Hazard Analysis and pFMEA

The relationship between a Hazard Analysis and a pFMEA often causes confusion.

ISO 14971:2007 deals with risk management and analyzes the ways in which a medical device could harm a patient. The analysis results in risk reduction measures to reduce the severity or probability of the harm. A common approach uses an Excel workbook in which one of the worksheets follows the process starting with the hazard and records the hazardous situation, harm, risk, risk reduction measures, *etc*. Since this starts with a hazard in the left-most column, it is Hazard Analysis. A hazard can occur in both normal and fault conditions, so failure analysis is not appropriate.

Failure analysis often uses an Excel worksheet that starts with a failure in the left-most column, identifies the failure mode, and then follows the process. A common process is Failure Modes and Effects Analysis, FMEA, or Failure Modes, Effects, and Criticality Analysis, FMECA. Often the process is an FMECA, but referred to as FMEA.

In this case, we are interested in the application of FMEAs and FMECAs to a production process. The application is usually called a Process FMEA or a pFMEA.

The pFMEA analyzes steps in the production process and determines the effects if the process step fails in a particular mode. Best practice also includes a process flow diagram to describe the process and the relationship among the process steps.

In general, there is no association between the HA and pFMEA, because they are analyzing different things with different methods. However, there are some exceptions.

One common exception happens when the process produces non-conforming product that “escapes”; it is released for distribution and shipped to a user or patient. A potential effect is patient or user harm.

In this case, the information from the pFMEA should to the HA. The HA will then analyze the hazard, sequence of events, hazardous situation, risk, and risk reduction. In this case, it is very important to recognize that in the HA severity and probability relate to the harm after the product ships. In the pFMEA, severity and probability relate to the effect on the product or process during production.

Another common exception occurs when the HA identifies a risk reduction that is a protective measure in the production process. In this case, the HA communicates with the process map to include the protective measure. Subsequently, the pFMEA analyzes the failure and modes of the protective measure.

The HA becomes part of the ISO 14971:2007 Risk Management File, the pFMEA does not. Often, the pFMEA is part of design transfer and, with the process map, becomes part of the Design History File.

Both the HA and pFMEA are dynamic documents, maintained during the whole product life cycle. Information from non-conforming products or complaints may result in updates either individually or jointly.

Both HA and pFMEA are powerful tools. They operate in different part of the product life-cycle addressing different issues. However, they often work together.