Risk in ISO 13485:2016

ISO 13485:2016 uses the word “risk” in many clauses of the standard. Clause 0.2 explains the concept in the standard.

Risk pertains to:

- Safety or performance requirements of the medical device
- Meeting applicable regulatory requirements

While the concept of risk is broad, including safety, performance, and regulatory requirements, the risk related definitions are more narrow. They come from ISO 14971:2007, a standard focused on safety, which it defines as freedom from unacceptable risk. The borrowed definitions are life-cycle, risk, and risk management.

This leaves some open question about risk related to performance requirements and risk related to safety requirements.

Clause 4.1.2.b requires a risk based approach to the control of the appropriate processes needed for the quality management system. Unfortunately, the standard does not define or describe a risk based approach. However, one can infer that for each processes:

- Determine any device safety or performance effects
- Determine any regulatory requirements effects

Based on the determination, analyze the process for the possibility that it might not meet a safety, performance, or regulatory requirement associated with the process. If so, take appropriate measures to reduce the risk to an acceptable level.

Proportionate To Risk

In some clauses, the standard asks for process control “proportionate to the risk”. These include:

4.1.5 on outsourced processes
4.1.6 on validation of QMS software
6.2 on the methodology to check the effectiveness of training
7.4.1 on criteria for the evaluation and selection of suppliers
7.4.1 on suppliers not fulfilling purchasing requirements
7.4.3 on the extent of verification activities for purchased product
7.5.6 on validation of production and service provision software
7.6 on validation of monitoring and measuring software
8.5.2 on corrective action
8.5.3 on preventive action

Process Tools

The issues above relate to processes and their control. This is not ISO 14971:2007 analysis, which deals with hazards – the situations in which the medical device could harm the patient or user. These are processes failures, so process tools are appropriate.

Clause 4.1.2 requires the device manufacturer to determine the processes needed for the quality management system and to determine the sequence and interaction of these processes. The appropriate tool is a high-level process map that identifies the QMS processes, shows the inputs to each process, and the outputs from each process. Arrows on the diagram can show how the output of one process becomes the input to another process. A SIPOC diagram for each process could supplement the high-level diagram. The additional level of detail can help describe the process interactions and identify any gaps.

Each process should have a flow diagram that identifies the major process steps and decision points. The flow diagram can help ensure the process is efficient, *i.e.*, does not have unnecessary steps, consumes the inputs from other processes, and produces the required outputs.

The process steps lead nicely to a process Failure Modes and Effects Analysis (FMEA). Analyze each process step to determine how it could fail (failure mode) and how the failure would affect each of safety, performance, and regulatory requirements (effect). Put control measures in place to prevent the failure or minimize its effect. If the process failure affects device safety, raise it the ISO 14971:2007 hazard analysis.

Implement process metrics effectiveness, efficiency, and cycle time. Effectiveness metrics measure how often the process output meets its requirement. Efficiency metrics determine the resources needed to produce conforming output. Cycle time metrics determine how long the process takes to produce conforming output. For each metric, determine a target value and a threshold for escalation when the process is not performing well.

The control measures determined from the FMEA are “proportionate to the risk” because they come from the analysis of the effect.

The metrics are part of process monitoring and measuring required by clause 8.2.5. They help determine if the controls are working correctly. The threshold for escalation could lead to correction or corrective action.