

	Standard Operating Procedure		SOP Number QS-103	Revision 7
	Pest Control Management		Effective Date 09/09/24	Page Page 1 of 6
Written by/ Date <i>KBurns 07/27/24</i>		Reviewed by/ Date <i>GM RL 07/29/24</i>		Approved by/ Date <i>Paul Reali 07-30-24</i>
Title: Quality Assurance Director		Title: Chief Operating Officer		Title: QA Compliance Supervisor

1.0 Purpose

The purpose of this procedure is to define the process for pest control and use of suitable rodenticides and insecticides to keep the facilities free from insects, rodents, and other vermin, ensuring compliance as applicable, for all aspects of Dietary Supplement, Pet Supplement, and Food Manufacturing, Labeling, Packaging, Holding, and Distribution, as outlined in the CFRs.

2.0 Scope

This procedure applies to all interior and exterior areas of Ion Nutritional Labs.

3.0 Definitions

- 3.1 **Non-restricted areas** – areas which include front lobby and office areas, areas external to the physical building, breakrooms, restrooms, and other areas where no product, components, or materials used in the manufacture of products will be stored or handled; open to the pest control technician to perform any necessary service
- 3.2 **Partially restricted areas** – areas which include raw material areas, finished goods storage areas, quarantine areas, packaging areas, production areas, and laboratories; serviced as necessary, but in order to prevent contamination, a Quality designee shall accompany the pest control contractor while servicing the respective areas, with only non-chemical treatments used in these areas
- 3.3 **Totally restricted areas** – areas which include manufacturing and packaging areas; not serviced by the pest control company but monitored for evidence of insects or rodents; service will be requested only if a problem is discovered and written approval has been

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granted by both Manufacturing Management and Quality Management

3.4 **Passive Treatment** – includes, but is not limited to the use of baits, traps and other non-chemical pest control methods

3.5 **CFR** – Code of Federal Regulations

3.6 **SDS** – Safety Data Sheets

4.0 References

4.1 E-601, SOP, Vendor Qualification

4.2 C-502, SOP, Record Storage, Retention, and Destruction

5.0 Responsibility

5.1 It is the responsibility of Quality Management to review pest control services and ensure that appropriate measures for pest control are taken when necessary.

6.0 General Requirements

6.1 A certified and licensed pest control service provider will be contracted to periodically treat the facility and perimeter of the building as required per this procedure.

6.2 The pest control contractor shall be trained on this procedure and the service provider will be included on the Approved Suppliers List per SOP E-601 Vendor Qualification. The contractor must sign off on the Contractor Agreement for Facility Access document which stresses GMP, Safety, PPE, and company enforced restrictions.

6.3 Only approved contractors will be allowed to perform pest control services inside the facility. A copy of the current business license, indemnity insurance, and state certification shall be retained in the Pest Control Management Manual.

6.4 The approved pest control contractor shall supply a list of pesticides, along with SDS for

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pesticides used within the facility. Only approved chemicals that conform to federal, state and local ordinances shall be used during treatment. All chemicals shall be used in a manner consistent with their labeling. Quality Management must approve the list of pesticides and provide written approval before a change in pesticides is made.

- 6.5 To minimize the possibility of pest infestation, live plants will not be permitted in areas where product, components, equipment, or tools that are used to manufacture product are handled, processed, inspected, or stored.
- 6.6 Insect light traps are strategically placed inside of the facilities to minimize the intrusion of flying insects. They are checked, cleaned, and maintained by the pest control contractor.
- 6.7 A Pest Sighting Report is maintained by the pest control service to document all reported pest sightings. If pests are sighted in any area, the area Supervisor or Manager is contacted and the sighting is entered into the Pest Sighting Service Report. A facility map is maintained to identify the location of internal and external pest control devices, such as bait stations and traps. The map is reviewed at least annually and updated by the pest control company as needed. A map will be maintained for each respective facility utilized by Ion Nutritional Labs, as appropriate.

7.0 Procedure

- 7.1 The pest control contractor will be escorted by Facility Management or designee to ensure no areas are contaminated. The pest control contractor shall apply pesticides on a monthly basis, at a minimum (with treatments no less than 45 days apart) with additional applications as required and/or requested.
- 7.2 The pest control contractor shall document the date of service, Technician name, the reason for visit, specific actions taken to address reported sightings (if not addressed in report) and initial the entry, indicating service completion.
- 7.3 The pest control contractor provides a report upon completion of service, indicating all areas treated and chemicals used. Quality Management reviews these reports periodically.

