Regulatory Requirements for Medical Device Calibration Programs

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Speaker Biography

- Dan O'Leary
  - Dan O'Leary is President of Ombu Enterprises, LLC, an education, training, and consulting company focusing on Operational Excellence using analytical skills and a systems approach to operations management.
  - Dan has more than 30 years experience in quality, operations, and program management in regulated industries including aviation, defense, medical devices, and clinical labs.
  - He holds a Masters Degree in Mathematics; is an ASQ certified Biomedical Auditor, Quality Auditor, Quality Engineer, Reliability Engineer, and Six Sigma Black Belt; and is certified by APICS in Resource Management.
- Ombu Enterprises, LLC
  - Ombu works with small manufacturing companies, offering training and execution in Operational Excellence. Focusing on the analytic skills and systems approach of operations management, Ombu helps companies achieve efficient, effective process and regulatory compliance.

Outline

- Understanding some metrology terms
- The concepts of traceability
- Calibration requirements of FDA QSR
- Chapter 7 of the FDA's Quality Systems Manual
- Calibration requirements of ISO 13485 and ISO 9001
- Comparing the QSR and ISO systems
- Summary and Conclusions
- Questions

Understanding Some Metrology Terms

VIM

- Metrology is an important international process
- For the vocabulary we use the *International Vocabulary of Metrology – Basic and General Concepts and Associated Terms*
- This is usually called VIM, based on the document's title in French
- It JCGM 200:2008 and is available at www.bipm.org

Accuracy

- 2.3 *measurand* means quantity intended to be measured

- 2.13 *measurement accuracy* (*accuracy of measurement* or *accuracy*) means closeness of agreement between a measured quantity value and a true quantity value of a measurand

Precision

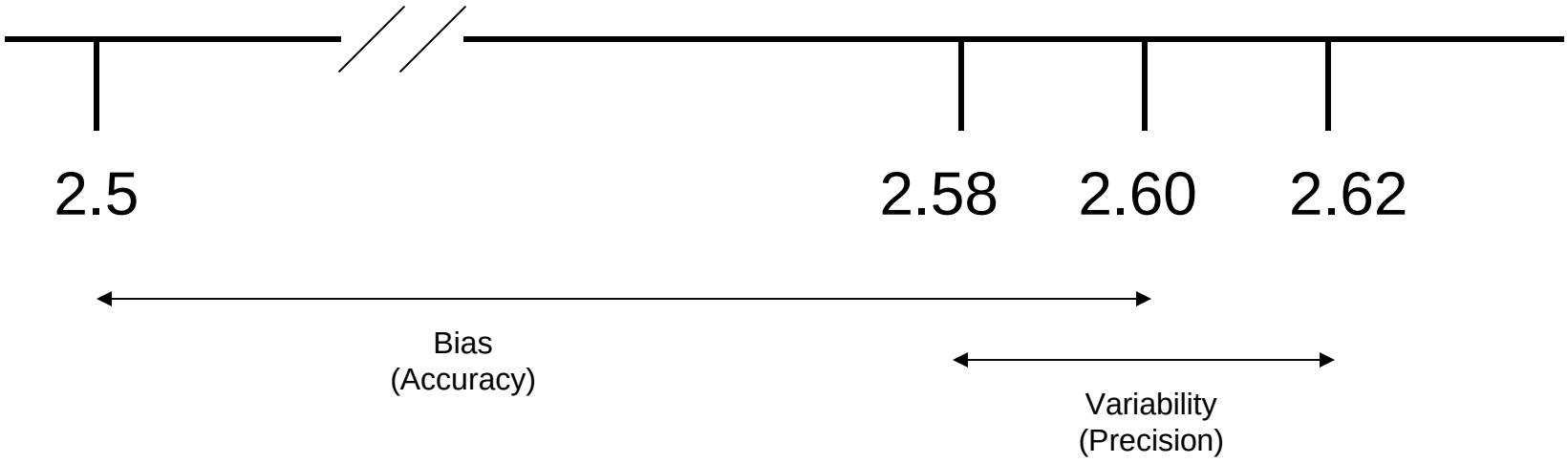
- 2.15 *measurement precision* (*precision*) means closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions

The Concepts

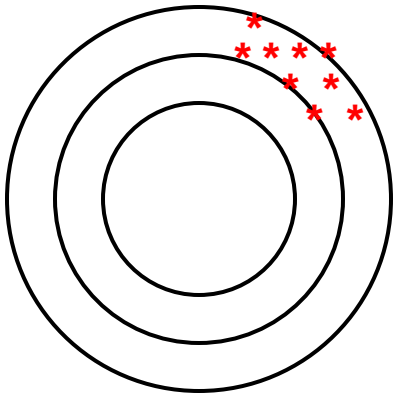
- The quantity we want to measure has a “true” value
- We use a measuring instrument and obtain a reading
  - If the measured value is close to the true value, the measuring system has high accuracy
- If we measure a quantity multiple times with the same system under the same conditions, we will get different values
  - If the spread of the values is small, the measuring system has high precision

The Number Line View

The “true” value is 2.5. Our instrument shows 2.60±0.02.
We take multiple readings:
The mean is 2.60.
The readings fall between 2.58 and 2.62

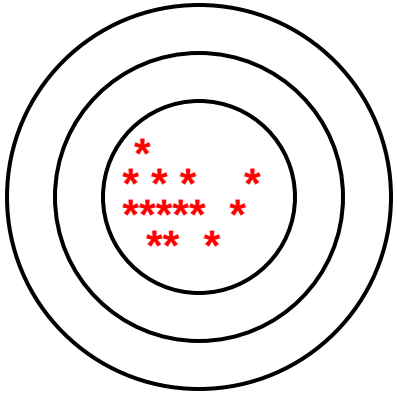


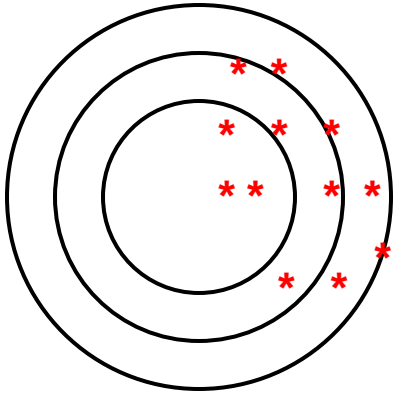
The Target View



Large Bias
High Precision

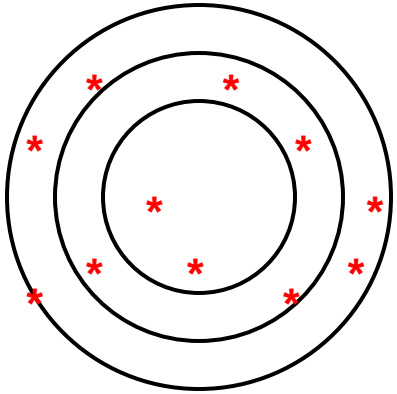
Low Bias
High Precision





Large Bias
Low Precision

Low Bias
Low Precision



Desired State

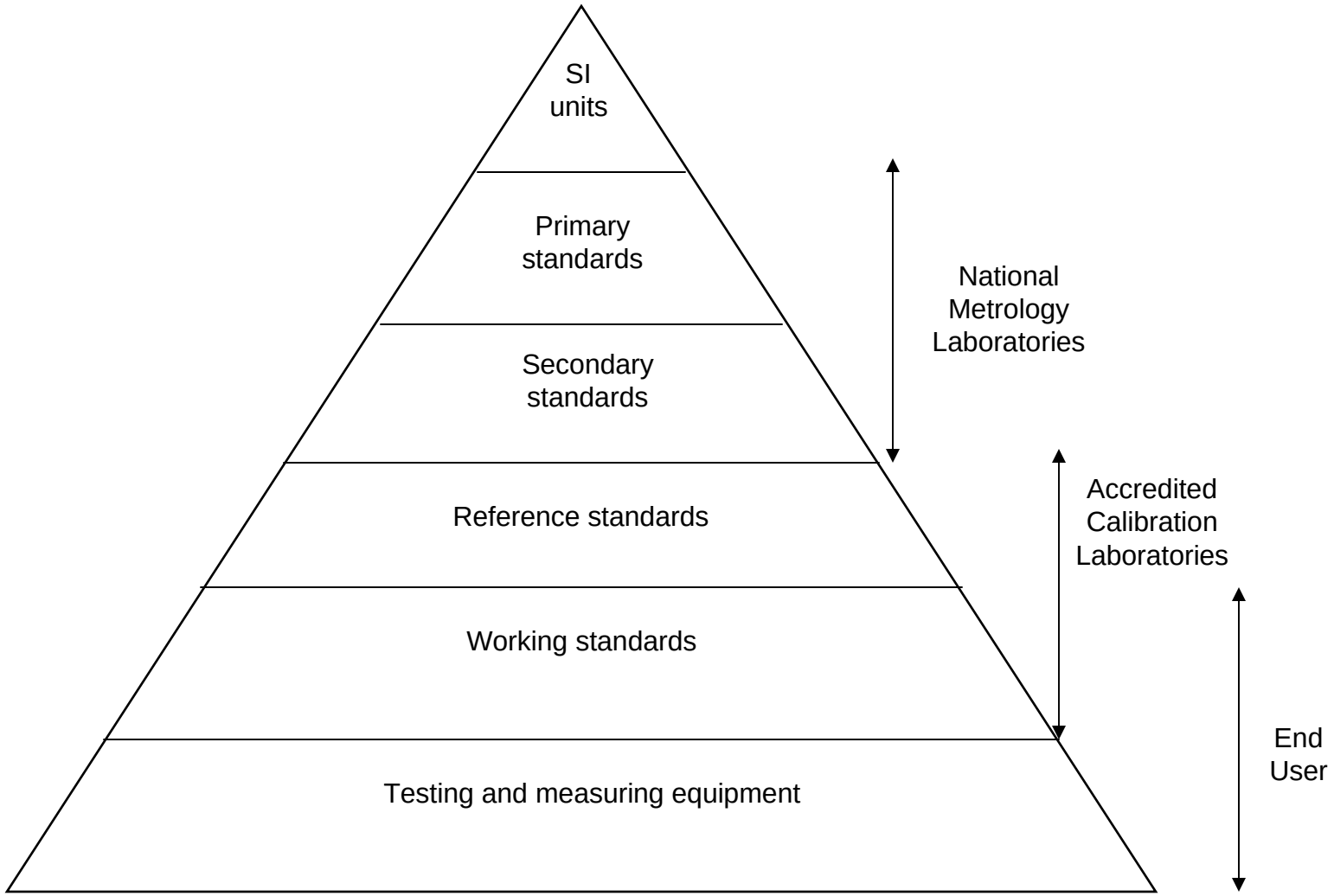
- When we take a series of measurements, we want two things:
  - The mean of the series should be the true value of the measurand
  - The variability of the series should be very small
- In daily work, we will probably measure the value one time and record the reading.

Concepts of Traceability

Traceability Definition

- 2.41 metrological traceability
- property of a **measurement result** whereby the result can be related to a reference through a documented unbroken chain of **calibrations,** each contributing to the **measurement uncertainty**

Hierarchy in a Calibration Program



Concepts of Traceability

- In practice, a piece of measuring equipment should be traceable
- There is an unbroken chain of calibration back to national units.
  - Your working equipment is compared against a standard.
  - The standard is compared against a higher standard.
  - The chain is documented through calibration certificates.

