ALTERNATIVE REPORTING REQUIREMENTS

10411.1 The following persons are exempt from the adverse event reporting requirements of this section:

- (a) A licensed practitioner who prescribes or administers devices intended for use in humans and manufactures or imports devices solely for use in diagnosing and treating persons with whom the practitioner has a "physician-patient" relationship;
- (b) An individual who manufactures devices intended for use in humans solely for the individual's use in research or teaching and not for sale. This includes any person who is subject to alternative reporting requirements under the investigational device exemption regulations, which require reporting of all adverse device effects; and
- (c) Dental laboratories or optical laboratories.

10411.2 If you are a manufacturer, importer, or user facility, you may request an exemption or variance from any or all of the reporting requirements in this section. You must submit the request to the Department in writing. Your request must include information necessary to identify you and the device; a complete statement of the request for exemption, variance, or alternative reporting; and an explanation why your request is justified.

10411.3 The Department may grant, in writing, to a manufacturer, importer, or user facility, an exemption or variance from, or alternative to, any or all of the reporting requirements in this section and may change the frequency of reporting to quarterly, semiannually, annually, or any other appropriate time period. The Department may grant these modifications in response to a request made pursuant to § 10411.2, or at the Department's discretion. When the Department grants modifications to the reporting requirements, we may impose other reporting requirements to ensure the protection of public health.

10411.4 The Department may revoke or modify in writing an exemption, variance, or alternative reporting requirement if the Department determines that revocation or modification is necessary to protect the public health.

10411.5 If the Department grants your request for a reporting modification, you must submit any reports or information required in our approval of the modification. The conditions of the approval will replace and supersede the regular reporting requirement specified in this part until such time that the Department revokes or modifies the alternative reporting requirements in accordance with § 10411.4.

10412 HOW TO REPORT ADVERSE EVENTS

10412.1 If you are a user facility, you must submit MDR reports to:

- (a) The manufacturer and to the Department no later than ten (10) business days after the day that you become aware of information that reasonably suggests that a device has or may have caused or contributed to a death; or
- (b) The manufacturer no later than ten (10) business days after the day that you become aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury. If the manufacturer is not known, you must submit this report to the Department.

10412.2 An importer shall submit MDR reports to:

- (a) The manufacturer and to the Department, no later than thirty (30) calendar days after the day that the importer becomes aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury; or
- (b) The manufacturer, no later than thirty (30) days calendar after receiving information that a device the importer marketed has malfunctioned and that this device or a similar device that the importer marketed would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

10412.3 If you are a manufacturer, you must submit MDR reports to the Department:

- (a) No later than thirty (30) calendar days after the day that you become aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury; or
- (b) No later than thirty (30) calendar days after the day that you become aware of information that reasonably suggests a device has malfunctioned and that this device or a similar device that you market would be likely to

cause or contribute to a death or serious injury if the malfunction were to recur; or

(c) Within five (5) business days if required by § 10422.

10412.4 Any information, including professional, scientific, or medical facts, observations, or opinions, may reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. An MDR reportable event is a death, a serious injury, or, if you are a manufacturer or importer, a malfunction that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

10412.5 If you are a user facility, importer, or manufacturer, you do not have to report an adverse event if you have information that would lead a person who is qualified to make a medical judgment reasonably to conclude that a device did not cause or contribute to a death or serious injury, or that a malfunction would not be likely to cause or contribute to a death or serious injury if it were to recur. Persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomedical engineers. You must keep in your MDR event files the information that the qualified person used to determine whether or not a device-related event was reportable.

10413 WHERE TO FIND REPORTING CODES USED WITH MEDICAL DEVICE REPORTS

10413.1 The Department shall publish adverse events on its website.

10413.2 The Department may sometimes use additional coding of information on the reporting forms or modify the existing codes. If the Department does make modifications, it shall make the new coding information available to all reporters.

10414 WHEN NOT TO FILE A REPORT

10414.1 If you become aware of information from multiple sources regarding the same patient and same reportable event, you may submit one (1) medical device report.

10414.2 You are not required to submit a medical device report if:

(a) You are a user facility, importer, or manufacturer, and you determine that the information received is erroneous in that a device-related adverse event did not occur. You must retain documentation of these reports in your MDR files for the time periods specified in § 10410; or

(b) You are a manufacturer or importer and you did not manufacture or import the device about which you have adverse event information. When you receive reportable event information in error, you must forward this

information to us with a cover letter explaining that you did not manufacture or import the device in question.

10415 INDIVIDUAL ADVERSE EVENT REPORTS: USER FACILITIES

10415.1 If you are a user facility, you must submit reports to the manufacturer or to the Department or both, as specified below:

- (a) When reporting a death, you must submit a report to the Department as soon as practicable but no more than ten (10) work days after the day that you become aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to the death of a patient of your facility. You must also submit the report to the device manufacturer, if known; or
- (b) When reporting a serious injury, you must submit a report to the manufacturer of the device no later than ten (10) work days after the day you become aware of information, from any source, that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of your facility. If the manufacturer is not known, you must submit the report to the Department.

10415.2 You must submit all information required in § 10416 that is reasonably known to you. This information includes information found in documents that you possess and any information that becomes available as a result of reasonable follow-up within your facility. You are not required evaluate or investigate the event by obtaining or evaluating information that you do not reasonably know.

10416 INDIVIDUAL ADVERSE EVENT REPORT DATA ELEMENTS FOR USER FACILITIES

10416.1 A user facility shall include the following information in its report, if reasonably known:

- (a) For patient information, the user facility shall submit the following:
 - (1) The patient's name or other identifier;
 - (2) The patient's age at the time of event, or date of birth;
 - (3) The patient's sex; and
 - (4) The patient's weight;
- (b) For an adverse event or product problem, the user facility shall submit the following:

- (1) Identification of the adverse event or product problem;
 - (2) Outcomes attributed to the adverse event (for example, death or serious injury). An outcome is considered a serious injury if it is:
 - (A) A life-threatening injury or illness;
 - (B) A disability resulting in permanent impairment of a body function or permanent damage to a body structure; or
 - (C) An injury or illness that requires intervention to prevent permanent impairment of a body structure or function;
 - (3) The date of the event;
 - (4) The date of report by the initial reporter;
 - (5) A description of event or problem, including a discussion of how the device was involved, nature of the problem, patient follow-up or required treatment, and any environmental conditions that may have influenced the event;
 - (6) A description of relevant tests, including dates and laboratory data; and
 - (7) A description of other relevant history, including preexisting medical conditions;
- (c) For device information, you must submit the following:
- (1) The brand name;
 - (2) The type of device;
 - (3) The manufacturer's name and address;
 - (4) The operator of the device (health professional, patient, lay user, other);
 - (5) The expiration date;
 - (6) The model, catalog, serial, lot, or other identifying number;
 - (7) The date of device implantation (month, day, and year);
 - (8) The date of device expiration (month, day, and year);

- (9) Whether the device was available for evaluation and whether the device was returned to the manufacturer; if so, the date it was returned to the manufacturer; and
 - (10) Concomitant medical products and therapy dates;
- (d) For initial reporter information, you must submit the following:
- (1) Name, address, and telephone number of the reporter who initially provided information to you, or to the manufacturer or distributor;
 - (2) Whether the initial reporter is a health professional;
 - (3) Occupation; and
 - (4) Whether the initial reporter also sent a copy of the report to the Department, if known; and
- (e) For user facility information, you must submit the following:
- (1) An indication that this is a user facility report (by marking the user facility box on the form);
 - (2) Your user facility number;
 - (3) Your address;
 - (4) Your contact person;
 - (5) Your contact person's telephone number;
 - (6) The date that you became aware of the event (month, day, year);
 - (7) The type of report (initial or follow-up);
 - (8) The report number of the initial report, if a follow-up report;
 - (9) The date of the report (month, day, and year);
 - (10) The approximate age of device;
 - (11) The event problem codes--patient code and device code (refer to the "MEDWATCH Medical Device Reporting Code Instructions");

- (12) Whether a report was sent to the Department and the date it was sent (month, day, and year);
- (13) The location where the event occurred;
- (14) Whether the report was sent to the manufacturer and the date it was sent (month, day, year); and
- (15) The manufacturer's name and address, if available.

10417 ANNUAL REPORTS

10417.1 You must submit to the Department an annual report on in writing or electronic equivalent. You must submit an annual report by January 1 of each year. You must clearly identify your annual report as such. Your annual report must include:

- (a) Your Centers for Medicare & Medicaid (CMS) provider number used for medical device reports, or the number that the Department assigns for reporting purposes;
- (b) Reporting year;
- (c) Your name and complete address;
- (d) The total number of reports attached or summarized;
- (e) The date of the annual report and report numbers identifying the range of medical device reports that you submitted during the report period;
- (f) The name, position title, and complete address of the individual designated as your contact person responsible for reporting to the Department and whether that person is a new contact for you; and
- (g) Information for each reportable event that occurred during the annual reporting period including:
 - (1) The report number;
 - (2) The name and address of the device manufacturer;
 - (3) The device brand name and common name;
 - (4) The product model, catalog, serial and lot numbers;
 - (5) A brief description of the event reported to the manufacturer or the Department; and

- (6) Where the report was submitted (for example, to the manufacturer, importer, or the Department).

10417.2 If you did not submit any medical device reports to manufacturers or us during the time period, you do not need to submit an annual report.

10418 INDIVIDUAL ADVERSE EVENT REPORTING REQUIREMENTS FOR IMPORTERS

10418.1 When reporting deaths or serious injuries, an importer shall submit a report to the Department, and a copy of this report to the manufacturer, as soon as practicable but no later than thirty (30) calendar days after the day that the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that one (1) of the importer's marketed devices may have caused or contributed to a death or serious injury.

10418.2 When reporting malfunctions, an importer shall submit a report to the manufacturer as soon as practicable but no later than thirty (30) calendar days after the day that you receive or otherwise become aware of information from any source, including user facilities, individuals, or through the importer's own research, testing, evaluation, servicing, or maintenance of one of the importer's devices, that reasonably suggests that one (1) of the devices has malfunctioned and that this device or a similar device that you market would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

10419 INDIVIDUAL ADVERSE EVENT REPORT DATA ELEMENTS FOR IMPORTERS

10419.1 You must include the following information in your report, if the information is known or should be known to you:

- (a) For patient information, you must submit the following:
 - (1) The patient's name or other identifier;
 - (2) The patient's age at the time of event, or date of birth;
 - (3) The patient's sex; and
 - (4) The patient's weight;
- (b) For adverse event or product problem, you must submit the following:
 - (1) Identification of the adverse event or product problem;

- (2) Outcomes attributed to the adverse event (for example, death or serious injury). An outcome is considered a serious injury if it is:
 - (A) A life-threatening injury or illness;
 - (B) A disability resulting in permanent impairment of a body function or permanent damage to a body structure; or
 - (C) An injury or illness that requires intervention to prevent permanent impairment of a body structure or function;
 - (3) The date of the event;
 - (4) The date of report by the initial reporter;
 - (5) The description of the event or problem, including a discussion of how the device was involved, nature of the problem, patient follow-up or required treatment, and any environmental conditions that may have influenced the event;
 - (6) A description of relevant tests, including dates and laboratory data; and
 - (7) A description of other relevant patient history, including preexisting medical conditions;
- (c) For device information, you must submit the following:
- (1) The brand name;
 - (2) The type of device;
 - (3) The manufacturer's name and address;
 - (4) The operator of the device (health professional, patient, lay user, other);
 - (5) The expiration date;
 - (6) The model, catalog, serial, lot, or other identifying numbers;
 - (7) The date of device implantation (month, day, and year);
 - (8) The date of device expiration (month, day, and year);

- (9) Whether the device was available for evaluation, and whether the device was returned to the manufacturer, and if so, the date it was returned to the manufacturer; and
 - (10) Concomitant medical products and therapy dates;
- (d) For initial reporter information, you must submit the following:
- (1) The name, address, and telephone number of the reporter who initially provided information to the manufacturer, user facility, or distributor;
 - (2) Whether the initial reporter is a health professional;
 - (3) Occupation; and
 - (4) Whether the initial reporter also sent a copy of the report to the Department, if known; and
- (e) For importer information, you must submit the following:
- (1) An indication that this is an importer report (by marking the importer box on the form);
 - (2) Your importer report number;
 - (3) Your address;
 - (4) Your contact person;
 - (5) Your contact person's telephone number;
 - (6) The date that you became aware of the event (month, day, and year);
 - (7) Type of report (initial or follow-up);
 - (8) The report number of the initial report, if a follow-up report;
 - (9) The date of the report (month, day, and year);
 - (10) The approximate age of the device;
 - (11) The event problem codes;

- (12) Whether a report was sent to the Department and the date it was sent (month, day, and year);
- (13) The location where event occurred;
- (14) Whether a report was sent to the manufacturer and the date it was sent (month, day, and year); and
- (15) The manufacturer's name and address, if available.

10420 INDIVIDUAL ADVERSE EVENT REPORTS REQUIREMENTS FOR MANUFACTURERS

- 10420.1 A manufacturer shall report to the Department no later than thirty (30) calendar days after the day that it receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device that it markets:
- (a) May have caused or contributed to a death or serious injury; or
 - (b) Has malfunctioned and the device or a similar device that it markets would likely cause or contribute to a death or serious injury, if the malfunction were to recur.
- 10420.2 The manufacturer shall submit all information required that is reasonably known to it. The following information is considered to be reasonably known:
- (a) Any information that can be obtained by contacting a user facility, importer, or other initial reporter;
 - (b) Any information in the manufacturer's possession; or
 - (c) Any information that the manufacturer can obtain by analysis, testing, or other evaluation of the device.
- 10420.3 The manufacturer is responsible for obtaining and submitting to the Department information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters.
- 10420.4 The manufacturer is also responsible for investigating each event and evaluating the cause of the event. If the manufacturer cannot submit complete information in a report, it shall provide a statement explaining why this information is incomplete and the steps it took to obtain the information. If the manufacturer later obtains any required information that was not available at the time it filed the initial report, it shall submit this information in a supplemental report.

10421 INDIVIDUAL ADVERSE EVENT REPORT DATA ELEMENTS FOR MANUFACTURERS

10421.1 You must include the following information in your reports, if known or reasonably known to your patient information, you must submit the following:

- (a) The patient's name or other identifier;
- (b) The patient's age at the time of event, or date of birth;
- (c) The patient's sex; and
- (d) The patient's weight;

10421.2 For an adverse event or product problem, you must submit the following:

- (a) Identification of the adverse event or product problem;
- (b) The outcomes attributed to the adverse event (for example, death or serious injury). An outcome is considered a serious injury if it is:
 - (1) Life-threatening injury or illness;
 - (2) A disability resulting in permanent impairment of a body function or permanent damage to a body structure; or
 - (3) Injury or illness that requires intervention to prevent permanent impairment of a body structure or function;
 - (4) The date of the event;
 - (5) The date of report by the initial reporter;
 - (6) A description of the event or problem, including a discussion of how the device was involved, nature of the problem, patient follow-up or required treatment, and any environmental conditions that may have influenced the event;
 - (7) A description of relevant tests, including dates and laboratory data; and
 - (8) Any other relevant patient history including preexisting medical conditions.

10421.3 For device information, you must submit the following:

- (a) The brand name;
- (b) The type of device;
- (c) Your name and address;
- (d) The operator of the device (health professional, patient, lay user, other);
- (e) The expiration date;
- (f) The model, catalog, serial, lot, or other identifying numbers;
- (g) The date of device implantation (month, day, and year);
- (h) The date of device explanation (month, day, and year);
- (i) Whether the device was available for evaluation, and whether the device was returned to you, and if so, the date it was returned to you; and
- (j) Concomitant medical products and therapy dates.

10421.4 For initial reporter information, you must submit the following:

- (a) Name, address, and phone number of the reporter who initially provided information to you, or to the user facility or importer;
- (b) Whether the initial reporter is a health professional;
- (c) Occupation; and
- (d) Whether the initial reporter also sent a copy of the report to the Department, if known.

10421.5 When reporting information for all manufacturers, you must submit the following:

- (a) Your reporting office's contact name and address and device manufacturing site;
- (b) Your telephone number;
- (c) Your report sources;
- (d) The date received by you (month, day, and year);
- (e) The type of report being submitted (for example, five (5) day, initial, or follow-up); and

- (f) Your report number.

10421.6 For device manufacturer information, you must submit the following:

- (a) The type of reportable event (death, serious injury, or malfunction);
- (b) The type of follow-up report, if applicable (such as, correction or a response to the Department's request);
- (c) If the device was returned to you and evaluated by you, you must include a summary of the evaluation. If you did not perform an evaluation, you must explain why you did not perform an evaluation;
- (d) The device manufacture date (month, day, and year);
- (e) Whether the device was labeled for single use;
- (f) The evaluation codes (including event codes, method of evaluation, result, and conclusion codes);
- (g) Whether remedial action was taken and the type of action;
- (h) Whether the use of the device was initial, reuse, or unknown;
- (i) Whether remedial action was reported as a removal or correction, and if it was, provide the correction or removal report number; and
- (j) Your additional narrative; or
- (k) Corrected data, including:
 - (1) Any information missing on the user facility report or importer report, including any event codes that were not reported or information corrected on these forms after your verification;
 - (2) For each event code provided by the user facility, under § 10416.1(e)(10) or the importer under § 10419.1(e)(10), you must include a statement of whether the type of the event represented by the code is addressed in the device labeling; and
 - (3) If your report omits any required information, you must explain why this information was not provided and the steps taken to obtain this information.

10422

FIVE (5)-DAY REPORTS FOR MANUFACTURERS

10422.1 You must submit a five (5)-day report to us no later than five (5) work days after the day that you become aware of:

- (a) An MDR reportable event that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. The manufacturer may become aware of the need for remedial action from any information, including any trend analysis; or
- (b) A written request by the Department for the submission of a five (5)-day report. If you receive such a written request from the Department, you must submit, without further request, a five (5)-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. We may extend the time period stated in the original written request if we determine it is in the interest of the public health.

10423 SUPPLEMENTAL REPORTS

10423.1 If you are a manufacturer, when you obtain information that you did not provide because it was not known or was not available when you submitted the initial report, you must submit the supplemental information to the Department within one (1) month of the day that you receive this information. On a supplemental or follow-up report, you must:

- (a) Indicate on the envelope and in the report that the report being submitted is a supplemental or follow-up report;
- (b) Submit the appropriate identification numbers of the report that you are updating with the supplemental information (for example, your original manufacturer report number and the user facility or importer report number of any report on which your report was based), if applicable; and
- (c) Include only the new, changed, or corrected information in the appropriate portion(s) of the respective form(s) for reports that cross reference previous reports.

10424 FOREIGN MANUFACTURERS

10424.1 Every foreign manufacturer whose devices are distributed in the United States shall designate a U.S. agent to be responsible for reporting in accordance with § 10510 of this subtitle. The designated agent accepts responsibility for the duties that such designation entails. Upon the effective date of these regulations, foreign manufacturers shall inform the Department, by letter, of the name and address of the agent designated under this section and § 10510 of this subtitle, and shall update this information as necessary. Such updated information shall be submitted

to the Department, within five (5) days of a change in the designated agent information.

10424.2 Designated agents of foreign manufacturers are required to:

- (a) Report to the Department in accordance with §§ 10420, 10421, 10422, and 10423;
- (b) Conduct or obtain from the foreign manufacturer the necessary information regarding the investigation and evaluation of the event to comport with the requirements of § 10420;
- (c) Forward MDR complaints to the foreign manufacturer and maintain documentation of this requirement;
- (e) Maintain complaint files in accordance with § 10410; and
- (f) Register, list, and submit premarket notifications in accordance with Chapter 105.

10499 DEFINITIONS

10499.1 As used in this chapter, the following terms and phrases shall have the meanings ascribed:

Ambulatory surgical facility (ASF) –a distinct entity that operates for the primary purpose of furnishing same-day outpatient surgical services to patients. An ASF may be either an independent entity (for example, not a part of a provider of services or any other facility) or operated by another medical entity (such as under the common ownership, licensure, or control of an entity). An ASF is subject to this regulation regardless of whether it is licensed by a Federal, state, municipal, or local government or regardless of whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the ASF must report that event regardless of the nature or location of the medical service provided by the ASF.

Become aware – an employee of the entity required to report has acquired information reasonably suggesting a reportable adverse event has occurred in the following situations:

- (a) Device user facilities are considered to have “become aware” when medical personnel as defined under the term “medical personnel” who are employed by or otherwise formally affiliated with the facility acquire such information about a reportable event;
- (b) Manufacturers are considered to have become aware of an event when:

- (1) Any employee becomes aware of a reportable event that is required to be reported within thirty (30) days or that is required; or to be reported within five (5) days under a written request; and
 - (2) Any employee, who is a person with management or supervisory responsibilities over persons with regulatory, scientific, or technical responsibilities, or a person whose duties relate to the collection and reporting of adverse events, becomes aware that a reportable MDR event or events, from any information, including any trend analysis, necessitate remedial action to prevent an unreasonable risk of substantial harm to the public health; and
- (c) Importers are considered to have become aware of an event when any employee becomes aware of a reportable event.

Caused or contributed – a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of:

- (a) Failure;
- (b) Malfunction;
- (c) Improper or inadequate design;
- (d) Manufacture;
- (e) Labeling; or
- (f) User error.

Device family - a group of one (1) or more devices manufactured by or for the same manufacturer and having the same:

- (a) Basic design and performance characteristics related to device safety and effectiveness;
- (b) Intended use and function;
- (c) Device classification and product code; and
- (d) Devices that differ only in minor ways not related to safety or effectiveness can be considered to be in the same device family. Factors such as brand name and common name of the device and whether the devices were introduced into commercial distribution under 21 U.S.C.

§ 351(k) or premarket approval application (PMA), may be considered in grouping products into device families.

Device user facility – a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility which is not a “physician's office.” School nurse offices and employee health units are not device user facilities.

Distributor – means any person (other than the manufacturer or importer) who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. One who repackages or otherwise changes the container, wrapper, or labeling is a manufacturer under this definition.

Expected life of a device – means the time that a device is expected to remain functional after it is placed into use. Certain implanted devices have specified “end of life” (EOL) dates. Other devices are not labeled as to their respective EOL, but are expected to remain operational through maintenance, repair, and upgrades for an estimated period of time.

Five (5)-day report – a medical device report that must be submitted by a manufacturer within five (5) business days.

Hospital – a distinct entity that operates for the primary purpose of providing diagnostic, therapeutic (medical, occupational, speech, physical), surgical, and other patient services for specific and general medical conditions. Hospitals include general, chronic disease, rehabilitative, psychiatric, and other special-purpose facilities. A hospital may be either independent (that is, not a part of a provider of services or any other facility) or may be operated by another medical entity (such as under the common ownership, licensure, or control of another entity). A hospital is covered by this regulation regardless of whether it is licensed by the District and regardless of whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the hospital must report that event regardless of the nature or location of the medical service provided by the hospital.

Importer – any person who imports a device into the District of Columbia and who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package.

Malfunction – the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims

made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed.

Manufacturer – any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. The term includes any person who:

- (a) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture;
- (b) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications;
- (c) Manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient; or
- (d) Is the U.S. agent of a foreign manufacturer.

MDR – medical device report.

MDR reportable event (or reportable event) – an event about which user facilities:

- (a) Become aware of information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury; or
- (b) An event about which manufacturers or importers have received or become aware of information that reasonably suggests that one (1) of their marketed devices:
 - (1) May have caused or contributed to a death or serious injury; or
 - (2) Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause a death or serious injury if the malfunction were to recur.

Medical personnel – an individual who:

- (a) Is licensed, registered, or certified by a State, territory, or other governing body to administer health care;
- (b) Has received a diploma or a degree in a professional or scientific discipline;

- (c) Is an employee responsible for receiving medical complaints or adverse event reports; or
- (d) Is a supervisor of such persons.

Nursing home – an independent entity (that is, not a part of a provider of services or any other facility) or one operated by another medical entity (such as under the common ownership, licensure, or control of an entity) that operates for the primary purpose of providing:

- (a) Skilled nursing care and related services for persons who require medical or nursing care;
- (b) Hospice care to the terminally ill; or
- (c) Services for the rehabilitation of the injured, disabled, or sick.

A nursing home is subject to this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the nursing home must report that event regardless of the nature or location of the medical service provided by the nursing home.

Outpatient diagnostic facility – a distinct entity that:

- (a) Operates for the primary purpose of conducting medical diagnostic tests on patients;
- (b) Does not assume ongoing responsibility for patient care; and
- (c) Provides its services for use by other medical personnel.
- (d) Examples include diagnostic radiography, mammography, ultrasonography, electrocardiography, magnetic resonance imaging, computerized axial tomography, and in-vitro testing. An outpatient diagnostic facility may be either independent (that is, not a part of a provider of services or any other facility) or operated by another medical entity (such as under the common ownership, licensure, or control of an entity). An outpatient diagnostic facility is covered by this regulation regardless of whether it is licensed by a Federal, State, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient diagnostic facility must report that event regardless of the nature or location of the medical service provided by the outpatient diagnostic facility.

Outpatient treatment facility – a distinct entity that operates for the primary purpose of providing nonsurgical therapeutic (medical, occupational, or physical) care on an outpatient basis or home health care setting.

- (a) Outpatient treatment facilities include ambulance providers, rescue services, and home health care groups. Examples of services provided by outpatient treatment facilities include:
 - (1) Cardiac defibrillation;
 - (2) Chemotherapy;
 - (3) Radiotherapy;
 - (4) Pain control;
 - (5) Dialysis;
 - (6) Speech or physical therapy; and
 - (7) Treatment for substance abuse;
- (b) An outpatient treatment facility may be either independent (that is, not a part of a provider of services or any other facility) or operated by another medical entity (such as under the common ownership, licensure, or control of an entity). An outpatient treatment facility is covered by this regulation regardless of whether it is licensed by a Federal, state, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient treatment facility must report that event regardless of the nature or location of the medical service provided by the outpatient treatment facility.

Patient of the facility – any individual who is being diagnosed or treated, or receiving medical care at or under the control or authority of the facility. For the purposes of this chapter, the definition encompasses employees of the facility or individuals affiliated with the facility, who in the course of their duties suffer a device-related death or serious injury that has or may have been caused or contributed to by a device used at the facility.

Physician's office – a facility that operates as the office of a physician or other health care professional (such as, dentist, chiropractor, optometrist, nurse practitioner, school nurse offices, school clinics, employee health clinics, or free-standing care units) for the primary purpose of examination, evaluation, and

treatment or referral of patients. A physician's office may be independent, a group practice, or part of a Health Maintenance Organization.

Permanent – impairment or damage to a body structure or function, excluding trivial impairment or damage.

Remedial action – any action other than routine maintenance or servicing of a device where such action is necessary to prevent recurrence of a reportable event.

Serious injury – an injury or illness that:

- (a) Is life-threatening;
- (b) Results in permanent impairment of a body function or permanent damage to body structure; or
- (c) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

Shelf life – as required on the manufacturer's baseline report, means the maximum time a device will remain functional from the date of manufacture until it is used in patient care. Some devices have an expiration date on their labeling indicating the maximum time they can be stored before losing their ability to perform their intended function.

Chapter 105 (Establishment Registration and Device Listing for Manufacturer and Initial Importers of Devices) is added to read as follows:

**CHAPTER 105 ESTABLISHMENT REGISTRATION AND
DEVICE LISTING FOR MANUFACTURER AND
INITIAL IMPORTERS OF DEVICES**

10500 WHO MUST REGISTER AND SUBMIT A DEVICE LIST

10500.1 An owner or operator of an establishment not exempt under Section 510(g) of the Act or § 10512 of this chapter who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use shall register and submit listing information for those devices in commercial distribution, except that registration and listing information may be submitted by the parent, subsidiary, or affiliate company for all the domestic or foreign establishments under the control of one (1) of these organizations when operations are conducted at more than one (1) establishment and there exists joint ownership and control among all the establishments. The term “device” includes all in vitro diagnostic products and in vitro diagnostic biological products not subject to licensing under the Public Health Service Act, 42 U.S.C. § 262.

- 10500.2 An owner or operator of an establishment located in the District shall register its name, place of business, and all establishments, and list the devices whether or not the output of the establishments or any particular device so listed enters interstate commerce. The registration and listing requirements shall pertain to any person who:
- (a) Initiates or develops specifications for a device that is to be manufactured by a second party for commercial distribution by the person initiating specifications;
 - (b) Manufactures for commercial distribution a device either for itself or for another person. However, a person who only manufactures devices according to another person's specifications, for commercial distribution by the person initiating specifications, is not required to list those devices;
 - (c) Repackages or re-labels a device;
 - (d) Acts as an initial importer; or
 - (e) Manufactures components or accessories which are ready to be used for any intended health-related purpose and are packaged or labeled for commercial distribution for such health-related purpose (for example, blood filters, hemodialysis tubing) or devices which of necessity must be further processed by a licensed practitioner or other qualified person to meet the needs of a particular patient (such as, a manufacturer of ophthalmic lens blanks).
- 10500.3 Registration or listing does not constitute an admission or agreement or determination that a product is a device within the meaning of Section 201(h) of the Act.
- 10500.4 Registration and listing requirements shall not pertain to any person who:
- (a) Manufacturers devices for another party who both initiated the specifications and commercially distributes the device;
 - (b) Sterilizes devices on a contract basis for other registered facilities who commercially distributes the devices; or
 - (c) Acts as a wholesale distributor and who does not manufacture, repackage, process, or re-label a device.
- 10500.5 Owners and operators of establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human cells, tissues, and cellular and tissue-based products that are regulated under the Federal Food, Drug, and Cosmetic Act must register and list those human cells, tissues, and

cellular and tissue-based products following the procedures set out in this chapter, instead of the procedures for registration and listing contained in this section, except that the additional listing information requirements in § 10506 remain applicable.

10501 TIME FOR ESTABLISHMENT REGISTRATION AND DEVICE LISTING

10501.1 An owner or operator of an establishment who has not previously entered into an operation shall register within thirty (30) days after entering into such an operation and submit device listing information at that time. An owner or operator of an establishment shall update its registration information annually within thirty (30) days after receiving registration forms. The Department of Health shall mail forms to the owners or operators of registered establishments according to a schedule based on the first letter of the name of the owner or operator. The schedule is as follows:

First letter of owner or operator name	Date DOH will mail forms
A, B, C, D, E	March
F, G, H, I, J, K, L, M	June
N, O, P, Q, R	August
S, T, U, V, W, X, Y, Z	November

10501.2 Owners or operators of all registered establishments shall update their device listing information every June and December or, at their discretion, at the time the change occurs.

10502 HOW AND WHERE TO REGISTER ESTABLISHMENTS AND LIST DEVICES

10502.1 The first registration of a device establishment shall be on Form FDA-2891 (Initial Registration of Device Establishment) or a similar form supplied by the Department. Subsequent annual registration shall be accomplished on Form FDA-2891a (Annual Registration of Device Establishment), furnished by the FDA, or a similar form furnished by the Department to establishments whose registration for that year was validated under § 10507.1. The forms shall be mailed to the owner or operators of all establishments via the official correspondent in accordance with the schedule as described in § 10501.1. The completed form shall be mailed no later than thirty (30) days after receipt from DOH.

10502.2 The initial listing of devices and subsequent June and December updates shall be on form FDA-2892 (Medical Device Listing) or similar form furnished by the Department. A separate form FDA-2892 or similar Department form shall be submitted for each device or device class listed with the Department. Devices having variations in physical characteristics such as size, packaging, shape, color, or composition should be considered to be one (1) device; provided, the variation does not change the function or intended use of the device.

10502.3 The listing obligations of the initial importer are satisfied as follows:

- (a) The initial importer is not required to submit a form FDA-2892 or its Department equivalent for those devices for which such initial importer did not initiate or develop the specifications for the device or repackage or re-label the device. However, the initial importer shall submit, for each device, the name and address of the manufacturer. Initial importers shall also be prepared to submit, when the Department requests, the proprietary name, if any, and the common or usual name of each device for which they are the initial importers; and
- (b) The initial importer shall update the information at the intervals specified in § 10505.

10503 INFORMATION REQUIRED OR REQUESTED FOR ESTABLISHMENT REGISTRATION AND DEVICE LISTING

10503.1 Form FDA-2891 and Form FDA-2891a or their Department equivalents are the approved forms for initially providing the information required by the Act and for providing annual registration, respectively. The required information includes the name and street address of the device establishment, including zip code, all trade names that the establishment uses, and the business trading name of the owner or operator of such establishment.

10503.2 The owner or operator shall identify the device activities of the establishment such as manufacturing, repackaging, or distributing devices.

10503.3 Each owner or operator is required to maintain a listing of all officers, directors, and partners for each establishment the owner or operator registers and to furnish this information to the Department upon request.

10503.4 Each owner or operator shall provide the name of an official correspondent who will serve as a point of contact between the Department and the establishment for matters relating to the registration of device establishments and the listing of device products. All correspondence relating to registration, including requests for the names of partners, officers, and directors, will be directed to the official correspondent. In the event no person is designated by the owner or operator, the

owner or operator of the establishment shall be the official correspondent.

10503.5 The designation of an official correspondent does not in any manner affect the liability of the owner or operator of the establishment or any other individual under 21 U.S.C. §§ 331(p) or any other provision of the Act.

10503.6 Form FDA-2892 or its Department equivalent is the approved form for providing the device listing information required by the Act. This required information includes the following:

- (a) The identification by classification name and number, proprietary name, and common or usual name of each device being manufactured, prepared, propagated, compounded, or processed for commercial distribution that has not been included in any list of devices previously submitted on form FDA-2892 or its Department equivalent;
- (b) The Code of Federal Regulations citation for any applicable standard for the device under 21 U.S.C. § 360d or 42 U.S.C. §§ 263f;
- (c) The Code of Federal Regulations or DOH citation for any applicable standard for the device under 21 U.S.C. §§ 360d or 42 U.S.C. §§ 263f;
- (d) The assigned FDA number or DOH number of the approved application for each device listed that is subject to 21 U.S.C. §§ 355 or 360e;
- (e) The name, registration number, and establishment type of every domestic or foreign device establishment under joint ownership and control of the owner or operator at which the device is manufactured, repackaged, or relabeled;
- (f) Whether the device, as labeled, is intended for distribution to and use by the general public;
- (g) Other general information requested on form FDA-2892 or its Department equivalent, such as:
 - (1) If the submission refers to a previously listed device, as in the case of an update, the document number from the initial listing document for the device;
 - (2) The reason for submission;
 - (3) The date on which the reason for submission occurred;

- (4) The date that the form FDA-2892 or its Department equivalent, was completed; and
- (5) The owner's or operator's name and identification number; and
- (h) Labeling or other descriptive information (for example, specification sheets or catalogs) adequate to describe the intended use of a device when the owner or operator is unable to find an appropriate Department classification name for the device.

10504 AMENDMENTS TO ESTABLISHMENT REGISTRATION

10504.1 Changes in individual ownership, corporate or partnership structure, or location of an operation shall be submitted on Form FDA-2891a or its Department equivalent at the time of annual registration, or by letter if the changes occur at other times. This information shall be submitted within thirty (30) days of such changes. Changes in the names of officers or directors of the corporation(s) shall be filed with the establishment's official correspondent and shall be provided to the Department upon receipt of a written request for this information.

10505 UPDATING DEVICE LISTING INFORMATION

10505.1 Form FDA-2892 or its Department equivalent shall be used to update device listing information. The preprinted original document number of each form FDA-2892 or its Department equivalent on which the device was initially listed shall appear on the form subsequently used to update the listing information for the device and on any correspondence related to the device.

10505.2 An owner or operator shall update the device listing information during each June and December or, at its discretion, at the time the change occurs. Conditions that require updating and information to be submitted for each of these updates are as follows:

- (a) If an owner or operator introduces into commercial distribution a device identified with a classification name not currently listed by the owner or operator, then the owner or operator must submit form FDA-2892 or its Department equivalent containing all the information required by § 10503.6;
- (b) If an owner or operator discontinues commercial distribution of all devices in the same device class (for example, with the same classification name), the owner or operator must submit a form containing the original document number on which the device class was initially listed, the reason for submission, the date of discontinuance, the owner or operator's name and identification number, the classification name and number, the proprietary name, and the common or usual name of the discontinued

device.

- (c) If commercial distribution of a discontinued device identified on a form filed under this section is resumed, the owner or operator must submit a notice of resumption containing:
 - (1) The original document number of the form initially used to list that device class;
 - (2) The reason for submission;
 - (3) The date of resumption; and
 - (4) All other information required.
- (d) If one (1) or more classification names for a previously listed device with multiple classification names has been added or deleted, the owner or operator must supply the original document number on which the device was initially listed and a supplemental sheet identifying the names of any new or deleted classification names.
- (e) Other changes to information will be updated as follows:
 - (1) Whenever a change occurs only in the owner or operator name or number (for example, whenever one company's device line is purchased by another owner or operator) it will not be necessary to supply a separate form for each device. In such cases, the new owner or operator must submit a letter informing the Department of the original document number on which device was initially listed for those devices affected by the change in ownership;
 - (2) The owner or operator must also submit update information whenever establishment registration numbers, establishment names, or activities are added to or deleted. The owner or operator must supply the original document number on which the device was initially listed, the reason for submission, and all other information required.
- (f) Updating is not required if the above information has not changed since the previously submitted list. Also, updating is not required if changes occur in proprietary names, in common or usual names, or to supplemental lists of unclassified components or accessories.

10506

ADDITIONAL LISTING INFORMATION

- 10506.1 Each owner or operator shall maintain a historical file containing the labeling and advertisements in use on the date of initial listing, and in use after October 10, 1978, but before the date of initial listing, as follows:
- (a) For each device subject to 21 U.S.C. §§ 360d or 360e of the act that is not a restricted device, a copy of all labeling for the device;
 - (b) For each restricted device, a copy of all labeling and advertisements for the device; and
 - (c) For each device that is neither restricted nor subject to 21 U.S.C. §§ 360d or 360e of the act, a copy of all labels, package inserts, and a representative sampling of any other labeling.
- 10506.2 In addition to the requirements set forth in this section, each owner or operator shall maintain in the historical file any labeling or advertisements in which a material change has been made any time after initial listing.
- 10506.3 Each owner or operator may discard labeling and advertisements from the historical file three (3) years after the date of the last shipment of a discontinued device by an owner or operator.
- 10506.4 Location of the file:
- (a) Currently existing systems for maintenance of labeling and advertising may be used for the purpose of maintaining the historical file as long as the information included in the systems fulfills the requirements of this section, but only if the labeling and advertisements are retrievable in a timely manner;
 - (b) The contents of the historical file may be physically located in more than one (1) place in the establishment or in more than one (1) establishment provided there exists joint ownership and control among all the establishments maintaining the historical file. If no joint ownership and control exists, the registered establishment must provide the Department with a letter authorizing the establishment outside its control to maintain the historical file; and
 - (c) A copy of the certification and disclosure statements as required by this chapter shall be retained and physically located at the establishment maintaining the historical file.
- 10506.5 Each owner or operator shall be prepared to submit to the Department, only upon specific request, the following information:
- (a) For a device subject to 21 U.S.C. §§ 360d or 360e of the act, that is not a

restricted device, a copy of all labeling for the device;

- (b) For a device that is a restricted device, a copy of all labeling for the device, a representative sampling of advertisements for the device, and for good cause, a copy of all advertisements for a particular device. A request for all advertisements will, where feasible, be accompanied by an explanation of the basis for such request;
- (c) For a device that is not a restricted device, the label and package insert for the device and a representative sampling of any other labeling for the device;
- (d) For a particular device, a statement of the basis upon which the registrant has determined the device is not a restricted device pursuant to 21 U.S.C. §§ 360d or 360e;
- (e) For a particular device, a statement of the basis for determining that the product is a device rather than a drug; or
- (f) For a device that the owner or operator has manufactured for distribution under a label other than its own, the names of all distributors for whom it has been manufactured.

10507 NOTIFICATION OF REGISTRANT

10507.1 The Department will provide to the official correspondent, at the address listed on the form, a validated copy of Form FDA-2891 or Form FDA-2891a (whichever is applicable) or their Department equivalent as evidence of registration. A permanent registration number will be assigned to each device establishment registered in accordance with these regulations.

10507.2 Owners and operators of device establishments who also manufacture or process blood or drug products at the same establishment shall also register with the Department.

10507.3 Although establishment registration and device listing are required to engage in the device activities described in § 10500, validation of registration and the assignment of a device listing number in itself does not establish that the holder of the registration is legally qualified to deal in such devices and does not represent a determination by the Department of Health as to the status of any device.

10508 INSPECTION OF ESTABLISHMENT REGISTRATION AND DEVICE LISTING

10508.1 A copy of the forms FDA-2891 that the registrant files shall be available for inspection at the Department. Upon request, verification of registration number

or location of a registered establishment shall be provided.

10508.2 The following information filed under the device listing requirements will be available for public disclosure:

- (a) Each form FDA-2892 or its Department equivalent submitted;
- (b) All labels submitted;
- (c) All labeling submitted;
- (d) All advertisements submitted; and
- (e) All data or information that has already become a matter of public knowledge.

10508.3 Requests for device listing information identified in § 10508.2 of this section shall be directed to the Department.

10508.4 Requests for device listing information not identified in § 10508.2 shall be submitted and handled as specified in these regulations.

**10509 MISBRANDING BY REFERENCE TO ESTABLISHMENT
REGISTRATION OR TO REGISTRATION NUMBER**

10509.1 Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding.

**10510 ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR U.S.
AGENTS OF FOREIGN MANUFACTURERS OF DEVICES**

10510.1 Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States shall register and list such devices in conformance with the requirements in 21 C.F.R. § 807.20, *et seq.*, unless the device enters a foreign trade zone and is re-exported from that foreign trade zone without having entered U. S. commerce. The official correspondent for the foreign establishment shall facilitate communication between the foreign establishment's management and representatives of the Department of Health for matters relating to the registration of device establishments and the listing of device products.

- 10510.2 Each foreign establishment required to register under § 10510.1 of this section shall submit the name, address, and phone number of its United States agent as part of its initial and updated registration information in accordance with 21 C.F.R. § 807.20, *et seq.* Each foreign establishment shall designate only one United States agent and may designate the United States agent to act as its official correspondent.
- 10510.3 The United States agent shall reside or maintain a place of business in the United States.
- 10510.4 Upon request from the Department, the United States agent shall assist DOH in communications with the foreign establishment, respond to questions concerning the foreign establishment's products that are imported or offered for import into the United States, and assist the Department in scheduling inspections of the foreign establishment. If the agency is unable to contact the foreign establishment directly or expeditiously, the Department may provide information or documents to the United States agent, and such an action shall be considered to be equivalent to providing the same information or documents to the foreign establishment.
- 10510.5 The foreign establishment or the United States agent shall report changes in the United States agent's name, address, or phone number to the Department within ten (10) business days of the change.
- 10510.6 No device may be imported or offered for import into the United States unless it is the subject of a device listing as required under 21 C.F.R. § 807.20, *et seq.* and is manufactured, prepared, propagated, compounded, or processed at a registered foreign establishment; however, this restriction does not apply to devices imported or offered for import under the investigational use provisions of this chapter or to a component, part, or accessory of a device or other article of a device imported under the Act. The establishment registration and device listing information shall be in the English language.

10511 EXEMPTIONS FOR DEVICE ESTABLISHMENTS

- 10511.1 The following classes of persons are exempt from registration in accordance with § 10500 in accordance with the provisions of 21 U.S.C. § 360 (g)(1), (g)(2), and g(3) because such registration is not necessary for the protection of the public health. The exemptions are limited to those classes of persons located in the District as defined in the Act:
- (a) A manufacturer of raw materials or components to be used in the manufacture or assembly of a device who would otherwise not be required to register under the provisions of 21 C.F.R. § 807.65;
 - (b) A manufacturer of devices to be used solely for veterinary purposes;

- (c) A manufacturer of general purpose articles such as chemical reagents or laboratory equipment whose uses are generally known by persons trained in their use and which are not labeled or promoted for medical uses;
- (d) Licensed practitioners, including physicians, dentists, and optometrists, who manufacture or otherwise alter devices solely for use in their practice;
- (e) Pharmacies, surgical supply outlets, or other similar retail establishments making final delivery or sale to the ultimate user. This exemption also applies to a pharmacy or other similar retail establishment that purchases a device for subsequent distribution under its own name (for example, a properly labeled health aid such as an elastic bandage or crutch) indicating "distributed by" or "manufactured for" followed by the name of the pharmacy;
- (f) Persons who manufacture, prepare, propagate, compound, or process devices solely for use in research, teaching, or analysis and do not introduce such devices into commercial distribution;
- (g) Carriers by reason of their receipt, carriage, holding, or delivery of devices in the usual course of business as carriers; or
- (h) Persons who dispense devices to the ultimate consumer or whose major responsibility is to render a service necessary to provide the consumer (for example, patient, physician, and layman) with a device or the benefits to be derived from the use of a device; for example, a hearing aid dispenser, optician, clinical laboratory, assembler of diagnostic X-ray systems, and personnel from a hospital, clinic, dental laboratory, orthotic or prosthetic retail facility, whose primary responsibility to the ultimate consumer is to dispense or provide a service through the use of a previously manufactured device.

10512 WHEN A PREMARKET NOTIFICATION SUBMISSION IS REQUIRED

10512.1 Except as provided otherwise, each person who is required to register his or her establishment pursuant to § 10500 must submit a premarket notification submission to the Department at least ninety (90) days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use which meets any of the following criteria:

- (a) The device is being introduced into commercial distribution for the first time; that is, the device is not of the same type as, or is not substantially equivalent to:
 - (1) A device in commercial distribution before May 28, 1976, or;

(2) A device introduced for commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II.

(b) The device is being introduced into commercial distribution for the first time by a person required to register, whether or not the device meets the criteria in paragraph (a) of this subsection; or

(c) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitutes significant changes or modifications that require a premarket notification:

(1) A change or modification in the device that could significantly affect the safety or effectiveness of the device (such as, a significant change or modification in design, material, chemical composition, energy source, or manufacturing process); or

(2) A major change or modification in the intended use of the device.

10512.2 A premarket notification under 21 C.F.R. § 807.81 is not required for a device for which a premarket approval application under Section 515 of the Act, or for which a petition to reclassify under Section 513 of the Act, is pending before the Department of Health.

10512.3 The appropriate Department employee may determine that the submission and grant of a written request for an exception or alternative satisfies the requirement in § 10512.1(c).

10512.4 In addition to complying with the requirements of this part, owners or operators of device establishments that manufacture radiation-emitting electronic products, as defined in the Act, shall comply with the reporting requirements of this chapter.

