Defense Health Agency

PROCEDURES MANUAL

SUBJECT: Medical Logistics Materiel Quality Procedures.

References: See Enclosure 1

1. <u>PURPOSE</u>. This Defense Health Agency-Procedures Manual (DHA-PM), based on the authority of References (a) and (b), and in accordance with the guidance of References (c) through (p), implements policy, assigns roles, and responsibilities and provides the Defense Health Agency's (DHA) procedures to:

    a. Establish standard medical logistics (MEDLOG) processes to receive, disseminate, adjudicate, and report Hazard Alert and Recall (HAR) messages and Product Quality Deficiency Reports (PQDRs) for medical or dental materiel found to be defective, unsafe, or otherwise unsatisfactory for use within the Military Health System (MHS). For non-prescription medication and food recalls, please see procedures outlined in Reference (p).

    b. Support the Combatant Commander by disseminating HAR and PQDR notifications.

    c. Establish the DHA MEDLOG Medical Materiel Quality Office (MMQO), HAR Program Manager, and HAR Coordinators at military medical treatment facilities (MTFs) and DHA components.

    d. Create a standard, repeatable process to receive, process, disseminate, adjudicate, report, or generate messages for materiel identified in HAR and PQDR notifications.

    e. Establish standard notification, removal, and disposition procedures for materiel identified in HAR and PQDR notifications.

2. <u>APPLICABILITY</u>. This DHA-PM applies to DHA, DHA components (activities reporting to DHA, i.e., markets, MTF), the Military Departments, and all personnel to include: assigned or attached active duty and Reserve members, members of the Commissioned Corps of the Public Health Service, federal civilians, contractors (when

required by the terms of the applicable contract), and other personnel assigned temporary or permanent duties at DHA, to include DHA regional and field activities (remote locations), and subordinate organizations administered and managed by DHA, to include MTFs under the authority, direction, and control of the DHA.

3. <u>POLICY IMPLEMENTATION</u>. It is DHA's instruction, pursuant to References (a) through (p), that the MEDLOG Enterprise Activity, in collaboration with Military Departments, United States Army Medical Materiel Agency Distribution Operations Center (USAMMA DOC), and DHA Clinical Quality Program establish standard MEDLOG materiel quality process and procedures within the MHS.

4. <u>RESPONSIBILITIES</u>. See Enclosure 2

5. <u>PROCEDURES</u>. See Enclosure 3

6. <u>PROPONENT AND WAIVERS</u>. The proponent of this publication is the Deputy Assistant Director (DAD), MEDLOG. When Activities are unable to comply with this publication the activity may request a waiver by providing justification that includes a full analysis of the expected benefits and must include a formal review by the activities senior legal officer. The activity director or senior leader will endorse the waiver request and forward them through their chain of command to the Director, DHA to determine if the waiver may be granted.

7. <u>RELEASABILITY</u>. **Cleared for public release**. This DHA-PM is available on the Internet from the Health.mil site at: https://health.mil/Reference-Center/Policies and is also available to authorized users from the DHA SharePoint site at: https://info.health.mil/cos/admin/pubs/SitePages/Home.aspx.

8. <u>EFFECTIVE DATE</u>. This DHA-PM:

   a. Is effective upon signature.

   b. Will expire 10 years from the date of signature if it has not been reissued or cancelled before this date in accordance with Reference (c).

9. <u>FORMS</u>. Forms referenced in this document can be retrieved from the following locations:

   a. SF 368, PQDR can be found at: https://www.gsa.gov/reference/forms.

   b. Stocked DD forms can be ordered from the Defense Logistics Agency at: https://forms.documentservices.dla.mil/order/.

(1) DD Form 1575, Suspended Tag – Materiel

(2) DD Form 1575-1, Suspended Label – Materiel

/S/
RONALD J. PLACE
LTG, MC, USA
Director

Enclosures
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ENCLOSURE 1

REFERENCES

(a) DoD Directive 5136.01, "Assistant Secretary of Defense for Health Affairs (ASD (HA))," September 30, 2013, as amended

(b) DoD Directive 5136.13, "Defense Health Agency (DHA)," September 30, 2013

(c) DHA-Procedural Instruction 5025.01, "Publication System," August 24, 2018

(d) Public Law 114-328. Section 702, "National Defense Authorization Act for Fiscal Year 2017," December 23, 2016

(e) DoD Instruction 6430.02, "Defense Medical Logistics Program," August 23, 2017

(f) DHA-Procedural Instruction 6430.02, "Defense Medical Logistics (MEDLOG) Enterprise Activity (EA)," September 27, 2018

(g) DoD Directive 5105.22, "Defense Logistics Agency (DLA)," June 29, 2017

(h) DoD Manual 4140.01, Volume 1, "DoD Supply Chain Materiel Management Procedures: Operational Requirements," December 13, 2018

(i) DoD Instruction 6025.13, "Medical Quality Assurance (MQA) and Clinical Quality Management in the Military Health System (MHS)," February 17, 2011, as amended

(j) Memorandum of Agreement between U.S. Army Medical Materiel Agency (USAMMA), Defense Philadelphia Supply Center (DPSC), Defense Medical Standardization Board (DMSB), Air Force Medical Support Agency and Naval Medical Logistics Command, November 2005[1]

(k) Defense Logistics Agency Joint Service Regulation JP 4155.24, "Product Quality Deficiency Report Program," July 20, 1993, as amended

(l) Code of Federal Regulations, Title 21, Chapter 1499

(m) The Joint Commission, "Comprehensive Accreditation Manual, EC 02.01.01 and MM 05.01.17," current edition[2]

(n) Implementation Guidance and DHA-Procedural Manual, 6025.13 "Clinical Quality Management in the Military Health System Volume 2: Patient Safety," August 29, 2019

(o) USAMMA Distribution Operations Center (DOC) Medical Materiel Quality Control (MMQC) and Medical Materiel Information (MMI) Standard Operating Procedures, August 5, 2019[3]

(p) DHA-MSR, 6025.01 "DoD Hazardous Food and Nonprescription Drug Recall System," September 6, 2018.

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[1] This document can be located at: https://community.max.gov/display/DoD/DHA-PM

[2] This document can be located at: https://www.jcrinc.com/products-and-services/publications/manuals/

[3] This document can be located at: https://community.max.gov/display/DoD/DHA-PM

ENCLOSURE 2

RESPONSIBILITIES

1. <u>DIRECTOR, DHA</u>. The Director, DHA will:

  a. Establish a MEDLOG Materiel Quality program.

  b. Designate Defense Medical Logistics Standard Support (DMLSS) as the authoritative information system (IS) used to manage medical materiel quality notifications.

  c. Ensure DHA Enterprise Activity and components follow the procedures outlined in this DHA-PM.

2. <u>SECRETARIES OF MILITARY DEPARTMENTS</u>. The Secretaries of Military Departments will ensure MTFs under their command and control maintain Alerts Tracker registration, receive Alerts Tracker messages, and comply with procedures outlined in this DHA-PM.

3. <u>COMBATANT COMMANDERS</u>. The Combatant Commanders will ensure commands under their command and control comply with procedures outlined in this DHA-PM.

4. <u>DIRECTOR, USAMMA DOC</u>. The DoD Medical Materiel Quality Control (MMQC) program is managed by USAMMA DOC while DHA MEDLOG provides policy oversight to MTFs. As the Lead Agency for MMQC messages, USAMMA DOC houses the automation application that disseminates MMQC notifications within the MHS in accordance with Reference (j). Additionally, USAMMA DOC provides lifecycle management of MMQC notifications at the headquarters level. USAMMA DOC will continue as HAR Administrator and aggregate all MMQC notifications in a central repository. The Director, USAMMA DOC will:

  a. Maintain a repository of archived MMQC messages.

  b. Release DoD specific HAR notifications (Defense Logistics Agency (DLA)-Troop Support, PQDR, DHA MEDLOG, etc.) through the Emergency Care Research Institute's (ECRI) DoD Only Channel and generate status reports through the Alerts Tracker.

  c. Identify and include all product identification information in HAR notifications.

  d. Continue disseminating messages to Operational Forces and Coast Guard.

5. <u>DIRECTOR, DEFENSE LOGISTICS AGENCY- TROOP SUPPORT (DLA-TS)</u>. As the Medical Materiel Executive Agent, the Director, DLA-TS will serve as the DoD focal point on matters regarding PQDR policy and processes PQDRs submitted by the MHS in accordance with Reference (k).

6. <u>DIRECTOR, JOINT MEDICAL LOGISTICS FUNCTIONAL DEVELOPMENT CENTER (JMLFDC)</u>. The Director, JMLFDC must:

    a. Develop technical requirements for the integration of the DMLSS Automated IS to the Enterprise Messaging System.

    b. Ensure 24 hour availability, 7 days each week, of the business-to-business connection to connection between Alerts Tracker and DMLSS to enable receipt and processing of Alert Tracker files and quickly resolves interface processing errors to minimize down time.

7. <u>ASSISTANT DIRECTORS, DHA</u>. The Assistant Directors, DHA must, ensure MEDLOG processes and procedures outlined in this DHA-PM are implemented and in compliance at DHA components.

8. <u>DEPUTY ASSISTANT DIRECTOR (DAD), MEDLOG</u>. DHA MEDLOG Directorate is the logistics focal point responsible for adjudicating medical materiel quality assurance (QA) discrepancies and PQDRs received from DHA Components. The DAD-MEDLOG must:

    a. Establish and provide management oversight of the DHA MEDLOG MMQO to administer and coordinate the HAR Notification Program in collaboration with USAMMA-DOC.

    b. Develop standard MEDLOG processes and procedures to implement this DHA-PM at DHA Components.

    c. Establish metrics that measure compliance of HAR Notification Program procedures as defined by this DHA-PM.

    d. Appoint/designate a Chief Medical Officer (CMO) to the MEDLOG Division to provide clinical advice and oversight of all PQDRs who must:

        (1) Monitor and adjudicate all Category (CAT) I PQDRs and ensure appropriate adjudication recommendations are submitted to DLA.

        (2) Downgrade CAT complaints, as appropriate, upon clinical analysis, research, and review.

(3) Notify Deputy Assistant Secretary of Defense, Health Readiness Policy and Oversight of all substantiated CAT I complaints.

e. Assign a clinician to the MMQO as HAR Program Manager to provide oversight of the medical materiel quality program.

f. Establish training requirements, monitor compliance, and track completion for roles assigned or reporting to the DHA MEDLOG MMQO.

g. Oversee and monitor MMQO actions and provide clinical disposition reports as necessary to DAD, Healthcare Operations, or Chief, Clinical Support Division.

h. Develop MEDLOG procedures and provide communication feedback to clinical quality management for MTF Directors to inform patients affected by materiel included in HAR notifications in accordance with Reference (n).

