DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
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BUMEDINST 6710.63D
BUMED-N4
15 Aug 2025

BUMED INSTRUCTION 6710.63D

From: Chief, Bureau of Medicine and Surgery

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

Ref: (a) 21 CFR 803
(b) DLM 4000.25, Volume 2, Chapter 24: Product Quality Deficiency Report Program, 26 November 2019
(c) NAVMED P-5132

1. Purpose. To provide guidance for the suspension, reporting, and disposition of medical and 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 6710.63C.

3. Scope and Applicability. This instruction applies to all Department of the Navy (DON) activities and expeditionary medicine family of systems having medical and dental materiel.

4. Background. Delivery of quality health care requires that medical and dental materiel be free of potential hazards. All DON medical 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), available at: https://www.dla.mil/Defense-Data-Standards/Committees/PQDR/, and reference (c). 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. Following the report of suspected defective medical and dental materiel to their responsible supervisor, all DON medical personnel must report the deficiency utilizing the process outlined on the DLA Troop Support Medical Supply Chain DMMonline portal. Deficiency reporting will occur per paragraphs 6 and 9 of this instruction. 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 Standard Form (SF) 368 Product Quality Deficiency Report (PQDR), must also be used to initiate all voluntary, mandatory, and vaccine adverse event reports to the FDA.

6. Responsibilities

a. The logistics department for each activity is responsible for submitting material defects through PQDR for subsequent reporting to DLA and Defense Health Agency as appropriate.

b. A thorough investigation of the product defect will require involvement of several 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:

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 or defective materiel immediately. To the max extent, a disinterested party must 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 must 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 at, 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 at: https://vaers.hhs.gov/index.html.

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 in subparagraph 9a, please direct DLA Troop Support Medical Customer Inquiries using the Customer Assistance link available on the Web site at: https://www.medical.dla.mil/CustomerAssistance/Help. When prompted, make sure to confirm that the customer is 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 or shipment status and other support issues. Customers may also contact the DLA Customer Interaction Center at: 1-877 DLA-CALL (352-2255).

b. FDA Consumer Safety Office at: 1-888-INFO-FDA (1-888-463-6332).

c. DLA Troop Support Lead Quality Program at: 1-877-DLA-CALL or via e-mail at: dlacontactcenter@dla.mil.

d. DHA Medical Logistics Division at: (301) 619-6817 or (301) 619-6833.

11. Records Management

a. Records created as a result of this instruction, regardless of format or media, must be maintained and dispositioned per the records disposition schedules located on the DON Assistant for Administration, Directives and Records Management Division portal page at https://portal.secnav.navy.mil/orgs/DUSNM/DONAA/DRM/Records-and-Information-Management/Approved%20Record%20Schedules/Forms/AllItems.aspx.

b. For questions concerning the management of records related to this instruction or the records disposition schedules, please contact the local records manager or the OPNAV Records Management Program (DNS-16).

12. Review and Effective Date. Per OPNAVINST 5215.17A, Logistics and Sustainment Policy and Programs (BUMED-N42) will review this instruction annually around the anniversary of its issuance date to ensure applicability, currency, and consistency with Federal, DoD, Secretary of the Navy and Navy policy and statutory authority using OPNAV 5215/40 Review of Instruction. This instruction will be in effect for 10 years, unless revised or cancelled in the interim and will be reissued by the 10-year anniversary date if it is still required, unless it meets one of the exceptions in OPNAVINST 5215.17A, paragraph 9. Otherwise, if the instruction is no longer required, it will be processed for cancellation as soon as the need for cancellation is known following the guidance in OPNAV M-5215.1 of May 2016.

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

14. 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/reportevent.html.

D. K. VIA

Releasability and distribution:
This instruction is cleared for public release and is available electronically only via the Navy Medicine Web site, https://www.med.navy.mil/Directives