



**LEARNING UDI
COMMUNITY**



AHRMM
Advancing Health Care through
Supply Chain Excellence

Unique Device Identifier (UDI) Impacts on Recall Management Regulatory Resource Guide

[AHRMM.ORG/LUC](https://www.ahrmm.org/luc)

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INTRODUCTION

The Regulatory and Glossary Task Force developed the Regulatory Task Force Resource Document providing summaries emphasizing the various publicly available guidance documents with specific Code of Federal Regulations (CFR) references.

Note: Although many Biologic manufacturers are adding the UDI identifiers at the request of health care advocates, please be aware that the UDI pertains to Medical Devices only. Recalls addressed in this document are for Medical Devices only. For Biologic or Drug Recall information, please review:

[Title 21 Chapter I](#) (search Drugs, Biologics for resources outside the subchapters below)

- [Drugs](#)
- [Biologics](#)

Resource Links

Following are Abstracts, processes, and information (with links) of details relevant to the AHRMM LUC activities and organizations using UDI to meet FDA Device labeling regulations.

FDA CDRH Programs that use structured data: The eMDR and UDI program offer examples of how to define a set of structured data for submission and how to make it publicly accessible.

- [eMDR HL7 Data Elements](#)
- [GUDID Data Elements Reference Table](#)

RECOMMENDATIONS TO IMPROVE UDI INTEGRATION IN RECALLS

1. Change standard wording from Unique Device Identifier (UDI), lot number, batch number, model number, or serial number to make UDI required, if available.
2. Create a multi-stakeholder initiative to develop a structured set of core data that can easily be transmitted from the manufacturer to FDA, validated, stored, and enhanced with FDA regulatory data, then made available to the public via searchable database, with API and download capability. Ideally, the data in GUDID and Recalls would be linked as part of an accessible set of data from FDA (Digital transformation meeting). The data to hospitals could also be structured and available via electronic transmission.
 - a. NOTE: HL7 UDI Domain Analysis Model will now include data fields linked to recall that comes out of AHRMM LUC.
3. Educate on value of UDI to hospital and manufacturer device tracking for recalls.

Regulations.Gov

Make a difference. Submit your comments and let your voice be heard.

Note: [Public Warning, Notification and Posting of Recalls and other Corrective Actions](#) contains two open comment documents (as of June 5, 2020)

- [Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C Guidance for Industry and FDA Staff \(Jan 18, 2018\)](#)
- [Public Warning and Notification of Recalls Under 21 CFR Part 7, Subpart C Guidance for Industry and FDA Staff \(Feb 7, 2019\)](#)

WHAT IS A RECALL – A VOLUNTARY ACTION

Recalls, Corrections and Removals Devices. A recall is a method of removing or correcting products that are in violation of laws administered by the Food and Drug Administration (FDA). Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective. [21 CFR 7](#) provides guidance so that responsible firms may conduct an effective recall.

Medical device recalls are usually conducted voluntarily by the manufacturer under [21 CFR 7](#). In rare instances, where the manufacturer or importer fails to voluntarily recall a device that is a risk to health, FDA may issue a recall order to the manufacturer under 21 CFR 810, Medical Device Recall Authority. 21 CFR 810 describes the procedures the FDA will follow in exercising its medical device recall authority under section 518(e) of the Federal Food, Drug, and Cosmetic Act (Act).

Under 21 CFR 806, Medical Device Correction and Removals, manufacturers and importers are required to make a report to FDA of any correction or removal of a medical device(s) if the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the Act caused by the device which may present a risk to health.

A voluntary action taken by a firm when they determine a device is misbranded or adulterated:

- Misbranded includes but is not limited to a false or misleading representation.
- Adulterated includes but is not limited to a device that does not meet the performance standard established under section 514 of the FD&C Act; a device that is not in conformance with any standard that is recognized under section 514 (c); a Class III device that does not have premarket approval; a banned device; a device that is not in conformance with applicable requirements under section 520(f)(1) or 520(f)(2); and if it is a device for which an exemption has been granted under section 520(g) for investigational use and the person granted the exemption fails to comply with the granted the exemption to comply with the requirements prescribed.

