manufacturers to use their own numbers.

The agency disagrees. A uniform numbering system is essential for FDA evaluation of reports, recordkeeping, filing and analyses. Because the manufacturer report number is based on the manufacturer registration number and all manufacturing sites are required to have a registration number, there is no additional burden on the manufacturer to comply with this requirement. If the manufacturer reporting site does not have a registration number, FDA will assign a temporary registration until the site is officially registered.

16. Several comments stated that the definition of ''necessitated immediate medical or surgical intervention'' (proposed § 803.3(o)), included as an element of the ''serious injury'' definition in § 803.3(aa), which is unclear, overly broad, and unduly burdensome. Some of these comments suggested that the terms ''timely'' and ''intervention'' be further defined or a standard for ''immediate intervention be set (e.g., within 6 hours). Other comments suggested that the event be reported only if significant intervention actually occurred.

In light of the 1992 amendments, most of the comments relating to the ''immediate medical or surgical intervention'' definition are no longer relevant. Section 5(a)(2) of the 1992 amendments revised and broadened the scope of reportable events that fall within the definition of ''serious injury'' by deleting the immediacy requirement from the definition. Under the 1992 amendments' revisions, FDA must require that injuries be reported that necessitate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure, that have or may have been caused by a device, regardless of the immediacy of the surgical or medical intervention.

FDA agrees with comments suggesting that an event be reported if significant intervention actually occurred. FDA believes, however, that any intervention is per se ''significant'' if it is necessary to preclude permanent impairment of a body function or permanent damage to a body structure.

17. Many comments stated that the definition of ''patient of the facility'' whose serious injuries and deaths user facilities must report(§ 803.3(v)) is too broad. Several comments objected to including individuals being diagnosed, treated, or receiving care ''under the auspices of'' the facility under this definition. Other comments objected to including employees of the facility who suffer death or serious injury from a device used at or by the facility as a ''patient of the facility.'' They further asserted that FDA does not have clear jurisdiction over these types of employee events and that MDR reports would duplicate reports required by other regulations (e.g., Occupational Safety and Health Administration (OSHA) regulations). A few comments suggested that the term ''patient'' be further defined.

The agency agrees that including any individuals treated or diagnosed ''under the auspices'' of a facility could be read very broadly to include certain individuals that are not intended to be covered by this regulation. Accordingly, FDA has revised this definition to include only individuals that are ''being diagnosed or treated and/or receiving medical care at or under the control or authority of the facility.''

FDA does not agree, however, that employees of the facility who are injured and/or receive medical care arising from a device-related event at the facility should be excluded from the definition of ''patient of the facility,'' and that information provided to other agencies for work-related injuries is duplicative of information required in an MDR report. FDA believes that facility employees who suffer injury or death in a device-related event reasonably fall within the meaning of the requirement under section 519(b)(1)(A) of the act to report such events that involve a ''patient of the facility.'' To ensure the safety and efficacy of devices, FDA needs information required in the MDR reports for all device-related adverse events regardless of the individual's employment relationship to the facility. MDR reports are required to provide information that is specifically tailored to help FDA determine the risks posed by a certain device and whether further action may be necessary. Reports required by other agencies relating to work injuries, such as OSHA, do not provide the MDR report information that is necessary for FDA to make these determinations. Accordingly, there is no unnecessary duplication involved in reporting.

18. A few comments stated that injuries must be reported because they are ''permanent,'' (proposed § 803.3(q)), should exclude ''trivial'' or ''cosmetic'' irreversible damage.

FDA agrees in part. To improve clarity, the agency has included the definition of ''permanent'' with the ''serious injury'' definition (§ 803.3(aa)). The agency has also modified the definition of ''serious injury'' to exclude trivial irreversible damage. While most cosmetic damage will be trivial, not all cosmetic damage would be considered trivial. Therefore, FDA is not excluding all cosmetic damage from this definition.

19. A few comments recommended that the definition of ''probability, probable, or probably'' in the reporting standard be clarified and suggested using a ''greater than 50 percent'' standard.

As discussed earlier in this document, the 1992 amendments deleted the term ''probability'' from the reporting standard and revised the standard for manufacturers and user facilities. Therefore, this definition has been removed from the final rule.

20. A few comments stated that the definition of a ''remedial action,'' (§ 803.3(y)), which is required to be reported under §§ 803.53(a) and 803.52(f)(7), is unclear. One comment suggested that the definition be deleted; another suggested that it be removed from the user reporting form.

The agency does not agree that this definition should be deleted. The agency should be aware of remedial actions taken in response to reportable events in order to thoroughly evaluate the event. However, the definition has been reworded for clarity. Also, the request for remedial action information has been removed from the user facility section of the final reporting form (FDA Form 3500A) because user facilities do not ordinarily undertake remedial actions. The revised definition of ''remedial action'' appears in § 803.3(y).

21. Several comments stated that the definition of a reportable ''serious injury or serious illness'' (§ 803.3(aa)) is overly broad and needs to be better defined. Another comment suggested that these terms be deleted from the manufacturer and distributor report forms altogether. One comment suggested that ''temporary damage'' be excluded from the definition.

The agency disagrees with comments that requirements to report serious injuries or illnesses should be deleted from the manufacturer and distributor reporting form. Section 519(a)(1)(a) of the act requires manufacturers to report serious injuries. Nor does FDA agree that the definitions of these terms are overly broad. The regulatory definition in § 803.3(aa) of the terms ''serious illness'' and ''serious injury'' are derived directly from the statutory definitions provided in section 519(a)(2) and (b)(5)(B) of the act, as amended by the 1992 amendments.

The SMDA added section 519(b)(5)(B) to require that user facilities report ''serious illnesses'' as well as ''serious injuries.'' The 1992 amendments