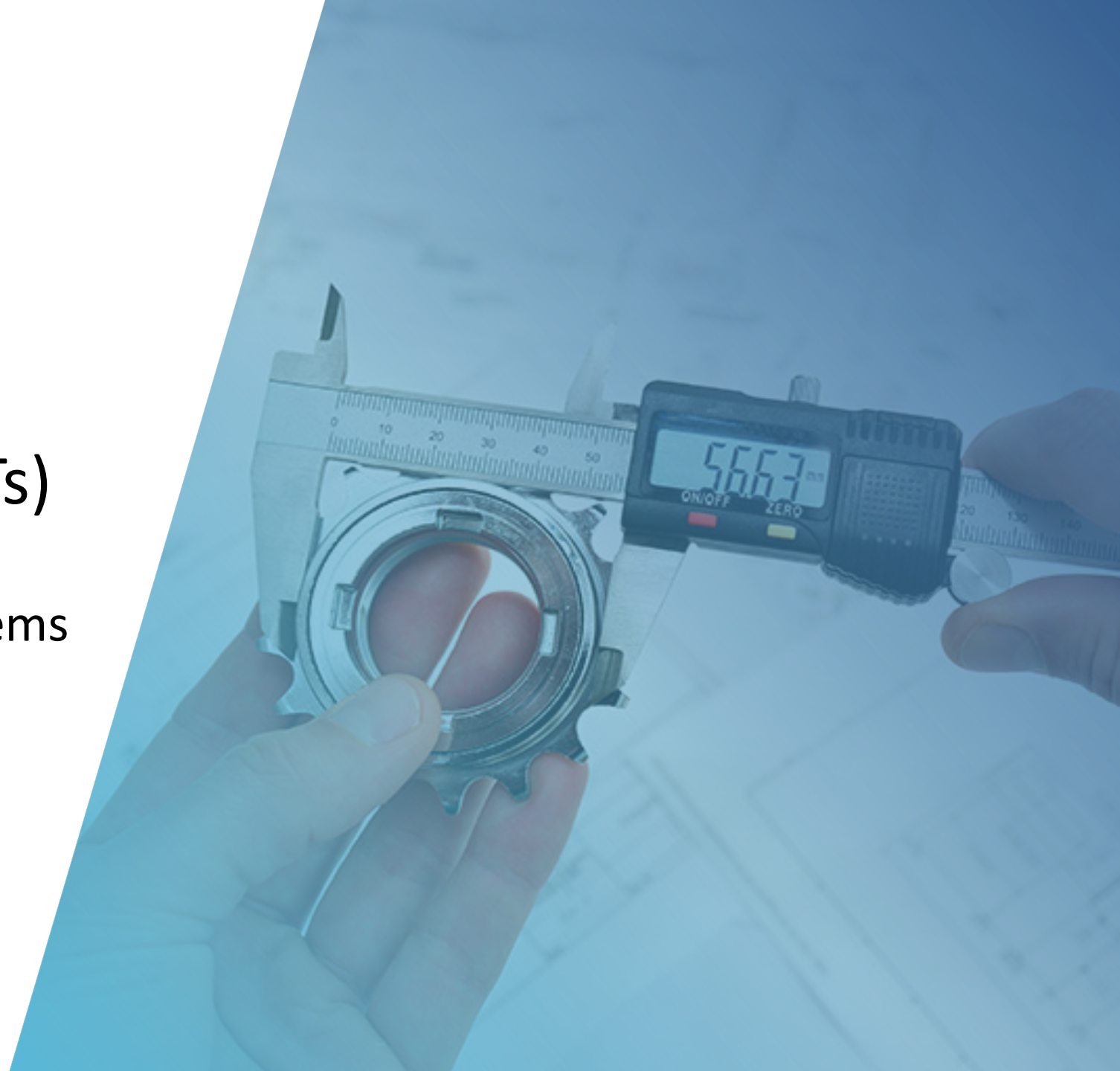
WEBINAR

Minimizing Calibration Out of Tolerances (OOTs)

