PHASE 4 ~ MANUFACTURING
Deliverable 19 ~ Product Risk Analysis

Due Date: http://rrg.utk.edu/resources/BME469/assignments.html#Deliverable19

INSTRUCTIONS. Perform a product risk analysis for your design. Your analysis is due electronically to Dr. Jeff Reinbolt (reinbolt@utk.edu) and should be included in your design history file as well.

Purpose

Product risk analysis and management are crucial to ensuring the safety and reliability of a medical device to meet FDA design control guidelines. Risk analysis facilitates communication among design engineers, development engineers, manufacturing/operations engineers, reliability/quality engineers, marketing and regulatory professionals, and clinical research professionals. It keeps critical items visible throughout the design stages and helps in the identification of tests needed to qualify the design or process. Risk analysis also provides the basis for evaluating the adequacy of changes in the product design, manufacturing process, materials, and so forth.

Critical Information

Failure modes and effects analysis (FMEA) is one of the most powerful and practical risk analysis tools used in industry to successfully improve product designs and manufacturing processes. FMEA is all about failure modes and their effects. *Failure* is the inability of a design or a process to perform its intended function. *Function* is the purpose of the design or process. A *failure mode* is the physical description of the manner in which an expected product or process function is not achieved.

A well-constructed FMEA will provide the following benefits:

- Identify reliability/safety-critical components and materials
- Provides a quantitative ranking of potential failure modes (Pareto analysis)
- A method to track improvements based on corrective action

Product Risk Analysis: FMEA

The FMEA team needs to investigate potential *failure modes*, *their effects*, and *their causes*. They should ask themselves three key questions:

- What are the many different ways in which a product or process can fail (failure mode identification)?
- What happens when a product or process fails (failure effects identification)?
- Why does the product or process fail (failure causes identification)?

Once the team has answered all three of these questions, they can write their results on an FMEA worksheet. For example, an *FMEA worksheet* may include the following columns:

1. *Item Function*. Enter the name and number of the part being analyzed. Enter the function being analyzed to meet the design intent.
2. *Potential Failure Mode*. Indicate the physical engineering description of the manner in which the part, subsystem, or system could fail to perform its design intent (e.g., broken gear, broken connector).
3. *Potential Effects of Failure Mode*. Describe briefly the effects of the failure mode on the function as perceived by the customer. Describe the effects of the failure in terms of what the customer might notice or experience (e.g., broken gear leading to "delayed clinical procedure").
4. *Severity*. Severity indicates the degree of seriousness of the effect of the potential failure mode on the next component, subsystem, or customer if it occurs. Severity scales typically range from 1 to 10 (with 1 being less severe and 10 being extremely severe).
5. *Potential Causes or Sources of Failure*. Potential causes or mechanisms of failure are indications of design weakness, the consequence of which is the failure mode. Identify and list all conceivable causes for each failure mode.
6. *Likelihood/Occurrence*. Occurrence is the estimated number of failures that could occur for a given failure cause over the design life. Similar to the severity scale, the occurrence scale also typically ranges from 1 to 10 (1 being extremely low likelihood of occurrence and 10 being extremely high likelihood of occurrence).
7. *Current Design Controls*. List current controls (design reviews, lab tests, mathematical studies, tolerance stackup studies, and prototype tests) being used. Three types of controls must be considered:
    a. Type 1: Controls that *prevent* the *cause or mechanism* from occurring
    b. Type 2: Controls that *detect* the *cause or mechanism* and lead to corrective actions
    c. Type 3: Controls that *detect* the *failure modes*
8. *Detection*. The objective of specifying detection in a design or process is to detect a design weakness as early as possible and then compensate for the weakness. The detection scale ranges from 1 to 10 (1 being highly detectable and 10 being highly undetectable).
9. *Risk Priority Number (RPN)*. The RPN is the product of the severity (*S*), occurrence (*O*), and detection (*D*) rankings above and is a measure of design risk. The RPN is used to rank order the design concerns, and its value ranges between 1 and 1000. For higher RPNs, the team must undertake efforts to reduce this calculated risk through corrective action.
10. *Recommended Action*. Include in this column the recommended action for each failure mode that is deemed critical.
11. *Responsible Party*. Identify the organization and/or individual responsible for the corrective action and the estimated completion time.
12. *Action Taken*. After an action has been implemented, enter a brief description of the actual action and the effective date.
13. *Revised RPN*. Reassess the the severity (*S*), occurrence (*O*), and detection (*D*) rankings after the recommended action has been implemented. Recalculate the resulting RPN to reflect the revised risk.