Measurement Quality Assurance
-or-
The Consequences of Bad Measurement Decisions

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Collaboration on Quality in the Space & Defense Industries
1. How does metrology affect me?
   • Measurement data affect your decisions

2. What do I need to look for?
   • Three essentials elements of “good” measurement data

3. What are the consequences of “bad” measurement-based decisions?

All measurement decisions have consequences...

The more critical the decision, the more critical the data. The more critical the data, the more critical the measurement.  

NASA Reference Publication 1342
Metrology is the “science of measurement and its application” (JCGM 200:2008).

- This includes all theoretical and practical aspects of measurement

**Measurements = Decisions**

Measurement data support decisions to...

- Establish research or investigative fact
- Establish scientific or legal fact
- Accept or reject a product
- Rework or complete a design
- Take corrective action or withhold it
- Continue or stop a process (including a space launch)

The objective of the design and control of measurement processes is to manage the risks taken in making decisions based on measurement data.
Defining Risk

Within the aviation, space, and defense industry, risk is generally expressed in terms of the **likelihood of occurrence** and the **severity of the consequences**.

AS9100D
Errors cause **Lowest level of Risk** to final product or service

International System of Units (SI)
Bureau International des Poids Mesures (BIPM)

Highest level of Accuracy
(scientific metrology)

Primary National Standard
National Metrology Institute

Calibrations
In-house or Commercial Calibration Labs

Measurements by End-Item users

Quality requirements must ensure the measurement will support the decision

A perfect instrument does not guarantee a “good” measurement...

Calibration requirements must ensure measuring and test equipment are acceptable and ready for use by end-users

Errors cause **Highest level of Risk** to final product or service

Secondary Standard
National Metrology Institute or Primary Standards Lab

Working Standards
Primary Standards Lab or other Labs

Lowest level of Accuracy
(end-item usage)
In metrology, risk occurs as:

**Measurement-related Risk:**
Risk of making incorrect measurement-based decisions
- Based on measurement process limitations or process mistakes

**Product or System Risk:**
The negative consequence of an incorrect measurement-based decision
- Quality or performance of end-products
- Increased cost of measurements without added value
**Probability of Incorrect Measurement Decisions**

**Measurement Uncertainty:** The doubt that exists about a measurement’s result
- Every measurement—even the most careful—always has a margin of doubt
- Uncertainty is the inherent limitation of a measurement process, due to instrumentation and process variation
- Measurement uncertainty does not include mistakes or process escapes

The **probability of an incorrect decision** is determined by:
- The amount of uncertainty in the measurement process
- Where the measurement result lies with respect to the tolerance limit (e.g., ±\(L\))
- Knowledge acquired from previous measurements of similar items (i.e., *a priori* distribution)
Measurement Risk and End-item Performance

Measurement uncertainty is inherent to the process or instruments and does not include mistakes, or process escapes

- Over specification of requirements costs money...
- However, under specification can be hazardous
Three essential components are required for measurements to adequately support decisions in a cost-effective manner:

1. **“Good requirements”** - Reasonable measurement tolerances that are based on system performance
2. **“Good equipment”** - Measuring and test equipment that is properly calibrated
3. **“Good measurements”** - End-user measurement processes/procedures that adequately support the end-product performance requirements

Like the legs of a three-legged stool, all three components are necessary.

If one leg is missing, the risk that the stool will fall over increases; likewise, the risk of an incorrect decision increases dramatically if one of these components is missing.
**Component 1 – “Good Requirements”**

*Reasonable* measurement **requirements** based on system performance.

Functional and Performance requirements:
- how the product is intended to perform
- For example, how high for a given set of conditions (“spacecraft will operate in an orbit between 400 and 650 kilometers”)

Design requirements:
- provides the realization for the Functional requirements
- the physical (e.g., size, weight, etc.) and operational (e.g., pressure, RPM, etc.) requirements of the product
- defines **acceptance criteria**

There must be a realistic **link** between the **functional** and **design requirements**, otherwise:
- the cost of verifying the measurement requirements will increase without adding value, or worse,
- verification of the design performance may not be adequate

*This component can have the largest impact on the subsequent cost of metrology and the achievable end item quality.*
ISO 9001:2015 and SAE AS9100D provide a standardized approach to “Good Requirements.”