Benchmarks, Best Practices, Systems

Presented by Curtis Keller and John Connelly



Welcome

- 45-minute webinar (including Q&A)
- Use the chat box to submit your questions and comments
- We'll address your questions at the end
- Webinar recording and slide deck will be emailed to all attendees

Moderator

John Connelly

Chief Commercial Officer, SIMCO

john.connelly@simco.com

- 39 years of experience in developing and servicing high tech products
- 12 years with SIMCO, including roles as VP of Services and GM of Software
- Previously with AT&T Bell Labs and numerous Silicon Valley start-ups

Guest Speaker

Curtis Keller

SIMCO Technical Director

curtis.keller@simco.com

- 37 years of calibration and quality experience in biomedical, aerospace, defense
- Joined SIMCO in 2007, based in Salt Lake City
- Previously with Intermountain Metrology Services, Stabro Labs, U.S. Marine Corps

Introduction

Agenda

- OOT Industry Benchmarks
- Best Practices for Minimizing OOTs
- Software Considerations

Why Important?

- Companies can easily spend **$5,000 per OOT** to assess its impact
- Impact of an OOT can range from negligible to life-impacting

Definitions

- An Out Of Tolerance (OOT) event occurs when an as-found calibration measurement falls outside of the required tolerance range
- Calibration with OOT measurement is deemed “Out Of Tolerance” or “Out Of Specification” or “Failed”

Leveraging 50+ years of serving lives-at-stake manufacturers

Serving 10 of 10 largest
U.S. Biomedical companies
(and 16 of top 20 global)

Serving 9 of 10 largest
U.S. Aero & Defense companies
(and 14 of top 20 global)

Benchmarks

Analyzed over **1 million** calibrations

performed by SIMCO and others

on behalf of our customers

(mostly lives-at-stake manufacturers)