Firm Initiated Recall

- On its own volition a firm can decide to initiate a recall.
- The recalling firm initiates a recall, or
- The firm that has primary responsibility for the manufacture and marketing of the product initiates the recall.

FDA Cited Regulations

- Food, Drug and Cosmetic Act (FD&C Act)
- 21 CFR Part 7 (Enforcement Policy)
- 21 CFR Part 806 (Mandatory Reports of Corrections and Removals), 810 and 820
- Federal Register (June 16, 1978), Part 7
- Regulatory Procedures Manual (RPM) (Chapter 7)

FDA Cited References

- Medical Technology Learning Institute Recalls from A-Z: Regulations, Decisions, Procedures, Best Practices (November 2008)
- Checklist for Reports of Correction or 806.10(a)(1-13)
- FDA 101: Product Recalls, From First Alert to Effectiveness Checks

How Manufacturers Report to FDA

Manufacturers have two ways to report corrections and removals:

1. [FDA Electronic Submission Software](https://www.fda.gov/media/107333/download) (eSubmitter – <https://www.fda.gov/media/107333/download>), or
2. E-mail.

Note: E-submitter (download). This is not user-friendly process (31-page instruction manual). Manufacturer using e-mail submission must report to the FDA's Office of Regulatory Affairs (ORA) Division Recall Coordinator (DRC) by state or region listed [here](#) (Search «Medical Device» <https://www.fda.gov/safety/industry-guidance-recalls/ora-recall-coordinators>).

What Manufacturers Send to FDA

1. Identity of the product involved.
2. Reason for the removal or correction and the date and circumstances under which the product deficiency or possible deficiency was discovered.
3. Evaluation of the risk associated with the deficiency or possible deficiency.
4. Total amount of such products produced and/or the timespan of the production.
5. Total amount of such products estimated to be in distribution channels.
6. Distribution information, including the number of direct accounts and, where necessary, the identity of the direct accounts.

7. A copy of the firm's recall communication if any has issued, or a proposed communication if none has issued.
8. Proposed strategy for conducting the recall.
9. Name and telephone number of the firm official who should be contacted concerning the recall.

Classification

Recall classification means the numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.

- Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
- Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

TYPES OF RECALLS

The FDA considers a [Field Action is a Recall](#). FDA uses the term “**recall**” when a manufacturer takes a **correction or removal** action to address a problem with a medical device that violates FDA law. Recalls occur when a medical device is defective, when it could be a risk to health, or when it is both defective and a risk to health.

A medical device recall does not always mean that you must stop using the product or return it to the company. A recall sometimes means that the medical device needs to be checked, adjusted, or fixed. If an implanted device (for example, an artificial hip) is recalled, it does not always have to be explanted from patients. When an implanted device has the potential to fail unexpectedly, companies often tell doctors to contact their patients to discuss the risk of removing the device compared to the risk of leaving it in place.

- Field Safety Notice (occasionally turns into a Recall)
- Product Advisory (occasionally also turns into a Recall)
- Voluntary Recall
- Mandatory Recall

Examples of Types of Actions That May Be Considered Recalls

The following are examples of types of actions considered for recalls include:

- Inspecting the device for problems
- Repairing the device
- Adjusting settings on the device

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- Re-labeling the device
- Destroying device
- Notifying patients of a problem

Public Warning Notifications

The purpose of a public warning is to alert the public that a product being recalled presents a serious hazard to health. As such, a public warning should include:

- a) Information to help identify the recalled product including images, numerical product information (e.g., lot number, expiration date, serial number, unique device identification **(UDI) number**), packaging information **or** brand names,
- b) The geographic areas and dates of distribution of the affected product,
- c) A thorough description of the product defect, health hazard involved, and reason(s) for recall (e.g., product testing, environmental sampling, etc.),
- d) The name and contact information for the recalling firm,
- e) Instructions to consumers or users,
- f) The number and nature of any illnesses/injuries/complaints associated with the product, related to the product defect, and
- g) A description of common symptoms of any illness of concern.

