QUALITY SYSTEMS INTENSIVE WORKSHOP

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

MODULE 2
MEASUREMENT AND SAMPLING

Developed as part of NSF ATE Grant #1304474 - Dec 2014

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

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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.

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- Inspection evaluates product quality by comparing measurement results with specifications.
  - Measurement of sample
  - Comparison against specification
  - Decision based on results
  - Corrective action, if necessary

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  - Metrology (measurement fundamentals & calibration)
  - Inspection Processes (specifications, drawings, tools)
  - Sampling

MEASUREMENTS

Specifications & Print Reading for Industry
Geometric Dimension and Tolerance
Introduction to Metrology

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 / DRAWINGS

- Specifications define expected performance limits
  - what are critical characteristics and their individual requirements
- To manufacture/build a product, part, assembly or structure a set of drawings need to provide the detail
  - Drawing: visual representation of product, component part, etc. which includes dimensions
    - Historically drawing was the blueprint

SPECIFICATON

- 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

SPECIFICATON

- Specifications can be word documents and/or drawings
- 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 dimensional description
  - 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), Solid Works, Inventor, etc

DRAWING

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

DRAWING

- American Society of Mechanical Engineers provides standard for industry
  - ASME Y14.5-2009 “Dimensioning & Tolerancing: Engineering Drawing and Related Documentation Practices”
    - Language and rules learned
    - Aids intra- & inter-company communication

Referred to as GD&T (geometric dimension & tolerance)

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

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  - Limit Dimensioning
    - 0.200 inches minimum
    - 0.200 inches maximum

Note: Unilateral and limiting 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
- Shapes
  - Circles, arcs
  - Squares, angles
- Symbols
  - Parallel, flatness, concentricity

Geometric Dimension & Tolerance

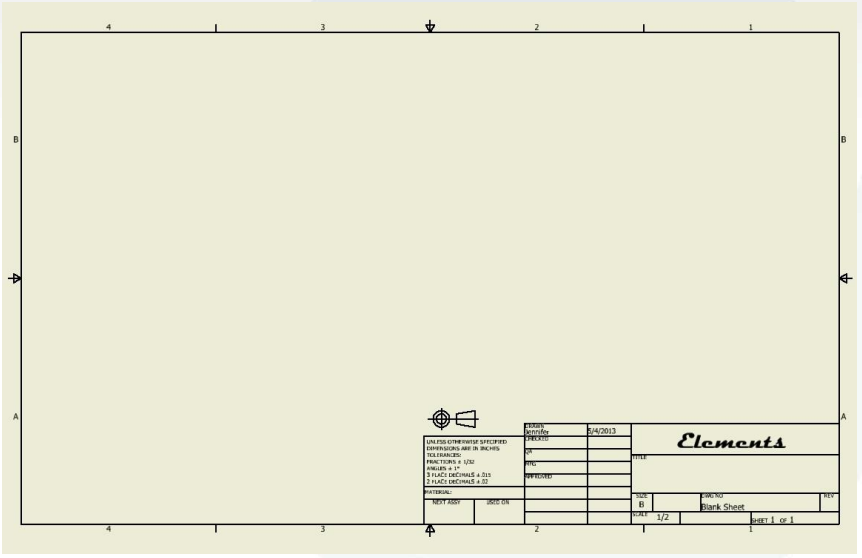
- ASME Y14.5-2009 provides specific rules for interpretation and application of symbols on drawings
  - Language and rules learned
  - Aids intra- & inter-company communication
- Use symbols instead of notes for geometric controls
  - Fit/form/function
  - Relationship between specific part features

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

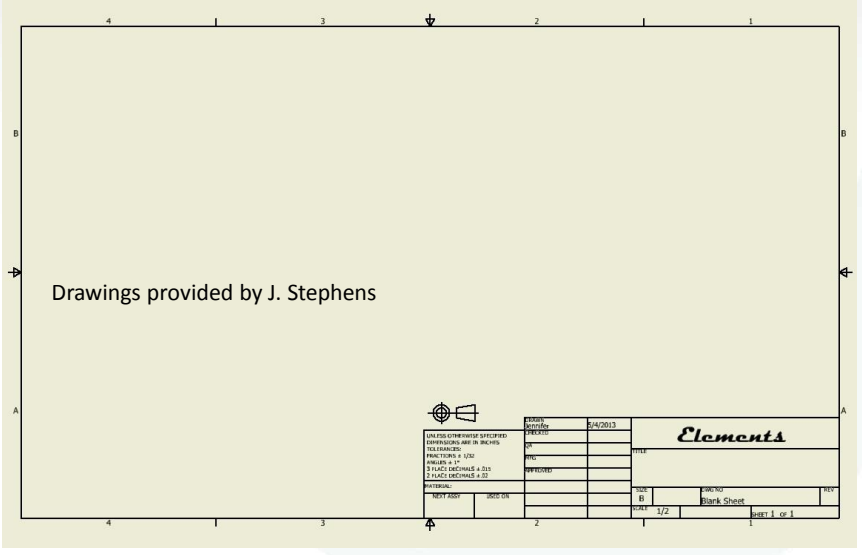
ASME Y14.5-2009
"Dimensioning & Tolerancing: Engineering Drawing and Related Documentation Practices"

UNDERSTANDING THE DRAWINGS



UNDERSTANDING THE DRAWINGS

Drawings provided by J. Stephens



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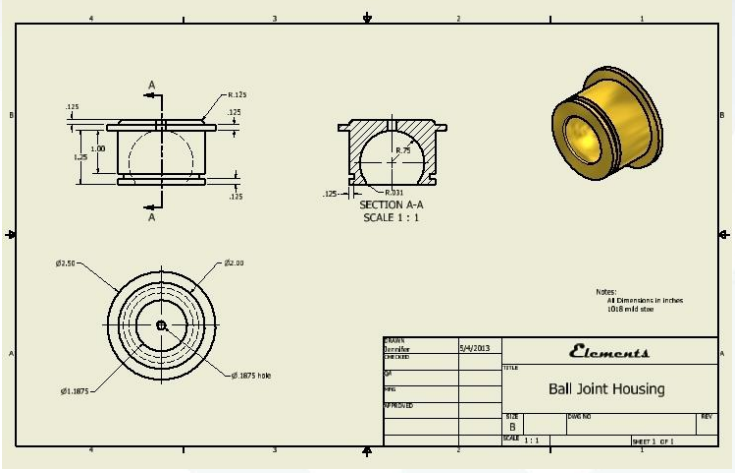
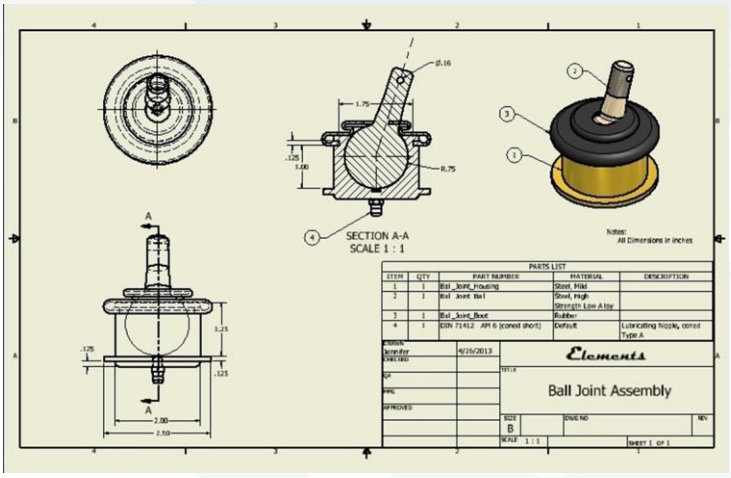


