

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

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Directive establishes policy for recalls involving medical devices, medical products, foods and food products.
- 2. SUMMARY OF MAJOR CHANGES:** This revised VHA Directive clarifies the Facility Recall Coordinator (FRC) responsibilities, and updates definitions provided.
- 3. RELATED ISSUES:** VHA Handbook 1050.01, VHA National Patient Safety Improvement Handbook.
- 4. RESPONSIBLE OFFICE:** The National Center for Patient Safety (10A4E) is responsible for the contents of this Directive. Questions may be addressed to 734-930-5890.
- 5. RESCISSIONS:** VHA Directive 2008-080, dated November 26, 2008 is rescinded.
- 6. RECERTIFICATION:** This VHA Directive is scheduled for recertification on or before last working day of July 2019.

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

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes policy for recalls involving medical devices, medical products, food and food products. *NOTE: For the purpose of this Directive, the Food and Drug Administration (FDA) definition of medical device is referenced (see subparagraph 6(h)), and medical products include drugs, food, implantable devices including human tissue, and prosthetics.* **AUTHORITY:** 38 U.S.C. 7301(b).

2. BACKGROUND:

a. FDA has oversight responsibilities over many products 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 is necessary to protect the public's safety, the FDA may seek legal action under the Food, Drug and Cosmetics Act to achieve the desired corrective action(s).

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

c. The information leading to the decision to issue a Recall, VHA Patient Safety Alert, or VHA 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 VA medical facilities, manufacturers, other Federal agencies (e.g., FDA, Department of Defense, etc.), or external organizations (e.g., the Joint Commission, Institute for Safe Medication Practices, ECRI Institute, etc.).

3. POLICY: It is VHA's policy that the National Center for Patient Safety (NCPS), Product Recall Office (PRO) will notify Veterans Integrated Service Networks (VISNs) and medical facility staff when FDA, manufacturers, or third-party external sources issue recalls of medical devices, medical products, food, or food products that are applicable to VHA, or when VHA issues such recalls.

4. RESPONSIBILITIES:

a. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management is responsible for:

(1) Ensuring information prepared by VHA programs (including NCPS, Pharmacy Benefits Management Services (PBM), Center for Engineering, Occupational Safety and Health (CEOSH) and others) about medical devices and medical products issued as Recalls, VHA

Patient Safety Alerts, Patient Safety Advisories, or other types of communications is accurate, timely, and provided in a format that is ready for distribution to VA medical facilities, as needed.

(2) Distributing Recalls, VHA Patient Safety Alerts, and Patient Safety Advisories to VA medical facilities using the VHA Alerts and Recalls web application, managed by NCPS.

(3) Coordinating with applicable offices (e.g., PBM, CEOSH, etc.) 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 1004.08 and VHA Handbook 1050.01).

(4) Ensuring that VA medical facilities accomplish appropriate recall and clinical activities within required timeframes.

(5) Ensuring the appropriate Subject Matter Experts (SME) as defined in VHA Handbook 1004.08 convene, if necessary, to decide if a large-scale patient notification of adverse events is needed.

b. **Director, National Center for Patient Safety.** The Director of NCPS is responsible for:

(1) Monitoring internal VHA and external sources for recall information. *NOTE: 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 their area of expertise.*

(2) Researching, classifying, and prioritizing potential recall information to determine the dissemination method and what entity has responsibility for implementing the required actions.

(3) Maintaining the electronic mail groups for Network Recall Coordinator's (NRC), Facility Recall Coordinator's (FRC) and backups for each group.

(4) Ensuring Recalls, VHA Patient Safety Alerts and VHA Patient Safety Advisories, and other types of required notifications and facility response due dates are assigned on the VHA Alerts and Recalls Web Application.

