SB 8-75-S3

DEPARTMENT OF THE ARMY SUPPLY BULLETIN

Army Medical Department Supply Information

Headquarters, Department of the Army, Washington, DC 20310-2300 20 March 2013

Effective until rescinded or superseded

REPORTING ERRORS AND RECOMMENDING IMPROVEMENTS

You can improve this publication. If you find any mistakes, or you know a way to improve it, please let us know. Mail your letter or DA Form 2028 (Recommended Changes to Publications and Blank Forms) directly to the US Army Medical Materiel Agency, ATTN: MCMR-MMF, Fort Detrick, MD 21702-5001. If you prefer using email, please address it to **usammacrm@amedd.army.mil.**

Table of Contents Page

SPECIAL NOTICE

THIS SUPPLY BULLETIN IS DEDICATED ENTIRELY TO MEDICAL MATERIEL INSTRUCTIONS FROM THE US ARMY MEDICAL MATERIEL AGENCY, DEPARTMENT OF DEFENSE AND SUPERSEDES THE PREVIOUS EDITION OF DA SB 8-75-S3

CHAPTER 1. OVERVIEW OF THE FORCE INTEGRATION AND OPERATIONS (FI&O) DIRECTORATE

1-1. THE FORCE INTEGRATION AND OPERATIONS (FI&O) DIRECTORATE

The Force Integration and Operations (FI&O) Directorate is the command focal point for synthesizing information between Stakeholders/Customers and US Army Medical Materiel Agency (USAMMA) Directorates and Program Management Offices (PMOs) to ensure medical logistics solutions are available to support Department of Defense (DOD) and Army Operations. This Directorate is comprised of the three Divisions shown below. The functions of each Division are outlined in the subsequent chapters of this document.

- Operations Division
- Customer Relations Management (CRM) Division
- Enterprise Requirements Planning (ERP) Division

a. As the single focal point for the management of information flow in and out of USAMMA, the FI&O Directorate processes essential requests for information from Stakeholders and Customers. It manages information flow for dissemination among the appropriate Directorates to coordinate USAMMA resources and ensure that the right materiel is in the right place at the right time.

b. Using a centralized inquiry tracking and response system, the Directorate performs central customer assistance/support services for Stakeholders and Customers. It provides information on USAMMA programs and services, ensures inquiries get to the right office in a timely manner, maintains appropriate status, and closes out inquiries when completed. The Directorate establishes internal relationships within USAMMA, conducts trend analyses, and coordinates with CRM and ERP-related activities such as the Logistics Assistance Program (LAP) and fiscal year forecasts. It also develops and maintains the USAMMA corporate communications and marketing plan.

1-2. RESERVE COMPONENT LIAISION OFFICER (RCLO)

a. The Reserve Component Liaison Officer (RCLO) advises the Commander on all medical materiel issues concerning the US Army Reserve (USAR). The RCLO coordinates with USAMMA's Directorates and separate offices on matters relating to Component, US Army Reserves (USAR COMPO 3) and Army National Guard (COMPO 2) readiness. The RCLO also coordinates with USAMEDCOM, US Army Reserve Command (USARC), Office of the Chief Army Reserve (OCAR) and the Army National Guard Bureau (NGB) on medical equipment issues.

b. The FI&O Directorate does not maintain 24/7 operations. Normal operating hours are Monday through Friday from 0700-1700. The staff has the means to monitor email and respond by phone for emergencies:

Telephone: DSN-343-4408/4432
Commercial: 301-619-4408/4432
Email: usammaeoc@amedd.army.mil

c. For additional Information, contact:

USAMMA
ATTN: MCMR-MMF-E
693 Neiman Street
Fort Detrick MD 21702-5001

CHAPTER 2. OPERATIONS DIVISION

2.1. OVERVIEW OF THE OPERATIONS DIVISION

a. The Operations Division has a thorough grasp of strategic concepts and vision as well as develops and articulates a strategy of task methodology. That methodology translates the USAMMA Commander's guidance into operational objectives and tasks to ensure medical logistics solutions are available to support DOD and Army global operations and contingencies. Additionally, it serves as principle staff consultant to the USAMMA Commander and key leaders in all aspects of future and current operational and contingency matters.

b. The Operations Division coordinates the central development, planning, and integration of the USAMMA Continuity of Operations Plan (COOP) and Operational Plan (OPLAN), engages the key leaders to create an optimal planning environment that supports and facilitates the achievement of mission goals and objectives, collaborates with enabling organizations to facilitate parallel planning and coordinates key aspects of joint and combined operations.

2-2. FUNCTIONS OF THE OPERATIONS DIVISION

a. The Operations Division translates vision and strategic concepts into operational objectives and tasks to posture USAMMA for:

- success in executing current and future operations requirements and
- coordinating responsibility for maintaining situational awareness of all ongoing operations, exercises and contingencies to ensure medical logistics solutions are available to support the global Army and DOD healthcare mission.

b. The Division coordinates with higher headquarters and other mission stakeholders to:

-provide timely and appropriate responses to requirements;
-generate, coordinate, and present reports, papers, briefings, and information updates; and
-plan, coordinate, and publish orders relevant to current operations, domestic emergencies and Homeland Defense (HLD).

c. Additionally, the Division serves as the USAMMA's focal point for the following requirements:

-operational and administrative taskings received from external agencies;
-conducting extensive independent examinations of open source and classified data sources to stay abreast of the operational environment;
-communicating with all levels of the command in order to secure cooperation and identifying and resolving systematic problems and shortfalls in order to facilitate the achievement of operational plans in support of Army and Joint peacetime and contingency operations.

d. The Operations Division has primary staff responsibility for:

-planning, identifying, coordinating and scheduling resource requirements;
-developing and preparing operation orders (OPORD) and fragmentary orders (FRAGO);
- overseeing and conducting rock drills and rehearsals to integrate responsibilities/actions;
-maintaining liaison with participating agencies;
-developing the overall concept of operation;
-establishing detailed milestones;
-conducting in-progress reviews for senior leadership;
-overseeing and conducting after action reviews; and
-briefing visiting military and civilian dignitaries.

e. The Operations Division is also responsible for:

(1) Establishing and operating the USAMMA Operations Center (OC) located within the Defense Medical Logistics Center (DMLC) Joint Operations Center (JOC) during emergency incidents. The OC is designed, equipped and staffed to provide support to the USAMMA Commander and key leaders in orchestrating a coordinated response related to all incidents by providing a secure, centralized location to implement command and control during a disaster or emergency. From the OC, the Commander synchronizes and controls operations to include emergency planning and directing the use of military and other resources in the accomplishment of the mission. OC Staff members:

- receive, monitor, and assess incident information, track available resources, monitor response units and resource requests, and

-communicate with response personnel to collect, analyze, display, and disseminate information.

(2) These critical requirements assist the Commander and key leaders in determining essential steps to mitigate the emergency as well as issue emergency information, warnings, and instructions to assigned personnel.

CHAPTER 3. CUSTOMER RELATIONS MANAGEMENT (CRM) DIVISION

3-1. CUSTOMER RELATIONS MANAGEMENT (CRM)

a. The Customer Relations Management (CRM) Division is the central access point for all customer inquiries at USAMMA and interacts directly with the customer to provide prompt and professional assistance regarding USAMMA's programs, products, and services. CRM has a Customer Relations Management Inquiry Form on the USAMMA website at http://www.usamma.amedd.army.mil/crm_form.cfm for the customer to provide detailed information on any assistance they might require.

