

# AQS 110

## Introduction to Metrology

This material is based upon work supported  
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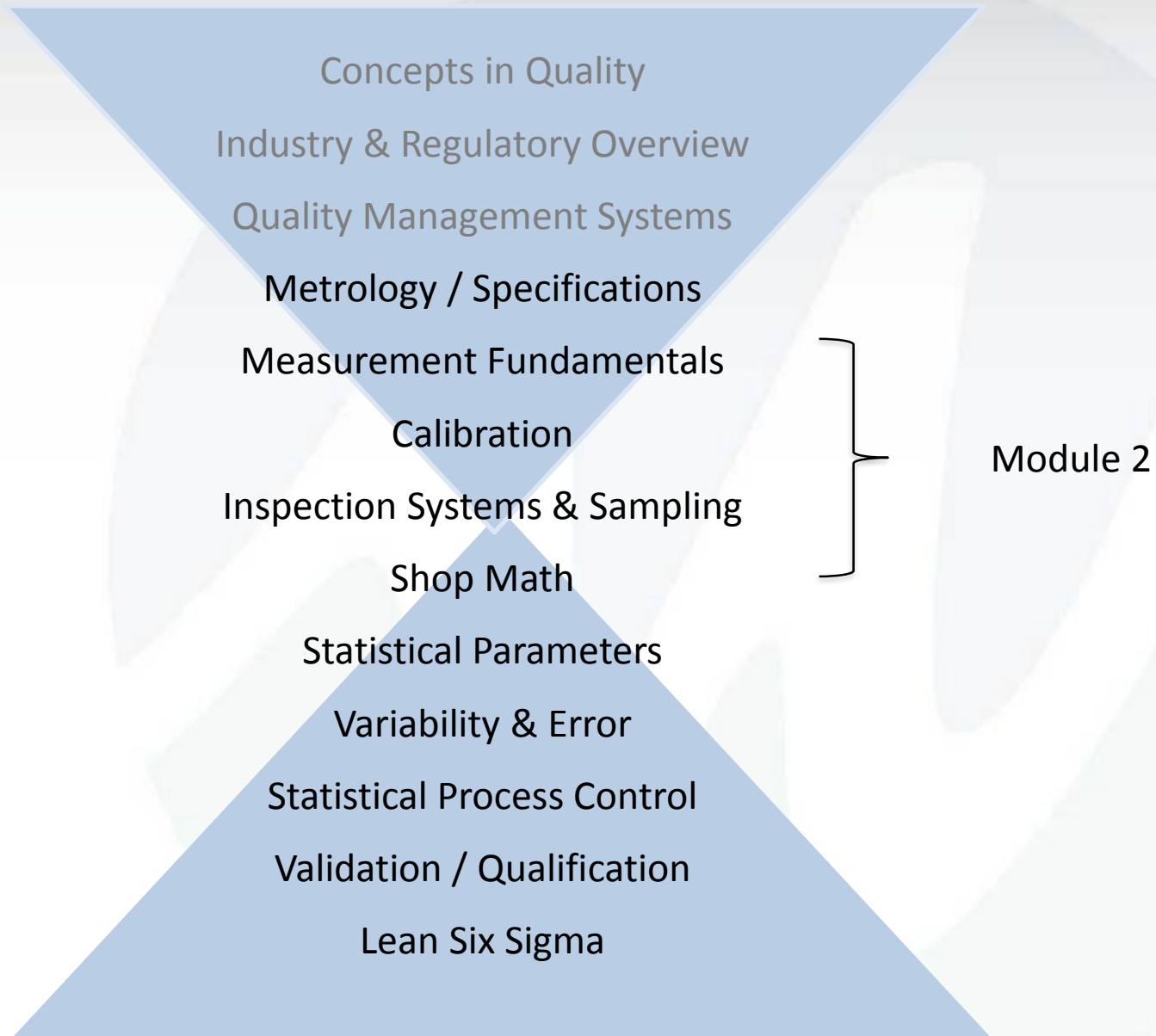
*Any opinions, findings, and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the National Science Foundation.*

# MODULE 2: METROLOGY (MEASUREMENT CONCEPTS)

- Specifications
- Measurement Fundamentals
- Calibration
- Inspection Systems & Sampling



# INTRODUCTION TO METROLOGY



# WHAT HAVE WE COVERED

- **Quality Management System**

- Say what you do
- Do what you Say
- Write it all Down

- **Quality Department**

- *Quality Assurance*

- plans, develops, and documents processes that optimize objectives
- Reviews and Evaluates
- Systems based (oversight)

- **Documentation**

- **Regulations**

# NEXT PHASE

- **Quality Management System**

- Say what you do
- Do what you Say
- Write it all Down
  
- Analyze the Results
- Act on the Difference

- **Quality Department**

- *Quality Assurance*

- plans, develops, and documents processes that optimize objectives
- Reviews and Evaluates
- Systems based (oversight)

- *Quality Control*

- evaluates products (services) and responds to non-conformities
- Inspection & Release
- Manufacturing Floor

# QUALITY CONTROL

*Quality is a product (or service) with the features and characteristics which determine desirability and can be controlled to meet certain basic requirements.*

- Inspection evaluates product quality by comparing measurement results with specifications.
  - Measurement of sample
  - Comparison against specification
  - Decision based on results
  - Corrective action, if necessary
- Metrology (measurement fundamentals)
- Inspection Processes (specifications, drawings, tools)
- Sampling

# WHY MEASURE

- Quality is a product (or service) with the features and characteristics which determine desirability and can be controlled to meet certain basic requirements.
  - Quality is determined by the Customer (end-user) based on their expectation and needs.
- Customers want expectations and needs met consistently

# WHY MEASURE

## – ISO 9001:2015

- Section 8.5 Production & Service Provision

- 8.5.1 Control of production and service provision

- The organization shall implement production and service provision under controlled conditions.*

- Controlled conditions shall include, as applicable: ...*

- b) the availability and use of suitable monitoring and measuring resources;*

- c) The implementation of monitoring and measurement activities at appropriate states to verify that criteria for control of processes or outputs, and acceptance criteria for products and services have been met; ...*



# WHY MEASURE

- 21CFR 820 Subpart G Production & Process Controls  
820.70 Production and process controls
  - a) General. Each manufacturer shall develop, conduct, control and monitor production processes to ensure that a device conforms to its specifications. ...
- 21CFR 820 Subpart H – Acceptance activities  
820.80 Receiving, in-process, and finished device acceptance.
  - a) General. Each manufacturer shall establish and maintain procedures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities. ...

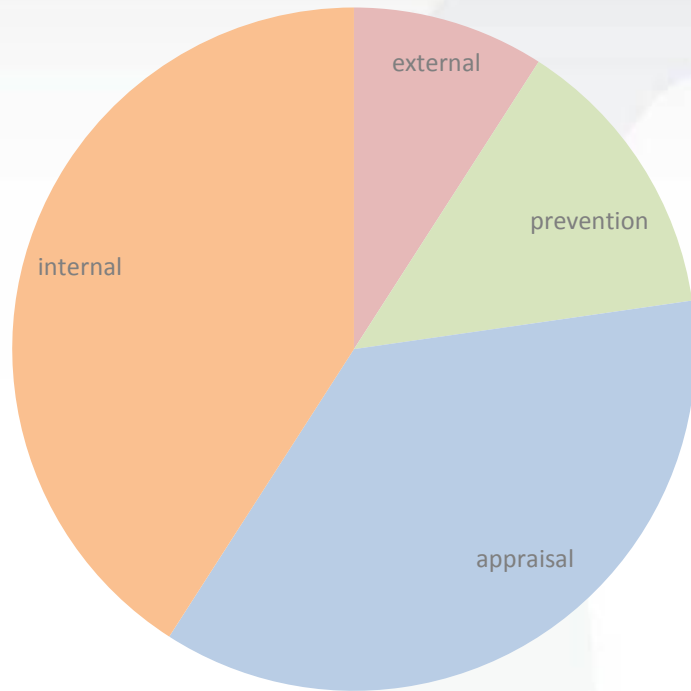
# WHY MEASURE

- Quality is a product (or service) with the features and characteristics which determine desirability and can be controlled to meet certain basic requirements.
- Customers want expectations and needs met consistently
- ISO9001:2015 / 21CFR820 requirements
- **Fit / Form / Function**
  - Fitness for use
  - Form is free of defect
  - Functions as intended
- **Manufacturing process defined**
  - Change and Variation

# PROCESS CHANGE / VARIATION

- Materials
  - New Vendor
  - Different Batch
- Method
  - Processing steps
  - Manual vs Automated
- Environment
  - Temperature / humidity
  - Vibration
  - Electromagnetic interference
- Machine
  - Wear
  - Different Models (Ages)
- Measurements
  - Equipment
  - On-line, Off-line
  - Manual vs. Automated
- Personnel
  - Training
  - Experience

# COST OF (PRODUCT) QUALITY



- Internal
  - Scrap, Rework
- Appraisal
  - Material Receipt Measurement
  - In-process/Final Inspection
- External
  - Returns, Warranty
- Prevention
  - Improvement, Planning

Quality is a value that **must be built** into the product.  
Quality **cannot be inspected** into the product.

# MEASUREMENT

- Measurement is a method for evaluating a property or characteristic of an object and describing it with a numerical or nominal value.
  - Dimensional (e.g. length, diameter, volume)
  - Functional (e.g. flow rate, tensile strength)
  - Chemical (e.g. material type, pH, etc.)
  - Service (e.g. time between calls, maintenance response, etc.)
  - Attribute (e.g. color, clarity, etc.)
  - etc.
- Measurements evaluate the fit/form/function of a product or service.

# METROLOGY

- Merriam-Webster dictionary

me·trol·o·gy noun \me-'tră-lə-jē\

- : the science of weights and measures or of measurement
- : a system of weights and measures

# METROLOGY

- Metrology – the science of measurement
- Broad field with three basic activities
  1. Definition of internationally accepted units of measurement
    - Seven (7) base units (dimensionally independent)

Quantity	Name	Symbol
Amount of a substance	mole	mol
Electric current	ampere	A
Length	meter	m
Luminous intensity	candela	cd
Mass	kilogram	kg
Temperature	kelvin	K
Time	second	s

# METROLOGY

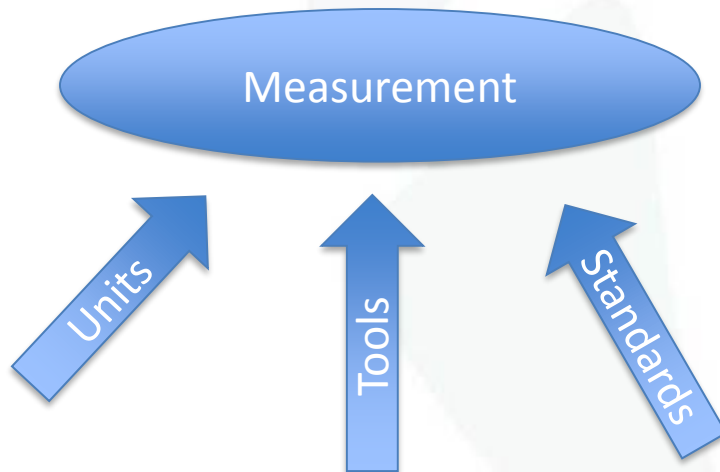
- Metrology – the science of measurement
- A broad field with three basic activities
  1. Definition of internationally accepted units of measurement
  2. Realization of these units of measurement in practice (i.e. Calipers, scales, thermometers, etc.)
  3. Application of chains of traceability linking measurements made in practice to reference standards
    - Calibration Practices
    - NIST traceability (National Institute Standards & Technology)



???

- **Metrology** – the science of measurement
  - Definition of internationally accepted units of measurement
  - Realization of these units of measurement in practice
  - Application of chains of traceability linking measurements made in practice to reference standards
- **Chemistry** is a branch of physical science that studies the composition, structure, properties and change of matter.
  - chiefly concerned with atoms and molecules and their interactions and transformations
  - For example, the properties of the chemical bonds between atoms to create chemical compounds ( $2\text{H}_2 + \text{O}_2 \rightarrow 2\text{H}_2\text{O}$ )
- **Biology** is a natural science concerned with the study of life and living organisms, including their structure, function, growth, evolution, distribution and taxonomy.

- **Metrology** – the science of measurement
  - Definition of internationally accepted **units** of measurement
  - Realization of these units of measurement in **practice (tools)**
  - Application of chains of traceability linking measurements made in practice to **reference standards**



- **Chemistry** is a branch of physical science that studies the composition, structure, properties and change of matter.
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  - For example, the properties of the chemical bonds between atoms to create chemical compounds ( $2\text{H}_2 + \text{O}_2 \rightarrow 2\text{H}_2\text{O}$ )
- **Biology** is a natural science concerned with the study of life and living organisms, including their structure, function, growth, evolution, distribution and taxonomy.

# METROLOGY

- Metrology – the science of measurement
  - Ensuring the suitability of measurement instruments, their calibration and quality control of measurements.
- Metrology is a broad field with three basic activities
  - Definition of internationally accepted units of measurement
  - Realization of these units of measurement in practice
  - Application of chains of traceability linking measurements made in practice to reference standards
- Three subfields that use the basic activities
  - Scientific/Fundamental - establishes units of measure

# METROLOGY

## Scientific (units of measure)

Quantity	Name	Symbol
Amount of a substance	mole	mol
Electric current	ampere	A
Length	meter	m
Luminous intensity	candela	cd
Mass	kilogram	kg
Temperature	kelvin	K
Time	second	s

# METROLOGY

- Three subfields that use the basic activities
  - Scientific/Fundamental - establishes units of measure
  - Legal – establishes statutory requirements
    - Ensures certification of measuring devices in one country is compatible with certification in another, facilitating trade in devices and products (i.e. taxi meters, alcohol content, speedometers, etc.)

# METROLOGY

```
graph TD; A[METROLOGY] --> B["Scientific<br/>(units of measure)"]; A --> C["Legal<br/>(harmonization for trade)"]
```

**Scientific**  
(units of measure)

**Legal**  
(harmonization for trade)

# METROLOGY

- Three subfields that use the basic activities
  - Scientific/Fundamental - establishes units of measure
  - Legal – establishes statutory requirements
  - Applied/Technical/Industrial - applies measurement science to manufacturing and other processes

# METROLOGY

```
graph TD; Metrology[METROLOGY] --> Scientific["Scientific<br/>(units of measure)"]; Metrology --> Legal["Legal<br/>(harmonization for trade)"]; Metrology --> Applied["Applied / Industrial<br/>(manufacturing/process measurements)"];
```

**Scientific**  
(units of measure)

**Legal**  
(harmonization for trade)

**Applied / Industrial**  
(manufacturing/process measurements)



# METROLOGY

```
graph TD; Metrology[METROLOGY] --- Scientific["Scientific<br/>(units of measure)"]; Metrology --- Legal["Legal<br/>(harmonization for trade)"]; Metrology --- Applied["Applied / Industrial<br/>(manufacturing / process measurements)"]; Applied --- QA["Used by Quality Assurance & Quality Control"]
```

Scientific  
(units of measure)

Legal  
(harmonization for trade)

Applied / Industrial  
(manufacturing / process measurements)

Used by Quality Assurance & Quality Control

# METROLOGY

- Applied/Industrial metrology applies measurement science to manufacturing and other processes
  - Ensuring the suitability of measurement instruments, their calibration and quality control of measurements.
  - Traceability of the calibration for the instruments necessary to ensure confidence in the measurements

Why is this important?

# METROLOGY

- Applied/Industrial metrology applies measurement science to manufacturing and other processes
  - Ensuring the suitability of measurement instruments, their calibration and quality control of measurements.
  - Traceability of the calibration for the instruments necessary to ensure confidence in the measurements

Pass/Fail (Ship the Product ?)

# METROLOGY

- ANSI/ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories
- ISO 10012:2003(E) Measurement Management Systems – Requirements for Measurement Processes and Measuring Equipment
- ISO “*International vocabulary of basic and general terms of metrology* (VIM 3<sup>rd</sup> Edition)

# METROLOGY

- ANSI/ISO/IEC 17025:2005 General Requirements for the Competence of **Testing and Calibration** Laboratories
  - implement a quality system aimed at improving ability to consistently produce valid results.
  - basis for accreditation from an accreditation body.
  - standard is about competence, accreditation is simply formal recognition of a demonstration of that competence
    - In many cases, suppliers and regulatory authorities will not accept test or calibration results from a lab that is not accredited.

Wikipedia.com

# METROLOGY

- ISO 10012:2003(E) Measurement Management Systems – **Requirements** for Measurement **Processes** and Measuring **Equipment**
  - “... provides guidance for the management of measurement process and metrological confirmation of measuring equipment used to support and demonstrate compliance with metrological requirements...”

Wikapeida.com

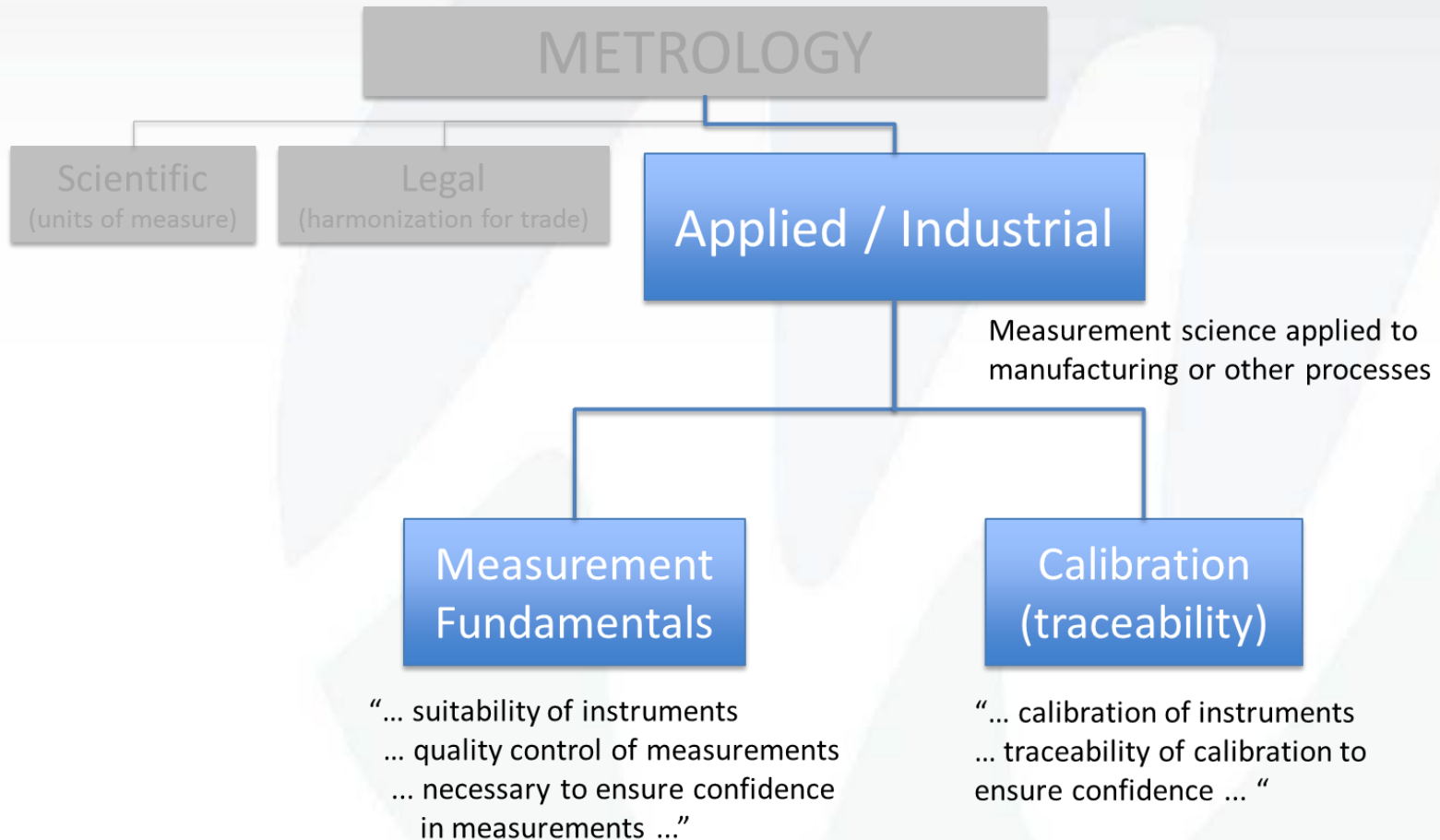
# METROLOGY

- Applied/Industrial metrology applies measurement science to manufacturing and other processes
  - Ensuring the suitability of measurement instruments, their calibration and quality control of measurements.
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Pass/Fail (Ship the Product ?)

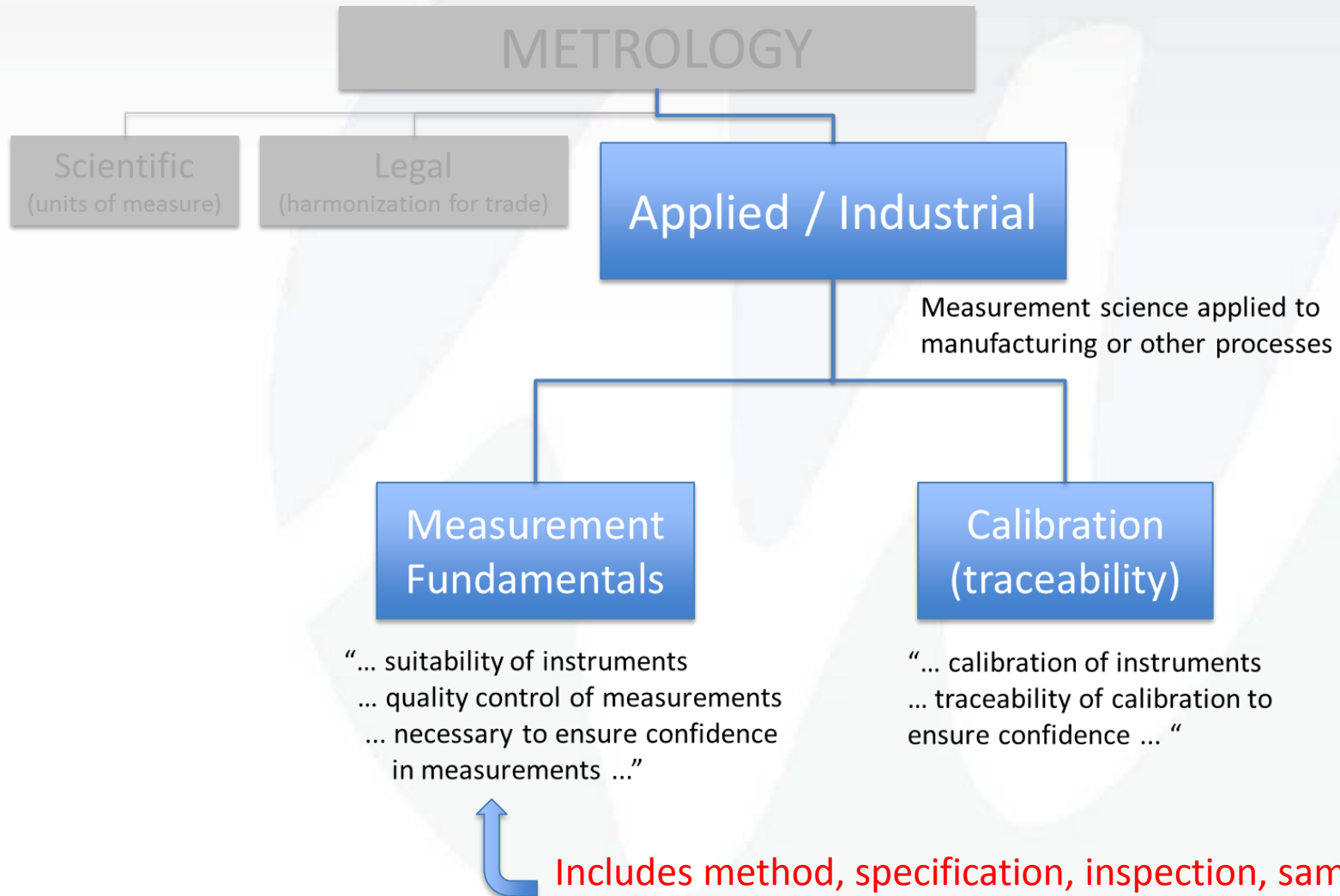
- Metrology Program
  - Measurement Fundamentals
  - Calibration (Traceability)

# METROLOGY

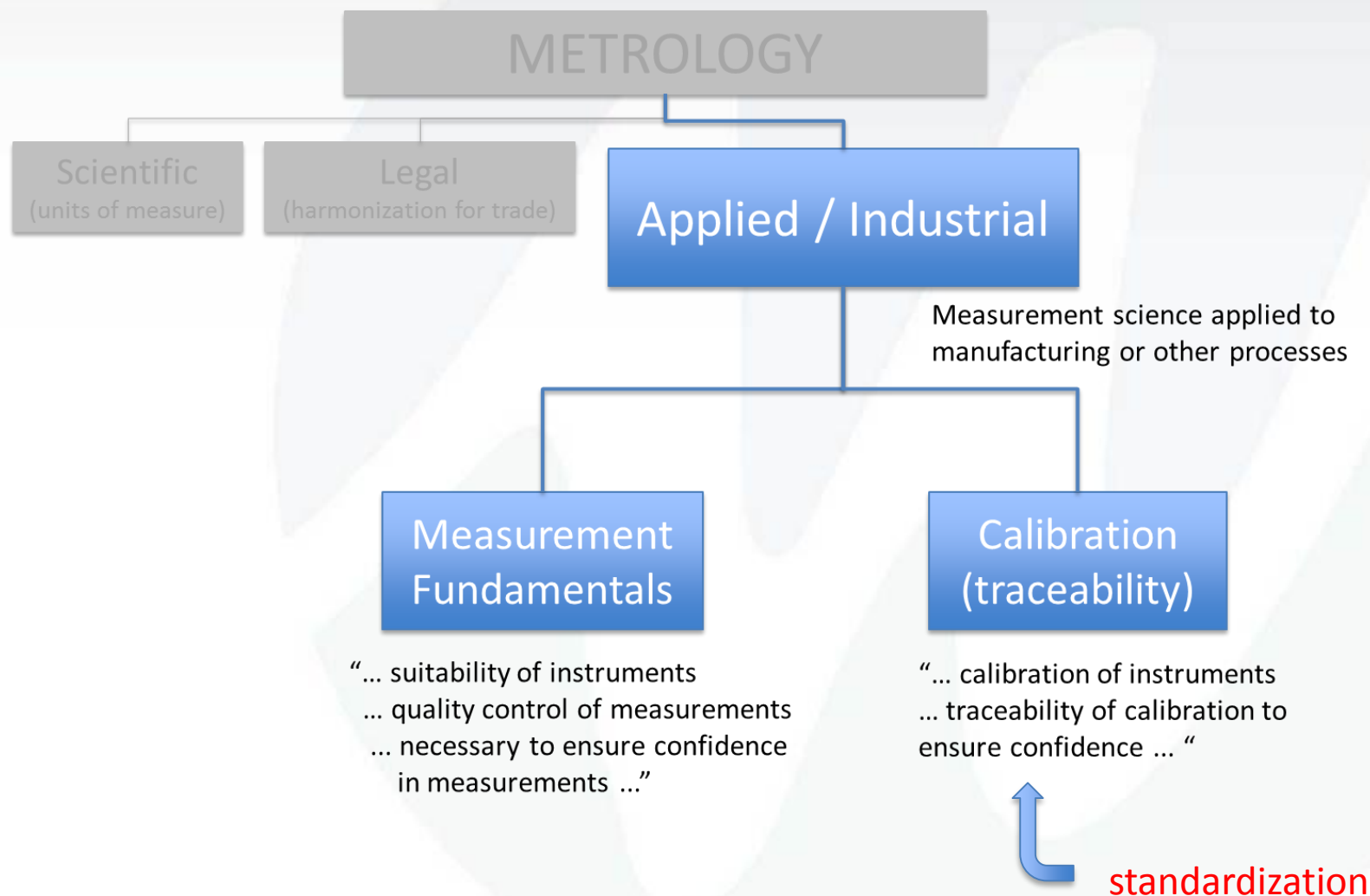




# METROLOGY



# METROLOGY



# METROLOGY PROGRAM

- Measurement Fundamentals
  - Accuracy
    - How close to the “true” value is the measured value
  - Precision
    - How repeatable is the measured value

# ACCURACY vs PRECISION



Accurate but  
not precise



Precise but  
not accurate



Neither accurate  
nor precise



Accurate  
And  
Precise



# MODULE 2: METROLOGY (MEASUREMENT CONCEPTS)

- **Specifications**
- Measurement Fundamentals
- Calibration
- Inspection Systems & Sampling



# MEASUREMENT (INSPECTION) PROCESS

- Customer Requirements
  - Specification
- Measurement Fundamentals
  - Methods, equipment
- Calibration System
  - Verification

# INSPECTION

- Customers want expectations and needs met consistently
  - Fitness for use
  - Form is free of defect
  - Functions as intended
- Evaluate product quality by comparing measurement results with specifications
- Inspection process:
  - Measurement of sample
  - Comparison against specification
  - Decision based on results
  - Corrective action, if necessary



# SPECIFICATIONS

- *Measurement is a process for evaluating a property or characteristic of an object and **describing it with a numerical or nominal value.***
- *Quality is a product (or service) with the features and characteristics which determine desirability and can be controlled to meet certain basic requirements.*

**Specifications = basic requirements**

# SPECIFICATIONS

- Specifications define expected performance limits
  - what are critical characteristics and their individual requirements
- Various industries
  - Services: Banks, Hospitals, Health Care, Restaurants, etc.
  - Electrical
  - Architectural
  - Etc.
- Manufacturing Industries
  - Drawings need to provide detail of
    - finished product; component part; assembly process
  - Drawings are visual representations of product, component part, etc. and include detailed dimensions
    - Define “fit, form, function”

# SPECIFICATONS

- Specifications can be word documents and/or drawings
  - Internal or External documents
  - Used by Customer to detail requirements
  - Used by R&D to design/evaluate
  - Used by Purchasing to buy
  - Used by Production to manufacture
  - Used by Quality to measure

# SPECIFICATONS

- Specifications can be word documents and/or drawings
  - Internal/External
  - Used by Customer, R&D, Purchasing, Manufacturing, QC, etc.
- **Will contain**
  - Description of material/component/assembly

# SPECIFICATONS

- Specifications can be word documents and/or drawings
  - Internal/External
  - Used by Customer, R&D, Purchasing, Manufacturing, QC, etc.
- **Will contain**
  - Description of material/component/assembly
  - **Manufacturer name/address**
  - **Material(s) of construction**

# SPECIFICATONS

- Will contain
  - Description of material/component/assembly
  - Manufacturer name/address
  - Material(s) of construction
  - Features or characteristics required
    - How they are to be measured
    - Measurement requirements, with tolerances
    - Can be dimensions, functionality, etc.
  - Delivery requirements
    - Packaging materials
    - Container sizes
    - Labeling
  - Additional requirements as necessary for Customer to convey needs to Supplier

*Review product specification examples*

# DRAWING

- Drawing is also a specification, but provides detailed picture and description of the requirements
  - Architectural
  - Electrical
  - Facilities (plumbing, HVAC, etc)
  - Part, Component, Product, Assembly
    - Historically, “blueprint” produced on paper using pencil/ink
    - Now created by computer aided design software (CAD)
      - AutoCAD® CREO (formerly ProE), Solidworks, Inventor, etc.

# DRAWING

- Drawings typically contain the following
  - Drawing Number
  - Name of part (and part number if different from drawing)
  - Name/address of preparer
  - Drawing Scale
  - Symbols, notes and specifications
  - Material specification, bill of materials (if applicable)



# UNDERSTANDING THE DRAWINGS

**Title Block:**  
 Company Name  
 Drawing Title, Size, Number, Revision  
 Scale, number of Page(s)

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONS $\pm 1/32$ ANGLES $\pm 1^\circ$ 3 PLACE DECIMALS $\pm 0.015$ 2 PLACE DECIMALS $\pm 0.02$		DRAWN Jennifer CHECKED QA ATG APPROVED	5/4/2013	<b>Elements</b>	
MATERIAL: NEXT ASSY USED ON				TITLE	
				SIZE B	DWG NO Blank Sheet
				SCALE 1/2	SHEET 1 OF 1

# UNDERSTANDING THE DRAWINGS

## Approvals:

Author (drawn by), Checker  
QA, Manufacturing, Others as required



UNLESS OTHERWISE SPECIFIED  
DIMENSIONS ARE IN INCHES  
TOLERANCES:  
FRACTIONS  $\pm 1/32$   
ANGLES  $\pm 1^\circ$   
3 PLACE DECIMALS  $\pm .015$   
2 PLACE DECIMALS  $\pm .02$

MATERIAL:

NEXT ASSY

USED ON

DRAWN	Jennifer	5/4/2013
CHECKED		
QA		
MFG		
APPROVED		

*Elements*

TITLE

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REV

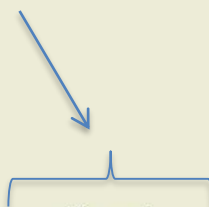
SCALE

1/2

SHEET 1 of 1

# UNDERSTANDING THE DRAWINGS

**Tolerance Block:**  
Default tolerance values



UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONS $\pm 1/32$ ANGLES $\pm 1^\circ$ 3 PLACE DECIMALS $\pm .015$ 2 PLACE DECIMALS $\pm .02$		DRAWN Dennifer	5/4/2013	<i>Elements</i>	
		CHECKED			
		QA		TITLE	
		APPROVED			
MATERIAL:				SIZE B	DWG NO Blank Sheet
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				SHEET 1 of 1	

# UNDERSTANDING THE DRAWINGS

Visual representation of part, component or assembly



UNLESS OTHERWISE SPECIFIED  
DIMENSIONS ARE IN INCHES  
TOLERANCES:  
FRACTIONS  $\pm 1/32$   
ANGLES  $\pm 1^\circ$   
3 PLACE DECIMALS  $\pm .015$   
2 PLACE DECIMALS  $\pm .02$

MATERIAL:

NEXT ASSY	USED ON

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PMG		
APPROVED		

**Elements**

TITLE

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REV

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SHEET 1 of 1

# UNDERSTANDING THE DRAWINGS

Rev #	Author	Reason

**Revision History**

After initial release this box is typically added to provide details regarding updates

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONS $\pm 1/32$ ANGLES $\pm 1^\circ$ 3 PLACE DECIMALS $\pm .015$ 2 PLACE DECIMALS $\pm .02$	
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DRAWN Jennifer	5/4/2013
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APPROVED	

<i>Elements</i>		
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SCALE 1/2	SHEET 1 OF 1	

# UNDERSTANDING THE DRAWINGS

Rev #	Author	Reason


  
  

## Notes Area

Comments related to the component, assembly, etc.  
Bill of Material (BOM)

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UNLESS OTHERWISE SPECIFIED  
DIMENSIONS ARE IN INCHES  
TOLERANCES:  
FRACTIONS ± 1/32  
ANGLES ± 1°  
3 PLACE DECIMALS ± .015  
2 PLACE DECIMALS ± .02

MATERIAL:

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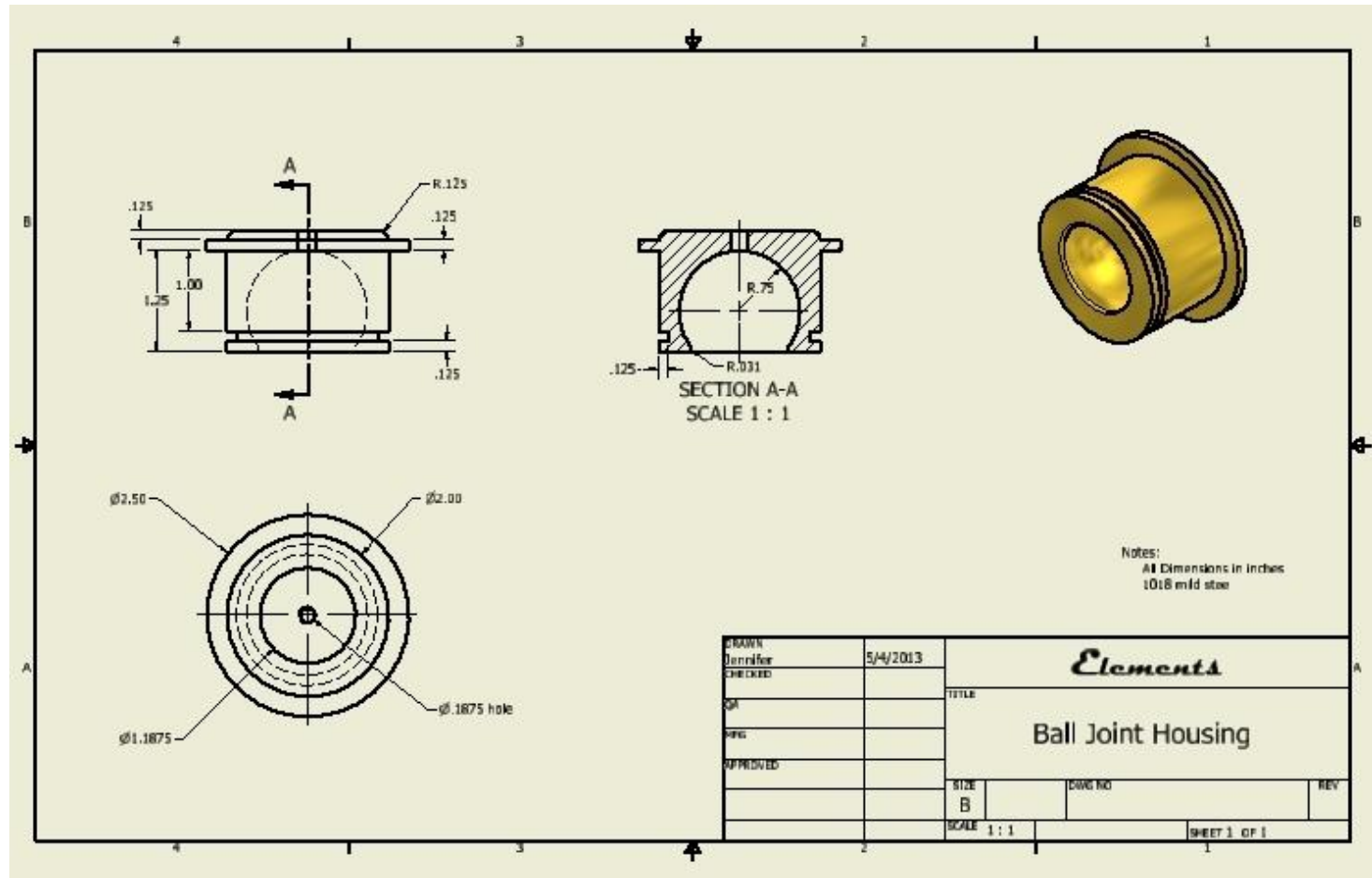
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APPROVED		TITLE
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		SHEET 1 OF 1

# DRAWING

- American Society of Mechanical Engineers provides standard for industry
  - ASME Y14.5-2009 “Dimensioning & Tolerancing: Engineering Drawing and Related Documentation Practices”

Referred to as GD&T (geometric dimension & tolerance)
- ASME Y14.5-2009 provides specific rules for interpretation and application of symbols on drawings
  - Language and rules learned
  - Aids intra- & inter-company communication
- Use **symbols** instead of notes for geometric controls
  - Fit/form/function
  - Relationship between specific part features

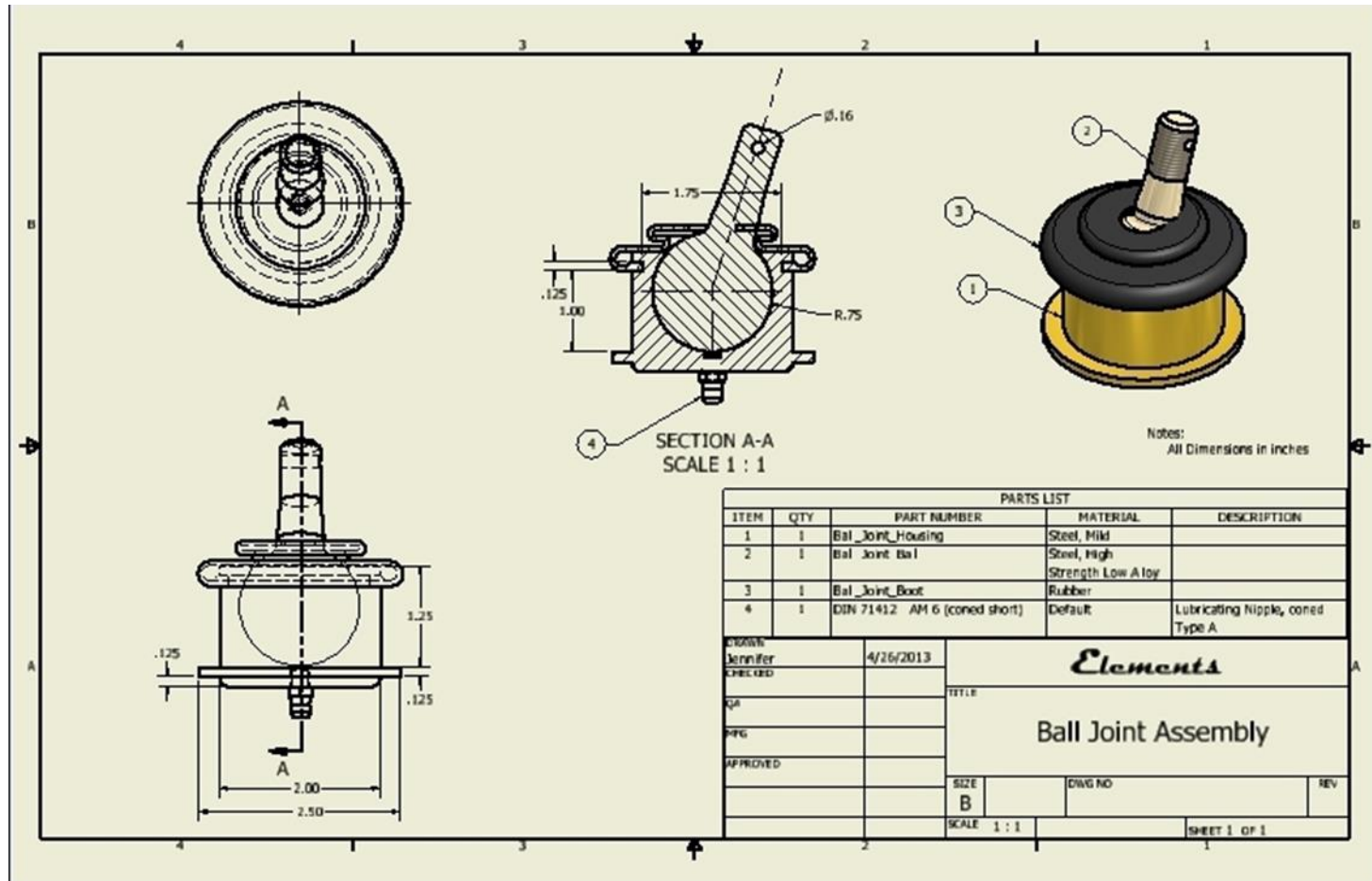
# UNDERSTANDING THE DRAWINGS



## COMPONENT



# UNDERSTANDING THE DRAWINGS



## ASSEMBLY

# UNDERSTANDING THE DRAWING

- Drawings depict
  - sizes, shapes, and locations of different features
  - along with tolerances (acceptable variation)
- Tolerance(s) – acceptable variation
  - Unilateral Tolerance
    - 0.200 inches + 0.005/-0.000 inches
  - Bilateral Tolerance
    - 0.200 inches +/- 0.005 inches
    - 0.200 inches +0.010 / -0.005 inches
  - Limit Dimensioning
    - 0.200 inches **minimum**
    - 0.200 inches **maximum**

