

## Procedure

Procedure: QP-6.4

Title: Environmental Practices

Eff. Date 05/30/2024

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### **1.0 PURPOSE:**

- 1.1 To identify the activities required to provide a working environment so that parts are not adversely affected during manufacture, storage and shipping are described.

### **2.0 SCOPE:**

- 2.1 This procedure applies to all production and warehouse areas in all buildings occupied by Moldgenix, LLC.

### **3.0 RESPONSIBILITY & AUTHORITY:**

- 3.1 The President is responsible to ensure compliance to this procedure company wide.
- 3.2 Quality Assurance is responsible to have air particulate count inspections and noise level count performed per schedule according to work instruction W40-75.
- 3.3 Some responsibilities may be outsourced and completed by an approved supplier / provider, such as pest control for the facilities.
- 3.4 All employees are responsible to ensure compliance to this procedure.

### **4.0 DOCUMENTATION REQUIRED:**

<u>ID</u>	<u>Description</u>
ARPTCTLG	Air Particle & Sound Level Log
EM-6.2	Employee Manual
QP-6.3	Infrastructure /Maintenance (including preventive maintenance)
W40-78	Preventive Maintenance for Buildings and Infrastructure
W40-75	Air Particle and Noise Level Count
W30-02	Corrective Action / Preventive Action Process

### **5.0 PROCEDURE:**

- 5.1 All production facilities are operated and maintained in accordance with appropriate health and environmental standards as required by various governmental agencies, the industry and the customer.
- 5.2 While Moldgenix, LLC. does not maintain certified clean environments at this time, some measures are taken to ensure the production areas are temperature and humidity controlled and air particulate counts are not excessive.
  - 5.2.1 Air particulate counts and noise level counts are checked quarterly and recorded on Air Particle Count & Sound Level Log (ARPTCTLG). Completed records are maintained by Quality Assurance. Reports are reviewed during management review.
  - 5.2.2 Temperature and humidity are constantly monitored manually by the President. Adequate heating and air conditioning is available throughout the facilities.
  - 5.2.3 Tacky mats are placed in key locations to reduce the number of particulate transfer from area to area.

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- 5.2.4 Air scrubbers are strategically located to ensure air particulate is reduced.
- 5.3 Various cleanliness, environmental and hygiene requirements are maintained by appropriate checklists.
  - 5.3.1 Maintenance personnel follow preventive maintenance schedules in accordance with QP-6.3 Infrastructure /Maintenance (including preventive maintenance) Procedures.
  - 5.3.2 Checklists are reviewed and maintained in accordance with QP-6.3 Infrastructure / Maintenance (incl. PM) Procedures and work instruction W40-78.
- 5.4 Both maintenance personnel and supervision must enforce the safety requirements in accordance with safety manual.
- 5.5 Cleanliness of washroom and toilet facilities is maintained with sanitary specialists by separate contract arrangements.
- 5.6 General mopping and cleaning of all office and manufacturing areas is performed once per week at a minimum.
- 5.7 Personal cleanliness and hygiene are required by all persons while in the workplace.
  - 5.7.1 All persons entering, working or passing through a manufacturing area must wear appropriate uniforms, hairnets, and beard nets.
  - 5.7.2 Visitors, contractors, and temporary employees are instructed on uniform and hair net/beard net requirements by the department head or other personnel escorting them into the building.
  - 5.7.3 Hairnets and beard nets are to be worn in such a manner as stated in the Employee Manual.
  - 5.7.4 Uniforms are provided by Moldgenix, LLC. and are to be worn in such a manner as stated in the Employee Manual.
- 5.8 Non-hazardous waste is removed per various checklists and stored in various dumpsters awaiting pickup by sub-contracted local trash company.
  - 5.8.1 Trash is collected based on a fixed monthly fee. Waste is not able to be tracked by weight or logged.
  - 5.8.2 When possible materials are recycled via sale of reground materials, re-use or local recycling centers. Currently only the resale of reground materials and recycling of plastic bags are able to be tracked and this information is available upon request.
- 5.9 Hazardous waste is stored in biohazard marked containers and is removed from these containers and disposed of by a sub-contracted service.
  - 5.9.1 Hazardous waste is collected based on a fixed fee. It is not tracked by weight or logged.
- 5.10 Water is discharged to the local sewer authority and is not trackable per vendor.
- 5.11 Incoming water provided is provided by the local water authority and usage is available upon request per quarterly statements that provide the number of gallons per quarter used.
- 5.12 Electricity is provided by a local utility company and its usage is available upon request per monthly statements.
- 5.13 Quality Assurance monitors production areas by internal and external auditing and corrective action processes.
- 5.14 Integrated Pest Management Program
  - 5.14.1 External windows, ventilation openings, doors and other openings are sealed when closed and proofed against dust, vermin and insects.