b. Through the use of an automated e-mail tracking system the CRM Division documents and manages all customer interactions for knowledge retention management and in order to develop an understanding of trends in customer inquiries. Oversight of all customer interactions allows CRM to ensure that we have the most relevant information available to respond quickly and accurately to common customer requests. It also enables CRM to target our public education efforts toward the most frequent customer inquiries through our presence at military conferences and through a Frequently Asked Question (FAQ) section published on the USAMMA's website at http://www.usamma.amedd.army.mil/tools/faq.cfm.

c. CRM also manages the Interactive Customer Evaluation (ICE) program for the agency and provides monthly analysis and statistics to higher leadership. The ICE system is a web-based tool for collecting feedback from the customer about the services provided by USAMMA. Each Directorate and PMO in USAMMA has their own ICE comment card available on the internet at https://ice.disa.mil/index.cfm?fa=site&site. Comment cards are also available at this link for any conferences which USAMMA hosts or participates in and CRM will assist the Directorates and PMOs in developing any unique comment cards as requested.

d. The CRM Division oversees and manages the monthly publication of the Army Medical Department (AMEDD) Supply Information in the Department of The Army (DA) Supply Bulletins (SBs)for USAMMA, as well as facilitating the publication of the SBs to Army Knowledge Online (AKO). The CRM Division is the liaison with the Army Publishing Directorate at Fort Belvoir, Virginia for all medical SB-related matters and has been appointed as the Printing Control office for the Agency.

3-2. OTHER AREAS MANAGED BY THE CRM DIVISION

a. The CRM Division also manages or participates in the following areas:

(1) Corporate Communication - Facilitates information flow and knowledge sharing across the organization.

(2) Customer Education - Provides customer education and training on USAMMA programs, services, and website tools.

(3) Internet Content – Participates on the USAMMA website committee for the coordination, maintenance, and update of information displayed on the USAMMA website.

(4) Conference Management - Responsible for logistical coordination and support for the bi-annual USAMMA Readiness conference. Also serves as the primary coordinator for Agency conference coverage and partners with the Medical Research and Materiel Command (MRMC) on a regular basis for attendance at conferences.

(5) Marketing - Serves as the primary Point of Contact (POC) for USAMMA's participation in specified events; gathers information on current market trends and business practices; and develops brochures to market the Agency.

b. For additional CRM information, please contact:

USAMMA
ATTN: MCMR-MMF-C
693 Neiman Street
Fort Detrick, MD 21702-5001
Telephone: DSN: 343-4301/1288 or Commercial 301-619-4301/1288
Email: usammacrm@amedd.army.mil

CHAPTER 4. ENTERPRISE REQUIREMENTS PLANNING (ERP) DIVISION

4-1. ENTERPRISE REQUIREMENTS PLANNING (ERP)

a. The Enterprise Requirements Planning (ERP) Division coordinates USAMMA requirements planning within the AMEDD enterprise to synchronize Army medical equipping missions with the USAMMA resources and capabilities in support of the Warfighter.

b. Functions and accountabilities of ERP are:

(1) Develop requirement for internal USAMMA activities from external stakeholders for equipping requirements such as:

(a) Army Modernization
(b) Operational Needs Statements (ONS)
(c) Request for Forces (RFF)
(d) Military Interdepartmental Purchase Request (MIPRs)

(2) Centralized requirements generation/communications.

(3) Coordination of USAMMA capabilities with external agencies [Office of the Surgeon General (OTSG), Headquarters, Department of the Army (HQDA) G-8 Forces Command (FORSCOM), NGB, USAR, et al].

(4) Personnel attend monthly Joint Assessment Conferences (JACs) with the USARs and Army NGB to assist with medical equipping readiness of deploying units.