ISO 9001:2015, Quality management systems — Requirements
8.1 Operational Planning and Control
The organization shall plan, implement, and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in clause 6, by:
   b. establishing criteria for:
      2. the acceptance of products and services;

8.3.1 Design and Development Planning
In determining the stages and controls for design and development, the organization shall consider:
   c. the required design and development verification activities

8.3.3 Design and Development Inputs
The organization shall consider:
   a. functional and performance requirements,

8.3.5 Design and Development Outputs
The organization shall ensure that design and development outputs:
   a. meet input requirements;
   c. include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
SAE AS9100D, Quality Management Systems — Requirements for Aviation, Space and Defense Organizations adds to ISO 9001 requirements

8.3.2 Design and Development Planning

Design and development planning shall consider the ability to provide, verify, test and maintain products and services (reference output of 8.1 a.)

8.3.4 Design and Development Controls

8.3.4.1 When tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed, and documented to ensure and prove the following:

a. test plans or specifications identify the test item being tested and the resources being used, define test objectives and conditions, parameters to be recorded and relevant acceptance criteria;

Monitoring and measuring devices used for testing shall be controlled as defined in clause 7.1.5.

At the completion of design and development, the organization shall ensure that reports, calculations, test results, etc., are able to demonstrate that the design meets the specification requirements for all identified operational conditions.
Case Study 1 – Component 1 - Passive Latch Torque
1. Measurement requirement for latch bolt torque: **8,000-8,500 inch-lbs**
   - Only lower torque limit linked to design requirements (maximum flight load)
2. Permissible bolt torque range per NASA standards: **8,000-10,200 inch-lbs**
3. Acceptable latch bolt torque for typical flight loads: **6,580-10,200 inch-lbs**

Application of existing NASA or Industry standards would have allowed the use of off-the-shelf torque systems that were readily available.
Managing and controlling the **accuracy of measuring equipment** is an essential component. Periodic **calibration** of measuring instruments provides the control and:

- Ensures instrument accuracy
- Links measurements to national or international units of measure
- Enables measurements made at different places and/or times to be meaningfully compared

**ISO 9001:2015, Quality management systems — Requirements**

7.1.5 Monitoring and Measuring Resources

7.1.5.1 General

The organization shall determine and provide the resources needed to **ensure valid and reliable results when** monitoring or **measuring is used to verify the conformity of products** and services to requirements.

7.1.5.2 Measurement Traceability

**When measurement traceability is a requirement,** or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

a. **calibrated or verified, or both, at specified intervals,** or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;

The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.
SAE AS9100D, *Quality Management Systems — Requirements for Aviation, Space and Defense Organizations* adds to ISO 9001 requirements

7.1.5 Monitoring and Measuring Resources

The organization shall establish, implement, and maintain a process for the **recall of monitoring and measuring equipment requiring calibration or verification**.

The organization **shall maintain a register** of the monitoring and measuring equipment. The register shall include the equipment type, unique identification, location, and **the calibration or verification method, frequency, and acceptance criteria**.

NOTE: Monitoring and measuring equipment can include, but are not limited to: test hardware, test software, automated test equipment (ATE), and plotters used to produce verification data. It also includes personally owned and customer supplied equipment used to provide evidence of product and service conformity.

Calibration or verification of monitoring and measuring equipment shall be carried out under suitable environmental conditions (see 7.1.4).
CoxHealth of Springfield, MO inadvertently overdosed 152 cancer patients, 76 of which received up to 70% higher than prescribed dosages.

The device, a BrainLAB stereotactic radiation system used to treat areas 1.1 centimeters or smaller, was initially incorrectly calibrated by the CoxHealth chief physicist in 2004.

The error went undetected for five years, until September 2009 when another CoxHealth physicist received training on the BrainLAB system.

