

Subpart O—Statistical Techniques**§ 820.250 Statistical techniques.**

(a) 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.

(b) 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.

PART 821—MEDICAL DEVICE TRACKING REQUIREMENTS**Subpart A—General Provisions**

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AUTHORITY: 21 U.S.C. 331, 351, 352, 360, 360e, 360h, 360i, 371, 374.

SOURCE: 58 FR 43447, Aug. 16, 1993, unless otherwise noted.

Subpart A—General Provisions**§ 821.1 Scope.**

(a) The regulations in this part implement section 519(e) of the Federal Food, Drug, and Cosmetic Act (the act) which requires the adoption of a meth-

od of device tracking by any person who registers under section 510 of the act and is engaged in the manufacture and distribution of devices the failure of which would be reasonably likely to have serious adverse health consequences if the devices are life-sustaining or life-supporting devices used outside of a device user facility or are permanently implantable devices. This part also applies to any other device that the Food and Drug Administration (FDA) designates as requiring a method of tracking to protect the public health. A device subject to this part either by statutory requirement or by FDA designation is referred to herein as a “tracked device.”

(b) These regulations are intended to ensure that tracked devices can be traced from the device manufacturing facility to the person for whom the device is indicated, that is, the patient. Effective tracking of devices from the manufacturing facility, through the distributor network (including distributors, retailers, rental firms and other commercial enterprises, device user facilities and licensed practitioners) and, ultimately, to any person for whom the device is intended is necessary for the effectiveness of remedies prescribed by the act, such as patient notification (section 518(a) of the act) or device recall (section 518(e) of the act). Although these regulations do not preclude a manufacturer from involving outside organizations in that manufacturer’s device tracking effort, the legal responsibility for complying with this part rests with manufacturers who must register under section 510 of the act, and that responsibility cannot be altered, modified, or in any way abrogated by contracts or other agreements.

(c) Each manufacturer of a tracked device shall implement a method of tracking devices by August 29, 1993.

(d) The primary burden for ensuring that the tracking system works rests upon the manufacturer. A manufacturer or any other person, including a distributor, final distributor, or multiple distributor, who distributes a device subject to tracking, who fails to comply with any applicable requirement of section 519(e) of the act or of this part, or any person who causes

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such failure, misbrands the device within the meaning of section 501(t)(2) of the act and commits a prohibited act within the meaning of sections 301(e) and 301(q)(1)(B) of the act.

(e) Any person subject to this part who permanently discontinues doing business is required to notify FDA at the time the person notifies any government agency, court, or supplier, and provide FDA with a complete set of its tracking records and information. However, if a person ceases distribution of a tracked device but continues to do other business, that person continues to be responsible for compliance with this part unless another person, affirmatively and in writing, assumes responsibility for continuing the tracking of devices previously distributed under this part. Further, if a person subject to this part goes out of business completely, but other persons acquire the right to manufacture or distribute tracked devices, those other persons are deemed to be responsible for continuing the tracking responsibility of the previous person under this part.

§ 821.2 Exemptions and variances.

(a) A manufacturer, importer, or distributor may seek an exemption or variance from one or more requirements of this part.

(b) A request for an exemption or variance shall be submitted in the form of a petition under § 10.30 of this chapter and shall comply with the requirements set out therein, except that a response shall be issued in 90 days. The Director or Deputy Directors, CDRH, or the Director, Office of Compliance, CDRH, shall issue responses to requests under this section. The petition shall also contain the following:

(1) The name of the device and device class and representative labeling showing the intended use(s) of the device;

(2) The reasons that compliance with the tracking requirements of this part is unnecessary;

(3) A complete description of alternative steps that are available, or that the petitioner has already taken, to ensure that an effective tracking system is in place; and

(4) Other information justifying the exemption or variance.

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(c) An exemption or variance is not effective until the Director, Office of Compliance and Surveillance, CDRH, approves the request under § 10.30(e)(2)(i) of this chapter.

(d) For petitions received under this section before August 29, 1993, FDA will, within 60 days, approve or disapprove the petition or extend the effective date of this part for the device that is the subject of the petition. Any extension that FDA grants to the effective date will be based upon the additional time FDA needs to complete its review of the petition.

[58 FR 43447, Aug. 16, 1993, as amended at 59 FR 31138, June 17, 1994]

§ 821.3 Definitions.

The following definitions and terms apply to this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 *et seq.*, as amended.

(b) *Importer* means the initial distributor of an imported device who is required to register under section 510 of the act and § 807.20 of this chapter. “Importer” does not include anyone who only performs a service for the person who furthers the marketing, i.e., brokers, jobbers, or warehousemen.

(c) *Manufacturer* means any person, including any importer, repacker and/or relabeler, who manufactures, prepares, propagates, compounds, assembles, or processes a device or engages in any of the activities described in § 807.3(d) of this chapter.

(d) *Device failure* means the failure of a device to perform or function as intended, including any deviations from the device’s performance specifications or intended use.

(e) *Serious adverse health consequences* means any significant adverse experience related to a device, including device-related events which are life-threatening or which involve permanent or long-term injuries or illnesses.

(f) *Permanently implantable device* means a device that is intended to be placed into a surgically or naturally formed cavity of the human body to continuously assist, restore, or replace the function of an organ system or structure of the human body throughout the useful life of the device. The term does not include any device which