

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
4.1	Risk management process	SOP Integrated Software Development
4.1.c	Risk controls	SOP Integrated Software Development, para. 3 Risk Table
4.1.d	Effectiveness of risk control measures	SOP Integrated Software Development SOP Post-Market Surveillance Risk Table
4.2	Management responsibilities	Quality Manual SOP Human Resources Management SOP Management Review Risk Management Plan
4.3	Competence of personnel	SOP Human Resources Management Training 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 10 Intended Use Risk Table
5.3	Safety characteristics	SOP Integrated Software Development, para. 1-3 Risk Table
5.4	Hazards and hazardous situations	SOP Integrated Software Development, para. 3 Risk Table
5.5	Risk estimation	SOP Integrated Software Development, para. 2 and 3 Risk Table
6	Risk evaluation	SOP Integrated Software Development, para. 2 and 3 Risk Table
7.1	Risk control option analysis	SOP Integrated Software Development, para. 3 Risk Table
7.2	Implementation of risk control measures	SOP Integrated Software Development, para. 6 Risk Table

Section	Title	Document
7.3	Residual risk evaluation	SOP Integrated Software Development, para. 10 Risk Management Report
7.4	Benefit-risk analysis	SOP Integrated Software Development, para. 10 Risk Management Report
7.5	Risks from risk control measures	SOP Integrated Software Development, para. 10 Risk Management Report
7.6	Completeness of risk control	SOP Integrated Software Development, para. 3 Risk Management Report
8	Overall residual risk evaluation	SOP Integrated Software Development, para. 10 Risk Management Report
9	Risk management review	SOP Integrated Software Development, para. 10 Risk 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