On February 2, 2024, FDA published the final rule to amend the Quality System (QS) regulation in 21 CFR part 820 (89 FR 7496, effective February 2, 2026). The revised 21 CFR part 820 is now titled the Quality Management System Regulation (QMSR). The QMSR harmonizes quality management system requirements by incorporating by reference the international standard specific for medical device quality management systems set by the International Organization for Standardization (ISO), ISO 13485:2016. The FDA has determined that the requirements in ISO 13485 are, when taken in totality, substantially similar to the requirements of the QS regulation, providing a similar level of assurance in a firm's quality management system and ability to consistently manufacture devices that are safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act).

This guidance document was issued prior to the effective date of the final rule. FDA encourages manufacturers to review the current QMSR to ensure compliance with the relevant regulatory requirements.

Distinguishing Medical Device Recalls from Medical Device Enhancements

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Guidance for Industry and Food and Drug Administration Staff

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Division of Analysis and Program Operations

Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to http://www.regulations.gov. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number FDA-2013-D-0114. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1819 to identify the guidance you are requesting.

Contains Nonbinding Recommendations

Distinguishing Medical Device Recalls from Medical Device Enhancements

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

FDA defines a device recall by regulation as a firm's removal or correction of a marketed device that the Agency considers to be in ***violation*** of the laws that it administers and against which the agency would initiate legal action, e.g., seizure. 21 CFR 7.3(g). The key factor in distinguishing a medical device recall from an enhancement is the existence of a violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 360h] or associated regulations enforced by the Agency.

Defects or performance failures of marketed medical devices can pose serious risks to public health. The recall process serves both to correct device defects and to notify users of potential risks and steps to minimize the impact of device failure or malfunction. Medical device recalls include voluntary recalls (covered by 21 CFR part 7, subpart C), either initiated by a firm on its own initiative or in response to a formal request from FDA, and mandatory recalls ordered by FDA under section 518 of the FD&C Act and 21 CFR part 810.[1] Typically, the medical device recall process under 21 CFR part 7, subpart C is initiated and coordinated by the firm. Subsequently the recall gets classified, monitored, and terminated by FDA district offices and the Center for Devices and Radiological Health (CDRH).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

[1] This guidance does not address mandatory recalls.

The recall process establishes a mechanism for firms that produce and market medical devices to take timely action to correct or remove violative devices. When a firm's recall process is operating effectively, the firm identifies a device defect or failure, determines if a recall is appropriate, and initiates the recall process. However, firms may have trouble identifying whether a change to a device meets the definition of a recall, the appropriate scope of a recall, and when FDA should be notified of a recall. All of these issues can result in inconsistent interpretation of regulations by firms, uncertainty in firms' regulatory responsibility, and delays between the times that a device defect or failure is identified and the time that the public is notified.

CDRH recognizes that continuous improvement activities, as part of an effective quality system, often have a favorable impact on medical device safety and are part of ongoing efforts to design and manufacture devices that meet the needs of the user and patient. When new iterations of a device involve changes to device design, for example, it does not necessarily mean that the existing device should be recalled.

This guidance is intended to: (1) clarify when a change to a device constitutes a medical device recall, (2) distinguish those instances from device enhancements that do not meet the definition of a medical device recall, and (3) clarify reporting requirements under 21 CFR part 806. Correctly categorizing a change to a device as a recall or an enhancement impacts the applicability and nature of industry responsibilities and FDA oversight. Clearly distinguishing medical device recalls from enhancements will assist FDA and firms in assessing when 21 CFR part 7, subpart C, should be followed. Additionally, this guidance seeks to address concerns that firms may have about making enhancements.

This guidance is organized in a question-and-answer format, providing responses to questions that FDA believes are helpful in properly distinguishing medical device recalls from medical device enhancements.

Throughout this guidance, the term "you" refers to the device manufacturer[2] or importer that initiates a correction or removal.

For purposes of this document, the terms "firm" and "manufacturer" are synonymous; both are used in regulatory references for medical device recalls.

III. Scope

This guidance applies to medical devices regulated by CDRH, whether or not they require or are exempt from premarket review.

This guidance does not address and does not apply to:

- Whether a new premarket submission is required;
- Radiation-emitting electronic product defects or failures to comply with radiation safety performance standards contained in 21 CFR Parts 1020 to 1050; and
- Methodologies for risk management or risk assessment.

IV. Definitions and Examples

Recall

As defined at 21 CFR 7.3(g), "recall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action,

[2] 21 CFR 806.2(h). Note that the term "manufacturer" is not defined in 21 CFR part 7.

e.g., seizure. Recall does not include a market withdrawal or a stock recovery." Recall does not include routine servicing. Recall also does not include an enhancement, as defined by this guidance.