9. CHIEF OF SUPPLY MANAGEMENT, MMQO. In accordance with Reference (f), DHA MEDLOG will establish and operate an MMQO. The Chief of Supply Management, MMQO must:

a. Inform DAD-MEDLOG of all FDA Class I HAR messages and associated actions.

b. Coordinate with USAMMA DOC to receive, validate, create, and disseminate HAR notifications as outlined in this DHA-PM and required via approved sources. Approved sources include FDA, ECRI, Manufacturer Alerts, DMLSS, Product Data Reporting and Evaluation Program, Theater Enterprise-Wide Logistics System (TEWLS).

c. Receive list of MTFs that do not respond to FDA Class I HAR messages from USAMMA DOC.

d. Notify DHA Chief, Clinical Quality Management Division of MTFs that do not respond to FDA Class I HAR messages within timelines outlined in this DHA-PM for action via the DAD-MEDLOG, CMO.

e. Assist and guide DHA components and MTFs until transitioned to DHA in the proper handling, suspension of use, or return of recalled materiel.

f. Receive reports from USAMMA DOC based on criteria identified by the MMQO.

g. Retain authority to generate single and aggregate HAR notification information reports.

h. Appoint a HAR Program Manager.

10. <u>DHA MEDLOG HAR PROGRAM MANAGER</u>. The HAR Program Manager serves as the HAR Program Coordinator in Alerts Tracker. The HAR Program Manager works within the MMQO and liaisons between DHA MEDLOG Directorate, Defense Logistics Agency Troop Support (DLA-Troop Support), USAMMA DOC, DHA Components, and MTFs in all clinical and technical QA matters and must:

a. Assist in the development of overarching procedural guidance; provide technical support and training to MTF HAR Coordinators and Clinical Teams at DHA Components in accordance with resources outlined in this DHA-PM.

b. Establish and provide access to program execution and reporting expectations for basic user training and/or coordinator training for assigned MTF HAR Coordinators on the designated authoritative IS or DoD authorized automated applications needed to receive and manage HAR notifications.

c. In coordination with Senior Service Representatives, establish HAR Account Coordinators to request user accounts in ECRI at the MTF.

d. Monitor and provide oversight for all HAR notifications and ensure all HAR notifications are disseminated to the MTF HAR Coordinators as appropriate.

e. Monitor and request status for all open FDA Class I HAR notifications in the alerts tracker, for example, the ECRI Alerts Tracker.

f. Document and maintain DHA Component and MTF actions for HAR notifications as reported by the HAR MTF Coordinator. Report non-responses for MTFs that do not respond to or acknowledge FDA Class I messages to the DAD-MEDLOG, Medical Materiel Quality Office.

g. Manage and receive updated DHA Component and MTF user registration lists from the Senior Service Representatives and DHA twice per fiscal year.

h. Provide all DHA Component and MTF user registration to ECRI and track HAR notification dissemination to DHA Components, MTFs, and registered users.

11. <u>LIAISON OFFICERS, DIRECT SUPPORT ORGANIZATIONS, DHA COMPONENTS AND/OR MARKETS</u>. Liaison Officers, Direct Support Organizations, DHA Components, and/or Markets will, receive and be informed of Critical Priority/Class I HAR notifications.

12. <u>MTF DIRECTOR</u>. The MTF Director must:

a. Appoint a clinician as HAR Coordinator from MTF clinical staff to oversee and manage HAR associated actions and ensure clinical functions are completed as directed in this PM. By

virtue of the program's clinical nature, the MTF Logistics Officer cannot also serve as HAR Coordinator. Also, the HAR Coordinator does not address operational needs or update support for Combatant Commanders

b. Appoint a MTF Logistics Officer to support the MTF Clinical Team and ensure logistics functions are completed in the authoritative IS in compliance with Reference (o).

c. Ensure each clinical department appoints primary and secondary HAR Representative(s) to work with the MTF Logistics Team, identify materiel included in HAR notifications within their respective departments, complete and submit necessary documentation, and fulfill all training requirements as directed by this DHA-PM. HAR Representatives will also coordinate with medical food inspection personnel, consistent with procedures outlined in Reference (p).

d. Follow procedures outlined in Reference (p) when the item is a food or non-prescription medication.

e. Establish an effective medical materiel quality program and designate appropriate logistics, pharmacy, dental, patient safety, risk management and clinical quality management participation in accordance with Reference (i) and References (l) through (p).

13. <u>MTF HAR COORDINATOR</u>. The MTF HAR Coordinator must:

a. Act as the HAR Facility Coordinator in Alerts Tracker and will be appointed by the MTF Director from the MTF Clinical Team.

b. In the Alerts Tracker, view and acknowledge all alerts and notifications received from approved sources according to required receipt response times detailed in Table 2. Category I or Category II deficiencies discovered during facility shutdowns on weekends or holidays should be reported or acknowledged on the next business day in compliance with Reference (k).

c. Ensure MTF clinical departments and the MTF Logistics Officer are informed by e-mail and acknowledge receipt of FDA Class I HAR notifications within timelines detailed in Table 2. This is a failsafe mechanism to ensure a level of visibility and transparency for HAR notifications.

d. If a HAR message requires patient notification, coordinate with MTF clinical departments, report findings and disposition to the MTF Director and the MMQO via the DHA MEDLOG, HAR Program Manager.

e. Ensure PQDRs for defective medical materiel are completed and received by designated personnel as outlined in this PM and in compliance with Reference (k).

f. Maintain managerial and reporting requirements or permissions in alert tracker for that specific DHA component.

g. Ensure appropriate users are registered in the alerts tracker for the appropriate roles prescribed in this DHA- PM (see Appendix 2).

14. <u>MTF LOGISTICS OFFICER</u>. The MTF Logistics Officer must:

a. Be responsible for ensuring all MEDLOG actions associated with HAR notifications are complete within timeframes outlined in this DHA-PM.

b. Ensure MEDLOG processes are actioned and completed in DMLSS, as well as submit findings/supporting documentation to the MTF HAR Coordinator. DMLSS is used interchangeably with "the authoritative IS" in this DHA-PM in accordance with DHA-IPM, "Use of DMLSS as the Authoritative IS" in military MTFs and DHA components upon publication.

c. Ensure the appropriate trained technical staff responsible for the functional management of affected product(s) action each HAR message as outlined in this DHA-PM. It is not recommended to combine the responsibilities of both the Materiel Management Category and Clinical/Biomedical Engineering Categories due to significant differences in the tasks required to complete the actions.

d. Identify an appropriate responsible functional manager to review HAR messages. The MTF Logistics Officer will adjudicate HAR messages affecting medical supplies and identify Healthcare Technology Management personnel to review and adjudicate all messages affecting maintenance significant medical devices and equipment in accordance with procedures outlined in this DHA-PM.

e. Designate a Logistics Team to support the dissemination of matched messages, identify and segregate materiel, follow HAR notification instructions for materiel disposition, and report findings and actions taken to the MTF Logistics Officer.

15. <u>MTF LOGISTICS TEAM</u>. The Logistics Team must:

a. Receive HAR notifications from approved sources to determine whether the MTF is affected by materiel that is subject to the HAR notice.

b. Identify affected materiel, follow notification instructions, complete disposition actions as required, and record actions taken in the approved authoritative IS.

c. Complete required actions within the HAR notification for product identifiers that match within MTF Catalog.

d. Identify items where product identifiers do not match within catalog and search for non-matched HAR messages. Coordinate with HAR Representatives to ensure deficient product reports (e.g., PQDRs) are completed and submitted to DLA through approved sources in compliance with Reference (k) and steps instructed in this DHA-PM.

e. Ensure disposition actions for HAR notifications and MMQC messages are documented and reported in accordance with the requirements described in this DHA-PM.

f. Ensure MTFs/DHA components with the capability to designate Pharmacy and Dental HAR Representatives action the recall message, coordinate with medical food inspection personnel in accordance with reference (p), and report actions taken directly to the MTF HAR Coordinator. MTFs/DHA Components without the capability to designate Pharmacy and Dental HAR Representatives may receive actions taken by pharmacy and dental designated representatives on materiel affected by HAR messages and coordinate return of recalled pharmacy and dental materiel with designated representatives according to timelines outlined in Table 2.

g. Ensure appropriate materiel management and logistics personnel are registered with ECRI as identified in this DHA-PM.

h. Ensure logistics actions described in this DHA-PM are complete in the approved authoritative IS and alerts tracker and report all logistics actions to the MTF HAR Coordinator as outlined in this DHA-PM and report any findings and/or actions to the MTF Logistics Officer.

15. <u>HAR REPRESENTATIVE</u>. Each MTF Department will assign a primary and secondary HAR Representative(s) to communicate with the MTF's Logistics Team, clinical departments and MTF HAR Coordinator as required by this PM and to coordinate with medical food inspection personnel regarding hazardous food and non-prescription drugs consistent with reference (p). HAR Representatives will receive HAR notifications and:

a. Assist the MTF Logistics Officer in completing logistics disposition actions as required.

b. Assist the MTF HAR Coordinator to identify, notify and complete necessary documentation when materiel affected by the HAR notification is found in their departments or administered to patients.

c. Collaborate with Logistics Team to complete PQDRs for materiel identified within their respective departments, as well as ensure necessary documentation is complete and submitted in accordance with Reference (k).