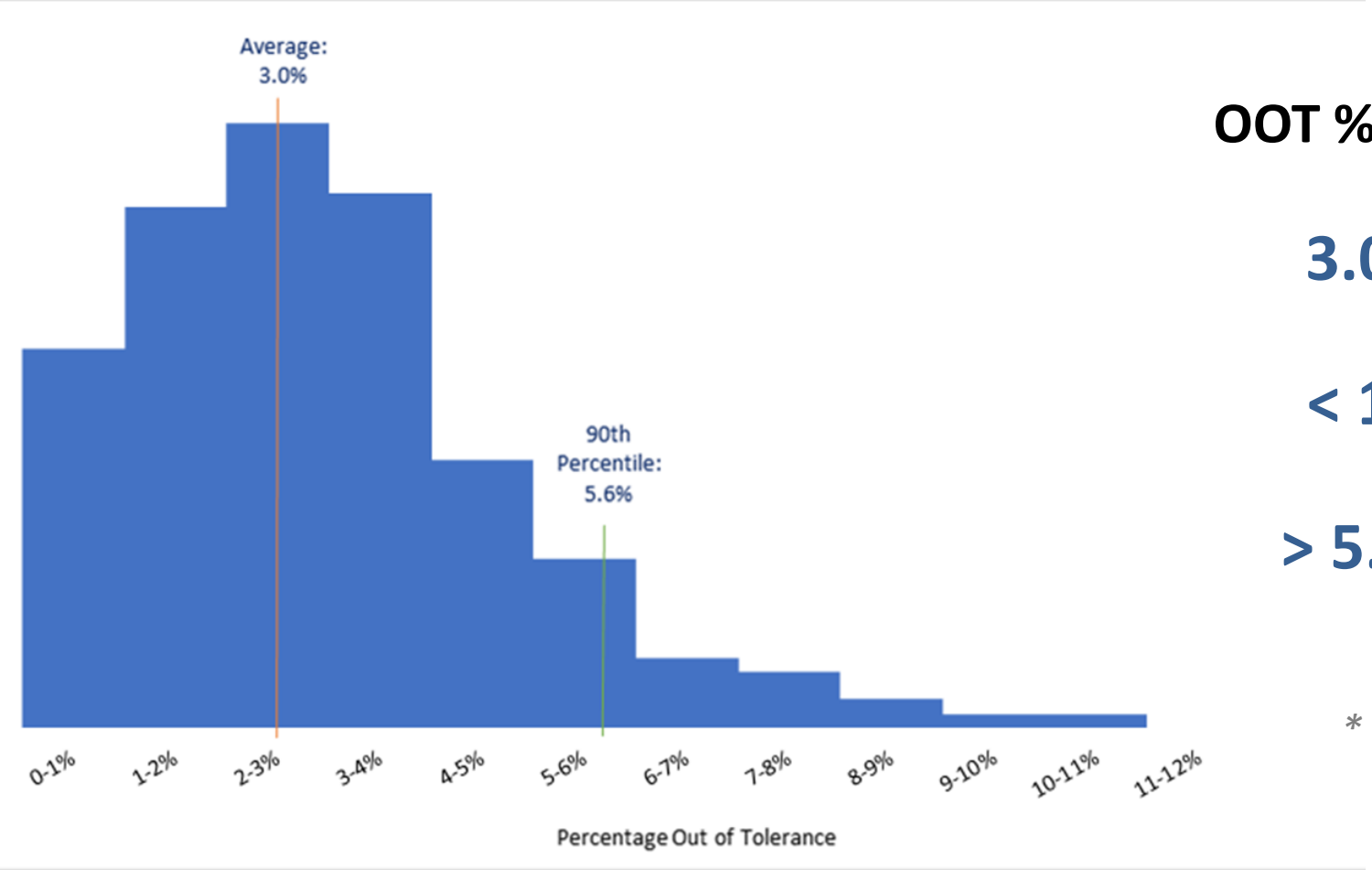
Benchmarks

3.0% OOT % across all calibrations

2.4% OOT % across all **electrical** calibrations

3.6% OOT % across all **mechanical** calibrations

Benchmarks

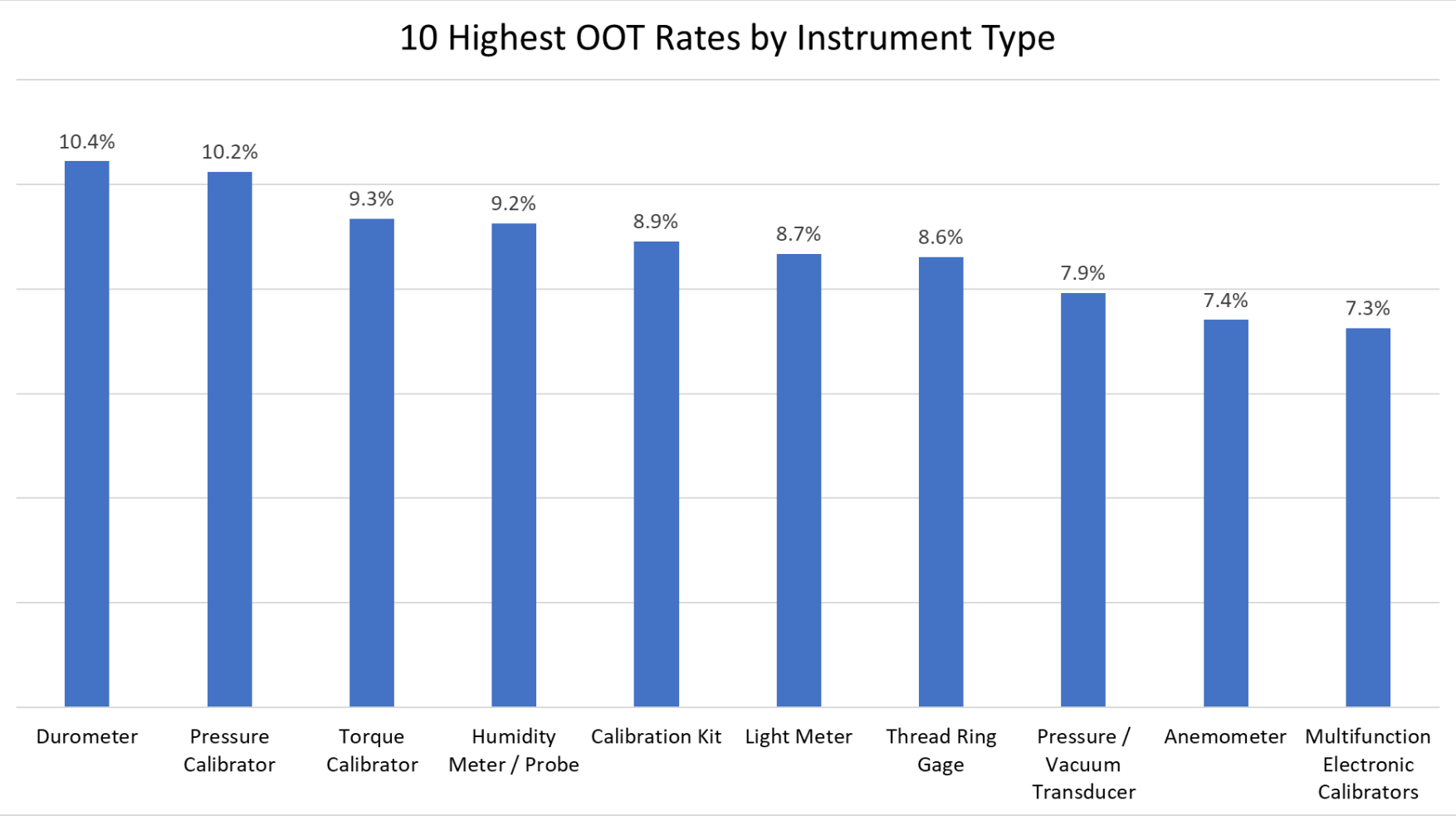


OOT % distribution of large* programs

3.0%	Average
< 1%	Best in Class
> 5.6%	Outside 90th percentile

** Large is defined as >300 cals/yr*

Benchmarks



Common Themes:

- Moving parts
- Environmentally sensitive
- Rough applications
- Inadequate protection

