



BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Pest Control for the Biopharmaceutical Development Program
SOP Number: 10301
Revision: 04

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1. PURPOSE

This procedure defines the method used for pest control within identified CGMP areas of the Biopharmaceutical Development Program (BDP) facilities.

2. SCOPE

This procedure is applicable to BDP facilities located at the ATRF Facility, Frederick, MD. This extends to flying insects, crawling insects, rodents, and birds. The BDP areas to be treated include, but are not limited to, Building A Floors 1, 2, and mezzanine and Building B Floors 1, 2, and 3.

3. RESPONSIBILITIES

- 3.1 BDP Facility Manager, who works for the Director of Manufacturing Program
 - Defines procedure
- 3.2 Facilities Maintenance and Engineering (FME) and Leidos Biomedical Contracts
 - Sets up interior pest control services using an outside contractor.
 - Relays written service reports to the BDP
- 3.3 The building landlord /Matan
 - Contracts exterior pest control services
- 3.4 BDP personnel / working in the locations specified in the scope of this SOP
 - Notifies Quality Engineering of any pests discovered within BDP spaces, both dead and alive.

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- 3.5 Biopharmaceutical Quality Assurance Engineering (BQAE)
- Provides quality oversight
 - Records, reviews, and files data

4. PROCEDURE

4.1 Contractor performs baiting of the ATRF interior including the exterior of CGMP facility perimeters to restrict pest invasion. Spraying is only performed on an as needed basis. CGMP areas are not sprayed or baited except by written request as a result of an approved Engineering Event (EE), per **SOP 21526 Engineering Event Management**.

4.1.1 Additional steps FME relays service reports after each service that involves BDP spaces.

4.1.2 Service Visits

4.1.2.1 Weekly for all first-floor exterior doors including mechanical closets with exterior access and all floors for stairwells.

4.1.2.2 Monthly for areas including MMIC, CUP, Manufacturing, Mezzanine, PA/QC, Development, and Loading Docks.

4.1.2.3 Service Reports include Products Application Summary detailing the products employed, Pest Activity which includes the device where found, the pest totals, and the pest type, Device Inspection Summary listing the work performed, Comments or Device Inspection Exceptions, Inspection Detail which lists the time, device details, and status including pest findings, and Products Applied section.

4.2 The ATRF landlord handles the contract for exterior pest control services.

4.3 Exterior Bait Stations

4.3.1 Outside bait stations are to be placed at various locations along the exterior of the facility.

4.3.2 The bait stations are inspected on a recommended monthly basis by the contractor.

4.3.3 Anticoagulant baits will be used in the bait stations and changed whenever necessary by the contractor.

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- 4.3.4 Exterior work is performed by a contractor selected by Matan, the landlord for the ATRF.
- 4.3.5 Bait stations and seasonal spraying are the only form of regular pest control employed for the facility exterior.
- 4.3.6 If immediate exterior pest control issues arise, a work order may be placed with FME.
- 4.4 Exterior Building Perimeters
 - 4.4.1 Landscaping plants shall not be planted around CGMP production facilities such that they can contact the building. At least 18 inches of pebbles or gravel will be maintained around the perimeter of CGMP production facilities, where grass or landscaping would otherwise be present, and will be kept free of weeds and debris.
 - 4.4.2 The contractor used by the landlord conducts at least two seasonal pest spraying on the exterior (typically spring and fall).
- 4.5 Interior Non-Toxic Glue Board Stations
 - 4.5.1 Interior, non-toxic glue board stations, inserted inside pest control boxes referred to as a “Tin Cat”, are placed up against interior walls on both sides of exterior doors and at other key locations such as between building wings or between functional areas.
 - 4.5.2 Stations are numbered and a placard is affixed to the wall above the location to verify presence and correct placement. A map showing BDP relevant GMP locations is included in Attachment 1.
 - 4.5.3 Glue board stations are configured to handle both rodents and crawling insects.
- 4.6 The detection of pests by BDP personnel in CGMP areas must be reported in writing to the BDP Facility Manager and the Quality Engineering and Validation Manager. Denote if they were dead or alive. The BDP Facility Manager notifies the ATRF FME contact via email, noting the Date, Building (room/area), and type of pest activity. If possible, collect the pest in a tube for analysis by the pest control specialist.
- 4.7 Insect Light Traps to Trap Flying Insects
 - 4.7.1 Insect Light Traps may be placed where needed. Optimal positioning prevents their light from attracting flying insects into the facility.