10513 EXEMPTION FROM PREMARKET NOTIFICATION

10513.1 A device is exempt from the premarket notification requirements of 21 C.F.R. § 807.85 if the device intended for introduction into commercial distribution is not generally available in finished form for purchase and is not offered through labeling or advertising by the manufacturer, importer, or distributor thereof for commercial distribution, and the device meets one (1) of the following conditions:

(a) It is intended for use by a patient named in the order of the physician or dentist (or other specially qualified person); or

- (b) It is intended solely for use by a physician or dentist (or other specially qualified person) and is not generally available to, or generally used by, other physicians or dentists (or other specially qualified persons).

10513.2 A distributor who places a device into commercial distribution for the time under his own name and a re-packager who places his or her own name on a device and does not change any other labeling or otherwise affect the device shall be exempt from the premarket notification requirements of 21 C.F.R. § 807.85 if:

- (a) The device was in commercial distribution before May 28, 1976; or
- (b) Another person filed the premarket notification on submission.

10514 INFORMATION REQUIRED IN A PREMARKET MODIFICATION SUBMISSION

10514.1 Each premarket notification submission shall contain the following information:

- (a) The device name, including both the trade or proprietary name and the common or usual name or classification name of the device;
- (b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission;
- (c) The class in which the device has been put under 21 U.S.C. § 360c and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basis for the person's determination that the device is not so classified;
- (d) Action taken by the person required to register to comply with the requirements under 21 U.S.C. § 360d for performance standards;
- (e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied;
- (f) A statement indicating the device is similar to or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device;
- (g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or

modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device;

- (h) A 21 U.S.C. § 360(k) summary as described in § 10517 or a 21 U.S.C. § 360(k) statement as described in § 10518;
- (i) A financial certification or disclosure statement or both;
- (j) For submissions claiming substantial equivalence to a device which has been classified into class III under the Act:
 - (1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990; and
 - (2) For which no final regulation requiring premarket approval has been issued under 21 U.S.C. § 360e(b), a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III summary). The 21 U.S.C. § 360(k) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (class III certification), as described in § 10518. This information does not refer to information that already has been submitted to the Department under the Act. Department may require the submission of the adverse safety and effectiveness data described in the class III summary or citation;
- (k) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification is truthful and accurate and that no material fact has been omitted; and
- (l) Any additional information regarding the device requested by the DOH that is necessary for the Department to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient information contained in the original premarket notification submission for the Department to make this determination and that the owner or operator may either submit the requested data or a new premarket notification containing the requested

information at least ninety (90) days before the owner or operator intends to market the device, or submit a premarket approval application in accordance with 21 U.S.C. § 360e. If the additional information is not submitted within thirty (30) days following the date of the request, the Department will consider the premarket notification to be withdrawn.

10515 FORMAT OF A PREMARKET NOTIFICATION SUBMISSION

10515.1 Each premarket notification submission pursuant to this chapter shall be submitted in accordance with this section. Each submission shall:

- (a) Be addressed to the Department of Health, 899 North Capitol Street, NE, Washington, DC 20002; and
- (b) Be in writing and sent to the addresses above if it is an inquiry regarding a premarket notification submission.

10515.2 The premarket notification submission shall be:

- (a) Bound into a volume or volumes, where necessary;
- (b) Submitted in duplicate on standard size paper, including the original and two copies of the cover letter;
- (c) Submitted separately for each product the manufacturer intends to market; and
- (d) Designated "21 U.S.C. § 360(k) Notification" in the cover letter.

10516 CONTENT AND FORMAT OF A 21 U.S.C. § 360(k) SUMMARY

10516.1 A 21 U.S.C. § 360(k) summary shall be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence. The Department will accept summaries as well as amendments thereto until such time as the Department issues a determination of substantial equivalence. All 21 U.S.C. § 360(k) summaries shall contain the following information:

- (a) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;
- (b) The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;
- (c) An identification of the legally marketed device to which the submitter claims equivalence. A legally marketed device to which a new device may

be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device which has been found to be substantially equivalent through the 21 U.S.C. § 360(k) premarket notification process;

- (d) A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties;
- (e) A statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. If the indication statements are different from those of the legally marketed device identified in paragraph (c) in this subsection, the 21 U.S.C. § 360(k) summary shall contain an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled; and
- (f) If the device has the same technological characteristics (for example, design, material, chemical composition, and energy source) as the predicate device identified in this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. If the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in this section.

10516.2 21 U.S.C. § 360(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on an assessment performance data shall contain the following information:

- (a) A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence;
- (b) A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific

reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence; and

- (c) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in § 10516.1(c) of this section.

10516.3 The summary should be in a separate section of the submission, beginning on a new page and ending on a page not shared with any other section of the premarket notification submission, and should be clearly identified as a "21 U.S.C. § 360(k) summary."

10516.4 The summary shall contain any other information that the Department reasonably deems necessary.

10517 CONTENT AND FORMAT OF A 21 U.S.C. § 360(k) STATEMENT

10517.1 A 21 U.S.C. § 360(k) statement submitted as part of a premarket notification shall state as follows:

"I certify that, in my capacity as (the position held in company by person required to submit the premarket notification, preferably the official correspondent in the firm), of (company name), I will make available all information included in this premarket notification on safety and effectiveness within thirty (30) days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information."

10517.2 The statement in § 10517.1 should be signed by the certifier, made on a separate page of the premarket notification submission, and be clearly identified as the "21 U.S.C. § 360(k) statement."

10517.3 If information is requested by the public regarding the premarket notification § 10517.1, the request shall be made in writing to the certifier, whose name will be published by Department on the list of premarket notification submissions for which substantial equivalence determinations have been made.

10517.4 Information provided to requestors will be a duplicate of the premarket notification submission, including any adverse information, but excluding all patient identifiers, trade secrets and confidential commercial information as defined in this chapter.

10518 FORMAT OF A CLASS III CERTIFICATION

10518.1 A class III certification submitted as part of a premarket notification shall state as follows:

“I certify, in my capacity as (position held in company), of (company name), that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety or effectiveness problems that have been reported for the (type of device). I further certify that I am aware of the types of problems to which the (type of device) is susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety or effectiveness problems about the (type of device) is complete and accurate.”

10518.2 The statement in § 10518.1 should be signed by the certifier, clearly identified as "class III certification," and included at the beginning of the section of the premarket notification submission that sets forth the class III summary.

10519 CONFIDENTIALITY OF INFORMATION

10519.1 The Department will disclose publicly whether there exists a premarket notification submission under this part:

- (a) Where the device is on the market (such as, introduced or delivered for introduction into interstate commerce for commercial distribution);
- (b) Where the person submitting the premarket notification submission discloses, through advertising or any other manner, his or her intent to market the device to scientists, market analysts, exporters, or other individuals who are not employees of, or paid consultants to, the establishment and who are not in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy; or
- (c) Where the device is not on the market and the intent to market the device has not been so disclosed, except where the submission is subject to an exception under this section.

10519.2 The Department will not disclose publicly the existence of a premarket notification submission for a device that is not on the market and where the intent to market the device has not been disclosed for ninety (90) days from the date of receipt of the submission, if:

- (a) The person submitting the premarket notification submission requests in the submission that the Department holds as confidential commercial information the intent to market the device, and submits a written certification to the Department:

- (1) That the person considers his intent to market the device to be confidential commercial information;
 - (2) That neither the person nor, to the best of his or her knowledge, anyone else, has disclosed through advertising or any other manner, his intent to market the device to scientists, market analysts, exporters, or other individuals, except employees of, or paid consultants to, the establishment or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy;
 - (3) That the person will immediately notify the Department if he or she discloses the intent to market the device to anyone, except employees of, or paid consultants to, the establishment or individuals in an advertising or law firm pursuant to commercial arrangements with appropriate safeguards for secrecy;
 - (4) That the person has taken precautions to protect the confidentiality of the intent to market the device; and
 - (5) That the person understands that the submission to the government of false information is prohibited; and
- (b) The Department agrees that the intent to market the device is confidential commercial information

10519.3

Where the Department determines that the person has complied with the procedures described in § 10519.2 with respect to a device that is not on the market and where the intent to market the device has not been disclosed, and the Department agrees that the intent to market the device is confidential commercial information, the Department will not disclose the existence of the submission for ninety (90) days from the date of its receipt by the agency. In addition, the Department will continue not to disclose the existence of such a submission for the device for an additional time when any of the following occurs:

- (a) The Department requests in writing additional information regarding the device pursuant to § 10514(h), in which case the Department will not disclose the existence of the submission until ninety (90) days after Department's receipt of a complete premarket notification submission; or
- (b) The Department determines that the device intended to be introduced is a class III device and cannot be marketed without premarket approval or reclassification, in which case the Department will not disclose the existence of the submission unless a petition for reclassification is submitted under the Act and its existence can be disclosed under this

chapter.

- 10519.4 The Department will make a 21 U.S.C. § 360(k) summary of the safety and effectiveness data available to the public within thirty (30) days of the issuance of a determination that the device is substantially equivalent to another device. Accordingly, even when a 21 U.S.C. § 360(k) submitter has complied with the conditions set forth in § 10519.2 and 10519.3, confidentiality for a premarket notification submission cannot be granted beyond thirty (30) days after the Department issues a determination of equivalency.
- 10519.5 Data or information submitted with, or incorporated by reference in, a premarket notification submission (other than safety and effectiveness data that have not been disclosed to the public) shall be available for disclosure by the Department when the intent to market the device is no longer confidential in accordance with this section, unless exempt from public disclosure. Upon final classification, data and information relating to safety and effectiveness of a device classified in class I (general controls) or class II (performance standards) shall be available for public disclosure. Data and information relating to safety and effectiveness of a device classified in class III (premarket approval) that have not been released to the public shall be retained as confidential unless such data and information become available for release to the public.
- 10519.6 The Department may not disclose, or use as the basis for reclassification of a device from class III to class II, any information reported to or otherwise obtained by the Department that falls within the exemption described for trade secrets and confidential commercial information. The exemption does not apply to data or information contained in a petition for reclassification submitted that has been determined to contain no deficiencies that prevent the Department from making a decision on it. Accordingly, all data and information contained in such petitions may be disclosed by the Department and used as the basis for reclassification of a device from class III to class II.
- 10519.7 For purposes of this section, safety and effectiveness data include data and results derived from all studies and tests of a device on animals and humans and from all studies and tests of the device itself intended to establish or determine its safety and effectiveness.

10520 MISBRANDING BY REFERENCE TO PREMARKET NOTIFICATION

- 10520.1 Submission of a premarket notification in accordance with this subsection, and a subsequent determination by the Department that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution before May 28, 1976, or is substantially equivalent to a device introduced into commercial distribution after May 28, 1976, that has subsequently been reclassified into class I or II, does not in any way denote official approval of the device. Any representation that creates an impression of

official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.

10521 DEPARTMENT OF HEALTH ACTION ON A PREMARKET NOTIFICATION

10521.1 After review of a premarket notification, the Department will:

- (a) Issue an order declaring the device to be substantially equivalent to a legally marketed predicate device;
- (b) Issue an order declaring the device to be not substantially equivalent to any legally marketed predicate device;
- (c) Request additional information;
- (d) Withhold the decision until a certification or disclosure statement is submitted to the Department; or
- (e) Advise the applicant that the premarket notification is not required. Until the applicant receives an order declaring a device substantially equivalent, the applicant may not proceed to market the device.

10521.2 The Department will determine that a device is substantially equivalent to a predicate device using the following criteria:

- (a) The device has the same intended use as the predicate device; and
- (b) The device:
 - (1) Has the same technological characteristics as the predicate device; or
 - (2) The device:
 - (A) Has different technological characteristics, such as a significant change in the materials, design, energy source, or other features of the device from those of the predicate device;
 - (B) The data submitted establishes that the device is substantially equivalent to the predicate device and contains information, including clinical data if deemed necessary by the DOH, that demonstrates that the device is as safe and as effective as a legally marketed device; and

- (C) Does not raise different questions of safety and effectiveness than the predicate device; and
- (3) The predicate device has not been removed from the market at the initiative of the DOH or has not been determined to be misbranded or adulterated by a judicial order.

10599 DEFINITIONS

10599.1 As used in this chapter, the following terms shall have the meanings ascribed:

21 U.S.C. § 360(k) summary – a summary of any information respecting safety and effectiveness. A summary of the safety and effectiveness information contained in a premarket notification submission upon which a determination of substantial equivalence can be based. Safety and effectiveness information refers to safety and effectiveness data and information supporting a finding of substantial equivalence, including all adverse safety and effectiveness information.

21 U.S.C. § 360(k) statement – a statement asserting that all information in a premarket notification submission regarding safety and effectiveness will be made available within thirty (30) days of a request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information to be made available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret or confidential commercial information.

Act – the Federal Food, Drug, and Cosmetic Act, approved June 25, 1938, 21 U.S.C. § 301, *et seq.*

Class III certification – a certification that the submitter as described in 21 U.S.C. § 360(k) has conducted a reasonable search of all known information about the class III device and other similar, legally marketed devices.

Class III summary – a summary of the types of safety and effectiveness problems associated with the type of device being compared and a citation to the information upon which the summary is based. The summary must be comprehensive and describe the problems to which the type of device is susceptible and the causes of such problems.

Classification – the term used by the Department and its classification panels to describe a device or class of devices for purposes of classifying devices.

Commercial distribution – any distribution of a device intended for human use which is held or offered for sale but does not include the following:

- (a) Internal or interplant transfer of a device between establishments within the same parent, subsidiary, or affiliate company;
- (b) Any distribution of a device intended for human use which has in effect an approved exemption for investigational use under 21 U.S.C. § 360j; or
- (c) Any distribution of a device that was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and that is classified into class III under 21 U.S.C. § 360c; provided that the device is intended solely for investigational use and is not required to have an approved premarket approval application.

Establishment – a place of business under one (1) management at one (1) general physical location at which a device is manufactured, assembled, or otherwise processed.

Initial importer – any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes the final delivery or sale of the device to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package.

Manufacture, preparation, propagation, compounding, assembly, or processing of a device – the making by chemical, physical, biological, or other procedures of any article that meets the definition of device in 21 U.S.C. § 321(h). These terms include the following activities:

- (a) Repackaging or otherwise changing the container, wrapper, or labeling of any device package in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer;
- (b) Initial importation of devices manufactured in foreign establishments;
- (c) Initiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating specifications; or
- (d) Initiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating specifications

Material changes – any change or modification in the labeling or advertisements that affects the identity or safety and effectiveness of the device. These changes may include, but are not limited to, changes in the common or usual or proprietary name, declared ingredients or components, intended use, contraindications,

warnings, or instructions for use. Changes that are not material may include graphic layouts, grammar, or correction of typographical errors which do not change the content of the labeling of, changes in lot number, and, for devices where the biological activity or known composition differs with each lot produced, the labeling containing the actual values for each lot.

Official correspondent – person designated by the owner or operator of an establishment who is responsible for the following:

- (a) The annual registration of the establishment;
- (b) Contact with the Department of Health for device listing;
- (c) Maintenance and submission of a current list of officers and directors to the Department; ;
- (d) The receipt of pertinent correspondence from the Department directed to and involving the owner or operator or any of the firm's establishments; and
- (e) The annual certification of medical device reports or forwarding the certification form to the person designated by that the firm designates as responsible for the certification.

Owner or operator – the corporation, subsidiary, affiliated company, partnership, or proprietor directly responsible for the activities of the registering establishment.

Representative sampling of advertisements – typical advertising material that gives the promotional claims made for the device.

Restricted device – a device for which the Department, by regulation under § 10310 of this subtitle, or otherwise under 21 U.S.C. § 360j(e), has restricted sale, distribution, or use only upon the written or oral authorization of a practitioner licensed by law to administer or use the device or upon such other conditions as the Department may prescribe.

U.S.-designated agent – the person, residing in the United States, designated and authorized by the owner or operator of a foreign manufacturer who exports devices into the United States and is responsible for:

- (a) Submitting medical device reporting (MDR) reports;
- (b) Submitting annual certifications;
- (c) Acting as the official correspondent;

- (d) Submitting registration information;
- (e) Submitting device listing information; and
- (f) Submitting premarket notifications on behalf of the foreign manufacturer.

Wholesale distributor – any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.

Chapter 106 (Premarket Approval of Medical Devices) is added to read as follows:

CHAPTER 106 PREMARKET APPROVAL OF MEDICAL DEVICES

10600 SCOPE

10600.1 This section provides procedures for the premarket approval of medical devices intended for human use.

10600.2 This section applies to any class III medical device, unless exempt under 21 U.S.C. § 360j, that:

- (a) Was not on the market (introduced or delivered for introduction into commerce for commercial distribution) before May 28, 1976, and is not substantially equivalent to a device on the market before May 28, 1976, or to a device first marketed on, or after that date, which has been classified into class I or class II;
- (b) Is required to have an approved premarket approval application (PMA) or a declared completed product development protocol under a regulation issued under 21 U.S.C. § 360e(b); or
- (c) Was regulated by the Department as a new drug or antibiotic drug before May 28, 1976, and therefore is governed by 21 U.S.C. § 360j(1).

10600.3 This part amends the conditions to approval for any premarket approval (PMA) approved before the effective date of this part. Any condition to approval for an approved PMA that is inconsistent with this part is revoked. Any condition to approval for an approved PMA that is consistent with this part remains in effect.

10601 PURPOSE

- 10601.1 The purpose of this part is to establish an efficient and thorough device review process that will:
- (a) Facilitate the approval of PMAs for devices that have been shown to be safe and effective and that otherwise meet the statutory criteria for approval; and
 - (b) Ensure the disapproval of PMAs for devices that have not been shown to be safe and effective or that do not otherwise meet the statutory criteria for approval. .

**10602 CONFIDENTIALITY OF DATA AND INFORMATION IN A
PREMARKET APPROVAL APPLICATION (PMA) FILE**

- 10602.1 A premarket approval application file (PMA file) includes all data and information submitted with or incorporated by reference in the PMA, any investigational device exemption (IDE) incorporated into the PMA, any PMA supplement, any report under § 10616, any master file, or any other related submission. Any record in the PMA file will be available for public disclosure in accordance with the provisions of this section. The confidentiality of information in a color additive petition submitted as part of a PMA is governed by § 10629.5.
- 10602.2 The existence of a PMA file may not be disclosed by the Department before an approval order is issued to the applicant unless it was previously publicly disclosed or acknowledged.
- 10602.3 If the existence of a PMA file has not been publicly disclosed or acknowledged, data or information in the PMA file are not available for public disclosure.
- 10602.4 If the existence of a PMA file has been publicly disclosed or acknowledged before an order approving, or an order denying approval of the PMA is issued, data or information contained in the file are not available for public disclosure before such order issues. DOH may, however, disclose a summary of portions of the safety and effectiveness data before an approval order or an order denying approval of the PMA issues if disclosure is relevant to public consideration of a specific pending issue.
- 10602.5 Notwithstanding § 10602.4, the Department will make available to the public upon request the information in the IDE that was required to be filed for investigations involving an exception from informed consent in § 10602.6. Persons wishing to request this information shall submit a request under the Freedom of Information Act of 1976, effective March 25, 1977 (D.C. Law 1-96, D.C. Official Code § 2-531, *et seq.* (2011 Repl. and 2012 Supp.)).
- 10602.6 The Institutional Research Board (IRB) responsible for the review, approval, and continuing review of the clinical investigation described in this section may

approve that investigation without requiring that informed consent of all research subjects be obtained if the IRB (with the concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation) finds and documents each of the following:

- (a) The human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions;
 - (1) Obtaining informed consent is not feasible because:
 - (A) The subjects will not be able to give their informed consent as a result of their medical condition;
 - (B) The intervention under investigation must be administered before consent from the subjects' legally authorized representatives is feasible; and
 - (C) There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation;
 - (2) Participation in the research holds out the prospect of direct benefit to the subjects because:
 - (A) Subjects are facing a life-threatening situation that necessitates intervention;
 - (B) Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects;
 - (C) Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity;
 - (D) The clinical investigation could not practicably be carried out without the waiver;

- (E) The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review; and
 - (F) The IRB has reviewed and approved informed consent procedures and an informed consent document consistent with 21 C.F.R § 50.25. These procedures and the informed consent document are to be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible. The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the clinical investigation consistent with paragraph (3)(E) of this subsection; and
- (3) Additional protections of the rights and welfare of the subjects will be provided, including, at least:
- (A) Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn;
 - (B) Public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits;
 - (C) Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results;
 - (D) Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation; and

- (E) If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a legally authorized representative, and asking whether he or she objects to the subject's participation in the clinical investigation. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

- 10602.7 The IRB is responsible for ensuring that procedures are in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document. The IRB shall also ensure that there is a procedure to inform the subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If a legally authorized representative or family member is told about the clinical investigation and the subject's condition improves, the subject is also to be informed as soon as feasible. If a subject is entered into a clinical investigation with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the clinical investigation is to be provided to the subject's legally authorized representative or family member, if feasible.
- 10602.8 The IRB determinations required by § 10602.6 and the documentation required by § 10602.10 are to be retained by the IRB for at least three (3) years after completion of the clinical investigation, and the records shall be accessible for inspection and copying by the Department.
- 10602.9 Protocols involving an exception to the informed consent requirement under this section must be performed under a separate IND application or IDE that clearly identifies such protocols as protocols that may include subjects who are unable to consent. The submission of those protocols in a separate IND or IDE is required even if an IND for the same drug product or an IDE for the same device already exists. Applications for investigations under this section may not be submitted as amendments.
- 10602.10 If an IRB determines that it cannot approve a clinical investigation because the investigation does not meet the criteria in the exception provided under § 10602.6 or because of other relevant ethical concerns, the IRB shall document its findings

and provide these findings promptly in writing to the clinical investigator and to the sponsor of the clinical investigation. The sponsor of the clinical investigation must promptly disclose this information to the Department and to the sponsor's clinical investigators who are participating or are asked to participate in this or a substantially equivalent clinical investigation of the sponsor, and to other IRBs that have been, or are, asked to review this or a substantially equivalent investigation by that sponsor.

- 10602.11 Upon issuance of an order approving, or an order denying approval of any PMA, the Department will make available to the public the fact of the existence of the PMA and a detailed summary of information submitted to the Department respecting the safety and effectiveness of the device that is the subject of the PMA and that is the basis for the order.
- 10602.12 After the Department issues an order approving, or an order denying approval of any PMA, the following data and information in the PMA file are immediately made available for public disclosure:
- (a) All safety and effectiveness data and information previously disclosed to the public, as such disclosure is defined in 21 C.F.R. § 20.81;
 - (b) Any protocol for a test or study unless the protocol is shown to constitute trade secret or confidential commercial or financial information under 21 C.F.R. § 20.61;
 - (c) Any adverse reaction report, product experience report, consumer complaint, and other similar data and information, after deletion of:
 - (1) Any information that constitutes trade secret or confidential commercial or financial information under 21 C.F.R. § 20.61; and
 - (2) Any personnel, medical, and similar information disclosure of which would constitute a clearly unwarranted invasion of personal privacy under 21 C.F.R. § 20.63; provided, however, that except for the information that constitutes trade secret or confidential commercial or financial information under 21 C.F.R. § 20.61, DOH will disclose to a patient who requests a report all the information in the report concerning that patient;
 - (d) A list of components previously disclosed to the public, as defined in 21 C.F.R. § 20.81;
 - (e) An assay method or other analytical method, unless it does not serve any regulatory purpose and is shown to fall within the exemption in 21 C.F.R. § 20.61 for trade secrets or confidential commercial or financial

information; and

- (f) All correspondence and written summaries of oral discussions relating to the PMA file.

10602.13 All safety and effectiveness data and other information not previously disclosed to the public are available for public disclosure if any one of the following events occurs and the data and information do not constitute trade secret or confidential commercial or financial information under 21 C.F.R. § 20.61:

- (a) The PMA has been abandoned. The Department will consider a PMA abandoned if:
 - (1) The applicant fails to respond to a request for additional information within one hundred eighty (180) days after the date the Department issues the request; or
 - (2) Other circumstances indicate that further work is not being undertaken with respect to it, and
 - (3) The applicant fails to communicate with the Department within seven (7) days after the date on which the Department notifies the applicant that the PMA appears to have been abandoned.
- (b) An order denying approval of the PMA was issued and all legal appeals have been exhausted;
- (c) An order withdrawing approval of the PMA has issued, and all legal appeals have been exhausted;
- (d) The device has been reclassified;
- (e) The device has been found to be substantially equivalent to a class I or class II device; or
- (f) The PMA is considered voluntarily withdrawn under § 10611 of this chapter.

10602.14 The following data and information in a PMA file are not available for public disclosure unless they have been previously disclosed to the public, or they relate to a device for which a PMA has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in 21 C.F.R. § 20.61:

- (a) Manufacturing methods or processes, including quality control procedures;
- (b) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which are not available for public disclosure under this provision is available for public disclosure; or
- (c) Quantitative or semi-quantitative formulas.

10602.15 The procedure for trade secrets and commercial or financial information which is privileged or confidential shall be as follows:

- (a) A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process;
- (b) Commercial or financial information that is privileged or confidential means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs;
- (c) Data and information submitted or divulged to the Department which falls within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure;
- (d) A person who submits records to the Department may designate part or all of the information in such records as exempt from disclosure under exemption 4 of the Freedom of Information Act. The person may make this designation either at the time the records are submitted to the government or within a reasonable time thereafter. The designation must be in writing. Where a legend is required by a request for proposals or request for quotations, pursuant to 48 C.F.R. § 352.215-12, then that legend is necessary for this purpose. Any such designation will expire ten (10) years after the records are submitted to the Department;
- (e) The procedures in this paragraph apply to records on which the submitter has designated information as provided in paragraph (d) of this subsection. These procedures also apply to records that were submitted to the Department when the agency has substantial reason to believe that information in the records could reasonably be considered exempt under exemption 4 of the Freedom of Information Act. Certain exceptions to

these procedures are set forth in paragraph (f) of this subsection. In addition:

- (1) When the Department receives a request for such records and determines that disclosure may be required, the Department will make reasonable efforts to notify the submitter about these facts. The notice will include a copy of the request, and it will inform the submitter about the procedures and time limits for submission and consideration of objections to disclosure. If the Department must notify a large number of submitters, notification may be done by posting or publishing a notice in a place where the submitters are reasonably likely to become aware of it;
 - (2) The submitter has five (5) working days from receipt of the notice to object to disclosure of any part of the records and to state all bases for its objections;
 - (3) The Department will give consideration to all bases that have been stated in a timely manner by the submitter. If the Department decides to disclose the records, the Department will notify the submitter in writing. This notice will briefly explain why the agency did not sustain the submitter's objections. The Department will include with the notice a copy of the records about which the submitter objected, as the agency proposes to disclose them. The notice will state that the Department intends to disclose the records five (5) working days after the submitter receives the notice unless a court orders the agency not to release them;
 - (4) If a requester files suit under the Freedom of Information Act to obtain records covered by this paragraph, the Department will promptly notify the submitter; and
 - (5) Whenever the Department sends a notice to a submitter under paragraph (e)(1) of this subsection, the Department will notify the requester that the Department is giving the submitter a notice and an opportunity to object. Whenever the DOH sends a notice to a submitter under paragraph (e)(3) of this subsection, the Department will notify the requester of this fact; and
- (f) The notice requirements in paragraph (e) of this subsection shall not apply in the following situations:
- (1) The Department decided not to disclose the records;
 - (2) The information was published previously or made generally available;

- (3) Disclosure is required by a regulation issued after notice and opportunity for public comment that specifies narrow categories of records that are to be disclosed under the Freedom of Information Act. In this case, however, a submitter may still designate records as described in paragraph (d) of this subsection, and in exceptional cases, the Department may, at its discretion, follow the notice procedures in paragraph (e) of this subsection;
- (4) The submitter did not designate the information requested as exempt from disclosure when the submitter had an opportunity to do so at the time of submission of the information or within a reasonable time thereafter, unless the Department has substantial reason to believe that disclosure of the information would result in competitive harm; or
- (5) The designation appears to be frivolous, but in this case the Department will still give the submitter the written notice required by Subsection (e)(3) (although this notice need not explain the Department's decision or include a copy of the records), and the Department will notify the requester as described in Subsection (e)(5).

10603 RESEARCH CONDUCTED OUTSIDE OF THE UNITED STATES

- 10603.1 A study conducted outside of the United States (U.S.) submitted in support of a PMA and conducted under an IDE shall comply with 21 C.F.R. § 812. A study conducted outside of the U.S. submitted in support of a PMA and not conducted under an IDE shall comply with the provisions in § 10424, as applicable.
- 10603.2 The Department will accept studies submitted in support of a PMA which have been conducted outside of the U.S. and begun on or after November 19, 1986, if the data are valid and the investigator conducted the studies in conformance with the "Declaration of Helsinki" or the laws and regulations of the country in which the research is conducted, whichever affords greater protection to the human subjects. If the standards of the country are used, the applicant shall state in detail any differences between those standards and the "Declaration of Helsinki" and explain why they offer greater protection to the human subjects.
- 10603.3 The Department will accept studies submitted in support of a PMA which have been conducted outside of the United States and begun before November 19, 1986, if the Department is satisfied that the data is scientifically valid and that the rights, safety, and welfare of human subjects have not been violated.
- 10603.4 A PMA based solely on foreign clinical data and otherwise meeting the criteria for approval under 21 C.F.R. § 812 may be approved if:

- (a) The foreign data are applicable to the U.S. population and U.S. medical practice;
- (b) The studies were performed by clinical investigators of recognized competence; and
- (c) The data may be considered valid without the need for an on-site inspection by the Department or, if the Department considers such an inspection to be necessary, the Department can validate the data through an on-site inspection or other appropriate means.

10603.5 Applicants are encouraged to meet with the Department officials in a "pre-submission" meeting when approval based solely on foreign data will be sought.

10604 SERVICE OF ORDERS

10604.1 Orders issued under this subsection will be served in person by a designated officer or employee of the Department on, or by registered mail to, the applicant or the designated agent at the applicant's or designated agent's last known address in the Department's records.

10605 PRODUCT DEVELOPMENT PROTOCOL (PDP)

10605.1 A class III device for which a product development protocol (PDP) has been declared completed by the Department under this chapter will be considered to have an approved PMA.

10606 APPLICATION

10606.1 The applicant or an authorized representative shall sign the PMA. If the applicant does not reside or have a place of business within the United States, the PMA shall be countersigned by an authorized representative residing or maintaining a place of business in the United States and shall identify the representative's name and address.

10606.2 Unless the applicant justifies an omission in accordance with § 10606.4, a PMA shall include:

- (a) The name and address of the applicant;
- (b) A table of contents that specifies the volume and page number for each item referred to in the table. A PMA shall include separate sections on nonclinical laboratory studies and on clinical investigations involving human subjects. A PMA shall be submitted in six (6) copies each bound in one (1) or more numbered volumes of reasonable size. The applicant shall include information that it believes to be a trade secret or confidential

commercial or financial information in all copies of the PMA and identify in at least one (1) copy the information that it believes to be trade secret or confidential commercial or financial information;

- (c) A summary in sufficient detail that the reader may gain a general understanding of the data and information in the application. The summary shall contain the following information:
 - (1) A general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended;
 - (2) An explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device. A brief description of the manufacturing process should be included if it will significantly enhance the reader's understanding of the device. The generic name of the device as well as any proprietary name or trade name should be included;
 - (3) A description of existing alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended;
 - (4) A brief description of the foreign and U.S. marketing history, if any, of the device, including a list of all countries in which the device has been marketed and a list of all countries in which the device has been withdrawn from marketing for any reason related to the safety or effectiveness of the device. The description shall include the history of the marketing of the device by the applicant and, if known, the history of the marketing of the device by any other person;
 - (5) An abstract of any information or report described in the PMA and a summary of the results of technical data. Such summary shall include a description of the objective of the study, a description of the experimental design of the study, a brief description of how the data was collected and analyzed, and a brief description of the results, whether positive, negative, or inconclusive. This section shall include the following:
 - (A) A summary of the nonclinical laboratory studies submitted in the application; and
 - (B) A summary of the clinical investigations involving human subjects submitted in the application including a discussion

of subject selection and exclusion criteria, study population, study period, safety and effectiveness data, adverse reactions and complications, patient discontinuation, patient complaints, device failures and replacements, results of statistical analyses of the clinical investigations, contraindications and precautions for use of the device, and other information from the clinical investigations as appropriate (any investigation conducted under an IDE shall be identified as such); and

(6) A discussion demonstrating that the data and information in the application constitute valid scientific evidence and provide reasonable assurance that the device is safe and effective for its intended use. A concluding discussion shall present benefit and risk considerations related to the device including a discussion of any adverse effects of the device on health and any proposed additional studies or surveillance the applicant intends to conduct following approval of the PMA;

(d) A complete description of:

(1) The device, including pictorial representations;

(2) Each of the functional components or ingredients of the device if the device consists of more than one (1) physical component or ingredient;

(3) The properties of the device relevant to the diagnosis, treatment, prevention, cure, or mitigation of a disease or condition;

(4) The principles of operation of the device; and

(5) The methods used in, and the facilities and controls used for, the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with current good manufacturing practice can make a knowledgeable judgment about the quality control used in the manufacture of the device;

(e) Reference to any performance standard under 21 U.S.C. § 360d or under 21 U.S.C. § 360hh in effect or proposed at the time of the submission and to any voluntary standard that is relevant to any aspect of the safety or effectiveness of the device and that is known to or that should reasonably be known to the applicant. The applicant shall:

- (1) Provide adequate information to demonstrate how the device meets, or justify any deviation from, any performance standard established under 21 U.S.C. § 360d or under 21 U.S.C. § 360kk; and
 - (2) Explain any deviation from a voluntary standard;
- (f) The following technical sections which shall contain data and information in sufficient detail to permit the Department to determine whether to approve or deny approval of the application:
- (1) A section containing results of the nonclinical laboratory studies with the device including microbiological, toxicological, immunological, biocompatibility, stress, wear, shelf life, and other laboratory or animal tests as appropriate. Information on nonclinical laboratory studies shall include a statement that each such study was conducted in compliance with 21 C.F.R. part 58, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance;
 - (2) A section containing results of the clinical investigations involving human subjects with the device including clinical protocols, number of investigators and subjects per investigator, subject selection and exclusion criteria, study population, study period, safety and effectiveness data, adverse reactions and complications, patient discontinuation, patient complaints, device failures and replacements, tabulations of data from all individual subject report forms and copies of such forms for each subject who died during a clinical investigation or who did not complete the investigation, results of statistical analyses of the clinical investigations, device failures and replacements, contraindications and precautions for use of the device, and any other appropriate information from the clinical investigations. Any investigation conducted under an IDE shall be identified as such. Information on clinical following:
 - (A) A statement with respect to each study that it either was conducted in compliance with the institutional review board regulations in 21 C.F.R. part 56, or was not subject to the regulations under 21 C.F.R. § 56.104 or 21 C.F.R. § 56.105, and that it was conducted in compliance with the informed consent regulations in 21 C.F.R., part 50; or if the study was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance; or

- (B) A statement that each study was conducted in compliance with Chapter 109 of this subtitle concerning sponsors of clinical investigations and clinical investigators, or if the study was not conducted in compliance, a brief statement of the reason for the noncompliance.
- (g) For a PMA supported solely by data from one (1) investigation, a justification showing that data and other information from a single investigator are sufficient to demonstrate the safety and effectiveness of the device and to ensure reproducibility of test results;
- (h) A bibliography of all published reports not submitted under § 10606.2(f), whether adverse or supportive, known to or that should reasonably be known to the applicant and that concern the safety or effectiveness of the device;
- (i) An identification, discussion, and analysis of any other data, information, or report relevant to an evaluation of the safety and effectiveness of the device known to or that should reasonably be known to the applicant from any source, foreign or domestic, including information derived from investigations other than those proposed in the application and from commercial marketing experience;
- (j) Copies of such published reports or unpublished information in the possession of or reasonably obtainable by the applicant if a Department advisory committee or the Department requests;
- (k) One or more samples of the device and its components, if requested by the Department. If it is impractical to submit a requested sample of the device, the applicant shall name the location at which the Department may examine and test one or more devices;
- (l) Copies of all proposed labeling for the device. Such labeling may include (for example, instructions for installation and any information, literature, or advertising that constitutes labeling under 21 U.S.C. § 321(m));
- (m) An environmental assessment prepared in the applicable format in § 10606.2(m)(1), unless the action qualifies for exclusion under § 10606.2(m)(2). If the applicant believes that the action qualifies for exclusion, the PMA shall provide information that establishes to the Department's satisfaction that the action requested is included within the excluded category and meets the criteria for the applicable exclusion;
 - (1) The following shall apply to environmental assessments:

- (A) An environmental assessment (EA) is a concise public document that serves to provide sufficient evidence and analysis for an agency to determine whether to prepare an environmental impact statement (EIS) or a finding of no significant impact (FONSI). The EA shall include brief discussions of the need for the proposal, of alternatives, of the environmental impacts of the proposed action and alternatives, and a listing of agencies and persons consulted. An EA shall be prepared for each action not categorically excluded. The EA shall focus on relevant environmental issues relating to the use and disposal from use of Department-regulated articles and shall be a concise, objective, and well-balanced document that allows the public to understand the agency's decision. If potentially adverse environmental impacts are identified for an action or a group of related actions, the EA shall discuss any reasonable alternative course of action that offers less environmental risk or that is environmentally preferable to the proposed action. The use of a scientifically justified tiered testing approach, in which testing may be stopped when the results suggest that no significant impact will occur, is an acceptable approach;
- (B) Generally, the Department requires an applicant to prepare an EA and make necessary corrections to it. Ultimately, the Department is responsible for the scope and content of EAs and may include additional information in environmental documents when warranted;
- (C) Information concerning the nature and scope of information that an applicant or petitioner shall submit in an EA may be obtained from the center or other office of the agency having responsibility for the action that is the subject of the environmental evaluation. Applicants and petitioners are encouraged to submit proposed protocols for environmental studies for technical review by agency staff. Applicants and petitioners also are encouraged to consult applicable Department EA guidance documents, which provide additional advice on how to comply with Department regulations;
- (D) EAs may incorporate by reference information presented in other documents that are available to the Department and to the public; and

- (E) The Department evaluates the information contained in an EA and any public input to determine whether it is accurate and objective, whether the proposed action may significantly affect the quality of the human environment, and whether an EIS or a FONSI will be prepared. The Department examines the environmental risks of the proposed action and the alternative courses of action, selects a course of action, and ensures that any necessary mitigating measures are implemented as a condition for approving the selected course of action; and
- (2) The classes of actions listed below are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or EIS:
- (A) Action on a device premarket notification submission under Chapter 105 of this subtitle;
 - (B) Classifications or reclassifications of a device;
 - (C) Issuance, amendment, or repeal of a standard for a class II medical device or an electronic product, and issuance of exemptions or variances from such a standard;
 - (D) Approval of a PMA or a notice of completion of a PDP or amended or supplemental applications or notices for a class III medical device if the device is of the same type and for the same use as a previously approved device;
 - (E) Changes in the PMA or a notice of completion of a PDP for a class III medical device that do not require submission of an amended or supplemental application or notice;
 - (F) Issuance of a restricted device regulation if it will not result in increases in the existing levels of use or changes in the intended uses of the product or its substitutes;
 - (G) Action on an application for an IDE or an authorization to commence a clinical investigation under an approved PDP; and
 - (H) Issuance of a regulation exempting from preemption a requirement of a State or political subdivision concerning a device, or a denial of an application for such exemption.

- (n) A financial certification, disclosure statement, or both; and
- (o) If necessary, the Department will obtain the concurrence of the appropriate Department advisory committee before requesting additional information.

10606.3 Pertinent information in Department files specifically referred to by an applicant may be incorporated into a PMA by reference. Information in a master file or other information submitted to the Department by a person other than the applicant will not be considered part of a PMA unless such reference is authorized in writing by the person who submitted the information or the master file. If a master file is not referenced within five (5) years after the date that it is submitted to the Department, the Department will return the master file to the person who submitted it.

10606.4 If the applicant believes that certain information required under § 10606.2(m) of this section to be in a PMA is not applicable to the device that is the subject of the PMA, and omits any such information from its PMA, the applicant shall submit a statement that identifies the omitted information and justifies the omission. The statement shall be submitted as a separate section in the PMA and identified in the table of contents. The Department will notify the applicant if it does not accept their justification for omission.

10606.5 The applicant shall periodically update its pending application with new safety and effectiveness information learned about the device from ongoing or completed studies that may reasonably affect an evaluation of the safety or effectiveness of the device or that may reasonably affect the statement of contraindications, warnings, precautions, and adverse reactions in the draft labeling. The update report shall be consistent with the data reporting provisions of the protocol. The applicant shall submit three (3) copies of any update report and shall include in the report that number that the Department assigns to the PMA. These updates are considered to be amendments to the PMA. The timeframe for reviewing the PMA will not be extended due to the submission of an update report unless the update is a major amendment under 21 C.F.R. § 814.37(c)(1). The applicant shall submit these reports:

- (a) Three (3) months after the filing date;
- (b) Following receipt of an approvable letter; and
- (c) At any other time as requested by the Department.

10606.6 If a color additive subject to Section 721 of the Act is used in or on the device and has not previously been listed for such use, then, submitting a color additive petition under 21 CFR, part 71, at the option of the applicant, the information may be submitted under 21 CFR, part 71 as part of the PMA. When submitted as part

of the PMA, the information shall be submitted in three (3) copies each bound in one or more numbered volumes of reasonable size. A PMA for a device that contains a color additive that is subject to Section 721 of the Act will not be approved until the color additive is listed for use in or on the device.

10606.7 If you are sending a PMA, PMA amendment, PMA supplement, or correspondence with respect to a PMA, you must send the submission to the Department.

**10607 PREMARKET APPROVAL APPLICATION AMENDMENTS AND
RESUBMITTED PREMARKET APPROVAL APPLICATION**

10607.1 An applicant may amend a pending PMA or PMA supplement to revise existing information or provide additional information.

10607.2 The Department may request the applicant to amend a PMA or PMA supplement with any information regarding the device that is necessary for the Department or the appropriate advisory committee to complete the review of the PMA or PMA supplement.

10607.3 A PMA amendment submitted to DOH shall include the PMA or PMA supplement number assigned to the original submission and, if submitted on the applicant's own initiative, the reason for submitting the amendment. The Department may extend the time required for its review of the PMA, or PMA supplement, as follows:

- (a) If the applicant on its own initiative or at the Department's request submits a major PMA amendment (for example, an amendment that contains significant new data from a previously unreported study, significant updated data from a previously reported study, detailed new analyses of previously submitted data, or significant required information previously omitted), the review period may be extended up to one hundred eighty (180) days; or
- (b) If an applicant declines to submit a major amendment that the Department requests, the review period may be extended for the number of days that elapse between the date of such request and the date that DOH receives the written response declining to submit the requested amendment.

10607.4 An applicant may on its own initiative withdraw a PMA or PMA supplement. If the Department requests an applicant to submit a PMA amendment and a written response to the Department's request is not received within one hundred eighty (180) days of the date of the request, the Department will consider the pending PMA or PMA supplement to be withdrawn voluntarily by the applicant.

10607.5 An applicant may resubmit a PMA or PMA supplement after withdrawing it or after it is considered withdrawn under § 10607.4, or after the Department has refused to accept it for filing, or has denied approval of the PMA or PMA supplement. A resubmitted PMA or PMA supplement shall comply with the requirements of § 10606 or § 10608, respectively, and shall include the PMA number assigned to the original submission and the applicant's reasons for resubmission of the PMA or PMA supplement.

10608 PREMARKET APPROVAL APPLICATION SUPPLEMENTS

10608.1 After the Department's approval of a PMA, an applicant shall submit a PMA supplement for review and approval by the Department before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA, unless the change is of a type for which the Department, under § 10608.6 of this section, has advised that an alternate submission is permitted or is of a type which, under 21 U.S.C. § 360e(d)(6)(A) and § 10608.7, do not require a PMA supplement under this paragraph. While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device:

- (a) New indications for use of the device;
- (b) Labeling changes;
- (c) The use of a different facility or establishment to manufacture, process, or package the device;
- (d) Changes in sterilization procedures;
- (e) Changes in packaging;
- (f) Changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device; and
- (g) Extension of the expiration date of the device based on data obtained under a new or revised stability or sterility testing protocol that the Department has not approved. If the protocol has been approved, the change shall be reported to the Department under § 10608.2.

10608.2 An applicant may make a change in a device after the Department's approval of a PMA for the device without submitting a PMA supplement if the change does not affect the device's safety or effectiveness and the change is reported to the Department in post-approval periodic reports required as a condition to approval of the device (for example, an editorial change in labeling which does not affect

the safety or effectiveness of the device).

- 10608.3 All procedures and actions that apply to an application under § 10606 also apply to PMA supplements except that the information required in a supplement is limited to that needed to support the change. A summary under 21 C.F.R. § 814.20(b)(3) is required for only a supplement submitted for new indications for use of the device, significant changes in the performance or design specifications, circuits, components, ingredients, principles of operation, or physical layout of the device, or when otherwise required by the Department. The applicant shall submit three copies of a PMA supplement and shall include information relevant to the proposed changes in the device. A PMA supplement shall include a separate section that identifies each change for which approval is being requested and explains the reason for each such change. The applicant shall submit additional copies and additional information if requested by the Department. The time frames for review of, and Department action on, a PMA supplement are the same as those provided in § 10609 for a PMA.
- 10608.4 After the Department approves a PMA, any change described in § 10608.5 of this section to reflect newly acquired information that enhances the safety of the device or the safety in the use of the device may be placed into effect by the applicant prior to the receipt under § 10604 of a written Department order approving the PMA supplement provided that:
- (a) The PMA supplement and its mailing cover are plainly marked "Special PMA Supplement -- Changes Being Effected;"
 - (b) The PMA supplement provides a full explanation of the basis for the changes;
 - (c) The applicant has received acknowledgement from the Department of receipt of the supplement; and
 - (d) The PMA supplement specifically identifies the date that such changes are being effected.
- 10608.5 The following changes are permitted by § 10608.4:
- (a) Labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association;
 - (b) Labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device;

- (c) Labeling changes that delete misleading, false, or unsupported indications; and
- (d) Changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or reliability of the device.

10608.6 The Department will identify a change to a device for which an applicant has an approved PMA and for which a PMA supplement under § 10608.1 is not required. The Department will identify such a change in an advisory opinion under 21 C.F.R. § 10.85, if the change applies to a generic type of device, or in correspondence to the applicant, if the change applies only to the applicant's device. The Department will require that a change for which a PMA supplement under § 10608 is not required be reported to DOH in:

- (a) A periodic report under § 10617; or
- (b) A thirty (30)-day PMA supplement.

