



CEMD 0920



Basic Manufacturing Skills Week 7



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Medical device assembly

Process

- Components (Raw Materials, Subassemblies – detailed in BOMs)
- Process documents (WIDs, BRs)
- In-process inspection:
- Inspection at any point in the production cycle before a final inspection and placement in finished goods inventory.
- Measuring or gaging a critical characteristic during the production process (critical to the final function of the product or critical to assuring the process is under control up to the point of inspection.)

In Process Inspection

- Example of in-process inspection measuring the dimension which is necessary to assure the process is under control.

A part starts off as a bar of metal, gets turned to a diameter in a lathe, is cut to length, then dropped in a jig where several cross holes are drilled at precise angles and distances from each other, then the holes are tapped to a specific thread, before being sent to an assembly point where this part (shaft) will be assembled with other parts to make a subassembly.

In Process Inspection Cont.

The diameter and length of the part (shaft) coming off the lathe may be critical to fitting in the jig for drilling, but only the angle of the threaded holes and the spacing between them is critical for the fit and function of the subassembly. The processor might measure the shafts after the lathe operation to assure the diameter and cutoff length are under control so the parts will fit precisely into the jig for the drilling. Obviously, if the shaft is too big or too small in diameter, it may not fit correctly into the jig for drilling and the rest of the process will be held up, so it is critical to the **process** that the shafts be of a specified diameter and length, but not critical to the **function of the subassembly** where only the angle and spacing of the tapped holes is critical (since the threading could conceivably overcome any tolerance buildup on the diameter as the mating part in the assembly engaged deeper or shallower into the thread.)

Many processors would measure the diameter and length, then perform SPC charting of the in-process inspection to track how tight a control over tolerances the process had.

In Process Inspection Cont. 2

- Functional Test
 - determination that the product does what it is supposed to do
- Quality Test
 - comparison to a standard
- In-process inspection is done because the feature may not be able to be inspected later on in the process
- Inspection done closer to the time of manufacture enables problems to be caught sooner

In-process Inspection Cont. 3

- For example in some devices, it is impossible to inspect the parts once they are assembled.
- They must be inspected “in-process” prior to final assembly.

Assembly methods

Permanent

- Thermal welding
- Adhesive bonding
- Solvent welding
- Metal or plastic staking

Semi-permanent

- Soldering - Press-fits
- Snap-fit

Non-permanent

- Bolting -Pinning
- Sewing

Assembly skills

- Manual dexterity
- In-process inspection
- Clean room habits
- ESD avoidance
- Technical writing:
 - Written communications done on the job, especially in fields with specialized vocabularies, such as science, engineering, technology, and the health sciences. The goal of technical writing is to enable readers to use a technology or understand a process or concept. The style is objective, direct and utilitarian.

Lab Objectives

- To learn about how to function in a controlled environment.
- To learn about typical assembly processes.
- To learn about inspection, data collection and analysis during medical device assembly.

Lab Objectives Cont.

- To become familiar with clean room routine and handling small delicate parts.
- To perform an assembly following a written process.
- To perform inspection using measuring tools, data collection and analysis during medical device assembly.

Assembly Challenges

- Medical devices are delicate
- Every activity must be carefully documented
- Most assembly takes place in a controlled environment
- Gowning is tedious and time-consuming
- Operators must wear gloves
- Extra training is required
- Extra cleaning is required

Assembly Challenges – Why Bother?

Would you want an implanted insulin pump to malfunction?

1. Automated cannula insertion system
2. Water tight housing
3. Insulin reservoir (capacity of 85 to 200 deliverable units)
4. Adhesive
5. Drive mechanism
6. Angled infusion set
7. Electronic circuitry for programming insulin delivery and enabling wireless communications
8. Power supply (batteries)

Controlled Environment

- Gowning
 - Clean vs. Dirty side of the gowning room
 - No gum or fuzzy clothing
 - Dress from the top down
 - Wash gloved hands
- Entering
 - Walk smoothly
 - Don't swing arms
 - No pencils or paper
 - Go directly to work station

Controlled Environment Contamination

- People cause almost all of the contamination
 - Drippy nose or open sores
 - Dirty gloves
 - Bringing contraband into the room
 - Careless gowning technique
 - Touching exposed skin with gloves
- Equipment causes some contamination
 - Unclean raw materials
 - Packaging
 - Dirty machinery

Why work in a controlled environment?

- Particles on product could be pyrogens
 - (Fever-causing)
- Foreign Material could damage product
 - Small parts clog or jam
 - Filters plug up during testing
- Open adhesives could attract dust
 - Wet coatings entrain particles
- Medical devices are supposed to look clean