§ 820.250  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

§ 821.1  Scope.

(a) The regulations in this part implement section 519(e) of the Federal Food, Drug, and Cosmetic Act (the act), which provides that the Food and Drug Administration may require a manufacturer to adopt a method of tracking a class II or class III device, if the device meets one of the following three criteria and FDA issues an order to the manufacturer: the failure of the device would be reasonably likely to have serious adverse health consequences; or the device is intended to be implanted in the human body for more than 1 year; or the device is a life-sustaining or life-supporting device used outside a device user facility. A device that meets one of these criteria and is the subject of an FDA order must comply with this part and is referred to, in this part, 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 the patient 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 are subject to tracking orders, and that responsibility cannot be altered, modified, or in any way abrogated by contracts or other agreements.

(c) 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 such failure, misbrands the device within the meaning of section 502(t)(2) of the act and commits a prohibited act...
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within the meaning of sections 301(e) and 301(q)(1)(B) of the act.

(d) 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.

[58 FR 43447, Aug. 16, 1993, as amended at 67 FR 5951, Feb. 8, 2002; 73 FR 34860, June 19, 2008]

§ 821.2 Definitions.

The following definitions and terms apply to this part:


(b) Importer means the initial distributor of an imported device who is subject to a tracking order. “Importer” does not include anyone who only furthers the marketing, e.g., brokers, jobbers, or warehousers.

(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) Device intended to be implanted in the human body for more than 1 year means a device that is intended to be placed into a surgically or naturally formed cavity of the human body for more than 1 year 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 a device that is intended and used only for temporary purposes or that is intended for explantation in 1 year or less.

(g) Life-supporting or life-sustaining device used outside a device user facility means a device which is essential, or yields information that is essential, to the restoration or continuation of a
§ 821.4 Imported devices.

For purposes of this part, the importer of a tracked device shall be considered the manufacturer and shall be required to comply with all requirements of this part applicable to manufacturers. Importers must keep all information required under this part in the United States.

Subpart B—Tracking Requirements

§ 821.20 Devices subject to tracking.

(a) A manufacturer of any class II or class III device that fits within one of the three criteria within §821.1(a) must track that device in accordance with this part, if FDA issues a tracking order to that manufacturer.

(b) When responding to premarket notification submissions and premarket approval applications, FDA will notify the sponsor by issuing an order that states that FDA believes the device meets the criteria of section 519(e)(1) of the act and, by virtue of the order, the sponsor must track the device.

(o) Unique device identifier (UDI) means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of §830.20 of this chapter. A unique device identifier is composed of:

(1) A device identifier—a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and

(2) A production identifier—a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:

(i) The lot or batch within which a device was manufactured;

(ii) The serial number of a specific device;

(iii) The expiration date of a specific device;

(iv) The date a specific device was manufactured.

(v) For an HCT/P regulated as a device, the distinct identification code required by §1271.290(c) of this chapter.

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§ 821.25 Device tracking system and content requirements: manufacturer requirements.

(a) A manufacturer of a tracked device shall adopt a method of tracking for each such type of device that it distributes that enables a manufacturer to provide FDA with the following information in writing for each tracked device distributed:

1. Except as required by order under section 518(e) of the act, within 3 working days of a request from FDA, prior to the distribution of a tracked device to a patient, the name, address, and telephone number of the distributor, multiple distributor, or final distributor holding the device for distribution and the location of the device;
2. Within 10 working days of a request from FDA for tracked devices that are intended for use by a single patient over the life of the device, after distribution to or implantation in a patient:
   i. The unique device identifier (UDI), lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of the devices;
   ii. The date the device was shipped by the manufacturer;
   iii. The name, address, telephone number, and social security number (if available) of the patient receiving the device, unless not released by the patient under § 821.55(a);
   iv. The date the device was provided to the patient;
   v. The name, mailing address, and telephone number of the prescribing physician;
   vi. The name, mailing address, and telephone number of the physician regularly following the patient if different than the prescribing physician; and
   vii. If applicable, the date the device was explanted and the name, mailing address, and telephone number of the explanting physician; the date of the patient’s death; or the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of.
3. Except as required by order under section 518(e) of the act, within 10 working days of a request from FDA for tracked devices that are intended for use by more than one patient, after the distribution of the device to the multiple distributor:
   i. The unique device identifier (UDI), lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of the devices;
   ii. The date the device was shipped by the manufacturer;
   iii. The name, address, and telephone number of the multiple distributor;
   iv. The name, address, telephone number, and social security number (if available) of the patient using the device, unless not released by the patient under § 821.55(a);
   v. The location of the device;
   vi. The date the device was provided for use by the patient;
   vii. The name, address, and telephone number of the prescribing physician; and
   viii. If and when applicable, the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of.

(b) A manufacturer of a tracked device shall keep current records in accordance with its standard operating procedure of the information identified in paragraphs (a)(1), (a)(2) and (a)(3)(i) through (a)(3)(iii) of this section on each tracked device released for distribution for as long as such device is in use or in distribution for use.

(c) A manufacturer of a tracked device shall establish a written standard operating procedure for the collection, maintenance, and auditing of the data specified in paragraphs (a) and (b) of this section. A manufacturer shall make this standard operating procedure available to FDA upon request. A manufacturer shall incorporate the following into the standard operating procedure:

1. Data collection and recording procedures, which shall include a procedure for recording when data which is required under this part is missing and could not be collected and the reason why such required data is missing and could not be collected;
2. A method for recording all modifications or changes to the tracking system or to the data collected and maintained under the tracking system,
§ 821.30  Tracking obligations of persons other than device manufacturers: distributor requirements.

