



GUIDE 14 **FIELD ACTIONS**

Recalls, corrections and quiet fixes

What a manufacturer may do about a problem in the field, what it must report, and how to find the actions that were never called a recall.



ABOUT

A recall is the field action everyone can see. It is not the only one. A software update, a revised instruction, a service bulletin, and a quiet change on the production line all fix problems in the field, and most of them never carry the word.

This guide explains the kinds of field action, the rules that decide which ones must be reported to FDA, where each one leaves a record, and how to read a field action for what the manufacturer knew when it started it.

FOR

Legal counsel who must establish what a manufacturer did about a known problem, and when.

Manufacturers — regulatory and quality teams who decide whether an action is reportable.

Hospitals — clinical engineering and supply-chain teams who receive notices and must act on them.

NOTE

This guide is general technical information. It is not legal or regulatory advice. Definitions and reporting periods are quoted from 21 CFR Parts 7 and 806 as in force in October 2026.

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01

Five kinds of action

The regulation uses two words for a field action. A *correction* is the repair, modification, adjustment, relabeling, destruction, or inspection of a device without physically removing it. A *removal* takes the device from its point of use to another place for the same purposes. A recall is a correction or a removal of a marketed product that FDA considers to be in violation of the law; FDA classifies it by the risk involved.

In practice a manufacturer has five ways to act on a problem in the field. They differ in visibility, not in what they tell you about the problem.

RECALL

A correction or removal reported to FDA and classified: Class I where there is a reasonable probability of serious harm or death, Class II where harm is temporary or reversible or serious harm is remote, Class III where harm is not likely.

NOTICE

A letter, bulletin, or safety notice to users: new instructions, a warning, a workaround, an inspection to perform. Often a correction by definition, whether or not it was reported.

UPDATE

A software or firmware release that changes device behaviour. When the change reduces a risk to health, it is a correction. When the release notes call it an improvement, read the bug list.

SERVICE

A service bulletin or a field-repair instruction: parts replaced at the next visit, a setting changed, a component inspected. Each visit leaves a servicing record.

QUIET
CHANGE

A design or production change made for new units only, with no action in the field. The record is in the design file, not the recall database.

NOTE

The question for each action is the same: what problem was it for, when did the manufacturer decide to act, and which units were left as they were?

FIGURE **Reportable, recorded, or neither**

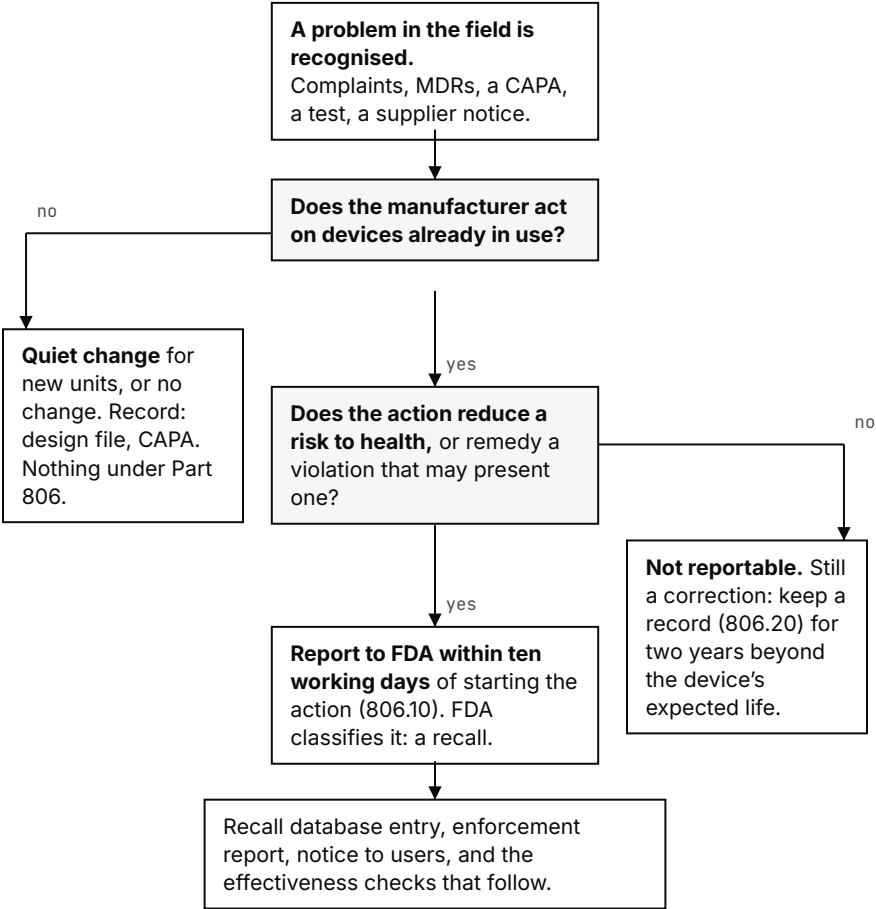


FIG 01 Three outcomes, three places to look. Exempt from Part 806: market withdrawals for minor violations, routine servicing, stock recovery, and changes that improve performance without reducing a risk to health. Each exemption is a decision, and the decision is recorded.

