

AQS 110

Introduction to Metrology

This material is based upon work supported
by the National Science Foundation under
Grant No. 1304474



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. ...

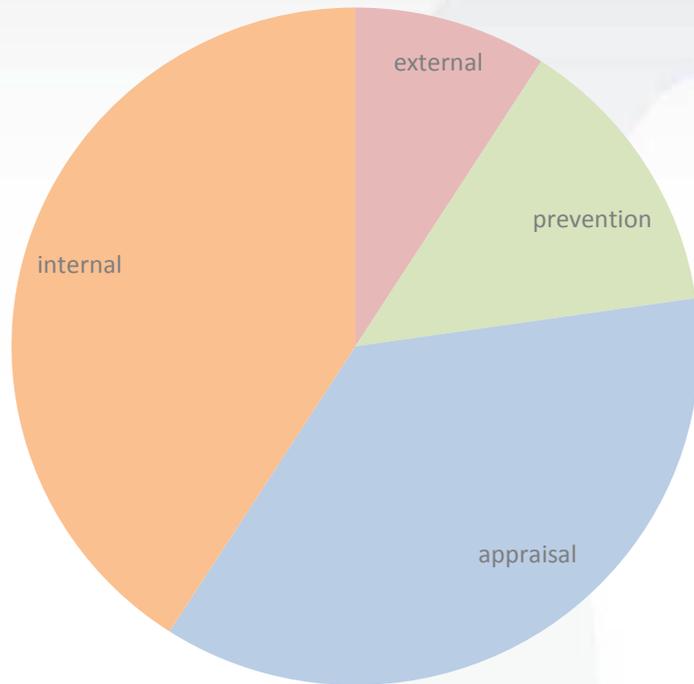
WHY MEASURE

- 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

: 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

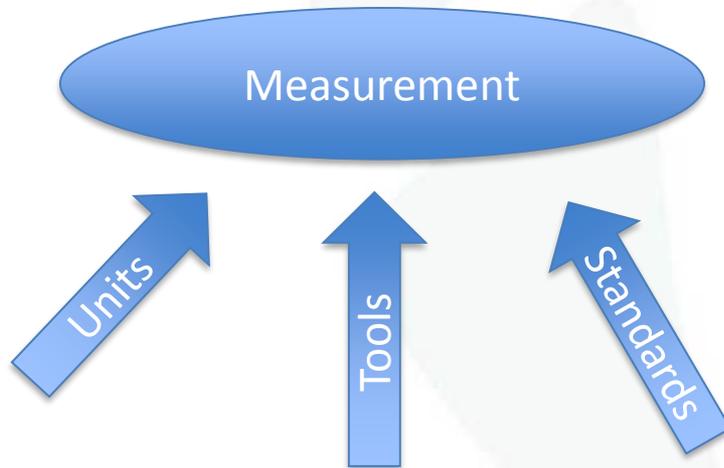
- Metrology – the science of measurement
- A broad field with three basic activities
 1. Definition of internationally accepted units of measurement
 2. Realization of these units of measurement in practice (i.e. Calipers, scales, thermometers, etc.)
 3. Application of chains of traceability linking 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.
 - 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

- 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  
(units of measure)"]; A --> C["Legal  
(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  
(units of measure)"]; Metrology --- Legal["Legal  
(harmonization for trade)"]; Metrology --- Applied["Applied / Industrial  
(manufacturing/process measurements)"];
```

Scientific
(units of measure)

Legal
(harmonization for trade)

Applied / Industrial
(manufacturing/process measurements)

METROLOGY

```
graph TD; Metrology[METROLOGY] --- Scientific["Scientific  
(units of measure)"]; Metrology --- Legal["Legal  
(harmonization for trade)"]; Metrology --- Applied["Applied / Industrial  
(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 3rd 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

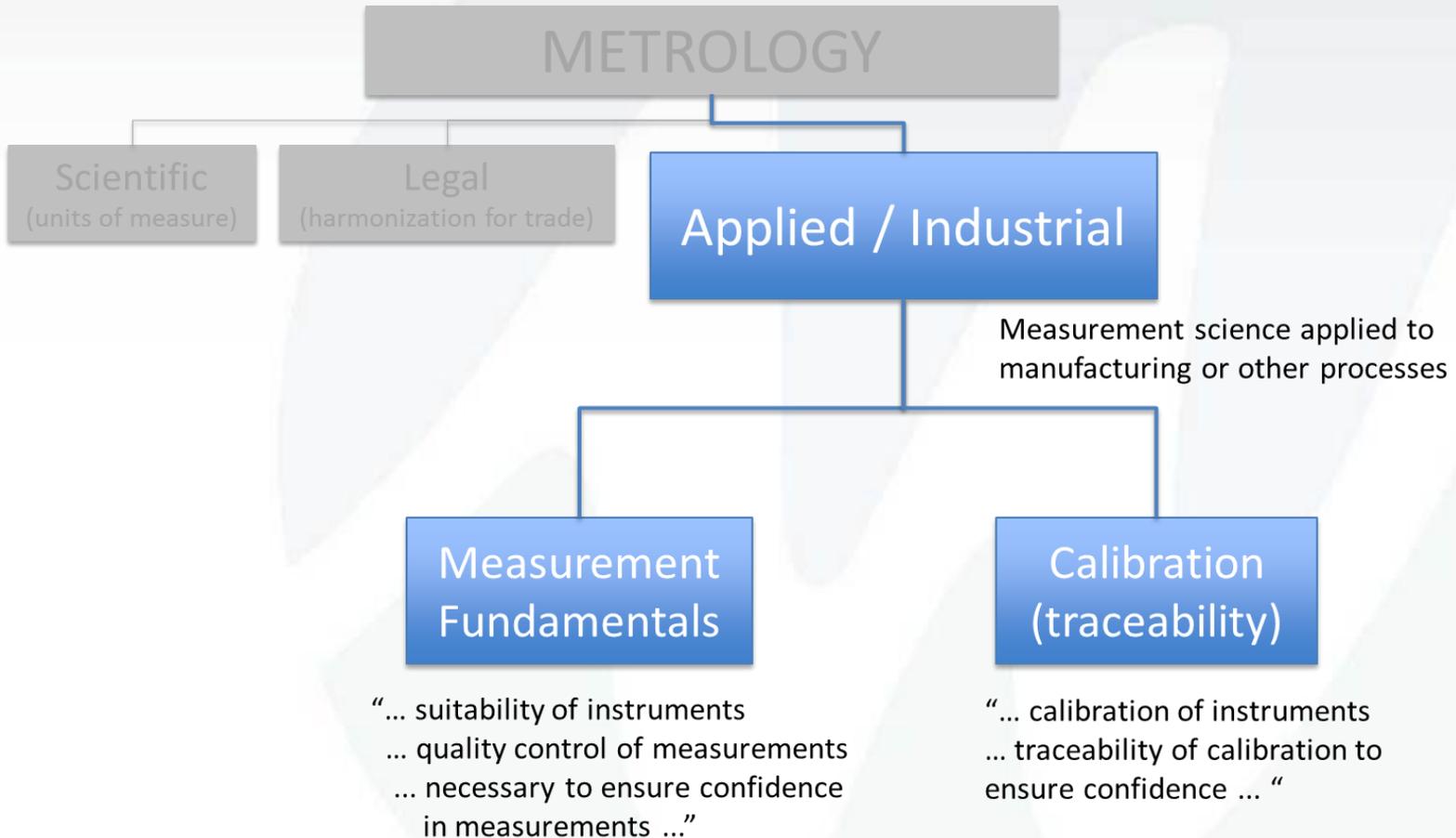
METROLOGY

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

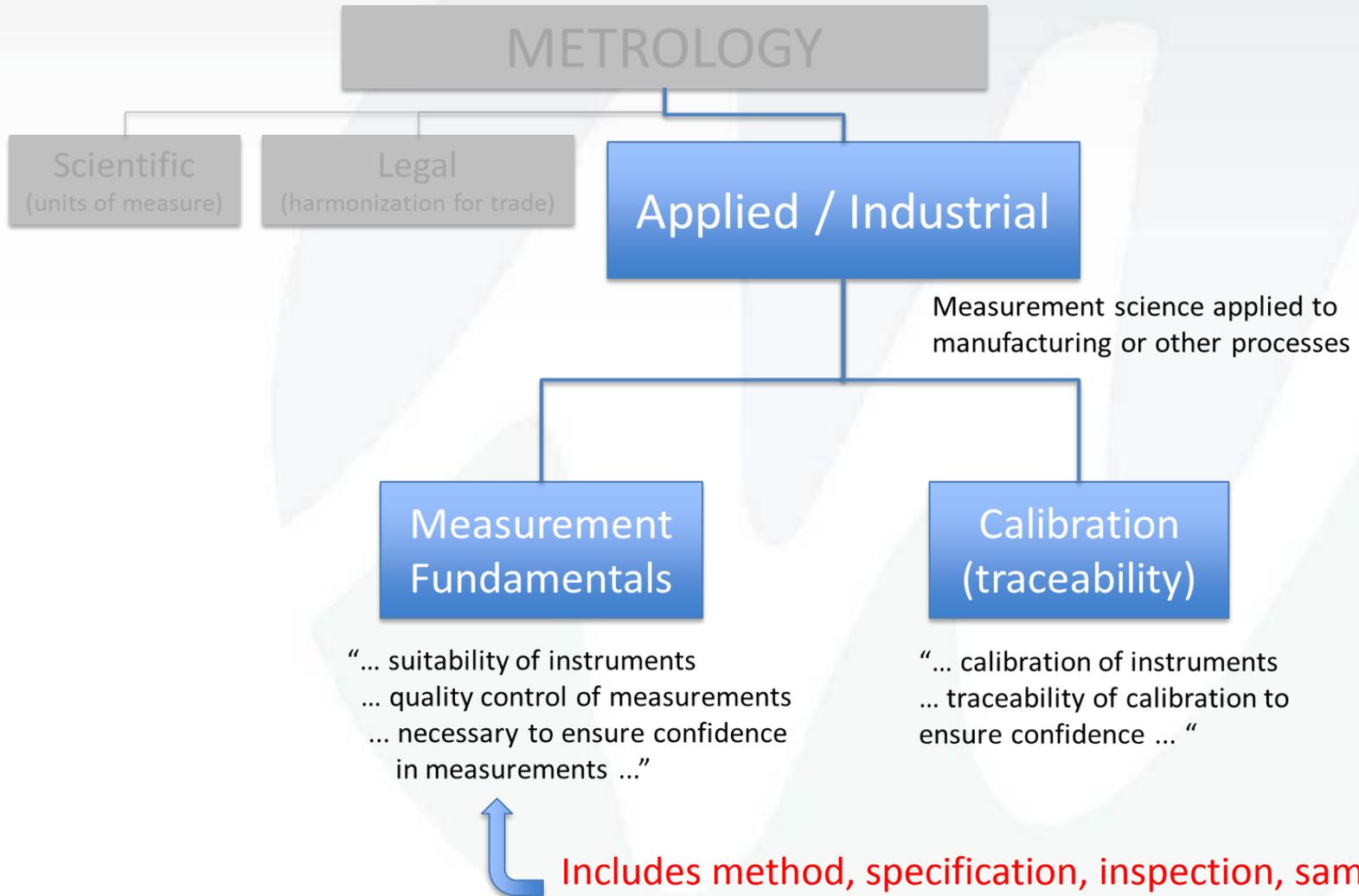
Pass/Fail (Ship the Product ?)

- **Metrology Program**
 - Measurement Fundamentals
 - Calibration (Traceability)

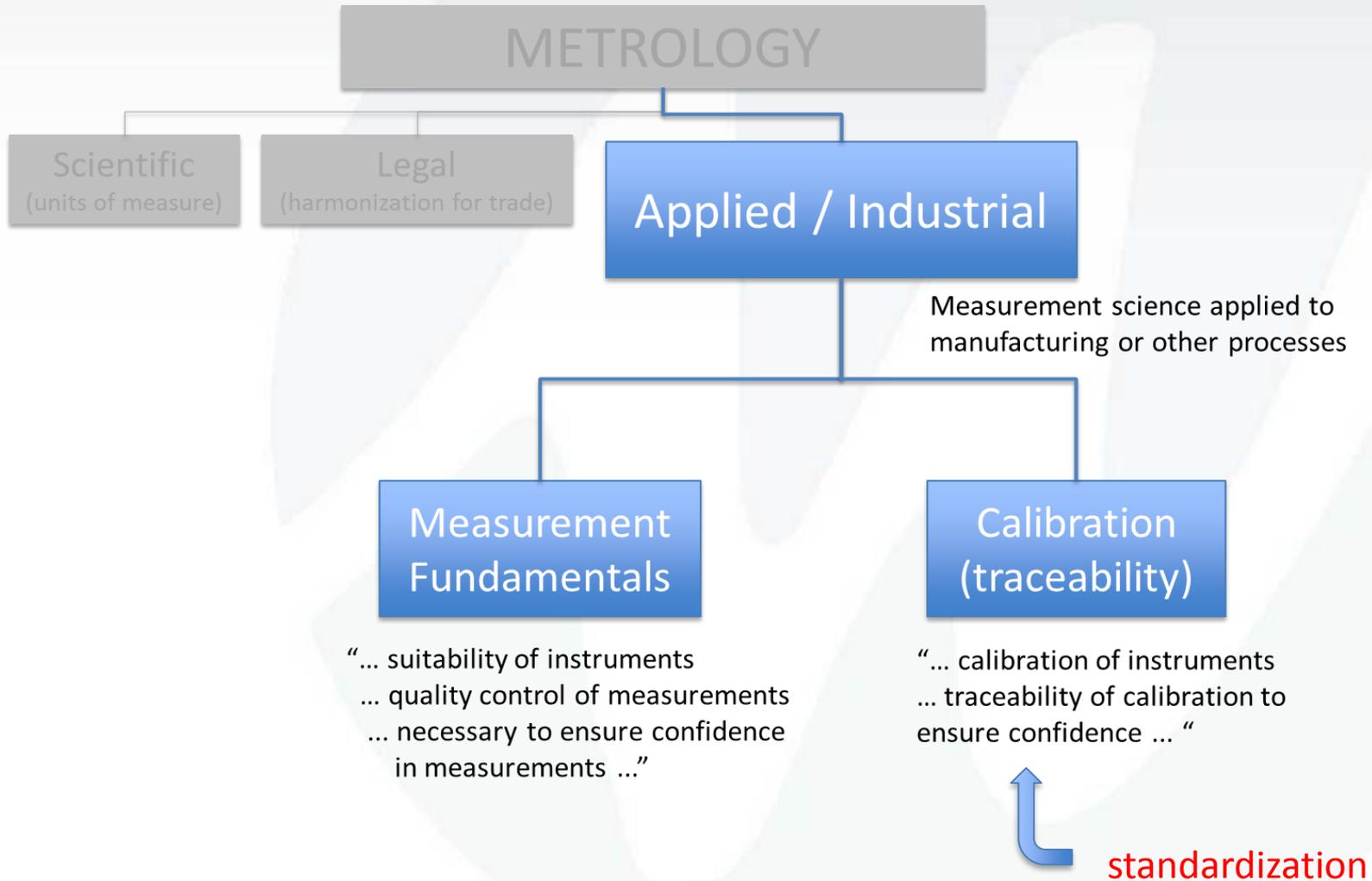
METROLOGY



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

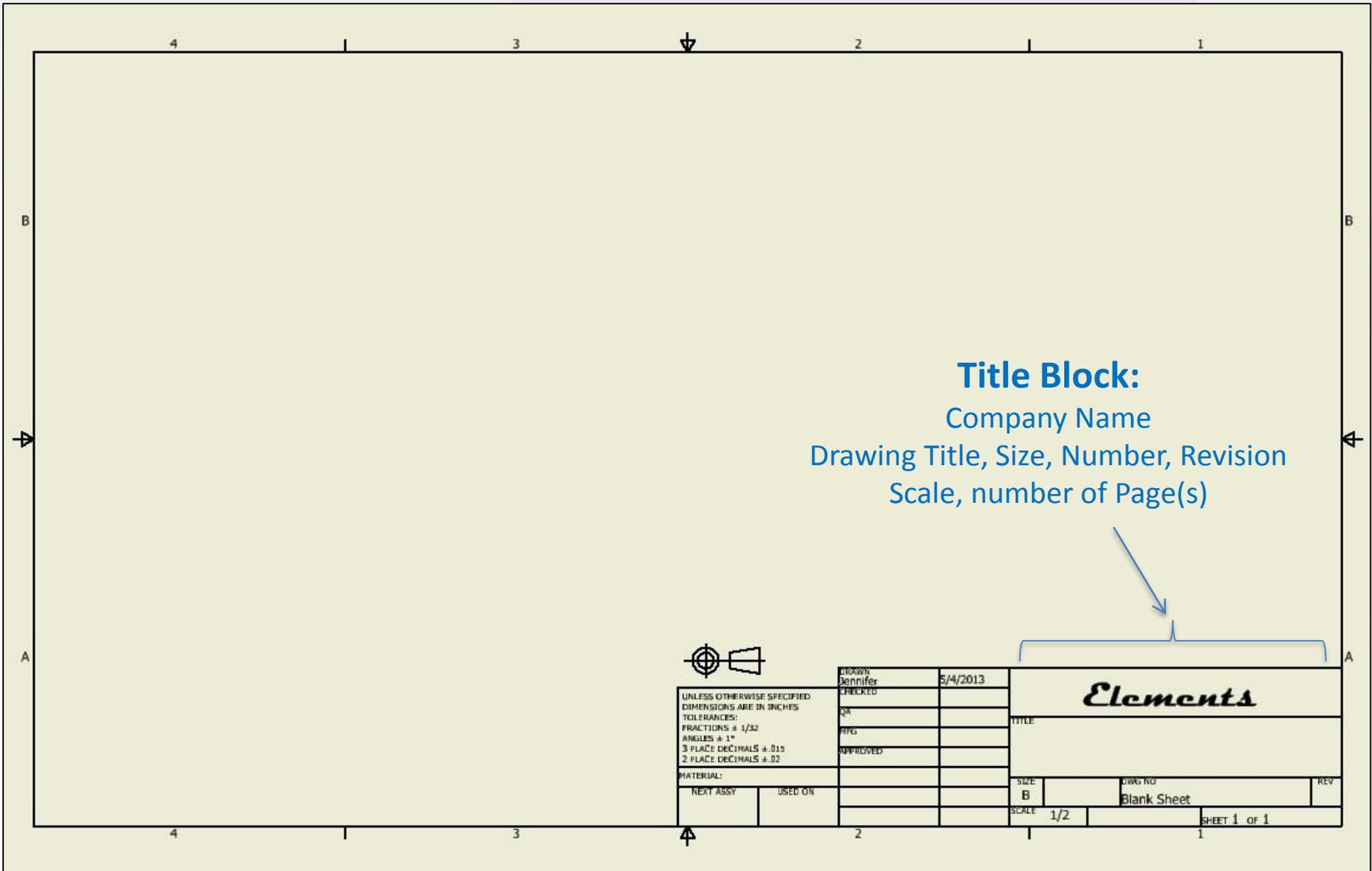
DRAWING

- 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)

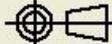
UNDERSTANDING THE DRAWINGS



UNDERSTANDING THE DRAWINGS

Approvals:

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



UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONS ± 1/32 ANGLES ± 1° 3 PLACE DECIMALS ± .015 2 PLACE DECIMALS ± .02		DRAWN Jennifer	5/4/2013	<i>Elements</i>		
		CHECKED				TITLE
		QA				
		MFG				
		APPROVED				
MATERIAL:				SIZE B	DWG NO Blank Sheet	
NEXT ASSY	USED ON			SCALE 1/2	REV	
					SHEET 1 of 1	

UNDERSTANDING THE DRAWINGS

Tolerance Block:
Default tolerance values

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONS ± 1/32 ANGLES ± 1° 3 PLACE DECIMALS ± .015 2 PLACE DECIMALS ± .02		DRAWN	Dennifer	5/4/2013
		CHECKED		
MATERIAL: NEXT ASSY USED ON		QA		
		APPROVED		
		SIZE	B	DWG NO
		SCALE	1/2	Blank Sheet
		REV		SHEET 1 of 1

UNDERSTANDING THE DRAWINGS

Visual representation of part, component or assembly

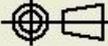
UNLESS OTHERWISE SPECIFIED:
 DIMENSIONS ARE IN INCHES
 TOLERANCES:
 FRACTIONS ± 1/32
 ANGLES ± 1°
 3 PLACE DECIMALS ± .015
 2 PLACE DECIMALS ± .02

DRAWN Jennifer		5/4/2013		Elements	
CHECKED					
QA					
MFG					
APPROVED				TITLE	
MATERIAL:				SIZE B	DWG NO Blank Sheet
NEXT ASSY	USED ON			SCALE 1/2	REV
				SHEET 1 of 1	

UNDERSTANDING THE DRAWINGS

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

Rev #	Author	Reason



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

MATERIAL:

NEXT ASSY	USED ON

DRAWN Jennifer	5/4/2013
CHECKED	
QA	
PIG	
APPROVED	

Elements

TITLE

SIZE B	DWG NO Blank Sheet	REV
SCALE 1/2	SHEET 1 of 1	

UNDERSTANDING THE DRAWINGS

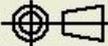
4	3	2	1
B			
<p>Notes Area</p> <p>Comments related to the component, assembly, etc. Bill of Material (BOM)</p>			
A			
4	3	2	1

Rev #	Author	Reason

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

MATERIAL:

NEXT ASSY	USED ON

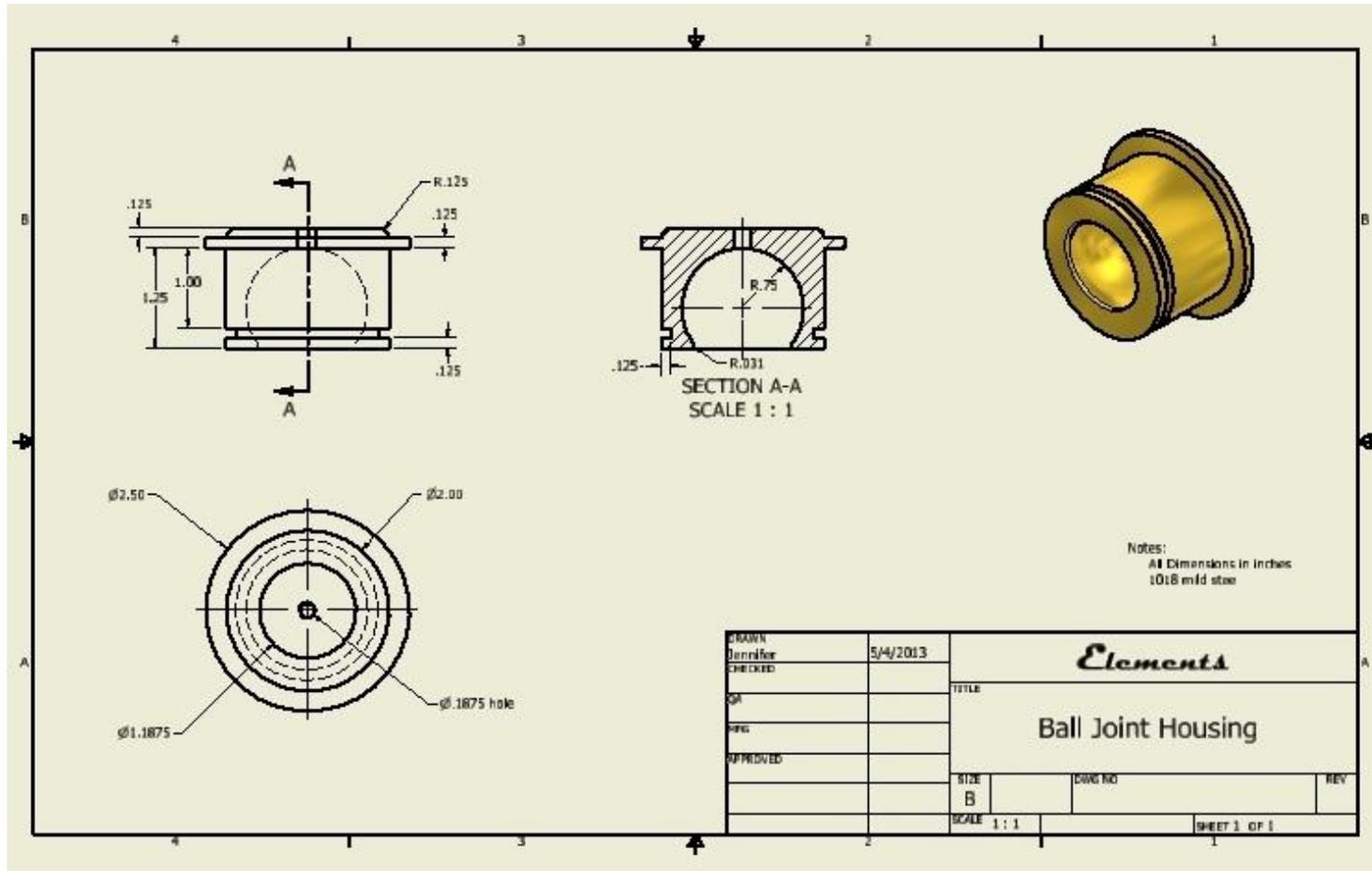


DRAWN Jennifer	5/4/2013	<i>Elements</i>
CHECKED		
QA		
APPROVED		
TITLE		
SIZE B	DWG NO Blank Sheet	REV
SCALE 1/2	SHEET 1 OF 1	

DRAWING

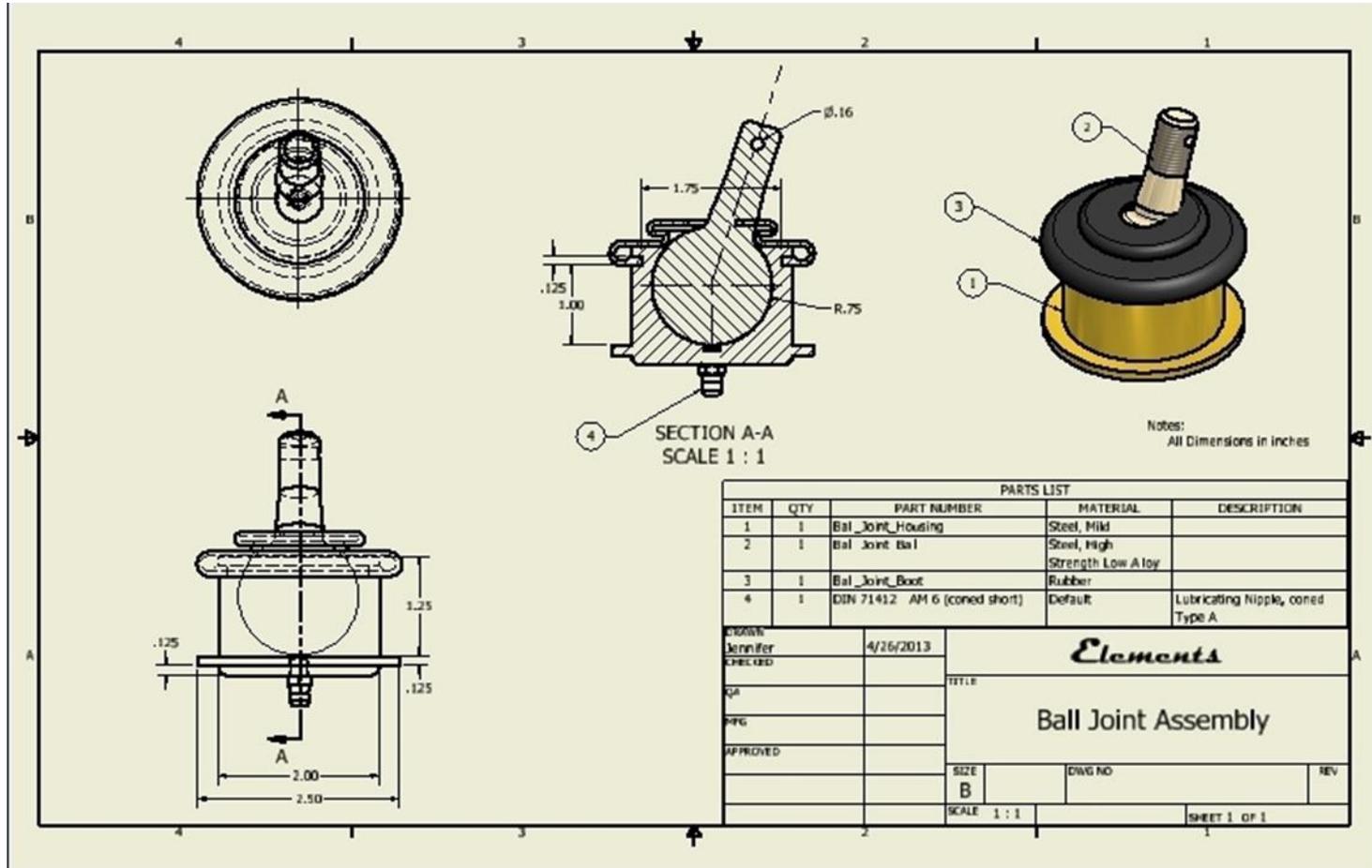
- American Society of Mechanical Engineers provides standard for industry
 - ASME Y14.5-2009 “Dimensioning & Tolerancing: Engineering Drawing and Related Documentation Practices”
Referred to as GD&T (geometric dimension & tolerance)
- ASME Y14.5-2009 provides specific rules for interpretation and application 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**

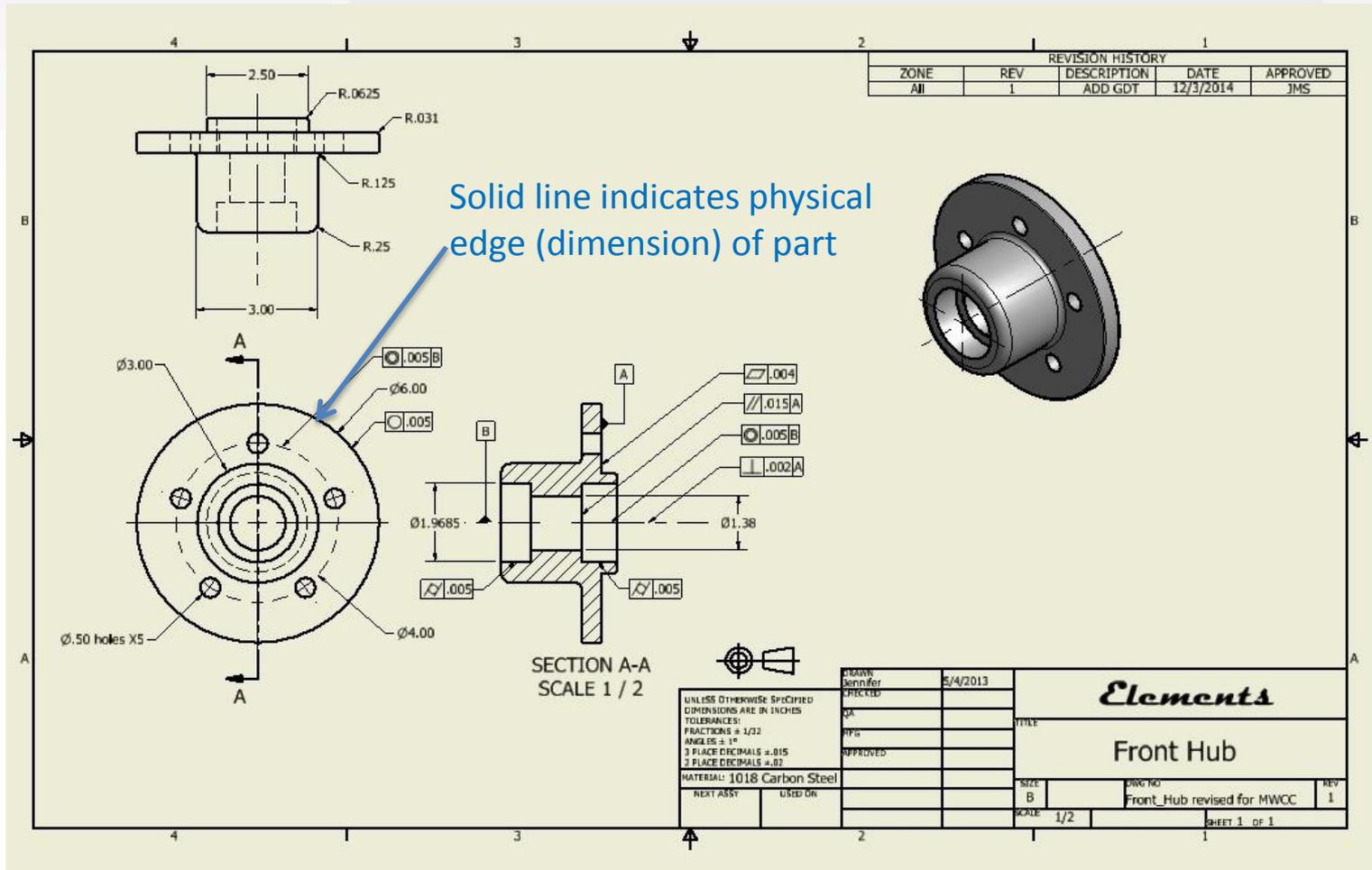
Note: limit dimensioning and unilateral tolerance are different