(5) Integrate FL8D requirements planning, all COMPOs, in accordance with (IAW) the Dynamic Army Resourcing Priority List (DARPL) and applied business rules, HQDA G-8 priorities and Intra-Agency Project Manager coordination relative to life-cycle requirements

(6) Provide current force structure information to all Agency entities for awareness of any impending force design updates and medical equipping implications; Program Objectives Memorandum (POM) builds and medical equipping requirements generation.

c. Prioritization of Units. The Army Resource Priority List (ARPL) and DARPL combined with HQDA G-8 and OTSG Operations/Logistics-approved Business Rules are the means for prioritizing the resources used in supporting units in all components of the Army. The AMEDD Investment Strategy (AIS), under the auspices of the OTSG, augments the ARPL/DARPL/ Business Rules and provides prioritization guidance for USAMMA during execution year spending and fielding. Further, AIS develops materiel requirements for the Army's long-range programming and budgeting processes. The ERP office at USAMMA utilizes the guidance of the AIS, ARPL, DARPL and the Army Synchronization Tool (AST) to provide the FL8D priorities for development of the overarching Executive Level Fielding Schedule (ELFS).

d. For additional ERP information, please contact:

USAMMA
ATTN: MCMR-MMF-P
693 Neiman Street
Fort Detrick, MD 21702-5001
Telephone: DSN: 343-4301/1288 or Commercial 301-619-4301/1288
Email: usammacrm@amedd.army.mil

e. For emergencies after normal duty hours, contact the Emergency Operations Division at the following phone number or email:

Telephone: DSN 343-4408 or Commercial 301-619-4408
Email: usammaeoc@amedd.army.mil

4-2. RESET

a. USAMMA conducts activities to restore the Army's medical equipment to a desired level of combat capability commensurate with future missions, and maintains accurate visibility over equipment repair, replacement, recapitalization and expenditures in order to sustain equipment availability and meet operational requirements.

b. Reset Functions under Medical Army Force Generation (ARFORGEN) are:

(1) Life-Cycle Management through the Life-Cycle Management Command (LCMC) in coordination with AMC (Army Material Command) and FORSCOM. USAMMA responsibilities and requirements are:

(a) Provide disposition instructions within 72 hrs of unit execution of Army Reset Management Tool (ARMT) plan.
(b) Work with units to identify projected return dates and lock in reset fielding dates.
(c) Reset medical Line Item Numbers (LINs)/National Item Identification Numbers (NIINs) via simultaneous equipment/set induction and Reset-Fielding/Direct Exchange (DX) at Home Station by Return (Rtn)+180 for COMPO 1 and Rtn+360 for COMPO 2 & 3 units.
(d) Resolve shipment discrepancies as necessary.

(2) Generate and submit Medical Sustainment Items (MSI) list and upload to Logistics Information Warehouse (LIW) for approval by (FORSCOM/HQ Army Materiel Command (AMC)/DA G4/DA G8). This directly affects the, National Equipment List (NEL), Reset Equipment List (REL), Unit Reset Planner and MYRESETPlans, automated tools in LIW.

(3) Reply to Requests for Information (RFIs) as needed with the following agencies: DA G-4/DA G-8/ OTSG, Brigade Combat Teams (BCTs); Division level units in theater of operations as well as at their home station; and individual units below Brigade and internal USAMMA directorates.

(4) As required, attend Division and Brigade Planning Conferences. Work with regional managers to generate briefing slides for Unit Equipping Reuse Conference (UERC) presentations. These depict individual unit reset posture and descriptive timelines to be followed during fielding processes.

(5) Represent USAMMA to the Army Sustainment Command (ASC) during bi-weekly AMC video teleconference (VTC) meetings.

(6) Represent USAMMA for the Army Reset Common Operating Picture (COP) IPT (Intergrading Planning Team) Bi-Weekly with Logistics Support Activity (LOGSA)\FORSCOM\AMC\ASC and several other LCMCs and Army Field Support Brigades (AFSBs).

(a) Analyze drill down slides and confirming USAMMA's fielding dates as well as equipment LIN fill requirements by fieldings.
(b) Supplies both an automated pull and upload of data to AMC through LOGSA that fills the Army Reset COP web tools query.

