

| | |
|---|------------------|
| Standard Operating Procedure Preventive Maintenance Review and Implementation | SOP No. 8.001 |
|---|------------------|

DCR No.: 97010
Revision No.: New

Effective: 6-10-97
Supersedes: New
Revision Date: New
Page No.: 1 of 8

1 Purpose

- 1.1 This SOP outlines and defines the system that is designed to schedule, control, document and assign responsibility for routine preventive maintenance, performed on equipment and systems to prevent malfunctions, reduce energy costs, prolong the useful life, and to protect the validated (where applicable) status of systems and equipment.
- 1.2 SOP's in the purview of the Service Department are reviewed annually to ensure that the instructions are consistent with the current industry standards, practices, and equipment manufacturing recommendations. Also, periodic review allows the Service Department to: 1) ensure that maintenance schedules are maintained and check lists are complete, and 2) assess current requirements for manpower, support equipment, and spare parts.
- 1.3 The performance of the preventive maintenance program (as determined by the content of the SOP's, the out put from the HP 700/96/ES scheduler, and the production of work orders) is audited annually.

2 Scope

- 2.1 This procedure establishes a system for contract preventive maintenance procedures, provided by Therma's Service Department.

3 Reference

- 3.1 N/A

4 Definitions

- 4.1 Specific instructions for each system or piece of equipment are developed by the Service Department in compliance with the equipment manufacturers specifications. Instructions, known as Preventive Maintenance SOPs (PM SOPs), describe the procedures to be followed, parts to be inspected or replaced, safety requirements, and special tools needed. These instructions are part of the Therma Standard Operating Procedures.

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 |
|--------------|---------|---------------|
| New | 8.001 | 2 of 8 |

- 4.1.1 Schedules are developed in accordance with the manufacture recommendations, accepted practices, and experience.
- 4.1.2 Schedules are developed at weekly, monthly, bi monthly, quarterly, semiannual, and annual intervals. Daily inspections to assure proper operation are not part of the preventive maintenance system; these activities are to be provided by the operating company (operating and cleaning SOPs) or the responsible party who maintains these systems or equipment.
- 4.1.3 The time intervals above (or time window to perform the task) can be no more than 7 days before or 7 days after the due date, due to climate considerations, short work weeks, or other variables such as scheduling conflicts.
- 4.1.4 Each of the routine preventive maintenance intervals scheduled to be performed by a Therma field technician, will be identified by a Field Verification Sticker (FVS), located on each piece of equipment at the equipment site. Each sticker will identify the system name, equipment ID number, Therma's SOP number, PM date (weekly, monthly, bi monthly, quarterly, semiannual, and annual) of when the activity took place, the next due date, and the employees initials and identification number. The FVS will be placed on site upon the first service call and replaced as needed due to wear and tear or on a annual basis.
- 4.1.5 The preventive maintenance schedule (PM dispatch) will be printed approximately 1 week in advance of the scheduled PM and placed into the assigned technician in box for that week by the Service Coordinator.
- 4.1.6 During a scheduled PM, the field technician will fill out an equipment maintenance log and preventive maintenance inspection (check list) form for each system or equipment. This form is to be used to generate a record of the work performed and a work order for any additional repairs.

5 Organization and Responsibilities

- 5.1 Quality Assurance: This department shall be responsible for review and audits of the system to ensure it's compliance with company procedures and cGMP.
- 5.2 Engineering: This department shall be responsible for providing technical advice for the preventive maintenance procedures for new and existing equipment.

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 |
|--------------|---------|---------------|
| New | 8.001 | 3 of 8 |

- 5.3 Service Department: This department shall be responsible for the generation and performance of standard operating procedures.
- 5.3.1 Service Department shall maintain standard operating procedures necessary to perform the preventive maintenance procedures to designated pieces of equipment.
- 5.3.2 Service Department shall maintain a record keeping system to maintain copies of (work orders, equipment maintenance logs and PM check lists) all the scheduled preventive maintenance procedures for traceability of the customers equipment.
- 5.3.3 It shall be the responsibility of the Service Manager to ensure that all schedules and procedures are maintained and followed by the Service Department staff.
- 5.3.4 It shall be the responsibility of the Field Service Technician to execute the preventive maintenance procedures as outlined in the service agreement and standard operating procedures.
- 5.4 Standard operating procedures for preventive maintenance shall be reviewed and approved by the Service Manager, technical departments, and QA.

6 Procedures

6.1 Service Agreement

- 6.1.1 The Service Account Manager (SAM) is responsible for filling out a Service Agreement with the customer.
- 6.1.2 The Service agreement will include the company name, equipment name, ID number, serial number, a list of the replacement parts to be replaced on a routine basis, and the PM interval (weekly, monthly, bi monthly, quarterly, semiannual, and annual). The information contained in the service agreement and the equipment manufactures operating and maintenance manual will be used to generate a local site preventive maintenance procedure (LSPM) SOP.
- 6.1.3 Inspects the returned paper work (work orders and equipment check list) from the field for completeness. If the records are incomplete the Service Account Manager will notify the technician to either correct or explain any omissions or errors.

| Revision No. | SOP No. | Page |
|--------------|---------|---------------|
| New | 8.001 | 4 of 8 |

6.2 Service Coordinator Responsibilities

- 6.2.1 Assigns a job number to each of the service agreements and maintains the job files.
- 6.2.2 Generates a field dispatch schedule for the field service technicians.
- 6.2.3 Scans in the field inspection/repair forms into the data base.