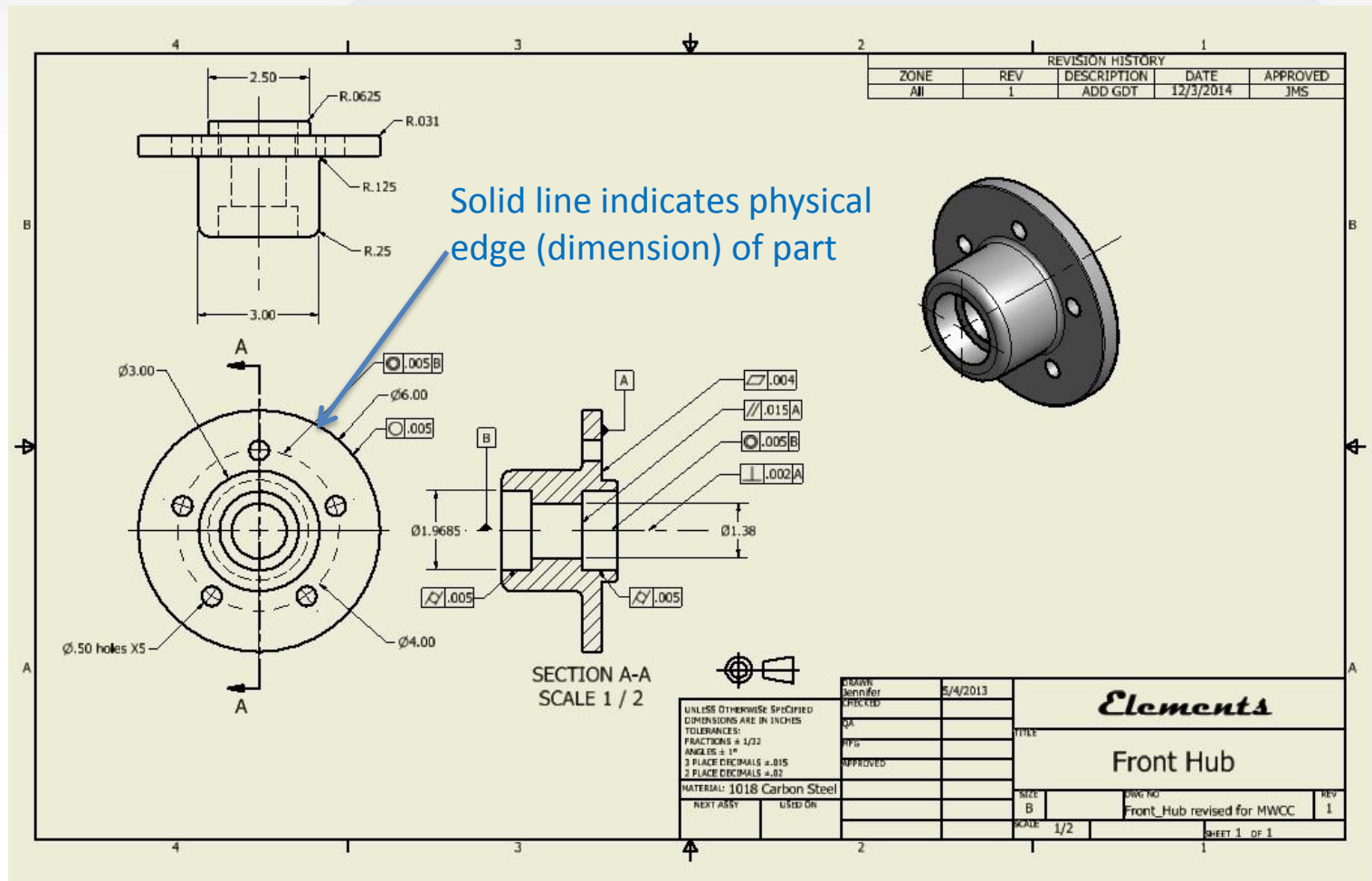
*Note: limit dimensioning and unilateral tolerance are different*

# UNDERSTANDING THE DRAWING

Depict part (component) with dimensions and specific symbols as needed for fit/form/function

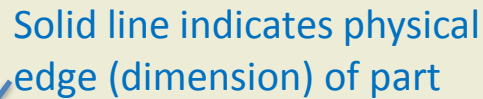
- Lines
  - Solid vs. dotted
  - Thick vs thin

# UNDERSTANDING THE DRAWINGS



Wheel Hub for Go-Kart

Dashed lines indicate hidden features



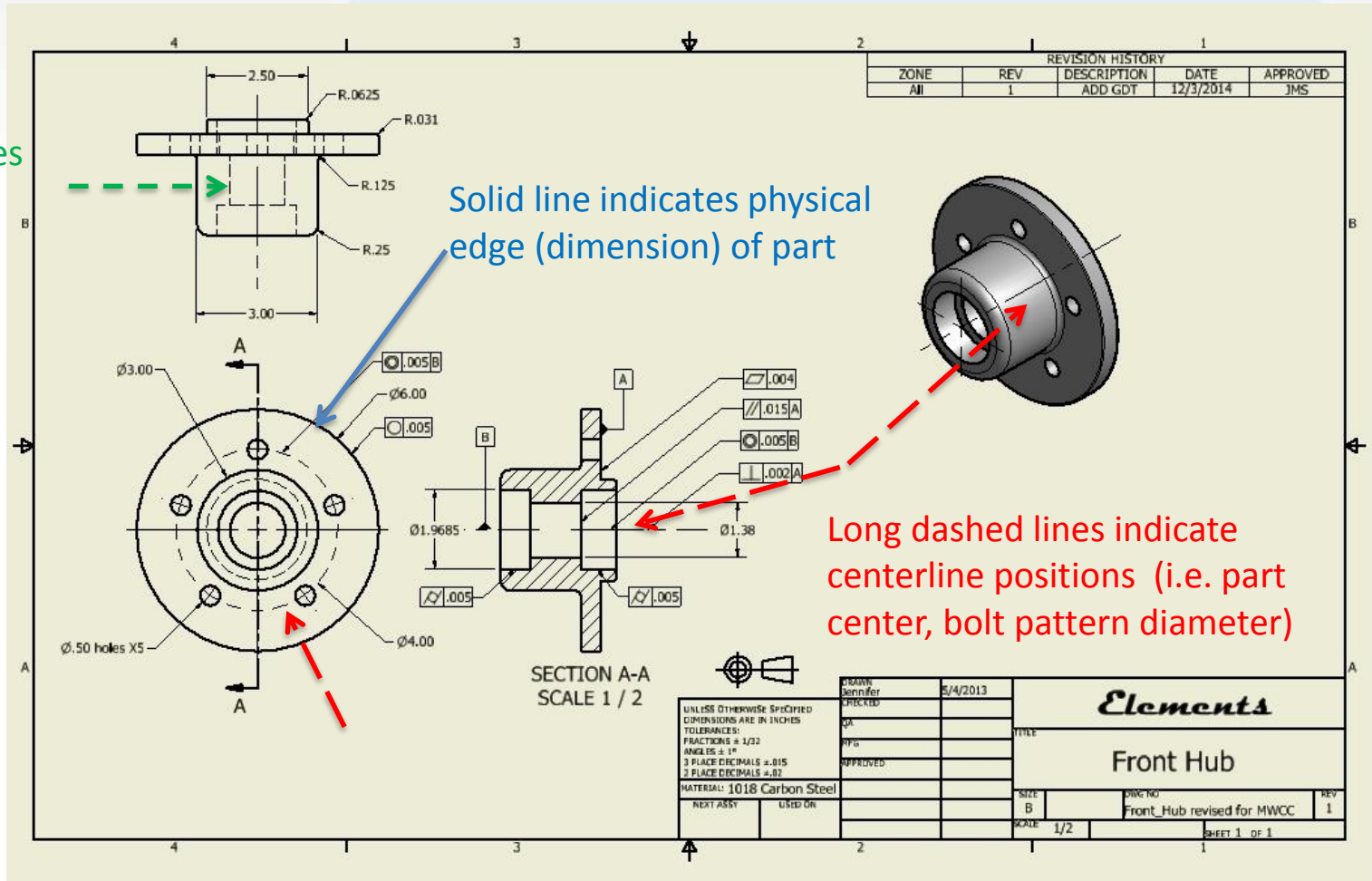
Developed as part of NSF ATE Grant #1304474

# UNDERSTANDING THE DRAWINGS

Dashed lines indicate hidden features

Solid line indicates physical edge (dimension) of part

Long dashed lines indicate centerline positions (i.e. part center, bolt pattern diameter)



Wheel Hub for Go-Kart

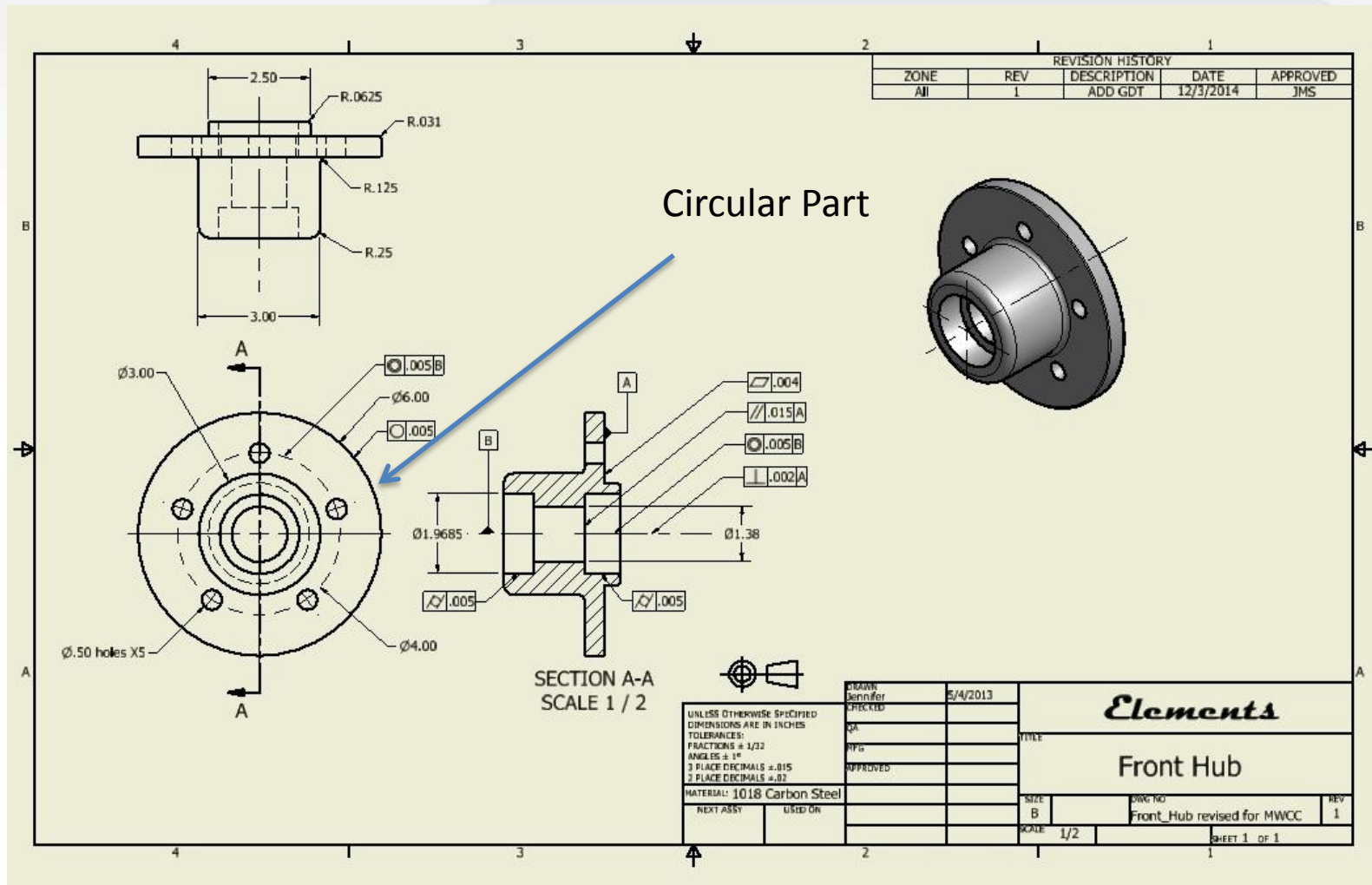
# UNDERSTANDING THE DRAWING

Depict part (component) with dimensions and specific symbols as needed for fit/form/function

- Lines
  - Solid vs. dotted
  - Thick vs thin
- Shapes
  - Circles, arcs
  - Squares, angles



# UNDERSTANDING THE DRAWINGS



Wheel Hub for Go-Kart















# UNDERSTANDING THE DRAWING

Depict part (component) with dimensions and specific symbols as needed for fit/form/function

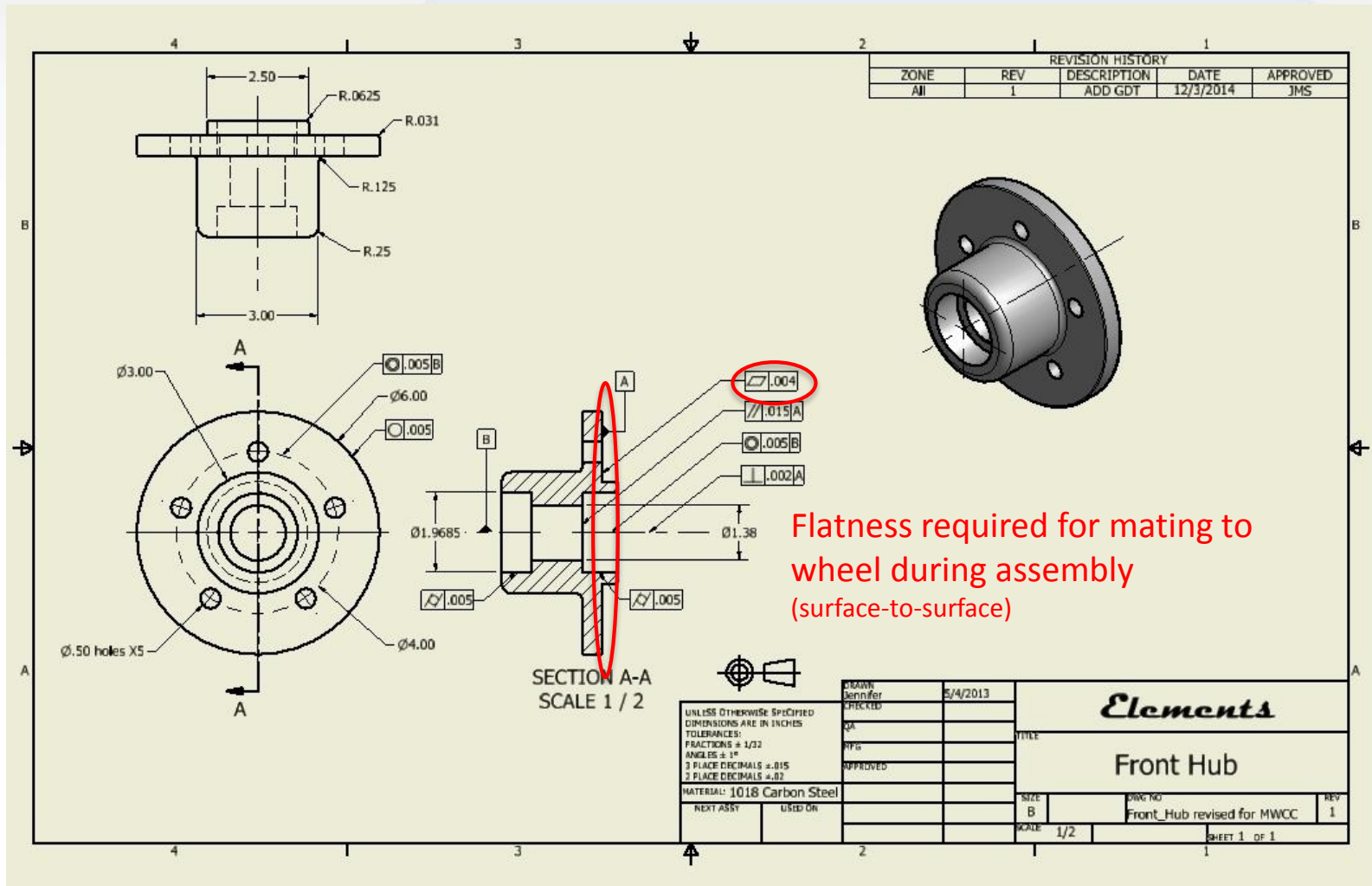
- Lines
  - Solid vs. dotted
  - Thick vs thin
- Shapes
  - Circles, arcs
  - Squares, angles
- Symbols
  - Parallel, flatness, concentricity

# GD&T SYMBOLS

GD & T Symbol	Control Type	Name
	Form	Straightness
	Form	Flatness
	Form	Circularity
	Form	Cylindricity
	Profile	Profile of Surface
	Profile	Profile of Line
	Orientation	Perpendicularity
	Orientation	Angularity
	Orientation	Parallelism
	Location	Position
	Location	Concentricity
	Location	Symmetry

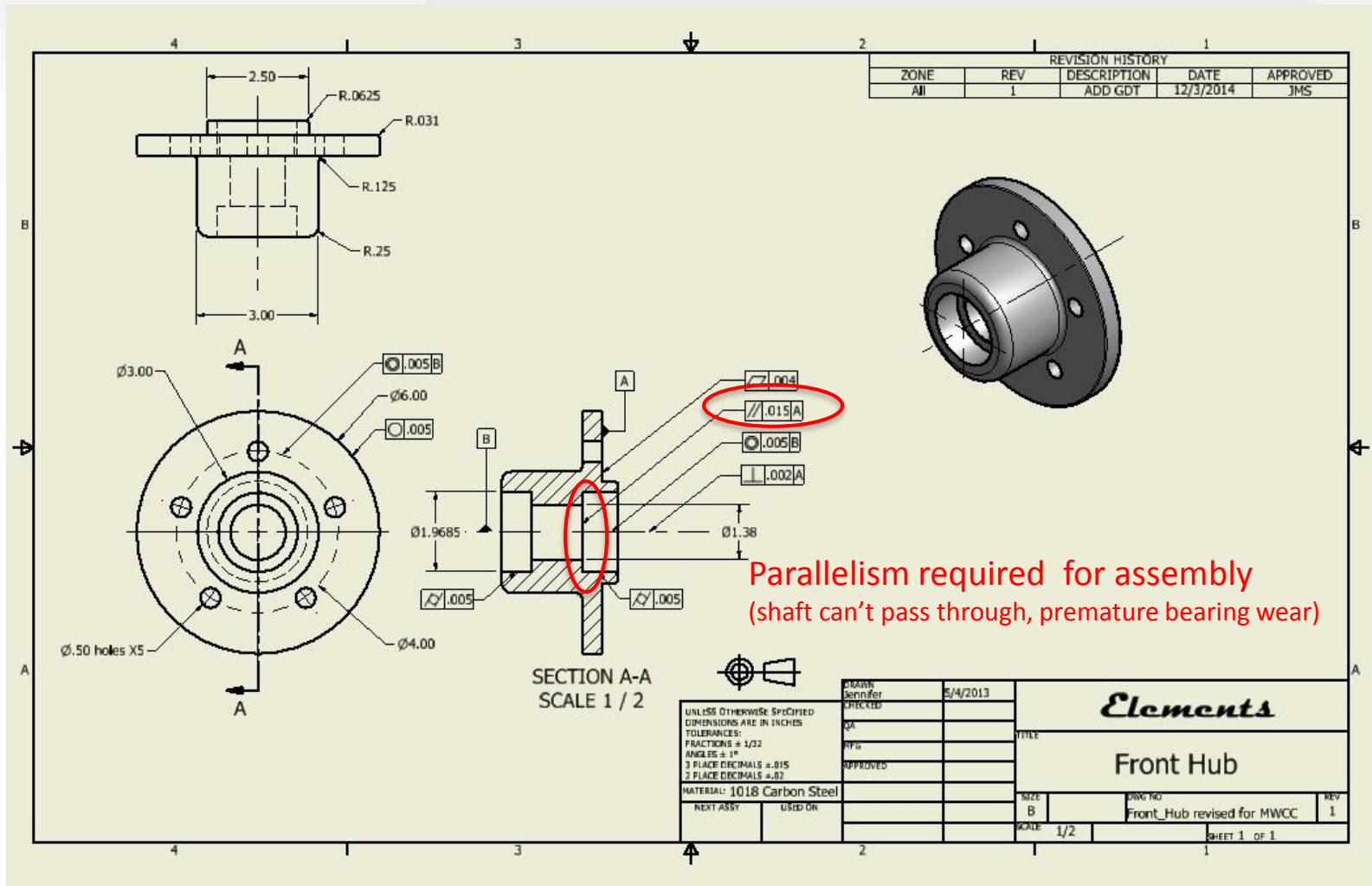
ASME Y14.5-2009  
 “Dimensioning & Tolerancing:  
 Engineering Drawing and Related  
 Documentation Practices”

# UNDERSTANDING THE DRAWINGS



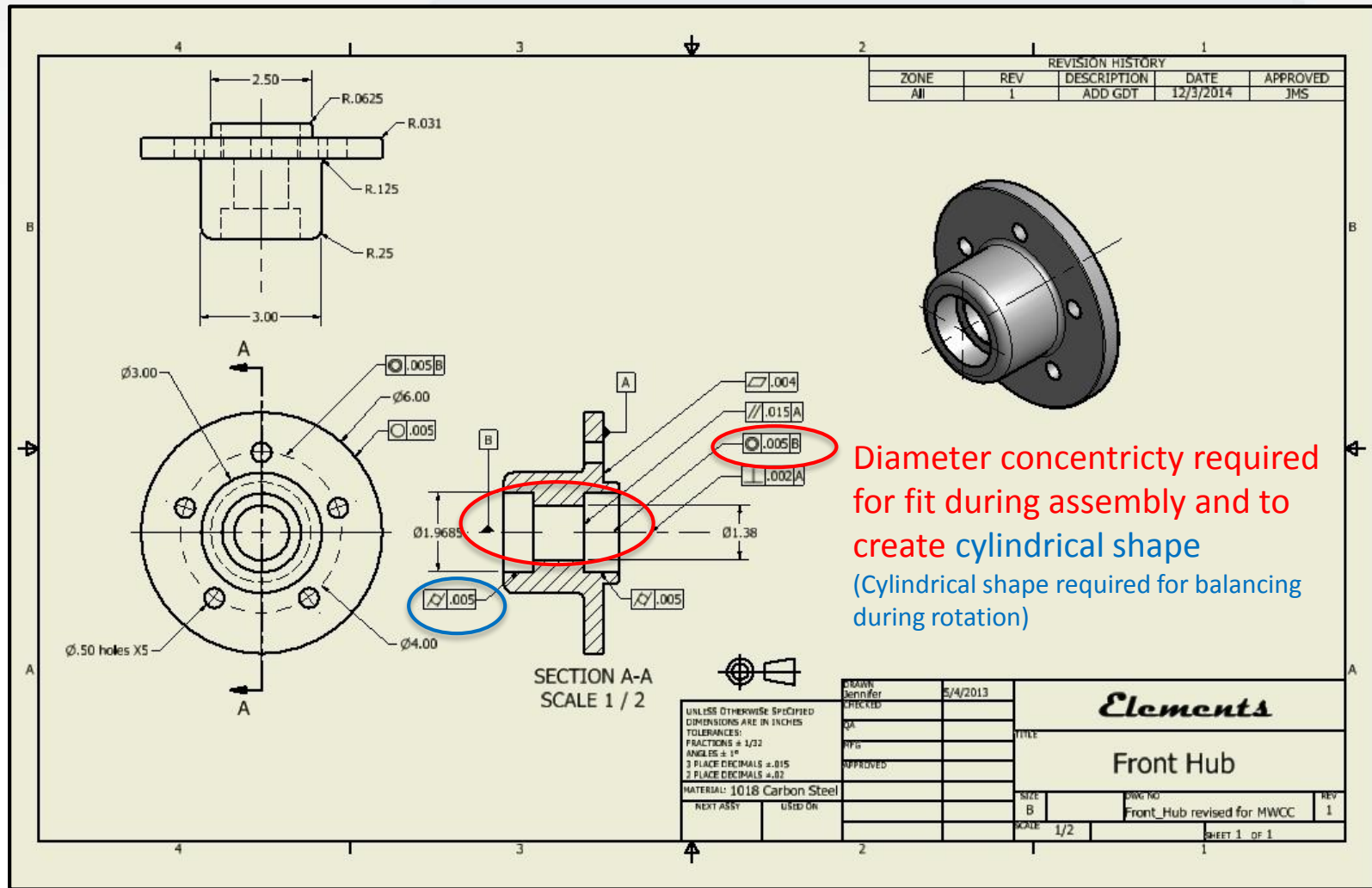
Wheel Hub for Go-Kart

# UNDERSTANDING THE DRAWINGS



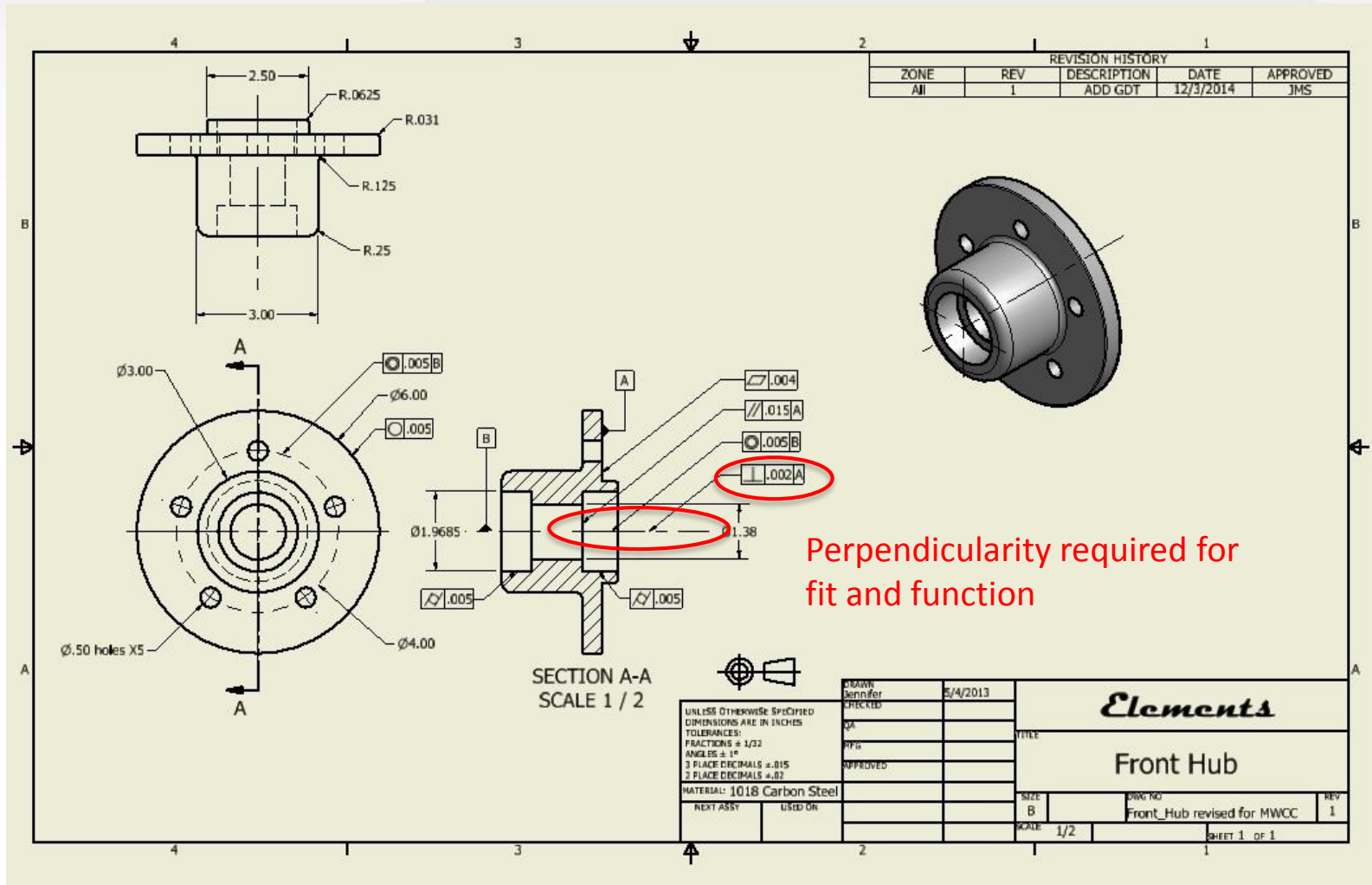
Wheel Hub for Go-Kart

# UNDERSTANDING THE DRAWINGS



Wheel Hub for Go-Kart

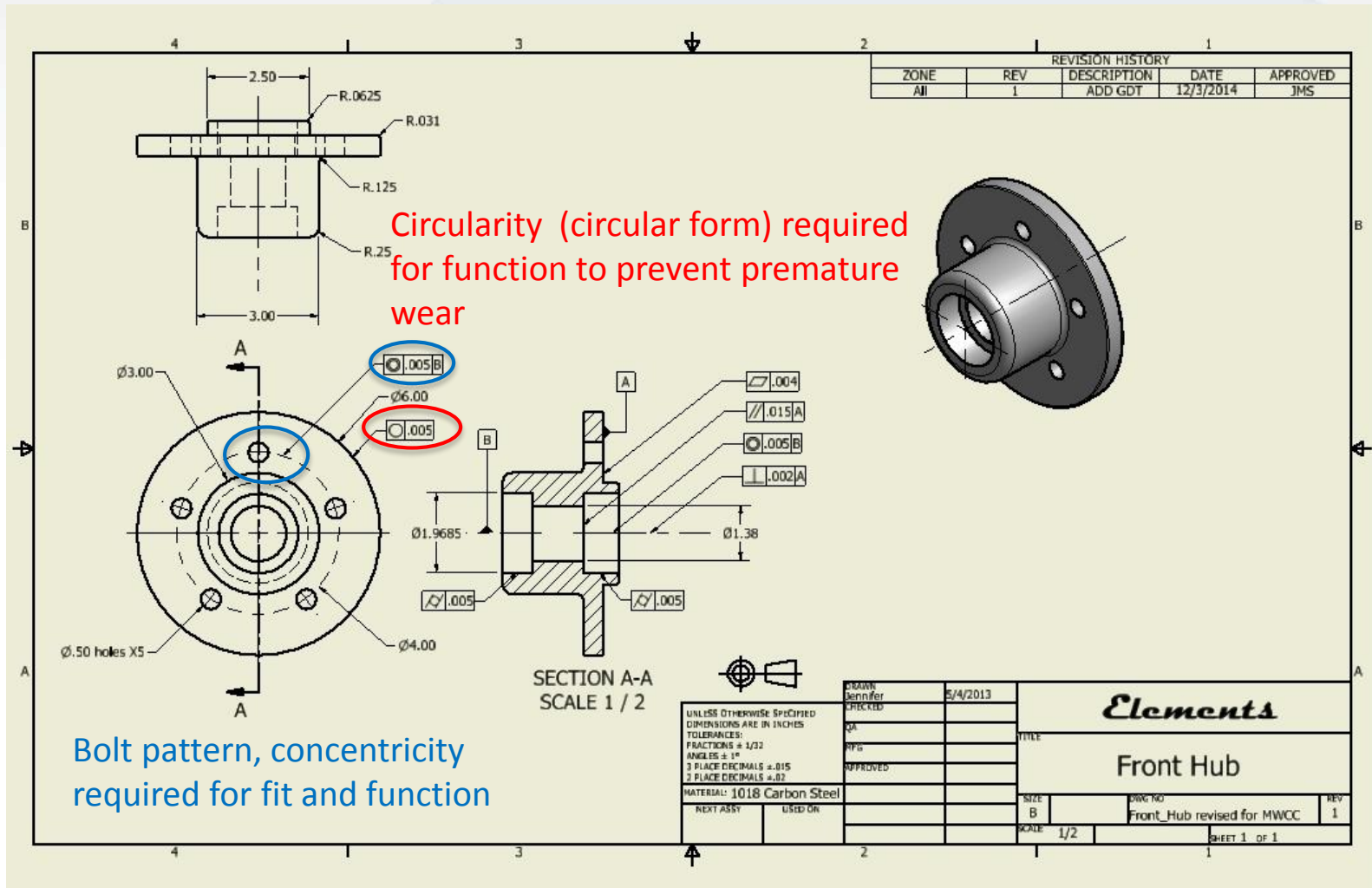
# UNDERSTANDING THE DRAWINGS



Wheel Hub for Go-Kart



# UNDERSTANDING THE DRAWINGS



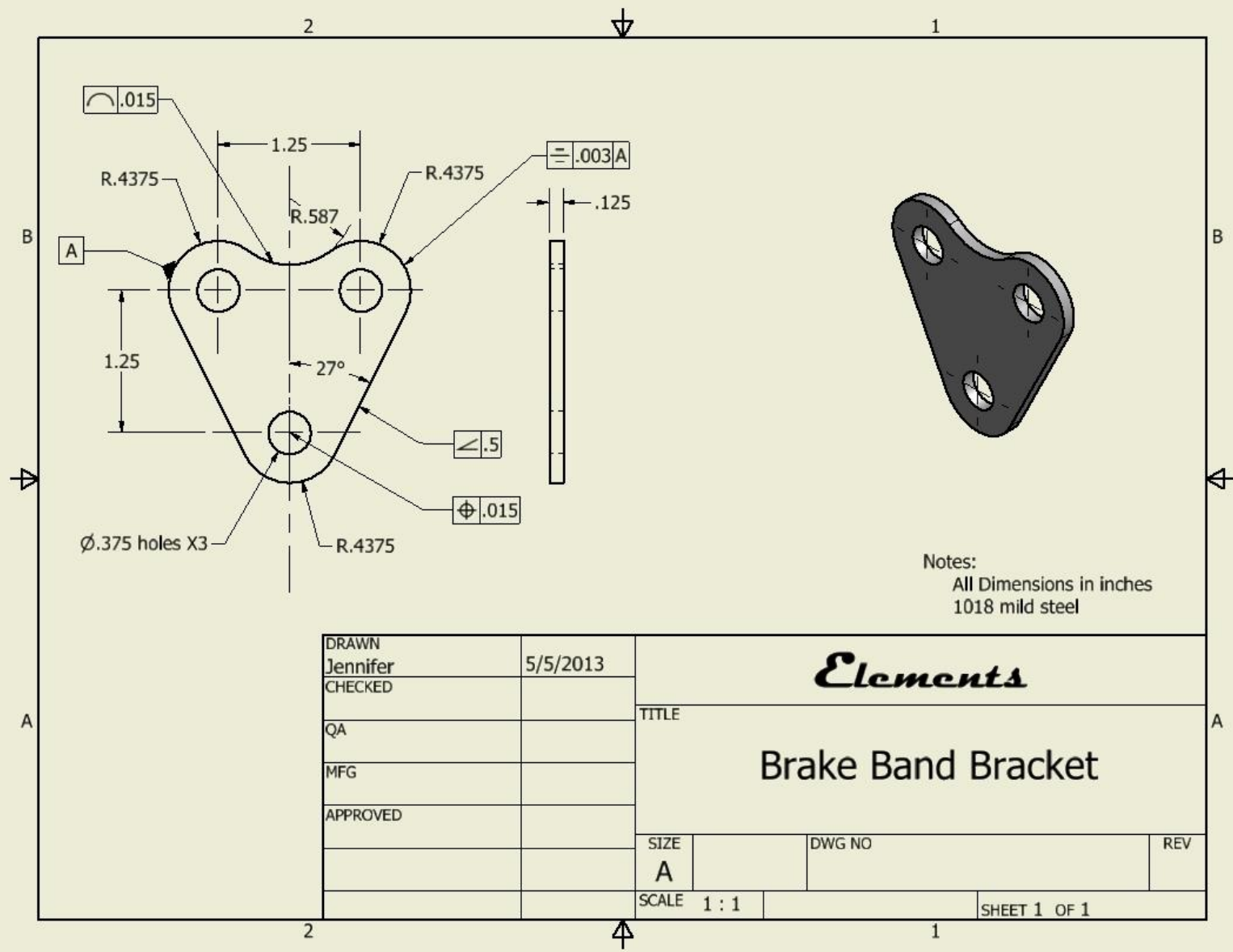
Wheel Hub for Go-Kart

# UNDERSTANDING THE DRAWINGS

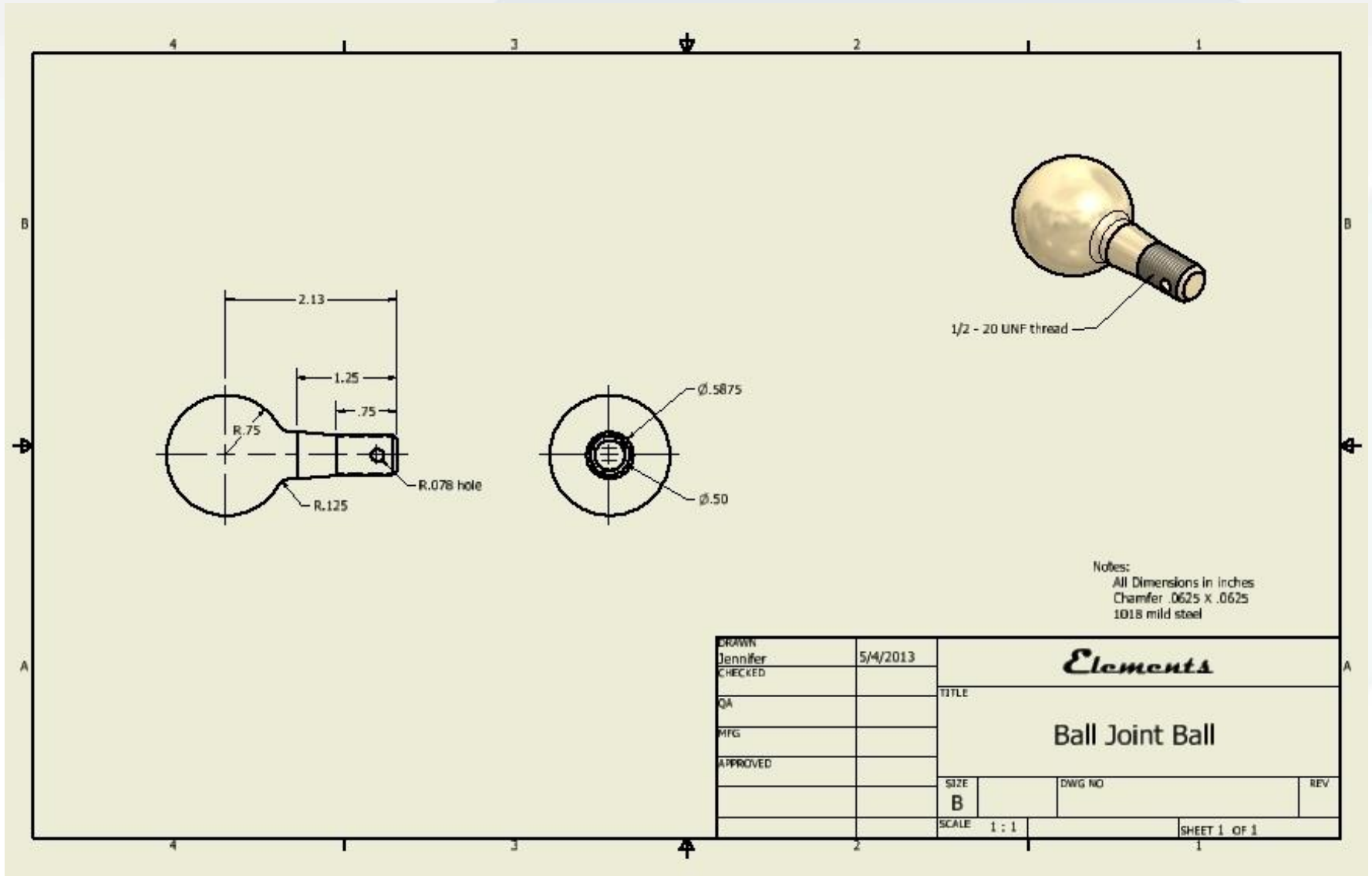
Drawing review – symbols, dimensions



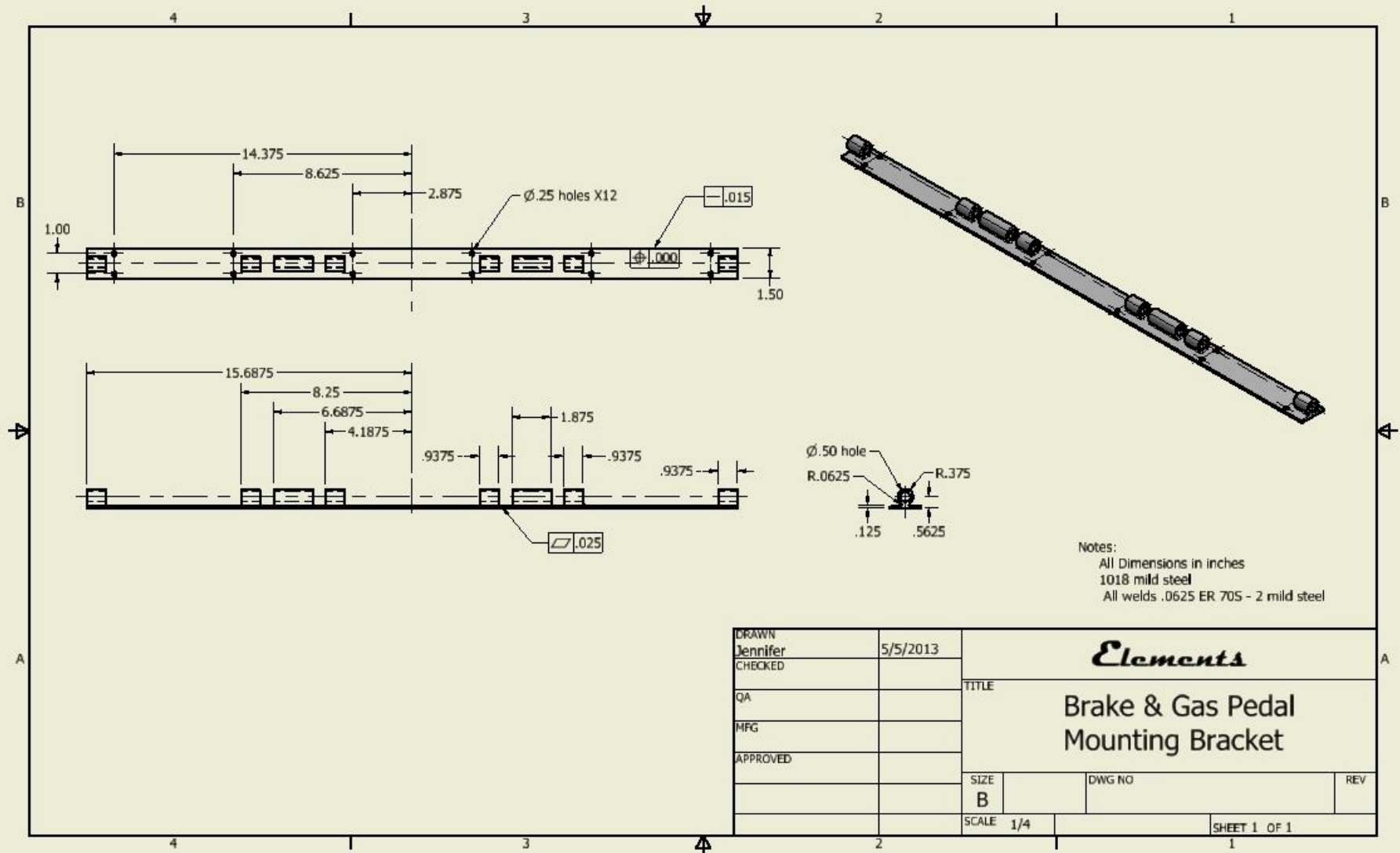
# DRAWING REVIEW



# DRAWING REVIEW



# DRAWING REVIEW





# MODULE 2: METROLOGY (MEASUREMENT CONCEPTS)

- Specifications
- **Measurement Fundamentals**
- Calibration
- Inspection Systems & Sampling



# MEASUREMENT TECHNIQUES (Equipment)

- Industry (product) specific
  - Dimensional
  - Materials Testing
  - Functional
  - Electrical
  - Etc.

