CEMD 0920

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Basic Manufacturing Skills Week 2

c3bc Community College Consortium for Bioscience Credentials

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FDA is NOT the only agency that Medical Device Manufacturers must satisfy

- Occupational Safety and Health Act of 1970 created the Occupational Safety and Health Administration (OSHA) within the Department of Labor
  - Mission: "to assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance"

OSHA published its Hazard Communication Standard (HCS) on November 25, 1983

HCS incorporates a 3-pronged approach:

- labels on containers
- development of material safety data sheets
- and employee training.

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Workplace Safety – the "Right to Know"

- The Hazard Communication standard (HCS) defines the concept of "Right to Know"
- It requires employers to inform and train workers about hazardous chemicals and substances in the workplace.
- Specifically employers must:
  - Provide workers with effective information and training on hazardous chemicals in their work area. This training must be in a language and vocabulary that workers can understand;
  - Keep a current list of hazardous chemicals that are in the workplace;
  - Make sure that hazardous chemical containers are properly labeled with the identity of the hazardous chemical and appropriate hazard warnings; and
  - Have and make available to workers and their representatives Material Safety Data Sheets (MSDS) for each substance that provide detailed information about chemical hazards, their effects, how to prevent exposure, and emergency treatment if an exposure occurs

Workplace Safety – the “Right to Know” Cont.

- In addition, Workers have the “Right to Know” the following:
  - Right to Know about Laws and Your Rights
  - Right to Get Copies of Workplace Injury and Illness Records
  - Injury and Illness Records
  - Right to Exposure Data
  - Right to Your Medical Records

Workplace Safety

- Right-to-know
  - MSDS for all chemicals
  - Hazmat spill containment equipment location
  - Fire extinguisher location
  - Chemical hazard label instructions
  - Eyewash station location
  - Defibrillator location
- Training
  - CPR, First aid

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Regulatory Agencies

- Occupational Safety & Health Administration (OSHA)
  - Mission: to assure safe and healthful working conditions for working men and women
  - Sets and enforces many safety standards
- National Institute for Occupational Safety & Health (NIOSH)
  - Mission: to study causes of workplace injuries / illnesses
  - Using study data, develops ways to help control hazards

Regulatory Agencies Cont.

- Environmental Protection Agency (EPA)
  - Mission: to protect land, air, and water
  - Develops and enforces protection regulations
- State agencies, when applicable
  - Some states set and enforce own workplace safety standards and environmental protection regulations
  - If so, then state standards and regulations must be at least as effective as the federal ones

Employer Responsibilities

- Provide a safe work environment
  - Proper training: e.g. new employee training and refreshers
  - Protections
  - Safety equipment: e.g. guards, engineering controls, personal protective equip.
  - Hazard communication: e.g. postings
  - Update employees of changes to or new standards
- Investigate and address safety and environmental hazards
- Comply with all standards and regulations

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Employer Responsibilities Cont.

- Keep accurate records of workplace injuries and illnesses, as well as “near misses”
  - Report all first aid rendered, medical treatments, and deaths
  - Provide financial aid to workers injured/made ill on the job: workers’ compensation, which pays medical expenses and lost wages from inability to work, and death benefits to survivors
- Report all environmental accidents
- Make all reports available to workers and their representatives

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Employee Responsibilities

- Understand federally mandated standards and regulations
- Obtain proper training and certifications for all equipment and procedures
- Follow company policies and rules
- Know locations of and how to use pertinent safety equipment: for example
    - First aid kits
    - Fire extinguishers
    - Hazardous spill clean-up kits

Employee Responsibilities Cont.

- Know what to do if there is an accident / illness
  - First response actions
  - Reporting
- Report / correct potential hazards or non-compliances
- Serve on safety / improvement committees, and/ or as a safety representative
- Participate in safety inspections
- Use “common” sense

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Personal Protective Equipment (ppe)

- Includes:
  - Eye protection
  - Ear protection
  - Head protection
  - Hand & arm protection
  - Foot protection
  - Lung protection
  - Protective clothing
  - Personal clean-up equipment

Hazardous Material Safety

- Material safety data sheets (MSDS)
  - Required hazard communication that must be posted
  - Identifies and describes the hazardous ingredients of a substance
  - Provides safe usage explanations
  - Lists health hazards
  - Suggests PPE

What is a Hazardous Material?

