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A Model for Managing Medical Device Alerts (Hazards and Recalls) for Healthcare Organizations; Approved Guideline

This document provides a framework for healthcare delivery organizations to respond to externally generated notifications of medical device hazards and recalls while focusing on the quality constructs of process control, occurrence management, and process improvement.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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A Model for Managing Medical Device Alerts (Hazards and Recalls) for Healthcare Organizations; Approved Guideline

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Abstract

Clinical and Laboratory Standards Institute (CLSI) document HS11-A—*A Model for Managing Medical Device Alerts (Hazards and Recalls) for Healthcare Organizations; Approved Guideline* provides a framework for healthcare delivery organizations to respond to externally generated notifications of medical device hazards and recalls while focusing on the quality constructs of process control, occurrence management, and process improvement. This guideline includes recommendations for managing medical device alerts including receipt and communication of hazard and recall information, and formulation of an internal plan. Implementation of this guideline will aid institutions in minimizing risk to patients and in the process, satisfying regulatory and accreditation requirements.

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Foreword

Risk managers have identified a broad need for healthcare facilities to have systems in place to ensure that appropriate actions are taken in response to medical device hazards and recalls.

This document provides guidance for healthcare organizations, enabling them to efficiently and effectively respond to externally generated communications alerting them to potentially unsafe conditions related to medical devices.

This document does not address the manufacturer's responsibilities, which are determined by regulatory agencies.

There are a few instances of deliberate duplication of information within this document. This will facilitate distribution of sections of the document within an organization.

Key Words

Alerts, hazards, medical devices, medical equipment, medical supplies, notices, notifications, recalls

A Model for Managing Medical Device Alerts (Hazards and Recalls) for Healthcare Organizations; Approved Guideline

1 Scope

This guideline provides a framework for healthcare delivery organizations to respond to externally generated notifications of medical device **Alerts** while focusing on the quality constructs of process control, occurrence management, and process improvement.

For the purpose of this guideline, the term "Alerts" will be used to describe any form of communication from an external source. These may include alerts, field corrections, hazards, notifications, recalls (mandatory or voluntary), and/or withdrawals.

The document includes recommendations for managing medical device Alerts including receipt and communication of hazard and recall information, and formulation of an internal plan. Implementation of this guideline will aid institutions in minimizing risk to patients and in the process, satisfying regulatory and accreditation requirements.

This document is **not** intended to:

- reiterate current regulation, including manufacturers' preparation for and response to medical device hazards;
- provide guidance for risk assessment of devices (e.g., failure mode and effects analysis); or
- provide guidance for responding to device-related incidents that occur in a specific institution.

2 Introduction

This guideline provides a single, focused approach to simplify and expedite the management of medical device Alerts. Though the document is focused on medical devices, the principles set forth can be applied to Alerts received for nonmedical devices (e.g., child-life, food). Thus, aspects of this document may assist facilities in developing plans to respond to a variety of Alerts.

3 Definitions

alert – a communication that describes a problem, hazard, or risk that may exist with or may be associated with the use of a specific product which may have adverse health consequences; **NOTE 1:** For the purpose of this guideline, the term Alerts will be used to describe any form of communication from an external source. These may include alerts, field corrections, hazards, notifications, recalls (mandatory or voluntary), and/or withdrawals; **NOTE 2:** This communication is typically issued by the product manufacturer, but may be issued by a regulatory agency or an independent source.

biologic – a drug that is prepared using a biological starting or source material (i.e., derived from a microorganism, plant, or animal) and various manufacturing techniques.[1]

contingency plan – a coordinated strategy that involves plans, procedures, and technical measures to enable the recovery of systems and continued operations after a disruption.

device – see **medical device** below.

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field correction – correction applicable to a device already released by the manufacturer; **NOTE:** A correction may be performed without removing the device to another location or returning it to the manufacturer.

hazard – a potential source of harm; **NOTE:** A hazard may harm either a healthcare provider or a healthcare recipient (ISO/IEC Guide 51).[2]

hazard notice – a formal communication that may be distributed from a variety of different sources alerting the public to a possible hazard.

mandatory recall – a mandate from a regulatory authority that a manufacturer recall a device that is a risk to health; **NOTE:** This may occur in instances where a manufacturer is no longer in business.

medical accessories – see **medical device** below.

medical device – any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more specific purpose(s); **NOTE:** Specific purposes may include: diagnosis, prevention, monitoring, treatment, or alleviation of disease; diagnosis, monitoring, treatment, alleviation of, or compensation for an injury; investigation, replacement, modification, or support of the anatomy or of a physiological process; supporting or sustaining life, control of conception; disinfection of medical devices (regulated as drugs in some jurisdictions); providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body; and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means (FDA).[3]

medical products – see **medical device** above.

medical supplies – see **medical device** above.

nonmedical supplies – for the purpose of this guideline, all materials brought into healthcare facilities that do not meet the definition of medical devices (e.g., maintenance products, drywall, toys).

notice – a communication of information regarding the risk associated with the use of a device issued by either the manufacturer of a product, distributor, or regulator; **NOTE:** Notices may warn user facilities, healthcare professionals, users, and patients of risks.

pharmaceutical – any synthetic substance or mixture of substances manufactured, sold, or represented for use in the diagnosis, treatment, mitigation, or prevention of a disease, disorder, abnormal physical state; restoring, correcting, or modifying organic functions in man; and which achieves its primary intended action in or on the human body by pharmacological, immunological, or metabolic means.

recalls – a method of removing or correcting products that are in violation of laws administered by a regulatory authority and that may represent a health hazard to the consumer or user; **NOTE 1:** Recalls are actions taken by manufacturers, distributors, importers, or regulatory agencies to carry out their responsibility to protect the public health; **NOTE 2:** Recalls may be classified into numerical categories (i.e., I, II, or III, as described below) by regulatory agencies (e.g., U.S. Food and Drug Administration, Health Canada, Australian Therapeutic Goods Agency) to indicate the relative degree of health hazard presented by the product being recalled. The FDA employs the following three-tiered classification system:

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- **Class I** – 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 II** – 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 III** – a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

recall termination (recall complete) – FDA communication that a recall is complete; **NOTE:** This is not considered an Alert.

risk – combination of the probability of occurrence of harm and the severity of that harm (ISO/IEC Guide 51).[2]

4 Responsibilities

In order to efficiently and effectively respond to an Alert, it is essential to designate personnel who will organize and oversee the process. This document defines two special personnel roles—the recall officer (RO) and the recall coordinator(s) (RC)—and notes that the departmental users and owners of the affected medical device have a responsibility to respond quickly when they are made aware of an Alert or asked to participate in the response to an Alert. Figure 1 provides a schematic representation of the general responsibilities of the RO and RC(s).

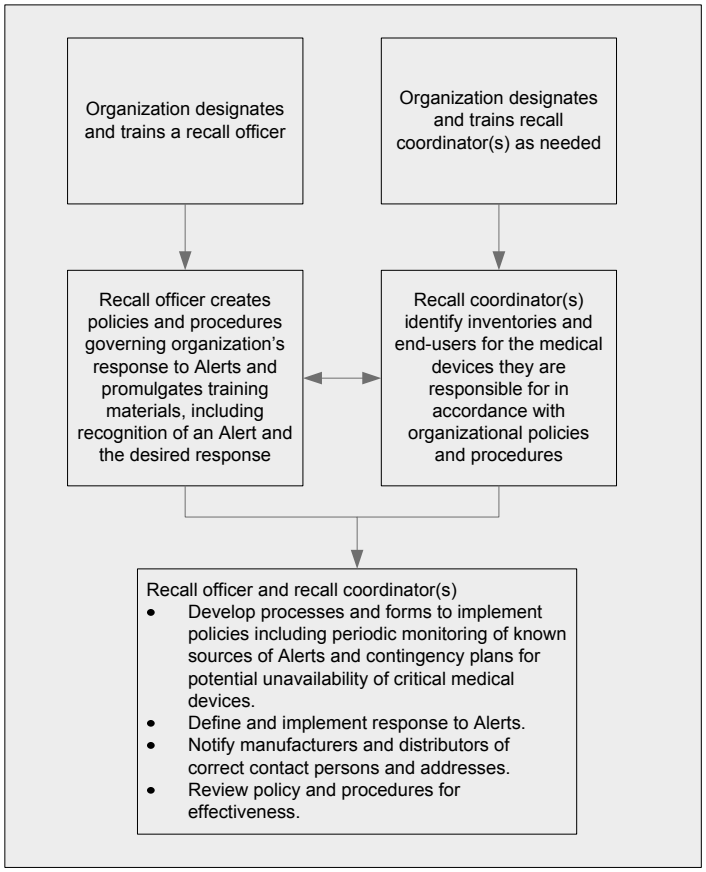

Figure 1. General Responsibilities of the Recall Officer (RO) and the Recall Coordinator(s) (RC)

The amount of time required for RO and RC responsibilities is related to the size and complexity of the institution.

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More detailed information on the roles and responsibilities of the RO and RC(s) are described in the following sections.

4.1 The Recall Officer

Each facility should assign responsibility for coordinating Alerts to a specific person or persons. For the purposes of this guideline, the individual performing this function will be designated as the recall officer (RO). Ultimately, the recall officer should be responsible for all issues related to the implementation of a plan to address the Alert at the facility.

4.1.1 Characteristics of the Recall Officer

Recall officers should be capable of performing the following tasks:

- comprehending regulatory issues related to device Alerts and ensuring that facility policies and procedures are consistent with the same;
- communicating effectively with staff in a variety of departments and programs;
- preparing, updating, and maintaining documentation;
- working with personnel in various departments to determine appropriate individuals to assist in addressing Alerts; and
- obtaining support from high-level personnel at the facility in the event that a specific Alert is not being handled expeditiously.