# DIMENSIONAL MEASUREMENTS

- Scales / Rulers
- Calipers
- Go / no-go
- Surface plates
- Ring gages
- Optical Comparator
- Vision systems
- Etc.

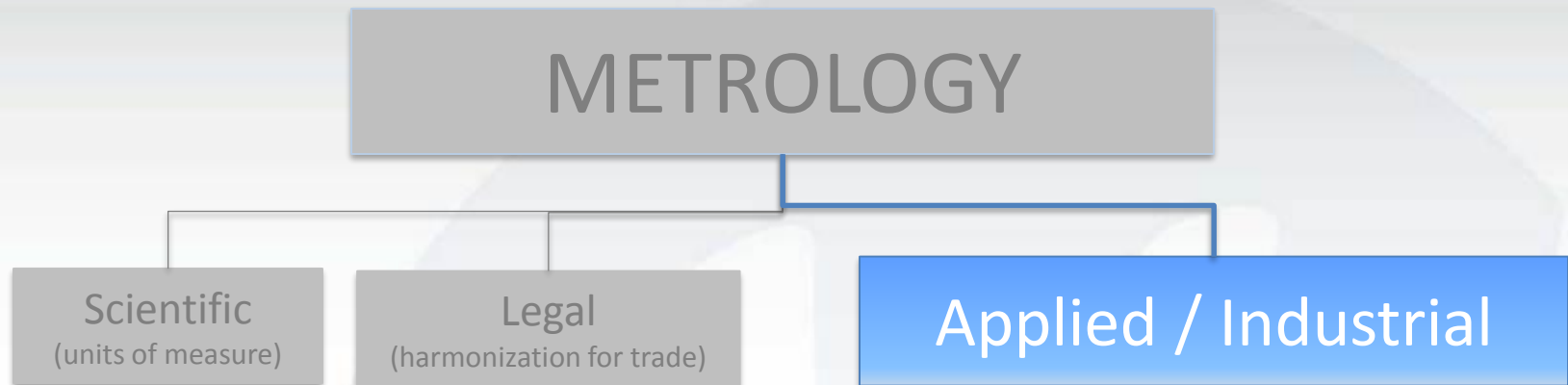
# MATERIALS TESTING

- Weight / Viscosity / Density
  - Scales / Analytical Balances
  - Hydrometers
  - Viscometer / Rheometer
- Identity Testing / Chemical Analysis
  - FTIR Spectroscopy
  - Chromatography
  - X-ray
- Universal Tester
  - Tensile
  - Elasticity



# FUNCTIONAL TESTING

- Flow Rate
- Pressure testing
  - Compression
  - Limits
- Universal Tester
  - Elasticity / Tensile
  - 3pt Flexibility
  - Peel Strength



*Measurement science applied to manufacturing or other processes*

- *Ensuring the suitability of measurement instruments, their calibration and quality control of measurements. [Measurement Fundamentals]*
- *Traceability of the calibration for the instruments necessary to ensure confidence in the measurements. [Calibration]*

# ACCURACY vs PRECISION



Accurate but  
not precise



Precise but  
not accurate



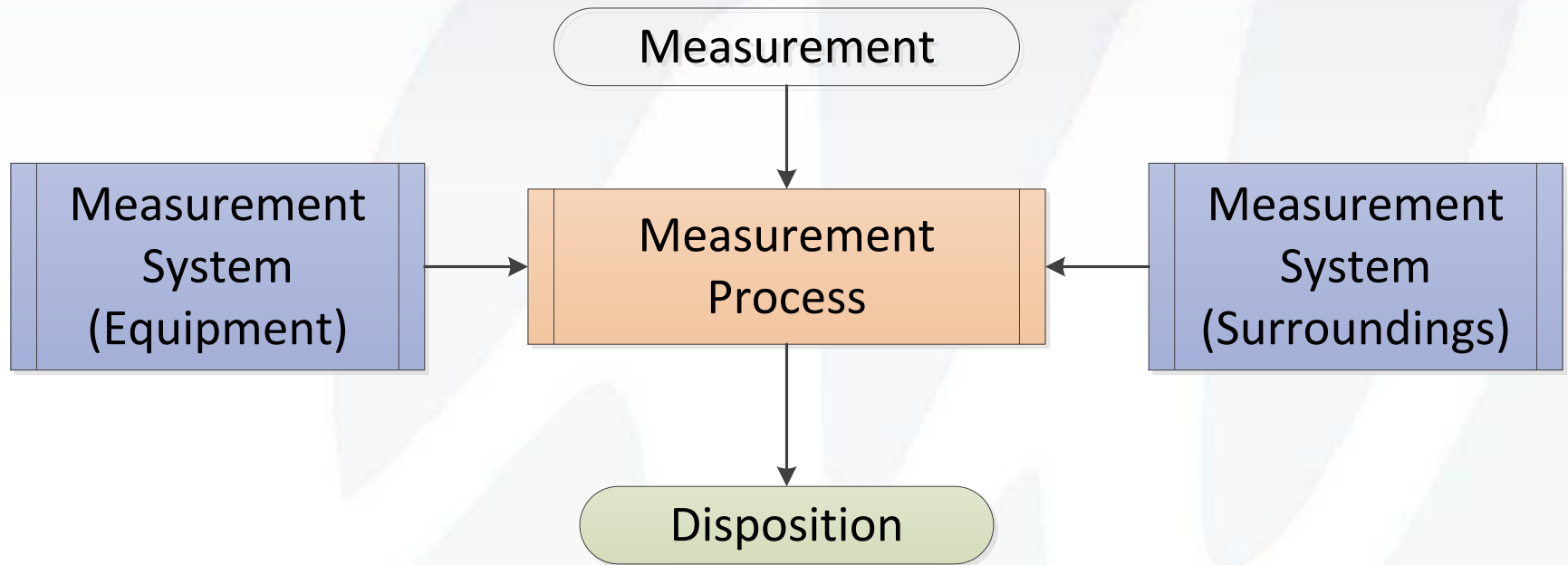
Neither accurate  
nor precise



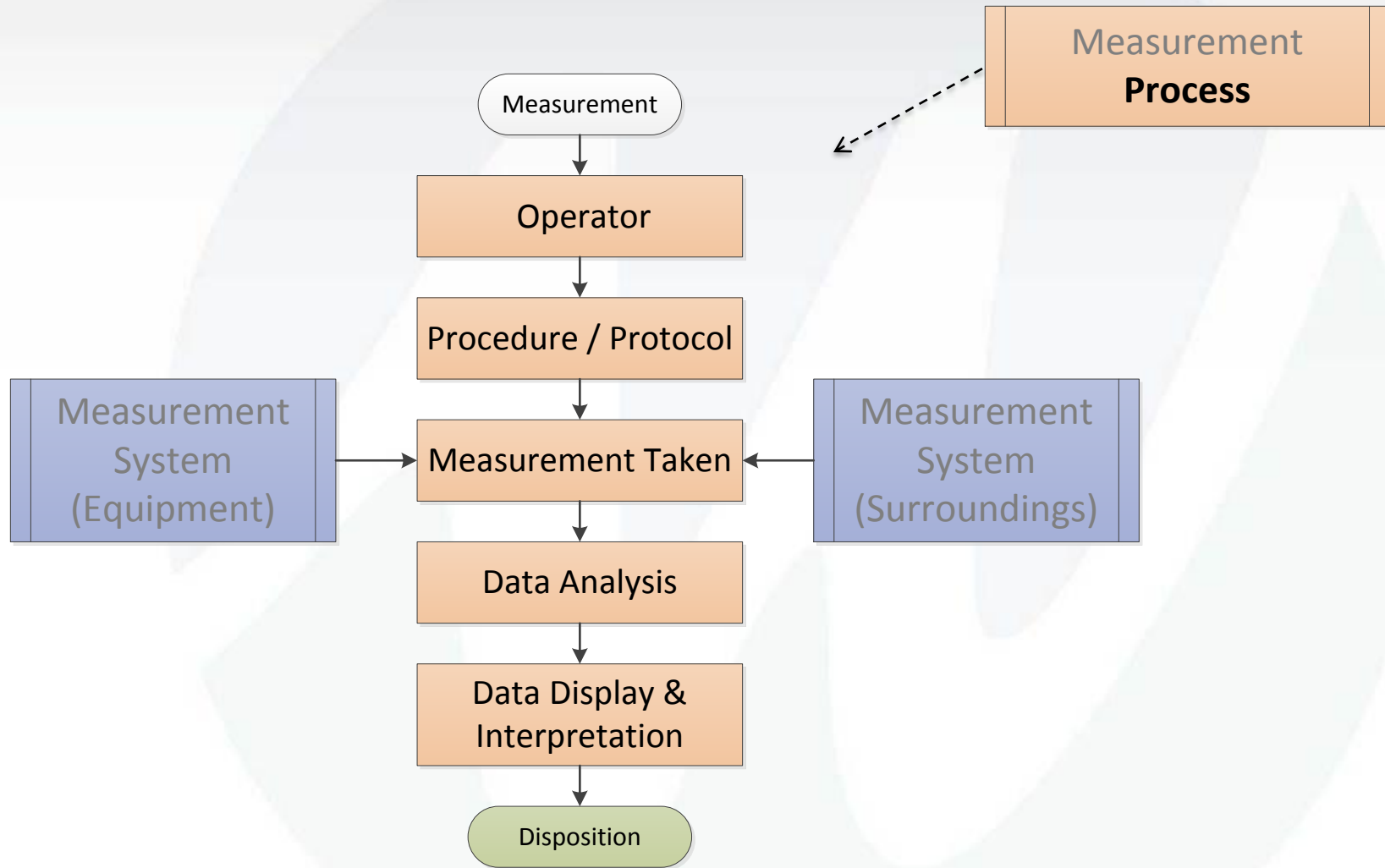
Accurate and  
Precise

**Customer expectation**  
**Product meets specification (fit/form/function)**

# METROLOGY - Taking a Measurement

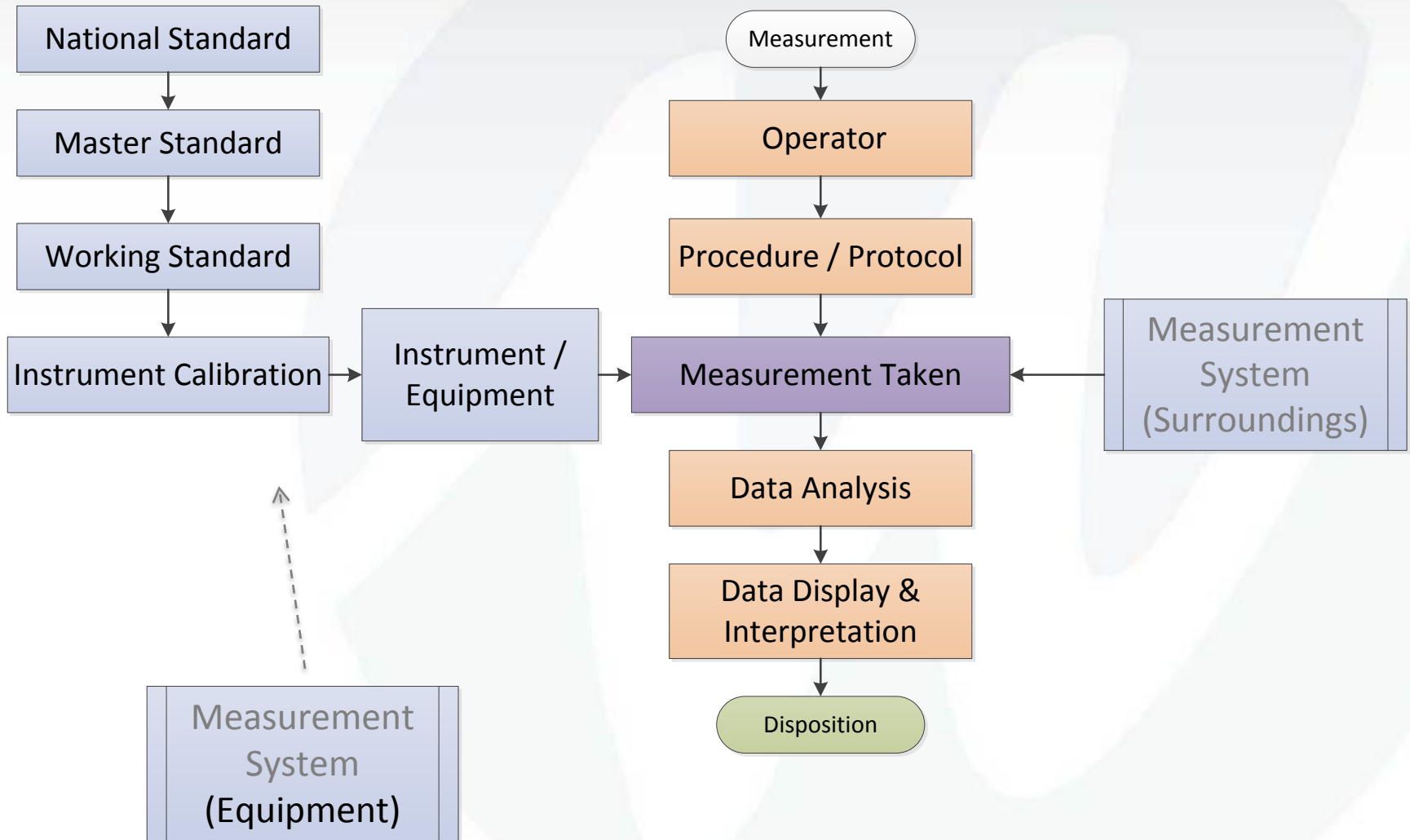


# METROLOGY - Taking a Measurement

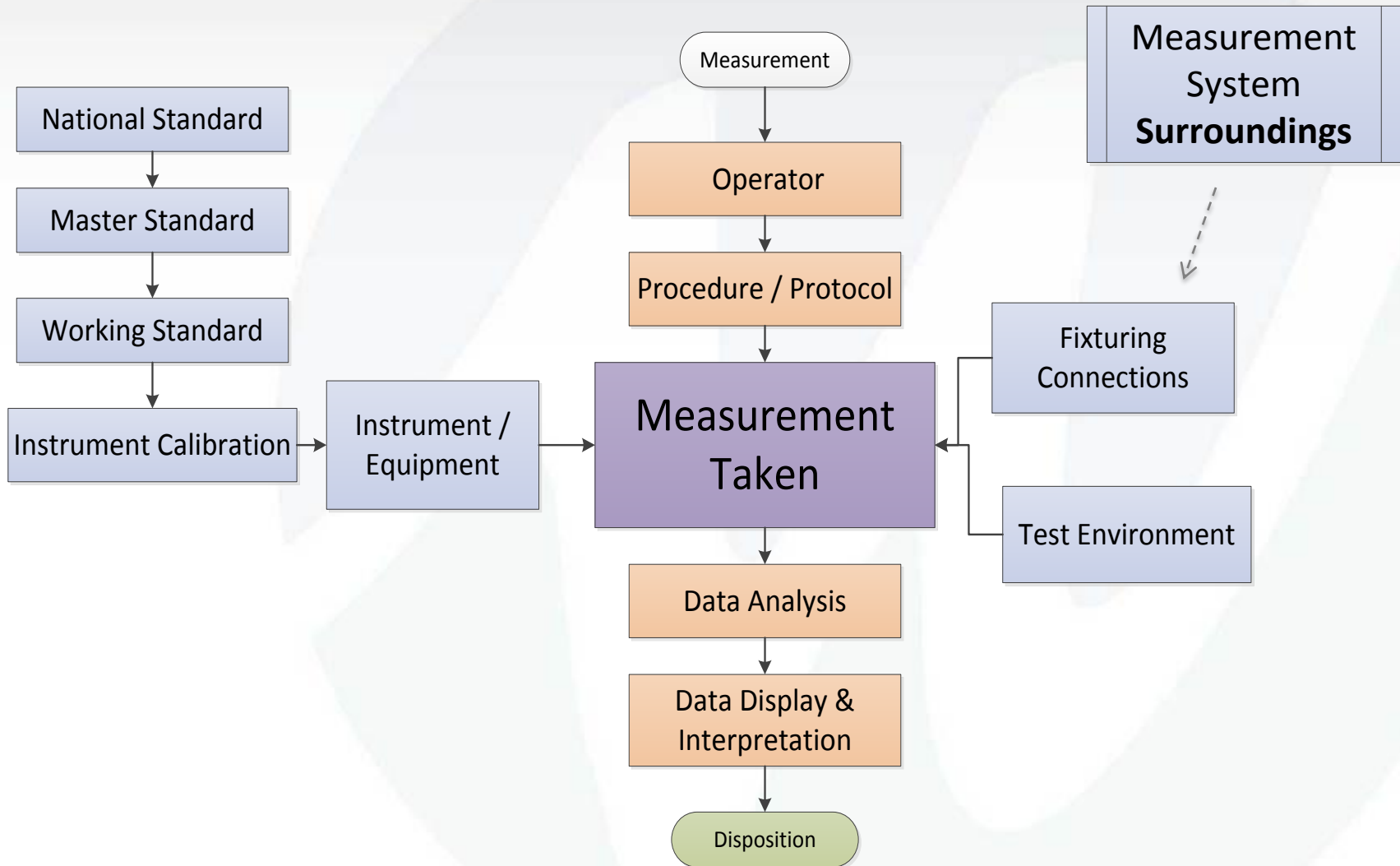


Quality Council of Indiana – CCT 2010

# METROLOGY - Taking a Measurement

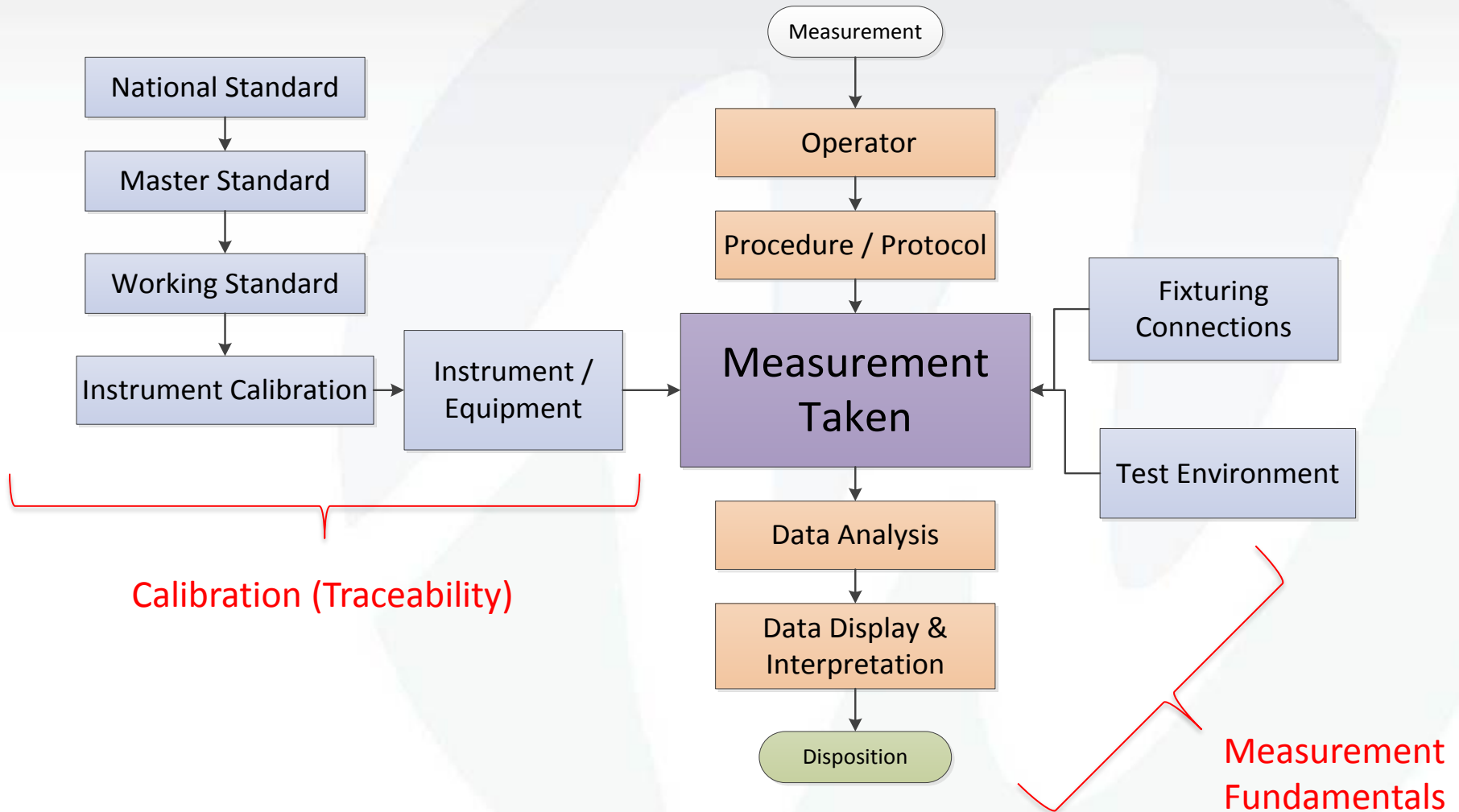


# METROLOGY - Taking a Measurement



Quality Council of Indiana – CCT 2010

# METROLOGY - Taking a Measurement

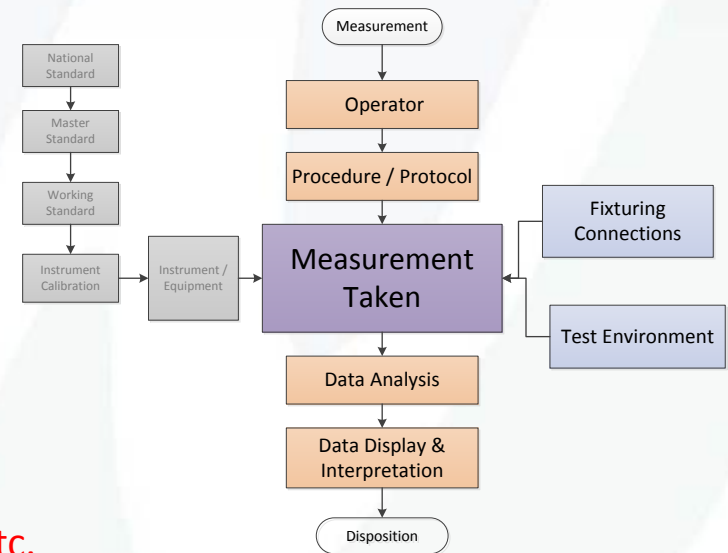


Quality Council of Indiana – CCT 2010



# METROLOGY PROGRAM

- **Measurement Fundamentals**
  - Methods
  - Equipment specifications
  - Confidence (Uncertainty) Programs
  - Environmental Controls
  - System
  - Capability
  - Standards Usage
  - Data



Course text describes as part of the calibration system

Context here is for measurement of products, processes, etc.

Will revisit concepts when discussing calibration.

# METROLOGY PROGRAM

- **Measurement Fundamentals**

- **Methods**
- Equipment specifications
- Quality (Confidence)
- Environmental Controls
- System
- Capability
- Standards Usage
- Data

# MEASUREMENT FUNDAMENTALS

- Methods

- Understanding the characteristics of what is to be measured

- Dimensional (e.g. length, diameter, volume)
    - Functional (e.g. flow rate, tensile strength)
    - Chemical (e.g. material type, pH)
    - Service (e.g. time between calls, maintenance response)
    - Attribute (e.g. color, clarity)

- How the measurement is taken

- Direct – actual characteristic measured with immediate readout for value

- Example: measuring length with ruler*

- Indirect – actual characteristic is not measured, but rather is calculated

- Example: flow of liquid in pipe is measured introducing constriction and measure the pressure*

# MEASUREMENT FUNDAMENTALS

- **Methods**

- Understanding the characteristics of what is to be measured (dimension, function, attribute, etc.)
- **How the measurement is taken**
  - Direct – actual characteristic measured with immediate readout for value
  - Indirect – actual characteristic is not measured, but rather is calculated
  - **Ratio – actual characteristic is not measured, but rather determined based on comparison**  
Example: using a beam balance to establish weight



# MEASUREMENT FUNDAMENTALS

- **Methods**
  - Understanding the characteristics of what is to be measured (dimension, function, attribute, etc.)
  - How the measurement is taken (direct, indirect, ratio)
  - **Logical organization of operations used**
    - Documentation (SOP, work instruction, test method, protocol, etc.)
    - Stepwise instruction on how to perform the test

# MEASUREMENT FUNDAMENTALS

- Standard Operating Procedure (SOP) or Work Instruction (WI)
  - Purpose
  - Scope
  - Equipment Needed
  - Safety Requirements
  - Personnel Responsibilities
  - Procedure
    - Includes sampling requirements, how to measure, where to measure
  - Records
    - Hand-written
    - Electronic collection
    - Report or summary

# METROLOGY PROGRAM

- **Measurement Fundamentals**

- Methods
- **Equipment specifications**
- Quality (Confidence)
- Environmental Controls
- System
- Capability
- Standards Usage
- Data

# MEASUREMENT FUNDAMENTALS

- Equipment specifications
  - Selection of the correct tool

What is being measured – dimension, function, attribute

Example: welding plastic during assembly

Characteristics: temperature & pressure

Temperature in Celsius or Fahrenheit

Pressure in Pascal, Bar or PSI (pounds per square inch)



# MEASUREMENT FUNDAMENTALS

- Equipment specifications
  - Selection of the correct tool
  - Ability to measure within the range necessary
    - Rule of thumb 10:1 ideal (4:1 acceptable, 1:1 if necessary)
    - Unnecessary Accuracy

What is being measured – dimension, function, attribute

Example: single lumen tubing versus dual lumen tubing

Characteristics: length, outer diameter, inner dimensions

length – ruler, caliper, vision system

outer diameter – caliper, pin gage, vision system

inner dimensions – depends on tube



# MEASUREMENT FUNDAMENTALS

- Equipment specifications
  - Selection of the correct tool
  - Ability to measure within the range necessary
    - Rule of thumb 10:1 ideal (4:1 acceptable, 1:1 if necessary)
    - Unnecessary Accuracy

What is being measured – dimension, function, attribute

Example: single lumen tubing versus dual lumen tubing

Characteristics: length, outer diameter, inner dimensions

Length specification 11 to 12 centimeters

Inner diameter specification 0.40 to 0.60 inches

# MEASUREMENT FUNDAMENTALS

- Equipment specifications
  - Selection of the correct tool
  - Ability to measure within the range necessary
    - Rule of thumb 10:1 ideal (4:1 acceptable, 1:1 if necessary)
    - Unnecessary Accuracy

What is being measured – dimension, function, attribute

Example: single lumen tubing versus dual lumen tubing

Characteristics: length, outer diameter, inner dimensions

Length specification: 11 to 12 centimeters

*adequate: ruler with centimeters and millimeter (0.1 cm)*

Inner diameter specification: 0.40 to 0.60 inches

*adequate: pin gage set that has 0.400 to 0.600 inch*

# MEASUREMENT FUNDAMENTALS

- Equipment specifications
  - Selection of the correct tool
  - Ability to measure within the range necessary
    - Rule of thumb 10:1 ideal (4:1 acceptable, 1:1 if necessary)
    - Unnecessary Accuracy

What is being measured – dimension, function, attribute

Example: single lumen tubing versus dual lumen tubing

Characteristics: length, outer diameter, inner dimensions

Length specification: 11 to 12 centimeters

*adequate: ruler with centimeters and millimeter (0.1cm)*

*“overkill”: calipers that measure  $\pm 0.001$  cm*

Inner diameter specification: 0.40 to 0.60 inches

*adequate: pin gage set that has 0.400 to 0.600 inch*

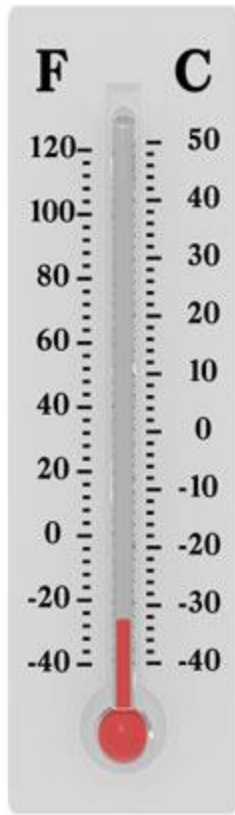
*“overkill”: vision system that measures  $\pm 0.00001$  inch*

# MEASUREMENT FUNDAMENTALS

- Equipment specifications
  - Selection of the correct tool
  - Ability to measure within the range necessary
    - Rule of thumb 10:1 ideal (4:1 acceptable, 1:1 if necessary)
    - Unnecessary Accuracy
  - Ease of use and readability

# MEASUREMENT FUNDAMENTALS

- Equipment specifications
  - Ease of use and readability



# MEASUREMENT FUNDAMENTALS

- Equipment specifications
  - Selection of the correct tool
  - Ability to measure within the range necessary
    - Rule of thumb 10:1 ideal (4:1 acceptable, 1:1 if necessary)
    - Unnecessary Accuracy
  - Ease of use and readability
  - Manual versus automation



# MEASUREMENT FUNDAMENTALS

- Equipment specifications
  - Selection of the correct tool
  - Ability to measure within the range necessary
    - Rule of thumb 10:1 ideal (4:1 acceptable, 1:1 if necessary)
    - Unnecessary Accuracy
  - Ease of use and readability
  - Manual versus automated

Example: length 12.3 inches

Outer diameter 0.50 inches

Inner diameter 0.050 inches

Length – ruler, caliper, vision system

Inner diameter – caliper, pin gage, vision system



# MEASUREMENT FUNDAMENTALS

- Equipment specifications  
What is being measured and accuracy needed?

The screenshot displays the Grainger website for an Electronic Digital Caliper (Item # 38P082). The page features a product image, technical specifications, and a comparison table.

**Technical Specs**

Item	Material
Electronic Digital Caliper	Stainless Steel Body, Plastic LCD Housing

Resolution: 0.0005"/0.01mm

Keyword: caliper

Range: Please Select | Jaw Depth: Please Select | SPC Output: Please Select | IP Rating: Please Select

☐ View Previously Purchased Products Only

Select items to compare: 11 Products

Compare / Item #	Mfr. Model #	Range	Jaw Depth	SPC Output	IP Rating	Availability	Price	Qty
<input type="checkbox"/> 38P080	0059006 6	0 to 100"/0 to 2545mm	6"	Yes		Item ships within 21 business days from supplier	\$8,366.00 / each	<input type="text"/>
<input type="checkbox"/> 38P085	0059030 5	0 to 12"/0 to 300mm	2.5"	No	67	Check Availability	\$359.25 / each	<input type="text"/>
<input type="checkbox"/> 38P075	0059006 1	0 to 12"/0 to 330mm	6"	Yes		Item ships within 7 business days from supplier	\$2,064.00 / each	<input type="text"/>

**Product Recommendations:**

- Electronic Digital Caliper, 0 to 6 In (Item # 38P082) - Price: \$194.75
- Digital Caliper, 0 to 6 In (Item # 21XK35) - Price: \$47.85
- Electronic Digital Caliper, 0 to 100 In (Item # 38P080) - Price: \$8,366.00

# MEASUREMENT FUNDAMENTALS

- Equipment specifications

What is being measured and accuracy needed?

WP27566 Digital Calipers - x

www.grainger.com/product/BROWN-SHARPE-Digital-Calipers-WP27566/\_/N-bia/Ntt-caliper?redirect=caliper&ssst=All&s\_pp=false&picUrl=/static.grainger.com/rp/is/image/Grainger/38P082\_AW01?smthumb\$

**Technical Specs**

Item: Electronic Digital Caliper  
Resolution: 0.0005"/0.01mm  
Material: Stainless Steel Body, Plastic LCD  
Housing

Keyword: caliper x

Range: Please Select  
Jaw Depth: Please Select  
SPC Output: Please Select  
IP Rating: Please Select

☐ View Previously Purchased Products Only

Select items to compare: 11 Products

Compare / Item #	Mfr. Model #	Range	Jaw Depth	SPC Output	IP Rating	Availability	Price	Qty
<input type="checkbox"/> 38P080	0059006 6	0 to 100"/0 to 2545mm	6"	Yes		Item ships within 21 business days from supplier	\$8,366.00 / each	<input type="text"/>
<input type="checkbox"/> 38P085	0059030 5	0 to 12"/0 to 300mm	2.5"	No	67	Check Availability	\$359.25 / each	<input type="text"/>
<input type="checkbox"/> 38P075	0059006 1	0 to 12"/0 to 330mm	6"	Yes		Item ships within 7 business days from supplier	\$2,064.00 / each	<input type="text"/>

Large range & jaw size →

**Electronic Digital Caliper, 0 to 6 In**  
Item # 38P082  
BROWN & SHARPE  
Price: \$194.75  
1 Add to Cart

**Digital Caliper, 0 to 6 In**  
Item # 21XK35  
JOHNSON  
Price: \$47.85  
1 Add to Cart

**Electronic Digital Caliper, 0 to 100 In**  
Item # 38P080  
BROWN & SHARPE  
Price: \$8366.00

# MEASUREMENT FUNDAMENTALS

- Equipment specifications

What is being measured and accuracy needed?

The screenshot displays the Grainger website for digital calipers. The main product shown is the Electronic Digital Caliper, Item # 38P082, with a resolution of 0.0005"/0.01mm. The page includes a 'Technical Specs' section, a 'Range' dropdown menu, and a 'Jaw Depth' dropdown menu. A comparison table lists 11 products, including the Electronic Digital Caliper, Item # 38P080, and the Digital Caliper, Item # 21XK35. The table columns include Compare / Item #, Mfr. Model #, Range, Jaw Depth, SPC Output, IP Rating, Availability, Price, and Qty.

Technical Specs

Item: Electronic Digital Caliper  
Resolution: 0.0005"/0.01mm  
Material: Stainless Steel Body, Plastic LCD  
Housing

Keyword: caliper

Range: Please Select  
Jaw Depth: Please Select  
SPC Output: Please Select  
IP Rating: Please Select

View Previously Purchased Products Only

Select items to compare: 11 Products

Compare / Item #	Mfr. Model #	Range	Jaw Depth	SPC Output	IP Rating	Availability	Price	Qty
38P080	0059006 6	0 to 100"/0 to 2545mm	6"	Yes		Item ships within 21 business days from supplier	\$8,366.00 / each	
38P085	0059030 5	0 to 12"/0 to 300mm	2.5"	No	67	Check Availability	\$359.25 / each	
38P075	0059006 1	0 to 12"/0 to 330mm	6"	Yes		Item ships within 7 business days from supplier	\$2,064.00 / each	

Electronic Digital Caliper, 0 to 6 In  
Item # 38P082  
BROWN & SHARPE  
Price: \$194.75  
1 Add to Cart

Digital Caliper, 0 to 6 In  
Item # 21XK35  
JOHNSON  
Price: \$47.85  
1 Add to Cart

Electronic Digital Caliper, 0 to 100 In  
Item # 38P080  
BROWN & SHARPE  
Price: \$8366.00

Reduced range and jaw size

# MEASUREMENT FUNDAMENTALS

- Equipment specifications

What is being measured and accuracy needed?

The screenshot displays a web browser window showing the Grainger.com product page for Electronic Digital Calipers. The page includes a technical specifications section, a comparison table of 11 products, and product details for three items.

