Based on the provided safety case pattern for the Generic Patient-Controlled Analgesia (GPCA) system, we will instantiate this pattern by replacing the placeholders with the specific information available from the domain information provided. Here, operational hazards ("Overinfusion" and "Underinfusion") and their mitigation strategies are highlighted, alongside related safety requirements and their substantiation.

### Hierarchical Tree Representation of the GPCA Safety Case:

- \*\*G1: Operational safety is verified in GPCA system\*\*

- \*\*S1: Argument over the satisfaction of all specs over GPCA system\*\* \_(undeveloped)\_

- \*\*G2: All operational hazards are mitigated\*\*

- \*\*S3: Argument over operational hazards\*\*

- \*\*G3: Overinfusion is mitigated\*\*

- \*\*S4: Argument over the applied scenarios of Overinfusion\*\*

- \*\*G4: Overinfusion is mitigated under programmed high rate scenario\*\*

- \*\*S5: Argument over all specs related to high rate scenario\*\*

- \*\*G5: Flow rate sensor is appropriate for high rate scenario\*\*

- \*\*S6: Argument the appropriateness of Flow rate sensor over properties\*\*

- \*\*G6: Response time property is appropriate for Flow rate sensor\*\*

- \*\*S7: Argument over the source of the response time property definition\*\*

- \*\*G7: FDA standard is appropriate and trustworthy\*\*

- \*\*Sn1: FDA standard document\*\*

- \*\*G8: Response time property definition is sufficient\*\*

- \*\*Sn2: Technical report on response time measurement\*\*

- \*\*G3: Underinfusion is mitigated\*\*

- \*\*S4: Argument over the applied scenarios of Underinfusion\*\*

- \*\*G4: Underinfusion is mitigated under low flow rate scenario\*\*

- \*\*S5: Argument over all specs related to low flow scenario\*\*

- \*\*G5: Alarm mechanism is appropriate for low flow scenario\*\*

- \*\*S6: Argument the appropriateness of Alarm mechanism over properties\*\*

- \*\*G6: Alarm trigger period property is appropriate for Alarm mechanism\*\*

- \*\*S7: Argument over the source of the alarm period property definition\*\*

- \*\*G7: Expert opinion is appropriate and trustworthy\*\*

- \*\*Sn1: Expert consultation record\*\*

- \*\*G8: Alarm period property definition is sufficient\*\*

- \*\*Sn2: Engineering analysis on alarm period\*\*

### Context and Justifications for Strategy and Goals:

- \*\*C1: All specs are given by GPCA system specifications\*\*

- \*\*S1 IncontextOf C1\*\*

- \*\*C2: Operational hazards are identified by risk assessment\*\*

- \*\*S3 IncontextOf C2\*\*

- \*\*C3: Scenarios are defined based on clinical use conditions\*\*

- \*\*S4 IncontextOf C3\*\*

- \*\*C4: Specs for high rate scenario derived from clinical requirements\*\*

- \*\*S5 IncontextOf C4\*\*

- \*\*C5: Properties for flow sensors documented in sensor specifications\*\*

- \*\*S6 IncontextOf C5\*\*

- \*\*C6: Sources include FDA standards and expert opinions\*\*

- \*\*S7 IncontextOf C6\*\*

This tree comprehensively covers all aspects of the safety requirements related to the GPCA system, emphasizing how to ensure the system is safe from operational hazards like Overinfusion and Underinfusion through various technical and practice-oriented strategies. Each of these strategies revolves around ensuring systems specifications meet the safety requirements, where ultimately all specifications, properties, and their sources are checked for appropriateness and reliability.