Underwriters Laboratories Inc.®

ISO 14971 Gap Analysis Checklist

Clause	Title	Item	Comments/Questions
3.2	Risk Management process	**Procedure describing the risk management process**	Does the procedure map to the elements in the standard?
3.3	Management Responsibilities	a. **Policy** for determining acceptable risk.	Can policy be used to determine acceptable risk?
		b. Provision of adequate resources.	May be part of general quality management system
		c. **Procedure for assigning staff** to risk management work.	May be part of general quality management system
		d. **Procedure(s) for review of risk management**	Does management review effectiveness at defined intervals?
3.4	Qualification of personnel	Training records for risk management training, tools training, etc.	May be part of general quality management system
3.5	Risk Management Plan	a. **Procedure for plan development.**	May be part of overall risk management procedure.
		b. Description of device.	Is there a clear and thorough statement of intended use?
		c. Verification plan.	Does it tie into design verification and validation activities?
		d. Allocation of responsibilities.	Is there a clear delineation of who is responsible for what?
		e. Summary of review activities.	Who does the review? When?
		f. Evidence of risk acceptability criteria.	Do the criteria derive from the policy on determining acceptable risk?
3.6	Risk Management File	Evidence of file structure for all risk management activities.	Are all risk management records readily retrievable from a file or file index?
4.1	Risk Analysis Procedure	**Procedure for risk analysis.**	May be part of overall risk management procedure.
4.2	Intended use/intended purpose, etc.	Record of safety issue analysis.	Is Annex A used? Is it modified for the specific products?
4.3	Hazard Identification	Record of hazard analysis	How is this done? Use of expert group? Outside sources? Product history? Are hazardous conditions identified?
4.4	Risk estimation	**Definition of methods used for estimating risks.**	Are there qualitative scales for probability and severity used? If so, are people trained in their use? How are risks handled where probability cannot be defined?

Clause	Title	Item	Comments/Questions
5.0	Risk evaluation	Record of risk evaluation activities	Are risks that need to be controlled identified for further action?
6.1	Risk reduction	**Procedure for risk control activities**	May be part of overall risk management procedure.
6.2	Option analysis	Record of risk control option analysis (including risk-benefit analysis, if appropriate).	Has the hierarchy been explicitly considered?
6.3	Implementation of risk control measures	Design inputs from risk management activities	What verification activities are performed? Note that this may happen outside the design stage.
6.4	Residual risk evaluation	Evidence, e.g., from design verification activities.	Are risks appropriately reevaluated (after implementation of risk controls)? Note that this may need to continue post-production.
6.5	Risk-Benefit Analysis	Evidence as necessary…see 6.2.	Who is involved? Have they quantified risks and benefits? If not, who makes these decisions?
6.6	Other generated hazards	Record of review of all risk controls for impact on new hazards.	Has the impact of risk control measures been evaluated?
6.7	Completeness of the risk evaluation	Record of review by a manager	Are all identified hazards and their consequences dealt with?
7	Overall risk evaluation	Records of related meetings, analysis, etc.	How is this accomplished? By consensus? Is senior management involved?
8	Risk management report	**a. Procedure for generating a Risk Management report.**	May be part of overall risk management procedure.
		b. Summary of risk management activities.	
		c. Traceability of hazards to residual risks.	Is the traceability matrix complete?
		d. Clearances.	Does it have sign-off by a senior manager?
9	Post-production information	a. **Procedures for linking information into risk management review**: • Manufacturing • CAPA • Servicing • Purchasing • etc. b. Records implementing procedures	What criteria are used to determine whether the risk analysis must be revisited? Who is involved? Are the outputs of prior risk management activities tied into the CAPA process?

***Note*:** Items in **bold** are critical elements that should be present even at the very beginning of implementation.