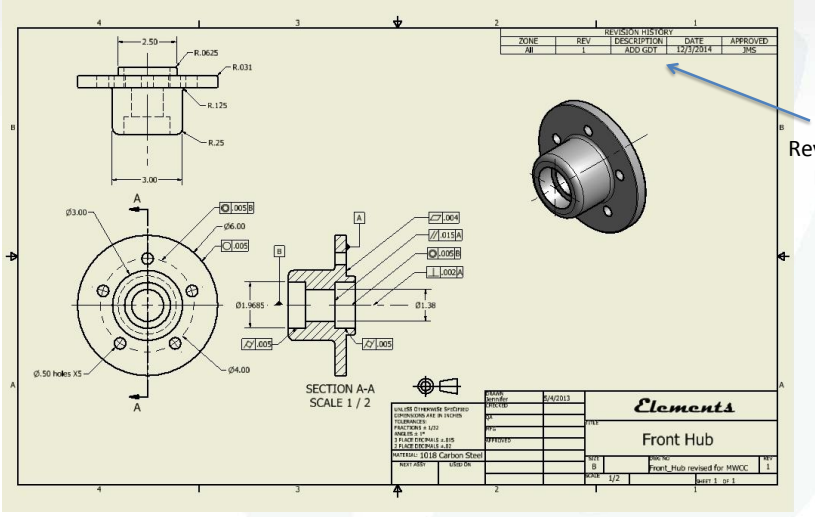
COMPONENT

UNDERSTANDING THE DRAWINGS



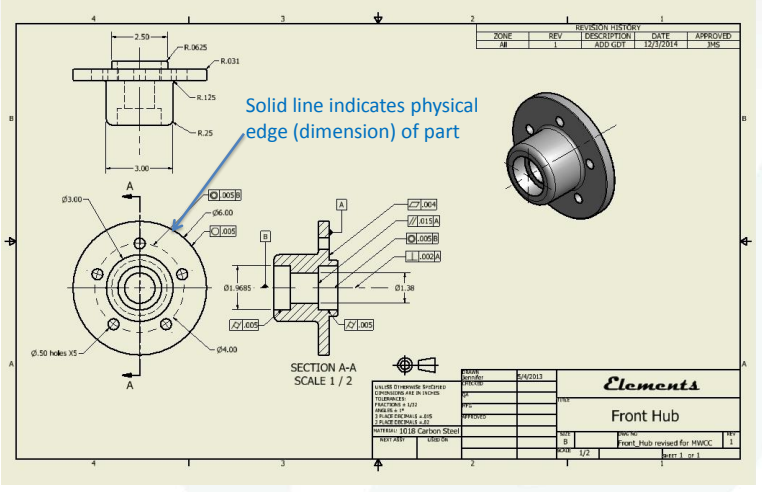
ASSEMBLY

UNDERSTANDING THE DRAWINGS



Wheel Hub for Go-Kart

UNDERSTANDING THE DRAWINGS



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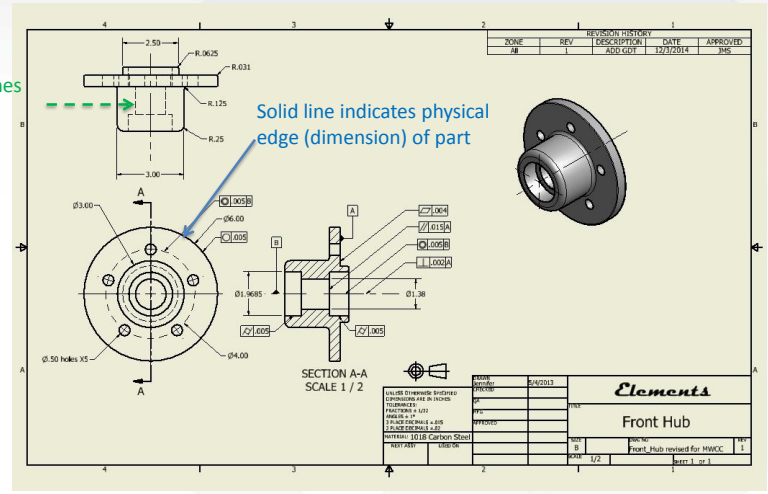
UNDERSTANDING THE DRAWINGS

Dashed lines indicate hidden features



Wheel Hub for Go-Kart

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UNDERSTANDING THE DRAWINGS

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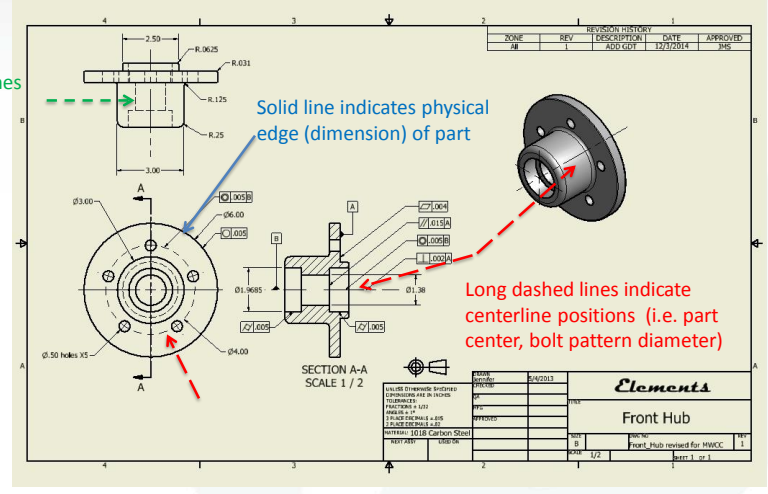

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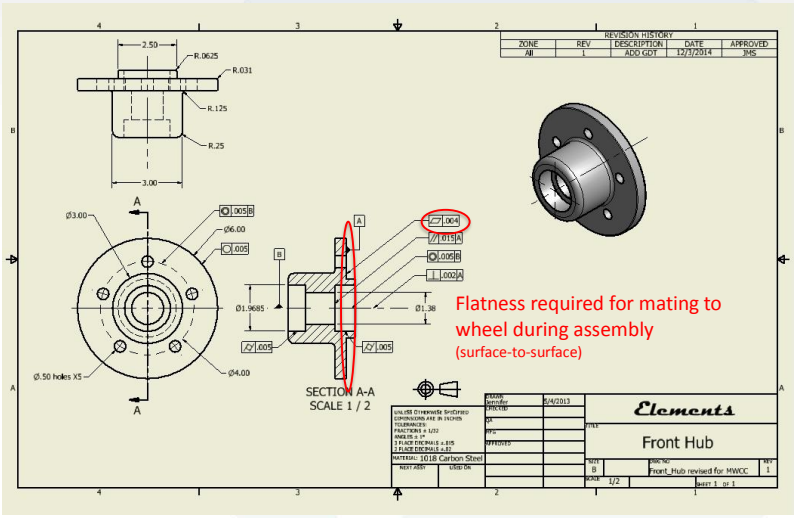

