Department of Veterans Affairs **VHA DIRECTIVE 2008-080**
Veterans Health Administration
Washington, DC 20420 **November 26, 2008**

RECALL OF DEFECTIVE MEDICAL DEVICES AND MEDICAL PRODUCTS, INCLUDING FOOD AND FOOD PRODUCTS

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes policy on recalls involving medical devices, medical products, foods and food products. ***NOTE:*** *For the purpose of this Directive, the Food and Drug Administration (FDA) definition of medical device is used (see subpar. 2d (11)), and medical products (see subpar. 2d (12)) include: drugs, subsistence (food and food service products), implantable devices including human tissue, and prosthetics.*

2. BACKGROUND

a. FDA has statutory authority to prescribe a recall and to rule on the extent and scope of the recall for items such as medical devices, infant formula, and human biological products that present a risk of injury, gross deception, deviations from good manufacturing processes, or are otherwise defective. FDA does not have the same statutory authority over other products, including drugs, foods, cosmetics, or supplements; however, it does have oversight responsibilities to ensure that appropriate recall actions are taken when necessary to protect the public's safety. When a product is determined to be potentially hazardous, FDA has a responsibility to monitor it so that the appropriate level of voluntary manufacturer action is taken to notify all users of the product and to provide instructions for its removal or recall if necessary. If a manufacturer does not take the appropriate voluntary action that FDA believes necessary, the FDA may seek legal action under the Food, Drug and Cosmetics Act to achieve the desired corrective action(s).

b. VHA Patient Safety Alerts, Recalls, and Patient Safety Advisories are used to notify Department of Veterans Affairs (VA) providers and users of unsafe or defective medical devices and medical products that may present an actual or potential threat to health or life and which must be corrected or removed from service or use.

c. The information leading to the decision to issue a VHA Patient Safety Alert, Recall, or Patient Safety Advisory may originate from a wide variety of internal and external sources, including safety reporting systems (e.g., VHA's Patient Safety Information System), Safe Medical Device Act reports, Biomedical Engineering at VHA medical facilities, manufacturers, other Federal agencies (e.g., FDA), or external organizations (e.g., The Joint Commission (TJC), Institute for Safe Medication Practices (ISMP), ECRI Institute).

d. **Definitions.** The following definitions are applicable within this Directive:

(1) **Biologic.** A biologic is a preparation, such as a drug, a vaccine, or an antitoxin, that is synthesized from human tissue, or their products, and which is used medically as a diagnostic, preventive, or therapeutic agent. Blood and blood products are regulated as both human biologics and drugs.

(2) **Center for Engineering, Occupational Safety and Health (CEOSH).** The Department of Veterans Affairs' (VA) CEOSH is the primary technical resource supporting VA engineering programs including VHA Biomedical Engineering. Repairable medical devices requiring investigation for potential safety or performance issues are managed at CEOSH.

(3) **Designated Service Area Specialist (DSAS).** Each DSAS and back-up serves as the subject matter expert in VHA within their area of expertise, and are the primary point of contact at VA Central Office for the Product Recall Office (PRO) within the National Center for Patient Safety (NCPS). DSASs advise the NCPS PRO on actions needed to address medical device and medical product issues, work with the PRO to develop recall notices, and assist the NCPS on the development of VHA Patient Safety Alerts or Patient Safety Advisories, when needed (see Att. B).

(4) **Drugs.** See subparagraph 2d(17).

(5) **Durable Medical Equipment (DME).** DME includes some items that are classified as medical devices and some that are classified as drugs, such as: oxygen concentrators, wheelchairs, hospital beds, home oxygen refills and liquid oxygen refills.

(6) **Facility.** A facility is a hospital, an ambulatory surgical facility, a nursing home, an outpatient diagnostic facility, or an outpatient treatment facility which is not a physician’s office.

(7) **Facility Designated Area Specialist (FDAS).** The FDAS serves as the primary point of contact at their facility in their service for the Facility Recall Coordinator (FRC). This individual serves as the expert at the facility in the individual's area of expertise, and assists and takes direction from the FRC to address issues related to device and product recalls (voluntary or otherwise) and manufacturer generated actions. FDASs advise the FRC on actions needed to address medical device and medical product issues, and work with the FRC to assist in developing and addressing recall notices.

(8) **Facility Recall Coordinator (FRC).** The FRC serves as the primary point of contact in the facility for all devices and product recalls (voluntary or otherwise) and manufacturer actions related to their products. The FRC coordinates the facility response and works with the appropriate FDAS to implement the program.