The Chain

- In theory, one could trace a piece of equipment on a US company's the shop floor, say a micrometer, back to NIST.
- Calibration certificates provide the required data.
- In practice, we don't.
  - Select the calibration laboratory and trust them
  - The supply chain for calibration services parallels the traceability chain for the measurement

The FDA's Quality System Regulation

Source of the QSR

- The Safe Medical Devices Act of 1990 (Pub. L. 101-629) encourages the FDA to work with foreign countries for mutual recognition of regulatory requirements.

- The result was the Quality System Regulation (QSR)

- The regulation was based on:
  - ANSI/ISO/ASQC Q9001-1994 *Quality Systems – Model for Quality Assurance in Design, Development, Production, Installation, and Servicing*
  - ISO/DIS 13485 *Quality Systems – Medical Devices – Particular Requirements for the Application of ISO 9001* (dated April 1996)

Relationship with ISO 9001 & ISO 13485

- The QSR is based on the 1994 version of ISO 9001.
  - This version had about twenty quality elements
  - ISO 13485 had not been issued, it was a Draft International Standard
  - That version added additional information to ISO 9001, it was not a stand alone document
- ISO 9001 and ISO 13485 have undergone major changes, moving from elements to the process approach
- QSR has **not** been updated to the process approach

The QSR Preamble

- FDA published draft regulations before the final version
- When they published the final regulations, they offered comments to explain their thinking.
- The comments are in the preamble, and each comment has a number. We look at some of the comments to illuminate the regulation.
- The preamble and regulation were published in the Federal Register: October 7, 1996 (Volume 61, Number 195), Pages 52601-52662.