**Technical Specs**

Item	Material
Electronic Digital Caliper	Stainless Steel Body, Plastic LCD Housing

Resolution 0.0005"/0.01mm

Keyword: caliper

Range: Please Select | Jaw Depth: Please Select | SPC Output: Please Select | IP Rating: Please Select

☐ View Previously Purchased Products Only

Select items to compare: 11 Products

Compare / Item #	Mfr. Model #	Range	Jaw Depth	SPC Output	IP Rating	Availability	Price	Qty
<input type="checkbox"/> 38P080	0059006 6	0 to 100"/0 to 2545mm	6"	Yes		Item ships within 21 business days from supplier	\$8,366.00 / each	<input type="text"/>
<input type="checkbox"/> 38P085	0059030 5	0 to 12"/0 to 300mm	2.5"	No	67	Check Availability	\$359.25 / each	<input type="text"/>
<input type="checkbox"/> 38P075	0059006 1	0 to 12"/0 to 330mm	6"	Yes		Item ships within 7 business days from supplier	\$2,064.00 / each	<input type="text"/>

**Product Details:**

- Electronic Digital Caliper, 0 to 6 In**  
Item # 38P082  
BROWN & SHARPE  
Price: \$194.75  
1 Add to Cart
- Digital Caliper, 0 to 6 In**  
Item # 21XK35  
JOHNSON  
Price: \$47.85  
1 Add to Cart
- Electronic Digital Caliper, 0 to 100 In**  
Item # 38P080  
BROWN & SHARPE  
Price: \$8366.00

Increased data output

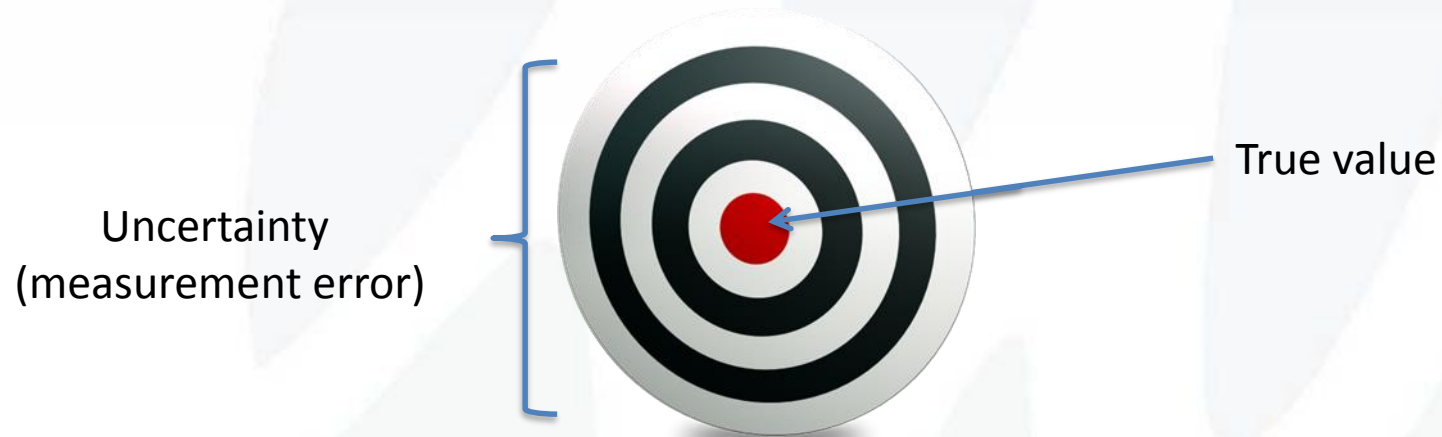
# METROLOGY PROGRAM

- **Measurement Fundamentals**

- Methods
- Equipment specifications
- **Quality (Confidence)**
- Environmental Controls
- System
- Capability
- Standards Usage
- Data

# MEASUREMENT FUNDAMENTALS

- Quality (Confidence)
  - Accuracy / precision
  - Uncertainty: range of probable values of “true value”



# MEASUREMENT FUNDAMENTALS

- Quality (Confidence)
  - Accuracy / precision
  - Uncertainty: range of probable values of “true value”
    - Measurement Error(s)
      - Random Error
      - Systematic Error
      - Environmental Error
      - Observational Error
      - Gross Human Error

Assumption:

Equipment has been calibrated and remains in calibration

# MEASUREMENT FUNDAMENTALS

- Quality (Confidence)
  - Accuracy / precision
  - Uncertainty: range of probable values of “true value”
    - Measurement Errors
      - **Random Error**: cause scatter in results (measure of dispersion) i.e. drafts, lack of resolution, noise, etc.



# MEASUREMENT FUNDAMENTALS

- Quality (Confidence)
  - Accuracy / precision
  - Uncertainty: range of probable values of “true value”
    - Measurement Errors
      - **Random Error**: cause scatter in results (measure of dispersion) i.e. drafts, lack of resolution, noise, etc.

Example: 10 weights taken one-after-the-other on the same scale

10.01, 10.02, 9.99, 10.01, 10.05,  
9.99, 10.00, 9.97, 9.99, 10.08

# MEASUREMENT FUNDAMENTALS

- Quality (Confidence)
  - Accuracy / precision
  - Uncertainty: range of probable values of “true value”
    - Measurement Errors
      - Random Error: cause scatter in results (measure of dispersion)  
i.e. drafts, lack of resolution, noise, etc.
      - **Systematic Error**: average offset from “true value” (bias)  
i.e. improper leveling, excessive wear, etc.

# MEASUREMENT FUNDAMENTALS

- Quality (Confidence)
  - Accuracy / precision
  - Uncertainty: range of probable values of “true value”
    - Measurement Errors
      - Random Error: cause scatter in results (measure of dispersion)  
i.e. drafts, lack of resolution, noise, etc.
      - **Systematic Error:** average offset from “true value” (bias)  
i.e. improper leveling, excessive wear, etc.



# MEASUREMENT FUNDAMENTALS

- Quality (Confidence)
  - Accuracy / precision
  - Uncertainty: range of probable values of “true value”
    - Measurement Errors
      - Random Error: cause scatter in results (measure of dispersion)  
i.e. drafts, lack of resolution, noise, etc.
      - Systematic Error: average offset from “true value” (bias)  
i.e. improper leveling, excessive wear, etc.
      - **Environmental Error**: temperature, vibration, pressure, etc.

# MEASUREMENT FUNDAMENTALS

- Measurement Errors
  - **Random Error**: cause scatter in results (measure of dispersion)  
i.e. drafts, lack of resolution, noise, etc.
  - **Systematic Error**: average offset from “true value” (bias)  
i.e. improper leveling, excessive wear, etc.
  - **Environmental Error**: temperature, vibration, pressure, etc.



# MEASUREMENT FUNDAMENTALS

- Quality (Confidence)
  - Accuracy / precision
  - Uncertainty: range of probable values of “true value”
    - Measurement Errors
      - Random Error: cause scatter in results (measure of dispersion) i.e. drafts, lack of resolution, noise, etc.
      - Systematic Error: average offset from “true value” (bias) i.e. improper leveling, excessive wear, etc.
      - Environmental Error: temperature, vibration, pressure, etc.
      - **Observational Error**: dial indicators (parallax & interpolation)

# MEASUREMENT FUNDAMENTALS

- Measurement Errors
  - **Observational Error:** dial indicators (parallax & interpolation)



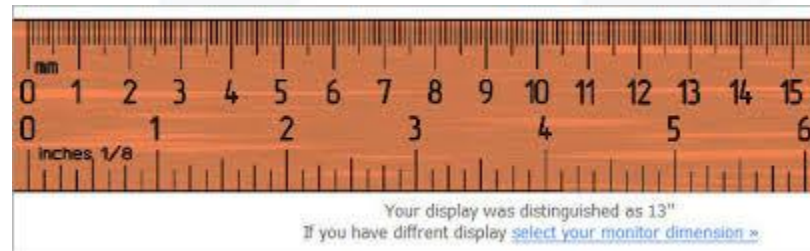
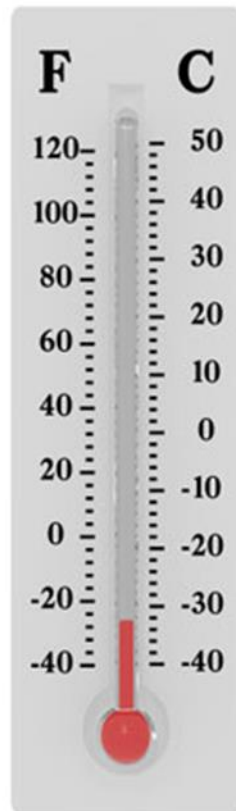
# MEASUREMENT FUNDAMENTALS

- Quality (Confidence)
  - Accuracy / precision
  - Uncertainty: range of probable values of “true value”
    - Measurement Errors
      - Random Error: cause scatter in results (measure of dispersion) i.e. drafts, lack of resolution, noise, etc.
      - Systematic Error: average offset from “true value” (bias) i.e. improper leveling, excessive wear, etc.
      - Environmental Error: temperature, vibration, pressure, etc.
      - Observational Error: dial indicators (parallax & interpolation)
      - **Gross Human Error**: misuse, blunders, mistakes (i.e. reading in kg, reporting in pounds)



# MEASUREMENT FUNDAMENTALS

- Measurement Errors
  - **Gross Human Error:** misuse, blunders, mistakes (i.e. reading in kg, reporting in pounds)



# METROLOGY PROGRAM

- **Measurement Fundamentals**

- Methods
- Equipment specifications
- Quality (Confidence)
- **Environmental Controls**
- System
- Capability
- Standards Usage
- Data

# MEASUREMENT FUNDAMENTALS

- Environmental Controls
  - Temperature, humidity, lighting, air quality, electromagnetic field, etc.
  - Effect on Measurement Tool
    - Temperature –
    - Moisture –
    - Lighting –
    - Air Quality –
    - Electromagnetic field -
    - Vibration -

# MEASUREMENT FUNDAMENTALS

- Environmental Controls
  - Temperature, humidity, lighting, air quality, electromagnetic field, etc.
  - Effect on Measurement [Tool](#)
    - Temperature – metal and glass expand/contract
    - Moisture – sensitive electrical equipment short out
    - Lighting – can you read the tool
    - Air Quality – dusty, salt air
    - Electromagnetic field - crowded production floor, machines interfere with each other
    - Vibration – sensitivity, tool wear

# MEASUREMENT FUNDAMENTALS

- Environmental Controls
  - Temperature, humidity, lighting, etc.
  - Effect on measurement tool
  - Effect on characteristic to be measured
    - Temperature – plastic shrinks as it cools
    - Moisture – hygroscopic (picks up moisture)
    - Lighting – reacts to ultraviolet rays, interference
    - Air Quality – contamination
    - Electromagnetic field - acoustics, interference

# MEASUREMENT FUNDAMENTALS

- Environmental Controls
  - Temperature, humidity, lighting, etc.
  - Effect on measurement tool
  - Effect on characteristic to be measured
  - Sensitivity (Accuracy) required

Be aware of where/how measurement taken and surrounding area  
Adjust tools, environment, specifications, etc. as necessary



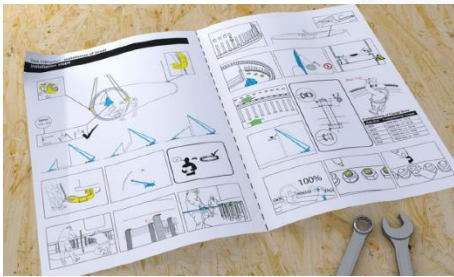
# METROLOGY PROGRAM

- **Measurement Fundamentals**

- Methods
- Equipment specifications
- Quality (Confidence)
- Environmental Controls
- **System**
- Capability
- Standards Usage
- Data

# MEASUREMENT FUNDAMENTALS

- System
  - Personnel, standards, devices fixtures, etc. used to conduct the measurement





# METROLOGY PROGRAM

- **Measurement Fundamentals**

- Methods
- Equipment specifications
- Quality (Confidence)
- Environmental Controls
- System
- **Capability**
- Standards Usage
- Data

# MEASUREMENT FUNDAMENTALS

- Capability
  - Ability of the measurement system to accurately/precisely measure the characteristic

Method + Personnel + Tool =

system



# MEASUREMENT FUNDAMENTALS

- Capability
  - Ability of the measurement system to accurately/precisely measure the characteristic

Method + Personnel + Tool =

system

Uncertainty  
(measurement error)



# MEASUREMENT FUNDAMENTALS

- Capability
    - Ability of the measurement system to accurately/precisely measure the characteristic
      - Bias
      - Linearity
      - Stability
      - Repeatability
      - Reproducibility
- Uncertainty (Error)



**Assumption:**  
Equipment has been calibrated and remains in calibration

# MEASUREMENT FUNDAMENTALS

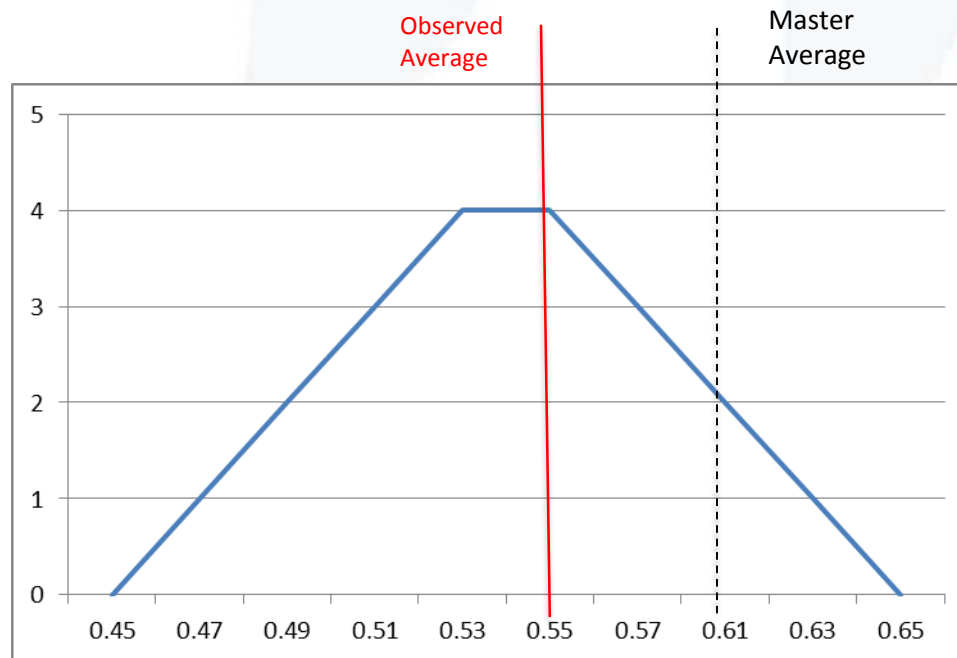
- Capability
  - Ability of the measurement system to accurately/precisely measure the characteristic
    - Bias: systematic offset  
difference between observed average and master average



Master average –  
determined using  
very precise tools

# MEASUREMENT FUNDAMENTALS

- Capability
  - Ability of the measurement system to accurately/precisely measure the characteristic
    - Bias: systematic offset  
difference between observed average and master average



Histogram of 24 measurements

Tool is measuring 0.05 small  
“negative” bias

# MEASUREMENT FUNDAMENTALS

- Capability
  - Ability of the measurement system to accurately/precisely measure the characteristic
    - Bias: systematic offset  
difference between observed average and master average

EXAMPLE: Opinion poll taken interviewing only those people living in large metropolitan areas on the West Coast.

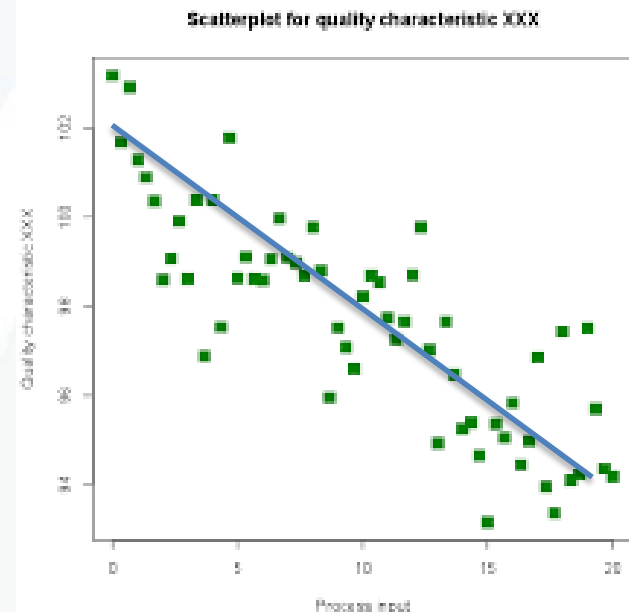
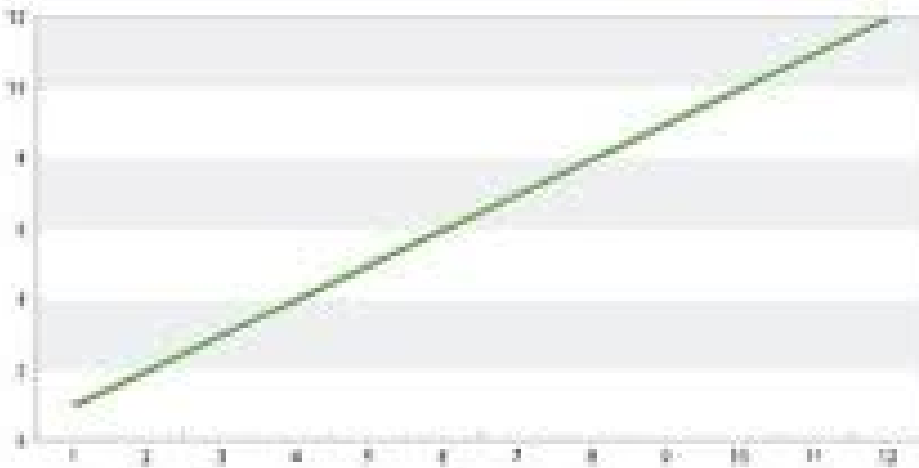
# MEASUREMENT FUNDAMENTALS

- Capability
  - Ability of the measurement system to accurately/precisely measure the characteristic
    - Bias: systematic offset
    - **Linearity: equally increasing (decreasing) increments**



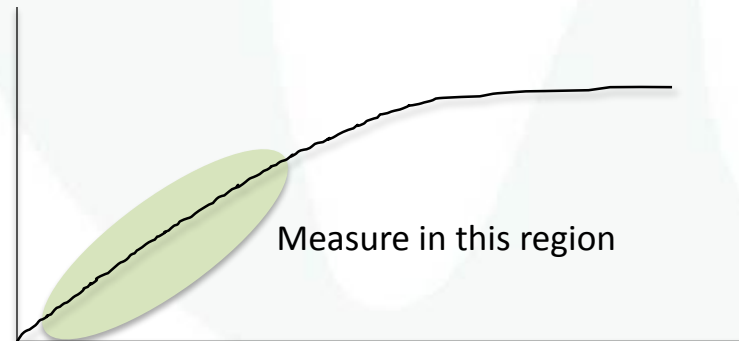
# MEASUREMENT FUNDAMENTALS

- Capability
  - Ability of the measurement system to accurately/precisely measure the characteristic
    - Bias: systematic offset
    - **Linearity: equally increasing (decreasing) increments**



# MEASUREMENT FUNDAMENTALS

- Capability
  - Ability of the measurement system to accurately/precisely measure the characteristic
    - Bias: systematic offset
    - **Linearity: equally increasing (decreasing) increments**
- ✓ Take measurements within the linear range (e.g. concentration curves, temperature effects)
- ✓ Selection of tool

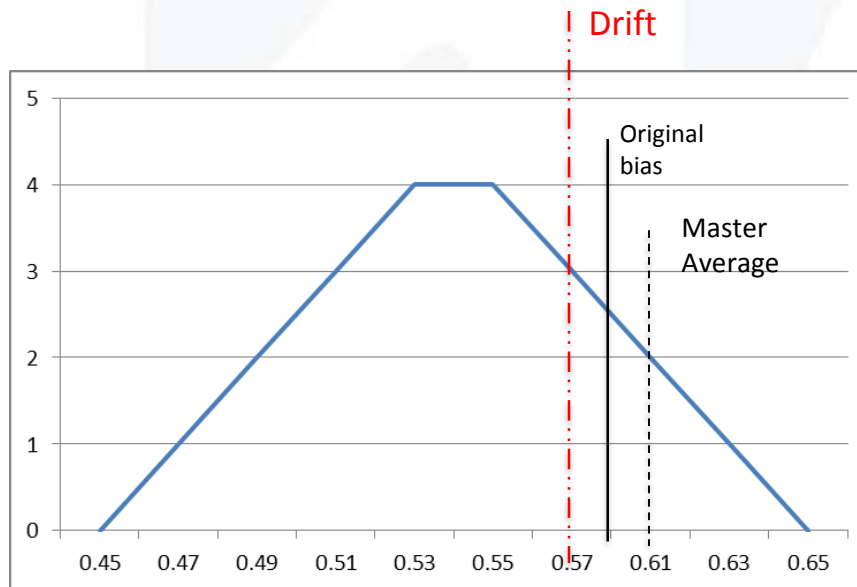


# MEASUREMENT FUNDAMENTALS

- Capability
  - Ability of the measurement system to accurately/precisely measure the characteristic
    - Bias: systematic offset
    - Linearity: equally increasing increments
    - **Stability: change in bias over time (i.e. drift)**

# MEASUREMENT FUNDAMENTALS

- Capability
  - Ability of the measurement system to accurately/precisely measure the characteristic
    - Bias: systematic offset
    - Linearity: equally increasing increments
    - **Stability: change in bias over time (i.e. drift)**



Tool is measuring 0.02 small  
“negative” bias

After 18 months continuous use,  
now measuring 0.04 small

# MEASUREMENT FUNDAMENTALS

- Capability
  - Ability of the measurement system to accurately/precisely measure the characteristic
    - Bias: systematic offset
    - Linearity: equally increasing increments
    - Stability: change in bias over time (i.e. drift)
    - **Repeatability: closeness of measurements from same instrument**

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    - **Reproducibility: closeness of measurements under the same conditions**

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    - Reproducibility: closeness of measurements under the **same conditions**



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  - Ability of the measurement system to accurately/precisely measure the characteristic
    - Bias: systematic offset
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    - Reproducibility: closeness of measurements under the same conditions

Gage R&R studies (repeatability & reproducibility)

machine affect on the measurement

human (environment) affect on the measurement

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  - Ability of the measurement system to accurately/precisely measure the characteristic
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Gage R&R studies (**repeatability** & reproducibility)  
machine affect on the measurement  
human (environment) affect on the measurement

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    - **Repeatability: closeness of measurements from same instrument**
    - **Reproducibility: closeness of measurements under the same conditions**

Gage R&R studies (**repeatability** & **reproducibility**)  
**machine** affect on the measurement  
**human (environment)** affect on the measurement

# MEASUREMENT FUNDAMENTALS

- Capability
  - Ability of the measurement system to accurately/precisely measure the characteristic
    - Bias: systematic offset
    - Linearity: equally increasing increments
    - Stability: change in bias over time (i.e. drift)
    - Repeatability: closeness of measurements from same *instrument*
    - Reproducibility: closeness of measurements under the same *conditions*

Also known as

Measurement System Analysis (MSA) or Gage R&R

*Looking at measurement system to ensure the results can be trusted.*

# METROLOGY PROGRAM

- **Measurement Fundamentals**

- Methods
- Equipment specifications
- Quality (Confidence)
- Environmental Controls
- System
- Capability
- **Standards Usage**
- Data

# MEASUREMENT FUNDAMENTALS

- Standards Usage
  - Traceability for materials used
  - Expect equipment to be ready for use
  - Depends on Industry and what is being measured

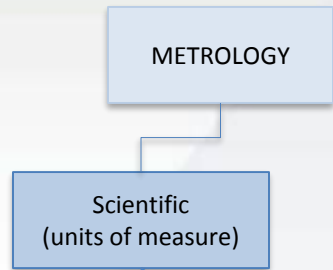
# MEASUREMENT FUNDAMENTALS

- Standards Usage (Traceability)
  - Per ISO/IEC 17025:2005, 5.6.2.1.1: “..For calibration laboratories, the programme for calibration of equipment shall ... ensure that calibrations and measurements ... are traceable to the International System of Units (SI) ... establishes traceability ... by means of an unbroken chain of calibrations or comparisons...”



# MEASUREMENT FUNDAMENTALS

- Standards Usage (Traceability)
  - Per ISO/IEC 17025:2005, 5.6.2.1.1: “by means of an unbroken chain of calibrations or comparisons...”
  - Two sources of standards
    - Bureau International des Poids et Mesures (BIPM)
      - Ensures worldwide uniformity and traceability to SI
    - National Institute of Standards & Technology (NIST)
      - US national standards
      - aka national metrology institute (NMI); highest level of traceability within a country



Quantity	Name	Symbol
Amount of a substance	mole	mol
Electric current	ampere	A
Length	meter	m
Luminous intensity	candela	cd
Mass	kilogram	kg
Temperature	kelvin	K
Time	second	s

# MEASUREMENT FUNDAMENTALS

- Standards Usage (Traceability)
  - Unbroken chain from user device to SI unit



METROLOGY

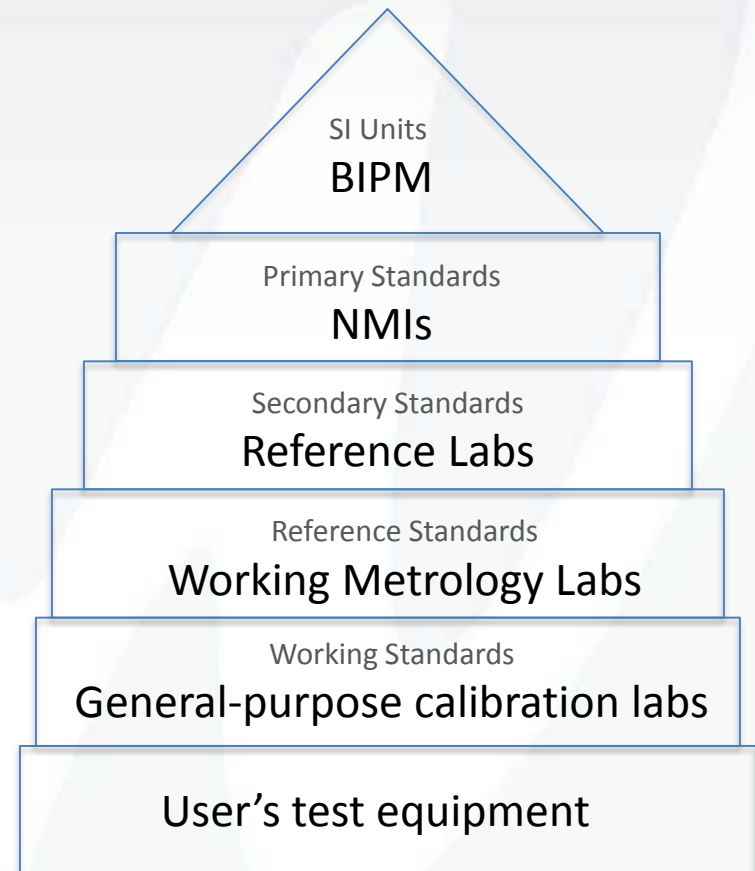
Scientific  
(units of measure)

SI Unit(s)

Quantity	Name	Symbol
Amount of a substance	mole	mol
Electric current	ampere	A
Length	meter	m
Luminous intensity	candela	cd
<b>Mass</b>	<b>kilogram</b>	<b>kg</b>
Temperature	kelvin	K
Time	second	s

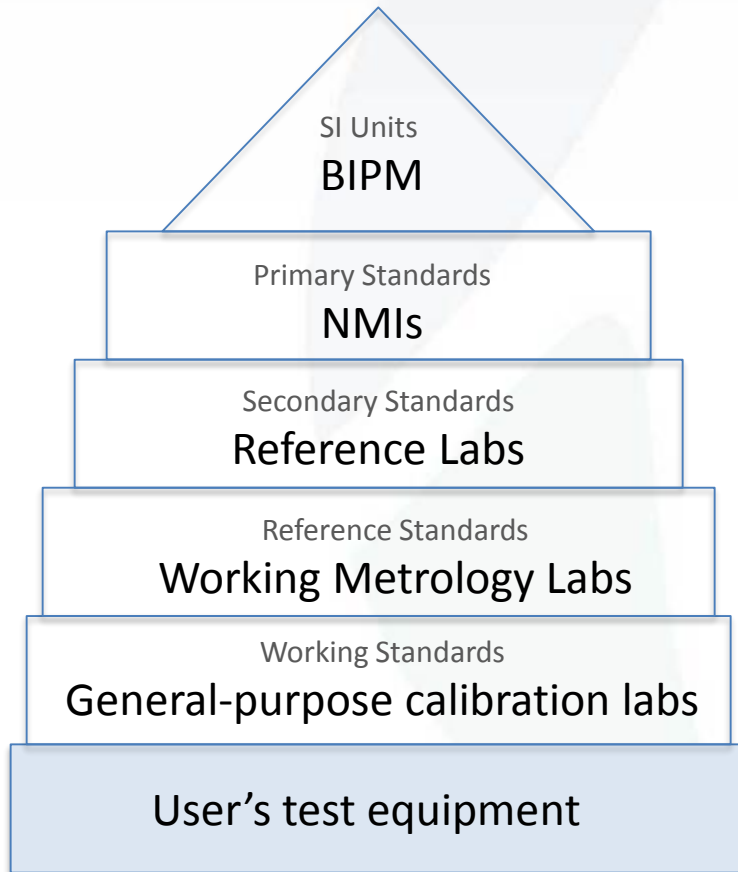
# MEASUREMENT FUNDAMENTALS

- Standards Usage  
(Traceability)
  - Unbroken chain from user device to SI unit



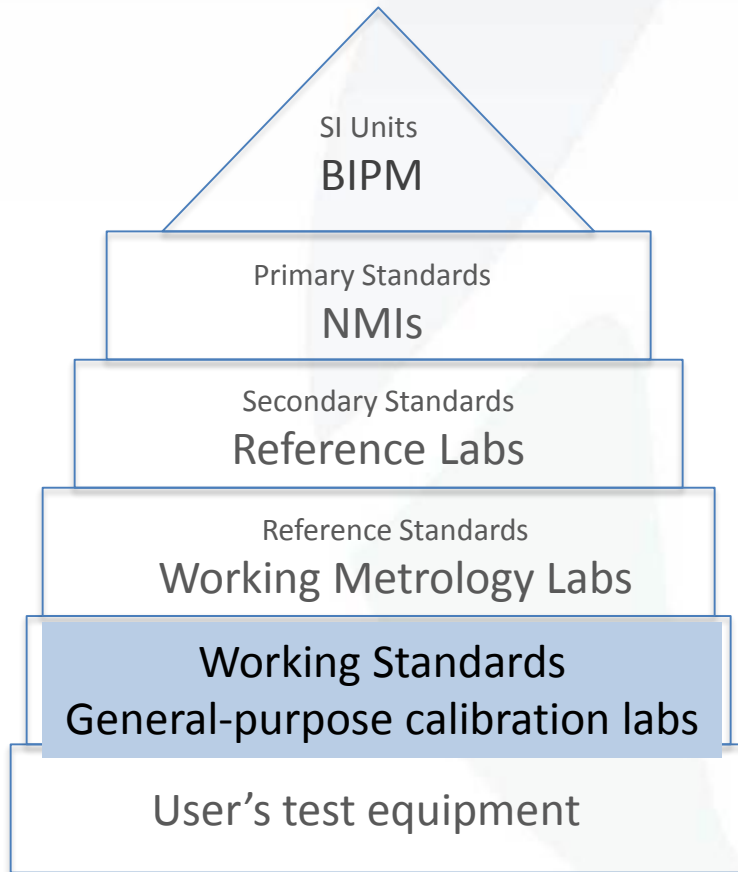
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- Standards Usage (Traceability)
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# MEASUREMENT FUNDAMENTALS

- Standards Usage (Traceability)
  - Unbroken chain from user device to SI unit

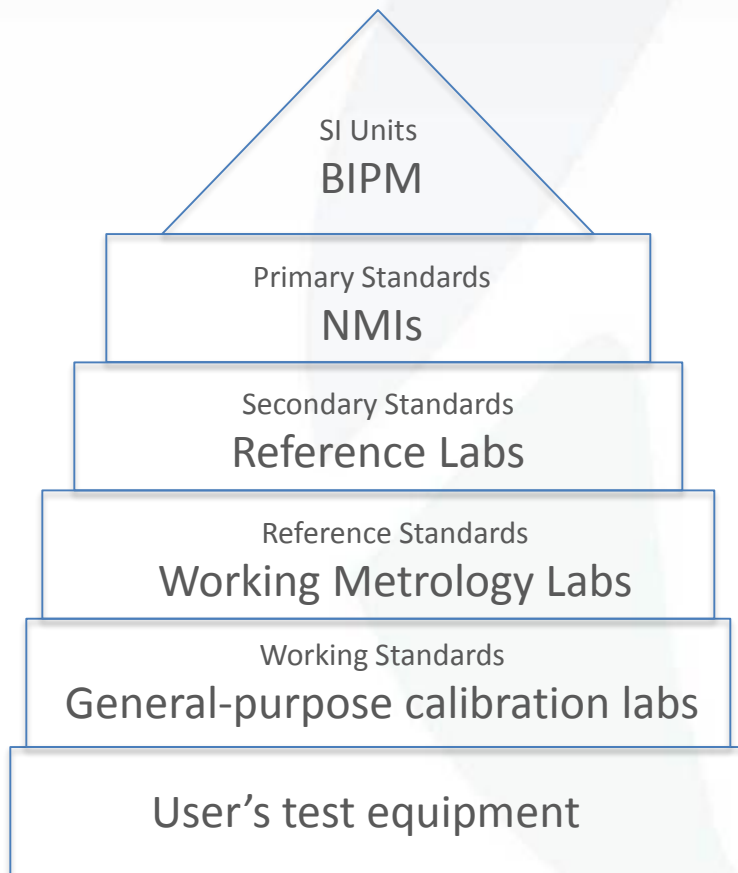


Calibrated weight set



# MEASUREMENT FUNDAMENTALS

- Standards Usage (Traceability)
  - Unbroken chain from user device to SI unit

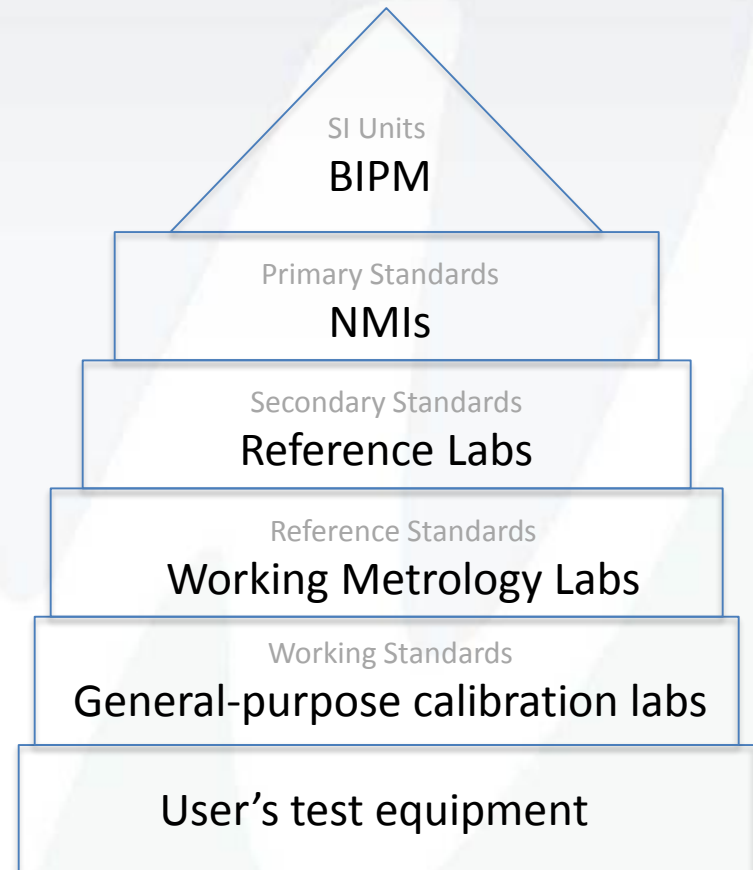


Traceable to NIST  
National Institute of Standards & Technology

- US national standards
- National metrology institute (NMI);

# MEASUREMENT FUNDAMENTALS

- Standards Usage  
(Traceability)
  - Unbroken chain from user device to SI unit
  - Documentation (certificate)







# Example weight certificate

# MEASUREMENT FUNDAMENTALS

- Standards Usage  
(Traceability)

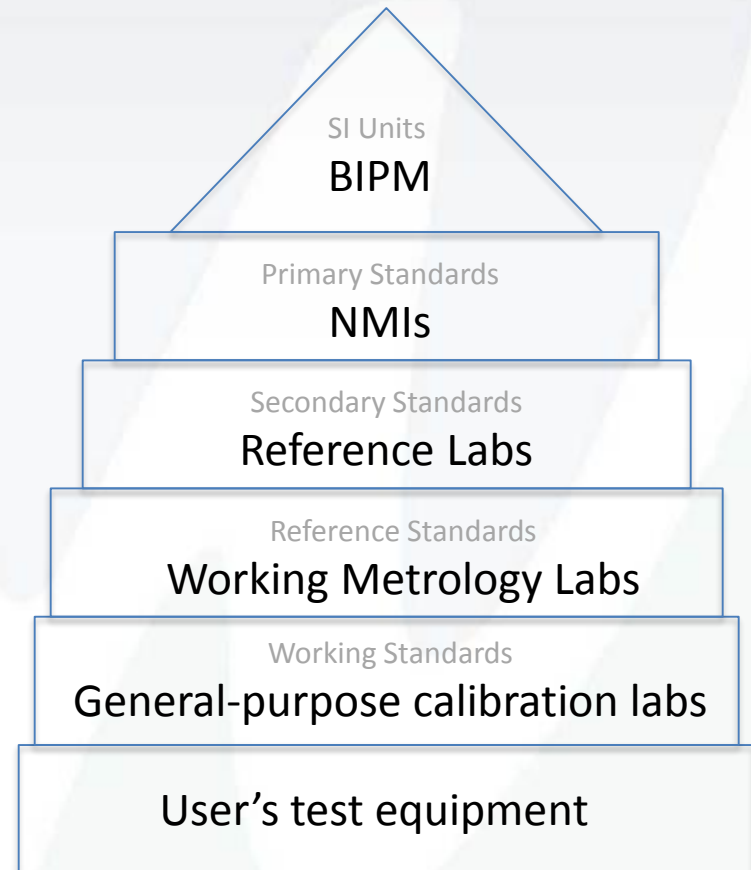
- Unbroken chain from user device to SI unit
- Documentation (certificate)
- Test Uncertainty Ratio (TUR)

stated accuracy of standard

---

stated accuracy of device  
under test

- 10:1 desired
- 4:1 acceptable



# MEASUREMENT FUNDAMENTALS

- Standards Usage
  - Traceability for materials used
  - Expect equipment to be ready for use
  - Depends on Industry and what is being measured
    - ❖ Dimensional
    - ❖ Materials Testing
    - ❖ Functional
    - ❖ Electrical
    - ❖ Etc.


# MEASUREMENT FUNDAMENTALS

- Standards Usage
  - Depends on Industry and what is being measured
    - ❖ Dimensional
    - ❖ Materials Testing
    - ❖ Functional
    - ❖ Electrical
    - ❖ Etc.
- Chemical Testing
  - pH meter
  - Standard (calibration) curves
- Verification of readiness at time of use
  - Regulatory requirements
    - Weights
    - Pipettors

# METROLOGY PROGRAM

- **Measurement Fundamentals**

- Methods
- Equipment specifications
- Quality (Confidence)
- Environmental Controls
- System
- Capability
- Standards Usage



**How to Trust  
the results**

# MEASUREMENT FUNDAMENTALS

Develop a measurement program

i.e. Juice boxes, prescription tablet,

or - pick something from your work history

# METROLOGY PROGRAM

- **Measurement Fundamentals**

- Methods
- Equipment specifications
- Quality (Confidence)
- Environmental Controls
- System
- Capability
- Standards Usage
- **Data**

# MEASUREMENT FUNDAMENTALS

- Data
    - Measurement results (data) used to make decisions
    - Type and quality provide adequate information about application
    - Measurement System units
      - Metric
      - English (US)
    - Unit Conversions
      - Dimensional Analysis Method
- original quantity \* conversion factor = equivalent quantity
- Example: 1 in = 25.4 mm  
1 L = 33.81 oz



# Unit Conversion

- Dimensional Analysis Method

original quantity \* conversion factor = equivalent quantity

0.695 in = ?? mm

1 in = 25.4 mm

$$0.695 \cancel{\text{in}} * \frac{25.4 \text{ mm}}{\cancel{\text{in}}} = 17.7 \text{ mm}$$

# Unit Conversion

- Dimensional Analysis Method

original quantity \* conversion factor = equivalent quantity

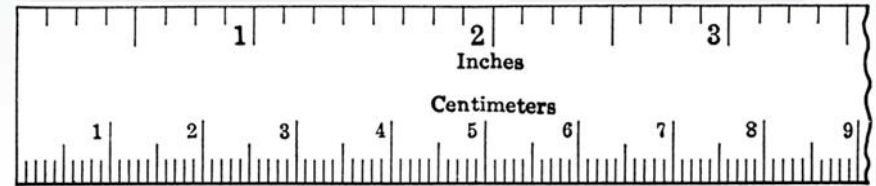
0.695 in = ?? mm

1 mm = 0.039 in

# MEASUREMENT FUNDAMENTALS

- Data
  - Measurement results (data) used to make decisions
  - Type and quality provide adequate information about application
  - Measurement System units (metric vs. english (US))
  - **Measurements are taken and recorded as required by the specification**
    - If specification uses metric system, measure using metric tools

# MEASUREMENT FUNDAMENTALS



# MEASUREMENT FUNDAMENTALS

- Data

- Measurement results (data) used to make decisions
- Type and quality provide adequate information about application
- Measurement System units (metric vs. english (US))
- Measurements are taken and recorded as required by the specification
  - If specification uses metric system, measure using metric tools
  - Record the number of digits required by specification and accuracy of the tool used
    - As directed by method (SOP)
    - 10:1 rule
    - Rounding

# MEASUREMENT FUNDAMENTALS

- Data
  - Measurements are taken and recorded as required by the specification
    - Rounding Rules
    - Rounding off: Process by which one reduces the number of figures in a value
      - If  $< 5$ , “round” down
      - If  $\geq 5$ , “round” up

Example – recording micrograms (0.000 g), balance displays 5 digits

0.06739 g    0.06751g    0.06791g

# MEASUREMENT FUNDAMENTALS

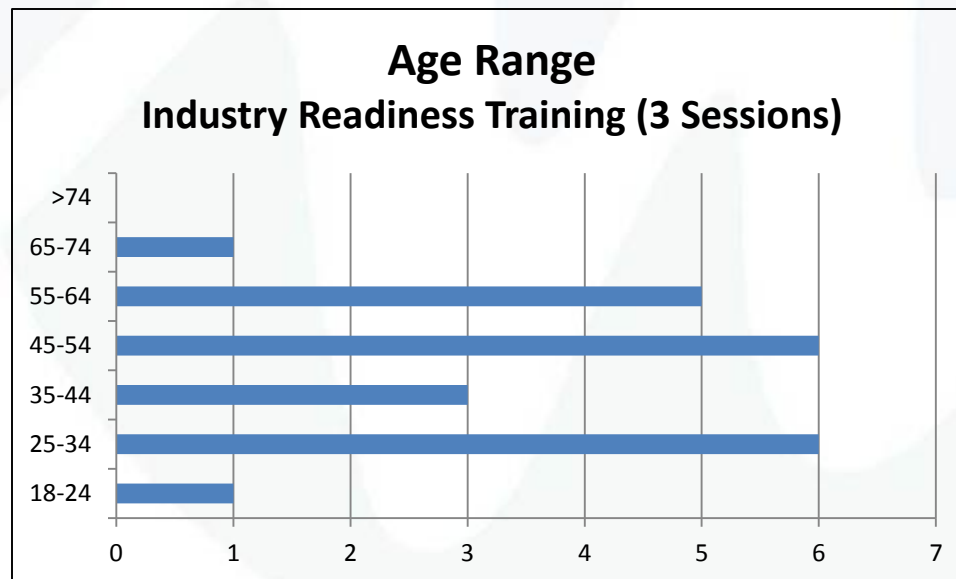
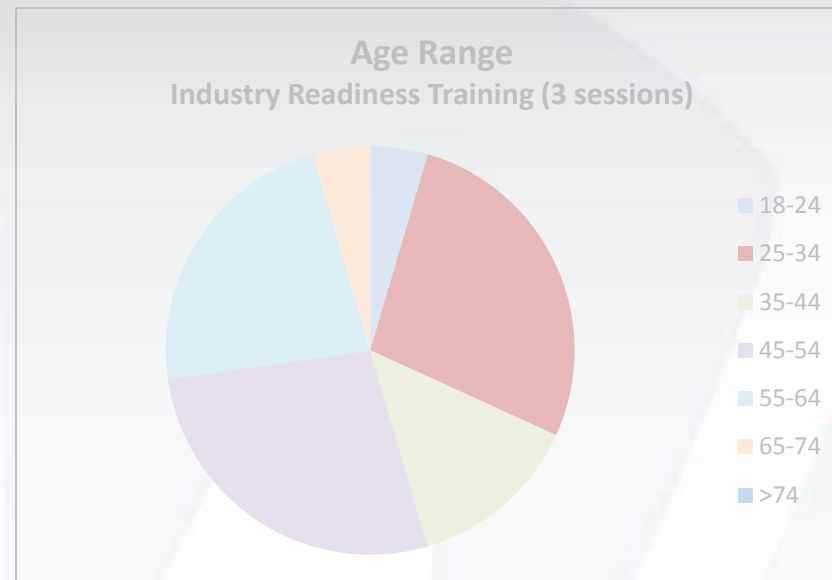
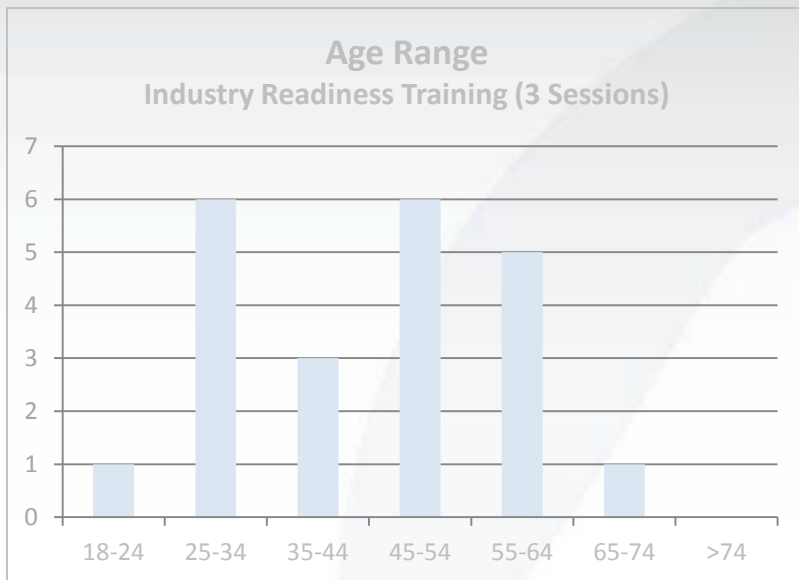
- Data

- Measurement results (data) used to make decisions
- Type and quality provide adequate information about application
- Measurement System units (metric vs. english (US))
- Measurements are taken and recorded as required by the specification
- Considerations
  - Format
  - Resolution
  - Readability
  - Suitability
  - Confidentiality

# MEASUREMENT FUNDAMENTALS

- Data
  - Measurement results (data) used to make decisions
  - Type and quality provide adequate information about application
  - Measurement System units (metric vs. english (US))
  - Measurements are taken and recorded as required by the specification
  - Considerations
    - Format: presentation (layout)
      - Graphically, table, number convention, font, etc.





