

and that any required corrective action has been undertaken.

§ 820.181 Device master record.

Each manufacturer shall maintain device master records (DMR's). Each manufacturer shall ensure that each DMR is prepared and approved in accordance with §820.40. 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.

§ 820.184 Device history record.

Each manufacturer shall maintain device history records (DHR's). Each manufacturer shall establish and maintain procedures to ensure that DHR's 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 part. 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 unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used.

[61 FR 52654, Oct. 7, 1996, as amended at 78 FR 58822, Sept. 24, 2013]

§ 820.186 Quality system record.

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 part that are not specific to a particular type of device(s), including, but not limited to, the records required by §820.20. Each manufacturer shall ensure that the QSR is prepared and approved in accordance with §820.40.

§ 820.198 Complaint files.

(a) 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:

- (1) All complaints are processed in a uniform and timely manner;
- (2) Oral complaints are documented upon receipt; and
- (3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting.

(b) 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.

(c) 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.

(d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter 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 §820.198(e), records of investigation

§ 820.200

under this paragraph shall include a determination of:

(1) Whether the device failed to meet specifications;

(2) Whether the device was being used for treatment or diagnosis; and

(3) The relationship, if any, of the device to the reported incident or adverse event.

(e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include:

(1) The name of the device;

(2) The date the complaint was received;

(3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;

(4) The name, address, and phone number of the complainant;

(5) The nature and details of the complaint;

(6) The dates and results of the investigation;

(7) Any corrective action taken; and

(8) Any reply to the complainant.

(f) 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.

(g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:

(1) A location in the United States where the manufacturer's records are regularly kept; or

(2) The location of the initial distributor.

[61 FR 52654, Oct. 7, 1996, as amended at 69 FR 11313, Mar. 10, 2004; 71 FR 16228, Mar. 31, 2006; 78 FR 58822, Sept. 24, 2013]

Subpart N—Servicing

§ 820.200 Servicing.

(a) Where servicing is a specified requirement, each manufacturer shall establish and maintain instructions and procedures for performing and

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verifying that the servicing meets the specified requirements.

(b) Each manufacturer shall analyze service reports with appropriate statistical methodology in accordance with § 820.100.

(c) Each manufacturer who receives a service report that represents an event which must be reported to FDA under part 803 of this chapter shall automatically consider the report a complaint and shall process it in accordance with the requirements of § 820.198.

(d) Service reports shall be documented and shall include:

(1) The name of the device serviced;

(2) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;

(3) The date of service;

(4) The individual(s) servicing the device;

(5) The service performed; and

(6) The test and inspection data.

[61 FR 52654, Oct. 7, 1996, as amended at 69 FR 11313, Mar. 10, 2004; 78 FR 58822, Sept. 24, 2013]

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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