ENCLOSURE 3

PROCEDURES

1. <u>INTRODUCTION</u>. Procedures outlined in this DHA-PM are intended to standardize HAR notification practices and provide guidance for the suspension, reporting, and disposition of medical or dental materiel found to be defective, unsafe, or otherwise unsatisfactory for use at DHA components.

    a. <u>HAR Notification Process</u>. The HAR notification process begins with the issuance of a hazard and safety alert and proceeds through to receipt of disposition feedback. Hazard and safety alerts can be issued by a variety of materiel manufacturers and distributors, as well as the FDA, DLA, and others in the medical community. Alerts are accessible through various methods that include email notifications from distributors or manufacturers, commercial company messaging, FDA website, and within DoD MEDLOG automated systems or websites.

    b. <u>Recalls</u>. Recalls, unlike hazard and safety alerts, can only be initiated by the product manufacturer or the FDA. Recall messages are available through the same methods as hazard and safety alerts and form the basis of HAR notification and MMQC messages.

    c. PQDR Procedures. Procedures outlined in this DHA-PM will also define PQDRs and their potential impact to MTFs. Users should understand that not all PQDRs will result in the creation of a HAR notification or MMQC message, but that HAR notifications or MMQC messages may require completion of deficiency reports. This DHA-PM details instructions for MTFs to initiate and exchange deficiency reporting information.

    d. <u>MMQC Migration Process</u>. This DHA-PM also covers initial migration processes that replaced the USAMMA DOC MMQC/MMI application with the ECRI Alert Tracker as the approved DoD commercial message source as described in Appendix 1. The ECRI Alert Tracker provides HAR notifications while maintaining communication with Theater Enterprise-Wide Logistics System (TEWLS), Joint Medical Asset Repository, and DMLSS applications for anticipated improved dissemination cycle times. However, DHA components must still action and complete logistics functions associated with HAR notifications in DMLSS.

2. <u>HAR MATERIEL PRIORITY CATEGORIES</u>

    a. <u>HAR classifications/terminology.</u> Table 1 defines HAR classifications and terminology used by various sources and automated systems to categorize HAR notifications based on significance but is not a one-to-one correlation. An alerts tracker Critical Priority identified in Table 1 is not the same as a FDA Class I Recall. DMLSS classifications listed correspond with the appropriate FDA class.

b. <u>USAMMA DOC Informational Messages</u>. USAMMA DOC Informational Messages will now appear in DoD Only Channel starting with "X." Further details regarding DMLSS classes are located in Reference (p).

Table 1. <u>HAR Materiel Priority Categories</u>

ECRI	USAMMA DOC	FDA	DMLSS
Critical Priority: Hazards, recalls, or other issues describing problems that, if left unresolved, are likely to result in serious health consequences for patients or users or other significant adverse consequences.	N/A	**Class I Recall:** a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.	**Class I**: Reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
High Priority: Hazards, recalls, or other issues describing problems that, if left unresolved, may lead to serious health consequences for patients or users, significant financial losses for the healthcare facility, or severe equipment damage	N/A	**Class II Recall:** a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.	**Class II:** Exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote
Normal Priority: Hazards, recalls, or other issues describing problems that, if left unresolved, may cause patient or staff injuries or other health problems, financial losses for the healthcare facility, or equipment damage. Although serious injuries or other significant adverse consequences may be possible, the probability of such consequences is low.	N/A	**Class III Recall:** a situation in which use of or exposure to a volatile product is not likely to cause adverse health consequences.	**Class III**: The use of, or exposure to, a violative product is not likely to cause adverse health consequences.
Not Prioritized: Alerts posted without a priority are considered "completed" or "terminated." These Alerts do not require any action on the part of the user. ECRI Institute publishes these Alerts to our database to allow users to search for product safety histories for certain devices.	**Informational**: Manuals, procedure, or updates for equipment, etc.	N/A	**Informational:** Alert is informational only.

3. <u>MMQO HAR PROCESS</u>. The MMQO is a DHA MEDLOG construct designed to coordinate with USAMMA DOC to process and action HAR notifications according to

responsibilities outlined in Enclosure 2 of this DHA-PM. The MMQO must track MTF responses and materiel disposition actions in compliance with timelines defined in Table 2.

4. <u>HAR MESSAGE SOURCES</u>. Medical alerts and recalls can be initiated by sources such as FDA, DHA, DLA, or other sources such as Prime Vendor, manufacturers, distributors, etc. Stakeholders must recommend HAR messages to USAMMA DOC for publication through DoD Only Channels. Initial receipt of medical alerts and recalls are known as HAR messages, which are received and monitored by USAMMA DOC and the DHA MEDLOG MMQO to determine priority, assemble source documentation, and analyze DoD relevance. HAR messages may be later converted to HAR notifications and disseminated to the MHS based on the results of this combined research.

   a. <u>HAR Notifications</u>. HAR notifications are generated in a format that contain materiel characteristics, product identifiers, disposition instructions, and other related materiel information. This information helps MTF Logistics and clinical staff identify potentially unsafe or harmful materiel and ensure the proper suspension of use, handling, and return of recalled products is accomplished.

   b. <u>Class I HAR Notifications.</u> USAMMA DOC along with the DHA MEDLOG MMQO monitors and requests status for all open Class I HAR notifications, documents and tracks DHA component progress, and reports non-responsive DHA components to Director, DHA via the Chief, MEDLOG Division.

   c. <u>Vendor Recalls/Alerts To MTF</u>. For recalls or alert notices received directly in the MTF from a vendor for items purchased, MTFs must immediately notify the MTF HAR Coordinator and MTF Logistics Officer for elevation to DHA MEDLOG and take action based on recall message directions. The MTF should retain the original notices and be prepared to update DMLSS when the MMQCs are downloaded.

5. <u>HAR MESSAGE VERIFICATION</u>. USAMMA DOC and the DHA MEDLOG MMQO conducts adequate research to associate materiel subjected to an alert or recall message with existing materiel that has been assigned a current national stock numbers (NSN) and other salient materiel characteristics, such as manufacturer part number or national drug code "NDC" is cross referenced. Matching an NSN to a particular product or materiel is critical but it is not the only method to determine whether materiel was procured, administered to, or utilized in patient care.

6. <u>MMQC/HAR RESEARCH</u>. USAMMA DOC will review all alerts, recalls, and notifications either assigned or sent to them from various sources to determine applicability, actions needed, and to:

a. DoD Relevance. Determine DoD relevance based on consignee lists, Medical Master Catalog, and verify NSNs when available.

b. NSN Match. Determine if a NSN match is found. If a NSN match is found, USAMMA DOC or the MMQO will add the NSN to the commercial source message and notify the HAR Program Manager, who will inform the HAR Unit Coordinators at MTFs to disseminate.

c. FDA Classification. Determine and verify FDA classification when available.

d. Source Documentation. Locate all source documentation available including FDA, DLA, and ECRI alerts or recalls as well as manufacturer and distributor letters.

e. Previously Released MMQC/HAR Messages. Verify any related MMQC/HAR messages, previously released, and determine the action needed.

7. MMQC/HAR CREATION. Upon receipt of an alert or notification from the various sources listed, USAMMA DOC will create the MMQC/HAR required as outlined in Figure 1. USAMMA DOC will create all immediate FDA Class I and CAT I PQDR within 24 hours. All other HAR notifications will be created within 5 business days.

a. DoD Only Channel. USAMMA DOC will create MMQC and non-alerts tracker messages that are DoD relevant in the DoD Only Channel.

b. Alerts Tracker. The alerts tracker will transmit all HAR messages via DMLSS, TEWLS, and Joint Medical Asset Repository (JMAR).

8. ALERT TYPES. The MMQO will action HAR messages based on classifications in Table 1, which determine dissemination, and response times outlined in Table 2.

a. Class I/Critical Priority. The most significant classifications are Critical Priority and FDA Class I as defined in Table 1. If left unresolved, these may cause serious health or other significant adverse consequences to patients or users including patient death. If the materiel included in the HAR message is either in use at a DHA component or patients were not notified of its use during patient care, serious health or other significant adverse consequences can arise.

(1) HAR messages identified as Critical Priority and FDA Class I require immediate processing and notification to DHA components.

(2) MMQO will receive acknowledgement from MTF HAR Unit Coordinators of Critical Priority/Class I HAR notifications within 24 hours but no later than 3 business days after dissemination. For example, if the MMQO notifies an MTF on a Friday, overseas commands may not receive the message until Saturday. In this case, the command must respond by the following Monday.

(3) The FDA Class I HAR notification depicted by Figure 2 is disseminated to MTF HAR Unit Coordinators at DHA components for processing. A DHA HAR Notification Executive Summary is released for all messages assigned FDA Class I after USAMMA DOC reviews the message for content and accuracy.
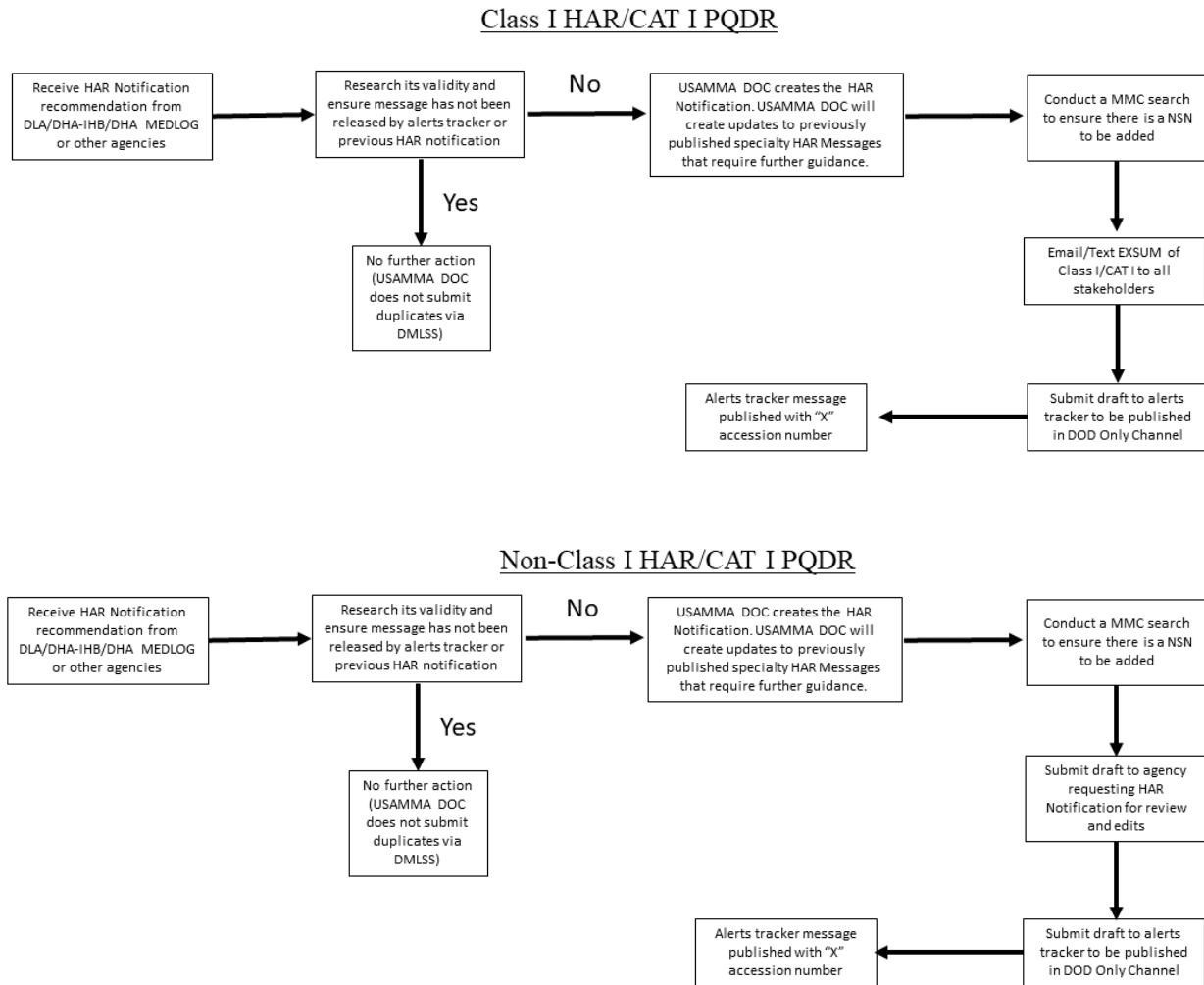
Figure 1. USAMMA DOC HAR/PQDR Process Overview