Is it possible to significantly reduce OOTs without compromising on quality?

Yes!

But there's a right approach and a wrong approach …


Wrong
Approach

10 Best Practices To Minimize OOTs

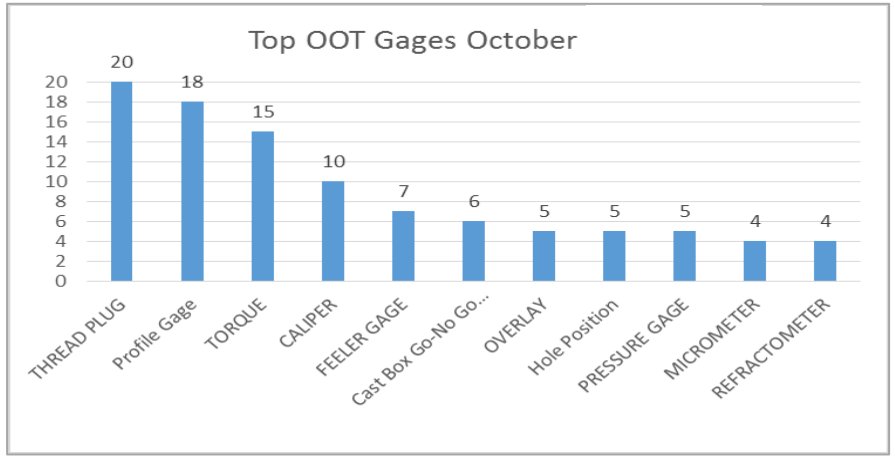
1. OOT Reporting & Analysis
2. Handling, Storage & Shipping
3. Preventive Maintenance
4. Intermediate Checks
5. Post-Calibration Adjustment
6. Decision Rules
7. Interval Adjustment
8. Limited Calibration – *Ranges/Functions*
9. Limited Calibration – *Tolerances*
10. Proactive Replacement