CHAPTER 5. DISTRIBUTION OPERATIONS CENTER (DOC)

5-1. VACCINES AND TEMPERATURE SENSITIVE MEDICAL PRODUCTS (TSMPs)

a. The *DOD Directive 6205.3* sets DOD policy for the use of vaccines for biological defense and designates the US Army as the DOD Executive Agent for the DOD Immunization Program for Biological Warfare Defense.

b. In 1998, the USAMMA was tasked with coordinating the distribution of anthrax vaccine from the manufacturer to DOD medical facilities. To accomplish this mission and in support of the Anthrax Vaccine Immunization Program (AVIP), USAMMA established the Distribution Operations Center (DOC) to work closely with tri-Service field and fixed medical activities. The DOC is partially funded by and an integral part of the DOD Military Vaccine (MILVAX) Agency.

c. As a result of Homeland Security Presidential Directive (HSPD) (21 on 18 Oct 2007) and the United States Government Accountability Office (GAO) Report 08-88 (23 Oct 2007), the Centers for Disease Control and Prevention (CDC) and DOD recognized that a shared anthrax vaccine inventory could improve life-cycle management of Strategic National Stockpile (SNS) dose inventory and provide significant savings to the US Government. This was accomplished in May 2008. In 2002, the DOC was also tasked with coordinating the DOD distribution of smallpox vaccine from the CDC to DOD medical facilities for the Smallpox Vaccination Program (SVP). In 2013, Vaccinia Immune Globulin was added to the Inter-agency Agreement between the CDC and DOD.

d. The DOC also supported the ordering and distribution of the Adenovirus vaccine in 2011, in support of the US Army Medical Materiel Development Activity (USAMMDA) effort to revive and maintain production.

e. The USAMMA DOC supports other DOD and Federal agencies when shipping TSMPs to ensure the cold chain is maintained. It also supports critical medical products to include Investigational New Drugs (INDs) and Foreign Military Sales (FMS).

f. The DOC is the Army Influenza (Flu) Vaccine Program Manager. The DOC gathers requirements and communicates requirement and distribution plans with the Defense Logistics Agency (DLA), MILVAX, and Army Commands.

g. To minimize loss of product and expedite delivery of vaccine to requesting sites, the DOC provides support for redistribution of TSMP when requested.

h. Additionally, the DOC creates, publishes, and disseminates Medical Materiel Quality Control (MMQC) messages to DOD medical facilities providing program, policy, and guidance for anthrax vaccine and smallpox vaccine, and Medical Materiel Instructions (MMI) messages to Army facilities reflecting program policy and guidance related to influenza vaccine.

i. The DOC provides consultation and training on Cold Chain Management (CCM) principles and procedures.

j. Sources of Information:

(1) Direct any questions regarding these vaccines and TSMPs to the USAMMA DOC at the following address:

USAMMA
ATTN: MCMR-MMO-D

693 Neiman St
Fort Detrick MD 21702-5001
DSN 343, Commercial 301-619-4198/4318/1197
Fax: 301-619-4468
Email: **USAMMADOC@amedd.army.mil**

(2) The USAMMA DOC World Wide Web (WWW) site is available on the USAMMA Homepage at **http://www.usamma.amedd.army.mil**, select "Vaccines and Temperature Sensitive Products" and follow appropriate prompts.

5-2. MEDICAL MATERIEL INSTRUCTIONS (MMIs)

a. Submitting Medical/Dental Product Quality Deficiency Reports (M/DPQDR) [formerly Medical Materiel Complaints (SF 380S)].

