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Determining the Revision Level of QSR Sections

When standards, such as ISO 9001 and ISO 13485, change, the whole standard gets a new revision year. For example, ISO 9001 recently changed from the 2000 version to the 2008 version.

This system does not apply to Federal Regulations. In particular, the FDA's Quality System Regulation (QSR) is one of these. Instead of changing the whole regulation, the FDA revises individual sections.

The US Government publishes Federal Regulations in the Code of Federal Regulations, usually abbreviated as CFR. The CFR has a series of Titles, each of which is a number. The medical device regulations (and many more) are in Title 21. Each title has Parts, which have Subparts and Sections. For example, the QSR is in 21 CFR Part 820; this is Title 21, Part 820 of the Code of Federal Regulations.

Each Part has Subparts, which have Sections. For example, Subpart G covers Production and Process Controls and has three sections:

820.70 Production and process controls
820.72 Inspection, measuring, and test equipment
820.75 Process validation

When the FDA revises the regulations, the revision typically occurs at the section level, not the part level. It would be equivalent to changing individual paragraphs of ISO 9001.

The FDA posts the current version of Title 21 on its website. Go to
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
The box in the middle of the page lists the Parts of Title 21. Scroll down to Part 820, click on it, and select Search Regulation(s). You will see the Subparts and Sections of Part 820.

At the bottom of the page, you will see "**Source**: 61 FR 52654, Oct. 7, 1996, unless otherwise noted". This means that Part 820 comes from Volume 61 of the Federal Register starting on page 52654. This is the default. If a particular section changed, there will be a note for the section.

Let's follow and example. Click on §820.198 and the section on Complaint Files will open. Scroll to the bottom and you will see, "[61 FR 52654, Oct. 7, 1996, as amended at 69 FR 11313, Mar. 10, 2004; 71 FR 16228, Mar. 31, 2006]"

This tells you the FDA amended the section two times after publishing the initial regulation. The details of the amendments are in the Federal Register. The first one is at 69 FR 11313 and the second one is at 71 FR 16228.

Go back to the full list and click on §820.40 and the section on Document Controls will open. Scroll to the bottom. You will notice there is no information in square brackets. This means the section hasn't changed since the initial publication.

If you want to read the details of the changes, you must look at the Federal Register. The Government Printing Office (GPO) manages the Federal Register. You can find specific information at http://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR

To continue the example, look at the first amendment to §820.198 (69 FR 11313, Mar. 10, 2004). Open the dates until you get to March 4, 2004. Now open up Health and Human Services Department (the home department for the FDA). Look under Rules and Regulations and you will the second entry includes the page of interest (11313).

You can look at either a text or PDF version. This change amended many Sections of the FDA Regulations, not just §820.198.