6.3 Field Service Technician Responsibilities

- 6.3.1 Entering and maintaining the equipment maintenance log (FN 8.001.1) for each piece of equipment that has been assigned to them by the SAM. The equipment log will track routine PM procedures that have been performed, as well as any non routine repairs that have been made to the equipment by a Therma Field Service Technician.
- 6.3.2 Maintaining a SOP (LSPM) binder assigned to them by the QA documentation group. The binder will have an "official" copy of each PM procedure and a copy of the equipment maintenance log.
- 6.3.3 Gathering the required tools and replacement parts (kit), required to perform the PM procedure as per SOP 5.002 (Tools and Equipment) before going out to the operating company.
- 6.3.4 Scheduling each of the PM procedures with the customer for that week as per step 4.1.5.
- 6.3.5 Filling out all of the required forms such as: Preventive Maintenance Inspection Report, Time and Material sheet, Inventory sheet, additional repairs quote, equipment maintenance log, and equipment check list.

| Revision No. | SOP No. | Page |
|--------------|---------|---------------|
| New | 8.001 | 5 of 8 |

6.3.6 If the equipment inspected is in substandard operating condition, the Service Account Manager and the Facility Site Manager are to be notified of any additional work that may be required to bring the equipment back into normal running condition; as per the design specifications and the O&M manuals.

7 Maintenance Records

- 7.1 Standard operating procedures will be provided and utilized for each maintenance procedure as part of Therma's pharmaceutical operation division . The SOP's will be written in general format as per SOP 1.004, (Guidelines for Preparation of Documentation). SOP's will be numbered, controlled, reproduced, and disseminated in accordance with the established procedures.
- 7.2 Equipment logs and PM check lists, will be provided and utilized for each maintenance procedure as part of Therma's pharmaceutical operation division. Each record will be identified by the operating company name, equipment ID number and LSPM SOP number.
- 7.3 Each customer will be provided a local site preventive maintenance (LSPM) binder, issued by Therma's Quality Assurance Department. The binder will contain SOP's and equipment logs for each piece of equipment.
- 7.4 Changes that result in the deletion of a job number, LSPM SOP's and system file's from the scheduling computer, will not be implemented until the SAM has a hard copy of the existing file. This file will be reviewed by the SAM prior to actual deletion, which is done by the service coordinator.
- 7.5 Equipment that has missed its routine PM due to any scheduling conflicts (step 4.1.3) will be reviewed by the SAM. A out of schedule report will be filled out and the operating company will be notified, to evaluate the response that should be taken.
- 7.6 Changes to a PM interval or changes in scope of work will be reviewed by the SAM as per a new service agreement, before the LSPM SOP's are to be revised.
- 7.7 Any change to the SOP will be reviewed approved in accordance with the change control procedure SOP 1.003 (Administration of Document Changes).

| Revision No. | SOP No. | Page |
|--------------|---------|--------|
| New | 8.001 | 6 of 8 |

8 Audit

- 8.1 For each file audited, review the corresponding repair history and PM SOP for completeness. Revise the maintenance intervals and scope of work and SOP's if necessary.
- 8.2 Number a list of accounts and equipment or systems sequentially, beginning with the number 0.
- 8.3 Compare the list with the number of PM procedures. Any deviation of a 1 to 1 correspondence with these two lists will be noted and explained as part of the annual report.
- 8.4 A statistical inspection audit will be performed annually, the number of files to audit equals the square root of the total number of files plus (step 8.3) one. Example: $[\sqrt{140}] + 1 = 12$, 12 = number of files to audit.
- 8.5 A random audit equal to the number of files (step 8.4) will be performed.

9 Audit Reports

- 9.1 At the completion of the audit, produce an audit report consisting of:
 - 9.1.1 A statement of the one to one correspondence between the equipment list and the SOP's.
 - 9.1.2 A statement that describes the audit results and lists the audited files by SOP numbers.
 - 9.1.3 A description of the failures or error that caused any file to be out of compliance with the PM schedule.
 - 9.1.4 A percent completeness will be determined by the using the total number of items to be checked against the number of failures found during a audit.
 - 9.1.4.1 $C =$ The total number of items to be checked.
 - $F =$ the number of failures.
 - $PA =$ percent completeness.
 - 9.1.4.2 Use the following calculation to determine the percent completeness.
 - 9.1.4.3 Example $[(C-F) \div C] \times 100\% = PA$ or $[(140 - 23) \div 140] \times 100\% = 83.6\%$

| | | |
|--------------|---------|---------------|
| Revision No. | SOP No. | Page |
| New | 8.001 | 7 of 8 |

10 Control access to the schedule

10.1 Only personnel in the service group will have access to the schedule program via a password.

10.2 Restrict access to the following service personnel:


10.2.1 Planning and scheduling coordinators

10.2.2 Service Manager


10.2.3 Data base administrator

| | | |
|--------------|---------|--------|
| Revision No. | SOP No. | Page |
| New | 8.001 | 8 of 8 |


Document Approval


 Service Manager

5-12-97
 Date


 Engineering Manager

5-29-97
 Date


 Quality Assurance Manager

6-7-97
 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.