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

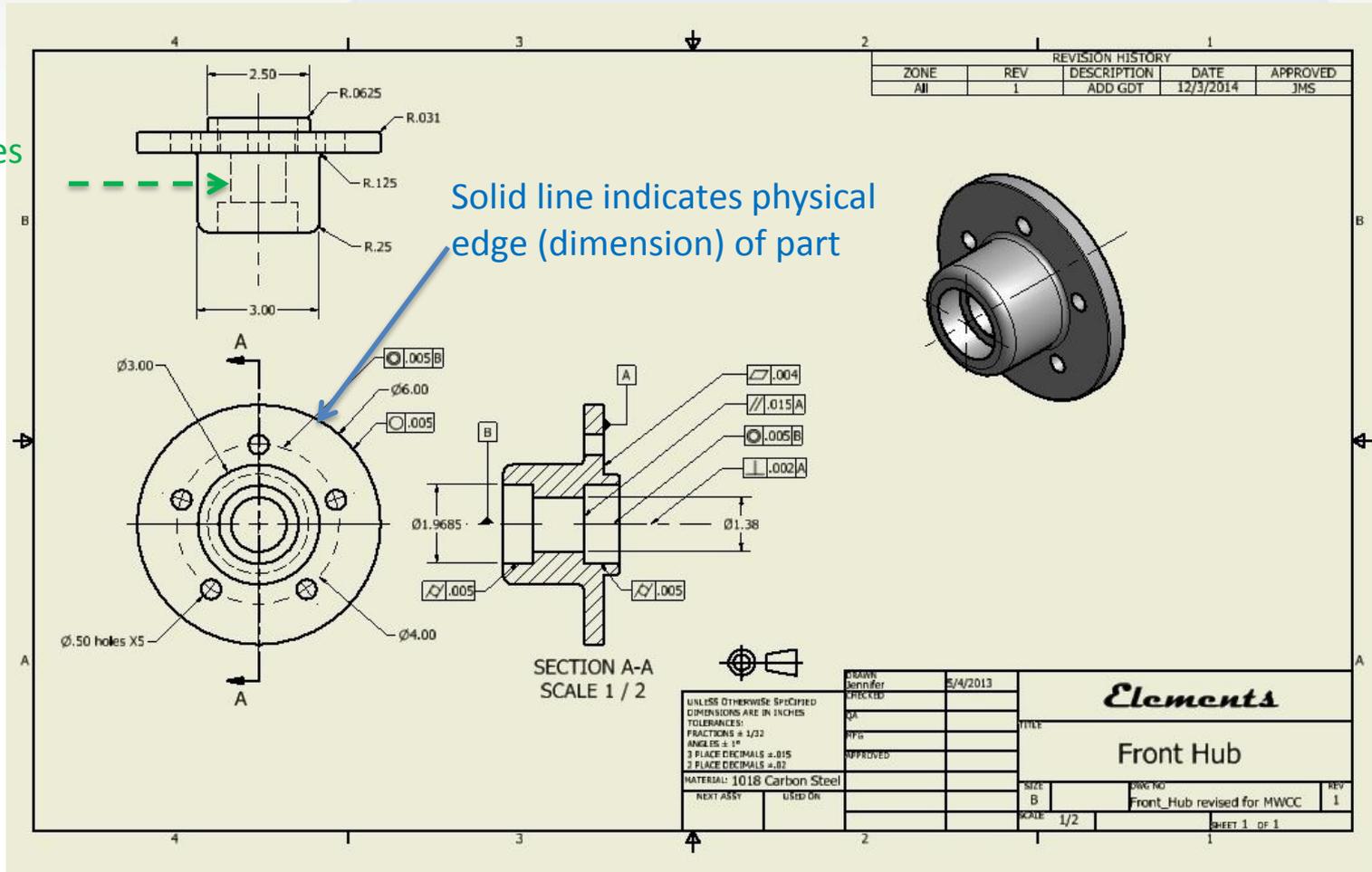


Wheel Hub for Go-Kart

UNDERSTANDING THE DRAWINGS

Dashed lines indicate hidden features

Solid line indicates physical edge (dimension) of part



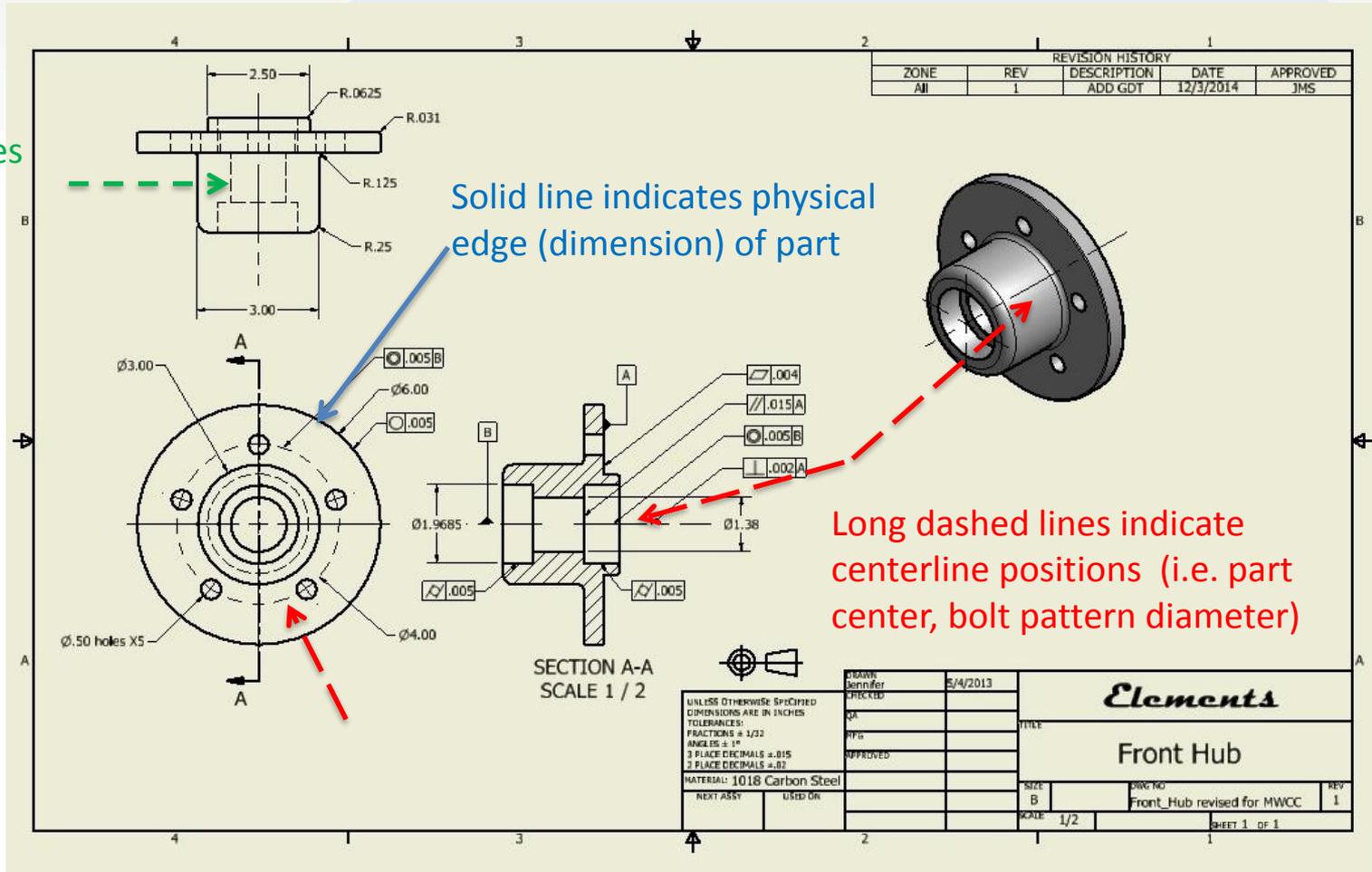
Wheel Hub for Go-Kart

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)



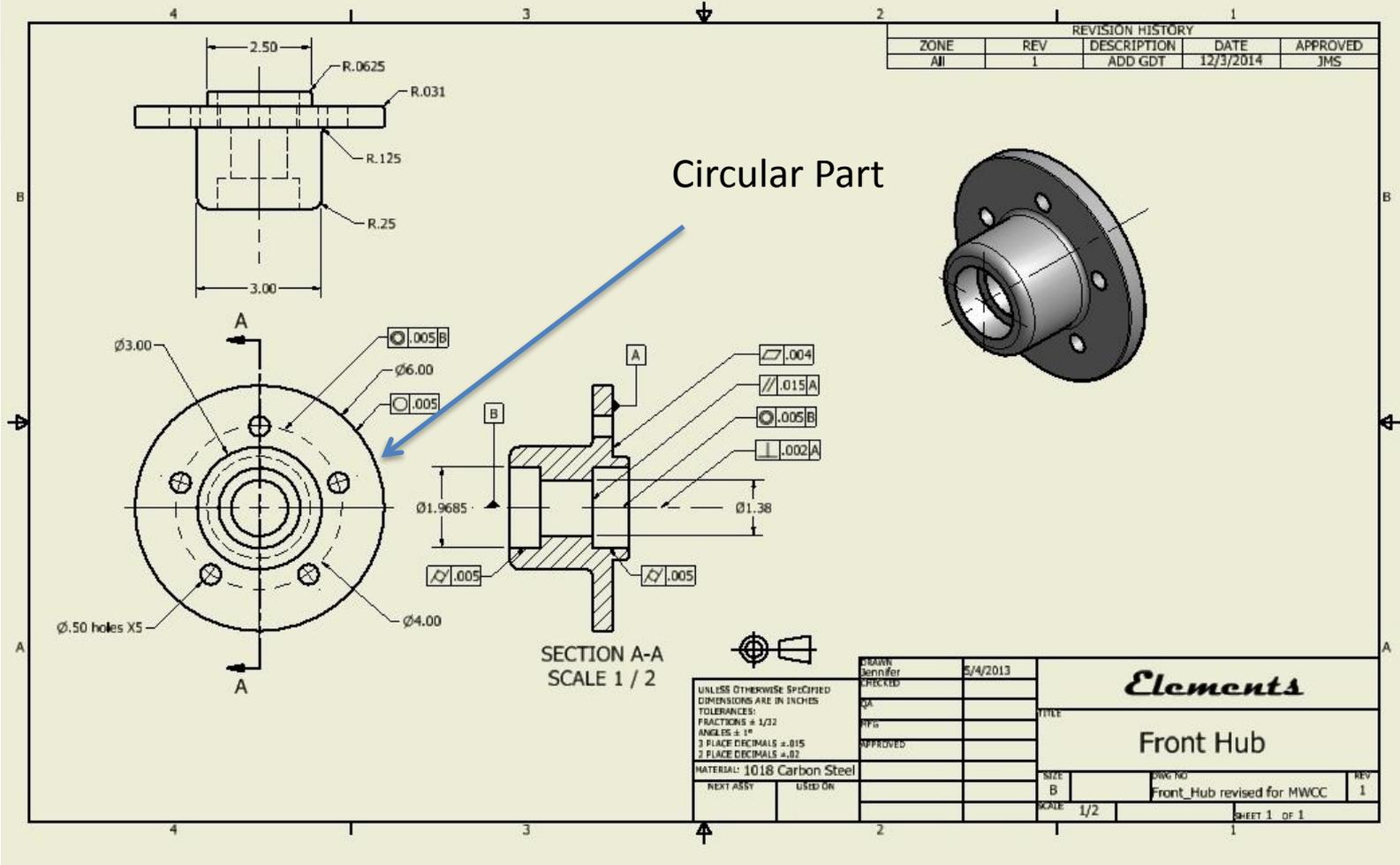
Wheel Hub for Go-Kart

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

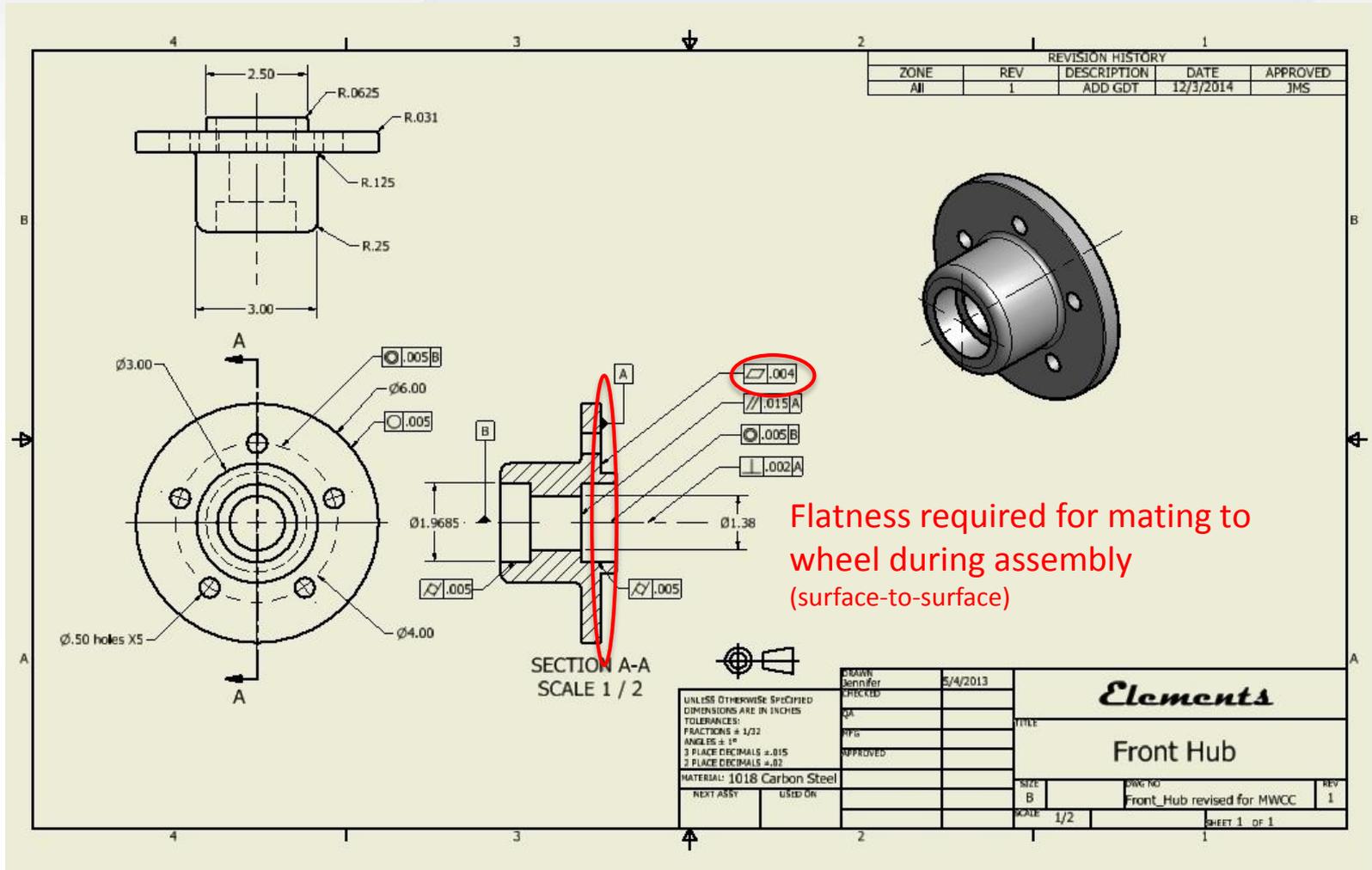
- Lines
 - Solid vs. dotted
 - Thick vs thin
- Shapes
 - Circles, arcs
 - Squares, angles
- Symbols
 - Parallel, flatness, concentricity

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”

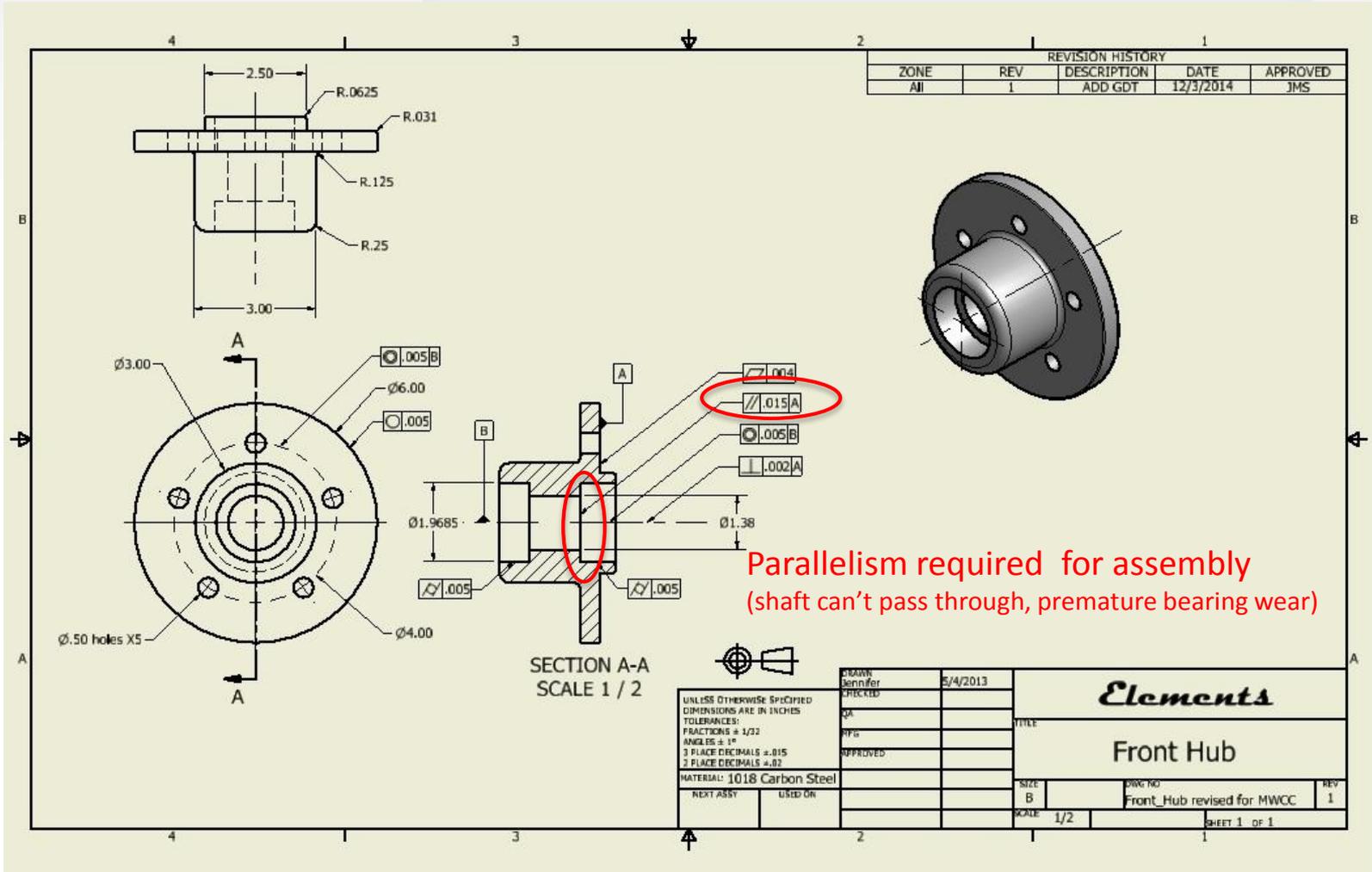
UNDERSTANDING THE DRAWINGS



Flatness required for mating to wheel during assembly (surface-to-surface)

Wheel Hub for Go-Kart

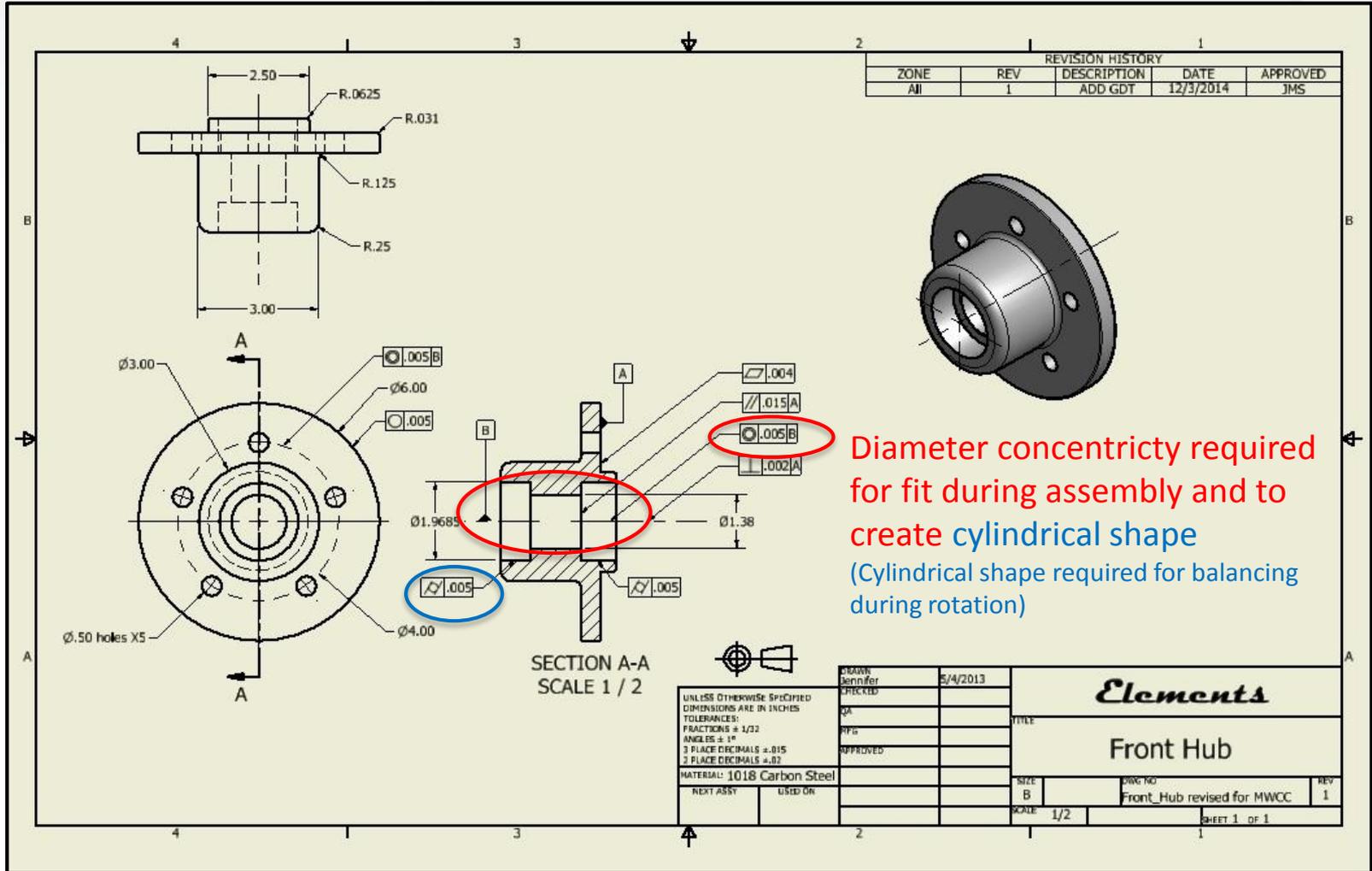
UNDERSTANDING THE DRAWINGS



Parallelism required for assembly
(shaft can't pass through, premature bearing wear)

Wheel Hub for Go-Kart

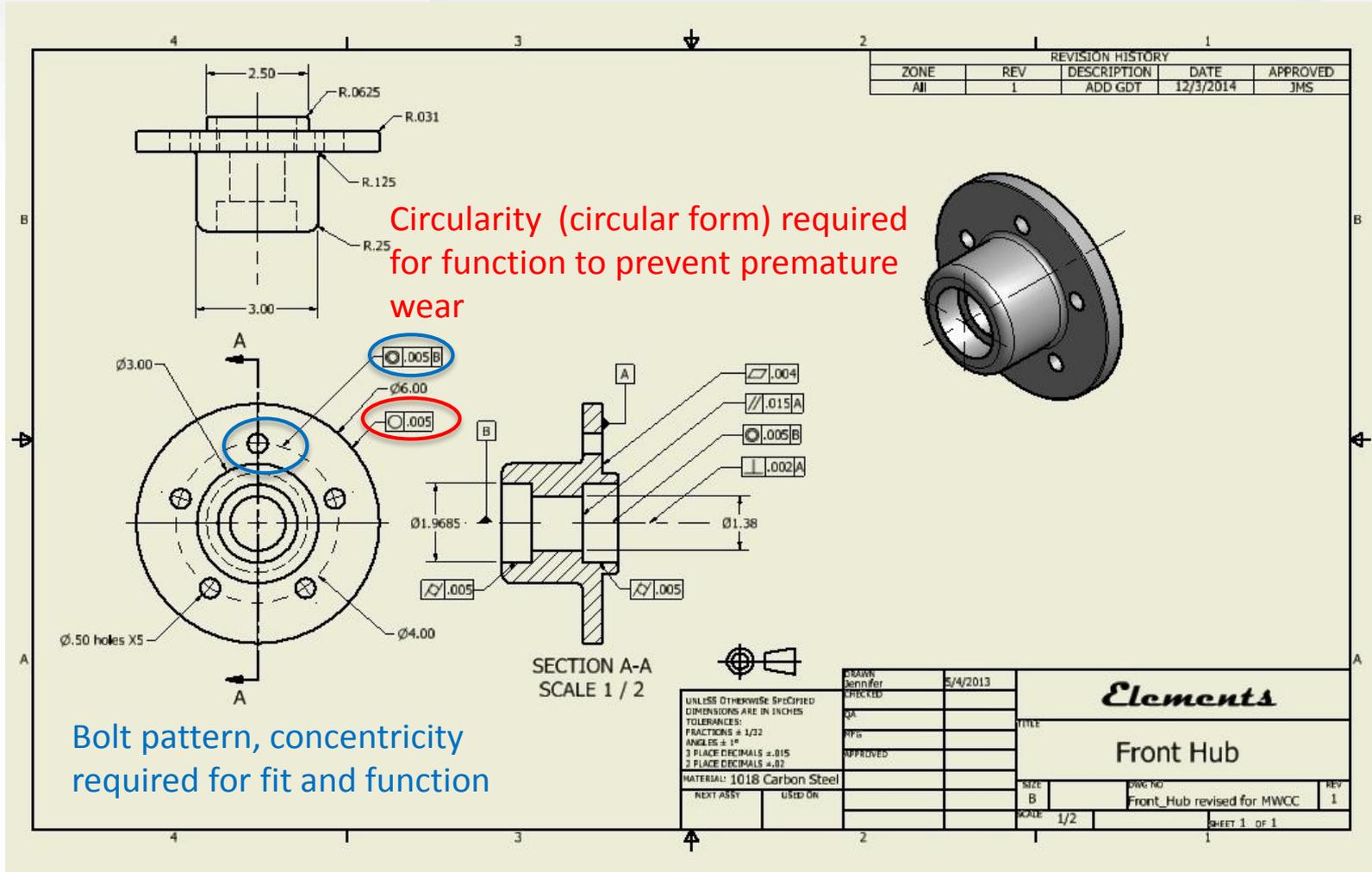
UNDERSTANDING THE DRAWINGS



Diameter concentricity required for fit during assembly and to create cylindrical shape (Cylindrical shape required for balancing during rotation)

