



United States
Environmental Protection
Agency

Office of the
Administrator
(2131)

EPA 233-B-00-001
May 2000

ENVIRONMENTAL MANAGEMENT GUIDE FOR SMALL LABORATORIES



3.5 Biologically Active Substances and Wastes

Labs that work with microorganisms, recombinant DNA (rDNA) technologies, lab animals, human body fluids (blood, urine, feces, tissues, etc.) or bloodborne pathogens are special and often require unique work environments. These labs must be managed so as to reduce the potential for personnel exposure and environmental release. Wastes generated from these activities must also be uniquely managed.

Regulatory Considerations

The Federal EPA does not generally regulate biologically active substances or wastes. Exceptions include air regulations for medical waste incinerators and chemical treatment systems, biotechnology products such as bioremediation microorganisms regulated under the Toxic Substance Control Act (TSCA), and biopesticides regulated under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). OSHA has established two standards that are applicable. In addition the Centers for Disease Control/National Institutes of Health (CDC/NIH) and National Research Council (NRC) have developed guidelines that labs should follow.

OSHA Standards	OSHA promulgated the Blood-borne Pathogen Standard (BBP) (29 CFR 1910.1030) to protect workers who may be exposed to blood and OPIM (e.g., human body fluids). In addition, OSHA has promulgated a standard on occupational exposure to TB (FR 62:54159 - 54309).
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Guidelines	The CDC/NIH published guidelines that apply to labs involved in working with infectious microorganisms and rDNA. <u>Biosafety in Microbiological and Biomedical Labs</u> describes four biosafety levels and associated standard and special microbiological practices, safety equipment, and facility design criteria. The guidelines for research involving rDNA provide recommendations on equipment and procedures specific to rDNA. In addition, the NRC developed the <u>Guide for the Care and Use of Laboratory Animals</u> . Information on how to obtain these publications is provided in section 4.0 of this Guide.
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Other Federal Agency Requirement	It is important to understand that other Federal agencies such as DOT, OSHA, and the Nuclear Regulatory Commission (NRC) have regulations that address various aspects of biological waste management. Information on how to contact these agencies for more information is also in Section 4.0 of this Guide.
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State, Tribal or Local Requirements	In addition to the federal standards and guidelines, many local regulations exist to ensure proper management of biologically active substances such as rDNA. Although there are no Federal EPA requirements for the management and disposal of biological waste (including medical waste) most states do define and regulate this waste stream. Medical waste is generally defined as any solid waste generated in the diagnosis, treatment, immunization of human beings or animals, in related research, or in the production or testing of “biologicals” including cultures and
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stocks, human blood and blood products, human pathological wastes, sharps, animal waste, and wastes from isolated patients.

It is important to consult with the state office of environmental management to obtain current requirements for the lab.

Management Issues

Small labs which handle biologically active substances should consult the standards and guidelines identified above in order to establish an effective biosafety program. This program should include the following:

- Assessment to identify employees with biohazard exposure potential as well as procedures that pose an environmental risk;
- Designation of a Biological Safety Officer;
- Development of a Biosafety Plan;
- Development of an Exposure Control Plan if subject to the BBP standard (this may be integrated into the Biosafety Plan);
- Training for each employee included under the plan;
- Application of appropriate controls, including engineering controls, protective equipment, work practice, and housekeeping techniques including universal precautions, biohazard container labeling and management;
- Development and implementation of decontamination procedures;
- Development and implementation of waste handling procedures;
- Lab inspections for work practices and engineering controls;
- Medical Surveillance Program;
- Recordkeeping program for exposure monitoring, incidents such as spills or releases, and waste disposal; and
- Development and implementation of programs to comply with OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030) if applicable.

Several states require generators to complete manifests for biological active wastes.

Several key aspects of the biosafety program are outlined below.

Biohazard Communication

Biohazards should be communicated through labeling and biohazard signs. Where biologically active substances and wastes are used, handled or stored, labs should use the universal biohazard symbol. This symbol is required for bags, sharps containers, containers of contaminated laundry, refrigerators, and freezers used to store, transport or ship blood or OPIM.

