facilities. Accordingly, FDA has revised the wording of the reporting standards in the final regulation for user facilities and manufacturers to reflect the exact wording in the 1992 amendments for these entities. Therefore, the final regulation requires user facilities and manufacturers to report certain adverse events whenever there is ''information that reasonably suggests that a device may have caused or contributed to a death or serious injury.''

The final rule describes, in § 803.20(c) ''[i]nformation that reasonably suggests that a device has or may have caused or contributed to an MDR reportable event'' to be any information, such as professional, scientific or medical facts and observations or opinions, that would reasonably suggest that a device has caused or may have caused or contributed to an MDR reportable event. Reports are not required when there is information that would cause a person who is qualified to make a medical judgment (e.g., a physician, risk manager, or biomedical engineer) to reach a reasonable conclusion that a device did not cause or contribute to an MDR reportable event. Information that leads to the conclusion that an event is not reportable must be retained in the MDR event files for the time periods specified in § 803.18.

The final rule further defines, in § 803.3(d), ''caused or contributed'' to mean that a death or serious injury was or may have been attributable to a medical device, or that a medical device was or may have been a factor in the adverse event including events occurring as the result of its failure, malfunction, improper or inadequate design, labeling, performance, manufacture, or user error. Devices may cause or contribute to MDR reportable events either directly or indirectly.

12. One comment stated that malfunctions of medical devices used for a nonmedical purpose should be exempted. Other comments stated that the term ''malfunction,'' as defined in § 803.3(m), needed clarification, especially with regard to implanted devices. Another comment asked who is required to report implant malfunctions.

Under this final regulation in subpart E of part 803 manufacturers must report certain malfunctions, including implant malfunctions, that would be likely to cause or contribute to an MDR reportable event, regardless of how the device is used. Although user facilities are not required by statute or regulation to report malfunctions, FDA encourages user facilities to report malfunction information to manufacturers and distributors. Malfunction reports provide important information to FDA concerning device safety.

Reporters do not need to assess the likelihood that a malfunction will recur. The fact that the malfunction occurred once leads to the presumption that the malfunction will recur. A malfunction is reportable if any one of the following is true: (1) The chance of a death or serious injury occurring as a result of a recurrence of the malfunction is not remote; (2) the consequences of the malfunction affect the device in a catastrophic manner that may lead to a death or serious injury; (3) the malfunction results in the failure of the device to perform its essential function and compromises the device's therapeutic, monitoring or diagnostic effectiveness which could cause or contribute to a death or serious injury, or other significant adverse device experiences required by regulation (the essential function of a device refers, not only to the device's labeled use, but for any use widely prescribed within the practice of medicine); (4) the malfunction involves a long- term implant or a device that is considered to be life-supporting or life-sustaining and thus is essential to maintaining human life; or (5) the manufacturer takes or would be required to take an action under sections 518 or 519(f) of the act as a result of the malfunction of the device or other similar devices.

Malfunctions are not reportable if they are not likely to result in a death, serious injury or other significant adverse device experience, that FDA, in a future rulemaking, may require by regulation. A malfunction which is or can be corrected during routine service or device maintenance must be reported if the recurrence of the malfunction would be likely to cause or contribute to a death or serious injury, or other significant adverse device experiences required by a future regulation.

13. Several comments stated that the definition of a ''manufacturer'' (§ 803.3(n)), who is subject to adverse event reporting requirements, is overly broad with regard to custom devices and devices modified by users. One comment suggested that the definition be modified to include manufacture for commercial distribution only.

FDA believes that for protection of the public health, the definition should be broad enough to provide for reporting by all persons engaged in the manufacture, preparation, propagation, compounding, assembly or processing of medical devices, who may receive information about adverse events related to medical devices, except those manufacturers exempted under section 519(c) of the act and § 803.19. Under section 519(c) of the act and § 803.19, a practitioner licensed by law to prescribe or administer devices intended for use in humans and who manufactures or imports devices solely for use in the course of that individual's professional practice is exempt from reporting. Manufacturers of devices not being commercially distributed but which are being used under an investigational device exemption are required to report adverse events under parts 812 and 813 (21 CFR parts 812 and 813) and are not required to submit reports under part 803. Parts 812 and 813, however, require reporting of all adverse device effects.

14. Many comments stated that the definition of ''MDR reportable event'' (§ 803.3(q)) is unclear, beyond the scope of SMDA, or otherwise in need of revision.

The definition of ''MDR reportable event'' has been modified to conform to revisions made to section 519 of the act by section 5 of the 1992 amendments. As defined in § 803.3(q), the revised definition of ''MDR reportable event'' mirrors the language of section 519(a)(1) and (b)(1) of the act, as amended by section 5 of the 1992 amendments.

FDA has further clarified terms contained in the definition of an ''MDR reportable event'' throughout this document. These include: ''caused or contributed,'' as defined in § 803.3(d) and discussed in section IV.B., comment 11 of this document; ''information that reasonably suggests that a device has or may have caused or contributed to a death or serious injury'' as defined in § 803.20(c) and discussed in section IV. B., comment 11 of this document; ''malfunction'' as defined in § 803.3(m) and discussed in section IV.B., comment 12 of this document; ''become aware'' as defined in § 803.3(c) and discussed in sections IV.A., comments 2 and 6, and IV.D., comment 27 of this document; and ''serious injury,'' as defined in § 803.3(aa) and discussed in section IV.B., comment 21 of this document. The terms ''necessitated medical or surgical intervention'' and ''permanent,'' which are now included in the definition of ''serious injury,'' are also clarified in this document. ''Necessitated medical or surgical intervention'' is discussed in section IV.B., comment 16 of this document. FDA believes that these added definitions and discussion of these terms this document provides adequate clarification of the term ''MDR reportable event.''

15. A few comments stated that the definition of ''manufacturer report number'' (§ 803.3(o)), should be changed to allow flexibility and permit