Wheel Hub for Go-Kart

UNDERSTANDING THE DRAWINGS

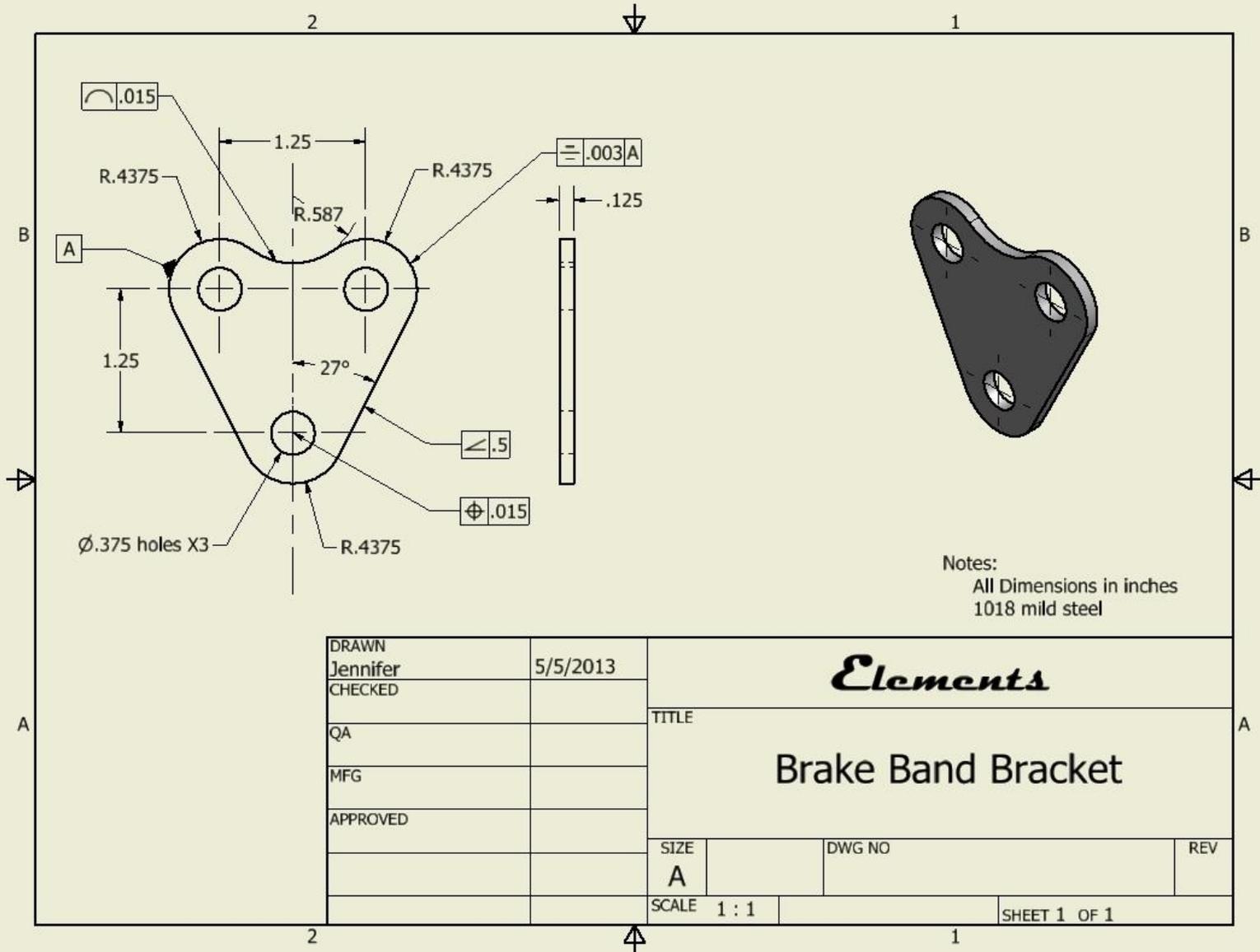


Wheel Hub for Go-Kart

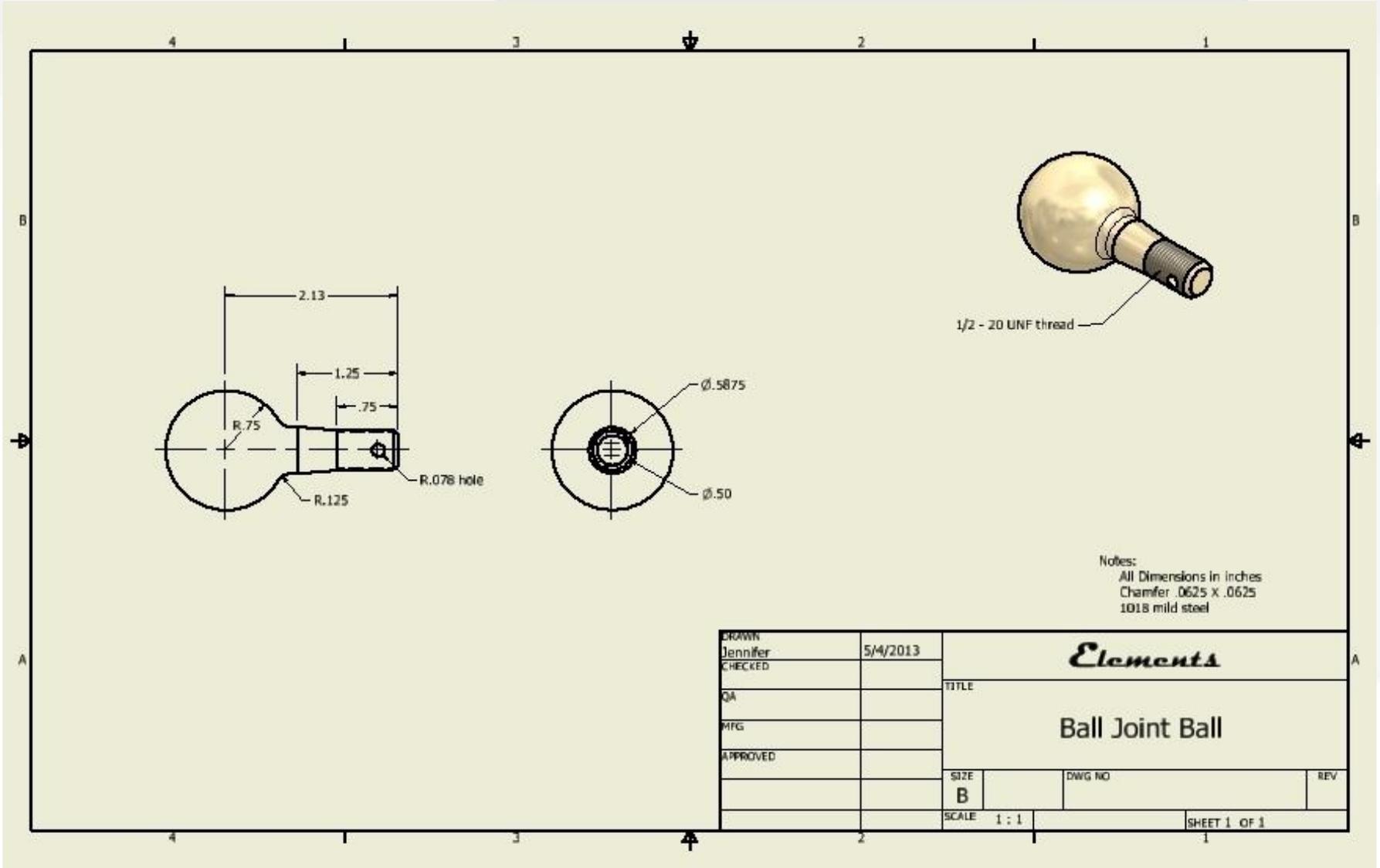
UNDERSTANDING THE DRAWINGS

Drawing review – symbols, dimensions

DRAWING REVIEW

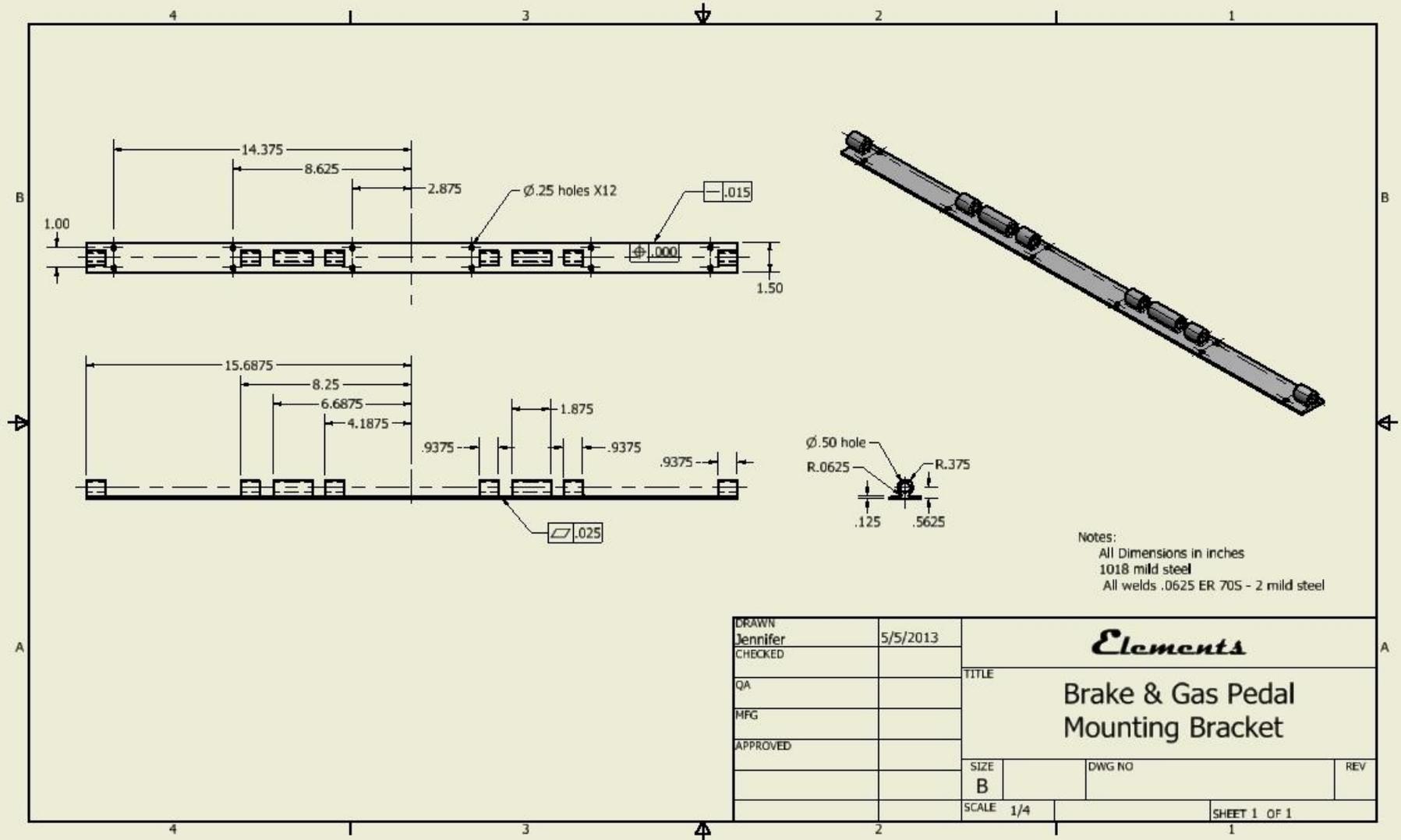


DRAWING REVIEW



DRAWN Jennifer	5/4/2013	<i>Elements</i>	
CHECKED			
QA		TITLE	
MFG		Ball Joint Ball	
APPROVED		SIZE B	REV
		DWG NO	
		SCALE 1 : 1	SHEET 1 OF 1

DRAWING REVIEW



DRAWN Jennifer	5/5/2013	Elements		
CHECKED				
QA		SIZE B	DWG NO	REV
MFG		SCALE 1/4	SHEET 1 OF 1	
APPROVED				



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

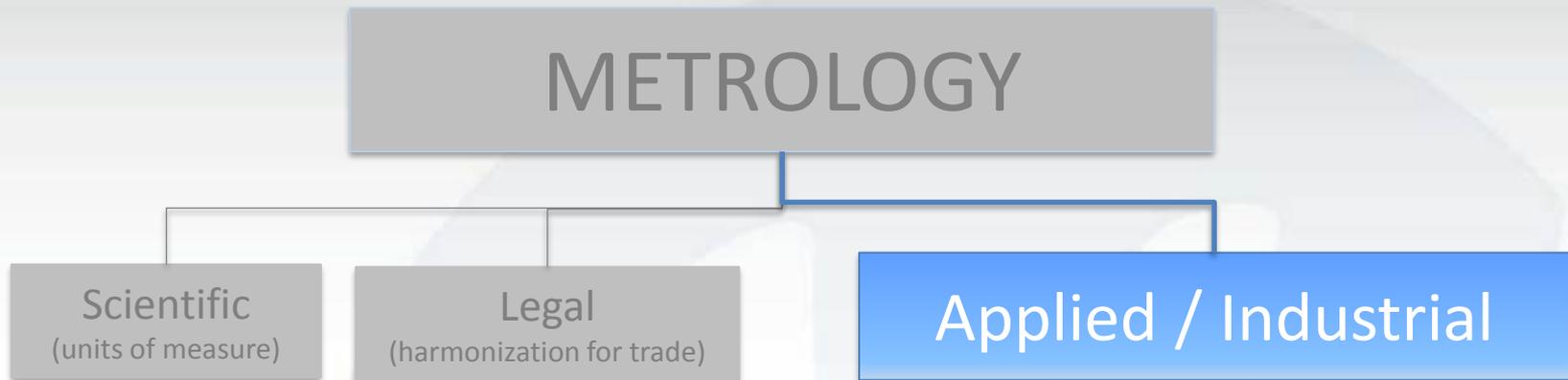
- Scales / Rulers
- Calipers
- Go / no-go
- Surface plates
- Ring gages
- Optical Comparator
- Vision systems
- Etc.

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



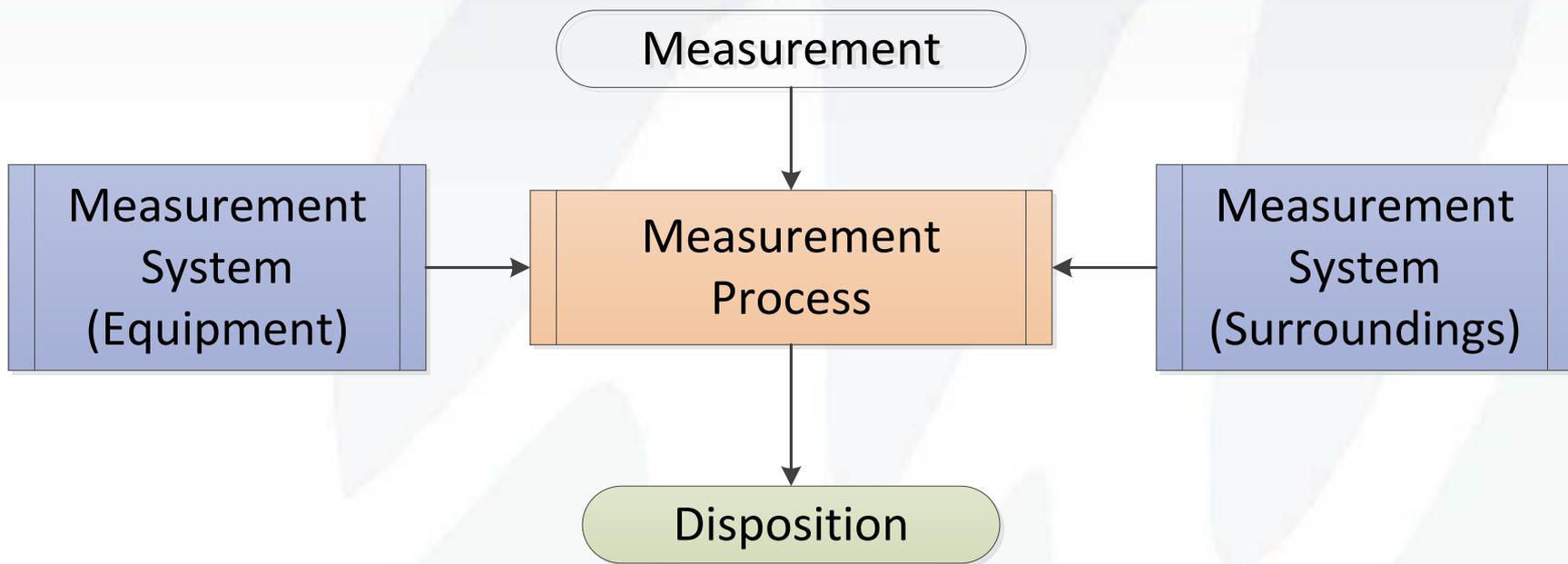
Neither accurate
nor precise



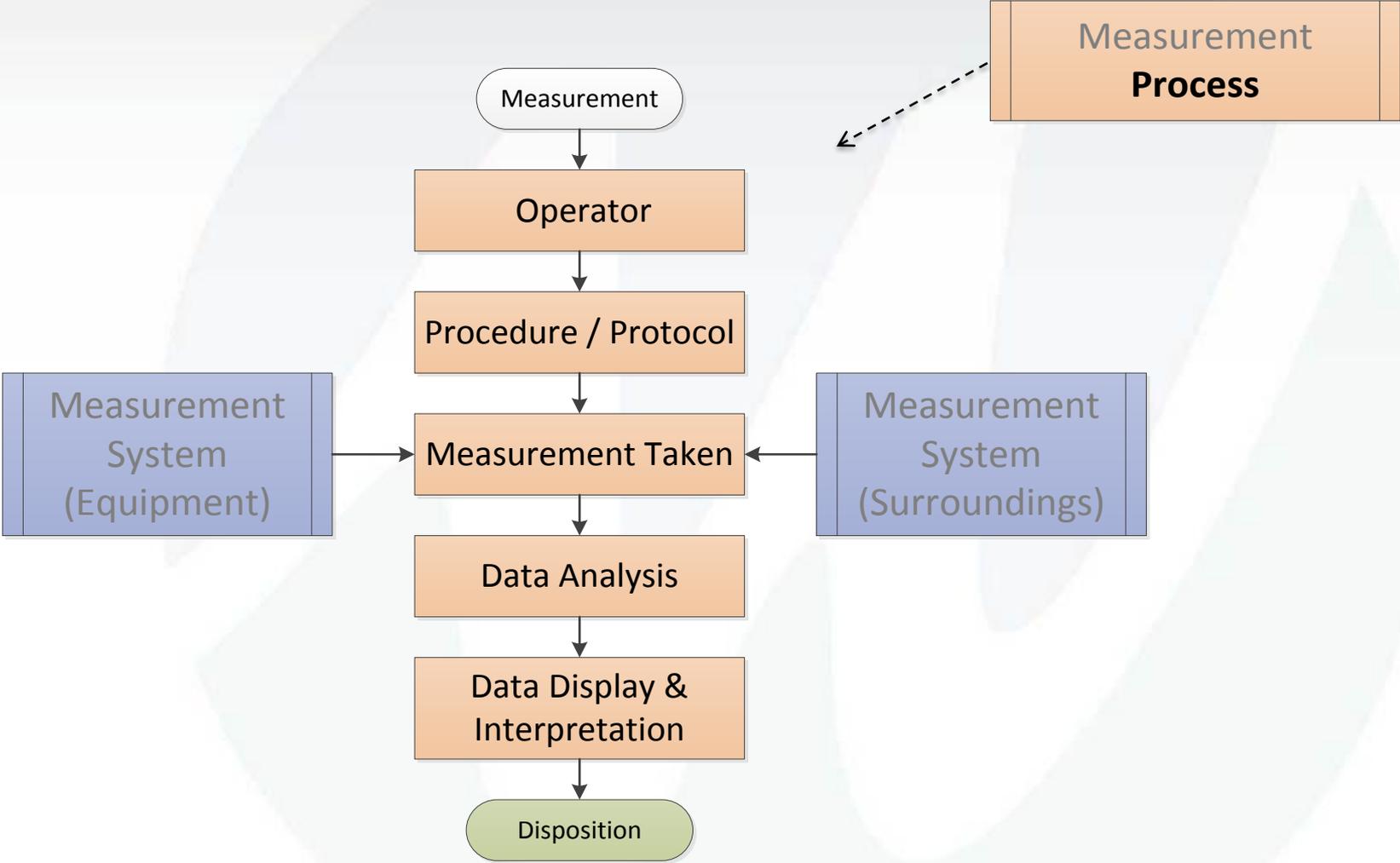
Accurate and
Precise

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

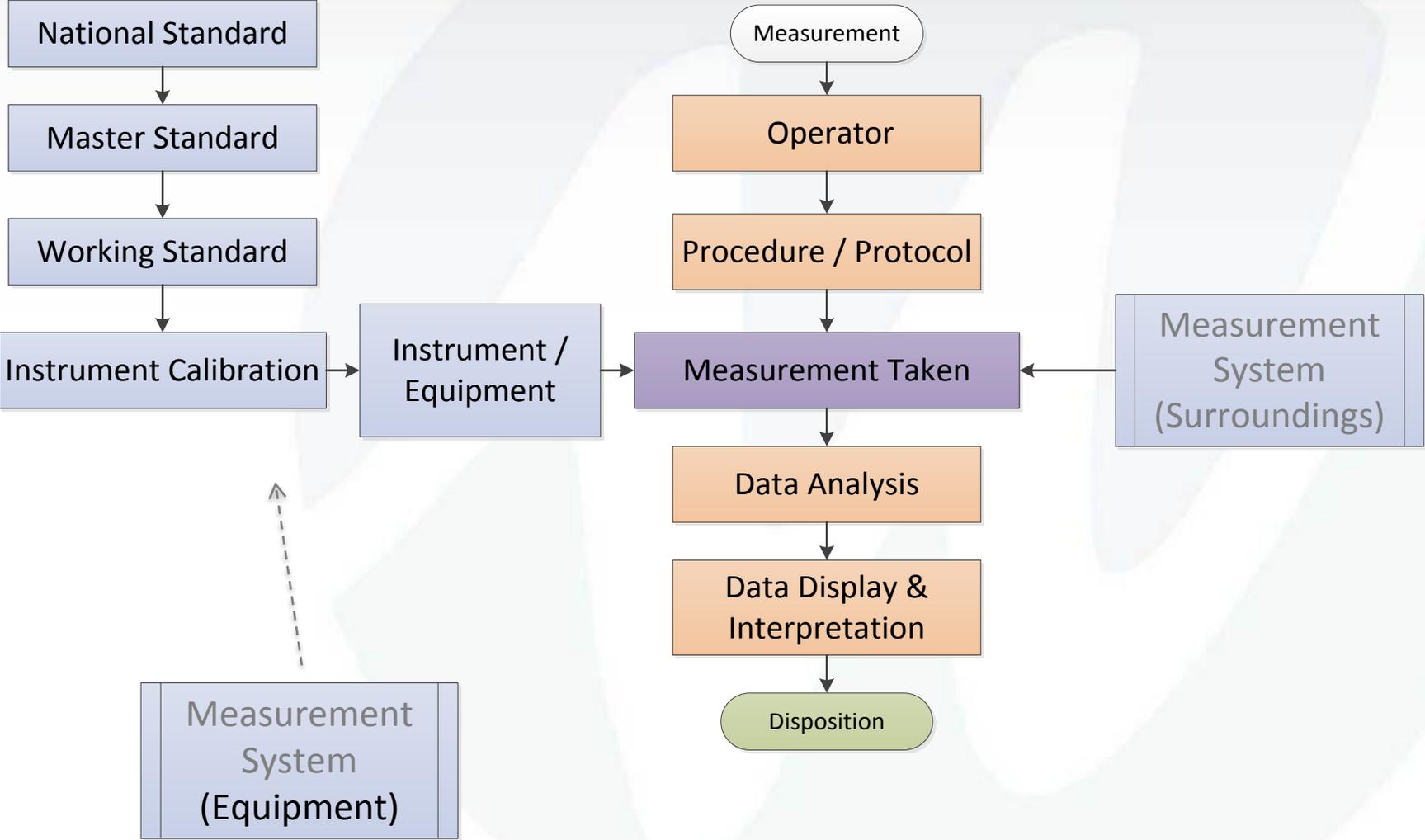
METROLOGY - Taking a Measurement



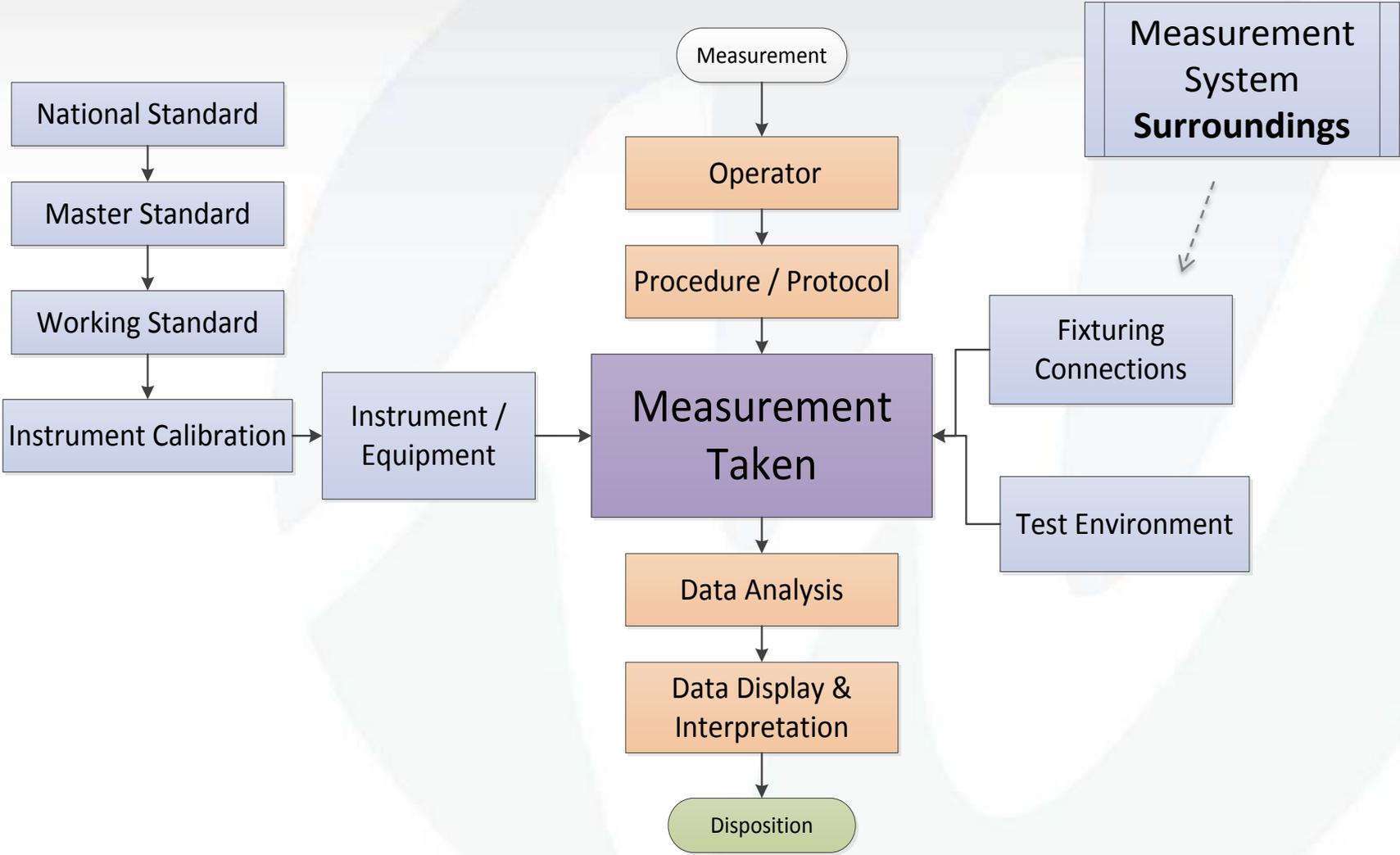
METROLOGY - Taking a Measurement



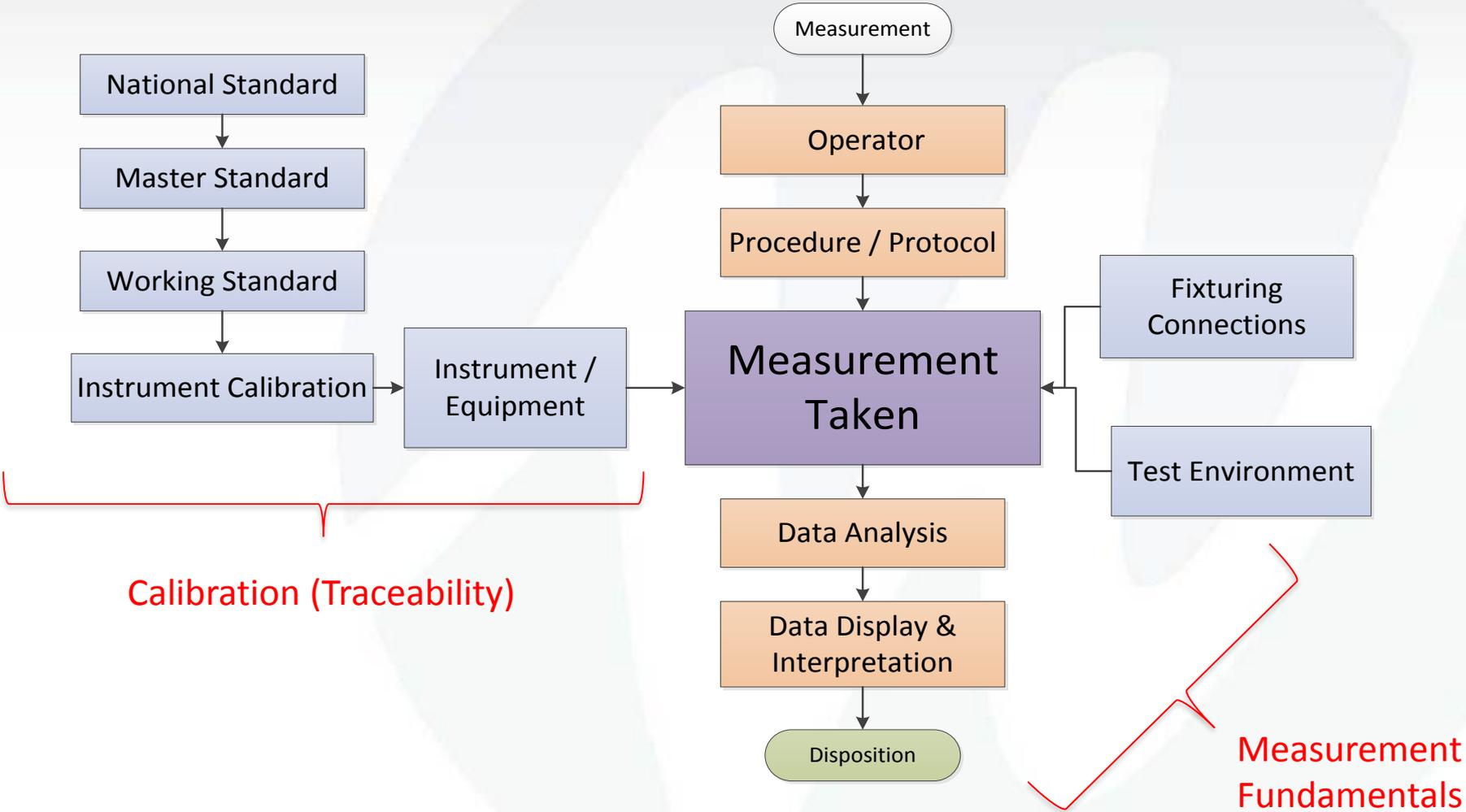
METROLOGY - Taking a Measurement



METROLOGY - Taking a Measurement

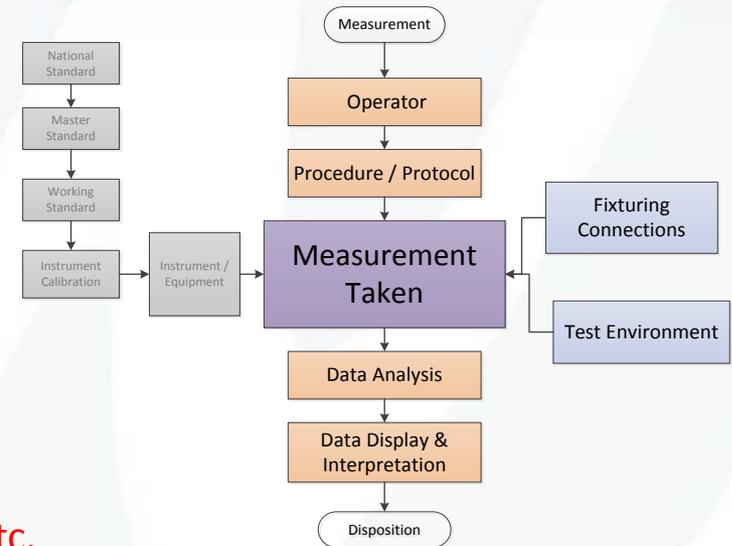


METROLOGY - Taking a Measurement



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

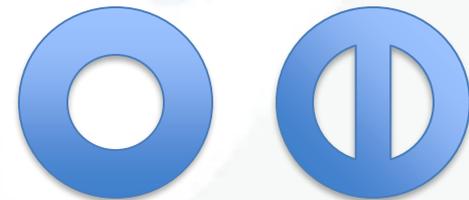
Example: single lumen tubing versus dual lumen tubing

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 ± 0.001 cm

Inner diameter specification: 0.40 to 0.60 inches

adequate: pin gage set that has 0.400 to 0.600 inch

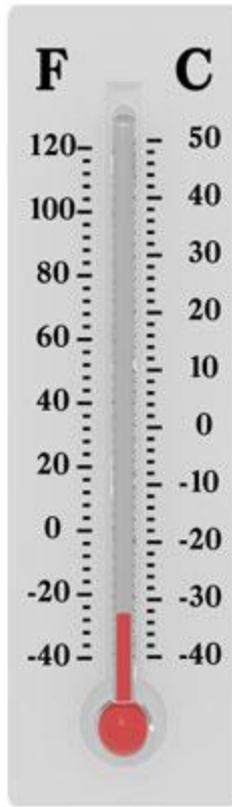
“overkill”: vision system that measures ± 0.00001 inch

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 shows a web browser window with the URL [www.grainger.com/product/BROWN-SHARPE-Digital-Calipers-WP27566/_N-bia/Ntt-caliper?redirect=caliper&sst=All&s_pp=false&picUrl=/static.grainger.com/rp/s/is/image/Grainger/38P082_AW01?smthumb\\$](http://www.grainger.com/product/BROWN-SHARPE-Digital-Calipers-WP27566/_N-bia/Ntt-caliper?redirect=caliper&sst=All&s_pp=false&picUrl=/static.grainger.com/rp/s/is/image/Grainger/38P082_AW01?smthumb$). The main content area features a product image of a digital caliper, technical specifications, and a comparison table.