Class I HAR/CAT I PQDR

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┌──────────────────┐      ┌──────────────────┐   No   ┌──────────────────┐      ┌──────────────────┐
│ Receive HAR      │      │ Research its     │ ─────► │ USAMMA DOC       │ ───► │ Conduct a MMC    │
│ Notification     │ ───► │ validity and     │        │ creates the HAR  │      │ search to ensure │
│ recommendation   │      │ ensure message   │        │ Notification.    │      │ there is a NSN   │
│ from DLA/DHA-IHB/│      │ has not been     │        │ USAMMA DOC will  │      │ to be added      │
│ DHA MEDLOG or    │      │ released by      │        │ create updates to│      └──────────────────┘
│ other agencies   │      │ alerts tracker or│        │ previously       │               │
└──────────────────┘      │ previous HAR     │        │ published        │               ▼
                          │ notification     │        │ specialty HAR    │      ┌──────────────────┐
                          └──────────────────┘        │ Messages that    │      │ Email/Text EXSUM │
                                   │ Yes              │ require further  │      │ of Class I/CAT I │
                                   ▼                  │ guidance.        │      │ to all           │
                          ┌──────────────────┐        └──────────────────┘      │ stakeholders     │
                          │ No further action│                                  └──────────────────┘
                          │ (USAMMA DOC does │                                           │
                          │ not submit       │                                           ▼
                          │ duplicates via   │        ┌──────────────────┐      ┌──────────────────┐
                          │ DMLSS)           │        │ Alerts tracker   │ ◄─── │ Submit draft to  │
                          └──────────────────┘        │ message published│      │ alerts tracker to│
                                                      │ with "X"         │      │ be published in  │
                                                      │ accession number │      │ DOD Only Channel │
                                                      └──────────────────┘      └──────────────────┘
```

Non-Class I HAR/CAT I PQDR