Example 1:
A marketed device guide wire has been associated with metal fractures that the firm attributes to the quality of the steel used in the device. The firm confirms that the device is not meeting labeled performance specifications, and violates applicable manufacturing requirements or conditions, making the device adulterated. Consequently, the firm changes to a new steel vendor. The firm takes the appropriate action to request that customers contact it for replacement of the faulty guide wires. FDA would generally consider these actions a recall.

Example 2:
An in vitro diagnostic (IVD) device firm markets a test to detect the level of a specific antigen in blood. The device is represented to have a 95% sensitivity to the specific antigen. Two years after initial marketing, the firm determines that the device sensitivity to the specific antigen, as manufactured, has decreased to 90%, thus not meeting performance specifications and making the device violative. As a result, the firm modifies the products in the field to "improve" the sensitivity from 90% to 95%. Because the firm's actions are returning the product to the quality it was represented to possess, FDA would generally consider these actions a recall.

Example 3:
Shortly after launch, the ergonomics of a marketed electrosurgical unit device are determined to be less-than-optimal, in that users have reported difficulty guiding the hand piece and the firm has received reports of serious injury associated with its use. The firm's investigations reveal that difficulty guiding the hand piece contributes to the serious injuries and that the hand piece is not performing as represented. The firm replaces all the hand pieces in the field and on all units currently in inventory, to eliminate the possibility of serious harm. FDA would generally consider these actions a recall.

Correction
Correction means repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal to some other location.[3]

Example 4:
A firm learns, and confirms, that one model of its infusion pumps has a computation error in its software, so that patients are receiving less volume than needed and represented, rendering the device violative. The firm sends representatives to install modified software to all affected devices within the facilities where the devices are known to exist. FDA would generally consider these actions as a correction falling within the definition of recall.

Removal
As used in the definition of "recall" at 21 CFR 7.3(g), removal means the physical removal of a device to some other location for repair, modification, adjustment, relabeling, destruction, or inspection.[4]

Example 5:
A firm receives feedback from consignees that certain blood gas analyzers need adjustment for failing calibration that cannot be completed on location by the hospital staff. The firm agrees to collect the analyzers from its consignees in

[3] 21 CFR 7.3(h).
[4] See 21 CFR 806.2(j) for the definition of the term "removal" as used in 21 CFR part 806 for reports of corrections and removals.

order to adjust them, assuring that they continue to function as represented. FDA would generally consider this action a removal falling within the definition of a recall.

Violation or Violative
For purposes of this document, violation and violative mean that the device does not comply with the FD&C Act or associated regulations enforced by the Agency.

Device Enhancement
Neither the FD&C Act nor FDA's regulations define device enhancement. For purposes of this guidance document, a device enhancement is (1) a change to improve the performance or quality of a device that is (2) *not* a change to remedy a violation of the FD&C Act or associated regulations enforced by the Agency. Device enhancements include, but are not limited to, changes designed to better meet the needs of the user, changes to make the device easier to manufacture, changes to improve a non-violative device's safety or performance, and changes to the appearance of the device that do not affect its use.

A device enhancement is not a medical device recall.

Example 6:
An IVD device firm markets a test to detect the level of a specific antigen in blood. The device is represented to have 95% sensitivity to the specific antigen. Two years after initial marketing, the firm modifies the product to improve the sensitivity to the antigen from 95% to 98%. This modification is determined to be an improvement to the safety and effectiveness of the device, and is determined to be unrelated to any known device violation. FDA would generally regard this action as a device enhancement, although it may require a regulatory submission.

Example 7:
A firm markets a new electrosurgical unit device. Shortly after launch, the ergonomics of the hand piece of the newly-marketed device are determined to be difficult to use. The firm determines that this difficulty does not change the risk of the device, and no violations of the FD&C Act or regulations are identified. The firm develops and incorporates a new hand piece into the electrosurgical unit device. FDA would generally consider this action to be a device enhancement, although it may require a regulatory submission.

Stock Recovery
Stock recovery means a firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e., the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.[5]

Example 8:
When conducting in-house final testing of its cardiac stent delivery system devices, a firm detects a failure of the balloons to fully expand, preventing deployment of the stent. The firm confirms that the device problems are associated with a manufacturing error that affects only five lots of devices manufactured during the last two days. All of the affected lots remain in the firm's possession, either within the manufacturing facility or in the firm's storage facility awaiting distribution. Because the firm initiated action to assure that none of the affected lots would be released for sale or use, FDA would generally consider this action to be a stock recovery and not a recall. A careful evaluation should occur to ensure that previously distributed devices will not have the same failure mode or risk consideration.