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- 5.14.2 External doors used for product access are protected by but not limited to:
- A self-closing device;
- 5.14.3 Internal doors for product access are protected by but not limited to:
- Air scrubbers;
  - Doors;
  - Seals
- 5.14.4 Traps and bait stations are located so as not to present a contamination risk to employees, product, packaging, containers or processing equipment.
- 5.14.5 The premises, its grounds, warehouse, external storage areas, machinery, vehicles and equipment are kept free of waste or accumulated debris so as not to provide harborage for pests and vermin.
- 5.14.6 Pest control is outsourced to Ehrlich (A Rentokil Steritech Company) who manages the integrated pest management program and performs service per contract.
- 5.14.6.1 The outsourced provider services Moldgenix, LLC. every other month unless otherwise requested by management.
- 5.14.6.2 The outsourced provider uses only approved chemicals; provides a pest control management plan that includes a site map showing the location of bait stations and vermin traps.
- 5.14.6.2.1 Scope of services covers but is not limited to the following pests: Mice, Rates, Cockroaches, Ants, Occasional Invaders, German Cockroaches, American Cockroaches, Non Wood-Boring Ants, Non Budding Ants, Stinging Insects, Termites, Exterior Fly Service. Full contractual requirements available upon request.
- 5.14.6.3 Sprayed pesticides are applied to exterior surfaces only as not to contaminate product, production/manufacturing areas.
- 5.14.6.4 Upon entering the premises, the outsourced service provider contacts the Administrative Assistant. Upon completion of inspections, the service provider confers with the President prior to leaving the premises to discuss any issues that require attention and go over findings.
- 5.14.6.4.1 When needed the President will initiate corrective action.
- 5.14.6.5 The outsourced provider provides Inspections for interior bait stations and exterior traps.
- 5.14.6.6 Pest Control Chemicals are not stored onsite. The application and disposal of chemicals are managed by the outsourced provider.
- 5.14.6.7 Records/Certifications are maintained by the provider but can be obtained at any time via our PestNetOnline account.
- 5.14.6.7.1 Pest Service reports are printed by the QAM and reviewed with the President, as needed, to determine if any Corrective action(s) are necessary. If any CA is required, they will be tracked through Corrective and Preventive Action Process per W30-02.

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### APPROVALS

Quality: \_\_\_\_\_ Date: MAY 30 2024

President: \_\_\_\_\_ Date: MAY 30, 24

### PREPARED BY:

Document Control Administrator: \_\_\_\_\_ Date: MAY 30 2024

### REVISION HISTORY

Revision Level	Change Description	Date
11	Updated procedure to current practice, responsibility, & pest management program/supplier	02/18/2021
12	Doc Req – remove W40-33 and add W40-78 and W30-02. Step 3.3 was QAE to compile report for Mgmt Review. 5.3.4 ref W40-78; 5.12.6.7.1 ref to W30-02 CAPA process was review during mgmt. review.	09/23/2021
13	.2) Quality Assurance was Operation Mgr reference W40-75; 4.0 add MonitoringProdActivities, ARPTCTLG and W40-75 then remove EnvironmentalCklst; 5.2.1) clarify min every 6 months counts record on Air Particulate Count & Sound Level Log. Records maintained by QA; 5.11) QA monitors areas by routine walk through of production area per checklist Monitoring Production Activities was DCA performs weekly environmental checks/ Any issues found are reported to person responsible was Environmental cklst is forwarded to MAS to address issues. 5.12.6.4 service provider was employee.	03/21/2023
14	Delete Rev. History per record retention practices. Ref CAR749: Updated 5.9 & 5.9.1 to include trash is collected based on a fixed monthly fee and waste is not able to be tracked or logged. Added 5.9.2 to cover recycling. Added 5.10.1 to cover hazardous waste is collected based on a fixed fee and is not tracked or logged. Added 5.11, 5.12, & 5.13 to cover electric, water discharge and incoming water requirements. Deleted rev history per retention practices.	11/14/2023
15	Remove 5.8 Pest control is performed by an outside service on a routine basis. Regularly scheduled inspections are performed to secure the facilities from any infestation. Renumber steps 5.8 thru 5.14.6.7.1 was 5.9 thru 5.15.6.7.1	01/15/2024
16	Changed 5.2.1 from at minimum every 6 months to quarterly & delete "monthly" from 5.14.16	02/16/2024
17	Deleted tms inc from form title. Changed any ref. of Total Molding Services, Inc. / TMS Inc. T.M.S., Inc. to Moldgenix, LLC. Deleted MonitoringProdActivities from references. Updated 5.1.3 to: 5.13 Quality Assurance monitors production areas by internal and external auditing and corrective action processes. Changed OM/operations manager to president	05/30/2024