

Chapter 1 Guidance, Regulations and Roles of Key Personnel

1.1 Introduction

This Biosafety Manual (BSM) provides a review of pertinent federal guidance and regulations, state regulations, information about safe work practices, safety equipment and personal protective equipment, and specific guidance for research with recombinant DNA (rDNA). Arkansas State's Biological

Safety Program is based on the premise that every member of the research community shares the responsibility for safety.

1.2 Guidance

US Center for Disease Control's (CDC) Biosafety in Microbiological and Biomedical Laboratories (BMBL)

5th Edition is the key guidance document for Biosafety. Although BMBL5 only recommends practices

("We wish to emphasize that the 5th edition of the BMBL remains an advisory document recommending

best practices for the safe conduct of work in biomedical and clinical laboratories from a biosafety perspective, and is not intended as a regulatory document though we recognize that it will be used that

way by some." BMBL5 Forward), unless otherwise specifically stated herein, compliance with all BMBL5

recommendations is mandatory for all laboratory biological activities (research, teaching, public service).

[Biosafety in Microbiological and Biomedical Laboratories \(BMBL\) 6th Edition | CDC Laboratories](#)

NIH Guidelines is also a key guidance document for this manual. Whereas BMBL5 recommends practices, NIH Guidelines specifies practices; "The purpose of the NIH Guidelines is to specify practices...." (NIH Guidelines Section I-A. Purpose). Although these NIH Guidelines closely follow the recommendations of BMBL6, in some cases the guidelines are more restrictive. In certain cases, this

manual will adopt the more restrictive practices of the Guidelines, regardless of whether rDNA is involved. The advent of multi-PI labs precludes separate consideration of BMBL6 and the Guidelines. In

such cases, the specific guideline will be referenced and explained.

[NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules \(NIH Guidelines\)](#)

1.3 Regulations

Ark. Code Ann. § 20-7-109 and Ark. Code Ann. §§ 20-32-101 - 112 Rules and Regulations Pertaining to the Management of Medical Waste from Generators and Health Care Related Facilities governs management of biological waste.

[Medical_Waste_Regs_2016_FINAL.pdf](#)

US Department of Transportation's 49CFR Subchapter C Hazardous Materials Regulations governs shipment of infectious (biohazardous) materials.

[eCFR :: 49 CFR Chapter I Subchapter C -- Hazardous Materials Regulations](#)

1.4 Roles of Key Personnel

1.4.1 Institutional Biosafety Committee (IBC)

- Review, approve and oversee rDNA research to ensure compliance with the NIH Guidelines.
- Determines necessity of health surveillance of personnel
- Set biosafety containment levels as required by the Guidelines
- Ensure proper training for IBC members, staff, PIs, and laboratory staff and
- Report any significant problems, violations or significant research-related accidents or illnesses to NIH within 30 days. See Appendix F.
- Provide expert advice to the BSO in helping ensure safe research with hazardous biological materials

1.4.2 Biological Safety Officer

The Biological Safety Officer (BSO) should:

- Conduct lab inspections
- Develop emergency and reporting procedures
- Investigate lab accidents
- Report recombinant DNA incidents, violations of the Guidelines to the IBC
- Provide general biosafety training and
- Serve on the IBC as a voting member
- Ensure safe research with all hazardous biological materials

1.4.3 Principal Investigator

The Principal Investigator (PI) should:

- Be proficient in good microbiological techniques
- Supervise staff to ensure safety practices are followed
- Develop lab-specific SOPs for spills, exposures and/or loss of containment
- Report research-related accidents and illnesses
- Correct unsafe work practices
- Ensure biological containment is maintained and
- Instruct laboratory staff on:
 - The risk of agents used in the lab
 - Safe work practices
 - Emergency procedures for spills and exposures
 - The reasons for vaccinations and serum collection, when applicable The PI must ensure that: proper biosafety, biological waste, and shipping/ transport procedures are followed by staff; lab-specific SOPs are developed and followed for spills, exposure, loss of containment, and reporting research-related accidents and illnesses; biological containment is maintained; unsafe work errors are corrected.

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