10608.7 The Department will identify, in the advisory opinion or correspondence, the type of information that is to be included in the report or thirty (30)-day PMA supplement. If the change is required to be reported to the Department in a periodic report, the change may be made before it is reported to the Department. If the change is required to be reported in a thirty (30)-day PMA supplement, the change may be made thirty (30) days after DOH files the thirty (30)-day PMA supplement unless the Department requires the PMA holder to provide additional information, informs the PMA holder that the supplement is not approvable, or disapproves the supplement. The thirty (30)-day PMA supplement shall follow the instructions in the correspondence or advisory opinion. Any thirty (30)-day PMA supplement that does not meet the requirements of the correspondence or advisory opinion will not be filed and, therefore, will not be deemed approved thirty (30) days after receipt.

10608.8 Under 21 U.S.C. § 360e(d) of the act, modifications to manufacturing procedures or methods of manufacture that affect the safety and effectiveness of a device subject to an approved PMA do not require submission of a PMA supplement his section and are eligible to be the subject of a thirty (30) day notice. A thirty (30) day notice shall describe in detail the change, summarize the data or information supporting the change, and state that the change has been made in accordance with the requirements of Chapter 107 of this subtitle. The manufacturer may distribute the device thirty (30) days after the date on which DOH receives the thirty (30) day notice, unless DOH notifies the applicant within thirty (30) days from receipt of the notice that the notice is not adequate. If the notice is not adequate, the Department will inform the applicant in writing that a one hundred thirty five (135) day PMA supplement is needed and shall describe what further information or action is required for acceptance of such change. The number of

days under review as a thirty (30) day notice shall be deducted from the one hundred thirty five (135) day PMA supplement review period if the notice meets appropriate content requirements for a PMA supplement.

10608.9 The submission and grant of a written request for an exception or alternative under §10313 or 21 C.F.R. § 809.11 satisfies the requirement in § 10608.1.

10609 TIME FRAME FOR REVIEWING A PREMARKET APPROVAL APPLICATION

10609.1 Within one hundred eighty (180) days after receipt of an application that is accepted for filing and to which the applicant does not submit a major amendment, the Department will review the PMA and, after receiving the appropriate Department advisory committee's report and recommendations, send the applicant an approval order under 21 C.F.R. § 814.44(d)(1), an approvable letter under 21 C.F.R. § 814.44(e), a not approvable letter under 21 C.F.R. § 814.44(f)(1) or (2), or an order denying approval under 21 C.F.R. § 814.45. The approvable letter and the not approvable letter will provide an opportunity for the applicant to amend or withdraw the application, or to consider the letter to be a denial of approval of the PMA under 21 C.F.R. § 814.45 and to request administrative review under sections 21 U.S.C. §§ 360e(d)(3) and (g).

10610 FILING A PREMARKET APPROVAL APPLICATION

10610.1 The filing of an application means that the Department has made a threshold determination that the application is sufficiently complete to permit a substantive review. Within forty five (45) days the Department receives a PMA, the agency will notify the applicant whether the application has been filed.

10610.2 If the Department does not find that any of the reasons in § 10610.5 for refusing to file the PMA application, the agency will file the PMA and will notify the applicant in writing of the filing. The notice will include the PMA reference number and the date the Department filed the PMA. The date of filing is the date that DOH receives a PMA. The one hundred eighty (180) day period for review of a PMA starts on the date of filing.

10610.3 If the Department refuses to file a PMA, the agency will notify the applicant of the reasons for the refusal. This notice will identify the deficiencies in the application that prevent filing and will include the PMA reference number.

10610.4 If the Department refuses to file the PMA, the applicant may:

- (a) Resubmit the PMA with additional information necessary to comply with § 10606. A resubmitted PMA shall include the PMA reference number of the original submission. If the resubmitted PMA is accepted for filing, the

date of filing is the date the Department receives the resubmission; or

- (b) Request in writing within ten (10) working days of the date of receipt of the notice refusing to file the PMA, an informal conference with the Department to review the Department's decision not to file the PMA. The Department will hold the informal conference within ten (10) working days of its receipt of the request and will render its decision on filing within five (5) working days after the informal conference. If, after the informal conference, the Department accepts the PMA for filing, the date of filing will be the date of the decision to accept the PMA for filing. If the Department does not reverse its decision not to file the PMA, the applicant may request reconsideration of the decision from the Department. The Department's decision will constitute final administrative action for the purpose of judicial review.

10610.5 The Department may refuse to file a PMA if any of the following applies:

- (a) The application is incomplete because it does not on its face contain all the information required;
- (b) The PMA does not contain each of the items required under § 10606 and justification for omission of any item is inadequate;
- (c) The applicant has a pending premarket notification with respect to the same device, and the Department has not determined whether the device falls within the scope of 21 C.F.R. § 814.1(c)(1)-(3);
- (d) The PMA contains a false statement of material fact; or
- (e) The PMA is not accompanied by a statement of either certification or disclosure.

10611 PROCEDURES FOR REVIEW OF A PREMARKET APPROVAL APPLICATION

10611.1 The Department will begin substantive review of a PMA after the PMA is accepted for filing under § 10610. The Department may refer the PMA to a panel on its own initiative, and will do so upon request of an applicant, unless the Department determines that the application substantially duplicates information previously reviewed by a panel. If the Department refers an application to a panel, the Department will forward the PMA, or relevant portions thereof, to each member of the appropriate Department panel for review. During the review process, the Department may communicate with the applicant as set forth under 21 C.F.R. § 814.37(b), or with a panel to respond to questions that may be posed by panel members or to provide additional information to the panel. The Department shall maintain a record of all communications with the applicant and

with the panel.

- 10611.2 The advisory committee shall submit a report to the Department which includes the committee's recommendation and the basis for such recommendation on the PMA. Before submission of this report, the committee shall hold a public meeting to review the PMA. This meeting may be held by a telephone conference under 21 C.F.R. § 14.22(g). The advisory committee report and recommendation may be in the form of a meeting transcript signed by the chairperson of the committee.
- 10611.3 The Department will complete its review of the PMA and the advisory committee report and recommendation and, within the later of one hundred eighty (180) days from the date of filing of the PMA under 21 C.F.R. § 814.42 or the number of days after the date of filing as determined under 21 C.F.R. § 814.37(c)(1)-(2), issue an approval order under 21 C.F.R. § 814.44(d), an approvable letter under 21 C.F.R. § 814.44(e), a not approvable letter under 21 C.F.R. § 814.44(f), or an order denying approval of the application under 21 C.F.R. § 814.45(a)(1)-(5).
- 10611.4 The Department will issue to the applicant an order approving a PMA if none of the reasons in 21 C.F.R. § 814.45(a) for denying approval of the application applies. The Department will approve an application on the basis of draft final labeling if the only deficiencies in the application concern editorial or similar minor deficiencies in the draft final labeling. Such approval will be conditioned upon the applicant incorporating the specified labeling changes exactly as directed and upon the applicant submitting to the Department a copy of the final printed labeling before marketing. The Department will also give the public notice of the order, including notice of and opportunity for any interested persons to request review under 21 U.S.C. § 360e(d)(3).
- 10611.5 The notice of approval will be placed on the Department's website and it will state that a detailed summary of information respecting the safety and effectiveness of the device, which was the basis for the order approving the PMA, including information about any adverse effects of the device on health, is available on the Internet and has been placed on public display, and that copies are available upon request. The Department will publish after each quarter a list of the approvals announced in that quarter. When a notice of approval is published, data and information in the PMA file will be available for public disclosure in accordance with § 10602.
- 10611.6 A request for copies of the current PMA approvals and denials document and for copies of summaries of safety and effectiveness shall be sent in writing to the Department.
- 10611.7 The Department will send the applicant an approvable letter if the application substantially meets the requirements of this section and the agency believes it can approve the application if specific additional information is submitted or specific

conditions are agreed to by the applicant.

10611.8 The approvable letter will describe the information the Department requires to be provided by the applicant or the conditions the applicant is required to meet to obtain approval. For example, the Department may require, as a condition to approval:

- (a) The submission of certain information identified in the approvable letter (for example, final labeling);
- (b) A Department inspection that finds the manufacturing facilities, methods, and controls in compliance with Chapter 107 and, if applicable, that verifies records pertinent to the PMA;
- (c) Restrictions imposed on the device; or
- (d) Post-approval requirements as described in 21 C.F.R. § 814.80, *et seq.*

10611.9 In response to an approvable letter the applicant may:

- (a) Amend the PMA as requested in the approvable letter;
- (b) Consider the approvable letter to be a denial of approval of the PMA under § 10612 and request administrative review under 21 U.S.C. § 360e(d)(3) by filing a petition in the form of a petition for reconsideration; or
- (c) Withdraw the PMA.

10611.10 The Department will send the applicant a not approvable letter if the agency believes that the application may not be approved for one or more of the reasons given in 21 C.F.R. § 814.45(a)(1)-(5). The not approvable letter will describe the deficiencies in the application, including each applicable ground for denial, and, where practical, will identify measures required to place the PMA in approvable form. In response to a not approvable letter, the applicant may:

- (a) Amend the PMA as requested in the not approvable letter (such an amendment will be considered a major amendment under 21 C.F.R. § 814.37(c)(1)-(2)); or
- (b) Consider the not approvable letter to be a denial of approval of the PMA under § 10612 and request administrative review by filing a petition in the form of a petition for reconsideration; or
- (c) Withdraw the PMA.

10611.11 DOH will consider a PMA to have been withdrawn voluntarily if:

- (a) The applicant fails to respond in writing to a written request for an amendment within one hundred eighty (180) days after the date the Department issues such request;
- (b) The applicant fails to respond in writing to an approvable or not approvable letter within one hundred eighty (180) days after the date the Department issues such letter; or
- (c) The applicant submits a written notice to the Department that the PMA has been withdrawn.

10612 DENIAL OF APPROVAL OF A PREMARKET APPROVAL APPLICATION

10612.1 The Department may issue an order denying approval of a PMA if the applicant fails to follow the requirements of this section or if, upon the basis of the information submitted in the PMA or any other information before the agency, the Department determines that any of the grounds for denying approval of a PMA specified in 21 U.S.C. §§ 360e(d)(2)(A)-(E) of the act, apply. In addition, the Department may deny approval of a PMA for any of the following reasons:

- (a) The PMA contains a false statement of material fact;
- (b) The device's proposed labeling does not comply with the requirements in Chapter 103 of this subtitle;
- (c) The applicant does not permit an authorized Department employee an opportunity to inspect at a reasonable time and in a reasonable manner the facilities, controls, and to have access to and to copy and verify all records pertinent to the application;
- (d) A nonclinical laboratory study that is described in the PMA and that is essential to show that the device is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good laboratory practice regulations and no reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study; or
- (e) Any clinical investigation involving human subjects described in the PMA, subject to the institutional review board regulations or informed consent regulations, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not

adequately protected.

- 10612.2 The Department will issue any order denying approval of the PMA in accordance with § 10604. The order will inform the applicant of the deficiencies in the PMA, including each applicable ground for denial under 21 U.S.C. § 360e(d)(2) and the regulations under this section, and, where practical, will identify measures required to place the PMA in approvable form. The order will include a notice of an opportunity to request review under 21 U.S.C. § 360e(d)(4).
- 10612.3 The Department will determine the safety and effectiveness of a device in deciding whether to approve or deny approval of a PMA. DOH may use information other than that submitted by the applicant in making such determination.
- 10612.4 The Department will give the public notice of an order denying approval of the PMA. The notice will be placed on the Department's website and it will state that a detailed summary of information respecting the safety and effectiveness of the device, including information about any adverse effects of the device on health, is available on the website and has been placed on public display and that copies are available upon request. The Department will publish after each quarter a list of the denials announced in that quarter. When a notice of denial of approval is made publicly available, data and information in the PMA file will be available for public disclosure under § 10602.
- 10612.5 A request for copies of the current PMA approvals and denials document and copies of summaries of safety and effectiveness shall be sent in writing to the Department.
- 10612.6 The Department will issue an order denying approval of a PMA after an approvable or not approvable letter has been sent and the applicant:
- (a) Submits a requested amendment but any ground for denying approval of the application under 21 U.S.C. § 360e(d)(2) still applies; or
 - (b) Notifies the Department in writing that the requested amendment will not be submitted; or
 - (c) Files a petitions for reconsideration under 21 U.S.C. § 360e (d)(3).

10613 WITHDRAWAL OF APPROVAL OF A PREMARKET APPROVAL APPLICATION

- 10613.1 The Department may issue an order withdrawing approval of a PMA if, from any information available to the agency, the Department determines that:

- (a) Any of the grounds under 21 U.S.C. §§ 360e(e)(1) (A)-(G) applies;
- (b) Any post-approval requirement imposed by the PMA approval order or by regulation has not been met;
- (c) A nonclinical laboratory study that is described in the PMA and that is essential to show that the device is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good laboratory practice regulations and no reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study; or
- (d) Any clinical investigation involving human subjects described in the PMA, subject to the institutional review board regulations in § 10630 or informed consent regulations, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected.

- 10613.2 The Department may seek advice on scientific matters from any appropriate Department advisory committee in deciding whether to withdraw approval of a PMA.
- 10613.3 The Department may use information other than that submitted by the applicant in deciding whether to withdraw approval of a PMA.
- 10613.4 Before issuing an order withdrawing approval of a PMA, the Department will issue the holder of the approved application a notice of opportunity for an informal hearing under 21 C.F.R., part 16.
- 10613.5 If the applicant does not request a hearing or if after the hearing is held the agency decides to proceed with the withdrawal, the Department will issue to the holder of the approved application an order withdrawing approval of the application. The order will be issued under § 10604, will state each ground for withdrawing approval, and will include a notice of an opportunity for administrative review under 21 U.S.C. § 360e (e)(2).
- 10613.6 The Department will give the public notice of an order withdrawing approval of a PMA. The notice will be published and will state that a detailed summary of information respecting the safety and effectiveness of the device, including information about any adverse effects of the device on health, has been placed on public display and that copies are available upon request. When a notice of withdrawal of approval is published, data and information in the PMA file will be available for public disclosure in accordance with § 10602.

10614 TEMPORARY SUSPENSION OF APPROVAL OF A PREMARKET APPROVAL APPLICATION

- 10614.1 This section describes the procedures that the Department will follow in exercising its authority under 21 U.S.C. § 360c(e)(3). This authority applies to the original PMA, as well as any PMA supplement(s), for a medical device.
- 10614.2 The Department will issue an order temporarily suspending approval of a PMA if the Department determines that there is a reasonable probability that continued distribution of the device would cause serious, adverse health consequences or death.
- 10614.3 If the Department believes that there is a reasonable probability that the continued distribution of a device subject to an approved PMA would cause serious, adverse health consequences or death, the Department may initiate and conduct a regulatory hearing to determine whether to issue an order temporarily suspending approval of the PMA.
- 10614.4 Pursuant to 21 C.F.R. part 16, the Department will initiate and conduct any regulatory hearing necessary for determining whether to issue an order temporarily supporting approval of a PMA. If the Department believes that immediate action to remove a dangerous device from the market is necessary to protect the public health, the agency may, in accordance with 21 C.F.R. § 16.60(h), waive, suspend, or modify any 21 C.F.R. part 16 procedure, pursuant to 21 CFR § 10.19.
- 10614.5 The Department will deem the PMA holder's failure to request a hearing within the timeframe specified by DOH in the notice of opportunity for hearing to be a waiver.
- 10614.6 If the PMA holder does not request a regulatory hearing or if, after the hearing, and after consideration of the administrative record of the hearing, the Department determines that there is a reasonable probability that the continued distribution of a device under an approved PMA would cause serious, adverse health consequences or death, the agency shall, under the authority of 21 U.S.C. § 360e(e)(3) of the act, issue an order to the PMA holder temporarily suspending approval of the PMA.
- 10614.7 Permanent withdrawal of approval of the PMA. If the Department issues an order temporarily suspending approval of a PMA, the agency shall proceed expeditiously, but within sixty (60) days, to hold a hearing on whether to permanently withdraw approval of the PMA in accordance with 21 U.S.C. § 360e(e)(1) and procedures set out in § 10613.

10615 GENERAL

10615.1 A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device.

10616 POST-APPROVAL REQUIREMENTS

10616.1 The Department may impose post-approval requirements in a PMA approval order or regulation at the time of approval of the PMA or by regulation subsequent to approval. Post-approval requirements may include as a condition to approval of the device:

- (a) Restriction of the sale, distribution, or use of the device as provided by 21 U.S.C. §§ 360e(d)(1)(B)(ii) or 360j(e);
- (b) Continuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use. The Department will state in the PMA approval order the reason or purpose for such requirement and the number of patients to be evaluated and the reports required to be submitted;
- (c) Prominently display on the labeling of a device and in the advertising of any restricted device of warnings, hazards, or precautions important for the device's safe and effective use, including patient information (for example, information provided to the patient on alternative modes of therapy and on risks and benefits associated with the use of the device);
- (d) Inclusion of identification codes on the device or its labeling, or in the case of an implant, on cards given to patients if necessary to protect the public health;
- (e) Maintenance of records that will enable the applicant to submit to the Department information needed to trace patients if such information is necessary to protect the public health. The Department will require that the identity of any patient be disclosed in records maintained under this paragraph only to the extent required for the medical welfare of the individual, to determine the safety or effectiveness of the device, or to verify a record, report, or information submitted to the agency;
- (f) Maintenance of records for specified periods of time and organization and indexing of records into identifiable files to enable DOH to determine whether there is reasonable assurance of the continued safety and effectiveness of the device;
- (g) Submission to the Department at intervals specified in the approval order of periodic reports containing the information required by § 10617.2;

- (h) Batch testing of the device; or
- (i) Such other requirements as the Department determines are necessary to provide reasonable assurance, or continued reasonable assurance, of the safety and effectiveness of the device.

10616.2 An applicant shall grant to the Department access to any records and reports required under the provisions of this chapter, and shall permit authorized Department employees to copy and verify such records and reports and to inspect at a reasonable time and in a reasonable manner all manufacturing facilities to verify that the device is being manufactured, stored, labeled, and shipped under approved conditions.

10616.3 Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA.

10617 REPORTS

10617.1 The holder of an approved PMA shall comply with the requirements in Chapter 104 and with any other requirements applicable to the device by other regulations in this section or by order approving the device.

10617.2 Unless the Department specifies otherwise, any periodic report shall:

- (a) Identify changes described in § 10608.1 and changes required to be reported to the Department under § 10608.2; and
- (b) Contain a summary and bibliography of the following information not previously submitted as part of the PMA:
 - (1) Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant;
 - (2) Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant. If, after reviewing the summary and bibliography, the Department concludes that the agency needs a copy of the unpublished or published reports, the Department will notify the applicant that copies of such reports shall be submitted; or
 - (3) Identify changes made pursuant to an exception or alternative under 21 C.F.R. § 801.128 or 21 C.F.R. § 809.11.

10618 PURPOSE AND SCOPE

10618.1 The purpose of this section is, to the extent consistent with the protection of the public health and safety and with ethical standards, to encourage the discovery and use of devices intended to benefit patients in the treatment or diagnosis of diseases or conditions that affect or are manifested in fewer than four thousand (4,000) individuals in the United States per year. This section provides procedures for obtaining:

- (a) Humanitarian use device (HUD) designation of a medical device; and
- (b) Marketing approval for the HUD notwithstanding the absence of reasonable assurance of effectiveness that would otherwise be required.

10618.2 Although a HUD may also have uses that differ from the humanitarian use, applicants seeking approval of any non-HUD use shall submit a PMA as required in § 10606 or a premarket notification as required in Chapter 105.

10618.3 Obtaining marketing approval for a HUD involves two (2) steps:

- (a) Obtaining designation of the device as a HUD from DOH, and
- (b) Submitting a humanitarian device exemption (HDE) to the Department.

10618.4 A person granted an exemption shall submit periodic reports as described in § 10632.1.

10618.5 The Department may suspend or withdraw approval of an HDE after providing notice and an opportunity for an informal hearing.

10619 DESIGNATION OF HUMANITARIAN USE DEVICES STATUS

10619.1 Prior to submitting an HDE application, the applicant shall submit a request for humanitarian use devices (HUD) designation to the Department. The request shall contain the following:

- (a) A statement that the applicant requests HUD designation for a rare disease or condition or a valid subset of a disease or condition which shall be identified with specificity;
- (b) The name and address of the applicant, the name of the applicant's primary contact person or resident agent, including title, address, and telephone number;
- (c) A description of the rare disease or condition for which the device is to be used, the proposed indication or indications for use of the device, and the reasons why such therapy is needed. If the device is proposed for an

indication that represents a subset of a common disease or condition, a demonstration that the subset is medically plausible should be included;

- (d) A description of the device and a discussion of the scientific rationale for the use of the device for the rare disease or condition; and
- (e) Documentation, with appended authoritative references, to demonstrate that the device is designed to treat or diagnose a disease or condition that affects or is manifested in fewer than four thousand (4,000) people in the United States per year. If the device is for diagnostic purposes, the documentation must demonstrate that fewer than four thousand (4,000) patients per year would be subjected to diagnosis by the device in the United States. Authoritative references include literature citations in specialized medical journals, textbooks, specialized medical society proceedings, or governmental statistics publications. When no such studies or literature citations exist, the applicant may be able to demonstrate the prevalence of the disease or condition in the United States by providing credible conclusions from appropriate research or surveys.

10619.2 Within forty-five (45) days of receipt of a request for HUD designation, the Department will take one (1) of the following actions:

- (a) Approve the request and notify the applicant that the device has been designated as a HUD based on the information submitted;
- (b) Return the request to the applicant pending further review upon submission of additional information. This action will ensue if the request is incomplete because it does not on its face contain all of the information required under § 10619.1(a). Upon receipt of this additional information, the review period may be extended up to forty five (45) days; or
- (c) Disapprove the request for HUD designation based on a substantive review of the information submitted. The Department may disapprove a request for HUD designation if:
 - (1) There is insufficient evidence to support the estimate that the disease or condition for which the device is designed to treat or diagnose affects or is manifested in fewer than four thousand (4,000) people in the U.S. per year;
 - (2) The Department determines that, for a diagnostic device, four thousand (4,000) or more patients in the United States would be subjected to diagnosis using the device per year; or
 - (3) The Department determines that the patient population defined in the request is not a medically plausible subset of a larger

population.

- 10619.3 The Department may revoke a HUD designation if the agency finds that:
- (a) The request for designation contained an untrue statement of material fact or omitted material information; or
 - (b) Based on the evidence available, the device is not eligible for HUD designation.

10619.4 The applicant shall submit two (2) copies of a completed, dated, and signed request for HUD designation to the Department.

10620 ORIGINAL APPLICATIONS

10620.1 The applicant or an authorized representative shall sign the HDE. If the applicant does not reside or have a place of business within the U.S., the HDE shall be countersigned by an authorized representative residing or maintaining a place of business in the U.S. and shall identify the representative's name and address.

10620.2 Unless the applicant justifies an omission in accordance with § 10620.4, an HDE shall include:

- (a) A copy of or reference to the Department's determination (in accordance with § 10619) that the device qualifies as a HUD;
- (b) An explanation of why the device would not be available unless an HDE were granted and a statement that no comparable device (other than another HUD approved under this section or a device under an approved IDE) is available to treat or diagnose the disease or condition. The application also shall contain a discussion of the risks and benefits of currently available devices or alternative forms of treatment in the United States; and
- (c) An explanation of why the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Such explanation shall include a description, explanation, or theory of the underlying disease process or condition, and known or postulated mechanism(s) of action of the device in relation to the disease process or condition.

10620.3 All of the information required to be submitted under § 10606.2(b), except that:

- (a) In lieu of the summaries, conclusions, and results from clinical investigations required under §§ 10606.2(c)(5)(B), (c)(6), and (f)(2), the

applicant shall include the summaries, conclusions, and results of all clinical experience or investigations (whether adverse or supportive) reasonably obtainable by the applicant that are relevant to an assessment of the risks and probable benefits of the device; and

- (b) In addition to the proposed labeling requirement set forth in § 10606.2(l) the labeling shall bear the following statement:

“Humanitarian Device. Authorized by District of Columbia law for use in the [treatment or diagnosis] of [specify disease or condition]. The effectiveness of this device for this use has not been demonstrated.”; and

- (c) The amount to be charged for the device and, if the amount is more than two hundred fifty dollars (\$250), a report by an independent certified public accountant, made in accordance with the Statement on Standards for Attestation established by the American Institute of Certified Public Accountants, or in lieu of such a report, an attestation by a responsible individual of the organization, verifying that the amount charged does not exceed the costs of the device's research, development, fabrication, and distribution. If the amount charged is two hundred fifty dollars (\$250) or less, the requirement for a report by an independent certified public accountant or an attestation by a responsible individual of the organization is waived.

10620.4 If the applicant believes that certain information required under § 10620.2 is not applicable to the device that is the subject of the HDE, and omits any such information from its HDE, the applicant shall submit a statement that identifies and justifies the omission. The statement shall be submitted as a separate section in the HDE and identified in the table of contents. If the justification for the omission is not accepted by the agency, the Department will so notify the applicant.

10620.5 Copies of all original HDE amendments and supplements, as well as any correspondence relating to an HDE, must be sent or delivered to the Department.

10621 HUMANITARIAN DEVICE EXEMPTION AMENDMENTS AND RESUBMITTED HUMANITARIAN DEVICE EXEMPTIONS

10621.1 An HDE or HDE supplement may be amended or resubmitted upon an applicant's own initiative, or at the request of DOH, for the same reasons and in the same manner as prescribed for PMAs in § 10607, except that the timeframes set forth in § 10607.3(a) and § 10607.4 do not apply.

10621.2 If the Department requests an HDE applicant to submit an HDE amendment, and a written response to the Department's request is not received within seventy-five (75) days of the date of the request, the Department will consider the pending

HDE or HDE supplement to be withdrawn voluntarily by the applicant. Furthermore, if the HDE applicant, on its own initiative or at the Department's request, submits a major amendment as described in § 10607.3(a), the review period may be extended up to seventy-five (75) days.

10622 SUPPLEMENTAL APPLICATIONS

10622.1 After the Department's approval of an original HDE, an applicant shall submit supplements in accordance with the requirements for PMAs under § 10608, except that a request for a new indication for use of a HUD shall comply with requirements set forth in § 10623. The timeframes for review of, and the Department's action on, an HDE supplement are the same as those provided in § 10625 for an HDE.

10623 NEW INDICATIONS FOR USE

10623.1 An applicant seeking a new indication for use of a HUD approved under this section shall obtain a new designation of HUD status in accordance with § 10619 and shall submit an original HDE in accordance with § 10620.

10623.2 An application for a new indication for use made under § 10620 may incorporate by reference any information or data previously submitted to the Department under an HDE.

10624 FILING A HUMANITARIAN DEVICE EXEMPTION

10624.1 The filing of an HDE means that the Department has made a threshold determination that the application is sufficiently complete to permit substantive review. Within thirty (30) days from the date an HDE is received by the Department, the agency will notify the applicant whether the application has been filed. The Department may refuse to file an HDE if any of the following applies:

- (a) The application is incomplete because it does not on its face contain all the information required under § 10620.2;
- (b) The Department determines that there is a comparable device available (other than another HUD approved under this section or a device under an approved IDE) to treat or diagnose the disease or condition for which approval of the HUD is being sought;
- (c) The application contains an untrue statement of material fact or omits material information; or
- (d) The HDE is not accompanied by a statement of either certification or disclosure, or both, as required by 21 C.F.R., part 54.

10624.2 The provisions contained in §§ 10610.2, 10610.3, and 10610.4 regarding notification of filing decisions, filing dates, the start of the seventy-five (75) day review period, and applicant's options in response to the Department's refusal to file decisions shall apply to HDEs.

10625 TIME FRAMES FOR REVIEWING A HUMANITARIAN DEVICE EXEMPTION

10625.1 Within seventy-five (75) days after receipt of an HDE that is accepted for filing and to which the applicant does not submit a major amendment, the Department will send the applicant an approval order, an approvable letter, a not approvable letter (under § 10626), or an order denying approval (under § 10627).

10626 PROCEDURES FOR REVIEW OF A HUMANITARIAN DEVICE EXEMPTION

10626.1 The Department will begin substantive review of an HDE after the HDE is accepted for filing under § 10624. The Department may refer an original HDE application to a panel on its own initiative, and shall do so upon the request of an applicant, unless the Department determines that the application substantially duplicates information previously reviewed by a panel. If the HDE is referred to a panel, the agency shall follow the procedures set forth under § 10611, with the exception that the Department will complete its review of the HDE and the advisory committee report and recommendations within seventy-five (75) days from receipt of an HDE that is accepted for filing under § 10624 or the date of filing as determined under § 10621, whichever is later. Within the later of these two timeframes, the Department will issue an approval order under § 10626.2, an approvable letter under § 10626.3, a not approvable letter under § 10626.4, or an order denying approval of the application under § 10627.1.

10626.2 The Department will issue to the applicant an order approving an HDE if none of the reasons in § 10627 for denying approval of the application applies. The Department will approve an application on the basis of draft final labeling if the only deficiencies in the application concern editorial or similar minor efficiencies in the draft final labeling. Such approval will be conditioned upon the applicant incorporating the specified labeling changes exactly as directed and upon the applicant submitting to the Department a copy of the final printed labeling before marketing. The notice of approval of an HDE will be published by the Department in accordance with the rules and policies applicable to PMAs submitted under § 10606. Following the issuance of an approval order, data and information in the HDE file will be available for public disclosure in accordance with § 10602.2 through § 10602.10, as applicable.

10626.3 The Department will send the applicant an approvable letter if the application substantially meets the requirements of this section and the agency believes it can approve the application if specific additional information is submitted or specific

conditions are agreed to by the applicant. The approvable letter will describe the information the Department requires to be provided by the applicant or the conditions the applicant is required to meet in order to obtain approval. For example, the Department may require as a condition to approval:

- (a) The submission of certain information identified in the approvable letter (such as, final labeling);
- (b) Restrictions imposed on the device under 21 U.S.C. § 360j(e);
- (c) Post-approval requirements; and
- (d) A Department inspection that finds the manufacturing facilities, methods, and controls in compliance with Chapter 106 and, if applicable, that verifies records pertinent to the HDE.

10626.4 The Department will send the applicant a not approvable letter if the agency believes that the application may not be approved for one (1) or more of the reasons given in § 10627. The not approvable letter will describe the deficiencies in the application and, where practical, will identify measures required to place the HDE in approvable form. The applicant may respond to the not approvable letter in the same manner as permitted for not approvable letters for PMAs under § 10611.9, with the exception that if a major HDE amendment is submitted, the review period may be extended up to seventy-five (75) days.

10626.5 The Department will consider an HDE to have been withdrawn voluntarily if:

- (a) The applicant fails to respond in writing to a written request for an amendment within seventy-five (75) days after the date DOH issues such request;
- (b) The applicant fails to respond in writing to an approvable or not approvable letter within seventy-five (75) days after the date the Department issues such letter; or
- (c) The applicant submits a written notice to the Department that the HDE has been withdrawn.

10627 DENIAL OF APPROVAL OR WITHDRAWAL OF APPROVAL OF A HUMANITARIAN DEVICE EXEMPTION

10627.1 The Department may deny approval or withdraw approval of an application if the applicant fails to meet the requirements of 21 U.S.C. § 360j(m) or of any condition of approval imposed by an IRB or by the Department, or any post-approval requirements imposed under § 10631. In addition, the Department may deny approval or withdraw approval of an application if, upon the basis of the

information submitted in the HDE or any other before the agency, the Department determines that:

- (a) There is a lack of a showing of reasonable assurance that the device is safe under the conditions of use prescribed, recommended, or suggested in the labeling thereof;
- (b) The device is ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof;
- (c) The applicant has not demonstrated that there is a reasonable basis from which to conclude that the probable benefit to health from the use of the device outweighs the risk of injury or illness, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment;
- (d) The application or a report submitted by or on behalf of the applicant contains an untrue statement of material fact, or omits material information;
- (e) The device's labeling does not comply with the requirements in Chapter 103;
- (f) A nonclinical laboratory study that is described in the HDE and that is essential to show that the device is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good laboratory practice regulations and no reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study;
- (g) Any clinical investigation involving human subjects described in the HDE, subject to the institutional review board regulations in § 10631 or the informed consent regulations in 21 C.F.R., part 50, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected;
- (h) The applicant does not permit an authorized Department employee an opportunity to inspect at a reasonable time and in a reasonable manner the facilities and controls, and to have access to and to copy and verify all records pertinent to the application; or
- (i) The device's HUD designation should be revoked in accordance with § 10619.3.

10627.2 If the Department issues an order denying approval of an application, the agency will comply with the same notice and disclosure provisions required for PMAs under §§ 10612.2 and 10612.4, as applicable.

10627.3 The Department will issue an order denying approval of an HDE after an approvable or not approvable letter has been sent and the applicant. The following also applies:

- (a) Submits a requested amendment but any ground for denying approval of the application under § 10627.1 still applies;
- (b) Notifies the Department in writing that the requested amendment will not be submitted; or
- (c) Petitions for review under 21 U.S.C. § 360e(d)(3) by filing a petition in the form of a petition for reconsideration under 21 C.F.R. § 10.33.

10627.4 Before issuing an order withdrawing approval of an HDE, the Department will provide the applicant with notice and an opportunity for a hearing as required for PMAs under §§ 10613.3 and 10613.4, and will provide the public with notice in accordance with § 10613.5, as applicable.

10628 TEMPORARY SUSPENSION OF APPROVAL OF A HUMANITARIAN DEVICE EXEMPTION

10628.1 An HDE or HDE supplement may be temporarily suspended for the same reasons and in the same manner as prescribed for PMAs in § 10614.

10629 CONFIDENTIALITY OF DATA AND INFORMATION

10629.1 The "HDE file" includes all data and information submitted with or referenced in the HDE, any IDE incorporated into the HDE, any HDE amendment or supplement, any report submitted under § 10631, any master file, or any other related submission. Any record in the HDE file will be available for public disclosure in accordance with the provisions of this section.

10629.2 Disclosure by the Department of the existence and contents of an HDE file shall be subject to the same rules that pertain to PMA's under § 10602.2 through 10602.10, as applicable.

10629.3 The HDE holder is responsible for ensuring that a HUD approved under this section is administered only in facilities having an IRB constituted and acting pursuant to §10631, including continuing review of use of the device. In addition, a HUD may be administered only if the IRB approves such use located at the facility or by a similarly constituted IRB that has agreed to oversee such use and to which the local IRB has deferred in a letter to the HDE holder, signed by the

IRB chair or an authorized designee. If, however, a physician in an emergency situation determines that approval from an IRB cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be administered without prior approval by the IRB located at the facility or by a similarly constituted IRB that has agreed to oversee such use. In such an emergency situation, the physician shall, within five (5) days after the use of the device, provide written notification to the chairman of the IRB of such use. Such written notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use.

10629.4 A holder of an approved HDE shall notify the Department of any withdrawal of approval for the use of a HUD by a reviewing IRB within five (5) working days after being notified of the withdrawal of approval.

10629.5 In regards to the confidentiality of data and information in color additive petitions: the following data and information in a color additive petition are available for public disclosure, unless extraordinary circumstances are shown, after the notice of filing of the petition is published or, if the petition is not promptly filed because of deficiencies in it, after the petitioner is informed that it will not be filed because of the deficiencies involved:

- (a) All safety and functionality data and information submitted with or incorporated by reference in the petition;
- (b) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information;
- (c) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:
 - (1) Names and any information that would identify the person using the product;
 - (2) Names and any information that would identify any third party involved with the report, such as a physician, hospital, or other institution;
 - (3) A list of all ingredients contained in a color additive, whether or not it is in descending order of predominance. A particular ingredient or group of ingredients shall be deleted from any such list prior to public disclosure if it is shown to fall within an exemption and a notation shall be made that any such ingredient list is incomplete;

- (4) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within an exemption; and
- (5) All records showing the Department's testing of or action on a particular lot of a certifiable color additive.

10629.6 The following data and information in a color additive petition are not available for public disclosure unless they have been previously disclosed to the public or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information:

- (a) Manufacturing methods or processes, including quality control procedures;
- (b) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure; and
- (c) Quantitative or semi-quantitative formulas.

10629.7 All correspondence and written summaries of oral discussions relating to a color additive petition are available for public disclosure when the color additive regulation is published by the Department.

10629.8 For purposes of this regulation, safety and functionality data include all studies and tests of a color additive on animals and humans and all studies and tests on a color additive for identity, stability, purity, potency, performance, and usefulness.

10630 [RESERVED]

10631 INSTITUTIONAL REVIEW BOARD REQUIREMENTS

10631.1 The HDE holder is responsible for ensuring that a HUD approved under this section is administered only in facilities having an IRB constituted and acting pursuant to these regulations, including continuing review of use of the device. In addition, a HUD may be administered only if such use has been approved by the IRB located at the facility or by a similarly constituted IRB that has agreed to oversee such use and to which the local IRB has deferred in a letter to the HDE holder, signed by the IRB chair or an authorized designee. If, however, a physician in an emergency situation determines that approval from an IRB cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be administered without prior approval by the IRB located at the facility or by a similarly constituted IRB that has agreed to oversee such use. In such an

emergency situation, the physician shall, within five (5) days after the use of the device, provide written notification to the chairman of the IRB of such use. Such written notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use.

10631.2 A holder of an approved HDE shall notify the Department of any withdrawal of approval for the use of a HUD by a reviewing IRB within five (5) working days after being notified of the withdrawal of approval.

10632 POST-APPROVAL REQUIREMENTS AND REPORTS

10632.1 An HDE approved under this section shall be subject to the post-approval requirements and reports set forth under 21 C.F.R. § 1.83, *et seq.*, as applicable, with the exception of § 10616.1(g). In addition, medical device reports submitted to the Department in compliance with the requirements of Chapter 104 shall also be submitted to the IRB of record.

10632.2 In addition to the reports identified in § 10632.1, the holder of an approved HDE shall prepare and submit the following complete, accurate, and timely reports:

- (a) An HDE applicant is required to submit reports in accordance with the approval order. Unless the Department specifies otherwise, any periodic report shall include:
 - (1) An update of the information required under § 10619.1 in a separately bound volume;
 - (2) An update of the information required under § 10620.2(b), (c), and (e);
 - (3) The number of devices that have been shipped or sold since initial marketing approval under this section and, if the number shipped or sold exceeds four thousand (4,000), an explanation and estimate of the number of devices used per patient. If a single device is used on multiple patients, the applicant shall submit an estimate of the number of patients treated or diagnosed using the device together with an explanation of the basis for the estimate;
 - (4) Information describing the applicant's clinical experience with the device since the HDE was initially approved. This information shall include safety information that is known or reasonably should be known to the applicant, medical device reports made under Chapter 104, any data generated from the post-marketing studies, and information (whether published or unpublished) that is known or reasonably expected to be known by the applicant that may affect an evaluation of the safety of the device or that may affect

the statement of contraindications, warnings, precautions, and adverse reactions in the device's labeling; and

- (5) A summary of any changes made to the device in accordance with supplements submitted under § 10622. If information provided in the periodic reports, or any other information in the possession of the Department, gives the agency reason to believe that a device raises public health concerns or that the criteria for exemption are no longer met, the agency may require the HDE holder to submit additional information to demonstrate continued compliance with the HDE requirements.

10632.3 An HDE holder shall maintain records of the names and addresses of the facilities to which the HUD has been shipped, correspondence with reviewing IRB's, as well as any other information that the IRB or the Department requests. Such records shall be maintained in accordance with the HDE approval order.

10699 DEFINITIONS

10699.1 As used in this chapter, the following terms shall have the meanings ascribed:

Act – the Federal Food, Drug, and Cosmetic Act, approved June 25, 1938, 31 U.S.C. § 301, *et seq.*

Humanitarian Device Exemption (HDE) – an application that is similar to a premarket approval (PMA) application, but is exempt from the effectiveness requirements of 21 U.S.C. §§ 360d and 360e of the Food, Drug, and Cosmetic Act.

Humanitarian Use Device (HUD) – a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than four thousand (4,000) individuals in the U. S. per year.

Investigational Device – a device, including a transitional device, that is the object of an investigation.

Investigational Device Exemption (IDE) – a process whereby an investigational device is allowed to be used in a clinical study in order to collect safety and effectiveness data required to support a premarket approval (PMA) application or a premarket notification (21 U.S.C. § 360(k)) submission to FDA.

Master File – a reference source that a person submits to the Department of Health master file may contain detailed information on a specific manufacturing facility, process, methodology, or component used in the manufacture, processing, or packaging of a medical device.

Person – any individual, partnership, corporation, association, scientific or academic establishment, Government agency, or organizational unit thereof, or any other legal entity.

PMA – any premarket approval application for a class III medical device, including all information submitted with or incorporated by reference therein. ``PMA" includes a new drug application for a device.

PMA amendment – information an applicant submits to the Department of Health to modify a pending PMA or a pending PMA supplement.

PMA supplement – a supplemental application to an approved PMA for approval of a change or modification in a class III medical device, including all information submitted with or incorporated by reference therein.

Reasonable probability – it is more likely than not that an event will occur.

Statement of material fact – a representation that tends to show that the safety or effectiveness of a device is more probable than it would be in the absence of such a representation. A false affirmation or silence or an omission that would lead a reasonable person to draw a particular conclusion as to the safety or effectiveness of a device also may be a false statement of material fact, even if the statement was not intended by the person making it to be misleading or to have any probative effect.

Serious, adverse health consequences – any significant adverse experience, including those which may be either life-threatening or involve permanent or long term injuries, but excluding injuries that are nonlife-threatening and that are temporary and reasonably reversible.

Thirty (30) - day PMA supplement – a supplemental application to an approved PMA in accordance with § 10608.

Transitional device – a device subject to 21 U.S.C. § 360j(1) of the act, that is, a device that the FDA considered to be a new drug or an antibiotic drug before May 28, 1976.

Chapter 107 (Quality System Regulation) is added to read as follows:

CHAPTER 107 QUALITY SYSTEM REGULATIONS

10700 SCOPE

10700.1 Current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. The requirements in this chapter govern the methods used in, and the facilities and controls used for, the design, manufacture,

packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The requirements in this chapter are intended to ensure that finished devices will be safe and effective and otherwise in compliance with District regulations. This chapter establishes basic requirements applicable to manufacturers of finished medical devices. If a manufacturer engages in only some operations subject to the requirements in this chapter, and not in others, that manufacturer need only comply with those requirements applicable to the operations in which it is engaged. With respect to class I devices, design controls apply only to those devices listed in § 10705(a)(2). This regulation does not apply to manufacturers of components or parts of finished devices, but such manufacturers are encouraged to use appropriate provisions of this regulation as guidance. Manufacturers of human blood and blood components are not subject to 21 C.F.R., part 606 or its Department of Health equivalent. Manufacturers of human cells, tissues, and cellular and tissue-based products (HCT/Ps), as defined in 21 C.F.R. § 1271.3(d), that are medical devices (subject to premarket review or notification, or exempt from notification, under an application submitted under the device provisions or under a biological product license application under the federal Public Health Service Act, 42 U.S.C. § 262 are subject to this chapter and are also subject to the donor-eligibility procedures set forth in 21 C.F.R., part 1271, subpart C and applicable current good tissue practice procedures in 21 C.F.R., part 1271, subpart D. In the event of a conflict between applicable regulations, the regulation specifically applicable to the device in question shall supersede the more general.

- 10700.2 The provisions of this chapter shall be applicable to any finished device as defined in this chapter, intended for human use, that is manufactured, imported, or offered for import in any State or Territory of the U.S., the District of Columbia, or the Commonwealth of Puerto Rico.
- 10700.3 In this regulation the term "where appropriate" is used several times. When a requirement is qualified by "where appropriate," it is deemed to be "appropriate" unless the manufacturer can document justification otherwise. A requirement is "appropriate" if non-implementation could reasonably be expected to result in the product not meeting its specified requirements or the manufacturer not being able to carry out any necessary corrective action.
- 10700.4 The quality system regulation in this chapter supplements regulations in other sections in this chapter except where explicitly stated otherwise. In the event of a conflict between applicable regulations in this chapter and in other sections in this chapter, the regulations specifically applicable to the device in question shall supersede any other generally applicable requirements.
- 10700.5 The failure to comply with any applicable provision in this chapter renders a device adulterated under 21 U.S.C. § 351. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action.

10700.6 If a manufacturer who offers devices for import into the U.S. refuses to permit or allow the completion of a Department inspection of the foreign facility for the purpose of determining compliance with this chapter, it shall appear for purposes of Chapter 103, that the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, or servicing of any devices produced at such facility that are offered for import into the U.S. do not conform to the requirements of 21 U.S.C. § 351j(f) and this section and that the devices manufactured at that facility are adulterated under 21 U.S.C. § 351(h).

10700.7 Any person who wishes to petition for an exemption or variance from any device quality system requirement must submit a petition for an exemption or variance according to the Department's administrative procedures.

10700.8 The Department may initiate and grant a variance from any device quality system requirement when the agency determines that such variance is in the best interest of the public health. Such variance will remain in effect only so long as there remains a public health need for the device and the device would not likely be made sufficiently available without the variance.

10701 QUALITY SYSTEM

10701.1 Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this chapter.

10702 MANAGEMENT RESPONSIBILITY

10702.1 Management with executive responsibility shall establish its policy and objectives for, and commitment to, quality. Management with executive responsibility shall ensure that the quality policy is understood, implemented, and maintained at all levels of the organization.

10702.2 Each manufacturer shall establish and maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the requirements of this chapter.

10702.3 Each manufacturer shall establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks.

10702.4 Each manufacturer shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of this chapter.

- 10702.5 Management with executive responsibility shall appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for:
- (a) Ensuring that quality system requirements are effectively established and effectively maintained in accordance with this chapter; and
 - (b) Reporting on the performance of the quality system to management with executive responsibility for review.

10702.6 Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this chapter and the manufacturer's established quality policy and objectives. The dates and results of quality system reviews shall be documented.

10702.7 Each manufacturer shall establish a quality plan which defines the quality practices, resources, and activities relevant to devices that are designed and manufactured. The manufacturer shall establish how the requirements for quality will be met.

10702.8 Each manufacturer shall establish quality system procedures and instructions. An outline of the structure of the documentation used in the quality system shall be established where appropriate.

10703 QUALITY AUDIT: TRAINED PERSONNEL

10703.1 Each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. Quality audits shall be conducted by individuals who do not have direct responsibility for the matters being audited. Corrective action(s), including a re-audit of deficient matters, shall be taken when necessary. A report of the results of each quality audit, and re-audit(s) where taken, shall be made and such reports shall be reviewed by management having responsibility for the matters audited. The dates and results of quality audits and re-audits shall be documented.

