

Goals / Definitions

Remove a hazard or reduce the level of its risk by adding precautions or control measure, as necessary.

Design review assessment consists of the identification of hazards and the analysis and evaluation of risks associated with device design.

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE
<ul style="list-style-type: none">Design risk assessment completed	<ul style="list-style-type: none">a) Create a risk management report to capture the combination product's overall residual risk, risk/benefit analysis, and overall conclusion of the product's safety profile.b) Alignment between design output and user needs defined in user requirements specification (URS)c) Refined device design if Instructions for Use cannot mitigate user errorsd) Confirmation that intended use statement is definede) Definition of critical device attributes	