

(1) The event for which a distributor, other than an importer, required to report under this part has received or become aware of information that reasonably suggests that there is a probability that a device has caused or contributed to a death, serious illness, or serious injury; or

(2) The event for which an importer required to report under this part has received or become aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury; or

(3) A malfunction, for which a distributor, other than an importer, required to report under this part has received or become aware of information that reasonably suggests that there is a probability that the device, if the malfunction were to recur, would be likely to cause or contribute to a death, serious illness, or serious injury; or

(4) A malfunction, for which an importer required to report under this part has received or become aware of information that reasonably suggests that a device has malfunctioned and that such device or a similar device would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(n)-(p) [Reserved]

(q) *Permanent* means nonreversible impairment or damage.

(r) *Probability, probable, or probably* means, for purposes of this section, that a person would have reason to believe, based upon an analysis of the event and device, that the device has caused or contributed to an adverse event. This term does not signify statistical probability.

(s) A *remedial action* is any recall, repair, modification, adjustment, relabeling, destruction, inspection, patient monitoring, notification, or any other action relating to a device that is initiated by a distributor, in response to information that it receives or otherwise becomes aware of, that reasonably suggests that one of its marketed devices has caused or contributed to an MDR reportable event.

(t) *Serious illness* means an event that:

(1) Is life threatening;

(2) Results in permanent impairment of a body function or permanent damage to the body structure; or

(3) Necessitates immediate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(u) *Serious injury* means an event that:

(1) Is life threatening;

(2) Results in permanent impairment of a body function or permanent damage to a body structure; or

(3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(v) [Reserved]

(w) *Work day* means Monday through Friday excluding Federal holidays. Federal holidays include New Year's Day, Martin Luther King Jr.'s Birthday, Presidents' Day, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, and Christmas Day.

(x) Any term defined in section 201 of the act shall have the same definition unless otherwise defined in this part.

§804.9 Public availability of reports.

(a) Any report, including any FDA record of a telephone report, submitted under this part is available for public disclosure in accordance with part 20 of this chapter.

(b) Before public disclosure of a report, FDA will delete from the report:

(1) Any information that constitutes trade secret or confidential commercial or financial information under §20.61 of this chapter; and

(2) Any personnel, medical, and similar information, including the serial numbers of implanted devices, which would constitute a clearly unwarranted invasion of personal privacy under §20.63 of this chapter; provided, that, except for the information under §20.61 of this chapter, FDA will disclose to a patient who requests a report all the information in the report concerning that patient.