Technical Specs

Item	Electronic Digital Caliper	Material	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="checkbox"/>
<input type="checkbox"/> 38P085	0059030 5	0 to 12"/0 to 300mm	2.5"	No	67	Check Availability	\$359.25 / each	<input type="checkbox"/>
<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="checkbox"/>

Product Recommendations:

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

MEASUREMENT FUNDAMENTALS

- Equipment specifications

What is being measured and accuracy needed?

The screenshot shows a web browser window displaying the product page for 'Electronic Digital Caliper' on Grainger.com. The page includes a product image, technical specifications, and a comparison table.

Technical Specs

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

Product Selection Options:

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

Comparison Table:

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="checkbox"/>
<input type="checkbox"/> 38P085	0059030 5	0 to 12"/0 to 300mm	2.5"	No	67	Check Availability	\$359.25 / each	<input type="checkbox"/>
<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="checkbox"/>

Product Details (Right Side):

- Electronic Digital Caliper, 0 to 6 In**
Item # 38P082
BROWN & SHARPE
Price: \$194.75
- Digital Caliper, 0 to 6 In**
Item # 21XK35
JOHNSON
Price: \$47.85
- Electronic Digital Caliper, 0 to 100 In**
Item # 38P080
BROWN & SHARPE
Price: \$8,366.00

Large range & jaw size



MEASUREMENT FUNDAMENTALS

- Equipment specifications

What is being measured and accuracy needed?

The screenshot displays a web browser window showing the product page for 'WP27566 Digital Calipers' on the Grainger website. The page includes a technical specifications section, a list of 11 products for comparison, and product details for three different caliper models.

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
<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="checkbox"/>
<input type="checkbox"/> 38P085	0059030 5	0 to 12"/0 to 300mm	2.5"	No	67	Check Availability	\$359.25 / each	<input type="checkbox"/>
<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="checkbox"/>

Product Details (Right Side):

- 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: \$8,366.00

Reduced range and jaw size

MEASUREMENT FUNDAMENTALS

- Equipment specifications

What is being measured and accuracy needed?

The screenshot displays a product page for an Electronic Digital Caliper. The main product shown is the Electronic Digital Caliper, Item # 38P082, priced at \$194.75. The technical specifications include a resolution of 0.0005"/0.01mm and a material of Stainless Steel Body, Plastic LCD Housing. The page also features a comparison table with 11 products, showing details such as Range, Jaw Depth, SPC Output, IP Rating, Availability, Price, and Qty. Three arrows on the left point to the comparison table, labeled "Increased data output".

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
<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="checkbox"/>
<input type="checkbox"/> 38P085	0059030 5	0 to 12"/0 to 300mm	2.5"	No	67	Check Availability	\$359.25 / each	<input type="checkbox"/>
<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="checkbox"/>

Product Details:

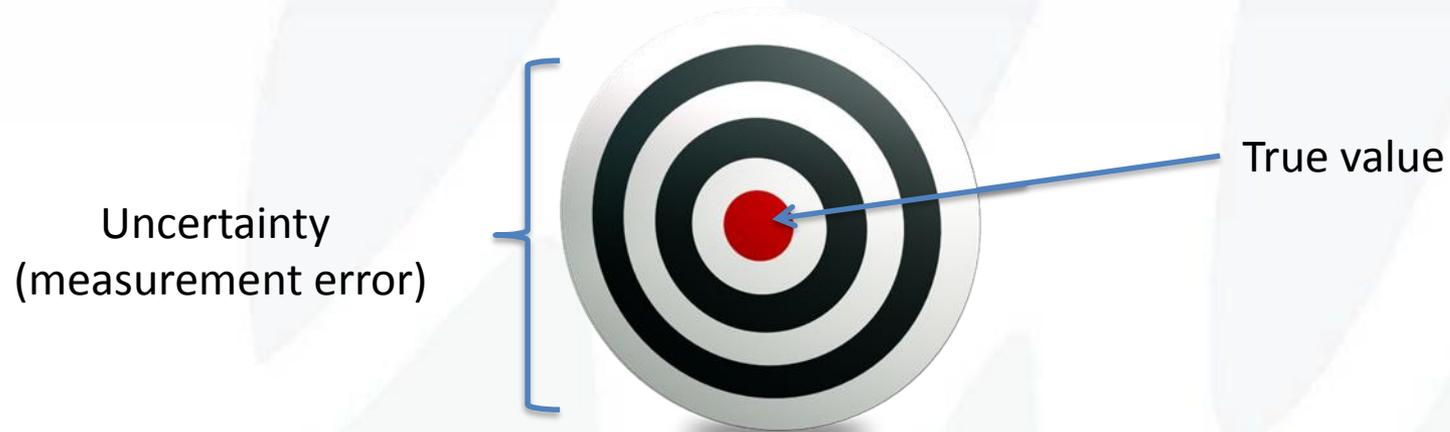
- Electronic Digital Caliper, 0 to 6 In**
Item # 38P082
BROWN & SHARPE
Price: \$194.75
- Digital Caliper, 0 to 6 In**
Item # 21XK35
JOHNSON
Price: \$47.85
- Electronic Digital Caliper, 0 to 100 In**
Item # 38P080
BROWN & SHARPE
Price: \$8,366.00

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)

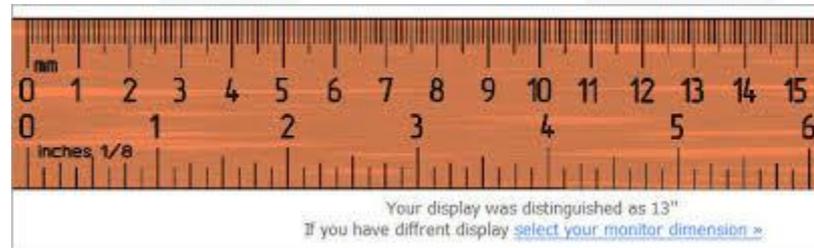
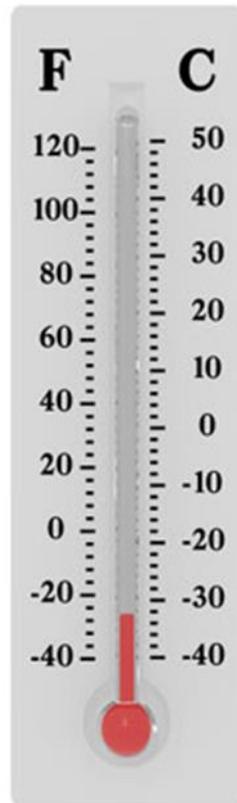


MEASUREMENT FUNDAMENTALS

- 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

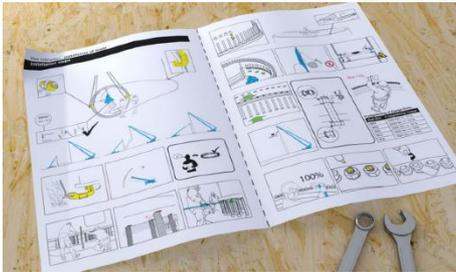


METROLOGY PROGRAM

- **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

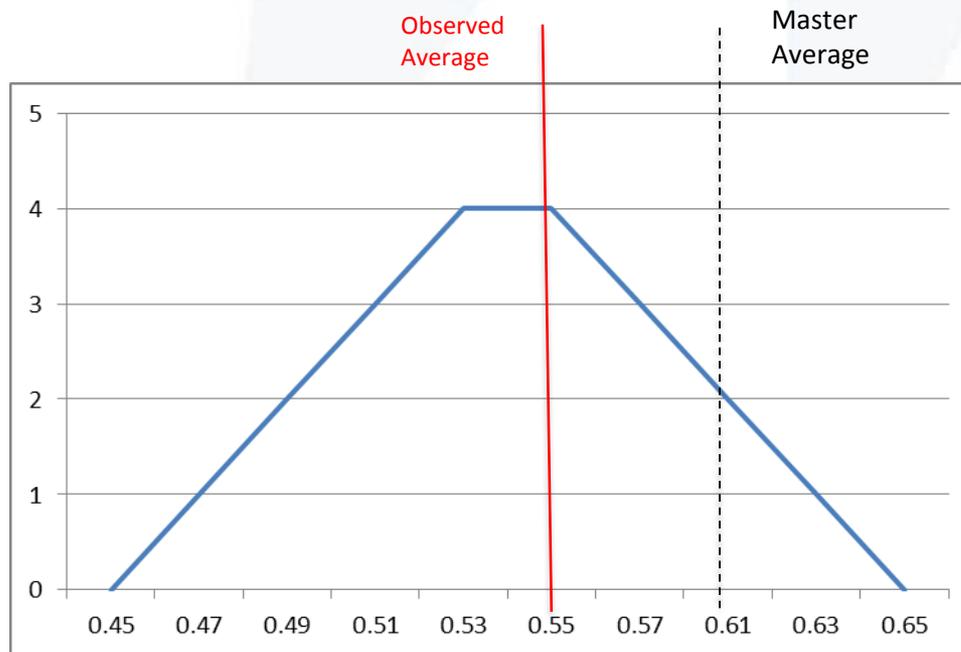
- Capability
 - Ability of the measurement system to accurately/precisely measure the characteristic
 - **Bias: systematic offset**
difference between observed average and master average



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

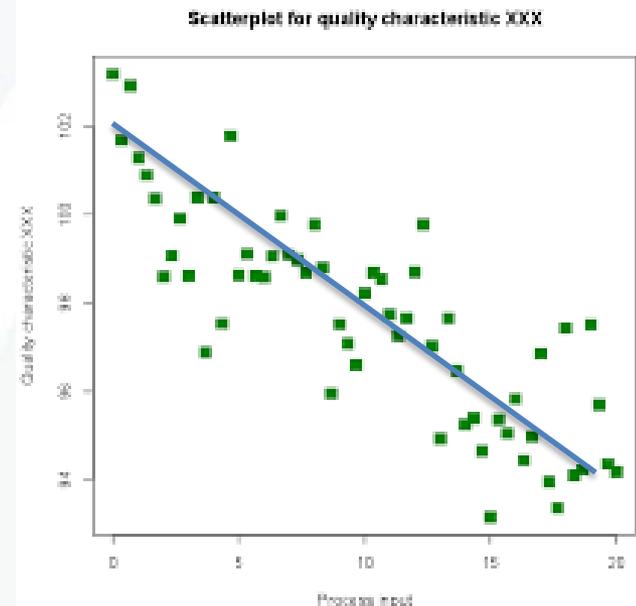
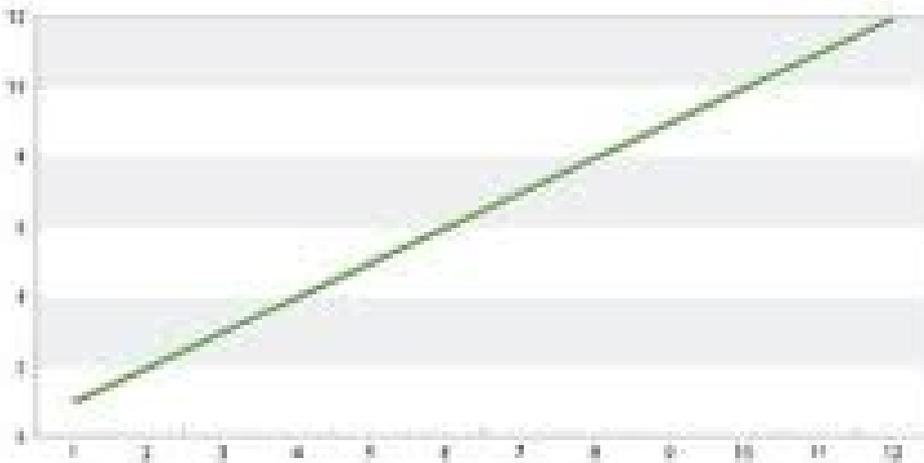
EXAMPLE: Opinion poll taken interviewing only those people living in large metropolitan areas on the West Coast.

MEASUREMENT FUNDAMENTALS

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

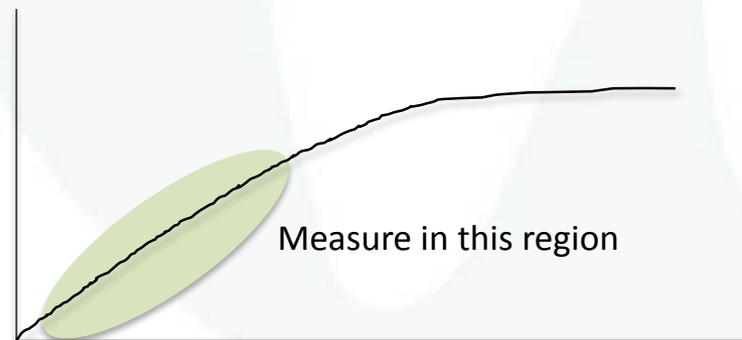
MEASUREMENT FUNDAMENTALS

- 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

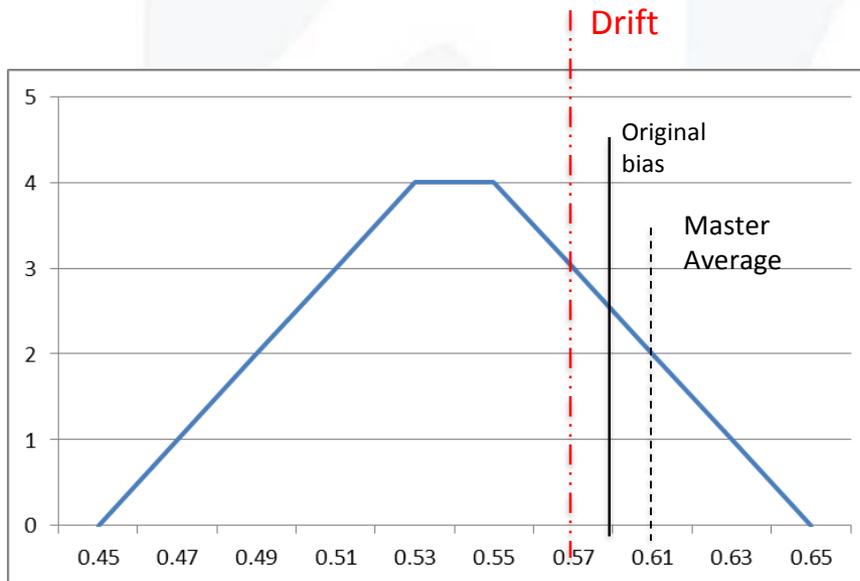


MEASUREMENT FUNDAMENTALS

- 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**

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**



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**

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**



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**



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**

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**

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**

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

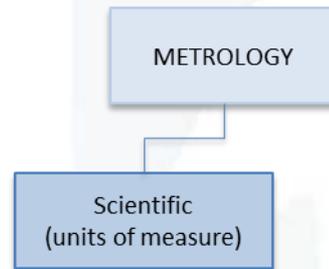
METROLOGY

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

MEASUREMENT FUNDAMENTALS

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

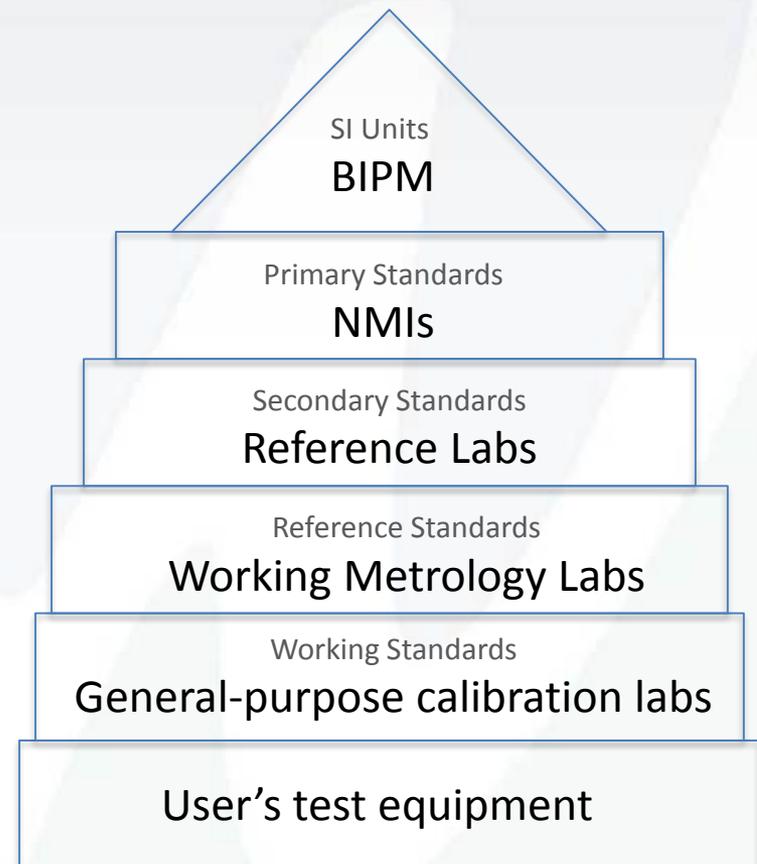


SI Unit(s)

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

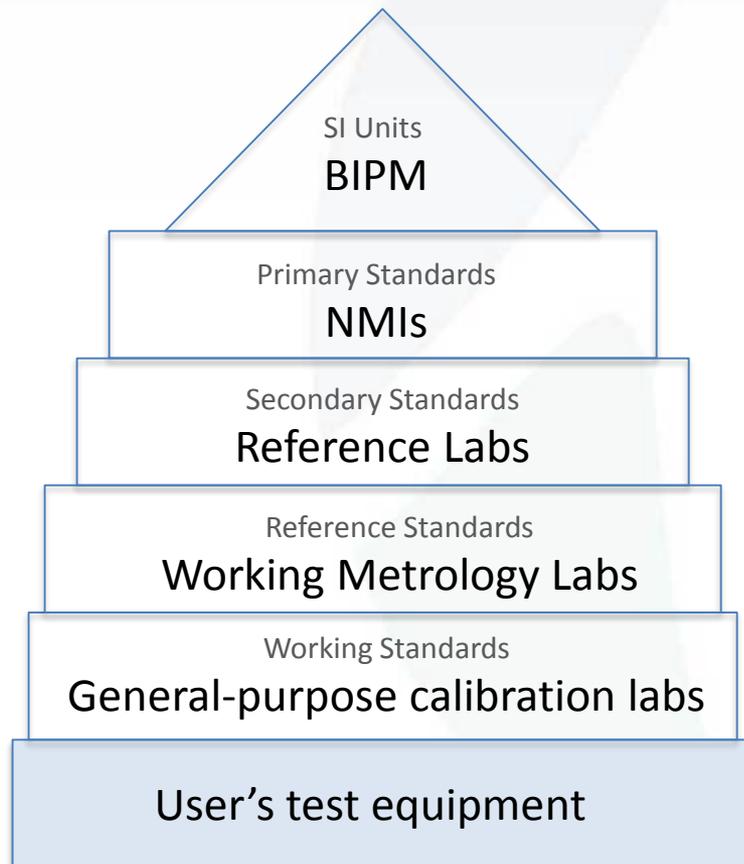
MEASUREMENT FUNDAMENTALS

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



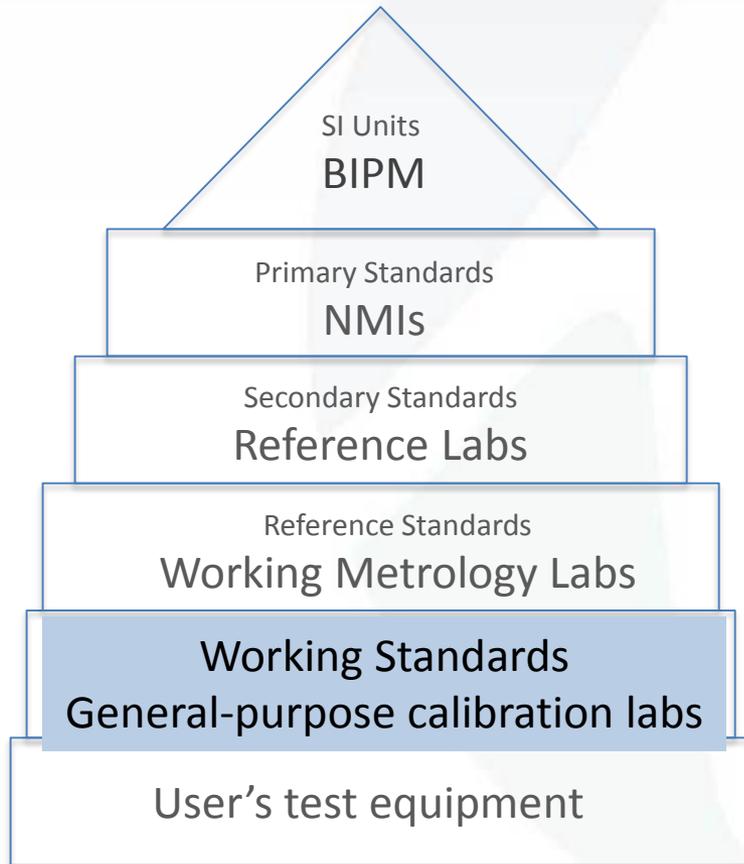
MEASUREMENT FUNDAMENTALS

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



MEASUREMENT FUNDAMENTALS

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

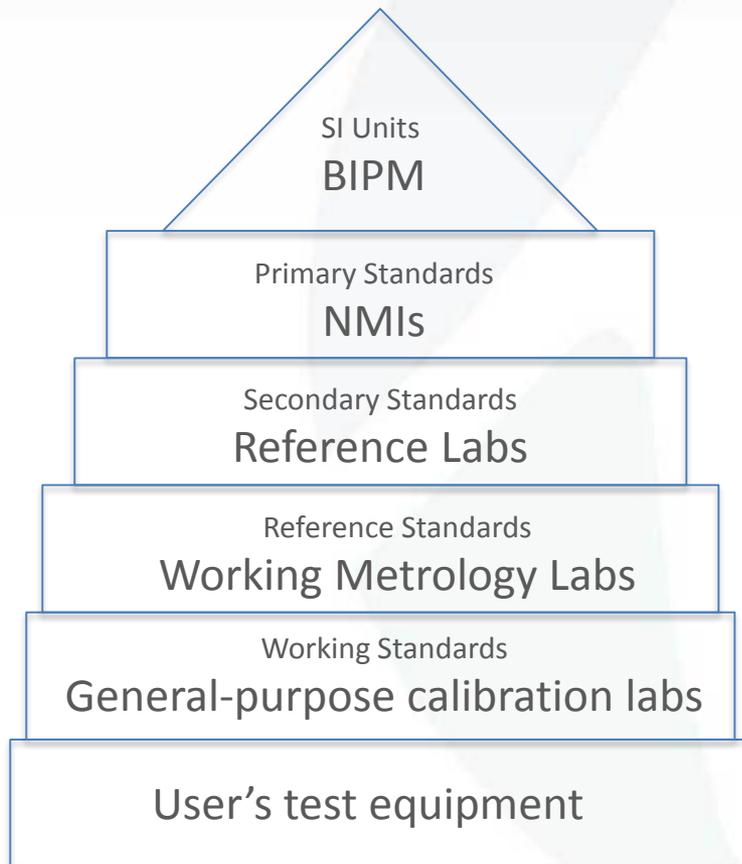


Calibrated weight set



MEASUREMENT FUNDAMENTALS

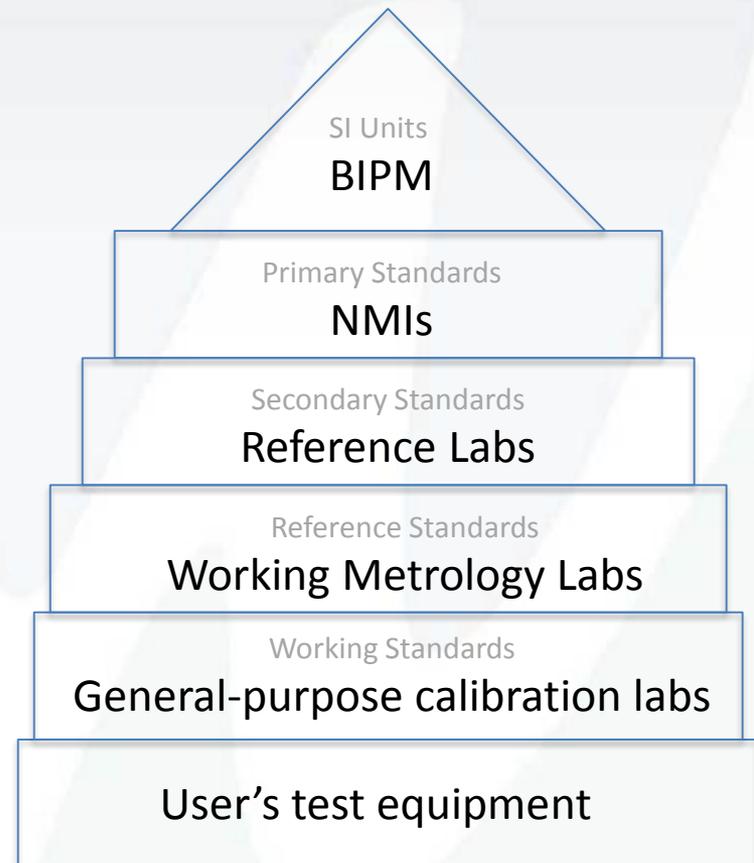
- Standards Usage (Traceability)
 - Unbroken chain from user device to SI unit



- 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)



A large, light blue, semi-transparent watermark of the letter 'W' is centered on the page. The watermark is composed of several overlapping, rounded shapes that form the letter's structure.