21 CFR §820.72
IM&TE

Control of IM&TE

Requirement 820.72(a)
Each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or **electronic inspection and test equipment**, is suitable for its intended purposes and is capable of producing **valid results**.

Discussion
This section applies to all IM&TE must be suitable for its intended purpose. The implicit requirement is that the manufacturer has established an intended purpose.

Preamble #137
FDA deleted the term "test software" … because FDA believes that "test software" is now covered under "electronic inspection and test equipment" in Sec. 820.72(a).

[C]omments stated that [IM&TE] may be "suitable for its intended purpose" and still not always "produce valid results." FDA believes that the term "valid results" is commonly understood and notes that it has been in the original CGMP regulation under Sec. 820.61 for 18 years. The requirement is for the equipment to work properly, thereby providing "valid results."

21 CFR §820.72 IM&TE

Control of IM&TE

Requirement 820.72(a)
Each manufacturer shall ESTABLISH and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained. The procedures shall include provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained.

Preamble #137
FDA revised the requirement … to make clear that the procedures must also ensure that the equipment is maintained and … that the procedure include provisions for handling, preservation, and storage of equipment …

ESTABLISH means define, document (in writing or electronically), and implement.

21 CFR §820.72
IM&TE

Control of IM&TE

Requirement 820.72(a)
These activities shall be documented.

Discussion
Documenting the activities means generating records that demonstrate the conformity. The activities include:
- calibration
- inspection
- checking
- maintenance
- handing
- preservation
- storage

Think of these activities as ensuring the IM&TE produces acceptable results, *i.e.,* do not introduce latent problems.

21 CFR §820.72
IM&TE

Calibration

Requirement 820.72(b)
Calibration procedures shall include specific directions and limits for accuracy and precision.

Discussion
This sentence defines the required content for calibration procedures. This includes:
- specific directions to perform the calibration
- limits for accuracy
- limits for precision

QSR does not define accuracy and precision.

We will define these terms later in the presentation.

21 CFR §820.72
IM&TE

Calibration

Requirement 820.72(b)
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.

Preamble #138
FDA has also added to this section 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.

Discussion
“When accuracy and precision limits are not met” means that the item of IM&TE has not met the requirements, *i.e.,* there is a possibility that the readings from the equipment is in error.
In the worst case, there is a possibility that nonconforming material was accepted as conforming!
The FDA expects the manufacturer to resolve this problem using CAPA.

21 CFR §820.72
IM&TE

Calibration Standards

Requirement 820.72(b)(1)
Calibration standards used for inspection, measuring, and test equipment shall be traceable to national or international standards.

Preamble #139
Several comments stated that [the regulations] should allow for the use of international standards.
FDA agrees and has rewritten the section … to allow the use of international standards. The standards used must be generally accepted by qualified experts as the prevailing standards.

Discussion
The original version expected traceability to the National Institute of Technology (NIST) standards, *i.e.,* traceability to US standards. Since many devices are manufactured outside the US, this means traceability to the local national standard.

QSR does not define traceability.

21 CFR §820.72
IM&TE

Calibration Standards

Requirement 820.72(b)(1)
If national or international standards are not practical or available, the manufacturer shall use an independent reproducible standard. If no applicable standard exists, the manufacturer shall establish and maintain an in-house standard.

Discussion
Conceivably, the national or international standards may not include an applicable standard. This is not usually a problem involving mass, length, etc.

One area that may have standards is the use of biological material for *in-vitro* diagnostic devices. Biological activity is important, but national or international standards have not always been developed. There may be standard reference material outside the standards organizations.

In the “worst” case a company may need to develop a standard for their own use, an in-house standard.

21 CFR §820.72
IM&TE

Calibration Records

Requirement 820.72(b)(2)
The equipment identification, calibration dates, the individual performing each calibration, and the next calibration date shall be documented.

Preamble #140
FDA did add “equipment identification” to the list of items that had to be documented in response to a comment that requested clarification in this regard, so that equipment is clearly identified in the calibration records even if the records are not displayed on or near the particular piece of equipment.

