

Complaint Documentation

The Context

Device manufacturers receive complaints. The complaint is evaluated for validity, documented, and in some cases investigated. A complaint, following the definition in §820.3(b), is an allegation of a deficiency related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device.

For some companies there is question of whether a warranty claim is a complaint. When a customer makes a warranty claim for a device, the customer alleges a deficiency in durability or reliability; treat every warranty claim as a complaint.

The Warning Letter

FDA sent a March 2, 2016 Warning Letter to Innovative Sterilization Technologies, LLC, a specification developer located in Dayton, Ohio. The Warning Letter was the result of an FDA inspection.

The Issue Cited

The Warning Letter cited a failure to establish and maintain adequate procedures for receiving, reviewing, evaluating, and investigating complaints as required by 21 CFR §820.198(a).

The citation says, “[Y]our ‘IST Customer Complaint Procedures/Work Instructions’ is not being implemented in that warranty repairs that meet the definition of a complaint are not documented and investigated per your complaint procedure. None of the 134 warranty repairs received between 1/27/2014 and 8/3/2015 were evaluated as possible complaints.” The Warning Letter then cites a specific example of a warranty repair that the company had not reviewed to determine if it meets the definition of a complaint or documented a failure investigation.

The Requirement

The Quality System Regulation requires, in §820.198(a), “Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit.” In addition, §820.198(c) requires, “Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.”

Recommendations

Ensure that your complaint procedures include an evaluation of warranty claims to determine if the claim is a complaint. It would be a rare case where the claim would not fit the complaint definition because the durability or reliability aspects would apply.

A warranty claim is a complaint that involves the failure of a device to meet a specification. Ensure the procedures require a documented investigation.

Include complaint documentation in the internal quality program. As part of the audit, check a sample of warranty claims to verify they are also documented as complaints. For an item in the sample that is both a warranty claim and a complaint, verify the documented investigation.