Automatic Failure Categories for Lab Inspections

Online Chemical Inventory

Every lab must have an inventory of all hazardous chemicals used or stored in the lab. Inventories must be updated as needed to reflect chemical storage and use changes, with a minimum annual review and update required. Failure to meet this requirement will result in an automatic failure of the lab inspection.

IBC Protocol

If the lab works with recombinant DNA, infectious microorganisms, replication-defective viral vectors, human or animal tissues or cell cultures, biological toxins, or hazardous chemicals in animals or tissue culture the lab must have an approved Recombinant DNA and Hazardous Research Materials Protocol. Failure to meet this requirement will result in an automatic failure of the lab inspection.

Gross Disregard for Use of Personal Protective Equipment (PPE)

Handling of hazardous chemicals should be performed per the lab-specific training and using lab best practices. When handling hazardous chemicals, appropriate PPE such as gloves, eye protection, face shields, lab coats, and closed-toe shoes as well as engineering controls such as fume hoods should be used. Appropriate PPE should be determined by the laboratory hazard assessment. Gross disregard of use of PPE will result in an automatic failure of the lab inspection.

Select Agent Toxins

Certain toxins are subject to Select Agent regulations. Registration with EH&S through a Recombinant DNA and Hazardous Research Materials Protocol is required regardless of quantity, though registration with the federal government is not required for exempt quantities of these toxins. All Select Agent toxins must be kept securely locked and a current, accurate inventory must be kept of acquisition, use, and disposal to ensure that the exempt quantity is never exceeded. Failure in any of these requirements will result in an automatic failure of the lab inspection.

DEA Controlled Substances

Certain drugs (narcotic and non-narcotic) and chemicals fall under the jurisdiction of the Missouri Bureau of Narcotics and Dangerous Drugs (BNDD) and the US Department of Justice (DOJ) Drug Enforcement Administration (DEA). These drugs and chemicals are known as Controlled Substances and must be maintained under certain restrictions. These materials must be securely locked in a substantially constructed cabinet and access to these materials must be restricted to individuals who have completed a background check through Human Resources (HR). Initial and annual physical inventory reconciliations must be performed and current records of acquisition, use, and disposal must be maintained and readily retrievable. Failure in any of these requirements will result in an automatic failure for the lab.
**Food/Beverage Consumption**

Consumption of food and beverages in the lab presents a risk for ingestion of hazardous chemical, biological, and/or radioactive materials. To eliminate this risk, consumption and storage of food and beverages outside of approved locations (“Clean Areas”) is not allowed. Evidence of food and/or beverage consumption will result in an automatic failure of the lab inspection.

**Unwanted Material/Hazardous Waste Management**

Regulatory agencies place great importance on the proper disposal of unwanted material/hazardous waste. To assist labs in maintaining compliance in this area, EH&S places an important focus on improper disposal or management of unwanted material/hazardous waste, including:

- Uncapped or open containers
- Improper labeling of containers
- Containers with a start date greater than the regulatory time limit

Failure of any of these items will result in an automatic failure of the lab inspection.

**Sharps**

Improper disposal of metal sharps in the regular trash and into biohazard waste containers not approved for sharps disposal present a risk to laboratory, custodial workers, vendors and waste handlers. Improper disposal of metal sharps into either of these containers will result in an automatic failure of the lab inspection.