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Approval

Name	Signature	Date
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Revision History

Revision #	Description of Change	Effective Date	DCR#
0	Original Document	-	-
1	_	05/07/97	_
2	Data modifications, add Close-out steps	03/09/12	11012
3	Add Revision History, Revise Header, Clarify Close-out steps	12/13/13	13006
4	Digitally Sign Table of Contents Approval, Web file storage	02JULZ019	17012



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1 Purpose

1.1 To establish a change control system for documenting and tracking administration changes to official documentation.

2 Scope

- 2.1 This procedure applies to documents under quality control such as: SOPs, forms and attachments. Changes to existing documentation and the addition and omission of new and existing documents will follow this procedure.
- 2.2 This system will also inform management as well as contract customers and clients of changes when necessary.

3 Responsibilities

3.1 The administration change system is managed by Quality Assurance (QA). It remains the joint responsibility of QA, Technical Operations, and department managers to assure that this procedure is utilized to document and control changes.

4 Procedures

- 4.1 The requester of the change will complete the information requested in a form FN 1.003.1 (Document Change Request [DCR]) detailing the proposed modification and the justification for the change. Include attachments and supporting information when appropriate.
 - 4.1.1 All edits to existing documents shall be noted with red pen.
 - 4.1.2 All edits to include initials of the editor and date of edit.
 - 4.1.3 Instructions for completing the DCR form FN1.003.1 are at the bottom of page 2 of the form.
- 4.2 The DCR form and documentation are reviewed by the requesters management for document editing and approval, and returned to the QA manager for approval.
- 4.3 The QA Manager assigns each DCR a document number and fills in the appropriate department names in the document routing slip for review and approval of the documentation.



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- 4.3.1 The DCR form shall be assigned identification numbers as follows: five digits first and second represent the year and third-fifth are sequentially assigned. Example: DCR 96001 is the first DCR of 1996.
- 4.3.2 The QA Manager shall then add the DCR into the DCR Log spreadsheet including: DCR #, SOP # / Form #, Requester and Open Date.
- 4.4 The DCR is routed to Documentation Services for word processing and editing.
 - 4.4.1 Therma Documentation Services(DS) shall copy each Active SOP or Form 'native' file (MS Word or Excel) to the Work In Progress (WIP) directory folder for SOPs and Forms respectively.
 - 4.4.2 Documentation Services(DS) shall perform all editing of the controlled documents in the files copied to the WIP directory.
 - 4.4.3 Edit 'DCR No.' in the header of SOP and footer of Forms to the current DCR number
 - 4.4.4 Edit the 'Revision No.' to existing plus one in the header of SOP and footer of Forms.
 - 4.4.5 Edit the 'Revision History' table per SOP 1.004. Leave blank space for the "Effective Date" of the current revision.
 - 4.4.5.1 The QCM shall write in the new effective date upon approval of the review committee. See following steps.
 - 4.4.5.2 Add Revision History as practicable. Insert a dash or hyphen where old records are unknown.
 - 4.4.6 Edit the existing document or create a new document as requested.
 - 4.4.7 Save and print the document for review and approval. Prints for review shall be single-sided and punched with three holes.
- 4.5 Therma Documentation Services(DS) shall route the complete DCR package to the requestor to review for completeness.



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- 4.6 Therma Documentation Services(DS) shall then route the DCR package to the review committee for review of the edits in three(3) cycles: 'REVIEW', 'FINAL REVIEW' and 'APPROVAL'.
 - 4.6.1 Each member shall review thoroughly for content and format. All edits shall be made in red ink and include the reviewer's initials and date.
 - 4.6.2 Each member shall check the box on the DCR Form when each round is complete. When a cover/transmittal page is used, member to indicate whether approved or comments/edits added.
 - 4.6.3 If no further edits are required during the 'APPROVAL' cycle, each member of the review committee shall sign the DCR form and the 'Approval' chart on the SOP document.
 - 4.6.4 After each round of review, members of the review committee shall return the DCR package to the QCM or DS. The QCM shall update the status of the package in the DCR Log spreadsheet.
 - 4.6.4.1 NOTE: Digital Signatures compliant with THERMA LLC IT Network & Data Policies may be applied to 'soft' digital copy of these documents in lieu of wet-signing 'hard' paper copy.
- 4.7 If the document requires further editing, repeat steps 4.4 through 4.6 until all of the edits are finalized and approved. Once approved, return the DCR Form and all documents to the QA Manager.
- 4.8 The QA/QC Manager shall review the package again for completeness and record the effective date, signature and date on the DCR Form.
- 4.9 For new documents created, the QA department assigns the appropriate number to the document per SOP 1.005 (Numbering Official Documents).
- 4.10 Therma Documentation Services(DS) shall scan each DCR package and save on the Therma data network into the DCR directory folder for the applicable year. Originals to be kept in the DCR binder for the year.
 - 4.10.1.1 Save SOP DCR scan files as: DCR ##### SOP #.###
 - 4.10.1.2 Save Form DCR scan files as DCR ##### FORM FN #.###.#