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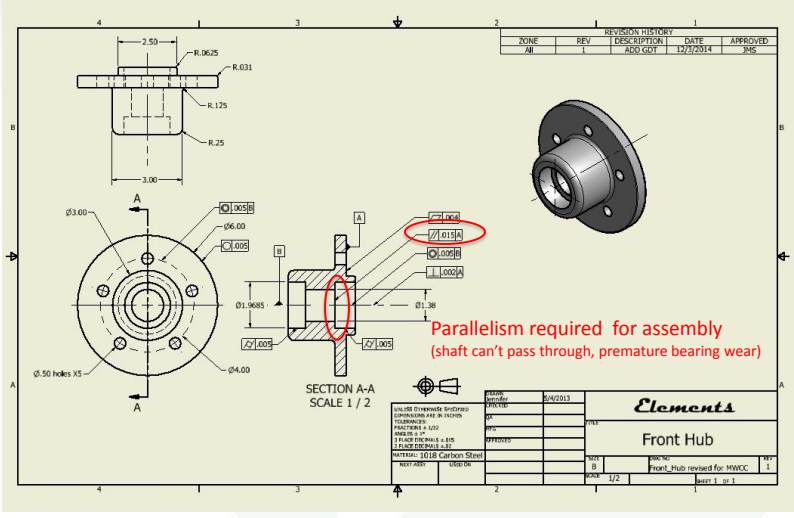

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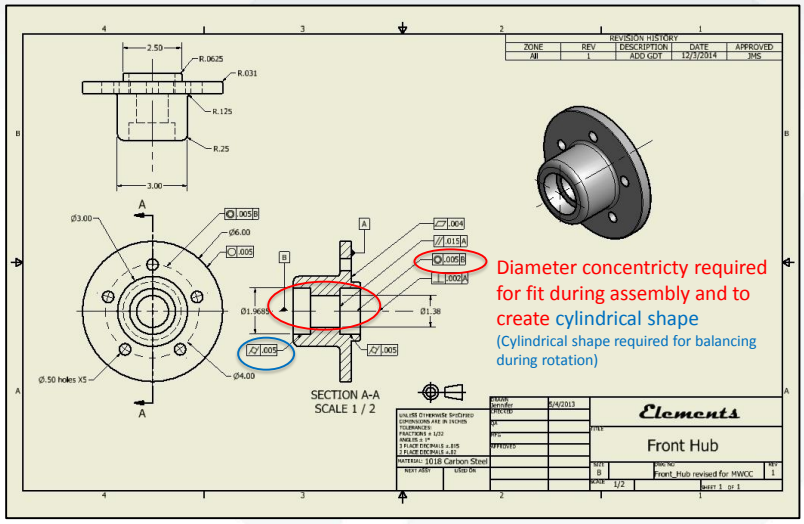
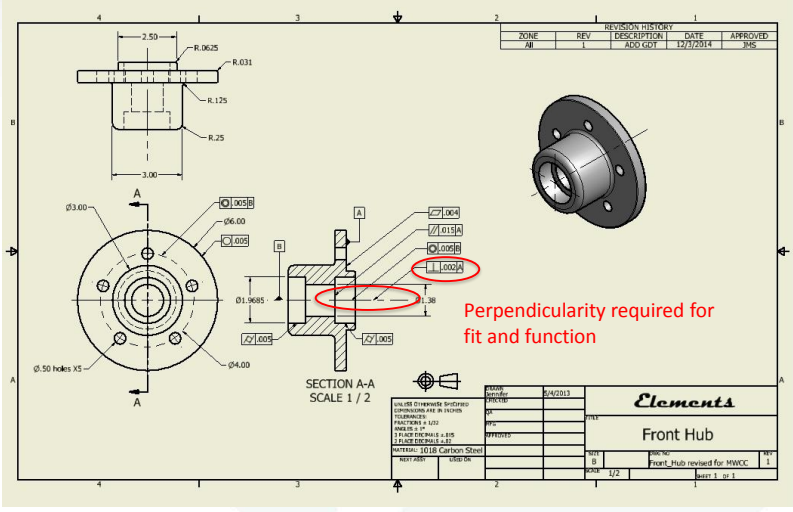


Diameter concentricty required for fit during assembly and to create cylindrical shape

(Cylindrical shape required for balancing during rotation)

Wheel Hub for Go-Kart

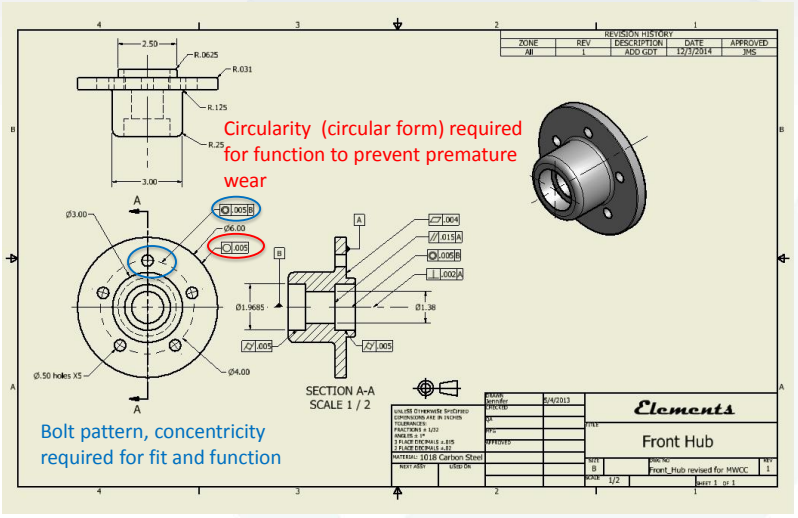
UNDERSTANDING THE DRAWINGS



Perpendicularity required for fit and function

Wheel Hub for Go-Kart

UNDERSTANDING THE DRAWINGS

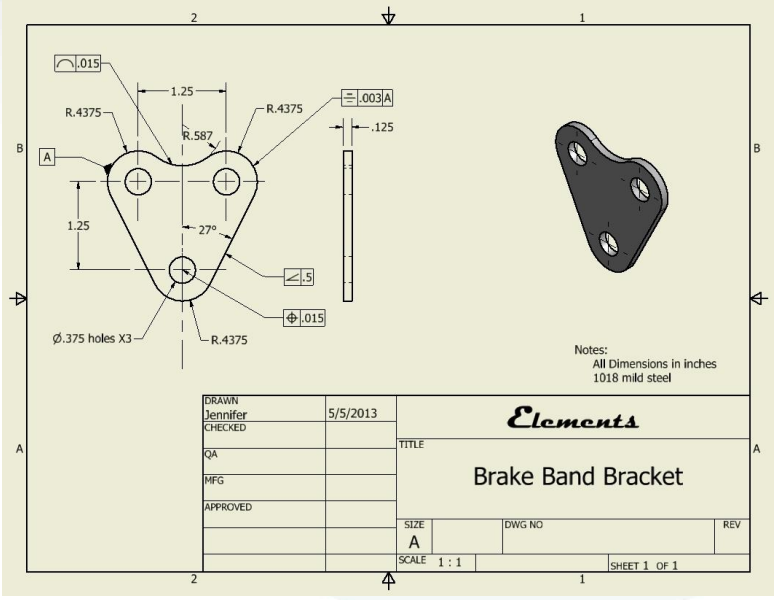


Wheel Hub for Go-Kart

DRAWING REVIEW

Drawing review – symbols, dimensions

DRAWING REVIEW



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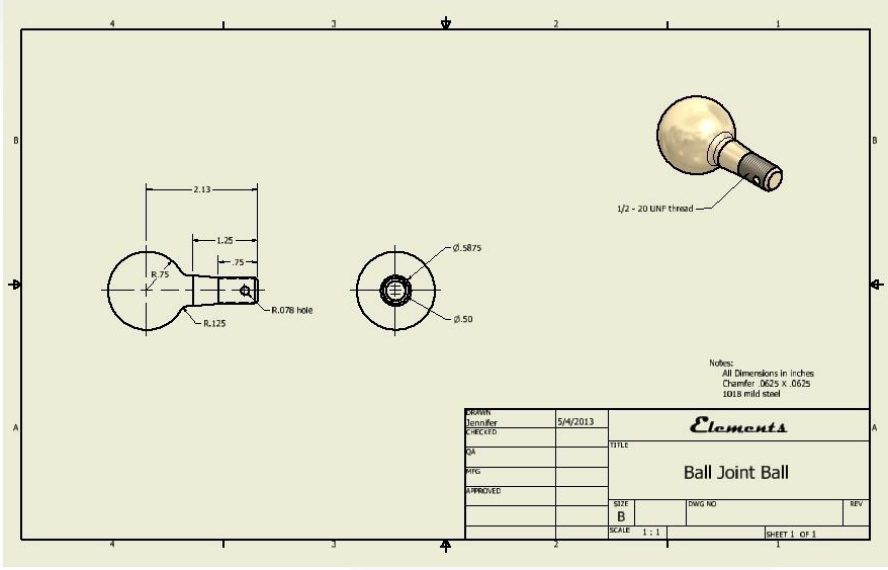

