Complaints and Reliability

In FDA QSR, a complaint includes communication that alleges a reliability deficiency in a device after release for distribution. Similarly, ISO 13485:2003 and ISO 13485:2016 includes reliability as an element of a complaint.

None of these standards (FDA QSR, ISO 13485:2003, and ISO 13485:2016) defines reliability. In the QSR preamble #72, the discussion of design input includes, "FDA emphasizes, however, that the section requires the manufacturer to ensure that the design input requirements are appropriate so the device will perform to meet its intended use and the needs of the user. In doing this, the manufacturer must define the performance characteristics, safety and **reliability** requirements, environmental requirements and limitations, physical characteristics, applicable standards and regulatory requirements, and labeling and packaging requirements, among other things, and refine the design requirements as verification and validation results are established."

The CDRH's Small Entity Compliance Guide, Chapter 15 Complaint Files, includes a sample procedure that defines product reliability as the failure rate or need for service adjustments greater than user expectation, *i.e.*, beyond the tolerable level of expected wear or malfunction.

The literature provides a good clarification. *Introduction to Reliability Analysis* by Zacks distinguishes between mission reliability (a device constructed for the performance of one mission only) and operational reliability (a system turned on or off intermittently for performing a certain function). The book uses missiles and aircraft radar systems as distinguishing examples, but it is easy to envision single use devices and, say, a diagnostic MRI system.

Recommendation
When reviewing complaints, classify them by the attributes in the definition, such as reliability or durability, remembering that the definitions in the three standards are not the same.

For a reliability complaint, look at the time the device was in service, distinguishing between mission reliability and operational reliability. Reliability is not a characteristic of a device, but of the population. As result, corrective action depends on data analysis, which should include both devices identified in complaints and devices still in the field and believed to be operational.

A good data analysis would start with the model for reliability based on the design input. This includes a description of the expected reliability distribution with its parameters. Using the data from complaints, service records, *etc*. determine if the observed reliability meets or exceeds the expected reliability.

Warning Letter Example
In a May 9, 2013 Warning Letter to Hospira, Inc., FDA cited then for failure to review, evaluate, and investigate complaints involving the possible failure of a device to meet any of its specifications, as required by 21 CFR §820.198(c).

The repair facility replaced about 58,000 failed components in about 20,000 infusion pumps over a seven-month period. The company did not enter these into the complaint system, although they

define a complaint as an allegation of a deficiency related to reliability, durability, or performance.

FDA said that their infusion pump complaint investigations are inadequate because they replace components without an investigation to determine if the complaint is a design, manufacturing, or supplier issue.

In addition, they don't determine if the problem is occurring across product families.

Warning Letter Analysis

While replacing components and returning devices to service is a good thing, a device manufacturer needs to analyze the data to determine if there is an issue with reliability or durability. QSR requires data analysis of both complaints and service records in 21 CFR §820.100(a)(1) using appropriate statistical methodology.

The analysis should estimate the reliability based on the data from complaints and service records. Compare the result with the design input reliability requirements to determine if the device meets them. If not, take corrective action following the methodology in 21 CFR §820.100.