02

Where the record is

Field actions leave records in two places: the public databases, which show what was reported, and the manufacturer's own files, which show what was decided. Start with the public record; it tells you what to ask for.

01

The public record

FDA's medical device recall database lists recalls by product, firm, and date, with the reason as the manufacturer stated it, the class, the lots or serial ranges affected, and the status. The weekly enforcement reports carry the same actions as they are classified. Both are reachable through openFDA.

Safety communications and letters to health care providers are published separately by FDA. Manufacturer notices are often on the company's website for a time, and then gone; ask the facility's clinical engineering department for its copy, and ask the manufacturer for the distribution list.

02

MAUDE, read for the action

Manufacturer MDR narratives after a field action often mention it: "the customer was advised to apply the software update", "the unit was within the scope of the field correction". Searching the narratives for the action's name finds events the recall database does not connect to it (guide 02).

03

The 806 file

Ask for every correction and removal for the device and its sister models (guide 05): the reports filed under 806.10, and the records kept under 806.20 for actions the manufacturer decided were not reportable. The second set is the one that matters most and is produced least. Each record must state the reason for the action and the reason it was not reported.

Ask also for the health hazard evaluation behind each decision. It is the manufacturer's own estimate of the risk at the time, written by its own medical and engineering reviewers.

04

Release notes, bulletins, and change orders

For software: every release note and the problem reports each release closed. For hardware: service bulletins, field-repair instructions, and the design change orders that changed production. Read each one for the problem it addresses, and compare the date with the first complaints of that problem.

A change order that reads "improvement" and closes a bug reported in three complaints is a correction in the sense of the regulation, whatever the title says.

- **CAUTION**

- Labeling is part of the device. A revised warning, a changed
- contraindication, or a new step in the instructions is a correction
- when it addresses a risk to health, and it has the same record
- obligations as a hardware fix.

03

Reading a field action

A field action is read for the problem, the scope, the timing, and the follow-through. The questions apply to a Class I recall and to a service bulletin alike.

01

What problem, in the manufacturer's words

The stated reason is a choice. Compare it with the complaint narratives and the CAPA root cause. A recall "to update labeling" after a CAPA with a design cause asks why the design was not the action.

02

Which units, and which were left out

Lot ranges, serial ranges, software versions, regions. Units outside the scope with the same design are the first question. A scope drawn around a component change is a scope drawn by cause.

03

When the clock started

The action date, the 806 report date, and the complaints and CAPA that led to it, on one timeline (guide 15). The regulation's clock is ten working days from the start of the action; the longer interval is usually the one before the decision.

04

What users were told to do

Stop use, inspect, apply a workaround, wait for a part. Compare the instruction with what the facility's records show was done with the unit, and when.

05

Whether it worked

Effectiveness checks: units reached, units corrected, and the complaint rate after. A recall that reached a third of the field left two thirds as they were.

06

Whether it was the first

Earlier actions on the same model or platform, under any name. A second action for one failure mode is a statement about the first.

04

The unit in question

Every field action divides the installed base into units that were corrected and units that were not. For the device in a specific matter, the question is which side it was on, and what that means.

Three records answer it. The manufacturer's effectiveness file shows whether the facility was notified and whether it acknowledged. The facility's clinical engineering records show whether the correction was applied, by whom, and when. The device itself shows its software version, the parts in it, and, in its service log, when they changed.

CORRECTED

The correction was applied before the event. The event then happened in a corrected device, and the correction did not prevent it. The action's own problem statement becomes evidence about the failure mode.

NOT YET

The notice was issued but not applied before the event. The questions move to the facility: was the notice received, and what did the procedure require. And to the manufacturer: how was the notice sent, and to whom.

OUT OF
SCOPE

The unit was outside the lots or versions the action covered. The scope decision, and the health hazard evaluation behind it, become the record to read.

KEY POINT

A field action is a manufacturer's statement that a problem existed and that it was worth acting on. The scope and the date say how far that statement goes.