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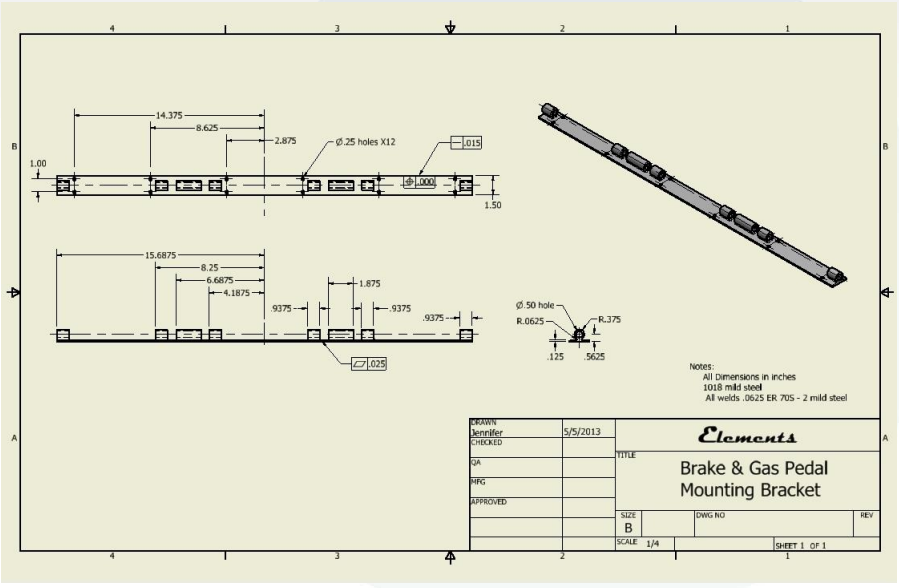

MEASUREMENTS

Specifications & Print Reading for Industry
Geometric Dimension and Tolerance
Introduction to Metrology

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.

MEASUREMENT SYSTEM

- Two measurement systems commonly used are:
  - Metric system
  - English system
- www.onlineconversion.com
- Measurements are taken and recorded as required by the specification
  - If specification uses metric system, measure using metric tools

METROLOGY

- Metrology – the science of measurement
  - Precision / Accuracy of measurements
- 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

- Metrology – the science of measurement
  - Ensuring the suitability of measurement instruments, their calibration and quality control of measurements.
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- Three subfields that use the basic activities
  - Scientific/Fundamental - establishes units of measure

METROLOGY

Scientific
(units of measure)

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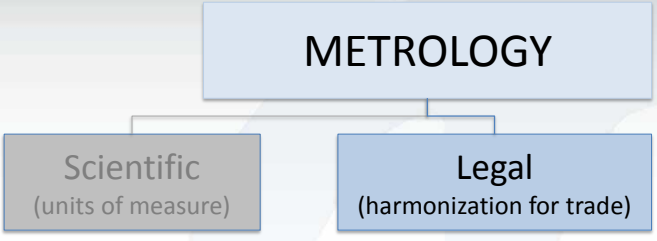
- Three subfields that use the basic activities
  - Scientific/Fundamental - establishes units of measure
  - Legal – establishes statutory requirements

    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.)



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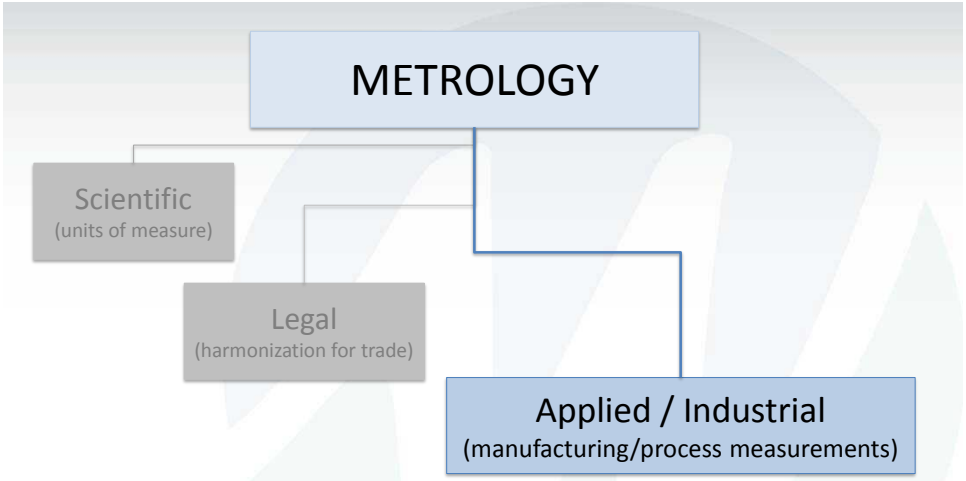
  - Applied/Technical/Industrial

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*



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.

Wikapedia.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

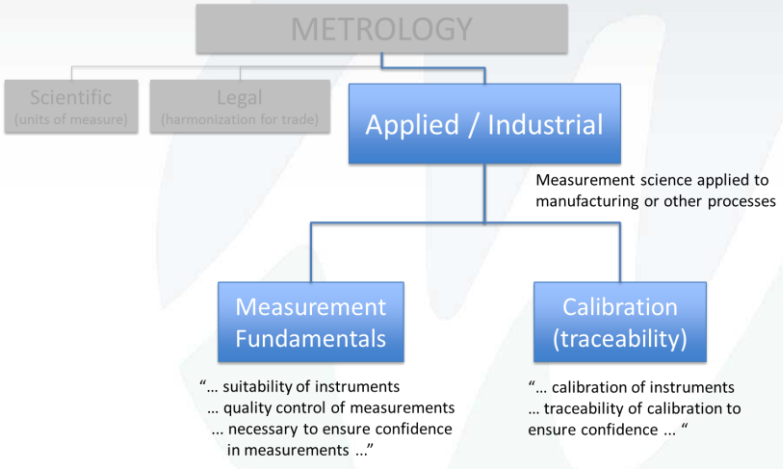
METROLOLGY

- Why bother?

