Out of Calibration Equipment

If you have ever found Inspection, Measuring, and Test Equipment, IM&TE, out of calibration, then you know this is a serious issue. For medical devices, the requirements in the Quality System Regulation and ISO 13485:2016 are clear.

Quality System Regulation
Calibration procedures shall include specific directions and limits for accuracy and precision. When accuracy and precision limits are not met, there shall be provisions for remedial action to reestablish the limits and to evaluate whether there was any adverse effect on the device's quality. These activities shall be documented. [§820.75(b)]

ISO 13485:2016
In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action in regard to the equipment and any product affected. [7.6]

Analysis
The wording in these two cases is different, but both lead to succinct statements of the circumstances.

- Calibration procedures specify the requirements including the limits for accuracy and precision.
- Calibration determines whether the piece of IM&TE satisfies the requirements.
- When the piece of IM&TE does not satisfy the requirements, restore it to a conforming state.
- Evaluate any adverse effect on device quality.
- Take action, based on the evaluation, on any affected devices.
- Keep records of all the associated activities.

QSR Preamble
A few comments on the draft QSR said that FDA should clarify the remedial action expected. FDA added the requirement that the calibration procedure include provisions for remedial action to “reestablish the limits and to evaluate whether there was any adverse effect on the device's quality” to clarify this remedial action requirement and its relationship to the requirements in Sec. 820.100 Corrective and Preventive Action. See Section 138 of the preamble.

Medical Device Single Audit Program
The MDSAP Audit Model, Production and Service Controls, audit task #14 includes, “Confirm that the organization assesses (and records) the validity of previous measurements when equipment is found not to conform to specified requirements, and takes appropriate action on the equipment and any product affected.”

The MDSAP Companion document provides guidance on evaluating the audit task. “When equipment is found to be out-of-tolerance: The organization may discover that monitoring or measuring equipment is no longer within its adjustment or calibration tolerance. In these situations, the organization must assess and record the validity of previous measuring results and take appropriate action on the equipment and any product affected.”

Calibration Certificates
Whether the calibration process is internal or outsourced, the result should include a calibration certificate with traceability information, as-received data, and as-calibrated data. A qualified person should review the data to ensure the piece of IM&TE meets the requirements. The problem starts when the as-received data shows the piece of IM&TE had not been meeting its requirements.

Evaluate Any Adverse Effect
The most important part of the evaluation involves classification of a product as conforming or nonconforming. An incorrect classification of a conforming product as non-conforming is probably not a problem. The product should have followed the process for control and disposition of non-conforming product. In fact, this may have disclosed the out-of-calibration IM&TE.

The more significant problem occurs when the verification step classifies a non-conforming product as conforming; the device may have even shipped.

The first step of the evaluation determines whether there is a problem. For example, there may be a bias in the measurement, but the tolerance is wide enough that the measurement step doesn't incorrectly classify the product.

For product incorrectly classified as conforming when it is not, follow the procedure for control and disposition of non-conforming product from §820.90 and ISO 13485:2016, 8.3.

For the piece of IM&TE, determine the cause of the out-of-calibration status and take corrective action following §820.100 and ISO 13485:2016, 8.5.2.