



DEPARTMENT OF THE NAVY

BUREAU OF MEDICINE AND SURGERY
WASHINGTON, D.C. 20372-5120

IN REPLY REFER TO
BUMEDINST 6710.63A
BUMED-42
22 Oct 90

BUMED INSTRUCTION 6710.63A

From: Chief, Bureau of Medicine and Surgery
To: Ships and Stations Having Medical Department Personnel
Subj: REPORTING AND PROCESSING OF DEFECTIVE OR UNSATISFACTORY
MEDICAL AND DENTAL MATERIEL
Ref: (a) SECNAVINST 5214.2B (NOTAL)
Encl: (1) Sample SF 380, Reporting and Processing Medical
Materiel Complaints/Quality Improvement Report

1. Purpose. To issue procedures for the suspension, reporting, and disposition of medical and dental materiel found to be defective or unsatisfactory. This instruction is a complete revision and must be read in its entirety.

2. Cancellation. BUMEDINST 6710.63 and MED 6700-16.

3. Scope. This instruction applies to all Navy and Marine Corps activities having medical and dental materiel.

4. Background. Delivery of quality healthcare requires that medical and dental materiel be free of potential hazards. All personnel are responsible for reporting suspected defective products to ensure no avoidable harm occurs.

5. Classification of Defective or Unsatisfactory Materiel

a. Type I. Materiel, including equipment, which has been determined to be harmful or defective to the extent that use has or may cause death, serious injury, or illness. Normally, only a physician or dentist will designate a complaint as Type I.

b. Type II. Materiel, other than equipment, which is suspected of being harmful, defective, deteriorated, or otherwise unsuitable for use.

c. Type III. Equipment which is determined to be unsatisfactory because of malfunction, design, or defects attributable to faulty materiel, workmanship, or performance.



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6. Suspension From Issue and Use

a. Type I or Type II. Suspend the entire quantity of suspected harmful or defective materiel immediately from issue and use. Segregate and mark materiel in such a manner to prevent its issue and use. Transfer defective or unsatisfactory materiel carried in the Navy Stock Account to condition code "J" and report to Fleet Material Support Office (FMSO) on the monthly Financial Inventory Report (FIR).

b. Type III. Equipment may be used unless the item presents a possible direct hazard (i.e., electrical shock, sharp edges, or other safety hazards).

7. Method of Reporting. Prepare reports on a SF 380, Reporting and Processing Medical Materiel Complaints Quality Improvement Report (see enclosure (1)). A Triservice quality assurance data base has been created to improve management of materiel complaints. This data base requires activities filing a complaint to assign a 14-digit complaint number consisting of unit identification code, julian date, the letter "A," and a 3-digit serial number. Enter this number on the SF 380 directly below the date in the upper right-hand corner. Submit reports as follows:

a. Type I Standard and Nonstandard Items. Report suspected defective materiel by priority message or telephone to Quality Assurance Branch, Defense Personnel Support Center, 2800 South 20th Street (DPSC-RQF), Philadelphia, PA 19101-8419 (DPSC) (PLA: DPSC PHILADELPHIA PA//DPSC-RQF//); with Naval Medical Logistics Command, Fort Detrick, Frederick, MD 21701-5015 (NAVMEDLOGCOM) (PLA: NAVMEDLOGCOM FT DETRICK MD//03//); and Defense Medical Standardization Board, Building 1423, Fort Detrick, Frederick, MD 21701-5013 (DMSB) (PLA: DEFENSE MEDICAL STANDARDIZATION BD FT DETRICK MD//11//), as information addressees. To confirm all complaints, submit an original and four copies of SF 380 to DPSC (Attn: DPSC-RQ) with copies to NAVMEDLOGCOM and DMSB. Make telephone reports to DPSC, Quality Assurance Branch, Philadelphia, PA, at (215) 952-2187/88 or AUTOVON 444-2187 during regular working hours or after regular working hours to the staff duty officer at (215) 952-2341 or AUTOVON 444-2341.

b. Types II and Standard and Nonstandard Items. Report by submitting the original and four copies of the SF 380 to DPSC (Attn: DPSC-RQ) with information copies to NAVMEDLOGCOM and DMSB.