METROLOLGY - References

- ISO9001:2015
  - Section 7.1.5 Monitoring & Measurement Resources
- ISO 134875:20165
  - Section 7.6 Control of monitoring & measurement equipment
- Pharmaceutical cGMPs (21CFR 211)
  - Subpart D – Equipment
    - 21CFR 211.68 Automatic, Mechanical and Electronic Equipment
  - Subpart I – Laboratory Controls
    - 21CFR 211.160 General Requirements
- Medical Device cGMPS (21CFR 820)
  - Subpart G – Production & Process Controls
    - 21CFR 820.72 Inspection, Measuring & Test Equipment

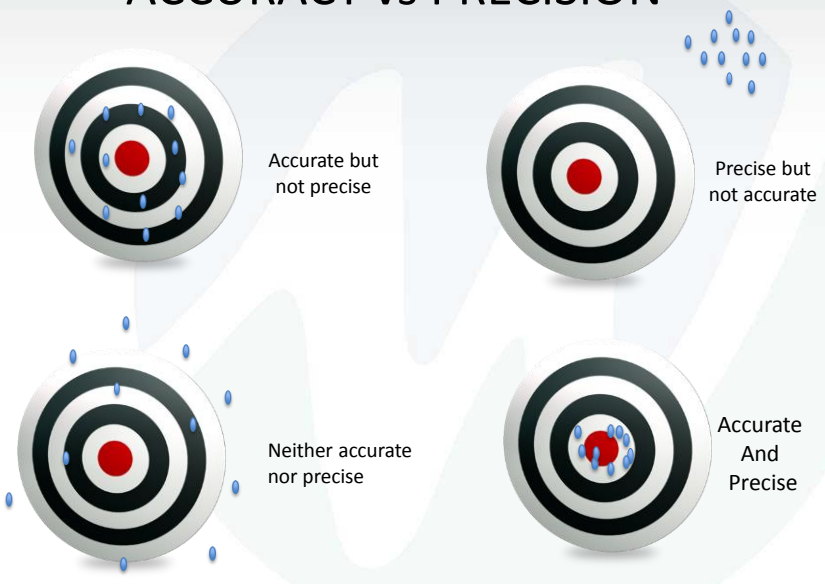
METROLOGY PROGRAM



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



METROLOGY PROGRAM

- Measurement Fundamentals
  - Methods, equipment
- Calibration System
  - Verification

METROLOGY PROGRAM

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

MEASUREMENT FUNDAMENTALS

- Methods
  - Logical organization of operations used
  - Understanding the characteristics of what is to be measured
  - How the measurement is taken (i.e. direct, indirect, ratio, etc.)
- System
  - Personnel, standards, devices fixtures, etc. used to conduct the measurement
- Capability
  - Ability of the measurement system to accurately/precisely measure the characteristic
    - Bias: systematic offset
    - Linearity: equally increasing increments
    - Repeatability: closeness of measurements from same instrument
    - Reproducibility: closeness of measurements under same conditions
    - Stability: change in bias over time (i.e. drift)

MEASUREMENT FUNDAMENTALS

- Methods
- System
- Capability
- Equipment specifications
- 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
  - Manual versus automation
- Environmental Controls
  - Temperature, humidity, lighting, etc.
  - Effect on measurement tool
  - Effect on characteristic to be measured

MEASUREMENT FUNDAMENTALS

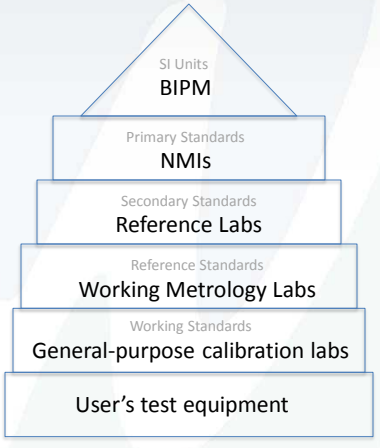
- Standards Usage (Traceability)
  - Per ISO/IEC 17025:2005, 5.6.2.1.1: "..For calibration laboratories, the programme for calibration of equipment shall … ensure that calibrations and measurements ... are traceable to the International System of Units (SI) … establishes traceability … by means of an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

MEASUREMENT FUNDAMENTALS

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

$$\frac{\text{stated accuracy of standard}}{\text{stated accuracy of device under test}}$$

  - 10:1 desired
  - 4:1 acceptable



MEASUREMENT FUNDAMENTALS

- Confidence (Uncertainty) Programs
  - Accuracy / precision
  - Uncertainty: range of probable values of "true value"
    - Measurement Errors
      - Random Error: scattered results (i.e. drafts)
      - Systematic Error: bias (i.e. excessive wear)
      - 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

Develop a measurement program

i.e. Juice boxes, prescription tablet,

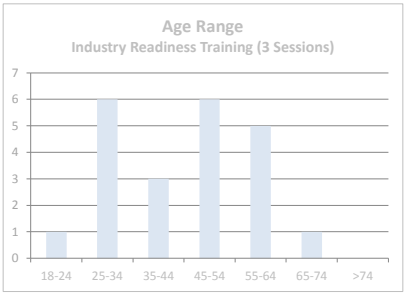
or - pick something from your work history

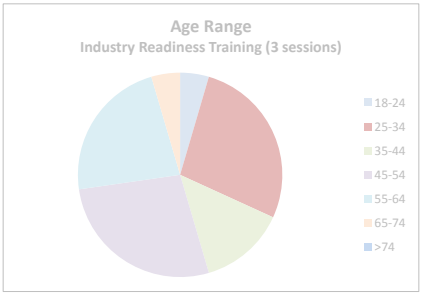
MEASUREMENT FUNDAMENTALS

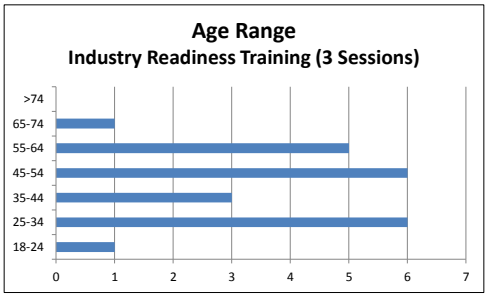
- Methods
- Capability
- Equipment specifications
- Standards Usage
- Environmental Controls
- Standards Usage
- Confidence (Uncertainty) Programs
- Data
  - Measurement results (data) used to make decisions
  - Type and quality provide adequate information about application
  - Considerations
    - Format
    - Resolution
    - Readability
    - Suitability
    - Confidentiality

MEASUREMENT FUNDAMENTALS

- Data
  - Measurement results (data) used to make decisions
  - Type and quality provide adequate information about application
  - Considerations
    - Format: presentation (layout)
      - Graphically, table, number convention, font, etc.
    - Resolution
    - Readability
    - Suitability
    - Confidentiality





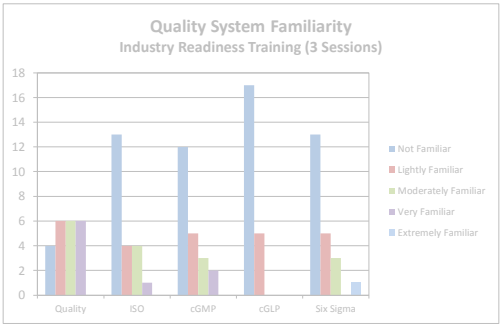


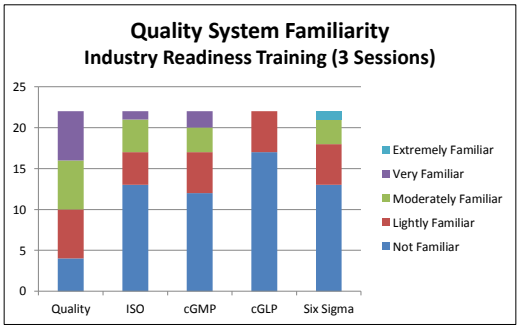
MEASUREMENT FUNDAMENTALS

- Data
  - Measurement results (data) used to make decisions
  - Type and quality provide adequate information about application
  - Considerations
    - Format: presentation (layout)
    - Resolution: least significant digit distinguishable
      0.001 vs 0.0001 vs 0.00001
    - Readability
    - Suitability
    - Confidentiality

