The Increased Need for FDA Laboratory to Keep Their Neighbors Informed: How the FDA Northeast Laboratory Answered New York State Requirement for a Permit for Handling Regulated Medical Waste

Paul, Barbara; Bobadilla, Allan; Harrison, Tracey; Leazer, John. FDA NEL; Al Khaldi, Sufian, FDA/ORA/ORS

Abstract

The FDA Northeast Laboratory operates in two primary areas; Food & Feed and Medical Products (NFFL and NMPL). Each area has its sub-specialties in either Microbiology or Chemistry and functions to detect contaminants in our regulated commodities. In the Microbiology laboratories of both areas, samples that are found to be positive, along with untested portions and laboratory controls must be processed to rid them of the infectious contaminants before they are carted away for final disposal. The Microbiology Branch also has a Biosafety Level 3 (BSL-3) suite where samples being tested for the most virulent pathogens are handled under strict containment. This laboratory has operated within the boundaries of the Select Agent law (42 CFR Part 73, Public Health) since its inception in 2004. Compliance to this law is monitored by the Federal Select Agent Program (FSAP). In 2017, New York State revised Title 6 of their Environmental Regulations to include Parts 360 and 365 (Quality Services), specifically, Management of Regulated Medical Waste (RMW). As a result of these revisions, the BSL-3 and any all microbiology laboratories not associated with a medical facility, must be permitted by the state to handle their RMW. The first requirement from the state was that the project be handled by a New York state-licensed Professional Engineer. Additionally, a core team was developed including environmental consultants, a budgetary analyst, an industrial hygienist, a microbiologist, the FDA Associate Director of Business, a management analyst and the Director of NFFL/NMPL. The main thrust of the project was to show a comprehensive understanding and management of waste processes on the property for the past several years. Also, a full presentation of the engineering structures leading from the laboratories through accumulation, storage, treatment procedures and cartage. Following the successful presentation of the application to the state, the neighboring public was invited to participate in a meeting for full disclosure of the operation of the laboratories' waste management. The project lasted for over a year with positive results: In February 2021, the FDA Northeast Laboratory received the NYS permit to continue handle its waste.

Introduction

In 2005, Title 42 of the Code of Federal Regulations (CFR) Public Health law (42) was revised to add a new Part (73) outlining the requirements for the control of Select Agents and Toxins. Each registered facility is inspected either by Division of Select Agents and Toxins (DSAT), CDC, or Animal and Plant Health Services (APHIS), USDA, on a triannual basis to ensure compliance to the regulations. The major concern of the regulations is the security of any select agent or toxin registered to be in that facility. The Northeast Laboratory of the FDA (NEL) felt safe under the regulations of DSAT.

In 2017, New York State revised their regulations for management of medical waste, 6-NYCRR-360/365 to include any laboratory that produced such waste and was not overseen by the Department of Health (NYS-DOH). This revision included a means of ensuring that waste generated by such laboratories were treated in a manner that prevented them from becoming a threat to the environment. Adherence to these laws became the responsibility of the Department of Environmental Conservation (NYS-DEC). At the NFFL we soon understood that this management would include waste generated from our general microbiology laboratory and well as our BSL-3 laboratory. This meant that NEL had to apply to NYS-DEC for a permit to handle their RMW.

Planning for Permit Application

Core Team

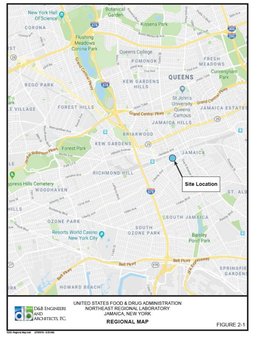
- Contractor: Mabbett and Associates
- FDA Headquarters Funding
- Contractor (Physical Engineer): D &B Assoc.
- Microbiologist
  Indust. Hygienist
  Manag. Analyst
  Lab Director
- Project Lead
  FDA Assoc. Dir. Business

Required Documents

The major portion of this project was gathering a variety of documents to demonstrate the generation, movement, treatment and storage of the BSL-2 and BSL-3 waste stream created from the processing of food and medical products in the NEL microbiology laboratories. It was necessary also, to present documents that outlined the impact of the processes to be undertaken, on the environment. A few of the details are presented as follows:

1. Facility Settings and written permission: Site location and vicinity map. Environmental Justice Plan per NYSDEC policy "CP-29 Environmental Justice and Permitting" and a full State Environmental Quality Review Act (SEQRA) form, Certificate of Occupancy

Full Environmental Assessment Form Part 1 - Project and Setting Instructions for Completing Part 1 Part 1 is to be completed by the applicant or project sponsor. Responses become part of the application for approval or funding, are subject to public review, and may be subject to further verification.



2. Engineering Report of the Property: This includes diagrams of all three floors and basement of the NFFL/NMPL with emphasis on the sites of generating, processing and final disposal or transport of RMW. The main microbiology laboratories occupy the 3rd floor of the NEL, disposal pick-up stage is on the first floor and local waste water treatment

Industrial Wastewater Decontamination System

Required Documents Cont'd

3. **Facility Manuals:** Detailed description of plans to collect, move, decontaminate and finally dispose of the RMW from both BSL-2 and BSL-3 lab sections. Description of RMW containers, autoclave and autoclave processes including validation and maintenance of control of transport of RMW to final place of disposal. Plans and procedures for Safety, Training, Biosafety at BSL-2 and 3 levels, Contingency Plans for Emergencies of different types, Spill and Safe Handling procedures.

BSL-2 Waste Stream

BSL-2 RMW Generated in laboratory → Collected in tared autoclave bag-lined pot → Pot removed to Room 3117, weighed, RMW weight calculated → RMW autoclaved 70 minutes → Transferred to Pick-up station for disposal as Municipal Solid Waste

BSL-3 Waste Stream

BSL-3 RMW Generated within BSCs in red bags → Bags closed and decontaminated on outer surfaces, removed from BSC, into larger red bag lining secondary container → Secondary container rolled to autoclave → RMW autoclaved 60 minutes, psi 15lbs → RMW removed to container await results of BI. Negative BI, packaged in plastic bag lined boxes, removed to final disposal off site.
Positive Bi, re-process autoclaving step

4. **Closure Cost Estimate:** This was necessary to show the cost were the laboratory to be disbanded and decontamination. The "1986 United States Environmental Protection Agency Guidance" document formed the basis of this estimate.

Documentation of Public Participation Meeting

When the DEC was satisfied that the application was complete, the core team was asked to do the following:

a) Make a redacted version of the full application available for public viewing

b) Notify the public, by newspapers, of a meeting in which team members would present the plan to handle NEL RMW in an environmentally safe manner.

c) Send the public's sign-in sheet, the presentation, public comments and answers to the DEC

Conclusion

The core team at the NEL found this process challenging primarily because of the need to find documents that were not often thought of or used. The process demanded many hours of self- education on the laws from the state, despite the readiness of the staff of the DEC to respond to our questions. Because this was such a time-consuming learning experience, the NEL core would willingly share what we gained with any other laboratory embarking on a similar project.

Acknowledgements

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1. Bill Gustavson , Director of Facilities Management, Hines Properties
2. Christopher post, Senior Engineer, Hines Properties
3. The Staff of the Microbiology Branch of the NEL

References

6 NYCRR Part 360 (Quality Services)
6 NYCRR Part 365 (Regulated Medical Waste)
42 CFR Part 73 (Public Health, Select Agents & Toxins)