(9) **Health and Beauty Care.** Health and beauty care items include products to enhance beautification and complexion, such as: lotions, creams, and body products that may be applied to the mouth, hair, face, or body.

(10) **Human Transplant Tissue.** Human transplant tissue includes: skin; heart valves; pericardium; bone; connective tissue; cartilage; saphenous vein and other blood vessels; heterografts (e.g., bovine vascular, porcine valve); and corneal transplants.

(11) **Medical Device.** A medical device is any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component

part or accessory that is intended to be used for the diagnosis, cure, mitigation, treatment, or prevention of a disease, injury, illness, or other condition; and is not a drug, human tissue, or used for sustenance.

(a) Repairable Medical Devices. Repairable medical devices are medical devices that can be repaired and returned to service.

(b) Non-repairable Medical Devices. Non-repairable medical devices include implants, catheters, and single-use devices.

(12) **Medical Product.** A medical product is any item other than a medical device that is used for diagnosis, treatment, or prevention of a disease, injury, illness, or other condition, for example a drug, human tissue, or food product.

(13) **Network Recall Coordinator (NRC).** The NRC is the primary point of contact in the Veterans Integrated Service Network (VISN) for device and product recalls (voluntary or otherwise) and manufacturer actions related to their products. The Chief Logistics Officer (CLO) is the NRC for their respective VISN and is responsible for:

(a) Working with the FRCs to implement the VHA product recall program,

(b) Providing training to the FRCs as needed, and

(c) Ensuring that VISN facilities meet the requirements of this Directive.

(14) **Nutritional Supplements.** Nutritional supplements are any products (other than tobacco) that are intended to supplement the diet and that bear, or contain, one or more of the following dietary ingredients: a mineral and/or vitamin, an herb or other botanical, an amino acid, a dietary substance for use by humans to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients. Nutrition and Food Service (NFS) nutritional supplements include therapeutic oral and tube feedings. Pharmacy Benefits Management (PBM) nutritional supplements include all others.

(15) **Patient Safety Advisories.** Patient Safety Advisories, issued to VISNs and facilities from the Deputy Under Secretary for Health for Operations and Management (10N), are recommendations providing guidance to address issues such as equipment design, product failure, procedures, or training and may recommend clinician action. Actions are general in nature and implementation may be subject to local judgment contingent on local conditions.

(16) **VHA Patient Safety Alerts.** VHA Patient Safety Alerts, issued to VISNs and facilities from the Deputy Under Secretary for Health for Operations and Management (10N), are mandates providing specific action to address actual or potential threats to life or health often requiring clinician action.

(17) **Pharmaceuticals (Drugs).** Pharmaceuticals are any substances defined by the United States (U.S.) Food, Drug and Cosmetic Act, recognized under in the official U.S.

Pharmacopoeia, and used in the diagnosis, treatment, or prevention of a disease, or as a component of a medication. Blood and blood products are regulated as both drugs and human biologics.

(18) **Prosthetic and Orthotics.** Prosthetic devices are surgical implants (e.g., pacemakers, hips and/or knees, stents); custom artificial limbs; sensory aids (e.g., hearing aids, eyeglasses); and orthotic devices (e.g., leg braces).

(19) **Recalls.** Recalls are notices issued by the NCPS PRO requiring nonclinical action in the field. The notices mandate actions that must be taken by the field to safeguard the life or health of VHA patients or staff; for example, pulling an unsafe product off the shelf and returning it to the supplier, as well as ensuring appropriate credit or reimbursement for the returned products is accomplished. Clinicians are not involved in these actions, but must be informed of recalls relevant to their work by the FRC or the FDAS. Recalls issued by the NCPS PRO include those issued by the FDA, and those that originate or are discovered internally within VHA (e.g., Patient Safety Information System reports) and from other external sources (e.g., ECRI Institute Alerts, manufacturer field notifications). Communications with the field that require specific clinical actions to ensure patient safety are issued through mechanisms other than a recall; for example, using a VHA Patient Safety Alert or Advisory.

(20) **Serious Illness or Injury.** A serious illness or injury is an illness or injury that is life threatening; or results in the permanent impairment of a body function or permanent damage to the body structure; or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(21) **Subsistence.** Subsistence is a food or food service product that provides necessary sustenance, nourishment, and support for daily dietary requirements for optimal health.