(a) A distributor, final distributor, or multiple distributor of any tracked device shall, upon purchasing or otherwise acquiring any interest in such a device, promptly provide the manufacturer tracking the device with the following information:

1. The name and address of the distributor, final distributor or multiple distributor;
2. The unique device identifier (UDI), lot number, batch number, model number, or serial number of the device or other identifier used by the manufacturer to track the device;
3. The date the device was received;
4. The person from whom the device was received;
5. If and when applicable, the date the device was explanted, the date of the patient’s death, or the date the device was returned to the distributor, permanently retired from use, or otherwise permanently disposed of.

(b) A final distributor, upon sale or other distribution of a tracked device for use in or by the patient, shall promptly provide the manufacturer tracking the device with the following information:

1. The name and address of the final distributor;
2. The unique device identifier (UDI), lot number, batch number, model number, or serial number of the device or other identifier used by the manufacturer to track the device;
3. The name, address, telephone number, and social security number (if available) of the patient receiving the device, unless not released by the patient under §821.55(a);
4. The date the device was provided to the patient or for use in the patient;
5. The name, mailing address, and telephone number of the prescribing physician;
6. The name, mailing address, and telephone number of the physician regularly following the patient if different than the prescribing physician; and
7. When applicable, the date the device was explanted and the name, mailing address, and telephone number of the explanting physician, the date of the patient’s death, or the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of.

(c)(1) A multiple distributor shall keep written records of the following each time such device is distributed for use by a patient:

1. The unique device identifier (UDI), lot number, batch number, model number, or serial number of the device or
other identifier used by the manufacturer to track the device;
   (ii) The name, address, telephone number, and social security number (if available) of the patient using the device;
   (iii) The location of the device, unless not released by the patient under §821.55(a);
   (iv) The date the device was provided for use by the patient;
   (v) The name, address, and telephone number of the prescribing physician;
   (vi) The name, address, and telephone number of the physician regularly following the patient if different than the prescribing physician; and
   (vii) When applicable, the date the device was permanently retired from use or otherwise permanently disposed of.

(2) Except as required by order under section 518(e) of the act, any person who is a multiple distributor subject to the recordkeeping requirement of paragraph (c)(1) of this section shall, within 5 working days of a request from the manufacturer or within 10 working days of a request from FDA for the information identified in paragraph (c)(1) of this section, provide such information to the manufacturer or FDA.

(d) A distributor, final distributor, or multiple distributor shall make any records required to be kept under this part available to the manufacturer of the tracked device for audit upon written request by an authorized representative of the manufacturer.

(e) A distributor, final distributor, or multiple distributor may petition for an exemption or variance from one or more requirements of this part according to the procedures in §821.2.

§ 821.55 Confidentiality.

(a) Any patient receiving a device subject to tracking requirements under this part may refuse to release, or refuse permission to release, the patient’s name, address, telephone number, and social security number, or other identifying information for the purpose of tracking.

(b) Records and other information submitted to FDA under this part shall be protected from public disclosure to the extent permitted under part 20 of this chapter, and in accordance with §20.63 of this chapter, information contained in such records that would identify patient or research subjects shall not be available for public disclosure except as provided in those parts.

(c) Patient names or other identifiers may be disclosed to a manufacturer or other person subject to this part or to a physician when the health or safety of the patient requires that such persons have access to the information. Such notification will be pursuant to agreement that the record or information will not be further disclosed except as the health aspects of the patient requires. Such notification does not constitute public disclosure and will not trigger the availability of the same information to the public generally.

§ 821.50 Availability.

(a) Manufacturers, distributors, multiple distributors, and final distributors shall, upon the presentation by an FDA representative of official credentials and the issuance of Form FDA 482 at the initiation of an inspection of an establishment or person under section 704 of the act, make each record and all information required to be collected and maintained under this part and all records and information related to the events and persons identified in such records available to FDA personnel.

§821.55 Confidentiality.

(a) Any patient receiving a device subject to tracking requirements under this part may refuse to release, or refuse permission to release, the patient’s name, address, telephone number, and social security number, or other identifying information for the purpose of tracking.

(b) Records and other information submitted to FDA under this part shall be protected from public disclosure to the extent permitted under part 20 of this chapter, and in accordance with §20.63 of this chapter, information contained in such records that would identify patient or research subjects shall not be available for public disclosure except as provided in those parts.

(c) Patient names or other identifiers may be disclosed to a manufacturer or other person subject to this part or to a physician when the health or safety of the patient requires that such persons have access to the information. Such notification will be pursuant to agreement that the record or information will not be further disclosed except as the health aspects of the patient requires. Such notification does not constitute public disclosure and will not trigger the availability of the same information to the public generally.
§ 821.60 Retention of records.

Persons required to maintain records under this part shall maintain such records for the useful life of each tracked device they manufacture or distribute. The useful life of a device is the time a device is in use or in distribution for use. For example, a record may be retired if the person maintaining the record becomes aware of the fact that the device is no longer in use, has been explanted, returned to the manufacturer, or the patient has died.

PART 822—POSTMARKET SURVEILLANCE

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SOURCE: 67 FR 38887, June 6, 2002, unless otherwise noted.