4.1.2 Specific Responsibilities of the Recall Officer

The specific responsibilities of the recall officer should include the following:

- development and/or updating of facility policies and procedures governing Alerts.
- ensuring that facility-specific policies and procedures are in accordance with accreditation and regulatory requirements governing medical device Alerts.
- reviewing Alerts to determine if the implicated medical device is in use at the facility.
- when applicable, determining the appropriate recall coordinator(s) (see Section 4.2) or persons to assist in managing a specific Alert.
- developing a specific plan to handle each Alert. When applicable, this should be done in conjunction with the recall coordinator(s) for the specific event.
  - In communication with the recall coordinator(s), the RO will establish the internal priority for an individual plan, recognizing that all Alerts do not require the same level of response (for example, see the FDA classifications in Section 3).
  - The RO will prepare instructions for users to return devices to the recalling firm. Such instructions and preparations for product return may also be provided by the recalling firm.

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  - The RO will prepare accompanying forms in the Alerts that assess inventory, subdistributors inventory, etc.

  - The RO will prepare internal communications.

  - The RO and RC will coordinate selection of the appropriate source for repairs, revisions, or corrections.

- when applicable, and in conjunction with the recall coordinator(s), providing interim reports to stakeholders on the progress of specific response plans.

- keeping records on the plan developed for each Alert and information on how the plan was carried out.

- communicating regularly with the recall coordinator(s) to:

  - get updates on progress of the response plan;

  - share any updated information on the Alert; and

  - determine what barriers, if any, have been encountered in implementing the plan.

- when applicable, communicating information on Alerts to stakeholders within the institution including:

  - facility administration;

  - risk management;

  - patient safety officers and committee; and

  - environmental safety officers.

- alerting the administration and risk management immediately if there is a high-profile Alert that impacts the facility (e.g., those that have received media attention or involve very commonly used devices).

- assisting the recall coordinator(s) and users of the device in determining what impact the Alert will have with respect to the availability of the device, and how that impact will be managed or mitigated.

- working with the recall coordinator(s) and users of the device to determine if any adverse events may have occurred as a result of the use of the medical device implicated in the Alert.

- assisting administration, risk management, patient safety officials, and others in determining the nature of the event that generated the Alert and whether or not patient notification is indicated.

- keeping records on Alerts that were reviewed but did not require action by the facility, including the reasons that no action was required.

- working with risk management and administration to determine appropriate document retention times for all items and ensuring safe storage of documents for the specified time.

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- working (with the recall coordinator(s), if applicable) to overcome any barriers to implementation of a specific response plan. This may require the assistance of higher level staff in specific departments or in administration.

- when applicable, serving as a liaison between the facility and any groups that serve as contractors that may be involved with the device to ensure that Alerts are appropriately addressed by the contractors.

- when applicable, contacting the manufacturer if an Alert does not appear to be applicable to the facility.

- preparing a final report on each Alert. Ideally, such a report would include information on:

  - the nature of the Alert;

  - the response plan developed;

  - details on how the response was carried out and the timeline of the response;

  - how many devices at the facility were implicated;

  - how the problem was mitigated by the manufacturer or others (repair, replacement, etc.); and

  - whether there were any adverse patient outcomes.

- ensuring that a back-up person is available to carry out the critical functions of the recall officer if the recall officer is unavailable.

- may participate in contingency planning.

4.2 The Recall Coordinator(s)

Though the recall officer has ultimate responsibility for ensuring that Alerts are acted upon, the RO may choose to delegate responsibility for carrying out some aspects of the response plan. Some response-related activities will be more effectively managed by individuals in departments with expertise related to the specific device (e.g., clinical engineering). For the purposes of this guideline, the designated individual(s) responsible for carrying out a specific response will be referred to as the recall coordinator(s) (RC).

4.2.1 Characteristics of the Recall Coordinator(s)

The recall coordinator(s) should be capable of performing the following tasks:

- working with the RO to develop a specific plan to address the Alert;

- locating all of the devices involved in a specific Alert and all of the users of the device;

- preparing, updating, and maintaining documentation; and

- communicating effectively with the manufacturer, staff, and the RO.

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4.2.2 Specific Responsibilities of the Recall Coordinator(s) (RC)

The specific responsibilities of the RC(s) may include:

- working with the RO to develop a specific plan to address the Alert;
- identifying the location of all medical devices implicated in the Alert;
- communicating with all affected department directors and managers;
- initial contact with and regularly updating the RO on the status of the plan;
- assisting the RO in identifying potential users of the medical device;
- assisting the RO and users of the device in determining:
  - what impact the Alert will have with respect to availability of the medical device at the facility and how that impact will be managed or mitigated; and
  - if any adverse events may have occurred as a result of the use of the medical device implicated in the Alert.
- informing the RO when barriers to implementation of the plan are encountered;
- assisting the RO in preparing interim and final reports on implementation of specific plans; and
- ensuring a back-up person is designated to act when the RC(s) is unavailable.

5 Risk Assessment

5.1 Inventory Management

A successful recall depends upon many things. Foremost is the quality of the inventory and asset records. Purchasing and stocking records are essential, not only for fixed and movable equipment, but for medical devices that may be regarded as accessories, supplies, or disposables. This may be complicated because clinical areas may purchase through various channels and therefore maintain an independent inventory, and may provide materials to other organizations. Small fixed or movable equipment may be hard to locate.

For the efficient and effective response to a medical device Alert, an inventory/asset-management process includes at least these elements:

- designation of responsibilities for inventory/asset management (i.e., knowing what they own, where it is located, how and when it was acquired, and if it was consumed or removed, loaned to another unit, etc.);
- effective inventory/asset recordkeeping in any office that performs a purchasing or inventory/asset-management function including accurate recording of the manufacturer name, device name and type, catalog or model number, and lot number or serial number;
- effective tracking of all devices entering and leaving the organization (including demonstration, patient- or practitioner-owned, etc.);

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- easy record retrieval by any of the above fields;

- facilitation and cooperation in affecting the response to the Alert, with administrators, managers, and users committed to the process;

- evaluations of the inventory/asset-management process are recommended when designing the desired process, and periodically (i.e., as part of the annual evaluation of the Medical Equipment Management Program described in JCAHO manuals); and

- for organizations accredited by JCAHO, integration into the Medical Equipment Management Program to identify those responsible for the inventory/asset data and information and implementation of Alert-related responsibilities.

5.2 Contingency Planning

Contingency planning involves developing plans, procedures, and technical measures to enable the recovery of systems and operations after a disruption. An organization must complete a risk analysis and develop a risk management strategy to design effective contingency plans. For an Alert, the risk is the possibility of lost use of a critical medical device due to a manufacturer's recall. The plan should include timely ability to provide care through the capability to:

- restore operations at an alternate site (e.g., transporting the patient if necessary);

- recover operations using an alternate medical device (e.g., using an existing medical device or renting a different model if necessary); and

- perform some or all of the affected clinical processes using other means.

The contingency plan should be routinely updated for responding to a recall.

As a general rule, medical devices should be assessed for criticality and the overall recovery plan reviewed annually or whenever significant medical device changes occur and may also be part of the equipment selection process. The plan itself should be tested whenever staff or processes change, and refined as required.

Training for personnel with contingency plan responsibilities should complement testing the plan. Training should be provided at least annually, and new hires should receive training shortly after they are hired.

6 Obtaining Alert Information

Healthcare organizations receive medical device Alerts from various sources, including directly from manufacturers and distributors (via mail, fax, e-mail, phone, and/or visit), the FDA, publications and subscription services, and organizations that provide this information as a membership benefit. Despite the availability of Alert information, there are serious challenges related to healthcare organizations dependably receiving this information, and with this information being promptly disseminated to the individuals within the organization who are responsible for the management and use of the affected medical devices. The following sections describe the sources of this information.

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6.1 Receiving Alert Information

Every healthcare organization should have a policy and procedure for dependably obtaining Alerts, ensuring they are then sent to the individual (recall officer) responsible for receiving, disseminating, and verifying responses to this information.

Alert information can be received in any department or location in a healthcare organization. Therefore, all employees—especially managerial and supervisory staff—should be aware of this policy, and, in particular, the fact that there is a single point of contact for this information. Staff should be reminded of this periodically (e.g., at management meetings, in the organization's publications and broadcast e-mails, and at appropriate committee meetings). Special notice should be given to all likely contact points for Alerts including:

- purchasing;
- mail room;
- risk management;
- safety officer;
- clinical/biomedical engineering;
- facilities;
- warehouse;
- accounting departments;
- offices of the chief executive;
- chief operating officer;
- chief financial officer;
- clinical department directors; and
- administrators.

A healthcare organization may determine that it should have a designated office or person who receives medical device Alerts, along with a second point of contact. For example, if the primary point of contact is in the clinical/biomedical engineering or materials management department, because these departments are responsible for the majority of medical devices, the safety or risk management department could be a second point of contact, because it is responsible for patient and staff safety issues.

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It is recommended that purchase and sale agreements include a provision for Alerts. The following is an example of such a provision:

> In the event of any Alert (recall, field correction, or other hazard-related communication) issued by Company to the FDA or to those who acquired a medical device purchased under this agreement, Company shall send two copies of such Alert, one to each of the following: [first, (the Recall Officer), title as Recall Officer, address, phone number, and fax number, and the second to the Risk Manager (or other appropriate person/title) with the address, phone number, and fax number defined]. Either party may change its notification address by giving written notice to that effect to the other party by the manner provided here.
>
> If an Alert is issued, Company shall notify [organization name] of any such recall or modification in accordance with applicable laws and regulations, within an appropriate time period in light of the nature of the Alert, and in any event as promptly as reasonably possible under the circumstances. Alerts shall include instructions and information regarding the medical device Alert or modification and appropriate action to be taken by [organization name]. Company shall not charge [organization name] for the replacement, modification, or repair of the medical device as part of the Alert, and Company shall pay or reimburse [organization name] for reasonable freight costs incurred by Buyer to return any affected medical device to Company.