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- 4.7.2 Electrocutation and sticky-board types or light traps may be used in uncontrolled areas. Only sticky-board light traps are permitted in or directly adjacent to controlled areas.
- 4.7.3 Each Insect Light Trap used is identified on the map (Attachment 1).
- 4.7.4 Insect Light Traps are inspected on a monthly basis.
- 4.7.5 The contractor will document pest activity, clean the unit as needed, and check bulb operation.
- 4.7.6 Bulb replacement will be performed annually and documented on the service form.
- 4.8 Chemical Agents
 - 4.8.1 Organic chlorine insecticides (DDT like) will not be permitted as a treatment agent due to EPA restrictions, slow biodegradability, and potential health hazard.
 - 4.8.2 Rodenticides, insecticides, and fungicides will not be used in the interior to the GMP facility unless registered with the EPA (7USC, 135) and approved for use by the Facilities Manager and the Quality Engineering and Validation Manager

5. DOCUMENTATION

- 5.1 Pest control service reports are provided to the BDP via FME and reviewed by a BDP representative from BQAE.
- 5.2 Review includes the following: ensuring proper frequency of service locations as identified in Attachment 1, completeness of document, and activity adjacent to CGMP and controlled environment spaces. Any activity in such spaces should be brought to the attention of QA management. Any questions, concerns, or other issues with the report should be relayed to the FME ATRF Facility Manager to be addressed by the pest control contractor.
- 5.3 Sign and date the report on the first page and file chronologically in the Pest Control Binder located in the MEF room.
- 5.4 The BDP is not provided documentation of the performance of Matan controlled exterior services. Concerns or relevant observations regarding exterior services may be submitted to the Leidos contracts department as Matan may not be contacted directly by the BDP.



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6. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
21526	Engineering Event Management