MEASUREMENT FUNDAMENTALS

- Data
  - Measurement results (data) used to make decisions
  - Type and quality provide adequate information about application
  - Considerations
    - Format: presentation (layout)
    - Resolution: least significant digit distinguishable
    - Readability: presentation, ease of observer interpretation
      - Digital vs manual readout
      - Graphs vs tables
    - Suitability
    - Confidentiality





MEASUREMENT FUNDAMENTALS

- Data
  - Measurement results (data) used to make decisions
  - Type and quality provide adequate information about application
  - 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
    - Confidentiality

MEASUREMENT FUNDAMENTALS

- Data
  - Measurement results (data) used to make decisions
  - Type and quality provide adequate information about application
  - 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 systems essential to ensure that measurements provide data needed to make informed, appropriate decisions

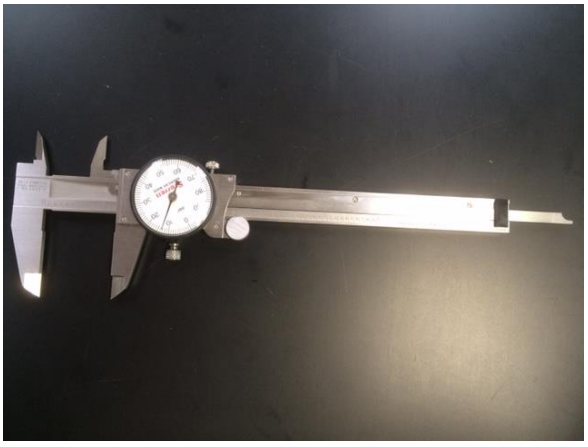
Review

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 is the science of measurement.
- Applied/Industrial metrology pertains to manufacturing and other processes
  - Ensuring the suitability of measurement instruments, their calibration and quality control of measurements.

Suitability = Measurement Fundamentals (Metrology program)

Measuring Instruments
Dial Calipers



Measuring Instruments
Digital Calipers

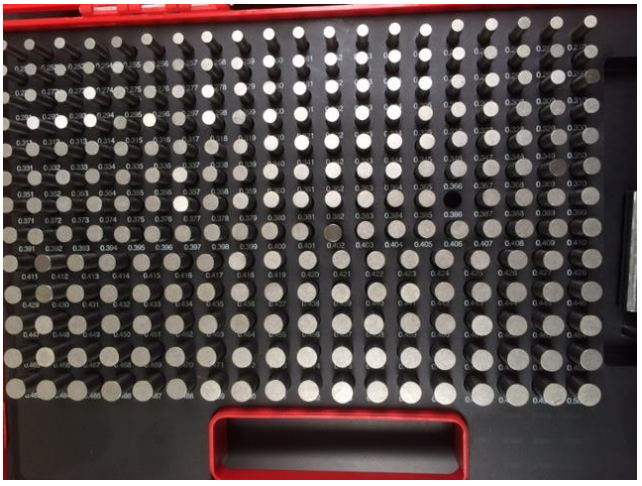
Measuring Instruments
Digital Calipers

Measuring Instruments
Micrometers

Measuring Instruments
Digital Micrometers

Measuring Instruments
Digital Micrometers

Measuring Instruments
Precision Pin Gages

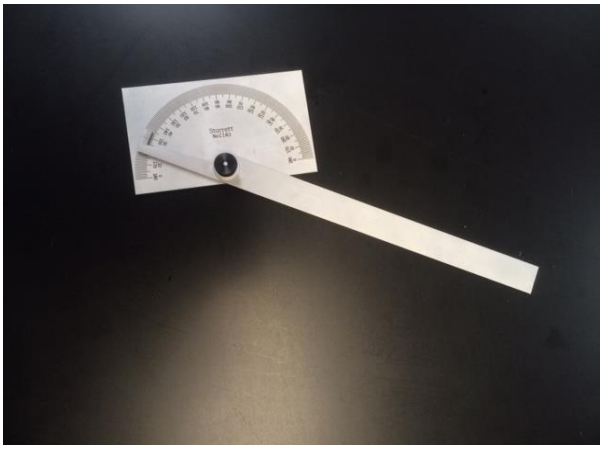


Measuring Instruments
Precision Pin Gages

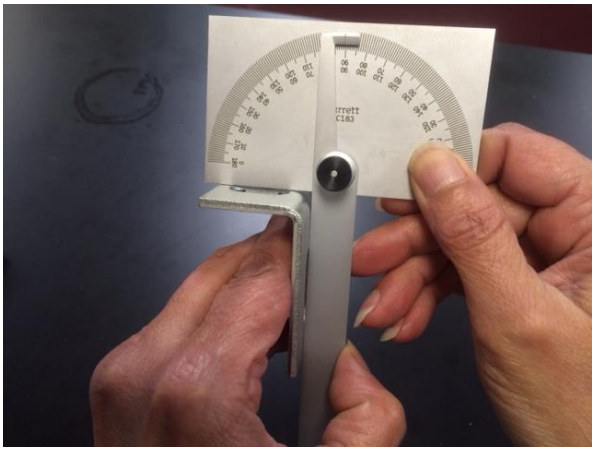
Measuring Instruments
Thread Gage

Measuring Instruments
Thread Gage

Measuring Instruments
Protractor



Measuring Instruments
Protractor



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
      - Reference
      - Working
      - secondary
  - Unit under test = second device

METROLOGY PROGRAM

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

METROLOGY PROGRAM

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  - Internal Process / External Vendor program
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  - Environmental Controls
  - Software Validation
  - Intervals
  - Scheduling
  - Labels
- **Measurement Fundamentals**
  - Methods
  - System
  - Capability
  - Equipment specifications
  - Environmental Controls
  - Standards Usage
  - Confidence (Uncertainty) Programs
  - Data

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

CALIBRATION SYSTEM

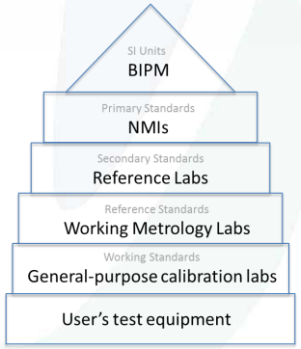
- Procedures (Methods)
  - Standard operating procedures and/or work instructions
    - Operation of equipment
    - Performance of calibration
  - Out-of-Tolerance occurrence (non-conformance)
    - Directly or indirectly affect process/product/safety
    - Documented investigation required
      - 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

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

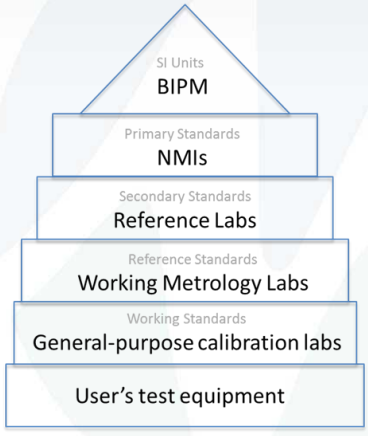


CALIBRATION SYSTEM

- 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
  - 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

CALIBRATION SYSTEM

- Measurement Traceability



CALIBRATION SYSTEM

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

CALIBRATION SYSTEM

- Software Validation
  - Opportunities
    - Calibration management
    - Device control software or data collection
    - Test procedure software
    - Statistical software
  - Standard References
    - 21 CFR Part 11, Electronic Records; Electronic Signatures
      - 211.68 Automated, mechanical and electrical equipment
      - 820.72 Inspection, measurement and test equipment
    - ISO 9001:2015 (7.1.5 Monitoring and Measurement Resources)
    - ISO 13485:2016 (7.6 Control of Monitoring & Measuring Equipment)