- Hazardous materials include
  - Chemicals: corrosives, flammables, oxidizers, reactives
  - Biologicals: blood, cells, microorganism
  - Radiation
  - Sharps

- Hazardous materials must be disposed of according to regulations / standards

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Fire Safety

- Prevention:
  - Approved storage containers and flammable cabinets
  - Ventilation
  - Fireproof waste containers
  - Appropriate work procedures
- Fire extinguisher usage:
    - **P**ull pin
    - **A**im low at base of fire
    - **S**queeze trigger / lever
    - **S**weep across fire

Electrical Safety

- Respect electrical circuits and wiring
  - Grounding
  - Circuit overload
  - Damaged wires
  - Circuit breakers and fuses
- Follow appropriate work procedures
- Lockout / tagout:
  - Process used to prevent equipment from starting or releasing energy while under repair / maintenance:
    - Equipment shut-down
    - Isolation from energy source(s)
    - Application of “accidental start-up” devices

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How can you protect workers?

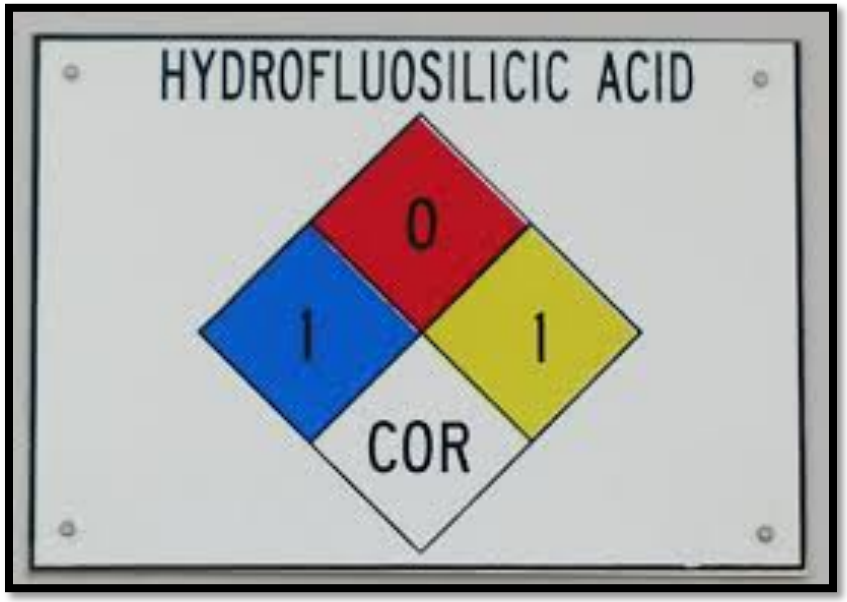
According to the OSHA Handbook

- The lockout / tag-out standard establishes the employer's responsibility to protect employee from hazardous energy sources on machines and equipment during service and maintenance.
- The standard gives each employer the flexibility to develop an energy control program suited to the needs of the particular workplace and the types of machines and equipment being maintained or serviced.
- This is generally done by affixing the appropriate lockout or tag-out devices to energy-isolating devices and by de-energizing machines and equipment. The standard outlines the steps required to do this.

National Fire Protection Association (NFPA) Labeling Standard

NFPA information is displayed on chemical container The symbol is a diamond with four colored sections

- Red (top)
  - Flammability Hazard
- Blue (Left)
  - Health Hazard
- Yellow (Right)
  - Instability Hazard
- White (Bottom)
  - Special hazards
    - Alkaline
    - Acidic
    - Corrosive
- Each Hazard has a rating 0-4
  - 0 = No hazard
  - 4 = very hazardous (depending on the nature of the hazard)



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DATA COLLECTION AND ANALYSIS

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Types of Data

Qualitative

- These are descriptive but not numerical…they may be all that is required for some in process inspections…

Examples:

- Comparing the color of samples
- Looking for visible defects
- Is something producing an electric current
- Does part A fit into a hole in part B

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Types of Data Cont.

- Quantitative
  - This type of data is numerical and requires the use of tools or analytical instruments.

Purpose of Data Collection

- Primarily for manufacturing process monitoring:
  - Output tracking
  - Quality assurance
    - Meet specifications?
    - Consistency?
    - Sign of issues or concerns?

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Use Proper Collection Method(s)

- Prior to collection, understand what data will be use for (e.g. what question is being asked?)
- Select appropriate assessment / measurement device; consider tolerances
- Collect appropriate data, in the appropriate format
- Review as you collect, stopping / repeating if necessary

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Data Analysis

- Why?

In order to make a determination / interpretation of the data/results.

- Often need to apply basic statistics for full value Examples of commonly used statistical values :
  - Average (avg) / mean
  - Standard deviation (SD)
  - Coefficient of Variation

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The Average (or Mean)- what is it?