# MEASUREMENT FUNDAMENTALS

- Data

- Measurement results (data) used to make decisions
- Type and quality provide adequate information about application
- Measurement System units (metric vs. english (US))
- Measurements are taken and recorded as required by the specification
- Considerations
  - Format: presentation (layout)
  - Resolution: least significant digit distinguishable  
0.001 vs 0.0001 vs 0.00001

# MEASUREMENT FUNDAMENTALS

- Resolution: least significant digit distinguishable  
0.001 vs 0.0001 vs 0.00001

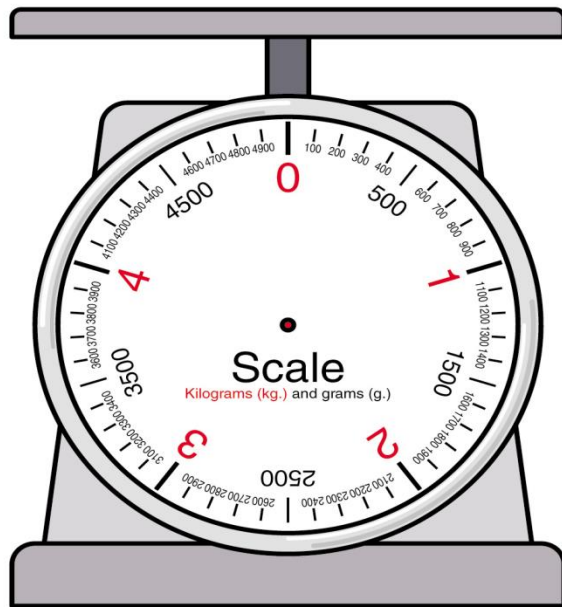


# MEASUREMENT FUNDAMENTALS

- Data
  - Measurement results (data) used to make decisions
  - Type and quality provide adequate information about application
  - Measurement System units (metric vs. english (US))
  - Measurements are taken and recorded as required by the specification
  - Considerations
    - Format: presentation (layout)
    - Resolution: least significant digit distinguishable
    - Readability: presentation, ease of observer interpretation
      - Digital vs manual readout

# MEASUREMENT FUNDAMENTALS

- Readability: presentation, ease of observer interpretation
  - Digital vs manual readout



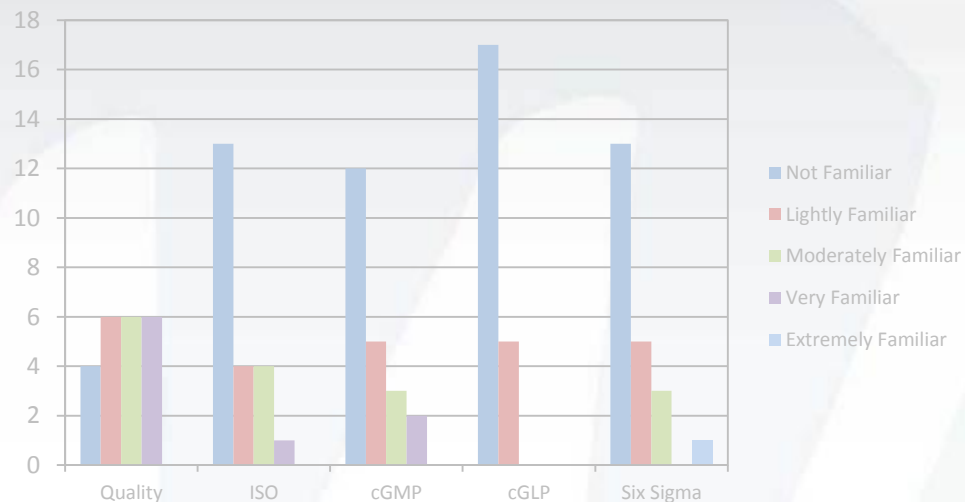
# MEASUREMENT FUNDAMENTALS

- Data

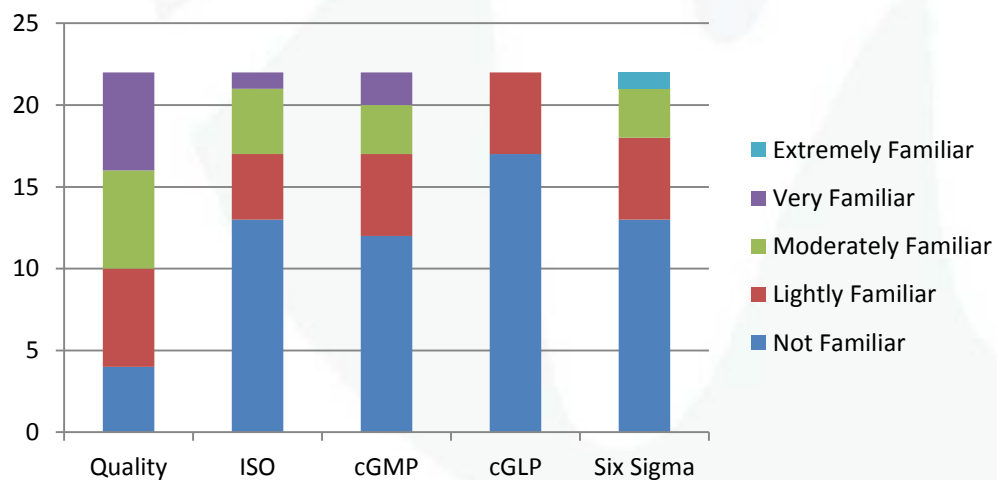
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- Measurements are taken and recorded as required by the specification
- Considerations
  - Format: presentation (layout)
  - Resolution: least significant digit distinguishable
  - Readability: presentation, ease of observer interpretation
    - Digital vs manual readout
    - Graph vs table of numbers

	Quality	ISO	cGMP	cGLP	Six Sigma
Not Familiar	4	13	12	17	13
Lightly Familiar	6	4	5	5	5
Moderately Familiar	6	4	3		3
Very Familiar	6	1	2		
Extremely Familiar					1

**Quality System Familiarity**  
Industry Readiness Training (3 Sessions)



**Quality System Familiarity**  
Industry Readiness Training (3 Sessions)



# MEASUREMENT FUNDAMENTALS

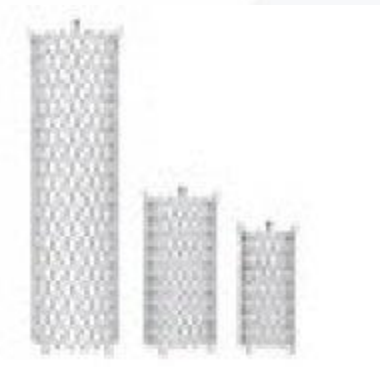
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- Measurement System units (metric vs. english (US))
- Measurements are taken and recorded as required by the specification
- Considerations
  - Format: presentation (layout)
  - Resolution: least significant digit distinguishable
  - Readability: presentation, ease of observer interpretation
  - Suitability: consider application derived from and intent of how it will be used
    - seldom occurring small changes over time



# MEASUREMENT FUNDAMENTALS

- Data
  - Suitability: consider application derived from and intent of how it will be used



Medical Stents

Evaluated 1" product manufactured from stainless steel

Want to use this data for a 3" product manufactured from polyethersulfone (plastic)

Not a good idea - different material; different size

# MEASUREMENT FUNDAMENTALS

- Data

- Measurement results (data) used to make decisions
- Type and quality provide adequate information about application
- Measurement System units (metric vs. english (US))
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- Considerations
  - Format: presentation (layout)
  - Resolution: least significant digit distinguishable
  - Readability: presentation, ease of observer interpretation
  - Suitability: consider application derived from and intent of how it will be used
  - Confidentiality: protection of results and the source (unauthorized disclosure)

# MEASUREMENT FUNDAMENTALS

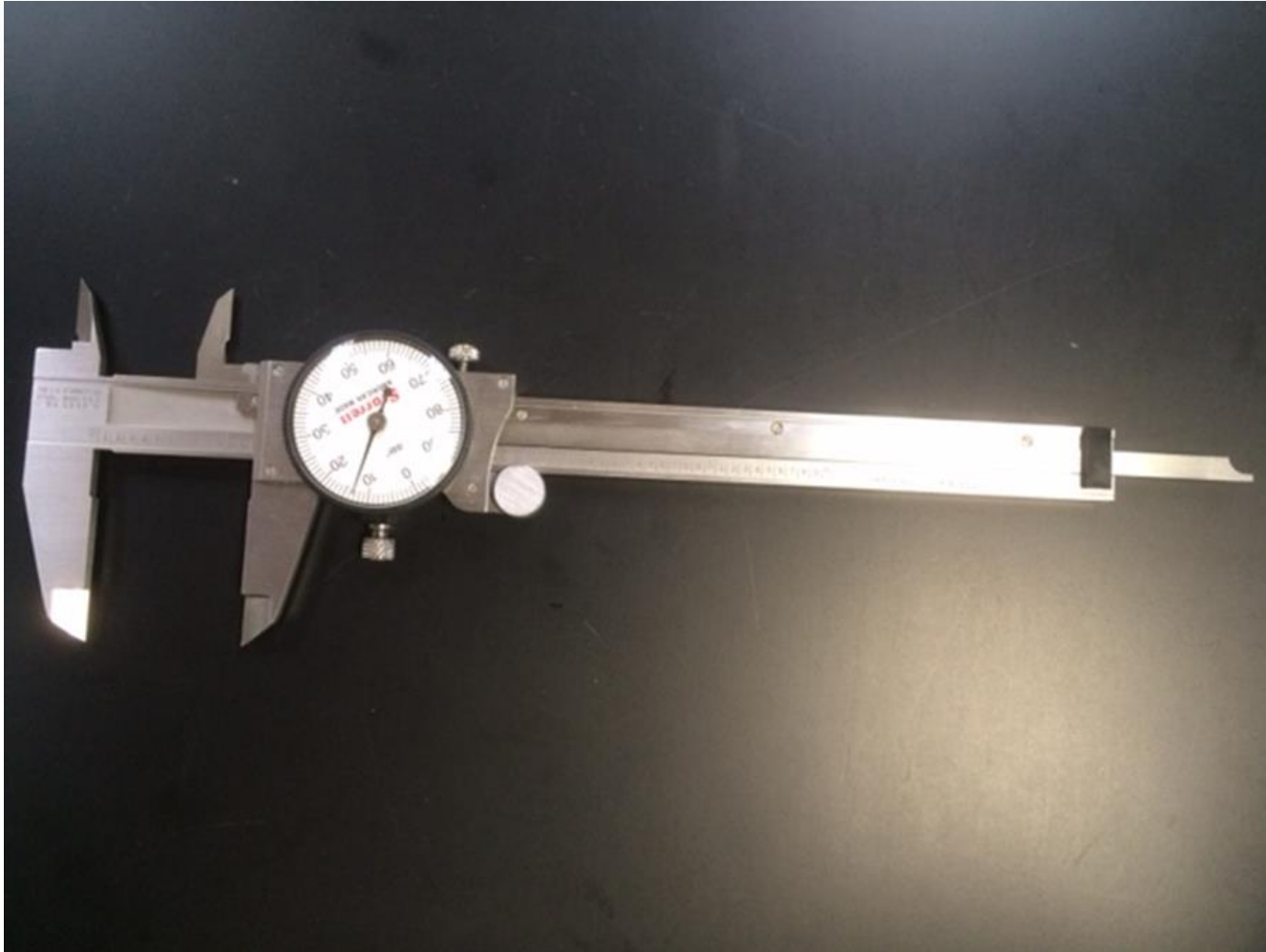
- Methods
- System
- Capability
- Equipment specifications
- Environmental Controls
- Standards Usage
- Confidence (Uncertainty) Programs
- Data

Consideration of the entire system is essential to ensure that measurements provide data needed to make informed, appropriate decisions

*How to trust the results*

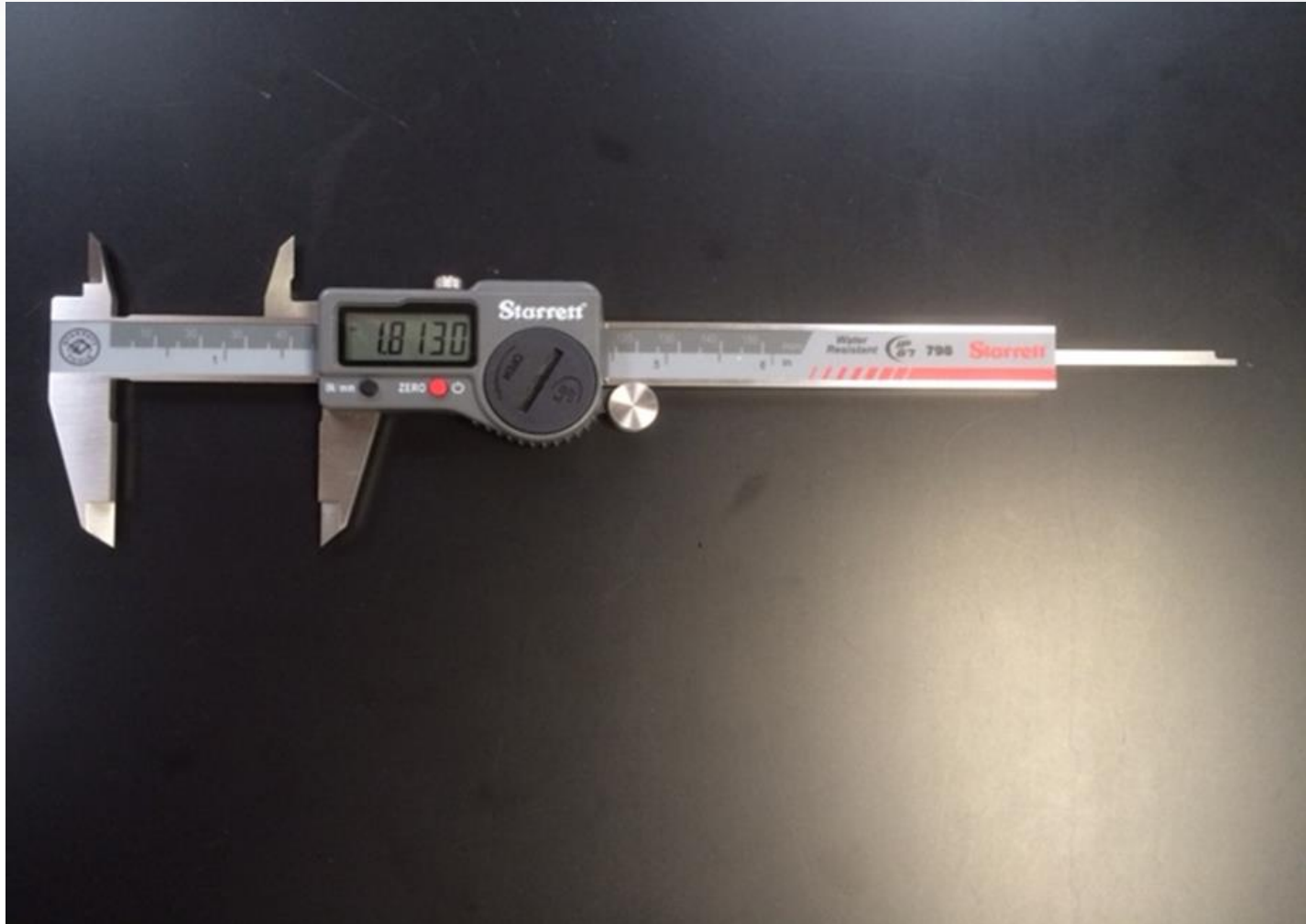
# Measuring Instruments

## DIAL CALIPERS



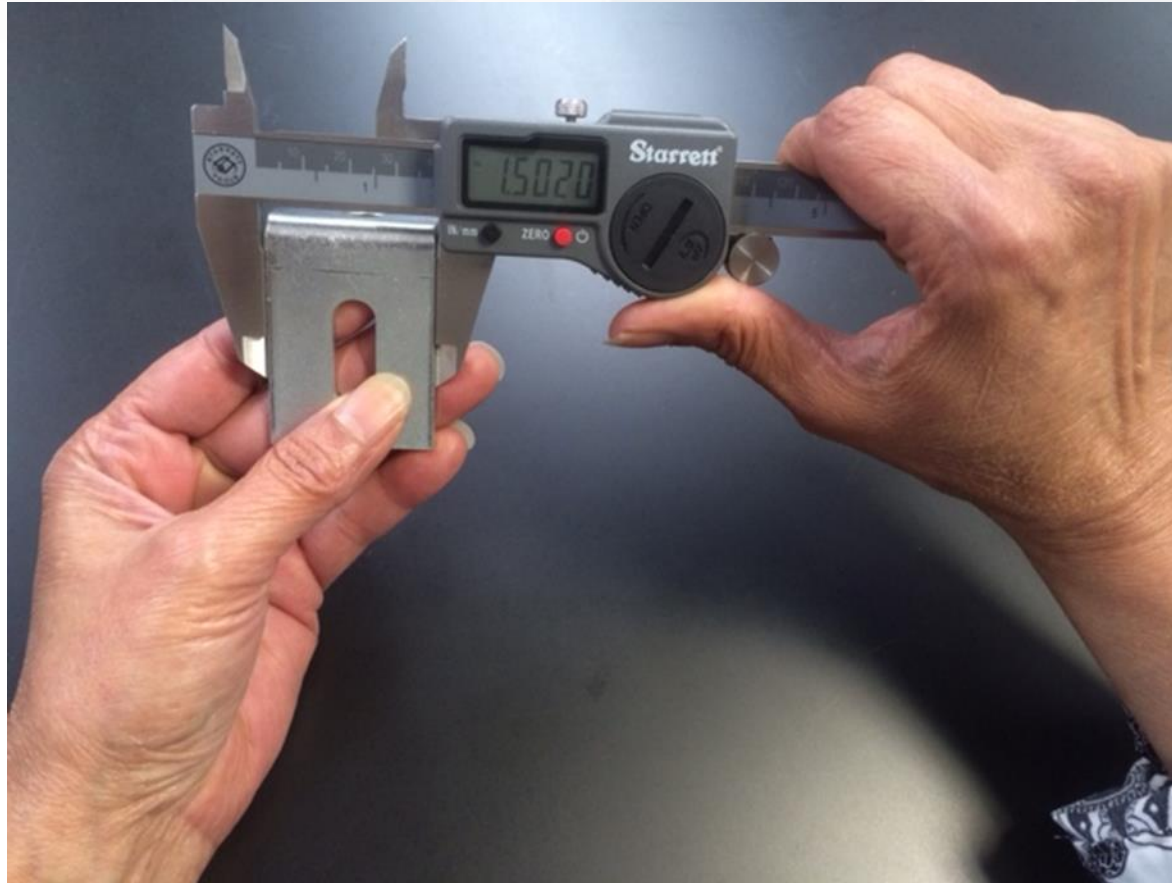
# Measuring Instruments

## DIGITAL CALIPERS



# Measuring Instruments

## DIGITAL CALIPERS



# Measuring Instruments

## MICROMETER





# Measuring Instruments

## DIGITAL MICROMETER





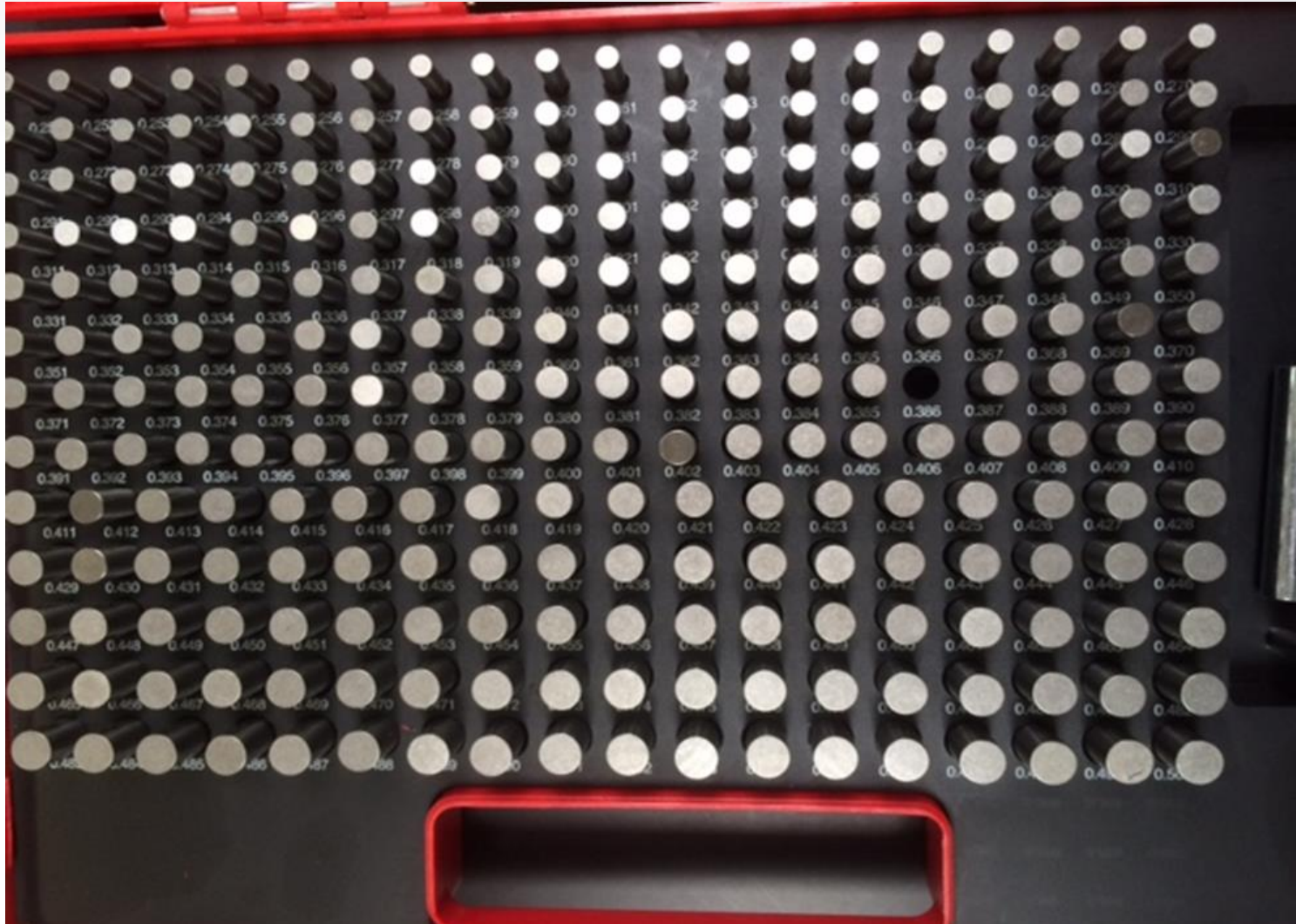
# Measuring Instruments

## DIGITAL MICROMETER



# Measuring Instruments

## PRECISION PIN GAGES



# Measuring Instruments

## PRECISION PIN GAGES





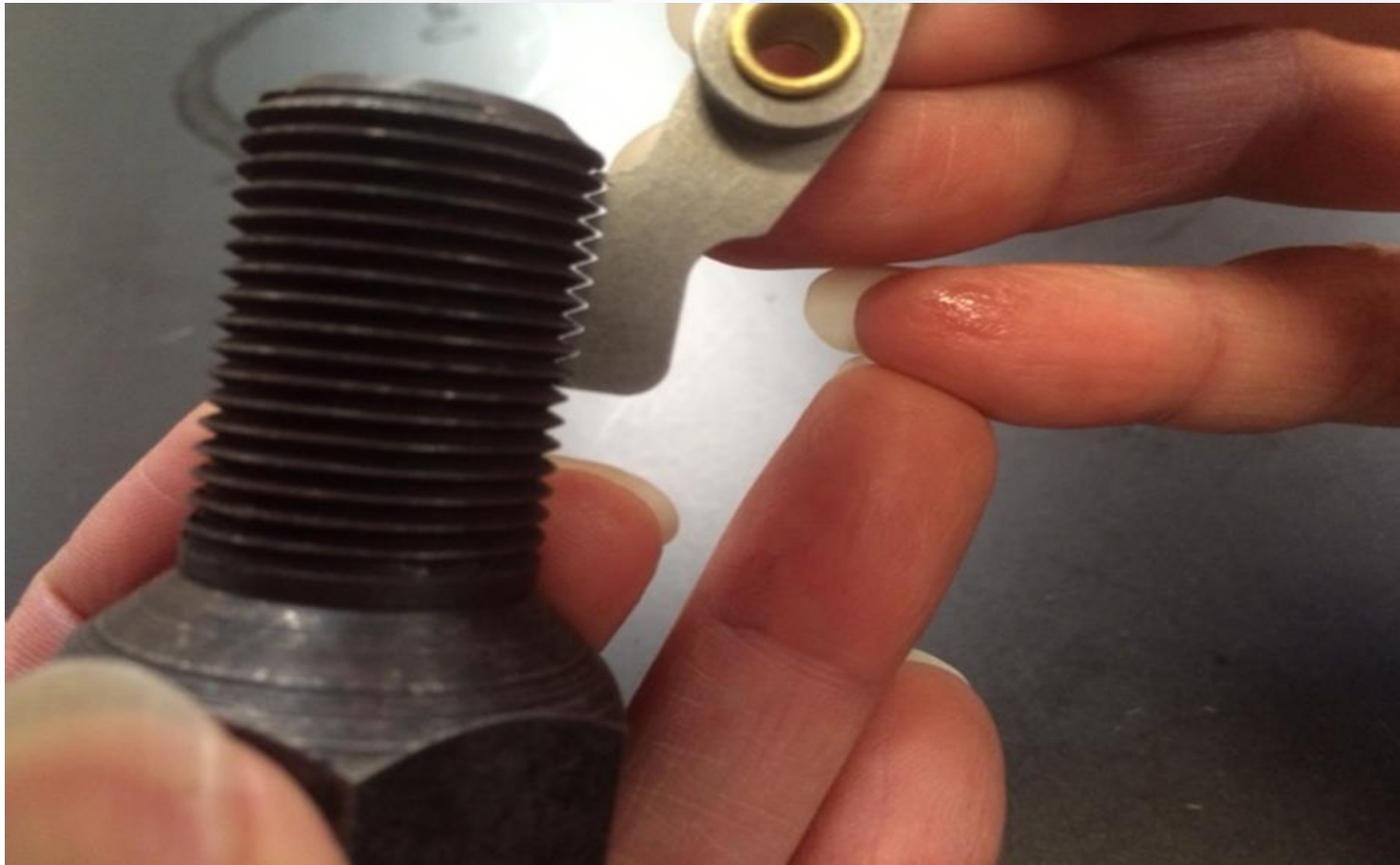
# Measuring Instruments

## THREAD GAGE



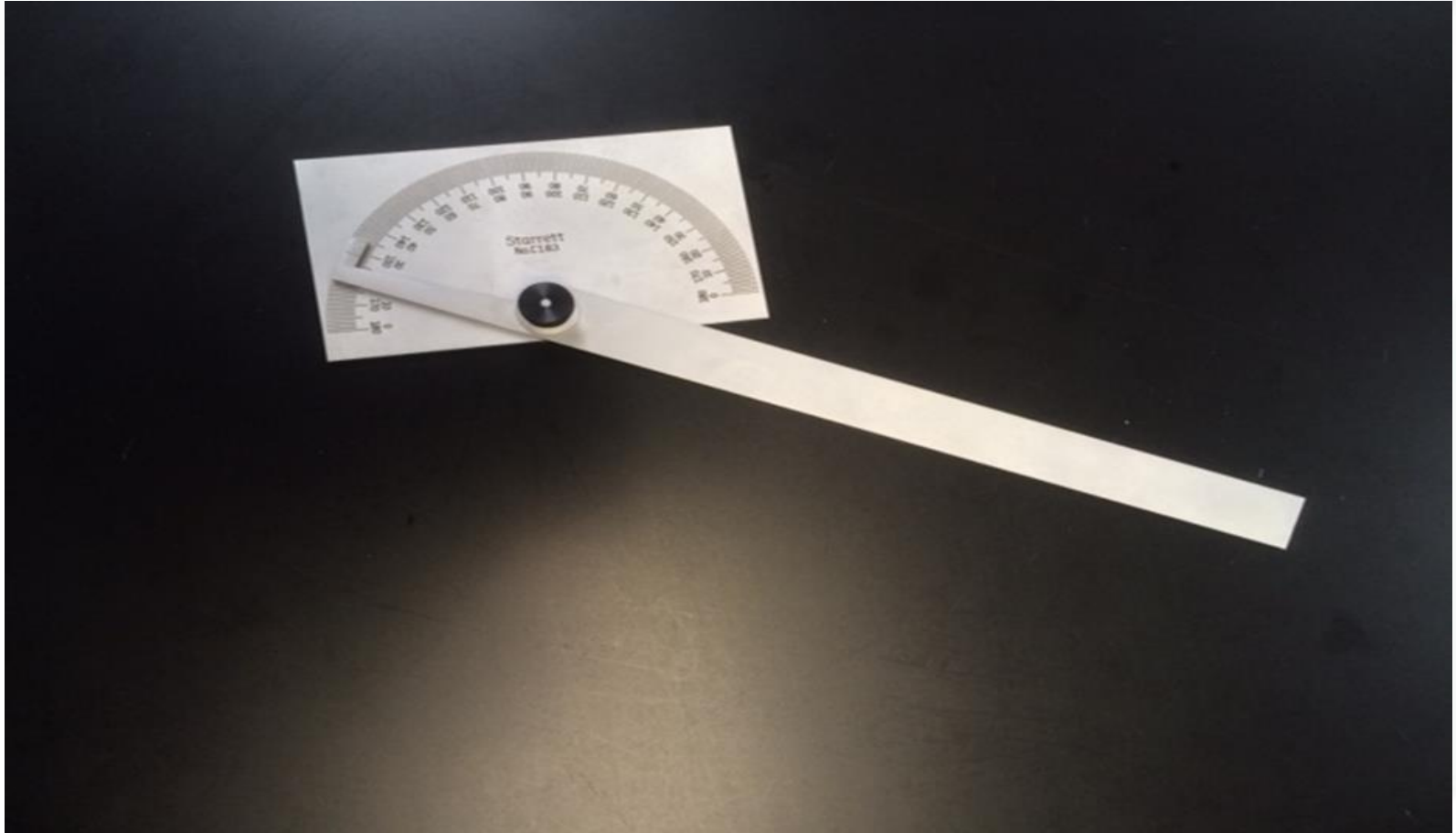
# Measuring Instruments

## THREAD GAGE



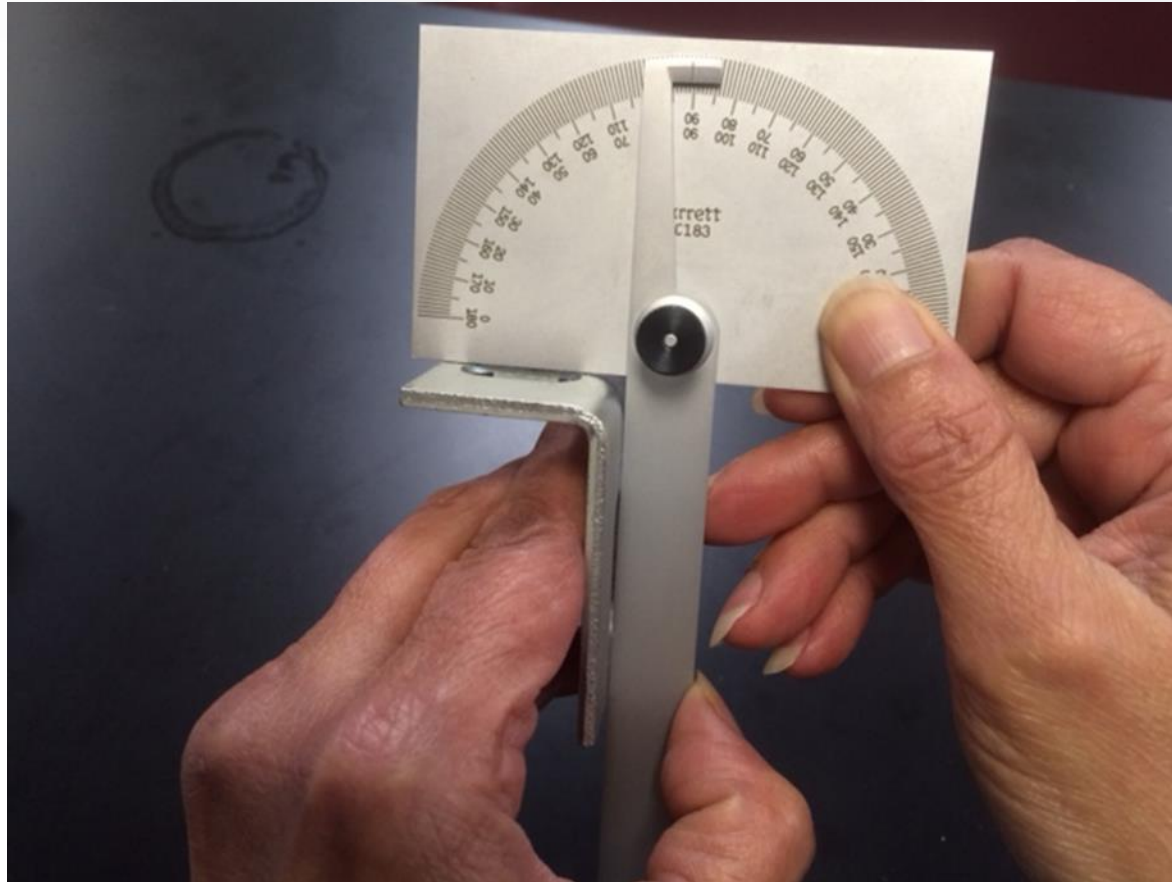
# Measuring Instruments

## PROTRACTOR



# Measuring Instruments

## PROTRACTOR







# MODULE 2: METROLOGY (MEASUREMENT CONCEPTS)

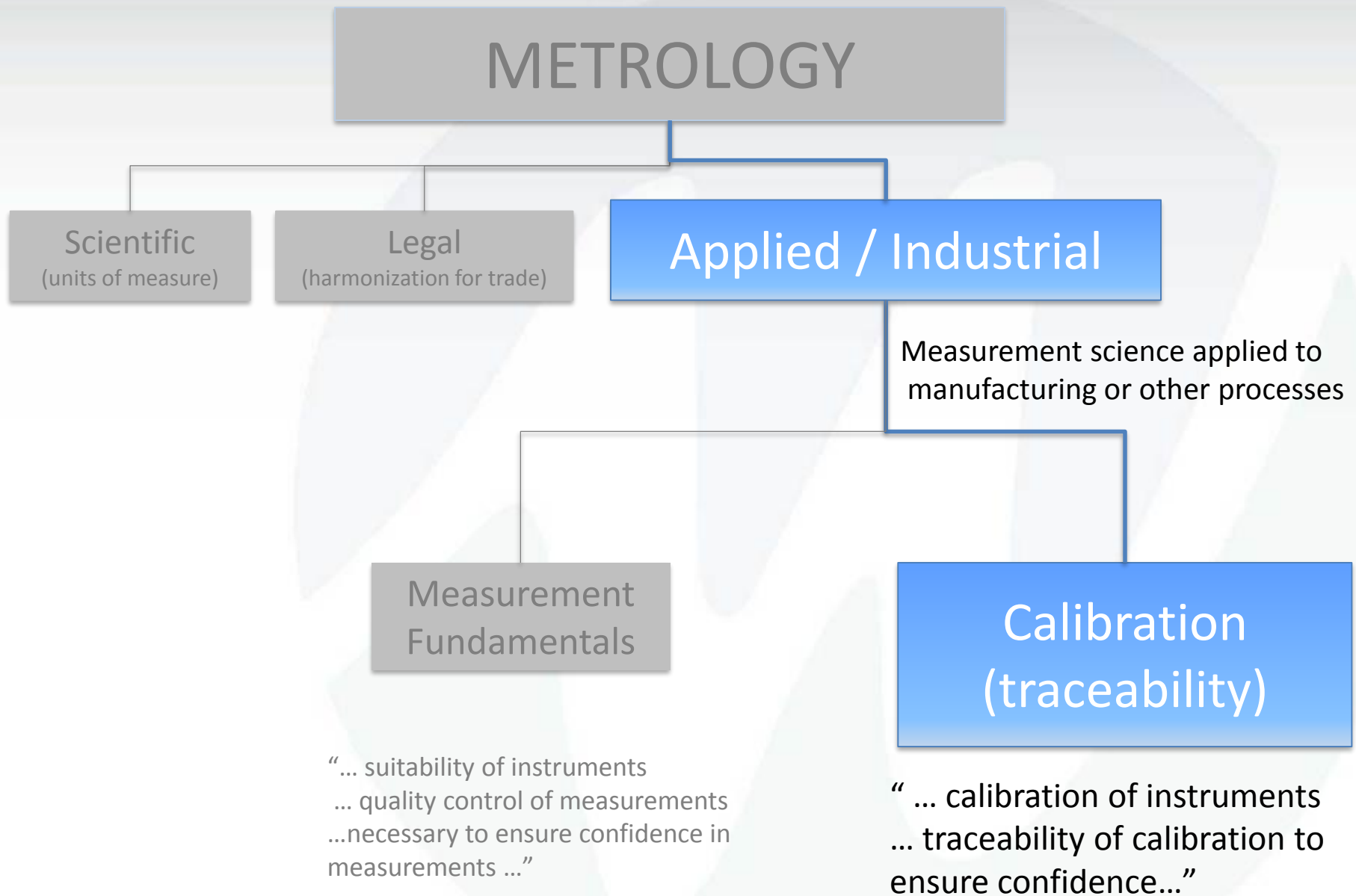
- Specifications
- Measurement Fundamentals
- **Calibration**
- Inspection Systems & Sampling



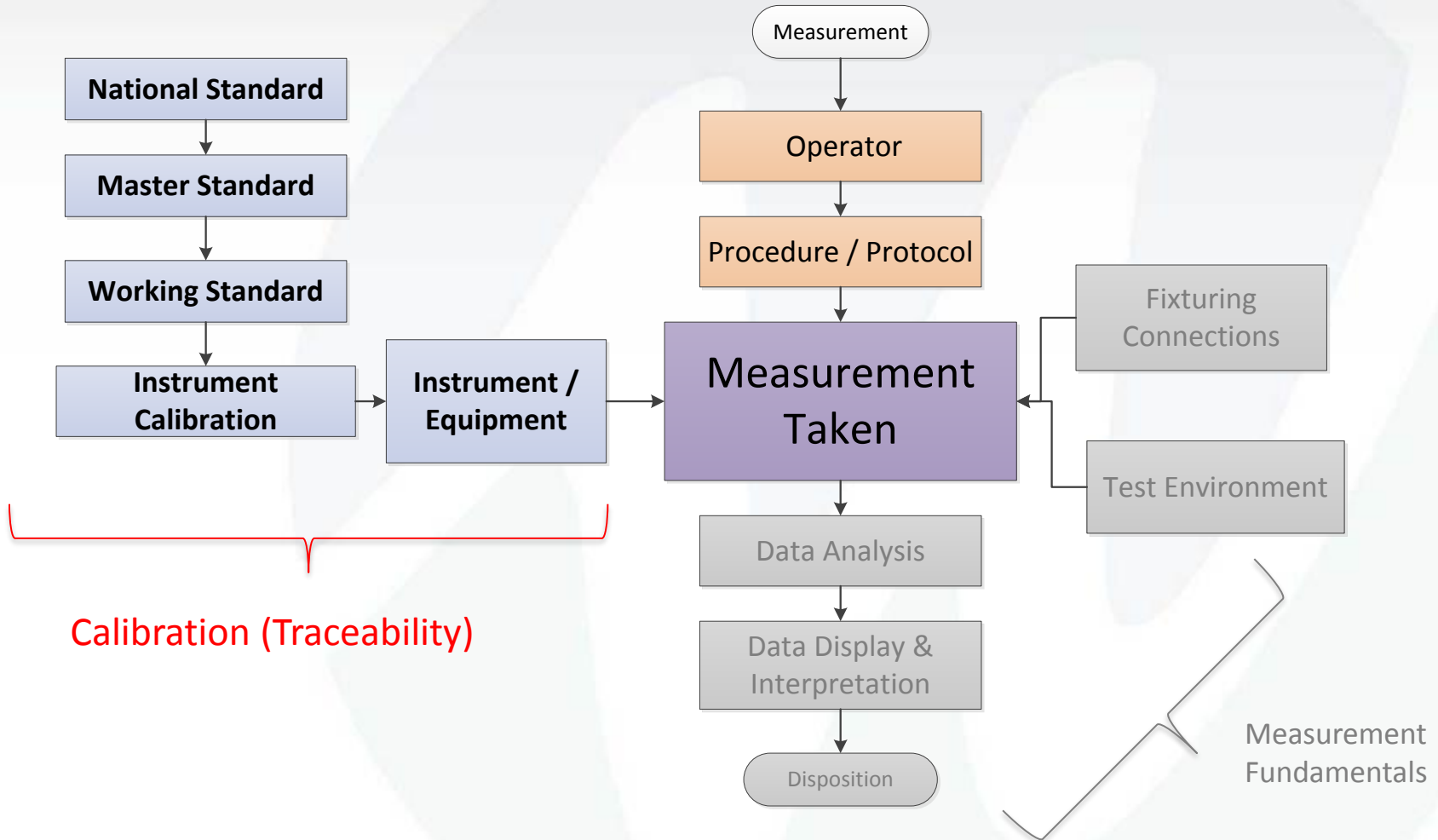
# Review

*Quality is a product (or service) with the features and characteristics which determine desirability and can be controlled to meet certain basic requirements.*

- Measurement is a method for **evaluating** a property or **characteristic** of an object and **describing it with a numerical or nominal value**.