Example weight certificate

MEASUREMENT FUNDAMENTALS

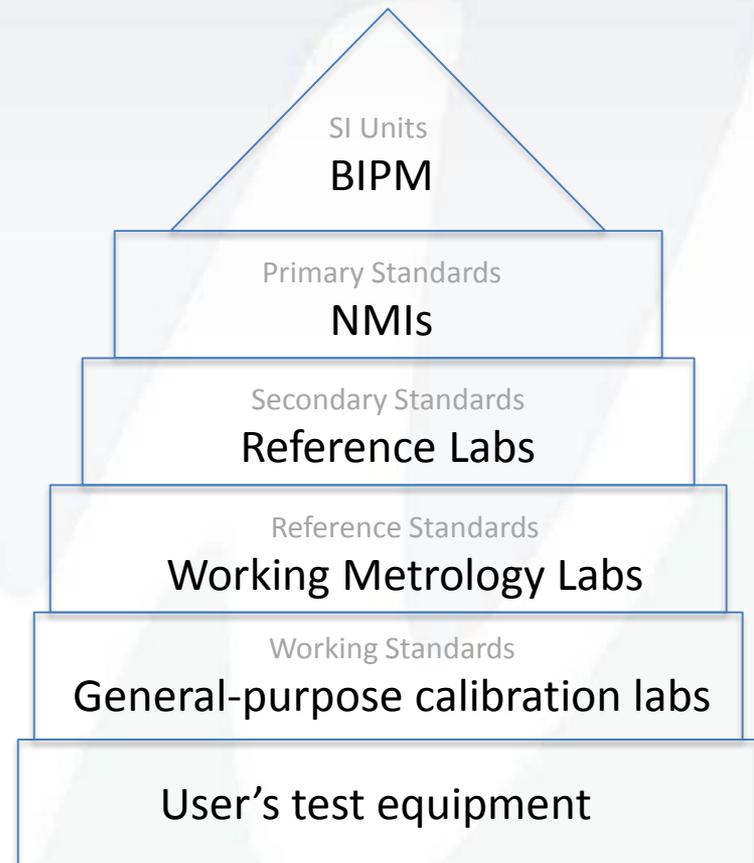
- Standards Usage
(Traceability)

- 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

$$0.695 \text{ in} = ?? \text{ mm}$$

$$1 \text{ in} = 25.4 \text{ mm}$$

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

Unit Conversion

- Dimensional Analysis Method

original quantity * conversion factor = equivalent quantity

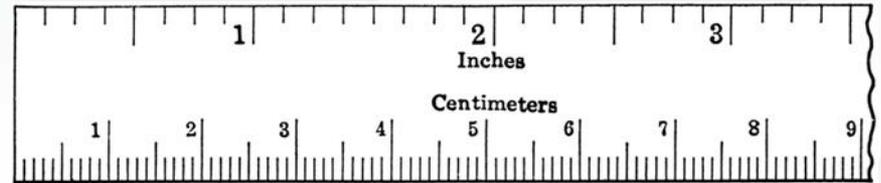
$$0.695 \text{ in} = ?? \text{ mm}$$

$$1 \text{ mm} = 0.039 \text{ in}$$

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 ≥ 5 , “round” up

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

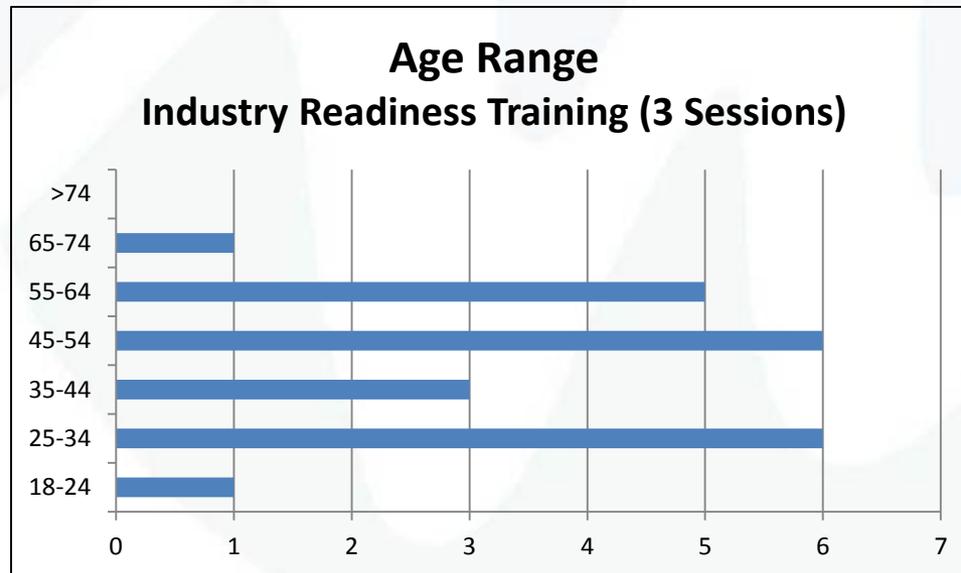
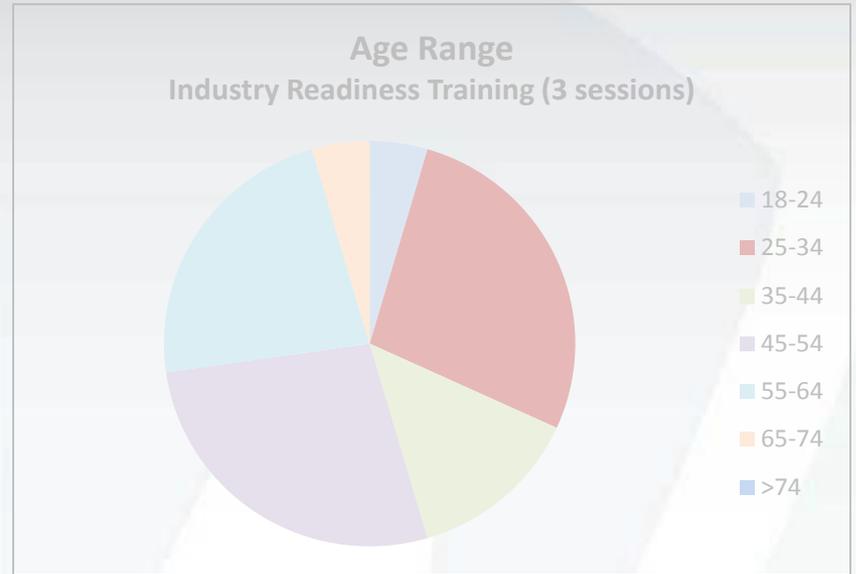
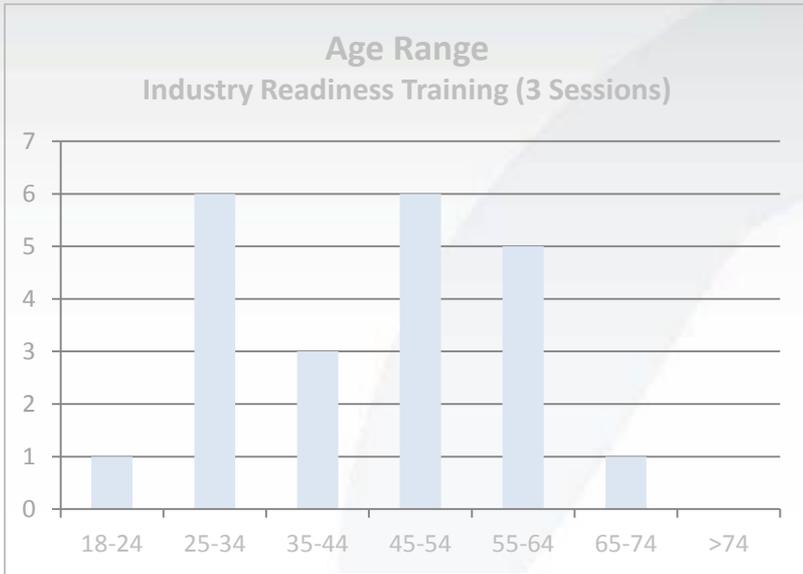
0.06739 g 0.06751g 0.06791g

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

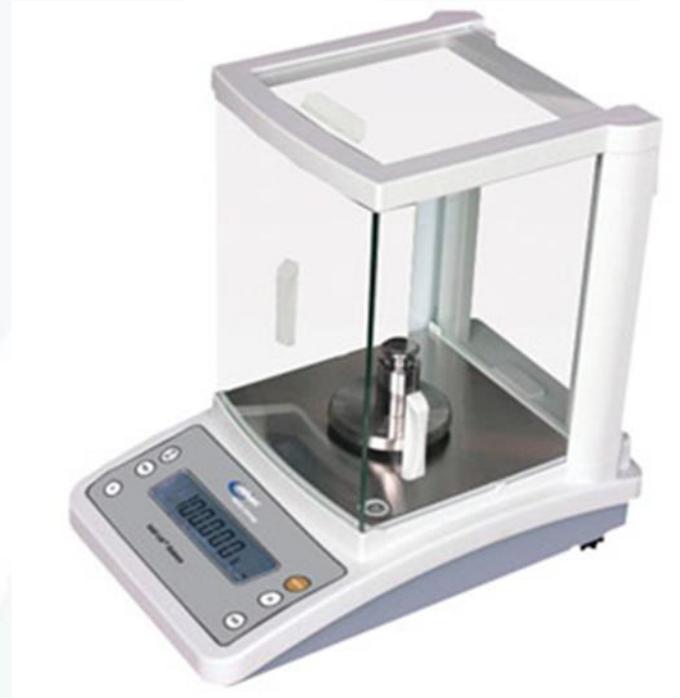
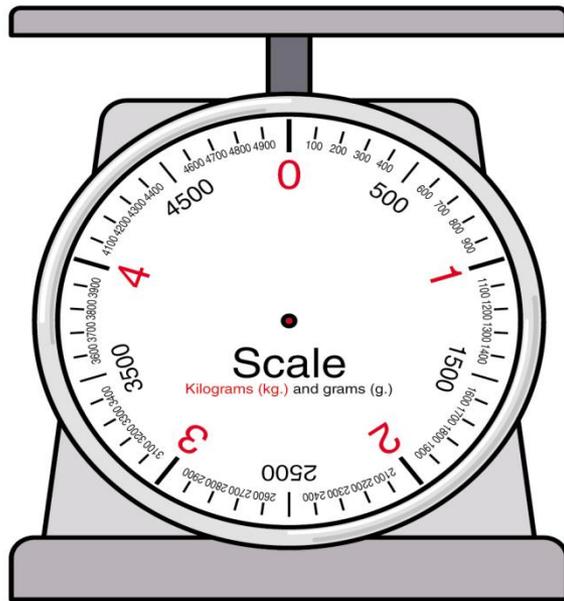


MEASUREMENT FUNDAMENTALS

- 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

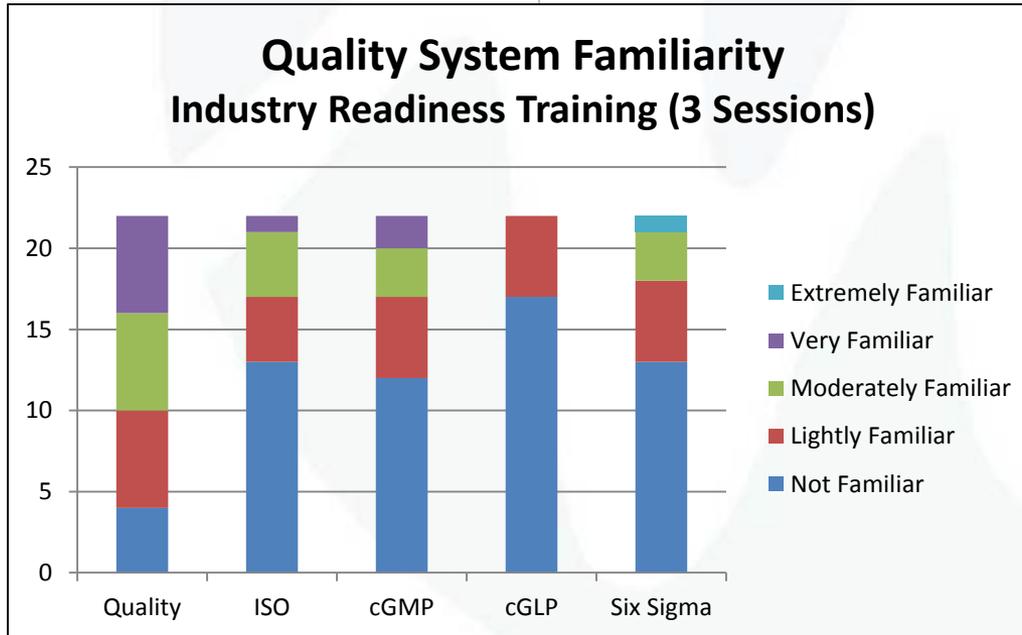
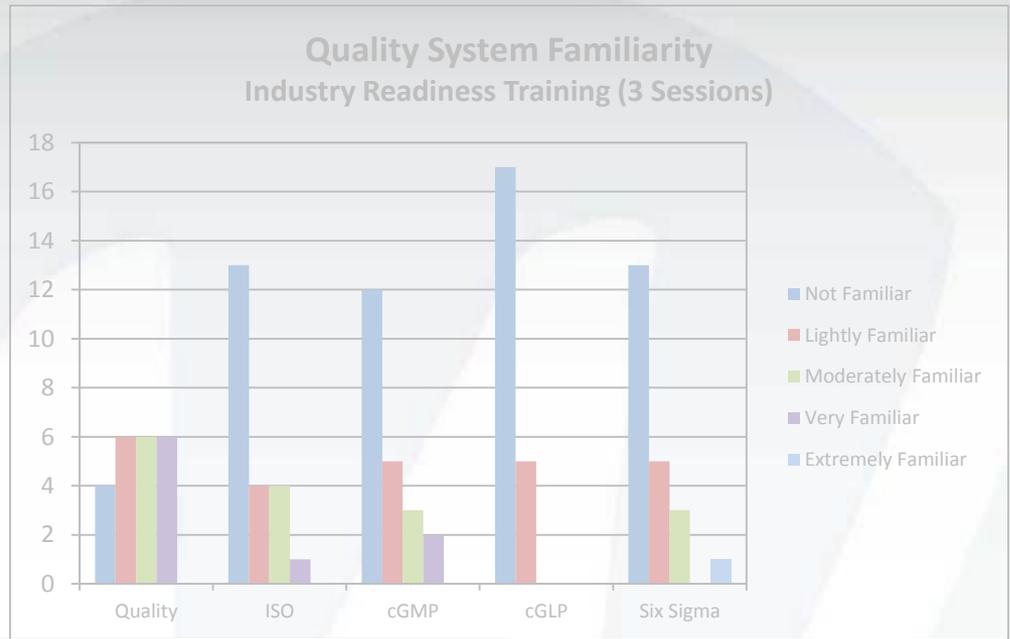


MEASUREMENT FUNDAMENTALS

- Data

- 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
 - **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	3
Very Familiar	6	1	2		
Extremely Familiar					1



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
 - 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))
- 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
 - Confidentiality: protection of results and the source (unauthorized disclosure)

MEASUREMENT FUNDAMENTALS

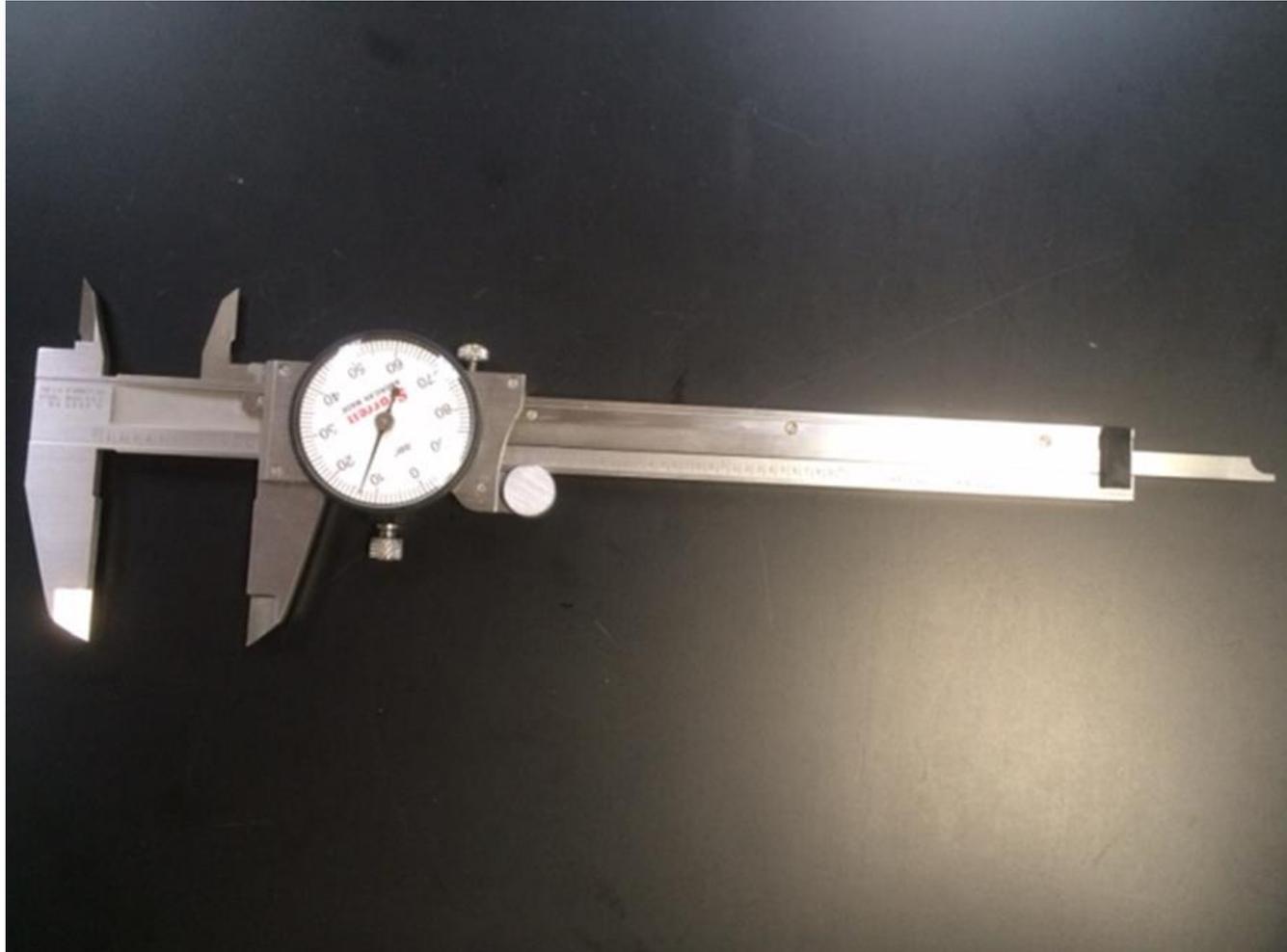
- Methods
- System
- Capability
- Equipment specifications
- Environmental Controls
- Standards Usage
- Confidence (Uncertainty) Programs
- Data

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

How to trust the results

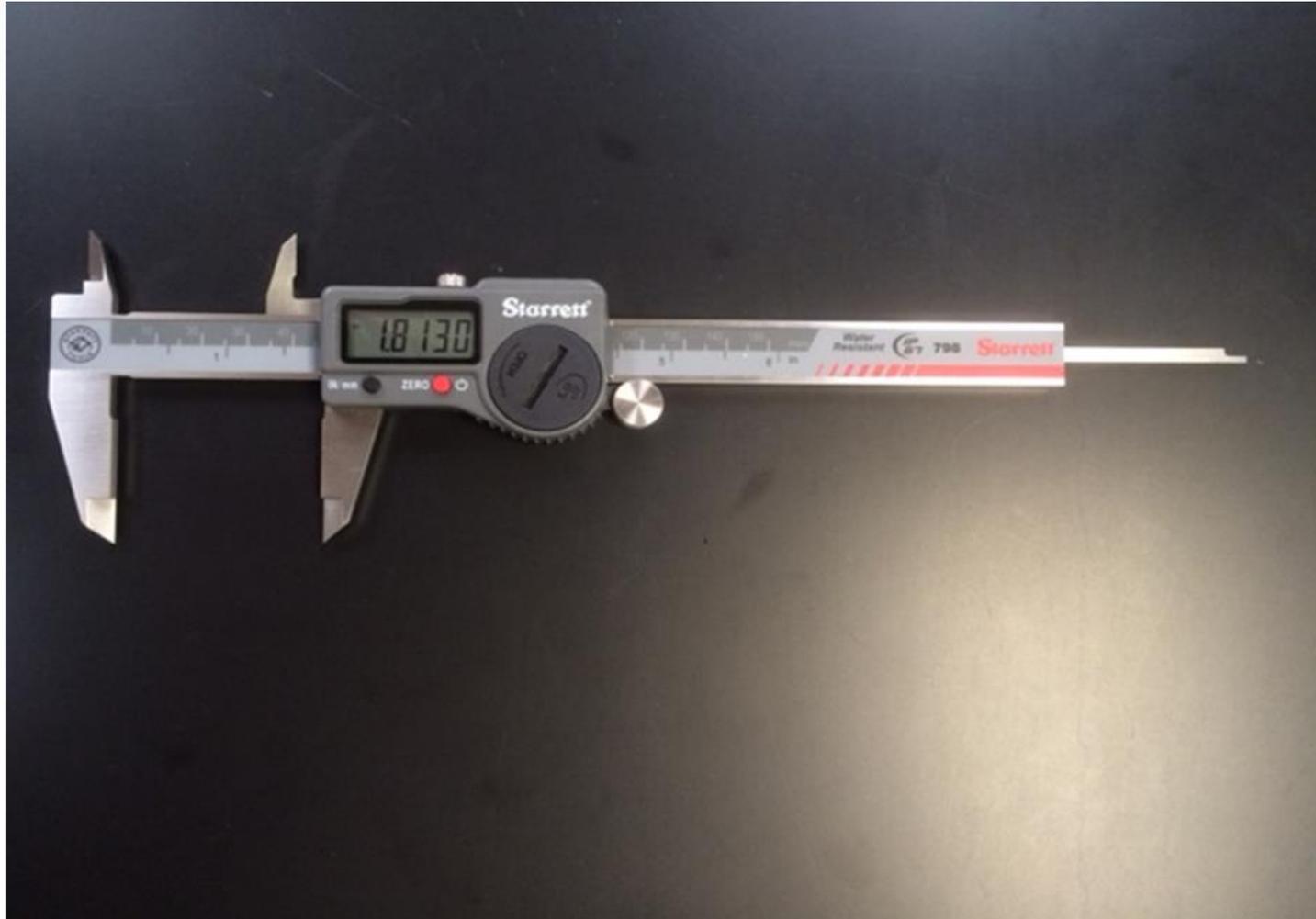
Measuring Instruments

DIAL CALIPERS



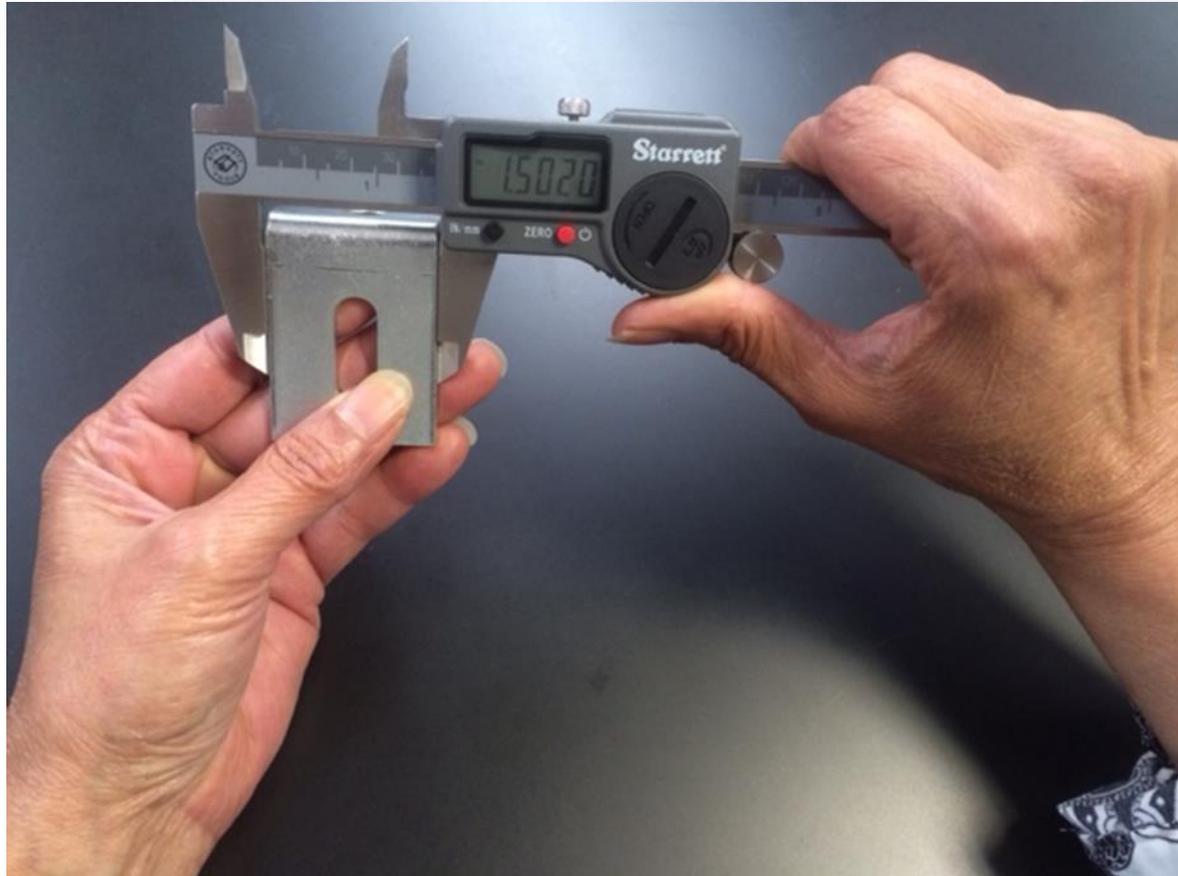
Measuring Instruments

DIGITAL CALIPERS



Measuring Instruments

DIGITAL CALIPERS



Measuring Instruments

MICROMETER



Measuring Instruments

DIGITAL MICROMETER



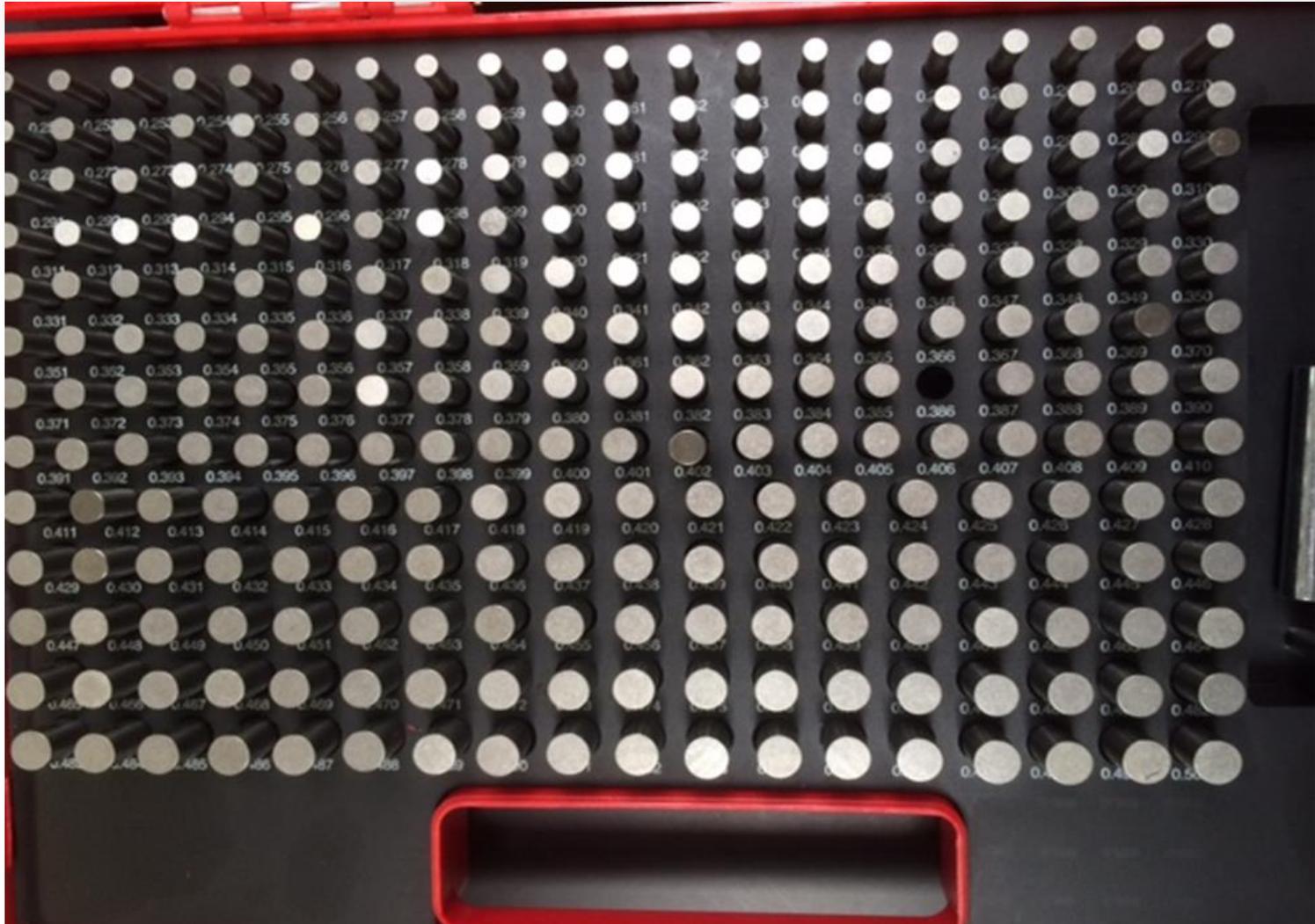
Measuring Instruments

DIGITAL MICROMETER



Measuring Instruments

PRECISION PIN GAGES



Measuring Instruments

PRECISION PIN GAGES



Measuring Instruments

THREAD GAGE



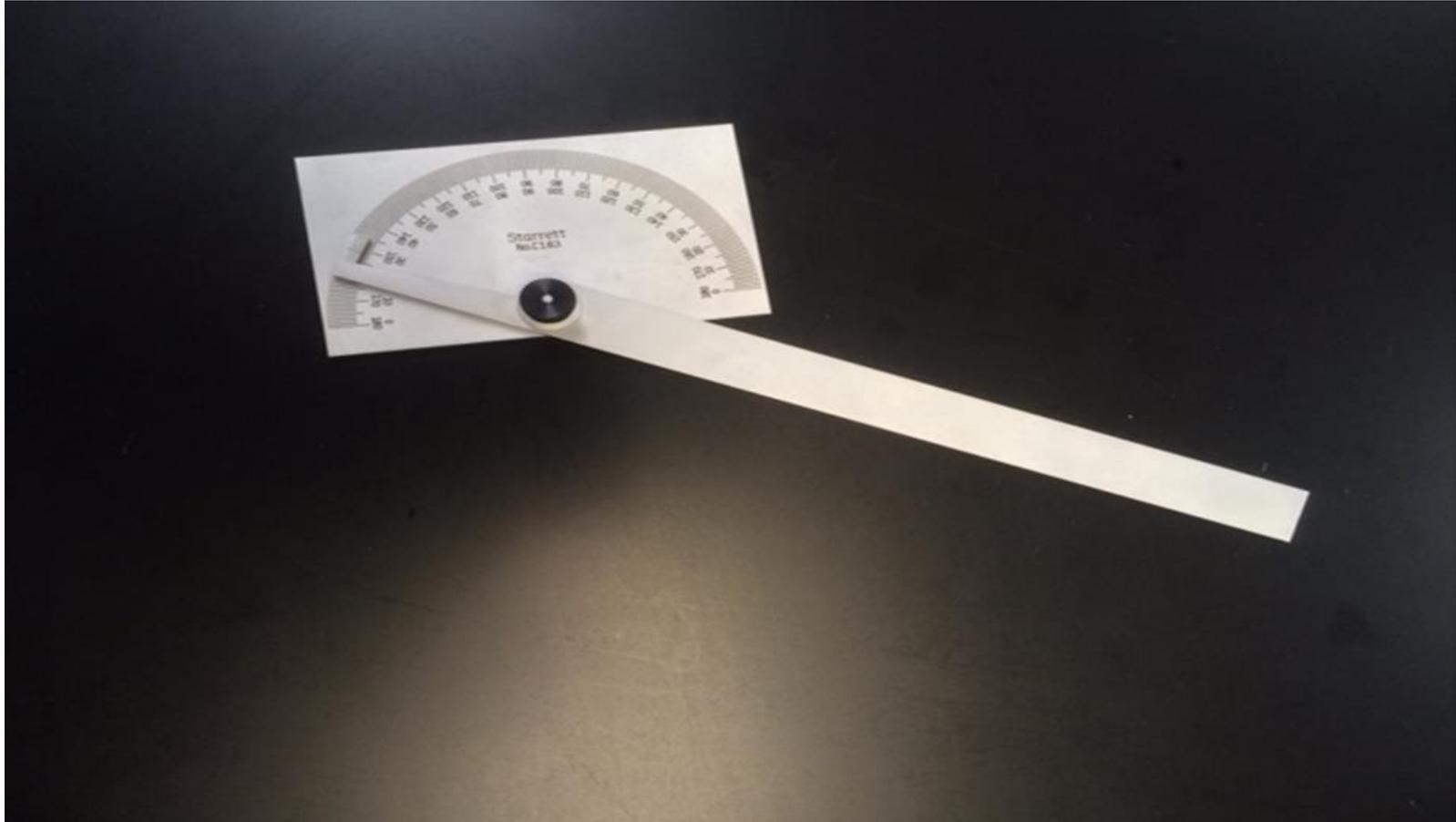
Measuring Instruments

THREAD GAGE



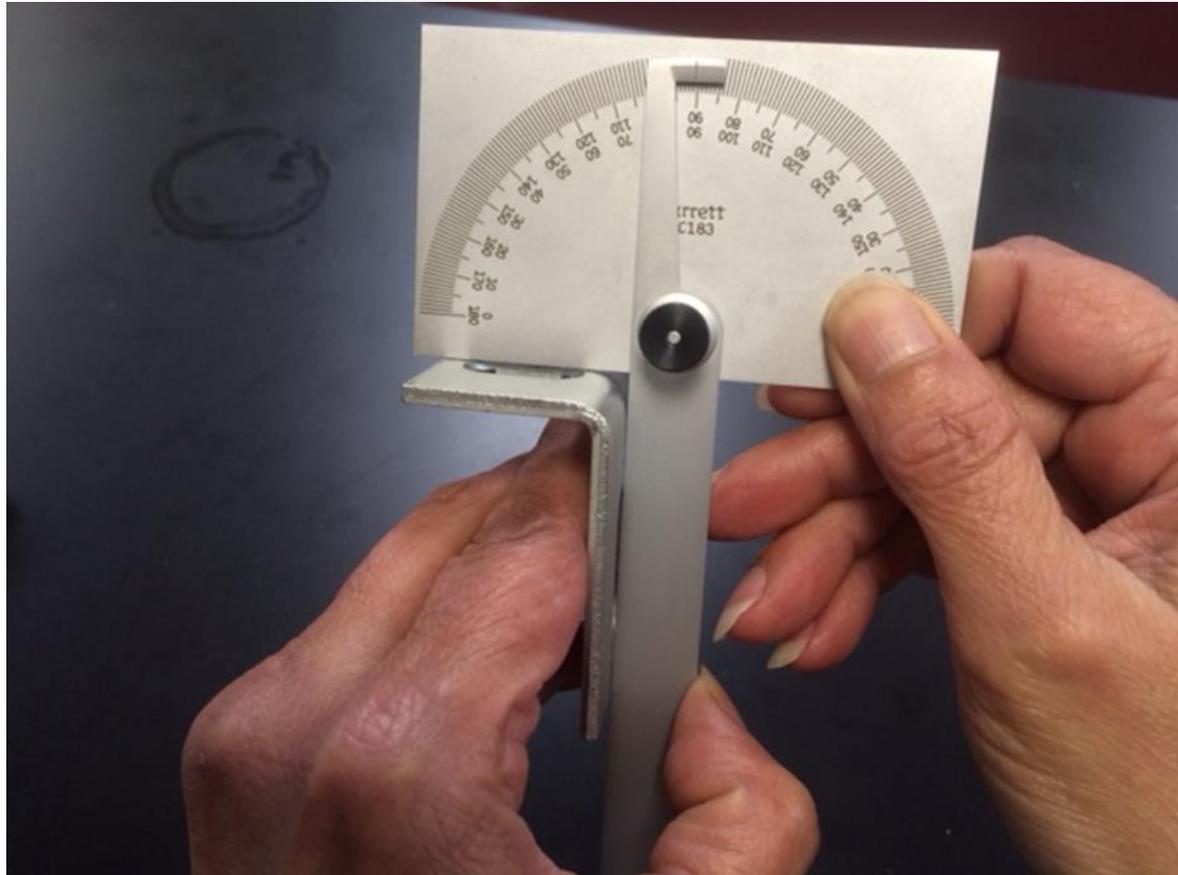
Measuring Instruments

PROTRACTOR



Measuring Instruments

PROTRACTOR





MODULE 2: METROLOGY (MEASUREMENT CONCEPTS)

