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| SOP Number: | Version: | Effective Date: |
| | 1.0; CURRENT; Most-Recent; Issued | 31-Aug-2019 |
| Title: | Operator's Manual Creation Process | |

1 PURPOSE / SCOPE

- 1.1 This document provides instructions for how to create and update operator's manuals.

- 1.3 This document does not cover how to release the operator's manuals.

2 PROCEDURE

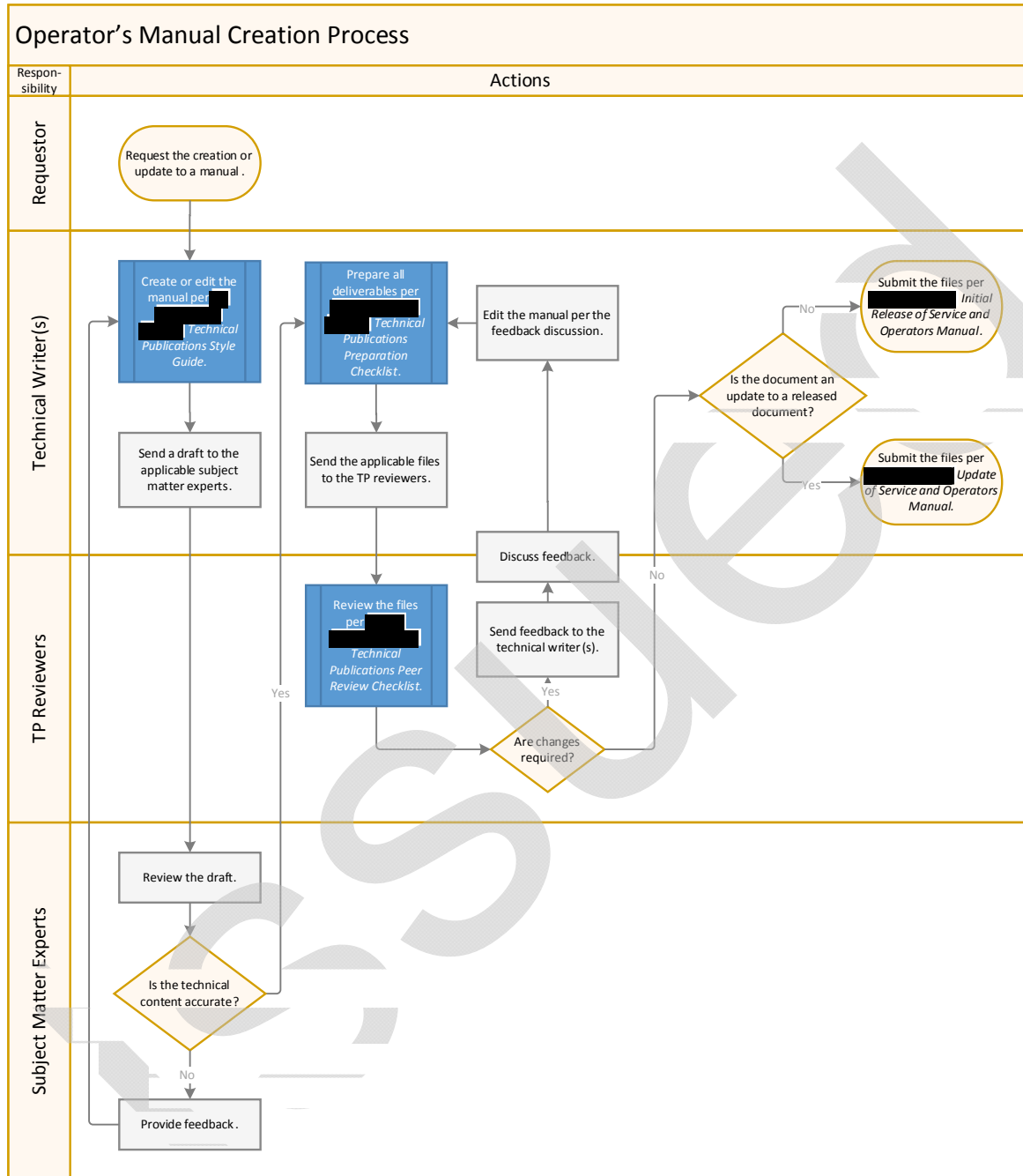
- 2.1 Create an operator's manual per Appendix I.

4 DEFINITIONS

- 4.1 **Operator's manuals** – Are documents acting as the directions for use of a medical system.
- 4.2 **Requestors** – Are individuals or a group that makes a request to create or alter an operator's manual. Requestors are typically internal customers or subject matter experts.
- 4.3 **Subject matter experts** – Are individuals with authority in a particular relevant area or topic.
- 4.4 **Technical writers** – Are individuals responsible for creating and formatting operator's manuals.
- 4.5 **TP** – Is the Technical Publications group which includes technical writers and TP reviewers.
- 4.5.1 **TP reviewers** – Are technical writers that review the deliverable files per *Technical Publications Peer Review Checklist*.
- 4.6 A TP reviewer cannot be the same technical writer that prepares the deliverable files per *Technical Publications Preparation Checklist*.

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APPENDIX I – Operator's Manual Creation Process



END OF DOCUMENT

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| Status: | Issued | Supersedes: | N/A |
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