10703.2 Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this chapter are correctly performed.

10703.3 Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented.

10703.4 As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs.

10703.5 Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.

10704 RESERVED

10705 DESIGN CONTROLS

10705.1 Each manufacturer of any class III or class II device, and the class I devices listed in § 10705.2, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

10705.2 The following class I devices are subject to design controls:

- (a) Devices automated with computer software; and
- (b) The devices listed in the following chart:

Device
Catheter, Tracheobronchial Suction.
Glove, Surgeon's.
Restraint, Protective.
System, Applicator, Radionuclide, Manual.
Source, Radionuclide Teletherapy.

10705.3 Each manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be reviewed, updated, and approved as design and development evolves.

10705.4 Each manufacturer shall establish and maintain procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. A designated person(s) shall review and approve the documented design input requirements. The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.

10705.5 Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. Design output procedures shall contain

or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified. Design output shall be documented, reviewed, and approved before release. The approval, including the date and signature of the individual(s) approving the output, shall be documented.

- 10705.6 Each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed. The results of a design review, including identification of the design, the date, and the individual(s) performing the review, shall be documented in the design history file (the DHF).
- 10705.7 Each manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the DHF.
- 10705.8 Each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be documented in the DHF.
- 10705.9 Each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.
- 10705.10 Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.
- 10705.11 Each manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this chapter.

10706 DOCUMENT CONTROLS

- 10706.1 Each manufacturer shall establish and maintain procedures to control all documents that are required by this chapter.
- 10706.2 Each manufacturer shall designate an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements of this chapter. The approval, including the date and signature of the individual(s) approving the document, shall be documented. Documents established to meet the requirements of this chapter shall be available at all locations for which they are designated, used, or otherwise necessary, and all obsolete documents shall be promptly removed from all points of use or otherwise prevented from unintended use.
- 10706.3 Changes to documents shall be reviewed and approved by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise. Approved changes shall be communicated to the appropriate personnel in a timely manner. Each manufacturer shall maintain records of changes to documents. Change records shall include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective.

10707 PURCHASING CONTROLS

- 10707.1 Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.
- 10707.2 Each manufacturer shall establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants. Each manufacturer shall:
- (a) Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented;
 - (b) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results; and
 - (c) Establish and maintain records of acceptable suppliers, contractors, and consultants.
- 10707.3 Each manufacturer shall establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services. Purchasing documents shall include, where possible, an agreement that the suppliers, contractors, and

consultants agree to notify the manufacturer of changes in the product or service so that manufacturers may determine whether the changes may affect the quality of a finished device. Purchasing data shall be approved in accordance with § 10706.

10708 IDENTIFICATION

10708.1 Each manufacturer shall establish and maintain procedures for identifying products during all stages of receipt, production, distribution, and installation to prevent mix-ups.

10709 TRACEABILITY

10709.1 Each manufacturer of a device that is intended for surgical implant into the body or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action. Such identification shall be documented in the device history record (DHR).

10710 PRODUCTION AND PROCESS CONTROLS

10710.1 Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Where process controls are needed they shall include:

- (a) Documented instructions, standard operating procedures (SOPs), and methods that define and control the manner of production;
- (b) Monitoring and control of process parameters and component and device characteristics during production;
- (c) Compliance with specified reference standards or codes;
- (d) The approval of processes and process equipment; and
- (e) Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

10710.2 Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or

where appropriate validated according to § 10713, before implementation and these activities shall be documented. Changes shall be approved in accordance with § 10706.

- 10710.3 Where environmental conditions could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures to adequately control these environmental conditions. Environmental control system(s) shall be periodically inspected to verify that the system, including necessary equipment, is adequate and functioning properly. These activities shall be documented and reviewed.
- 10710.4 Each manufacturer shall establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and product or environment could reasonably be expected to have an adverse effect on product quality. The manufacturer shall ensure that maintenance and other personnel who are required to work temporarily under special environmental conditions are appropriately trained or supervised by a trained individual.
- 10710.5 Each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.
- 10710.6 Buildings shall be of suitable design and contain sufficient space to perform necessary operations, prevent mix-ups, and assure orderly handling.
- 10710.7 Each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use.
- 10710.8 Each manufacturer shall establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met. Maintenance activities, including the date and individual(s) performing the maintenance activities, shall be documented.
- 10710.9 Each manufacturer shall conduct periodic inspections in accordance with established procedures to ensure adherence to applicable equipment maintenance schedules. The inspections, including the date and individual(s) conducting the inspections, shall be documented.
- 10710.10 Each manufacturer shall ensure that any inherent limitations or allowable tolerances are visibly posted on or near equipment requiring periodic adjustments or are readily available to personnel performing these adjustments.
- 10710.11 Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain

procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.

- 10710.12 When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented.

10711 INSPECTION, MEASURING, AND TEST EQUIPMENT

- 10711.1 Each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained. The procedures shall include provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained. These activities shall be documented.

- 10711.2 Calibration procedures shall include specific directions and limits for accuracy and precision. When accuracy and precision limits are not met, there shall be provisions for remedial action to reestablish the limits and to evaluate whether there was any adverse effect on the device's quality. These activities shall be documented.

- 10711.3 Calibration standards used for inspection, measuring, and test equipment shall be traceable to national or international standards. If national or international standards are not practical or available, the manufacturer shall use an independent reproducible standard. If no applicable standard exists, the manufacturer shall establish and maintain an in-house standard.

- 10711.4 The equipment identification, calibration dates, the individual performing each calibration, and the next calibration date shall be documented. These records shall be displayed on or near each piece of equipment or shall be readily available to the personnel using such equipment and to the individuals responsible for calibrating the equipment.

10712 PROCESS VALIDATION

- 10712.1 Where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. The validation activities and results, including the date and signature of the individual(s) approving the validation and where appropriate the major equipment validated, shall be

documented.

- 10712.2 Each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met.
- 10712.3 Each manufacturer shall ensure that validated processes are performed by qualified individual(s).
- 10712.4 For validated processes, the monitoring and control methods and data, the date performed, and, where appropriate, the individual(s) performing the process or the major equipment used shall be documented.
- 10712.5 When changes or process deviations occur, the manufacturer shall review and evaluate the process and perform revalidation where appropriate. These activities shall be documented.

10713 RECEIVING, IN-PROCESS, AND FINISHED DEVICE ACCEPTANCE

- 10713.1 Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities.
- 10713.2 Each manufacturer shall establish and maintain procedures for acceptance of incoming product. Incoming product shall be inspected, tested, or otherwise verified as conforming to specified requirements. Acceptance or rejection shall be documented.
- 10713.3 Each manufacturer shall establish and maintain acceptance procedures, where appropriate, to ensure that specified requirements for in-process product are met. Such procedures shall ensure that in-process product is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received, and are documented.
- 10713.4 Each manufacturer shall establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria. Finished devices shall be held in quarantine or otherwise adequately controlled until released. Finished devices shall not be released for distribution until:
- (a) The activities required in the device master record (DMR) are completed;
 - (b) The associated data and documentation is reviewed;
 - (c) The release is authorized by the signature of a designated individual(s);
and

(d) The authorization is dated.

10713.5 Each manufacturer shall document acceptance activities required by this chapter. These records shall include:

(a) The acceptance activities performed;

(b) The dates on which acceptance activities are performed;

(c) The results;

(d) The signature of the individual(s) conducting the acceptance activities;
and

(e) Where appropriate, the equipment used. These records shall be part of the DHR.

10714 ACCEPTANCE STATUS

10714.1 Each manufacturer shall identify by suitable means the acceptance status of the product, to indicate the conformance or nonconformance of the product with acceptance criteria. The identification of acceptance status shall be maintained throughout manufacturing, packaging, labeling, installation, and servicing of the product to ensure that only products which have passed the required acceptance activities is distributed, used, or installed.

10715 NON-CONFORMING PRODUCT

10715.1 Each manufacturer shall establish and maintain procedures to control products that do not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming products. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented.

10715.2 Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming products. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming products and the signature of the individual(s) authorizing the use.

10715.3 Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure

that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.

10716 CORRECTIVE AND PREVENTIVE ACTION

10716.1 Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

- (a) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;
- (b) Investigating the cause of nonconformities relating to product, processes, and the quality system;
- (c) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;
- (d) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;
- (e) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;
- (f) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and
- (g) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

10716.2 All activities required under this section, and their results, shall be documented.

10717 DEVICE LABELING

10717.1 Each manufacturer shall establish and maintain procedures to control labeling activities.

10717.2 Labels shall be printed and applied so as to remain legible and affixed during the customary conditions of processing, storage, handling, distribution, and where appropriate, use.

- 10717.3 Labeling shall not be released for storage or use until a designated individual(s) has examined the labeling for accuracy including, where applicable, the correct expiration date, control number, storage instructions, handling instructions, and any additional processing instructions. The release, including the date and signature of the individual(s) performing the examination, shall be documented in the DHR.
- 10717.4 Each manufacturer shall store labeling in a manner that provides proper identification and is designed to prevent mix-ups.
- 10717.5 Each manufacturer shall control labeling and packaging operations to prevent labeling mix-ups. The label and labeling used for each production unit, lot, or batch shall be documented in the DHR.
- 10717.6 Where a control number is required by § 10709, that control number shall be on or shall accompany the device through distribution.

10718 DEVICE PACKAGING

- 10718.1 Each manufacturer shall ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.

10719 HANDLING

- 10719.1 Each manufacturer shall establish and maintain procedures to ensure that mix-ups, damage, deterioration, contamination, or other adverse effects to products do not occur during handling.

10720 STORAGE

- 10720.1 Each manufacturer shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mix-ups, damage, deterioration, contamination, or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate.
- 10720.2 Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.

10721 DISTRIBUTION

10721.1 Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution. Where a device's fitness for use or quality deteriorates over time, the procedures shall ensure that expired devices or devices deteriorated beyond acceptable fitness for use are not distributed.

10721.2 Each manufacturer shall maintain distribution records which include or refer to the location of:

- (a) The name and address of the initial consignee;
- (b) The identification and quantity of devices shipped;
- (c) The date shipped; and
- (d) Any control number(s) used.

10722 INSTALLATION

10722.1 Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures. Instructions and procedures shall include directions for ensuring proper installation so that the device will perform as intended after installation. The manufacturer shall distribute the instructions and procedures with the device or otherwise make them available to the person(s) installing the device.

10722.2 The person installing the device shall ensure that the installation, inspection, and any required testing are performed in accordance with the manufacturer's instructions and procedures and shall document the inspection and any test results to demonstrate proper installation.

10723 GENERAL REQUIREMENTS

10723.1 All records required by this chapter shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of the Department designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available for review and copying by Department employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up.

10723.2 Records that the manufacturer deems confidential may be marked to aid the Department in determining whether information may be disclosed as public

information.

10723.3 All records required by this chapter shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than two (2) years from the date of release for commercial distribution by the manufacturer.

10723.4 This section does not apply to the reports required by § 10702.3 Management review, § 10703 Quality audits, and supplier audit reports used to meet the requirements of § 10707.1 Evaluation of suppliers, contractors, and consultants, but does apply to procedures established under these provisions. Upon request of a designated employee of the Department, an employee in management with executive responsibility shall certify in writing that the management reviews and quality audits required in this chapter, and supplier audits where applicable, have been performed and documented, the dates on which they were performed, and that any required corrective action has been undertaken.

10724 DEVICE MASTER RECORD

10724.1 Each manufacturer shall maintain device master records (DMR). Each manufacturer shall ensure that each DMR is prepared and approved in accordance with § 10706. The DMR for each type of device shall include, or refer to the location of, the following information:

- (a) Device specifications including appropriate drawings, composition, formulation, component specifications, and software specifications;
- (b) Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications;
- (c) Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used;
- (d) Packaging and labeling specifications, including methods and processes used; and
- (e) Installation, maintenance, and servicing procedures and methods.

10725 DEVICE HISTORY RECORD

10725.1 Each manufacturer shall maintain Device History Records (DHRs). Each manufacturer shall establish and maintain procedures to ensure that DHRs for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the DMR and the requirements of this chapter.

The DHR shall include, or refer to the location of, the following information:

- (a) The dates of manufacture;
- (b) The quantity manufactured;
- (c) The quantity released for distribution;
- (d) The acceptance records which demonstrate the device is manufactured in accordance with the DMR;
- (e) The primary identification label and labeling used for each production unit; and
- (f) Any device identification(s) and control number(s) used.

10726 QUALITY SYSTEM RECORD

10726.1 Each manufacturer shall maintain a quality system record (QSR). The QSR shall include, or refer to the location of, procedures and the documentation of activities required by this chapter that are not specific to a particular type of device(s), including, but not limited to, the records required by § 10702. Each manufacturer shall ensure that the QSR is prepared and approved in accordance with § 10706.

10727 COMPLAINT FILES

10727.1 Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:

- (a) All complaints are processed in a uniform and timely manner;
- (b) Oral complaints are documented upon receipt; and
- (c) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to the Department under Chapter 104, Medical Device Reporting.

10727.2 Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.

10727.3 Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and

another investigation is not necessary.

10727.4 Any complaint that represents an event which must be reported to the Department under Chapter 104 shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by § 10726.5, records of investigation within this section shall include a determination of:

- (a) Whether the device failed to meet specifications;
- (b) Whether the device was being used for treatment or diagnosis; and
- (c) The relationship, if any, of the device to the reported incident or adverse event.

10727.5 When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in §10726.1. The record of investigation shall include:

- (a) The name of the device;
- (b) The date the complaint was received;
- (c) Any device identification(s) and control number(s) used;
- (d) The name, address, and phone number of the complainant;
- (e) The nature and details of the complaint;
- (f) The dates and results of the investigation;
- (g) Any corrective action taken; and
- (h) Any reply to the complainant.

10727.6 When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.

10727.7 If a manufacturer's formally designated complaint unit is located outside of the U. S., records required by this section shall be reasonably accessible in the U.S. at either:

- (a) A location in the U.S. where the manufacturer's records are regularly kept;
or
- (b) The location of the initial distributor.

10728 SERVICING

10728.1 Where servicing is a specified requirement, each manufacturer shall establish and maintain instructions and procedures for performing and verifying that the servicing meets the specified requirements.

10728.2 Each manufacturer shall analyze service reports with appropriate statistical methodology in accordance with § 10716.

10728.3 Each manufacturer who receives a service report that represents an event which must be reported to the Department under Chapter 104 shall automatically consider the report a complaint and shall process it in accordance with the requirements of § 10728.

10728.4 Service reports shall be documented and shall include:

- (a) The name of the device serviced;
- (b) Any device identification(s) and control number(s) used;
- (c) The date of service;
- (d) The individual(s) servicing the device;
- (e) The service performed; and
- (f) The test and inspection data.

10729 STATISTICAL TECHNIQUES

10729.1 Where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics.

10729.2 Sampling plans, when used, shall be written and based on a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur the sampling plans are reviewed. These activities shall be documented.

10799 DEFINITIONS

10799.1

As used in this chapter, the following terms shall have the meanings ascribed:

Act – the Federal Food, Drug, and Cosmetic Act, approved June 25, 1938, 21 U.S.C. § 301, *et seq.*

Complaint - any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.

Component - any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.

Control number - any distinctive symbols, such as a distinctive combination of letters or numbers, or both, from which the history of the manufacturing, packaging, labeling, and distribution of a unit, lot, or batch of finished devices can be determined.

Design history file (DHF) - a compilation of records which describes the design history of a finished device.

Design input – the physical and performance requirements of a device that are used as a basis for device design.

Design output – the results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labeling, and the device master record.

Design review – a documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.

Design validation – establishing by objective evidence that device specifications conform to users' needs and intended use(s).

Device history record (DHR) – a compilation of records containing the production history of a finished device.

Device master record (DMR) – a compilation of records containing the procedures and specifications for a finished device.

Establish – define, document (in writing or electronically), and implement.

Finished device – any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

Lot or batch – one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.

Management with executive responsibility – those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer's quality policy and quality system.

Manufacturer – any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

Manufacturing material – any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a byproduct constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer.

Nonconformity – the non-fulfillment of a specified requirement.

Process validation – establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

Product – components, manufacturing materials, in-process devices, finished devices, and returned devices.

Quality – the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.

Quality audit – a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives.

Quality policy - the overall intentions and direction of an organization with respect to quality, as established by management with executive responsibility.

Quality system - the organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Remanufacturer – any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.

Rework – action taken on a nonconforming product so that it will fulfill the specified DMR requirements before it is released for distribution.

Specification – any requirement with which a product, process, service, or other activity must conform.

Validation – confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

Verification – confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

A new Chapter 108 (PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS (GENERAL), IONIZING RADIATION EMITTING PRODUCTS, LIGHT-EMITTING PRODUCTS, AND SONIC, INFRASONIC, AND ULTRASONIC RADIATION EMITTING PRODUCTS) is added to read as follows:

**CHAPTER 108 PERFORMANCE STANDARDS FOR
ELECTRONIC PRODUCTS (GENERAL),
IONIZING RADIATION EMITTING PRODUCTS,
LIGHT-EMITTING PRODUCTS, AND SONIC,
INFRASONIC, AND ULTRASONIC RADIATION
EMITTING PRODUCTS**

**10800 EXAMPLES OF ELECTRONIC PRODUCTS SUBJECT TO THE
RADIATION CONTROL FOR HEALTH AND SAFETY ACT OF 1968**

10800.1 The following listed electronic products are intended to serve as illustrative examples of sources of electronic product radiation to which these regulations apply:

(a) Examples of electronic products which may emit X-rays and other ionizing electromagnetic radiation, electrons, neutrons, and other particulate radiation include:

(1) Ionizing electromagnetic radiation:

(A) Television receivers;

(B) Accelerations; and

- (C) X-ray machines (industrial, medical, research, and educational);
- (2) Particulate radiation and ionizing electromagnetic radiation:
 - (A) Electron microscope; and
 - (B) Neutron generators;
- (b) Examples of electronic products which may emit ultraviolet, visible, infrared, microwaves, radio, and low frequency electromagnetic radiation include:
 - (1) Ultraviolet:
 - (A) Biochemical and medical analyzers;
 - (B) Tanning and therapeutic lamps;
 - (C) Sanitizing and sterilizing devices;
 - (D) Black light sources; and
 - (E) Welding equipment;
 - (2) Visible:
 - (A) White light devices;
 - (3) Infrared:
 - (A) Alarm systems;
 - (B) Diathermy units; and
 - (C) Dryers, ovens, and heaters;
 - (4) Microwave:
 - (A) Alarm systems;
 - (B) Diathermy units;
 - (C) Dryers, ovens, and heaters;

- (D) Medico-biological heaters;
 - (E) Microwave power generating devices;
 - (F) Radar devices;
 - (G) Remote control devices; and
 - (H) Signal generators;
- (5) Radio and low frequency:
- (A) Cauterizers;
 - (B) Diathermy units;
 - (C) Power generation and transmission equipment;
 - (D) Signal generators; and
 - (E) Electro-medical equipment;
- (c) Examples of electronic products which may emit coherent electromagnetic radiation produced by stimulated emission include:
- (1) Laser:
- (A) Art-form, experimental, and educational devices;
 - (B) Biomedical analyzers;
 - (C) Cauterizing, burning, and welding devices;
 - (D) Cutting and drilling devices;
 - (E) Communications transmitters; and
 - (F) Range-finding devices;
- (2) Maser:
- (A) Communication transmitters; and
- (d) Examples of electronic products which may emit infrasonic, sonic, and ultrasonic vibrations resulting from operation of an electronic circuit

include:

- (1) Infrasonic:
 - (A) Vibrators;
- (2) Sonic:
 - (A) Electronic oscillators; and
 - (B) Sound amplification equipment; and
- (3) Ultrasonic:
 - (A) Cauterizers;
 - (B) Cell and tissue disintegrators;
 - (C) Cleaners;
 - (D) Diagnostic and non-destructive testing equipment; and
 - (E) Ranging and detection equipment.

10801 RECOMMENDATIONS FOR THE USE OF SPECIFIC AREA GONAD SHIELDING ON PATIENTS DURING MEDICAL DIAGNOSIS X-RAY PROCEDURES

10801.1 Specific area gonad shielding covers an area slightly larger than the region of the gonads. It may therefore be used without interfering with the objectives of the examination to protect the germinal tissue of patients from radiation exposure that may cause genetic mutations during many medical x-ray procedures in which the gonads lie within or are in close proximity to the x-ray field. Such shielding should be provided when the following conditions exist:

- (a) The gonads will lie within the primary x-ray field, or within close proximity (about five centimeters (5 cm)), despite proper beam limitation. Except as provided in § 10801.2 or 10801.3. The following applies to specific area gonads:
 - (1) Specific area testicular shielding should always be used during those examinations in which the testes usually are in the primary x-ray field, such as examinations of the pelvis, hip, and upper femur;

- (2) Specific area testicular shielding may also be warranted during other examinations of the abdominal region in which the testes may lie within or in close proximity to the primary x-ray field, depending upon the size of the patient and the examination techniques and equipment employed. Some examples of these are: Abdominal, lumbar spine and lumbosacral spine examinations, intravenous pyelograms, and abdominal scout film for barium enemas and upper GI series. Each x-ray facility should evaluate its procedures, techniques, and equipment and compile a list of such examinations for which specific area testicular shielding should be routinely considered for use. As a basis for judgment, specific area testicular shielding should be considered for all examinations of male patients in which the pubic symphysis will be visualized on the film;
- (3) Specific area gonad shielding should never be used as a substitute for careful patient positioning, the use of correct technique factors and film processing, or proper beam limitation (confinement of the x-ray field to the area of diagnostic interest), because this could result in unnecessary doses to other sensitive tissues and could adversely affect the quality of the radiograph; and
- (4) Specific area gonad shielding should provide attenuation of x-rays at least equivalent to that afforded by twenty-five hundredths of a millimeter (0.25 mm) of lead.

(b) The clinical objectives of the examination will not be compromised:

- (1) Specific area testicular shielding usually does not obscure needed information except in a few cases such as oblique views of the hip, retrograde urethrograms and voiding cystourethrograms, visualization of the rectum and, occasionally, the pubic symphysis. Consequently, specific area testicular shielding should be considered for use in the majority of x-ray examinations of male patients in which the testes will lie within the primary beam or within five centimeters (5 cm) of its edge. It is not always possible to position shields on male patients so that no bone is obscured. Therefore, if all bone structure of the pelvic area must be visualized for a particular patient, the use of shielding should be carefully evaluated. The decision concerning the applicability of shielding for an individual patient is dependent upon consideration of the patient's unique anthropometric characteristics and the diagnostic information needs of the examination; or
- (2) The use of specific area ovarian shielding is frequently impractical at present because the exact location of the ovaries is difficult to

estimate, and the shield may obscure visualization of portions of adjacent structures such as the spine, ureters, and small and large bowels. However, it may be possible for practitioners to use specific area ovarian shielding during selected views in some examinations; and

- (c) The patient has a reasonable reproductive potential.
 - (1) Specific area shielding need not be used on patients who cannot or are not likely to have children in the future.

10801.2 The following table of statistical data regarding the average number of children expected by potential parents in various age categories during their remaining lifetimes is provided for x-ray facilities that wish to use it as a basis for judging reproductive potential:

Expected Number of Future Children Versus Age of Potential Parent³		
Age	Male parent	Female parent
Fetus	2.6	2.6
0 to 4	2.6	2.5
5 to 9	2.7	2.5
10 to 14	2.7	2.6
15 to 19	2.7	2.6
20 to 24	2.6	2.2
25 to 29	2.0	1.4
30 to 34	1.1	.6
35 to 39	.5	.2
40 to 44	.2	.04
45 to 49	.07	0
50 to 54	.03	0
55 to 64	.01	0
Over 65	0	0

10802 RECOMMENDATION FOR QUALITY ASSURANCE PROGRAMS IN DIAGNOSTIC RADIOLOGY FACILITIES

³ Derived from data published by the National Center for Health Statistics, "Final Natality Statistics 11070," HRA 74-1120. vol. 22, No. 12, Mar. 20, 1974.

- 10802.1 Quality assurance programs are recommended for all diagnostic radiology facilities.
- 10802.2 A quality assurance program should contain the elements listed in § 10802.3 through 10802.23. The extent to which each element of the quality assurance program is implemented should be determined by an analysis of the facility's objectives and resources conducted by its qualified staff or by qualified outside consultants. The extent of implementation should be determined on the basis of whether the expected benefits in radiation exposure reduction, improved image quality, or financial savings will compensate for the resources required for the program.
- 10802.3 Responsibility and authority for the overall quality assurance program as well as for monitoring, evaluation, and corrective measures should be specified and recorded in a quality assurance manual.
- 10802.4 The owner or practitioner in charge of the facility has primary responsibility for implementing and maintaining the quality assurance program.
- 10802.5 Staff technologists will generally be delegated a basic quality assurance role by the practitioner in charge. Responsibility for specific quality control monitoring and maintenance techniques or quality administration procedures may be assigned, provided that the staff technologists are qualified by training or experience for these duties. The staff technologists should also be responsible for identifying problems or potential problems requiring actions beyond the level of their training. They should bring these problems to the attention of the practitioner in charge, or his or her representative, so that assistance in solving the problems may be obtained from inside or outside the facility.
- 10802.6 In facilities where they are available, physicists, supervisory technologists, or quality control technologists should have a major role in the quality assurance program. Such specialized personnel may be assigned responsibility for day-to-day administration of the program, may carry out monitoring duties beyond the level of training of the staff technologist or, if desired by the facility, may relieve the staff technologists of some or all of their basic monitoring duties. Staff service engineers may also be assigned responsibility for certain preventive or corrective maintenance actions.
- 10802.7 Responsibility for certain quality control techniques and corrective measures may be assigned to personnel qualified by training or experience, such as consultants or industrial representatives, from outside of the facility, provided there is a written agreement clearly specifying these services.
- 10802.8 In large facilities, responsibility for long-range planning of quality assurance goals and activities should be assigned to a quality assurance committee as

described in § 10802.22.

- 10802.9 Before purchasing new equipment, the staff of the diagnostic radiology facility should determine the desired performance specifications for the equipment. Initially, these specifications may be stated in terms of the desired performance of the equipment, or prospective vendors may be informed solely of the functions the equipment should be able to perform and asked to provide the performance specifications of items from their equipment line that can perform these functions. In either case, the responses of the prospective vendors should serve as the basis for negotiations to establish the final purchase specifications, taking into account the state of the art and balancing the need for the specified performance levels with the cost of the equipment to meet them. The final purchase specifications should be in writing and should include performance specifications. The availability of experienced service personnel should also be taken into consideration in making the final purchase decisions. Any understandings with respect to service personnel should be incorporated into the purchase specifications. After the equipment is installed, the facility should conduct a testing program, as defined in its purchase specifications, to ensure that the equipment meets the agreed upon specifications, including applicable Federal and State specifications and the records of the acceptance testing should be retained throughout the life of the equipment for comparison with monitoring results in order to assess continued acceptability of performance.
- 10802.10 A routine quality control monitoring and maintenance system incorporating state-of-the-art procedures should be established and conducted on a regular schedule. The purpose of monitoring is to permit evaluation of the performance of the facility's x-ray system(s) in terms of the standards for image quality established by the facility (as described in § 10802.17) and compliance with applicable Federal and State regulatory requirements. The maintenance program should include corrective maintenance to eliminate problems revealed by monitoring or other means before they have a serious deleterious impact on patient care. To the extent permitted by the training of the facility staff, the maintenance program should also include preventive maintenance, which could prevent unexpected breakdowns of equipment and disruption of departmental routine.
- 10802.11 The parameters to be monitored in a facility should be determined by that facility on the basis of an analysis of expected benefits and cost. Such factors as the size and resources of the facility, the type of examinations conducted, and the quality assurance problems that have occurred in that or similar facilities should be taken into account in establishing the monitoring system. The monitoring frequency should also be based upon need and can be different for different parameters.
- 10802.12 Although the parameters to be monitored will vary somewhat from facility to facility, every diagnostic radiology facility should consider monitoring the following five (5) key components of the x-ray system:

- (a) Film processing;
- (b) Basic performance characteristics of the x-ray unit;
- (c) Cassettes and grids;
- (d) View boxes; and
- (e) Darkroom.

10802.13 Examples of parameters of the above-named components and of more specialized equipment that may be monitored are as follows:

- (a) For film processing:
 - (1) An index of speed;
 - (2) An index of contrast;
 - (3) Base plus fog;
 - (4) Solution temperatures; and
 - (5) Film artifact identification;
- (b) For basic performance characteristics of the x-ray unit:
 - (1) For fluoroscopic x-ray units:
 - (A) Table-top exposure rates;
 - (B) Centering alignment;
 - (C) Collimation;
 - (D) kVp accuracy and reproducibility;
 - (E) mA accuracy and reproducibility;
 - (F) Exposure time accuracy and reproducibility;
 - (G) Reproducibility of x-ray output;
 - (H) Focal spot size consistency;

- (I) Half-value layer; and
 - (J) Representative entrance skin exposures;
- (2) For image-intensified systems:
- (A) Resolution;
 - (B) Focusing;
 - (C) Distortion;
 - (D) Glare;
 - (E) Low contrast performance; and
 - (F) Physical alignment of camera and collimating lens;
- (3) For radiographic x-ray units:
- (A) Reproducibility of x-ray output;
 - (B) Linearity and reproducibility of mA stations;
 - (C) Reproducibility and accuracy of timer stations;
 - (D) Reproducibility and accuracy of kVp stations;
 - (E) Accuracy of source-to-film distance indicators;
 - (F) Light or x-ray field congruence;
 - (G) Half-value layer;
 - (H) Focal spot size consistency; and
 - (I) Representative entrance skin exposures;
- (4) For automatic exposure control devices:
- (A) Reproducibility;
 - (B) kVp compensation;
 - (C) Field sensitivity matching;

- (D) Minimum response time; and
 - (E) Backup timer verification;
- (c) For cassettes and grids:
 - (1) For cassettes:
 - (A) Film or screen contact;
 - (B) Screen condition;
 - (C) Light leaks; and
 - (D) Artifact identification;
 - (2) For grids:
 - (A) Alignment and focal distance; and
 - (B) Artifact identification;
- (d) For view boxes:
 - (1) Consistency of light output with time;
 - (2) Consistency of light output from one (1) box to another; and
 - (3) View box surface conditions;
- (e) For darkrooms:
 - (1) Darkroom integrity; and
 - (2) Safe light conditions;
- (f) For specialized equipment:
 - (1) For tomographic systems:
 - (A) Accuracy of depth and cut indicator;
 - (B) Thickness of cut plane;
 - (C) Exposure angle;

- (D) Completeness of tomographic motion;
 - (E) Flatness of tomographic field;
 - (F) Resolution;
 - (G) Continuity of exposure;
 - (H) Flatness of cassette; and
 - (I) Representative entrance skin exposures; and
- (2) For computerized tomography:
- (A) Precision (noise);
 - (B) Contrast scale;
 - (C) High and low contrast resolution;
 - (D) Alignment; and
 - (E) Representative entrance skin exposures.

10802.14 The maintenance program should include both preventive and corrective aspects.

10802.15 Preventive maintenance should be performed on a regularly scheduled basis with the goal of preventing breakdowns due to equipment failing without warning signs detectable by monitoring. Such actions have been found cost effective if responsibility is assigned to facility staff members. Possible preventive maintenance procedures are visual inspection of the mechanical and electrical characteristics of the x-ray system (covering such things as checking conditions of cables, watching the tomographic unit for smoothness of motion, assuring cleanliness with respect to spilling of contaminants in the examination room or the darkroom, and listening for unusual noises in the moving parts of the system), following the manufacturer's recommended procedures for cleaning and maintenance of the equipment, and regular inspection and replacement of switches and parts that routinely wear out or fail. The procedures included would depend upon the background of the staff members available. Obviously, a large facility with its own service engineers can do more than an individual practitioner's office.

10802.16 For maximum effectiveness, the quality assurance program should make provisions, as described in § 10802.18 for ascertaining whether potential problems are developing. If potential or actual problems are detected, corrective maintenance should be carried out to eliminate them before they cause a major

impact on patient care.

10802.17 Standards of acceptable image quality should be established. Ideally, these should be objective. Acceptability limits for the variations of parameter values, but they may be subjective (for example, the opinions of professional personnel, in cases where adequate objective standards cannot be defined). These standards should be routinely reviewed and redefined as needed, as described in § 10802.23 of this chapter.

10802.18 The facility's quality assurance program should include means for two (2) levels of evaluation:

- (a) On the first level, the results of the monitoring procedures should be used to evaluate the performance of the x-ray system(s) to determine whether corrective actions are needed to adjust the equipment so that the image quality consistently meets the standards for image quality. This evaluation should include analysis of trends in the monitoring data as well as the use of the data to determine the need for corrective actions on a day-by-day basis. Comparison of monitoring data with the purchase specifications and acceptance testing results for the equipment in question is also useful; and
- (b) On the second level, the facility quality assurance program should also include means for evaluating the effectiveness of the program itself. Possible means include ongoing studies of the retake rate and the causes of the repeated radiographs, examination of equipment repair and replacement costs, subjective evaluation of the radiographs being produced, occurrence and reasons for complaints by radiologists, and analysis of trends in the results of monitoring procedures such as sensitometric studies. Of these, ongoing studies of the retake rate (reject rate) and its causes are often the most useful and may also provide information of value in the first level of evaluation. Such studies can be used to evaluate potential for improvement, to make corrections, and to determine whether the corrective actions were effective. The number of rejects should be recorded daily or weekly, depending on the facility's analysis of its needs. Ideally, the reasons for the rejection should also be determined and recorded. Should determining these reasons be impossible on a regular basis with the available staff, the analysis should be done for a two (2)-week period after major changes have occurred in diagnostic procedures or the x-ray system and at least semi-annually.

10802.19 The program should include provisions for the keeping of records on the results of the monitoring techniques, any difficulties detected, the corrective measures applied to these difficulties, and the effectiveness of these measures. The extent and form of these records should be determined by the facility on the basis of its needs. The facility should view these records as a tool for maintaining an effective quality assurance program and not view the data in them as an end in itself but

rather as a beginning. For example, the records should be made available to vendors to help them provide better service. More importantly, the data should be the basis for the evaluation and the reviews suggested in §§ 10802.18 and 10802.23.

10802.20 A quality assurance manual should be written in a format permitting convenient revision as needed and should be made readily available to all personnel. The content of the manual should be determined by the facility staff, but the following items are suggested as providing essential information:

- (a) A list of the individuals responsible for monitoring and maintenance techniques;
- (b) A list of the parameters to be monitored and the frequency of monitoring;
- (c) A description of the standards, criteria of quality, or limits of acceptability that have been established for each of the parameters monitored;
- (d) A brief description of the procedures to be used for monitoring each parameter;
- (e) A description of procedures to be followed when difficulties are detected to call these difficulties to the attention of those responsible for correcting them;
- (f) A list of the publications in which detailed instructions for monitoring and maintenance procedures can be found. Copies of these publications should also be readily available to the entire staff, but they should be separate from the manual. (Publications providing these instructions can usually be obtained from the Department or private sources, although the facility may wish to make some modifications to meet its needs more effectively);
- (g) A list of the records, with sample forms, that the facility staff has decided should be kept. The facility staff should also determine and note in the manual the length of time each type of record should be kept before discarding; and
- (h) A copy of each set of purchase specifications developed for new equipment and the results of the acceptance testing for that equipment.

10802.21 The program should include provisions for appropriate training for all personnel with quality assurance responsibilities. This should include both training provided before the quality assurance responsibilities are assumed and continuing education to keep the personnel up-to-date. Practical experience with the techniques conducted under the supervision of experienced instructors, either in the facility or in a special program, is the most desirable type of training. The use

of self-teaching materials can be an adequate substitute for supervised instruction, especially in continuing education programs, if supervised instruction is not available.

10802.22 A facility whose size would make it impractical for all staff members to meet for planning purposes should consider the establishment of a quality assurance committee whose primary function would be to maintain lines of communication among all groups with quality assurance or image production or interpretation responsibilities. For maximum communication, all departments of the facility with x-ray equipment should be represented. The committee may also be assigned policy-making duties such as some or all of the following:

- (a) Assign quality assurance responsibilities;
- (b) Maintain acceptable standards of quality; and
- (c) Periodically review program effectiveness. Alternatively, the duties of this committee could be assigned to an already-existing committee such as the Radiation Safety Committee. In smaller facilities, all staff members should participate in the committee's tasks. The Quality Assurance Committee should report directly to the head of the radiology department, or, in facilities where more than one (1) department operates x-ray equipment, to the chief medical officer of the facility. The committee should meet on a regular basis.

10802.23 The facility's quality assurance program should be reviewed by the Quality Assurance Committee or the practitioner in charge to determine whether its effectiveness could be improved. Items suggested for inclusion in the review include:

- (a) The reports of the monitoring and maintenance techniques to ensure that they are being performed on schedule and effectively. These reports should be reviewed at least quarterly;
- (b) The monitoring and maintenance techniques and their schedules to ensure that they continue to be appropriate and in step with the latest developments in quality assurance. They should be made current at least annually;
- (c) The standards for image quality to ensure that they are consistent with the state-of-the-art and the needs and resources of the facility. These standards should be evaluated at least annually;
- (d) The results of the evaluations of the effectiveness of the quality assurance actions to determine whether changes need to be made. This

determination should be made at least annually; and

- (e) The quality assurance manual should also be reviewed at least annually to determine whether revisions are needed.

10803 RECOMMENDATION ON ADMINISTRATIVELY REQUIRED DENTAL X-RAY EXAMINATIONS

10803.1 The Department recommends that dental x-ray examinations be performed only after careful consideration of the dental or other health needs of the patient, that is, when the patient's dentist or physician judges them to be necessary for diagnosis, treatment, or prevention of disease. Administratively required dental x-ray examinations are those required by a remote third party for reasons not related to the patient's immediate dental needs. These x-ray examinations are usually a source of unnecessary radiation exposure to the patient. Because any unnecessary radiation exposure should be avoided, third parties should not require dental x-ray examinations unless they can demonstrate that such examinations provide a direct clinical benefit to the patient, and the patient's dentist or physician agrees with that assessment.

10803.2 Some examples of administrative x-ray examinations that should not be required by third parties are those intended solely:

- (a) To monitor insurance claims or detect fraud;
- (b) To satisfy a prerequisite for reimbursement;
- (c) To provide training or experience; or
- (d) To certify qualifications or competence.

10803.3 This recommendation is not intended to preclude dental x-ray examinations ordered by the attending practitioner, based on the patient's history or physical examination, or those performed on selected populations shown to have significant yields of previously undiagnosed disease. This recommendation is also not intended to preclude the administrative use by third parties of dental radiographs that are taken on the order of the patient's dentist or physician as a necessary part of the patient's clinical care.

10804 APPLICABILITY

10804.1 The provisions of this chapter are applicable as follows:

- (a) All manufacturers of electronic products are subject to § 10815;

- (b) Manufacturers, dealers, and distributors of electronic products are subject to the provisions set forth in table 1 of this section, unless excluded by paragraph (c) or an exemption has been granted under § 10818 or 10819; and
- (c) The requirements as specified in table 1 of this section are not applicable to:
 - (1) Manufacturers of electronic products intended solely for export if such product is labeled or tagged to show that the product meets all the applicable requirements of the country to which such product is intended for export;
 - (2) Manufacturers of electronic products listed in table 1 of this section if such product is sold exclusively to other manufacturers for use as components of electronic products to be sold to purchasers, with the exception that the provisions are applicable to those manufacturers certifying components of diagnostic x-ray systems pursuant to provisions of § 10853.5 of this chapter;
 - (3) Manufacturers of electronic products that are intended for use by the U.S. Government and whose function or design cannot be divulged by the manufacturer for reasons of national security, as evidenced by government security classification; or
 - (4) Assemblers of diagnostic x-ray equipment subject to the provisions of § 10853.6 of this chapter, provided the assembler has submitted the report required by § 10853.7 or 10853.8 of this chapter and retains a copy of such report for a period of five (5) years from its date.

Table 1. -- Record and Reporting Requirements By Product

Manufacturer				
Products	Product reports § 10808	Supplemental reports § 10809	Abbreviated reports § 10810	Annual reports § 10811
DIAGNOSTIC X-RAY ⁴				
(10853, 10854, 10855)				
Computed tomography	X	X		X
X-ray system ⁵	X	X		X
Tube housing assembly	X	X		X
X-ray control	X	X		X
X-ray high voltage generator	X	X		X
X-ray table or cradle			X	
X-ray film changer			X	
Vertical cassette holders mounted in a fixed location and cassette holders with front panels			X	
Beam-limiting devices	X	X		X
Spot-film devices and image intensifiers manufactured after April 26, 1977	X	X		X
Cephalometric devices manufactured after February 25, 1978			X	
Image receptor support devices for mammographic X-ray systems manufactured after September 5, 1978			X	

⁴ Report of Assembly (Form FDA 2579) is required for diagnostic x-ray components; see 21 CFR § 1020.30(d)(1) through (d)(3).

⁵ Systems records and reports are required if a manufacturer exercises the option and certifies the system as permitted in 21 C.F.R. § 1020.30(c).

CABINET X RAY				
Baggage inspection	X	X		X
Other	X	X		X
Products intended to produce particulate radiation or x-rays other than diagnostic or cabinet diagnostic x-ray				
Medical			X	X
Analytical			X	X
Industrial			X	X
TELEVISION PRODUCTS				
<25 kilovolt (kV) and <0.1 milliroentgen per hour (mR/hr.) IRLC ^{6,7}			X	X fn6
(gteqt) 25kV and <0.1mR/hr IRLC	X	X		X
(gteqt) 0.1mR/hr IRLC	X	X		X
MICROWAVE/RF				
MW ovens	X	X		X
MW diathermy			X	
MW heating, drying, security systems			X	
RF sealers, electromagnetic induction and heating equipment, dielectric heaters (2-500 megahertz)			X	
OPTICAL				
Phototherapy products	X	X		
Laser products				

⁶ Determined using the isoexposure rate limit curve (IRLC) under phase III test conditions (21 C.F.R. § 1020.10(c)(3)(iii)).

⁷ Annual report is for production status information only.

Class I lasers and products containing such lasers ⁸	X			X
Class I laser products containing class IIa, II, IIIa, lasers ⁹	X			X
Class IIa, II, IIIa lasers and products other than class I products containing such lasers ¹⁰	X	X		X
Class IIIb and IV lasers and products containing such lasers ¹¹	X	X		X
Sunlamp products				
Lamps only	X			
Sunlamp products	X	X		X
Mercury vapor lamps				
T lamps	X	X		X
R lamps			X	
ACOUSTIC				
Ultrasonic therapy	X	X		X
Diagnostic ultrasound			X	
Medical ultrasound other than therapy or diagnostic	X	X		
Nonmedical ultrasound			X	

Table 1. -- Record and Reporting Requirements By Product			
Manufacturer			

⁸ Determination of the applicable reporting category for a laser product shall be based on the worst-case hazard present within the laser product.

⁹ Id.

¹⁰ Id.

¹¹ Id.

			Dealer & Distributor
Products	Test records	Distribution	Distribution
	§ 10816.1(a) ¹²	records	records
		§ 10816.1(b) ¹³	§§ 10812 and 10813
DIAGNOSTIC X-RAY ¹⁴ (10853, 10854, 10855)			
Computed tomography	X	X	X
X-ray system ¹⁵	X	X	X
Tube housing assembly	X	X	
X-ray control	X	X	X
X-ray high voltage generator	X	X	X
X-ray table or cradle	X	X	X
X-ray film changer	X	X	
Vertical cassette holders mounted in a fixed location and cassette holders with front panels	X	X	X
Beam-limiting devices	X	X	X
Spot-film devices and image intensifiers manufactured after intensifiers manufactured after April 26, 1977	X	X	X
Cephalometric devices manufactured after February 25, 1978	X	X	
Image receptor support devices for mammographic X-ray systems manufactured after September 5, 1978	X	X	X

¹² However, authority to inspect all appropriate documents supporting the adequacy of a manufacturer's compliance testing program is retained.

¹³ The requirement includes §§ 10817 and 10814, if applicable.

¹⁴ Report of Assembly is required for diagnostic x-ray components; *see* § 10853.7 through 10853.9.

¹⁵ Systems records and reports are required if a manufacturer exercises the option and certifies the system as permitted in § 10853.6.

CABINET X RAY			
Baggage inspection	X	X	X
Other	X	X	
PRODUCTS INTENDED TO PRODUCE PARTICULATE RADIATION OR X-RAYS OTHER THAN DIAGNOSTIC OR CABINET DIAGNOSTIC X-RAY			
Medical	X	X	
Analytical	X	X	
Industrial	X	X	
TELEVISION PRODUCTS (§ 10851)			
1t25 kilovolt (kV) and 1t0.1 milliroentgen per hour (mR/hr.) IRLC ^{16,17}			
1t25 kV and 1t0.1 mR/hr. IRLC			
t]25kV and 1t0.	X	X	
MICROWAVE/RF			
MW ovens	X	X	
MW diathermy			
MW heating, drying, security systems			
RF sealers, electromagnetic induction and heating equipment, dielectric heaters (2-500 megahertz)			
OPTICAL			
Phototherapy products			
Laser products			

¹⁶ Determined using the isexposure rate limit curve (IRLC) under phase III test conditions (§ 10851.4(c)).

¹⁷ Annual report is for production status information only.

Class I lasers and products containing such lasers ¹⁸	X		
Class I laser products containing class IIa, II, IIIa, lasers ¹⁹	X	X	
Class IIa, II, IIIa lasers and products other than class I products containing such lasers ²⁰	X	X	X
Class IIIb and IV lasers and products containing such lasers ²¹	X	X	X
Sunlamp products			
Lamps only			
Sunlamp products	X	X	X
Mercury vapor lamps			
T lamps			
R lamps			
ACOUSTIC			
Ultrasonic therapy	X	X	X
Diagnostic ultrasound			
Medical ultrasound other than therapy or diagnostic			
Nonmedical ultrasound			

10805 NOTIFICATION TO USER OF PERFORMANCE AND TECHNICAL DATA

10805.1 The Director and Deputy Director of the Center for Devices and Radiological Health, as authorized under delegated authority, may require a manufacturer of a radiation emitting electronic product to provide to the ultimate purchaser, at the time of original purchase, such performance data and other technical data related to safety of the product as the Director or Deputy Director finds necessary.

10806 CONFIDENTIALITY OF INFORMATION

¹⁸ Determination of the applicable reporting category for a laser product shall be based on the worst-case hazard present within the laser product.