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

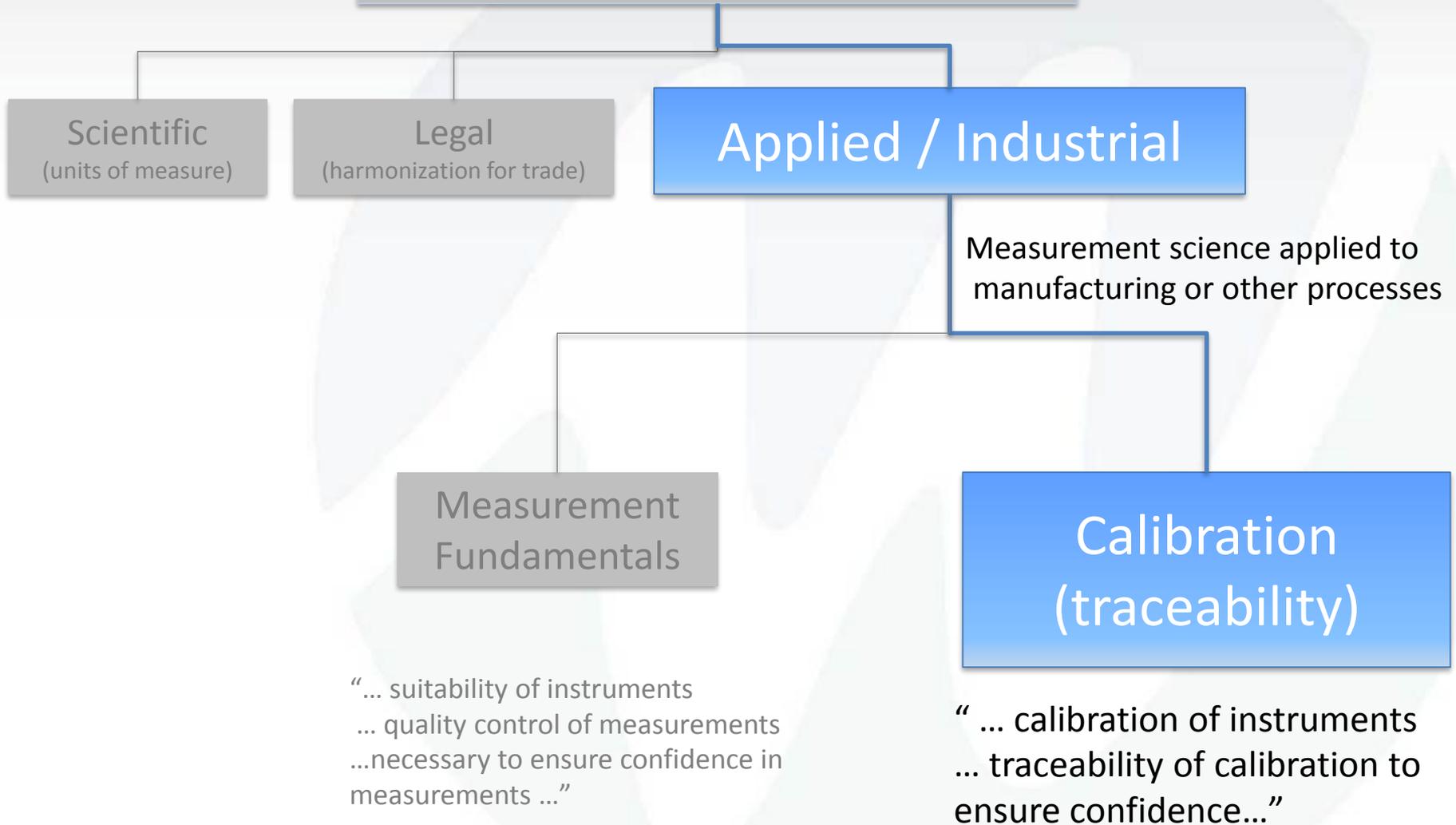


Review

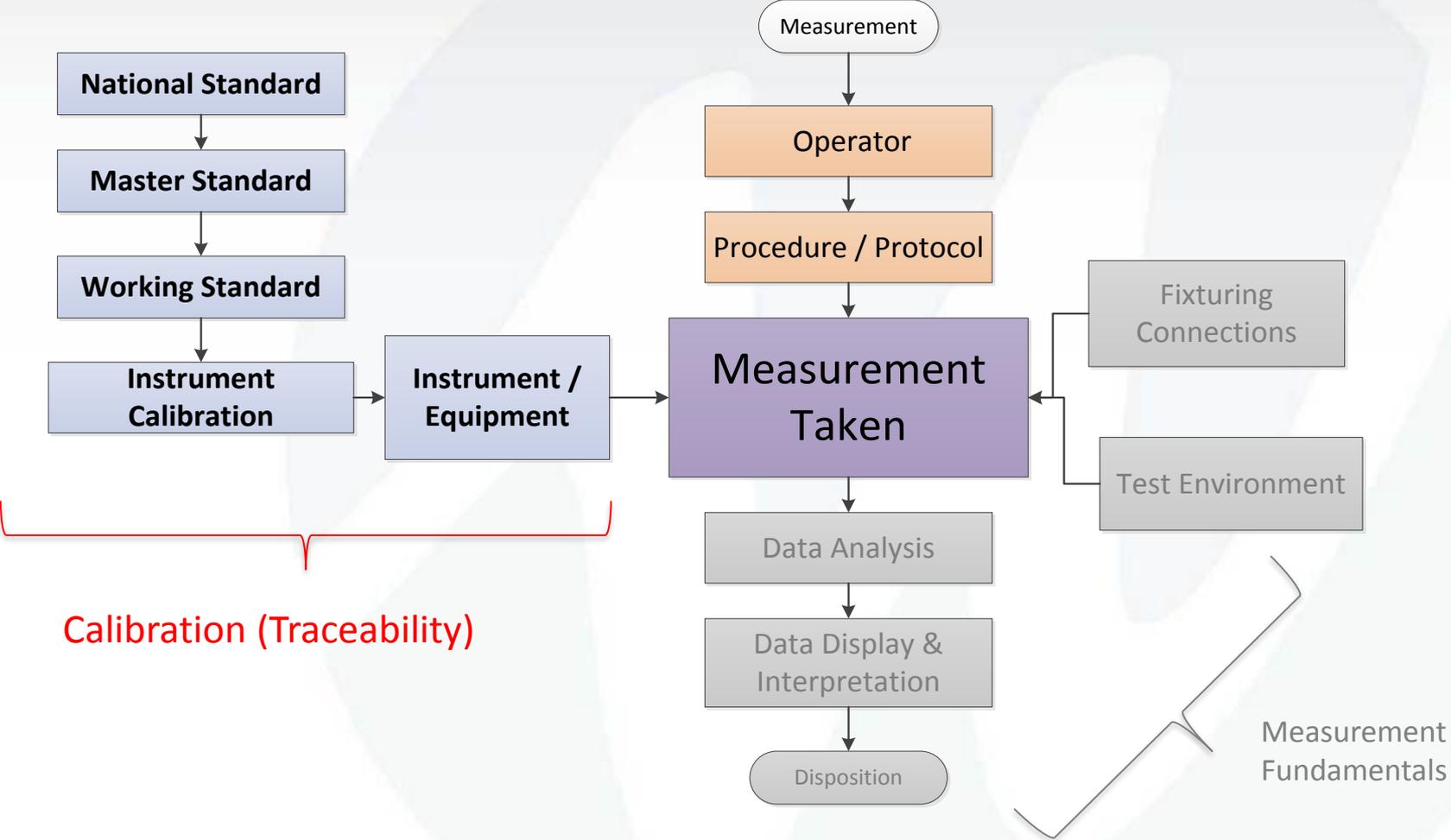
Quality is a product (or service) with the features and characteristics which determine desirability and can be controlled to meet certain basic requirements.

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

METROLOGY



METROLOGY - Taking a Measurement



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



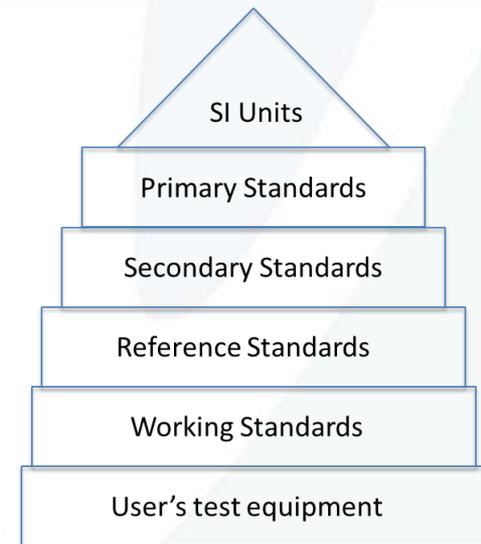
Neither accurate
nor precise



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

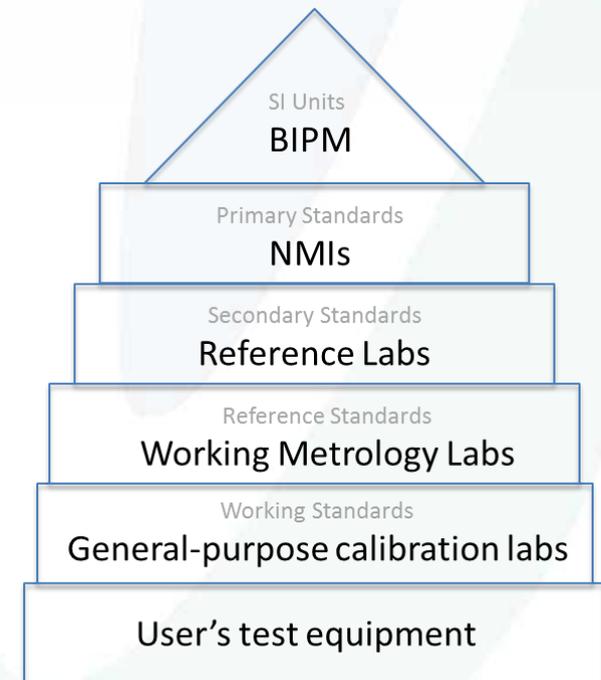
Discussion will be regarding a calibration system (program) as it applies to a manufacturer

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

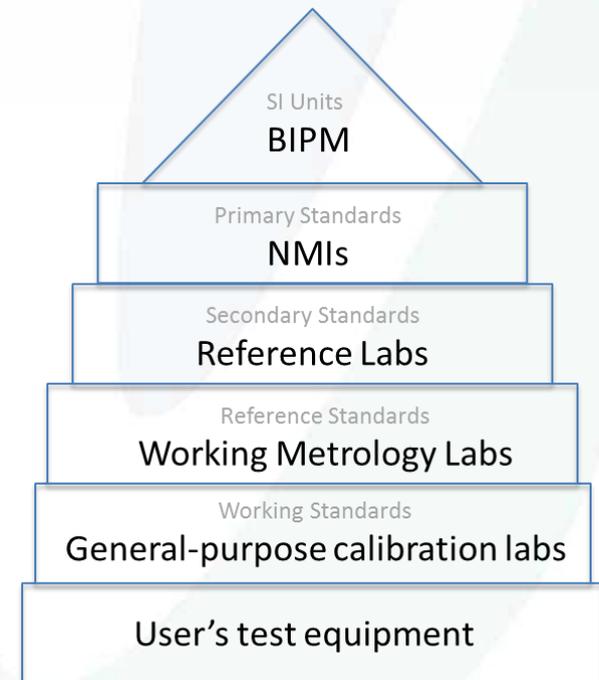
CALIBRATION SYSTEM

- 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 ± 0.005 inches

calipers used are capable of ± 0.0001 inches

Calibration standard = ± 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

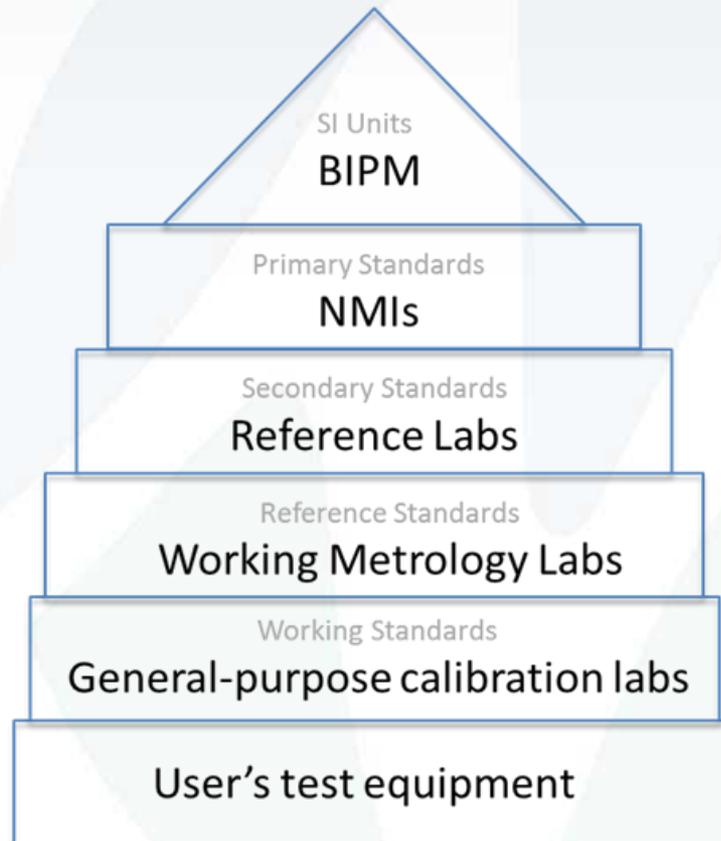
METROLOGY PROGRAM

- Calibration System

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

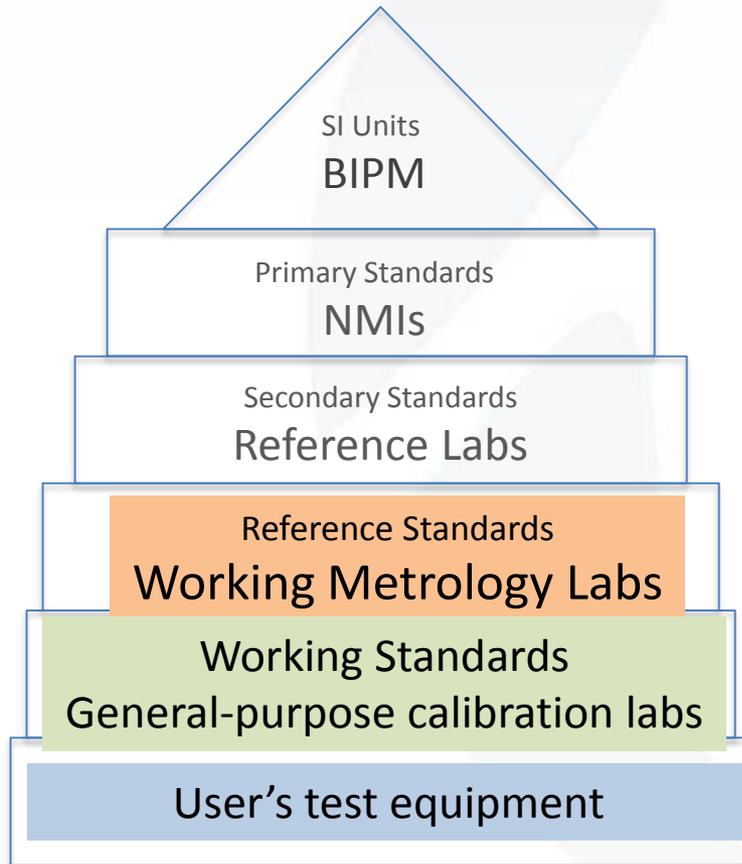
CALIBRATION SYSTEM

- Measurement Traceability



CALIBRATION SYSTEM

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

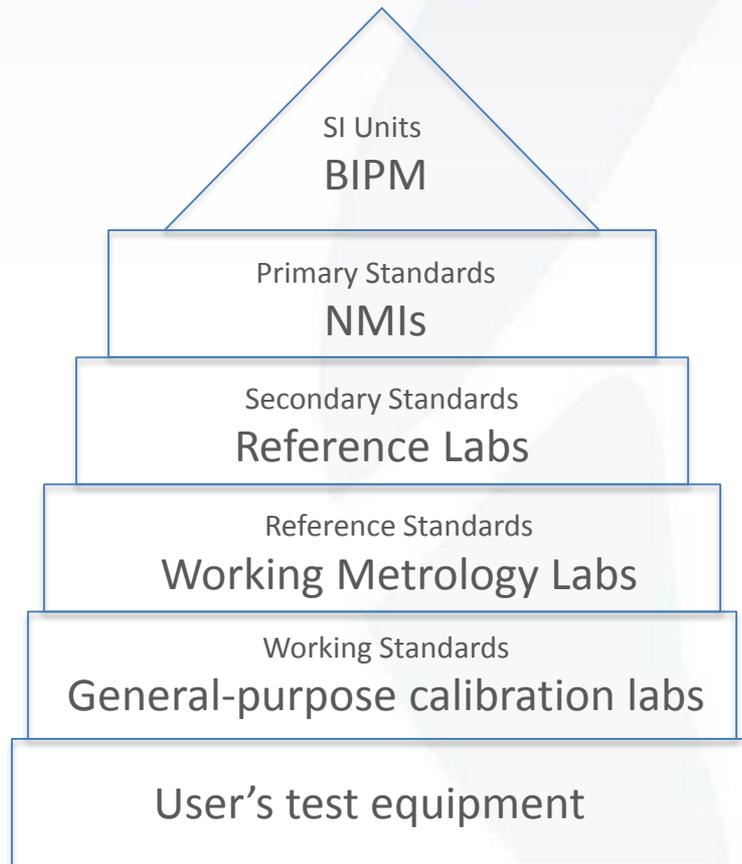


Calibrated weight set



CALIBRATION SYSTEM

- Measurement Traceability

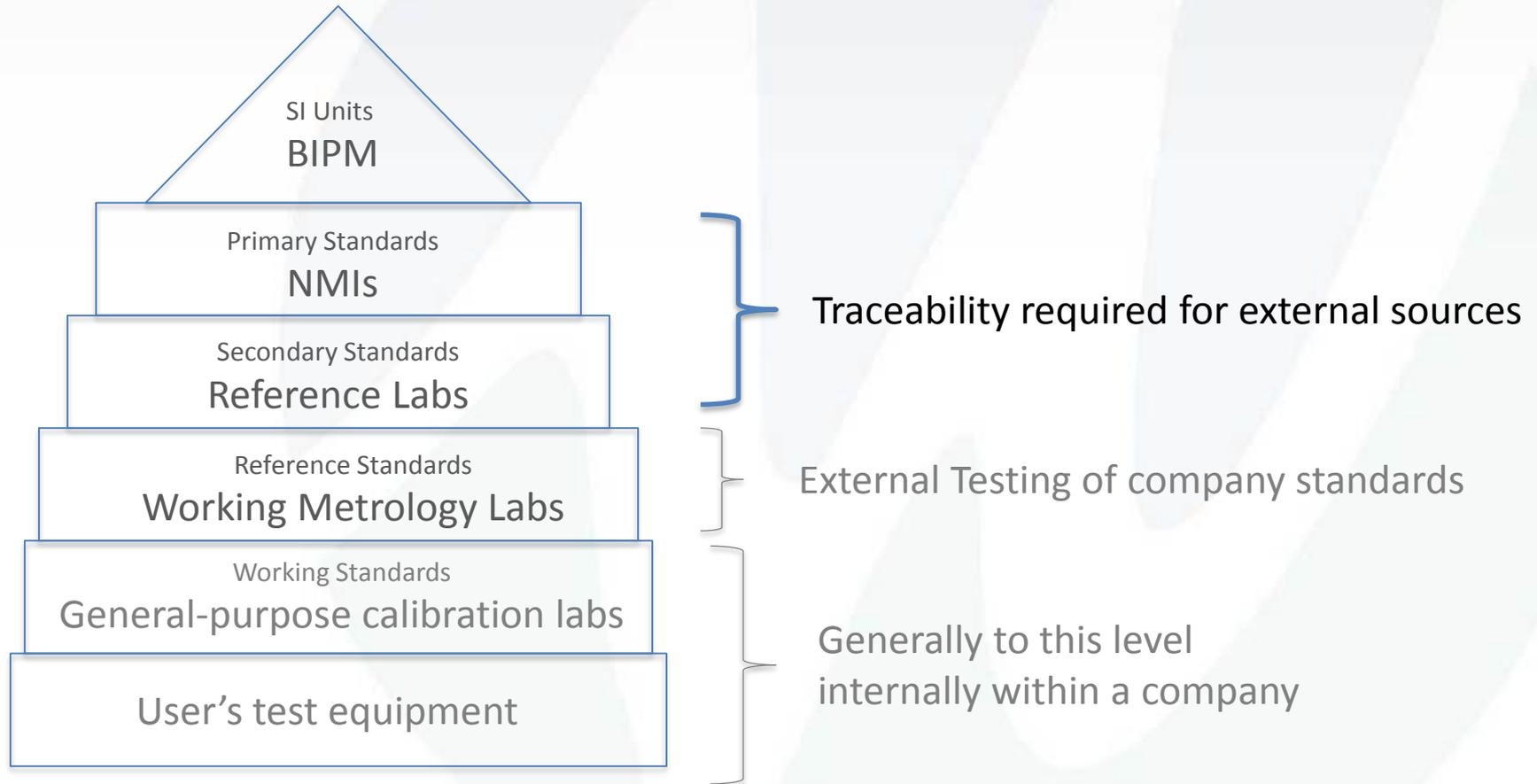


Traceable to NIST
National Institute of Standards & Technology

- 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)

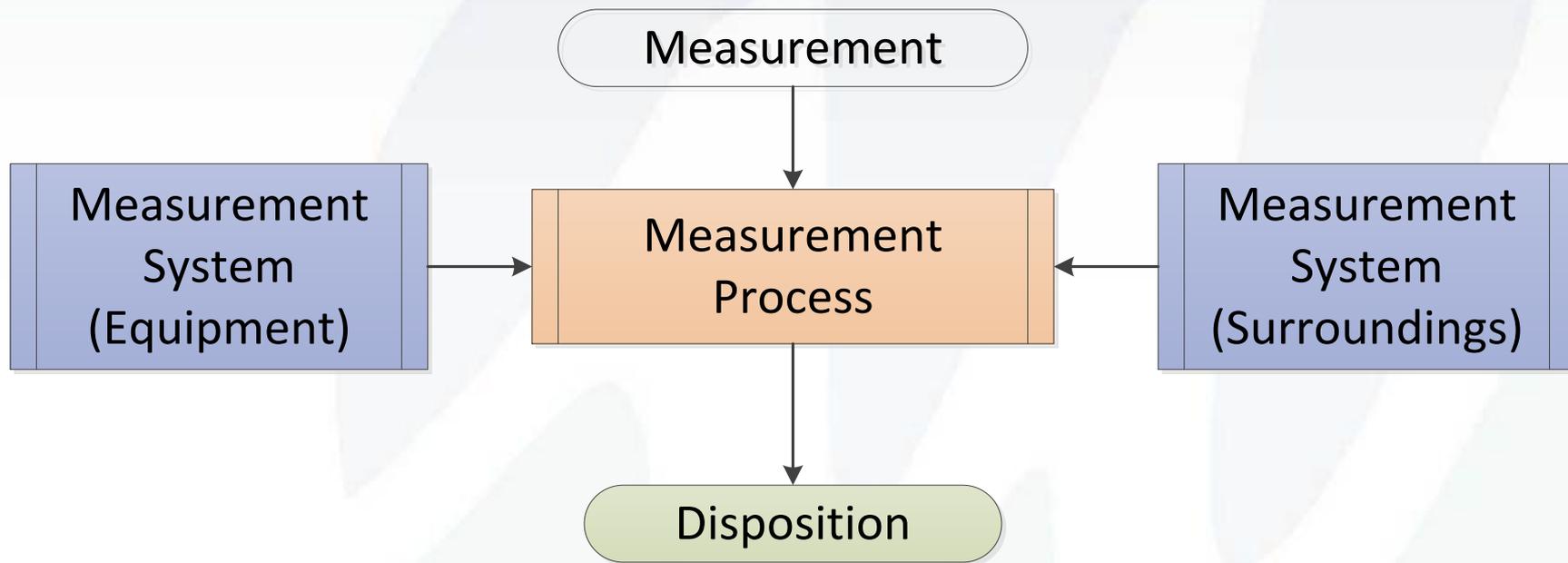
CALIBRATION SYSTEM

- 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 displays a grid of calibration labels. A central callout box highlights the label's structure, which includes a green header and three input fields for identification and scheduling.

CALIBRATION	
I.D. NO. _____	
BY _____ DATE _____	
DUE _____	

CALIBRATION

I.D. NO. _____

BY _____ DATE _____

DUE _____

CALIBRATION SYSTEM - Labels

LIMITED CALIBRATION	
TESTED RANGE	___ TO ___
I.D.#	DATE
BY	DUE

CALIBRATION SYSTEM - Labels

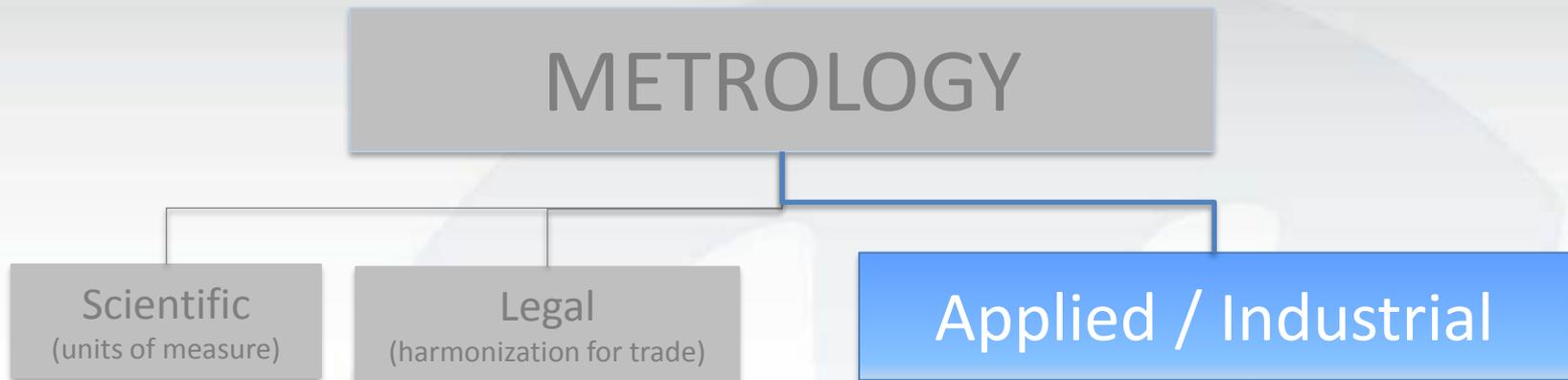


CALIBRATION SYSTEM - Labels





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**



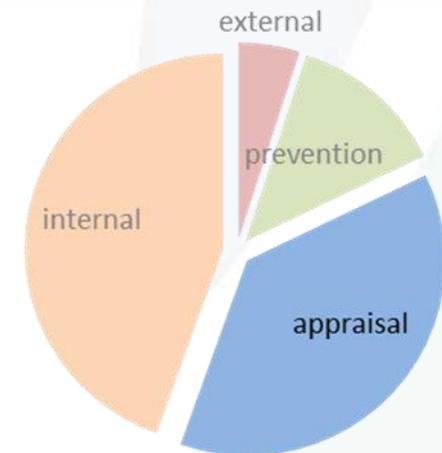
INSPECTION

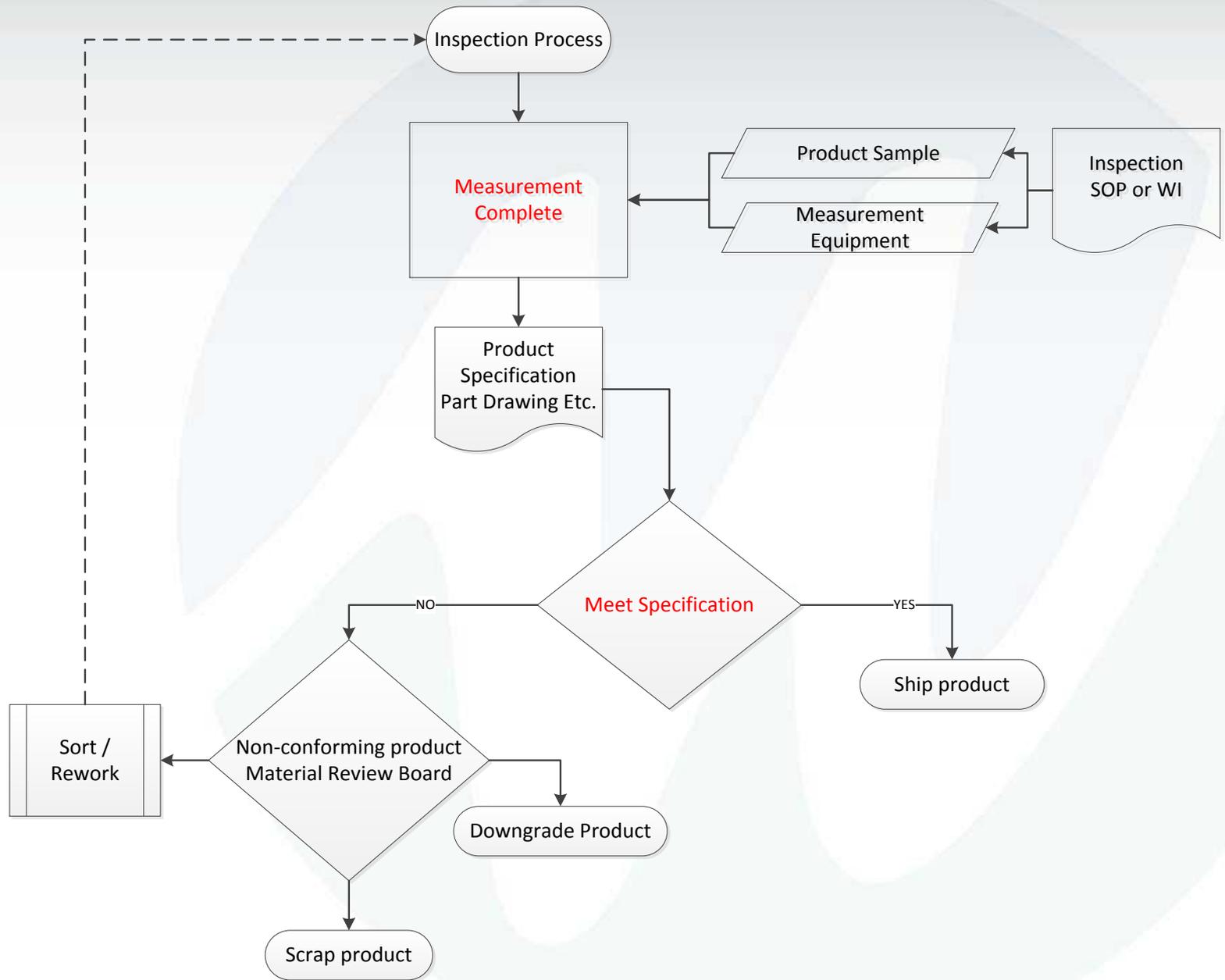
Quality is a product (or service) with the features and characteristics which determine desirability and can be controlled to meet certain basic requirements.