# METROLOGY - Taking a Measurement



Quality Council of Indiana – CCT 2010

# CALIBRATION

- Comparison between measurements:
  - one of known magnitude or correctness
  - another measurement made in as similar a way as possible with a second device.

# ACCURACY vs PRECISION



Accurate but  
not precise



Precise but  
not accurate



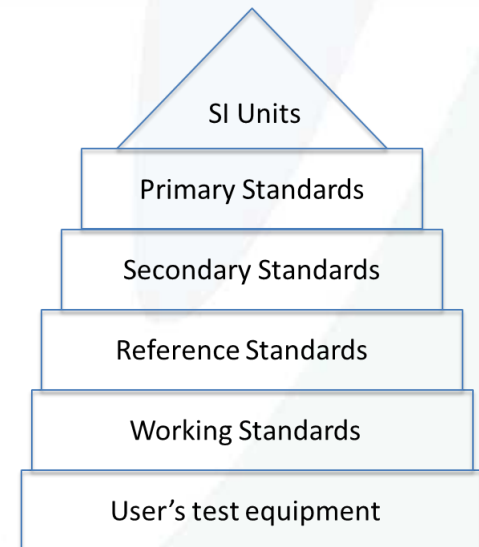
Neither accurate  
nor precise



Accurate  
And  
Precise

# CALIBRATION

- Comparison between measurements:
  - one of known magnitude or correctness
  - another measurement made in as similar a way as possible with a second device.
- Standard = device with known (or assigned) correctness
  - Standard types
    - International
    - National
    - Secondary
    - Reference
    - Working
- Unit under test = second device



# CALIBRATION

- ANSI/ISO/IEC 17025:2005 General Requirements for the Competence of **Testing and Calibration** Laboratories
  - implement a quality system aimed at improving ability to consistently produce valid results.
  - basis for accreditation from an accreditation body.
  - standard is about competence, accreditation is simply formal recognition of a demonstration of that competence
    - In many cases, suppliers and regulatory authorities will not accept test or calibration results from a lab that is not accredited.

Wikipedia.com

*This document is the standard and provides the requirements for a quality management system that can be accredited (a process comparable but different from certification). It encompasses all aspects of the laboratory.*



# CALIBRATION

- ISO 10012:2003(E) Measurement Management Systems – **Requirements** for Measurement **Processes** and Measuring **Equipment**
  - “... provides guidance for the management of measurement process and metrological confirmation of measuring equipment used to support and demonstrate compliance with metrological requirements...”

Wikapeida.com

*This is a guidance document for implementation, but is not used for registration/certification of the laboratory.*

# METROLOGY PROGRAM

- **Calibration System**
  - Adequacy of equipment & standards
  - Procedures (Methods)
  - Internal Process / External Vendor program
  - Intervals
  - Uncertainty (Confidence)
  - Scheduling
  - Environmental Controls
  - Software Validation
  - Labels
  - Measurement Traceability
- Similar to measurement fundamentals

# METROLOGY PROGRAM

- **Calibration System**

- Internal Process / External Vendor program
- Procedures (Methods)
- Adequacy of equipment & standards
- Measurement Traceability
- Quality (Confidence)
- Environmental Controls
- Software Validation
- Intervals
- Scheduling
- Labels

- **Measurement Fundamentals**

- Methods
- System
- Capability
- Equipment specifications
- Environmental Controls
- Standards Usage
- Quality (Confidence)
- Data

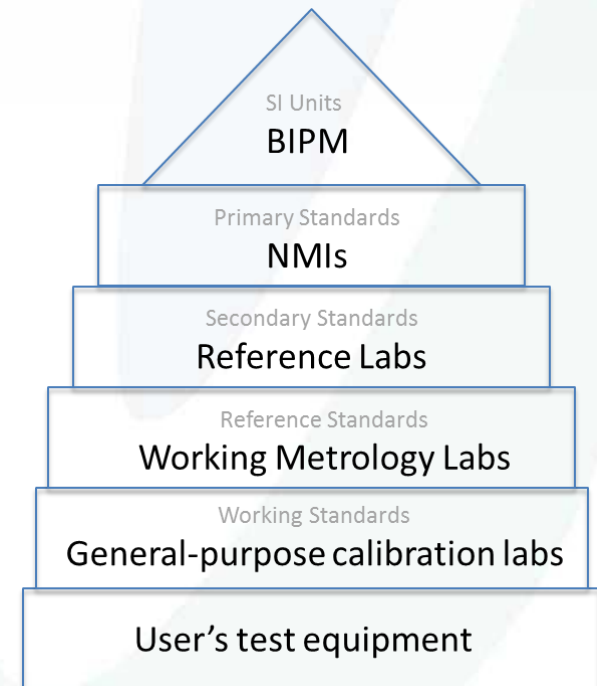
*Discussion will be regarding a calibration system (program) as it applies to a manufacturer*

# METROLOGY PROGRAM

- Calibration System
  - **Internal Process / External Vendor program**
  - Procedures (Methods)
  - Adequacy of equipment & standards
  - Measurement Traceability
  - Uncertainty (Confidence)
  - Environmental Controls
  - Software Validation
  - Intervals
  - Scheduling
  - Labels

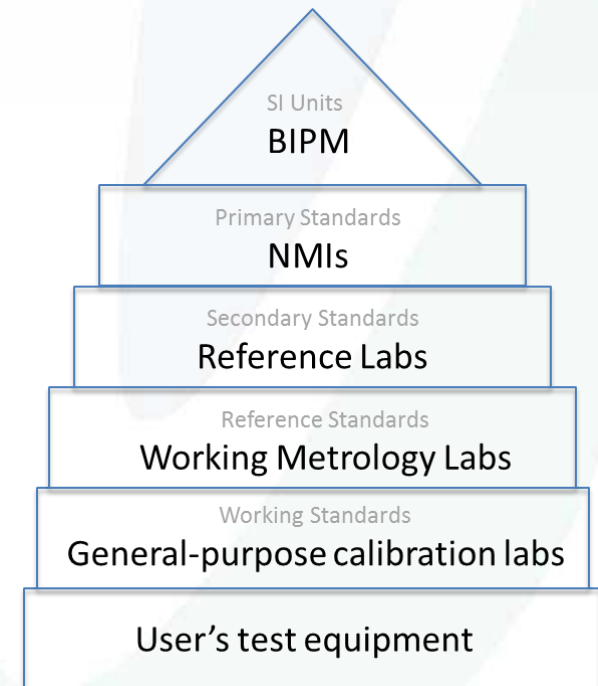
# CALIBRATION SYSTEM

- Adequacy of equipment & standards
- Procedures (Methods)
- **Internal Process** / External Vendor program
  - Typically working standards used for product / process
  - Reference standards may be available within Calibration department for use on working standards



# CALIBRATION SYSTEM

- Adequacy of equipment & standards
- Procedures (Methods)
- **Internal Process** / External Vendor program
  - Typically working standards used for product / process
  - Reference standards may be available within Calibration department for use on working standards
  - Reference standards then sent out or serviced in place for their calibration



# CALIBRATION SYSTEM

- Adequacy of equipment & standards
- Procedures (Methods)
- Internal Process / External Vendor program
  - Considered supplier of critical service
  - Accreditation and/or compliance
    - ISO 17025:2005
    - AL2A
  - Qualified per SOP and listed on approved vendor list
  - Send device or service on-site
    - Transportation
    - Contractor

# CALIBRATION SYSTEM

- Adequacy of equipment & standards
- Procedures (Methods)
- Internal Process / External Vendor program
  - Considered supplier of critical service
  - Accreditation and/or compliance
    - ISO 17025:2005
    - AL2A
  - Qualified per SOP and listed on approved vendor list
  - Send device or service on-site
  - Provides report
    - Methodology used with reference (i.e. ASTM, ANSI, etc)
    - Results: Certificate of Calibration
      - As Found/As Left, Range tested, results of testing (individual data points)
      - Uncertainty, measurement conditions, standard used & traceability
      - Signed & dated



# METROLOGY PROGRAM

- Calibration System
  - Internal Process / External Vendor program
  - **Adequacy of equipment & standards**
  - Procedures (Methods)
  - Measurement Traceability
  - Uncertainty (Confidence)
  - Environmental Controls
  - Software Validation
  - Intervals
  - Scheduling
  - Labels

# CALIBRATION SYSTEM

- Adequacy of equipment & standards
  - Consider accuracy, stability and range
    - Rule of thumb 10:1 ideal (4:1 acceptable, 1:1 if necessary)

*Standard vs Device Under Test*

*Product specification  $1.255 \pm 0.005$  inches*

*calipers used are capable of  $\pm 0.0001$  inches*

*Calibration standard =  $\pm 0.00001$*

# METROLOGY PROGRAM

- Calibration System
  - Internal Process / External Vendor program
  - Adequacy of equipment & standards
  - **Procedures (Methods)**
  - Measurement Traceability
  - Uncertainty (Confidence)
  - Environmental Controls
  - Software Validation
  - Intervals
  - Scheduling
  - Labels

# CALIBRATION SYSTEM

- Adequacy of equipment & standards
- Procedures (Methods)
  - Standard operating procedures and/or work instructions
    - Operation of equipment
    - Performance of calibration

## *Work Instruction or SOP*

- *Purpose*
- *Scope*
- *Equipment Needed*
- *Safety Requirements*
- *Personnel Responsibilities*
- *Procedure*
  - Operation of calibration equipment
  - How to perform calibration
  - Response to Out-of-Tolerance
- *Records*
  - Range calibrated (full, partial)

# CALIBRATION SYSTEM

- Adequacy of equipment & standards
- **Procedures (Methods)**
  - Standard operating procedures and/or work instructions
    - Operation of equipment
    - Performance of calibration
  - **Out-of-Tolerance occurrence (non-conformance)**

# CALIBRATION SYSTEM

- Adequacy of equipment & standards
- Procedures (Methods)
  - Standard operating procedures and/or work instructions
  - **Out-of-Tolerance occurrence (non-conformance)**
    - Directly or indirectly affect process/product/safety
    - Documented investigation required
      - Unique equipment ID number
      - Calibration timing (date, previous, interval)
      - Calibration range / limits
      - Test points and measurement error
      - AS FOUND and AS LEFT
      - Adjustments/repairs
      - Evidence of mishandling, overload, lack of maintenance/cleaning, etc.
      - Interval adjustment (?)
      - Standard(s) used and their calibration date

# CALIBRATION SYSTEM

- Adequacy of equipment & standards
- Procedures (Methods)
  - Standard operating procedures and/or work instructions
  - **Out-of-Tolerance occurrence (non-conformance)**
    - Directly or indirectly affect process/product/safety
    - Documented investigation required
    - **Risk assessment for product**
      - Review investigation results
      - Engineer / Product Manager review

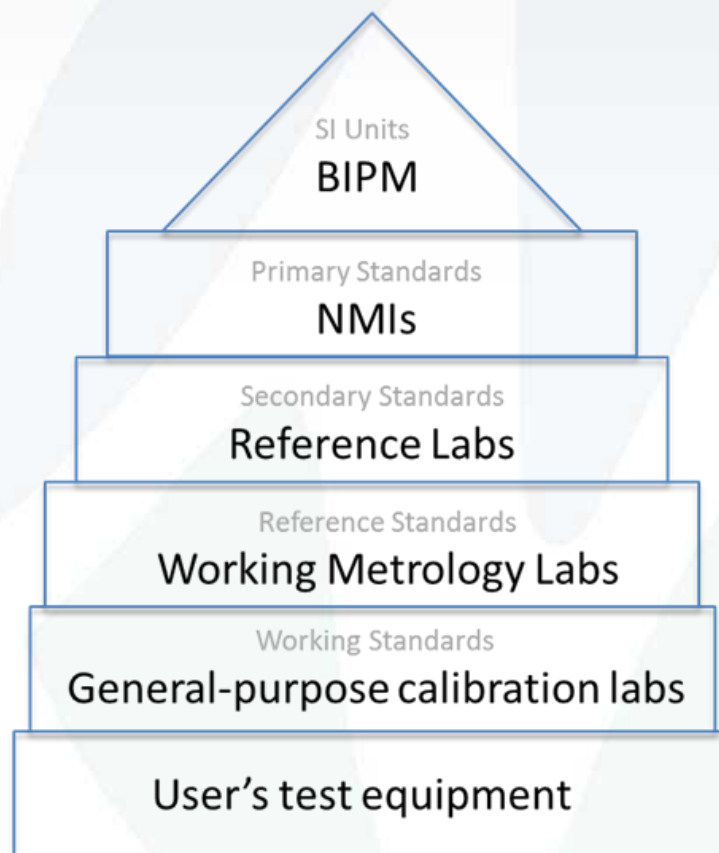
# METROLOGY PROGRAM

- Calibration System
  - Internal Process / External Vendor program
  - Adequacy of equipment & standards
  - Procedures (Methods)
  - **Measurement Traceability**
  - Uncertainty (Confidence)
  - Environmental Controls
  - Software Validation
  - Intervals
  - Scheduling
  - Labels



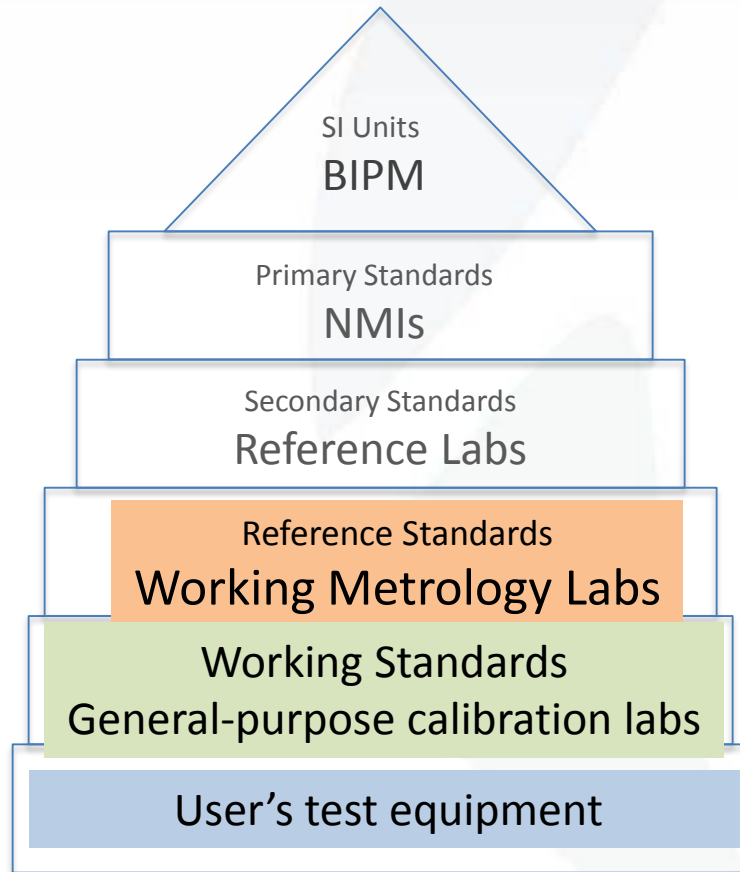
# CALIBRATION SYSTEM

- Measurement Traceability



# CALIBRATION SYSTEM

- Measurement Traceability
  - For measurement equipment need unbroken chain from user device to SI unit

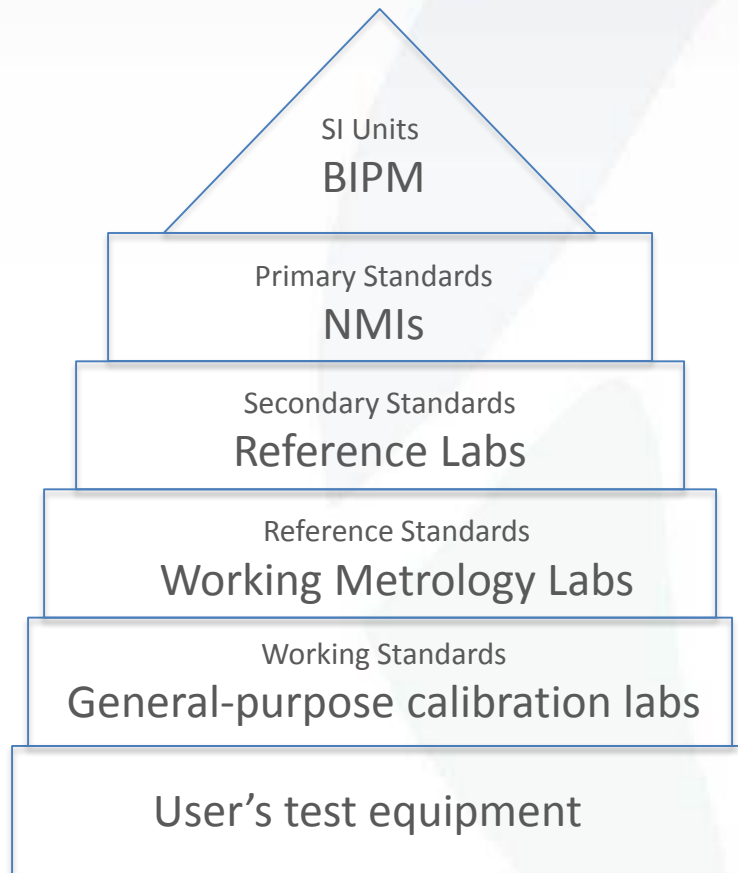


Calibrated weight set



# CALIBRATION SYSTEM

- Measurement Traceability

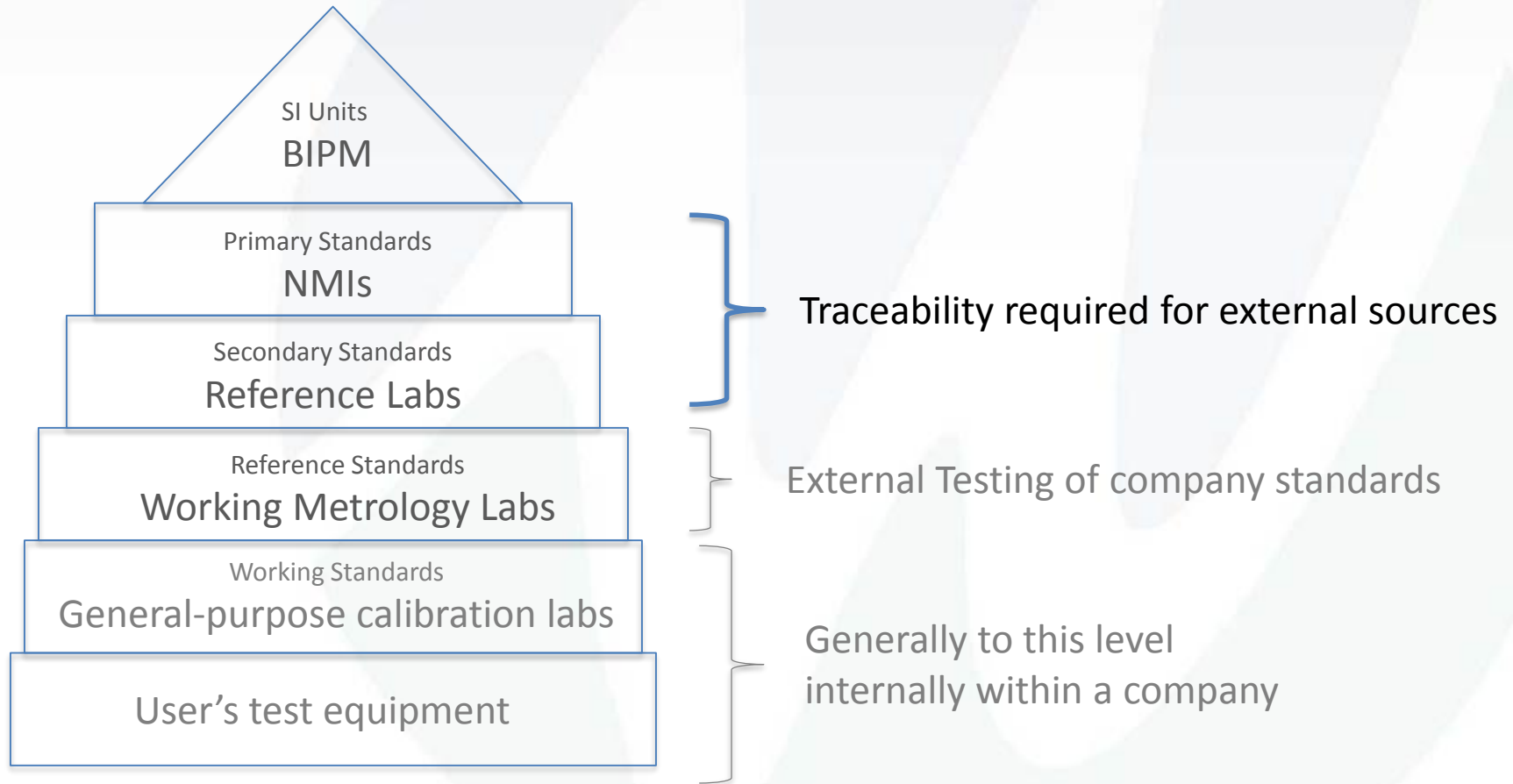


Traceable to NIST  
National Institute of Standards & Technology

- US national standards
- National metrology institute (NMI);

# CALIBRATION SYSTEM

- Measurement Traceability



# METROLOGY PROGRAM

- Calibration System
  - Internal Process / External Vendor program
  - Adequacy of equipment & standards
  - Procedures (Methods)
  - Measurement Traceability
  - **Uncertainty (Confidence)**
  - Environmental Controls
  - Software Validation
  - Intervals
  - Scheduling
  - Labels

# CALIBRATION SYSTEM

- Uncertainty (Confidence)
  - Reliability level, demonstrating within tolerance over a period of time and within an acceptable level for the device under test
    - Pass/fail
    - Adjustments/cleaning required
    - Repairs needed

# CALIBRATION SYSTEM

- Measurement Uncertainty

“.... No measurement is exact. When a quantity is measured, the outcome depends on the measuring system, the measurement procedure, the skill of the operator, the environment, and other effects.

Even if the quantity were to be measured several times, in the same way and in the same circumstances, a different measured value would in general be obtained each time, assuming the measuring system has sufficient resolution to distinguish between the values....” Wikipedia.org

# CALIBRATION SYSTEM

- Uncertainty of Measurement (Variation)
  - ISO 9001:2008, ISO/TS 16949:2009 require an understanding
  - ISO 17025:2005 requires calibration labs to extensively document for accreditation
  - ISO/IEC Guide 98-3 (2008) “Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)



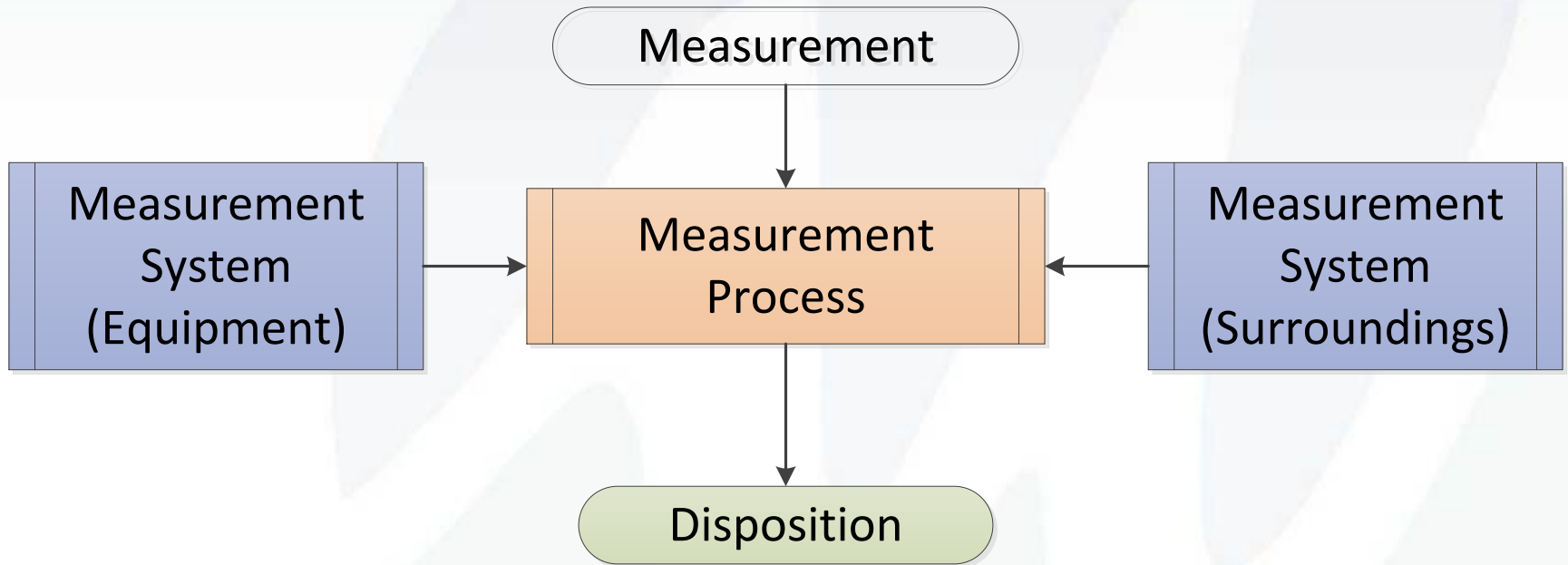
# CALIBRATION SYSTEM

- Previously (Measurement Fundamentals)
  - Measurement Error
    - Random Error: cause scatter in results (measure of dispersion)
    - Systematic Error: average offset from “true value”
    - Environmental Error: temperature, vibration, pressure, etc.
    - Observational Error: dial indicators (parallax & interpolation)
    - Gross Human Error: misuse, blunders, mistakes
  - Capability
    - Bias: systematic offset
    - Linearity: equally increasing increments
    - Stability: change in bias over time (i.e. drift)
    - Repeatability: closeness of measurements from same *instrument*
    - Reproducibility: closeness of measurements under the same *conditions*

# CALIBRATION SYSTEM

- Changing from random/systemic error to **Uncertainty and Uncertainty Budget**
- Previously (Measurement Fundamentals)
  - Measurement Error
    - Random Error: cause scatter in results (measure of dispersion)
    - Systematic Error: average offset from “true value”
    - Environmental Error: temperature, vibration, pressure, etc.
    - Observational Error: dial indicators (parallax & interpolation)
    - Gross Human Error: misuse, blunders, mistakes
  - Capability
    - Bias: systematic offset
    - Linearity: equally increasing increments
    - Stability: change in bias over time (i.e. drift)
    - Repeatability: closeness of measurements from same *instrument*
    - Reproducibility: closeness of measurements under the same *conditions*

# METROLOGY - Taking a Measurement



Measurement Uncertainty (error) occurs throughout the entire process

# UNCERTAINTY BUDGET

Influence	Magnitude	Type	Distribution	Divisor	Standard Uncertainty (quotient)	Variance (square)	Comments
Instrument							
Fixture							
Environment							
Calibration							
Sample							
Analysis							
Expanded Uncertainty							

Notes: (descriptions of assumptions made throughout the analysis)

# UNCERTAINTY BUDGET

- Calculating the budget, beyond introductory course
- Awareness of
  - Influences (measurement fundamental & calibration)
    - ❖ Sample
    - ❖ Equipment (measurement tools, fixtures, etc.)
    - ❖ Environment
    - ❖ Personnel
    - ❖ Method (measurement, calibration, data analysis, etc.)
  - Magnitude
    - sensitivity of equipment
    - calibrated range
  - Type
    - A (experimentally determined)
    - B (reported from other source)

# METROLOGY PROGRAM

- Calibration System
  - Internal Process / External Vendor program
  - Adequacy of equipment & standards
  - Procedures (Methods)
  - Measurement Traceability
  - Uncertainty (Confidence)
  - **Environmental Controls**
  - Software Validation
  - Intervals
  - Scheduling
  - Labels

# CALIBRATION SYSTEM

- Environmental Controls
  - Calibration laboratory
  - Device under test
    - Bring to laboratory
    - Bring standards to device
  - Considerations
    - temperature, humidity, barometric pressure
    - vibration, electromagnetic interference, voltage regulation, etc.

# CALIBRATION SYSTEM

## Environmental Control Handout

(Quality Council of Indiana CCT)



# METROLOGY PROGRAM

- Calibration System
  - Internal Process / External Vendor program
  - Adequacy of equipment & standards
  - Procedures (Methods)
  - Measurement Traceability
  - Uncertainty (Confidence)
  - Environmental Controls
  - **Software Validation**
  - Intervals
  - Scheduling
  - Labels

# CALIBRATION SYSTEM

- Software Validation
  - Opportunities
    - Calibration management
    - Device control software or data collection
    - Test procedure software
    - Statistical software

# CALIBRATION SYSTEM

- Software Validation
  - Standard References
    - ISO/IEC 17025:2005 5.4.7.2

“...when computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data...”
    - ANSI/ISO/ASQ Q10012-2003 states

“... software used in the measurement processes and calculation of results shall be documented, identified and controlled to ensure suitability for continued use ... testing shall be to the extent necessary to ensure valid measurement results.”
    - 21 CFR Part 11, Electronic Records; Electronic Signatures
      - 211.68 Automated, mechanical and electrical equipment
      - 820.72 Inspection, measurement and test equipment
    - ISO 9001:2008 & 13485:2003 7.6 Control of Monitoring and Measuring equipment

# CALIBRATION SYSTEM

- Software Validation
  - GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems (2012)
    - Good Automated Manufacturing Practices, International Society for Pharmaceutical Engineering
  - Documented requirements
    - Intended use of system
    - Operational/functional requirements from user point of view
    - Risk assessment, including criticality, of software
    - Safety requirements (i.e. software control high voltage)

# CALIBRATION SYSTEM

- **Software Validation**
  - Opportunities
  - Standard References
  - GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems (2012)

# METROLOGY PROGRAM

- Calibration System
  - Internal Process / External Vendor program
  - Adequacy of equipment & standards
  - Procedures (Methods)
  - Measurement Traceability
  - Uncertainty (Confidence)
  - Environmental Controls
  - Software Validation
  - **Intervals**
  - Scheduling
  - Labels

# CALIBRATION SYSTEM

- Intervals (Frequency)
  - Designed to maintain uncertainty within acceptable limits
  - Days, Monthly, quarterly, semi-annual, annual, bi-annual
    - Verification at time-of-use
      - pH meters
      - Scales
  - Use and history assist in determination

# METROLOGY PROGRAM

- Calibration System
  - Internal Process / External Vendor program
  - Adequacy of equipment & standards
  - Procedures (Methods)
  - Measurement Traceability
  - Uncertainty (Confidence)
  - Environmental Controls
  - Software Validation
  - Intervals
  - **Scheduling**
  - Labels



# CALIBRATION SYSTEM

- Scheduling
  - Identification of due dates before expiration
  - Notification of individuals
  - Identification of equipment status
    - In-use, retired, lost, at-time-of-use (seldom)
  - Use of validated software

# METROLOGY PROGRAM

- Calibration System
  - Internal Process / External Vendor program
  - Adequacy of equipment & standards
  - Procedures (Methods)
  - Measurement Traceability
  - Uncertainty (Confidence)
  - Environmental Controls
  - Software Validation
  - Intervals
  - Scheduling
  - **Labels**

# CALIBRATION SYSTEM

- Labels
  - Key to status identification of equipment
  - Out-of-date means out-of-calibration
  - Range specified must be followed
  - Traceability of equipment to records

# CALIBRATION SYSTEM - Labels

The image shows a stack of calibration labels. The top label is highlighted with a green header and white body. It contains the following text:

**CALIBRATION**

I.D. NO. \_\_\_\_\_

BY \_\_\_\_\_ DATE \_\_\_\_\_

DUE \_\_\_\_\_

The background shows several other identical labels stacked behind it, slightly offset to the left and right.