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- 4.11 Therma Documentation Services(DS) shall maintain the documents on the Therma Corp data network and web based file storage.
 - 4.11.1 DS shall move the now effective SOP or SOP Form 'native' file to the appropriate 'ACTIVE' directory folder on the network drive 'QA'.
 - 4.11.2 DS shall then move the previous revision of the SOP or SOP Form 'native' file to the 'ARCHIVE' directory folder on the network drive 'QA'.
 - 4.11.3 DS shall then scan all signed effective documents and save the Portable Document Format (PDF) file to the appropriate PDF folder in the 'ACTIVE' directory folder on the network drive 'QA'.
 - 4.11.3.1 Scanning to be in color at 300 d.p.i. resolution.
 - 4.11.4 DS shall then move the previous revision (PDF) file to the *''ARCHIVE'* directory folder.
 - 4.11.5 DS shall then save a copy of the PDF scan file to the Therma Corp data network as directed by the QCM for 'Read-Only' access by Therma Corp employees.
- 4.12 The proper closure of the DCR includes the following data file management and distribution activities performed by the QCM.
 - 4.12.1 The QCM shall verify that effective originals of the SOP or SOP Form and attached documentation are filed in the "MASTER QC SOP" binder located in the QCM's fire file.
 - 4.12.2 The QCM shall verify that the 'native' file for the newly effective SOP has been moved from the 'WIP' to the 'ACTIVE' network directory folder.
 - 4.12.3 The QCM shall verify that the previous versions of the 'native' file has been moved from 'ACTIVE' to 'ARCHIVE' network directory folder.
 - 4.12.4 The QCM shall verify that the PDF scan version of the newly effective document is saved to the 'ACTIVE' network directory folder and the previous version has been moved to the 'ARCHIVE' network directory folder.



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- 4.12.5 The QCM shall verify that the newly effective PDF scan file document is saved to the Therma Corp data network as directed by the QCM and the previous revision has been removed.
- 4.13 Therma Documentation Services(DS) shall then update the Therma QC SOP Table of Contents to include the latest revision(s) of SOPs & Forms.
 - 4.13.1 DS shall perform edits and print a draft copy for the QCM to review.
 - 4.13.2 Upon acceptance, the QCM shall initial and date the first page of the draft QC SOP Table of Contents.
 - 4.13.3 The QCM shall then secure the 'PDF' version and apply digital signature with date and save as the current official Therma QC SOP Table of Contents on the network drive 'QA'.
 - 4.13.4 DS shall insert signed Table of Contents into the MASTER QC SOP binders in the QCM fire file cabinet and discard previous revision.
 - 4.13.5 DS Shall then move the previous revision of the Table of Contents to the 'ARCHIVE' network directory folder.
 - 4.13.6 DS shall then save a copy of the PDF file to the Therma Corp data network as directed by the QCM and web-based server for 'Read-Only' access by Therma Corp employees.
 - 4.13.7 The QCM shall verify that the newest PDF file document is saved to the network drive 'QA', the network directory folder 'T:\Therma QC SOP\, web-based file server and that the previous revision(s) have been removed.
- 4.14 The Therma QCM shall then communicate the revision(s) to Therma's SOP users including Project Management, Engineering, Production Shops, Service and Process Systems personnel.
 - 4.14.1 This notice may be provided by email and shall include list of individual documents which have been revised.
 - 4.14.2 QCM and PM's shall coordinate to identify employees as candidates for training to the newly revised or released SOP or Form.



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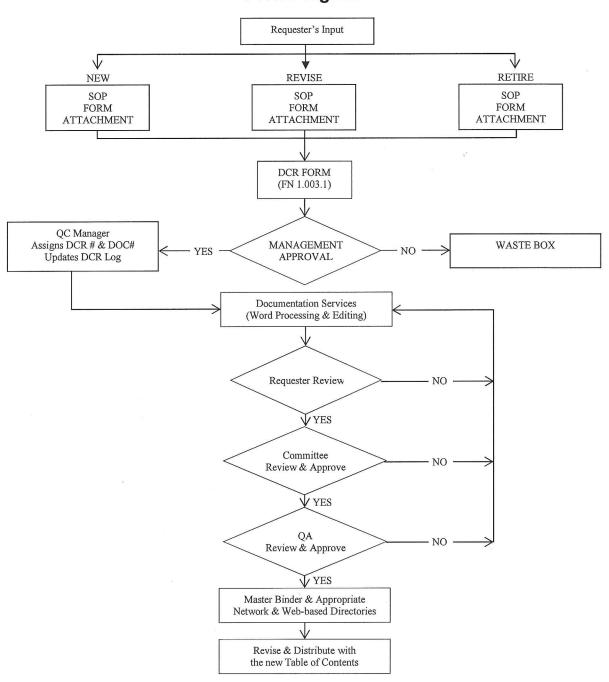
- 4.14.3 QCM shall arrange for training as required.
- 4.14.4 QCM shall arrange for documenting SOP training for future records including the following information: Date; SOP's and SOP Forms Trained; Names of Trainees in attendance.
- 4.14.5 As required, QCM shall provide evidence of QC SOP training to Therma PM.
- 4.15 Therma QCM shall verify completion of the DCR form, file management steps and distribution steps. Once verified, the QCM shall edit the DCR Log spreadsheet to include the new 'Effective Date' for the DCR/SOP and indicate 'ORIGINAL IN MASTER'. The QCM shall save the DCR log file.



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Figure 1: Document Change Control Process
Flow Diagram



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