# ISO 14971:2019 Mapping of Requirements to Documents

This table maps all requirements of the ISO 14971:2019 (by section) to the relevant documents.

Note that the document names in the “Fulfilled in Document” column are based on the OpenRegulatory templates. You’ll probably have a different system for assigning document names, so feel free to rename them.

## ISO 14971:2019

| Section | Title | Document |
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| 4.1 | Risk management process | SOP Integrated Software Development |
| 4.1.c | Risk controls | SOP Integrated Software Development, para. 3Risk Table |
| 4.1.d | Effectiveness of risk control measures | SOP Integrated Software DevelopmentSOP Post-Market SurveillanceRisk Table |
| 4.2 | Management responsibilities | Quality ManualSOP Human Resources ManagementSOP Management ReviewRisk Management Plan |
| 4.3 | Competence of personnel | SOP Human Resources ManagementTraining Matrix |
| 4.4 | Risk management plan | Risk Management Plan |
| 4.5 | Risk management file | Risk Table |
| 5.1 | Risk analysis process | SOP Integrated Software Development, para. 2, 3 and 10 |
| 5.2 | Intended use and reasonably foreseeable misuse | SOP Integrated Software Development, para. 2, 3 and 10Intended UseRisk Table |
| 5.3 | Safety characteristics | SOP Integrated Software Development, para. 1-3Risk Table |
| 5.4 | Hazards and hazardous situations | SOP Integrated Software Development, para. 3Risk Table |
| 5.5 | Risk estimation | SOP Integrated Software Development, para. 2 and 3Risk Table |
| 6 | Risk evaluation | SOP Integrated Software Development, para. 2 and 3Risk Table |
| 7.1 | Risk control option analysis | SOP Integrated Software Development, para. 3Risk Table |
| 7.2 | Implementation of risk control measures | SOP Integrated Software Development, para. 6Risk Table |
| 7.3 | Residual risk evaluation | SOP Integrated Software Development, para. 10Risk Management Report |
| 7.4 | Benefit-risk analysis | SOP Integrated Software Development, para. 10Risk Management Report |
| 7.5 | Risks from risk control measures | SOP Integrated Software Development, para. 10Risk Management Report |
| 7.6 | Completeness of risk control | SOP Integrated Software Development, para. 3Risk Management Report |
| 8 | Overall residual risk evaluation | SOP Integrated Software Development, para. 10Risk Management Report |
| 9 | Risk management review | SOP Integrated Software Development, para. 10Risk Management Report |
| 10.1 | Production and post-production activities | SOP Post-Market Surveillance |
| 10.2 | Information collection | SOP Post-Market Surveillance, para. 2 |
| 10.3 | Information review | SOP Post-Market Surveillance, para 2 and 3 |
| 10.4 | Actions | SOP Post-Market Surveillance, para 2 and 3 |