Documenting the Hazard Analysis Process

ISO 14971:2007 and the EU version, EN ISO 14971:2012, define a process for medical device risk management. The process, with differences in each version, identifies situations in which the medical device could harm the patient or user and takes action to reduce the risk to an acceptable level.

The standard requires a risk management file that contains the documents associated with the process. One is the Risk Management Plan, described in Clause 3.4, which has six required elements. One of the elements is the criteria for risk acceptability. The most common approach uses a Risk Matrix that is a table of severity and likelihood. The body of the table provides the estimated risk for each combination of severity and likelihood. In addition, the Risk Matrix identifies the estimated risks that are acceptable. Some estimated risks may be unconditionally acceptable, some may be conditionally acceptable, and some may be unacceptable. The Risk Matrix, in this form, provides input to the Risk Evaluation and Residual Risk Evaluation steps.

The risk management file provides traceability for each identified hazard to:

- the risk analysis
- the risk evaluation
- the implementation and verification of the risk control measures
- the assessment of the acceptability of any residual risk

While the standard doesn't prescribe a method to provide the traceability, the most common approach uses an Excel worksheet. In the standard, a hazard (potential source of harm) could be in either a normal or a fault condition. This precludes the use of an FMEA, since it only analyzes failures (fault conditions). In addition, the standard ask for the sequence of events leading from the hazard to the hazardous situation. The FMEA analyzes single point failures, so, again it is not the appropriate tool.

Risk Management needs a new tool, which we term Hazard Analysis. An FMEA implemented in the spreadsheet model, has a failure in the left column and the failure mode in the next column to the right. By analogy, the Hazard Analysis has the hazard in the left column followed by the sequence of events and the hazardous situation in subsequent columns to the right.

In this model, the column headings are the process steps. Each row represents the analysis of a hazard. The same hazard could be in multiple rows, since the analysis could reveal more than one sequence of events or more than one hazardous situation.

Describing process steps as worksheet column headings tends to make the process look linear, so decision points, usually implemented as a Yes/No response guides the process.

The list below describes the recommended column headings.

Row # – A unique number assigned to the row for identification. While some companies may use a significant numbering system, simple integer values work best.

Hazard – Identify the hazard. The best approach is to use simple terms modeled after the entries in the standard's Table E.1.

Known or Foreseeable – Identify the value of the attribute for the hazard under analysis.

Normal or Fault – Identify the value of the attribute for the hazard under analysis.

Sequence of Events – Identify the sequence of events that convert the hazard into a hazardous situation. The best approach is to use a few steps (1 to 5) modeled after the entries in the standard's Table E.3.

Harm – Identify the harm to the patient or user. The harm occurs when the patient or user is exposed to the hazardous situation.

Severity – Identify the severity of the harm using values from the Risk Matrix in the Risk Management Plan.

Likelihood – Identify the likelihood that the harm occurs with specific severity using values from the Risk Matrix in the Risk Management Plan.

Estimated Risk – Identify the estimated risk using the value from the body of the Risk Matrix for the combination of severity and likelihood.

Note: The columns from "Hazard" to "Estimated Risk" inclusive are in Clause 4 Risk Analysis.

Risk Reduction Required – Evaluate the estimated risk using the risk acceptability criteria in the Risk Management Plan to determine if the risk needs to be reduced. The entry is Yes/No.

Note: This column is in Clause 5 Risk Evaluation

Risk Reduction Measures Selected – State the risk reduction measures you select. Use the priority order listed in Clause 6.2. Be very specific, since, under ISO 13485:2016, these risk reduction measures are also design inputs.

Implementation Verification – The Risk Management Plan contains the methods to perform implementation verification. The entry is a pointer to a report that describes the result. One approach is to use the design verification report, which shows that the design output matches the design input that came from the risk reduction measure.

Effectiveness Verification – The Risk Management Plan contains the methods to perform effectiveness verification. The entry is a pointer to a report that describes the result. In some cases, the design validation can also be the effectiveness verification.

Residual Risk – The residual risk is the risk remaining after implementing the risk reduction measures. State the residual risk.

Residual Risk Severity – Identify the severity of the residual risk using values from the Risk Matrix in the Risk Management Plan.

Residual Risk Likelihood – Identify the likelihood that the residual risk occurs with specific severity using values from the Risk Matrix in the Risk Management Plan.

Estimated Residual Risk – Identify the estimated residual risk using the value from the body of the Risk Matrix for the combination of severity and likelihood.

Further Residual Risk Reduction Required – Evaluate the estimated residual risk using the risk acceptability criteria in the Risk Management Plan to determine if the residual risk needs to be reduced. The entry is Yes/No.

Risk/Benefit Required – If the estimated residual risk is unacceptable and there are no further risk reduction measures, then conduct a risk/benefit analysis. The entry is Yes/No. Note: In EN ISO 14971:2012, the entry must always be Yes.

Benefit Outweighs the Residual Risk – If the response to “Risk/Benefit Required” is No, the entry is N/A. Otherwise the entry is Yes/No based on the conclusion of the Risk/Benefit Analysis.

Risk/Benefit Information – If the response to “Risk/Benefit Required” is No, the entry is N/A. Otherwise enter a pointer to risk/benefit analysis.

Disclose Residual Risk – Determine if you will disclose the residual risk to the patient or user. The entry is Yes/No. Note: In EN ISO 14971:2012, the entry must always be Yes.

Residual Risk Information – If the response to “Disclose Residual Risk” is No, the entry is N/A. Otherwise enter a pointer to information to disclose.

Residual Risk Verification – While not a requirement, good practice dictates verifying the residual risk is actually disclosed. If the response to “Disclose Residual Risk” is No, the entry is N/A. Otherwise enter a pointer to the verification report.

New Hazard or Hazardous Situation – The hazard analysis could have created a new hazard or hazardous situation. If so, enter the hazard or hazardous situation in a new row, put the row's number here. As part of the completeness check, conduct the hazard analysis for the new row.

Note: The columns from "Risk Reduction Measures Selected" to "New Hazard or Hazardous Situation" inclusive are in Clause 6 Risk Control.