The headline of the public warning should include the brand name, type of product, and the hazard prompting the recall (e.g., “XYZ chocolate chip cookies recalled for potential Salmonella contamination.”). In some cases, it may also be necessary to include the recalling firm’s supply-chain relationships in order to alert the public of the product being recalled. When possible, the FDA encourages firms to provide specifics about firms it sold product to in order to help people better identify and avoid recalled product.

[Introduction to Medical Device Recalls. Industry Responsibilities.](https://www.fda.gov/media/78333/download) See <https://www.fda.gov/media/78333/download> - FDA unknown author.

[Recall Communication. Medical Device Model Notification Letter.](#) FDA Ronny Brown Acting Chief, Recall Branch

GUIDANCE DOCUMENTS

- [Regulatory Procedure Manual](#)
- [Public Warning Guidance](#)
- [Industry Guidance for Recalls.](#) Information on Recalls of FDA Regulated Products
- [Medical Device Safety.](#) The FDA monitors reports of adverse events and other problems with medical devices and alerts health professionals and the public when needed to ensure proper use of devices and the health and safety of patients.
- [CDHR Learn.](#) Learning modules are available describing many aspects of medical device and radiation emitting product regulations, covering both premarket and post market topics.

- [Medical Device “Model” – Recall New Release](#). Model (example) letter of the Recall notice (web)
- [Medical Device “Model” Recall Notification Letter and Response Form_](#) (Fillable)
- [Regulatory Procedure Manual Chapter 7 Recall Procedures](#). FDA staff process for management of a recall. See Appendices in the Regulatory Procedure Manual for a list of recommended forms for handling a recall.
 - [510\(k\) Requirements During Firm-Initiated Recalls, K95-1”](#) - Blue Book Memo (issued 11/21/95) on FDA website but ‘File not Found’.
 - [Device Recalls: A Study of Quality Problems](#) , document #273, contact dice@cdrh.fda.gov (I contacted DICE for a copy of this).

UDI Conforming Amendment Related to Recall

§ 806.10 Reports of corrections and removals. * * * * * (c) * * * (5) The unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

FDA Recall Lists and Databases (Data sets)

The FDA reports to Public with Public Facing reports, databases, websites, and query tools. Multiple Recall resources exist for medical devices throughout the FDA's website with differing information. There are also different datasets and databases for Biologics and Drugs that are not listed here.

[Medical Device Recall \(Yearly Lists\)](#). The FDA posts summaries of information about the most serious medical device recalls. These products are on the list because there is a reasonable chance that they could cause serious health problems or death. Use the yearly lists to find information about Class I medical device recalls and some Class II and III recalls of interest to patients.

[Medical Device Recall \(Database\)](#). A searchable database of “Posted” Recalls. Searches are limited to a return of 500 items.

[OpenFDA](#). Easy access to public data, to create a new level of openness and accountability, to ensure the privacy and security of public FDA data, and ultimately to educate the public and save lives. The concept was to index high-value, high priority and scalable public-access data, format, and document that data in developer and consumer-friendly standards and make that data available via a public-access portal that enables developers to use it quickly and easily in applications.

[Recall Device Reference Fields](#). Spreadsheet of fields, field types and descriptions for OpenFDA

Compliance Dashboard. Certain information in these datasets may not be presented or may have changed since the posting. The dataset is updated monthly and only includes recalls that have been classified. If you need to present more recent or more complete data for official purposes or have questions about obtaining other data, please contact the Division of Freedom of Information about what materials may be available in electronic reading rooms or inquire about other datasets that would satisfy your needs.

Current recall data used in this Dashboard is based upon the Enforcement Reports. Only recalls classified on or after 06/08/2012 are displayed on the dashboard.

For detailed information about individual recalls, please see the Enforcement Reports and public releases and public notices.

Enforcement Reports. All recalls monitored by FDA are included in the Enforcement Report once they are classified and may be listed prior to classification when FDA determines the firm's removal or correction of a marketed product(s) meets the definition of a recall. Once FDA completes the hazard assessment, the Enforcement Report entry will be updated with the recall classification.

