

QOP-73-02	Design Risk Management		
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Risk management/analysis requirements in ISO 13485 Clause 7.3 Design Control and in 21 CFR 820.30 Design Controls are rather weak and indefinite. However, national regulatory interpretations and guidelines clearly (and strongly) clarify that risk analysis must be used in the design of medical devices. 'ISO 14971, Medical Devices - Application of Risk Management to Medical Devices' is most frequently cited as a reference, but full compliance with ISO 14971 is generally not required.

This procedure together with ISOXpress ISO 14971 Risk Management Software respond to these regulatory guidelines for conducting risk analysis studies in design of medical devices. They generally comply with ISO 14971 Clause 4 Risk Analysis, Clause 5 Risk Evaluation, and Clause 6 Risk Control.

However, note that the procedure and the software don't address the broader ISO 14971 requirements for the overall life cycle risk management (which is normally not expected, unless full compliance with the whole ISO 14971 is explicitly required).

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for conducting risk analysis studies in design of medical devices.

II APPLICATION

This procedure applies to the design and development of new medical devices, including their packaging and labeling, and to existing device modifications and upgrades.

III PROCEDURE

1 Responsibilities

1.2 Chief Engineer is responsible for planning risk management activities, determining what risk analysis studies shall be conducted, and at which design stages; for assigning personnel (or external consultants) to conduct the studies; for evaluating the results of the studies; and for implementing any risk reduction measures recommended by the studies.

1.3 The President is responsible for formulating and/or approving the risk acceptability policy that will be used as the basis for determining whether the risk identified by the risk analysis studies is acceptable or not. (For Hazard Analysis studies such policy is expressed in the location of the risk zones in the risk matrix.) Where appropriate, risk acceptability policy may be specific to a particular study, taking into account intended and unintended uses, patient population, level of operator/user training/education, culture, etc.

2 Risk management file

You should define here more specifically the form and format of the risk management file. If the file is an actual physical file containing (paper) documents, define where it is kept and who is responsible for maintaining and controlling the file. If there is no actual file but just a reference list, identify this list and define how it is maintained and controlled.

- 2.1 Risk management file is established and maintained for each type/model of medical device. The file is maintained by the Chief Engineer.
- 2.2 Risk management file need not physically contain all the records or other documents; however, it contains at least references to all required documentation. The file can be in any form or type of medium.

Most items required in the risk management file are automatically generated and reported by the ISOXpress ISO 14971 software. The only items not covered by the software are the Risk Management Plan and the Production and Post-production Information

- 2.3 At a minimum the risk management file contains the following information/documents:

- Risk management plan,
- Intended uses and safety-related characteristics of the medical device;
- Known and foreseeable hazards associated with the medical device in both normal and fault conditions;
- Hazardous situations and estimation of risks associated with each hazard;
- Risk evaluation (for each hazardous situation);
- Risk control measures and their implementation and verification (where the initially evaluated risk is not acceptable);
- Assessment of acceptability of residual risk(s);
- Production and post-production Information.

3 Risk management planning

- 3.1 Chief Engineer is responsible for establishing a risk management plan for each medical device design, or design modification project. At a minimum the plan includes:
- The scope of the planned risk management activities, identifying and describing the medical device, and the life-cycle phases for which each element of the plan is applicable.
 - Assignment of responsibilities and authorities;
 - Requirements for review of risk management activities;
 - Criteria for risk acceptability;
 - Verification activities;
 - Activities related to collection and review of relevant product and post-production information
- 3.2 Not all parts of the risk management plan need to be created at the same time. Various elements of the plan can be developed over time, as required by the overall design/development program and/or life-cycle phases of the medical device.
- 3.3 If the plan changes during the life-cycle of the medical device, the changes are maintained together with, and are cross-referenced to the original plan.
- 3.4 Risk management plan and any revisions or amendments are maintained in the risk management file.

4 Risk Analysis Studies

- 4.1 Design risk analysis studies are conducted in an early preliminary design phase, so that the design can be easily changed when it is necessary to incorporate risk reduction measures recommended by the studies.
- 4.2 Risk analysis studies and personnel assignments are scheduled into the design project plan in accordance with procedure QOP-73-01, Design Control, and form QF-73-01-1, Design Project Plan.

This procedure assumes that you are using the ISOXpress ISO 14971 Risk Management Software for conducting your design-phase risk analysis studies. While ISO 13485 and most national regulations reference ISO 14971, it is not mandatory. Where appropriate you can use other techniques, such as Fault Tree Analysis (FTA), Hazard and Operability Study (HAZOP), Hazard Analysis and Critical Control Points (HACCP), etc. Edit the clause below as applicable.

- 4.3 Risk analysis techniques used in the design life-cycle phases are normally based on the ISO 14971 standard. However, other top-down techniques, such as Fault Tree Analysis (FTA), Hazard Analysis and Critical Control Points (HACCP), Hazard and Operability Study (HAZOP), etc., may also be used when more appropriate. Chief Engineer decides which technique is to be used for any particular study.
- 4.4 The ISO 14971 Hazard Analysis Process study is implemented using the ISOXpress ISO 14971 Risk Management software published by AQA Co., Inc. (www.isoxp.com). The study is developed in the following seven steps:
- **Identify the medical device and the scope of the risk study:** Identify and describe the medical device; scope (life cycle phases, market, use environment, user population, etc.) of the study; and identify the organization and persons responsible for the development, review and approval of the study.
 - **Establish risk matrix for the study:** Define the probability levels and severities of harms appropriate for the study, and establish the risk matrix for the study. The risk matrix, and in particular the location of the risk zones, reflects the company's risk acceptability policy and criteria.
 - **Establish a list of generic hazards that may apply to the medical device:** Define a broad pool of generic hazards that may apply to medical devices. Later in the study these generic hazards will be associated with relevant safety characteristics and uses/misuses of the device.
 - **Consider uses and characteristics related to the safety of the medical device, and the associated factors and hazards:** Establish a broad and generic list of safety related characteristics and uses/misuses that could apply to the medical device. Consider each characteristic and/or use, select those that actually apply to the subject device, and associate them with appropriate hazards. This step will produce a specific list of hazards that will be used in the risk analysis study
 - **Conduct risk analysis and risk evaluation:** For each hazard, define hazardous situations, sequences of events and harms, and estimate the associated probabilities and severities of harms and work out the risks (based on the risk matrix).

- **Investigate unacceptable risks and define/implement risk control measures to reduce these risks:** If the risk falls into an ‘Unacceptable’ or ‘Investigate’ risk region in the risk matrix, establish risk control measures to reduce the risk and then estimate the new (reduced) probability and/or severity, and determine the residual risk.
- **Generate and publish (approve and release) the Risk Study Report:** Save the study into a file and generate a PDF Risk Study Report. Review, approve and release the report as a controlled document and maintain it in the Risk Management File.

4.5 Detailed instructions for developing risk analysis studies are included in the help and tutorial files of the ISOXpress ISO 14971 Risk Management software.

IV ASSOCIATED DOCUMENTS

- Operational Procedure QOP-71-02, Process Risk management
- Operational Procedure QOP-73-01, Design Control
- Operational Procedure QOP-73-03, Control of Design and Process Changes
- ISO 14971, Medical Devices - Application of Risk Management to Medical Devices
- Help and tutorial files in the ISOXpress ISO 14971 Risk Management software

V ASSOCIATED RECORDS

- **Risk Study Reports:** Results of risk analysis generated by ISOXpress ISO 14971 Risk Management software.