C&R - A Short Overview

There are two related parts of the regulations that should not be confused. Part 7 Subpart C is an internal FDA regulation for recalls of all FDA products. Part 806 Reports of Corrections and Removals applies to medical device manufacturers.

Part 7 and Part 806 have some terms in common, but they don't have the same definitions. Device manufacturers should use the Part 806 terms.

Device manufacturers report under Part 806. FDA determines if it is a recall and, if so, the recall class under Part 7.

Having decided to take a field action, the manufacturer determines where the activity takes place. If it is at the site of the device, it is a correction, but if the device is taken from the site, it is a removal. The report number encodes the distinction.

There are three ways to report. File a C&R report under Part 806, file an MDR under Part 803, or file a repair/replacement/repurchase plan under Part 1004 (electronic products only). Never file an MDR under Part 803 thinking it covers the Part 806 requirement. The MDR form doesn't contain all the required information. Device manufacturers have received Warning Letters for incomplete reports. §806.10 describes the required information and timing.

The default is that any changes to a device in the field is reportable. However, there are exceptions:

- Improve the performance or quality of a device
- Market withdrawals (§806.2(h))
- Routine servicing (§806.2(k))
- Stock recoveries (§806.2(l))
- Cyber security based changes

If the change improves the performance or quality unrelated to reducing a risk to health or remedy a violation of the FD&C Act, then it is not reportable.

A market withdrawal involves either no violation of the act or a minor violation that FDA would not pursue. The guidance document's example is an incorrect street address on a label. The manufacturer sends out stickers to place over the label. The incorrect label is a violation, the stickers are a correction, and the violation is minor, so not reportable.

Routine servicing means standard preventive action including replacing components before failure (batteries) or after a wear-out failure. If one device has an early failure, it is probably routine servicing, but if many devices in the population experience early failures, there is a reliability problem. Servicing analysis under §820.200 would reveal the reliability problem. This

should result in a complaint under §820.198, which requires investigation under §820.198(c) because the device has failed to meet specification. Fixing the devices in the field is reportable.

Stock recovery means taking back the device before it has left the manufacturer's control. The control point is in §820.90(d) where the device is released for distribution. If the device, lot, or batch is under the manufacturer's control and pulled-back, then it is a stock recovery. One way to determine this uses the distribution records. If the device, lot, or batch is not included in the §820.160(b) distribution records, then it is probably a stock recovery.

Cyber security is covered in the post-market cybersecurity guidance document. Cybersecurity routine updates and patches to address cybersecurity vulnerabilities and exploits are improvements and are not reportable.

Manufacturer's actions to correct device cybersecurity vulnerabilities and exploits that may pose a risk to health are reportable, but there is an exception based on enforcement discretion. The manufacturer must meet four conditions to gain the exception.

- There are no known serious adverse events or deaths associated with the vulnerability
- Communicate with customers and the user community within 30 days of learning about the vulnerability
- Distribute a validated fix to customers and the user community within 60 days of learning about the vulnerability
- Actively participate as a member of an Information Sharing Analysis Organization, ISAO, that shares vulnerabilities and threats that impact medical devices

If you don't report the C&R, then create and maintain the records required under §806.20.