3. POLICY: It is VHA's policy to notify VISNs and facilities when recalls involving medical devices or medical products that are applicable to VHA are issued by the FDA, manufacturers, third-party external sources, or are internally generated. ***NOTE:*** *Recall notification is distributed by the National Center for Patient Safety; the typical recall communication paths are shown in Attachment A.*

4. ACTION

a. **Deputy Under Secretary for Health for Operations and Management (10N).** The Deputy Under Secretary for Health for Operations and Management is responsible for:

(1) Ensuring information prepared by VHA programs (including NCPS, CEOSH and others) about medical devices and medical products issued as VHA Patient Safety Alerts and Patient Safety Advisories is accurate, timely, and provided in a format that is ready for distribution to VHA medical facilities.

(2) Distributing VHA Patient Safety Alerts and Patient Safety Advisories to VHA medical facilities.

(3) Coordinating with the Office of Patient Care Services (11) and the Office of Public Health and Environmental Hazards (13) in cases where patient notification is a part of the recall process, to implement current VHA policy regarding the disclosure of adverse events to patients (see VHA Handbook 1050.01 and current VHA policy for information on the disclosure of adverse events to patients).

(4) Ensuring that facilities accomplish appropriate recall and clinical activities on required timelines.

(5) Ensuring the appropriate VHA officials convene, if necessary, a Clinical Risk Assessment Advisory Board to decide if a large-scale notification of adverse events is needed.

b. **Director, National Center for Patient Safety (NCPS).** The NCPS Director is responsible for ensuring that the PRO:

(1) Monitors internal VHA and external sources for recall information. The PRO may, upon request, develop a Memorandum of Understanding (MOU) with a VHA Program Office to permit the Program Office to administer (i.e., monitor, research, disseminate, follow up) the recall program for medical devices, medical products, food or food products under their jurisdiction.

(2) Researches, classifies, and prioritizes potential recall information to determine the dissemination method and what entity has responsibility for implementing the required actions.

(a) Directs the dissemination of Recalls by the VISN CLO who serves as the NRC.

(b) Issues VHA Patient Safety Alerts or Patient Safety Advisories pertaining to Recalls, through 10N, if clinician action or resolution is required.

(3) Establishes and maintains the electronic mail groups on Outlook for NRCs, FRCs, and backup FRCs.

(4) Ensures VHA Patient Safety Alerts and Recalls and due dates are posted to the VHA Alert and Recall Management System Web site.

(5) Coordinates with the appropriate DSAS on Recalls that may require clinician action or other resolution, as necessary.

c. **VHA Chief Officer.** Each VHA Chief Officer is responsible for appointing a DSAS and a back-up DSAS for each service or program under their supervision. ***NOTE:*** *See Attachment B for DSAS offices with technical responsibility.*

d. **Designated Service Area Specialist (DSAS).** The appropriate DSAS is responsible for:

(1) Advising the Product Recall Office (10X), within one business day following contact

from 10X, as to type and if clinician involvement with patients is required (e.g., physician to interrogate patient's pacemaker, physician to review patient records for infection) and, when needed, identifying alternate devices, medical products, or food to ensure the affected product(s) are sequestered or returned to the supplier so that essential activities are not adversely impacted.

(2) Serving as the primary contact and subject matter expert for all internally-identified recalls within their assigned area of expertise or specialty and communicating these to the PRO.

(3) Assisting the PRO when contact is needed with external entities (e.g., FDA, Centers for Disease Control and Prevention (CDC), manufacturers) during the investigation and implementation of action plans.

(4) Reporting to the PRO (10X) any problems identified by their subordinate chain that may necessitate a recall, VHA Patient Safety Alert, or Patient Safety Advisory. Examples include, but are not limited to:

(a) Voluntary recall notices of which they become aware, and

(b) Observed clinical problems with medical devices and products.

(5) Providing the PRO (10X) with contact information including name, department and service, phone number and email address of the DSAS and back-ups, and updating this information whenever staff changes occur.

(6) Meeting the requirements of subparagraphs 4d(1), 4d(2), 4d(3), 4d(4), and 4d(5) during normal business hours regardless of situations, such as: vacant positions, business, travel, vacations, or staff illness.

e. **National Acquisition Center (NAC).** The NAC is responsible for:

(1) Serving as the primary contact point for all national contracts.

