DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
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FALLS CHURCH, VA 22042

IN REPLY REFER TO
BUMEDINST 6710.63C
BUMED M42
13 Mar 2015

BUMED INSTRUCTION 6710.63C

From: Chief, Bureau of Medicine and Surgery

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

Ref: (a) 21 CFR 803
(b) DLAR 4155.24/AR 702-7/SECNAVINST 4855.5A/AFR 74-6
(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, and durable and single-use products.

2. Cancellation. BUMEDINST 6710.63B

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 Navy medical department personnel are responsible for reporting suspected defective medical and 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). Reference (b) is available at: http://www2.dla.mil/j-6/dlmso/elibrary/manuals/joint.asp. The Defense Logistics Agency (DLA) is the responsible agency 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 and military medicine practitioners shall report the deficiency utilizing the process outlined on the DLA Troop Support Medical Supply Chain DMMonline portal. This will allow the Services to centralize the reporting of any defective and unsafe medical materiel, as well as all voluntary, mandatory, and vaccine adverse events to the FDA. In addition, the SF-368, Product Quality Deficiency Report (PQDR), shall also be used to initiate all voluntary, mandatory, and vaccine adverse event reports to the FDA.

6. Responsibilities

a. The head, material management department for each activity is responsible for the investigation of the material defect and any resulting recall of product and subsequent reporting to DLA, Defense Health Agency (DHA) Medical Logistics Shared Division, United States Army Medical Research and Materiel Command (USAMRMC), Naval Medical Logistics Command (NAVMEDLOGCOM), and the FDA.

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

7. Defective, Unsafe, or Unsatisfactory Materiel Categories. DoD medical materiel complaints are categorized as either Category I or II, defined below:

a. Category I. Category I complaints can only be submitted with approval of an authorizing medical or dental officer. A Category I complaint is the most serious, and is described as an item of materiel that predictably could cause or has resulted in serious injury, illness, or loss of life, including events occurring as a result of:

(1) Failure

(2) Malfunction

(3) Improper or inadequate design

(4) Manufacture

(5) Labeling

(6) User error

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 including:

(1) Systemic equipment failures

(2) Defective devices

(3) Incorrect or deficient labeling

(4) Foreign or particulate matter in liquids or solids

(5) Imperfectly manufactured items which are off-color, off-taste, or off-odor

(6) Suspected sub-potency or super-potency of drugs and biologics

(7) Pinholes in tubing

(8) Faulty calibrations

(9) Poor quality products

8. Suspension from Issue and Use. Suspend all items, including sequestering medical equipment as appropriate, from use and quarantine the entire quantity of suspected harmful and/or defective materiel immediately. Segregate and mark the materiel in a manner which prevents its issue and use. Keep the original failure settings on equipment, until a full investigation is completed and warrants either its replacement or release from quarantine.

9. Method of Reporting

a. The SF 368 shall also be used to initiate all voluntary, mandatory, and vaccine adverse event reports to the FDA. Additional information regarding completion of this report is available online through the DLA Troop Support Medical Supply Chain DMMonline portal: https://www.medical.dla.mil/Portal/Customer/ProductQualityDeficiency.aspx.

b. Once the report is initiated, follow the DLA guidance on the form to ensure all applicable blocks of the PQDR are complete prior to electronic submission.

c. For vaccine adverse events, submit a report to the Vaccine Adverse Event Reporting System (VAERS). Additional information regarding VAERS submission is available through the Department of Health and Human Service's VAERS online portal: http://vaers.hhs.gov/esub/index.

d. This instruction does not cover adverse drug reactions to pharmaceuticals. Adverse drug reactions are defined as events related to a medication that are noxious, unintended, and occur at normal doses used in humans for prophylaxis, diagnosis, or therapy of disease, or modification of physiological function. All adverse drug reactions should be reported per local policies and procedures via the Patient Safety Reporting System.

10. Points of Contact

a. For any issues or inquiries related to the DLA DMMONline portal referenced above please direct DLA Troop Support Medical Customer Inquiries using the Customer Assistance link available on the Web site: https://www.medical.dla.mil/CustomerAssistance/PublicPages/Customer Assistance.aspx.

When prompted, make sure to confirm that you are not able to log in. This will direct to the appropriate customer assistance and will not require a DMMOnline portal account. DLA customers can use the DLA Customer Interaction Center for requisition/shipment status and other support issues. You may also contact the DLA Customer Interaction Center at 1-877 CLA-CALL (352-2255).

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

c. DLA Troop Support Lead Quality Program at (215) 737-2891 or DSN 444-2891. If unavailable, contact the DLA Troop Support Medical Customer Inquiries at (215) 737-2111 or DSN 444-2111; 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.

d. DHA medical logistics shared division, Supply Specialist at (301) 619-4093/2186 or DSN 343-4093/2186.

11. Records. Records created as a result of this instruction, regardless of media and format, shall be managed per SECNAV M-5210.1 of January 2012.

12. Reports. The reports required in paragraphs 5, 9a, 9c, and 9d are exempt from reports control per SECNAV M-5314.1 of December 2005, part IV, paragraph 7k.

13. Forms

a. The SF 368 (REV. 5/2011) is available at: https://www.medical.dla.mil/Portal/Customer/ProductQualityDeficiency.aspx.

b. The Vaccine Adverse Event Reporting System (VAERS) Form-1 is available at: https://vaers.hhs.gov/esub/step1.

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