

Risk Analysis	Document number / Version
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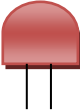


Approvals	Name / Date / Signature
	Risk Management Owner
	R&D
	QA/RA
	Manufacturing
	Medical
	Sales / Marketing

Type of Risk Analysis	<input type="checkbox"/> Hazard Analysis
	<input type="checkbox"/> System Level
	<input type="checkbox"/> Product Level
	<input type="checkbox"/> Process Level

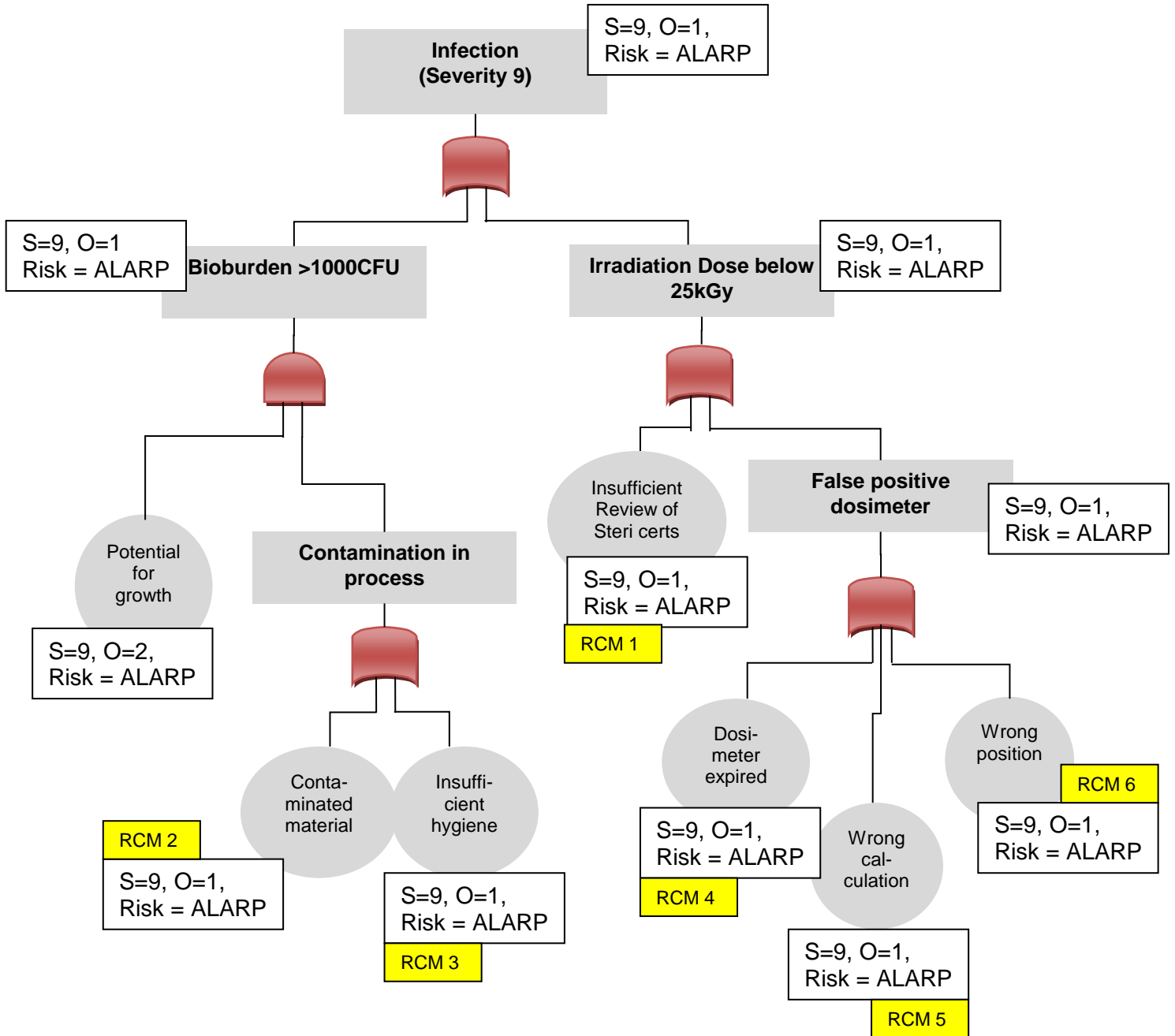
Referenced Documents	Document number /version / Title
	Risk Management Plan
	PMS Report / PSUR
	Clinical Evaluation

Intended Use	Describe the intended use of the system/product/process
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Approach and Risk Acceptability criteria	<p>This risk analysis was generated in accordance to SOP Risk Management. Roles, responsibilities, approval requirements are given in SOP Risk Management.</p> <p>A 2-dimensional risk evaluation approach was chosen as per SOP Risk Management, using</p> <ul style="list-style-type: none"> Severity ratings (S) as per table 1 of SOP Risk Management Occurrence ratings (O) as per as per table 2 of SOP Risk Management Risk Acceptability criteria are given in table 3 of SOP Risk Management.
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Definitions	<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <p>AND</p>  </div> <div style="text-align: center;"> <p>OR</p>  </div> <div style="text-align: center;"> <p>Risk Control Measure</p> <div style="border: 1px solid black; background-color: yellow; padding: 2px; display: inline-block;">RCM 3</div> </div> <div style="text-align: center;"> <p>Root Cause</p>  </div> </div>
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Risk Analysis, Control and Evaluation



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List of Risk Control Measures

Number	Risk Control Measure	Reference	Note

Risks arising from Risk Control Measures

- None of the risk control measures above generated an additional potential hazard.
- The following risk control measures stated above have generated additional potential hazards:

Conclusion

- It is confirmed that there are no unacceptable risks and any risk in the ALARP region is reduced as far as possible.
- Or**
- There is/are risk(s) in the unacceptable regions and further risk control measure is required.