6.2 Alert Information Sources

There are a variety of sources from which Alert information can be obtained. Healthcare organizations should not depend upon any single source for Alert information. Not all sources provide all Alerts, nor do they provide consistent content (e.g., format, terminology, severity, recommended distribution, and recommended actions).

Manufacturers and distributors are the initial source of most Alerts. However, depending solely on company notifications does have drawbacks. There is no standard format or content for Alerts from manufacturers and distributors, and there is no consistency on where they are sent. There is also no dependable way for users to inform manufacturers and distributors where to send Alerts. The recommendation for an Alert provision in purchase and sale agreements (see Section 6.1) is not a guarantee that vendors will comply and it does not address the existing inventory, but in the future, it could help vendors who are conscientious about notifying their customers about problems.

NOTE: In the U.S., the FDA is the primary source for medical device hazard and recall information since manufacturers and distributors must, by law, inform them of all recall actions. However, there can be significant delays in the publication of Alerts by the FDA. The FDA issues information about its new recalls in *FDA Enforcement Reports*, a weekly publication available on the Internet at http://www.fda.gov/opacom/Enforce.html. The *FDA Enforcement Reports* are available for purchase from Government Printing Office bookstores or on the Internet at http://www.gpo.gov. The FDA also publishes *Recalls, Market Withdrawals, and Safety Alerts* at www.fda.gov/opacom/7alerts.html. Safety Alerts, Public Health Advisories, and other FDA safety notices can be received by e-mail by subscribing at list.nih.gov/cgi-bin/wa?SUBED1=dev-alert&A=1.

There are a number of independent sources of medical device Alerts. Typically, these sources actively search the FDA reports and a number of other, primary sources, investigate to gather complete information about the devices involved and the actions required or recommended, and provide information in a standard format.

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6.2.1 Software Alert Management Systems

More recently, software Alert management systems have been developed. These systems collect information from a variety of sources, interpret and analyze the information, and enter it into a database. A computerized system sends selected information to member organizations, based on criteria established by the organization (e.g., devices the organization owns or stocks). Within the organization, applicable reports are sent to different departments, automating the distribution function. Departments respond online, and tracking and recordkeeping are done by the system.

Please refer to Appendix A for other types of Alert information.

7 Planning and Implementing a Strategy for Responding to Alerts

An organization's ability to respond to Alerts in an organized, efficient, and effective way requires preparedness, designation of key functional individuals, and establishment of policy and procedures appropriate to the complexity of the organization and the medical devices it uses. The role of the RO is especially critical in ensuring that Alerts are received, allocated to the appropriate RC(s), assessed, responded to as appropriate, and archived for retrieval and review as needed. The additional responsibility of the RO to periodically review the policy and procedures associated with Alert response ensures that the strategy continues to be effective and efficient as experience is gained and as circumstances within and outside of the organization change.

7.1 Segmentation of the Alert Response Strategy

The organization's strategy for determining how it will respond to an Alert can be divided into three segments:

- the segment describing the actions an organization can take in order to put an effective response plan in place;
- the segment describing ongoing efforts by the organization to identify relevant Alerts and respond appropriately to them; and
- the segment describing the efforts of the organization to review the effectiveness of the Alert activities, and to correct or improve them as necessary.

7.2 Checklist for the Alert Response Strategy

A checklist to use in assessing progress toward completing the strategy, and in following progress in responding to individual Alerts, is presented in Appendix B.

7.3 Organization Preparedness

Preparedness includes several activities described below.

7.3.1 Designation of a Recall Officer (RO)

The organization should designate an RO (see Section 4.1.1) and define the responsibilities of the RO (see Section 4.1.2).

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7.3.2 Establishment of Alert Policy and Procedure(s)

One of the key responsibilities of the RO is to create an Alert response policy (see Appendix C), in cooperation with other relevant groups (e.g., management, engineering, inventory managers) and to promulgate training materials dealing with policy. These procedures will provide the roadmap for how Alerts are to be handled by the organization. An important part of the organization's policy and procedures for handling Alerts is the section dealing with how to respond when a critical medical device is the topic of the Alert (see Section 7.3.5). Ongoing review of the policy and procedures is also a responsibility of the RO, to assess its effectiveness and efficiency, and to provide recommendations for its improvement or adaptation to changes occurring within (e.g., new products, medical device, or staff) or outside of (e.g., regulatory or certification requirements) the organization.

7.3.3 Designation of Recall Coordinator(s) (RC)

The organization should designate a sufficient number of RCs (see Section 4.2.1) based on the size of the organization and the extent of its inventory of medical devices. RCs should be designated based on their knowledge of the medical devices and/or end-users over which they are to exercise their RC responsibilities, and should be given the appropriate authority to exercise those responsibilities. RCs should be thoroughly familiar with the organization's response policy and procedures. Typically, RC responsibility will be one that is added to an existing position; but in a large organization, stand-alone RC positions may be appropriate. RC responsibilities (see Section 4.2.2) typically include monitoring for Alerts, assessing RO-assigned Alerts as to whether or not they apply to the organization, cooperating with the RO to develop response plans, and executing those response plans.

7.3.4 Training of General Staff

The recall officer, typically with the assistance of the recall coordinator(s), should make all employees aware of the importance of Alerts, by promulgating training materials that deal with the Alert response policy and procedures. Because not all Alerts are sent to the correct contact person or to the proper address, employees in administrative and supervisory positions, purchasing staff (who may receive Alerts incorrectly or incompletely addressed), or those performing mail receipt or distribution functions especially should be made aware of the importance of Alerts and should share this information with their staff. Such awareness training materials could include examples of typical Alert formats to aid in their recognition, and phone numbers or e-mail addresses of whom to contact if such an Alert is received.

7.3.5 Definition of Critical Medical Devices

The RO, in cooperation with the RC(s), should identify those who maintain inventories of medical devices in use in the organization, which are critical to the organization's role (such as those involved in life support or providing life-supporting decision making) (see Section 5.2). Contingency plans should be established as to the organization's course of action should such critical medical devices become unavailable because of an Alert.

7.3.6 Voluntary Monitoring for Alerts

The RO, in cooperation with the RC(s), should identify mechanisms (see Section 6) available to the organization by which it can voluntarily monitor for Alerts (e.g., the FDA's site and listservs). In addition, subscription services are available to which organizations can subscribe to receive Alerts. (See Appendix E for sample Alerts.)

7.3.7 Communicating With Manufacturers and Distributors

The RO, in cooperation with the RC(s), should consider updating manufacturers and distributors of medical devices in use by the organization, especially critical medical devices as defined above, regarding

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the appropriate contact name and address to be used in the event of an Alert, and keep such information up to date.

7.3.8 Identification of Medical Device Inventory Locations and End-users

The RC(s) should create and maintain lists of storage repositories for the medical devices for which he or she has RC responsibility. In addition, lists of end-users of the medical devices (at department and unit level) should be created and maintained (see Section 5.1).

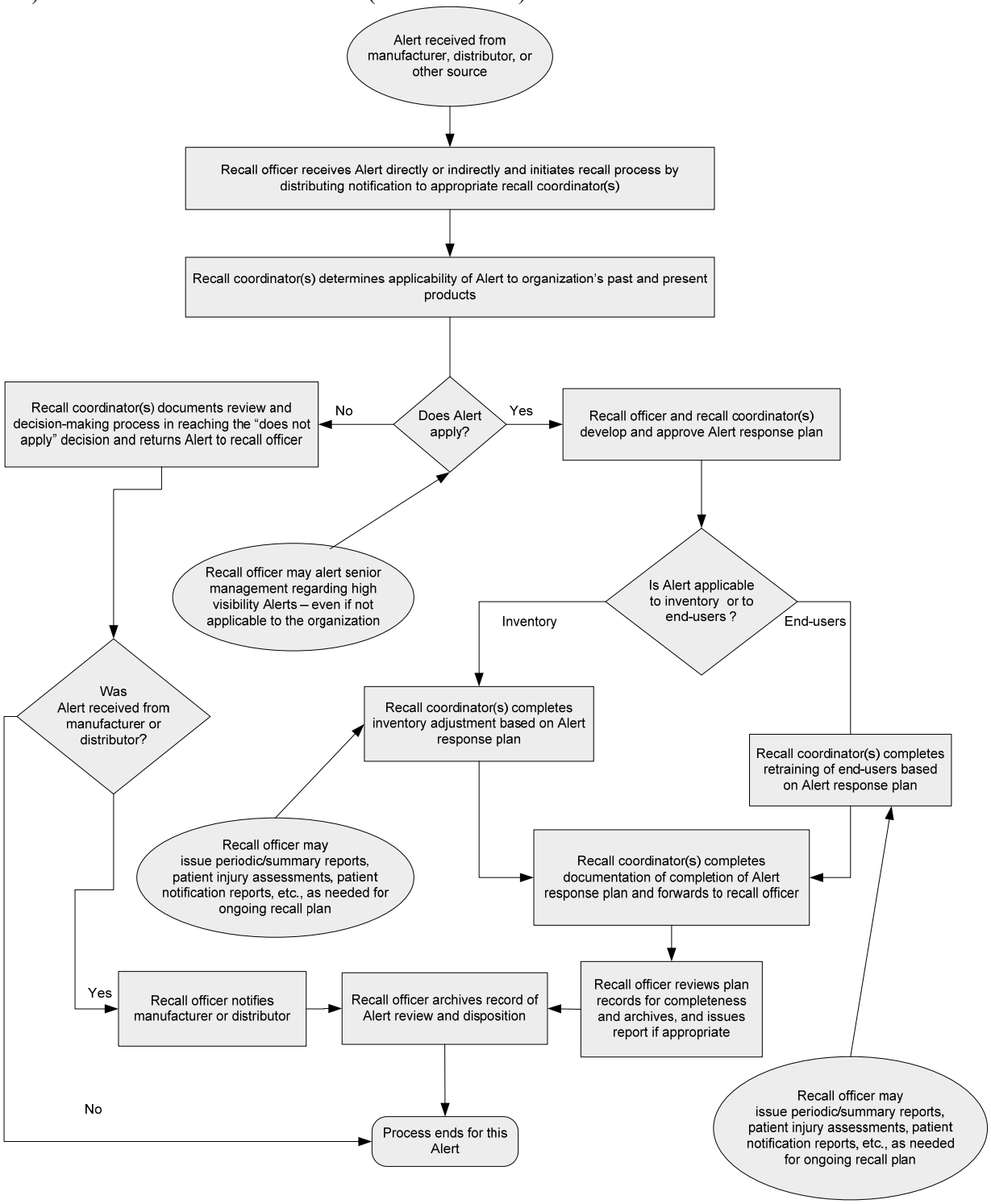

Figure 2. Monitoring and Response Segment of an Alert Response Strategy

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7.4 Monitoring for and Responding to Alerts