```
┌──────────────────┐      ┌──────────────────┐   No   ┌──────────────────┐      ┌──────────────────┐
│ Receive HAR      │      │ Research its     │ ─────► │ USAMMA DOC       │ ───► │ Conduct a MMC    │
│ Notification     │ ───► │ validity and     │        │ creates the HAR  │      │ search to ensure │
│ recommendation   │      │ ensure message   │        │ Notification.    │      │ there is a NSN   │
│ from DLA/DHA-IHB/│      │ has not been     │        │ USAMMA DOC will  │      │ to be added      │
│ DHA MEDLOG or    │      │ released by      │        │ create updates to│      └──────────────────┘
│ other agencies   │      │ alerts tracker or│        │ previously       │               │
└──────────────────┘      │ previous HAR     │        │ published        │               ▼
                          │ notification     │        │ specialty HAR    │      ┌──────────────────┐
                          └──────────────────┘        │ Messages that    │      │ Submit draft to  │
                                   │ Yes              │ require further  │      │ agency requesting│
                                   ▼                  │ guidance.        │      │ HAR Notification │
                          ┌──────────────────┐        └──────────────────┘      │ for review and   │
                          │ No further action│                                  │ edits            │
                          │ (USAMMA DOC does │                                  └──────────────────┘
                          │ not submit       │                                           │
                          │ duplicates via   │                                           ▼
                          │ DMLSS)           │        ┌──────────────────┐      ┌──────────────────┐
                          └──────────────────┘        │ Alerts tracker   │ ◄─── │ Submit draft to  │
                                                      │ message published│      │ alerts tracker to│
                                                      │ with "X"         │      │ be published in  │
                                                      │ accession number │      │ DOD Only Channel │
                                                      └──────────────────┘      └──────────────────┘
```

Figure 2. FDA Class I HAR Notification Example

b. <u>Class II/High Priority</u>. FDA Class II and High Priority Alerts are defined in Table 1. FDA Class II Alerts identify materiel in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. High Priority Alerts describe issues or problems that, if left unresolved, may lead to patient or user death, serious injuries or permanent health problems, significant financial losses for the healthcare facility, or severe equipment damage.

c. <u>Class III/Normal Priority</u>. FDA Class III Alerts and Normal Priority Alerts are defined in Table 1. FDA Class III Alerts identify materiel in which use of or exposure to a violative product is not likely to cause adverse health consequences. Normal Priority Alerts describe problems that, if left unresolved, may cause patient or staff injuries or other health problems, financial losses for the healthcare facility, or equipment damage. Although serious injuries or other significant adverse consequences may be possible, the probability of such consequences is low.

d. Not Prioritized/Informational. Not Prioritized Alerts posted without a priority are considered "completed" or "terminated." Not prioritized messages are disseminated as "Informational" in DMLSS. Informational messages are created when manufacturers provide additional materiel information such as a manual update or FDA safety alert.

e. Market Withdrawal. Occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing, or distribution problems would be a market withdrawal.
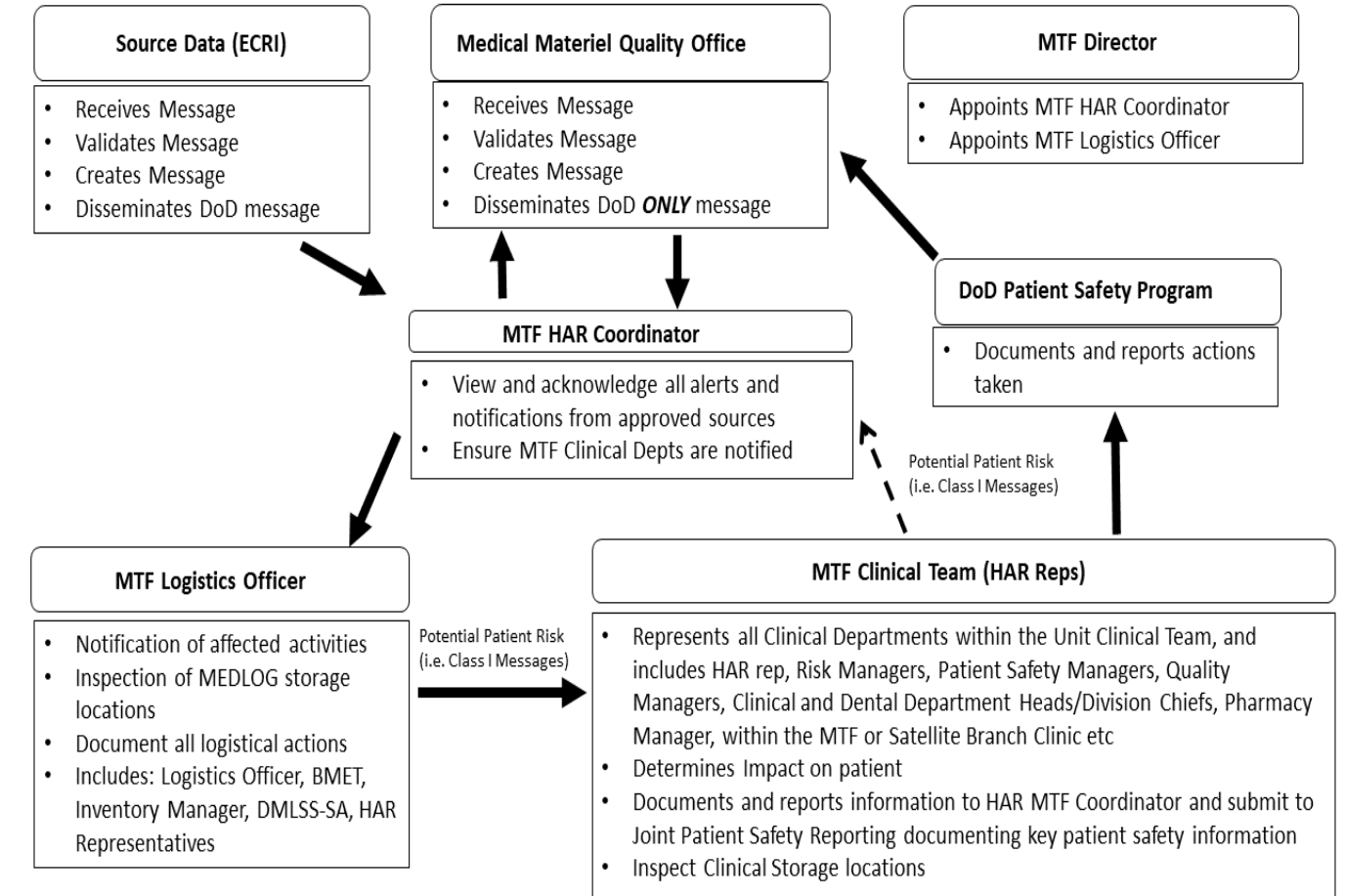
f. Medical Device Safety Alert. Issued in situations where a medical device may present an unreasonable risk of substantial harm. In some cases, these situations also are considered recalls.

g. Unclassified. HAR messages that are not classified as I, II, or III by the FDA, but identified as a recall, are considered unclassified. The message is still created and disseminated to all MTFs.

h. All Food and Drug Activity (ALFOODACT) Messages. ALFOODACT messages are issued for hazardous food and non-prescription drugs, consistent with Reference (p) and this publication.

Figure 3. HAR Functional Responsibilities

When message pertains to a food or non-prescription drug, refer to processes outlined in reference (p)

Source Data (ECRI)

- Receives Message
- Validates Message
- Creates Message
- Disseminates DoD message

Medical Materiel Quality Office

- Receives Message
- Validates Message
- Creates Message
- Disseminates DoD *ONLY* message

MTF Director

- Appoints MTF HAR Coordinator
- Appoints MTF Logistics Officer

MTF HAR Coordinator

- View and acknowledge all alerts and notifications from approved sources
- Ensure MTF Clinical Depts are notified

DoD Patient Safety Program

- Documents and reports actions taken

Potential Patient Risk (i.e. Class I Messages)

MTF Logistics Officer

- Notification of affected activities
- Inspection of MEDLOG storage locations
- Document all logistical actions
- Includes: Logistics Officer, BMET, Inventory Manager, DMLSS-SA, HAR Representatives

Potential Patient Risk (i.e. Class I Messages)

MTF Clinical Team (HAR Reps)

- Represents all Clinical Departments within the Unit Clinical Team, and includes HAR rep, Risk Managers, Patient Safety Managers, Quality Managers, Clinical and Dental Department Heads/Division Chiefs, Pharmacy Manager, within the MTF or Satellite Branch Clinic etc
- Determines Impact on patient
- Documents and reports information to HAR MTF Coordinator and submit to Joint Patient Safety Reporting documenting key patient safety information
- Inspect Clinical Storage locations

9. <u>HAR NOTIFICATION TIMELINES</u>.

a. <u>Dissemination and Response Times</u>. Dissemination and response times associated with each Priority category are detailed in Table 2. DHA MEDLOG MMQO and USAMMA DOC will receive MTF and DHA components' acknowledgement of receipt within timelines listed in Table 2.

b. <u>Weekends/Holidays</u>. Pursuant to Reference (k), Category I or Category II PQDR deficiencies discovered during facility shutdowns on weekends or holidays should be reported or acknowledged on the next business day.

<u>Table 2. Required Action Timelines</u>

Priority	MTF HAR Coordinator	MTF Medical Logistics
Critical Priority or FDA Class I	Acknowledge receipt in alerts tracker with 24 hours	Research and retrieve matched materiel or open work order in DMLSS within 72 hours
High Priority or FDA Class II	Acknowledge receipt in alerts tracker with 48 hours	Retrieve matched materiel or open a work order in DMLSS within 10 calendar days
Normal Priority or FDA Class III	Acknowledge receipt in alerts tracker within 96 hours	Retrieve matched materiel or open a work order in DMLSS within 10 calendar days
Not Prioritized	Acknowledge receipt in alerts tracker within 96 hours	Retrieve matched materiel or open a work order in DMLSS within 30 calendar days

10. <u>MTF PROCESS</u>. MTFs must monitor and receive HAR notifications, identify affected materiel, complete required disposition actions, and inform any staff or patients who may be affected in compliance with References (e) through (h) and References (j) through (l). This DHA-PM does not direct MTFs or include instructions to notify patients who may be affected by recalled materiel, as patient notification is not an inherent MEDLOG function or process. MTFs should follow guidance outlined in References (i) and (l) through (n) for patient notification procedures.

a. <u>MTF HAR Coordinators</u>. MTF HAR Coordinators must forward HAR notifications to, and confirm receipt by, MTF Clinical Teams, HAR Representatives, and MTF Logistics Team. MTF HAR Coordinators will:

(1) Ensure required logistics/clinical actions are completed within timelines outlined in Table 2 as well as report findings and materiel disposition to the MTF Director and the DHA MMQO.

(2) Rely on the MTF Logistics Officer to ensure the logistics actions illustrated in Figure 4 are complete.

(3) Receive documentation from the Logistics Officer that details specific MEDLOG actions completed for each HAR message.

(4) Ensure all clinical actions are completed by MTF clinical staff and appropriate patient notification steps taken in the event potentially unsafe materiel was administered.

b. <u>MTF Logistics Team</u>. The MTF Logistics Officer will ensure all MEDLOG actions associated with HAR notifications are completed within timeframes outlined in this DHA-PM. The Logistics Officer will also oversee the MTF Logistics Team, who must make every effort to determine if materiel included in HAR notifications was procured, acquired or is in use at MTFs and DHA components. To accomplish this, the MTF Logistics Team must work both auto-matched and non-matched materiel as described in this DHA-PM.

c. <u>Matched</u>. DMLSS performs an automatic search to MTF Catalog records to determine if salient characteristics included in the HAR notification are associated with materiel received or procured by the MTF. This process, commonly known as auto matching, provides an efficient, reliable method for MTFs to identify materiel subject to HAR Notifications. HAR Notifications that describe materiel successfully auto matched in the MTF catalog should follow actions outlined in Figure 4. The MTF Logistics Team will:

(1) Receive all HAR notifications/MMQC messages in DMLSS and perform materiel inventory research on matched messages. Respond to MTF HAR Coordinator for Class I/Critical Priority within timelines outlined in Table 2.

(2) Notify affected MTF Clinical Departments to include satellite medical and dental units, as applicable.

(3) Inspect MEDLOG storage locations, contingency assemblages, Patient Movement Items, and MEDLOG managed storage locations for affected materiel and remove as required.

(4) Ensure HAR Representatives inspect MTF clinical department's storage locations for affected materiel, to include satellite medical and dental units, and coordinate removal of affected materiel with the respective Department Head/Division Chief, Department/Division Custodian and HAR Representative.

(5) Medical equipment found that matches HAR notification descriptions require evaluation by certified Biomedical Equipment Technicians (BMET).

(6) Equipment maintenance, handling or removal should only be executed by qualified BMETs certified to remove affected equipment in accordance with disposition instructions contained within the HAR Notification.

(7) Suspend all affected materiel in segregated storage and affix DD Form 1575, Suspended Tag – Materiel or DD Form 1575-1, Suspended Label – Materiel until all disposition instructions are received and actions complete.

