Complaints and Warranty Claims

One common question is whether a warranty claim is a complaint as defined in the Quality System Regulation, QSR. As explained below, every warranty claim is a QSR complaint.

The Definition
QSR defines a complaint as "any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution". [§820.3(b)]

The complaint definition includes an allegation of a deficiency in one or more attributes. The allegation may not be substantiated, but, in the customer's view, the device has a deficiency. An allegation related to one the attributes is sufficient to start the complaint process in §820.198. Some deficiency allegations are not QSR complaints. For example, an allegation of a late delivery of a conforming device would not be a QSR complaint.

A warranty claim is an allegation of a deficiency of one of the attributes. Unfortunately, QSR doesn't define the terms. However, a warranty claim would likely fall under performance. It might also be reliability, durability, or perhaps other attributes.

Warning Letters
Warning Letters provide insights into these issues. In particular, some companies consider that a device under warranty cannot be a complaint. Others consider that only devices under warranty can be complaints. The warranty status of a device is not an element of the complaint definition; it should not enter into the complaint classification decision.

Another area of concern in Warning Letters is repairs, either in or out of warranty. In these cases, the repair is usually a complaint because it involves performance, durability, or reliability.

Actions to Take

Review your complaint procedures and remove any reference to warranty in determining if the report is a complaint.

Review your complaint procedure and remove any reference to repair in determining if the report is a complaint.

Review your returned goods procedure and ensure it requires evaluation to determine if the request constitutes a complaint.

Review your repair procedure and ensure it requires evaluation to determine if the repair constitutes a compliant.

If any of these reviews requires a revision to the procedure, conduct a retrospective review of the associated records to determine if any of them is also a complaint.

Warning Letters Involving Warranty
Innovative Sterilization Technologies, LLC March 2, 2016
Specifically, your [procedure] 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.

Your response states a retrospective review of all warranty repairs will be reviewed to determine if they meet the definition of a complaint. If it meets the definition of a complaint, it will be added to your complaint file. Please provide an update on the progress of these corrective actions.

KBD, Inc. December 15, 2011
[Your firm's procedure] does not adequately state how to document a complaint to ensure that it is reviewed and evaluated. The procedure does not require a KBD/Non-conforming Product form to be filled out for a complaint if it was not under warranty. Not all complaints have been documented and reviewed in a uniform manner.

We reviewed your firm's response … and conclude that it is not adequate. Your firm provided a revised [procedure]. However, this procedure does not address complaints where units are not intended for return.

Ohio Medical Corporation July 22, 2009
For example, six customer inquiries received for warranty repairs on devices that were not working should have been designated as complaints; however, the inquiries are not found in the complaint log because the inquiry database has separate categories for "Warranty Repair" and "Complaints". The complaint-handling procedure does not clearly define the categories used by Customer Service to ensure that all complaint inquiries are correctly classified.

Riverpoint Medical May 1, 2013
For example, your Complaint Handling Procedure, 820.198, effective August 16, 2012, does not require communications alleging deficiencies related to identity, quality, durability, reliability, safety, effectiveness, or performance of the MedLED™ line of headlamps be handled as a complaint unless the device is under warranty. The intended use of MedLED™ devices is to provide light during surgical procedures. Our investigator reviewed five Returned Goods Authorizations for MedLED™ devices in which he observed 17 device issues, such as exposed battery pack wiring and wiring shorts, which were not identified or handled as complaints.

We have reviewed your response and concluded that it was inadequate because your Complaint Handling procedure 820.198 included in your response states that MedLED™ units returned after the warranty period are not considered to be verified complaints. Your procedure does not require MedLED™ devices that were returned for alleged deficiencies related to identity, quality, durability, reliability, safety, effectiveness, or performance to be handled as complaints.

Your response states that the MedLED™ lifetime/warranty period is 1-year. In the MedLED™ Product Catalog collected during the inspection, the MedLED™ is described as "having long life

with excellent durability". Your response is inadequate because you did not include documentation of the expected life of the MedLED™ product line to justify not handling MedLED™ products returned outside the warranty period as complaints. You did not provide labeling in your response that addresses the expected lifetime of the MedLED™ product line.

Shanghai Apolo Medical Technology Co., LTD February 23, 2012
The complaint procedure failed to define a communication concerning a problem or deficiency, or concerning the quality, durability, reliability, safety, effectiveness, or performance of a device that is under warranty as a complaint.

We reviewed your response and conclude that it is not adequate. Your firm did not provide evidence to demonstrate that it has an adequate complaint handling system in place. In addition, the response does not address correction or review of pre-existing complaints.

So-Low Environmental Equipment Co., Inc. May 21, 2013
Specifically, your firm records what you consider to be "FDA complaints" related to your medical freezers on a form titled "FDA Service Log". The only complaints documented on these forms are for freezers that are still under warranty; each freezer has a 1-year warranty. Your management stated that the life cycle of the device is [redacted] years.