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- 7.4 Baits are enclosed in labeled, tamper-proof bait stations. Anticoagulant rodenticides may be used in non-restricted areas only. No pesticide materials shall be used in partially and totally restricted areas as part of the normal monthly extermination program.
- 7.5 The pest control contractor may only apply pesticide in non-restricted areas.
- 7.6 A barrier application of pesticide on the outside perimeter of the facility/building shall be used to deter the invasion of insects and rodents as needed.
- 7.7 The pest control contractor may only use passive treatment, non-chemical (traps, baits) in partially restricted areas.
- 7.8 The pest control contractor may not apply pesticides or use passive treatment in totally restricted areas.
- 7.9 If service is required or suggested in totally restricted areas, the following is required:
- 7.9.1 Quality and Production Management must provide written approval prior to pest control service.
- 7.9.2 Service shall be performed only when production is not in process and when all product and equipment have been shut down, covered, or stored away.
- 7.9.3 A Production and/or Quality designee must accompany the pest control contractor during service treatment to ensure that equipment and product are not contaminated.
- 7.9.4 Chemicals shall not be sprayed directly onto products, tables, equipment, ceilings, and work-surfaces or under shelving.
- 7.9.5 The pest control contractor shall comply with all company-defined contamination control procedures when servicing controlled areas.
- 7.9.6 After treatment, Production and Quality Management will jointly determine if any follow-up cleaning is required prior to commencing operations in the treated area.

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All decisions and rationale must be documented.

- 7.9.7 Authorized personnel may perform follow-up cleaning or repairs necessary to aid in the control and eradication of insects and pests.
- 7.10 The pest control contractor shall notify Production or Facility Management of any area that needs special cleaning or repairs to prevent infestations by pests.
- 7.11 The pest control contractor must inform Quality Management of any changes of chemicals, pesticides used and their usage. This change must be documented and approved prior to the change by Quality Management.
- 7.12 The pest control contractor shall dispose of unused pest control chemicals and empty containers in accordance with regulatory requirements and ensure that empty chemical containers are not used. The contractor will also maintain and retain all chemicals/traps.

8.0 Records

- 8.1 The Pest Control Management Manual will be maintained by Quality and will include all documentation related to pest control.
- 8.2 Any activity directly affecting product quality will be reported during Management Review.
- 8.3 Facility Management is required to be made aware of the measures to be taken when they or employees come in contact with the bait station. Should contact be made, the respective Manager or Supervisor should be contacted and SDS should be referenced. Seek medical attention if required. SDS that are associated with the stations/chemicals are located in the Pest Control Management Manual. Should any aspect of the Pest Control Program be altered or changed, retraining will be provided by the qualified Pest Control Technician employed by the pest control service.
- 8.4 The pest control contractor shall conduct an annual assessment of the facility to include trend reports. Trend reports for pest activity are provided quarterly. A Quality Assurance

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Review and Program Assessment will also be conducted.

8.5 The program should be reviewed at least annually.

The service books and all related documentation will be maintained as per SOP C-502 Record Storage, Retention, and Destruction.

9.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	02/06/14	Updated approved insecticides; general clarification throughout.	14-0129	L. Derrick
1	03/25/14	Clarified requirements; new service provider	14-0265	S. Millar
2	09/12/14	Added quality approval of pest control list. Clarified that only non-chemical treatments are to be used in partially restricted areas.	14-0732	D. Popp
3	01/22/15	Added reference to OTC and Management Review.	15-0086	S. Millar
4	04/10/17	Revised to reflect control of chemicals by pest control service and management training requirements	17-0390	S. Millar
5	10/11/17	Define treatment of no less than 45 days apart	17-1257	S. Millar
6	10/28/20	Scheduled document review. Revised to reflect Pest Control Management Manual and remove reference to old style manually documented service log.	CC-20-0749	S. Millar
7	07/26/24	Scheduled review: updated product types, clarified procedure throughout.	CC-24-0331	K. Burris