CALIBRATION SYSTEM

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

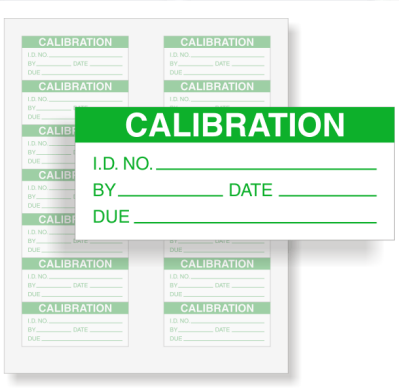
CALIBRATION SYSTEM

- 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
- 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
- Labels

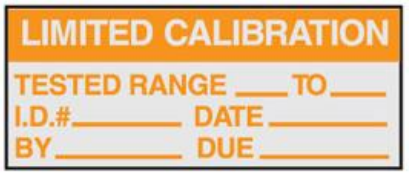
CALIBRATION SYSTEM

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

CALIBRATION SYSTEM - Labels



CALIBRATION SYSTEM - Labels



CALIBRATION SYSTEM - Labels

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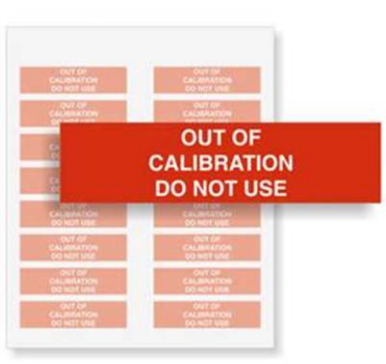
CALIBRATION SYSTEM - Labels



Developed as part of NSF ATE Grant #1304474

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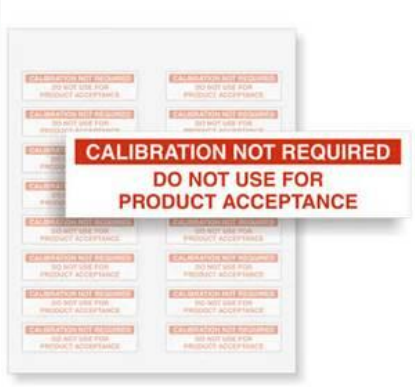
CALIBRATION SYSTEM - Labels

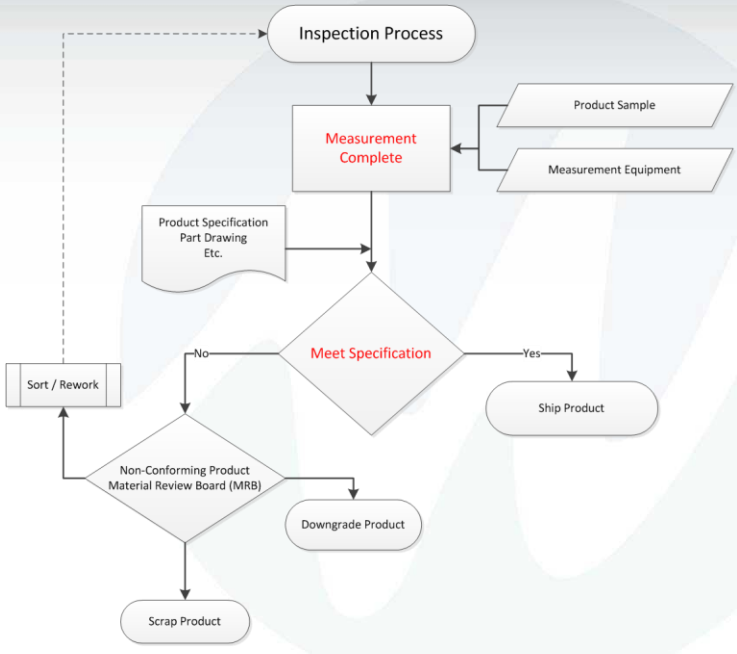


INSPECTION

Inspection Methods
Sampling

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



INSPECTION

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  - Decision based on results
  - Corrective action, if necessary

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

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

- Lean Six Sigma
  - Lean Manufacturing
    - Reduces (eliminates) waste)
    - Focused on creating the most value with the least amount of work

      DOWNTIME

      defects

      waiting for inspection

      transportation to QC

      excess processing (rework)
  - Six Sigma
    - Identifying (removing) defects
    - Minimizing process variability

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

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

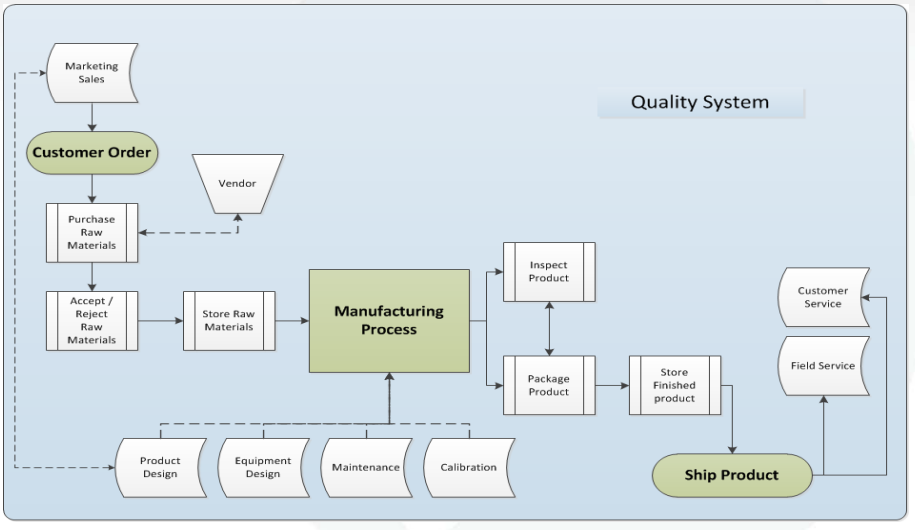
INSPECTION

- 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

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

- Inspection 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

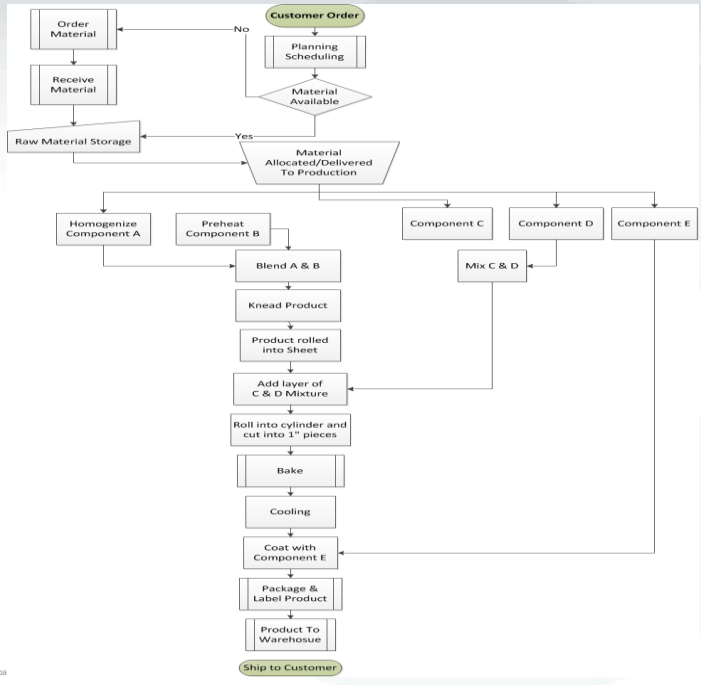
- Picture of various steps/tasks in a process
  - how the operation tasks are connected
  - the order in which they need to be completed.
- Variety of flow chart types, with specific symbols,
  - basic flowchart shapes (US units)

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.