Once the Alerts response policy and procedures have been established, the RO and RC(s) have been designated, and the remaining preparedness steps described above have been completed, the organization moves into the segment of the recall response strategy that includes routine monitoring for, and responding to, Alerts (see Figure 2). Within this segment, the organization is monitoring (see Section 7.3.6) while also being prepared to receive and forward Alerts to the RO.

Records of the organization's responses should be established and archived for:

- alerts directly sent to the organization by a distributor or manufacturer, regardless of whether or not the Alert applied to the organization. Responses to Alerts not applicable to the organization may be very brief, but serve the purpose of documenting due diligence on the part of the organization to Alerts that were expected, for whatever reason, to apply to the organization; and

- alerts that were determined to apply to the organization and were discovered through the monitoring process established by the RO and RC(s) (see Section 7.3.6). Alerts discovered through this monitoring process that do not apply to the organization need not be documented.

The RO should receive, either directly (see Section 7.3.7) or indirectly (see Section 7.3.4), all Alerts that have been received anywhere in the organization. If necessary, the RO should refer the Alert to the appropriate RC(s) for review as to their applicability to the organization.

NOTE: Records of the disposition of Alerts that do not apply to the organization should be retained if they have been received directly from a manufacturer or distributor. The reason for this is that the sender had reason to believe that the Alert applied to the organization; thus the burden of proof as to why no action was taken by an organization may be on the organization.

The organization should communicate with the manufacturer if an Alert does not apply; the manufacturer's or the organization's records may be erroneous.

The RO, upon determination of whether or not the Alert applies to the organization, may elect to communicate the results of the assessment to senior management, if the criticality or notoriety of the Alert is high, or if required to do so by the organization's policies and procedures.

If the Alert does apply to the organization, then the RO, in cooperation with the RC(s), should develop a plan for responding to the Alert. Throughout the process of the response plan, the RO is responsible for monitoring its progress and adjusting the plan or the resources devoted to its completion to ensure that it is completed in a timely fashion. Typically, a response plan will include the following items:

- a list of the medical devices, their locations, and their end-users, that are covered by the Alert. The effect on medical devices and end-users must be evaluated during the development of each response plan.

- the need to invoke a critical medical device contingency plan. If the Alert applies to medical devices or services of a critical nature (see Section 7.3.5) and if the nature of the response is such that their availability is at risk, the response plan may involve invoking contingency plans for providing continuity of service.

- an assignment of what needs to be done, depending on the nature of the Alert. In some cases, medical devices will need to be sequestered for destruction or return to the manufacturer or distributor. In other cases, medical devices, operating instructions, or labeling may need to be modified as instructed

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in the Alert. In yet other cases, end users will need to be retrained in the use of the device as specified in the Alert. Precisely what needs to be done should be specified in the response plan.

- the identification of resources assigned to the response plan. The responsible individuals performing specific tasks are typically specified in this plan.

- the timelines for all activities, when each will be accomplished, and how the determination will be made that the response plan is complete. The need for any interim reports and their timing also are typically defined in a response plan (see Section 8).

- the records that need to be kept, their format, and identifying those responsible for generating them and forwarding them to the RO. Records are a critical part of the plan, since without records, documentation of the successful completion of the plan will not be possible.

Following the completion of the response, the RO should review all documents for completeness and accuracy, summarize the response outcome in a report, and archive the documents for future reference as needed. As noted above, a record should also be archived of the review and disposition of Alerts that did not apply to an organization, if they were sent to the organization by a manufacturer or distributor. Senior management may need to be notified of the outcome of the response, if either the criticality or notoriety was high, or if required by the organization's policy and procedures.

7.5 Reviewing the Effectiveness of the Alert Response Strategy

On a periodic basis (e.g., annually, or at the time of quality system management reviews), the RO should provide a summary (see Section 12.3) of the effectiveness of the Alert response strategy. Such a report would typically include:

- a summary of responses that were executed, including their outcomes and their impact on the organization;

- an assessment of the efficiency and effectiveness of the Alert response policy and procedures; and

- recommendations for corrections or improvements to the Alert response policy and procedures.

8 Internal Communication

Effective response to an Alert requires a coordinated effort from several people within a healthcare system. Internal communication between all affected parties is essential in ensuring that the necessary actions are carried out.

8.1 Internal Communications of Alerts

Each facility must have a communications plan to disseminate information on Alerts to those responsible for any aspect of managing the affected medical device. This includes both users and personnel who manage purchasing, stocking, distributing, cleaning/disinfecting, or maintaining a device. In some instances, this responsibility will be assigned to the RC(s). For devices that are used by a small number of people and in limited locations in the facility, the RC(s) may be able to communicate directly with all relevant parties. However, the facility should also develop a communication strategy that is capable of quickly reaching a much wider audience, potentially the entire facility staff, if the Alert affects a device that may be used, processed, or stored in multiple locations. For example, this may be accomplished via broadcast e-mails or pages, or by posting Alerts in prominent locations.

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In the event an Alert requires that a device be removed from service, users must know: 1) whom to contact if they encounter an affected device; and 2) what plans are in place so that operations can continue without the device. Managers responsible for inventory must know to halt distribution of the affected device and to retrieve and sequester any of the devices they may have already distributed. They will also need to know what to do with the devices (e.g., return to manufacturer, send to clinical engineering for repair).

In the event of an Alert requiring modified use of a device, formal inservice training sessions for all users with documentation of attendance may be needed.

8.2 Communication Responsibilities of the Recall Officer (RO)

The recall officer (RO) is ultimately responsible for ensuring the Alert is effectively acted upon.

8.2.1 With the Recall Coordinator(s)

The RO should:

- communicate the nature of the Alert to the RC(s);
- collaborate with the RC(s) to create the recall action plan; and
- communicate regularly with the RC(s) to ensure the plan is being carried out and that no barriers are being encountered.

8.2.2 With Healthcare Facility Administration

The RO should alert the administration immediately if there is a high-profile Alert that impacts the facility (i.e., those that have received media attention or involve very commonly used devices). It is also advisable that the RO alert the administration about high-profile recalls that do not impact the facility.

Once a response plan is enacted, the RO should maintain ongoing communication with the administration, or follow existing facility procedures, if applicable, for communicating the Alert.

8.2.3 All Facility Staff

All facility staff must contact the RO in the event that they receive an Alert. All employees, especially those in locations like the mail room or purchasing, where Alerts are likely to be received, must know how to reach the RO.

8.2.4 Users of the Affected Device

Users of the affected device should know that they are expected to report any adverse outcomes that may have resulted from use of the device and any problems they may encounter due to device unavailability. If an RC(s) is coordinating the Alert, the RO and RC(s) may determine that inquiries and reports from users will go to the RC(s). However, this must be clearly communicated to the users and contact information for the RC(s) must be provided.

9 Communication to Patients and Family

Communication and disclosure of an Alert should be a vital part of an organization's patient safety program. Discussions with the patient or family may be warranted if the Alert results in a change in the patient's treatment plan or causes an unanticipated outcome. Examples warranting disclosure may include

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prescribing of an antibiotic due to exposure of a contaminated medical device or removal or increased monitoring of a defective implant. There are no criteria that dictate when disclosures are not necessary. However, it is generally accepted that there is no obligation to discuss an Alert if the item never reached the patient. Decisions on patient notification should be discussed and made collaboratively between clinicians, administrators, and risk management staff. These discussions should include what compensation or allowances the facility may provide to affected patients, for example, reimbursement for antibiotics or waiving of fees for removal or monitoring of an implant.

If disclosure is deemed appropriate, the RO, administrative staff, and risk management staff should support the clinicians in their discussion with patients.

Discussion of an Alert with the patient or family typically includes:

- an objective statement of what happened;
- clear conveyance of regret;
- identification of steps already taken to prevent reoccurrence;
- discussion of any change in the patient's care plan and addressing of any areas of particular concern to the patient;
- what compensation or allowances the facility will provide; and
- identification of whom the patient or family will hear from next in the organization and what (if any) steps will need to be taken.

After the discussion, the patient or family should be able to relay back their understanding of the explanation. All discussions should then be documented.

NOTE: This guideline is not intended as legal advice or a description of the legal considerations an RO or facility administrator must bear in mind when implementing a disclosure practice.

10 Testing and Training

Testing of the Alert response plan is a critical element of a program. Testing, drill exercises, or "paper drills" (i.e., questionnaires to evaluate knowledge and ability to respond) mimicking an Alert enable the identification and remediation of plan deficiencies. Testing also helps evaluate the ability of appropriate staff to implement the plan quickly and effectively. Each plan element should be tested to confirm the accuracy of the individual procedures and the overall effectiveness of the plan. For example, the following areas should be addressed in an Alert contingency test:

- initial receipt and forwarding of Alerts;
- device location and removal process;
- documentation of actions;
- restoration of normal operations; and
- patient and staff communication and disclosure.