(1) The Product Quality Deficiency Report (PQDR) program is governed by the joint regulation DLAR 4155.24 Product Quality Deficiency Report Program. All medical materiel complaints, regardless of procurement source, should be submitted on a M/DPQDR located on the DLA website at: https://www.medical.dla.mil/Portal/Customer/ProductQualityDeficiency.aspx . The M/DPQDR should be submitted to report materiel or equipment that has been determined to be harmful and/or defective that may result in death, injury, or illness. The M/DPQDRs are categorized into two types:

• **Category I**: Materiel determined by use or testing to be harmful or defective to the extent that its use has or may cause death, injury, or serious illness. Category I complaints must be approved by a Medical Officer at the reporting site.

• **Category II**: Drugs, devices, supplies, or equipment suspected of being harmful, defective, deteriorated, or unsatisfactory because of malfunction or design, which are attributable to faulty materiel, workmanship and/or quality inspection, or performance or are otherwise unsuitable for use.

(2) The M/DPQDR is the customer's way of alerting the system that there is a quality deficiency with a medical or dental product. Deficiencies should be submitted on standard and nonstandard items. It is also the vehicle for submitting Safe Medical Device (SMD) incidents. Examples of discrepancies that should be reported on the M/DPQDR are:

- Wrong or deficient labeling
- Foreign or particulate matter in liquids and solids
- Imperfectly manufactured items which are off-color, off-taste, and off-odor
- Suspected sub-potency or super-potency
- Defective devices
- Pinholes in tubing
- Faulty calibrations
- Systemic equipment failures
- Poor quality products

(3) The submitter will receive a copy of the e-mail that has been sent to DLA – Troop Support (DLA-TS), the Defense Medical Materiel Program Office (DMMPO) and the Services' Medical Logistic Offices at Ft. Detrick. Once the form is received, DLA-TS will assign a Report Control Number (RCN) in the Product Data Reporting and Evaluation Program (PDREP), and respond back to you. For a Category I PQDR, they will reply within one business day and provide a final reply within 20 business days. For a Category II PQDR, acknowledgement of receipt will be within three business days and final reply within 30 days.

(4) Report the circumstances of Category I immediately to DLA-TS, through the M/DPQDR.

(5) The *21 CFR* prescribes reporting certain materiel/equipment conditions to the Food & Drug Administration (FDA) under the Safe Medical Devices Act (SMDA). Logistics personnel will coordinate and provide a copy of the Complaint Form to the Risk Manager as part of the Risk Management Program. The Risk Manager is required under Joint Commission on Accreditation of Healthcare Organization (JCAHO) to review the SMDA information on the Complaint Form and assess the potential risk.

b. DOD-MMQC Messages and DA MMI Messages:

(1) The DOD-MMQC process is an Integrated Medical Logistics Group initiative, designed to simultaneously disseminate Quality Control information and rapidly notify hospitals, clinics, and medical units of potentially hazardous medical materiel. These messages contain urgent Quality Assurance (QA) data emanating from pharmaceutical and/or medical device and equipment manufacturers regarding their products or notification of hazards, alerts and recalls stemming from a PQDR.

(2) Once recall notification is received at the Defense Logistics Agency – Troop Support, research is conducted by DLA-TS and USAMMA's DOC to equate the product with National Stock Numbers (NSNs). The DOC then incorporates information into the DOD-MMQC message format that contains Service-specific requirements, POC, reason for message, disposition instructions, and any other product related information. The program's primary purpose is to aid the Service-specific logisticians, supply managers, pharmacists, clinicians, medical maintenance personnel, in assuring that the proper use, handling, and return of recalled product is accomplished to protect patient safety.

(3) The FDA Recalls are classified as follows:

Class I: A situation in which there is a reasonable probability that use of, or exposure to, a dangerous product will cause serious adverse health consequences or death.

Class II: A situation in which the use of, or exposure to, a dangerous product may cause adverse health consequences.

Class III: A situation in which the use of, or exposure to, a dangerous product is not likely to cause adverse health consequences.

(4) The DOC also disseminates DA MMI messages that contain information specific to the Army only.

