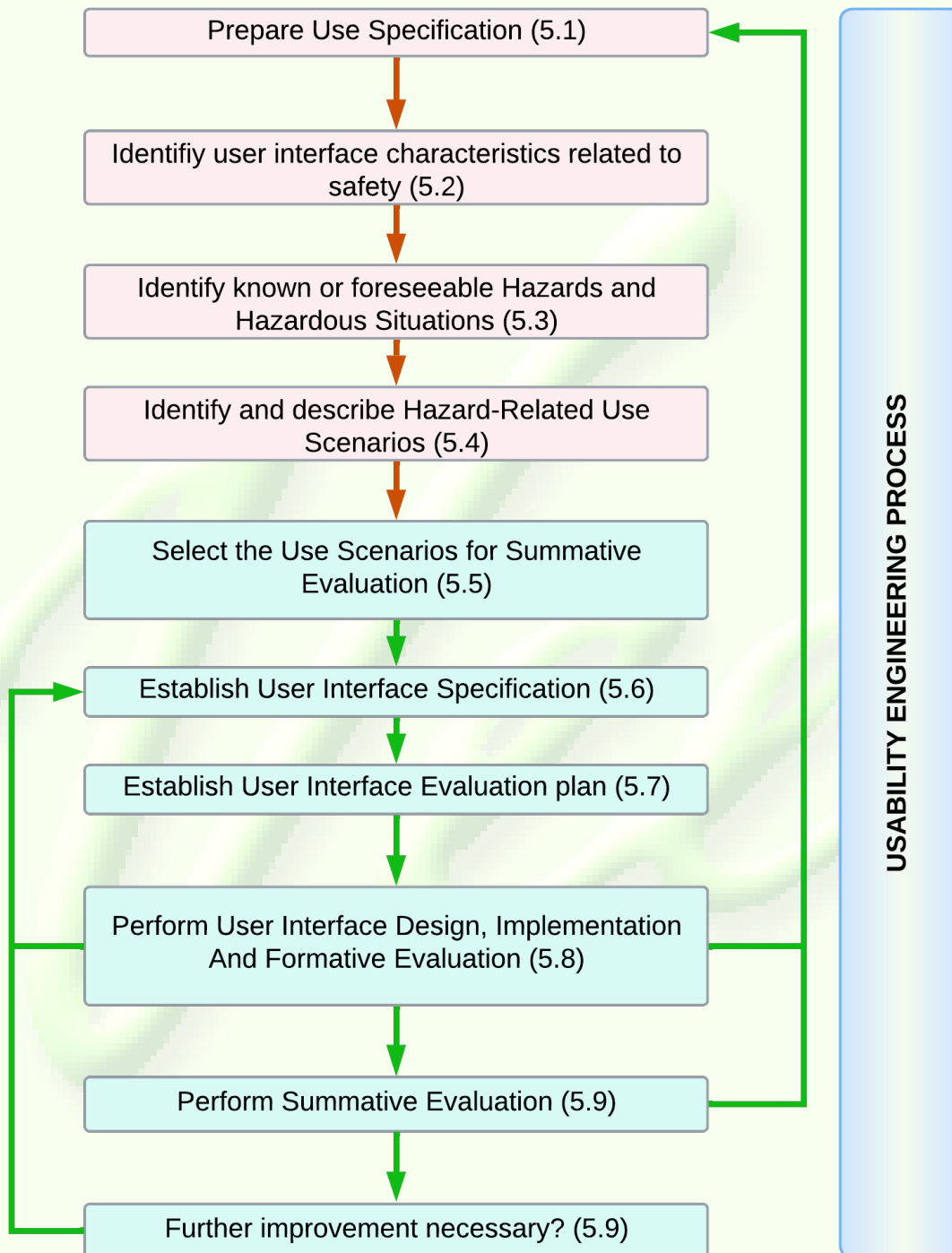


USABILITY ENGINEERING PROCESS



USABILITY PLAN/ REPORT

1. Usability Plan

- 1.1. Personnel and responsibilities in risk management process
- 1.2. Description of the medical device and designation of user interface
- 1.3. Planned usability engineering analyses and studies
- 1.4. Planned user interface design process, tools, and techniques
- 1.5. Traceability
- 1.6. Iterative improvement
- 1.7. Element of usability engineering file
- 1.8. List of applicable standards

2. Usability Report

- 2.1. Device summary
- 2.2. Establish user interface specification
- 2.3. Establish user interface evaluation plan
- 2.4. Formative evaluation results
- 2.5. Summative evaluation (usability test) results
- 2.6. Accompanying document
- 2.7. Benefit outweigh risk
- 2.8. Conclusion