[5] 21 CFR 7.3(k).

A stock recovery, which applies only to undistributed devices, is not a recall. Distributed devices require a recall when they manifest violations for which a stock recovery was initiated.

Market Withdrawal
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 Food and Drug Administration or which involves no violation, e.g., normal stock rotation practices, routine equipment adjustments and repairs, etc.[6] A market withdrawal is not a recall.

> Example 9:
> A firm decides to remove its examination gloves from the market due to an incorrect address on the device label. This is a minor violation against which FDA generally would not initiate legal action. FDA would consider the removal of the distributed examination gloves to be a market withdrawal.

Routine Servicing
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.[7]

> Example 10:
> A firm receives feedback from consignees that certain blood gas analyzers need routine servicing that cannot be completed on location by the hospital staff. The firm agrees to collect the analyzers from its consignees in order to service them. FDA would not generally consider this action to be a recall because the device was not violative.

V. Recall Identification

Q: Is your product a device?
A: The recall identification procedures described in this guidance apply to all products that meet the definition of "device" in section 201(h) of the FD&C Act [21 U.S.C. 321(h)]. All other products, including electronic products that do not meet the definition of a device, are outside the scope of this guidance.

Q: Are you considering making a correction to or removal of your device?
A. If you are not making or considering a correction to or removal of your device, such as a change to the device, then your actions do not fall within the scope of a medical device recall. Common areas of postmarket change that could represent a device recall include changes to the device design, device labeling (including updating the labeling of a distributed product), and updated marketing materials.

Q: Are you currently marketing the device to which you are considering or making changes?
A: Only marketed devices can be recalled.[8] Changes to a device that has not been marketed or has not left the direct control of the manufacturer generally fall within the definition of a stock recovery and are excluded from the definition of a recall.

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[6] 21 CFR 7.3(j)
[7] 21 CFR 806.2(l). Note that the term "routine servicing" is not defined in 21 CFR part 7.
[8] For purposes of identifying a medical device recall, devices distributed for use in a clinical study under an Investigational Device Exemption (IDE) are not considered to be marketed.

VI. Differentiating Violative Devices from Non-Violative Devices

Only changes to devices to remedy a violation of the laws administered by FDA and against which the agency would initiate legal action fall within the definition of a medical device recall. For example, if a device is being corrected to address a Quality System violation (see 21 CFR part 820), then the correction would generally be considered a recall.

Changes to non-violative devices are considered to be device enhancements and not medical device recalls. The questions in this section are intended to help clarify whether or not the device would be considered violative.

Q: Are the changes intended to resolve a failure to meet specifications or failure of the device to perform as represented?
A: FDA generally considers devices that fail to meet represented specifications or that fail to perform as represented to be of a quality below that which they purport or are represented to possess, rendering them adulterated under section 501(c) of the FD&C Act [21 U.S.C. 351(c)]. Changes intended to resolve a failure to meet specifications or failure of the device to perform as represented would generally constitute recalls.

An increase in overall failure rate,[9] increase in a single failure mode rate,[10] or the identification of a new failure mode may suggest a failure of the device to perform as represented. A change to the marketed device to address a failure to perform as represented, including a failure to perform to represented specifications, would generally constitute a medical device recall.

> Example 11:
> A marketed implantable device is represented to have a battery life of 5 years under normal conditions of use. If the firm changes battery suppliers for the sole purpose of extending the life of the device from 5 years to 5.5 years, then FDA would generally consider these actions to be a device enhancement.
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> Example 12:
> A marketed implantable device is represented to have a battery life of 5 years under normal conditions of use. If the firm is aware of battery failures contributing to adverse events, and, prior to the end of the represented battery life, the firm changes batteries to address the battery failure in distributed devices, then FDA would generally consider this action a recall.
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> Example 13:
> Medical device software in a marketed infusion pump controls display of parameters for drug delivery. If the firm revises the software in order to meet user requests for larger displays, with no evidence that the software programming has failed to perform as represented, then FDA would generally consider these actions to be a device enhancement.
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> Example 14:
> Medical device software in a marketed infusion pump controls display of parameters for drug delivery. If the firm is aware that the device is failing to display parameters as represented and the software in distributed devices is modified to address this failure, then FDA would generally consider this action to be a recall.

[9] For purposes of this guidance, "overall failure rate" means the total rate of device failure regardless of cause.
[10] For purposes of this guidance, "failure mode" means a specific method or type of failure. For example, a stent delivery device with balloon inflation could have known failure modes of (1) rupture due to over-inflation and (2) rupture due to material degradation.

