

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 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 or 804 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 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.

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.

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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 method 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