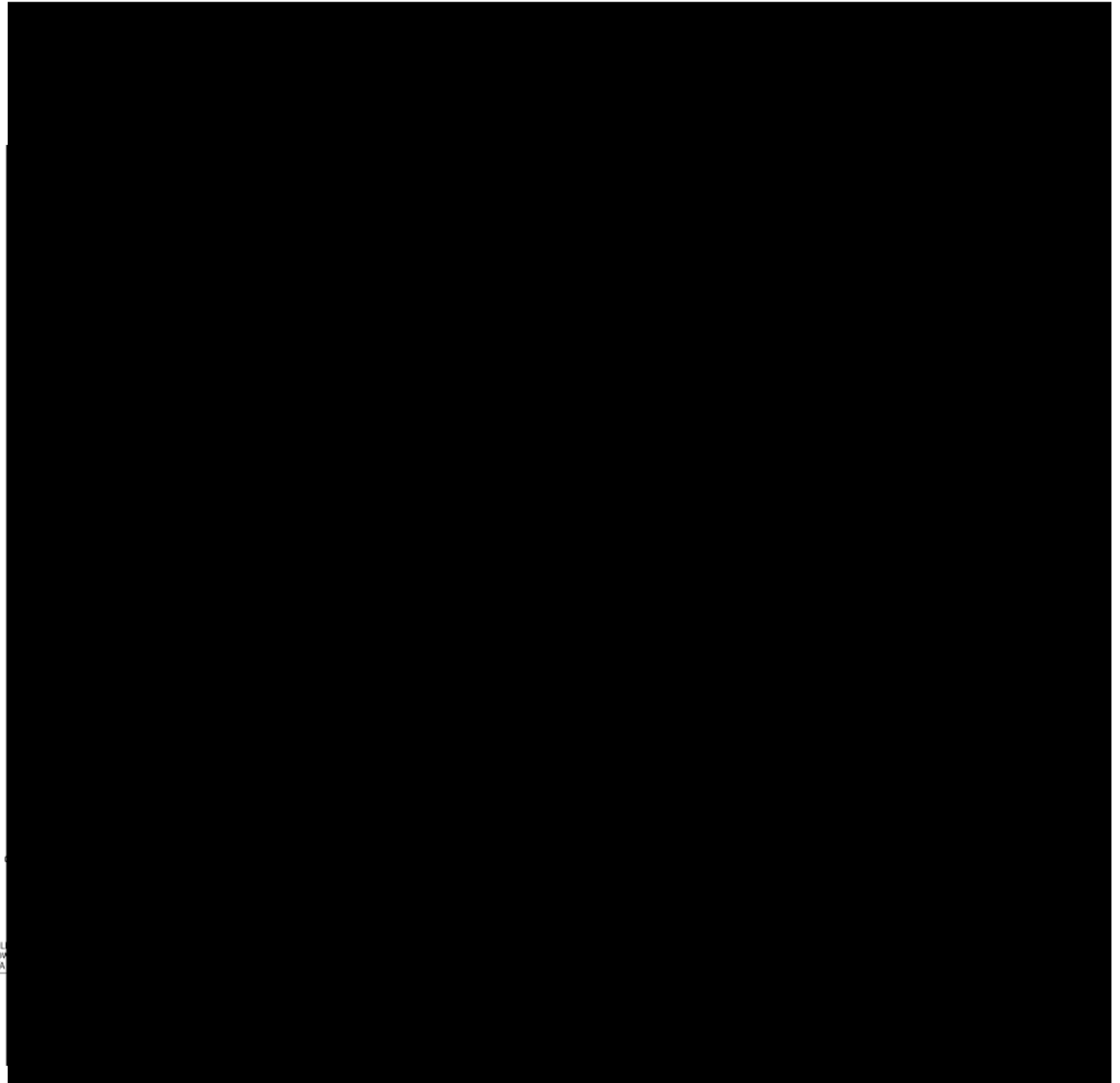
7. ATTACHMENTS

Attachment 1 Map of BDP GMP relevant pest control device locations (Pages 1-6)

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Attachment 