left to FDA, the manufacturer or another third party. Other comments suggested that the manufacturer should not be required to verify data or provide data about which it has no knowledge. Other comments suggested that user facilities do not have the appropriate expertise to analyze events or make determinations concerning the reportability of events.

FDA agrees that user facilities should not be required to conduct in-depth analyses of events and has deleted certain requirements regarding information relating to evaluation and testing. User facilities serve principally as conduits of information and thus are required only to fill out information that is known to them. However, the statute and regulations still require user facilities to make an initial determination as to whether an event should be reported under the regulation's criteria. Accordingly, FDA has retained elements that relate to this determination. In § 803.30, FDA explains user facilities' obligations to obtain information about adverse events.

FDA believes that the manufacturer who is responsible for placing a device into interstate commerce is the appropriate entity to initially investigate and evaluate whether, and why, the device may have caused or contributed to a reportable event or malfunctioned and that such malfunction is a reportable event. In order for FDA to determine whether the risk posed by a device necessitates action to protect the public health, the manufacturer is also required to verify data and provide missing information after investigating the event. If after an investigation the information cannot be determined, a manufacturer must explain in the MDR report why the information cannot be obtained.

The agency agrees that an analysis of reports for patterns and trends may be more appropriately conducted by the manufacturer or FDA. FDA will conduct statistical analyses of report information submitted. The agency expects that manufacturers will conduct trend analyses as part of their CGMP.

52. Several comments suggested that numerical event and evaluation codes should not be used on the adverse event reporting form. Other comments stated that the codes lacked accuracy or were insufficient.

The agency disagrees. It is the manufacturer's responsibility to evaluate reports to determine causation. It is reasonable that an evaluation will result in the assignment or identification of failure modes and that these can be communicated to FDA in the form of a structured vocabulary or ''coded'' data. In developing these codes, the agency has used the experience gained from reviewing nearly 400,000 reports submitted since 1984. The use of these codes is essential to the rapid evaluation of device risks and processing of reports by computer. Regardless of whether the codes are specific enough to describe a particular event, the event must be fully described in the narrative section of the reporting form.

The list of codes for use with the final form (FDA Form 3500A or FDA approved electronic equivalent) has been expanded for completeness and modified to improve accuracy. The agency will continue to improve the accuracy of its codes as needed.

53. Various comments suggested that the following elements be removed from the form: Degree of certainty, labelled usage, result of analysis, list of other devices, purchase date, service and maintenance items, event description, and medical status of the patient.

FDA has deleted requirements for user facilities and manufacturers to report service and maintenance information and to state the degree of certainty concerning whether the device caused or contributed to an adverse event. FDA believes the burden of requiring this information would usually outweigh the benefit of assessing the cause of an adverse event. FDA, however, has retained the requirements for manufacturers to report use indications specified in the labeling and device analyses because this information is valuable in determining causation of the event. FDA has deleted the requirements to report these elements for user facilities because the agency believes the manufacturer is the most appropriate source for this information. All user facilities and manufacturers will still be required to provide information regarding concomitant product use, age of the device, event description and certain patient information. FDA believes this information is important to assess adverse events and should be available to user facilities as well as manufacturers.

G. Manufacturer Annual Certification Report (§ 803.57)

54. A few comments stated that this section is redundant, overly broad and burdensome, exceeds the scope of the SMDA and should be deleted. Another comment suggested that certification be limited to events involving class III devices.

The agency cannot agree. Section 519(d) of the act states that each manufacturer required to make reports under section 519(a) of the act must submit annual statements certifying the number of reports filed or that no reports were filed during the previous 12-month period. The provisions of this regulation pertaining to the statutory certification requirement merely explain what information should be contained in the submission. Furthermore, FDA does not agree that certification should be limited to reports about adverse events involving class III devices. Any device, regardless of its classification, can pose serious risks that need to be reported to FDA.

55. Some comments suggested that the certification be limited to the number of reports actually filed, and that liability should attach only in instances of known reporting violations.

The agency disagrees. The purpose of this provision is to ensure reporter compliance with MDR requirements by certifying that all reportable events have been submitted. Such purpose would be thwarted and the certification requirement rendered meaningless if it were limited to simply certifying the number of reports submitted instead of all reportable events known to the certifying entity. The legislative history of section 519(d) of the act references a U.S. General Accounting Office recommendation that the certification state that the reporter ''filed a specific number of reports * * * and that the firm received or became aware of information concerning only these events.'' (H. Rept. 808, 101st Cong., 2d sess. 23 (1990)).

Accordingly, consistent with Congress' intent, FDA is requiring certification that all known reportable events were reported. This requirement does not impose liability for adverse events that are unknown to the reporter because the reporting requirements are triggered only when the reporting entity ''becomes aware'' of a reportable event.

56. Several comments stated that the purpose of certification should be to verify reports, not to certify with absoluteness; therefore the standard should be changed to ''reasonably certain'' and a disclaimer should be added.

The agency disagrees. Section 519(d) of the act specifically states that firms shall certify, not verify their reports. As discussed in the previous paragraph, the purpose of this provision is to ensure that the reporter complies with the law by certifying that it has submitted all the reports it was required to submit. This purpose would not be accomplished by verifying the report.

57. One comment asked for clarification about who is required to certify. Another comment suggested that