



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..."

Biosafety Risk Assessment

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

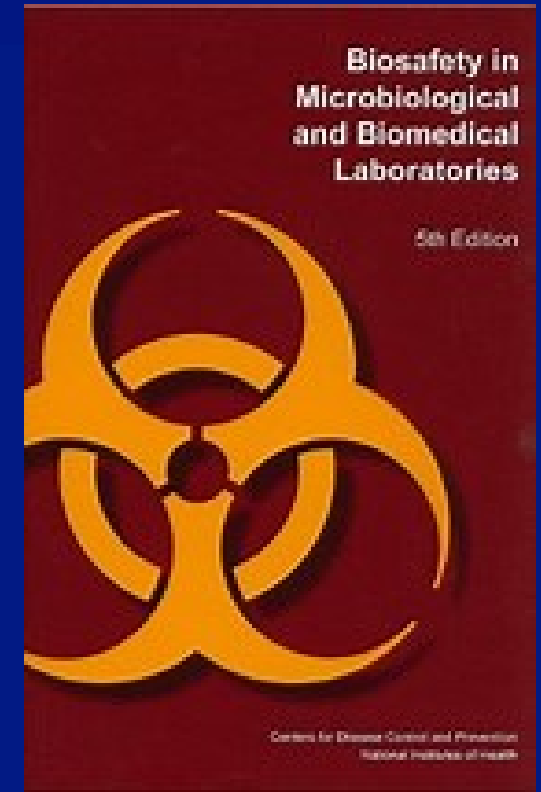
...." allows a laboratory to determine the relative level of **risks** its different activities pose"

...." 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.

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

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

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**

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- 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

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- 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**

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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**

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"**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.



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"

Institute for Animal Health Pirbright, England, 2007

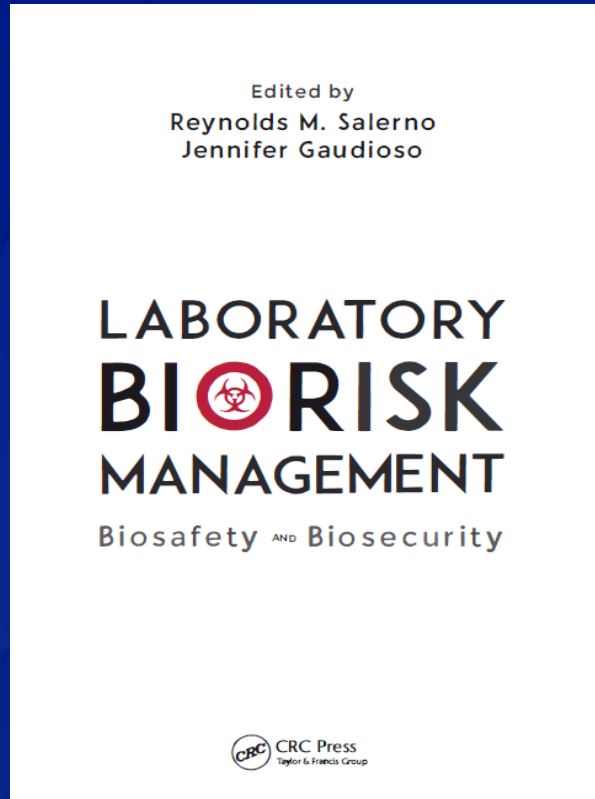
"the reports assign most of the blame for the outbreak to the Institute for Animal Health (IAH), a government lab at the same site in Pirbright that owned the **aging** network of underground wastewater pipes and **was aware that it needed maintenance.**"

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?**”

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 Gaudio 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: Irsat@cdc.gov or 404-718-2000

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