When asked if your firm keeps any documentation of complaints related to freezers that are no longer under warranty, your management stated that they will make notes on the outside envelope that the device history record is enclosed in when the customer calls. These "notes" on the DHR envelopes are not tracked or analyzed as complaints.

The adequacy of your firm's response cannot be determined at this time. Your response states that you are redesigning your corrective action system and list complaints as a subset of this system. However, your response lacks sufficient detail on the changes you are making to this system to assess its adequacy.

Teh Lin Prosthetic & Orthopedic, Inc. December 23, 2011
Complaint files did not include the returned or repaired devices under warranty.

Tosoh Bioscience, Inc. August 5, 2016
Service calls received on analyzers under warranty are not considered complaints, as defined by your procedures, and no complaint investigation is performed.

Your response is not adequate. Your response states that you are revising your procedures, but it does not address performing a retrospective review of Ticket Reports to determine which reports should have been documented as a complaint, and that these complaints will be evaluated and failure investigations will be performed, if necessary.

VBM Medizintechnik GmbH December 7, 2010
For example, your complaint handling procedure does not define the term "complaint" in accordance with 21 CFR §820.3(b); rather it defines complaints by the product warranty status.

Your response … is not adequate. Your response states that the [procedure] has yet to be revised to reflect the QS regulation definition of the term "complaint". Your response did not address the identification of complaints from your existing population of repairs or why the complaint procedure was deficient to begin with.

Warning Letters Involving Repairs
Cane S.p.A. July 29, 2015
Your firm identified 501 repairs for Primary Immunodeficiency (PID) pumps in 2013 and 2014. 26 out of 30 repair and maintenance report records reviewed during the inspection were confirmed to include repairs that constituted complaints. These repairs, which included errors of piston operation and failures to sound alarms, had no evidence of complaint investigation or evaluation for MDR reporting.

We reviewed your firm's response and conclude that it is not adequate. Your firm described an additional complaint procedure that covers field complaints. Your firm states it will revise procedures to ensure that repairs are handled as complaints, and require evaluation for … the need for investigation. However, updated procedures were not provided in the response, nor was there discussion of a retrospective review of previous repairs to determine whether they represented complaints.

Conkin Surgical Instruments Ltd. January 12, 2015
Your firm failed to consider unscheduled repairs of Valtchev Uterine Mobilizers returned by customers as complaints.

Dako Denmark A/S August 21, 2013
Your firm failed to document the following … repairs as complaints when the repairs met your firm's complaint definition.

We reviewed your firm's response and conclude that it is not adequate. Your firm did not provide a description and evidence that a systemic corrective action was considered to address this deficiency to include a retrospective review of all oral, written, and electronic information received alleging deficiencies related to a device to ensure that it was appropriately determined if it is a complaint treated as such when applicable.

Hospira, Inc. May 9, 2013
Your repair facility replaced 58,438 failed components in 20,067 infusion pumps from July 2012 to January 2013, and these device component failures were not entered into your complaint system when a complaint is defined, by your firm's procedures, to be "any communication that alleges deficiencies related to the reliability, durability, or performance of a product after its release for distribution".

We have reviewed your response and have determined that it is inadequate because it lacks detail on how your firm's complaint handling system will be revised to ensure complaints are investigated moving forward.

Insert Depot, Inc. January 29, 2014
A review of your Repair Log of returned product revealed complaints for the following Tony Riso 25/30 Multifunction Ultrasonic Scalers (identified by their device serial number) that were not documented according to your Complaint Handling Procedure: [redacted]

Nurse Assist, Inc. October 21, 2011
Your firm's Return Goods Authorization (RGA) for all enteral pumps from June 2009, to present totaled 65 RGAs. A total of 37 out of 65 RGAs indicated a device defect, or device falling to meet its performance characteristics, such as hold errors, dose volume errors, flow problems with viscous fluid, and pumps not working. None of these were documented as complaints, nor were they evaluated and processed using your firm's complaint handling procedure. Out of the 37 RGAs, 16 RGAs had no evaluation, no investigation, and no repairs conducted, and the returned devices were placed back into device inventory for future sale.

We cannot determine the adequacy of your firm's response at this time. Your response stated that, your firm will complete revising the procedures to add additional information in order to more thoroughly establish the complaint status of returned goods. However, your firm has not explained whether it will conduct and document a retrospective review of all RGAs using the revised procedures to investigate allegations of possible pump failures in order to implement appropriate corrective action.

Quality Electrodynamics, LLC April 10, 2015
MRI Coils that are returned for repairs are not being evaluated to determine if they meet the definition of a complaint. A search of your repair database for the past 2 years using the words artefacts/artifacts, burns, and heat revealed 10 reports of burns and 28 reports of heat that were not documented, evaluated and/or investigated as complaints.

Your response dated is not adequate. Although your response states that you have revised your procedure to include additional keywords to trigger complaints from returned products, it does not address conducting a retrospective review of your repairs to determine if any of the repairs are complaints and evaluating and/or investigating these complaints.