¹⁹ Id.

²⁰ Id.

²¹ Id.

10806.1 The Secretary or his or her representative shall not disclose any information reported to or otherwise obtained by him or her, pursuant to this chapter, which concerns or relates to a trade secret or other matter referred to in Section 1905 of Title 18 of the United States Code, except that such information may be disclosed to other officers or employees of the Department and of the other agencies concerned with carrying out the requirements of the Act. Nothing in this section shall authorize the withholding of information by the Secretary, or by any officers or employees under his or her control, from the duly authorized committees of the Congress.

10807 SUBMISSION OF DATA AND REPORTS

10807.1 All submissions such as reports, test data, product descriptions, and other information required by this chapter, or voluntarily submitted to the Department, shall be filed with the number of copies prescribed by the Department and shall be signed by the person making the submission.

10807.2 [Reserved]

10807.3 Where the Department issues guides or instructions have been for the submission of material required by this chapter, such as test data, product reports, abbreviated reports, supplemental reports, and annual reports, the material submitted shall conform to the applicable reporting guides or instructions. Where it is not feasible or where it would not be appropriate to conform to any portion of a prescribed reporting guide or instruction, an alternate format for providing the information requested by that portion of the guide or instruction may be used provided the submitter of such information submits adequate explanation and justification for use of an alternate format. If the Department determines that such justification is inadequate and that it is feasible or appropriate to conform to the prescribed reporting guide or instruction, the agency may require resubmission of the information in conformance with the reporting guide or instruction.

10807.4 Where the submission of quality control and testing information is common to more than one (1) model, or model family of the same product category, a "common aspects report" consolidating similar information may be provided, if applicable.

10808 PRODUCT REPORTS

10808.1 Every manufacturer of a product or component requiring a product report as set forth in Table 1 of § 10804 shall submit a product report to the Department, prior to the introduction of such product into commerce. The report shall be distinctly marked "Radiation Safety Product Report of (name of manufacturer)" and shall:

- (a) Identify which listed product is being reported;

- (b) Identify each model of the listed product together with sufficient information concerning the manufacturer's code or other system of labeling to enable the Director to determine the place of manufacture;
- (c) Include information on all components and accessories provided in, on, or with the listed product that may affect the quantity, quality, or direction of the radiation emissions;
- (d) Describe the function, operational characteristics affecting radiation emissions, and intended and known uses of each model of the listed product;
- (e) State the standard or design specifications, if any, for each model with respect to electronic product radiation safety. Reference may be made to a District standard, if applicable;
- (f) For each model, describe the physical or electrical characteristics, such as shielding or electronic circuitry, incorporated into the product in order to meet the standards or specifications reported pursuant to paragraph (e);
- (g) Describe the methods and procedures employed, if any, in testing and measuring each model with respect to electronic product radiation safety, including the control of unnecessary, secondary, or leakage electronic product radiation, the applicable quality control procedures used for each model, and the basis for selecting such testing and quality control procedures;
- (h) For those products which may produce increased radiation with aging, describe the methods and procedures used, and frequency of testing of each model for durability and stability with respect to electronic product radiation safety. Include the basis for selecting such methods and procedures, or for determining that such testing and quality control procedures are not necessary;
- (i) Provide sufficient results of the testing, measuring, and quality control procedures described in accordance with paragraphs (g) and (h) to enable the Department to determine the effectiveness of those test methods and procedures;
- (j) Report for each model all warning signs, labels, and instructions for installation, operation, and use that relate to electronic product radiation safety; and
- (k) Provide, upon request, such other information as the Department may reasonably require to enable it to determine whether the manufacturer has acted or is acting in compliance with the Act and any standards prescribed

thereunder, and to enable the Department to carry out the purposes of the Act.

10809 SUPPLEMENTAL REPORTS

10809.1 Prior to the introduction into commerce of a new or modified model within a model or chassis family of a product listed in Table 1 of § 10804 for which a report under § 10808 is required, each manufacturer shall submit a report with respect to such new or modified model describing any changes in the information previously submitted in the product report. Reports will be required for changes that:

- (a) Affect actual or potential radiation emission; and
- (b) Affect the manner of compliance with a standard or manner of testing for radiation safety.

10810 ABBREVIATED REPORTS

10810.1 Manufacturers of products requiring abbreviated reports as specified in Table 1 of § 10804 shall submit, prior to the introduction of such product, a report distinctly marked "Radiation Safety Abbreviated Report" which shall include:

- (a) Firm and model identification;
- (b) A brief description of operational characteristics that affect radiation emissions, transmission, leakage, or that control exposure;
- (c) A list of applications or uses;
- (d) Radiation emission, transmission, or leakage levels; and
- (e) If necessary, additional information as may be requested to determine compliance with the Act and this chapter.

10811 ANNUAL REPORTS

10811.1 Every manufacturer of products requiring an annual report as specified in Table 1 of § 10804 shall submit an annual report summarizing the contents of the records required to be maintained by § 10816.1 and providing the volume of products produced, sold, or installed.

10811.2 Reports are due annually by September 1. Such reports shall cover the twelve (12) month period ending on June 30 preceding the due date of the report.

10811.3 New models of a model family that do not involve changes in radiation emission or requirements of a performance standard do not require supplemental reports prior to introduction into commerce. These model numbers should be reported in quarterly updates to the annual report.

10812 RECORDS TO BE OBTAINED BY DEALERS AND DISTRIBUTORS

10812.1 Dealers and distributors of electronic products for which there are performance standards and for which the retail price is fifty dollars (\$50) or more shall obtain such information as is necessary to identify and locate first purchasers if the product is subject to this section by virtue of Table 1 of § 10804.

10812.2 Such information shall include:

- (a) The name and mailing address of the distributor, dealer, or purchaser to whom the product was transferred;
- (b) Identification and brand name of the product;
- (c) Model number and serial or other identification number of the product; and
- (d) Date of sale, award, or lease.

10812.3 The information obtained pursuant to this section shall be forwarded immediately to the appropriate manufacturer of the electronic product, or preserved as prescribed in § 10813.

10813 DISPOSITION OF RECORDS OBTAINED BY DEALERS AND DISTRIBUTORS

10813.1 Information obtained by dealers and distributors pursuant to § 10812 shall immediately be forwarded to the appropriate manufacturer unless:

- (a) The dealer or distributor elects to hold and preserve such information and to immediately furnish it to the manufacturer when advised by the manufacturer or the Department of Health, that such information is required; and
- (b) The dealer or distributor, upon making the election under § 10813.1(a) of this section, promptly notifies the manufacturer of such election. Such notification shall be in writing and shall identify the dealer or distributor and the electronic product or products for which the information is being accumulated and preserved.

10813.2 Every dealer or distributor who elects to hold and preserve information required pursuant to § 10812 shall preserve the information for a period of five (5) years from the date of the sale, award, or lease of the product, or until the dealer or distributor discontinues dealing in, or distributing the product, whichever is sooner. If the dealer or distributor discontinues dealing in, or distributing the product, such information as obtained pursuant to § 10812 shall be furnished at that time, or before, to the manufacturer of the product.

10814 CONFIDENTIALITY OF RECORDS FURNISHED BY DEALERS AND DISTRIBUTORS

10814.1 All information furnished to manufacturers by dealers and distributors pursuant to this chapter shall be treated by such manufacturers as confidential information which may be used only as necessary to notify persons pursuant to Section 535 of the Act.

10815 REPORTING OF ACCIDENTAL RADIATION OCCURRENCES

10815.1 Manufacturers of electronic products shall, where reasonable grounds for suspecting that such an incident has occurred, immediately report to the Department all accidental radiation occurrences reported to or otherwise known to the manufacturer and arising from the manufacturing, testing, or use of any product introduced or intended to be introduced into commerce by such manufacturer. Reasonable grounds include, but are not necessarily limited to, professional, scientific, or medical facts or opinions documented or otherwise, that concludes or leads to the conclusion that such an incident has occurred.

10815.2 Such reports shall be addressed to the Department, and the reports and their envelopes shall be distinctly marked "Report on 10815" and shall contain all of the following information where known to the manufacturer:

- (a) The nature of the accidental radiation occurrence;
- (b) The location at which the accidental radiation occurrence occurred;
- (c) The manufacturer, type, and model number of the electronic product or products involved;
- (d) The circumstances surrounding the accidental radiation occurrence, including causes;
- (e) The number of persons involved, adversely affected, or exposed during the accidental radiation occurrence, the nature and magnitude of their exposure or injuries and, if requested by the Department, the names of the persons involved;

- (f) The actions, if any, which may have been taken by the manufacturer, to control, correct, or eliminate the causes and to prevent reoccurrence; and
- (g) Any other pertinent information with respect to the accidental radiation occurrence.

10815.3 If a manufacturer is required to report to the Director under § 10815.1 and also is required to report under Chapter 104, the manufacturer shall report in accordance with Chapter 104. If a manufacturer is required to report to the Director under §10815.1 and is not required to report under Chapter 104, the manufacturer shall report in accordance with §10815.1 of this section. A manufacturer need not file a separate report under this section if an incident involving an accidental radiation occurrence is associated with a defect or noncompliance and is reported pursuant to § 10823.

10816 RECORDS TO BE MAINTAINED BY MANUFACTURERS

10816.1 Manufacturers of products listed under Table 1 of § 10804 shall establish and maintain the following records with respect to such products:

- (a) Description of the quality control procedures with respect to electronic product radiation safety;
- (b) Records of the results of tests for electronic product radiation safety, including the control of unnecessary, secondary or leakage electronic product radiation, the methods, devices, and procedures used in such tests, and the basis for selecting such methods, devices, and procedures;
- (c) For those products displaying aging effects which may increase electronic product radiation emission, records of the results of tests for durability and stability of the product, and the basis for selecting these tests;
- (d) Copies of all written communications between the manufacturer and dealers, distributors, and purchasers concerning radiation safety including complaints, investigations, instructions, or explanations affecting the use, repair, adjustment, maintenance, or testing of the listed product; and
- (e) Data on production and sales volume levels if available.

10816.2 In addition to the records required by § 10816.1, manufacturers of products listed in § 10816.3 shall establish and maintain the following records with respect to such products:

- (a) A record of the manufacturer's distribution of products in a form which will enable the tracing of specific products or production lots to distributors or to dealers in those instances in which the manufacturer

distributes directly to dealers; and

(b) Records received from dealers or distributors pursuant to § 10813.

10816.3 Manufacturers shall maintain reports for the following radiation-emitting products:

- (a) Ultrasonic products;
- (b) Microwave heating equipment;
- (c) High voltage vacuum switches;
- (d) Rectifier tubes;
- (e) Shunt regulator tubes;
- (f) Cathode ray tubes intended to be operated at voltages greater than five thousand volts (5000 V) but less than fifteen thousand volts (15,000 V);
- (g) Ultraviolet lamps and products containing such lamps intended for irradiation of any part of the human body by light of wavelength in air less than three hundred twenty nanometers (320 nm) to perform a diagnostic or therapeutic function;
- (h) Television receivers that meet the District standard, provided the voltage of the cathode ray tube cannot exceed fifteen thousand volts (15,000 V);
- (i) High voltage vacuum switches, rectifier tubes, shunt regulator tubes, and cathode ray tubes intended to be operated at voltages of fifteen thousand (15,000) or greater;
- (j) Products in addition to television receivers that are subject to radiation standards; and
- (k) Diagnostic x-ray, cabinet x-ray, microwave ovens, laser products, and sunlamp.

10817 PRESERVATION AND INSPECTION OF RECORDS

10817.1 Every manufacturer required to maintain records pursuant to this part, including records received pursuant to § 10813, shall preserve such records for a period of five (5) years from the date of the record.

10817.2 Upon reasonable notice by an officer or employee duly designated by the Department, manufacturers shall permit such officer or employee to inspect

appropriate books, records, papers, and documents as are relevant to determining whether the manufacturer has acted or is acting in compliance with Federal standards.

10817.3 Upon request of the Department of Health, a manufacturer of products listed in Table 1 of § 10804 shall submit to the Director, copies of the records required to be maintained by § 10816.2.

10818 SPECIAL EXEMPTIONS

10818.1 Manufacturers of electronic products may submit to the Director a request, together with accompanying justification, for exemption from any requirements listed in Table 1 of § 10804. The request must specify each requirement from which an exemption is requested. In addition to other information that is required, the justification must contain documented evidence showing that the product or product type for which the exemption is requested does not pose a public health risk and meets at least one (1) of the following criteria:

- (a) The products cannot emit electronic product radiation in sufficient intensity or of such quality, under any conditions of operation, maintenance, service, or product failure, to be hazardous;
- (b) The products are produced in small quantities;
- (c) The products are used by trained individuals and are to be used by the same manufacturing corporation or for research, investigation, or training;
- (d) The products are custom designed and used by trained individuals knowledgeable of the hazards; or
- (e) The products are produced in such a way that the requirements are inappropriate or unnecessary.

10818.2 The Director may, subject to any conditions that the Director deems necessary to protect the public health, exempt manufacturers from all or part of the record and reporting requirements of this part on the basis of information submitted in accordance with § 10818.1 of this section or such other information which the Department may possess if the Department determines that such exemption is in keeping with the purposes of the Act.

10818.3 The Department will provide written notification of the reason for any denial. If the exemption is granted, the Department will provide written notification of:

- (a) The electronic product or products for which the exemption has been granted;

- (b) The requirements from which the product is exempted; and
- (c) Such conditions as are deemed necessary to protect the public health and safety. Copies of exemptions shall be available upon request from the Department.

10818.4 The Department may exempt certain classes of products from the reporting requirements listed in Table 1 of § 10804, provided that the Department finds that such exemption is in keeping with the purposes of the Act.

10818.5 Manufacturers of products for which there is no applicable performance standard and for which an investigational device exemption has been approved or for which a premarket approval application has been approved in accordance with § 10611.4 of this chapter are exempt from submitting all reports listed in Table 1 of § 10804.

10819 EXEMPTIONS FOR MANUFACTURERS OF PRODUCTS INTENDED FOR THE DISTRICT OF COLUMBIA

10819.1 Upon application therefore by the manufacturer, the Department may exempt from the provisions of this chapter a manufacturer of any electronic product intended for use by departments or agencies of the District of Columbia provided such department or agency has prescribed procurement specifications governing emissions of electronic product radiation and provided further that such product is of a type used solely or predominantly by departments or agencies of the District of Columbia.

10820 APPLICABILITY

10820.1 The provisions of this chapter are applicable to electronic products which were manufactured after October 18, 1968.

10821 DEFECT IN ELECTRONIC PRODUCTS

10821.1 For the purpose of this chapter, an electronic product shall be considered to have a defect which relates to the safety of use by reason of the emission of electronic product radiation if:

- (a) It is a product which does not utilize the emission of electronic product radiation in order to accomplish its purpose, and from which such emissions are unintended, and as a result of its design, production or assembly;
- (b) It emits electronic product radiation which creates a risk of injury, including genetic injury, to any person;

- (c) It fails to conform to its design specifications relating to electronic radiation emissions;
- (d) It is a product which utilizes electronic product radiation to accomplish its primary purpose and from which such emissions are intended, and as a result of its design, production, or assembly;
- (e) Fails to conform to its design specifications relating to the emission of electronic product radiation;
- (f) Without regard to the design specifications of the product, emits electronic product radiation unnecessary to the accomplishment of its primary purpose which creates a risk of injury, including genetic injury to any person; or
- (g) Fails to accomplish the intended purpose.

10822 EFFECT OF REGULATION ON OTHER LAWS

10822.1 The remedies provided for in this chapter shall be in addition to and not in substitution for any other remedies provided by law and shall not relieve any person from liability at common law or under statutory law.

10823 DISCOVERY OF DEFECT OR FAILURE OF COMPLIANCE BY MANUFACTURER – NOTICE REQUIREMENTS

10823.1 Any manufacturer who discovers that any electronic product produced, assembled, or imported by him or her, which product has left its place of manufacture, has a defect or fails to comply with an applicable District standard shall:

- (a) Immediately notify the Department in accordance with § 10825; and
- (b) Except as authorized by § 10828, furnish notification with reasonable promptness to the following persons:
 - (1) The dealers or distributors to whom such product was delivered by the manufacturer; and
 - (2) The purchaser of such product and any subsequent transferee of such product (where known to the manufacturer or where the manufacturer upon reasonable inquiry to dealers, distributors, or purchasers can identify the present user).

10823.2 If a manufacturer is required to notify the Department under Chapter 104, the manufacturer shall report in accordance with Chapter 104.

10824 DETERMINATION BY THE DEPARTMENT OF HEALTH THAT PRODUCT FAILS TO COMPLY OR HAS A DEFECT

10824.1 If, the Department through testing, inspection, research, or examination of reports or other data, determines that any electronic product does not comply with an applicable standard issued pursuant to the Act or has a defect, he or she shall immediately notify the manufacturer of the product in writing specifying:

- (a) The defect in the product or the manner in which the product fails to comply with the applicable standard;
- (b) The Department's findings, with references to the tests, inspections, studies, or reports upon which such findings are based; and
- (c) A reasonable period of time during which the manufacturer may present his views and evidence to establish that there is no failure of compliance or that the alleged defect does not exist or does not relate to safety of use of the product by reason of the emission of electronic product radiation.

10824.2 The manufacturer shall have an opportunity for a regulatory hearing before the Department.

10824.3 Every manufacturer who receives a notice under §10824.1 shall immediately advise the Department in writing of the total number of such product units produced and the approximate number of such product units which left the place of manufacture.

10824.4 If, after the expiration of the period of time specified in the notice, the Department determines that the product has a defect or does not comply with an applicable standard and the manufacturer has not applied for an exemption, he or she shall direct the manufacturer to furnish the notification to the persons specified in § 10823.1(b) in the manner specified in § 10826. The manufacturer shall within fourteen (14) days from the date of receipt of such directive furnish the required notification.

10825 NOTIFICATION BY THE MANUFACTURER TO THE DEPARTMENT OF HEALTH

10825.1 The notification to the Department required by § 10823.1(a) shall be confirmed in writing and, in addition to other relevant information which the Department may require, shall include the following:

- (a) Identification of the product or products involved;

- (b) The total number of such product units so produced, and the approximate number of such product units which have left the place of manufacture;
- (c) The expected usage for the product if known to the manufacturer;
- (d) A description of the defect in the product or the manner in which the product fails to comply with an applicable standard;
- (e) An evaluation of the hazards reasonably related to defect or the failure to comply with the standard;
- (f) A statement of the measures to be taken to repair such defect or to bring the product into compliance with the standard;
- (g) The date and circumstances under which the defect was discovered; and
- (h) The identification of any trade secret information which the manufacturer desires be kept confidential.

10826 NOTIFICATION BY THE MANUFACTURER TO AFFECTED PERSONS

10826.1 The notification to the persons specified in § 10823.1(b) shall be in writing and, in addition to other relevant information which the Department may require, shall include:

- (a) The information prescribed by § 10825.1(a) and (d), as well as instructions with respect to the use of the product pending the correction of the defect;
- (b) A clear evaluation in nontechnical terms of the hazards reasonably related to any defect or failure to comply;
- (c) The following statement:

“The manufacturer will, without charge, remedy the defect or bring the product into compliance with each applicable District of Columbia standard in accordance with a plan to be approved by the Department of Health, the details of which will be included in a subsequent communication to you.”; and

- (d) Provided, that if at the time the notification is sent, the Department has approved a plan for the repair, replacement, or refund of the product, the notification may include the details of the approved plan in lieu of the above statement.

10826.2 The envelope containing the notice shall not contain advertising or other extraneous material, and such mailings will be made in accordance with this

section.

- 10826.3 Number 10 white envelopes shall be used, and the name and address of the manufacturer shall appear in the upper left corner of the envelope.
- 10826.4 The following statement is to appear in the far left third of the envelope in the type and size indicated and in reverse printing, centered in a red rectangle three and three-fourths inches (3 $\frac{3}{4}$ in.) wide and two and one-quarter inches (2 $\frac{1}{4}$ in.) high:
- “Important--Electronic Product Radiation Warning”
- 10826.5 The statement shall be in three (3) lines, all capitals, and centered. "Important" shall be in thirty six (36) point Gothic Bold type. "Electronic Product" and "Radiation Warning" shall be in thirty six (36) point Gothic Condensed type.
- 10826.6 Envelopes with markings similar to those prescribed in this section shall not be used by manufacturers for mailings other than those required by this chapter.
- 10826.7 The notification shall be sent:
- (a) By certified mail to purchasers of the product and to subsequent transferees;
 - (b) By certified mail or other more expeditious means to dealers and distributors; and
 - (c) Where products were sold under a name other than that of the manufacturer of the product, the name of the individual or company under whose name the product was sold may be used in the notification required by this section.

10827 COPIES OF COMMUNICATIONS SENT TO PURCHASERS, DEALERS, OR DISTRIBUTORS

- 10827.1 Every manufacturer of electronic products shall furnish to the Department a copy of all notices, bulletins, or other communications sent to the dealers or distributors of such manufacturers or to purchasers (or subsequent transferees) of electronic products of such manufacturer regarding any defect in such product or any failure of such product to comply with an applicable District standard.
- 10827.2 In the event the Department deems the content of such notices to be insufficient to protect the public health and safety, the Department may require additional notice to such recipients, or may elect to make or cause to be made such notification by whatever means it deems appropriate.

10828 APPLICATION FOR EXEMPTION FROM NOTIFICATION REQUIREMENTS

- 10828.1 A manufacturer may at the time of giving the written confirmation required by § 10825 or within fifteen (15) days of the receipt of any notice from the Secretary pursuant to § 10824.1(a), apply for an exemption from the requirement of notice to the persons specified in § 10823.1(b).
- 10828.2 The application for exemption shall contain the information required by § 10825 and in addition shall set forth in detail the grounds upon which the exemption is sought.

10829 GRANTING THE EXEMPTION

- 10829.1 If, in the judgment of the Department, the application filed pursuant to § 10828 states reasonable grounds for an exemption from the requirement of notice, the Department shall give the manufacturer written notice specifying a reasonable period of time during which he or she may present his or her views and evidence in support of the application.
- 10829.2 Such views and evidence shall be confined to matters relevant to whether the defect in the product or its failure to comply with an applicable District standard is such as to create a significant risk of injury, including genetic injury, to any person and shall be presented in writing unless the Department determines that an oral presentation is desirable. Where such evidence includes nonclinical laboratory studies, the data submitted shall include, with respect to each such study, either a statement that the study was conducted in compliance with the requirements set forth in 21 C.F.R., part 58, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance. When such evidence includes clinical investigations involving human subjects, the data submitted shall include, with respect to each clinical investigation either a statement that each investigation was conducted in compliance with the requirements set forth in 21 C.F.R., part 56 or a statement that the investigation is not subject to such requirements in accordance with 21 C.F.R., § 56.104 or 21 C.F.R. § 56.105, and a statement that each investigation was conducted in compliance with the requirements set forth in 21 C.F.R., part 50.
- 10829.3 If, during the period of time afforded the manufacturer to present his views and evidence, the manufacturer proves to the Department's satisfaction that the defect or failure to comply does not create a significant risk of injury, including genetic injury, to any person, the Department shall issue an exemption from the requirement of notification to the manufacturer and shall notify the manufacturer in writing specifying:

- (a) The electronic product or products for which the exemption has been issued; and
- (b) Such conditions as the Department deems necessary to protect the public health and safety.

10829.4 Any person who contests denial of an exemption shall have an opportunity for a regulatory hearing before the Department.

10830 MANUFACTURER'S OBLIGATION TO REPAIR, REPLACE, OR REFUND COST OF ELECTRONIC PRODUCTS

10830.1 If any electronic product fails to comply with an applicable District standard or has a defect and the notification specified in § 10823.1(b) is required to be furnished, the manufacturer of such product shall:

- (a) Without charge, bring such product into conformity with such standard or remedy such defect and provide reimbursement for any expenses for transportation of such product incurred in connection with having such product brought into conformity or having such defect remedied;
- (b) Replace such product with a like or equivalent product which complies with each applicable District standard and which has no defect relating to the safety of its use; or
- (c) Refund the product's cost to the purchaser.

10830.2 The manufacturer shall take the action required by this section in accordance with a Department-approved plan pursuant to § 10834.

10831 PLANS FOR THE REPAIR OF ELECTRONIC PRODUCTS

10831.1 Every plan for bringing an electronic product into conformity with applicable District standards or for remedying any defect in such product shall be submitted to the Department in writing, and in addition to other relevant information which the Department may require, shall include:

- (a) Identification of the product involved;
- (b) The approximate number of defective product units which have left the place of manufacture;
- (c) The specific modifications, alterations, changes, repairs, corrections, or adjustments to be made to bring the product into conformity or remedy any defect;

- (d) The manner in which the operations described in § 10831.1(c) will be accomplished, including the procedure for obtaining access to, or possession of, the products and the location where such operations will be performed;
- (e) The technical data, test results or studies demonstrating the effectiveness of the proposed remedial action;
- (f) A time limit, reasonable in light of the circumstances, for completion of the operations;
- (g) The system by which the manufacturer will provide reimbursement for any transportation expenses incurred in connection with having such product brought into conformity or having any defect remedied; and
- (h) The text of the statement which the manufacturer will send to the persons specified in § 10823.1(b) informing such persons:
 - (1) That the manufacturer, at his or her expense, will repair the electronic product involved;
 - (2) Of the method by which the manufacturer will obtain access to or possession of the product to make such repairs;
 - (3) That the manufacturer will reimburse such persons for any transportation expenses incurred in connection with making such repairs: and
 - (4) Of the manner in which such reimbursement will be effected.

10831.2 An assurance that the manufacturer will provide the Department with progress reports on the effectiveness of the plan, including the number of electronic products repaired.

10832 PLANS FOR THE REPLACEMENT OF ELECTRONIC PRODUCTS

10832.1 Every plan for replacing an electronic product with a like or equivalent product shall be submitted to the Department in writing, and in addition to other relevant information which the Department may require, shall include:

- (a) Identification of the product to be replaced;
- (b) A description of the replacement product in sufficient detail to support the manufacturer's contention that the replacement product is like or equivalent to the product being replaced;

- (c) The approximate number of defective product units which have left the place of manufacture;
- (d) The manner in which the replacement operation will be effected including the procedure for obtaining possession of the product to be replaced;
- (e) A time limit, reasonable, in light of the circumstances for completion of the replacement;
- (f) The steps which the manufacturer will take to insure that the defective product will not be reintroduced into commerce, until it complies with each applicable District standard and has no defect relating to the safety of its use;
- (g) The system by which the manufacturer will provide reimbursement for any expenses for transportation of such product incurred in connection with effecting the replacement; and
- (h) The text of the statement which the manufacturer will send to the persons specified in § 10823.1(b) of this chapter informing such persons:
 - (1) That the manufacturer, at its expense, will replace the electronic product involved;
 - (2) Of the method by which the manufacturer will obtain possession of the product and effect the replacement;
 - (3) That the manufacturer will reimburse such persons for any transportation expenses incurred in connection with effecting such replacement; and
 - (4) Of the manner in which such reimbursement will be made.

10832.2 An assurance that the manufacturer will provide the Department with progress reports on the effectiveness of the plan, including the number of electronic products replaced.

10833 PLANS FOR REFUNDING THE COST OF ELECTRONIC PRODUCTS

10833.1 Every plan for refunding the cost of an electronic product shall be submitted to the Department in writing, and in addition to other relevant information which the Department may require, shall include:

- (a) Identification of the product involved;

- (b) The approximate number of defective product units which have left the place of manufacture;
- (c) The manner in which the refund operation will be effected including the procedure for obtaining possession of the product for which the refund is to be made;
- (d) The steps which the manufacturer will take to ensure that the defective products will not be reintroduced into commerce until it complies with each applicable District standard and has no defect relating to the safety of its use;
- (e) A time limit, reasonable in light of the circumstances, for obtaining the product and making the refund;
- (f) A statement that the manufacturer will refund the cost of such product together with the information the manufacturer has used to determine the amount of the refund; and
- (g) The text of the statement which the manufacturer will send to the persons specified in § 10823.1(b) informing such persons:
 - (1) That the manufacturer, at his or her expense, will refund the cost of the electronic product plus any transportation costs;
 - (2) Of the amount to be refunded exclusive of transportation costs; and
 - (3) Of the method by which the manufacturer will obtain possession of the product and make the refund.

10833.2 An assurance that the manufacturer will provide the Secretary with progress reports on the effectiveness of the plan, including the number of refunds made.

10834 APPROVAL OF PLAN

10834.1 If, after review of any plan submitted pursuant to this chapter, the Department determines that the action to be taken by the manufacturer will expeditiously and effectively fulfill the manufacturer's obligation under § 10830 in a manner designed to encourage the public to respond to the proposal, the Department will send written notice of approval of such plan to the manufacturer. Such approval may be conditioned upon such additional terms as the Department deems necessary to protect the public health and safety. Any person who contests denial of a plan shall have an opportunity for a regulatory hearing before the Department.

10835 [RESERVED]

10836 [RESERVED]

10837 [RESERVED]

10838 [RESERVED]

10839 [RESERVED]

10840 [RESERVED]

10841 [RESERVED]

10842 [RESERVED]

10842 [RESERVED]

10843 [RESERVED]

10844 SCOPE

10844.1 The standards listed in this chapter are applicable to electronic products as specified herein, to control electronic product radiation from such products. Standards so prescribed are subject to amendment or revocation and additional standards may be prescribed as are determined necessary for the protection of the public health and safety.

10845 CERTIFICATION

10845.1 Every manufacturer of an electronic product for which an applicable standard is in effect under this chapter shall furnish to the dealer or distributor, at the time of delivery of such product, the certification that such product conforms to all applicable standards under this chapter.

10845.2 The certification shall be in the form of a label or tag permanently affixed to or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use, unless the applicable standard prescribes some other manner of certification. All such labels or tags shall be in English.

10845.3 Such certification shall be based upon a test, in accordance with the standard, of the individual article to which it is attached or upon a testing program which is in accordance with good manufacturing practices. The Department may disapprove such a testing program on the grounds that it does not assure the adequacy of safeguards against hazardous electronic product radiation or that it does not assure that electronic products comply with the standards prescribed under this chapter.

10845.4 In the case of products for which it is not feasible to certify in accordance with § 10845.2, upon application by the manufacturer, the Department may approve an alternate means by which such certification may be provided.

10846 IDENTIFICATION

10846.1 Every manufacturer of an electronic product to which a standard under this chapter is applicable shall set forth the information specified in § 10846.2 and § 10846.3. This information shall be provided in the form of a tag or label permanently affixed or inscribed on such products so as to be legible and readily accessible to view when the product is fully assembled for use or in such other manner as may be prescribed in the applicable standard. Except for foreign equivalent abbreviations all such labels or tags shall be in English.

10846.2 The full name and address of the manufacturer of the product; abbreviations such as "Co.," "Inc.," or their foreign equivalents and the first and middle initials of individuals may be used. Where products are sold under a name other than that of the manufacturer of the product, the full name and address of the individual or company under whose name the product was sold may be set forth, provided such individual or company has previously supplied the Department with sufficient information to identify the manufacturer of the product.

10846.3 The place of manufacture may be expressed in code provided the manufacturer has previously supplied the Department with the key to such code.

10846.4 The month and year of manufacture shall be provided clearly and legibly, without abbreviation, and with the year shown as a four (4) digit number as follows:

Manufactured: (Insert Month and Year of Manufacture.)

10846.5 Every manufacturer of an electronic product to which a standard under this chapter is applicable shall provide to the Department a list identifying each brand name which is applied to the product together with the full name and address of the individual or company for whom each product so branded is manufactured.

10847 VARIANCES

10847.1 Upon application by a manufacturer (including an assembler), the Department may grant a variance from one (1) or more provisions of any performance standard for an electronic product subject to such standard when the Director determines that granting such a variance is in keeping with the purposes of the act, and:

- (a) The scope of the requested variance is so limited in its applicability as not to justify an amendment to the standard; or

- (b) There is not sufficient time for the promulgation of an amendment to the standard.

10847.2 The issuance of the variance shall be based upon a determination that:

- (a) The product utilizes an alternate means for providing radiation safety or protection equal to or greater than that provided by products meeting all requirements of the applicable standard;
- (b) The product performs a function or is intended for a purpose which could not be performed or accomplished if required to meet the applicable standards, and suitable means for assuring radiation safety or protection are provided; or
- (c) One (1) or more requirements of the applicable standard are not appropriate, and suitable means for assuring radiation safety or protection are provided.

10847.3 If you are submitting an application for variances or for amendments or extensions thereof, you must submit an original and two (2) copies to the Department.

10847.4 The application for variance shall include the following information:

- (a) A description of the product and its intended use;
- (b) An explanation of how compliance with the applicable standard would restrict or be inappropriate for this intended use;
- (c) A description of the manner in which it is proposed to deviate from the requirements of the applicable standard;
- (d) A description of the advantages to be derived from such deviation;
- (e) An explanation of how alternate or suitable means of radiation protection will be provided;
- (f) The period of time it is desired that the variance be in effect, and, if appropriate, the number of units the applicant wishes to manufacture;
- (g) In the case of prototype or experimental equipment, the proposed location of each unit;
- (h) Such other information required by regulation or by the Department, to evaluate and act on the application;

- (i) With respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the good laboratory practice regulations or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance; and
- (j) If the electronic product is used in a clinical investigation involving human subjects, is subject to the requirements for institutional review set forth in 21 C.F.R., part 56, and is subject to the requirements for informed consent set forth in 12 C.F.R., part 50, the investigation shall be conducted in compliance with such requirements.

10847.5 The application for amendment or extension of a variance shall include the following information:

- (a) The variance number and expiration date;
- (b) The amendment or extension requested and basis for the amendment or extension;
- (c) A description of the effect of the amendment or extension on protection from radiation produced by the product; and
- (d) An explanation of how alternate or suitable means of protection will be provided.

10847.6 The Department may approve or deny, in whole or in part, a requested variance or any amendment or extension thereof, and the Director shall inform the applicant in writing of this action on a requested variance, amendment, or extension. The written notice will state the manner in which the variance differs from the standard, the effective date and the termination date of the variance, a summary of the requirements and conditions attached to the variance, any other information that may be relevant to the application or variance, and, if appropriate, the number of units or other similar limitations for which the variance is approved. Each variance will be assigned an identifying number.

10847.7 The Department shall amend or withdraw a variance whenever the Department determines that this action is necessary to protect the public health or otherwise is justified by this chapter. Such action will become effective on the date specified in the written notice of the action sent to the applicant, except that it will become effective immediately upon notification to the applicant when the Department determines that such action is necessary to prevent an imminent health hazard.

10847.8 All applications for variances and for amendments and extensions thereof and all correspondence (including written notices of approval) on these applications will be available to the public except for information regarded as confidential under

Section 537 of the Act.

- 10847.9 The manufacturer of any product for which a variance is granted shall modify the tag, label, or other certification required by § 10845 to state:
- (a) That the product is in conformity with the applicable standard, except with respect to those characteristics covered by the variance;
 - (b) That the product is in conformity with the provisions of the variance; and
 - (c) The assigned number and effective date of the variance.

10848 EXEMPTIONS FOR PRODUCTS INTENDED FOR UNITED STATES GOVERNMENT USE

- 10848.1 Upon application by a manufacturer (including the assembler), the Department may grant an exemption from any performance standard for an electronic product, or class of products, otherwise subject to such standard when the Department determines that such electronic product or class is intended for use by departments or agencies of the U.S. and meets the criteria set forth in § 10848.2 or § 10848.3.
- 10848.2 The procuring agency shall prescribe procurement specifications for the product or class of products governing emissions of electronic product radiation, and the product or class shall be of a type used solely or predominantly by a department or agency of the U.S.
- 10848.3 The product or class of products is intended for research, investigations, studies, demonstration, training, or for reasons of national security.
- 10848.4 The U.S. department or agency that intends to procure or manufacture a product or class of products subject to electronic product radiation safety standards contained in this chapter should consult with the Department whenever it is anticipated that the specifications for the product or class must deviate from, or be in conflict with, such applicable standards. Such consultation should occur as early as possible during development of such specifications. The department or agency should include in the specifications all requirements of such standards that are not in conflict with, or are not inappropriate for, the special or unique uses for which the product is intended. The procuring agency should indicate to the Department if it desires to be notified of the approval, amendment, or withdrawal of the exemption.
- 10848.5 If you are submitting an application for exemption, or for amendment or extension thereof, you must submit an original and two copies to the Department. For an exemption under the criteria prescribed in § 10848.2 of this section, the application shall include the information prescribed in § 10848.6(a) through (m) of this section. For an exemption under the criteria prescribed in § 10848.3 of this

section, the application shall include the information prescribed in § 10848.6(c) through (m). An application for exemption, or for amendment or extension thereof, and correspondence relating to such application shall be made available for public disclosure, except for confidential or proprietary information.

10848.6 Information classified for reasons of national security shall not be included in the application. Except as indicated in this section, the application for exemption shall include the following:

- (a) The procurement specifications for the product or class of products that govern emissions of electronic product radiation;
- (b) Evidence that the product or class of products is of a type used solely or predominantly by departments or agencies of the U.S.;
- (c) Evidence that such product or class of products is intended for use by a department or agency of the U.S.;
- (d) A description of the product or class of products and its intended use;
- (e) An explanation of how compliance with the applicable standard would restrict or be inappropriate for this intended use;
- (f) A description of the manner in which it is proposed that the product or class of products shall deviate from the requirements of the applicable standard;
- (g) An explanation of the advantages to be derived from such deviation;
- (h) An explanation of how means of radiation protection will be provided where the product or class of products deviates from the requirements of the applicable standard;
- (i) The period of time it is desired that the exemption be in effect, and, if appropriate, the number of units to be manufactured under the exemption;
- (j) The name, address, and telephone number of the manufacturer or his agent;
- (k) The name, address, and telephone number of the appropriate office of the U.S. department or agency purchasing the product or class of products;
- (l) Such other information required by regulation or by the Department, to evaluate and act on the application. Where such information includes nonclinical laboratory studies, the information shall include, with respect to each nonclinical study, either a statement that each study was conducted

in compliance with the requirements set forth in 21 C.F.R., part 58, or, if the study was not conducted in compliance, a statement that describes in detail all differences between the practices used in the study and those required in the regulations. When such information includes clinical investigations involving human subjects, the information shall include, with respect to each clinical investigation, a statement that each investigation was conducted in compliance with the requirements set forth in 21 C.F.R., part 56, or a statement that the investigation is not subject to such requirements in accordance with 21 C.F.R. §§ 56.104 or 56.105 and a statement that each investigation was conducted in compliance with the requirements set forth in 21 C.F.R., part 50; and

- (m) With respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

10848.7 An exemption is granted on the basis of the information contained in the original application. Therefore, if changes are needed in the radiation safety specifications for the product, or its use, or related radiation control procedures such that the information in the original application would no longer be correct with respect to radiation safety, the applicant shall submit in advance of such changes a request for an amendment to the exemption. He or she also shall submit a request for extension of the exemption, if needed, at least sixty (60) days before the expiration date. The application for amendment or extension of an exemption shall include the following information:

- (a) The exemption number and expiration date; and
- (b) The amendment or extension requested and basis for the amendment or extension.

10848.8 If the radiation safety specifications for the product or class of products or the product's or class of products' use or related radiation control procedures differ from the description provided in the original application, a description of such changes.

10848.9 The Department may grant an exemption including in the written notice of exemption such conditions or terms as may be necessary to protect the public health and safety and shall notify the applicant in writing of his or her action. The conditions or terms of the exemption may include specifications concerning the manufacture, use, control, and disposal of the excess or surplus exempted product of class of products as provided in the Code of Federal Regulations, Title 41, Subtitle C. Each exemption will be assigned an identifying number.

10848.10 The Department shall amend or withdraw an exemption whenever the Department determines that such action is necessary to protect the public health or otherwise is justified by provisions of the act or this chapter. Such action shall become effective on the date specified in the written notice of the action sent to the applicant, except that it shall become effective immediately when the Director determines that it is necessary to prevent an imminent health hazard.

10848.11 The manufacturer of any product for which an exemption is granted shall provide the following identification in the form of a tag or label permanently affixed or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use or in such other manner as may be prescribed in the exemption:

CAUTION

This electronic product has been exempted from Department of Health radiation safety performance standards prescribed in Chapter 108 (Radiological Health), pursuant to Exemption No. _____, granted on _____.

10849 SPECIAL TEST PROCEDURE

10849.1 The Department may, on the basis of a written application by a manufacturer, authorize test programs other than those set forth in the standards under this chapter for an electronic product if he or she determines that such products are not susceptible to satisfactory testing by the procedures set forth in the standard and that the alternative test procedures assure compliance with the standard.

10850 ELECTRONIC PRODUCTS INTENDED FOR EXPORT

10850.1 The performance standards prescribed in this chapter shall not apply to any electronic product which is intended solely for export if:

- (a) Such product and the outside of any shipping container used in the export of such product are labeled or tagged to show that such product is intended for export; and
- (b) Such product meets all the applicable requirements of the country to which such product is intended for export.

10851 TELEVISION RECEIVERS

10851.1 The provisions of this section are applicable to television receivers manufactured subsequent to January 15, 1970.

10851.2 Radiation exposure rates produced by a television receiver shall not exceed one half milliroentgens per hour (0.5 mR/hr.) at a distance of five centimeters (5 cm)

from any point on the external surface of the receiver, as measured in accordance with this section.

10851.3 Compliance with the exposure rate limit defined in § 10851.2 shall be determined by measurements made with an instrument, the radiation sensitive volume of which shall have a cross section parallel to the external surface of the receiver with an area of ten square centimeters (10 cm²) and no dimension larger than five centimeters (5 cm). Measurements made with instruments having other areas must be corrected for spatial non-uniformity of the radiation field to obtain the exposure rate average over a ten square centimeter (10 cm²) area.

10851.4 All measurements shall be made with the receiver displaying a usable picture and with the power source operated at supply voltages up to the maximum test voltage of the receiver and, as applicable, under the following specific conditions:

- (a) On television receivers manufactured subsequent to January 15, 1970, measurements shall be made with all user controls adjusted so as to produce maximum x-radiation emissions from the receiver;
- (b) On television receivers manufactured subsequent to June 1, 1970, measurements shall be made with all user controls and all service controls adjusted to combinations which result in the production of maximum x-radiation emissions; and
- (c) On television receivers manufactured subsequent to June 1, 1971, measurements shall be made under the conditions described in § 10851.4(b), together with conditions identical to those which result from that component or circuit failure which maximizes x-radiation emissions.

10851.5 The manufacturer shall permanently affix or inscribe a warning label, clearly legible under conditions of service, on all television receivers which could produce radiation exposure rates in excess of the requirements of this section as a result of failure or improper adjustment or improper replacement of a circuit or shield component. The warning label shall include the specification of operating high voltage and an instruction for adjusting the high voltage to the specified value.

10852 COLD-CATHODE GAS DISCHARGE TUBES

10852.1 The provisions of this section are applicable to cold-cathode gas discharge tubes designed to demonstrate the effects of a flow of electrons or the production of x-radiation as specified herein.

10852.2 Radiation exposure rates produced by cold-cathode gas discharge tubes shall not exceed ten milliroentgens per hour (10 mR/hr.) at a distance of thirty centimeters (30 cm.) from any point on the external surface of the tube, as measured in

accordance with this section.

- 10852.3 The divergence of the exit beam from tubes designed primarily to demonstrate the effects of x-radiation, with the beam blocking device in the open position, shall not exceed Pi steradians.
- 10852.4 Compliance with the exposure rate limit defined in § 10852.2 shall be determined by measurements averaged over an area of one hundred square centimeters (100 cm²) with no linear dimension greater than twenty centimeters (20 cm).
- 10852.5 Measurements of exposure rates from tubes in enclosures from which the tubes cannot be removed without destroying the function of the tube may be made at a distance of thirty centimeters (30 cm) from any point on the external surface of the enclosure, provided:
- (a) In the case of enclosures containing tubes designed primarily to demonstrate the production of x-radiation, measurements shall be made with any beam blocking device in the beam blocking position; or
 - (b) In the case of enclosures containing tubes designed primarily to demonstrate the effects of a flow of electrons, measurements shall be made with all movable or removable parts of such enclosure in the position which would maximize external exposure levels.
- 10852.6 Measurements shall be made under the conditions of use specified in instructions provided by the manufacturer.
- 10852.7 Measurements shall be made with the tube operated under forward and reverse polarity.
- 10852.8 Manufacturers shall provide, or cause to be provided, with each tube to which this section is applicable, appropriate safety instructions, together with instructions for the use of such tube, including the specification of a power source for use with the tube.
- 10852.9 Each enclosure or tube shall have inscribed on or permanently affixed to it, tags or labels, which identify the intended polarity of the terminals and:
- (a) In the case of tubes designed primarily to demonstrate the heat effect, fluorescence effect, or magnetic effect, a warning that application of power in excess of that specified may result in the production of x-rays in excess of allowable limits; and
 - (b) In the case of tubes designed primarily to demonstrate the production of x-radiation, a warning that this device produces x-rays when energized.

10852.10 The tag or label required by this section shall be located on the tube or enclosure so as to be readily visible and legible when the product is fully assembled for use.

10853 DIAGNOSTIC X-RAY SYSTEMS AND THEIR MAJOR COMPONENTS

10853.1 The provisions of this section are applicable to:

- (a) The following components of diagnostic x-ray systems:
 - (1) Tube housing assemblies, x-ray controls, x-ray high-voltage generators, x-ray tables, cradles, film changers, vertical cassette holders mounted in a fixed location and cassette holders with front panels, and beam-limiting devices manufactured after August 1, 1974;
 - (2) Fluoroscopic imaging assemblies manufactured after August 1, 1974, and before April 26, 1977, or after June 10, 2006;
 - (3) Spot-film devices and image intensifiers manufactured after April 26, 1977;
 - (4) Cephalometric devices manufactured after February 25, 1978;
 - (5) Image receptor support devices for mammographic x-ray systems manufactured after September 5, 1978;
 - (6) Image receptors that are electrically powered or connected with the x-ray system manufactured on or after June 10, 2006; and
 - (7) Fluoroscopic air kerma display devices manufactured on or after June 10, 2006;
- (b) Diagnostic x-ray systems, except computed tomography x-ray systems, incorporating one (1) or more of such components. However, such x-ray systems shall be required to comply only with those provisions of this section and §§ 10854 and 10855, which relate to the components certified in accordance with § 10853.5 and installed into the systems;
- (c) Computed tomography (CT) x-ray systems manufactured before November 29, 1984; and
- (d) CT gantries manufactured after September 3, 1985.