Discussion
Based on the requirement, the calibration requirements have four basic elements:
- equipment identification
- the date of calibration
- the name of the person who did the calibration
- and the next calibration date

While not required as part of the documentation, the manufacturer should document the calibration procedure and revision, as well as the state of the equipment when received for calibration.

21 CFR §820.72
IM&TE

Calibration Records

Requirement 820.72(b)(2)
These records shall be displayed on or near each piece of equipment or shall be readily available to the personnel using such equipment and to the individuals responsible for calibrating the equipment.

Preamble #140
FDA did add “equipment identification” to the list of items that had to be documented in response to a comment that requested clarification in this regard, so that equipment is clearly identified in the calibration records even if the records are not displayed on or near the particular piece of equipment.

Discussion
The calibration records don’t need to be on the equipment, but they must be readily available. The traditional calibration sticker is not the only approach.

If the manufacturer doesn’t use the traditional calibration sticker, the equipment’s unique identity should be easy to determine.

Warning Letters

This section includes excerpts of FDA Warning Letters related to Calibration

Warning Letter

Care Rehab and Orthopedic Products, Inc.
April 22, 2008

- Failure to establish and maintain procedures to assure that equipment is routinely calibrated, inspected, checked, and maintained as required by 21 CFR 820.72(a).
- For example, the impedance meter has not been calibrated since 12/27/01.
- We have reviewed your response and have concluded that it is inadequate because, although you have promised correction you did not provide documentation of calibration of instruments … and related calibration SOPs.

Warning Letter

Mainline Technology, Inc.

January 23, 2009

- Failure to ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results, as required by 21 CFR 820.72(a).
- Your firm has no procedures to ensure that equipment is routinely calibrated, inspected, checked and maintained. For example, procedures for calibration, inspection, checks, and maintenance of your firm's digital scales, autoclave, and spectrophotometer used in the manufacture and testing of your strep A and chg. in vitro diagnostics were not available.

Warning Letter
Fuji System Corp
August 18, 2008

- Failure to ensure that calibration procedures include specific directions and limits for accuracy and precision, as required by 21 CFR 820.72(b).
- For example, the temperature gauges used for monitoring the package sealing equipment are not calibrated using limits for accuracy. Specifically, during calibration, temperatures exhibited on sealing apparatuses range from less that [redacted] to greater than [redacted] however, there is no indication as to which temperature ranges are acceptable to ensure monitoring gauges are operating with calibration standards.
- We have reviewed your response and have concluded that it is inadequate because it only states that validation of the heat sealer used on sterilized packaging is conducted [redacted] and provides a correction completion date of June 2008. Your firm should submit documentation as evidence of the implementation of the correction and the corrective action that demonstrates that the temperature gauges used for monitoring package sealing equipment were calibrated using limits for the accuracy.

Warning Letter

Lifestyle GP Company LLC
September 4, 2008

- Failure to ensure that the calibration of the inspection, measuring, and test equipment is traceable to national or international standards, as required by 21 CFR 820.72(b)(1).
- Specifically, your firm failed to insure that the test lens set manufactured by [redacted] was manufactured and calibrated to NIST standards.

Warning Letter

Philips Lifeline, Inc.

February 29, 2008

- Failure to document calibration dates, the individual performing each calibration, and the next calibration date for inspection, measurement and test equipment, as required by 21 C.F.R. § 820.72(b)(2).
- For example, there is no documentation of the calibration dates, the individuals performing the calibration, or the next calibration date for the multi-meter used in repair of the personal response system HW units for testing battery voltage, testing conductivity of circuits on printed circuit boards, and assessing shorted circuits.

Medical Device Quality Systems Manual

Chapter 7

Equipment and Calibration

Medical Device Quality Systems Manual

- Designed to help manufacturers understand and implement the QSR requirements.
- The manual has 18 Chapters and a lot of information.
- Published in December 1996, it has not kept up with technology
- Go to www.fda.gov and use the search engine to find “Medical Device Quality Systems Manual”

Calibration Requirements

Selection?