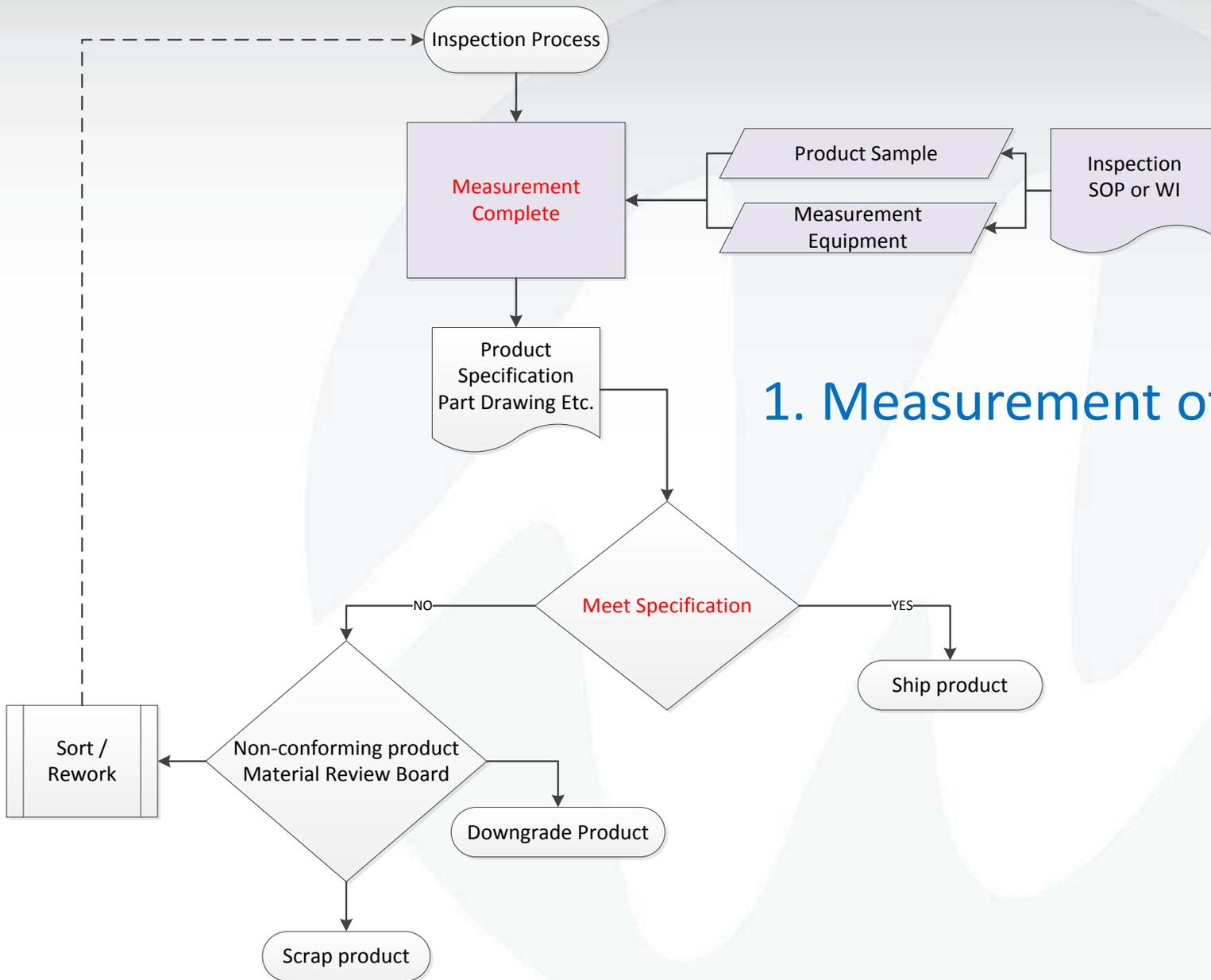
- Customers want expectations and needs met consistently
 - Fitness for use
 - Form is free of defect
 - Functions as intended
- Evaluate product quality by comparing measurement results with specifications

INSPECTION

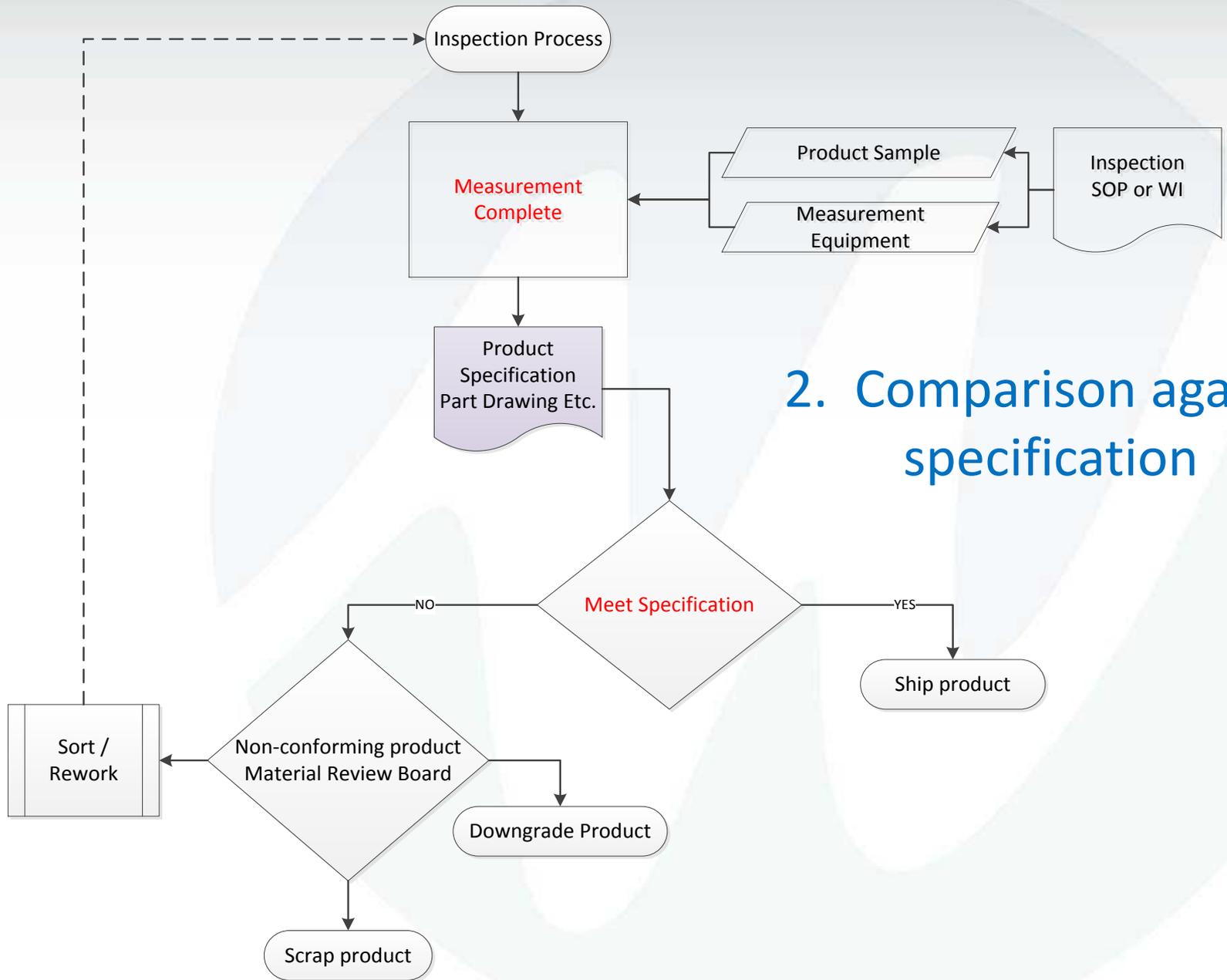
- Inspection process:
 1. Measurement of sample
 2. Comparison against specification
 3. Decision based on results
 4. Corrective action, if necessary



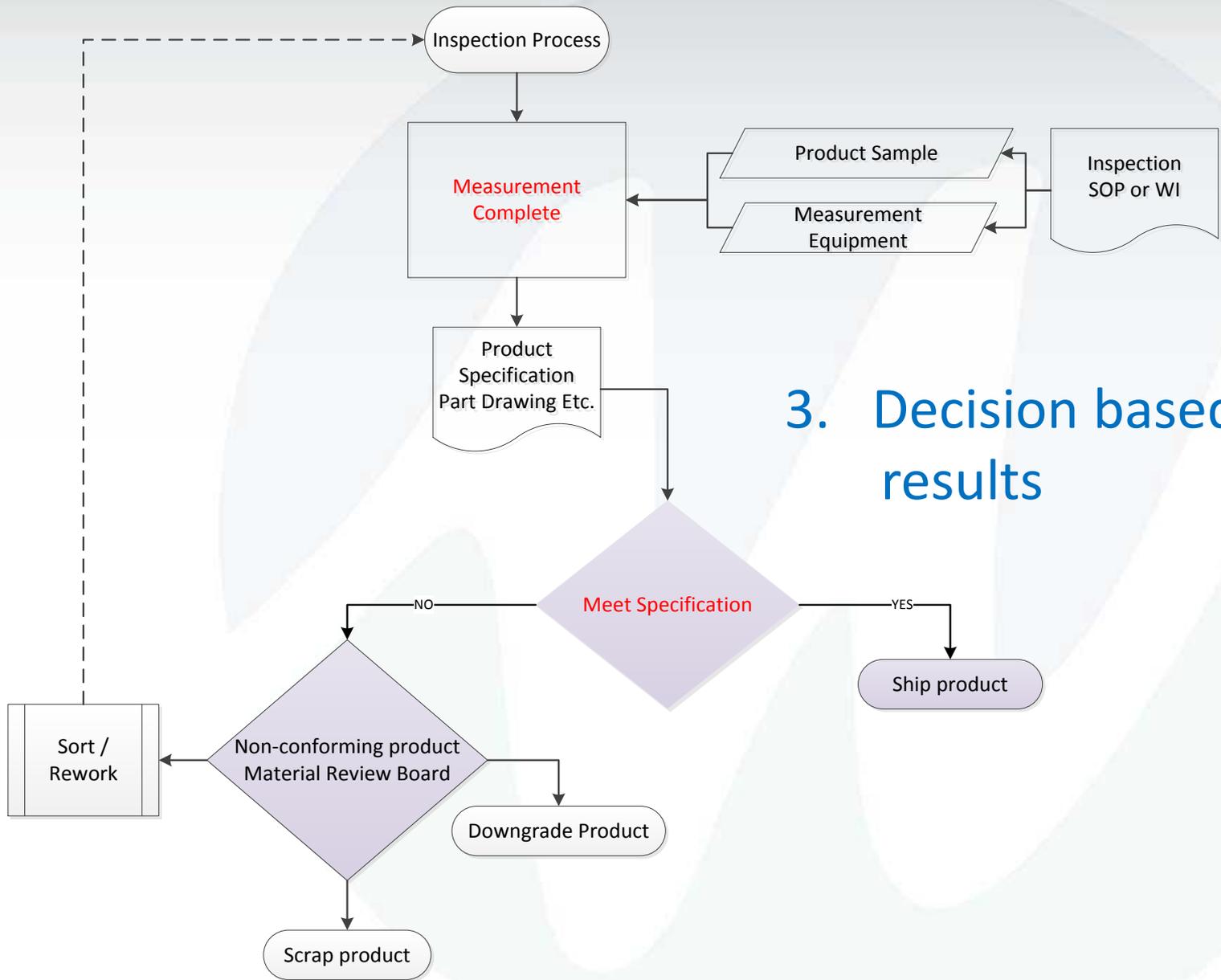




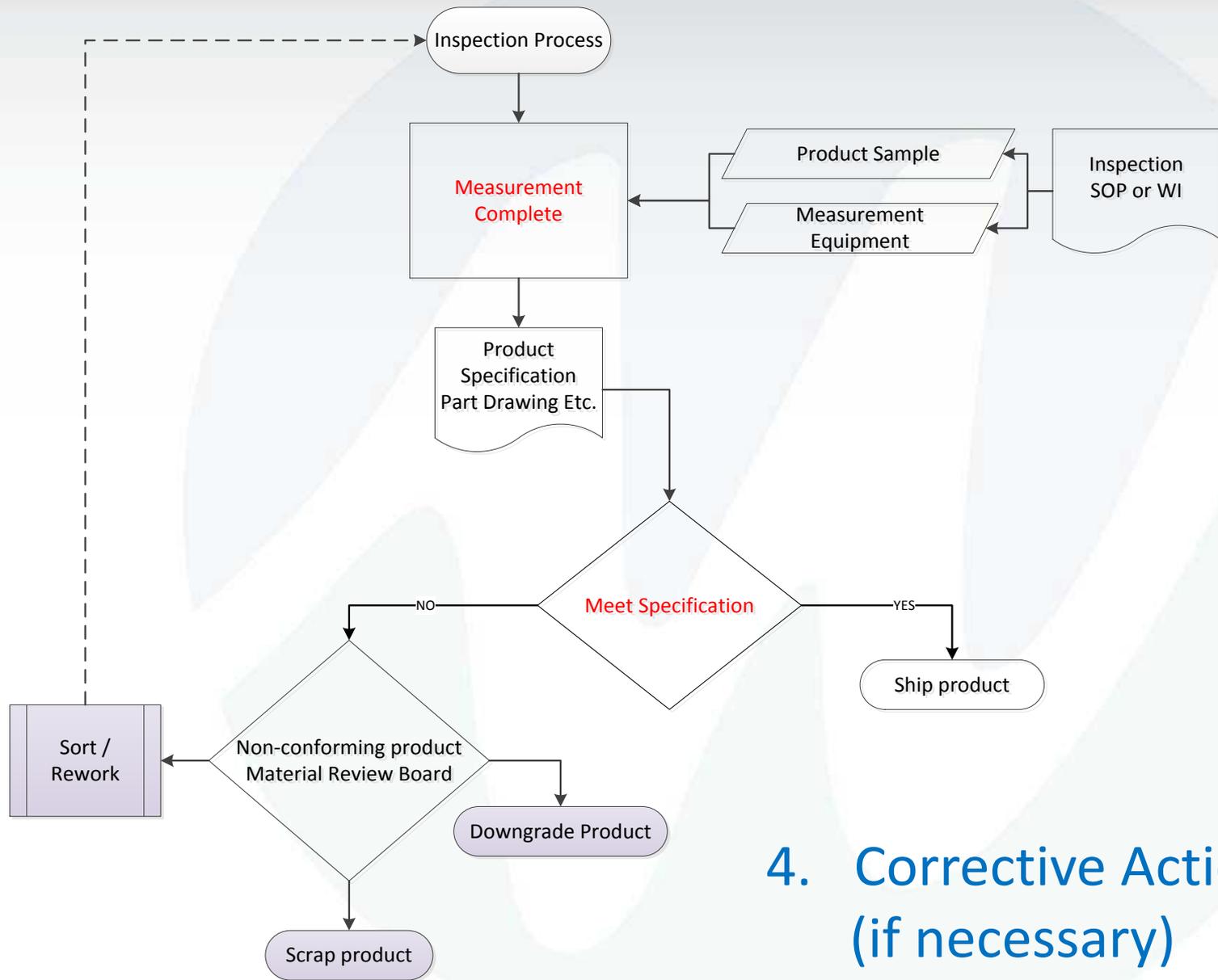
1. Measurement of Sample



2. Comparison against specification



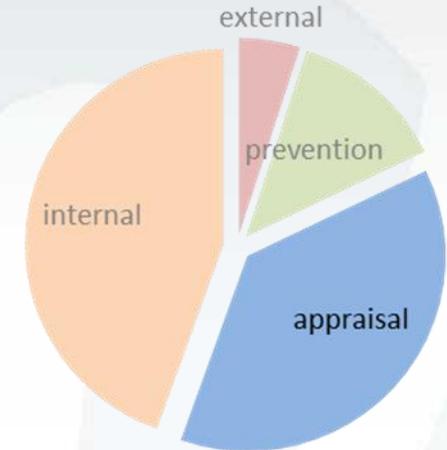
3. Decision based on results



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 Type – why are we checking?

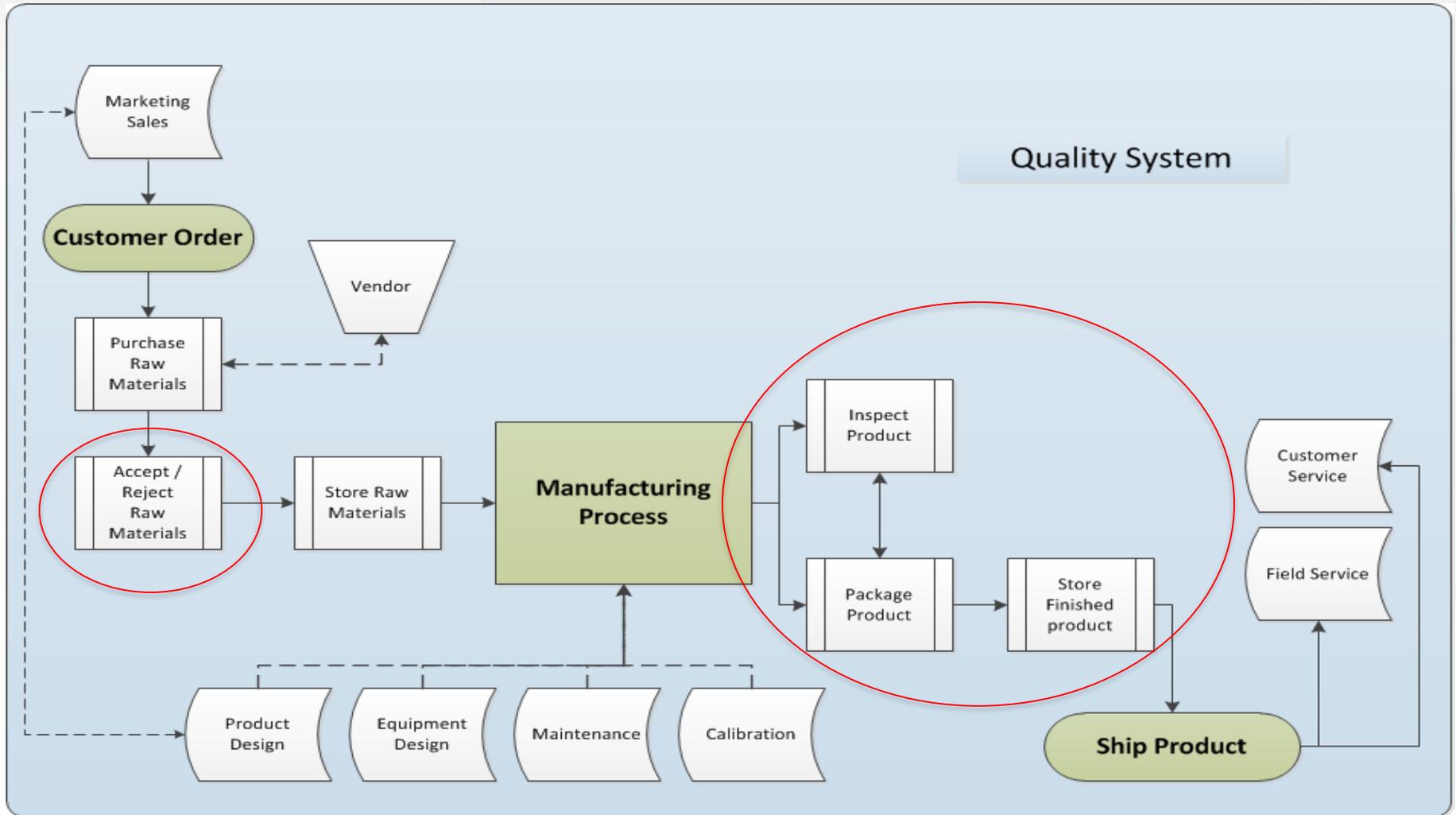
INSPECTION TYPES

- 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

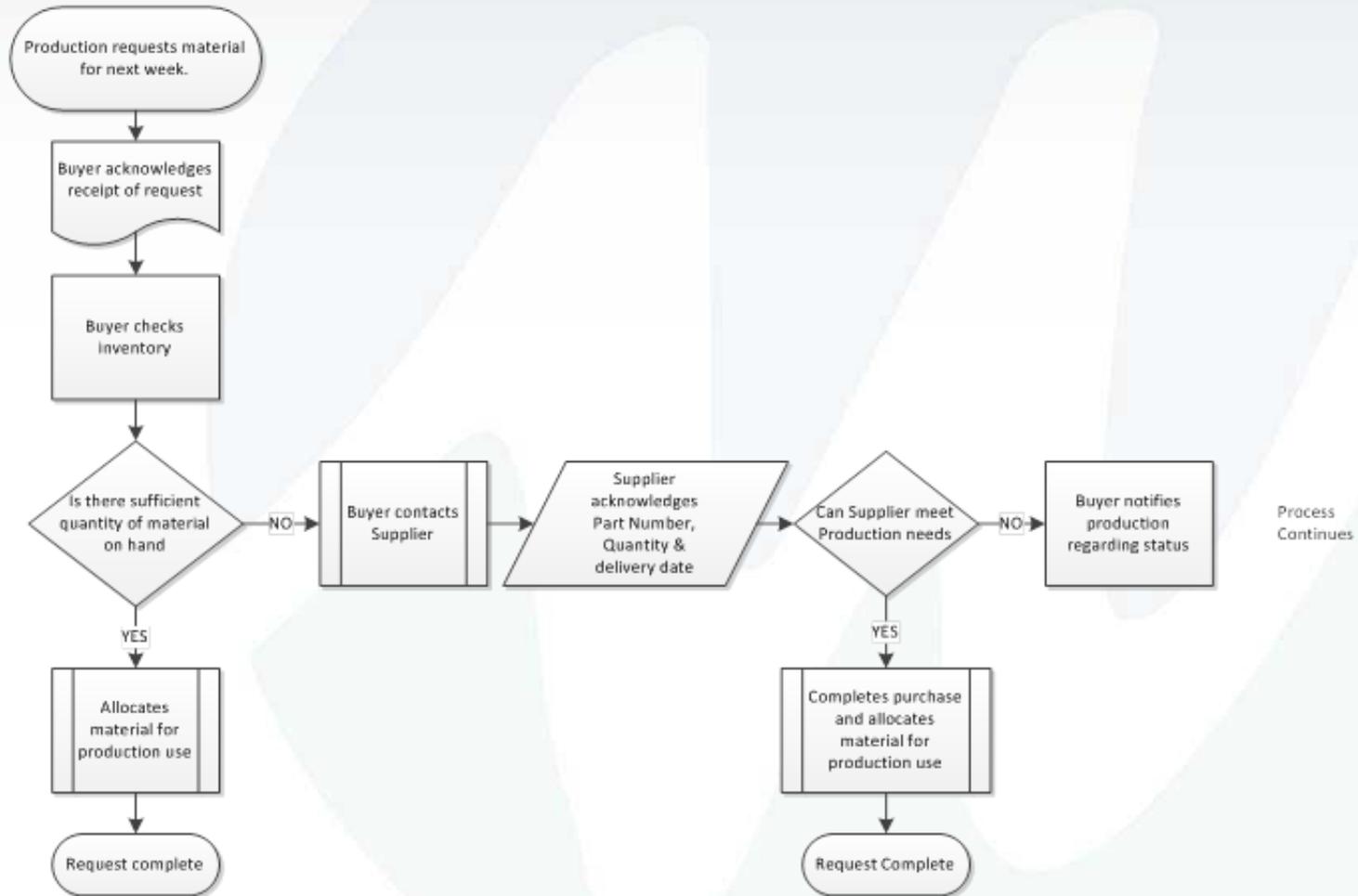
SEVEN QUALITY TOOLS

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

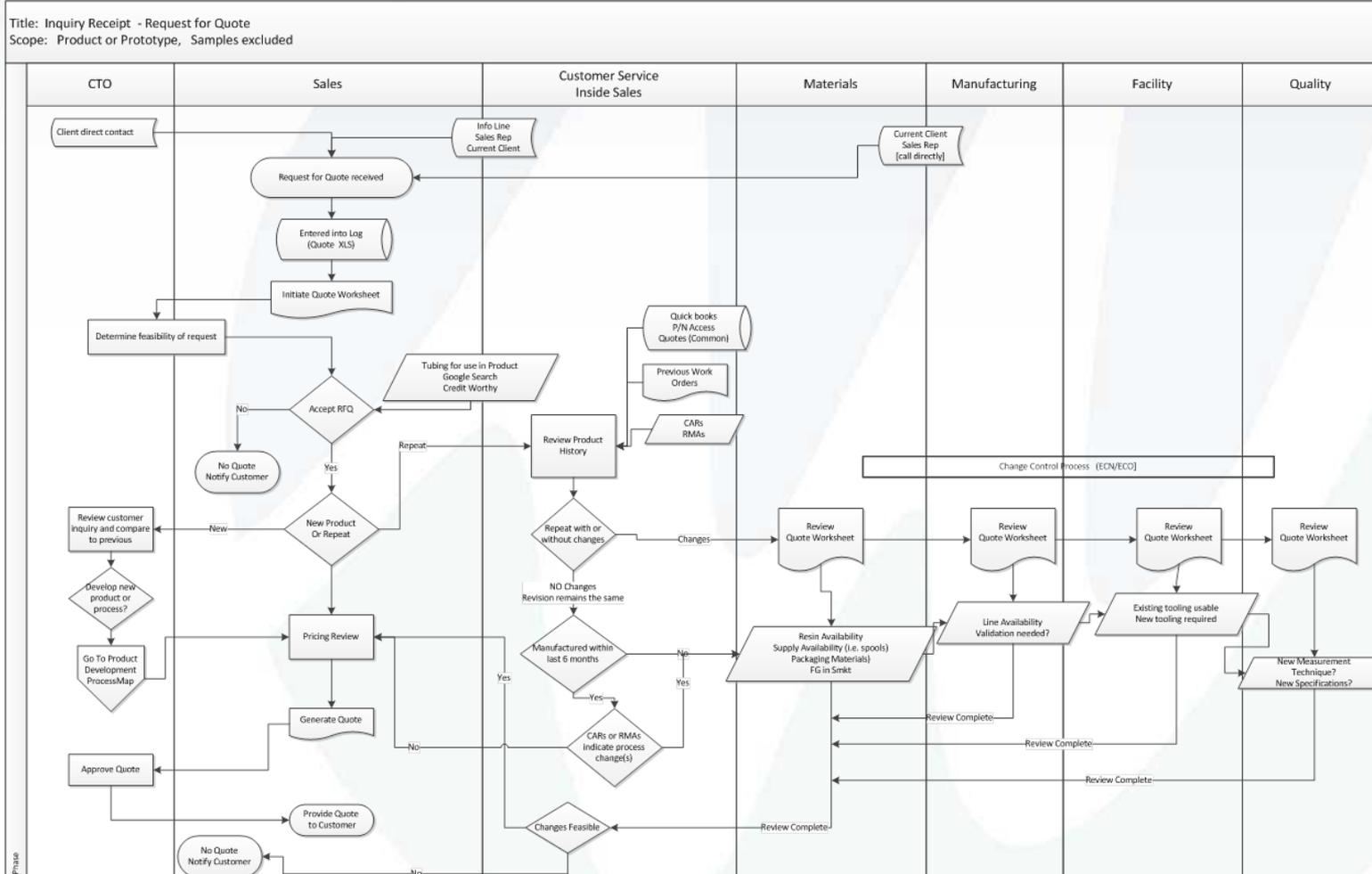
STANDARD FLOW CHART



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

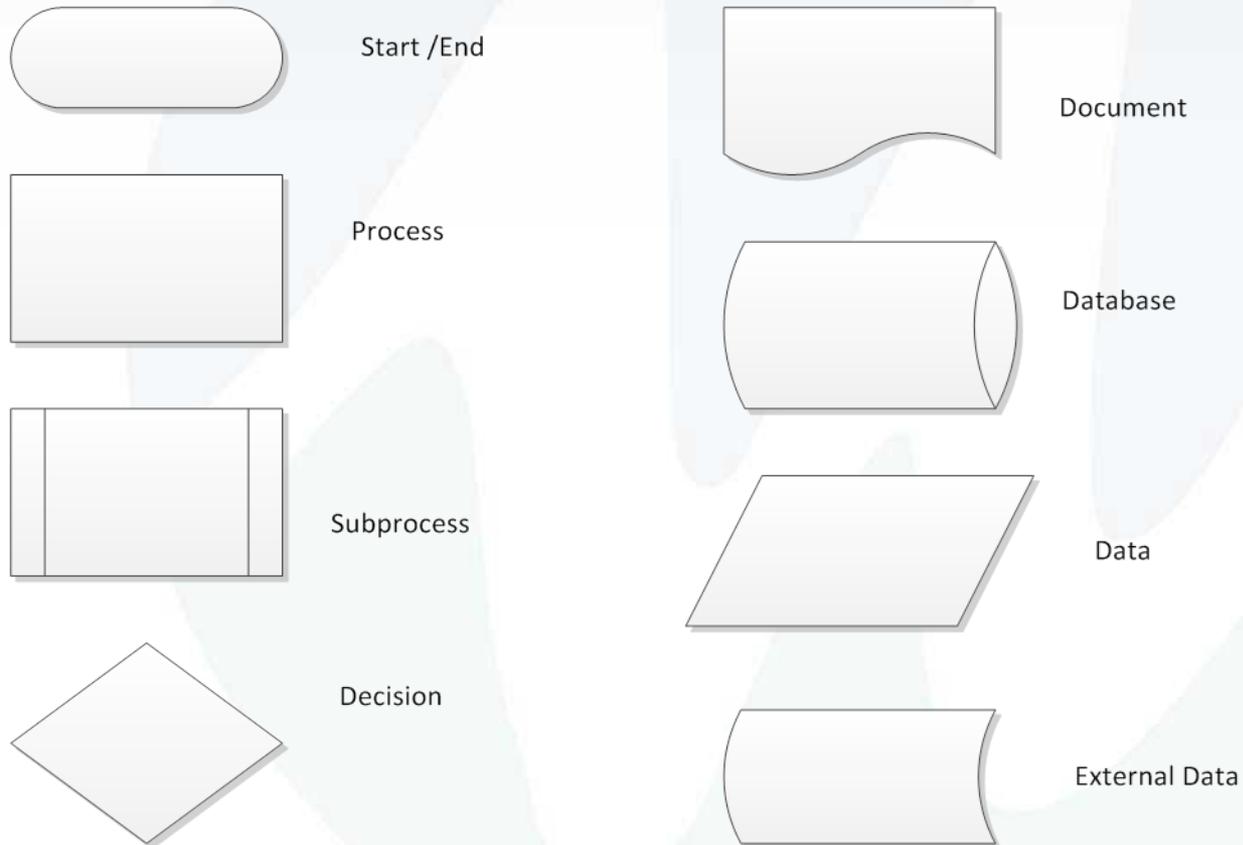
- Picture of various steps/tasks in a process
 - how the operation tasks are connected
 - the order in which they need to be completed.
- **Variety of flow chart types, with specific symbols,**
 - Regular – depicts activities/tasks
 - Cross-Functional – adds person/department that is responsible for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