Recall Device Enforcement Reference Fields. Spreadsheet of fields, field types and descriptions for Enforcement Reference.

Recalls, Market Withdrawals and Safety Alerts. The list below provides information gathered from press releases and other public notices about certain recalls of FDA-regulated products. Not all recalls have press releases or are posted on this page.

Additional Information about Recalls. The list of recalls provides information gathered from press releases and other public notices about certain recalls of FDA-regulated products.

Archive for Recalls, Market Withdrawals & Safety Alerts. The Recalls, Market Withdrawals & Safety Alerts are available on FDA's website for three years before being archived. **FDA.gov Archive.** Use this search function to search for text in pages and files in the FDA.gov Web Archive. After you click Search the Archive, the results appear on the FDA.gov Archive-It site.

Warnings and Notification

Public Warning and Notification of Recalls Under 21 CDR Part 7, Subpart C. Draft guidance for Industry and FDA staff (January 2018).

Federal Register

Federal Register - UDI The Unique Device Identification (UDI) provide for More Rapid, More Efficient Resolution of Device Recalls. Delays in identifying recalled devices can result in the continued use of those devices on patients and involves an increased risk for patient harm. A

device labeled with a UDI can be identified rapidly and with great precision. The more rapidly a recall is implemented and completed, the more rapidly the risks presented are reduced or eliminated.

Federal Register Notices. The Federal Register (FR) is the official daily publication for rules, proposed rules, and notices of federal agencies and organizations, as well as executive orders and other presidential documents. In order to create or revise an existing regulation, FDA will publish a proposed rule in the FR and request comments. FDA will then evaluate all comments received and publish a final rule. Once a proposed rule is finalized, it is published in the Code of Federal Regulations (CFR).

FDA Recall Regulations

NOTE: CFR - Code of Federal Regulations Title 21. For up-to-date reference do not use the FDA website rather for the most up-to-date version of CFR Title 21, go to the [Electronic Code of Federal Regulations \(eCFR\)](#)

The Food and Drug Administration will review the information submitted, advise the firm of the assigned recall classification, recommend any appropriate changes in the firm's strategy for the recall, and advise the firm that its recall will be placed in the weekly FDA Enforcement Report. Pending this review, the firm need not delay initiation of its product removal or correction.

[Title 21 CFR 7 Subpart A](#) [7.3 Definitions \(Glossary\)](#)

[Title 21 CFR 7 Subpart C](#) [§7.40 Recall policy.](#) [§7.41 Health hazard evaluation and recall classification.](#) [§7.42 Recall strategy.](#) [§7.45 Food and Drug Administration-requested recall.](#) [§7.46 Firm-initiated recall.](#)

What Manufacturers Should Provide

§7.49 Recall communications

- a) General. A recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled and the strategy developed for that recall. In general terms, the purpose of a recall communication is to convey:
 - 1) That the product in question is subject to a recall.
 - 2) That further distribution or use of any remaining product should cease immediately.
 - 3) Where appropriate, that the direct account should in turn notify its customers who received the product about the recall.
 - 4) Instructions regarding what to do with the product.

- b) Implementation. A recall communication can be accomplished by telegrams, mailgrams, or first-class letters conspicuously marked, preferably in **bold red type**,¹ on the letter and the envelope: “drug [or food, biologic, etc.] recall [or correction].” The letter and the envelope should be also marked: “urgent” for class I and class II recalls and, when appropriate, for class III recalls. Telephone calls or other personal contacts should ordinarily be confirmed by one of the above methods and/or documented in an appropriate manner.²
- c) Contents.
- 1) A recall communication should be written in accordance with the following guidelines:³
 - i. Be brief and to the point.
 - ii. Clearly identify the product, size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product.
 - iii. Explain concisely the reason for the recall and the hazard involved, if any.
 - iv. Provide specific instructions on what should be done with respect to the recalled products; and
 - v. Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product, e.g., by sending a postage-paid, self-addressed postcard or by allowing the recipient to place a collect call to the recalling firm.
 - 2) The recall communication should not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message. Where necessary, follow-up communications should be sent to those who fail to respond to the initial recall communication.
- d) Responsibility of recipient. Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm and, where necessary, extend the recall to its consignees in accordance with paragraphs (b) and (c) of this section.