10853.2 The following provisions of this section are applicable to CT x-ray systems manufactured or remanufactured on or after November 29, 1984:

- (a) Subsection 10853.1;
- (b) Subsection 10853.4(r) "CT";
- (c) Subsection 10853.4(z) "Dose";
- (d) Subsection 10853.4(jjj) "Scan";
- (e) Subsection 10853.4(kkk) "Scan Time";
- (f) Subsection 10853.4(rrr) "Technique Factors";
- (g) Subsection 10853.4(sss) "Tomogram";
- (h) Subsection 10853.17(f) through (h); and
- (i) Subsection 10853.28.

10853.3 The provisions of this section, including those provisions in 21 C.F.R. § 1020.33 , are applicable to CT x-ray systems manufactured or remanufactured on or after September 3, 1985. The date of manufacture of the CT system is the date of manufacture of the CT gantry.

10853.4 As used in this section and §§ 10854 and 10855 the following definitions apply:

- (a) **Accessible surface** - the external surface of the enclosure or housing provided by the manufacturer;
- (b) **Accessory component** -
 - (1) A component used with diagnostic x-ray systems, such as a cradle or film changer, that is not necessary for the compliance of the system with applicable provisions of this chapter but which requires an initial determination of compatibility with the system;
 - (2) A component necessary for compliance of the system with applicable provisions of this chapter but which may be interchanged with similar compatible components without affecting the system's compliance, such as one (1) of a set of interchangeable beam-limiting devices; or
 - (3) A component compatible with all x-ray systems with which it may be used and that does not require compatibility or installation instructions, such as a tabletop cassette holder;
- (c) **Air kerma** - kerma in air (*see* definition of Kerma);

- (d) **Air kerma rate (AKR)** - the air kerma per unit time;
- (e) **Aluminum equivalent** - the thickness of aluminum (type 1100 alloy) n1²² affording the same attenuation, under specified conditions, as the material in question;
- (f) **Articulated joint** - a joint between two (2) separate sections of a tabletop in which a joint provides the capacity for one (1) of the sections to pivot on the line segment along which the sections join;
- (g) **Assembler** - any person engaged in the business of assembling, replacing, or installing one (1) or more components into a diagnostic x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services;
- (h) **Attenuation block** - a block or stack of type 1100 aluminum alloy, or aluminum alloy having equivalent attenuation, with dimensions twenty centimeters (20 cm) or larger by twenty centimeters (20 cm) or larger by three and eight tenths centimeters (3.8 cm), that is large enough to intercept the entire x-ray beam;
- (i) **Automatic exposure control (AEC)** - a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation;
- (j) **Automatic exposure rate control (AERC)** - a device which automatically controls one (1) or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation per unit time;
- (k) **Beam axis** - a line from the source through the centers of the x-ray fields;
- (l) **Beam-limiting device** - a device which provides a means to restrict the dimensions of the x-ray field;
- (m) **C-arm fluoroscope** - a fluoroscopic x-ray system in which the image receptor and the x-ray tube housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient;

²² n1 The nominal chemical composition of type 1100 aluminum alloy is ninety-nine percent (99 %) minimum aluminum, twelve hundredths percent (0.12%) of copper, as given in "Aluminum Standards and Data" (§ 11069). Copies may be obtained from The Aluminum Association, New York, NY.

- (n) **Cantilevered tabletop** -a tabletop designed such that the unsupported portion can be extended at least one hundred centimeters (100 cm) beyond the support;
- (o) **Cassette holder** -a device, other than a spot-film device, that supports or fixes the position of an x-ray film cassette during an x-ray exposure;
- (p) **Cephalometric device** -a device intended for the radiographic visualization and measurement of the dimensions of the human head;
- (q) **Coefficient of variation** -the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

- (2) A device:
 - (A) Whose patient support structure is interposed between the patient and the image receptor during normal use;
 - (B) Which is equipped with means for patient restraint; and
 - (C) Which is capable of rotation about its long (longitudinal) axis.

- (v) **CT gantry** -tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames, and covers which hold or enclose these components;
- (w) **Cumulative air kerma** -the total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation;
- (x) **Diagnostic source assembly** -the tube housing assembly with a beam-limiting device attached;
- (y) **Diagnostic x-ray system** -an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization;
- (z) **Dose** -the absorbed dose as defined by the International Commission on Radiation Units and Measurements. The absorbed dose(D) is the energy deposited per unit mass of medium ($D=de/dm$), in units of joules per kilogram (J/kg), where the special name for the unit of absorbed dose is gray (Gy);
- (aa) **Equipment** -x-ray equipment;
- (bb) **Exposure (X)** -the quotient of dQ divided by dm ($X=dQ/dm$) where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons and positrons liberated or created by photons in air of mass, dm are completely stopped in air in units of coulomb per kilogram (C/kg). A second meaning of exposure is the process or condition during which the x-ray tube produces x-ray radiation;
- (cc) **Field emission equipment** -equipment which uses an x-ray tube in which electron emission from the cathode is due solely to action of an electric field;
- (dd) **Fluoroscopic air kerma display device** -a device, subsystem, or component that provides the display of AKR and cumulative air kerma

required by § 10855.31. It includes radiation detectors, if any, electronic and computer components, associated software, and data displays;

- (ee) **Fluoroscopic imaging assembly** -a subsystem in which x-ray photons produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. It includes the image receptor(s), electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly;
- (ff) **Fluoroscopic irradiation time** -the cumulative duration during an examination or procedure of operator-applied continuous pressure to the device, enabling x-ray tube activation in any fluoroscopic mode of operation;
- (gg) **Fluoroscopy** -a technique for generating x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term "radioscopy" in the standards of the International Electrotechnical Commission;
- (hh) **General purpose radiographic x-ray system** -any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions;
- (ii) **Half-value layer (HVL)** -the thickness of specified material which attenuates the beam of radiation to an extent such that the AKR is reduced to one-half (1/2) of its original value. In this definition the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded;
- (jj) **Image intensifier** -a device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density;
- (kk) **Image receptor** -any device, such as a fluorescent screen, radiographic film, x-ray image intensifier tube, solid-state detector, or gaseous detector, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term "image receptor" shall mean the preselected portion of the device;
- (ll) **Image receptor support device** -for mammography x-ray systems, that part of the system designed to support the image receptor during a mammographic examination and to provide a primary protective barrier;
- (mm) **Isocenter** -the center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center;

- (nn) **Kerma** -the quantity as defined by the International Commission on Radiation Units and Measurements. The kerma (K) is the quotient of $dE[tr]$ by dm , where $dE[tr]$ is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of material; thus $K=dE[tr]/dm$, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as "air kerma;"
- (oo) **Last-image-hold (LIH) radiograph** -an image obtained either by retaining one (1) or more fluoroscopic images, which may be temporally integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure;
- (pp) **Lateral fluoroscope** -the x-ray tube and image receptor combination in a biplane system dedicated to the lateral projection. It consists of the lateral x-ray tube housing assembly and the lateral image receptor that are fixed in position relative to the table with the x-ray beam axis parallel to the plane of the table;
- (qq) **Leakage radiation** -radiation emanating from the diagnostic source assembly except for:
- (1) The useful beam; and
 - (2) Radiation produced when the exposure switch or timer is not activated.
- (rr) **Leakage technique factors** -the technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation. They are defined as follows:
- (1) For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being ten millicoulombs (10 mC) or the minimum obtainable from the unit, whichever is larger;
 - (2) For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential; and
 - (3) For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube

current for the maximum-rated peak tube potential;

(ss) **Light field** -that area of the intersection of the light beam from the beam-limiting device and one (1) of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illuminance is one-fourth of the maximum in the intersection;

(tt) **Line-voltage regulation** -the difference between the no-load and the load line potentials expressed as a percent of the load line potential; that is,

$$\text{Percent line-voltage regulation} = 100(V[n] - V[i])/V[i]$$

where:

$V[n]$ = No-load line potential and

$V[i]$ = Load line potential.

(uu) **Maximum line current** -the root mean square current in the supply line of an x-ray machine operating at its maximum rating;

(vv) **Mode of operation** - for fluoroscopic systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog or digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting air kerma, AKR, or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected;

(ww) **Movable tabletop** -a tabletop which, when assembled for use, is capable of movement with respect to its supporting structure within the plane of the tabletop;

(xx) **Non-image-intensified fluoroscopy** -fluoroscopy using only a fluorescent screen;

(yy) **Peak tube potential** -the maximum value of the potential difference across the x-ray tube during an exposure;

- (zz) **Primary protective barrier** -the material, excluding filters, placed in the useful beam to reduce the radiation exposure for protection purposes;
- (aaa) **Pulsed mode** -operation of the x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one (1) or more exposure intervals of duration less than one-half (1/2) second;
- (bbb) **Quick change x-ray tube** -an x-ray tube designed for use in its associated tube housing such that:
 - (1) The tube cannot be inserted in its housing in a manner that would result in noncompliance of the system with the requirements of § 10853.23 and 10853.25;
 - (2) The focal spot position will not cause noncompliance with the provisions of this section or § 10854 or § 10855;
 - (3) The shielding within the tube housing cannot be displaced; and
 - (4) Any removal and subsequent replacement of a beam-limiting device during reloading of the tube in the tube housing will not result in noncompliance of the x-ray system with the applicable field limitation and alignment requirements of §§ 10854 and 10855;
- (ccc) **Radiation therapy simulation system** -a radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field;
- (ddd) **Radiography** -a technique for generating and recording an x-ray pattern for the purpose of providing the user with an image(s) after termination of the exposure;
- (eee) **Rated line voltage** -the range of potentials, in volts, of the supply line specified by the manufacturer at which the x-ray machine is designed to operate;
- (fff) **Rated output current** -the maximum allowable load current of the x-ray high-voltage generator;
- (ggg) **Rated output voltage** -the allowable peak potential, in volts, at the output terminals of the x-ray high-voltage generator;
- (hhh) **Rating** -the operating limits specified by the manufacturer;
- (iii) **Recording** -producing a retrievable form of an image resulting from x-ray photons;

- (jjj) **Scan** -the complete process of collecting x-ray transmission data for the production of a tomogram. Data may be collected simultaneously during a single scan for the production of one (1) or more tomograms;
- (kkk) **Scan time** -the period of time between the beginning and end of x-ray transmission data accumulation for a single scan;
- (lll) **Solid state x-ray imaging device** -an assembly, typically in a rectangular panel configuration, that intercepts x-ray photons and converts the photon energy into a modulated electronic signal representative of the x-ray intensity over the area of the imaging device. The electronic signal is then used to create an image for display or storage;
- (mmm)**Source** -the focal spot of the x-ray tube;
- (nnn) **Source-image receptor distance (SID)** -the distance from the source to the center of the input surface of the image receptor;
- (ooo) **Source-skin distance (SSD)** -the distance from the source to the center of the entrant x-ray field in the plane tangent to the patient skin surface;
- (ppp) **Spot-film device** -a device intended to transport or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of the fluoroscopic image receptor for the purpose of producing a radiograph;
- (qqq) **Stationary tabletop** -a tabletop which, when assembled for use, is incapable of movement with respect to its supporting structure within the plane of the tabletop;
- (rrr) **Technique factors** -the following conditions of operation:
 - (1) For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliamperere-seconds (mAs);
 - (2) For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses;
 - (3) For CT equipment designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of the tube current, x-ray pulse width, and the number of x-ray pulses in mAs;
 - (4) For CT equipment not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs

and the scan time when the scan time and exposure time are equivalent; and

- (5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs;
- (sss) **Tomogram** -the depiction of the x-ray attenuation properties of a section through a body;
- (ttt) **Tube** -an x-ray tube, unless otherwise specified;
- (uuu) **Tube housing assembly** -the tube housing with tube installed. It includes high-voltage or filament transformers and other appropriate elements when they are contained within the tube housing;
- (vvv) **Tube rating chart** -the set of curves which specify the rated limits of operation of the tube in terms of the technique factors;
- (www) **Useful beam** -the radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated;
- (xxx) **Variable-aperture beam-limiting device** -a beam-limiting device which has the capacity for stepless adjustment of the x-ray field size at a given SID;
- (yyy) **Visible area** -the portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image;
- (zzz) **X-ray control** -a device which controls input power to the x-ray high-voltage generator or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure;
- (aaaa) **X-ray equipment** -an x-ray system, subsystem, or component thereof which include:
 - (1) Mobile, mounted on a permanent base with wheels or casters for moving while completely assembled;
 - (2) Portable, designed to be hand-carried; and
 - (3) Stationary, which is installed in a fixed location.
- (bbbb) **X-ray field** -that area of the intersection of the useful beam and any one (1) of the set of planes parallel to and including the plane of the image

receptor, whose perimeter is the locus of points at which the AKR is one-fourth (1/4) of the maximum in the intersection;

- (cccc) **X-ray high-voltage generator** -a device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements;
- (dddd) **X-ray subsystem** -any combination of two (2) or more components of an x-ray system for which there are requirements specified in this section and §§ 10854 and 10855;
- (eeee) **X-ray system** -an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system;
- (ffff) **X-ray table** -a patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, fluoroscopic image receptor, or spot-film device beneath the tabletop; and
- (gggg) **X-ray tube** -any electron tube which is designed for the conversion of electrical energy into x-ray energy;

10853.5 Manufacturers of products subject to §§ 10853, 10854, and 10855 shall certify that each of their products meet all applicable requirements when installed into a diagnostic x-ray system according to instructions. This certification shall be made under the format specified in § 10845. Manufacturers may certify a combination of two (2) or more components if they obtain prior authorization in writing from the Department. Manufacturers shall not be held responsible for noncompliance of their products if that noncompliance is due solely to the improper installation or assembly of that product by another person; however, manufacturers are responsible for providing assembly instructions adequate to assure compliance of their components with the applicable provisions of §§ 10853, 10854, and 10855.

10853.6 An assembler who installs one (1) or more components certified as required by § 10853.5 shall install certified components that are of the type required by § 10854 or § 10855 and shall assemble, install, adjust, and test the certified components according to the instructions of their respective manufacturers. Assemblers shall not be liable for noncompliance of a certified component if the

assembly of that component was according to the component manufacturer's instruction.

10853.7 All assemblers who install certified components shall file a report of assembly, except as specified in § 10853.8(a) through (d). The report will be construed as the assembler's certification and identification under §§ 10845 and 10846. The assembler shall affirm in the report that the manufacturer's instructions were followed in the assembly or that the certified components as assembled into the system meet all applicable requirements of §§ 10853 through 10855. All assembler reports must be on a form that the Department prescribes. Completed reports must be submitted to the Department and the purchaser within fifteen (15) days following completion of the assembly.

10853.8 Reports of assembly need not be submitted for any of the following:

- (a) Reloaded or replacement tube housing assemblies that are reinstalled in or newly assembled into an existing x-ray system;
- (b) Certified accessory components that have been identified as such to the Department in the report required under § 10808 of this chapter;
- (c) Repaired components, whether or not removed from the system and reinstalled during the course of repair, provided the original installation into the system was reported; or
- (d) Components installed temporarily in an x-ray system in place of components removed temporarily for repair, provided the temporarily installed component is identified by a tag or label bearing the following information:

Temporarily Installed Component

This certified component has been assembled, installed, adjusted, and tested by me according to the instructions provided by the manufacturer.

Signature

Company Name

Street Address, P.O. Box

City, State, Zip Code

Date of Installation.

- 10853.9 The replacement of the temporarily installed component by a component other than the component originally removed for repair shall be reported as specified in § 10853.6.
- 10853.10 In addition to the identification requirements specified in § 10846 of this chapter, manufacturers of components subject to this section and §§ 10854 and 10855, except high-voltage generators contained within tube housings and beam-limiting devices that are integral parts of tube housings, shall permanently inscribe or affix thereon the model number and serial number of the product so that they are legible and accessible to view. The word "model" or "type" shall appear as part of the manufacturer's required identification of certified x-ray components. Where the certification of a system or subsystem, consisting of two or more components, has been authorized under §10853.5, a single inscription, tag, or label bearing the model number and serial number may be used to identify the product.
- 10853.11 In a similar manner, manufacturers of tube housing assemblies shall also inscribe or affix thereon the name of the manufacturer, model number, and serial number of the x-ray tube which the tube housing assembly incorporates.
- 10853.12 Except as specified in § 10853.13, the replacement of an x-ray tube in a previously manufactured tube housing assembly certified under § 10853.5 constitutes manufacture of a new tube housing assembly, and the manufacturer is subject to the provisions of § 10853.10. The manufacturer shall remove, cover, or deface any previously affixed inscriptions, tags, or labels that are no longer applicable.
- 10853.13 The requirements of § 10853.12 shall not apply to tube housing assemblies designed and designated by their original manufacturer to contain quick change x-ray tubes. The manufacturer of quick-change x-ray tubes shall include with each replacement tube a label with the tube manufacturer's name, the model, and serial number of the x-ray tube. The manufacturer of the tube shall instruct the assembler who installs the new tube to attach the label to the tube housing assembly and to remove, cover, or deface the previously affixed inscriptions, tags, or labels that are described by the tube manufacturer as no longer applicable.
- 10853.14 Manufacturers of components listed in § 10853.1 shall provide to assemblers subject to § 10853.6 and, upon request, to others at a cost not to exceed the cost of publication and distribution, instructions for assembly, installation, adjustment, and testing of such components adequate to assure that the products will comply with applicable provisions of this section and §§ 10854 and 10855, when assembled, installed, adjusted, and tested as directed. Such instructions shall include specifications of other components compatible with that to be installed when compliance of the system or subsystem depends on their compatibility. Such specifications may describe pertinent physical characteristics of the components or may list by manufacturer model number the components which are compatible. For x-ray controls and generators manufactured after May 3, 1994, manufacturers shall provide:

- (a) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;
- (b) A statement of the maximum line current of the x-ray system based on the maximum input voltage and current characteristics of the tube housing assembly compatible with rated output voltage and rated output current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, the manufacturer shall provide information necessary to allow the assembler to determine the maximum line current for the particular tube housing assembly(ies); and
- (c) A statement of the technique factors that constitute the maximum line current condition described in paragraph (b).

10853.15 Manufacturers of x-ray equipment shall provide to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, manuals or instruction sheets which shall include the following technical and safety information:

- (a) For x-ray equipment to which this section and §§ 10854 and 10855 are applicable, there shall be provided:
 - (1) Adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the equipment; and
 - (2) A schedule of the maintenance necessary to keep the equipment in compliance with this section and §§ 10854 and 10855.

10853.16 For each tube housing assembly, there shall be provided:

- (a) Statements of the leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices for which the tube housing assembly manufacturer states compatibility, the minimum filtration permanently in the useful beam expressed as millimeters (mm) of aluminum equivalent, and the peak tube potential at which the aluminum equivalent was obtained;
- (b) Cooling curves for the anode and tube housing; and
- (c) If the tube is designed to operate from different types of x-ray high-voltage generators (such as single-phase self rectified, single-phase half-wave rectified, single-phase full-wave rectified, 3-phase 6-pulse, 3-phase 12-pulse, constant potential, capacitor energy storage) or under modes of operation such as alternate focal spot sizes or speeds of anode rotation

which affect its rating, specific identification of the difference in ratings shall be noted.

10853.17 For the x-ray control and associated x-ray high-voltage generator, there shall be provided:

- (a) A statement of the rated line voltage and the range of line-voltage regulation for operation at maximum line current;
- (b) A statement of the maximum line current of the x-ray system based on the maximum input voltage and output current characteristics of the tube housing assembly compatible with rated output voltage and rated current characteristics of the x-ray control and associated high-voltage generator. If the rated input voltage and current characteristics of the tube housing assembly are not known by the manufacturer of the x-ray control and associated high-voltage generator, the manufacturer shall provide necessary information to allow the purchaser to determine the maximum line current for his particular tube housing assembly(ies);
- (c) A statement of the technique factors that constitute the maximum line current condition described in § 10853.17(b) of this section;
- (d) In the case of battery-powered generators, a specification of the minimum stated of charge necessary for proper operation;
- (e) Generator rating and duty cycle;
- (f) A statement of the maximum deviation from the pre-indication given by labeled technique factor control settings or indicators during any radiographic or CT exposure where the equipment is connected to a power supply as described in accordance with this paragraph. In the case of fixed technique factors, the maximum deviation from the nominal fixed value of each factor shall be stated;
- (g) A statement of the maximum deviation from the continuous indication of x-ray tube potential and current during any fluoroscopic exposure when the equipment is connected to a power supply as described in accordance with this paragraph; and
- (h) A statement describing the measurement criteria for all technique factors used in § 10853.17(c), (f), and (g); for example, the beginning and endpoints of exposure time measured with respect to a certain percentage of the voltage waveform.

10853.18 For each variable-aperture beam-limiting device, there shall be provided:

- (a) Leakage technique factors for all combinations of tube housing assemblies and beam-limiting devices for which the beam-limiting device manufacturer states compatibility; and
- (b) A statement including the minimum aluminum equivalent of that part of the device through which the useful beam passes and including the x-ray tube potential at which the aluminum equivalent was obtained. When two (2) or more filters are provided as part of the device, the statement shall include the aluminum equivalent of each filter.

10853.19 For x-ray systems manufactured on or after June 10, 2006, that produce images using the fluoroscopic image receptor, the following information shall be provided in a separate, single section of the user's instruction manual or in a separate manual devoted to this information:

- (a) For each mode of operation, a description of the mode and detailed instructions on how the mode is engaged and disengaged. The description of the mode shall identify those technique factors and system controls that are fixed or automatically adjusted by selection of the mode of operation, including the manner in which the automatic adjustment is controlled. This information shall include how the operator can recognize which mode of operation has been selected prior to initiation of x-ray production; and
- (b) For each mode of operation, a descriptive example(s) of any specific clinical procedure(s) or imaging task(s) for which the mode is recommended or designed and how each mode should be used. Such recommendations do not preclude other clinical uses.

10853.20 For fluoroscopic x-ray systems manufactured on or after June 10, 2006, the following shall be provided:

- (a) A schedule of maintenance for any system instrumentation associated with the display of air kerma information necessary to maintain the displays of AKR and cumulative air kerma within the limits of allowed uncertainty specified by § 10855.35 and, if the capability for user calibration of the display is provided, adequate instructions for such calibration;
- (b) Identification of the distances along the beam axis:
 - (1) From the focal spot to the isocenter, and
 - (2) From the focal spot to the reference location to which displayed values of AKR and cumulative air kerma refer according to § 10855.31(d).
- (c) A rationale for specification of a reference irradiation location alternative to fifteen centimeters (15 cm.) from the isocenter toward the x-ray source

along the beam axis when such alternative specification is made according to § 10855.33.

10853.21 RESERVED

10853.22 The control panel containing the main power switch shall bear the following warning statement, legible and accessible to view:

"Warning: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules are observed."

10853.23 The leakage radiation from the diagnostic source assembly measured at a distance of one meter (1 m) in any direction from the source shall not exceed eighty-eight hundredths milligray (0.88 mGy) air kerma (vice one hundred milliroentgen (100 mR) exposure) in one (1) hour when the x-ray tube is operated at the leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of one hundred square centimeters (100 cm²) with no linear dimension greater than twenty centimeters (20 cm).

10853.24 The radiation emitted by a component other than the diagnostic source assembly shall not exceed an air kerma of eighteen microGy (18 microGy) (vice two milliroentgen (2 mR) exposure) in one (1) hour at five centimeters (5 cm) from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of one hundred square centimeters (100 cm²) with no linear dimension greater than twenty centimeters (20 cm.).

10853.25 The HVL of the useful beam for a given x-ray tube potential shall not be less than the appropriate value shown in Table 1 in this section under the heading "Specified Dental Systems," for any dental x-ray system designed for use with intraoral image receptors and manufactured after December 1, 1980; under the heading "I -- Other X-Ray Systems," for any dental x-ray system designed for use with intraoral image receptors and manufactured before December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006; and under the heading "II -- Other X-Ray Systems," for all x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006. If it is necessary to determine such HVL at an x-ray tube potential which is not listed in table 1 in this subsection, linear interpolation or extrapolation may be made.

Positive means²³ shall be provided to ensure that at least the minimum filtration needed to achieve the above beam quality requirements is in the useful beam during each exposure. Table 1 follows:

Table 1.				
X-Ray Tube Voltage		Minimum HVL		
(kilovolt peak)		(mm of aluminum)		
Designed	Measured	Specified	I -- Other X-	II -- Other X-
Operating	Operating	Dental	Ray Systems²⁴	Ray Systems²⁵
Range	Potential	Systems²⁶		
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

²³ In the case of a system, which is to be operated with more than one (1) thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector which will prevent x-ray emissions if the minimum required filtration is not in place.

²⁴ Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006.

²⁵ All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

²⁶ Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.

- 10853.26 Fluoroscopic systems manufactured on or after June 10, 2006, incorporating an x-ray tube(s) with a continuous output of one kilowatt (1 kW) or more and an anode heat storage capacity of one million (1,000,000) heat units or more shall provide the option of adding x-ray filtration to the diagnostic source assembly in addition to the amount needed to meet the HVL provisions of § 10853.25. The selection of this additional x-ray filtration shall be either at the option of the user or automatic as part of the selected mode of operation. A means of indicating which combination of additional filtration is in the x-ray beam shall be provided.
- 10853.27 For capacitor energy storage equipment, compliance shall be determined with the maximum selectable quantity of charge per exposure.
- 10853.28 Except when used in a CT x-ray system, the aluminum equivalent of each of the items listed in table 2 in paragraph (n) of this section, which are used between the patient and image receptor, may not exceed the indicated limits. Compliance shall be determined by x-ray measurements made at a potential of 100 kilovolts peak and with an x-ray beam that has an HVL specified in table 1 in § 10853.25 for the potential. This requirement applies to front panel(s) of cassette holders and film changers provided by the manufacturer for patient support or for prevention of foreign object intrusions. It does not apply to screens and their associated mechanical support panels or grids. Table 2 follows:

Table 2.	
Item	Maximum Aluminum Equivalent (millimeters)
1. Front panel(s) of cassette holders (total of all)	1.2
2. Front panel(s) of film changer (total of all)	1.2
3. Cradle	2.3
4. Tabletop, stationary, without articulated joints	1.2
5. Tabletop, movable, without articulated joint(s) (including stationary subtop)	1.7
6. Tabletop, with radiolucent panel having one articulated joint	1.7
7. Tabletop, with radiolucent panel having two or more articulated joints	2.3
8. Tabletop, cantilevered	2.3
9. Tabletop, radiation therapy simulator	5.0

- 10853.29 On battery-powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.
- 10853.30 RESERVED
- 10853.31 Diagnostic x-ray components and systems certified in accordance with § 10845 of this chapter shall not be modified such that the component or system fails to comply with any applicable provision of this chapter unless a variance in accordance with § 10847 of this chapter or an exemption under 21 U.S.C. §§ 360kk(a)(5) or 360oo(b) of the act, has been granted.
- 10853.32 The owner of a diagnostic x-ray system who uses the system in a professional or commercial capacity may modify the system, provided the modification does not result in the failure of the system or component to comply with the applicable requirements of this section or of §§ 10854 and 10855. The owner who causes such modification need not submit the report, provided the owner records the date and the details of the modification in the system records and maintains this information, and provided the modification of the x-ray system does not result in a failure to comply with §§ 10854 and 10855.

10854 RADIOGRAPHIC EQUIPMENT

- 10854.1 The provisions of this section apply to equipment for radiography, except equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, or computed tomography x-ray systems manufactured on or after November 29, 1984.
- 10854.2 The technique factors to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls are used, in which case the technique factors which are set prior to the exposure shall be indicated. On equipment having fixed technique factors, this requirement may be met by permanent markings. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.
- 10854.3 Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.
- 10854.4 Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half (1/2) second. Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero (0). It shall not be possible to make an exposure when the timer is set to a zero (0) or off position if either position is provided.

- 10854.5 During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.
- 10854.6 When an automatic exposure control is provided:
- (a) Indication shall be made on the control panel when this mode of operation is selected;
 - (b) When the x-ray tube potential is equal to or greater than fifty-one kilovolts peak (51 kVp), the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two (2) pulses and the minimum exposure time for all other equipment shall be equal to or less than one sixtieth (1/60) second or a time interval required to deliver five milliampereseconds (5 mAs), whichever is greater;
 - (c) Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than sixty kilowatt-seconds (60 kW) per exposure or the product of x-ray tube current and exposure time shall be limited to not more than six hundred milliampereseconds (600 mAs) per exposure, except when the x-ray tube potential is less than fifty-one kilovolts peak (51 kVp), in which case the product of x-ray tube current and exposure time shall be limited to not more than two milliampereseconds (2,000 mAs) per exposure; and
 - (d) A visible signal shall indicate when an exposure has been terminated at the limits described in § 10854.6 and manual resetting shall be required before further automatically timed exposures can be made.
- 10854.7 Deviation of technique factors from indicated values shall not exceed the limits given in the information provided in accordance with § 10853.17.
- 10854.8 The following requirements shall apply when the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of § 10853.17.
- 10854.9 For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma shall be no greater than five hundredths (0.05).
- 10854.10 Determination of compliance shall be based on ten (10) consecutive measurements taken within a time period of one (1) hour. Equipment manufactured after September 5, 1978, shall be subject to the additional requirement that all variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement. The percent

line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation shall be within plus or minus one (+/- 1) of the mean value for all measurements. For equipment having automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of twelve (12) pulses on field emission equipment rated for pulsed operation or no less than one-tenth (0.10) second per exposure on all other equipment.

- 10854.11 The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer in accordance with the requirements of § 10853.17 for any fixed x-ray tube potential within the range of forty percent (40%) to one hundred percent (100%) of the maximum rated.
- 10854.12 The average ratios of air kerma to the indicated milliamperere-seconds product (mGy/mAs) obtained at any two consecutive tube current settings shall not differ by more than one tenth (0.10) times their sum. This is: $X[1] - X[2] \leq 0.10(X[1] + X[2])$; where X[1] and X[2] are the average mGy/mAs values obtained at each of two (2) consecutive milliamperere-seconds selector settings or at two (2) settings differing by no more than a factor of two (2) where the milliamperere-seconds selector provides continuous selection.
- 10854.13 For equipment manufactured after May 3, 1994, the average ratios of air kerma to the indicated milliamperere-seconds product (mGy/mAs) obtained at any two (2) consecutive mAs selector settings shall not differ by more than one tenth (0.10) times their sum. This is: $X[1] - X[2] \leq 0.10 (X[1] + X[2])$; where X[1] and X[2] are the average mGy/mAs values obtained at each of two (2) consecutive milliamperere-seconds selector settings or at two (2) settings differing by no more than a factor of two (2) where the milliamperere seconds selector provides continuous selection.
- 10854.14 Determination of compliance will be based on ten (10) exposures, made within one (1) hour, at each of the two (2) settings. These two (2) settings may include any two (2) focal spot sizes except where one (1) is equal to or less than forty-five hundredths millimeter (0.45 mm) and the other is greater than forty-five hundredths millimeter (0.45 mm). For purposes of this requirement, focal spot size is the focal spot size specified by the x-ray tube manufacturer. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation at any one (10) combination of technique factors shall be within plus or minus one (1) of the mean value for all measurements at these technique factors.
- 10854.15 Except when spot-film devices are in service, mobile, portable, and stationary general purpose radiographic x-ray systems shall meet the following requirements:

- (a) A means for stepless adjustment of the size of the x-ray field shall be provided. Each dimension of the minimum field size at an SID of one hundred centimeters (100 cm) shall be equal to or less than five centimeters (5 cm);
- (b) Means for visually defining the perimeter of the x-ray field shall be provided. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam;
- (c) When a light localizer is used to define the x-ray field, it shall provide an average illuminance of not less than one hundred sixty (160) lux (fifteen (15) foot-candles) at one hundred centimeters (100 cm) or at the maximum SID, whichever is less. The average illuminance shall be based on measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement; and
- (d) The edge of the light field at one hundred centimeters (100 cm) or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than four (4) in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than three (3) in the case of beam-limiting devices designed for use on mobile and portable equipment. The contrast ratio is defined as $I[1]/I[2]$, where $I[1]$ is the illuminance three millimeters (3 mm) from the edge of the light field toward the center of the field; and $I[2]$ is the illuminance three millimeters (3 mm) from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of one millimeter (1 mm).

10854.16 Except when spot-film devices are in service, stationary general purpose x-ray systems shall meet the following requirements in addition to those prescribed in § 10854.16:

- (a) Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within two percent (2%) of the SID, and to indicate the SID to within two percent (2%);
- (b) The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

- (c) Indication of field size dimensions and SIDs shall be specified in centimeters or inches and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent (2%) of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and
- (d) Compliance measurements will be made at discrete SIDs and image receptor dimensions in common clinical use (such as SIDs of one hundred (100), one hundred fifty (150), and two hundred (200) centimeters or thirty-six (36), forty (40), forty-eight (48), and seventy-two (72) inches and nominal image receptor dimensions of thirteen (13), eighteen (18), twenty-four (24), thirty (30), thirty-five (35), forty (40), and forty-three (43) centimeters or five (5), seven (7), eight (8), nine (9), ten (10), eleven (11), twelve (12), fourteen (14), and seventeen (17) inches or at any other specific dimensions at which the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate.

10854.17 Equipment for use with intraoral image receptors. Radiographic equipment designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

- (a) If the minimum source-to-skin distance (SSD) is eighteen centimeters (18 cm) or more, the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than seven centimeters (7 cm); and
- (b) If the minimum SSD is less than eighteen centimeters (18 cm), the x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than six centimeters (6 cm).

10854.18 Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

10854.19 Radiographic systems designed only for mammography and general purpose radiography systems, when special attachments for mammography are in service, manufactured on or after November 1, 1977, and before September 30, 1999, shall be provided with means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designated SID except the edge of the image receptor designed to be adjacent to the chest wall where the x-ray field may not extend beyond this edge by more than two percent (2%) of the SID. This requirement can be met with

a system that performs as prescribed in § 10854.23(a), (b), and (c). When the beam-limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in § 10854.23(b) and (c) shall be the maximum SID for which the beam-limiting device or aperture is designed.

- 10854.20 Mammographic beam-limiting devices manufactured on or after September 30, 1999, shall be provided with a means to limit the useful beam such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor by more than two percent (2%) of the SID. This requirement can be met with a system that performs as prescribed in § 10854.23(a), (b), and (c). For systems that allow changes in the SID, the SID indication specified in § 10854.23(b) and (c) shall be the maximum SID for which the beam-limiting device or aperture is designed.
- 10854.21 Each image receptor support device manufactured on or after November 1, 1977, intended for installation on a system designed for mammography shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.
- 10854.22 Radiographic systems not specifically covered in § 10854.16, 10854.17, 10854.23(b), 10854.23(c), and 10854.31, and systems covered in paragraph (a), which are also designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent (2%) of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:
- (a) A system which performs in accordance with §§ 10854.16 and 10854.17; or when alignment means are also provided, may be met with either;
 - (b) An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or
 - (c) A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall

indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

- 10854.23 The requirements of this section shall apply to radiographic systems which contain positive beam limitation (PBL).
- 10854.24 When a PBL system is provided, it shall prevent x-ray production when:
- (a) Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than three percent (3%) of the SID; or
 - (b) The sum of the length and width differences as stated in § 10854.25(a) without regard to sign exceeds 4 percent of the SID; and
 - (c) The beam limiting device is at an SID for which PBL is not designed for sizing.
- 10854.25 When provided, the PBL system shall function as described in § 10854.25 whenever all the following conditions are met:
- (a) The image receptor is inserted into a permanently mounted cassette holder;
 - (b) The image receptor length and width are less than fifty centimeters (50 cm);
 - (c) The x-ray beam axis is within plus or minus three degrees ($\pm 3^\circ$) of vertical and the SID is ninety centimeters (90 cm.) to one hundred thirty centimeters (130 cm.) inclusive; or the x-ray beam axis is within plus or minus three degrees ($\pm 3^\circ$) of horizontal and the SID is ninety centimeters (90 cm) to two hundred five centimeters (205 cm) inclusive;
 - (d) The x-ray beam axis is perpendicular to the plane of the image receptor to within plus or minus three degrees (3°); and
 - (e) Neither tomographic nor stereoscopic radiography is being performed.
- 10854.26 Compliance with the requirements of § 10854.25 shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of § 10854.26 are met. Compliance shall be determined no sooner than five (5) seconds after insertion of the image receptor.
- 10854.27 The PBL system shall be capable of operation such that, at the discretion of the operator, the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. Each dimension of the

minimum field size at an SID of one hundred centimeters (100 cm) shall be equal to or less than five centimeters (5 cm). Return to PBL function as described in § 10854.25 shall occur automatically upon any change of image receptor size or SID.

10854.28 A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SIDs and image receptor sizes. A key shall be required for any override capability that is accessible to the operator. It shall not be possible to remove the key while PBL is overridden. Each such key switch or key shall be clearly and durably labeled as follows:

“For X-ray Field Limitation System Failure”.

10854.29 The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.

10854.30 The following requirements shall apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

- (a) Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor which has been selected on the spot-film selector. Such adjustment shall be accomplished automatically when the x-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation;
- (b) Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three percent (3%) of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed four percent (4%) of the SID. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor;
- (c) The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to

within two percent (2%) of the SID; and

- (d) Means shall be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:
 - (1) For spot-film devices used on fixed-SID fluoroscopic systems which are not required to, and do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed one hundred square centimeters (125 cm²); or
 - (2) For spot-film devices used on fluoroscopic systems that have a variable SID or stepless adjustment of the field size, the minimum field size, at the greatest SID, shall be containable in a square of five centimeters by five centimeters (5 cm x 5 cm).

10854.31 A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic x-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows:

“For X-ray Field Limitation System Failure”.

10854.32 X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-skin distance to not less than:

- (a) Eighteen centimeters (18 cm) if operable above fifty kilovolts peak (50 kVp); or
- (b) Ten centimeters (10 cm) cm if not operable above fifty kilovolts peak (50 kVp).

10854.33 Mobile and portable x-ray systems other than dental shall be provided with means to limit the source-skin distance to not less than thirty centimeters (30 cm).

10854.34 The x-ray control shall provide visual indication whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

10854.35 Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated before initiation of the exposure. This indication shall be both on the x-ray control and at or near the tube housing assembly which has been selected.

10854.36 Radiation emitted from the x-ray tube shall not exceed:

- (a) An air kerma of twenty-six hundredths microgray (0.26 microGy) (vice three hundredths milliroentgens (0.03 mR) exposure) in one minute (1 min.) at five centimeters (5 cm) from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated. Compliance shall be determined by measurements averaged over an area of one-hundred square centimeters (100 cm²) with no linear dimension greater than twenty centimeters (20 cm); and
- (b) An air kerma of eighty-eight hundredths microgray (0.88 mGy) (vice one hundred milliroentgens (100 mR) exposure) in one hour (1 hr.) at one hundred centimeters (100 cm) from the x-ray source, with the beam-limiting device fully open, when the system is discharged through the x-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power. Compliance shall be determined by measurements of the maximum air kerma per discharge multiplied by the total number of discharges in one hour (1 hr.) (duty cycle). The measurements shall be averaged over an area of one hundred square centimeters (100 cm²) with no linear dimension greater than twenty centimeters (20 cm).

10854.37 For x-ray systems manufactured after September 5, 1978, and before September 30, 1999, which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the air kerma five centimeters (5 cm) from any accessible surface beyond the plane of the image receptor supporting device does not exceed eighty-eight hundredths microgray (0.88 mGy) (vice 0.1 mR exposure) for each activation of the tube.

10854.38 For mammographic x-ray systems manufactured on or after September 30, 1999:

- (a) At any SID where exposures can be made, the image receptor support device shall provide a primary protective barrier that intercepts the cross section of the useful beam along every direction except at the chest wall edge;
- (b) The x-ray system shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in § 10854.38(a); and
- (c) The transmission of the useful beam through the primary protective barrier shall be limited such that the air kerma five centimeters (5 cm) from any accessible surface beyond the plane of the primary protective barrier does not exceed eighty-eight hundredths microgray (0.88 mGy) (vice 0.1 mR exposure) for each activation of the tube.

10854.39 Compliance with the requirements of § 10854.37 and 10854.38(c) for transmission shall be determined with the x-ray system operated at the minimum SID for which it is designed, at the maximum rated peak tube potential, at the maximum rated product of x-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and by measurements averaged over an area of one hundred square centimeters (100 cm²) with no linear dimension greater than twenty centimeters (20 cm). The sensitive volume of the radiation measuring instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.

10855 FLUOROSCOPIC EQUIPMENT

10855.1 The provisions of this section apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor, except computed tomography x-ray systems manufactured on or after November 29, 1984.

10855.2 The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The AKR due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the fluoroscopic image receptor shall not exceed 3.34×10^{-3} percent of the entrance AKR, at a distance of ten centimeters (10 cm.) from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. Radiation therapy simulation systems shall be exempt from this requirement provided the systems are intended only for remote control operation and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information required in § 10853.14. Additionally, the manufacturer shall provide to users, under § 10853.15(a)(1), precautions concerning the importance of remote control operation.

10855.3 The AKR shall be measured in accordance with § 10855.12. The AKR due to transmission through the primary barrier combined with radiation from the fluoroscopic image receptor shall be determined by measurements averaged over an area of one hundred square centimeters (100 cm²) with no linear dimension greater than twenty centimeters (20 cm). If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned thirty centimeters (30 cm) above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than thirty centimeters (30 cm). Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam ten centimeters (10 cm) from the point of

measurement of entrance AKR and between this point and the input surface of the fluoroscopic imaging assembly.

- 10855.4 For fluoroscopic equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance with § 10855.7 through 10855.9 shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.
- 10855.5 Means shall be provided to permit further limitation of the x-ray field to sizes smaller than the limits of § 10855.7 through 10855.9. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or the capability of a visible area of greater than three hundred square centimeters (300 cm^2), shall be provided with means for stepless adjustment of the x-ray field. Equipment with a fixed SID and the capability of a visible area of no greater than three hundred square centimeters (300 cm^2) shall be provided with either stepless adjustment of the x-ray field or with a means to further limit the x-ray field size at the plane of the image receptor to one hundred twenty five square centimeters (125 cm^2) or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size containable in a square of five centimeters by five centimeters ($5 \text{ cm} \times 5 \text{ cm}$). This paragraph does not apply to non-image-intensified fluoroscopy.
- 10855.6 The x-ray field produced by non-image-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided for stepless adjustment of field size. The minimum field size, at the greatest SID, shall be containable in a square of five centimeters by five centimeters ($5 \text{ cm} \times 5 \text{ cm}$).
- 10855.7 For fluoroscopic equipment manufactured before June 10, 2006, other than radiation therapy simulation systems, the following applies:
- (a) Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than four percent (4%) of the SID; and
 - (b) For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.
- 10855.8 For fluoroscopic equipment manufactured on or after June 10, 2006, other than radiation therapy simulation systems, the maximum area of the x-ray field in the

plane of the image receptor shall conform with one (1) of the following requirements:

- (a) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to thirty four centimeters (34 cm) in any direction, at least eighty percent (80%) of the area of the x-ray field overlaps the visible area of the image receptor; or
- (b) When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than thirty four centimeters (34 cm) in any direction, the x-ray field measured along the direction of greatest misalignment with the visible area of the image receptor does not extend beyond the edge of the visible area of the image receptor by more than two centimeters (2 cm).

10855.9 For x-ray systems manufactured on or after June 10, 2006, the following applies:

- (a) Neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than four percent (4%) of the SID; and
- (b) The error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

10855.10 If the fluoroscopic x-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled as follows:

“For X-ray Field Limitation System Failure”.

10855.11 X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial radiographic images from the fluoroscopic image receptor, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

10855.12 For fluoroscopic equipment, the following requirements apply:

- (a) Equipment provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current that will result in an AKR in excess of eighty-eight milligray (88 mGy) per minute (vice ten roentgen per minute (10 R/min.) exposure rate) at the measurement point specified in § 10855.15, except as specified in § 10855.12(e);
- (b) Equipment provided without AERC shall not be operable at any combination of tube potential and current that will result in an AKR in excess of forty four milligray (44 mGy) per minute (vice five roentgen per minute (5 R/min.) exposure rate) at the measurement point specified in § 10855.15, except as specified in § 10855.12(e);
- (c) Equipment provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of eighty-eight milligray (88 mGy) per minute (vice ten roentgen per minute (10 R/min.) exposure rate) in either mode at the measurement point specified in § 10855.15, except as specified in § 10855.12(e);
- (d) Equipment may be modified in accordance with § 10853.31 to comply with § 10855.13. When the equipment is modified, it shall bear a label indicating the date of the modification and the statement:

“Modified to comply with 22 DCMR B § 10855.23”.
- (e) Exceptions to the § 10855.12 requirements for fluoroscopic equipment are as follows:
 - (1) During recording of fluoroscopic images; or
 - (2) When a mode of operation has an optional high-level control, in which case that mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of the rates specified in § 10855.12(a), (b), or (c) at the measurement point specified in § 10855.15, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

10855.13 Fluoroscopic equipment manufactured on or after May 19, 1995:

- (a) Shall be equipped with AERC if operable at any combination of tube potential and current that results in an AKR greater than forty-four

milligray (44 mGy) per minute (vice five roentgen per minute (5 R/min.) exposure rate) at the measurement point specified in § 10855.15. Provision for manual selection of technique factors may be provided; and

- (b) Shall not be operable at any combination of tube potential and current that will result in an AKR in excess of eighty-eight milligray (88 mGy) per minute (vice ten roentgen per minute (10 R/min.) exposure rate) at the measurement point specified in § 10855.15, except as specified in § 10855.14.

10855.14 Exceptions to the § 10855 requirements for fluoroscopic equipment are as follows:

- (a) For equipment manufactured prior to June 10, 2006, during the recording of images from a fluoroscopic image receptor using photographic film or a video camera when the x-ray source is operated in a pulsed mode;
- (b) For equipment manufactured on or after June 10, 2006, during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with a recorded image(s) after termination of the exposure. Such recording does not include images resulting from a last-image-hold feature that are not recorded; and
- (c) When a mode of operation has an optional high-level control and the control is activated, in which case the equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of one hundred seventy-six milligray (176 mGy) per minute (vice twenty roentgen per minute (20 R/min.) exposure rate) at the measurement point specified in § 10855.15. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

10855.15 Compliance with § 10855.12 shall be determined as follows:

- (a) If the source is below the x-ray table, the AKR shall be measured at one centimeter (1 cm) above the tabletop or cradle;
- (b) If the source is above the x-ray table, the AKR shall be measured at thirty centimeters (30 cm) above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;
- (c) In a C-arm type of fluoroscope, the AKR shall be measured at thirty centimeter (30 cm) from the input surface of the fluoroscopic imaging

assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than thirty centimeters (30 cm) from the input surface of the fluoroscopic imaging assembly;

- (d) In a C-arm type of fluoroscope having an SID less than forty-five centimeters (45 cm), the AKR shall be measured at the minimum SSD; and
- (e) In a lateral type of fluoroscope, the air kerma rate shall be measured at a point fifteen centimeters (15 cm) from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than fifteen centimeters (15 cm) to the centerline of the x-ray table.