It is a number that describes where the middle is in that group of numbers.

It is a measure of the CENTER of a group of numbers

The Average (or Mean)- what is it? Cont.

Is calculated by adding a group of numbers and then dividing by the count of those numbers

Example:

What is the average of 2, 3, 3, 5, 7, and 10?

$$2 + 3 + 3 + 5 + 7 + 10 = 30$$

Then :

$$30/6 = 5$$

Standard Deviation - what is it?

This is a measure of how far the group of numbers is scattered away from the middle, or average value

So new things to think about:

- Describe a bell curve.
- Talk about median, mean, & standard deviation in a normal distribution.
- Talk about control charts and control limits.
- Relate the two charts (distribution chart and control chart).

Real world:

- +/- 1 Std Dev = 68.26% of the curve
- +/- 2 Std Dev = 95.44 % of the curve
- +/- 3 Std Dev = 99.73% of the curve
- +/- 4 Std Dev = 99.99937% of the curve
- +/- 5 Std Dev = 99.99999943 of the curve
- +/- 6 Std Dev = 99.9999999802% of the curve

Remember-

- So…
- Average tells you where the middle is in a group of numbers. It is a representative of the group.
- Standard Deviation tells you how much the numbers in the group vary away from the average.

But sometimes there is a problem using the Standard Deviation…

When you compare one type of data to another, you will probably get very different average and standard deviations from the different processes. That makes them really hard to compare to each other.

Using the Coefficient of Variation (CV) overcomes that by expressing variation relating the Standard Deviation to the average (mean)

$$CV = (SD / mean)(100\%)$$

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Coefficient of Variation

For example:

1. Suppose you are managing three groups working in the same medical device company, but each group makes a unique part
2. Your annual bonus is linked to your production numbers
3. You have a training budget, but only enough to train 1 group each year.
4. You must decide which group needs it most.
5. You collect the in-process inspection data from each group for the current week.
6. None of the groups had any discrepancy reports for the week (all products within spec) and all of them have different kinds of measurements.
7. How can you compare them?

Coefficient of Variation Cont.

- The data looks like this…which group will you train?
- The average and standard deviation tell you how dispersed each group is around the average.
- But, the Standard Deviation isn't easy to use when comparing groups with very different average values. You can't easily tell which group is MORE scattered than the other.
- If you divide the standard deviation by the average, then you are finding a ratio that is RELATIVE to the average value. Multiplying by 100 turns it into a percent.
- So, here is the answer:
- Titanium group's variance is 5% of the average
- Liquid group's variance is 9.39% of the average
- Voltage group's variance is 8.26% of the average
- The Liquid group is the most variable! They are most at risk for going out of specification, so they are good candidates for the extra training!

	Titanium housing (mm)	Liquid Propellant (mL)	Voltage Regulators (volts)
Average	195.13	4.25	11.52
Standard Deviation	10.30	0.40	0.95
CV	5.28	9.39	8.26

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Coefficient of Variation Cont. 2

To reiterate…

The coefficient of variation (CV) is useful because when you compare one type of data to another, you will probably get very different average and standard deviation. That makes them really hard to compare to each other.

The CV overcomes that by expressing variation relative to the average

$$CV = (SD / mean)(100\%)$$

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Keep in mind

- So…
- Average tells you where the middle is in a group of numbers. It is a representative of the group.
- Standard Deviation tells you how much the numbers in the group vary away from the average.
- Coefficient of Variation tells you how much the numbers in the group vary away from the average as a percentage of the average value

Why collect groups of data on product variation?

- Because the key to controlling a process (and delivering quality) is controlling variation
- Useful tool : statistical process control (SPC)
  - Method of monitoring process during operation to control quality during production rather than afterward by inspection
  - Requires data gathering and charting
  - Can be used to predict potential problems as well as improve process

Don’t check your brain at the door!

- Some math to help on the next page:
- CV = Std Dev/mean Remember: mean = ave
- CV*mean = Std Dev

- Note that + or – the Std Dev = the upper and lower control limits, centered on the mean.

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Statistical Process Control (SPC) CHART

- The control chart is a graph used to study how a process changes over time.
- A control chart always has a central line for the average, an upper line for the upper control limit and a lower line for the lower control limit.
- The control lines are determined from historical data in the Validation files
- By comparing current data to these lines, you can draw conclusions about whether the process variation is consistent (in control) or is unpredictable (out of control, affected by special causes of variation).
- IF the process is out of control, corrective action may be required!