(5) These messages are available via two media (Reference Department of the Army SB 8-75-S1 dated 20 January 2013 [chapter 4, paragraph 4-7] and SB 8-75-11 dated 20 November 2012 [chapter 4, paragraph 4-2]):

(a) The World Wide Web (WWW) (available on the USAMMA Homepage at **http://www.usamma.amedd.army.mil**. Select "DOD-MMQC Messages & Images" and follow appropriate prompts.

(b) Electronic Mail. Register to receive DOD-MMQC and MMI messages via e-mail by subscribing on USAMMA's website (address above). Select "DOD-MMQC Messages & Images" then "Subscribe to MMQC Messages Here" and provide all required information.

(6) These messages are also disseminated via:

(a) Files-transfer protocol (HTTPS) to US Army Medical Materiel Center, Europe (USAMMCE) and US Army Medical Materiel Center-Korea (USAMMC-K)
(b) Joint Medical Asset Repository (JMAR)
(c) Defense Medical Logistics Supply System (DMLSS)

c. Safe Medical Device Act (SMDA) of 1990.

(1) References:

(a) AR 40-61, dated 28 Jan 2005, Chapter 4, Section V, Para 4-13 and 4-14
(b) FDA Medical Device Report *(*MDR*)* Regulation (Website: **www.fda.gov**)
(c) Medical/Dental Product Quality Deficiency Report (M/DPQDR)

(2) Effective 28 November 1991, all Medical Treatment Facilities (MTFs) are required to report device-related deaths, serious injuries, and reportable malfunctions (see PQDR above).

(3) The M/DPQDR and the MedWatch 3500A Mandatory Reporting Form will continue to be used in submitting the incidents. It is not limited to devices, and includes equipment as well as pharmaceuticals. All Activities should continue to submit M/DPQDRs, IAW AR 40-61, dated 28 Jan 2005, Chapter 4, Section V, Para 4-13 and 4-14.

(4) User-facilities such as hospitals and nursing homes are legally required to report suspected medical device-related deaths to both the FDA and the manufacturer, if known, and serious injuries to the manufacturer or to FDA, if the manufacturer is unknown. These reports must be made on the MedWatch 3500A Mandatory Reporting Form.

(5) The statutory authority for the MDR regulation is section 519(a) of the Federal Food Drug & Cosmetic (FFD&C) Act as amended by the SMDA of 1990. The SMDA requires user facilities to report:

(a) device-related deaths to the FDA and the device manufacturer;
(b) device-related serious injuries to the manufacturer, or to FDA if the manufacturer is not known; and
(c) on an annual basis, submit to FDA a summary of all reports submitted during that period.

(6) The SMDA requires FDA to issue regulations requiring distributors to report device-related deaths, serious injuries and reportable malfunctions. In addition, the SMDA requires distributors and manufacturers to certify to FDA the number of MDR reports filed or that no reports have been filed. All manufacturers of finished medical devices and components, which are ready for use, including foreign manufacturers are now subject to the requirements of the MDR regulation, despite registration status.

d. Questions regarding these medical materiel instructions may be directed to:

USAMMA
ATTN: MCMR-MMO-D
693 Neiman St
Fort Detrick MD 21702-5001
DSN 343-4300/3242 or Commercial 301-619-4300/3242

