

| | |
|---|------------------|
| Standard Operating Procedure Guidelines for Preparation of Turnover Package | SOP No. 3.011 |
|---|------------------|

DCR No.: 00038
Revision No.: 2

Effective: 07-15-93
Supersedes: 07-15-93
Revision Date: 09-11-00
Page No.: 1 of 3

- 1 Purpose
 - 1.1 To establish a standard guideline for preparation of turnover package (TOP) documentation.
- 2 Scope
 - 2.1 This procedure applies to all commissioning/validation facilities and supporting utilities projects.
- 3 Responsibility
 - 3.1 Project Manager (PM) is responsible for performing the procedures listed in section 4.
 - 3.2 Auditor is responsible for reviewing TOP documentation periodically.
- 4 Procedures
 - 4.1 Assign a TOP number (A common number would be project's job number.).
 - 4.2 Coordinate with engineer and auditor to review system specifications, facility design and project requirements.
 - 4.3 Obtain a copy of generic TOP's Table of Contents, FN 3.011.1, revision number 4 and TOP matrix, FN 3.011.2, revision number 1.
 - 4.4 List all systems on the TOP matrix, FN 3.011.2. Use the same list on all four (4) groups (Design, Purchasing, Installation, and Commissioning).

 Note: Examples of mechanical utilities are chiller water, heating water, etc. Process utilities include clean dry air (CDA), deionized (DI) water, vacuum, etc. Plumbing would have potable and industrial water, sanitary and industrial waste, etc.
 - 4.5 Mark the appropriate, squares with a "T" (for Therma) on the TOP matrix, FN 3.011.2, to indicate which documents will be provided to customer by Therma.

THIS DOCUMENT CONTAINS PROPRIETARY INFORMATION OF THERMA CORPORATION. ALL INFORMATION SHALL (A) BE RETAINED IN CONFIDENCE; (B) NOT BE REPRODUCED IN WHOLE OR IN PART; AND (C) NOT BE USED OR INCORPORATED IN ANY PRODUCT EXCEPT UNDER EXPRESSED WRITTEN AGREEMENT WITH THERMA CORPORATION.

| Revision No. | SOP No. | Page |
|--------------|---------|---------------|
| 2 | 3.011 | 2 of 3 |

- 4.6 If appropriate, submit the TOP matrix to customer for review and approval.
- 4.7 Follow the approved TOP matrix to generate an appropriate TOP table of contents.

Note: Electronic copies of these documents are available from the Quality Assurance department.
- 4.8 Set up file folders per the approved TOP matrix.
- 4.9 Train all personnel who may be handling critical documents about the filing system.
- 4.10 Collect the required documents and file in an appropriate file folder.
- 4.11 When completion of the various phases of construction, notify auditor to review the TOP documentation for completeness.
- 4.12 Make adequate copies per project requirements.
- 4.13 Collate the TOP documents into three-ring binders with dividers.

Note: For validated pharmaceutical projects, utilize ***ThermaTrac*** for management of the critical documents. Steps 4.8, 4.9, and 4.10 are affected by the use of ***ThermaTrac***.

5 Review and Approval

- 5.1 PM shall submit the completed TOP documentation and give to customer for review.

| Revision No. | SOP No. | Page |
|--------------|---------|--------|
| 2 | 3.011 | 3 of 3 |

Document Approval


Operations Manager

8/28/00
Date


Engineering Manager

7/5/00
Date


Quality Assurance Manager

9-5-00
Date

THIS DOCUMENT CONTAINS PROPRIETARY INFORMATION OF THERMA CORPORATION. ALL INFORMATION SHALL (A) BE RETAINED IN CONFIDENCE; (B) NOT BE REPRODUCED IN WHOLE OR IN PART; AND (C) NOT BE USED OR INCORPORATED IN ANY PRODUCT EXCEPT UNDER EXPRESSED WRITTEN AGREEMENT WITH THERMA CORPORATION.