(2) Ensuring that all contracts administered by the NAC (e.g., National, Blanket Purchase Agreements, Federal Supply Schedules) have standardized language in purchase orders and contracts requiring vendors to notify the National Contracting Officer and the PRO (10X) of any actions required by the field regarding their products (e.g., recalls - voluntary or otherwise, manufacturer field actions) or other product safety issues.

(3) Contacting the PRO within one business day following receipt of product safety or other relevant information from the vendor.

f. **VISN Director.** The VISN Director is responsible for:

(1) Designating the VISN CLO as the NRC, identifying a back-up NRC, providing current information to the PRO (10X).

(2) Ensuring that VISN facilities identify a primary FRC and back-up FRC.

(3) Ensuring that VISN-initiated contracts require vendors to notify the Contracting Officer of any actions required by the field regarding their products (e.g., recalls - voluntary or otherwise, manufacturer field actions) or other product safety issues.

g. **Network Recall Coordinator (NRC).** The NRC is the VISN CLO who is responsible for:

(1) Submitting the names, phone numbers, and email addresses of the members of the VISN FRC mail group (comprised of the FRCs and the back-up FRCs within the VISN) to the PRO (10X) and updating the PRO (10X) when any changes are made to the group.

(2) Ensuring every VHA facility in the VISN has a program for responding to recalls (voluntary or otherwise), manufacturer field actions, or other recall issues that are not dependent upon a single individual. Responses include, but are not limited to: identifying numbers and locations of medical devices and products; removing, sequestering, and returning the products for credit; and providing suitable alternate products so that essential activities are not adversely impacted.

(3) Reporting potential hazards identified by the medical centers, hospitals, and outpatient clinics to the PRO (10X).

(4) Contacting the PRO (10X) within one business day following receipt of recall related or product safety information from vendors. ***NOTE:*** *This includes information described in subparagraph 4d(4).*

(5) Monitoring recall activities within the VISN and following up with the facilities that have not responded by the due date, as identified by the VHA Alert and Recall Management System Web site.

(6) Establishing a process for auditing facility recall programs within the VISN annually by using a tracer methodology. A minimum of three recalls per facility need to be tracked from notification to resolution each fiscal year. Identified system deficiencies must be corrected within 30 business days.

(7) Ensuring that Recalls, including those related to VHA Patient Safety Alerts or Patient Safety Advisories, are executed as directed.

h. **VISN Contracting Officer.** The VISN Contracting Officer is responsible for:

(1) Ensuring that all contracts including purchase orders administered by the facility have standardized language requiring vendors to notify the Contracting Officer, the FRC, and the PRO (10X) of any actions required on medical devices and medical products related to recalls (voluntary or otherwise), manufacturer field actions, or other product safety issues.

(2) Notifying the FRC of recalls or important product safety issues received from facility-initiated contract vendors.

i. **Facility Director.** Each facility Director is responsible for:

(1) Ensuring recalled medical devices or medical products are not used at any facility under their jurisdiction.

(2) Designating a FRC and back-up FRC(s).

(3) Ensuring all recalls are completed by the due date specified on the VHA Alert and Recall Management System Web site.

(4) Designating FDASs, and alternates, for all categories identified in Attachment B.

(5) Ensuring that action status or recommendations of Recalls, VHA Patient Safety Alerts, and Patient Safety Advisories are implemented and documented on the VHA Alert and Recall Management System Web site.

(6) Reporting internally-identified equipment design or product failure experiences that may cause serious adverse health consequences or death, or temporary or medically reversible adverse health consequences, to the PRO (10X) and the NRC. ***NOTE:*** *This must be done as soon as possible and before final Root Cause Analysis results.*

(7) Establishing a process to identify and resolve issues with recalled devices, which have been implanted in VA patients at non-VA facilities, including affiliates or private institutions.

(8) Ensuring that facility-initiated contracts require vendors to notify the Facility Contracting Officer of any recalls or important product safety issues as described in subparagraph 4j(2).

j. **Facility Recall Coordinator (FRC).** The FRC is responsible for:

(1) Coordinating and disseminating logistics-related recall information to the FDASs, and verifying actions are completed within the facility by the due date. If parties other than those identified in the recall are impacted or are needed to successfully implement the recall, the FRC must ensure these additional parties (e.g., Materiel's Management, Operating Room (OR) supervisor) are informed of their required responsibilities.

