

Safe Medical Device Act (SMDA)/Medical Device Reporting (MDR)

1. Introduction. This instruction provides the necessary guidance to enable biomedical equipment technicians (BMETs) to manage the Safe Medical Devices Act (SMDA) and Medical Device Reporting (MDR) programs for the Air Force Medical Service (AFMS). This guidance outlines the responsibilities for end users, local BMETs, Medical Logistics, and regional MERCs.
2. Background.

The Safe Medical Devices Act of 1990, 21 U.S.C. 360i, section 519 and Food and Drug Administration (FDA) 21 CFR, parts 803,807, and 821 imposed new reporting requirements on the medical device industry and users of medical devices. Food and Drug Administration Modernization Act (FDAMA) was enacted on November 21, 1997. Section 211 of FDAMA amended section 519 (e) (1) of the act to authorize FDA, in its discretion, to issue orders that require a manufacturer to track a class II or class III device if the failure of the device would be reasonably likely to have serious adverse health consequences, or the device is intended to be implanted in the human body for more than 1 year, or is life sustaining or life supporting and used outside a device user facility. Section 519 (e) (2) of the act, as amended by FDAMA, provides that patients receiving a tracked device may refuse to provide their name, address, social security number, or other identifying information, for tracking purposes. Accordingly, tracking may be required under section 519 (e), as amended by FDAMA, only if FDA issues an order and only if the criteria described previously are met. FDAMA tracking provisions became effective on February 19, 1998. In addition, user facilities are required to report to the manufacturer and the FDA information that reasonably suggests a medical device may have caused or contributed to the death, serious injury, or serious illness of a patient or other individual.
3. Definitions.
 - 3.1 Medical Device – A device, article, or system employed for the prevention, diagnosis, or treatment of disease in humans that do not normally enter metabolic pathways. Simply, it is anything used in treatment or diagnosis, not a drug.
 - 3.2 Serious injury or illness – Injury or illness that is life threatening, results in permanent damage or serious impairment of body function or permanent or serious damage to a body structure, or necessitates medical or surgical intervention to preclude permanent or serious impairment of a body function or permanent or serious damage to a body structure.
 - 3.3 Type I Complaint – Materiel which has been determined by use or tests to be harmful or defective to the extent that its use has or may cause death, injury, or illness.
 - 3.4 Type II Complaint - Materiel other than equipment which is suspected of being harmful, defective, deteriorated, or otherwise unsuitable for use.
 - 3.5 Type III Complaint – Equipment which is determined to be unsatisfactory because of malfunction, design, defects (attributable to faulty materiel, workmanship and/or quality inspection, or performances).
4. Responsibilities.
 - 4.1 MTF Responsibilities.
 - 4.1.1 Commander – Establishes and maintains a written program to ensure compliance with the SMDA and appoints a designated person to coordinate the program for the facility.
 - 4.1.2 Quality/Risk Manager – Provides overall analysis of the SMDA program and oversight on incidents.
 - 4.1.3 Medical Logistics – Tracks life sustaining or life supporting supplies used within and outside of the medical facility. Submits Standard Form 380 (SF 380) for complaints involving medical supplies.
 - 4.1.4 Biomedical Equipment – Investigates medical device (equipment) problems in accordance with pertinent directives. Works with the Quality/Risk Manager, Medical Logistics, and Safety Officer on equipment/device-related problems. Submits FDA Form 3500A using ECRI's Computerized Product Reporting System (CPRS).
 - 4.1.5 Environment of Care Committee (EOCC) – Provides oversight and review of all incidents involving medical devices. Determines if incident needs to be sent to the manufacturer and FDA under the SMDA.