- GMP calibration requirements are:
  - routine calibration according to written procedures
  - documentation of the calibration of each piece of equipment requiring calibration
  - specification of accuracy and precision limits;
  - training of calibration personnel
  - use of standards traceable to the National Institute of Standards and Technology (NIST), other recognizable standards, or when necessary, in-house standards
  - provisions for remedial action to evaluate whether there was any adverse effect on the device's quality

Equipment Selection

- The manufacturer usually purchases IM&TE from external suppliers.
  - Purchasing the equipment invokes the purchasing requirements in 820.50.
- The manufacturer needs to specify the requirements.
  - For IM&TE the requirements should include:
    - Suitability for its intended use
    - Accuracy limits
    - Precision limits

Procedures

- Procedures should enable qualified people to properly perform the calibration
- An equipment calibration procedure includes:
  - purpose and scope
  - frequency of calibration
  - equipment and standards required
  - limits for accuracy and precision
  - preliminary examinations and operations
  - calibration process description
  - remedial action for product
  - documentation requirements

Metrology Management

- Management needs to understand the scope, significance, and complexity of the program
- Metrology management includes the selection and training of calibration personnel
- People involved in metrology should have some of these characteristics:
  - technical education and experience in the area of job assignment
  - basic knowledge of metrology and calibration concepts
  - an understanding of basic principles of measurement disciplines

Calibration Records

- The records must include:
  - The equipment identification
  - The calibration dates
  - The name of the person performing the calibration
  - The next calibration date
- The records often take two forms:
  - The equipment's calibration sticker
  - The calibration card

Calibration Stickers

CALIBRATION DATE _____

BY _____

DUE _____

This version shows the date of calibration, who performed it, and when the next calibration is due.

CAL ID No.

_____

This version only shows the ID number and represents the minimum information. The number should refer to readily available information.

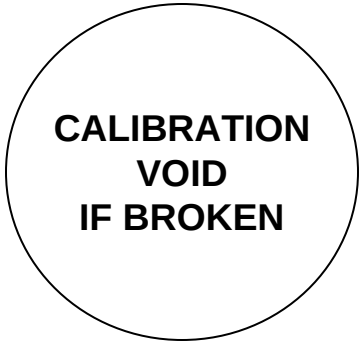
CALIBRATION
VOID
DO NOT USE

This version is for equipment that is not calibrated or otherwise unsuitable for use. The equipment is usually placed in a quarantine area as well.

Calibration Stickers

NOT A CALIBRATED INSTRUMENT

This version is used for IM&TE that isn't used for conformance. For example, the maintenance department may have a volte meter to determine if a circuit has power.



This version seals equipment and may cover recessed adjustments or seal an instrument case.

Calibration Card

- The book has an example of a calibration card that records specific information for each piece of IM&TE.

Here is an example of the card's header

CALIBRATION CARD

TYPE _____	MANUFACTURER _____
MODEL _____	SERIAL NO. _____
DATE OF PURCHASE _____	ASSIGNED _____
LOCATION _____	CAL. CYCLE _____

Calibration Card

- The card has a table to enter information
  - Date of last calibration
  - Reason of calibration (Normal, Broken, Rough use, *etc*.)
  - Date of next calibration
  - Calibration Information (accuracy, precision, defects, lubrication, cleaning, *etc*.)
- It also contains a place to record the identify of the person or company who normally calibrates the equipment.

Calibration Cycle Card

- The book recommends a tickler file to help with calibration recall
  - Use calibration cycle card with the equipment's identity.
  - Create a file with a folder for each month.
  - Put the card in the appropriate month's folder and then move it when the calibration is complete.
  - For example, an item on a 6-month recall cycle, calibrated in May, would have it's card moved to November.

Automation

- It is easy to envision a spreadsheet or database that handles the roles of the calibration card and the calibration cycle card.
- Consider two things if you implement the an automated system.
  - You will need to validate it for its intended use as required by 820.70(i)
  - You will need to determine if you are using electronic records as described in 21 CFR Part 11 and the associated guidance document

Traceability

- In the US, traceability is the National Institute of Standards and Technology (NIST)
  - Traceability requires the establishment of an unbroken chain of comparisons to stated references.
  - This means that the IM&TE in a company is part of a chain that goes back to NIST.