Note: (n) *Consignee* means anyone who received, purchased, or used the product being recalled.

¹ Recall Notification Language see <https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices>.

² The FDA should be notified to update this by eliminating telegrams and mailgrams – neither is used currently and to add emails with return receipt notification, etc.

³ The FDA as part of the current efforts to modernize electronic communications should insert URLs, etc., as a routing part of FDA recall communications.

What FDA Provides to Public

§7.50 Public notification of recall

FDA Enforcement Report

The Food and Drug Administration will promptly make available to the public in the weekly FDA Enforcement Report a descriptive listing of each new recall according to its classification, whether it was Food and Drug Administration-requested or firm-initiated, and the specific action being taken by the recalling firm. The Food and Drug Administration will intentionally delay public notification of recalls of certain drugs and devices where the agency determines that public notification may cause unnecessary and harmful anxiety in patients and that initial consultation between patients and their physicians is essential. The report will not include a firm's product removals or corrections which the agency determines to be market withdrawals or stock recoveries. The report, which also includes other Food and Drug Administration regulatory actions, e.g., seizures that were affected and injunctions and prosecutions that were filed, is available upon request from the Office of Public Affairs (HFI-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857

Title 21 CFR 7 Subpart C

§7.53 Recall status reports.

§7.55 Termination of a recall.

§7.59 General industry guidance.

Title 21 CFR 8 Chapter I Subchapter H Part 806

§806.2 Definitions.

- Medical Devices: Reports of Corrections and Removals, Proposed Rule, March 23, 1994
- Medical Devices; Reports of Corrections and Removals; Final Rule; May 19, 1997
- Medical Devices; Reports of Corrections and Removals; Direct to Final Rule; August 7, 1998
- Medical Devices; Reports of Corrections and Removals; Companion to Direct Final Rule; August 7, 1998
- Medical Device Reports; Reports of Corrections and Removals; Establishment Registration and Device Listing; Premarket Approval Supplements; Quality System Regulation; Importation of Electronic Products; Technical Amendment, Final Rule March 10, 2004
- 806.10(f) No report of correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under 21 CFR 803 [MEDICAL DEVICE REPORTING OR 21 CFR 1004 REPURCHASE, REPAIRS, OR REPLACEMENT OF ELECTRONIC PRODUCTS](#)
- Manufacturers and importers must keep records of those corrections and removals that are not required to be reported to FDA. However, if a report is not required under [21 CFR 806](#), the firm may voluntarily report under [21 CFR 7](#).

(m) *Stock recovery* means the correction or removal of a device that has not been marketed or that has not left the direct control of the manufacturer, i.e., the device is located on the

premises owned, or under the control of, the manufacturer, and no portion of the lot, model, code, or other relevant unit involved in the corrective or removal action has been released for sale or use.

(n) *Unique device identifier (UDI)* means an identifier that adequately identifies a device through its distribution and use by meeting the requirements of §830.20 of this chapter. A UDI is composed of:

- (1) A *device identifier*—a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device; and
- (2) A *production identifier*—a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:
 - (i) The lot or batch within which a device was manufactured.
 - (ii) The serial number of a specific device.
 - (iii) The expiration date of a specific device.
 - (iv) The date a specific device was manufactured.
 - (v) For an HCT/P regulated as a device, the distinct identification code required by §1271.290(c) of this chapter.

[Note: 62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998: 78 FR 58821, Sept. 24, 2013]

Corrections and Removals - 21 CFR 806.10

(5) The unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.

