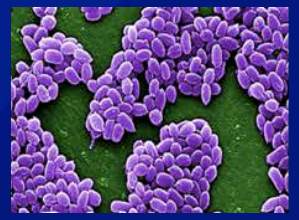


Biosafety Risk Assessments

August 15-17, 2018
Responsible Official Workshop

Assessment of BSAT Biosafety Risks

Select Agent Regulations (SAR) Section 12

(Biosafety/Biocontainment)

An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin given its intended use.

Risk

" Risk, in general, is defined as a function of the likelihood an adverse event involving a specific hazard and/or threat will occur, and its consequences."

" The likelihood of risk affects whether or not the incident happens… "

" The consequences of risk occur after the incident has happened…"

in Laboratory Biosafety and Biosecurity Risk Assessment Technical Guidance Document. Sandia National Laboratories p6 -18 http://www.aam.org.ar/descarga-archivos/Laboratory-Biosafety-Biosecurity-Guidance.pdf

Biosafety Risk Assessment

" An analytical procedure designed to characterize safety risks in a laboratory. "

…." allows a laboratory to determine the relative level of risks its different activities pose"

…." helps guide risk mitigation decisions so they are targeted to the most important risk."

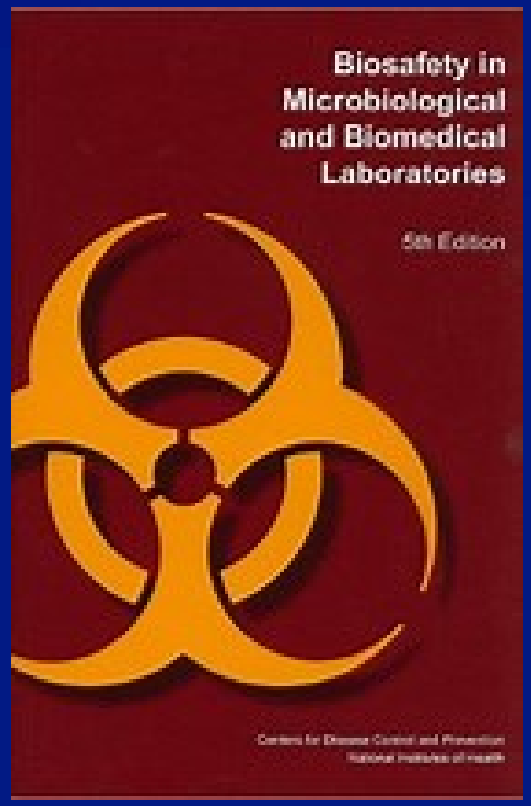
…." should consider every activity and procedure in a laboratory that involves infectious disease agents.

in Laboratory Biosafety and Biosecurity Risk Assessment Technical Guidance Document. Sandia National Laboratories , p7

http://www.aam.org.ar/descarga-archivos/Laboratory-Biosafety-Biosecurity-Guidance.pdf

Laboratory Biosafety Hazards

- Hazardous Characteristics of Agents
- Hazards Associated with Laboratory Procedures
- Hazards Associated with Work Practices and Safety Equipment
- Hazards Associated with Facility Safeguards



in Laboratory Biosafety and Biosecurity Risk Assessment Technical Guidance Document. Sandia National Laboratories , p7
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Hazardous Characteristics of Agents

SAR Section 12 Biosafety/Biocontainment

The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent …. and must include the following provisions:

- The hazardous characteristics of each agent or toxin

BMBL

- Pathogenicity / virulence of agent
- Route(s) / method(s) of transmission
- Agent stability
- Infectious dose
- Concentration and volume of agent
- Scale and manipulation of agent

Hazards Associated with Laboratory Procedures

SAR Section 12 Biosafety/Biocontainment

The biosafety plan must include the following provisions:

- the biosafety risk associated with laboratory procedures related to the select agent or toxin

- written procedures for each validated method used for disinfection, decontamination or destruction, as appropriate, of all contaminated or presumptively contaminated materials