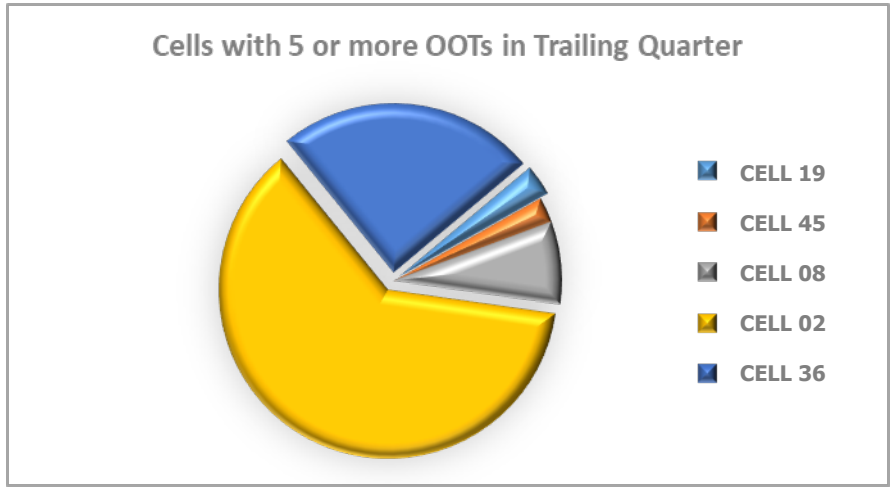
Apply as appropriate to fit your program's needs

Best Practice 1

OOT Reporting & Analysis

- Can’t manage without measurement and analysis
- Categorize and pareto OOTs by instrument type, manufacturer, model, user group, service provider
- Perform root cause analysis on largest OOT sources
- Define and execute appropriate actions
- Set performance goals and monitor regularly





Best Practice 2

Handling, Storage & Shipping

- Common sources of instrument failures:
  - Improper usage and handling
  - Improper storage
  - Improper packaging and shipping
- Requires frequent analysis, auditing, and education
- Consider Lean 5S (sort, set-in-order, shine, standardize, sustain) implementation to organize tools and eliminate waste

Best Practice 3

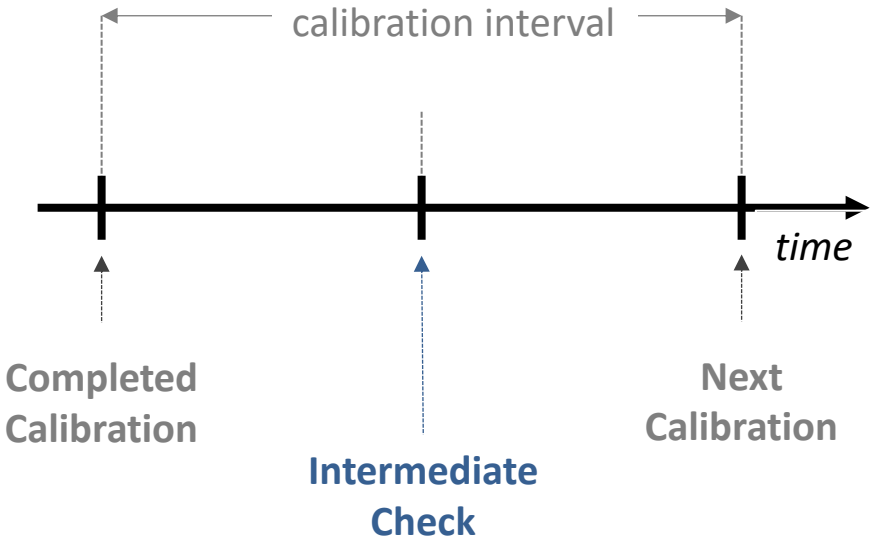
Preventive Maintenance

- Preventive Maintenance (PM) on instruments can **reduce OOTs** and **extend their life**
- Don’t ignore the broader system encompassing an instrument when planning PMs
- Integrated software can help to synchronize PM and calibration schedules, reducing downtime