It is important that a test or exercise be designed in such a way as to minimally disrupt normal operations, or ideally, offer no disruptions. The coordinator of the test should discuss test dates and plans with key stakeholders within the facility. Test results and lessons learned should be documented and reviewed by

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test participants and other personnel as appropriate. Information collected during the test and posttest reviews that improve plan effectiveness should be incorporated into updated contingency plans.

Training for personnel with response plan responsibilities should complement testing. Training of all possible participants in a recall should be provided at least annually; new hires who will have plan responsibilities should receive training shortly after they are hired. Training of appropriate staff should also occur when a new device is purchased and put into use.

NOTE: In the U.S., for facilities that are JCAHO-accredited, this training could be incorporated into other education essential for medical equipment and emergency preparedness training under JCAHO's Environment of Care requirements.

It is acceptable to use a real Alert as a periodic test of the plan. A mock Alert would only be necessary in the event that there hasn't been an Alert that affects the organization during the period. The same procedure applies to the review of an actual Alert.

11 Recordkeeping

Efficient and effective recordkeeping and record recovery permits the organization to:

- respond quickly and do so only once (there may be numerous redundant Alerts over long periods of time); and

- handle the public relations aspects of a significant Alert.

A paper log or a paper filing system implies that the record can be found in only one way (e.g., by date, manufacturer, or device type). A spreadsheet or database facilitates access to the record by any one of numerous attributes (see Appendix D for sample database fields). It also allows for multiple entries when fields may have multiple common names (e.g., the manufacturer changes its name, or a device type is referred to by a nickname), and tracks the details inherent in a response to an Alert that requires action.

When establishing a recordkeeping system, use of standard nomenclature (e.g., FDA, ECRI), where possible, should be considered. The system should be consistent with the organization's policies on records, such as security and privacy, and should be available to selected individuals (e.g., password-protected on a shared drive).

Record retention is recommended for all reports, and for the following:

- a copy of the Alert to RC(s) and others.

- a list of the RC(s) to whom the Alert was sent, the date it was sent, and the date a response was received.

- any follow-up, including requests from assistance to higher authorities, to obtain 100% response.

- the response from the RC(s):

  - affirming that a search of records or a physical search was conducted;

  - documenting that the search by the RC(s) or others yielded:

    (a) no indication that the item was or had been on the premises,

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(b) an indication that the organization had, and continues to have the item, or

(c) an indication that the organization had, but no longer has the item.

- a record of subsequent actions depending upon the category above, (a), (b), or (c):
  - if the item has not been on the premises, then no further documentation is required. A log of negative responses, including telephoned or e-mailed negative responses, could be maintained if desired.
  - if the item has been on the premises, a record of any actions (e.g., removing the device from a patient, communication with the patient) that may have been necessary due to its use on/with/in patients (e.g., an electrosurgery unit, an exam light, or an implant).
  - if the item is currently on the premises, a copy of the Alert response policy and procedures and documentation of actions that are being taken consistent with the Alert, advice and decisions from those responsible for patient care, clinical engineering, the patient safety officer, and relevant others.
- if there was training of users and/or maintainers, records consistent with existing policies (possibly managed by Human Resources or the supervisor).
- if modifications, relabeling, or replacement of a medical device, appropriate documentation (e.g., in biomedical/clinical engineering or in central supply) in a separate file or within individual maintenance histories.
- removal, destruction, or other disposition of accessories and supplies (e.g., in materials management).

12 Reporting

Interim reports on the status of an ongoing activity may be desirable for complex or lengthy action plans. The need for interim reports should be determined by the RO and RC(s) at the initiation of the action plan.

12.1 Interim Report

An interim report may be useful when addressing lengthy issues or to communicate important decisions. For example, an Alert recommends not using a device until the manufacturer modifies it. If the organization does not have an alternate approach, it may require changes in medical practice, acquisition of other devices, and training of staff. The organization will have made several urgent decisions in response to the recall. After facilitating the response, the RC(s) should document the situation in sufficient detail to ensure that all who should know are fully informed.

12.2 Final Report

Development of a final report is recommended to document all relevant information upon completion of the Alert.

The Final Report summarizes the Alert and the organization's response. If modifications in a patient's care resulted from the response, there should be sufficient detail to enable tying the report to the patient's record (see Section 9). This report is normally distributed to the risk manager, the organization's attorney,

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the person responsible for the clinical department, and may also include the administration and materials management/purchasing.

12.3 Annual Evaluation

Each year, the institution should evaluate the effectiveness of its Alert procedures based on feedback and input from the RO, RC(s), and others involved with the recall process.

12.4 Final Summary

Development and implementation of a short final summary for the Safety Committee and the Patient Safety Committee (or Patient Safety Officer) should ordinarily not contain any personally identifiable information.

The purpose of the final summary is to inform members of the committees, who may have relevant information that would otherwise be missed, to identify any shortcomings in processes (e.g., lack of support from users) or in the specific response (cannot locate all of the devices), and to complete the communication cycle in a way that may contribute to interdepartmental and interdisciplinary performance improvement.

The report should include information on:

- who received the Alert from the RO;
- when the Alert was distributed and when responses were received from the RC(s), users, and other affected parties;
- the nature of the responses and subsequent actions;
- any adverse effects on patient care; and
- recommendations for future actions, including performance improvement.

NOTE: If the report includes any shortcomings, an update may be required at a later date.

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References

[1] Biologic and Genetic Therapies Directorate. Available at: http://www.hc-sc.gc.ca/hpfb-dgpsa/bgtd-dpbtg/index_biologics_e.html. Accessed 14 December 2004.

[2] ISO. *Safety aspects—Guidelines for their inclusion in standards*. ISO/IEC Guide 51. Geneva: International Organization for Standardization; 1999.

[3] FDA. *Medical Devices; Medical Device User Facility and Manufacturer Reporting, Certification and Registration* (Codified at 21 CFR Parts 803 and 807). 60 Federal Register. 63578; 1995.

Websites

U.S. Food and Drug Administration	http://www.fda.gov
U.S. Food and Drug Administration Public Health Notifications	http://www.fda.gov/cdrh/safety.html
Joint Commission on Accreditation of Healthcare Organizations	http://www.jcaho.org

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Appendix A. Other Types of Hazard and Recall Information

Some healthcare facilities may want to expand their Alerts management program to include other types of products. FirstGov for Consumers is a website (www.consumer.gov) with links to many federal information resources available online. Among them is a link to www.recalls.gov, which is a convenient source for recalls from six agencies: Consumer Product Safety Commission, Food and Drug Administration, National Highway Traffic Safety Administration, U.S. Department of Agriculture, U.S. Environmental Protection Agency, and U.S. Coast Guard.

Sources of safety information on specific types of products and services of interest to healthcare facilities include the following:

- Prescription and over-the-counter drugs and biologics are regulated by the FDA. MedWatch, the FDA Safety Information and Adverse Event Reporting Program, provides safety information and a mechanism for healthcare professionals and consumers to report suspected problems. Safety information can be obtained online by subscribing to MedWatch E-list at www.fda.gov/medwatch.

- Consumer products are often used in healthcare organizations, especially toys and games in pediatrics and child-life, and appliances and tools in occupational therapy departments. The Consumer Product Safety Commission (CPSC) works to ensure the safety of consumer products (e.g., toys, cribs, tools, household chemicals, appliances). Consumers can subscribe to their press releases and recalls at www.cpsc.gov/cpsclist.asp.

- Worker health and safety are overseen by the Occupational Safety and Health Administration (OSHA). OSHA establishes standards, investigates complaints, and provides consultation services. Their website (www.osha.gov) has information on specific hazards and injury prevention. OSHA also monitors state health and safety programs for workers. There are 24 states and two territories with OSHA-approved plans. OSHA's Hazard Communication Standard (HCS) requires manufacturers and importers to evaluate the hazards of their chemicals, and to convey this hazard information via labels and material safety data sheets (MSDS). Employers with hazardous chemicals must have labels and MSDS for their workers and train them to handle these chemicals. OSHA issues Hazard Information Bulletins that may be found by accessing the following link:

  http://www.osha.gov/pls/oshaweb/owasrch.new_search_results?p_text=Hazard%20information%20bulletin&p_title=&in_clause='FULL_SITE'&p_status=CURRENT&p_category=&p_logger=1.

- Fire, electrical, and life safety codes, standards, research, training, and education are developed and provided by the National Fire Protection Association (NFPA). The NFPA issues press releases on safety issues (http://www.nfpa.org/newsreleaselist.asp?categoryID=488). One can subscribe at: http://www.nfpa.org/itemDetail.asp?categoryID=493&itemID=18961&URL=Press%20Room/Headlines%20by%20e-mail.

- Food safety is overseen by a long list of agencies, each with specific responsibilities.