10855.16 Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in § 10855.12.

10855.17 RESERVED

10855.18 During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated. Deviation of x-ray tube potential and current from the indicated values shall not exceed the maximum deviation as stated by the manufacturer in accordance with § 10853.17.

10855.19 Means shall be provided to limit the source-skin distance to not less than thirty-eight centimeters (38 cm) on stationary fluoroscopes and to not less than thirty centimeters (30 cm) on mobile and portable fluoroscopes. In addition, for fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this section, provisions may be made for operation at shorter source-skin distances but in no case less than twenty centimeters (20 cm). When provided, the manufacturer must set forth precautions with respect to the optional means of spacing, in addition to other information as required in § 10853.15.

10855.20 For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than forty-five centimeters (45 cm), means shall be provided to limit the source-skin distance to not less than nineteen centimeters (19 cm). Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distances specified in this subsection, provisions may be made for operation at shorter source-skin distances but in no case less than ten centimeters (10 cm). When provided, the

manufacturer must set forth precautions with respect to the optional means of spacing, in addition to other information as required in § 10853.17.

10855.21 Fluoroscopic equipment manufactured before June 10, 2006, shall be provided with means to preset the cumulative irradiation time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative irradiation-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset. Fluoroscopic equipment may be modified in accordance with § 10853.31 and 10853.32 to comply with the requirements of § 10853.23. When the equipment is modified, it shall bear a label indicating the statement:

“Modified to comply with 22 DCMR B § 10853.23”.

10855.22 As an alternative to the requirements of this section, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between x-ray examinations.

10855.23 For x-ray controls manufactured on or after June 10, 2006, there shall be provided for each fluoroscopic tube:

- (a) A display of the fluoroscopic irradiation time at the fluoroscopist's working position. This display shall function independently of the audible signal described in § 10855.24. The following requirements apply:
 - (1) When the x-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every six (6) seconds;
 - (2) The fluoroscopic irradiation time shall also be displayed within six (6) seconds of termination of an exposure and remain displayed until reset; and
 - (3) Means shall be provided to reset the display to zero (0) prior to the beginning of a new examination or procedure.

10855.24 A signal audible to the fluoroscopist shall sound for each passage of five (5) minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least two (2) seconds.

10855.25 In addition to the other requirements of this section, mobile and portable fluoroscopes shall provide an image receptor incorporating more than a simple

fluorescent screen.

- 10855.26 Fluoroscopic equipment manufactured on or after June 10, 2006, shall be equipped with means to display last-image-hold (LIH) following termination of the fluoroscopic exposure.
- 10855.27 For an LIH image obtained by retaining pre-termination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure.
- 10855.28 For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the technique factors for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure.
- 10855.29 Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.
- 10855.30 The predetermined or selectable options for producing the LIH radiograph shall be described in the information required by § 10853.17. The information shall include a description of any technique factors applicable for the selected option and the impact of the selectable options on image characteristics and the magnitude of radiation emissions.
- 10855.31 Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working position the AKR and cumulative air kerma. The following requirements apply for each x-ray tube used during an examination or procedure:
- (a) When the x-ray tube is activated and the number of images produced per unit time is greater than six (6) images per second, the AKR in milligram per minute shall be continuously displayed and updated at least once every second;
 - (b) The cumulative air kerma in units of milligram shall be displayed either within five (5) seconds of termination of an exposure or displayed continuously and updated at least once every five (5) seconds;
 - (c) The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma; and
 - (d) The AKR and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one (1) of the following reference

locations specified according to the type of fluoroscope. The reference location shall be identified and described specifically in the information provided to users according to § 10853.20(c).

- 10855.32 For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of lateral type, the reference locations shall be the respective locations specified in § 10855.15(a), (b), or (e) for measuring compliance with air kerma rate limits.
- 10855.33 For C-arm fluoroscopes, the reference location shall be fifteen centimeters (15 cm.) from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin.
- 10855.34 Means shall be provided to reset to zero (0) the display of cumulative air kerma prior to the commencement of a new examination or procedure.
- 10855.35 The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than plus or minus thirty-five percent (35%) over the range of six milligray per minute (6 mGy/min.) and one hundred milligray (100 mGy) to the maximum indication of AKR and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than three (3) seconds.

10856 HIGH INTENSITY MERCURY VAPOR DISCHARGE LAMPS

- 10856.1 The provisions of this section apply to any high-intensity mercury vapor discharge lamp that is designed, intended, or promoted for illumination purposes and is manufactured or assembled after March 7, 1980, except as described in § 10856.6.
- 10856.2 As used in this section the following definitions apply:
- (a) **High-intensity mercury vapor discharge lamp** - any lamp including any "mercury vapor" and "metal halide" lamp, with the exception of the tungsten filament self-ballasted mercury vapor lamp, incorporating a high-pressure arc discharge tube that has a fill consisting primarily of mercury and that is contained within an outer envelope;
 - (b) **Advertisement** - any catalog, specification sheet, price list, and any other descriptive or commercial brochure and literature, including videotape and film, pertaining to high-intensity mercury vapor discharge lamps;
 - (c) **Packaging** - any lamp carton, outer wrapping, or other means of containment that is intended for the storage, shipment, or display of a high-intensity mercury vapor lamp and is intended to identify the contents

or recommend its use;

- (d) **Outer envelope** - the lamp element, usually glass, surrounding a high-pressure arc discharge tube, that, when intact, attenuates the emission of shortwave ultraviolet radiation;
- (e) **Shortwave ultraviolet radiation** - ultraviolet radiation with wavelengths shorter than three hundred twenty nanometers (320 nm);
- (f) **Cumulative operating time** - means the sum of the times during which electric current passes through the high-pressure arc discharge;
- (g) **Self-extinguishing lamp** - means a high-intensity mercury vapor discharge lamp that is intended to comply with the requirements of § 10856.6 as applicable; and
- (h) **Reference ballast** - is an inductive reactor designed to have the operating characteristics as listed in Section 7 in the American National Standard Specifications for High-Intensity Discharge Lamp Reference Ballasts (ANSI C82.5-1977)²⁷ or its equivalent.

10856.3 Each high-intensity mercury vapor discharge lamp shall:

- (a) Meet the requirements of either § 10856.5 or § 10856.9; and
- (b) Be permanently labeled or marked in such a manner that the name of the manufacturer and the month and year of manufacture of the lamp can be determined on an intact lamp and after the outer envelope of the lamp is broken or removed. The name of the manufacturer and month and year of manufacture may be expressed in code or symbols, provided the manufacturer has previously supplied the Director, Center for Devices and Radiological Health, with the key to the code or symbols and the location of the coded information or symbols on the lamp.

10856.4 In lieu of permanently affixing or inscribing tags or labels on the product as required by §§ 10845.2 and 10846.1, the manufacturer of any high-intensity mercury vapor discharge lamp may permanently affix or inscribe such required tags or labels on the lamp packaging uniquely associated with the applicable lamp.

10856.5 Each self-extinguishing lamp manufactured after March 7, 1980 shall cease operation within a cumulative operating time not to exceed fifteen (15) minutes following complete breakage or removal of the outer envelope (with the exception

²⁷ Copies are available from American National Standards Institute, 1430 Broadway, New York, NY 10018.

of fragments extending fifty millimeters (50 mm) or less from the base shell).

- 10856.6 Each self-extinguishing lamp manufactured after September 7, 1981, shall cease operation within a cumulative operating time not to exceed fifteen (15) minutes following breakage or removal of at least three square centimeters (3 cm²) of contiguous surface of the outer envelope.
- 10856.7 Each self-extinguishing lamp shall be clearly marked with the letter "T" on the outer envelope and on another part of the lamp in such a manner that it is visible after the outer envelope of the lamp is broken or removed.
- 10856.8 Lamp packaging for each self-extinguishing lamp shall clearly and prominently display:
- (a) The letter "T"; and
 - (b) The wording: "This lamp should self-extinguish within fifteen (15) minutes after the outer envelope is broken or punctured. If such damage occurs, TURN OFF AND REMOVE LAMP to avoid possible injury from hazardous shortwave ultraviolet radiation."
- 10856.9 Any high-intensity mercury vapor discharge lamp that does not comply with § 10856.5 shall be clearly and legibly marked with the letter "R" on the outer envelope and on another part of the lamp in such a manner that it is visible after the outer envelope of the lamp is broken or removed.
- 10856.10 Lamp packaging for each high-intensity mercury vapor discharge lamp that does not comply with § 10856.5 shall clearly and prominently display:
- (a) The letter "R"; and
 - (b) The wording "WARNING: This lamp can cause serious skin burn and eye inflammation from shortwave ultraviolet radiation if outer envelope of the lamp is broken or punctured. Do not use where people will remain for more than a few minutes unless adequate shielding or other safety precautions are used. Lamps that will automatically extinguish when the outer envelope is broken or punctured are commercially available."
- 10856.11 Advertising for any high-intensity mercury vapor discharge lamp that does not comply with § 10856.5 shall prominently display the following wording: "WARNING: This lamp can cause serious skin burn and eye inflammation from shortwave ultraviolet radiation if outer envelope of the lamp is broken or punctured. Do not use where people will remain for more than a few minutes unless adequate shielding or other safety precautions are used. Lamps that will automatically extinguish when the outer envelope is broken or punctured are

commercially available.".

10856.12 Any high-intensity mercury vapor discharge lamp under test for compliance with the requirements set forth in § 10856.5 shall be started and operated under the following conditions as applicable:

- (a) Lamp voltage, current, and orientation shall be those indicated or recommended by the manufacturer for operation of the intact lamp;
- (b) The lamp shall be operated on a reference ballast;
- (c) The lamp shall be started in air that has a temperature of twenty five plus or minus five degrees Celsius (25+/-5° C). Heating and movement of the air surrounding the lamp shall be that produced by the lamp and ballast alone;
- (d) If any test is performed in an enclosure, the enclosure shall be not less than two hundred twenty-seven thousandth cubic meters (0.227 m³ (eight cubic feet (8 cu. ft.))); and
- (e) Any lamp designed to be operated only in a specific fixture or luminaire that the lamp manufacturer supplies or specifies shall be tested in that fixture or luminaire. Any other lamp shall be tested with no reflector or other surrounding material.

10857 ULTRASONIC THERAPY PRODUCTS

10857.1 The provisions of this section are applicable as specified herein to any ultrasonic therapy product for use in physical therapy manufactured on or after February 17, 1979.

10857.2 As used in this section the following definitions apply:

- (a) **Amplitude modulated waveform** - a waveform in which the ratio of the temporal-maximum pressure amplitude spatially averaged over the effective radiating surface to the root-mean-square pressure amplitude spatially averaged over the effective radiating surface is greater than one and five hundredths (1.05);
- (b) **Applicator** - that portion of a fully assembled ultrasonic therapy product that is designed to emit ultrasonic radiation and which includes one or more ultrasonic transducers and any associated housing;
- (c) **Beam cross-section** - the surface in any plane consisting of the points at which the intensity is greater than five percent (5%) of the spatial-

maximum intensity in that plane;

- (d) **Beam nonuniformity ratio** - the ratio of the temporal-average spatial-maximum intensity to the temporal-average effective intensity;
- (e) **Centroid of a surface** - the point whose coordinates are the mean values of the coordinates of the points of the surface;
- (f) **Collimating applicator** - an applicator that does not meet the definition of a focusing applicator as specified in the paragraph "Focusing applicator" of this section and for which the ratio of the area of at least one beam cross-section, whose centroid is twelve centimeters (12 cm) from the centroid of the effective radiating surface, to the area of the effective radiating surface is less than two (2);
- (g) **Continuous-wave waveform** - a waveform in which the ratio of the temporal-maximum pressure amplitude spatially averaged over the effective radiating surface to the root-mean-square pressure amplitude spatially averaged over the effective radiating surface is less than or equal to one and five hundredths (1.05);
- (h) **Diverging applicator** - means an applicator that does not meet the definition of a collimating applicator or a focusing applicator as specified in paragraphs "Collimating applicator" and "Focusing applicator" of this section;
- (i) **Effective intensity** - the ratio of the ultrasonic power to the focal area for a focusing applicator. For all other applicators, the effective intensity is the ratio of the ultrasonic power to the effective radiating area. Effective intensity is expressed in watts per square centimeter (W/cm^2);
- (j) **Effective radiating area** - the area consisting of all points of the effective radiating surface at which the intensity is five percent (5%) or more of the maximum intensity at the effective radiating surface, expressed in square centimeters (cm^2);
- (k) **Effective radiating surface** - the surface consisting of all points five millimeters (5 mm) from the applicator face;
- (l) **Focal area** - the area of the focal surface, expressed in square centimeters (cm^2);
- (m) **Focal length** - the distance between the centroids of the effective radiating surface and the focal surface, for a focusing applicator, expressed in centimeters (cm);

- (n) **Focal surface** - the beam cross-section with smallest area of a focusing applicator;
- (o) **Focusing applicator** - an applicator in which the ratio of the area of the beam cross-section with the smallest area to the effective radiating area is less than one-half ($1/2$);
- (p) **Generator** - that portion of a fully assembled ultrasonic therapy product that supplies electrical energy to the applicator. The generator may include, but is not limited to, a power supply, ultrasonic frequency oscillator, service controls, operation controls, and a cabinet to house these components;
- (q) **Maximum beam non-uniformity ratio** - the maximum value of the beam non-uniformity ratio characteristic of a model of an ultrasonic therapy product;
- (r) **Operation control** - any control used during operation of an ultrasonic therapy product that affects the ultrasonic radiation emitted by the applicator;
- (s) **Pressure amplitude** - the instantaneous value of the modulating waveform, and is $p_1(t)$ in the expression for a pressure wave, $p(t)=p_1(t)p_2(t)$, where $p(t)$ is the instantaneous pressure, $p_1(t)$ is the modulating envelope, and $p_2(t)$ is the relative amplitude of the carrier wave normalized to a peak height of one (1). All are periodic functions of time (t_0 at any point in space. The period of $p_1(t)$ is greater than the period of $p_2(t)$);
- (t) **Pulse duration** - a time interval, expressed in seconds, beginning at the first time the pressure amplitude exceeds the minimum pressure amplitude plus ten percent (10%) of the difference between the maximum and minimum pressure amplitudes, and ending at the last time the pressure amplitude returns to this value;
- (u) **Pulse repetition rate** - the repetition frequency of the waveform modulating the ultrasonic carrier wave expressed in pulses per second (pps);
- (v) **Service control** - any control provided for the purpose of adjustment that is not used during operation and can affect the ultrasonic radiation emitted by the applicator, or can alter the calibration or accuracy of an indicator or operation control;

- (w) **Ultrasonic frequency** - the frequency of the ultrasonic radiation carrier wave, expressed in Hertz (Hz), kilohertz (kHz), or megahertz (MHz);
- (x) **Ultrasonic power** - the total power emitted in the form of ultrasonic radiation by the applicator averaged over each cycle of the ultrasonic radiation carrier wave, expressed in watts;
- (y) **Ultrasonic therapy product** –
 - (1) Any device intended to generate and emit ultrasonic radiation for therapeutic purposes at ultrasonic frequencies above sixteen kilohertz (16kHz.); or
 - (2) Any generator or applicator designed or specifically designated for use in a device as specified in paragraph (a); and
- (z) **Ultrasonic transducer** - a device used to convert electrical energy of ultrasonic frequency into ultrasonic radiation or vice versa.

10857.3 The requirements of this section are applicable to each ultrasonic therapy product as defined in paragraphs (a) and (b) of § 10857.2 when the generator and applicator are designated or intended for use together, or to each generator when the applicator(s) intended for use with the generator does not contain controls that affect the functioning of the generator.

10857.4 A means shall be incorporated to indicate the magnitudes of the temporal-average ultrasonic power and the temporal-average effective intensity when emission is of continuous-wave waveform. The error in the indication of the temporal-average ultrasonic power shall not exceed plus or minus twenty percent (+/- 20%) for all emissions greater than ten percent (10%) of the maximum emission.

10857.5 A means shall be incorporated to indicate the magnitudes of the temporal-maximum ultrasonic power and the temporal-maximum effective intensity when the emission is of amplitude-modulated waveform. The sum of the errors in the indications of the temporal-maximum ultrasonic power and the ratio of the temporal-maximum effective intensity to the temporal-average effective intensity specified in § 10857.14 of this section shall not exceed plus or minus twenty percent (+/-20%) for all emissions greater than ten percent (10%) of the maximum emission.

10857.6 A means shall be incorporated to enable the duration of emission of ultrasonic radiation for treatment to be preset and such means shall terminate emission at the end of the preset time. Means shall also be incorporated to enable termination of emission at any time. Means shall be incorporated to indicate the magnitude of the duration of emission (expressed in minutes) to within one-half minute (0.5) minute of the preset duration of emission for setting less than five (5) minutes, to

within ten percent (10%) of the preset duration of emission for settings of from five (5) minutes to ten (10) minutes, and to within one (1) minute of the preset duration of emission for settings greater than ten (10) minutes.

- 10857.7 A means shall be incorporated for indicating the magnitudes of pulse duration and pulse repetition rate of the emitted ultrasonic radiation, if there are operation controls for varying these quantities.
- 10857.8 A means shall be incorporated for indicating the magnitude of the ultrasonic frequency of the emitted ultrasonic radiation, if there is an operation control for varying this quantity.
- 10857.9 A means shall be incorporated to provide a clear, distinct, and readily understood visual indicator when and only when electrical energy of appropriate ultrasonic frequency is being applied to the ultrasonic transducer(s).
- 10857.10 In addition to the labeling requirements in Chapter 103 and the requirements of §§ 10845 and 10846, each ultrasonic therapy product shall be subject to the applicable labeling requirements of this section.
- 10857.11 Each operation control shall be clearly labeled identifying the function controlled and, where appropriate, the units of measure of that function. If a separate control and indicator are associated with the same function, then labeling the appropriate units of measure of that function is required for the indicator but not for the control.
- 10857.12 Each service control that is accessible without displacement or removal of any part of the ultrasonic therapy product shall be clearly labeled identifying the function controlled and shall include the phrase "for service adjustment only."
- 10857.13 Each generator shall bear a label that states:
- (a) The brand name;
 - (b) Model designation, and unique serial number or other unique identification so that it is individually identifiable;
 - (c) Ultrasonic frequency (unless there is an operation control for varying this quantity); and
 - (d) Type of waveform (continuous wave or amplitude modulated).
- 10857.14 Generators employing amplitude-modulated waveforms shall also bear a label that provides the following information: Pulse duration and pulse repetition rate (unless there are operation controls for varying these quantities), an illustration of the amplitude-modulated waveform, and the ratio of the temporal-maximum

effective intensity to the temporal-average effective intensity. (If this ratio is a function of any operation control setting, then the range of the ratio shall be specified, and the waveform illustration shall be provided for the maximum value of this ratio.).

- 10857.15 Each applicator shall bear a label that provides the following information:
- (a) The brand name, model designation, and unique serial number or other unique identification so the applicator is individually identifiable;
 - (b) A designation of the generator(s) for which the applicator is intended; and
 - (c) The ultrasonic frequency, effective radiating area, maximum beam nonuniformity ratio, type of applicator (focusing, collimating, diverging), and for a focusing applicator the focal length and focal area.
- 10857.16 Labels required by this section shall be permanently affixed to or inscribed on the ultrasonic therapy product; they shall be legible and clearly visible. If the size, configuration, or design of the ultrasonic therapy product would preclude compliance with the requirements of this paragraph, the Director, Center for Devices and Radiological Health, may approve alternate means of providing such labels.
- 10857.17 Tests on which certification pursuant to § 10845 is based shall account for all measurement errors and uncertainties. Such tests shall also account for increases in emission and degradation in radiation safety that occur with age.
- 10857.18 Except as provided in § 10849, tests for compliance with each of the applicable requirements of this section shall be made:
- (a) For all possible combinations of adjustments of the controls listed in the operation instructions;
 - (b) With the ultrasonic radiation emitted into the equivalent of an infinite medium of distilled, degassed water at thirty degrees Celsius (30 °C) for measurements concerning the ultrasonic radiation; and
 - (c) With line voltage variations in the range of plus or minus ten percent (+/- 10%) of the rated value specified by the manufacturer.
- 10857.19 Measurements for determination of the spatial distribution of the ultrasonic radiation field shall be made with a detector having dimensions of less than one (1) wavelength in water or an equivalent measurement technique.
- 10857.20 The manufacturer of an ultrasonic therapy product shall provide or cause to be provided to servicing dealers and distributors, and to others upon request, at a cost

not to exceed the cost of preparation and distribution adequate instructions for operations, service, and calibration, including a description of those controls and procedures that could be used to increase radiation emission levels, and a schedule of maintenance necessary to keep equipment in compliance with this section. The instructions shall include adequate safety precautions that may be necessary regarding ultrasonic radiation exposure.

10857.21 The manufacturer of an ultrasonic therapy product shall provide as an integral part of any user instruction or operation manual that is regularly supplied with the product, or, if not so supplied, shall cause to be provided with each ultrasonic therapy product, and to others upon request, at a cost not to exceed the cost of preparation and distribution the following:

- (a) Adequate instructions concerning assembly, operation, safe use, any safety procedures and precautions that may be necessary regarding the use of ultrasonic radiation, and a schedule of maintenance necessary to keep the equipment in compliance with this section. The operation instructions shall include a discussion of all operation controls, and shall describe the effect of each control;
- (b) Adequate description of the spatial distribution of the ultrasonic radiation field and the orientation of the field with respect to the applicator. This will include a textual discussion with diagrams, plots, or photographs representative of the beam pattern. If there is more than one (1) ultrasonic transducer in an applicator and their positions are not fixed relative of each other, then the description must specify the spatial distribution of the ultrasonic radiation field emitted by each ultrasonic transducer and present adequate examples of the combination field of the ultrasonic transducers with regard to safe use. The description of the ultrasonic radiation field shall state that such description applies under conditions specified in § 10857.18(b);
- (c) Adequate description, as appropriate to the product, of the uncertainties in magnitude expressed in terms of percentage error, of the ultrasonic frequency effective radiating area, and, where applicable, the ratio of the temporal-maximum effective intensity to the temporal-average effective intensity, pulse duration, pulse repetition rate, focal area, and focal length. The errors in indications specified in §§ 10857.4 and 10857.5 shall be stated in the instruction manual; and
- (d) A listing of controls, adjustments, and procedures for operation and maintenance, including the warning "Caution--use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy."

10899

DEFINITIONS

10899.1 As used in this chapter, the following terms shall have the meanings ascribed:

Accidental radiation occurrence - a single event or series of events that has/have resulted in injurious or potentially injurious exposure of any person to electronic product radiation as a result of the manufacturing, testing, or use of an electronic product.

Act – the Federal Food, Drug, and Cosmetic Act, approved June 25, 1938, 21 U.S.C. § 301, *et seq.*

Ambulatory surgical facility (ASF) - a distinct entity that operates for the primary purpose of furnishing same day outpatient surgical services to patients. An ASF may be either an independent entity (for example, not a part of a provider of services or any other facility) or operated by another medical entity (such as, under the common ownership, licensure, or control of an entity). An ASF is subject to this regulation regardless of whether it is licensed by a federal, state, municipal, or local government or regardless of whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the ASF must report that event regardless of the nature or location of the medical service provided by the ASF.

Audiologist - any person qualified by training and experience to specialize in the evaluation and rehabilitation of individuals whose communication disorders center in whole or in part in the hearing function. In some states audiologists must satisfy specific requirements for licensure.

Beam blocking device - a movable or removable portion of any enclosure around a cold-cathode gas discharge tube, which may be opened or closed to permit or prevent the emergence of an exit beam.

Become aware - when an employee of the entity required to report has acquired information that reasonably suggests a reportable adverse event has occurred.

- (a) If you are a device user facility, you are considered to have "become aware" when medical personnel, as defined in this subsection, who are employed by or otherwise formally affiliated with your facility, obtain information about a reportable event.
- (b) If you are a manufacturer, you are considered to have become aware of an event when any of your employees becomes aware of a reportable event that is required to be reported within thirty (30) calendar days or that is required to be reported within five (5) work days because the Department requested reports in accordance with § 10422.1(b). You are also considered to have become aware of an event when any of your employees with management or supervisory responsibilities over persons with

regulatory, scientific, or technical responsibilities, or whose duties relate to the collection and reporting of adverse events, becomes aware, from any information, including any trend analysis, that a reportable MDR event or events necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.

- (c) If you are an importer, you are considered to have become aware of an event when any of your employees becomes aware of a reportable event that is required to be reported by you within thirty (30) days.

Business day - Monday through Friday, except federal holidays.

Caused or contributed - when a death or serious injury was or may have been attributed to a medical device, or that a medical device was or may have been a factor in a death or serious injury, including events occurring as a result of:

- (a) Failure;
- (b) Malfunction;
- (c) Improper or inadequate design;
- (d) Manufacture;
- (e) Labeling; or
- (f) User error.

Chassis family - a group of one (1) or more models with all of the following common characteristics:

- (a) The same circuitry in the high voltage, horizontal oscillator, and power supply sections;
- (b) The same worst component failures;
- (c) The same type of high voltage hold-down or safety circuits; and
- (d) The same design and installation.

Classification name - the term used by the Department and its classification panels to describe a device or class of devices for purposes of classifying devices under Section 513 of the Federal Food, Drug, and Cosmetic Act.

Class III certification - a certification that the submitter pursuant to 21 U.S.C. § 360(k) has conducted a reasonable search of all known information about the

class III device and other similar, legally marketed devices.

Class III summary - a summary of the types of safety and effectiveness problems associated with the type of device being compared and a citation to the information upon which the summary is based. The summary must be comprehensive and describe the problems to which the type of device is susceptible and the causes of such problems.

Cold-cathode gas discharge tube - an electronic device in which electron flow is produced and sustained by ionization of contained gas atoms and ion bombardment of the cathode.

Commerce -

- (a) Commerce between any place in any State and any place outside thereof, and
- (b) Commerce wholly within the District of Columbia.

Commercial distribution - any distribution of a device intended for human use which is held or offered for sale but does not include the following:

- (a) Internal or interplant transfer of a device between establishments within the same parent, subsidiary, or affiliate company;
- (b) Any distribution of a device intended for human use which has in effect an approved exemption for investigational use under 21 U.S.C. § 360j(g) and Chapter 109 of this subtitle;
- (c) Any distribution of a device, before the effective date of Chapter 109 of this subtitle, that was not introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and that is classified into class III under 21 U.S.C. § 360c(f); provided that the device is intended solely for investigational use, and under 21 U.S.C. § 360c(f)(2)(A) the device is not required to have an approved premarket approval application as provided in 21 U.S.C. § 360e; or
- (d) For foreign establishments, the distribution of any device that is neither imported nor offered for import into the U.S.

Design input - the physical and performance requirements of a device that are used as a basis for device design.

Design output - the results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, its

packaging and labeling, and the device master record.

Design review - a documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.

Design validation - establishing by objective evidence that device specifications conform to user needs and intended use(s).

Device history record (DHR) - a compilation of records containing the production history of a finished device.

Device master record (DMR) - a compilation of records containing the procedures and specifications for a finished device.

Device user facility - a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility as defined in this subsection, which is not a physician's office as defined in this subsection. School nurse offices and employee health units are not device user facilities.

Diagnostic radiology facility - any facility in which an x-ray system(s) is used in any procedure that involves irradiation of any part of the human body for the purpose of diagnosis or visualization. Offices of individual physicians, dentists, podiatrists, and chiropractors, as well as mobile laboratories, clinics, and hospitals are all examples of diagnostic radiology facilities.

Director –the Director of the Department of Health or his or her designee.

Dispenser - any person, partnership, corporation, or association engaged in the sale, lease, or rental of hearing aids to any member of the consuming public or any employee, agent, sales person, or representative of such a person, partnership, corporation, or association.

Department –the District of Columbia Department of Health.

Distributor - a person engaged in the business of offering electronic products for sale to dealers, without regard to whether such person is or has been primarily or customarily engaged in such business.

District standard - a performance standard.

Ear specialist - any licensed physician who specializes in diseases of the ear and is medically trained to identify the symptoms of deafness in the context of the total health of the patient, and is qualified by special training to diagnose and treat hearing loss. Such physicians are also known as otolaryngologists, otologists, and otorhinolaryngologists.

Electromagnetic radiation - includes the entire electromagnetic spectrum of radiation of any wavelength. The electromagnetic spectrum illustrated in Figure 1 includes, but is not limited to, gamma rays, x-rays, ultra-violet, visible, infrared, microwave, radiowave, and low frequency radiation.

Electronic product -

- (a) Any manufactured or assembled product which, when in operation:
 - (1) Contains or acts as part of an electronic circuit; and
 - (2) Emits (or in the absence of effective shielding or other controls would emit) electronic product radiation; or
- (b) Any manufactured or assembled article that is intended for use as a component, part, or accessory of a product described in paragraph (a)(1) and which, when in operation, emits (or in the absence of effective shielding or other controls would emit) such radiation.

Establish - define, document (in writing or electronically), and implement.

Establishment - a place of business under one (1) management at one (1) general physical location at which a device is manufactured, assembled, or otherwise processed.

Exit beam - that portion of the radiation which passes through the aperture resulting from the opening of the beam blocking device.

Expected life of a device - the time that a device is expected to remain functional after it is placed into use. Certain implanted devices have specified "end of life" (EOL) dates. Other devices are not labeled as to their respective EOL, but are expected to remain operational through activities such as maintenance, repairs, or upgrades, for an estimated period of time.

Exposure -the sum of the electrical charges on all of the ions of one (1) sign produced in air when all electrons liberated by photons in a volume element of air are completely stopped in air divided by the mass of the air in the volume element. The special unit of exposure is the roentgen. One (1) roentgen equals 2.5810×10^{-4} coulombs/kilogram.

External surface - the cabinet or enclosure provided by the manufacturer as part of the receiver. If a cabinet or enclosure is not provided as part of the receiver, the external surface shall be considered to be a hypothetical cabinet, the plane surfaces of which are located at those minimum distances from the chassis sufficient to enclose all components of the receiver except that portion of the neck and socket of the cathode-ray tube which normally extends beyond the plane surfaces of the enclosure.

Five (5)-day report - a medical device report that must be submitted by a manufacturer to us under § 10422 on a form or an electronic equivalent approved

under § 10406, within five (5) work days.

21 U.S.C. § 360(k) statement - a statement under 21 U.S.C. § 360c(i), asserting that all information in a premarket notification submission regarding safety and effectiveness will be made available within thirty (30) days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information to be made available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret or confidential commercial information, as defined in § 10602.11.

21 U.S.C. § 360(k) summary (summary of any information respecting safety and effectiveness) - a summary, submitted under 21 U.S.C. § 360c(i), of the safety and effectiveness information contained in a premarket notification submission upon which a determination of substantial equivalence can be based. Safety and effectiveness information refers to safety and effectiveness data and information supporting a finding of substantial equivalence, including all adverse safety and effectiveness information.

Humanitarian device exemption (HDE) - a premarket approval application submitted pursuant to this section seeking a humanitarian device exemption from the effectiveness requirements of 21 U.S.C. §§ 360d and 360e.

Health authority –a physician designated to administer state and local laws relating to public health.

Hearing aid - any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

Hospital - a distinct entity that operates for the primary purpose of providing diagnostic, therapeutic (such as medical, occupational, speech, and physical), surgical, and other patient services for specific and general medical conditions. Hospitals include general, chronic disease, rehabilitative, psychiatric, and other special-purpose facilities. A hospital may be either independent (for example, not a part of a provider of services or any other facility) or may be operated by another medical entity (such as, under the common ownership, licensure, or control of another entity). A hospital is covered by this regulation regardless of whether it is licensed by a federal, state, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the hospital must report that event regardless of the nature or location of the medical service provided by the hospital.

Humanitarian use device (HUD) - a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested

in fewer than four thousand (4,000) individuals in the United States per year.

Investigational device exemption (IDE) – an agreement through which the federal government permits the testing of a new medical device in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval or Premarket Notification (510(k) submission to the Food and Drug Administration.

Infrasonic, sonic (or audible) and ultrasonic waves - refers to energy transmitted as an alteration (pressure, particle displacement or density) in a property of an elastic medium (gas, liquid, or solid) that can be detected by an instrument or listener.

Initial importer - any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes the final delivery or sale of the device to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package. Any term defined in Section 201 of the Act shall have that meaning.

Lot or batch - one (1) or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.

Malfunction - the failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the intended use for which the device is labeled or marketed, as defined in § 9301.

Management with executive responsibility - those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer's quality policy and quality system.

Master file - a reference source that a person submits to the Department of Health. A master file may contain detailed information on a specific manufacturing facility, process, methodology, or component used in the manufacture, processing, or packaging of a medical device.

Manufacturer - any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedure. The term includes any person who either:

- (a) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original

place of manufacture;

- (b) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications;
- (c) Manufactures components or accessories that are devices that are ready to be used and are intended to be commercially distributed and intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient; or
- (d) Is the U.S. agent of a foreign manufacturer.

Manufacturer - any person engaged in the business of manufacturing, assembling, or importing electronic products. (21 C.F.R., Subchapter J, Radiological Health).

Manufacturer or importer report number - the number that uniquely identifies each individual adverse event report submitted by a manufacturer or importer. This number consists of the following three parts:

- (a) The Department of Health registration number for the manufacturing site of the reported device, or the registration number for the importer. If the manufacturing site or the importer does not have an establishment registration number, the Department will assign a temporary MDR reporting number until the site is registered in accordance with Chapter 105 of this subtitle. The Department will inform the manufacturer or importer of the temporary MDR reporting number;
- (b) The four (4)-digit calendar year in which the report is submitted; and
- (c) The five (5) -digit sequence number of the reports submitted during the year, starting with 00001. (For example, the complete number will appear as follows: 1234567-1995-00001.).

Manufacturing material - any material or substance used in or used to facilitate the manufacturing process, a concomitant constituent, or a byproduct constituent produced during the manufacturing process, which is present in or on the finished device as a residue or impurity not by design or intent of the manufacturer.

Material change - includes any change or modification in the labeling or advertisements that affects the identity or safety and effectiveness of the device. These changes may include, but are not limited to, changes in the common or usual or proprietary name, declared ingredients or components, intended use, contraindications, warnings, or instructions for use. Changes that are not material may include graphic layouts, grammar, or correction of typographical errors which do not change the content of the labeling, changes in lot number, and, for

devices where the biological activity or known composition differs with each lot produced, the labeling containing the actual values for each lot.

Maximum test voltage – one hundred thirty root mean squared volts (130 V_{RMS}) if the receiver is designed to operate from nominal one hundred ten to one hundred twenty root mean squared volt (120-130 V_{RMS}) power sources. If the receiver is designed to operate from a power source having some voltage other than from nominal one hundred ten to one hundred twenty root mean squared volts (110-120 V_{RMS}) maximum test voltage means one hundred ten percent (110%) of the nominal root mean squared voltage specified by the manufacturer for the power source.

MDR - means medical device report.

MDR reportable event (or reportable event) -

- (a) An event that user facilities become aware of that reasonably suggests that a device has or may have caused or contributed to a death or serious injury; or
- (b) An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices:
 - (1) May have caused or contributed to a death or serious injury, or
 - (2) Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Medical device –an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

- (a) Recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them;
- (b) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals;
- (c) Intended to affect the structure or any function of the body of man or other animals; and
- (d) Does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent

upon being metabolized for the achievement of its primary intended purposes.

Medical personnel - an individual who:

- (a) Is licensed, registered, or certified by a State, territory, or other governing body, to administer health care;
- (b) Has received a diploma or a degree in a professional or scientific discipline;
- (c) Is an employee responsible for receiving medical complaints or adverse event reports; or
- (d) Is a supervisor of these persons.

Model - any identifiable, unique electronic product design, and refers to products having the same structural and electrical design characteristics and to which the manufacturer has assigned a specific designation to differentiate between it and other products produced by that manufacturer.

Model family - products having similar design and radiation characteristics but different manufacturer model numbers.

Modified model - a product that is redesigned so that actual or potential radiation emission, the manner of compliance with a standard, or the manner of radiation safety testing is affected.

Newly acquired information - data, analyses, or other information not previously submitted to the agency, which may include (but are not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (for example, meta-analyses) if the studies, events or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to the Department of Health.

Nonconformity - the non-fulfillment of a specified requirement.

Nursing home - means:

- (a) An independent entity (such as, not a part of a provider of services or any other facility) or one operated by another medical entity (for example, under the common ownership, licensure, or control of an entity) that operates for the primary purpose of providing:
 - (1) Skilled nursing care and related services for persons who require medical or nursing care;

- (2) Hospice care to the terminally ill; or
 - (3) Services for the rehabilitation of the injured, disabled, or sick.
- (b) A nursing home is subject to this regulation regardless of whether it is licensed by a federal, state, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the nursing home must report that event regardless of the nature or location of the medical service provided by the nursing home.

Official correspondent - the person designated by the owner or operator of an establishment as responsible for the following:

- (a) The annual registration of the establishment;
- (b) Contact with the Department for device listing;
- (c) Maintenance and submission of a current list of officers and directors to the Department of Health upon the request of the Department of Health;
- (d) The receipt of pertinent correspondence from the Department directed to and involving the owner or operator or any of the firm's establishments; and
- (e) The annual certification of medical device reports required by 21 C.F.R. § 804.30 or forwarding the certification form to the person designated by the firm as responsible for the certification.

Outpatient diagnostic facility - a distinct entity that:

- (a) Operates for the primary purpose of conducting medical diagnostic tests on patients;
- (b) Does not assume ongoing responsibility for patient care; and
- (c) Provides its services for use by other medical personnel.

Outpatient diagnostic facilities include outpatient facilities providing radiography, mammography, ultrasonography, electrocardiography, magnetic resonance imaging, computerized axial tomography, and in vitro testing. An outpatient diagnostic facility may be either independent (for example, not a part of a provider of services or any other facility) or operated by another medical entity (such as, under the common ownership, licensure, or control of an entity). An outpatient diagnostic facility is covered by this regulation regardless of whether it

is licensed by a federal, state, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient diagnostic facility must report that event regardless of the nature or location of the medical service provided by the outpatient diagnostic facility.

Outpatient treatment facility - a distinct entity that operates for the primary purpose of providing nonsurgical therapeutic (medical, occupational, or physical) care on an outpatient basis or in a home health care setting. Outpatient treatment facilities include ambulance providers, rescue services, and home health care groups. Examples of services provided by outpatient treatment facilities include the following: Cardiac defibrillation, chemotherapy, radiotherapy, pain control, dialysis, speech or physical therapy, and treatment for substance abuse. An outpatient treatment facility may be either independent (for example, not a part of a provider of services or any other facility) or operated by another medical entity (such as, under the common ownership, licensure, or control of an entity). An outpatient treatment facility is covered by this regulation regardless of whether it is licensed by a federal, state, municipal, or local government or whether it is accredited by a recognized accreditation organization. If an adverse event meets the criteria for reporting, the outpatient treatment facility must report that event regardless of the nature or location of the medical service provided by the outpatient treatment facility.

Owner or operator - the corporation, subsidiary, affiliated company, partnership, or proprietor directly responsible for the activities of the registering establishment.

Owner or consignee - the person who has the rights of a consignee under the provisions of Sections 483, 484, and 485 of the Tariff Act of 1930, as amended (19 U.S.C. §§ 1483, 1484, 1485).

Particulate radiation -

- (a) Charged particles, such as protons, electrons, alpha particles, or heavy particles, which have sufficient kinetic energy to produce ionization or atomic or electron excitation by collision, electrical attractions, or electrical repulsion; or
- (b) Uncharged particles, such as neutrons, which can initiate a nuclear transformation or liberate charged particles having sufficient kinetic energy to produce ionization or atomic or electron excitation.

Patient of the facility - any individual who is being diagnosed or treated or receiving medical care at or under the control or authority of the facility. This includes employees of the facility or individuals affiliated with the facility who, in the course of their duties, suffer a device-related death or serious injury that has or

may have been caused or contributed to by a device used at the facility.

Permanent - irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

Phototherapy product - means any ultraviolet lamp, or product containing such lamp, that is intended for irradiation of any part of the living human body by light in the wavelength range of two hundred to four hundred nanometers (200-400 nm.), in order to perform a therapeutic function.

Physician's office - a facility that operates as the office of a physician or other health care professional for the primary purpose of examination, evaluation, and treatment or referral of patients. Examples of physician offices include dentist offices, chiropractor offices, optometrist offices, nurse practitioner offices, school nurse offices, school clinics, employee health clinics, or freestanding care units. A physician's office may be independent, a group practice, or part of a Health Maintenance Organization.

Premarket Approval Application (PMA) - any premarket approval application for a class III medical device, including all information submitted with or incorporated by reference therein. "PMA" includes a new drug application for a device under 21 U.S.C. § 360j(1).

PMA amendment - information an applicant submits to the Department of Health to modify a pending PMA or a pending PMA supplement.

PMA supplement - a supplemental application to an approved PMA for approval of a change or modification in a class III medical device, including all information submitted with or incorporated by reference therein.

Process validation - establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

Product - components, manufacturing materials, in- process devices, finished devices, and returned devices.

Purchaser - the first person who, for value, or as an award or prize, acquires an electronic product for purposes other than resale, and includes a person who leases an electronic product for purposes other than subleasing.

Quality - the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.

Quality administration procedures - are those management actions intended to guarantee that monitoring techniques are properly performed and evaluated and that necessary corrective measures are taken in response to monitoring results.

These procedures provide the organizational framework for the quality assurance program.

Quality assurance - the planned and systematic actions that provide adequate confidence that a diagnostic x-ray facility will produce consistently high quality images with minimum exposure of the patients and healing arts personnel. The determination of what constitutes high quality will be made by the facility producing the images. Quality assurance actions include both "quality control" techniques and "quality administration" procedures.

Quality assurance program - an organized entity designed to provide "quality assurance" for a diagnostic radiology facility. The nature and extent of this program will vary with the size and type of the facility, the type of examinations conducted, and other factors.

Quality audit - a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives.

Quality control techniques - are those techniques used in the monitoring (or testing) and maintenance of the components of an x-ray system. The quality control techniques thus are concerned directly with the equipment.

Rework - action taken on a nonconforming product so that it will fulfill the specified DMR requirements before it is released for distribution.

Sale or purchase - includes any lease or rental of a hearing aid to a member of the consuming public who is a user or prospective user of a hearing aid.

Serious, adverse health consequences - any significant adverse experience, including those which may be either life-threatening or involve permanent or long term injuries, but excluding injuries that are nonlife-threatening and that are temporary and reasonably reversible.

Serious injury - an injury or illness that:

- (a) Is life-threatening;
- (b) Results in permanent impairment of a body function or permanent damage to a body structure; or
- (c) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

Service controls - all of those controls on a television receiver provided by the manufacturer for purposes of adjustment which, under normal usage, are not accessible to the user.

Specification - any requirement with which a product, process, service, or other activity must conform.

State - a state, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

Statement of material fact - a representation that tends to show that the safety or effectiveness of a device is more probable than it would be in the absence of such a representation. A false affirmation or silence or an omission that would lead a reasonable person to draw a particular conclusion as to the safety or effectiveness of a device also may be a false statement of material fact, even if the statement was not intended by the person making it to be misleading or to have any probative effect.

Television receiver - an electronic product designed to receive and display a television picture through broadcast, cable, or closed circuit television.

Thirty (30)-day PMA supplement - a supplemental application to an approved PMA in accordance with § 10608.6.

United States (designated) agent - a person residing or maintaining a place of business in the United States whom a foreign establishment designates as its agent. This definition excludes mailboxes, answering machines or services, or other places where an individual acting as the foreign establishment's agent is not physically present.

Usable picture - a picture in synchronization and transmitting viewable intelligence.

Used hearing aid - any hearing aid that has been worn for any period of time by a user. However, a hearing aid shall not be considered "used" merely because it has been worn by a prospective user as a part of a bona fide hearing aid evaluation conducted to determine whether to select that particular hearing aid for that prospective user, if such evaluation has been conducted in the presence of the dispenser or a hearing aid health professional selected by the dispenser to assist the buyer in making such a determination.

User controls - all of those controls on a television receiver, provided by the manufacturer for purposes of adjustment, which on a fully assembled receiver under normal usage, are accessible to the user.

User facility report number - the number that uniquely identifies each report submitted by a user facility to manufacturers and to us. This number consists of the following three parts:

- (a) The user facility's ten (10) digit Centers for Medicare and Medicaid Services (CMS) number (if the CMS number has fewer than 10 digits, fill the remaining spaces with zeros);
- (b) The four (4) digit calendar year in which the report is submitted; and
- (c) The four-digit sequence number of the reports submitted for the year, starting with 0001. (For example, a complete user facility report number will appear as follows: 1234560000-2004-0001. If a user facility has more than one CMS number, it must select one (1) that will be used for all of its MDR reports. If a user facility has no CMS number, it should use all zeros in the appropriate space in its initial report (such as, 0000000000-2004-0001). We will assign a number for future use and send that number to the user facility. This number is used in the Department's record of the initial report, in subsequent reports, and in any correspondence with the user facility. If a facility has multiple sites, the primary site may submit reports for all sites and use one (1) reporting number for all sites if the primary site provides the name, address, and CMS number for each respective site.).

Validation - confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

Verification - confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

Wholesale distributor - any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.

X-ray system - an assemblage of components for the controlled production of diagnostic images with x-rays. It includes minimally an x-ray high voltage generator, an x-ray control, a tube-housing assembly, a beam-limiting device, and the necessary supporting structures. Other components that function with the system, such as image receptors, image processors, view boxes, and darkrooms, are also parts of the system.