Although the calibration error was corrected, as of February 2012, the CoxHealth BrainLAB program remains suspended while lawsuits are settled.
Component 3 - “Good Measurements”

Adequate **measurement processes/procedures** to **control errors** that could lead to **incorrect decisions** based on measurement data

- A properly calibrated instrument does not guarantee a “good” measurement result

**ISO 9001:2015, Quality management systems — Requirements**

8.6 Release of Products and Services

The organization shall implement planned arrangements, at appropriate stages, to **verify that the product and service requirements have been met**.

The organization shall retain documented information on the release of products and services. The documented information shall include:

a. **evidence of conformity with the acceptance criteria**.
SAE AS9100D, *Quality Management Systems — Requirements for Aviation, Space and Defense Organizations* adds to ISO 9001 requirements

8.6 Release of Products and Services
When required to demonstrate product qualification, the organization shall ensure that retained documented information *provides evidence that the products and services meet the defined requirements.*

7.3 Awareness
The organization shall ensure that persons doing work under the organization’s control are aware of:

f. *their contribution to product or service conformity;*
Case Study 3 - Component 3 - Hubble Space Telescope

• Hubble Space Telescope (HST) launched April 24, 1990

• On-orbit checkout revealed HST could not be properly focused

• Ensuing investigation indicated the primary mirror was not built to specifications

• A servicing mission to correct the error was flown in December 1993 at a cost of over $1 billion USD
Case Study 3 - Component 3 - Hubble Space Telescope

“The project manager must understand the accuracy of critical measurements.”

- Error was ten times specification
- The optical test used to manufacture mirror was set-up incorrectly
- The RvNC and INC clearly showed the error, yet both were discounted
- There was a mindset to discount any independent measurements less accurate than the RNC
- Discounting the INC and RvNC data was, in essence, “shopping for the answer they wanted”

**RNC:** Reflective Null Corrector. Designed and built by Perkin-Elmer, the manufacturer of the primary mirror.

**RvNC:** Refractive Null Corrector. Standard for producing primary telescopes.

**INC:** Inverse Null Corrector. Designed to simulate a perfect mirror as a check for the RNC.
Obtaining “Good” Measurement Data

When examining measurement-based failures, in many, if not most cases, multiple components are inadequate.

Good Requirements

Good Measurements

Good Equipment
Case Study 4 – Air Force B-2A Crash

The loss of the U.S. Air Force B-2 bomber in February 2008 is a dramatic example of measurement-based decisions leading to catastrophe.

Performance requirement: Altimeter ± 75 feet of field elevation.

Actual reading: + 136 feet of field elevation at take-off.

- The **proximate cause** was moisture in the Air Data System (ADS) which introduced large errors during a **field calibration** of several aircraft Port Transducer Units.

- The **measurement procedure** did not account, nor mitigate for moisture **Component 3**

- There was a lack of understanding how the ADS **requirements were linked** to operational aircraft flight safety **Component 1**

- Although the calibration procedure was followed, an incorrect measurement-based decision led to the loss of a $1.4 billion asset, fortunately without loss of life.
Measurements support decisions – accept, reject, rework, scrap, or even launch a space vehicle.

Essential Components:

1. **Design** specifications must be **linked** to **functional** requirements
   a) ISO 9001:2015 – 8.1, 8.3.1, 8.3.3, 8.3.5 and AS9100D – 8.3.2, 8.3.4, 8.3.4.1
   b) Over specification is expensive,
   c) Under specification can be hazardous

2. **Calibration** ensures the **accuracy** of measuring equipment
   a) ISO 9001:2015 and AS9100D - 7.1.5
   b) Links units of measurement to International standards (i.e., provides a pedigree)

3. Measurement **processes** must **control errors** that may lead to incorrect measurement-based decisions
   a) ISO 9001:2015 – 8.6 and AS9100D – 7.3, 8.6
   b) Proper selection and utilization of measuring equipment
   c) Control/mitigate other relevant sources of error in the measurement process
"To measure is to know."

"If you can not measure it, you can not improve it."

"I often say that when you can measure what you are speaking about, and express it in numbers, you know something about it..."

William Thomson (Lord Kelvin)

The more critical the decision, the more critical the data. The more critical the data, the more critical the measurement.

NASA Reference Publication 1342