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## Comparison of ISO 14971:2000 and 2007

| Clause | Change  | Impact or reason  |
|--------|---|---|
| 1      | Deleted "and accessories"   | Done to be consistent with GHTF definition of medical device, which can include accessories as well.  |
| 2.6    | Add "in vitro device"   | Consistent with other IVD standards   |
| 2.7    | Add "life cycle"  | Clarified that life cycle ends with ultimate disposal or decommissioning of the device.   |
| 2.9    | Adopted GHTF definition of "medical Device"   | For consistency with global medical device regulations  |
| 2.11   | Add "post-production"   | Clarification   |
| 2.20   | Add "risk estimation"   | For completeness  |
| 2.26   | Add "top management"  | Emphasizes who is responsible for management oversight.   |
| 2.27   | Add "use error"   | To align definitions with IEC 62366   |
| 3.1    | Use phrase "establish, document and maintain throughout the life-cycle"   | In analogy to ISO 13485, this means that manufacturers must establish a single overall risk management procedure. Before, it was not clear that a single procedure was necessary. |
| Fig. 1 | Revised and expanded  | To align with the ISO 14971 clauses and headings.   |
| 3.2    | "Manufacturer" replaced by "top management."  | To emphasize that top management is responsible for leading risk management and its oversight.  |
| 3.2    | Changed order of bullets  | Emphasizes what is normally part of the quality system and what ISO 14971 really adds..   |
| 3.3    | Edited  | Implies a team of specialists may be used to perform risk management, i.e., one person does not have to be endowed with all the necessary skills.                                 |
| 3.4    | Added sixth item as part of the plan: "activities related to collection and review of production and post-production information. | Planning for post-market activities must begin at the earliest stages.  |
| 3.4    | Added Note 3 on risk acceptability criteria.  | Explains better what is really needed. Makes the point that ALARP is a policy decision by the manufacturer and is not required by ISO 14971.                                      |
| 3.5    | Use phrase "establish and maintain"   | In analogy to ISO 13485, this means that the risk management file must be under document control.   |



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| 3.5        | Traceability explicitly included in the risk management file            | This along with the change to the risk management report was requested by manufacturers since the traceability matrix can be very large and the risk management report was intended to be a summary. |
| Old Fig. 2 | Moved to Annex B  | The presence of the figure with the normative text was interpreted by some to be a requirement. This emphasizes that it is not.  |
| 4.1        | Edited  | Clarifies that when a prior risk analysis is used as a baseline the impact of the changes must be carefully assessed.  |
| 4.2        | Changed "describe" to "document" and "list" to "identify and document." | Further emphasizes the connection with the QMS, and the auditor will expect to see records documenting these activities.   |
| 4.3        | Changed "compile a list" to "compile documentation"                     | More than a simple list is now necessary. Manufacturers must document hazard identification activities.  |
| 4.4        | Changed "hazard" to "hazardous situation."                              | Clarifies that it is the hazardous situation that is of concern.   |
| 4.4        | Use phrase "reasonably foreseeable sequences of events."                | Clarifies that more than single point failures should be considered.   |
| 5          | Edited  | Consistency.   |
| 6.2        | Edited  | Clarifies that a risk benefit analysis is a possible <u>option</u> when the risk cannot be reduced to the predetermined acceptable level(s), not a requirement.                                      |
| 6.3        | Added note.   | Clarified that verification of effectiveness of risk controls can be part of design validation activities.   |
| 6.4        | Change "all relevant information" to "the manufacturer shall decide..." | Clarifies that it is the manufacturers responsibility to decide what information is relevant, i.e., which residual risks to disclose and how to do it.   |
| 6.5        | Edited  | Clarifies that a risk benefit analysis is a possible <u>option</u> when the risk cannot be reduced to the predetermined acceptable level(s), not a requirement.                                      |
| 7          | Edited  | Clarifies that a risk benefit analysis is a possible <u>option</u> when the risk cannot be reduced to the predetermined acceptable level(s), not a requirement.                                      |



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| 8       | Removed requirement for traceability in the report. Defines the report as documentation of a review that the risk management plan has been implemented, the overall residual risk is acceptable, and appropriate methods are in place to review production and post-production information. | Makes the risk management report more like a product release document. Ensures that production and post-production information gathering activities are in place prior to design release.     |
| 9       | Added suggested sources of information, e.g., information from users, operators, installers, maintainers; information from standards; and publicly available information on the same or similar devices.  | Encourages the expansion in the scope of production and post-production information assessed.   |
| Annex A | Formerly Annex H. Updated to reflect the changes in Clauses 1 through 9.  | Moved to Annex A per ISO/IEC rules for rationales.  |
| Annex B | Formerly Figure 2   | Figure moved to the annex to emphasize that it was informative information and not a requirement of the standard.   |
| Annex C | Formerly Annex A. Several questions reformatted for clarity, and questions added to reflect comments on ISO 14971:2000.   | Several annexes were reordered to reflect their reference in the normative section.   |
| Annex D | Formerly Annex E. Greatly expanded and edited to parallel the text in clauses 4 through 6.  | Greatly expanded discussion of risk concepts. Text now parallels clauses of the standard. Discussion of ALARP was moved to end of Annex to emphasize that it is not required by the standard. |
| Annex E | Formerly Annex D. Significantly reordered and revised.  | Puts in perspective the concepts of hazards, hazardous situations, and harms. Emphasizes the need to consider sequences of events.  |
| Annex F | New Annex   | Comments requested specific guidance on the risk management plan.   |
| Annex G | Formerly annex F. Added sections on Preliminary Hazard Analysis and on Hazard Analysis Critical Control Points  | Requested in the comments on early drafts.  |
| Annex H | Essentially a new annex. Formerly was Annex B, but is greatly expanded and parallels the text in the normative part of the standard.  | Important in that this annex was created by ISO TC212 WG3 to fill a significant void in ISO 14971:2000. Explains in detail how to apply the standard to IVDs.                                 |
| Annex I | Formerly Annex C. Essentially unchanged.  |   |



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| Annex J | New Annex. | Comments requested specific guidance on information for safety and information on residual risk. |
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