In addition to labels, post a biohazard sign at the entrance to a lab. The sign should include the universal biohazard symbol, the agent in use, the criteria for entry (e.g., vaccinations, PPE) and the biosafety level. HBV/HIV research labs also require the name and telephone number of a contact person; this is a good idea for all areas.

Biohazard Training

All lab employees should be adequately trained prior to beginning work with biologically active substances. Training should occur at the time of initial assignment and whenever a change in work tasks or operations create new exposure situations. Training should be tailored to the specific job.

Biological Waste Management Program

Proper management ensures that biologically active waste is properly handled from cradle to grave. The following elements of a biological waste management program should be in place to reduce exposure to employees and the public:

- Segregate infectious waste from the general trash;
- Use the universal biological hazard symbol on infectious waste containers;
- Select the packaging material that is appropriate for the type of waste handled:
 - Plastic bags for solid or semisolid infectious waste,
 - Puncture resistant containers for sharps, and
 - Bottles, flasks, or tanks for liquids;
- Use packaging that maintains its integrity during storage and transportation;
- Do not compact infectious waste or packaged infectious waste before treatment;
- Minimize storage time;
- Select the most appropriate treatment option for your waste. Consider steam sterilization, incineration, thermal inactivation, and chemical disinfection. Note that in most cases, it is acceptable to discharge blood and blood products to the sanitary sewer, but check first with your local POTW; and
- Contact state, tribal or local authorities to identify approved treatment disposal options.

Use a licensed medical waste vendor for transportation.

Some states require transporters of infectious waste have additional permits.

Pollution Prevention and Biologically Active Substances

An effective biological waste program not only protects workers and the environment, it can also lead to cost savings from waste reduction or prevention. Lab staff and management should pursue opportunities to use materials with a lower biohazard level or alternative procedures to reduce the material handling and disposal requirements of the program.

Is It All Biological Waste?

Clinical labs in a hospital were using sharps containers for disposal of most of their biohazardous material. This was not required by the state. By changing to a corrugated disposable box with a bag liner, the labs reduced costs from \$75,000 annually to \$7,000.

The elimination of the unnecessary plastic sharp containers also helped reduce air pollution loading for the on-site incinerator.

BIOLOGICALLY ACTIVE SUBSTANCES AND WASTES PROGRAM CHECKLIST	
Action	Notes
1. Verify the lab has all applicable EPA, OSHA, CDC/NIH, DOT, and NRC regulations and guidelines available.	
2. Determine if the lab established an effective biosafety program that includes the following: • An assessment to identify employees with biohazard exposure potential; • Designation of a Biological Safety Officer; • Development of a biosafety plan (to include an Exposure Control Plan); • Employee training; • Application of appropriate controls; • Development of decontamination and waste handling procedures; • Inspections of work practices and engineering controls; • Medical surveillance program; • Recordkeeping program; and • Development of a bloodborne pathogen program.	
3. Verify that the universal biohazard symbol is placed prominently on all bags, sharps containers, containers of contaminated laundry, refrigerators, and freezers used to store, transport or ship blood or OPIM.	
4. Ensure biohazard signs are posted at the entrance to all labs using or storing biohazards. The signs should include: • The universal biohazard symbol; • The agent in use; • The criteria for entry; and • The biosafety level.	
5. Verify employee training occurred prior to working with biologically active substances and whenever there is a change in the work task or operations that create new exposure situations,	

BIOLOGICALLY ACTIVE SUBSTANCES AND WASTES PROGRAM CHECKLIST	
Action	Notes
6. Ensure the lab developed and implemented an infectious waste management program that includes the following elements: • Guidelines to separate infectious waste from general trash; • Labeling requirements (use of the universal biological hazard symbol on all containers); • Guidelines on selecting the appropriate type of packaging material to contain the infectious waste and to maintain its integrity during storage and transportation; • Requirements that do not allow for the compaction of infectious waste prior to treatment; • Procedures in place to minimize storage time; and • Guidelines for selection of the most appropriate treatment option for the waste.	
7. Determine if lab staff and management developed or studied opportunities for pollution prevention or waste management.	