(8) Document actions taken in DMLSS QA record, such as customer turn-ins or transfers of inventory to stratification state "Suspended," will include quantities and document numbers for audit purposes. Negative replies, such as "no product found in MTF" should also be recorded.

(9) Ensure equipment alerts and recalls are documented with a DMLSS Work Order (WO) number and reference the WO number in the comments field in the MMQC message.

(10) Notify the MTF HAR Coordinator of the date of the recall/alert, source (DoD MMQC, ECRI, FDA, etc.), item description and quantities removed from use, WO number, and completion date for any resulting maintenance actions for materiel made subject to a HAR notification within message timelines outlined in this DHA-PM.

(11) Ensure required logistics actions taken as a result of HAR Notifications are performed by the MTF Logistics Team and closed in DMLSS by the appropriate MTF Logistics Team member(s) in accordance with timelines outlined in Table 2.

Figure 4. MTF/DHA Component Logistics Team Process
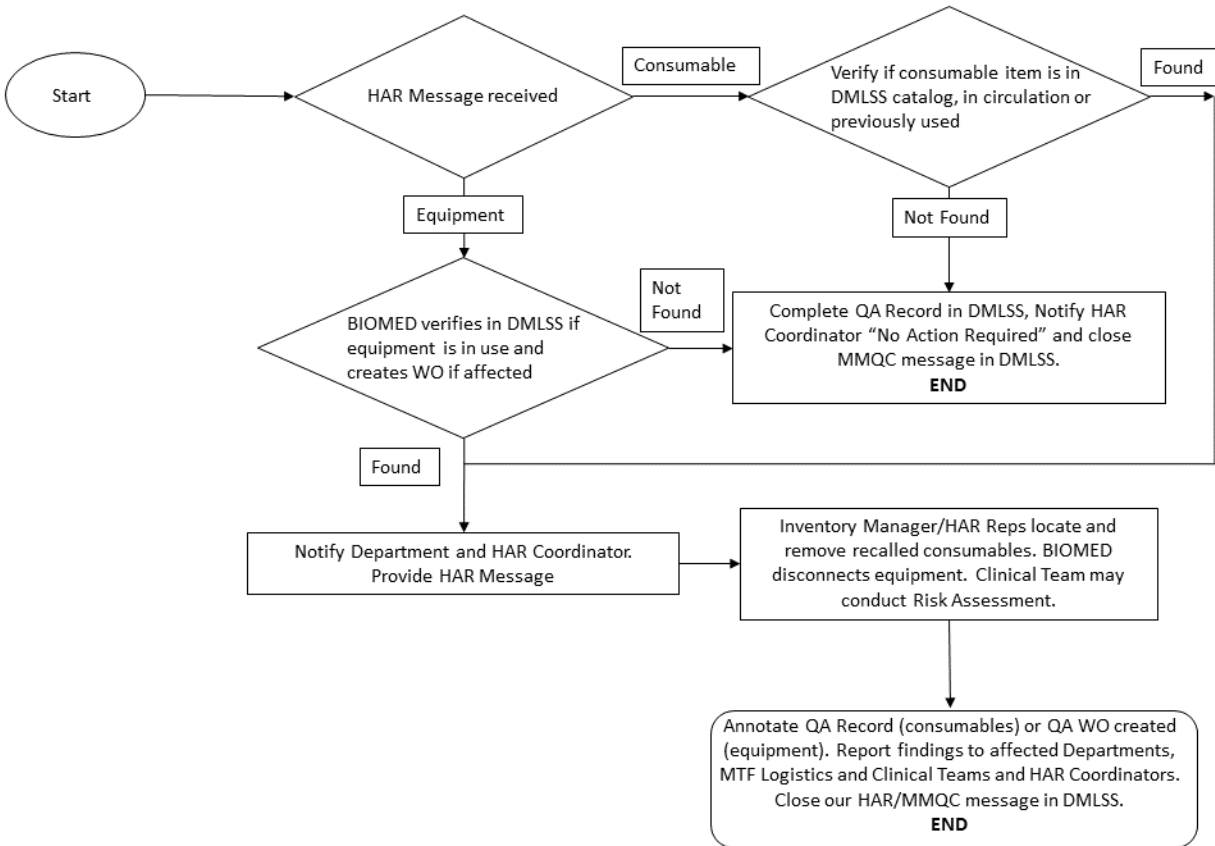
d. <u>Non-Matched</u>. All non-matched notifications require manual research to ensure locally purchased items are not overlooked. In instances where materiel subject to HAR notifications are unsuccessfully auto matched to an existing item ID, MTFs and DHA components should adhere to the following procedures:

(1) The MTF Logistics Officer will make every reasonable effort to match information included in the HAR notification to products within the MTF's master inventory catalog, using product description, brand-name and all item identification information detailed to determine if materiel was procured, acquired or is in use.

(2) If found, the MTF Logistics Team should add the item ID to the MMQC message. This will assist in notifying customers and clinical departments of recalled materiel and prompt clinical departments to perform searches within their respective clinical areas. The MTF Logistics Team will now treat the message as matched and handle according to auto-matched procedures.

(3) In the event the MTF Logistics Officer is unsuccessful in matching item identification information in the HAR notification to materiel within the MTF Master Catalog or should the MTF Logistics Officer determine a match is impossible to make, they must inform the

HAR Unit Coordinator that materiel subject to the HAR Notification does not appear in the MTF catalog and enter "No Record Found" in the QA Record, QA Action, and select "Close."

(4) Should clinical departments find additional materiel after the HAR message closure, the custodian will turn-in additional materiel to Medical Logistics. If the clinical department determines non-matched materiel was administered to or used on a patient, the HAR Representative or Clinical Department Head will report these findings to the MTF HAR Coordinator within 24 hours of the finding. The MTF HAR Coordinator will inform and recommend further actions to the MTF Director. The MTF Director will review and approve the consolidated report and forward to the DHA Market/Intermediate Headquarters in compliance with Reference (n).

    e. Reports. The MTF Logistics Officer will use the DHA DMLSS BO Report HAR for consumables and equipment. For Healthcare Technology Management, this report does not replace initiating a Work Order (WO) for equipment affected by HAR notifications.

(1) The QA report and WO should detail logistics actions taken, affected lots, clinical departments involved, disposition, and roles of MTF Staff involved prior to editing the QA record or closing the WO.

(2) The MTF Logistics Officer must also ensure a copy of the WO is forwarded to the Department Head/Division Chief, Department/Division Custodian of the affected MTF Department and the MTF HAR Coordinator but will not engage, initiate, or participate in any patient notification procedures.

11. PQDR PROCESS. DLA Troop Support (Troop Support)-Medical is the DoD Executive Agent responsible for managing medical and dental PQDRs, in accordance with Reference (k), while DHA MEDLOG serves as the clinical focal point supporting DLA PQDR program in accordance with Reference (e). PQDRs may apply to medical or dental products in MTFs and DHA components. This DHA-PM provides procedures for DHA components to maintain a reliable and standard system for investigating PQDRs, use all realistic methods to avoid closing a PQDR with an undetermined cause, correct the existing deficiency, provide disposition instructions for deficient materiel, and identify actions to prevent recurrence of deficiencies before closing PQDRs as directed by Reference (k).

    a. PQDR Purpose. PQDRs are used to document deficiencies and provide as much information as is available that may help determine the root cause of the deficiency, identify corrective action to be taken, and inform others of the discovered deficiency.

    b. HAR Notification. Dependent upon MMQO clinical review and CMO validation, a PQDR may or may not result in the creation of a HAR notification.

    c. PQDR Creation. When MTF staff determine that a deficiency exists, they will need to complete a PQDR to document defective products using form SF 368, Product Quality Deficiency Report (PQDR). Clinical departments should engage the assigned HAR

Representative to ensure the form is completed properly and forwarded to the MTF Logistics Officer for processing. Examples of deficiencies to document include:

    (1) Suspected counterfeit materiel.

    (2) Systemic equipment failures or faulty equipment.

    (3) Defective products.

    (4) Incorrect or deficient labeling.

    (5) Foreign particulate or matter in liquids and solids.

    (6) Items which are off-color, off-taste, or off-odor.

    (7) Suspected pharmaceuticals and biologics.

    (8) Pinholes in tubing.

    (9) Poor quality products.

    d. <u>PQDR Categories</u>. Department of Defense Medical Materiel Complaints are categorized as either Category I or II.

    (1) 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 failure, malfunction, improper or inadequate design, manufacture, labeling, and user error.

    (2) Category II complaints are all other complaints that do not meet the severity level for a Category I. These complaints will be processed as a Category II complaint including: systemic equipment failures, defective devices, incorrect or deficient labeling, foreign or particulate matter in liquids or solids, imperfectly manufactured items that are off-color, off-taste, or off-odor; suspected sub-potency or super-potency of drugs and biologics, pinholes in tubing, faulty calibrations, and poor quality products.

    e. <u>PQDR Submission</u>. Detailed instructions to complete SF 368, Product Quality Deficiency Report (PQDR) and PQDR submission are found in Reference (k). The MTF Logistics Officer or designee submits PQDRs to DLA-TS via the following methods:

    (1) Report the issue using the QA Complaint option in DMLSS. This option will help DHA components locate the proper form to complete.

    (2) Download and complete the SF 368 from DMM online at: https://www.medical.dla.mil/Portal/Customer/ProductQualityDeficiency.aspx.

(3) Attach and send the completed SF 368 via email to the MTF HAR Coordinator, DLA-TS to: DSCPmedqual@dla.mil and USAMMA DOC at: usarmy.detrick.medcom-usamma.mbx.sf380@mail.mil.

12. <u>MMQO PQDR PROCEDURES</u>

a. <u>Clinical Evaluation</u>. DHA MEDLOG Division, MMQO via the Chief, Quality and Optimization (Q&O) Branch receives medical and dental PQDRs by DLA for clinical evaluation and adjudication at: mailboxusarmy.detrick.medcom-dmsb.other.dmsb-sf368@mail.mil. The Chief, Q&O will:

(1) Receive and review PQDRs and acknowledge receipt of Category I PQDRs within 24 hours and within 3 calendar days for Category II PQDRs. In accordance with Reference (k), if the acknowledgement period falls during scheduled facility shutdown periods (weekends or holidays), the period will extend to the next business day.

(2) Validate complaint category and assign to appropriate DHA MEDLOG or MMQO staff (Nurse, Pharmacy, BMET, etc.) for clinical evaluation while adhering to processes outlined in Figure 6 of this DHA-PM and Reference (k).

(3) Refer validated Category I PQDRs to the CMO, DHA MEDLOG Division for final adjudication and forward PQDR close- out letter for CMO approval and signature.

(a) <u>Category Upgrades</u>. The Chief, Q&O may recommend category upgrades for CMO approval. Any upgrade to Category I requires approval by the DHA MEDLOG CMO.

(b) <u>DHA MEDLOG CMO Notification Process</u>. The CMO will notify the MEDLOG Director and the Deputy Assistant Secretary Defense, Health Affairs Health Readiness Policy and Oversight of investigation, disposition of any category upgrade, and submit close out letter for Category I PQDRs.

(4) Monitor and adjudicate all Category II PQDRs.

(5) Forward all requests to downgrade complaint priority/class categories to the DHA MEDLOG CMO for approval.

b. <u>MMQO Investigation Steps</u>. In coordination with the originating MTF and in accordance with Reference (k), MMQO clinicians processing PQDRs will:

(1) Validate information contained within the SF 368, PQDR.

(2) Request further information as needed to ensure the issue is understood.

(3) Investigate whether other staff were involved in the complaint to fully understand the issue reported in the PQDR.

(4) Assess whether this is a new product complaint or a duplicate of a previously submitted product complaint.

(5) Determine whether staff are familiar with the product.

(6) Assess materiel disposition and determine whether the MTF still has the suspected deficient product.

(7) Determine manufacturer points of contact or whether manufacturer recommendations exist.

(8) Validate whether patients were involved or whether injury or harm resulted from the use of the affected materiel. If so, the HAR Program Manager should identify the Clinical Quality Division Representative and determine whether a Joint Patient Safety Report was submitted in accordance with Reference (n).

(9) Validate FDA information (e.g., Manufacturer and User Facility Device Experience) submission. If FDA has been notified, establish what was reported and when the notification occurred and review relevant databases for administrative information of product or similar reports (Medical Master Catalog, FDA Manufacturer and User Facility Device Experience database, MMQCs, other PQDRs, etc.).

(10) Investigation outcome may result in the recommendation for PQDR category upgraded to Category I complaint and HAR notification creation. DHA MEDLOG will provide determination to USAMMA DOC for dissemination in the DoD Only Channel according to the procedures outlined in this DHA-PM.

c. <u>Process Alerts</u>. If affected materiel has an NSN and the complaint is substantiated for action, a DHA MEDLOG Supply Specialist may need to perform a Defense Medical Logistics Item Identification System action to:

(1) "Inactivate" the NSN pending the final outcome of the investigation.