(5) Coordinating with appropriate NCPS staff and Designated Service Area Specialist (DSAS) on recalls that may require clinician action or other resolution, as necessary.

c. **VHA Chief Officer.** Each VHA Chief Officer who manages programs with responsibilities associated with the PRO is responsible for:

(1) Appointing a DSAS and a back-up DSAS for each service or program under their supervision. *NOTE: For the list of DSAS offices with associated responsibilities, see Appendix A.*

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

d. **Designated Service Area Specialist.** Each Designated Service Areas Specialist (DSAS) is responsible for:

- (1) Responding within 1 business day to informational requests submitted to them by NCPS.
- (2) Informing the PRO if actions beyond a standard recall are required. These actions may include, but are not limited to, clinician involvement with patients and, when necessary, identifying alternatives to ensure that essential activities are not adversely impacted.
- (3) 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.
- (4) 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.
- (5) Reporting to the PRO any problems identified to the DSAS that may necessitate a Recall, VHA Patient Safety Alert, or VHA Patient Safety Advisory. Examples include, but are not limited to:
 - (a) Voluntary recall notices of which they become aware; and
 - (b) Observed clinical problems in their area of expertise.
- (6) Meeting the requirements of paragraphs 4.d.(1) through d.(5) during normal business hours regardless of situations such as: vacant positions, business, travel, vacations, or staff illness.

e. **National Acquisition Center.** The National Acquisition Center (NAC), which includes the Denver Acquisition and Logistics Center (DALC) is responsible for:

- (1) Serving as the primary point of contact for VA's Federal Supply Schedule and some health care related national contracts.
- (2) Ensuring that all contracts administered by the NAC (e.g., national, national Blanket Purchase Agreements, Federal Supply Schedules) have standardized language in purchase orders and contracts requiring vendors to notify the appropriate NAC Contracting Officer and the PRO 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 1 business day following receipt of product safety or other relevant information from the vendor.

f. **Strategic Acquisition Center.** The Strategic Acquisition Center (SAC) is responsible for:

- (1) Serving as the primary point of contact for VA's Medical/Surgical national contracts and some health care related national contracts and orders.

(2) Ensuring that all contracts administered by the SAC (e.g., national, national Blanket Purchase Agreements, and delivery/task orders) have standardized language in purchase orders and contracts requiring vendors to notify the appropriate SAC Contracting Officer and the PRO 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 1 business day following receipt of product safety or other relevant information from the vendor.

g. **Veterans Integrated Service Network Director.** The Veterans Integrated Service Network (VISN) Director is responsible for:

(1) Designating the VISN Chief Logistics Officer (CLO) as the NRC, identifying a back-up NRC, and ensuring this information is kept current and transmitted to the PRO.

(2) Ensuring each VA medical facility in the VISN identifies 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.

h. **Network Recall Coordinator.** The Network Recall Coordinator (NRC) for each VISN is responsible for:

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

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

(3) Ensuring that VA medical facilities within the VISN meet the requirements of this Directive.

(4) Creating an Outlook mail group containing all FRCs and Back-up FRCs within their VISN. This mail group must follow the naming convention "VHA NCPS Recalls FRC Vxx (xx represents the two digit VISN number, ex: 01, 12, 23, etc.). This mail group must be kept current by adding and deleting members to reflect changes made to FRCs and FRC back-ups at the individual VA medical facilities within the VISN. The NCPS PRO will utilize this mail group as the primary means of contacting FRCs and FRC back-ups regarding matters involving recalls.

(5) Ensuring every VA medical facility in the VISN utilizes the PRO site for responding to recalls (voluntary or otherwise), manufacturer field actions, or other issues that are not dependent upon a single individual.

(6) Reporting potential hazards identified by the VA medical facilities, hospitals, and outpatient clinics to the PRO.

(7) Contacting the PRO within 1 business day following receipt of recall notifications that may impact VHA and are not yet published by the PRO.

(8) Monitoring recall activities within the VISN and following up with any VA medical facilities that have not responded by the due date, as identified by the VHA Alert and Recall Web site application.

(9) Establishing a process for auditing facility recall programs within the VISN annually and reporting the findings to the PRO. A minimum of three recalls per facility should be tracked from notification to resolution each fiscal year.

(10) Ensuring that recalls are executed as directed.

i. **Veterans Integrated Service Network Contracting Officer.** The Veterans Integrated Service Network (VISN) Contracting Officer is responsible for:

(1) Ensuring that all contracts and purchase orders administered by the VISN and its medical facility(ies) include standard language requiring vendors to notify the Contracting Officer, the facility(ies), and the PRO 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.

j. **VA Medical Facility Director.** Each VA medical facility Director is responsible for:

(1) Ensuring recalled medical devices and medical products are not used at any facility under their jurisdiction, unless otherwise directed by the Deputy Under Secretary for Health for Operations and Management, the Director of NCPS, or the appropriate DSAS.