Traceability

- For standards or instruments, they are physically moved to NIST.
  - If you contract the calibration service the supplier will have a set of standards
- NIST offers Standard Reference Materials (SRM). These are often used in chemical, biological, medical, and environmental fields.
  - IVD manufacturers often need to know the strength or potency of biological materials

Traceability

- In rare cases, there is no external standard available.
- The manufacturer should develop an in-house standard, maintain it, and safeguard it.
  - FDA recommends the maintenance of two in-house standards, one for use and one for back-up
- In-house standards must be described in:
  - the Device Master Record (DMR) 820.181 or
  - the Quality System Record (QSR) 820.186

Audit of the Calibration Program

- The Calibration Program should be included in the Audit Program (820.22)
- The audit should check:
  - Maintenance of an adequate calibration schedule
  - maintaining records of calibration
  - written calibration procedures
  - records of calibration
  - trained calibration personnel
  - standards traceable to NIST or other independent reproducible standards.
- The same points apply to internal (1st party) and supplier (2nd party) audits
- For internal audits ensure:
- The calibration supplier was selected and is monitored following 820.50
- receiving includes certification that the equipment was calibrated under controlled conditions using traceable standards

Calibration and ISO 13485 & ISO 9001

ISO 13485 & ISO 9001

- The requirements are in Clause 7.6 Control of monitoring and measuring devices
- Both standards have the same basic requirements.
- ISO 13485 adds a requirement for documented procedures
  - Where ISO 13485 differs from ISO 9001, the changes are in blue italics. We follow the same convention.

Terminology

- Quality management has many terms that have specific meaning.
- Be sure you have the dictionaries that define these terms.
- ISO 9000:2005 *Quality management systems – Fundamentals and vocabulary*
  - When you encounter a technical term, look it up here first.
- ISO/TC 176/SC 2/N 526R2 *Guidance on the Terminology used in ISO 9001 and ISO 9004*
  - Contains the terms not in ISO 9000:2005

Clause 7.6

Monitoring & Measuring

The organization shall determine the monitoring and measuring to be undertaken … to provide evidence of conformity of product to determined requirements (7.2.1).

Discussion

Clause 7.2.1 requires that you determine the requirements, stated and unstated, for the product. This sentence says you must determine what you will monitor and measure.

Monitor means observe and check over a period of time; maintain regular close observation over.

Measure means ascertain the size, amount, or degree of (something) by comparison with a standard unit or with an object of known size

Clause 7.6

Monitoring & Measuring

The organization shall determine the … monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (7.2.1).

Discussion

Clause 7.2.1 ask that you to determine the requirements, stated and unstated, for the product. This sentence says you must determine the monitoring and measuring devices you will use for the planned monitoring and measuring.

Monitor means observe and check over a period of time; maintain regular close observation over.

Measure means ascertain the size, amount, or degree of (something) by comparison with a standard unit or with an object of known size

Clause 7.6

Documented Procedures

The organization shall establish documented procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Discussion

The previous two slides established the monitoring and measuring requirements and determined the equipment.

ISO 13485 requires documented procedures to ensure:

- monitoring and measuring can be carried out
- monitoring and measuring is carried out

The activities must be consistent with the requirements.

Clause 7.6

Calibrated or Verified

Measuring equipment shall be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards;

Discussion

You must check measuring equipment to make sure it “tells the truth”.

Either check it before each use or at specified intervals.

Use measurement standards as part of the check.

The measurement standards must be traceable to national (NIST in the US) or international standards.

Calibration means a set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards [VIM]

Clause 7.6

Calibrated or Verified

Where no such [international or national measurement] standards exist, the basis used for calibration or verification shall be recorded

Discussion

In some cases a national or international standard may not exist. This is common in biological material, such might be used in an IVD.

You need to trace define the material for the standard and document the detailed information.

Clause 7.6

Adjustments

Measuring equipment shall be adjusted or re-adjusted as necessary

Discussion
Equipment often has the capability for adjustment. This requirement ensures that you make the necessary adjustments to keep the equipment operating correctly.

Clause 7.6

Adjustments

Measuring equipment shall be identified to enable the calibration status to be determined

Discussion

The operator must be able to readily determine the calibration status. The traditional method is a sticker showing the next calibration due date.

Some equipment is verified every day, so the result is recorded in a log, not by changing the sticker. In this case, the equipment should have an identification number so somebody can check the log.

Equipment may be out of calibration or out of service, so it needs to be marked.

Clause 7.6

Adjustments

Measuring equipment shall be safeguarded from adjustments that would invalidate the measurement result

Discussion

The intent is to ensure that somebody cannot inadvertently make an adjustment that impacts the measurement. Typically, operator adjustments are on the front panel and calibration adjustments are inside.