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Appendix A. (Continued)

Agency	Responsibilities	Website
National Food Safety Information Network	Website with links to government food safety information	www.foodsafety.gov
Food and Drug Administration (FDA)	Food sold in interstate commerce (except meat and poultry), bottled water, wine beverages with less than 7% alcohol	www.cfsan.fda.gov
Centers for Disease Control and Prevention (CDC)	Food-borne diseases	www.cdc.gov
U.S. Department of Agriculture (USDA)	Meat and poultry products	www.fsis.usda.gov
Cooperative State Research, Education, and Extension Service	Research and education on food safety Local cooperative extension services	www.csrees.usda.gov
National Agricultural Library, USDA/FDA Foodborne Illness Education Information Center	Educational materials on preventing food-borne illness	www.nal.usda.gov/fnic
U.S. Environmental Protection Agency (EPA)	Drinking water, toxic waste, pesticides	www.epa.gov
National Seafood Inspection Laboratory (NSIL)	Fish and seafood products	www.nmfs.noaa.gov/sfa/sfweb/nsil
Alcohol and Tobacco Tax and Trade Bureau (TTB)	Alcoholic beverages (except wine beverages containing less than 7% alcohol)	www.ttb.gov/alcohol/index.htm
U.S. Customs and Border Protection	Imported foods	www.cbp.gov/xp/cgov/import/commercial_enforcement/
Federal Trade Commission (FTC)	Enforces laws protecting consumers from fraudulent or deceptive practices	www.ftc.gov
State and Local Governments	Inspections; halt sale of unsafe food within state borders	State and local health, agriculture, and environmental agencies

- Motor vehicle safety is the responsibility of the National Highway Traffic Safety Administration (NHTSA). They establish and enforce safety standards for motor vehicles and equipment, investigate safety defects, and provide consumer information. Their website for recalls is www-odi.nhtsa.dot.gov/cars/problems/recalls; their Auto Safety Hotline is 888-327-4236.

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Appendix B. Sample Action Plan Checklist

Action Plan Checklist Effective Date: mm/dd/yy
Document Number/Version Number

Program Preparedness

- ☐ Has the organization designated a recall officer and specified the duties and authority associated with the position?
- ☐ Has the organization prepared, reviewed, and approved the necessary policy and procedures associated with the organization's response to Alerts?
- ☐ Has the organization designated recall coordinator(s) in sufficient number and specified the duties and authority associated with the position?
- ☐ Has the span of devices and/or end-users associated with each recall coordinator been specified?
- ☐ Are all medical devices and end-users covered by assigned recall coordinator(s)?
- ☐ Has the recall coordinator(s) been trained in the Alert response policy and procedures?
- ☐ Have the recall officer and recall coordinator(s) established a plan to monitor likely locations (e.g., Internet sites maintained by manufacturers or regulatory agencies, commercial notification services, professional journals) where Alerts may appear?
- ☐ Have the recall officer and recall coordinator(s) identified critical medical devices (i.e., those required for life support) and established contingency plans in the event that an Alert requires them to be removed from service?
- ☐ Have manufacturers and distributors from whom Alerts might be received been notified regarding the correct contact person(s) and address(es) to which such communications should be sent?
- ☐ Has the organization alerted its entire staff, particularly in locations such as purchasing, mailrooms, and administrative services, to the importance of Alerts, how to recognize them, and what to do with them when they are received?
- ☐ Have the user and owners been informed that they share the responsibility for preparing for and responding to Alerts with the RO and RC(s)?

Monitoring and Initial Response Processes
(for each Alert, regardless of relevance to the organization)

- ☐ Has the Alert been received by the recall officer in a timely fashion? If not, can improvement be made for future similar communications (e.g., training, monitoring, manufacturer, or distributor communication)?
- ☐ Was the Alert distributed by the recall officer to the proper recall coordinator(s)? If not, what is required to improve the process (e.g., back-up for recall officer)?
- ☐ Have responses been received from each recall coordinator in a timely fashion? If not, what can be done to avoid the delay in the future (e.g., recall officer follow-up, back-up for recall coordinator(s), designation of additional recall coordinator(s))?

Facility Name/Location Page 1 of 3
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Appendix B. (Continued)

Action Plan Checklist Effective Date: mm/dd/yy
Document Number/Version Number

☐ Is the Alert of sufficient criticality or notoriety that senior management should be notified, regardless of whether or not it applied to the organization? If so, has senior management been notified regarding the Alert, its relevance to the organization, and other pertinent details (e.g., what plans are being undertaken to respond)?

☐ Did the Alert received from a manufacturer or distributor apply to the organization? If not, has the recall officer reviewed, approved, and archived the documentation regarding the Alert, so that future questions regarding the organization's response can be readily available?

Response Plan and Execution
(in cases where the Alert applied to the organization)

☐ Has the recall officer developed, with the involvement of the recall coordinator(s) and users/owners, and approved a response plan, that includes:
- what needs to be done to respond to the Alert?
- who is responsible for each action in the response plan?
- when each activity in the response plan is due to be completed?
- what records will be generated during the course of the response plan to document its successful completion?
- the timing of interim update reports to senior management, if required?

☐ If the Alert requires retraining of end-users:
- have all end-users been identified?
- has the necessary information been passed to all identified end-users?
- have appropriate SOPs, user manuals, etc., been updated to reflect the changes in the Alert?
- if necessary, have changes to the medical device (e.g., relabeling) been made?
- have means been determined to document that the new information has been received and/or that new competency has been established by the end-users?
- have records of information transfer, and, if needed, of new competency by the end-user, been created?

☐ If the Alert affects a medical device:
- have all repositories of the affected device been identified?
- has appropriate action (e.g., sequestration, disposal, adjustment, relabeling, return to vendor) been taken for each item in each identified repository of the affected medical device?
- has appropriate action been taken to respond to insufficient supply or delay in receipt of a replacement medical device if necessary?
- if necessary, have end-users been notified regarding the Alert response plan and the impact it may have on their use of the medical device?
- have records of medical device disposition in response to the Alert response plan been created?

☐ Are timelines being met as agreed upon in the Alert response plan? If not, the recall officer must follow up and make necessary adjustments to plan timelines or to resources devoted to the Alert response plan.

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Appendix B. (Continued)

Action Plan Checklist Effective Date: mm/dd/yy
Document Number/Version Number

☐ Are interim reports to senior management required per the Alert response plan? If so, the recall officer or recall coordinator(s) must create and distribute such reports.

☐ Have all records of response plan activities been received by the recall officer and reviewed for acceptability prior to archiving? If not, the recall officer must follow up to ensure proper documentation is available to close out the response plan.

☐ Has the recall officer reviewed, approved, and archived all response records for completeness, and published the final report? If not, future questions regarding the organization's response to the Alert may be difficult or impossible to demonstrate.

Postnotification Activities

☐ Has the recall officer issued periodic reports regarding the effectiveness of the organization's recall policy and procedures, including recommendations for any changes necessary to correct or improve the organization's responses to Alerts?

☐ Has senior management of the organization reviewed the efficiency and effectiveness of the recall policy and procedures, and responded to the recall officer's recommendations?

Facility Name/Location Page 3 of 3
[filename/path]

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Appendix C. Sample Policy Development Checklist

Medical Device Alert Response Plan

1) Purpose

2) Scope

3) Definitions

4) Responsibilities
   a) Administration
   b) Recall officer
   c) Recall coordinator(s)
   d) Staff

5) Medical Devices
   a) Items covered under this plan
   b) Criticality category
   c) Purchase and sale agreement terminology
   d) Manufacturer notification of recall officer name and address
   e) Contingency plans
      i) Critical items – specific plans prepared in advance
      ii) Less critical items – plans developed as needed

6) Monitoring of Alerts
   a) Overall process
   b) Identify staff responsible for monitoring
      i) All are responsible to be aware and to be able to identify
   c) Where to monitor
      i) Internet sites
      ii) Commercial notification services
      iii) Professional e-mail listservs and newsletters
      iv) Professional literature
      v) Mail

7) Receiving an Alert
   a) Identifying
   b) Alerting the RO and RC(s)
   c) Assessing inventory for device
   d) Educating staff in response to the Alert
   e) Removing device, if appropriate: proper storage and labeling, process for return or destruction
   f) Development and/or initiation of contingency plans, if appropriate
   g) Monitoring process changes and outcomes
   h) Documenting actions
   i) Reporting actions

8) Testing of Processes
   a) Drill exercises
   b) Paper drills
   c) Review of actual Alerts

9) Training
   a) Identifying appropriate staff
   b) Upon hire
   c) Upon receipt of new equipment
   d) Annual basis

10) Annual Assessment of Program
   a) In the U.S., incorporate into JCAHO's Environment of Care Medical Equipment Management and Emergency Preparedness programs

11) Resources

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Appendix D. Sample Database Fields

Healthcare organizations may want to develop a simple relational database to facilitate their Alert recordkeeping. The following is a suggested set of tables and fields for such a database.

Alerts Table:

- Alert number (internal control number)
- Recall officer
- Recall coordinator(s)
- Date received
- Alert type (FDA class I, II, or III recall, or safety Alert)
- Alert source (FDA, manufacturer, distributor, third party, press release; enter type and specific document; if possible, keep a copy of the Alert on file)
- Product (generic and trade names)
- Manufacturer (including address, phone number, and contact)
- Model/catalog number (may be several numbers)
- Serial/lot number (may be several numbers)
- Distributor (including address, phone number, and contact)
- Recommended action (brief description, e.g., modify, repair, notify/train users, remove from service, replace as soon as possible)

Departments Table (list of departments that received Alert form):

- Alert number (ties entries to Alerts table)
- Department (select from drop-down list for consistency)
- Person/title notified
- Date notified
- Person/title responding
- Date of response
- Response (not applicable, applicable – response incomplete, applicable – response complete)
- Notes (e.g., difficulties, adverse outcomes, missing inventory)

Alert Response Plan Table:

- Alert number (ties entries to Alerts table)
- Departments/staff to notify
- Milestones planned (including responsible person, dates)
- Milestones completed (including dates)
- Contingency plans (e.g., for items removed from service or stock/inventory)
- Notes (e.g., difficulties, adverse outcomes, missing inventory)

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Appendix E. Sample Alerts

Critical-Priority Action Item: ECRI Hazard Report

Child Dies When Ventilator Alarms Fail to Warn of Tracheostomy Tube Occlusion

UNDNS Term: Ventilators, Portable/ Home Care [I7-423]

Device: Portable Ventilators

Problem:

ECRI recently investigated the death of a ventilator-dependent child who was being cared for at home. The ventilator settings were configured so that when the patient's tracheostomy tube became occluded with pulmonary secretions (i.e., a mucous plug), no alarms were activated to indicate that the patient's lungs were not being adequately ventilated. The child died as a result of the occlusion.