# CALIBRATION SYSTEM - Labels

<b>LIMITED CALIBRATION</b>	
TESTED RANGE ____ TO ____	
I.D.# _____	DATE _____
BY _____	DUE _____

# CALIBRATION SYSTEM - Labels



# CALIBRATION SYSTEM - Labels



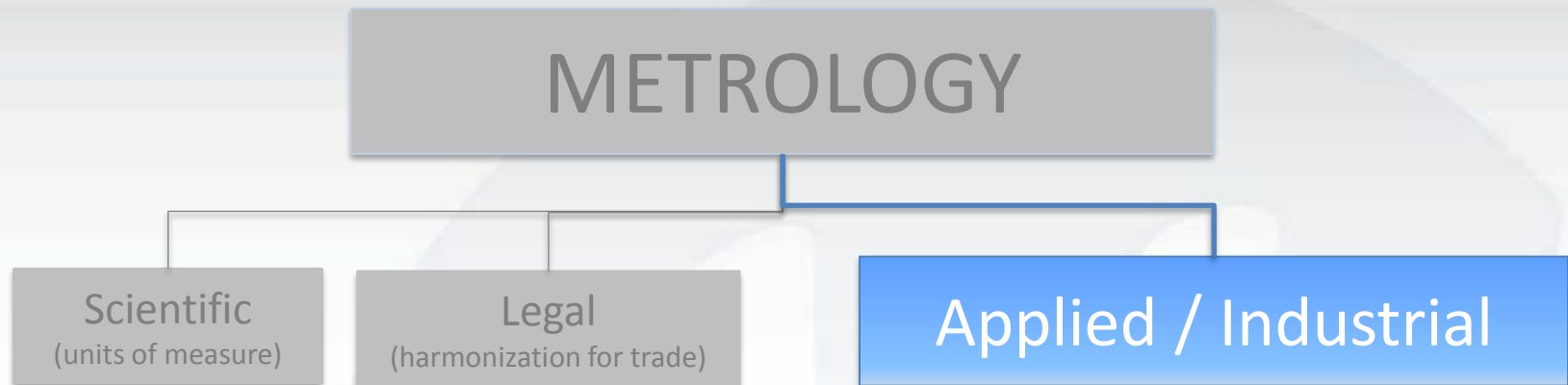
# CALIBRATION SYSTEM - Labels







# METROLOGY - Summary



*Measurement science applied to manufacturing or other processes*

- *Ensuring the suitability of measurement instruments, their calibration and quality control of measurements. [Measurement Fundamentals]*
- *Traceability of the calibration for the instruments necessary to ensure confidence in the measurements. [Calibration]*

# ACCURACY vs PRECISION



Accurate but  
not precise



Precise but  
not accurate



Neither accurate  
nor precise



Accurate and  
Precise

**Customer expectation**  
**Product meets specification (fit/form/function)**

# METROLOGY PROGRAM

- **Measurement Fundamentals**

- Methods
- System
- Capability
- Equipment specifications
- Environmental Controls
- Standards Usage
- Confidence (Uncertainty) Programs
- Data

- **Calibration System**

- Internal Process / External Vendor program
- Procedures (Methods)
- Adequacy of equipment & standards
- Measurement Traceability
- Quality (Confidence)
- Environmental Controls
- Software Validation
- Intervals
- Scheduling
- Labels

# MODULE 2: METROLOGY (MEASUREMENT CONCEPTS)

- Specifications
- Measurement Fundamentals
- Calibration
- **Inspection Systems & Sampling**



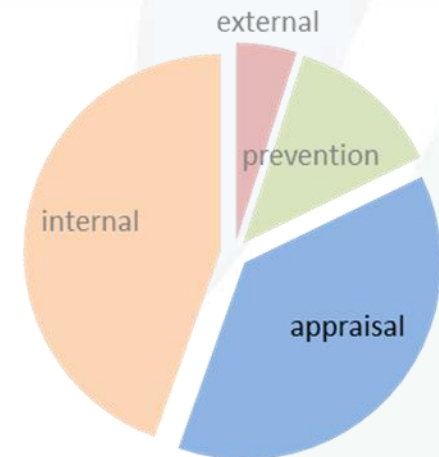
# INSPECTION

*Quality is a product (or service) with the features and characteristics which determine desirability and can be controlled to meet certain basic requirements.*

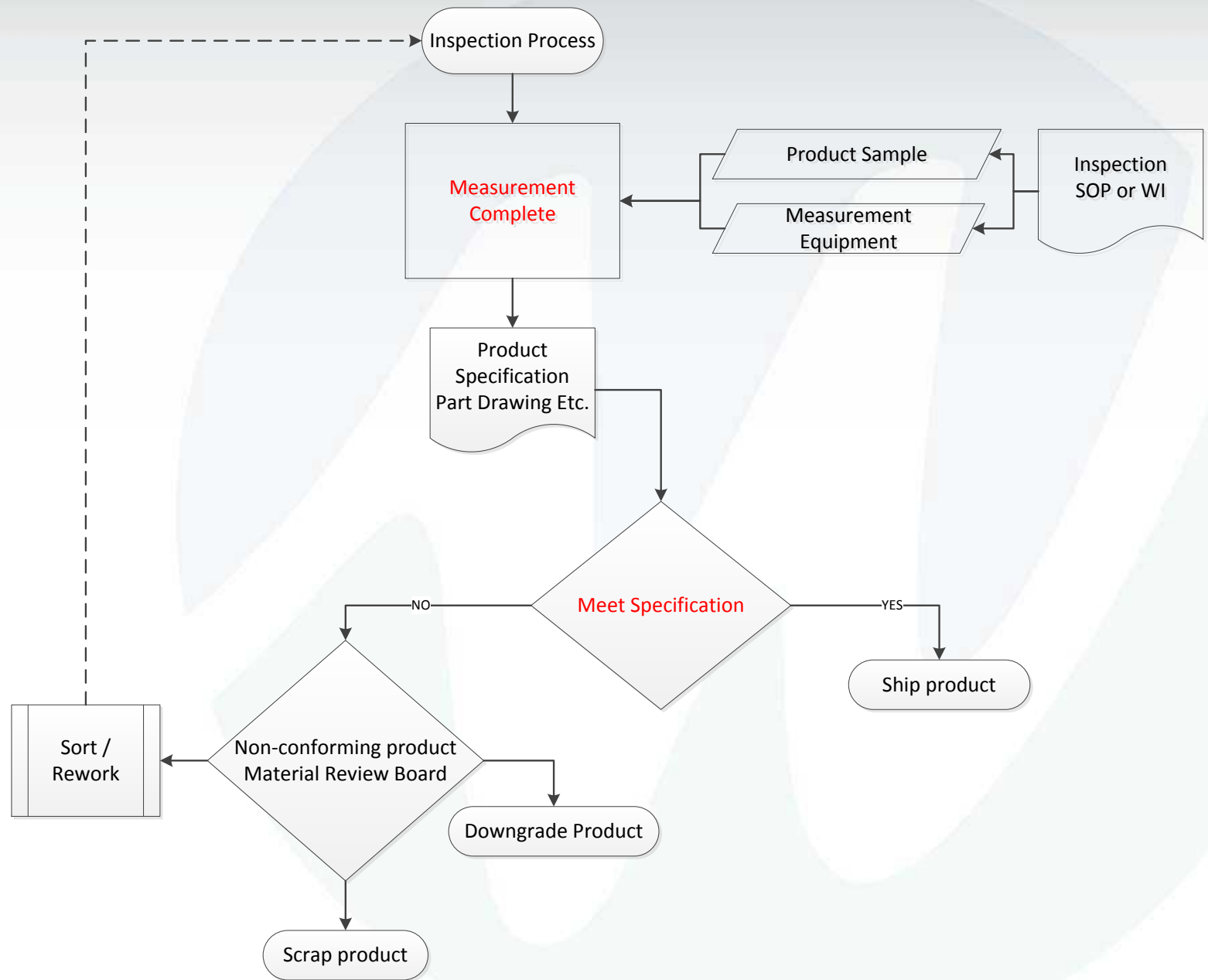
- Customers want expectations and needs met consistently
  - Fitness for use
  - Form is free of defect
  - Functions as intended
- Evaluate product quality by comparing measurement results with specifications

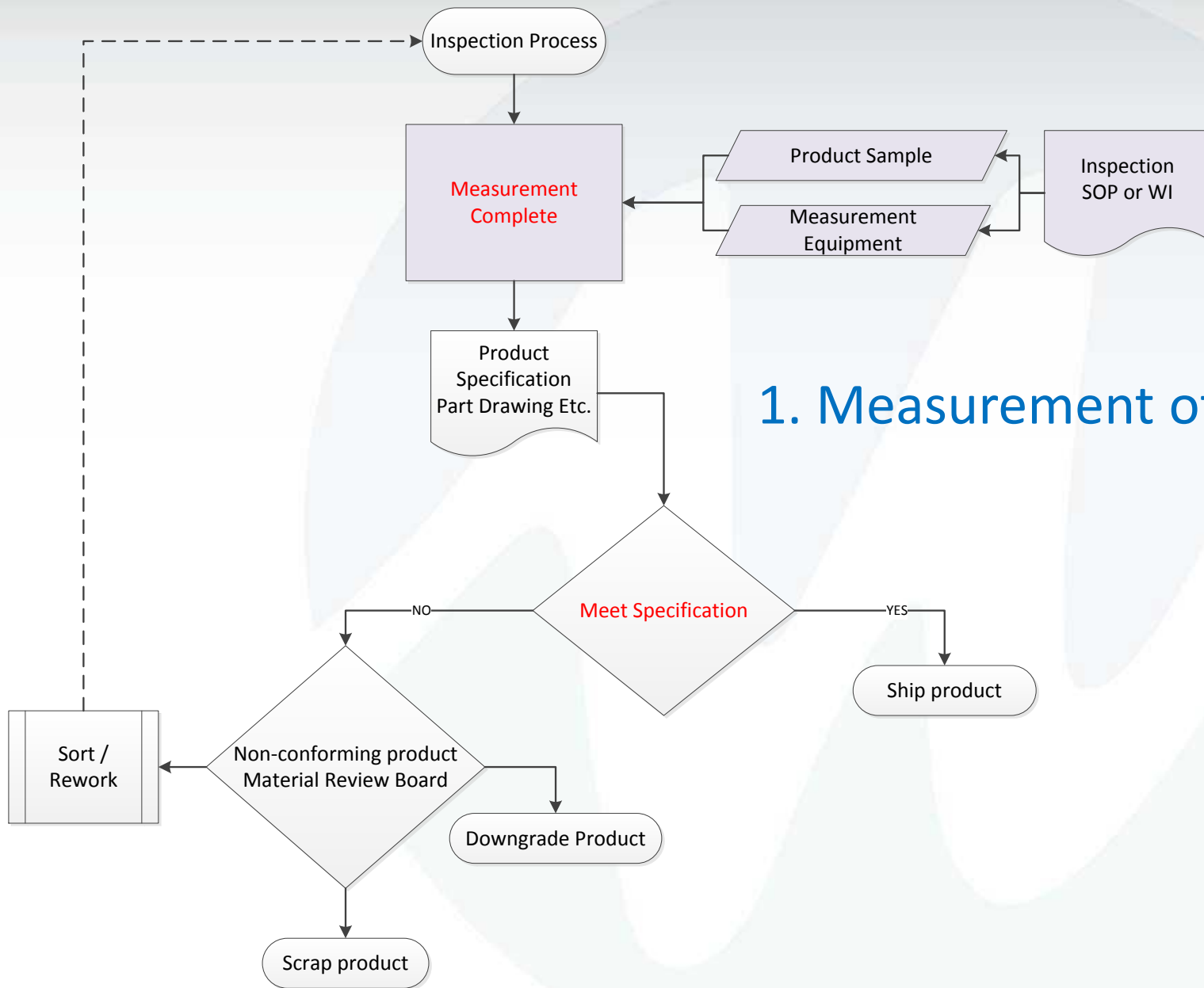
# INSPECTION

- Inspection process:
  1. Measurement of sample
  2. Comparison against specification
  3. Decision based on results
  4. Corrective action, if necessary

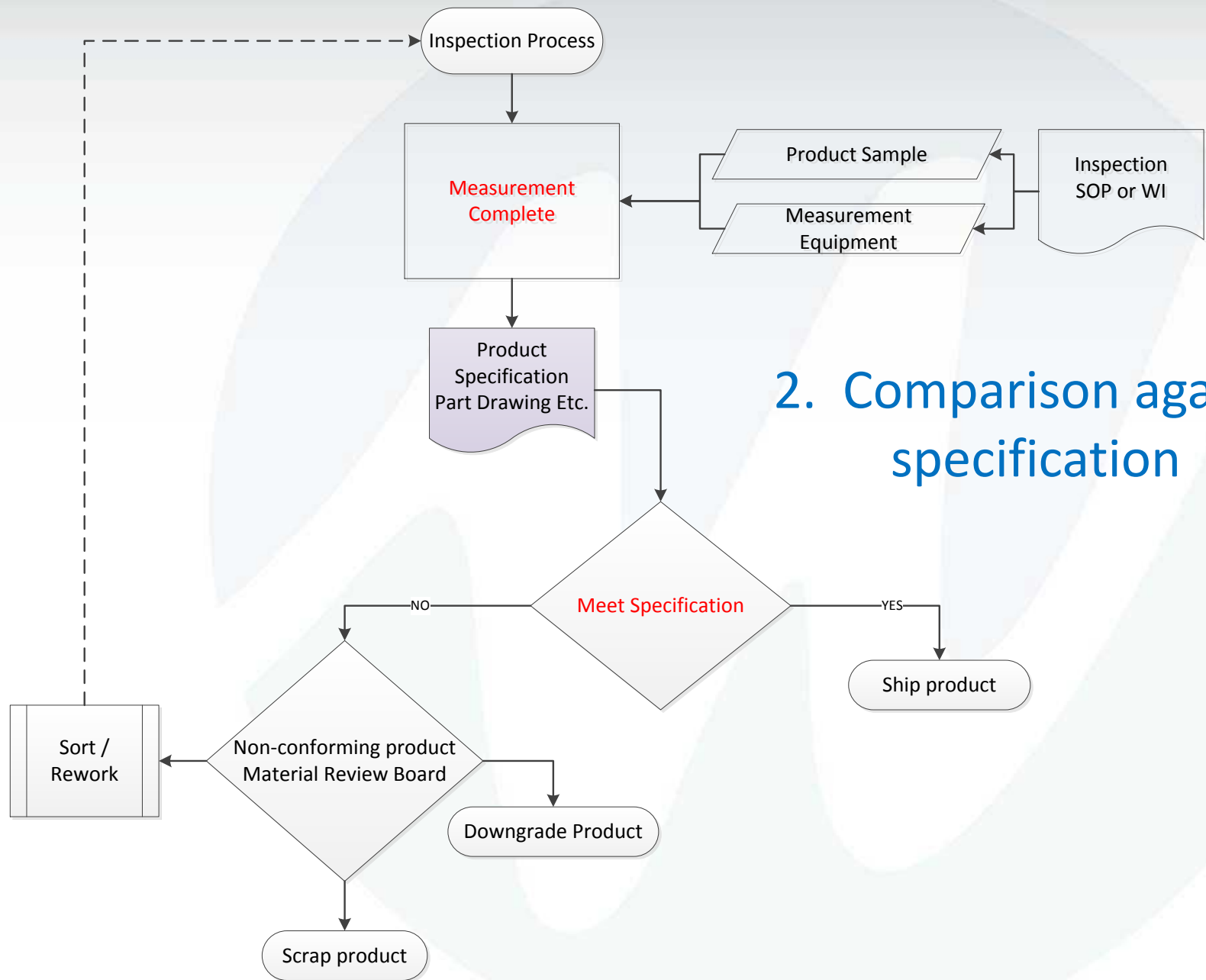




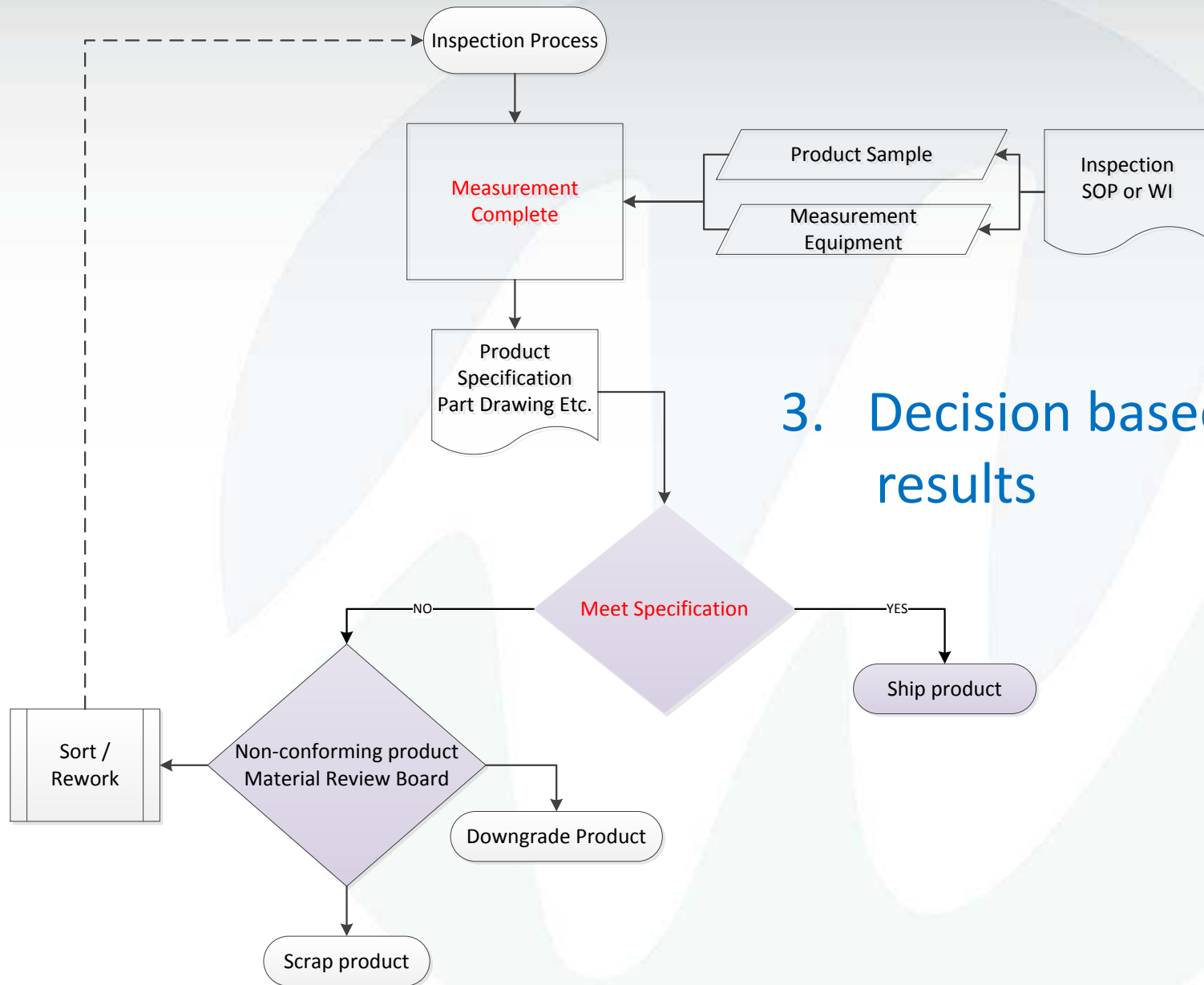




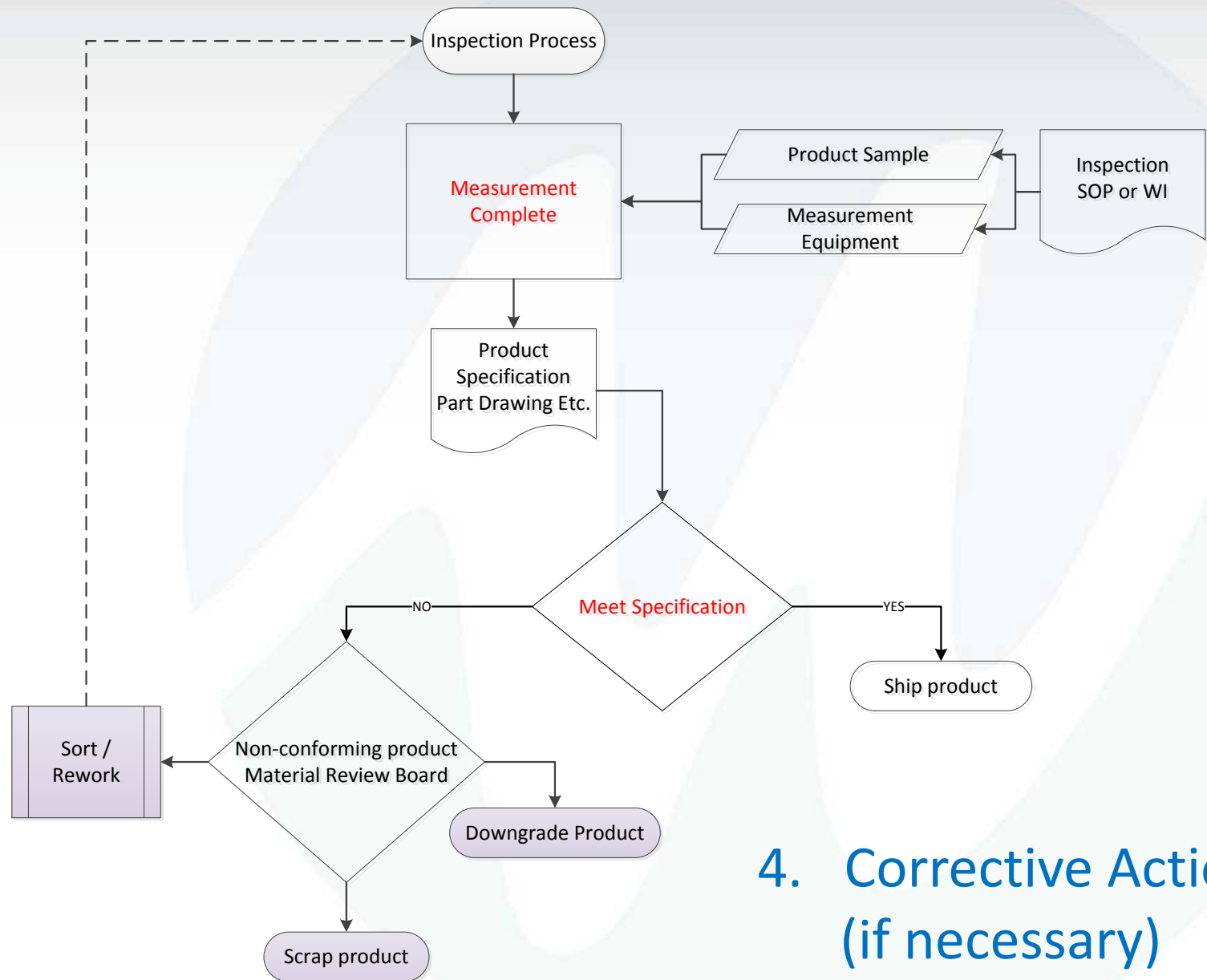
# 1. Measurement of Sample



## 2. Comparison against specification



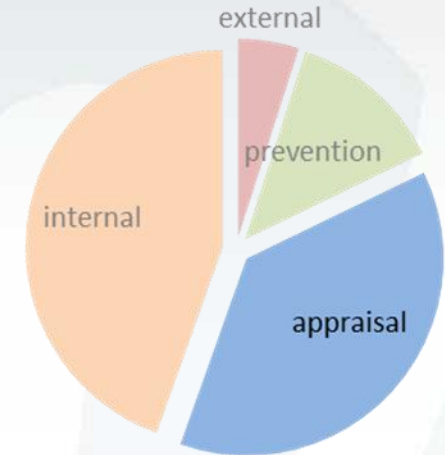
### 3. Decision based on results



## 4. Corrective Action (if necessary)

# INSPECTION

- Inspection process:
  1. Measurement of sample
  2. Comparison against specification
  3. Decision based on results
  4. Corrective action, if necessary



**Inspection is after the fact –  
materials used, product built, labor spent**

**Quality is a value that *must be built into* the product.  
Quality *cannot be inspected into* the product**

# INSPECTION

- Inspection process:
  1. Measurement of sample
  2. Comparison against specification
  3. Decision based on results
  4. Corrective action, if necessary

# INSPECTION PROCESS

*Evaluate product quality by comparing measurement results with specifications (Fit, Form, Function)*

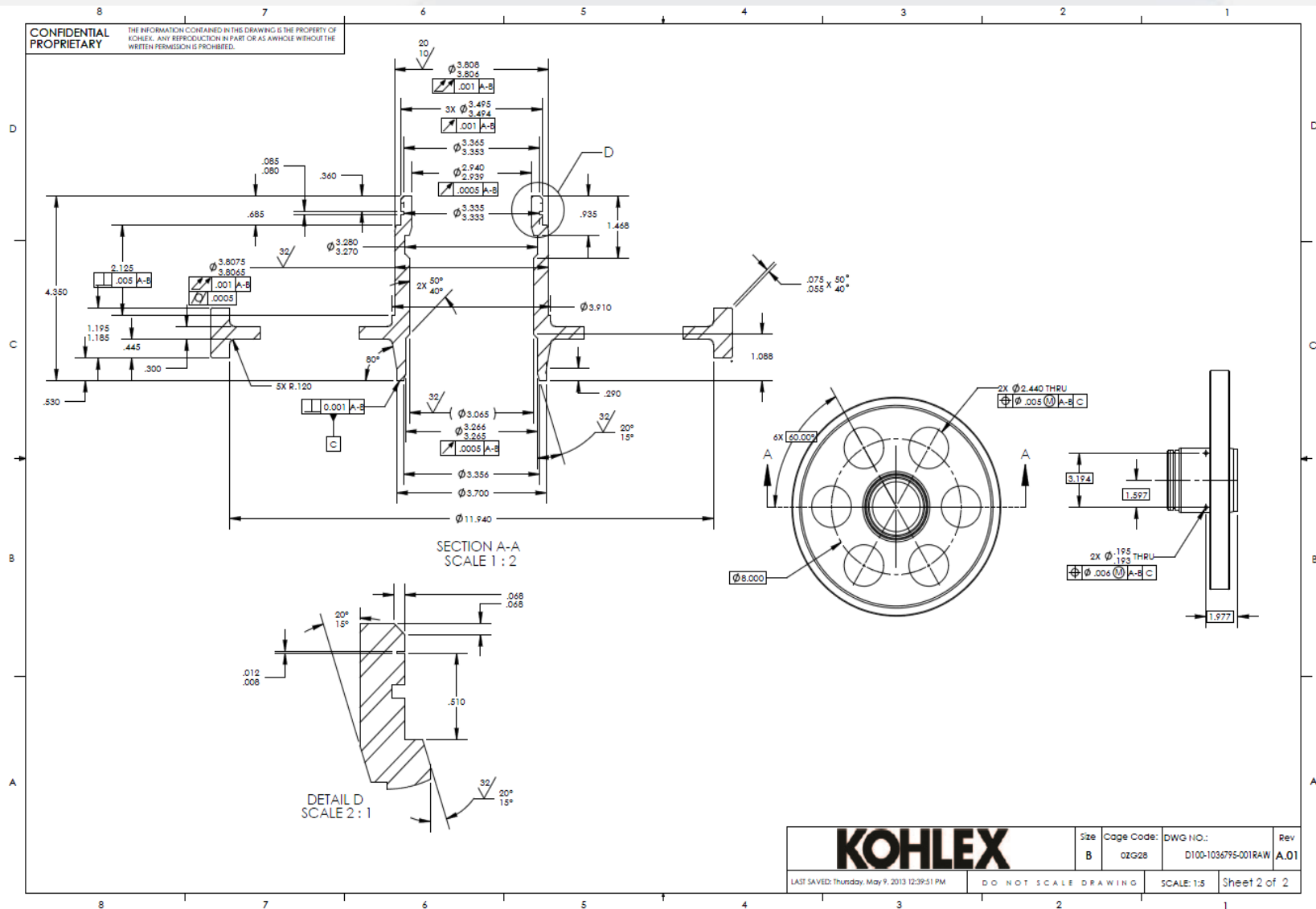
- Measurement of the sample
  - Measurement method determined
  - Characteristics to be measured
    - Critical: if defective would cause failure of product
    - Major: if defective could cause loss of function
    - Minor: no affect to fit/form/function

*Characteristic importance agreed to by Customer & Supplier*

- CTQ (critical to quality)
- CTF (critical to function)
- Not required by Customer but critical to supplier
- First article (run) versus routine production



# INSPECTION PROCESS



# INSPECTION PROCESS

- Inspection Type – why are we checking?

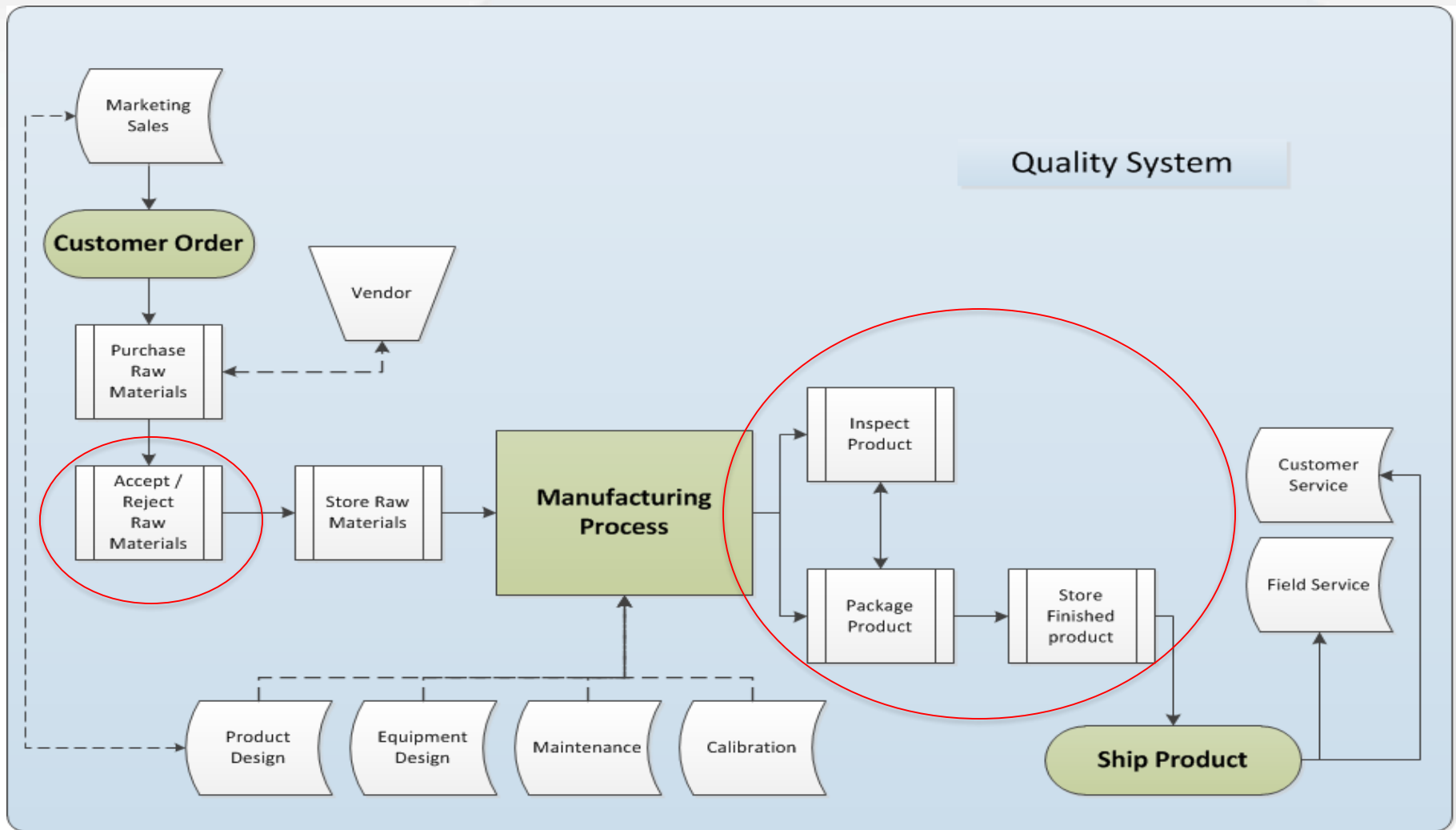
# INSPECTION TYPES

- Acceptance Sampling
  - Incoming
  - During Manufacturing
  - Prior to Release
- Detail Inspection
  - Sorting good from bad
- Repeatability / Reproducibility
  - Equipment Checks
  - Measurement System Studies
- Pre-Control or Control Sampling
  - Evaluate process changes

# INSPECTION TYPES

- Acceptance Sampling
  - Incoming
  - During Manufacturing
  - Prior to Release
- Detail Inspection
  - Sorting good from bad
- Repeatability / Reproducibility
  - Equipment Checks
  - Measurement System Studies
- Pre-Control or Control Sampling
  - Evaluate process changes

# PROCESS FLOW - MANUFACTURING



# INSPECTION POINTS

- Inspection Points – what (where) are we checking
  - Flow Chart / Run Chart
    - Identifies critical manufacturing/process steps
    - Sample entry points

# SEVEN QUALITY TOOLS

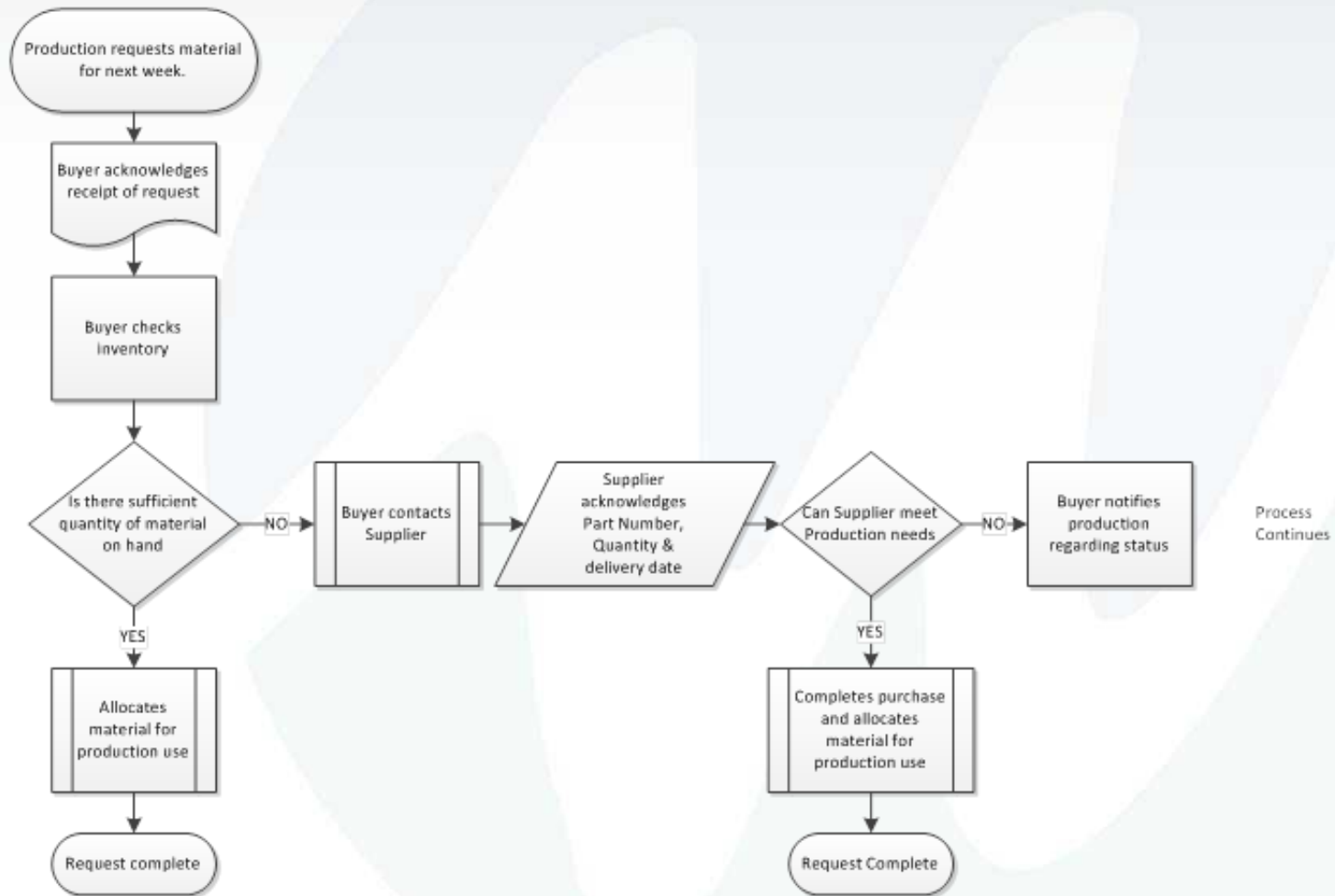
1. Flow Chart / Run Chart
2. Check Sheet
3. Control Charts
4. Cause and Effect Diagram (a.k.a. Ishikawa or Fishbone)
5. Histogram
6. Pareto Chart
7. Scatter Plot (Diagram)

# SEVEN QUALITY TOOLS – Flow Chart

- Picture of various steps/tasks in a process
  - how the operation tasks are connected
  - the order in which they need to be completed.
- Variety of flow chart types, with specific symbols,
  - Regular (standard): depicts activities/tasks



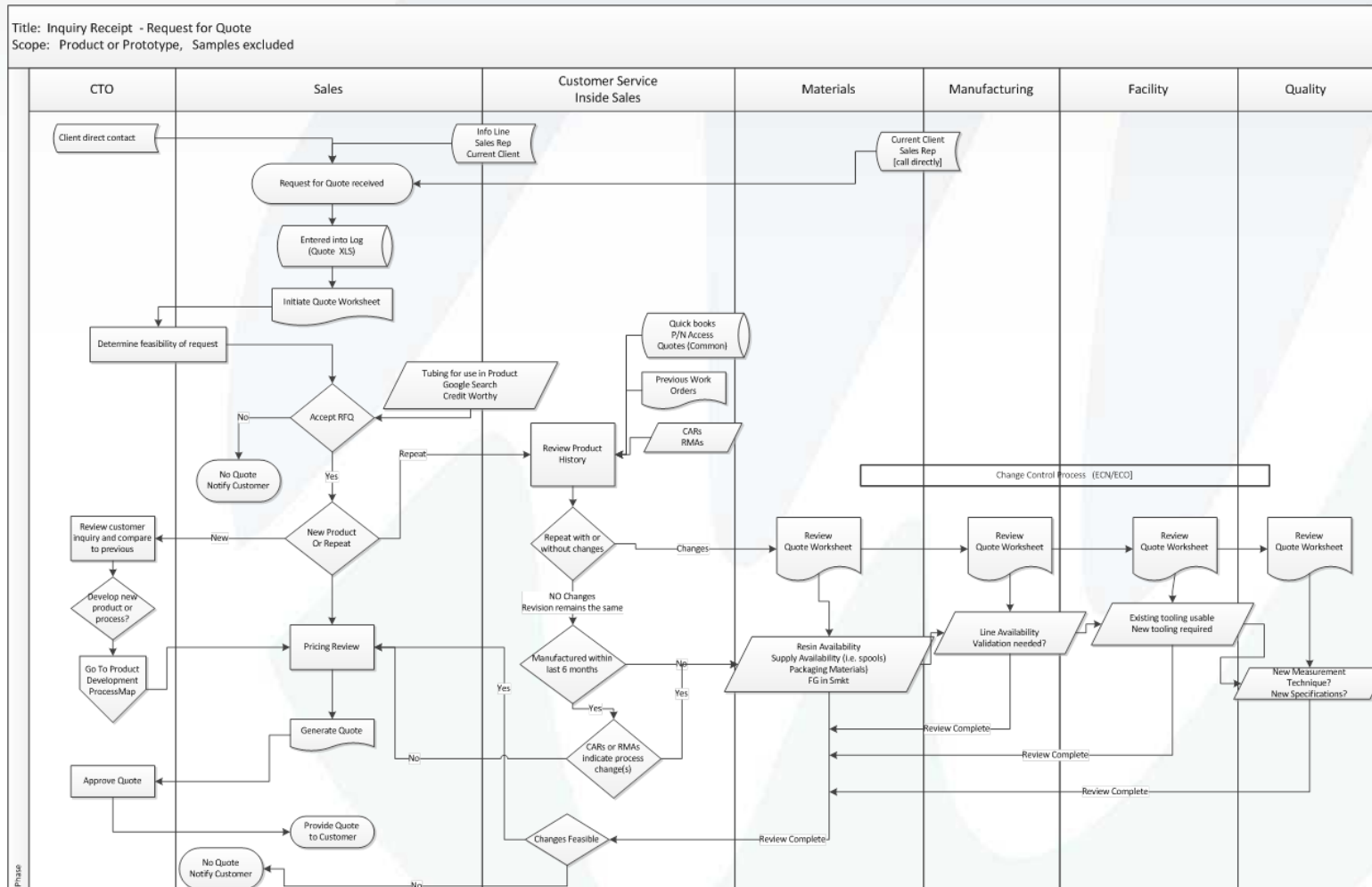
# STANDARD FLOW CHART



# SEVEN QUALITY TOOLS – Flow Chart

- Picture of various steps/tasks in a process
  - how the operation tasks are connected
  - the order in which they need to be completed.
- Variety of flow chart types, with specific symbols,
  - Regular (standard): depicts activities/tasks
  - Cross-Functional – adds person/department that is responsible for activity

# CROSS FUNCTION FLOW CHART



# SEVEN QUALITY TOOLS – Flow Chart

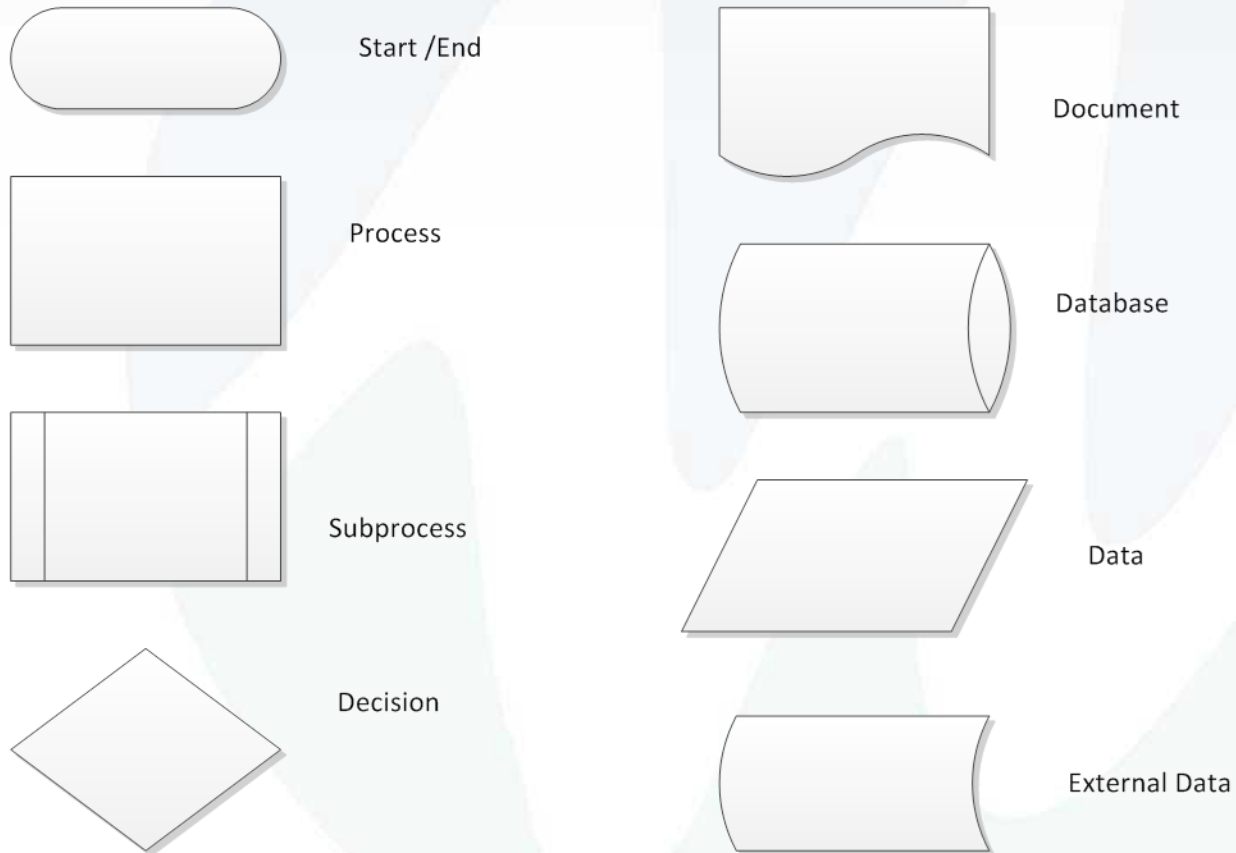
- Picture of various steps/tasks in a process
  - how the operation tasks are connected
  - the order in which they need to be completed.
- **Variety of flow chart types, with specific symbols,**
  - Regular – depicts activities/tasks
  - Cross-Functional – adds person/department that is responsible for activity
  - Multi-Level – Starts at beginning with high level activities, individual tasks are then outlined on a lower level (separate page).

# SEVEN QUALITY TOOLS – Flow Chart

- Picture of various steps/tasks in a process
  - how the operation tasks are connected
  - the order in which they need to be completed.
- Variety of flow chart types, with specific symbols,
  - **Regular – depicts activities/tasks**
  - Cross-Functional – adds person/department that is responsible for activity
  - Multi-Level – Starts at beginning with high level activities, individual tasks are then outlined on a lower level (separate page).