Best Practice 4

Intermediate Checks

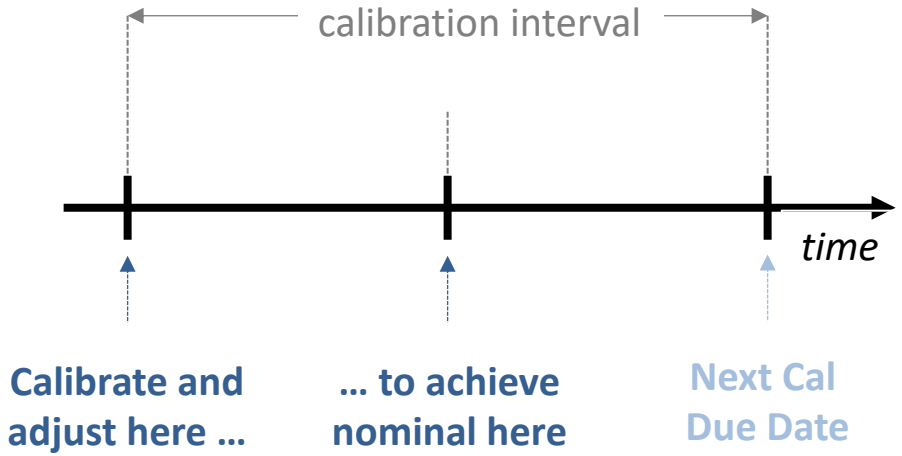
- Intermediate checks are mid-cycle partial verifications of critical measurements
- For problem instruments that are prone to fail and environments that are hard on instruments
- Not a substitute for full calibrations
- Integrated software can automate scheduling and synchronize with PM, where appropriate



Best Practice 5

Post-Calibration Adjustment

- For instruments with known, measurable drift over time (i.e., time-based instruments)
- Typically adjusted to achieve nominal at mid-cycle
- Don’t mistake random errors or uncertainty for drift – this can result in inappropriate adjustments that increase the OOT risk

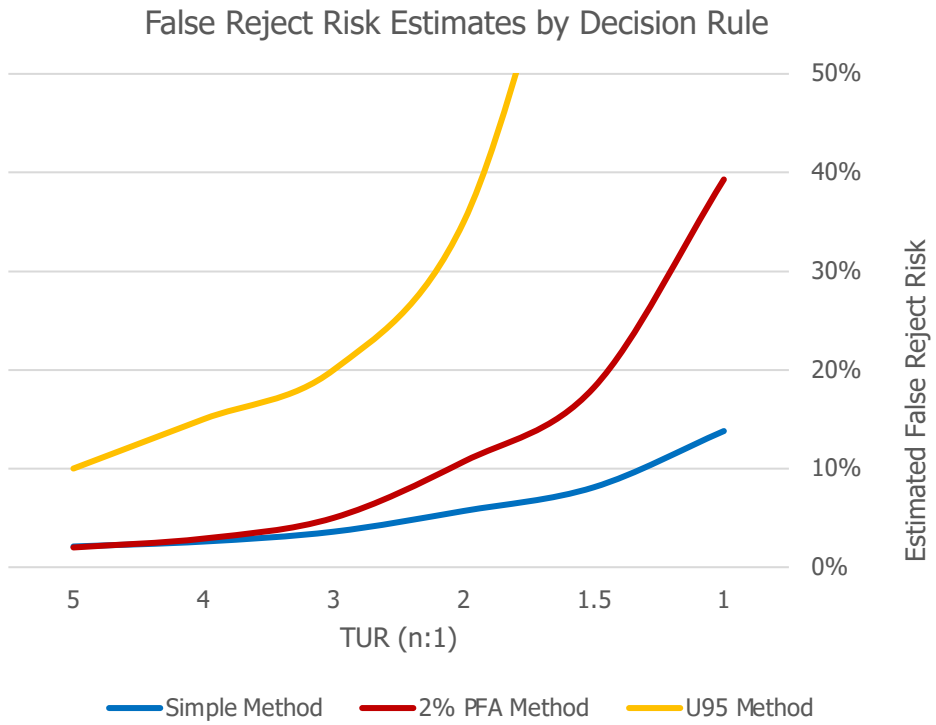


Best Practice 6

Decision Rules

- ISO/IEC 17025:2017 requires selecting a decision rule for each accredited calibration
- Multiple decision rule options, each accounting for measurement uncertainty in a unique way
- Overly stringent decision rules can result in unnecessary OOTs; select wisely

