(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.

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 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.