The standard approach is have a seal that must be broken to get at the calibration adjustments. They are often adhesive paper circles placed so they must be broken if the equipment is opened.

Adjustment means the operation of bringing a measuring instrument into a state of performance suitable for its use [VIM]

Clause 7.6

Protection

Measuring equipment shall be protected from damage and deterioration during handling, maintenance, and storage

Discussion

Be sure the equipment isn't damaged by use, handling, maintenance, or storage.

For example, if you drop a piece of equipment and create latent damage, you won't be able to detect it by looking. You should have it recalibrated.

Similarly, equipment that could be damage by temperature extremes or excessive moisture should be stored (especially long term storage) inside a heated facility.

Don't store sensitive electronic test equipment in an unheated trailer in the parking lot for 12 months!

Clause 7.6

Out of calibration equipment

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 on the equipment and any product affected.

Discussion

When equipment is calibrated, determine its state before making adjustments. If it does not satisfy the requirements, it calls into question the measurements made with the equipment.

You need to assess the validity of the measurements made. Basically, this means answering two questions:

- Did we classify nonconforming product as conforming?
- Did we classify conforming product as nonconforming?

Knowing the answer you can determine the appropriate action on the product.

Clause 7.6

Software

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

Discussion

Software used in monitoring and measuring needs to be confirmed. Think of this as verification and validation.

The confirmation happens before the software is used initially and whenever it is necessary to reconfirm.

Two things could trigger reconfirmation

- The same software has new intended application, e.g., a new model of an existing product
- Revised software used in the current intended application, e.g., a new algorithm, code optimization, *etc*.

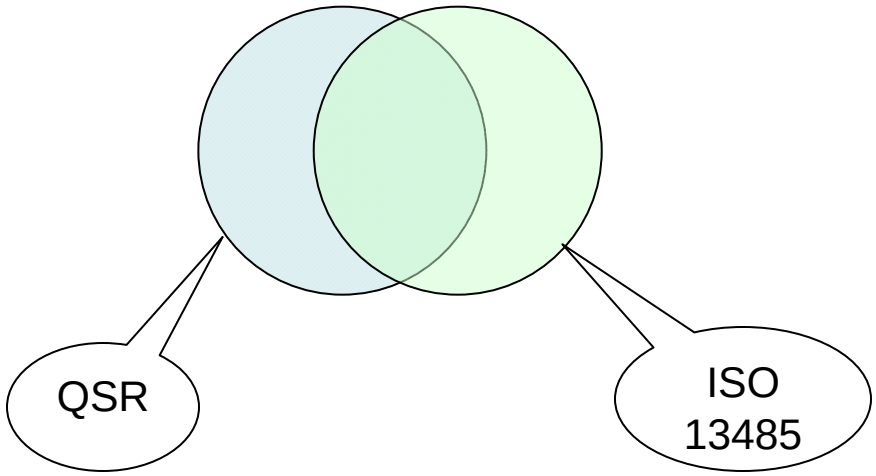
In addition, a nonconformity may point to the need to reconfirm software.

Confirm means to meet specified requirements

Comparing the Systems

QSR & ISO 13485 Comparison

- The two system are very similar
- The requirements are not contradictory, but additive.
  - Each system has requirements not in the other



Some Examples of Differences

Element	QSR	ISO 13485
Accuracy & precision	Calibration procedures specify limits for accuracy and precisions	Equipment must be suitable
Records	Must show the equipment identification, calibration dates, the individual performing each calibration, and the next calibration date	Equipment must be identified
Define measuring points	Implicit in QSR	Monitoring and measuring points must be identified and linked to product characteristics
Safeguard against adjustments	No specific requirement	Measuring equipment shall be safeguarded from adjustments that would invalidate the measurement result
Software	Covered in 820.70(i)	Must be confirmed

Summary & Conclusions

Summary

- Accuracy and precision define the requirements for a measurement and its associated equipment
- Equipment should be traceable to national standards
- Both FDA's QSR and ISO 13485 define the requirements for a medical device manufacturer's calibration program.
- The FDA provides guidance and good practices in the Quality Systems Manual

Conclusions

- Medical device manufacturers often operate in two systems: QSR & ISO 13485
- These systems are complimentary, not contradictory!
- An effective calibration system requires attention to detail and good record keeping.

QUESTIONS