- 4.1.6 Medical personnel (physicians, nurses, medical technicians, technologists, biomedical equipment repair personnel) – When they become aware of information that reasonably suggests a reportable event occurred, reports that information to the Quality/Risk Manager using established procedures.
- 4.2 Medical Equipment Repair Center (MERC) - During annual visits to each location, MERC personnel will ensure that all facilities, to include ANG and AFRC locations, are complying with this document. Any discrepancies must be included in the MERC trip report.
- 4.3 AFMLO Clinical Engineering Branch – AFMLO/FOE will monitor the SMDA/MDR programs through the use of the monthly data feed from the MTFs and ECRI. AFMLO/FOE will modify this guidance as needed.
5. MDR Procedures.
- 5.1 Identification – Whenever a medical device (equipment or supply) is suspected to have caused injury, the department will immediately report it on an AF Form 765, Hospital Incident Report, or IAW local policy. The device will be impounded to include all accessories and disposables.
- 5.1.1 Equipment - The equipment involved will be brought to medical maintenance immediately. The item will not be cleaned until after the investigation (unless infection control procedures require cleaning). The control settings will not be changed and all disposables will be kept with the unit for inclusion on the incident report. Contaminated equipment will be labeled using AF Form 980, Caution Tag IAW local policy.
- 5.1.2 Supply Item - The supply item will be brought to Medical Logistics to be impounded and investigated. The packing material will be delivered with the item to help identify lot numbers, expiration dates, and distributors.
- 5.2 Reporting – Reporting of medical device incidents will be accomplished using FDA Form 3500A thru ECRI's Computerized Product Reporting System (CPRS). ECRI will then forward a copy to the manufacturer and the FDA as necessary. Reporting of medical supplies will be done using the SF 380 Reporting and Processing Medical Materiel Complaints Quality Improvement Report. This report will be forwarded to DSCP-MRCM.
- 5.2.1 These reports are to be completed by the appointed Medical Logistics personnel and forwarded within 10 working days of when the facility became aware of an MDR event. A Type I medical materiel complaint is completed for each MDR event meeting the criteria of paragraph 2. Type III complaints are not mandatory however, AFMLO/FOE encourages the reporting of these incidents.
- 5.3 Civilian facilities are required to submit an annual summary to the FDA. DSCP/ECRI compiles these summaries for all Air Force facilities and completes all FDA reporting requirements based on data accumulated from the submissions.
6. Tracking
- 6.1 The manufacturer of a tracked device has primary responsibility for tracking the device from manufacturing through distribution to the end user by issue, implant, explant, and retirement. However, medical personnel must ensure manufacturers receive information in a timely manner. The following local procedures ensure medical facility compliance with SMDA tracking requirements:
- 6.2 Equipment – Upon receipt of each equipment item intended for use outside the facility by one or more patients, Medical Maintenance (BMET) will ensure the manufacturers tracking form is completed and returned. The Medical Logistics system (MEDLOG/DMLSS) Historical Maintenance Record (HMR) will be used to track equipment and maintenance history. If equipment subject to tracking is used outside the facility and is assigned to a specific patient, additional information will be recorded and maintained by Medical Logistics (MEMO). The additional information will include: the name, address, telephone number, and social security number of the patient receiving the equipment, date the device was provided to the patient; telephone number of the prescribing physician; name, mailing address, and telephone number of the physician assigned to follow-up with the patient if different than the prescribing physician; and the date the equipment is returned.
- 6.3 Implantables/Explantables subject to tracking – The department (service or clinic) that implants or explants a tracked device must notify the manufacturer as soon as possible, but no later than three working days. Usually, the manufacturer provides a form with the tracked device, but if the form is not enclosed, the following information must be provided:
- 6.3.1 Lot, batch, model, or serial number of the device or other identifier necessary to track the device.
- 6.3.2 Name, address, telephone number, and social security (if available) of the patient receiving the device.
- 6.3.3 Date the device was provided (implanted/explanted) to the patient.

6.3.4 Name, mailing address, and telephone number of the prescribing physician and the physician assigned follow-up with the patient if different from the prescribing physician.

6.3.5 Additionally for explanted devices; date of the patient's death and the date the device was returned to the manufacturer, permanently retired, or otherwise permanently disposed.

6.3.6 Patient Refusals – Patients may refuse to have their device tracked. Such refusals should be documented by the product, model, and serial number, and the information provided to the manufacturer.

6.4 All tracked items in WRM fall under the same SMDA requirements as those found in the MTFs however, once the asset is deployed and records transferred to another account, the item will be reported to the manufacturer as such. The location of the deployed asset will not be provided to the manufacturer due to national security issues. BMETs must ensure a program is in place to identify all items requiring tracking, both in operating and WRM accounts.

6.4.1 If you receive a trackable item back from deployment or from excess, you must notify the manufacturer of the new location of that asset.

6.5 The manufacturer of a tracked item must be notified when a tracked item has been condemned or transferred to a new location. BMETs should ensure this is accomplished prior to turning in any trackable item to DRMO or Excess.