8. Processing Materiel Complaints. Process medical and dental materiel complaint reports in the following manner:

a. DMSB. DMSB, in coordination with DPSC, evaluates all Type I complaints on the basis of information furnished in the report. If additional information is required, the DMSB will contact the reporting activity. If the complaint is substantiated as meeting Type I criteria, the Surgeon General from each military service will direct suspension from issue and use for all stock worldwide pending completion of laboratory evaluation. When Navy suspends stock, NAVMEDLOGCOM releases an Address Indicator Group (AIG) message and publishes a notice in the Navy Medical and Dental Materiel Bulletin (NMDMB). If the DMSB does not substantiate a Type I complaint, it will be downgraded to a Type II or III complaint and passed on to DPSC for action.

b. DPSC. DPSC evaluates all Type I, II, and III complaints on standard stock items. The evaluation may include requests for additional information and samples of suspended stock for laboratory testing by the manufacturer, the Food and Drug Administration, the National Institutes of Health, or the military service' laboratories. If DPSC confirms any report of defective or unsatisfactory materiel, the three military services medical logistics commands will be notified of action to be taken.

c. NAVMEDLOGCOM. NAVMEDLOGCOM monitors all complaints involving standard or nonstandard medical and dental materiel and coordinates the exchange of all Navy complaints with other services' medical logistics activities. If the need to suspend an item from issue or use is warranted and the suspension is of an urgent nature, NAVMEDLOGCOM must:

(1) For Type I complaints. Issue an immediate AIG message announcing the suspension.

(2) For Type II or III complaints. Provide information to field activities by AIG message.

(3) Publish the suspension in the NMDMB. Disposition instructions will be sent by message or in the NMDMB after resolution of the complaint. If a complaint is not substantiated, NAVMEDLOGCOM notifies the reporting activity of appropriate action to be taken.

d. Field Activities. Activities having suspended materiel in stock must report quantities of such materiel to NAVMEDLOGCOM, when requested. Activities may respond by letter, message, or use the suspension report included in the NMDMB. Negative reports are not required unless requested.

9. Samples. When samples are required for testing and evaluation, DPSC will request quantities of the item from the

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reporting activity through NAVMEDLOGCOM. Quantities of consumable type items shipped for testing must be expended from the records and accounted for as a loss by survey referencing the message and this instruction as authority.

10. Action

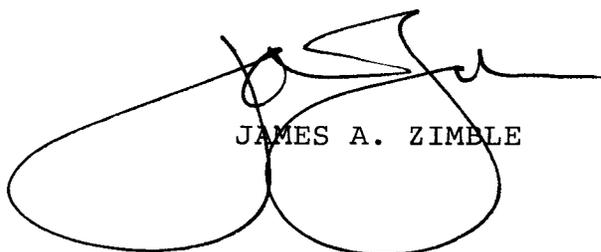
a. All naval Medical Department personnel are responsible for reporting items considered injurious, unsatisfactory, or potentially hazardous to patients or staff to their supervisor or another person in charge. Following evaluation at the activity, report suspected defective or unsatisfactory materiel per this instruction. Do not report complaints involving individual patient sensitivities or adverse reactions.

b. Medical and dental materiel managers must coordinate and submit the SF 380 complaint report for their activity.

11. Reports Exemption. The requirements contained in paragraph 10 are exempt from reports control by reference (a), part IV, paragraph G8.

12. Forms. The SF 380 (12-81), Reporting and Processing Medical Materiel Complaints and Quality Improvement Report, NSN 7540-01-127-0790 is available from the Federal Supply System through normal supply procurement procedures.