The circumstances that led to this child's death are not unusual, and other ventilator-dependent patients could experience similar problems.

This incident occurred while the ventilator was delivering pressure-controlled breaths. The high-pressure alarm was set for this patient, but such an alarm will not be effective (i.e., it will not sound) in this particular scenario when the ventilator is set to deliver pressure-controlled breaths. A mucous plug manifests as a decrease in compliance or an increase in resistance. With pressure-controlled breaths, the ventilator will respond to such a change by decreasing the delivered flow (and volume) to maintain the set pressure level. Since the pressure never reaches the high-pressure-alarm setting, this alarm will not sound.

A mucous plug, which can occlude and dislodge the tracheostomy tube, is most likely to occur during periods of increased pulmonary secretion (e.g., infections) and when the patient is agitated or mobile or is undergoing positional changes. At these times, the patient's airway may need to be suctioned more frequently to remove secretions. To aid secretion removal, humidification may need to be increased (e.g., by raising the humidifier temperature), and the use of heat and moisture exchangers may need to be limited because these devices dry out secretions.

During pressure-controlled ventilation, volume alarms need to be used and properly set to warn caregivers of situations in which the patient is not receiving adequate ventilation. For example, in the reported incident, a minute-volume alarm would have been activated to warn of the decrease in delivered volume; however, it was turned off to allow the patient to speak. If the minute-volume alarm is disabled for clinical purposes, then additional external monitors, such as a pulse oximeter and/or end-tidal carbon dioxide ($ETCO_2$) monitor, should be used.

Most ventilator-dependent children receiving care in the home setting are given pulse oximeters; however, we do not believe that pulse oximeters are always used. In addition, while a pulse oximeter may be useful in notifying caregivers of problems such as tracheostomy tube occlusion, it may not alarm as quickly as a low-minute-volume alarm; the patient's blood oxygen level must first decrease to the low alarm setting, which typically takes more time than that required for the low-minute volume alarm to activate. Thus, the patient's condition may continue to deteriorate before the pulse oximeter alarm sounds. Another issue regarding use of pulse oximetry at home is that the low alarm setting may need to be increased to recognize hypoxemic episodes (in which blood oxygenation is deficient) more quickly.

Action Needed:

1. Alert respiratory therapy and ventilator home care personnel to this problem and to our report.
2. Verify that low-minute-volume alarms are set properly when pressure-controlled breaths are delivered to home care, long-term care, or transport patients. Also, use $ETCO_2$, and/or pulse oximeter alarms, especially if volume alarms cannot be used.
3. Suction the patient's airway more frequently during periods of increased pulmonary secretion and when the patient is agitated or mobile or is being repositioned. To aid secretion removal, increase humidification and limit the use of heat and moisture exchangers.

Source: ECRI. Child dies when ventilator alarms fail to warn of an occluded tracheostomy tube [hazard report]. *Health Devices* 2004 Sep;33(9):335-6.

Accession No.: A5848
Suggested Distribution: Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Nursing, Pediatrics, Pulmonology/Respiratory Therapy, Risk Management/Continuous Quality Improvement, Home Care

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Appendix E. (Continued)

[Company]—[Device Name] Nebulizer Medication Bottles: May Fail to Deliver Medication

UMDNS Term: Nebulizers, Nonheated [15-045]

Device: [Device Name]

Identifier: Serial Nos.: [Serial Numbers]; Lot Nos.: [Lot Numbers]; 63,560 units distributed between April 2003 and April 2004 in the U.S.

Manufacturer: [Company Name and Address]

Problem: The vibrating mechanism on the above medication bottles may stop functioning, causing a failure to transmit vibration from the above nebulizers and potentially resulting in a lack of nebulization. The manufacturer initiated a recall by removal notice dated November 2, 2004. Note that the nebulizer itself is not subject to this recall. FDA has designated this recall Class II Recall No. Z-0382-05.

Action Needed: Verify that you have received the November 2, 2004, removal notice and stock verification form from [Company] or your distributor. Identify and isolate any affected product in your inventory. (Note that medication bottles with either a blue dot or a blue O-ring were manufactured after corrections were made and are not subject to the recall.) Fill out the stock verification form, and return it to [Company], Attn: Quality Control Manager, by mail at the above address or by fax at [Fax Number]. If you have affected product, contact [Company] customer service by telephone at [Phone Number] to obtain a return authorization number. Return any affected product by UPS freight collect consignee billing to [Company Name and Address], using [Company]'s UPS account number, which is indicated in the letter. Include your return authorization number on all correspondence. [Company] will send you replacement medication bottles upon receipt of affected product. For further information, contact [Company] customer service by telephone at the above number.

Source: *FDA Enforcement Rep* 2005 Jan 19; letter submitted by manufacturer.

Comment: During our verification process, ECRI found that the *FDA Enforcement Report* listed an incorrect serial number. The correct identifying information for this recall is listed above.

Action Priority: High

Accession No.: A6092

Suggested Distribution: Anesthesia, Critical Care, CSR/Materials Management, Home Care, Pharmacy/IV Therapy, Pulmonology/Respiratory Therapy

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Summary of Delegate Comments and Subcommittee Responses

HS11-P: *A Model for Managing Medical Device Hazards and Recalls; Proposed Guideline*

General

1. I am fine with the concepts but think the document is repetitive, as it addresses the same provisions in several places.

- **The Foreword has been expanded to provide a rationale for deliberate duplication of information throughout the guideline.**

2. I think the organizational structure is particularly heavy for labs but also for some hospitals. I would think only very large hospitals have a recall officer who only handles recall alerts. The document says the recall coordinators have other responsibilities; it implies that the recall officer just deals with recalls, but I didn't see that written so I may have misinterpreted. In most instances, the individuals with these responsibilities actually also have other job responsibilities. I recommend that we approve the document, but the system could be more practical and feasible for today's healthcare workplace.

- **The following text has been added to Section 4 for clarification: "The amount of time required for RO and RC responsibilities is related to the size and complexity of the institution."**

3. I think a facility could learn from recall alert drills but doubt that many will have them.

- **Section 10 has been modified to clarify the subcommittee's intent that drills can be "physical" or conducted through questionnaires. The text now reads: "Testing of the Alert response plan is a critical element of a program. Testing, drill exercises, or "paper drills" (i.e., questionnaires to evaluate knowledge and ability to respond) mimicking an Alert enable the identification and remediation of plan deficiencies."**

4. The committee has eight members but only six names appear as authors. Why is there a discrepancy?

- **Those individuals listed on the "author page" of the document contributed directly to writing the text of the guideline; therefore, only those authors have been included. The full subcommittee membership is listed on page iii.**

5. The document does not indicate how the laboratory supervisor or manager interfaces with the recall coordinator or recall officer. These key individuals should also be added to Section 6.1 on Receiving Alert Information.

- **Paragraph 2 of Section 6.1 has been modified for clarification, and now reads: "Alert information can be received in any department or location in a healthcare organization. Therefore, all employees—especially managerial and supervisory staff—should be aware of this policy…"**

  In addition, Section 7.3.4 on Training of General Staff has been modified for clarification, and now reads: "The recall officer, typically with the assistance of the recall coordinator(s), should make all employees aware of the importance of Alerts, by promulgating training materials that deal with the Alert response policy and procedures. Because not all Alerts are sent to the correct contact person or to the proper address, employees in administrative and supervisory positions, purchasing staff (who may receive Alerts incorrectly or incompletely addressed), or those performing mail receipt or distribution functions especially should be made aware of the importance of Alerts and should share this information with their staff. Such awareness training materials could include examples of typical Alert formats to aid in their recognition, and phone numbers or e-mail addresses of whom to contact if such an Alert is received.

6. The committee may wish to consider amending the title to ensure that the purchaser knows that the intended user is a healthcare organization.

- **The title has been modified to read, "A Model for Managing Medical Device Alerts (Hazards and Recalls) for Healthcare Organizations."**

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7. This document is titled "A Model for Managing Medical Device Hazards and Recalls; Proposed Guideline." However, under the scope you open by providing the definition for an alert that includes recall. This is somewhat confusing.

- **See response to Comment 6.**

Section 1, Scope

8. The scope statement indicates that the document is for healthcare organizations; however, Section 8.8.2 refers specifically to hospitals. We suggest that this difference be resolved.

- **The term "hospital" has been replaced with the term "healthcare."**

9. In the second paragraph of the Scope, instead of the term alert, I suggest you consider using the term "communications" in that I think it better reflects what you are trying to say. The following definition is offered: "Communications" will be used to describe any form of information to alert users about the problem that presents a significant risk of adverse health consequences. These may include safety alerts, notices, field corrections, safety bulletins, hazards, urgent device recall (mandatory or voluntary), product information, and/or product withdrawals."

- **The use of the term "communication" has been avoided in HS11 because its usual meaning is not easily restricted to information only from an external source. Further, the word Alert communicates a sense of urgency.**

Section 3, Definitions

10. Under the heading Definitions, the term "Alert" should be revised. Consider changing the language as follows: "a communication that describes a potential problem or problem, hazard, or risk that may exist or may be associated with the use of a specific product, which may have adverse health consequences."

- **The definition has been modified to read: "a communication that describes a problem, hazard, or risk that may exist with or may be associated with the use of a specific product which may have adverse health consequences."**

11. The term "contingency plan"—consider revising the sentence as follows: "a coordinated strategy that involves plans, procedures, and technical measures to enable the recovery of systems and continued operations after a disruption or shut down."

- **The definition has been modified to read: "a coordinated strategy that involves plans, procedures, and technical measures to enable the recovery of systems and continued operations after a disruption."**

12. The following definition is offered for the term "field correction": "correction applicable to a device already released by the manufacturer. A correction may be performed without removing the device to another location or returning it to the manufacturer."