INSPECTION

- Inspection Points
  - Flow Chart / Run Chart
    - Identifies critical manufacturing/process steps
    - Sample entry points

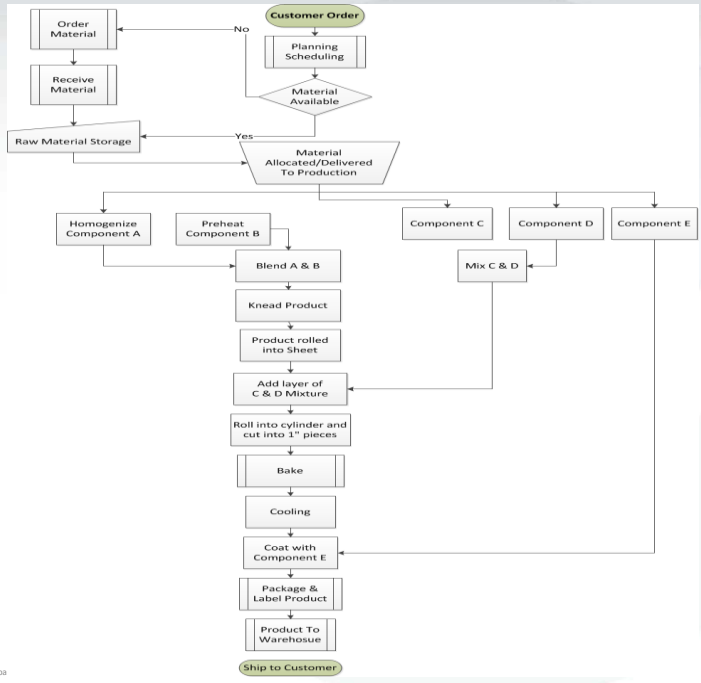


INSPECTION

- Flow Chart / Run Chart
  - Identifies critical manufacturing/process steps
  - Sample entry points
- Inspection Points – Raw Materials
  - Source (at the vendor)
    - Qualification / First Article
    - Final Release (CoA, CoC)
    - Dock-to-stock Qualified
  - Receiving

INSPECTION

- Inspection Points - Product
  - Source (at vendor)
  - Receiving (upon entry to facility)
  - Set-up (prior to first product)
  - In-process (during production, on-line)
  - Audit
    - During manufacture, random selection
    - Warehouse (packaging)
  - Final
    - Prior to release
      - Next phase
      - Inventory
      - Shipment / Customer



INSPECTION

- Inspection Points
- Inspection Procedure (Method)
  - Specify tools needed
  - Safety Precautions
  - Instructions for tool use and how to take measurement

INSPECTION

- Inspection Points
- Inspection Procedure (Method)
  - Specify tools needed
  - Safety Precautions
  - Instructions for tool use and how to take measurement
  - Sample requirements
  - Applicable standard (specification)
  - Records required

INSPECTION

- Inspection Points
- 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

INSPECTION

- Inspection Points
- 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
- 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)

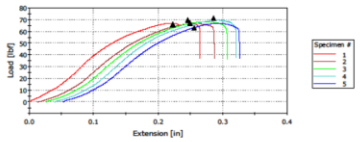
INSPECTION

- Automated output

Tensile Test Cable Black Ties

TENSILE TEST
TARGET: 100LBS.
LCL: 50 LBS.

LOAD OVER EXTENSION



	SHIFT	DATECODE:	INSPECTOR	PART #
1	<None>	1001014	SAM J.	AL-07-50-9-C
2	<None>	1001014	SAM J.	AL-07-50-9-C
3	<None>	1001014	SAM J.	AL-07-50-9-C
4	<None>	1001014	SAM J.	AL-07-50-9-C
5	<None>	1001014	SAM J.	AL-07-50-9-C
Maximum				
Mean				
Minimum				
Range				
Standard deviation				

	MATERIAL	MAT'L LOT #:	CAVITY #:	FAIL MODE
1	CABLE TIE	121214		PAWL
2	CABLE TIE	121214		PAWL
3	CABLE TIE	121214		PAWL
4	CABLE TIE	121214		PAWL
5	CABLE TIE	121214		PAWL
Maximum				
Mean				
Minimum				
Range				
Standard deviation				

	LOOP TENSILE STRENGTH [lbf]
1	67.03
2	66.83
3	68.18
4	69.64

10/1/2014 10:01:47 AM Page 1 of 2

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

INSPECTION TECHNIQUES

- Qualitative
  - Robust aroma
  - Frothy appearance
  - Strong taste
  - Burgundy cup
- Quantitative
  - 12 ounce cappuccino
  - Serving temperature 150 ^{o}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
    - 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)

Visual inspection – effectiveness example

Count the number of f's

The responsibility, authority, and the interrelation of personnel who manage, perform, and verify work affecting quality shall be defined and documented, particularly for personnel who need the organizational freedom and authority to:

a) initiate action to prevent the occurrence of any nonconformities relating to product, process, and quality system;

d) verify the implementation of solutions;

e) control further processing, delivery, or installation of nonconforming product until the deficiency or unsatisfactory condition has been corrected.

Developed as part of NSF ATE Grant #1304474

Count the number o**F** **F**'s

The responsibility, authority, and the interrelation o**F** personnel who manage, per**F**orm, and veri**F**y work a**FF**ecting quality shall be de**F**ined and documented, particularly **F**or personnel who need the organizational **F**reedom and authority to:

a) initiate action to prevent the occurrence o**F** any noncon**F**ormities relating to product, process, and quality system;

d) veri**F**y the implementation o**F** solutions;

e) control **F**urther processing, delivery, or installation o**F** noncon**F**orming product until the de**F**iciency or unsatis**F**actory condition has been corrected.

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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

SAMPLING

- In Manufacturing, a portion of
  - Product lot / batch
  - Daily production
  - Shipment
  - Etc.
- In Service
  - 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

SAMPLING: PLANS

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

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

Ensuring SAMPLE represents ALL potential product/service is also critical.

SAMPLING: PLANS

- 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.
    - Collection

SAMPLING: PLANS - 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: PLANS - COLLECTION

- When/where within the manufacturing process
  - Maintain traceability of the product
- 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

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RANDOM sample required to estimate population (lot)

SAMPLING: PLANS

- Need planned strategy and logistics
  - How/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.
    - Collection
    - Handling
      - Special equipment
      - Environment
    - Storage
      - Test immediately
      - Preparation

SAMPLING: PLANS

- What is the sample?
- Need planned strategy and logistics
  - How/when can they be taken
  - Who provides (selects) the sample
    - QC
    - Production
    - Customer
    - Vendor
    - Study Leader
  - Will samples be put back into batch
    - Example: Fishery catch/release
  - Quantity to measure / select

SAMPLING: QUANTITY

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

"sampling (statistical)" Wikapedia.com

SAMPLING: QUANTITY

- Two types of data
  - Variable (quantitative)
  - Attribute (qualitative)
- Generally accepted standards
  - 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: 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
    - Producers risk (Type I error) – reject a batch that is good
    - Consumer risk (Type II error) – accept a batch that is bad
- Statistics 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 …

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- 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: QUANTITY

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  - 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: QUANTITY

Z1.4 and Z1.9 examples

MEASUREMENT EXPLORATION

Sample plan examples

Bead Experiment – can I ship it?

Metal Parts – against drawings