# SEVEN QUALITY TOOLS – Flow Chart (US)

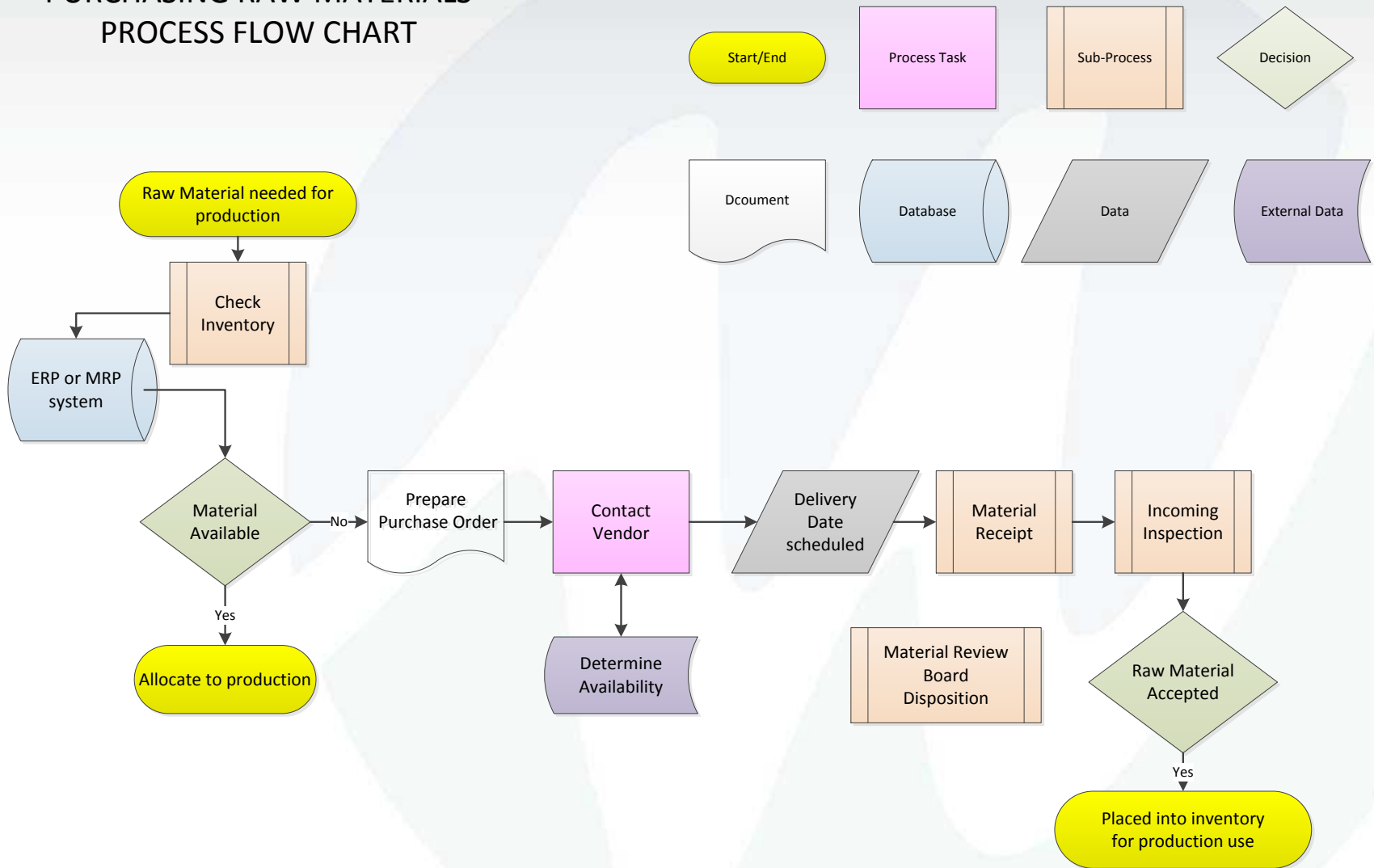
## Standard (typical) symbols



# SEVEN QUALITY TOOLS – Flow Chart

- Solid lines and arrows are used to connect the symbols and direct the user. Dotted lines may also sometimes be used. The difference between solid and dotted lines would be indicated on the flowchart.
- Start/End: indicates the starting point and ending point of the task/operation/process being depicted.
- Process: indicates an action step in the operation being depicted.
- Document: indicates a document will be needed or a document will be created
- Decision: typically contains a question and directs the user based on the response
- Data: used to indicate what results are expected or what information may be needed.
- Subprocess: used when one of the action steps is the result of another process that is not included on the current flowchart.

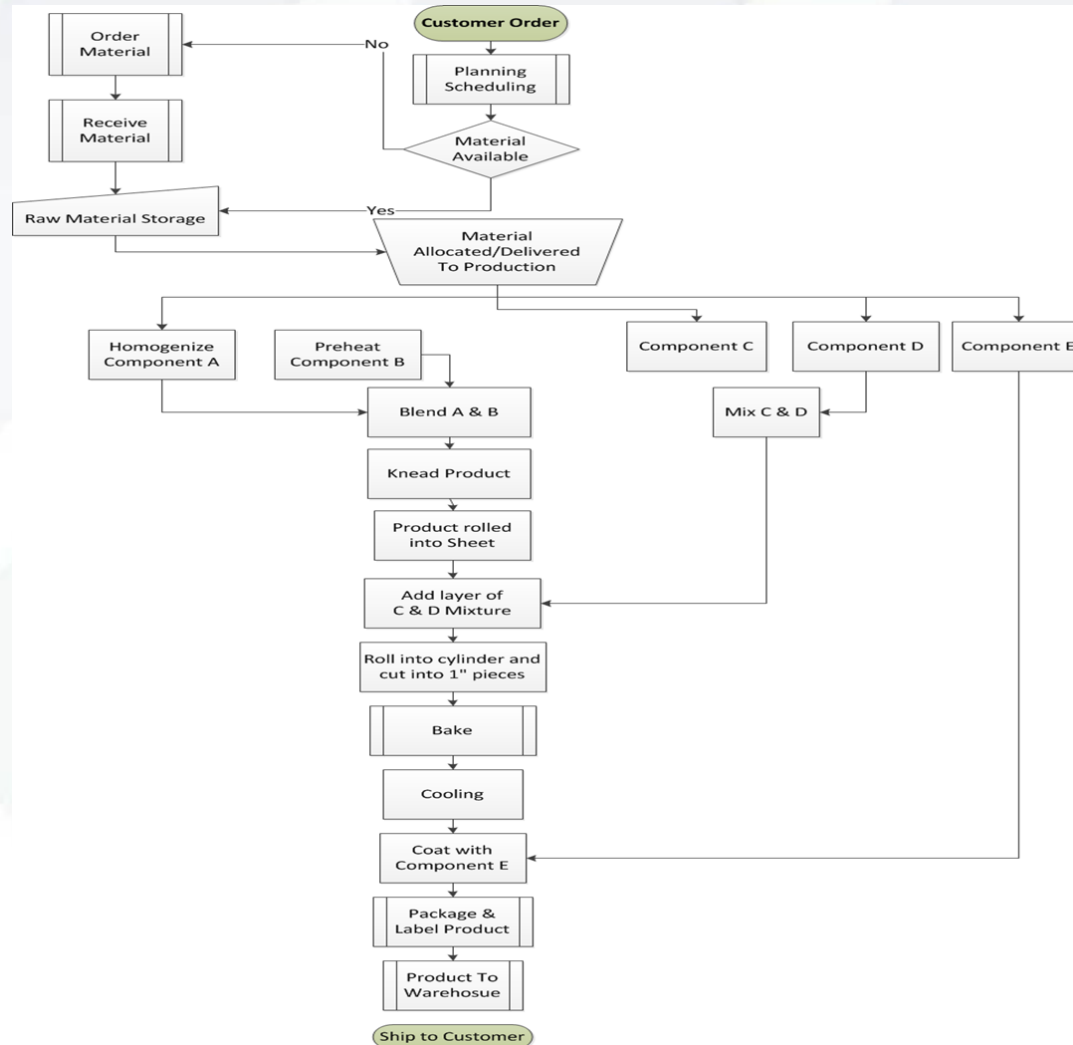
# PURCHASING RAW MATERIALS PROCESS FLOW CHART





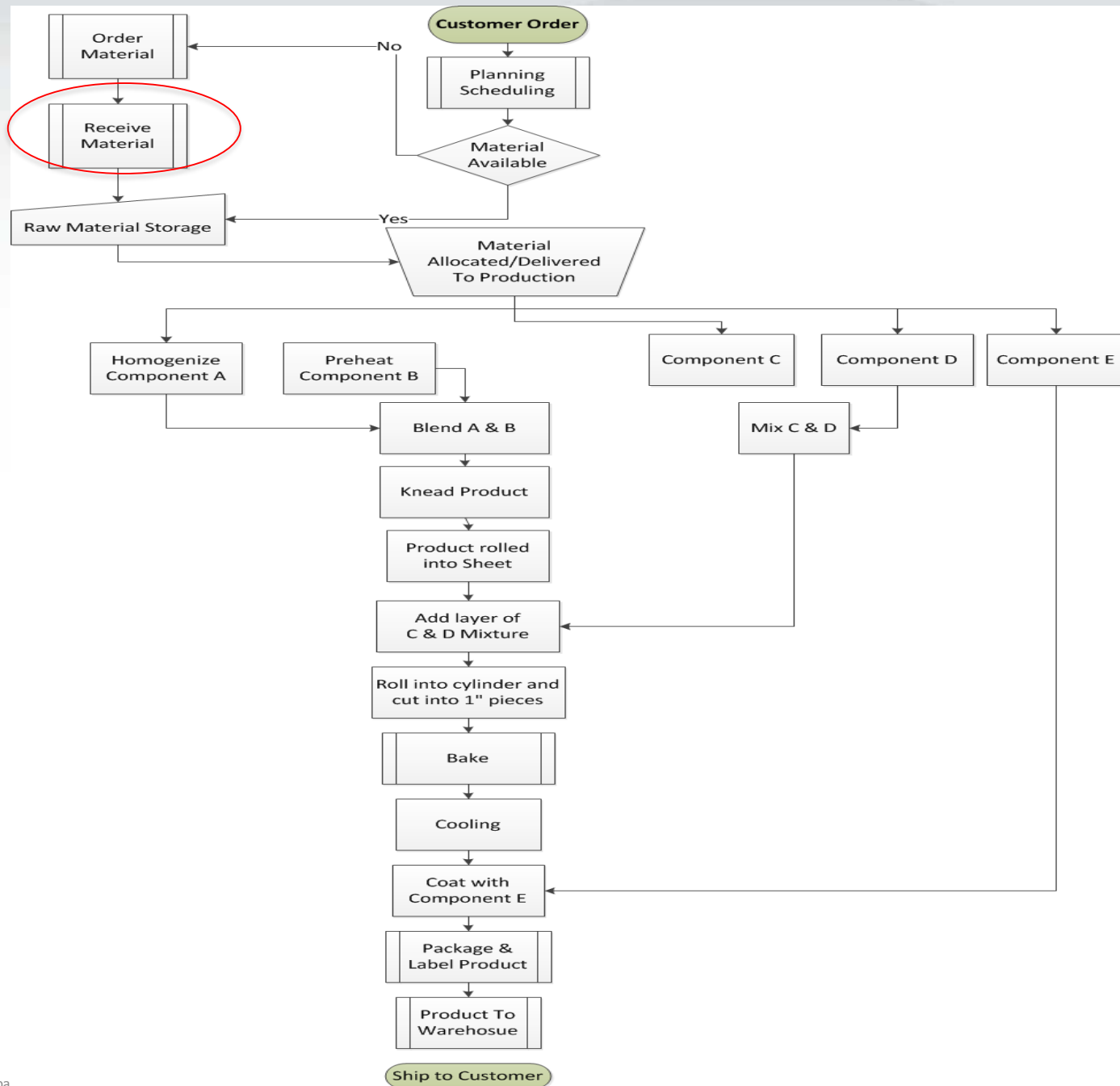
# INSPECTION PROCESS

- Inspection Points – what (where) are we checking



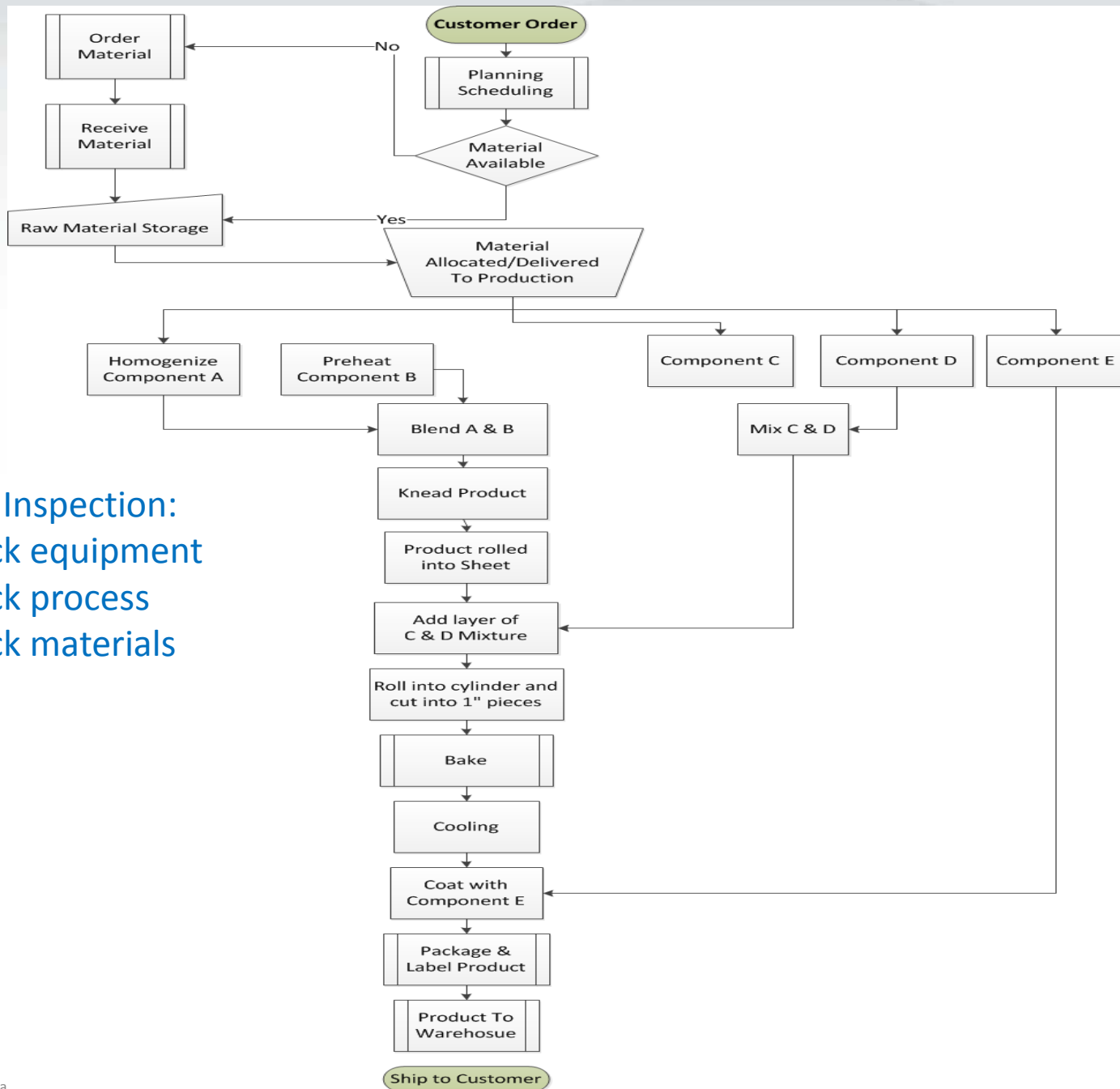
# INSPECTION POINT(S)

- Raw Materials
  - Source (at the vendor)
    - Qualification / First Article
    - Final Release (CoA, CoC)
    - Dock-to-stock Qualified
  - Receiving
    - Incoming Quality
    - Prior to release to inventory
    - Accept/Reject materials or components



# INSPECTION POINT(S)

- Product
  - Set-up
    - Equipment
    - Process
    - Prior to acceptance of first product

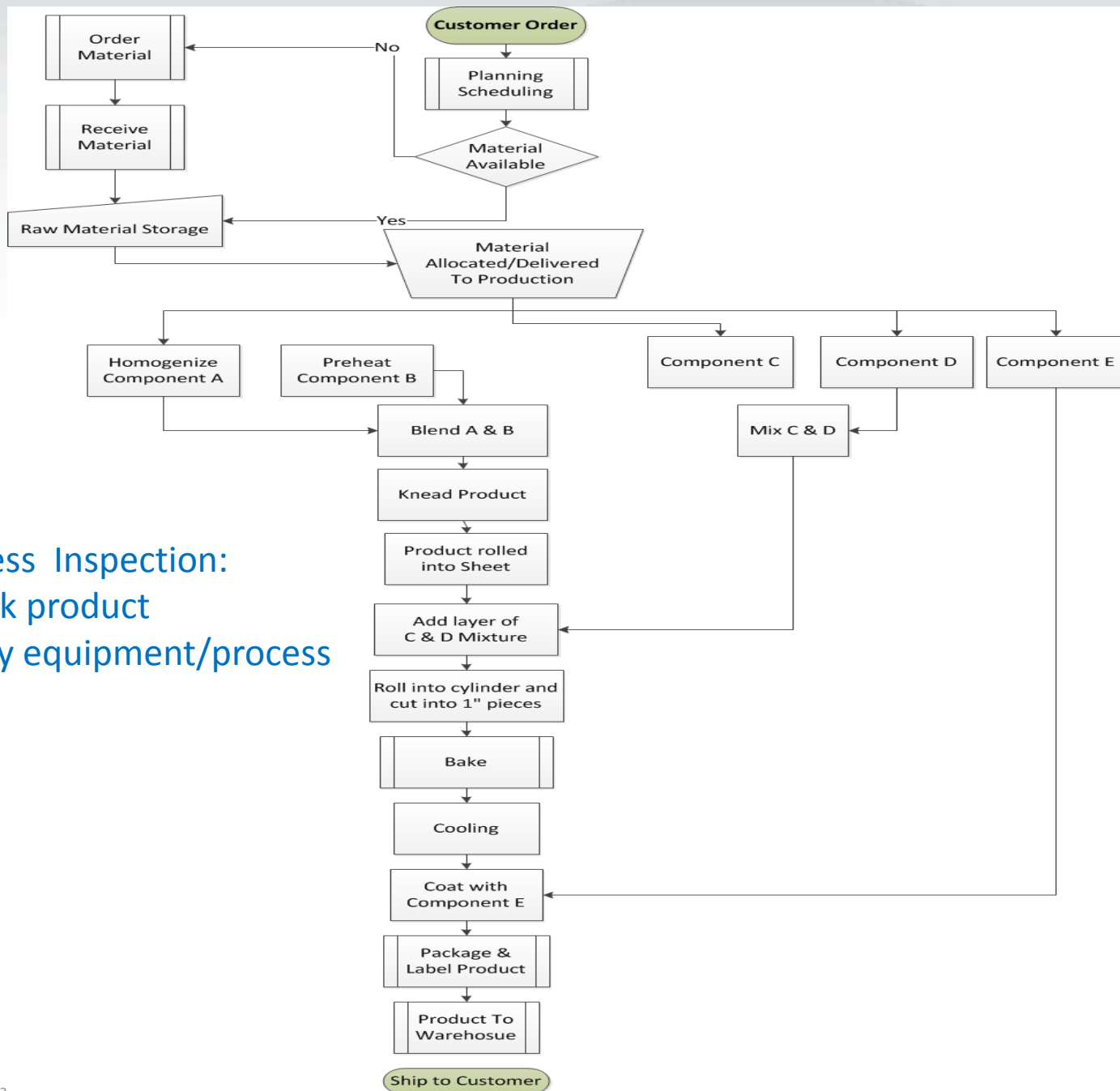


### Set-Up Inspection:

- ✓ Check equipment
- ✓ Check process
- ✓ Check materials

# INSPECTION POINT(S)

- Product
  - Set-up
    - Equipment
    - Process
    - Prior to acceptance of first product
  - In-process
    - Intermittent checking
      - Equipment/Process check between shifts
      - After addition of new material lot
      - Time period
    - In-line product testing



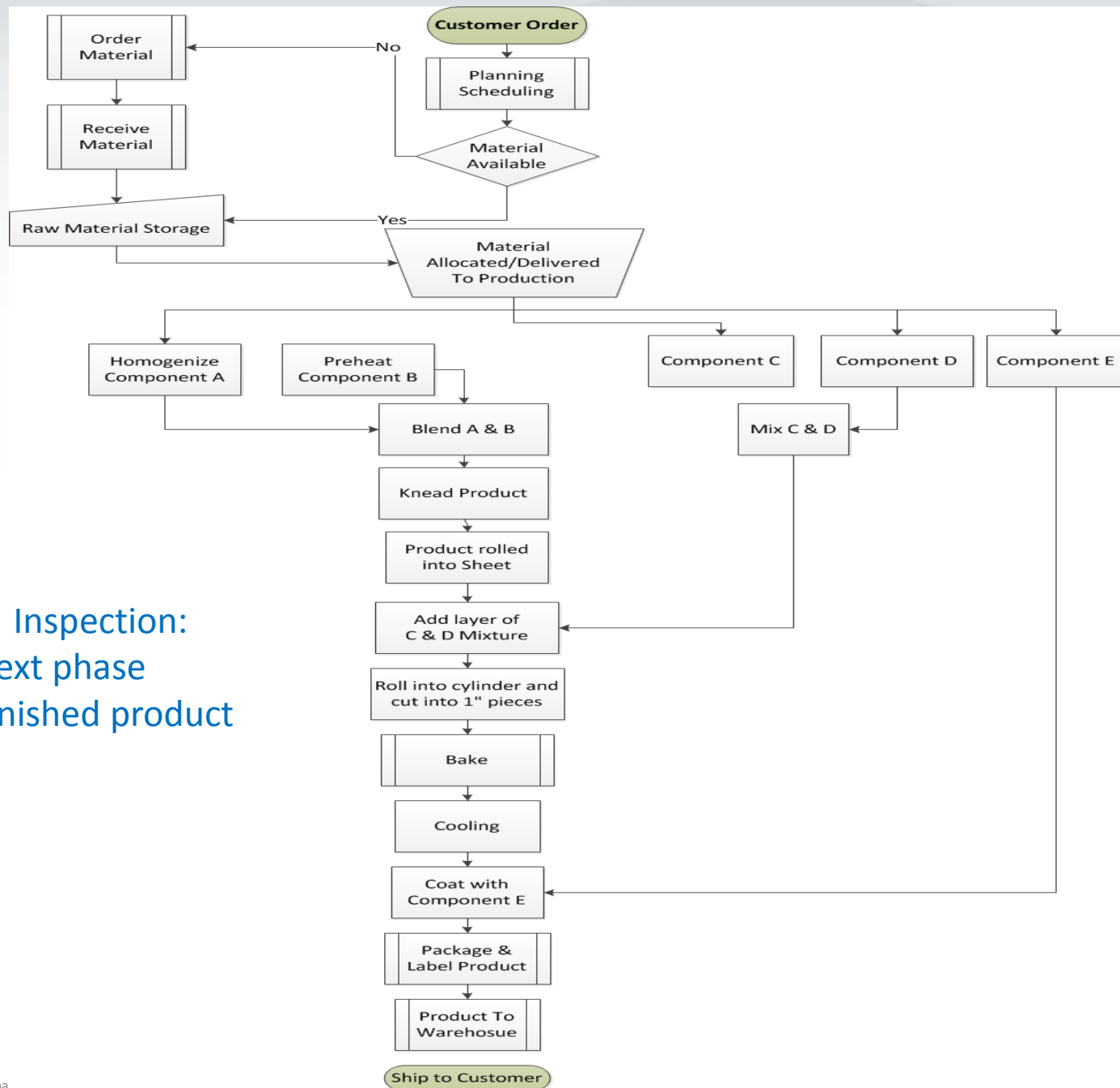
### In-process Inspection:

- ✓ Check product
- ✓ Verify equipment/process

# INSPECTION POINT(S)

- Product
  - Set-up (prior to first product)
  - In-process (during production, on-line)
  - Final
    - Prior to release
      - Next phase
      - Inventory
      - Shipment / Customer





Final Inspection:

- ✓ Next phase
- ✓ Finished product

# INSPECTION POINT(S)

- Inspection Points - **Product**
  - Set-up (prior to first product)
  - In-process (during production, on-line)
  - Final (ready for release)
  - Audit
    - During manufacture, random selection
    - Warehouse (packaging)

# INSPECTION PROCEDURE

- Inspection Procedure (Method)
  - Specify tools needed
  - Safety Precautions
  - Instructions for tool use and how to take measurement
  - Sample requirements
  - Applicable standard (specification)
  - Records required
  - What's done with acceptable or non-acceptable parts

Described in Standard Operating Procedure  
(aka Work Instruction, Test Method, Protocol)

# INSPECTION PROCESS

- Quality Records
  - Data collection sheets
  - Check Sheets
  - Automated Output

# SEVEN QUALITY TOOLS

1. Flow Chart / Run Chart
2. Check Sheet
3. Control Charts
4. Cause and Effect Diagram (a.k.a. Ishikawa or Fishbone)
5. Histogram
6. Pareto Chart
7. Scatter Plot (Diagram)

# INSPECTION – Check Sheet

Company Name \_\_\_\_\_

Document Number: \_\_\_\_\_

Revision Number: \_\_\_\_\_

Effective Date: \_\_\_\_\_

Page: 1 of 1

## Standard Operating Procedure for Quality Testing 0.9% Sodium Chloride Using Conductivity – Data Record

### Approvals:

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Date: October 22, 2014

Document Reviewer: \_\_\_\_\_

Date: \_\_\_\_\_

### Sample Identification

Batch # \_\_\_\_\_

Lot # \_\_\_\_\_

Prepared by / date \_\_\_\_\_

Conductivity Meter Identification Number: \_\_\_\_\_

Calibration Solution	Manufacturer	
	Catalogue Number	
	Lot Number	
	Expiration Date	

Calibration was successful as per SOP #2

\_\_\_\_\_  
(operator/date)

\_\_\_\_\_  
(witness/date)

\_\_\_\_\_ ml sample of the batch listed above was obtained from production:

\_\_\_\_\_  
(production technician/date)

\_\_\_\_\_  
(received by/date)

\_\_\_\_\_  
(witness/date)

Conductivity measurement: \_\_\_\_\_

Target value = 15.97 (range 15.31 – 16.63)

\_\_\_\_\_  
(operator/date)

\_\_\_\_\_  
(witness/date)

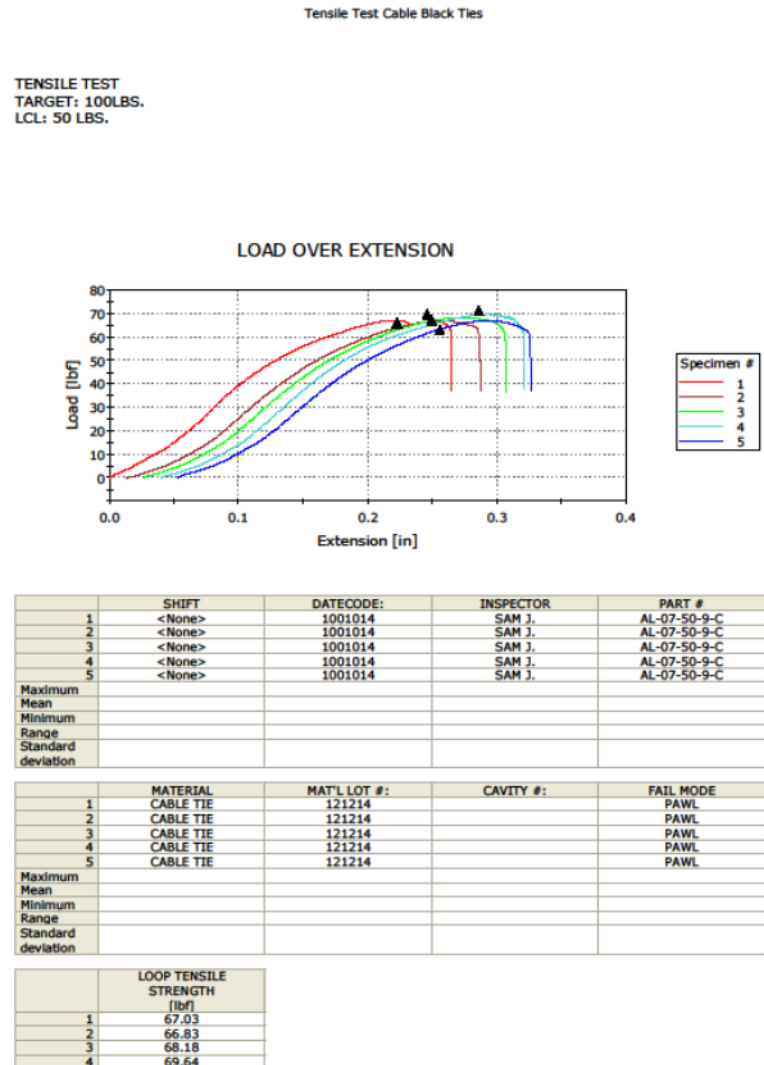
Comments:

Testing completed by: \_\_\_\_\_

(Quality Assurance/date)

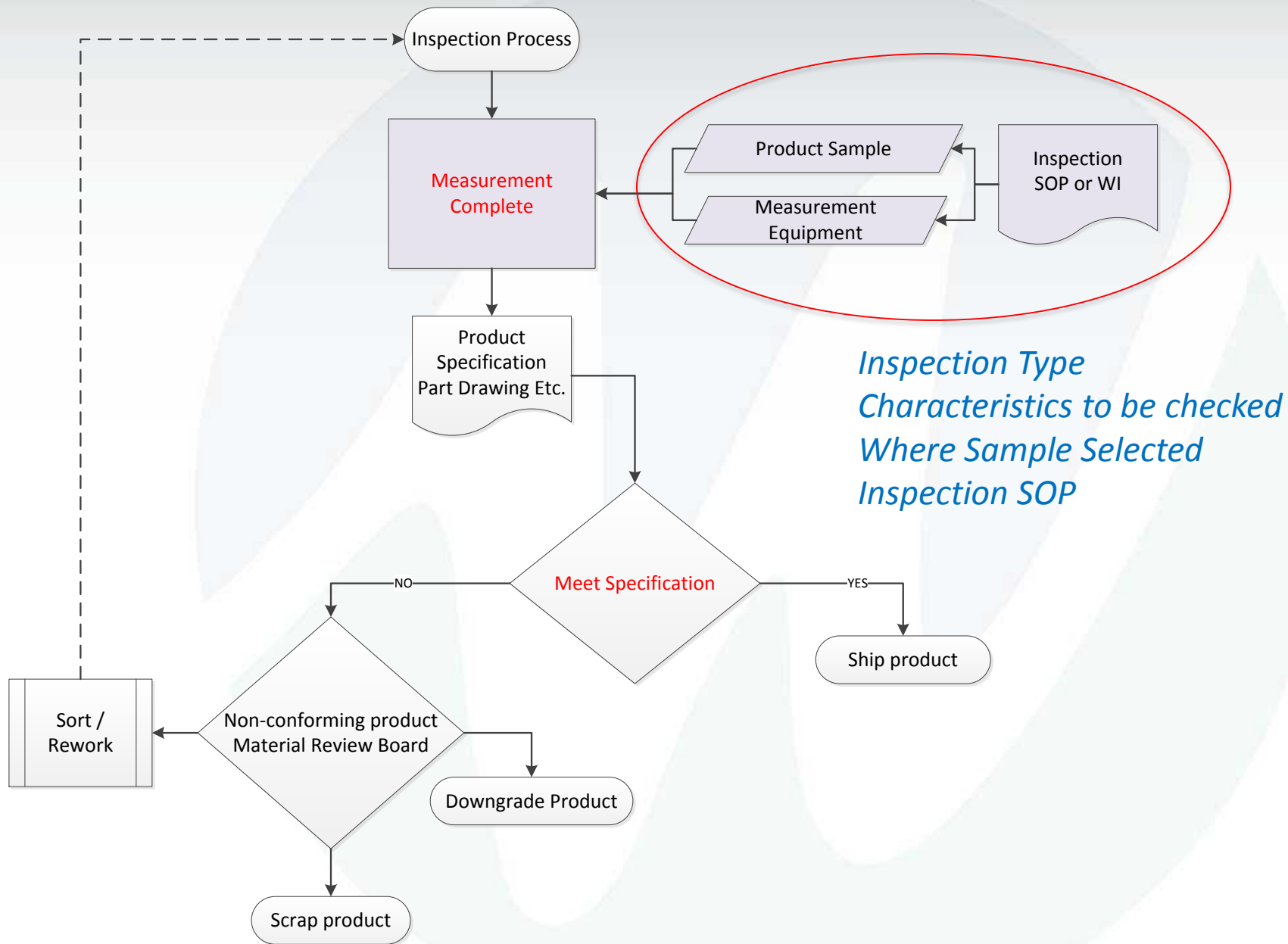
# INSPECTION

- Automated output



10/1/2014 10:01:47 AM

Page 1 of 2





# INSPECTION TECHNIQUES

A large, stylized, light blue and green logo is centered in the background. It features a circular shape with a white 'W' or 'M' inside, and a green 'U' or 'J' shape below it.

# INSPECTION TECHNIQUES

- Inspection can be conducted
  - Visually
  - Using hand tools (e.g. calipers)
  - Using automated equipment (e.g. vision systems)
  - Quantitative or qualitative
  - Destructive or non-destructive
  - 100% or sampled

# INSPECTION TECHNIQUES

- Inspection can be
  - Quantitative (aka Variable) or Qualitative
    - Numerical
    - Can be measured
    - Continuous value or discrete values

# INSPECTION TECHNIQUES

- Inspection can be
  - Quantitative or **Qualitative (aka Attribute)**
    - Descriptive; can be observed but not measured
    - Typically pass/fail

# INSPECTION TECHNIQUES



Morning Dunkin (or Starbucks)  
Vanilla Latte

# INSPECTION TECHNIQUES



- Qualitative
  - Robust aroma
  - Frothy appearance
  - Strong taste
  - Burgundy cup
- Quantitative
  - 12 ounce cappuccino
  - Serving temperature 150 °F
  - 7-inch mug
  - Cost \$4.95

# INSPECTION TECHNIQUES

- Inspection can be
  - Quantitative or qualitative
  - **Destructive** or non-destructive
    - Sample removed from lot/batch and cannot be returned
    - Sample altered during testing/measurement

Examples?

# INSPECTION TECHNIQUES

- Inspection can be
  - Quantitative or qualitative
  - Destructive or **Non-Destructive**
    - Sampled in-line (in-process) and remains with the product
    - Sample not altered during testing/measurement

Examples?



# INSPECTION TECHNIQUES

- Inspection can be
  - Quantitative or qualitative
  - Destructive or non-destructive
  - Conducted 100% or via sampling

# INSPECTION TECHNIQUES

- Inspection can be
  - Quantitative or qualitative
  - Destructive or non-destructive
  - **Conducted 100%** or via sampling
    - Is not 100% accurate / effective
      - Rule of thumb = 80% effective
    - Not always possible / feasible
      - Destructive versus non-destructive
      - Continuous process
    - Can be conducted on-line (in-process)

COUNT THE NUMBER OF F'S

TWO OF  
THE MOST POWERFUL  
AND EFFECTIVE  
OF ALL HUMAN FEARS  
ARE THE FEAR OF FAILURE  
AND THE FEAR  
OF SUCCESS.

Count the number of F's

Two of the most powerful  
and effective of all human  
fears are the fear of failure  
and the fear of success.

Count the number of **F**'s

Two of the most powerful  
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13

# INSPECTION TECHNIQUES

- Inspection can be
  - Quantitative or qualitative
  - Destructive or non-destructive
  - Conducted 100% or via **Sampling**

# SAMPLING

- What is the sample?
  - selection of a **subset** of individuals from within a statistical population to **estimate** characteristics of **the whole** population
- In Manufacturing, a portion of
  - Product lot / batch
  - Daily production
  - Shipment
  - Etc.
- In Service Industries
  - Transactions handled
  - Survey results
  - Etc.
- Audits – documentation
  - Specific department
  - Time period
  - Etc.

# SAMPLING

- Advantages (vs 100%)
  - Economy
  - Less opportunity for product damage
  - Lot-by-lot examination
  - Applicable for destructive testing
  - Lot rejection versus piece rejection
- Disadvantages (vs 100%)
  - Risk of reject good / bad lot
  - Greater administration costs
  - Additional planning/documentation
  - Less actual info about the product
  - Will not find ALL defective
  - Maintains quality level, doesn't drive improvement



# INSPECTION TECHNIQUE - SAMPLING

- What is the sample?
  - selection of a subset of individuals from within a statistical population to estimate characteristics of the whole population
- Conducting inspection to determine if product acceptable for release
  - Acceptable Quality Level (AQL)
    - Maximum percent defectives
    - Agreed to with Customer

# SAMPLING – STATISTICS

- Sample: selection of a subset of individuals from within a statistical population to estimate characteristics of the whole population
- Acceptable Quality Level
- Statistics Preview
  - Probability: how likely to occur, be found, etc.
    - Ranges 0 – 1  
Zero chance of occurrence up to 100% chance of occurrence

# SAMPLING – STATISTICS

- Sample: selection of a subset of individuals from within a statistical population to estimate characteristics of the whole population
  - Acceptable Quality Level
  - Statistics Preview
    - Probability: how likely to occur, be found, etc.
      - Ranges 0 – 1  
Zero chance of occurrence up to 100% chance of occurrence
- AQL  $\leq 0.001$  0.1% defective 99.9% acceptable
- Mutually exclusive or not mutually exclusive
    - Mutually exclusive = if one or the other occur, but not both (i.e. heads vs tails for coin)
    - Not Mutually exclusive = both can occur at the same time (i.e. rolling a 3 on a single roll of two dice)

# SAMPLING – STATISTICS

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  - Dependent or Independent events (variable)

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    - Independent: events not contingent on each other

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Example: Jar with 10 marbles (3 red, 7 white)

Likelihood (probability) of selecting 2 red in a row

Dependent: pull first marble, then second marble without replacement

Independent: pull first marble, put it back, and then pull second marble

# SAMPLING

- What is the sample?
- Need planned strategy and logistics
- Reminder
  - **Measurement Fundamentals**
    - Methods
    - System
    - Capability
    - Equipment specifications
    - Environmental Controls
    - Standards Usage
    - Confidence (Uncertainty) Programs
    - Data

Consideration of measurement/production systems essential to ensure that measurements provide data needed to make informed, appropriate decisions

# SAMPLING

- What is the sample?
- Need planned strategy and logistics

*Consideration of measurement/production systems essential to ensure that measurements provide data needed to make informed, appropriate decisions*

Ensuring SAMPLE represents ALL potential product/service is critical.  
*Not mutually exclusive and independent*



# SAMPLING - Strategy

- Need planned strategy and logistics
  - How (where)/when can samples be taken
    - Flow chart / Run Chart
    - Intermediate, finished product
      - Form of the sample (gas, liquid, solid, assembly, etc.)
      - Recorded calls, database print-out
      - Etc.

# SAMPLING STRATEGY - Collection

- Collection - When/where within the manufacturing process
  - Maintain traceability of the product
- Sampling Methods
  - Random
    - Every piece/part/sample has the opportunity to be chosen
  - Systemic (specified collection frequency)
    - Beginning, middle, end of production run
    - Each shift, hourly, every 100<sup>th</sup> piece
  - Stratified
    - Top, middle, bottom (i.e. soil sample)

# SAMPLING STRATEGY - Collection

- Sampling Methods
    - Random
    - Systemic
    - Stratified
  - ✓ Assumes uniformity (homogeneity)
  - ✓ Beware of BIAS
    - One lot of material / operator / line / machine
    - A-shift vs B vs C
    - Summer vs Winter
    - Northeast vs Midwest vs South vs West
- RANDOM sample required to  
estimate population (lot)**  
*Not mutually exclusive & independent*

# SAMPLING - Strategy

- Need planned strategy and logistics
  - How/when can samples be taken
    - Flow chart / Run Chart
    - Intermediate, finished product
    - Collection
    - Handling
      - Special equipment
      - Environment
    - Storage
      - Test immediately
      - Preparation
  - Who provides (selects) the sample
    - QC
    - Production
    - Customer
    - Vendor
    - Study Leader

# SAMPLING - Strategy

- Need planned strategy and logistics
  - How/when can they be taken
  - Who provides the sample
  - Will samples be put back into batch
    - Example: Fishery catch/release
  - Quantity to measure / select

# SAMPLING STRATEGY - Quantity

- Methods vary for measurement needs
  - **Product(s) manufactured**
  - Services provided
  - Clinical Trials for new drugs
  - US Citizens for voter preference

“sampling (statistical)” Wikipedia.com

# SAMPLING STRATEGY - Quantity

- Two types of data
  - Variable (quantitative)
  - Attribute (qualitative)
- Generally accepted standards (sampling plans)
  - Attribute (ANSI ASQ Z1.4-2008)
    - classifies products as conforming or non-conforming
    - accept or reject the lot
    - larger sample sizes
  - Variable (ANSI ASQ Z1.9-2008)
    - use actual measurements of the product to make decisions
    - estimates how close to nominal or specifications a process is running
    - smaller sample sizes

# SAMPLING STRATEGY - Quantity

- Generally accepted standards (sampling plans)
  - Attribute (ANSI ASQ Z1.4-2008)
  - Variable (ANSI ASQ Z1.9-2008)
- Attribute and Variable plans both rely on acceptable quality limits (AQL)
  - AQL estimates the percent defective in the group sampled
  - The plans are based on statistical estimates and assumptions with associated errors
    - Producers risk (Type I error) – reject a batch that is good
    - Consumer risk (Type II error) – accept a batch that is bad
- ANSI/ASQ Standards statistics are based on  
AQL = 0.10 or 99.9% good



# IS 99.9% GOOD ENOUGH

A standard of 99.9% effectiveness sounds impressive, but consider that if 99.9% was good enough, then ...

- Every day
  - Hospitals would give twelve newborns to wrong parents
  - Two planes landing at Chicago O'Hare would be unsafe
- Each year
  - Footwear companies would ship 114,500 mismatched pairs of shoes
  - IRS would lose two million documents
  - 20,000 incorrect drug prescriptions

[claims-portal.com](http://claims-portal.com)

# SAMPLING STRATEGY - Quantity

- Generally accepted standards
  - Attribute (ANSI ASQ Z1.4-2008)
  - Variable (ANSI ASQ Z1.9-2008)
- Attribute and Variable plans both rely on acceptable quality limits (AQL)
  - AQL estimates the percent defective in the group sampled
  - The plans are based on statistical estimates and assumptions with associated errors
  - Statistics based on AQL = 0.10 or 99.9% good
- C=0 by Nicholas L. Squeglia also has general industry acceptance.
- Additional plans:
  - Dodge-Romig Sampling Tables; MIL-STD-1916 or -1235

# SAMPLING STRATEGY - Quantity

Z1.4 and Z1.9 examples



# MODULE 2 - SUMMARY

- Discussion directed toward manufacturing and physical products
  - Principles cover all industries (including service)
  - Metrology – the science of measurement

*What information (data) do I need and how do I know it is correct (reliable).*

# REVIEW – Metrology & Calibration

- Measurement Fundamentals & Calibration System
- Specifications are documents that contain requirements necessary for Customer to convey needs to Supplier
- GD&T per ASME Y14.5-2009 used for part/product drawings to communicate geometric controls via symbols
  - Fit/form/function
  - Relationship between specific part features

# REVIEW – Inspection & Sampling

- Inspection Types
  - Acceptance Sampling
- Sample Planning & Logistics
  - Traceability
  - When/where/who to sample
  - Collection methods
  - Quantity needed (Sample plans vs 100%)
- Inspection process:
  - Measurement of sample
  - Comparison against specification
  - Decision based on results
  - Corrective action, if necessary



## Module 2

# Measurement Fundamentals