(2) "Update" NSN information to meet the recommended or new product configuration or information.

(3) "Condemn" the NSN if necessary.

(4) Submit information to the USAMMA DOC MMQC Notification Coordinator for distribution to the MHS.

d. <u>PQDR Category I Administrative Close-Out</u>. Category 1 PQDRs are sent immediately to DHA MEDLOG for adjudication. The CMO will notify Director, DHA, AD-CS and DHA Patient Safety Program of any substantiated Category 1 PQDRs. Only the CMO can adjudicate and downgrade Category 1 PQDRs. The CMO will ensure adjudicated PQDRs are sent to DLA TS, the originating MTF and retained by the MMQO for a minimum of 5 years.

Figure 5. DHA MEDLOG PQDR Clinical Adjudication Process
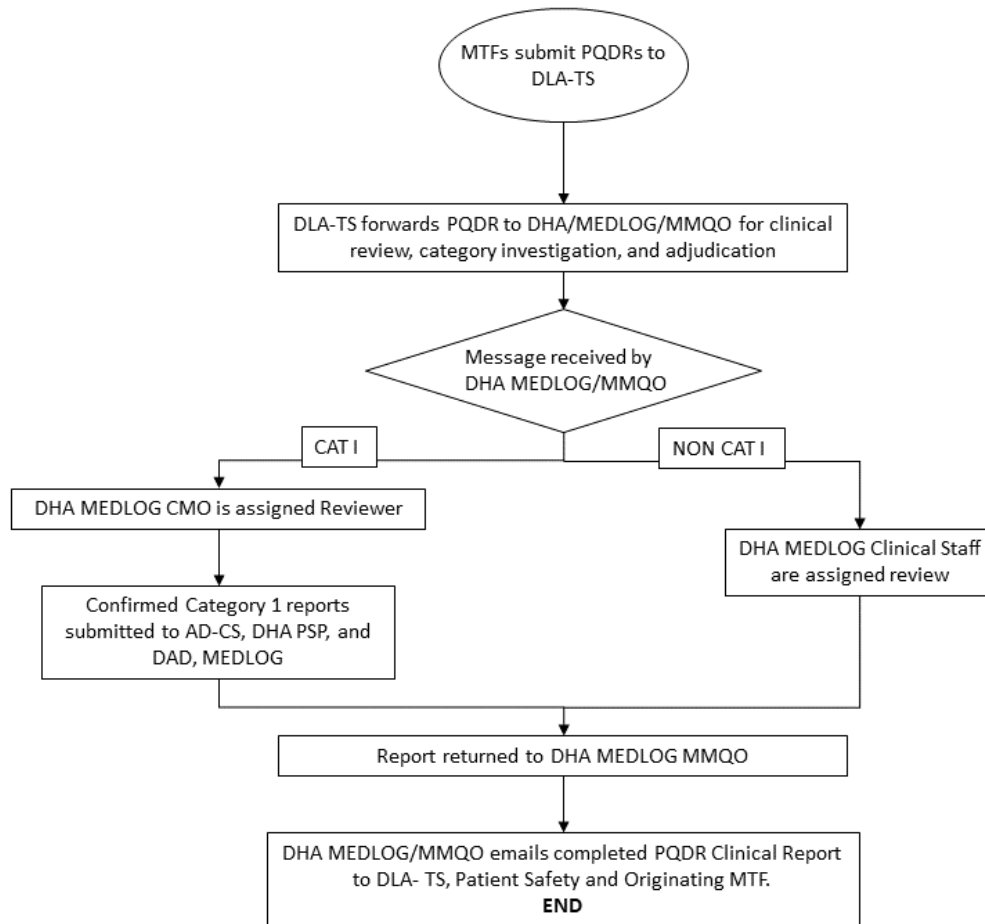
13. OUTCOMES AND MEASURES. Medical materiel quality procedures outlined in this DHA- PM create a reliable, efficient, and interoperable logistics process for DHA components. This will ensure MTFs and DHA components timely receive, validate, distribute, record disposition, and complete required MEDLOG actions for HAR notifications. This DHA-PM also prescribes DHA MEDLOG clinical oversight and adjudication that promotes patient and staff safety.

    a. Action Items. All actionable items received by the DHA MEDLOG MMQO will be closely monitored to ensure that every HAR notification is resolved in accordance with guidance delineated in this DHA-PM.

    b. Assessments. The DHA MEDLOG MMQO may perform assessments as deemed necessary for training and/or audit purposes. For FDA Class I Recalls, "Acknowledgement" and "Report Action" taken timelines for MTFs and DHA components will be assessed according to Table 2.

c. <u>Metrics</u>. Metrics outlined below will be established to monitor HAR notification procedures and timelines implemented by this DHA-PM.

(1) USAAMA DOC will continue to receive Class I Acknowledgements and provide timelines to the DHA MEDLOG MMQO.

(2) Metrics/reports are available at both the MMQO or MTF levels. Please refer to Reference (p) for ALFOODACT metrics and reports.

(a) <u>MMQO Reports</u>. Some reports available in Alerts Tracker are number of recalls by classification, number of recalls by materiel type (Pharmacy, Medsurg, Biomed, etc.), Class 1/ Critical acknowledgement receipts, outstanding (not closed) recall dispositions for all types, and total number of applicable alerts. In addition some reports are available in the Joint Medical Asset Repository (JMAR), which includes average response time, average time to notification, number of sites responded, and number of sites reported. These reports are not conclusive in JMAR.

(b) <u>MTF HAR Coordinator Reports</u>. Some reports available in Alerts Tracker are number of work orders generated as a result of a specific alert, by site, or enterprise wide, total number of Medical equipment alerts received for a specified time period, summary pie chart of recent alert dispositions for each site, bar graph of the number of alerts resolved and unresolved for each site user for a specified period, alert disposition status and date for High/Critical alerts for a specified time period, and a list of applicable open alerts for all users in a facility.

14. <u>TRAINING</u>. Required users must complete Alerts Tracking training at: https://www.ecri.org/components/AlertsTracker/Resources/User%20Training%201/story_html5. html. HAR Unit Coordinators must complete required training at: https://www.ecri.org/components/AlertsTracker/Resources/Alerts%20Tracker%20Coordinator% 20Training%20DoD/story_html5.html

APPENDIX 1

STEPS TO PULL HAR BUSINESS OBJECTS REPORT METRICS IN JMAR

1. Select Asset Visibility

2. Select Inventory/ Due In/ Due Out

3. Under Navigation Menu: Select Inventory Due-In/Due-Out Standard Reports

4. Under Quality Assurance: Select MMQC Message Summary Metrics. Metrics can filtered by various specifications

5. Select run report based on filtered specifications. Metrics identified are average response time, average time to notification, Number of sites responded, Number of sites reported are not a conclusive list of metrics that can be pulled for reports.

Figure 6. SAMPLE DHA HAR Business Objects Report

Last Refresh Date: 03-11-20 2:54:36 PM GMT-04:00 Avg Response Time = Min(MMQC Responded Date) to Max(Site Co

Page: 1/1 Avg Time to Notification = Message Release Date to Min (Site MMQC

Total Messages: 1 # Sites Not Responded = All DMLSS Sites - # of Sites Reported

Sites Reported = # Sites Responded to the Message

1/1/2020 12:00:00 AM DHA HT0016 I

FDA Classification	Link to Response Details	Link to USAMMA	Narration Tx	Message Release Date	Product Count	ECRI Alert ID	ECRI Alert Priority	ECRI Alert Version Number	ECRI Accession Number	ECRI Change Reason	ECRI Last Publication Date	Expected Response s Qty	Responses Received Qty	% Messages Completed	Average Notification on Time (Days)	Average Site Response Time (Days)	Sites Reported	Sites Not Reported	% Sites Responded	Total Reported OH Qty	AF Reported OH Qty	Army Reported OH Qty	Navy Reported OH Qty	Marines Reported OH Qty	DHA Reported OH Qty
I	MMQC-20-5487	MMQC-20-5487	HEADLINE: TELEFLEX-COMFORT FLO HUMIDIFICATION SYSTEMS: WATER MAY FLOOD COLUMN AND ENTER CIRCUIT UNDER CERTAIN CIRCUMSTANCES, POTENTIALLY RESULTING IN ASPIRATION OF FLUID INTO THE NOSE AND LUNGS (FDA CLASS I) ACTION: IDENTIFY, ISOLATE, AND DISCONTINUE USE OF ANY AFFECTED SYSTEMS IN YOUR INVENTORY. IF YOU HAVE AFFECTED SYSTEMS, VERIFY THAT YOU HAVE RECEIVED THE DECEMBER 13, 2019, URGENT MEDICAL DEVICE RECALL LETTER AND RECALL ACKNOWLEDGMENT FORM FROM TELEFLEX. TELEFLEX STATES THAT IT HAS UPDATED THE COLUMN DESIGN. REGARDLESS OF WHETHER YOU HAVE AFFECTED PRODUCT, COMPLETE THE RECALL ACKNOWLEDGMENT FORM AND RETURN IT TO TELEFLE	02/14/2020	6	X641X25	CRITICAL	2.0	A33963		2/13/2020	6	6	100.00%	0	13.33	1	0	100%	0	0	0	0	0	0

Report Summary | **MMQC Message Summary** | Avg Response Time by Classifica | # Sites Notified by Classificat | # Sites Responded by Classifica | R ...

APPENDIX 1

APPENDIX 2

HAR ROLES AND RESPONSIBILITY TABLE

POSITION TITLES	ROLES	RESPONSIBILITY	ORGANIZATION AFFILIATION
DHA MEDLOG HAR Program Manager	• The HAR Program Manager works within the MMQO • Responsible for acting as a liaison between DHA MEDLOG Directorate, Defense Logistics Agency Troop Support (DLA-Troop Support), USAMMA DOC, DHA Components, and MTFs in all clinical and technical QA matters • Acts as an Alerts Tracker Account Coordinators	• Assist in the development of overarching procedural guidance • Provide technical support and training to MTF HAR Coordinators and Clinical Teams at DHA Components • Establish and provide access to program execution and reporting expectations for basic user training and/or coordinator training for assigned MTF HAR Coordinators on the designated authoritative IS or DoD authorized automated applications needed to receive and manage HAR notifications • Assist with establishing and registering user accounts requests in ECRI at the MTF. • Alerts Tracker Accounts Coordinators are responsible for managerial permissions at the highest level of the account and all of the facilities within that account (i.e. Army hospitals, Air Force bases, DHA Components)	DHA MEDLOG
MTF Director	• Responsible for establishing an effective medical materiel quality program and designate appropriate logistics, pharmacy, dental, patient safety, risk management and clinical quality management participation	• Appoint a clinician as HAR Coordinator from MTF clinical staff to oversee and manage HAR associated actions and ensure clinical functions • Appoint a MTF Logistics Officer to support the MTF Clinical Team and ensure logistics functions are completed in the authoritative IS • Ensure each clinical department appoints a primary and secondary HAR Representative(s) to work with the MTF Logistics Team, identify materiel included in HAR	MTF

		notifications within their respective departments, complete and submit necessary documentation, and fulfill all training requirements HAR Representatives will also coordinate with medical food inspection personnel • Follow procedures outlined in DHA-MSR, 6025.01 "DoD Hazardous Food and Nonprescription Drug Recall System," when the item is a food or non-prescription medication	
MTF HAR Coordinator	• The MTF HAR Coordinator will act as the HAR Facility Coordinator in ECRI Alerts Tracker • Appointed by the MTF Director from the MTF Clinical Team.	• View and acknowledge all alerts and notifications received from approved sources in the Alerts Tracker according to required receipt response times detailed in Table 2. • Acknowledge and report Category I or Category II on the next business day if deficiencies are discovered during facility shutdowns on weekends or holidays • Ensure MTF clinical departments and the MTF Logistics Officer are informed by e-mail and acknowledge receipt of FDA Class I HAR notifications • Coordinate with MTF clinical departments, report findings and disposition to the MTF Director and the MMQO via the DHA MEDLOG, HAR Program Manager if HAR message requires patient notification, • Ensure PQDRs for defective medical materiel are completed and received by designated personnel • Maintain managerial and reporting requirements or permissions in alert tracker for that specific DHA component as a Facility Coordinators. Facility Coordinators only have permissions for that specific facility • Ensure appropriate users are	MTF

		registered in the alerts tracker for the appropriate roles	
MTF Logistics Officer	• Responsible for ensuring all MEDLOG actions associated with HAR notifications are complete within timeframes • Act as a Tracking Assigned User. Tracking users are assigned to receive Alerts content for a specific specialty area	•Ensure MEDLOG processes are actioned and completed in DMLSS, as well as submit findings/supporting documentation to the MTF HAR Coordinator • Ensure the appropriate trained technical staff responsible for the functional management of affected product(s), action each HAR message • Identify appropriate responsible functional manager to review and adjudicate HAR messages affecting medical supplies and identify Healthcare Technology Management personnel to review and adjudicate all messages affecting maintenance significant medical devices and equipment • Designate a Logistics Team to support the dissemination of matched messages, identify and segregate materiel, follow HAR notification instructions for materiel disposition, and report findings and actions • Assigns Alerts on a daily basis according to their category or channel. These users are expected to resolve all Alerts that are assigned to them • Ensure appropriate materiel management and logistics personnel are registered with ECRI as identified • Ensure logistics actions described in this DHA-PM are complete in the approved authoritative IS and alerts tracker; report all logistics actions to the MTF HAR Coordinator	MTF

| Logistics Team | • Responsible for acknowledging, resolving, and closing alerts and acts as an assigned tracking users | • Receive HAR notifications from approved sources to determine whether the MTF is affected by materiel that is subject to the HAR notice