(2) Working with the Facility Contract Officers to obtain recalls or important product safety issues received from facility-initiated contracts, including information described in subparagraph 4d(4).

(3) Maintaining an up-to-date list of the FDASs including name, email address, and phone numbers and providing this list to the NRC.

(4) Verifying that the appropriate action has been taken, e.g., identifying numbers and locations of medical devices and products; removing, sequestering, and returning the products for credit; and providing suitable alternate products so that essential activities are not adversely impacted.

(5) Documenting action status on the VHA Alert and Recall Management System Web site.

(6) Providing a system for maintaining records that details the steps taken to resolve recalls, such as: distribution lists, response times, number of items identified, final disposition of affected items, and date resolved.

(7) Contacting the PRO (10X) and the NRC with any recalls or important product safety issues received from facility-initiated contracts or locally-identified product or device issues potentially impacting product or patient safety (e.g., recall letter sent from supplier to OR or Chief of Supply, Processing and Distribution (SPD)), including information described in subparagraph 4d(4).

k. **Facility Designated Area Specialist (FDAS).** FDAS are responsible for:

(1) Providing technical expertise on completing recalls in coordination with the FRC.

(2) Serving as the subject matter expert and investigator on internally-identified hazards within their area of expertise or specialty.

(3) Communicating recall information to their respective DSAS, when national notification may be appropriate, including the described in subparagraph 4d(4).

(4) Implementing actions specified by the FRC by the due date, and reporting back to the FRC when those actions have been completed.

l. **Acquisition and Materiel Management Service.** The facility Acquisition and Materiel Management Service is responsible for:

(1) Sequestering affected product when requested by the due date, as directed by the FRC.

(2) Providing suppliers with product reply or return documentation to expedite completion of recall.

(3) Ensuring the facility is credited or otherwise compensated for returned goods.

5. REFERENCES

a. Accreditation Manual for Healthcare Facilities, TJC.

b. Title 21 Code of Federal Regulations Volume 1, Chapter 1, Parts 7, 107, 806, and 1270.

c. FDA Office of Regulatory Affairs' Office of Enforcement. Guidance for Industry: Product Recalls, including Removals and Corrections, found at Web site: http://www.fda.gov/ora/compliance_ref/recalls/ggp_recall.htm

d. VHA Directive 2008-002, Disclosure of Adverse Events to Patients.

6. FOLLOW-UP RESPONSIBILITY: The National Center for Patient Safety (10X) is responsible for the contents of this Directive. Questions may be addressed to 734-930-5890.