What Medical Device Manufacturers Report to the FDA

- **§See 21 CFR 806.10(c)**
 1. Registration number, date the report is made, sequence number (001, 002, etc.), “C” for Correction or “R” for Removal.
 2. Name, address, phone number, and contact person of the firm responsible for conducting the correction or removal.
 3. Brand name and common name of the device and intended use.
 4. FDA marketing status, i.e., 510(k), PMA, pre-amendment status and device listing number.
 5. Model/catalog number, lot/serial number
 6. Manufacturer’s contact information (name, address, phone number, contact person) if different from item #2 above.

7. Description of event(s) and the corrective and removal actions that have been and are expected to be taken.
8. Any illness or injuries that have occurred with the use of the device. If applicable, include any Medical Device Report (MDR) numbers submitted under 21 CFR 803.
9. The number of devices subject to the Correction or Removal.
10. Date of manufacture or distribution; expiration date or expected life.
11. Name, address, and telephone number of all consignees (domestic and foreign) and the dates and number of devices distributed to each consignee.
12. A copy of all communications regarding the correction or removal.
13. A statement as to why any required information is not available and a date when it will be submitted.

Mandatory Device Recalls 21 CFR 810.10 - Cease Distribution and Notification Order

- See <https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices#4> for additional information.
- 21 CFR 821.25 - Device Tracking (manufacturers) and 21 CFR 821.30 - Device Tracking (distributors).

NOTE: Device tracking requirements are only for a small subset of devices – not all implants. The wording below is used throughout ‘conforming amendment regulations except for mandatory recalls. The use of “or” should be changed to “and”

- (i) The unique device identifier (UDI), lot number, batch number, model number, *or* serial number of the device *or* other identifier necessary to provide for effective tracking of the devices.

21 CFR 810

- Medical Device Recall Authority; Final Rule, November 20, 1996
- Medical Device Recall Authority; Proposed Rule, June 14, 1994

Device Tracking (Manufacturers) 21 CFR 821.25 Recalls

- See <https://www.fda.gov/medical-devices/postmarket-requirements-devices/recalls-corrections-and-removals-devices#4> for additional information.
- 21 CFR 821.25 - Device Tracking (manufacturers) and [21 CFR 821.30](#) - Device Tracking (distributors).

OTHER RELEVANT LINKS

United Kingdom (UK)

- Medicines and Healthcare Products Regulatory Agency
- Alerts and recalls for drugs and medical devices
- <https://www.gov.uk/drug-device-alerts/spinal-implant-magec-system-model-x-rods-risk-of-failure-in-use-mda-2020-010>.

ANSI X12

<http://www.x12.org/x12-work-products/x12-transaction-sets.cfm>

HL7

<https://www.hl7.org/fhir/overview.html>

REGULATORY DEFINITIONS (RESOURCES: 21 CFR PART 7 AND FDA WEBSITE)

Consignee means distributor, hospital.

Correction means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.

Market withdrawal means a firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA, or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.

Recall means a firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. Recall does not include a market withdrawal or a stock recovery.

Recall strategy means a planned course of action to be taken in conducting a specific recall, which addresses the depth of recall, need for public warnings, and extent of effectiveness checks for the recall.

Recalling firm means the firm that initiates a recall or, in the case of a Food and Drug Administration-requested recall, the firm that has primary responsibility for the manufacture and marketing of the product to be recalled.

Removal means the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.

Risk to health means (1) A reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or (2) That use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote.

Routine servicing means any regularly scheduled maintenance of a device, including the replacement of parts at the end of their normal life expectancy, e.g., calibration, replacement of batteries, and responses to normal wear and tear. Repairs of an unexpected nature, replacement of parts earlier than their normal life expectancy, or identical repairs or replacements of multiple units of a device are not routine servicing.

Stock recovery means the correction or removal of a device that has not been marketed or that has not left the direct control of the manufacturer, i.e., the device is located on the premises owned, or under the control of, the manufacturer, and no portion of the lot, model, code, or other relevant unit involved in the corrective or removal action has been released for sale or use.

Health Hazard Evaluation - *An evaluation of the health hazard presented by a product being recalled or considered for recall will be conducted by an ad hoc committee of Food and Drug.*