• Identify affected materiel, follow notification instructions, and complete disposition actions as required and record actions taken in the approved authoritative IS
• Complete required actions within the HAR notification for product identifiers that match within MTF Catalog
• Identify items where product identifiers do not match within catalog, and search for non-matched HAR messages.
• Coordinate with HAR Representatives to ensure deficient product reports (e.g., PQDRs) are completed and submitted to DLA through approved sources
• Ensure disposition actions for HAR notifications and MMQC messages are documented and reported
• MTFs/DHA components with the capability to designate Pharmacy and Dental HAR Representatives will ensure they action the recall message, coordinate with medical food inspection personnel and report actions taken directly to the MTF HAR Coordinator on materiel affected by HAR messages and coordinate return of recalled pharmacy and dental materiel with designated representatives
• These users are expected to resolve all Alerts that are assigned to them | MTF |

HAR Representative	• Responsible for communicating with the MTF's Logistics Team, clinical departments, and MTF HAR Coordinator • Responsible for coordinating with medical food inspection personnel regarding hazardous food and non-prescription drugs consistent • Responsible for acting as a Tracking FYI user	• Receive HAR notifications in their specific category for information purposes only • These users are not expected to resolve their HAR Notifications to them • Assist the MTF Logistics Officer in completing logistics disposition actions as required. • Assist the MTF HAR Coordinator to identify, notify and complete necessary documentation when materiel affected by the HAR notification is found in their departments or administered to patients • Collaborate with Logistics Team to complete PQDRs for materiel identified within their respective departments, as well as ensure necessary documentation	MTF
Alerts Tracker Coordinators	• Coordinators have managerial and reporting permissions in the system • Managerial and reporting permissions are directly related to their level within a hierarchy for coordinators • There are two types of Coordinators	• Account Coordinators - have managerial permissions at the highest level of the account and all of the facilities within that account (i.e. Army hospitals or Air Force bases) • Facility Coordinators - only have permissions for that specific facility	DHA MEDLOG/MTF
Alerts Tracker Users	• Tracking users have the ability to collaborate with other users across the organization within Alerts Tracker • Tracking users do not have managerial or reporting privileges in the system • There are two types of Tracking Users	• Assigned Users assigns Alerts on a daily basis according to their category or channel. These users are expected to resolve all Alerts that are assigned to them • FYI Users receives the Alerts in their specific category for information purposes only. These users are not expected to resolve their Alerts. Alerts will drop off of their lists after 2 weeks	MTF

GLOSSARY

PART I. ABBREVIATIONS AND ACRONYMS

BMET	Biomedical Equipment Technicians
CAT	Category
CMO	Chief Medical Officer
DAD	Deputy Assistant Director
DHA	Defense Health Agency
DHA-PM	Defense Health Agency Procedural Manual
DLA	Defense Logistics Agency
DMLSS	Defense Medical Logistics Standard Support
DOC	Distribution Operations Center
ECRI	Emergency Care Research Institute
FDA	Food and Drug Administration
HAR	Hazard Alert and Recall
IS	Information System
JMAR	Joint Medical Asset Repository
MEDLOG	Medical Logistics
MHS	Military Health System
MMQC	Medical Materiel Quality Control
MMQO	Medical Materiel Quality Office
MTF	Military Medical Treatment Facility
NSN	National Stock Number
PQDR	Product Quality Deficiency Report
QA	Quality Assurance
Q&O	Quality and Optimization
TEWLS	Theater Enterprise-Wide Logistics System

USAMMA-DOC   United States Army Medical Materiel Agency Distribution Operations Center

WO   Work Order

<u>PART II</u>. <u>DEFINITIONS</u>

<u>Alerts Tracker</u>. A commercial off the shelf system used to manage HAR notifications.

<u>Alerts Tracker's DoD Only Channel</u>. A channel within ECRI Institute's Alerts Tracker that will disseminate DoD only related recalls.

<u>approved sources</u>. Approved sources are the origin of any HAR notices. This may include, but is not limited to, the FDA, ECRI, manufacturer alerts, recalls, or notifications regarding hazardous materiel.

<u>authoritative IS</u>. Feeder system to financially accountable systems for accountable property officers for DHA Components. DMLSS is the authoritative information system.

<u>Category I</u>. A DLA-TS reference to a PQDR complaint that 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 failure; Malfunction Improper, or inadequate design, manufacture, labeling, and user error.

<u>Category II</u>. A DLA-TS reference to a PQDR complaint that refers to all other complaints that do not meet the severity level for a Category I will be processed as a Category II complaint including: systemic equipment failures, defective devices, incorrect or deficient labeling, foreign or particulate matter in liquids or solids, imperfectly manufactured items which are off- color, off-taste, or off-odor, Suspected sub-potency or super-potency of drugs and biologics, pinholes in tubing, faulty calibrations, and poor quality products.

<u>Class I recall</u>. An FDA classification that refers to a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

<u>Class II recall</u>. An FDA classification that refers to a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

<u>Class III recall</u>. An FDA classification that refers to a situation in which use of or exposure to a volatile product is not likely to cause adverse health consequences, but that violate FDA labeling or manufacturing laws.

<u>clinical departments</u>. Any department within a facility that provides patient care and/or patient support that utilizes pharmaceuticals, medical supplies and/or medical equipment.

clinician. A health professional that is directly involved in or delivers patient care.

coordinators. Individuals with managerial and reporting permissions in ECRI. Managerial and reporting permissions are directly related to their level within a hierarchy for coordinators. There are two types of Coordinators: Account Coordinators and Facility Coordinators. Account Coordinators have managerial permissions at the highest level of the account and all of the facilities within that account. Facility Coordinators have permissions for a specific facility, MTF, Market or DHA Component.

Critical Priority. Hazards, recalls, or other issues describing problems that, if left unresolved, are likely to result in serious health consequences for patients or users, or other significant adverse consequences.

DHA Components. Activity/Command under the authority, direction and control of the Director, DHA, structured below a DHA Market or Defense Health Region, that does not provide direct patient care (i.e. optical fabrication centers, research, training, standalone labs, Markets, regional health commands, etc.).

DoD Specific HAR Notification. A notification for a HAR that is specific to DoD materiel only.

HAR Facility Coordinator. An ECRI role assigned to the MTF HAR Coordinator.

Hazard Alert and Recall. A message or notification that details methods to handle or remove potentially unsafe materiel due to deficiency in quality, efficacy or safety, or are otherwise in violation of laws administered by the Food and Drug Administration (FDA).

hazardous food and nonprescription drugs. See Reference (p).

High Priority. An ECRI prioritization of hazards, recalls, or other issues describing problems that, if left unresolved, may lead to serious health consequences for patients or users, significant financial losses for the healthcare facility, or severe equipment damage.

informational alerts. A USAMMA DOC reference that refers to manuals, procedure, or updates for equipment, etc.

market withdrawal. FDA terminology that occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems would be a market withdrawal.

Medical Device Safety Alert. An FDA alert that is issued in situations where a medical device may present an unreasonable risk of substantial harm. In some case, these situations also are considered recalls.

medical materiel. Medical or dental consumable supplies, equipment, pharmaceuticals or vaccines.

MEDLOG managed storage locations. Areas within MTFs or DHA Component (e.g., warehouses, medical logistics storage rooms, receiving dock, etc.) designated to store materiel.

MTF. Any fixed facility of the DoD that is outside of a deployed environment and used primarily for health care; and any other location used for purposes of providing health care services as designated by the Secretary of Defense.

MTF Catalog. The core central repository of medical, surgical and pharmaceutical materiel available for purchase by the MTF or DHA Component from DLA-Troop Support (Depot and direct vendor delivery), prime vendors, peacetime and readiness electric catalog and Theatre Lead Agent for Medical Materiel programs.

MTF clinical staff. Membership includes all clinical staff.

MTF Clinical Team. Membership includes HAR Coordinator, Risk Managers, Patient Safety Managers, Quality Managers, Clinical and Dental Department Heads/Division Chiefs, Pharmacy and Dental HAR Managers, within the MTF or Satellite Branch Clinic and any other MTF clinical staff the MTF Director deems necessary.

MTF Logistics Team. Membership includes Logistics Officer, Healthcare Technology Management, DMLSS-SA, Inventory/ Supply personnel, Department HAR Representatives, Prime Vendor Representatives and additional MEDLOG/materiel management personnel deemed necessary by the Logistics Officer.

Normal Priority. An ECRI prioritization of hazards, recalls, or other issues describing problems that, if left unresolved, may cause patient or staff injuries or other health problems, financial losses for the healthcare facility, or equipment damage. Although serious injuries or other significant adverse consequences may be possible, the probability of such consequences is low.

Not Prioritized. An ECRI prioritization of alerts posted without a priority are considered "completed" or "terminated." These Alerts do not require any action on the part of the user.

Tracking Users. Individuals assigned to receive alerts content for a specific specialty area. Tracking users have the ability to collaborate with other users across the organization within Alerts Tracker. Tracking users do not have managerial or reporting privileges in the system.

Unclassified. A USAMMA DOC reference that refers to an alert not yet classified by FDA as a Class I, II, III. USAMMA DOC does not assign classifications; only FDA assigns classification.