Q: Is the labeling for the device to which you are considering making changes false or misleading, does it fail to bear adequate directions for use, or does it otherwise violate the FD&C Act or FDA regulations?[11]
A: Devices with false or misleading labeling are misbranded under section 502(a) of the FD&C Act [21 U.S.C. 352(a)]. Devices that fail to bear adequate directions for use as defined at 21 CFR 801.5 are misbranded under section 502(f)(1) of the FD&C Act [21 U.S.C. 352(f)(1)] (unless exempt).[12] Devices that fail to meet applicable labeling requirements identified in 21 CFR parts 801 and 809, subpart B, also violate the laws administered by FDA.

A change to a marketed device to address false or misleading labeling or other labeling violations would generally constitute a medical device recall. However, the addition of a new warning or other changes to the labeling of a *non-violative* device would not meet the definition of a recall.

> Example 15:
> Labeling of a device in global distribution is modified to meet the needs of one or more foreign device regulators. The prior labeling already contained comprehensive risk information; however, the revised labeling provides greater emphasis to certain risks associated with device use, as requested by foreign regulators. The risks were previously included in the labeling. The device meets all labeling requirements and performance specifications. Additionally, the labeling change did not introduce any changes to device specifications, and was not initiated to address any device violations. FDA would generally consider this action to be a device enhancement.

Q: Are you otherwise out of compliance with FDA regulations?
A: You should conduct a careful, thorough, and adequate assessment for each proposed change to your device. If the result of your assessment indicates that the change is made to correct or remove a violative marketed device to bring it into compliance with the laws administered by FDA, then the change would likely constitute a medical device recall.

VII. 806 Reporting Requirements

Under 21 CFR part 806, Medical Devices; Reports of Corrections and Removals, manufacturers and importers must submit a correction and removal report (806 report) to FDA for any correction or removal of a medical device that was initiated by such manufacturer or importer to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act caused by the device that may present a health risk, with certain exceptions.[13] FDA has a role in determining whether or not an action reported under part 806 would be considered a recall.

Q: Must you file an 806 report for a recall?
A recall must be reported to FDA under part 806 if the violation targeted by the recall may present a risk to health and if the recall has not already been reported under 21 CFR parts 803 or 1004. A risk to health means (1) a reasonable probability that use of or exposure to the device will cause serious adverse health consequences or death; or (2) that use of or exposure to the device may cause temporary or medically reversible adverse health consequences or an outcome where the probability of serious adverse health consequences is remote.[14] Medical device enhancements do not require the submission of an 806 report.

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[11] Labeling is defined in section 201(m) of the FD&C Act as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." The term "accompanying such article" is not restricted to labels that are attached to or in the article or package in which it is transported, and labeling can include posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, fillers, and information on a manufacturer's web page.
[12] Prescription devices that meet the requirements of 21 CFR 801.109 are exempt from section 502(f)(1) of the FD&C Act. Other exemptions are set forth at 21 CFR part 801, subpart D.
[13] 21 CFR 806.10(a). See 21 CFR 806.2(d) for the definition of the term "correction."
[14] 21 CFR 806.2(k).

A required 806 report must be submitted to FDA within 10 working days from the time that the firm initiates the recall, in accordance with 21 CFR 806.10(b). Regulatory requirements regarding what must be included in an 806 report are available at 21 CFR 806.10(c). In general, reports should be made to the FDA District Office in which the reporting facility is geographically located.

The device manufacturer or importer that initiates a correction or removal of a device that is not required to be reported to FDA under part 806 must maintain records of the correction or removal. Under the regulations, the manufacturer or importer must retain all records for a period of two years beyond the expected life of the device, even if the manufacturer or importer has ceased to manufacture or import the device. If there is a change in ownership, records required to be maintained must be transferred to the new manufacturer or importer of the device and maintained for the required period of time.[15] Regulatory requirements regarding records of corrections and removals not required to be reported to FDA can be found at 21 CFR 806.20.

VIII. Other Regulatory Considerations

Q: Once you have determined whether the change represents a medical device recall or enhancement, do you have any regulatory obligations?

A: This guidance does not attempt to address all regulatory obligations associated with a change to a marketed device. Whether a change to a marketed device constitutes a recall or enhancement, you should carefully review the change under applicable regulations and guidance documents. Relevant analysis includes whether the change triggers a requirement for a premarket submission, for example under 21 CFR 807.81(a)(3) or 814.39.[16, 17]

[15] 21 CFR 806.20(c).

[16] See "Deciding When to Submit a 510(k) for a Change to an Existing Device (K97-1)" (issued January 10, 1997).

[17] For medical devices approved under a Premarket Approval application, refer to "Guidance for Industry and FDA Staff; Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" (issued December 11, 2008).