



DEPARTMENT OF THE NAVY

BUREAU OF MEDICINE AND SURGERY
2300 E STREET NW
WASHINGTON DC 20372-5300

IN REPLY REFER TO

BUMEDINST 6710.63B
BUMED-M4B2
31 Mar 2008

BUMED INSTRUCTION 6710.63B

From: Chief, Bureau of Medicine and Surgery

To: Ships and Stations with Medical and Dental Department Personnel

Subj: REPORTING OF DEFECTIVE, UNSAFE, OR UNSATISFACTORY MEDICAL AND DENTAL MATERIEL

Ref: (a) CFR, Title 21, Food and Drugs, Part 803
(b) DLAR 4155.24 of 20 Jul 1993
(c) NAVMED P-5132

1. Purpose. To provide guidance for the suspension, reporting, and disposition of medical and/or dental materiel found to be defective, unsafe, or otherwise unsatisfactory for use. Materiel includes, but is not limited to: pharmaceuticals, biologics, monitoring and diagnostic equipment, durable and single-use products.
2. Cancellation. BUMEDINST 6710.63A.
3. Scope. This instruction applies to all Navy and Marine Corps activities having medical and dental materiel.
4. Background. Delivery of quality health care requires that medical and dental materiel be free of potential hazards. All Naval Medical Department personnel are responsible for reporting suspected defective medical and/or dental materiel to their responsible supervisor to ensure that avoidable harm is prevented. Federal legislation has increased the authority of the Food and Drug Administration (FDA) in monitoring medical safety, while assuring an effective recall program. Reference (a) requires the FDA and the manufacturer to be notified of all deaths, serious injuries, or illnesses caused by medical devices. Further guidance is provided in references (b) and (c). The Defense Logistics Agency has designated the Defense Supply Center, Philadelphia (DSCP) as the responsible agent to handle reporting of unsafe and defective medical equipment to the FDA for the Department of Defense (DoD).
5. Policy. All Navy Medical Treatment Facilities (MTF) and military medicine practitioners shall utilize the new web-based electronic reporting format utilizing the DSCP DMMonline portal. This will allow the Services to centralize the reporting of any defective and/or unsafe medical materiel. In addition, this electronic form shall also be used to initiate all voluntary, mandatory, and vaccine adverse event reports to the FDA. This ensures that DSCP and the Defense Medical Standardization Board (DMSB) is aware of all events and is able to assist and coordinate efforts with the FDA on behalf of Military Medicine.

6. Responsibilities

a. Head, Materiel Management Department for each activity is responsible for the investigation of the materiel defect and any resulting recall of product and subsequent reporting to DSCP, Naval Medical Logistics Command (NAVMEDLOGCOM), and/or the FDA.

b. A thorough investigation of product defect will require involvement of several medical facility resources to include (but not limited to): risk management, quality assurance, safety coordinator, biomedical engineering, responsible division and department heads, and ultimately officers in charge or commanding officers.

7. Defective, Unsafe, or Unsatisfactory Materiel. Examples of some of the types of deficiencies in equipment and materiel which should be reported (but are not limited to) include:

- a. Systemic equipment failures.
- b. Defective devices.
- c. Incorrect or deficient labeling.
- d. Foreign or particulate matter in liquids or solids.
- e. Imperfectly manufactured items which are off-color, off-taste, or off-odor.
- f. Suspected sub-potency or super-potency of drugs and biologics.
- g. Pinholes in tubing.
- h. Faulty calibrations.
- i. Poor quality products.

8. Categories. DoD medical materiel complaints are categorized as either Category I or II, defined below:

a. Category I. A Category I complaint is the most serious, and is described as an item of materiel or an event subsequent to use of that materiel, that could cause or has resulted in serious injury, illness, or loss of life. Category I complaints can only be submitted with approval of a Medical or Dental Officer.

b. Category II. All other complaints that do not meet the severity level for a Category I will be processed as a Category II complaint.

9. Suspension from Issue and Use. Suspend all items from use and quarantine the entire quantity of suspected harmful and/or defective materiel immediately. Segregate and mark materiel in a manner which prevents its issue and use, until a full investigation is completed warranting either its replacement or release from quarantine.

10. Method of Reporting

a. Reports should be initiated online, using the electronic link established through DSCP's DMMonline portal: https://dmmonline.dscp.dla.mil/forms/mpqdr_entry_new.asp. Additional information regarding completion of this report is available from this site.

b. Once the report is initiated, follow the DSCP guidance on the form to ensure all applicable blocks of the Product Quality Deficiency Report (PQDR) are complete prior to electronic submission.

c. Upon electronic filing of the report, DSCP will automatically review the form for completeness, and will contact the filing facility for any additional questions, including the completion of any additional required forms, such as the FDA Voluntary/Mandatory Reports (FDA Forms 3500/3500A respectively), FDA Medical Device Reporting (FDA Form 3419), or Vaccine Adverse Event Reports (FDA VAERS Form-1). DSCP will coordinate the filing of all additional reports and the DMMonline submission protocol will initiate this process.

d. DSCP will then forward the PQDR to the DMSB, Fort Detrick, Maryland, for further investigation and final adjudication. DMSB will, as a matter of their investigation, also contact the filing facility, and maintain liaison with DSCP, NAVMEDLOGCOM, and the FDA where applicable.

e. In cases where a Category I complaint is substantiated, DMSB will work with the United States Army Medical Materiel Agency (USAMMA), who acts for the Services, to draft necessary message traffic to inform the Services and higher authority.

f. NAVMEDLOGCOM monitors all complaints involving standard or nonstandard medical and dental materiel and coordinates the communication of all Navy complaints with other Services medical logistics activities. If the need to suspend an item from issue or use is warranted or a recall needs to be initiated, NAVMEDLOGCOM will work in coordination with DMSB, USAMMA, DSCP, and FDA to ensure all appropriate steps are taken. When samples are required for testing and evaluation, DSCP will request quantities of the item from the reporting activity through NAVMEDLOGCOM.

11. Points of Contact

a. FDA Consumer Safety Officer at (240) 632-6816 or FAX (240) 632-6824. For medical device questions call (240) 276-3150.

b. DSCP Lead Quality Program at (215) 737-2891 or DSN 444-2891. If unavailable, contact the DSCP Emergency Supply Operations Center (ESOC) at (215) 737-2111/2112 or DSN 444-2111/2112 or FAX (215) 737-2081/7109 or DSN 444-2081/7109. After normal work hours, the above numbers will transfer to the Staff Duty Officer at (215) 737-2341 or DSN 444-2341.

c. USAMMA, Supply Specialist, Distribution Operations at (301) 619-4300 or DSN 343-4300.

d. DMSB, Supply Specialist at (301) 619-2186/4093 or DSN 343-2186/4093.

12. Forms

a. The Medical/Dental PQDR form is available electronically at The Warfighter's Medical Logistics Portal, https://dmmonline.dscp.dla.mil/forms/mpqdr_entry_new.asp.

b. The following Food and Drug Administration forms are available electronically at <http://www.fda.gov/cdrh/mdr/mdr-forms.html>:

FDA Form 3500 (10/05), MedWatch Reporting
FDA Form 3500A (10/05), Mandatory MedWatch Reporting
FDA Form 3419 (4/00), Medical Device Reporting Annual User Facility Report

FDA Form 3500 can also be filled via an online reporting process available at <https://www.accessdata.fda.gov/scripts/medwatch/>.

c. The Vaccine Adverse Event Reporting System forms and instructions are available electronically at <http://vaers.hhs.gov/>.



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