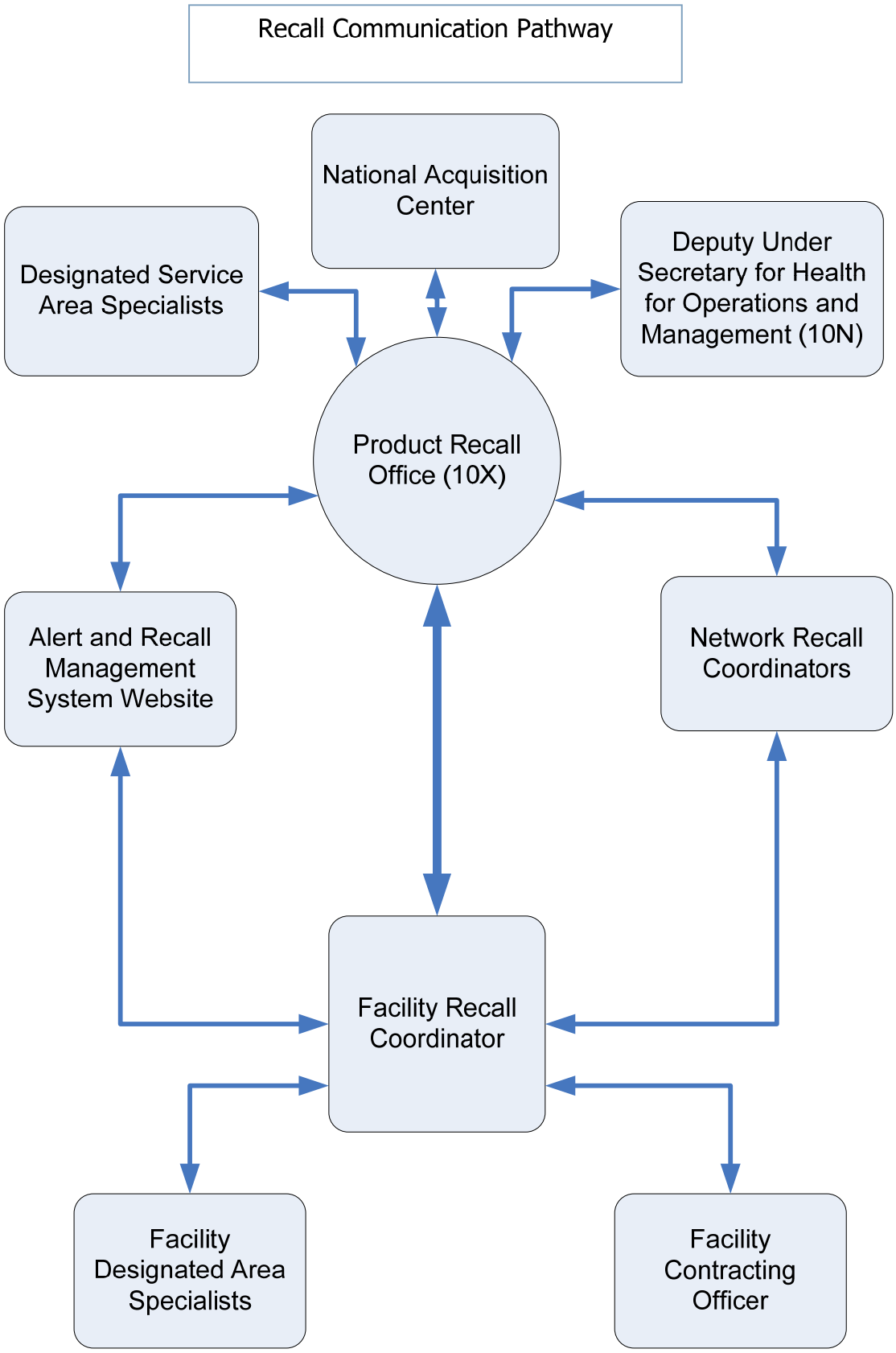
7. RESCISSIONS: VHA 2004-047, dated August 31, 2004 is rescinded. This VHA Directive expires November 30, 2013.

Michael J. Kussman, MD, MS, MACP
Under Secretary for Health

Attachments

DISTRIBUTION: CO: E-mailed 12/1/2008
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mail 12/1/2008

ATTACHMENT A



ATTACHMENT B

DESIGNATED SERVICE AREA SPECIALIST (DSAS) CATEGORIES AND THE OFFICES WITH TECHNICAL RESPONSIBILITIES

The following are the DSAS categories and the offices with technical responsibilities within the recall program:

1. For Biologics (Human), the contact offices are Pathology and Laboratory Medicine Service, Patient Care Services Office (PCS) (115) for blood and blood products; Surgical Service, PCS (111B) for tissue and tissue products; and Pharmacy Benefits Management (PBM) Service, PCS (119) for drugs, vaccines, or antitoxins synthesized from human tissue. Surgical Service coordinates with the Office of Dentistry, PCS (112D) as appropriate.

2. For Durable Medical Equipment (DME) and Prosthetics and Orthotics, the contact office is Prosthetics and Sensory Aids Service, PCS (113).

3. Implantable cardiac devices are handled by the National Program Director for Cardiology (PCS) (111A).

4. For Health and Beauty Care, the contact office is the Veterans Canteen Service (VCS). The VCS coordinates with PBM Service, PCS (119), as appropriate.

5. For Human Transplant Tissue, the contact office is Surgical Service, PCS (111B).

6. For non-repairable medical devices, the contact office is the appropriate specialty or subspecialty program office within the Office of Patient Care Services PCS (11).

7. For nutritional supplements, the contact office is the PBM group, PCS (119) for pharmaceutical nutritional supplements, and the Nutrition and Food Service (NFS) group, PCS (111N) for inpatient nutritional supplements (oral supplements and oral and tube feedings). PBM and NFS coordinate with VCS and the National Acquisition Center (NAC), as appropriate.

8. For pharmaceuticals (drugs), the contact office is the PBM Service (119).

9. For repairable medical devices, the contact office is the Center for Engineering and Occupational Safety and Health (CEOSH). ***NOTE:*** *CEOSH supports the VHA Biomedical Engineering program.*

10. For subsistence, the contact office is NFS, PCS (111N). The NFS coordinates with the VCS and the NAC as appropriate.