# IEC 62366-1:2015 Mapping of Requirements to Documents

This table maps all requirements of the IEC 62366-1:2015 (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.

| Section | Title | Fulfilled in Document |
| --- | --- | --- |
| 4.1.1 | Usability Engineering Process | SOP Integrated Software Development |
| 4.1.2 | Risk Control as it relates to User Interface design | Risk Table |
| 4.1.3 | Information for Safety as it relates to Usability | Usability Evaluation Report |
| 4.2 | Usability Engineering File | Usability Evaluation Plan, Report |
| 4.3 | Tailoring of the Usability Engineering effort | Usability Evaluation Plan |
| 5.1 | Prepare Use Specification | SOP Integrated Software Development |
| 5.2 | Identify User Interface characteristics related to Safety and potential Use Errors | Software Requirements List |
| 5.3 | Identify known or foreseeable Hazards and Hazardous Situations | Risk Table |
| 5.4 | Identify and describe Hazard-Related Use Scenarios | List of Hazard-Related Use Scenarios |
| 5.5 | Select the Hazard-Related Use Scenarios for Summative Evaluation | List of Hazard-Related Use Scenarios |
| 5.6 | Establish User Interface Specification | Software Requirements List |
| 5.7.1 | Establish User Interface Evaluation Plan / General | Usability Evaluation Plan |
| 5.7.2 | Formative Evaluation planning | Usability Evaluation Plan |
| 5.7.3 | Summative Evaluation planning | Usability Evaluation Plan |
| 5.8 | Perform User Interface design, implementation and Formative Evaluation | SOP Integrated Software Development |
| 5.9 | Perform Summative Evaluation of the Usability of the User Interface | Usability Evaluation Protocol |
| 5.10 | User Interface of Unknown Provenance | (not applicable) |

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