- **The suggested text has been incorporated as a "NOTE."**

13. The following definition is offered for the term "hazard": "an exposure to danger or risk."

- **In accord with CLSI's Organizational Policy on Harmonization, the ISO definition for the term "hazard" has been adopted.**

14. The term "incident" should include in the Note: "This may include close calls, near misses, malfunctions and product defects, and sentinel events."

- **The definition has been deleted. The word "incident" in this guideline is used in an explanatory manner in the Scope and is not used to provide guidance. The subcommittee thanks the commenter for raising the issue.**

15. The term "mandatory recall"—recommend including the word "unreasonable" risk to health to the definition.

- **The definition has been maintained as written. The commenter's suggested change has a U.S. regulatory focus that may or may not be adopted globally. It is not the subcommittee's intent to address distinctions made by different regulatory agencies (e.g., the rationale behind the use of the term "Alert").**

16. The following definition is offered for the term "notice": "a communication of information regarding the risk associated with the use of a device issued by either the manufacturer of a product, distributor, or regulator. Notices may warn user facilities, healthcare professionals, users, and patients of risks and provides information on what actions should be taken or eliminate the risk."

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- **The commenter's suggestion has been accepted with modification. The definition now reads: "a communication of information regarding the risk associated with the use of a device issued by either the manufacturer of a product, distributor or regulator; NOTE: Notices may warn user facilities, healthcare professionals, users, and patients of risks."**

17. Consider including a definition for "risk."

- **In response to the commenter's suggestion, the ISO definition of "risk" has been incorporated.**

18. "Recall complete" is more appropriately referred to as "recall termination."

- **The commenter's suggestion has been accepted with modification. The text has been modified as follows: "Recall termination (recall complete) – FDA communication that a recall is complete; NOTE: This is not considered an Alert."**

Section 4.1, The Recall Officer

19. Several of the main responsibilities have not been included: 1) preparing instructions for users to return devices to the recalling firm; 2) preparing accompanying forms in the alerts that assess inventory, subdistributors inventory, etc.; 3) preparing proposed alert notifications; and 4) participating in Health Hazard Evaluations.

- **As suggested, the following text has been added to Section 4.1.2, bullet 5, as sub-bullets: preparing instructions for users to return devices to the recalling firm; and preparing accompanying forms in the alerts that assess inventory, subdistributors inventory, etc.**

  The concept of participating in contingency planning has been incorporated as the last bullet in Section 4.1.2, and has been added to Section 5.2 to clarify the intent of the responsibility.

Section 7.5, Reviewing the Effectiveness of the Alert Response Strategy

20. The RO reporting program: I suggest revising the timeframe indicated for providing periodic Alert Response reports according to the specific alert. In a Class I recall situation, the reports should be prepared and discussed with management at least quarterly. They should also be provided to the regulatory authority on an agreed upon time frame.

- **The subcommittee does not agree with revising the timeframe for review of Alert Response reports. The commenter is referred to Section 4.1.2: "when applicable, communicating information on Alerts to stakeholders within the institution including:**

  - facility administration;
  - risk management;
  - patient safety officers and committee; and
  - environmental safety officers.

Section 8.2.2, With Healthcare Facility Administration

21. The RO should assess if the hospital or facility will experience a problem if the recall device is taken out of service for any period of time. Determine if the firm needs replacement devices that will reduce/eliminate the facility from experiencing shortages, delays in treatment or undue burdens, for example revalidating new equipment or securing new devices. Another responsibility of the RO would be determining whether repairs, revisions, or corrections would be better performed by firm representatives instead of hospital staff.

- **The commenter is referred to Section 5.2 on Contingency Planning. Also, the following sub-bullet has been added to Section 4.1.2, bullet 5 for clarification: "The RO and RC will coordinate selection of the appropriate source for repairs, revisions, or corrections."**

Section 9, Communication to Patients and Family

22. The discussion of patient notification does not include a discussion on the audit evaluation on the effectiveness checks conducted. This is a critical area especially for patient notification. The manufacturer needs to evaluate the adequacy of their performance in notifying the target audience of the potential problems, problems, and risks. If the audit reveals the notification is not adequate, additional steps should be taken to ensure risks/adverse consequences are communicated.

- **Audit evaluation of effectiveness checks by the manufacturer is beyond the scope of this guideline.**

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The Quality System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The approach is based on the model presented in the most current edition of CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care.* The quality system approach applies a core set of "quality system essentials" (QSEs), basic to any organization, to all operations in any healthcare service's path of workflow (i.e., operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The quality system essentials (QSEs) are:

Documents & Records	Equipment	Information Management	Process Improvement
Organization	Purchasing & Inventory	Occurrence Management	Service & Satisfaction
Personnel	Process Control	Assessment	Facilities & Safety

HS11-A addresses the quality system essentials (QSEs) indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI/NCCLS Publications section on the following page.

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
				X HS1							

Adapted from CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care*.

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Related CLSI/NCCLS Publications*

HS1-A2 **A Quality Management System Model for Health Care; Approved Guideline—Second Edition (2004).** This document provides a model for providers of healthcare services that will assist with implementation and maintenance of effective quality management systems.

* Proposed-level documents are being advanced through the Clinical and Laboratory Standards Institute consensus process; therefore, readers should refer to the most current editions.

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Chang Gung Memorial Hospital (Taiwan)
Children's Healthcare of Atlanta (GA)
Children's Hospital (NE)
Children's Hospital Central California
Children's Hospital & Clinics (MN)
Childrens Hospital of Wisconsin
Children's Hospital Medical Center (Akron, OH)
Chinese Association of Advanced Blood Bankers (Beijing)
Christus St. John Hospital (TX)
City of Hope National Medical Center (CA)
Clarian Health - Methodist Hospital (IN)
CLSI Laboratories (PA)
Community College of Rhode Island
Community Hospital of Lancaster (PA)
Community Hospital of the Monterey Peninsula (CA)
CompuNet Clinical Laboratories (OH)
Covance Central Laboratory Services (IN)
Creighton University Medical Center (NE)
Detroit Health Department (MI)
DFS/CLIA Certification (NC)
Diagnostic Accreditation Program (Vancouver, BC, Canada)
Diagnósticos da América S/A (Brazil)
Dianon Systems (OK)
Dr. Everett Chalmers Hospital (New Brunswick, Canada)
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Headwaters Health Authority (Alberta, Canada)
Health Network Lab (PA)
Health Partners Laboratories (VA)
High Desert Health System (CA)
Highlands Regional Medical Center (FL)
Hoag Memorial Hospital Presbyterian (CA)

Hôpital Maisonneuve - Rosemont (Montreal, Canada)
Hôpital Saint-Luc (Montreal, Quebec, Canada)
Hospital Consolidated Laboratories (MI)
Hospital de Sousa Martins (Portugal)
Hospital for Sick Children (Toronto, ON, Canada)
Hotel Dieu Grace Hospital (Windsor, ON, Canada)
Humility of Mary Health Partners (OH)
Hunter Area Health Service (Australia)
Hunterdon Medical Center (NJ)
Indiana University
Innova Fairfax Hospital (VA)
Institute of Medical and Veterinary Science (Australia)
International Health Management Associates, Inc. (IL)
Island Hospital (WA)
Jackson Health System (FL)
Jacobi Medical Center (NY)
John H. Stroger, Jr. Hospital of Cook County (IL)
Johns Hopkins Medical Institutions (MD)
Kaiser Permanente (MD)
Kantonsspital (Switzerland)
Karolinska University Hospital
King Abdulaziz Medical City – Jeddah (Saudi Arabia)
King Faisal Specialist Hospital (Saudi Arabia)
LabCorp (NC)
Laboratoire de Santé Publique du Quebec (Canada)
Laboratorio Dr. Echevarne (Spain)
Laboratório Fleury S/C Ltda. (Brazil)
Laboratorio Manlab (Argentina)
Laboratory Alliance of Central New York
Laboratory Corporation of America (NJ)
Lakeland Regional Medical Center (FL)
Lawrence General Hospital (MA)
Lewis-Gale Medical Center (VA)
L'Hotel-Dieu de Quebec (Canada)
Libero Instituto Univ. Campus BioMedico (Italy)
Lindy Boggs Medical Center (LA)
Loma Linda Mercantile (CA)
Long Beach Memorial Medical Center (CA)
Long Island Jewish Medical Center (NY)
Los Angeles County Public Health Lab (CA)
Maimonides Medical Center (NY)
Martin Luther King/Drew Medical Center (CA)
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Medical College of Virginia Hospital
Medical Research Laboratories International (KY)
Medical University of South Carolina
Memorial Medical Center (Napoleon Avenue, New Orleans, LA)
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Methodist Hospital (San Antonio, TX)
Mid America Clinical Laboratories (IN)
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Montreal General Hospital (Canada)
Mount Sinai Hospital (NY)
National Healthcare Group (Singapore)
National Serology Reference Laboratory (Australia)
NB Department of Health & Wellness (New Brunswick, Canada)
The Nebraska Medical Center
Nevada Cancer Institute
New Britain General Hospital (CT)
New England Fertility Institute (CT)
New York City Department of Health & Mental Hygiene
New York University Medical Center
NorDx (ME)
North Carolina State Laboratory of Public Health
North Central Medical Center (TX)
North Coast Clinical Laboratory (OH)
North Shore Hospital Laboratory (Auckland, New Zealand)
North Shore - Long Island Jewish Health System Laboratories (NY)
North Shore University Hospital (NY)
Northern Plains Laboratory (ND)
Northwestern Memorial Hospital (IL)
Ochsner Clinic Foundation (LA)
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St. Barnabas Medical Center (NJ)
St. Christopher's Hospital for Children (PA)
St-Eustache Hospital (Quebec, Canada)
St. John Hospital and Medical Center (MI)
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The Permanente Medical Group (CA)
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