This procedure addresses ISO 13485 clause 4.1.2 b) calling for risk based approach to the control of QMS processes, and to numerous other requirement for application of risk management to specific processes.

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for identifying and evaluating risks.

II APPLICATION

This procedure applies to risks related to the QMS, and in particular to:

Application of risk management to the 5 items listed below is explicitly required in the ISO 13485 standard. Edit as appropriate (for example, if you don't use software in production, delete the reference to production.

- Product design and development
- Manufacturing processes
- Purchasing,
- Suppliers and subcontractors
- Verification of purchased product
- Validation of software used in production, service provision, and the QMS

III PROCEDURE

1 Risk identification

1.1 The need for risk identification is determined on the basis of information and trends regarding the performance and effectiveness of the QMS. In particular:

Edit this list as appropriate. For example, if you don't perform servicing, delete any references to service records.

- Regulatory requirements
- Product safety requirements and considerations
- Product and service nonconformities
- Process problems and nonconformities
- Supplier quality performance records
- Reject and scrap rates
- Field service records
- On time delivery performance
- Production equipment maintenance records
- Customer feedback and complaints
- Quality management system audit records

- Data loss/corruption incidents, network outages, etc.

1.2 Risks are identified and evaluated when quality performance data indicates that there are trends of decreasing quality capability and/or effectiveness of the quality management system. For example: increasing incidence of product nonconformity; excessive equipment problems; or increasing number of audit findings against the same quality system process or department.

3 Initiating risk management projects

3.1 Risks are identified, evaluated and addressed in IMSXpress > Risk Management module; within a framework of a Risk Management Project.

3.2 Risk management projects may be proposed by any organizational unit and any employee in the company. Requests for initiating a risk management project are submitted to <Quality> or <Engineering>, as appropriate. Only <Quality> and <Engineering> have the authority to initiate, or approve the initiation of risk management projects. This is to prioritize and direct resources where risk control is most urgent.

4 Risk management project

4.1 Risk management projects are initiated in IMSXpress > Risk Management module using electronic form EF-380-1 Risk Project.

4.2 When initiating a new project, select in form EF-380-1 the risk assessment method that will be used for the project:

- **Hazard Evaluation**: This is a method for evaluating hazards and related harms, rather than estimating the actual risks. The method is based on evaluating hazardous situations and associated harms (risk cases), and existing controls that reduce the likelihood of the hazardous situation occurring and/or reduce the severity of the harm. The evaluation results in a decision whether additional controls need to be implemented to further reduce risk. Although no a full fledged risk analysis, it is an excellent method for demonstrating 'risk based thinking' without going into formal and complex risk analysis studies. This method should not be used when evaluating risks related to the safety of medical devices.
- **Risk Matrix Analysis**: This is a structured, formal method for assessing risks using a risk matrix. The risk matrix for the project is defined using a template provided in form EF-380-01 (click the Risk Matrix tab in the form). This method is often referred to in technical literature as a Preliminary Hazard Analysis (PHA). It is a top-down approach, using a list of known hazards as input for the risk analysis. The risk matrix method is the most flexible and versatile, as it can be applied to any product, process or system, and does not require detailed knowledge about the system to be analyzed. Where appropriate, the risk matrix Analysis method should be used when evaluating risks related to the safety of medical devices.
- **Other Method**: Select this item when some other risk assessment method will be used, for example: Failure Mode Effects Analysis (FMEA), Failure Mode, Effects and Criticality Analysis (FMECA), Fault Tree Analysis (FTA), Hazard Analysis and Critical Control Points (HACCP), etc.

4.3 Risk management projects are periodically reviewed to ensure that they remain relevant and up to date. Review dates are scheduled, and the review are documented in form EF-380-1 in the 'Reviews' block.

5 Hazards

5.1 Hazards are conditions, circumstances, practices or other 'things' that can be a source of harm or loss. Hazards do not cause harms; they just make harms possible. Hazards are usually constant, i.e., they are always there, unless the hazard is completely removed.