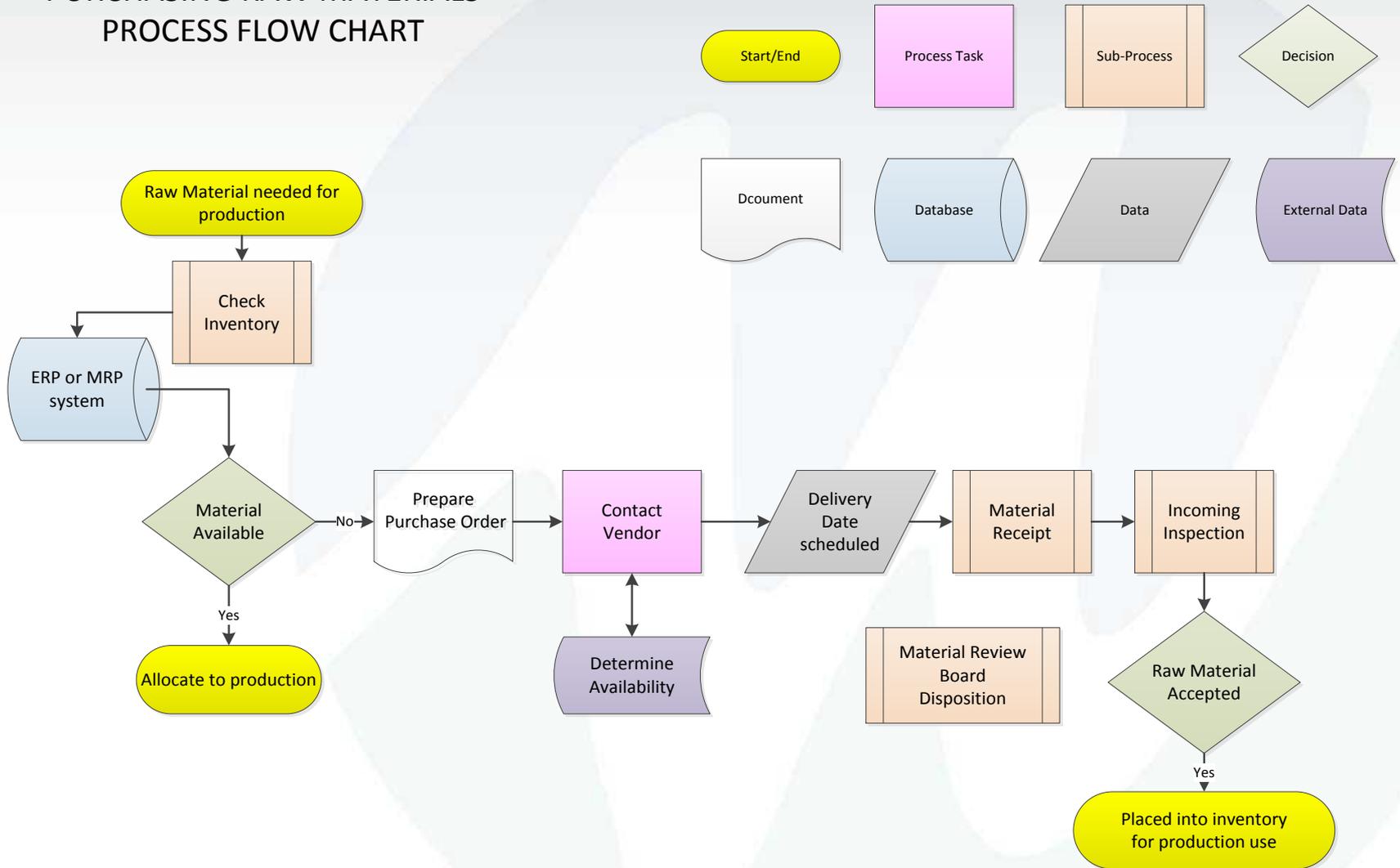
Standard (typical) symbols



SEVEN QUALITY TOOLS – Flow Chart

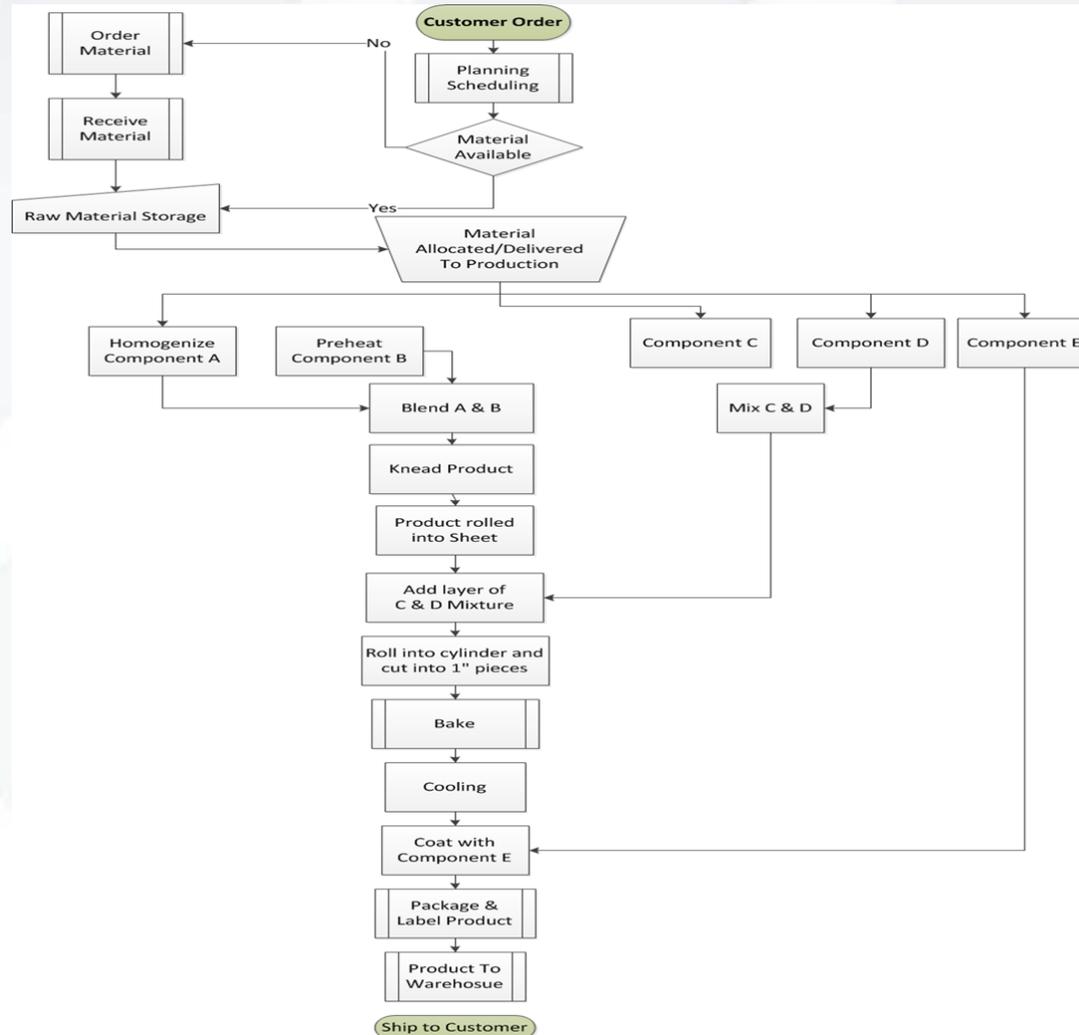
- Solid lines and arrows are used to connect the symbols and direct the user. Dotted lines may also sometimes be used. The difference between solid and dotted lines would be indicated on the flowchart.
- Start/End: indicates the starting point and ending point of the task/operation/process being depicted.
- 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



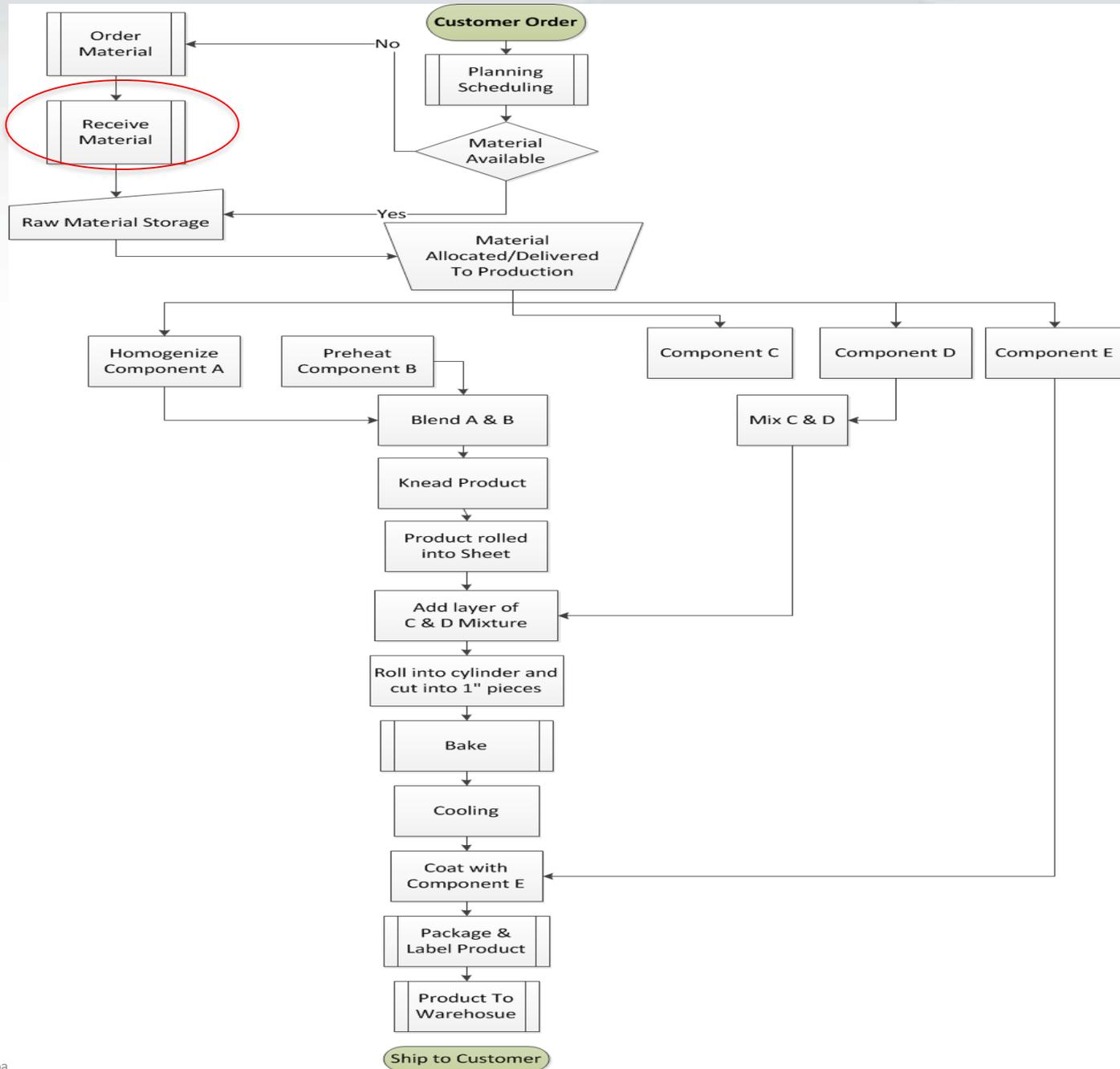
INSPECTION PROCESS

- Inspection Points – what (where) are we checking



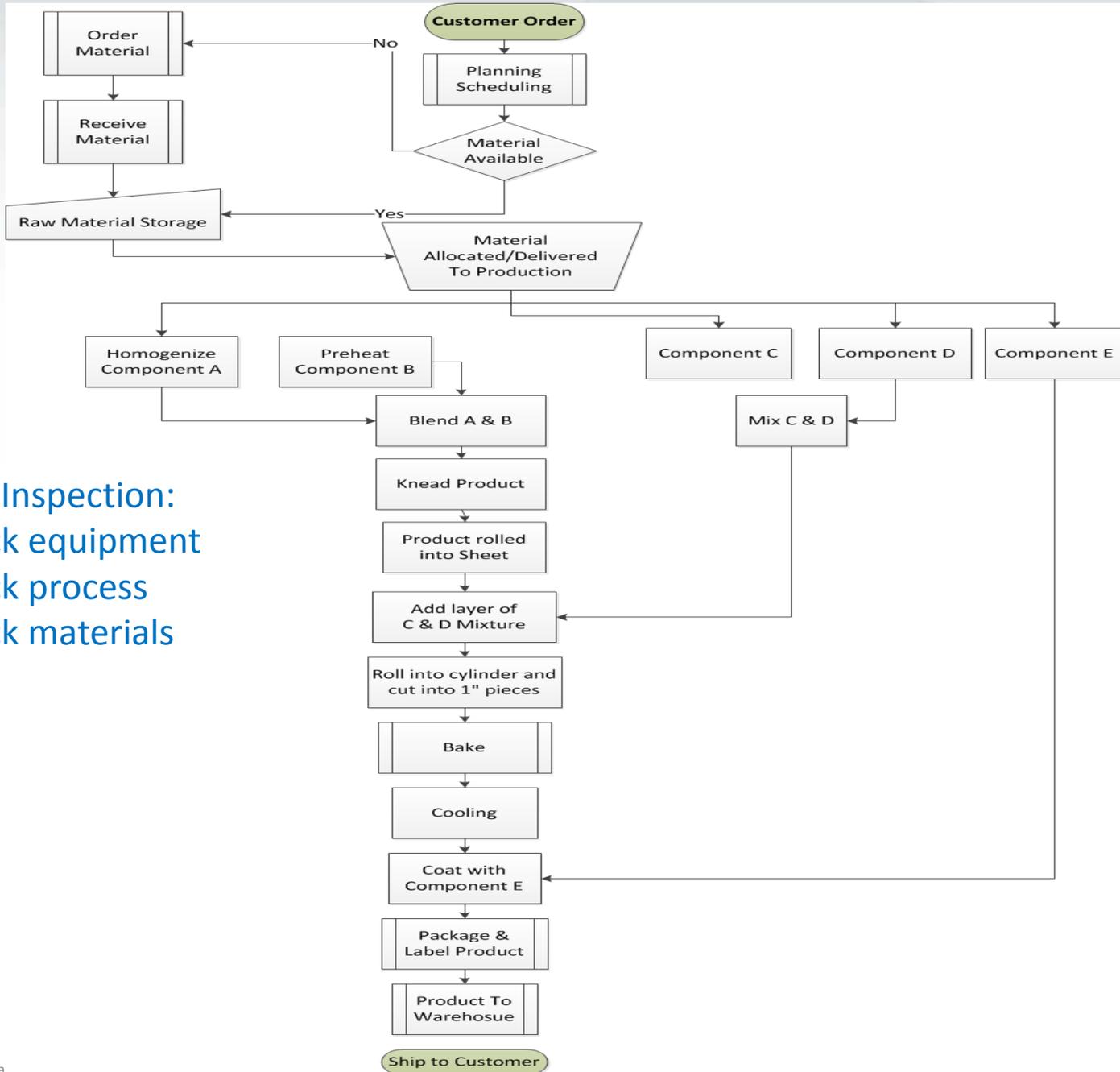
INSPECTION POINT(S)

- 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

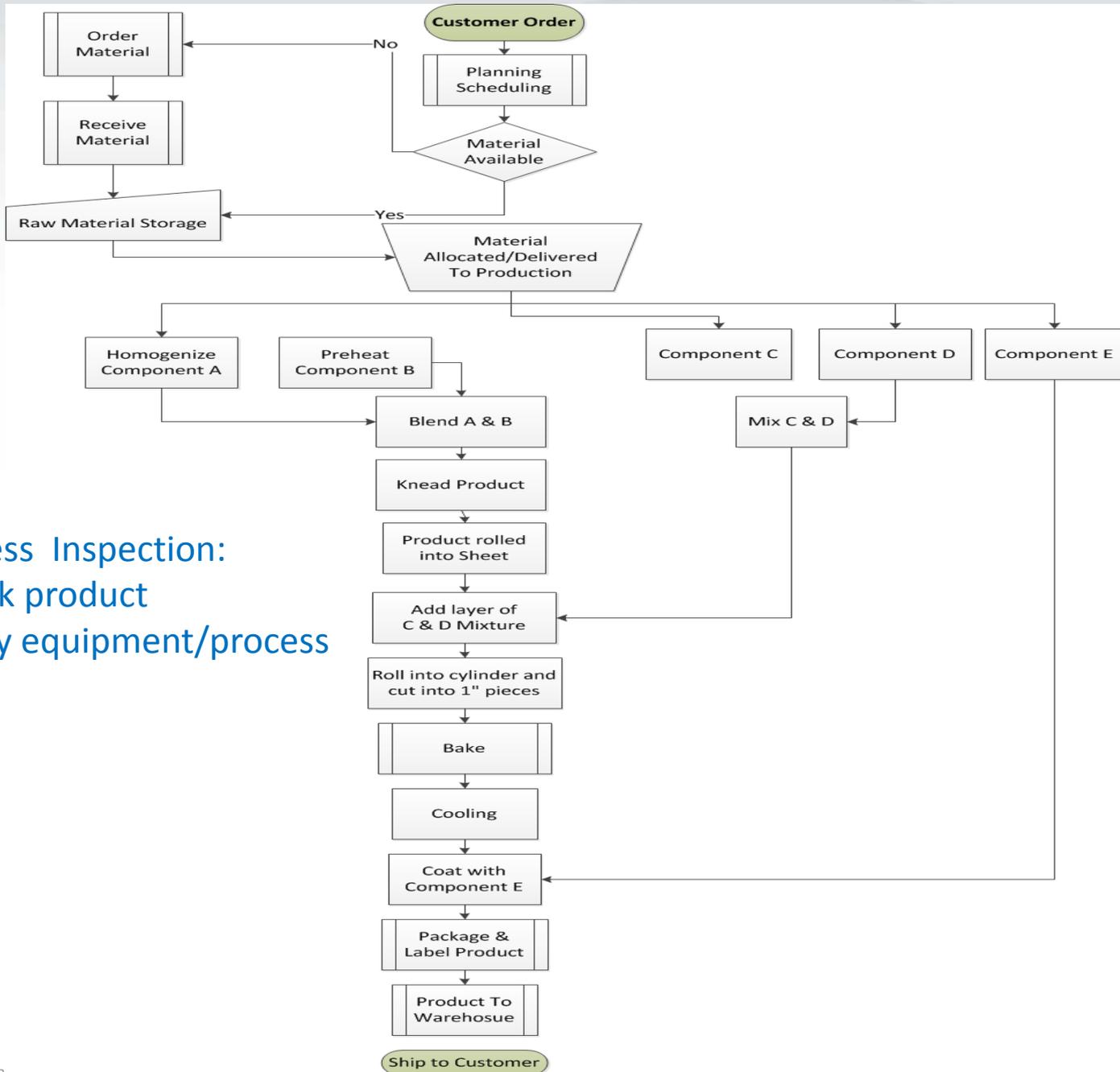


Set-Up Inspection:

- ✓ 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

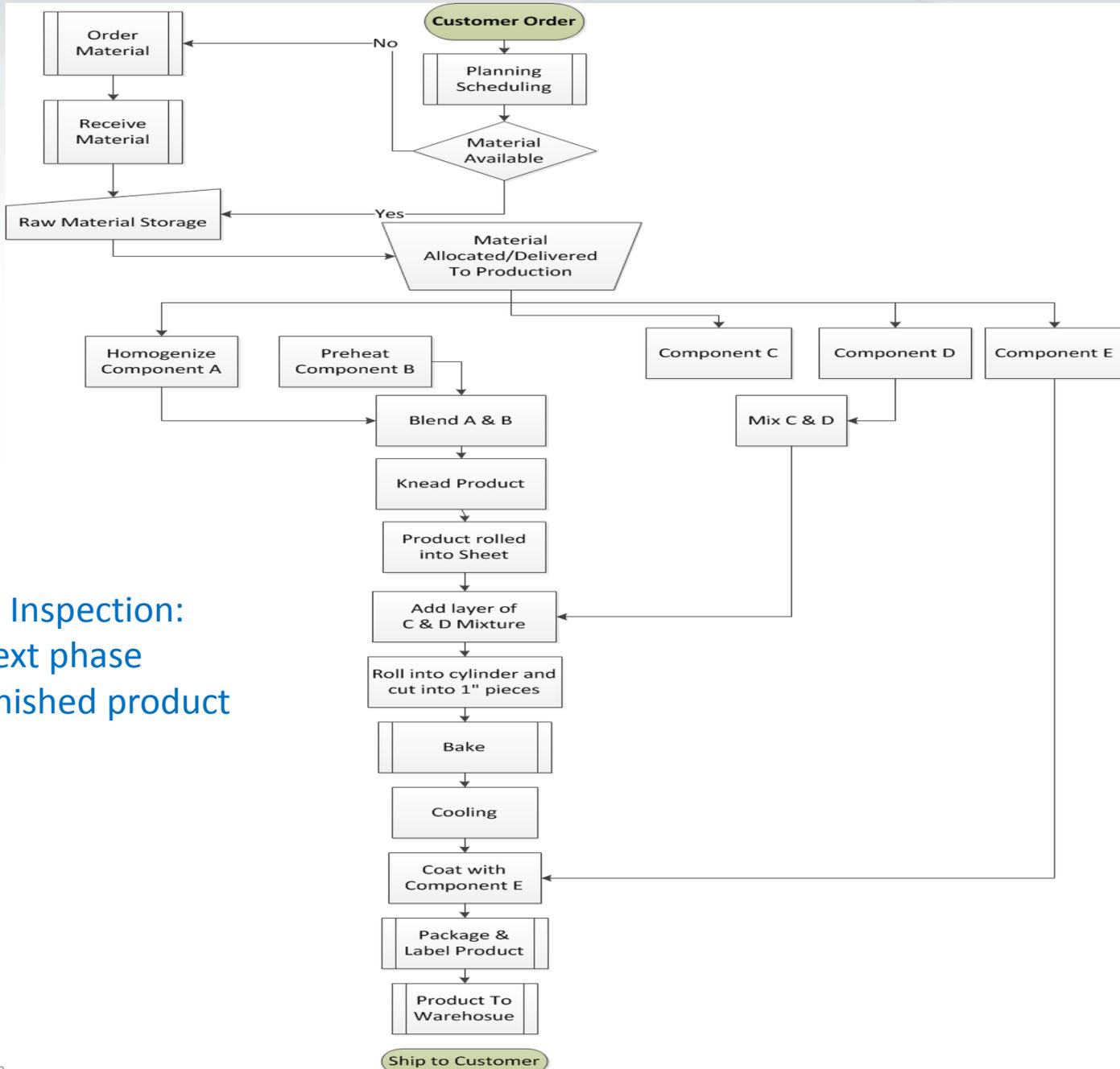


In-process Inspection:

- ✓ 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:

Document Preparer: Rhonda Doll

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)

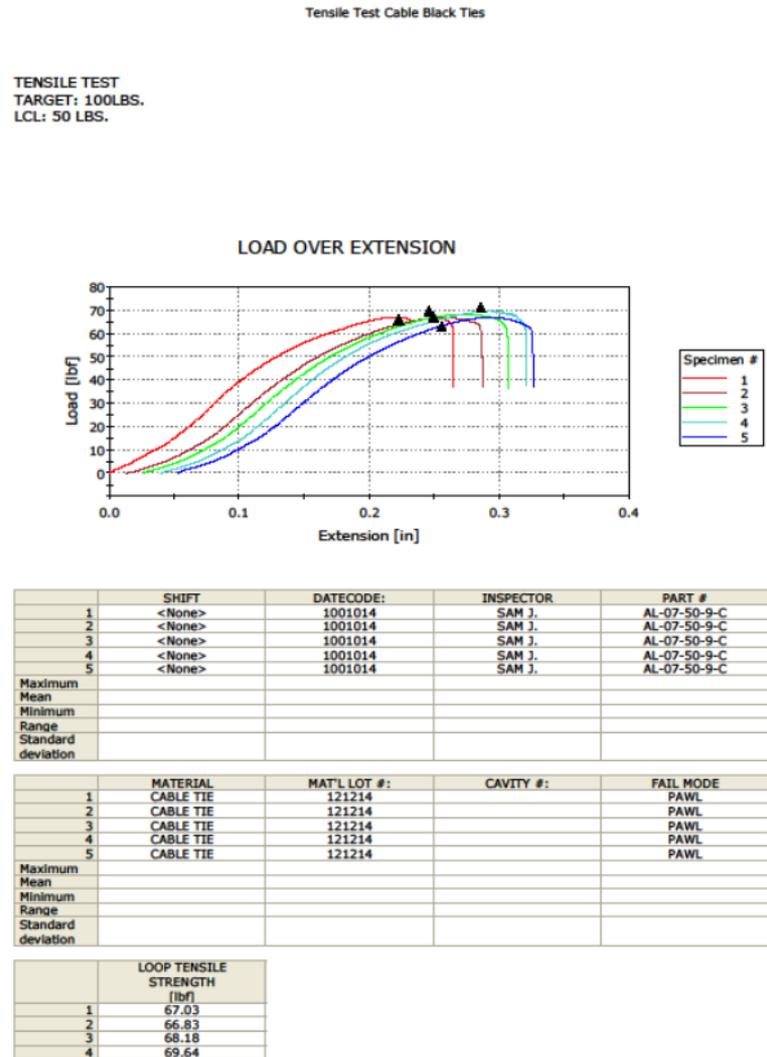
Comments:

Testing completed by: _____

(Quality Assurance/date)

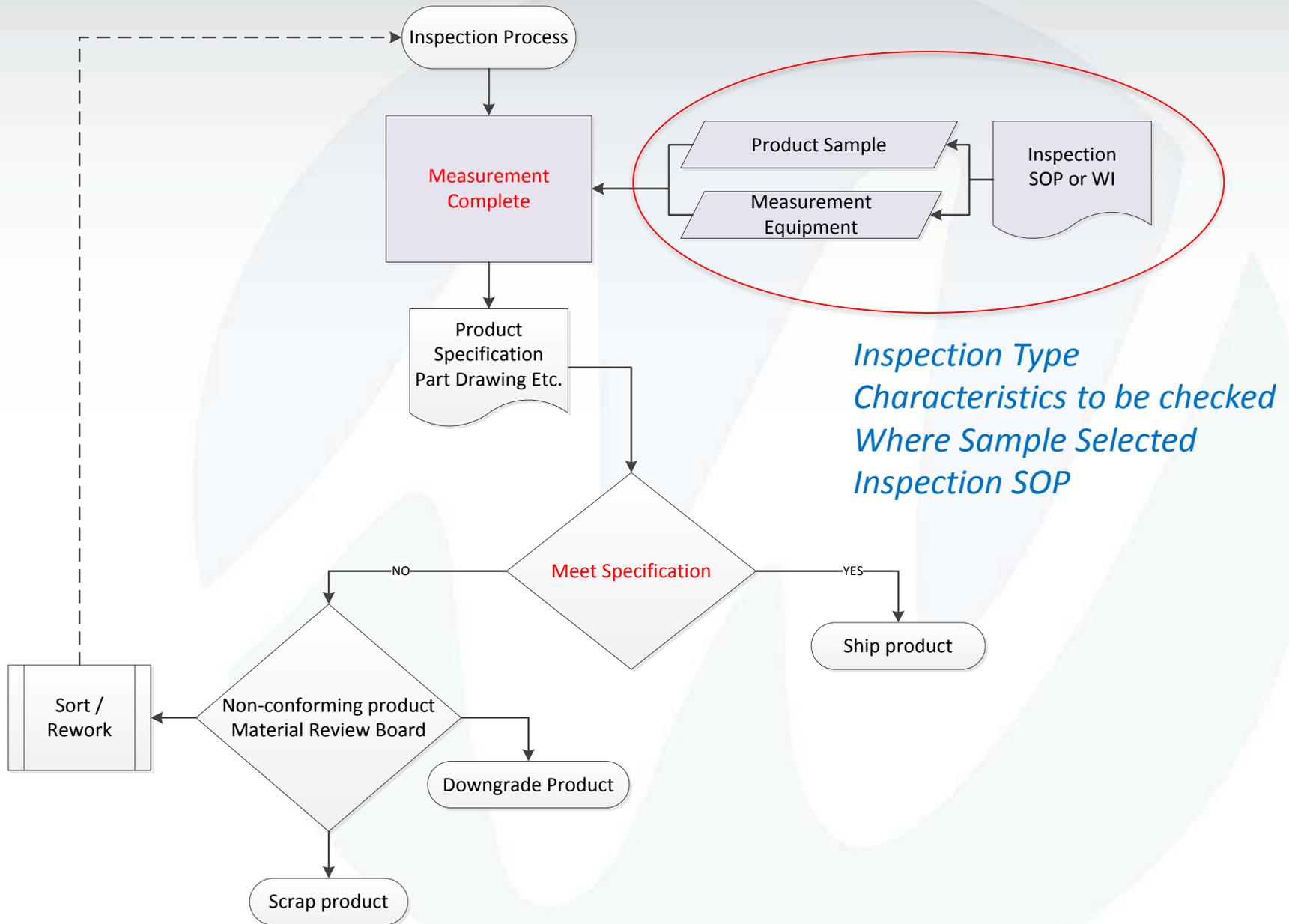
INSPECTION

- Automated output



10/1/2014 10:01:47 AM

Page 1 of 2



INSPECTION TECHNIQUES

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

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

- **Statistics Preview**
 - Probability: how likely to occur, be found, etc. (0 – 1)
 - Mutually exclusive or not mutually exclusive
 - Mutually exclusive = if one or the other occur, but not both
 - Not Mutually exclusive = both can occur at the same time
 - **Dependent or Independent events (variable)**

SAMPLING – STATISTICS

- **Statistics Preview**
 - Probability: how likely to occur, be found, etc. (0 – 1)
 - Mutually exclusive or not mutually exclusive
 - Mutually exclusive = if one or the other occur, but not both
 - Not Mutually exclusive = both can occur at the same time
 - **Dependent or Independent events (variable)**
 - **Dependent: one event contingent on the occurrence of another event**
 - **Independent: events not contingent on each other**

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. (0 – 1)
 - Mutually exclusive or not mutually exclusive
 - Mutually exclusive = if one or the other occur, but not both
 - Not Mutually exclusive = both can occur at the same time
 - **Dependent or Independent events (variable)**
 - Dependent: one event contingent on the occurrence of another event
 - Independent: events not contingent on each other

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 100th 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

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