1 Map of BDP GMP relevant pest control device locations (Page 1 of 6)



FL= Fly Light (Insect Light Trap)

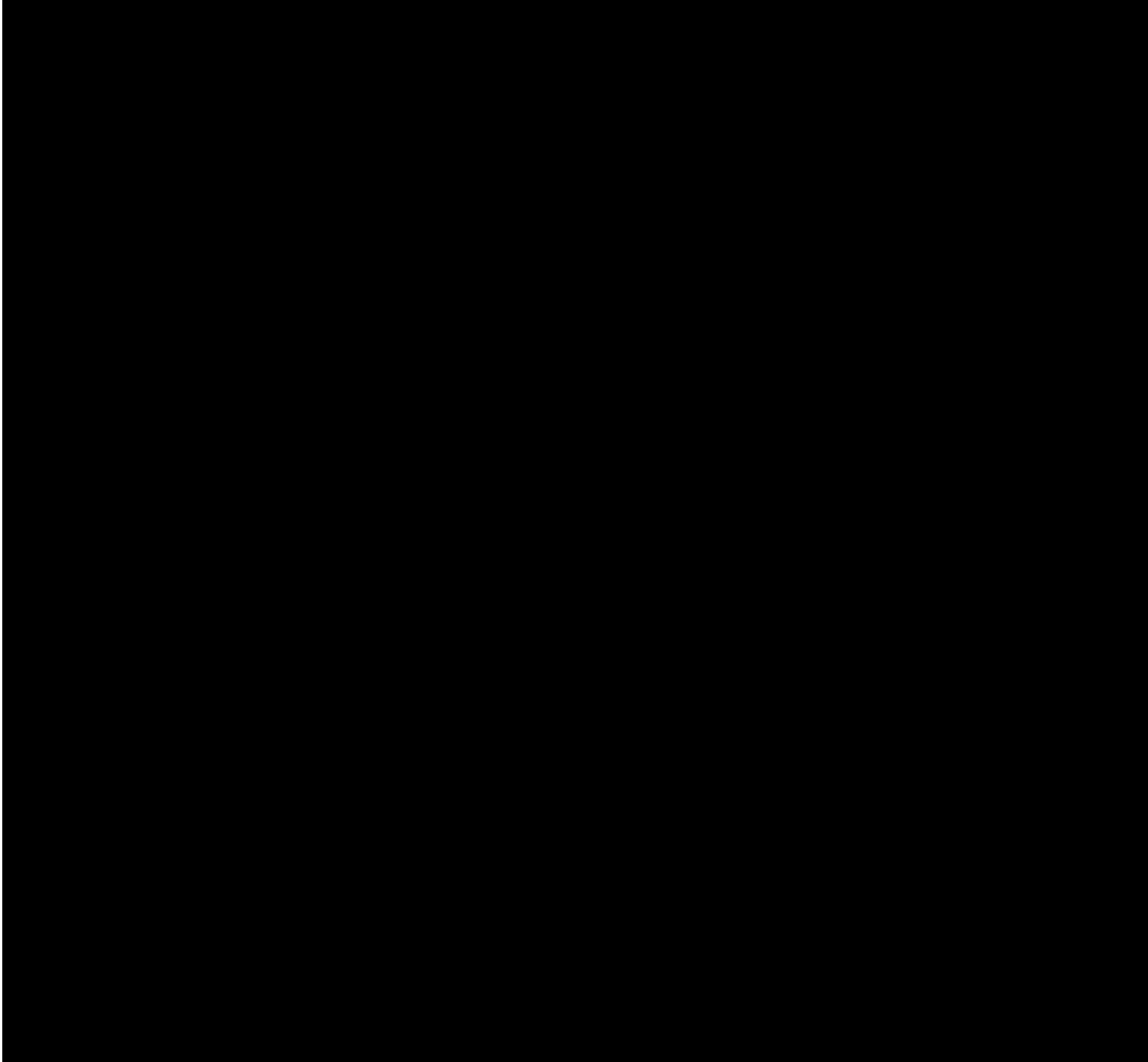
All areas portrayed in North up layout.