BMBL

- Parenteral inoculations (sharps)
- Spills and splashes
- Ingestion
- Animal bites and scratches
- Inhalation exposures to aerosols
- Procedures involving animals
- Agent concentration
- Procedural complexity

Hazards Associated with Work Practices and Safety Equipment

SAR Section 12 Biosafety/Biocontainment

The biosafety plan must include the following provisions:

Safeguards in place with associated work practices including:

- personal protective equipment,
- safety equipment and
- containment equipment

BMBL

Protection depends on:

- worker adherence to good microbiological practices
- correct safety equipment use
- worker training, experience and knowledge
- Correct use of personal protective equipment

Hazards Associated with Facility Safeguards

SAR Section 12 Biosafety/Biocontainment

The biosafety plan must include the following provisions:

Safeguards in place to protect entity personnel, the public, and the environment from exposure to the select agent or toxin including, but not limited to:

.....engineering controls and other facility safeguards

BMBL

"Facility safeguards help prevent the accidental release of an agent from the laboratory"

"Consideration of facility safeguards is an integral part of the risk assessment"

Examples:

- Heating, ventilation, and air conditioning (HVAC) systems

- Autoclaves and effluent decontamination systems (EDS)

Facility Maintenance-Related Risk Assessments

Institute for Animal Health
Pirbright, England, 2007

On August 3, 2007, a Foot-and-mouth disease virus (FMD) outbreak was confirmed on two farms in Surrey, England. The source of the FMD was determined to be a release from a vaccine production facility at the Institute for Animal Health (IAH) located near Pirbright, England.

in Enserink, M., Science Vol 317, p. 1486, 14 September 2007

Institute for Animal Health
Pirbright, England, 2007

"Neglected, leaky pipes and England's record-setting wet summer likely combined to cause the country's recent outbreak of foot-and-mouth disease (FMD)."

"the National Farmers' Union puts the accident's economic impact at more than $100 million"

in Enserink, M., Science Vol 317, p. 1486, 14 September 2007

Institute for Animal Health
Pirbright, England, 2007

"the reports assign most of the blame for the outbreak to the Institute for Animal Health (IAH), a government lab at the same site in Pirbright that owned the aging network of underground wastewater pipes and was aware that it needed maintenance."

in, Enserink, M., Science Vol 317, p. 1486, 14 September 2007

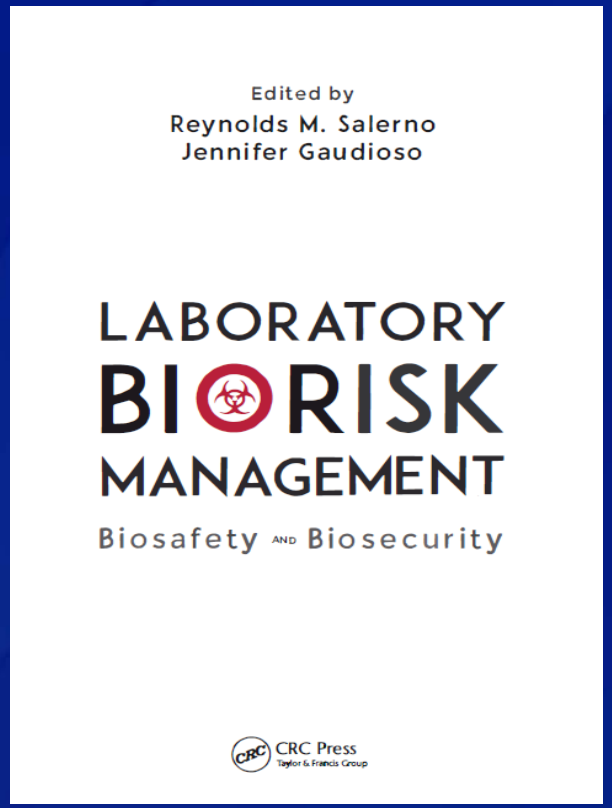
Institute for Animal Health
Pirbright, England, 2007