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

(3) Ensuring that all recalls are completed by the due date specified on the VHA Alerts and Recalls Web site application.

(4) Ensuring that action status or recommendations of Recalls, VHA Patient Safety Alerts, and Patient Safety Advisories, or other types of notifications are documented on the VHA Alerts and Recalls Web site application.

(5) 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 and the NRC. ***NOTE: This must be done as soon as possible and before the final Root Cause Analysis results are completed.***

k. **Facility Recall Coordinator.** Each Facility Recall Coordinator (FRC) is responsible for:

(1) Coordinating and maintaining a facility-wide network of Facility Designated Area Specialists (FDAS) who can respond accurately and authoritatively to recall information provided to the facility. FDASs must represent all areas of the hospital, e.g., a drug recall may affect an outpatient clinic as well as the inpatient and outpatient pharmacies. Therefore, groups

of FDASs must be established and maintained by the FRC to ensure proper coverage throughout the facility.

(2) Resetting FDAS passwords and updating user access, as needed, on the Web site.

(3) Verifying that the appropriate action has been taken, e.g., identifying numbers and locations of medical devices and products; and removing, sequestering, and returning the products for credit.

(4) Documenting the completion of all required actions on the VHA Alerts and Recalls Web site application for recalls.

(5) Contacting the PRO 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 Operating Room Manager), including information described in subparagraph 4d(4).

1. **Facility Designated Area Specialist.** Each Facility Designated Area Specialist (FDAS) is 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 the FRC, when notification to the PRO is needed.

(4) Sequestering affected products when required and reporting on the Web site as directed by the FRC.

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

5. REFERENCES:

a. VHA Handbook 1004.08.

b. VHA Handbook 1050.01.

c. 21 CFR parts 7, 107, 803, 806, and 1270.

d. FDA Office of Regulatory Affairs' Office of Enforcement. Guidance for Industry: Product Recalls, including Removals and Corrections, found at Web site:

www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm

6. **DEFINITIONS:** The following definitions are applicable within this Directive:

- a. **Biologic.** A biologic is a preparation, such as a drug, a vaccine, or an antitoxin, that is synthesized from living organisms or their products and used as a diagnostic, preventive, or therapeutic agent.
- b. **Cosmetics Items.** Cosmetic items are products used to cleanse or enhance beautification and complexion, such as: lotions, creams, shampoos, toothpastes, and deodorants.
- c. **Designated Service Area Specialist.** A DSAS is the individual who serves as the subject matter expert within VHA for a specific area of expertise. The DSAS is the primary point of contact at VHA Central Office for the PRO within NCPS (10A4E). 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. *NOTE: See Appendix A for a listing of known DSAS categories and corresponding offices of technical responsibility.*
- d. **Dietary Supplement.** Congress defined the term "dietary supplement" in the Dietary Supplement Health and Education Act (DSHEA) of 1994 (Public Law 103-417, codified at 21 U.S.C. Chapter 9) as a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can also be extracts or concentrates, and may be found in many forms, such as: tablets, capsules, softgels, gelcaps, liquids, or powders. They can also be in other forms, such as a bar, but if they are, information on their label must not represent the product as a conventional food or a sole item of a meal or diet. Whatever their form may be, DSHEA places dietary supplements in a special category under the general umbrella of "foods," not drugs, and requires that every supplement be labeled a dietary supplement.
- e. **Facility Designated Area Specialist.** A Facility Designated Area Specialist (FDAS) is the individual who serves as the primary point of contact at the medical facility for the FRC, in a particular area of service, and who receives assignments from the FRC to assist in addressing issues related to device and product recalls (voluntary or otherwise) and manufacturer generated actions. FDASs advise the FRC on actions needed to address recall notices.
- f. **Facility Recall Coordinator.** A Facility Recall Coordinator (FRC) is an individual who serves as the primary point of contact in the facility for all recall actions, coordinates the facility response, and works with the appropriate FDASs to implement the recall program.
- g. **Implants and Prosthetics.** Implants and Prosthetics are medical implants or devices or tissues that are placed inside or on the surface of the body. Many implants are prosthetics, intended to replace missing body parts. Other implants deliver medication, monitor body functions, or provide support to organs and tissues.
- h. **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 in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals. Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology; laser surgical devices; and in vitro diagnostic products,

such as general purpose laboratory equipment, reagents, and test kits. Repairable Medical Devices (RMD) are a subset of medical devices that are generally repaired when they fail and may receive scheduled maintenance and upgrades; RMD is typically managed by Biomedical Engineering.