For more info, see ILAC G8:09/2019 Guidelines on Decision Rules and Statements of Conformity, or contact your SIMCO rep

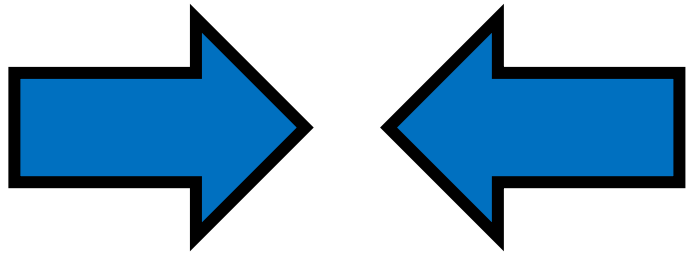


Best Practice 7

Interval Adjustment

- Default should be OEM recommendation, but …
- Can shrink intervals to reduce OOT number and impact

1. **Static (one-time) Adjustment**
   - Consider for models with high OOT rates
   - Trade off: increased calibration costs and downtime for decreased OOT count and impact
2. **Dynamic (continuous) Adjustment**
   - Interval adjusted after each calibration, based on history
   - Variety of algorithms; automate via software



For more info, see NCSLI RP-1 or contact your SIMCO rep

Best Practice 8

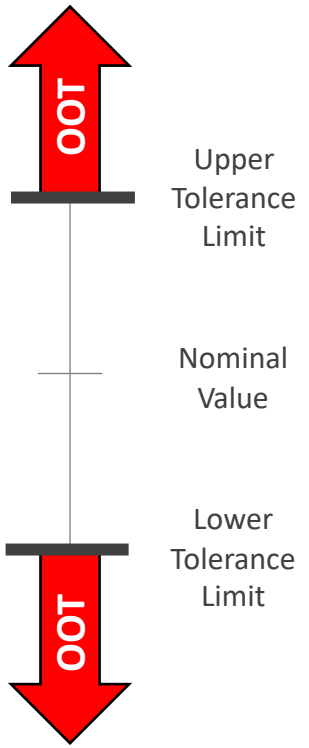
Limited Calibration – *Omitted Ranges / Functions*

- Default should be full instrument calibration, but …
- Can narrow scope, defining a limited calibration, if you're 100% confident that instrument usage will remain limited
- Example: multimeter used only as voltmeter
- Extends the life of an instrument with partial failure
- Document and ensure controls are in place to enforce limited utilization

Best Practice 9

Limited Calibration – *Modified Tolerances*

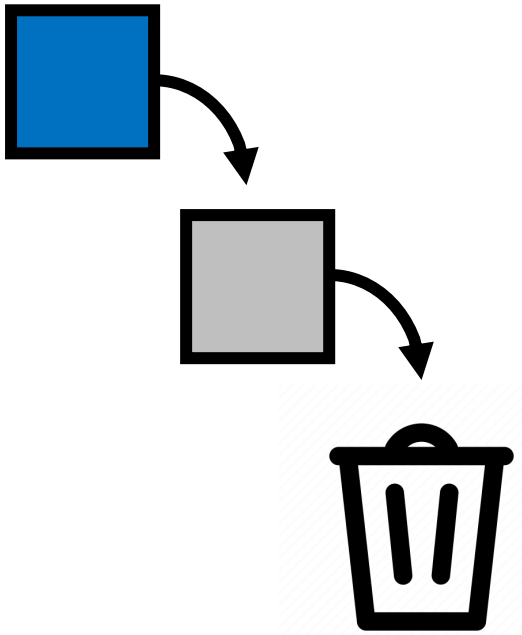
- Default should be OEM recommendation, but …
- Tolerances are frequently much better than needed
- *Can be* modified based on your unique requirements
- Document and obtain cross-team (Engineering, Quality Manufacturing) alignment on custom tolerances



