

 Precision Swiss Products, Inc.	Document # SOP-4.5-001	Revision 1
Document Title Infrastructure and Work Environment	Effective Date 07/05/23	
	Document Type Standard Operating Procedure	

1. Purpose:

To establish guidelines for the work environment and preventative maintenance program for machines and infrastructure. These guidelines will:

- a. Ensure the safety of our employees and visitors
- b. Improve system reliability
- c. Decrease cost of replacements by doing continual maintenance
- d. Prevent/decrease system downtime
- e. Provide suitable environment for social, psychological and physical factors

2. Scope:

This procedure will cover the machine and infrastructure preventative maintenance programs, as well as the work environment requirements. This includes:

- a. Operator and Maintenance department responsibilities for machine maintenance to prevent issues
- b. Maintenance responsibilities for facilities/infrastructure maintenance activities to prevent issues, including pest control, building and workspace and utilities.
- c. Process hardware and software
- d. Work environment

3. Terms, Acronyms and Definitions:

- a. Preventative maintenance (PM): is the act of performing regularly scheduled maintenance activities to help prevent unexpected failures in the future
- b. On the Job Training (OTJ): is a practical approach to acquiring new competencies and skills needed for a job in a real, or close to real, working environment

4. References:

- a. DOC-4.5-002 (CA Coolant Log- Lathe)
- b. DOC-4.5-003 (CA Coolant Log- Mill)
- c. DOC-4.5-004 (NC Coolant Log- Mill and Lathe)
- d. DOC-4.5-005 (Swiss Preventative Maintenance Requirements)
- e. DOC-4.5-006 (PSP West- Swiss PM Sign off)
- f. DOC-4.5-007 (PSP East- Swiss PM Sign off)
- g. DOC-4.5-008 (Lathe Preventative Maintenance Requirements)
- h. DOC-4.5-009 (PSP West- Lathe PM Sign off)
- i. DOC-4.5-010 (PSP East- Lathe PM Sign off)

- j. DOC-4.5-011 (Mill Preventative Maintenance Requirements)
- k. DOC-4.5-012 (PSP West- Mill PM Sign off)
- l. DOC-4.5-013 (PSP East- Mill PM Sign off)
- m. DOC-4.5-014 (Finishing Preventative Maintenance Requirements & Sign off)
- n. DOC-4.5-015 (DI Water Tank Preventative Maintenance Requirements & Sign off)
- o. DOC-4.5-016 (RO Water Tank Preventative Maintenance Requirements & Sign off)
- p. DOC-4.5-017 (Chemical Log)
- q. PSP-FC-03-005 (Lathe Start Up Checklist)
- r. PSP-FC-03-007 (Mill Start Up Checklist)
- s. PSP-FC-03-009 (EDM- Aie Start Up Checklist)
- t. PSP-FC-03-010 (Tumbler Start Up Checklist)

5. Responsibilities and Authority:

a. Maintenance/Facilities Manager:

- i. Responsible for implementing and maintaining systems and programs to maintain equipment and adhere to customer and regulatory compliance.
- ii. Develops the preventative maintenance (PM) requirements for all equipment and supporting services that are subject to control.
- iii. Completes the PM's as required per the determined schedule
- iv. Identifies and documents maintenance requirements and intervals for maintenance activities.
- v. Ensuring that any new or moved equipment has been validated prior to use on production if necessary (reference Validation SOP)
- vi. Ensure daily cleaning and maintenance tasks are completed including but not limited to the cleaning of machines, the manufacturing floor, front office, break rooms and bathrooms.
- vii. Entering all chemicals in the facility into the DOC-4.5-017 (Chemical Log) and monitoring this log to ensure its accuracy
- viii. Logging all SDS appropriately

b. Leads/Supervisors:

- i. Responsible for ensuring their employees assist with the routine cleanliness of the company and for communicating all key items for their department, to their employees.

c. HR:

- i. Responsible for ensuring that a suitable social and psychological environment is provided to all employees.

d. Quality Assurance:

- i. responsible for reviewing and verifying that PM records (listed below in the records section) are completed, signed off and saved.

6. Inputs:

- a. Vendor recommended equipment maintenance intervals for fluids, filters and mechanical parts
- b. Ongoing technical evaluations and recommendations
- c. Fire and OSHA requirements
- d. Electrical and air requirements

- e. Management meetings and employee feedback to determine employee morale and provide suitable working environments
- f. SDS chemical information

7. Infrastructure:

The organization's infrastructure is designed to counteract environmental conditions that could have an adverse effect on the product. Preventative measures include, but are not limited to:

- a. Pest control: performed through an outside service and signed off by a member of maintenance, quality or management
- b. Temperature controlled environment: This is required in the quality department (QC) where first article and final inspection occurs.
 - i. QC inspection room: shall be temperature controlled and set between 65 and 72 degrees. If the temperature falls outside of those ranges, the QC team will address the outside ranges if it is a risk or not.
 - ii. Shop floor: is not considered temperature controlled, however the air conditioning is set to turn on once the temperature hits 72 degrees.
- c. Electrical lighting: installed, repaired, or replaced by an outside vendor or a member of the organization depending on the situation.
- d. Any other additional infrastructure maintenance that is required is completed through a contract with the landlord of the building. They are responsible for any maintenance of heating, air conditioning, landscaping, maintenance of fire risers and sprinklers, extensive plumbing, as well as structural integrity of the building itself.

