

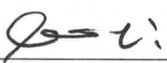



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Changes from previous version:

Section	Summary of Changes	Change Control Number


	<p style="text-align: center;">STANDARD OPERATING PROCEDURE</p> <p style="text-align: center;">Pest Control</p>	<p>Document: FAC001-1 Effective Date: 05Feb2025 Status: Effective Page 1 of 2</p>
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1. PURPOSE

The purpose of this document is to describe the procedure in case of emergency on site.

2. SCOPE

This SOP applies to the emergency response of the Synoligo site.

3. INTERNAL REFERENCES

Document ID	Title
QUA013	Supplier Qualification
QUA006	Record Retention

4. EXTERNAL REFERENCES

Document ID	Title
	21 CFR Part 820, Medical Device; Current Good Manufacturing Practice (cGMP) Final Rule; Quality System Regulation, Food and Drug Administration, Federal Register
	ISO 9001, Quality management systems -Requirements, International Organization for Standardization
	ISO 13485, Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes, International Organization for Standardization

5. RESPONSIBILITIES

Job Function and/or Department	Responsibility
All Personnel	It is the responsibility of all employees who generate regulated waste to comply with this procedure.

6. DEFINITION

Term	Definition

7. PROCEDURE

- 7.1. At no time shall chemical pesticides be used inside either facility.
- 7.2. Quality Assurance is responsible for selecting and retaining the pest control supplier. This supplier shall be subject to Supplier Qualification per QUA013 Supplier Qualification Procedure.
- 7.3. Strategically placed rodent stations shall be placed inside and around the perimeter of the buildings. This shall be the foremost method of averting any rodent infestation.
- 7.4. Insect light traps shall be employed in areas deemed necessary as determined by Pest Control Service Provider and Synoligo.
- 7.5. A current pest control map shall be maintained illustrating locations of rodent control stations and insect light traps.
- 7.6. If an employee witnesses any evidence of the presence of pest infestation, they shall inform Quality Assurance or their supervisor immediately. The Pest Sighting Log shall be completed as documentation of the employee's observations. Synoligo will then inform the supplier and appropriate methods of eradication shall be discussed.
- 7.7. If the supplier deems that additional steps need to be taken during their pest control visits, such advice shall be considered by Synoligo on a case-by-case basis and further action taken as needed.
- 7.8. Application of appropriate products applied to the outside perimeter of the building shall be considered to avert the seasonal challenge of ants or other insect infestation.
- 7.9. After each visit a signed copy of the service report shall be given to QA or Facilities to initial/date, and to keep on file as objective evidence of pest control service.
- 7.10. Records will be retained with QA in accordance with QUA006 Records Retention Policy.