5.2 For each risk management project identify all relevant hazards and enter them into IMSXpress > Risk Management module (select the project and enter hazards into the 'Hazards' grid).

6 Risk cases

6.1 Risk Case is a realization of hazard into en event that causes harm or loss. Hazardous event is linked to a specific hazard: it occurs when a hazard is realized.

6.2 In theory, the number of all possible risk cases is the number of the combinations of all possible hazardous events and all possible harms resulting from these events. However, not all event-harm combinations will be relevant, and even when possible, may not be worth considering when it is obvious that they will evaluate to low risk. In practice, it is sufficient to analyze just a few risk cases per hazard to cover the most realistic and significant risks.

6.3 Risk cases are documented and analyzed in IMSXpress > Risk Management module using electronic form EF-380-2 Risk Case.

7 Risk assessment using Hazard Evaluation method

7.1 For the Hazard Evaluation method, the processing of a risk case follows these basic steps:

a) Document the hazardous event and the resulting harm that defines the risk case.

b) Document the existing measures that are already implemented to control risk. This is the 'What is being already done?' to reduce the risk.

c) Evaluate whether additional risk reduction actions and/or controls should be implemented to further reduce the risk. This is the 'What else can be done?' question.

d) If the evaluation determines that additional risk reduction is required, create a new action/control or use an existing action that was already implemented to reduce risks in another risk case or project.

8 Risk assessment using Risk Matrix Analysis method and Other methods

When the QMS must comply with EU Directives, the risk must be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed'. The practical implication is that risk at any level cannot be accepted by default, irrespective how low it is, without justification that the risk is at the lowest possible level (refer to ISO 13485 Annex ZA, ZB, and ZC)

8.1 For the Risk Matrix Analysis method and Other Risk Analysis methods, the processing of a

risk case follows these basic steps:

a) Document the hazardous event (or sequence of events) and the resulting harm that defines the risk case.

b) Determine the initial risk prior to the implementation of any risk reduction actions or controls.

c) Evaluate the acceptability of the initial risk. If the risk is to high (usually Medium or High) implement one or more risk reduction actions or controls

d) Determine the residual risk after the implementation of risk reduction actions or controls (if no additional actions or controls were implemented, the residual risk will be the same as the initial risk).

e) Evaluate the acceptability of the residual risk. If the risk is to high (usually Medium or High) implement additional risk reduction actions or controls, or strengthen existing controls.

Repeat steps d) and e) until the residual risk is acceptable

8.2 Form EF-380-2 has built-in tools for determining risks for the Risk Matrix Analysis method. When using Other Methods, external worksheets, spreadsheets, or other tools may be required. Any such worksheets should be enclosed with the risk case record as attachments.

9 Risk reduction actions and controls

9.1 New risk reduction actions and controls can be initiated directly from the risk case form (EF-380-2). To do that, click the 'Add New' button in the Additional Risk Reduction/Actions block. When there is already an existing risk reduction action/control that you want to credit to risk reduction in your risk case, click the 'Add Existing' button instead, and select the suitable control.

9.2 The process for initiating and implementing risk reduction actions/controls is documented in operational procedure QOP-042-2 Risk Reduction Actions and Controls.

10 Closing out risk cases

10.1 Before closing out a risk case, it may be appropriate in some cases to add notes to justify why no additional risk reduction measures were not implemented (cost-benefit analysis); or to document or reference appropriate contingency response should the harm or loss contemplated in the risk case actually happen. These kinds of notes should be documented in form EF-380-2 under the 'Notes' tab.

10.2 When all the required risk reduction actions/controls have been implemented, the risk case form EF-380-2 should be closed out by the <Quality>.

IV ASSOCIATED FORMS AND DOCUMENTS

- Electronic Form EF-380-1 Risk Project
- Electronic Form EF-380-2 Risk Case
- Operational Procedure QOP-041-2 Risk Reduction Actions and Controls