8. Equipment Maintenance (hardware and software):

- a. Hardware:
 - i. All manufacturing equipment that can affect the conformity of the product is maintained based on the organization's maintenance schedule.
 - ii. The maintenance schedule is a combination of both the manufacturer's maintenance schedule recommendation as well as the organization's internal knowledge and requirements.
 - iii. The schedule is saved in the secured server and is adjusted by the maintenance manager as needed, and a copy is located in every department for reference.
 - iv. Machines get calibrated during installation of the initial machine, and only recalibrated if determined to be necessary.
- b. Software:
 - i. All software used during production is controlled and maintained to ensure the intended function.
 - ii. Manufacturing equipment programs are revision controlled and can be traced back to a specific product and its unique revision.
 - iii. Software used for measurement and monitoring equipment is validated through the calibration process and verified through first part inspection that is performed with calibrated equipment.
- c. Transportation services:
 - i. The company delivery truck is maintained based on the manufacturer required service schedule and is completed by an outside vendor.
- d. Information and communication technology:
 - i. The organization's communication and IT services are maintained by an outside IT vendor.

9. Work Environment:

In addition to the actions taken for the physical factors listed above, the organization provides the following to ensure a suitable work environment regarding human factors:

- a. Provides non-discrimination and harassment trainings
- b. Hosts post work activities such as company BBQ's, lunch events and company parties
- c. Provides PTO, with a cap to ensure it is taken in a timely manner
- d. Paid sick leave days
- e. personal choice holidays
- f. 401K
- g. Cross training to prevent burn out and increase knowledge of the employees

Environmental conditions at the organization are similar to those at a standard machine shop. All requirements for health, cleanliness, clothing and any other aspects regarding environmental conditions that could adversely affect the quality of the product are communicated through job specific training, job descriptions, employee handbook, procedures, work instructions and on the job training (OTJ).

In any situation where an employee is required to work under special environmental conditions, the employee is provided with training to ensure their competence and is provided with the appropriate Personal Protective Equipment (PPE).

There is no open food or drink to be kept or consumed on the manufacturing floor, shipping area, purchasing/receiving areas, or in the quality control department where there could be contamination to parts. Drinks with lids or a cap on them, such as water bottles, tumblers, coffee mugs/cups with a lid are considered acceptable.

There is no smoking or vaping allowed in or near the facility at any time.

All employees are responsible for and required to clean up their work areas prior to leaving at the end of their shift.

10. Scrap and Recycling:

- a. Scrap material is recycled when possible
- b. A scrap certificate of destruction is issued to the organization from the company who collects the scrap material

11. Outputs:

- a. Efficiently operating machines and equipment
- b. Safe work environment for the employees and guests
- c. Enjoyable work environment for the employees

12. Quality Records:

- a. Completed, signed and saved preventative maintenance (PM) records for all applicable manufacturing and finishing areas
- b. Pest control records
- c. Scrap CoD

Record Name	Owner	Location	Record Media
Monthly PM sign off	Quality Assurance	PSP QMS: RECORDS\MAINTEN ANCE	Electronic
Pest control	Maintenance	PSP QMS: RECORDS\MAINTEN ANCE	Electronic
Scrap CoD	Maintenance	PSP QMS: RECORDS\MAINTEN ANCE	Electronic
Temperature Control	Quality	Sensoscific	Electronic/web based

Revision History			
Revision	Description of Change	Approver	Effective Date
1	Initial release. Changed document # and streamlined process	Daniela Kozar	07/05/23

GATE TEST- Submit to Trainer once complete

Gate test is only required for new employees, initial release training and major revision updates. If gate test is not required for an up rev for current employees, it will state as such in the "description of change" section on the revision history above.

Each answer is worth 1 point. If a question has multiple answers, and the employee gets part of the question correct, they will receive a point for each correct answer in that question.

100% is considered a passing grade. If 100% is not achieved, the employee must retake the training and gate test.

1. Improving system reliability is part of the purpose for establishing the infrastructure and work environment SOP.

- a. True
- b. False

2. Name one of the positions who can sign off on Pest Control statements.

3. The QC inspection room temperature shall be between _____

- a. 67 and 74 degrees
- b. 65 and 72 degrees
- c. 63 and 73 degrees
- d. 65 and 76 degrees

4. All manufacturing equipment that can affect the _____ of the product is maintained on the organization's maintenance schedule.

- a. congruence
- b. reliability
- c. conformity
- d. finish
- e. all of the above

5. All software used during production is _____ and _____ to ensure the intended function.
- labeled and categorized
 - controlled and maintained
 - structured and purchased
 - tested and verified
6. When an employee is required to work under special environmental conditions, the employee is provided with training and the appropriate PPE.
- True
 - False
7. Please show your trainer where the following PM Logs are located both on the shop floor and in the QMS (master sheets and records).
- Swiss, Lathe, Milling
 - Finishing
 - RO or DI water
 - Coolant Logs

EMPLOYEE NAME: _____

EMPLOYEE SIGNATURE: _____

DATE OF TRAINING: _____

TRAINER NAME: _____

TRAINER SIGNATURE: _____

SCORE: ____ / ____ %