05 Where actions hide

Most field actions are not labelled. These are the places where an engineering reviewer finds them when the recall database is empty.

01 **Release notes**
A "stability improvement" that closes a crash reported from the field. The known-anomalies list of the previous release shows what was known.

02 **Service bulletins**
Parts replaced "at next preventive maintenance" across the installed base, with no notice to users.

03 **Change orders**
A production change that follows the complaints; new units are different, old units are not.

04 **Labeling revisions**
A warning added, a limit changed, a step inserted. The change record states the reason, or should.

05

Sales and customer letters

Letters that read as product news and contain an instruction.

06

806.20 records

The manufacturer's own list of actions it decided not to report, with its reasons.

07

Other markets

A field safety notice issued in the EU or elsewhere for the same device, where the US record is silent.

NOTE

Each of these is a request item under guide 05. A production that contains the recall file but none of these has answered a narrower question than the one that was asked.

CHECKLIST

Field actions at a glance

- ☐ FDA recall database and enforcement reports searched for the device, sister models, and the manufacturer
- ☐ FDA safety communications and manufacturer notices collected; facility's copies obtained
- ☐ MAUDE narratives searched for the name of each action
- ☐ 806.10 reports and 806.20 records requested, with reasons
- ☐ Health hazard evaluations requested for each decision
- ☐ Release notes, known-anomalies lists, service bulletins, and change orders requested
- ☐ Labeling revisions obtained with change records
- ☐ Field notices from other markets checked
- ☐ For each action: problem, scope, dates, instruction, effectiveness, earlier actions
- ☐ The unit in question placed inside or outside each action's scope
- ☐ Facility records checked for receipt and application of each notice
- ☐ Dates placed on the timeline with the complaints and CAPAs (guide 15)

SOURCES

Sources and further reading

eCFR — 21 CFR Part 806, Medical Devices; Reports of Corrections and Removals (806.2, 806.10, 806.20)

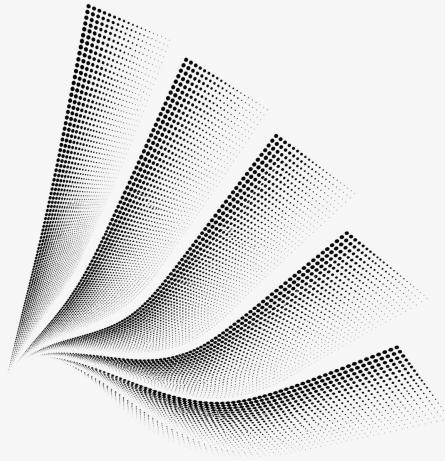
[ecfr.gov](https://www.ecfr.gov)

eCFR — 21 CFR Part 7, Subpart A (7.3 definitions and recall classes) and Subpart C (recalls)

[ecfr.gov](https://www.ecfr.gov)

FDA — Medical Device Recalls database and Enforcement Reports

accessdata.fda.gov



SERVICES

We find the actions that were not called recalls

We read release notes, bulletins, and change orders as engineers, connect each one to the complaints it answered, and establish which side of each action the unit in question was on.

01

Field-action search

Public databases, MAUDE narratives, and the manufacturer's 806 file, release notes, and change orders, read for the problem behind each action.

02

The unit's status

Software version, parts, and service history of the device, compared with the scope and the instruction of each action.

03

Testing the fix

Where a correction claims to resolve a failure mode, we test the corrected and the uncorrected configuration on the bench.

TERMS

Terms used in this guide

Correction

Repair, modification, adjustment, relabeling, destruction, or inspection of a device without its physical removal to some other location.

Removal

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

Recall

A correction or removal of a marketed product that FDA considers to be in violation of the law, classified by the risk involved. Market withdrawals and stock recoveries are not recalls.

Class I, II, III recall

Class I: reasonable probability of serious harm or death. Class II: temporary or reversible harm, or remote probability of serious harm. Class III: harm not likely.

Market withdrawal

A correction or removal for a minor violation that would not be subject to legal action, or involving no violation. Exempt from reporting.

Field safety notice

A manufacturer's communication to users about a field action, in the terms used outside the United States.

806 report

The report a manufacturer must file with FDA within ten working days of starting a correction or removal that reduces a risk to health, or remedies a violation that may present one.

806 record

The manufacturer's internal record of a correction or removal that it decided not to report, with its reasons, kept for two years beyond the expected life of the device.

Tell us about the device.

Send a short description of the device, the event, and any deadlines. We will tell you what to preserve now and recommend the next steps.

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