Stocked:
CO, NAVPUBFORMCEN
5801 Tabor Ave.
Phila., PA 19120-5099



JAMES A. ZIMBLE

REPORTING AND PROCESSING MEDICAL MATERIEL COMPLAINTS/ QUALITY IMPROVEMENT REPORT		DATE	
		NO. N12345-9000-A001	
TO	COMMANDER DEFENSE PERSONNEL SUPPORT CENTER 2800 SOUTH 20TH STREET (DPSC-RQF) PHILADELPHIA, PA 19101-8419	FROM	COMMANDING OFFICER NAVAL HOSPITAL 1 ELM BLVD. ANYWHERE, USA 56789 UIC - 12345
TYPE OF COMPLAINT ▶		18. FOR VA USE	
1A. FOR DOD USE <input type="checkbox"/> I <input checked="" type="checkbox"/> II <input type="checkbox"/> III		<input type="checkbox"/> QUALITY COMPLAINT <input type="checkbox"/> NEW ITEM <input type="checkbox"/> SIMILAR ITEM	
2. NATIONAL STOCK NO. 6515-00-453-4609		3. ITEM DESCRIPTION Anesthesia Set, Spinal, Disposable	
4. NAME AND ADDRESS OF MANUFACTURER Travenol Laboratories, Inc. Deerfield, IL 60015		5. NAME OF CONTRACTOR (If other than the manufacturer) 6. CONTRACT NO. OR PURCHASE ORDER NO. DIA 120-76-C-0350	
7A. VA DEPOT VOUCHER NO. N/A	7B. DOD REQUISITION NO. N12345-2188-0001	8. LOT NO. G107 S9A and G108 S3	
9. CONTROL NO. 0001	10. MANUFACTURER'S SERIAL NO. 1234	11. MODEL NO. 5678	
12. DATE MANUFACTURED Nov 1989	13. DATE PACKED Nov 1989	14. EXPIRATION DATE Dec 1992	
15. SOURCE (Name of Depot) DD Mechanicsburg, PA	16. QUANTITY ON HAND 180 units	17. QUANTITY SUSPENDED 180 units	
COMPLETE ITEM 18A. THROUGH 18F. FOR DOD TYPE I COMPLAINTS ONLY			
18A. TOTAL NO. PATIENTS INVOLVED		18B. TOTAL NO. REACTIONS	18C. SEVERE OR UNUSUAL REACTIONS
18D. REACTIONS REQUIRING HOSPITALIZATION	18E. LENGTH OF HOSPITALIZATION	18F. VACCINE <input type="checkbox"/> INITIAL <input type="checkbox"/> BOOSTER INTERVAL _____	
19. CAUSE OF COMPLAINT (Explanation of unsatisfactory condition, deficiency, or description of reaction. Complete 19 through 22 for ALL complaints.) Suspected contamination of sets. Routine spinal anesthesia administered to two patients whose first indications of reactions occurred on day following the blocks when symptoms of menigeal irritation developed. The anesthetics were administered by (1) a staff anesthesiologist and (2) a senior resident. No breaks in technique were found to account for the symptoms.			
20A. TYPED NAME OF INITIATOR (For Type I MC/DC/NC) I. M. DOCTOR, CAPT, MC, USN		20B. AUTOVON/FTS TELEPHONE NO. 444-7890	20C. COMMERCIAL TELEPHONE NO. (123) 456-7890
21A. TYPED NAME OF SUPPLY OFFICER N. I. STOCK, LT, MSC, USN		21B. SIGNATURE OF SUPPLY OFFICER (Signature)	21C. DATE (Date)
21D. AUTOVON/FTS TELEPHONE NO. 444-3434		21E. COMMERCIAL TELEPHONE NO. AREA CODE (123) 456-3434	

REPORTING AND PROCESSING MEDICAL MATERIEL COMPLAINTS/QUALITY IMPROVEMENT REPORT (Continued)

22 RECOMMENDATIONS AND/OR ADDITIONAL REMARKS

Routine spinal anesthesia was administered to total of 21 patients. Two patients had reactions. One was readmitted for two days for evaluation. The second patient was cleared of symptoms without prolonged hospitalization. Because two cases in two days is similar to clustering of this type case associated with a break in cleaning technique seen prior to the introduction of disposable trays, the spinal trays must be considered suspect.

23 ACTION TAKEN

24 NAME (Action Officer)

25 TITLE AND ORGANIZATION

26 DATE