GLOSSARY

2013 GLOSSARY FOR SB 8-75-S3

Abbreviation/Acronym	Definition
AIS	AMEDD Investment Strategy
AKO	Army Knowledge Online
AMC	Army Materiel Command
AMEDD	Army Medical Department
AR	Army Regulation
ARFORGEN	Army Force Generation
ARMT	Army Reset Management Tool
ARPL	Army Resource Priority List
ASC	Army Sustainment Command
AST	Army Synchronization Tool
AVIP	Anthrax Vaccine Immunization Program
BCT	Brigade Combat Team
CCM	Cold Chain Management
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
COMPO	Component
COOP	Continuity of Operations Plan
COP	Common Operating Picture
CRM	Customer Relations Management
DA	Department of the Army
DAASC	Defense Automatic Addressing Service Center
DARPL	Dynamic Army Resource Priority List
DOC	Distribution Operations Center
DLA	Defense Logistics Agency
DLA-TS	Defense Logistics Agency-Troop Support
DMLC	Defense Medical Logistic Center
DMLSS	Defense Medical Logistics Supply System
DMMPO	Defense Medical Materiel Program Office
DOD	Department of Defense
DOD-MMQC	Department of Defense Medical Materiel Quality Control
DSN	Defense Switched Network
DX	Direct Exchange
ELFS	Executive Level Fielding Schedule
ERP	Enterprise Requirements Planning
FAQ	Frequently Asked Questions
FDA	Food and Drug Administration
FFD&C	Federal Food Drug and Cosmetic
FI&O	Force Integration and Operations
FMS	Foreign Military Sales
FORSCOM	Forces Command
FRAGO	Fragmentary Orders
FTP	File Transfer Protocol

2013 GLOSSARY FOR SB 8-75-S3

Abbreviation/Acronym	Definition
GAO	Government Accountability Office
HLD	Homeland Defense
HQDA	Headquarters, Department of the Army
HSPD	Homeland Security Presidential Directive
IAW	In accordance with
ICE	Interactive Customer Evaluation
IND	Investigational New Drugs
JCAHO	Joint Commission on Accreditation of Healthcare Organization
JOC	Joint Operations Center
JMAR	Joint Medical Asset Repository
LCMC	Life-Cycle Management Command
LIN	Line Item Number
LIW	Logistics Information Warehouse
LOGSA	Logistics Support Activity
MILVAX Agency	Military Vaccine Agency
MIPR	Military Interdepartmental Purchase Request
MMI	Medical Materiel Information
MMQC	Medical Materiel Quality Control
MRMC	Medical Research and Materiel Command
MSI	Medical Sustainment Item
NEL	National Equipment List
NGB	National Guard Bureau
NIIN	National Item Identification Number
NSN	National Stock Number
OC	Operations Center
OCAR	Office of the Chief, Army Reserve
ONS	Operational Needs Statement
OPORD	Operations Order
OPLAN	Operational Plan
OTSG	Office of the Surgeon General
PDREP	Product Data Reporting and Evaluation Program
PMO	Project Management Office
POC	Point of Contact
POM	Program Objective Memorandum
PQDR	Product Quality Deficiency Report
QDR	Quality Deficiency Report
RCLO	Reserve Component Liaison Officer
RCN	Report Control Number
REL	Reset Equipment List

2013 GLOSSARY FOR SB 8-75-S3

Abbreviation/Acronym	Definition
RFF	Request for Forces
RFI	Request for Information
RTN	Return
SB	Supply Bulletin
SF	Standard Form
SDR	Supply Discrepancy Reporting
SMDA	Safe Medical Devices Act
SNS	Strategic National Stockpile
SVP	Smallpox Vaccine Program
TSMP	Temperature Sensitive Medical Product
UERC	Unit Equipping Reuse Conference
USAMEDCOM	United States Army Medical Command
USAMMA	United States Army Medical Materiel Agency
USAMMCE	United States Army Medical Materiel Center, Europe
USAMMCE-K	United States Army Medical Materiel Center-Korea
USAMMDA	United States Army Medical Materiel Development Activity
USAMRMC	United States Army Medical Research and Materiel Command
USAR	United States Army Reserve
USARC	United States Army Reserve Command
VTC	Video Teleconference
WWW	World Wide Web

2013 - DA SB 8-75-S3 INDEX

SB 8-75-S3

By Order of the Secretary of the Army:

RAYMOND T. ODIERNO
General, United States Army
Chief of Staff

Official:

JOYCE E. MORROW
Administrative Assistant to the
Secretary of the Army

1307704

Distribution:

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