According to Andrew Mathieson, an environmental health expert at the University of the West of England in Bristol:

"The findings are a blow to the reputation of IAH….. But they should also serve as a more general warning….. What about the many other research establishments of the same age?"

in Enserink, M., Science Vol 317, p. 1486, 14 September 2007

Maintenance-Related Hazard Assessments



Chapter 7. *Operations and Maintenance Concepts.* Pinard W., Breitenbaumer, S. and Kumin, *D*. (2015)

In Laboratory Biorisk Management. Salerno, RM and Gaudioso J., Eds. CRC Press.

Laboratory Hazard Environments

LOW HAZARD LAB ENVIRONMENTS

- Access to laboratory equipment and systems at all times
- No special safety measures
- Low constraints for disposal of materials
- Low requirements for space to be safely accessible
- Planned and unplanned stand-downs

Laboratory Hazard Environments

HIGH HAZARD LAB ENVIRONMENTS

- Limited access to laboratory equipment and systems for maintenance
- Special safety and security measures needed for workers
- Maintenance work may be limited in scope during operations
- Complex procedures for entry and exit of materials and workers
- Required planning prior for any stand-downs

Laboratory Hazard Environments

EXTREME HAZARD LAB ENVIRONMENTS

- Access to laboratory equipment and systems strictly limited
- Special safety and security measures
- Specialized PPE for maintenance workers in "hot" zones
- Maintenance work very limited during operations
- Complex procedures for entry and exit of materials
- Limited maintenance should be allowed during operations

Maintenance Strategies for Biological Laboratories

Reactive Maintenance

Preventive Maintenance

Predictive Maintenance

Reliability Centered Maintenance

Reactive Maintenance

ADVANTAGES

- "Run it until it breaks"
- Most commonly used strategy
- Corrective action taken upon failure or obvious threat of failure
- Early in operation, little or no cost for maintenance
- Maximizes use of parts

DISADVANTAGES

- Can lead to unpredictable failure events
- Relies on failure to initiate action
- Failure could have either a minor or a significant risk
- Unscheduled shutdowns could be required

Preventive Maintenance

ADVANTAGES

- The periodic and planned actions taken to maintain a piece of equipment within designed operating conditions
- Maintenance performed at pre-determined stage
- Shutdowns can be planned
- Lowers likelihood of failure
- Provides predictability and flexibility about when equipment will be inoperable

DISADVANTAGES

- Replaces parts before they break
- Does not eliminate catastrophic failure entirely
- Unscheduled shutdowns could be required

Predictive Maintenance

ADVANTAGES

- Uses measurements to quantify the level of degradation
- Does not rely on fixed predetermined time intervals
- Reduces likelihood of failure by detecting equipment wear
- Can extend equipment life

DISADVANTAGES

- Costs of monitoring equipment
- Requires continuous or periodic monitoring

Reliability Centered Maintenance

- “The process that is used to determine the most effective approach to maintenance" (National Aeronautics and Space Administration)

- Realizes that some equipment is more important than others and some failures will not compromise safety

- Not time dependent

- Combines benefits of predictive and preventive strategies

- Involves identifying actions that will reduce the probability of failure and which are cost effective

Breakout Exercise:

Assessment of Risks Associated with Maintenance Strategies used in High Containment Laboratories

Breakout Exercises

1. Select the oldest and / or most complex registered laboratory at your institute.

2. Identify maintenance strategies in use for key infrastructure components including:
    a. HVAC system and filters
    b. Utilities (electrical, back-up power)
    c. EDS
    d. Autoclaves, waste digesters and other solid waste disposal systems

3. Identify obstacles, limitations and other maintenance related problems

Discussion

Federal Select Agent Program

CDC: lrsat@cdc.gov or 404-718-2000

APHIS: AgSAS@aphis.usda.gov or 301-851-3300 option 3 (voice only)