CRR: Lab Safety

Compliance Risk Areas

Compliance Risk Areas	Related Governing Laws, Rules, Regulations, or University Policies

• Biosafety and Occupational Health Dept.	• NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)
	• Federal Select Agent Program:
	  ○ 42 CFR Part 73 - Select Agents and Toxins
	  ○ 7 CFR Part 331 - Possession, Use and Transfer of Select Agents and Toxins (plant pathogens)
	  ○ 9 CFR Part 121 - Possession, Use and Transfer of Select Agents and Toxins (animal agents)
	• Public Health Security and Bioterrorism Preparedness and Response Act of 2002
	• Biosafety in Microbiological and Biomedical Laboratories (BMBL) (CDC/NIH)
	• BOR Policy:
	  ○ Activities Involving Potentially Hazardous Biological Agents
	  ○ Activities Involving Potentially Hazardous Biological Agents

Call the Chief Compliance Officer at (612) 626-7852 with questions.

	○ Additional Procedures for Using Recombinant or Synthetic Nucleic Acid Molecules ○ Additional Procedures for Storing and Using Select Agents ○ Procedures for Dual Use Research of Concern • OSHA 29 CFR 1910.1030 Bloodborne Pathogens Standard • Respiratory Protection Standard (29 CFR 1910.134 and 29 CFR 1926.103) • U.S. Department of Transportation (DOT), 49 CFR Part 40 and the Federal Motor Carrier Safety Administration (FMCSA), 49 CFR Part 382 • U.S. Department of Transportation (DOT), 49 CFR Part 40 and the Federal Transit Administration (FTA), 49 CFR Part 655 • Guide for the Care and Use of Laboratory Animals (Guide), Eighth Edition (National Research Council 2011)
• Regulated Waste Division	• US Environmental Protection Agency (40 CFR Part 261- 268) • Minnesota Rules Chapters 7001,7045,7150,7151 Board of Regents Policy: Health and Safety • Environmental Management ○ Waste Management and Disposal

• Department of Radiation Safety	• U.S. Nuclear Regulatory Commission (NRC) (Title 10 Code of Federal Regulations)
	• MN Department of Health -Radiation Control Section (MDH) All-University Radiation Protection Committee (AURPC) Board of Regents Policy: Health and Safety
	• Radiation Safety
	  ○ Human Use of Ionizing Radiation
	  ○ Radioactive Material Use
	  ○ Use of Ionizing Radiation Producing Devices

General compliance question(s) for each risk area

1. How is compliance with relevant policies and procedures monitored?
2. What is the frequency of the monitoring?
3. Are there any recent (within 3 years) internal audit and/or external audit findings? If yes, how were the findings addressed?
4. In the past three years has there been a report of an injury that resulted in serious injury or death?
5. What are the typical noncompliance issues found and how are they corrected?
6. Describe the internal safety audit program. How are audits scheduled, who conducts them, how are findings managed/tracked?
7. Describe the training program and the role of Safety Officers. How is that training tracked and maintained?

Biosafety

1. How is compliance with the NIH Guidelines for Research Involving Recombinant or

Synthetic Nucleic Acid Molecules monitored?

   a. What aspect of these guidelines, if any, are the most difficult to achieve?

2. How is compliance with the CDC guidelines Biosafety in Microbiological and Biomedical Laboratories monitored?

   a. What aspect of these guidelines, if any, are the most difficult to achieve?

3. How is compliance with the UMN Regents Policy Activities Involving Potentially Hazardous Biological Agents monitored?

   a. What aspect of this policy, if any, are the most difficult to achieve?

4. How is the individual employee's day-to-day compliance with the Exposure Control Plan for Bloodborne and Other Pathogens monitored?
5. How are individuals who are required to complete the Bloodborne Pathogen Training Program identified?
6. What is the current compliance rate with the Bloodborne Pathogen Training Program?
7. In the past three years how many workplace exposures have there been involving recombinant DNA?
8. In the past three years how many sharps exposures (e.g. needle sticks) have been reported?
9. How is compliance with the sharps injury log completion and retention requirements monitored?
10. Are sharps injury logs reviewed periodically for safety issue trending? If so, please describe the process.
11. In the past three years, how many positive drug and alcohol random tests have been found?
12. How is compliance with the Drug and Alcohol Regulations and retention requirements monitored?
13. How is compliance with autoclave testing log completion and retention requirements monitored in BSL-3 labs?
14. How is compliance with federal, state, and international requirements related to the shipping, of biological materials monitored?
15. How is the transfer or disposal of biological materials monitored?

16. How is the compliance to the Guide for the Care and Use of Laboratory Animals monitored?
17. Describe the process for reporting biosafety compliance to senior leadership, including the typical content of the reports and the senior leaders who receive the reports.

Regulated Waste Division

1. Have there been any rule changes by the EPA in the last three years that significantly changed activities related to hazardous waste? If so, what were the results of the changes?
2. What is the current compliance rate with employee training requirements related to hazardous waste?
3. How is compliance with the University's Chemical Waste Disposal Procedures monitored?
4. How is compliance with federal, state, and international requirements related to the shipping, transfer, or disposal of hazardous waste and hazardous materials monitored?
5. Describe the process for reporting hazardous waste compliance to senior leadership, including the typical content of the reports and the senior leaders who receive the reports.

Department of Radiation Safety

1. Which steps in the review and approval process used by the All-University Radiation Protection Committee (AURPC) are the most difficult to achieve?
2. How is compliance with the radiation safety badge program monitored?
3. In the past three years has there been an accidental exposure involving ionizing radiation? If so, please describe.
4. For each of the following, describe how record keeping is tracked, managed and monitored:
    a. Permits
    b. Registration

c. Safety Surveys
d. Record keeping
e. Incident reporting

5. What is the 3 year compliance rate with radiation safety survey completion?
6. What is the current compliance rate with employee training requirements related to Radiation Safety?
7. Describe the process for reporting radiation safety to senior leadership, including the typical content of the reports and the senior leaders who receive the reports.