Chapter 109 (Investigational Device Exemptions) is added to read as follows:

CHAPTER 109 INVESTIGATIONAL DEVICE EXEMPTIONS

10900 SCOPE

10900.1 The purpose of this chapter is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use, and to that end to maintain optimum freedom for scientific investigators in their pursuit of this purpose. This chapter provides procedures for the conducting clinical investigations of devices. An approved IDE permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device. An IDE approved under § 10910 or considered approved under § 10901 exempts a device from the requirements of the following sections of the Act and regulations issued thereunder:

- (a) Misbranding under 21 U.S.C. § 352;
- (b) Registration, listing, and premarket notification under 21 U.S.C. § 360;
- (c) Performance standards under 21 U.S.C. § 360d;
- (d) Premarket approval under 21 U.S.C. § 360e;
- (e) A banned device regulation under 21 U.S.C. § 360f;
- (f) Records and reports under 21 U.S.C. § 360i;
- (g) Restricted device requirements under 21 U.S.C. § 360j(e);
- (h) Good manufacturing practice requirements under 21 U.S.C. § 360j(f) except for the requirements found in § 10705 of this subtitle, if applicable (unless the sponsor states an intention to comply with these requirements under §§ 10907.2 (c) or 10927.2(d)(5) of this subtitle); and
- (i) Color additive requirements.

10901 APPLICABILITY

10901.1 This chapter applies to all clinical investigations of devices to determine safety and effectiveness, except as provided in § 10901.3.

10901.2 The following categories of investigations are considered to have approved applications for IDE unless the Department has notified a sponsor under § 10907.1(a) that approval of an application is required:

- (a) An investigation of a device other than a significant risk device, if the device is not a banned device and the sponsor:
 - (1) Labels the device in accordance with § 10902;
 - (2) Obtains investigational review board (IRB) approval of the investigation after presenting the reviewing IRB with a brief explanation of why the device is not a significant risk device, and maintains such approval;
 - (3) Ensures that each investigator participating in a § 10907.1(a) investigation of the device obtains from each subject under the investigator's care, informed consent and documents it, unless documentation is waived by an IRB under 21 CFR § 56.109(c).
 - (4) Complies with the requirements of § 10918 with respect to monitoring investigations;
 - (5) Maintains the records required under § 10927.2(d) and (e) makes the reports required under § 10929.2 (a)-(c) and (e)-(j);
 - (6) Ensures that participating investigators maintain the records required by § 10927.1(c)(1) and make the reports required under § 10929.1(a), (b), (e), and (g); and
 - (7) Complies with the prohibitions in § 10903 against promotion and other practices; and
- (b) An investigation of a device other than one subject to § 10901.5, if the investigation was begun on or before July 16, 1980, and to be completed, and is completed, on or before January 19, 1981.

10901.3 This chapter, with the exception of § 10926, does not apply to investigations of the following categories of devices:

- (a) A device, other than a transitional device, in commercial distribution immediately before May 28, 1976, when used or investigated in accordance with the indications in labeling in effect at that time;
- (b) A device, other than a transitional device, introduced into commercial distribution on or after May 28, 1976, that the Department has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling the Department reviewed under §§ 10512 through 10521 in determining substantial equivalence;

- (c) A diagnostic device, if the sponsor complies with applicable requirements in § 10901.3(h) and if the testing:
 - (1) Is noninvasive,
 - (2) Does not require an invasive sampling procedure that presents significant risk,
 - (3) Does not, by design or intention, introduce energy into a subject, and
 - (4) Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure;
- (d) A device undergoing consumer preference testing, testing of a modification, or testing of a combination of two (2) or more devices in commercial distribution, if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk;
- (e) A device intended solely for veterinary use;
- (f) A device shipped solely for research on or with laboratory animals and labeled in accordance with § 10902.3;
- (g) A custom device as defined in § 10999, unless the device is being used to determine safety or effectiveness for commercial distribution; and
- (h) A shipment or other delivery of an in vitro diagnostic product shall:
 - (1) For a product in the laboratory research phase of development, and not represented as an effective in vitro diagnostic product, all labeling bears the statement, prominently placed: “For Research Use Only. Not for use in diagnostic procedures.”; and
 - (2) For a product being shipped or delivered for product testing prior to full commercial marketing (for example, for use on specimens derived from humans to compare the usefulness of the product with other products or procedures which are in current use or recognized as useful), all labeling bears the statement, prominently placed: “For Investigational Use Only. The performance characteristics of this product have not been established.”.

10901.4 In the case of a class II or class III device described in § 10901.3(a) or (b), this section applies beginning on the date stipulated in a Department regulation or order that calls for the submission of premarket approval applications for an

unapproved class III device, or establishes a performance standard for a class II device.

- 10901.5 A sponsor that, on July 16, 1980, has an effective investigational new drug application (IND) for an investigation of a device shall continue to comply with the requirements of 21 C.F.R., part 312 until ninety (90) days after that date. To continue the investigation after that date, a sponsor shall comply with § 10901.2(a), if the device is not a significant risk device, or shall have obtained Department approval under § 10910 of an IDE application for the investigation of the device.

10902 LABELING OF INVESTIGATIONAL DEVICES

- 10902.1 An investigational device or its immediate package shall bear a label with the following information: the name and place of business of the manufacturer, packer, or distributor (in accordance with § 10300), the quantity of contents, if appropriate, and the following statement:

“CAUTION--Investigational device. Limited by District of Columbia law to investigational use.”

The label or other labeling shall describe all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions.

- 10902.2 The labeling of an investigational device shall not bear any statement that is false or misleading and shall not represent that the device is safe or effective for the purposes for which it is being investigated.

- 10902.3 An investigational device shipped solely for research on or with laboratory animals shall bear on its label the following statement:

“CAUTION--Device for investigational use in laboratory animals or other tests that do not involve human subjects.”.

10903 PROHIBITION OF PROMOTION AND OTHER PRACTICES

- 10903.1 A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not:
- (a) Promote or test market an investigational device, until after the Department has approved the device for commercial distribution;
 - (b) Commercialize an investigational device by charging the subjects or investigators for a device a price larger than that necessary to recover costs of manufacture, research, development, and handling; or

- (c) Represent that an investigational device is safe or effective for the purposes for which it is being investigated.

10903.2 If data developed by the investigation indicate in the case of a class III device that premarket approval cannot be justified or in the case of a class II device that it will not comply with an applicable performance standard or an amendment to that standard, the sponsor shall promptly terminate the investigation.

10904 WAIVERS

10904.1 A sponsor may request the Department to waive any requirement of this section. A waiver request, with supporting documentation, may be submitted separately or as part of an application to the address in § 10906.

10904.2 The Department may, by letter, grant a waiver of any requirement that the Department finds is not required by the Act and is unnecessary to protect the rights, safety, or welfare of human subjects.

10904.3 Any requirement shall continue to apply unless and until the Department waives it.

10905 IMPORT AND EXPORT REQUIREMENTS

10905.1 In addition to complying with other requirements of this part, a person who imports or offers for importation an investigational device subject to this part shall be the agent of the foreign exporter with respect to investigations of the device and shall act as the sponsor of the clinical investigation, or ensure that another person act as the agent of the foreign exporter and the sponsor of the investigation.

10905.2 A person exporting an investigational device subject to this section shall obtain Department prior approval, as required by Chapter 103 of this title or comply with the Act.

10906 ADDRESS FOR INVESTIGATIONAL DEVICE EXEMPTION CORRESPONDENCE

10906.1 If you are sending an application, supplemental application, report, request for waiver, request for import or export approval, or other correspondence relating to matters covered by this part, you must address it to the Department of Health, 899 North Capitol St., N.E., 2nd Floor, Washington, DC 20002. You must state on the outside wrapper of each submission what the submission is, for example, an “IDE application,” a “supplemental IDE application,” or a “correspondence concerning an IDE (or an IDE application).”

10907 APPLICATION

- 10907.1 A sponsor:
- (a) Shall submit an application to the Department if the sponsor intends to use a significant risk device in an investigation, intends to conduct an investigation that involves an exception from informed consent under § 10602.6, or if DOH notifies the sponsor that an application is required for an investigation;
 - (b) Shall not begin an investigation for which the Department's approval of an application is required until the Department has approved the application;
 - (c) Shall submit three (3) copies of a signed "Application for an Investigational Device Exemption" (IDE application), together with accompanying materials, by registered mail or by hand to the address in § 10906. Subsequent correspondence concerning an application or a supplemental application shall be submitted by registered mail or by hand; or
 - (d) Shall submit a separate IDE for any clinical investigation involving an exception from informed consent under § 10602.6. Such a clinical investigation is not permitted to proceed without the prior written authorization of the Department. The Department shall provide a written determination thirty (30) days after the Department receives the IDE or earlier.
- 10907.2 If the investigation involves an exception to informed consent, the sponsor shall prominently identify on the cover sheet that the investigation is subject to the requirements of informed consent under § 10602.6.
- 10907.3 An IDE application shall include, in the following order:
- (a) The name and address of the sponsor;
 - (b) A complete report of prior investigations of the device and an accurate summary of those sections of the investigational plan described in § 10908.1(a) through (e) or, in lieu of the summary, the complete plan. The sponsor shall submit to the Department a complete investigational plan and a complete report of prior investigations of the device if no IRB has reviewed them, if the Department has found an IRB's review inadequate, or if the Department requests them;
 - (c) A description of the methods, facilities, and controls used for the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally

familiar with good manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of the device;

- (d) An example of the agreements to be entered into by all investigators to comply with investigator obligations under this part, and a list of the names and addresses of all investigators who have signed the agreement;
- (e) A certification that all investigators who will participate in the investigation have signed the agreement, that the list of investigators includes all the investigators participating in the investigation, and that no investigators will be added to the investigation until they have signed the agreement;
- (f) A list of the name, address, and chairperson of each IRB that has been or will be asked to review the investigation and a certification of the action concerning the investigation taken by each such IRB;
- (g) The name and address of any institution at which a part of the investigation may be conducted that has not been identified in accordance with § 10907.3(f);
- (h) If the device is to be sold, the amount to be charged and an explanation of why sale does not constitute commercialization of the device;
- (i) A claim for categorical exclusion or an environmental assessment under 21 C.F.R. § 25.30 or 21 C.F.R. § 25.34, or an environmental assessment under 21 C.F.R. § 25.40;
- (j) Copies of all labeling for the device;
- (k) Copies of all forms and informational materials to be provided to subjects to obtain informed consent; and
- (l) Any other relevant information the Department requests for review of the application.

10907.4 The Department may request additional information concerning an investigation or revision in the investigational plan. The sponsor may treat such a request as a disapproval of the application for purposes of requesting a hearing.

10907.5 Information previously submitted to the Department in accordance with this chapter ordinarily need not be resubmitted, but may be incorporated by reference.

10908 INVESTIGATIONAL PLAN

10908.1 The investigational plan shall include, in the following order:

- (a) The name and intended use of the device and the objectives and duration of the investigation;
- (b) A written protocol describing the methodology to be used and an analysis of the protocol demonstrating that the investigation is scientifically sound;
- (c) A description and analysis of all increased risks to which subjects will be exposed by the investigation; the manner in which these risks will be minimized; a justification for the investigation; and a description of the patient population, including the number, age, sex, and condition;
- (d) A description of each important component, ingredient, property, and principle of operation of the device and of each anticipated change in the device during the course of the investigation;
- (e) The sponsor's written procedures for monitoring the investigation and the name and address of any monitor;
- (f) Copies of all labeling for the device;
- (g) Copies of all forms and informational materials to be provided to subjects to obtain informed consent;
- (h) A list of the names, locations, and chairpersons of all IRBs that have been or will be asked to review the investigation, and a certification of any action taken by any of those IRBs with respect to the investigation;
- (i) The name and address of each institution at which a part of the investigation may be conducted that has not been identified in § 10908.1(h); and
- (j) A description of records and reports that will be maintained on the investigation in addition to those prescribed in §§ 10927, 10928, and 10929.

10909 REPORT OF PRIOR INVESTIGATIONS

10909.1 The report of prior investigations shall include reports of all prior clinical, animal, and laboratory testing of the device and shall be comprehensive and adequate to justify the proposed investigation.

10909.2 The report also shall include:

- (a) A bibliography of all publications, whether adverse or supportive, that are relevant to an evaluation of the safety or effectiveness of the device,

copies of all published and unpublished adverse information, and, if requested by an IRB or the Department, copies of other significant publications;

- (b) A summary of all other unpublished information (whether adverse or supportive) in the possession of, or reasonably obtainable by, the sponsor that is relevant to an evaluation of the safety or effectiveness of the device; and
- (c) If information on nonclinical laboratory studies is provided, a statement that all such studies have been conducted in compliance with applicable requirements in the good laboratory practice regulations in 21 C.F.R., part 58, or if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance. Failure or inability to comply with this requirement does not justify failure to provide information on a relevant nonclinical test study.

10910 DEPARTMENT OF HEALTH ACTION ON APPLICATIONS

10910.1 The Department will notify the sponsor in writing of the date it receives an application. DOH may approve an investigation as proposed, approve it with modifications, or disapprove it. An investigation may not begin until:

- (a) Thirty (30) days after the Department receives the application at the address in § 10906 for the investigation of a device other than a banned device, unless DOH notifies the sponsor that the investigation may not begin; or
- (b) The Department approves, by order, an IDE for the investigation.

10910.2 The Department may disapprove or withdraw approval of an application if it finds that:

- (a) There has been a failure to comply with any requirement of this part or the act, any other applicable regulation or statute, or any condition of approval imposed by an IRB or the Department;
- (b) The application or a report contains an untrue statement of a material fact, or omits material information required by this section;
- (c) The sponsor fails to respond to a request for additional information within the time prescribed by the Department; and
- (d) There is reason to believe that the risks to the subjects are not outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained, or informed consent is inadequate, or the

investigation is scientifically unsound, or there is reason to believe that the device as used is ineffective;

- (e) It is otherwise unreasonable to begin or to continue the investigation owing to the way in which the device is used or the inadequacy of:
 - (1) The report or prior investigations or the investigational plan;
 - (2) The methods, facilities, and controls used for the manufacturing, processing, packaging, storage, and, where appropriate, installation of the device; or
 - (3) Monitoring and reviewing the investigation.

10910.3 If the Department disapproves an application or proposes to withdraw approval of an application, the Department will notify the sponsor in writing.

- (a) A disapproval order will contain a complete statement of the reasons for disapproval and a statement that the sponsor has an opportunity to request a hearing under 21 C.F.R., part 16.
- (b) A notice of a proposed withdrawal of approval will contain a complete statement of the reasons for withdrawal and a statement that the sponsor has an opportunity to request a hearing. The Department will provide the opportunity for hearing before withdrawal of approval, unless the Department determines in the notice that continuation of testing under the exemption will result in an unreasonable risk to the public health and orders withdrawal of approval before any hearing.

10911 SUPPLEMENTAL APPLICATIONS

10911.1 The following are required for changes the in investigational plan:

- (a) Except as described in paragraphs (b) through (d), a sponsor must obtain approval of a supplemental application under § 10910.1, and IRB approval when appropriate (*see* 21 C.F.R. §§ 56.110 and 56.111), prior to implementing a change to an investigational plan. If a sponsor intends to conduct an investigation that involves an exception to informed consent of this chapter, the sponsor shall submit a separate IDE application in accordance with § 10907.1.
- (b) The requirements of subsection (a) regarding the Department approval of a supplement do not apply in the case of a deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. Such deviation shall be reported to the Department within five (5) working days after the sponsor learns of it (*see* § 10929.1(d)).

- (c) A sponsor may make certain changes without prior approval of a supplemental application under paragraph (a) if the sponsor determines that these changes meet the criteria described in § 10911.2 and 10911.3, on the basis of credible information defined in § 10911.4, and the sponsor provides notice to the Department within five (5) working days of making these changes; and

10911.2 The requirements in § 10911.1(a) regarding the Department approval of a supplement do not apply to developmental changes in the device (including manufacturing changes) that do not constitute a significant change in design or basic principles of operation and that are made in response to information gathered during the course of an investigation.

10911.3 The requirements in § 10911.1(a) regarding the Department approval of a supplement do not apply to changes to clinical protocols that do not affect:

- (a) The validity of the data or information resulting from the completion of the approved protocol, or the relationship of likely patient risk to benefit relied upon to approve the protocol;
- (b) The scientific soundness of the investigational plan; or
- (c) The rights, safety, or welfare of the human subjects involved in the investigation.

10911.4 The definition of credible information shall be as follows:

- (a) Credible information to support developmental changes in the device (including manufacturing changes) includes data generated under the design control procedures of § 10705, preclinical or animal testing, peer reviewed published literature, or other reliable information such as clinical information gathered during a trial or marketing; or
- (b) Credible information to support changes to clinical protocols is defined as the sponsor's documentation supporting the conclusion that a change does not have a significant impact on the study design or planned statistical analysis, and that the change does not affect the rights, safety, or welfare of the subjects. Documentation shall include information such as peer reviewed published literature, the recommendation of the clinical investigator(s), or the data gathered during the clinical trial or marketing.

10911.5 Changes meeting the criteria in § 10911.2 and 10911.3 that are supported by credible information as defined in paragraph § 10911.4 may be made without prior Department approval if the sponsor submits a notice of the change to the IDE not later than five (5) working days after making the change. Changes to

devices are deemed to occur on the date the device, manufactured incorporating the design or manufacturing change, is distributed to the investigator(s). Changes to a clinical protocol are deemed to occur when a clinical investigator is notified by the sponsor that the change should be implemented in the protocol or, for sponsor-investigator studies, when a sponsor-investigator incorporates the change in the protocol. Such notices shall be identified as a “notice of IDE change.”

- 10911.6 For a developmental or manufacturing change to the device, the notice shall include a summary of the relevant information gathered during the course of the investigation upon which the change was based; a description of the change to the device or manufacturing process (cross-referenced to the appropriate sections of the original device description or manufacturing process); and, if design controls were used to assess the change, a statement that no new risks were identified by appropriate risk analysis and that the verification and validation testing, as appropriate, demonstrated that the design outputs met the design input requirements. If another method of assessment was used, the notice shall include a summary of the information which served as the credible information supporting the change.
- 10911.7 For a protocol change, the notice shall include a description of the change (cross-referenced to the appropriate sections of the original protocol); an assessment supporting the conclusion that the change does not have a significant impact on the study design or planned statistical analysis; and a summary of the information that served as the credible information supporting the sponsor's determination that the change does not affect the rights, safety, or welfare of the subjects.
- 10911.8 The requirements of § 10911.1(a) do not apply to minor changes to the purpose of the study, risk analysis, monitoring procedures, labeling, informed consent materials, and IRB information that do not affect:
- (1) The validity of the data or information resulting from the completion of the approved protocol, or the relationship of likely patient risk to benefit relied upon to approve the protocol;
 - (2) The scientific soundness of the investigational plan; or
 - (3) The rights, safety, or welfare of the human subjects involved in the investigation. Such changes shall be reported in the annual progress report for the IDE, under § 10929.2(e).
- 10911.9 A sponsor shall submit to the Department a certification of any IRB approval of an investigation or a part of an investigation not included in the IDE application. If the investigation is otherwise unchanged, the supplemental application shall consist of an updating of the information required by § 10907.2 and § 10907.3 and a description of any modifications in the investigational plan required by the IRB as a condition of approval. A certification of IRB approval need not be included

in the initial submission of the supplemental application, and such certification is not a re-condition for agency consideration of the application. Nevertheless, a sponsor may not begin a part of an investigation at a facility until the IRB has approved the investigation, the Department has received the certification of IRB approval, and the Department, under § 10910.1, has approved the supplemental application relating to that part of the investigation (*see* 21 C.F.R. § 56.103(a)).

10912 TREATMENT USE OF AN INVESTIGATIONAL DEVICE

- 10912.1 A device that is not approved for marketing may be under clinical investigation for a serious or immediately life-threatening disease or condition in patients for whom no comparable or satisfactory alternative device or other therapy is available. During the clinical trial or prior to final action on the marketing application, it may be appropriate to use the device in the treatment of patients not in the trial under the provisions of a treatment IDE.
- 10912.2 The purpose of this section is to facilitate the availability of promising new devices to desperately ill patients as early in the device development process as possible, before general marketing begins, and to obtain additional data on the device's safety and effectiveness. In the case of a serious disease, a device ordinarily may be made available for treatment use under this section after all clinical trials have been completed. In the case of an immediately life-threatening disease, a device may be made available for treatment use under this section prior to the completion of all clinical trials.
- 10912.3 For the purpose of this section, an “immediately life-threatening” disease means a stage of a disease in which there is a reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.
- 10912.4 For purposes of this section, “treatment use” of a device includes the use of a device for diagnostic purposes.
- 10912.5 The Department shall consider the use of an investigational device under a treatment IDE if:
- (a) The device is intended to treat or diagnose a serious or immediately life-threatening disease or condition;
 - (b) There is no comparable or satisfactory alternative device or other therapy available to treat or diagnose that stage of the disease or condition in the intended patient population;
 - (c) The device is under investigation in a controlled clinical trial for the same use under an approved IDE, or such clinical trials have been completed; and

- (d) The sponsor of the investigation is actively pursuing marketing approval or clearance of the investigational device with due diligence.

10912.6 Applicants for the treatment use of an IDE shall abide by the following:

- (a) A treatment IDE application shall include, in the following order:
 - (1) The name, address, and telephone number of the sponsor of the treatment IDE;
 - (2) The intended use of the device, the criteria for patient selection, and a written protocol describing the treatment use;
 - (3) An explanation of the rationale for use of the device, including, as appropriate, either a list of the available regimens that ordinarily should be tried before using the investigational device, or an explanation of why the use of the investigational device is preferable to the use of available marketed treatments;
 - (4) A description of clinical procedures, laboratory tests, or other measures that will be used to evaluate the effects of the device and to minimize risk;
 - (5) Written procedures for monitoring the treatment use and the name and address of the monitor;
 - (6) Instructions for use for the device and all other labeling as required under § 10902;
 - (7) Information that is relevant to the safety and effectiveness of the device for the intended treatment use. Information from other IDE's may be incorporated by reference to support the treatment use;
 - (8) A statement of the sponsor's commitment to meet all applicable responsibilities under this section and 21 C.F.R., part 56 and to ensure compliance of all participating investigators with the informed consent requirements of 21 C.F.R., part 50;
 - (9) An example of the agreement to be signed by all investigators participating in the treatment IDE and certification that no investigator will be added to the treatment IDE before the agreement is signed; and

- (10) If the device is to be sold, the price to be charged and a statement indicating that the price is based on manufacturing and handling costs only; and
- (b) A licensed practitioner who receives an investigational device for treatment use under a treatment IDE is an “investigator” under the IDE and is responsible for meeting all applicable investigator responsibilities under this part and 21 C.F.R., parts 50 and 56.

10912.7 The Department may act on treatment IDE applications in the following manner:

- (a) Treatment use may begin thirty (30) days after the Department receives the treatment IDE submission at the address specified in § 10906, unless the Department notifies the sponsor in writing earlier than the thirty (30) days that the treatment use may or may not begin. The Department may approve the treatment use as proposed or approve it with modifications;
- (b) DOH may disapprove or withdraw approval of a treatment IDE if:
 - (1) The criteria specified in § 10912.5 are not met or the treatment IDE does not contain the information required in § 10912.6;
 - (2) The Department determines that any of the grounds for disapproval or withdrawal of approval listed in § 10910.2(a) through (e) apply;
 - (3) The device is intended for a serious disease or condition and there is insufficient evidence of safety and effectiveness to support such use;
 - (4) The device is intended for an immediately life-threatening disease or condition and the available scientific evidence, taken as a whole, fails to provide a reasonable basis for concluding that the device:
 - (A) May be effective for its intended use in its intended population; or
 - (B) Would not expose the patients to whom the device is to be administered to an unreasonable and significant additional risk of illness or injury;
 - (5) There is reasonable evidence that the treatment use is impeding enrollment in, or otherwise interfering with the conduct or completion of, a controlled investigation of the same or another investigational device;

- (6) The device has received marketing approval or clearance or a comparable device or therapy becomes available to treat or diagnose the same indication in the same patient population for which the investigational device is being used;
 - (7) The sponsor of the controlled clinical trial is not pursuing marketing approval or clearance with due diligence;
 - (8) Approval of the IDE for the controlled clinical investigation of the device has been withdrawn; or
 - (9) The clinical investigator(s) named in the treatment IDE are not qualified by reason of their scientific training or experience to use the investigational device for the intended treatment use; and
- (c) If DOH disapproves or proposes to withdraw approval of a treatment IDE, DOH will follow the procedures set forth in § 10910.3.

10912.8 Treatment use of an investigational device is conditioned upon the sponsor and investigators complying with the safeguards of the IDE process and the regulations governing informed consent and institutional review boards.

10912.9 The sponsor of a treatment IDE shall submit progress reports on a semi-annual basis to all reviewing IRB's and the Department until the filing of a marketing application. These reports shall be based on the period of time since initial approval of the treatment IDE and shall include the number of patients treated with the device under the treatment IDE, the names of the investigators participating in the treatment IDE, and a brief description of the sponsor's efforts to pursue marketing approval or clearance of the device. Upon the filing of a marketing application, progress reports shall be submitted annually in accordance with § 10929.2(e). The sponsor of a treatment IDE is responsible for submitting all other reports required under § 10929.

10913 CONFIDENTIALITY OF DATA AND INFORMATION

10913.1 The Department will not disclose the existence of an IDE unless its existence has previously been publicly disclosed or acknowledged, until DOH approves an application for premarket approval of the device subject to the IDE; or a notice of completion of a product development protocol for the device has become effective.

10913.2 The Department shall make available summaries or data under the following conditions:

- (a) DOH will make publicly available, upon request, a detailed summary of information concerning the safety and effectiveness of the device that was

the basis for an order approving, disapproving, or withdrawing approval of an application for an IDE for a banned device. The summary shall include information on any adverse effect on health caused by the device.

- (b) If a device is a banned device or if the existence of an IDE has been publicly disclosed or acknowledged, data or information contained in the file is not available for public disclosure before approval of an application for premarket approval or the effective date of a notice of completion of a product development protocol except as provided in this section. The Department may, in its discretion, disclose a summary of selected portions of the safety and effectiveness data, that is, clinical, animal, or laboratory studies and tests of the device, for public consideration of a specific pending issue.
- (c) If the existence of an IDE file has not been publicly disclosed or acknowledged, no data or information in the file are available for public disclosure except as provided in this subsection.
- (d) Notwithstanding subsection (b), the Department will make available to the public, upon request, the information in the IDE that was required to be filed in Docket Number 95S-0158 in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., Rm. 1-23, Rockville, MD 20857, for investigations involving an exception from informed consent. Persons wishing to request this information shall submit a request under the Freedom of Information Act.

10913.3 Upon request or on its own initiative, the Department shall disclose to an individual on whom an investigational device has been used a copy of a report of adverse device effects relating to that use.

10913.4 Except as otherwise provided in this section, the availability for public disclosure of data and information in an IDE file shall be handled in accordance with § 10602.

10914 GENERAL RESPONSIBILITIES OF SPONSORS

10914.1 Sponsors are responsible for selecting qualified investigators and providing them with the information they need to conduct the investigation properly, ensuring proper monitoring of the investigation, ensuring that IRB review and approval are obtained, submitting an IDE application to the Department, and ensuring that any reviewing IRB and the Department are promptly informed of significant new information about an investigation. Additional responsibilities of sponsors are described in §§ 10907 through 10913 and §§ 10927 through 10929.

10915 DEPARTMENT OF HEALTH AND INSTITUTIONAL REVIEW BOARD APPROVAL

10915.1 A sponsor shall not begin an investigation or part of an investigation until an IRB and the Department have both approved the application or supplemental application relating to the investigation or part of an investigation.

10916 SELECTING INVESTIGATORS AND MONITORS

10916.1 A sponsor shall select investigators qualified by training and experience to investigate the device.

10916.2 A sponsor shall ship investigational devices only to qualified investigators participating in the investigation.

10916.3 A sponsor shall obtain from each participating investigator a signed agreement that includes:

- (a) The investigator's curriculum vitae;
- (b) Where applicable, a statement of the investigator's relevant experience, including the dates, location, extent, and type of experience;
- (c) If the investigator was involved in an investigation or other research that was terminated, an explanation of the circumstances that led to termination;
- (d) A statement of the investigator's commitment to:
 - (1) Conduct the investigation in accordance with the agreement, the investigational plan, this section and other applicable Department regulations, and conditions of approval imposed by the reviewing IRB or the Department;
 - (2) Supervise all testing of the device involving human subjects; and
 - (3) Ensure that the requirements for obtaining informed consent are met; and
- (e) Sufficient accurate financial disclosure information to allow the sponsor to submit a complete and accurate certification or disclosure statement as required under 21 C.F.R., part 54. The sponsor shall obtain a commitment from the clinical investigator to promptly update this information if any relevant changes occur during the course of the investigation and for one (1) year following completion of the study. This information shall not be submitted in an IDE application, but shall be submitted in any marketing application involving the device.

10916.4 A sponsor shall select monitors qualified by training and experience to monitor the investigational study in accordance with this part and other applicable Department regulations.

10917 INFORMING INVESTIGATORS

10917.1 A sponsor shall supply all investigators participating in the investigation with copies of the investigational plan and the report of prior investigations of the device.

10918 MONITORING INVESTIGATIONS

10918.1 A sponsor who discovers that an investigator is not complying with the signed agreement, the investigational plan, the requirements of this part or other applicable Department regulations, or any conditions of approval imposed by the reviewing IRB or the Department shall promptly either secure compliance, or discontinue shipments of the device to the investigator and terminate the investigator's participation in the investigation. A sponsor shall also require such an investigator to dispose of or return the device, unless this action would jeopardize the rights, safety, or welfare of a subject.

10918.2 In the event of unanticipated adverse device effects:

- (a) A sponsor shall immediately conduct an evaluation of any unanticipated adverse device effect; and
- (b) A sponsor who determines that an unanticipated adverse device effect presents an unreasonable risk to subjects shall terminate all investigations or parts of investigations presenting that risk as soon as possible. Termination shall occur not later than five (5) working days after the sponsor makes this determination and not later than fifteen (15) working days after the sponsor first received notice of the effect.

10918.3 If the device is a significant risk device, a sponsor may not resume a terminated investigation without IRB and Department approval. If the device is not a significant risk device, a sponsor may not resume a terminated investigation without IRB approval and, if the investigation was terminated under § 10918.2(b), Department approval.

10919 EMERGENCY RESEARCH

10919.1 A sponsor shall monitor the progress of all investigations involving an exception from informed consent under 21 C.F.R., part 50. When the sponsor receives from the IRB information concerning the public disclosures under 21 C.F.R. § 50.24(a)(7)(ii) and (a)(7)(iii), the sponsor shall promptly submit to the IDE file and to Department, copies of the information that was disclosed, identified by the IDE number.

10919.2 The sponsor also shall monitor such investigations to determine when an IRB determines that it cannot approve the research because it does not meet the criteria in the exception in 21 C.F.R. § 50.24(a) or because of other relevant ethical concerns. The sponsor promptly shall provide this information in writing to the Department, investigators who are asked to participate in this or a substantially equivalent clinical investigation, and other IRB's that are asked to review this or a substantially equivalent investigation.

10920 INSTITUTIONAL REVIEW BOARD COMPOSITION, DUTIES, AND FUNCTIONS

10920.1 An IRB reviewing and approving investigations under 21 C.F.R., part 56 shall comply with the requirements in these regulations in all respects, including its composition, duties, and functions

10921 INSTITUTIONAL REVIEW BOARD APPROVAL

10921.1 An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all investigations covered by this part.

10921.2 If no IRB exists or if the Department finds that an IRB's review is inadequate, a sponsor may submit an application to the Department.

10922 INSTITUTIONAL REVIEW BOARD'S CONTINUING REVIEW

10922.1 The IRB shall conduct its continuing review of an investigation in accordance with 21 C.F.R., part 56.

10923 SIGNIFICANT RISK DEVICE DETERMINATIONS

10923.1 If an IRB determines that an investigation, presented for approval under § 10901.2(a)(2), involves a significant risk device, it shall so notify the investigator and, where appropriate, the sponsor. A sponsor may not begin the investigation except as provided in § 10910.1.

10924 GENERAL RESPONSIBILITIES OF INVESTIGATORS

10924.1 An investigator is responsible for ensuring that an investigation is conducted according to the signed agreement, the investigational plan and applicable Department regulations, for protecting the rights, safety, and welfare of subjects under the investigator's care, and for the control of devices under investigation. An investigator also is responsible for ensuring that informed consent is obtained in accordance with 21 C.F.R., part 50. Additional responsibilities of investigators are described in §§ 10927 through 10929.

10925 SPECIFIC RESPONSIBILITIES OF INVESTIGATORS

- 10925.1 An investigator may determine whether potential subjects would be interested in participating in an investigation, but shall not request the written informed consent of any subject to participate, and shall not allow any subject to participate before obtaining IRB and Department approval.
- 10925.2 An investigator shall conduct an investigation in accordance with the signed agreement with the sponsor, the investigational plan, this part and other applicable Department regulations, and any conditions of approval imposed by an IRB or the Department.
- 10925.3 An investigator shall permit an investigational device to be used only with subjects under the investigator's supervision. An investigator shall not supply an investigational device to any person not authorized under this section to receive it.
- 10925.4 A clinical investigator shall disclose to the sponsor sufficient accurate financial information to allow the applicant to submit complete and accurate certification or disclosure statements required in 21 C.F.R., part 54. The investigator shall promptly update this information if any relevant changes occur during the course of the investigation and for one (1) year following completion of the study.
- 10925.5 Upon completion or termination of a clinical investigation or the investigator's part of an investigation, or at the sponsor's request, an investigator shall return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs.

10926 DISQUALIFICATION OF A CLINICAL INVESTIGATOR

- 10926.1 If the Department has information indicating that an investigator has repeatedly or deliberately failed to comply with the requirements of Chapter 109 or 21 C.F.R., parts 50 or 56, or has repeatedly or deliberately submitted false information either to the sponsor of the investigation or in any required report, the Department will furnish the investigator written notice of the matter under complaint and offer the investigator an opportunity to explain the matter in writing, or, at the option of the investigator, in an informal conference. If an explanation is offered and accepted by the Department, the disqualification process will be terminated. If an explanation is offered but not accepted by the Department, the investigator will be given an opportunity for a regulatory hearing before the Department on the question of whether the investigator is entitled to receive investigational devices.
- 10926.2 After evaluating all available information, including any explanation presented by the investigator, if the Department determines that the investigator has repeatedly or deliberately failed to comply with the requirements of Chapter 109 or 21 C.F.R., parts 50 or 56, or has deliberately or repeatedly submitted false information either to the sponsor of the investigation or in any required report, the Department will notify the investigator, the sponsor of any investigation in which

the investigator has been named as a participant, and the reviewing IRB that the investigator is not entitled to receive investigational devices. The notification will provide a statement of basis for such determination.

10926.3 Each IDE and each cleared or approved application submitted under §§ 10512 through 10521 or Chapters 106 or 109 of this subtitle containing data reported by an investigator who has been determined to be ineligible to receive investigational devices will be examined to determine whether the investigator has submitted unreliable data that are essential to the continuation of the investigation or essential to the approval or clearance of any marketing application.

10926.4 If the Department determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the data remaining are inadequate to support a conclusion that it is reasonably safe to continue the investigation, the Department will notify the sponsor who shall have an opportunity for a regulatory hearing. If a danger to the public health exists, however, the Department shall terminate the IDE immediately and notify the sponsor and the reviewing IRB of the determination. In such case, the sponsor shall have an opportunity for a regulatory hearing before the Department on the question of whether the IDE should be reinstated.

10926.5 If the Department determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the continued clearance or approval of the marketing application for which the data were submitted cannot be justified, the Department will proceed to withdraw approval or rescind clearance of the medical device in accordance with the applicable provisions of the Act.

10926.6 An investigator who has been determined to be ineligible to receive investigational devices may be reinstated as eligible when the Department determines that the investigator has presented adequate assurances that the investigator will employ investigational devices solely in compliance with the provisions of Chapter 109 or 21 C.F.R., parts 50 or 56.

10927 RECORDS

10927.1 A participating investigator shall maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation:

- (a) All correspondence with another investigator, an IRB, the sponsor, a monitor, or the Department, including required reports;
- (b) Records of receipt, use or disposition of a device that relate to:
 - (1) The type and quantity of the device, the dates of its receipt, and the batch number or code mark;

- (2) The names of all persons who received, used, or disposed of each device; and
 - (3) Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of;
- (c) Records of each subject's case history and exposure to the device. Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. Such records shall include:
- (1) Documents evidencing informed consent and, for any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent. The case history for each individual shall document that informed consent was obtained prior to participation in the study;
 - (2) All relevant observations, including records concerning adverse device effects (whether anticipated or unanticipated), information and data on the condition of each subject upon entering, and during the course of, the investigation, including information about relevant previous medical history and the results of all diagnostic tests; and
 - (3) A record of the exposure of each subject to the investigational device, including the date and time of each use, and any other therapy;
- (d) The protocol, with documents showing the dates of and reasons for each deviation from the protocol; and
- (e) Any other records that the Department requires to be maintained by regulation or by specific requirement for a category of investigations or a particular investigation.

10927.2

A sponsor shall maintain the following accurate, complete, and current records relating to an investigation:

- (a) All correspondence with another sponsor, a monitor, an investigator, an IRB, or the Department, including required reports;
- (b) Records of shipment shall include the name and address of the consignee, type and quantity of device, date of shipment, and batch number or code

mark. Records of disposition shall describe the batch number or code marks of any devices returned to the sponsor, repaired, or disposed of in other ways by the investigator or another person, and the reasons for and method of disposal;

- (c) Signed investigator agreements including the financial disclosure information required to be collected under § 10916.3(e) in accordance with 21 C.F.R., part 54;
- (d) For each investigation subject to § 10901.2(a) of a device other than a significant risk device, the records described in §10927.2(e) and the following records, consolidated in one location and available for the Department inspection and copying:
 - (1) The name and intended use of the device and the objectives of the investigation;
 - (2) A brief explanation of why the device is not a significant risk device;
 - (3) The name and address of each investigator;
 - (4) The name and address of each IRB that has reviewed the investigation;
 - (5) A statement of the extent to which the good manufacturing practice regulation in Chapter 107 will be followed in manufacturing the device; and
 - (6) Any other information required by the Department.
- (e) Records concerning adverse device effects (whether anticipated or unanticipated) and complaints; and
- (f) Any other records that the Department requires to be maintained by regulation or by specific requirement for a category of investigation or a particular investigation.

10927.3 An IRB shall maintain records in accordance with 21 C.F.R., part 56.

10927.4 An investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period of two (2) years after the latter of the following two (2) dates:

- (a) The date on which the investigation is terminated or completed; or

- (b) The date that the records are no longer required for purposes of supporting a PMA or a notice of completion of a product development protocol.

10927.5 An investigator or sponsor may withdraw from the responsibility to maintain records for the period required in §10927.4 and transfer custody of the records to any other person who will accept responsibility for them under this section, including the requirements of § 10928. Notice of a transfer shall be given to the Department not later than ten (10) working days after transfer occurs.

10928 INSPECTIONS

10928.1 A sponsor or an investigator who has authority to grant access shall permit authorized Department employees, at reasonable times and in a reasonable manner, to enter and inspect any establishment where devices are held (including any establishment where devices are manufactured, processed, packed, installed, used, or implanted or where records of results from use of devices are kept).

10928.2 A sponsor, IRB, or investigator, or any other person acting on behalf of such a person with respect to an investigation, shall permit authorized Department employees, at reasonable times and in a reasonable manner, to inspect and copy all records relating to an investigation.

10928.3 An investigator shall permit authorized Department employees to inspect and copy records that identify subjects, upon notice that the Department has reason to suspect that adequate informed consent was not obtained, or that reports required to be submitted by the investigator to the sponsor or IRB have not been submitted or are incomplete, inaccurate, false, or misleading.

10929 REPORTS

10929.1 An investigator shall prepare and submit the following complete, accurate, and timely reports:

- (a) An investigator shall submit to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than ten (10) working days after the investigator first learns of the effect;
- (b) An investigator shall report to the sponsor, within five (5) working days, a withdrawal of approval by the reviewing IRB of the investigator's part of an investigation;
- (c) An investigator shall submit progress reports on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less often than yearly;

- (d) An investigator shall notify the sponsor and the reviewing IRB (*see* 21 C.F.R. § 56.108(a)(3) and (4)) of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. Such notice shall be given as soon as possible, but in no event later than five (5) working days after the emergency occurred. Except in such an emergency, prior approval by the sponsor is required for changes in or deviations from a plan, and if these changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of human subjects, the Department and IRB in accordance with § 10911.1 also is required;
- (e) If an investigator uses a device without obtaining informed consent, the investigator shall report such use to the sponsor and the reviewing IRB within five (5) working days after the use occurs;
- (f) An investigator shall, within three (3) months after termination or completion of the investigation or the investigator's part of the investigation, submit a final report to the sponsor and the reviewing IRB; and
- (g) An investigator shall, upon request by a reviewing IRB or the Department, provide accurate, complete, and current information about any aspect of the investigation.

10929.2

A sponsor shall prepare and submit the following complete, accurate, and timely reports:

- (a) A sponsor who conducts an evaluation of an unanticipated adverse device effect under § 10918.2 shall report the results of such evaluation to the Department and to all reviewing IRBs and participating investigators within ten (10) working days after the sponsor first receives notice of the effect. Thereafter the sponsor shall submit such additional reports concerning the effect as the Department requests;
- (b) A sponsor shall notify the Department and all reviewing IRBs and participating investigators of any withdrawal of approval of an investigation or a part of an investigation by a reviewing IRB within five (5) working days after receipt of the withdrawal of approval;
- (c) A sponsor shall notify all reviewing IRBs and participating investigators of any withdrawal of the Department approval of the investigation, and shall do so within five (5) working days after receipt of notice of the withdrawal of approval;
- (d) A sponsor shall submit to the Department, at six (6) month intervals, a current list of the names and addresses of all investigators participating in

the investigation. The sponsor shall submit the first of such lists six (6) months after the Department approval;

- (e) At regular intervals, and at least yearly, a sponsor shall submit progress reports to all reviewing IRB's. In the case of a significant risk device, a sponsor shall also submit progress reports to the Department. A sponsor of a treatment IDE shall submit semi-annual progress reports to all reviewing IRBs and Department in accordance with § 10912.6 and annual reports in accordance with this section;
- (f) A sponsor shall notify the Department and all reviewing IRBs of any request that an investigator return, repair, or otherwise dispose of any units of a device. Such notice shall occur within thirty (30) working days after the request is made and shall state why the request was made;
- (g) In the case of a significant risk device, the sponsor shall notify the Department within thirty (30) working days of the completion or termination of the investigation and shall submit a final report to the Department and all reviewing the IRBs and participating investigators within six (6) months after completion or termination. In the case of a device that is not a significant risk device, the sponsor shall submit a final report to all reviewing IRBs within six (6) months after termination or completion;
- (h) A sponsor shall submit to the Department a copy of any report by an investigator under § 10929.1(e) of use of a device without obtaining informed consent, within five (5) working days of receipt of notice of such use;
- (i) If an IRB determines that a device is a significant risk device, and the sponsor had proposed that the IRB consider the device not to be a significant risk device, the sponsor shall submit to the Department a report of the IRB's determination within five (5) working days after the sponsor first learns of the IRB's determination; and
- (j) A sponsor shall, upon request by a reviewing IRB or the Department, provide accurate, complete, and current information about any aspect of the investigation.

10999 DEFINITIONS

10999.1 As used in this chapter, the following terms shall have the meanings ascribed:

Act – the Federal Food, Drug, and Cosmetic Act. approved June 25, 1938, 21 U.S.C. § 301, *et seq.*

Custom device - a device that:

- (a) Necessarily deviates from devices generally available or from an applicable performance standard or premarket approval requirement in order to comply with the order of an individual physician or dentist;
- (b) Is not generally available to, or generally used by, other physicians or dentists;
- (c) Is not generally available in finished form for purchase or for dispensing upon prescription;
- (d) Is not offered for commercial distribution through labeling or advertising; and
- (e) Is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice.

Department – District of Columbia Department of Health.

DOH – District of Columbia Department of Health.

Implant – A device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of thirty (30) days or more. The Department may, in order to protect public health, determine that devices placed in subjects for shorter periods are also “implants” for purposes of this part.

Institution – a person, other than an individual, who engages in the conduct of research on subjects or in the delivery of medical services to individuals as a primary activity or as an adjunct to providing residential or custodial care to humans. The term includes, for example, a hospital, retirement home, confinement facility, academic establishment, and device manufacturer. The term has the same meaning as “facility” in 21 U.S.C. § 360j(g).

Institutional review board (IRB) – any board, committee, or other group formally designated by an institution to review biomedical research involving subjects and established, operated, and functioning in conformance with 21 C.F.R., part 56. The term has the same meaning as “institutional review committee” in 21 U.S.C. § 360j(g).

Investigational device – a device, including a transitional device, that is the object of an investigation.

Investigation – a clinical investigation or research involving one (1) or more subjects to determine the safety or effectiveness of a device.

Investigator – an individual who actually conducts a clinical investigation (for example, under whose immediate direction the test article is administered or dispensed to, or used involving a subject) or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team.

Monitor (n) – an individual designated by a sponsor or contract research organization to oversee the progress of an investigation. The monitor may be an employee of a sponsor or a consultant to the sponsor, or an employee of or consultant to a contract research organization.

Monitor (v) – to oversee an investigation.

Noninvasive – when applied to a diagnostic device or procedure, means one that does not by design or intention:

- (a) Penetrate or pierce the skin or mucous membranes of the body, the ocular cavity, or the urethra, or
- (b) Enter the ear beyond the external auditory canal, the nose beyond the nares, the mouth beyond the pharynx, the anal canal beyond the rectum, or the vagina beyond the cervical os. For purposes of this part, blood sampling that involves simple venipuncture is considered noninvasive, and the use of surplus samples of body fluids or tissues that are left over from samples taken for non-investigational purposes is also considered noninvasive.

Person – includes any individual, partnership, corporation, association, scientific or academic establishment, Government agency or organizational unit of a Government agency, and any other legal entity.

Significant risk device – an investigational device that:

- (a) Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- (b) Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- (c) Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or

- (d) Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

Sponsor – a person who initiates, but who does not actually conduct, the investigation, that is, the investigational device is administered, dispensed, or used under the immediate direction of another individual. A person other than an individual that uses one (1) or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators.

Sponsor-investigator – an individual who both initiates and actually conducts, alone or with others, an investigation, that is, under whose immediate direction the investigational device is administered, dispensed, or used. The term does not include any person other than an individual. The obligations of a sponsor-investigator under this section include those of an investigator and those of a sponsor.

Subject – a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease.

Termination – a discontinuance, by sponsor or by withdrawal of IRB or the Department approval, of an investigation before completion.

Transitional device – a device subject to 21 U.S.C. § 360(j)(1), that is, a device that the Department considered to be a new drug or an antibiotic drug before May 28, 1976.

Unanticipated adverse device effect – any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.