Best Practice 10

Proactive Replacement

- For models with operating costs that increase significantly over time
- Plan proactive replacements to minimize waste
  (i.e., downtime, excessive calibration, repair, and PM costs)
- Define replacement trigger(s) – based on time, OOTs, product failures, annual spend, etc.
- Requires a CapEx commitment that should be justified by OpEx savings



Summary: Many Ways To Minimize OOTs

1. OOT Reporting & Analysis
2. Handling, Storage & Shipping
3. Preventive Maintenance
4. Intermediate Checks
5. Post-Calibration Adjustment
6. Decision Rules
7. Interval Adjustment
8. Limited Calibration – *Ranges/Functions*
9. Limited Calibration – *Tolerances*
10. Proactive Replacement

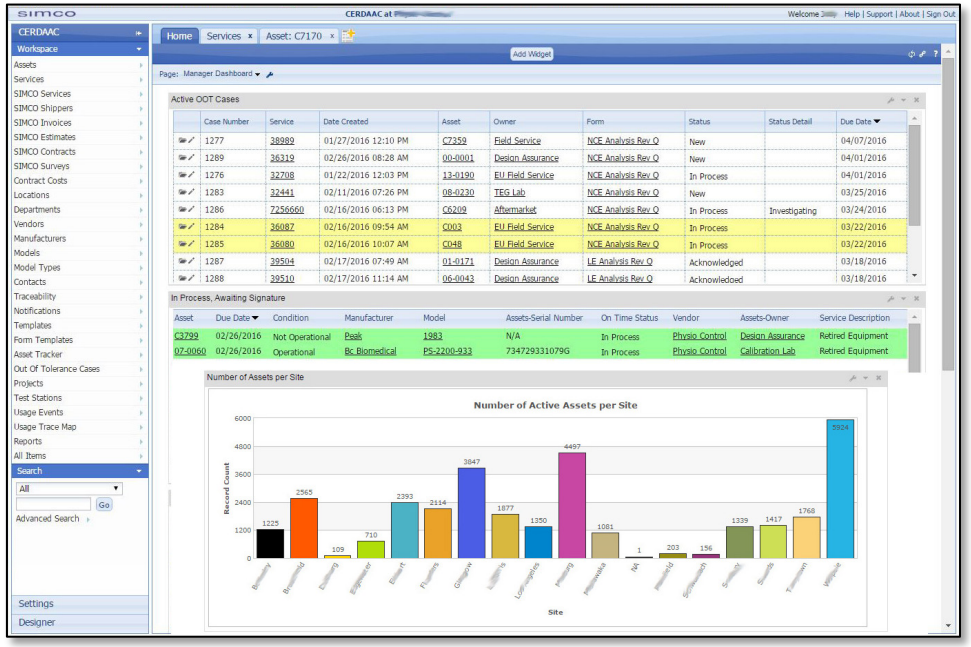
< 1% = best-in-class **3% = average** **> 5.6% = 90+ Percentile**

Start With The Right Software

- Choosing the right software will enable, enforce, and streamline these best practices
- Look for software that provides:
  - ✓ Automated OOT notifications
  - ✓ OOT reports and dashboards by instrument type, make, model, user group, and service provider
  - ✓ Integrated OOT case mgmt & reporting
  - ✓ Easy traceability to assist impact assessment
  - ✓ Coordinated scheduling of service events (calibrations, PMs, intermediate checks)
  - ✓ Controlled process for documenting tolerances, intervals, calibration scope, decision rules …

CERDAAC Will Help You Minimize OOTs

- CERDAAC® Manufacturing Support Cloud
- Digitally transforms manufacturing support – calibration, PM, repair, testing, validation …
- Secure, scalable, accessible anywhere
- Pre-validated for life science compliance
- Highly configurable to each user's role / needs
- Used by over 3,000 companies



For more info, or to see a demo, contact your SIMCO rep

Q&A

How can SIMCO help you minimize OOTs and optimize your program?

SIMCO

Quality Calibration & Software Services

www.simco.com

866-299-6029

Thank you for attending!

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