i. **Network Recall Coordinator.** The Network Recall Coordinator (NRC) is the Veterans Integrated Service Network Chief Logistics Officer, who serves as the primary point of contact within the VISN for all recall actions.

j. **Pharmaceuticals (Drugs).** The term Pharmaceuticals (Drugs), means a finished dosage form, for example, tablet, capsule, solution, etc., that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.

k. **Product Recall Office.** The Product Recall Office (PRO) is the office that manages the recall program within VHA and is located within the National Center for Patient Safety (NCPS).

l. **Recalls.** Recalls, as used in this directive, are notices issued by the PRO based upon recall notifications from external sources such as the FDA or the product manufacturer, that require an action to remove the product from use. Recall classifications by the FDA include:

(1) **Class I recall** is 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.

(2) **Class II recall** is 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.

(3) **Class III recall** is a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

(4) **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.

m. **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. Permanent means irreversible impairment or damage to a body structure or function, excluding trivial impairment or damage.

n. **Tissue and Tissue Products.** Tissue and tissue products are human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient, and are regulated as a human cell, tissue and cellular and tissue-based product (HCT/P). Examples of

such tissues are bone, skin, corneas, ligaments, tendons, dura matter, heart valves, hematopoietic stem or progenitor cells derived from peripheral and cord blood, oocytes and semen.

o. **VHA Patient Safety Advisories.** VHA Patient Safety Advisories are issued to VISNs and VA medical facilities by the Deputy Under Secretary for Health for Operations and Management. VHA Patient Safety Advisories include recommendations to address issues with equipment design, product failure, procedures, or training and may recommend clinician action. Recommendations are general in nature and implementation of the specific recommendations is subject to local judgment contingent on local conditions, as long as they meet or exceed the published recommendations.

p. **VHA Patient Safety Alerts.** VHA Patient Safety Alerts are issued to VISNs and VA medical facilities by the Deputy Under Secretary for Health for Operations and Management. The VHA Patient Safety Alerts mandate specific actions to address actual or potential threats to life or health and may require clinician action.

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 (10P4D), Office of Patient Care Services (PCS) for blood and blood products; Surgical Service (10NC2), Office of Operations and Management (10N) for tissue and tissue products; and Pharmacy Benefits Management (PBM) Service (10P4P), PCS for drugs, vaccines, or antitoxins synthesized from human tissue. Surgical Service coordinates with the Office of Dentistry (10NC7), Office of Operations and Management (10N) as appropriate.
2. For Durable Medical Equipment (DME), and Prosthetics and Orthotics, the contact office is Prosthetics and Sensory Aids Service, PCS (10P4K).
3. Implantable cardiac devices are handled by Surgical Services (10NC2), PCS.
4. For Health and Beauty Care, the contact office is the Veterans Canteen Service (VCS) (10NAE). The VCS coordinates with PBM Service (10P4P), PCS, as appropriate.
5. For Human Transplant Tissue, the contact office is Surgical Service (10NC2), Office of Operations and Management (10N).
6. For non-repairable medical devices, the contact office is the appropriate specialty or subspecialty program office within PCS (10P4).
7. For nutritional supplements, the contact office is the PBM service (10P4P), PCS for pharmaceutical nutritional supplements, and the Nutrition and Food Service (NFS) (10P4E), PCS 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 (10P4P), PCS.
9. For repairable medical devices, the contact office is the VHA Center for Engineering, Occupational Safety and Health (CEOSH).
10. For Food, the contact office is NFS (10P4E), PCS, and the Veterans Canteen Service.
11. For Radiology and Nuclear Medicine, the contact office is Nuclear Medicine and Radiation Safety Service (10P4D), PCS.