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Attachment 1 Map of BDP GMP relevant pest control device locations (Page 2 of 6)

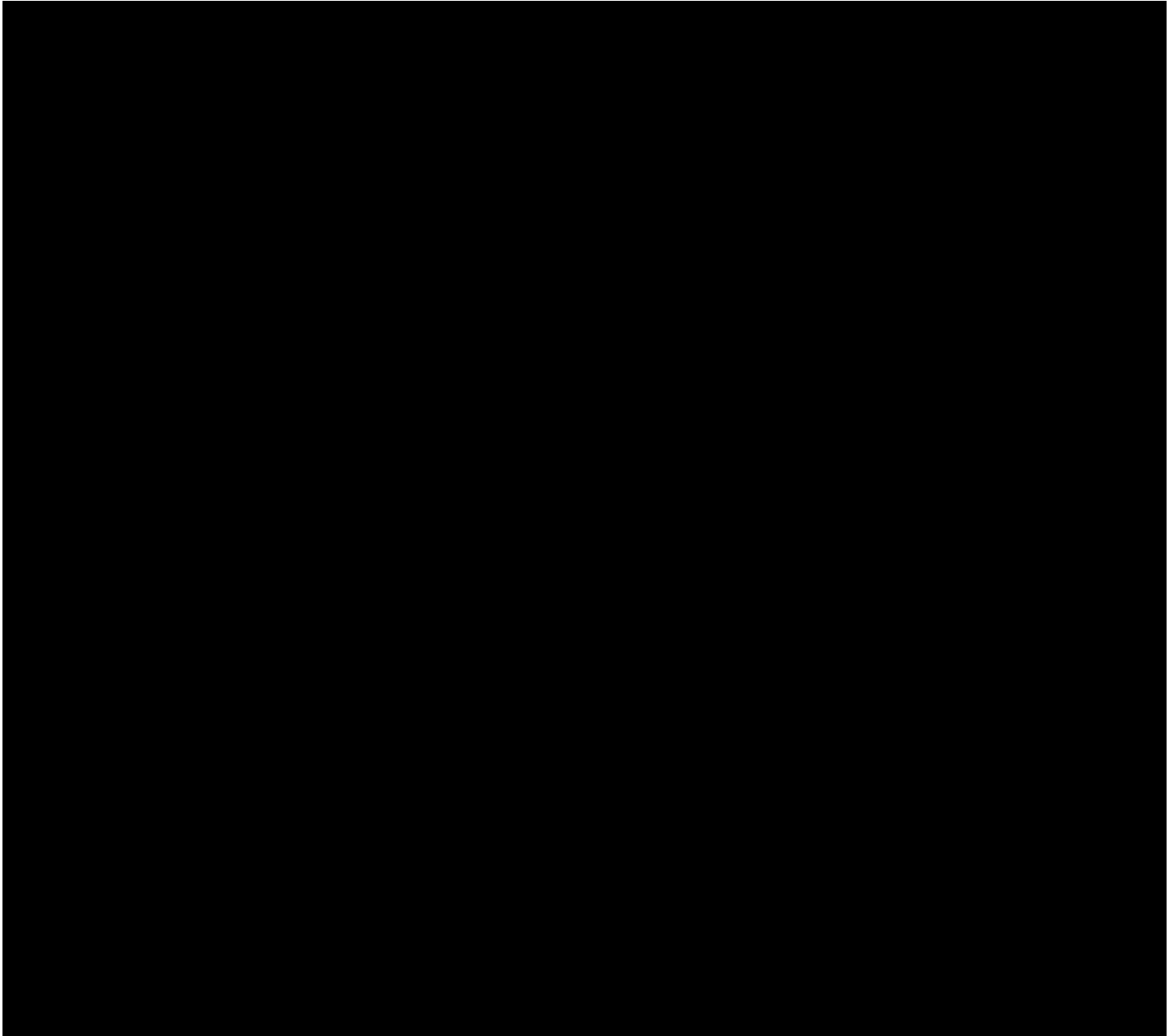




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Attachment 1 Map of BDP GMP relevant pest control device locations (Page 3 of 6)

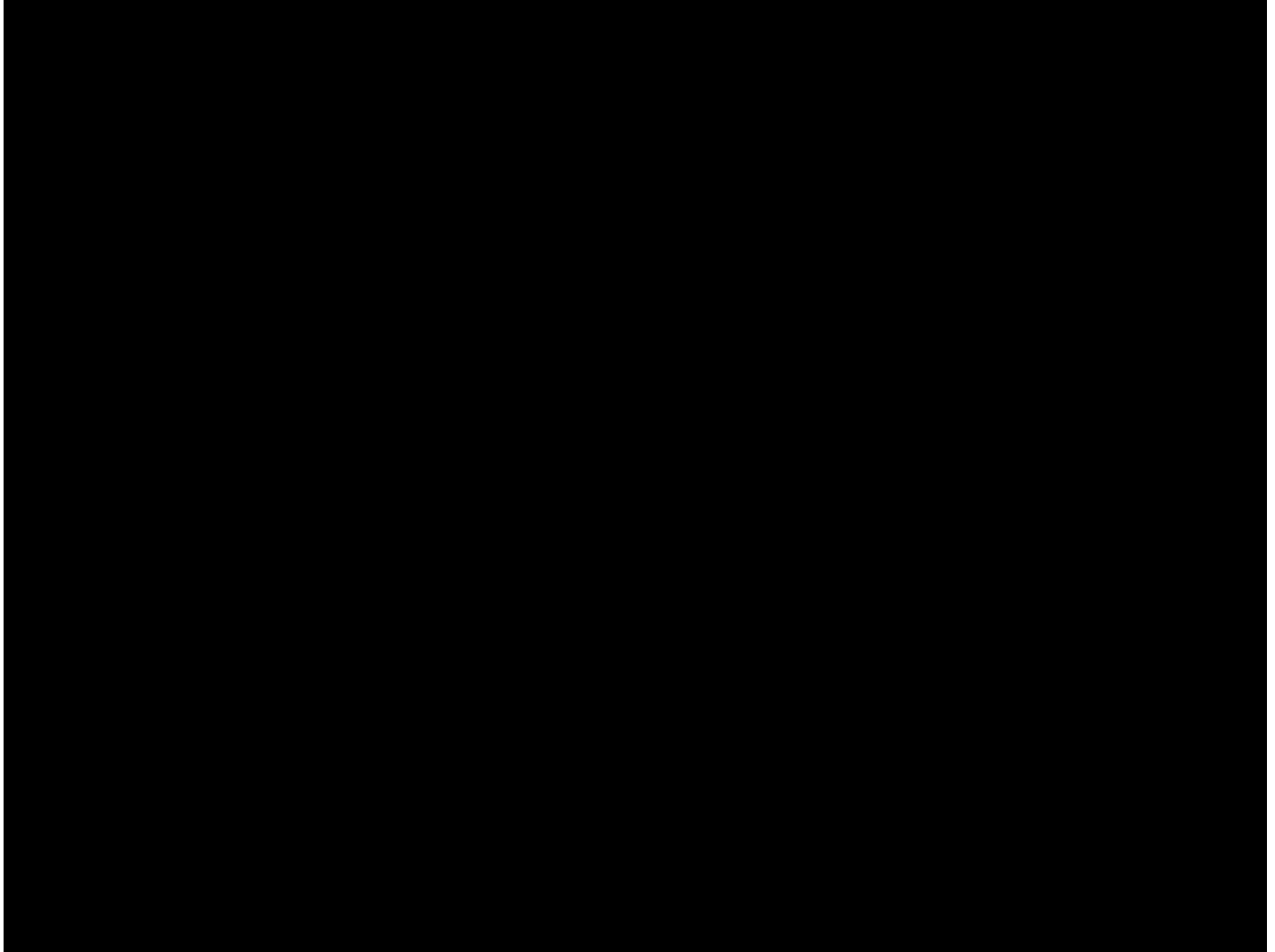




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Attachment 1 Map of BDP GMP relevant pest control device locations (Page 4 of 6)

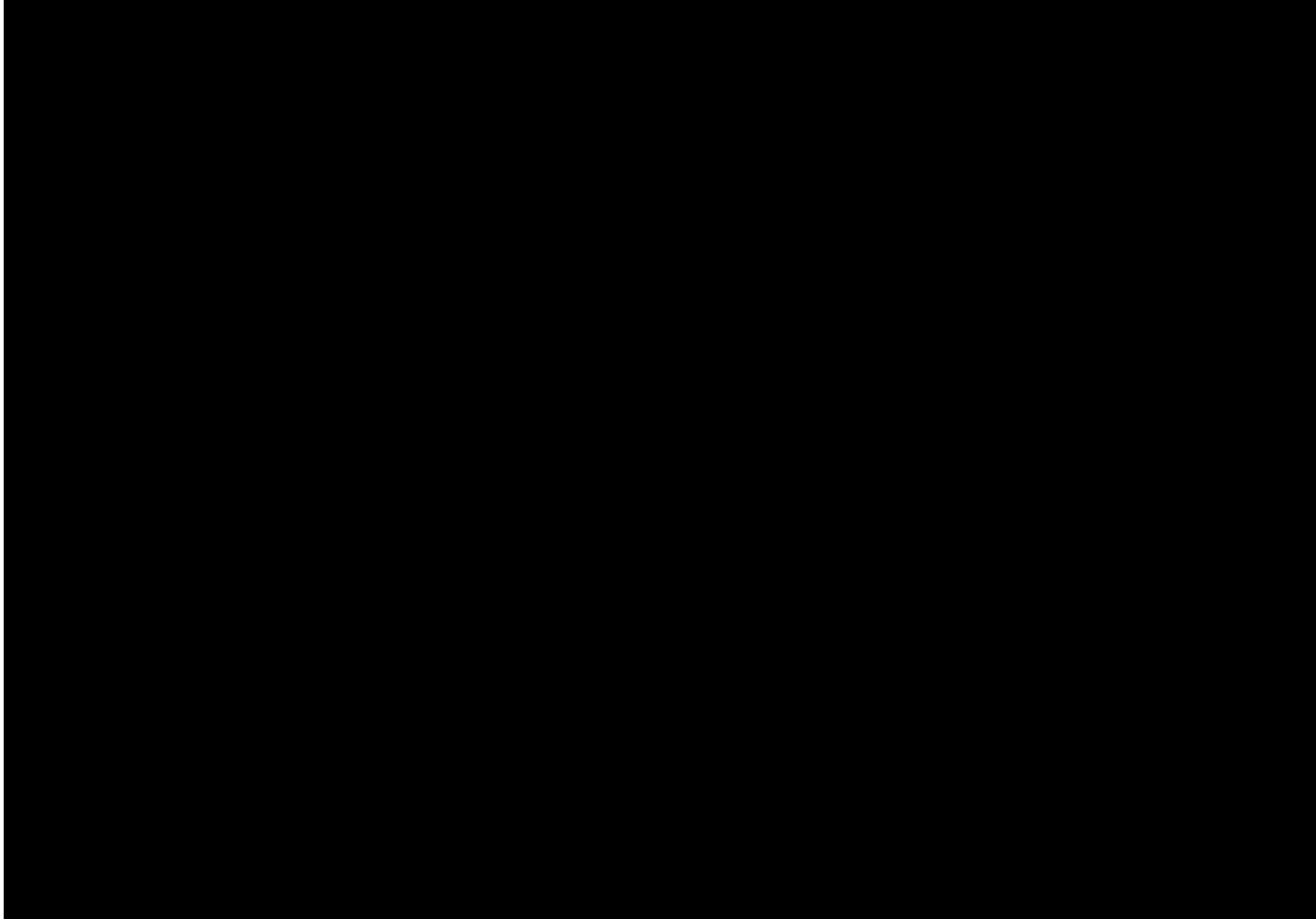




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Attachment 1 Map of BDP GMP relevant pest control device locations (Page 5 of 6)





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Attachment 1 Map of BDP GMP relevant pest control device locations (Page 6 of 6)

