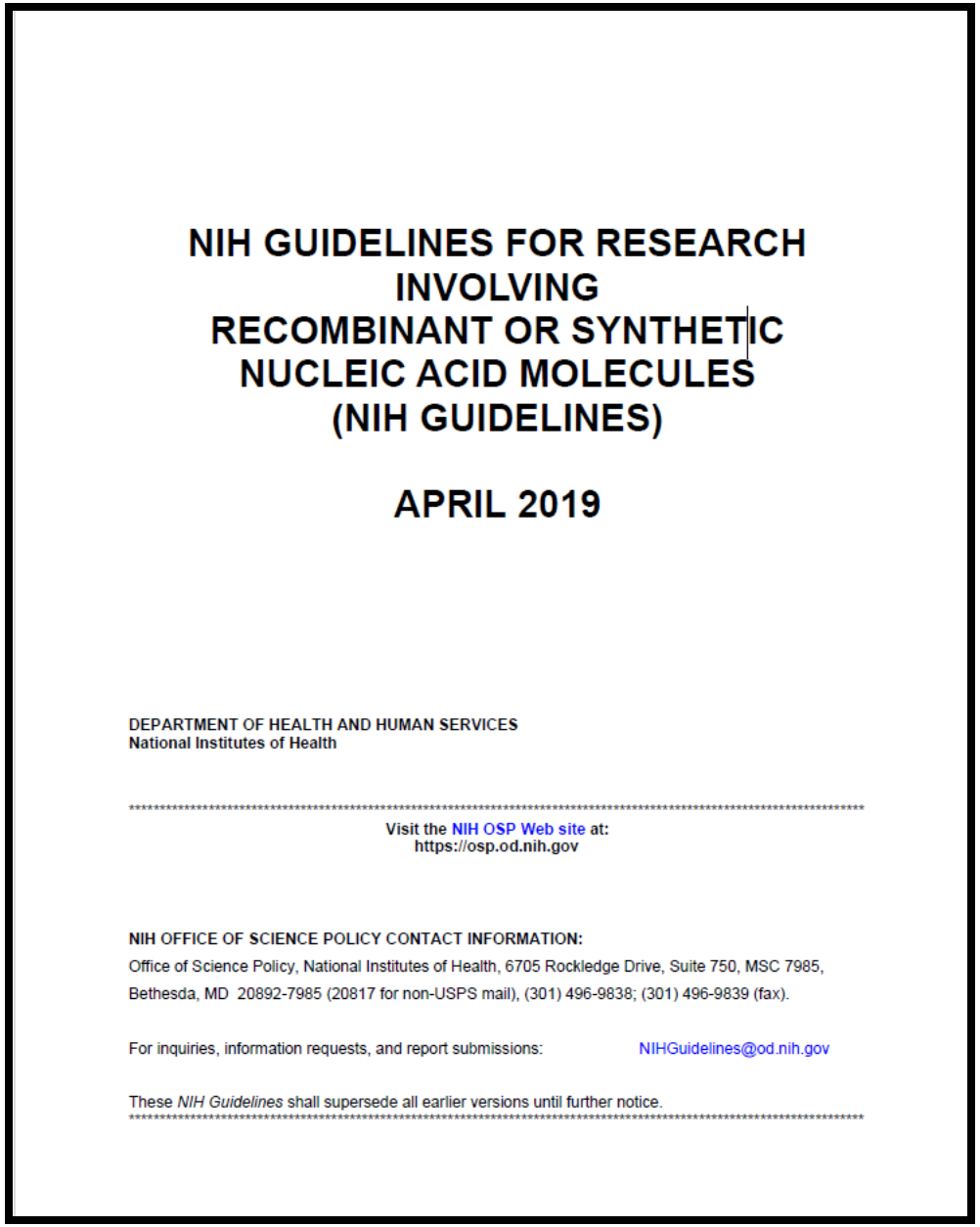
BioSafety Regulations:

- Policies, rules, and procedures for businesses and personnel working in facilities handling microbiological agents such as bacteria, viruses, parasites
- Varying levels. What is safe for Devens?
- Working with CDC and NIH Guidelines, BOH, DEC Legal Counsel and DEC IPS Peer Review Consultants, and MD



NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (NIH GUIDELINES)

APRIL 2019

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

Visit the NIH OSP Web site at:
https://osp.od.nih.gov

NIH OFFICE OF SCIENCE POLICY CONTACT INFORMATION:
Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), (301) 496-9838; (301) 496-9839 (fax).

For inquiries, information requests, and report submissions: NIHGuidelines@od.nih.gov

These *NIH Guidelines* shall supersede all earlier versions until further notice.

Table 1: Classification of Infectious Microorganisms by Risk Group

Risk Group Classification	NIH Guidelines for Research involving Recombinant DNA Molecules 2002[2]	World Health Organization Laboratory Biosafety Manual 3rd Edition 2004[1]
Risk Group 1	Agents not associated with disease in healthy adult humans.	(No or low individual and community risk) A microorganism unlikely to cause human or animal disease.
Risk Group 2	Agents associated with human disease that is rarely serious and for which preventive or therapeutic interventions are *often* available.	(Moderate individual risk; low community risk) A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.
Risk Group 3	Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).	(High individual risk; low community risk) A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.
Risk Group 4	Agents likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk).	(High individual and community risk) A pathogen that usually causes serious human or animal disease and can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.[3]

CDC 24/7

4 BIOSAFETY LAB LEVELS

CDC

BSL1

BSL1

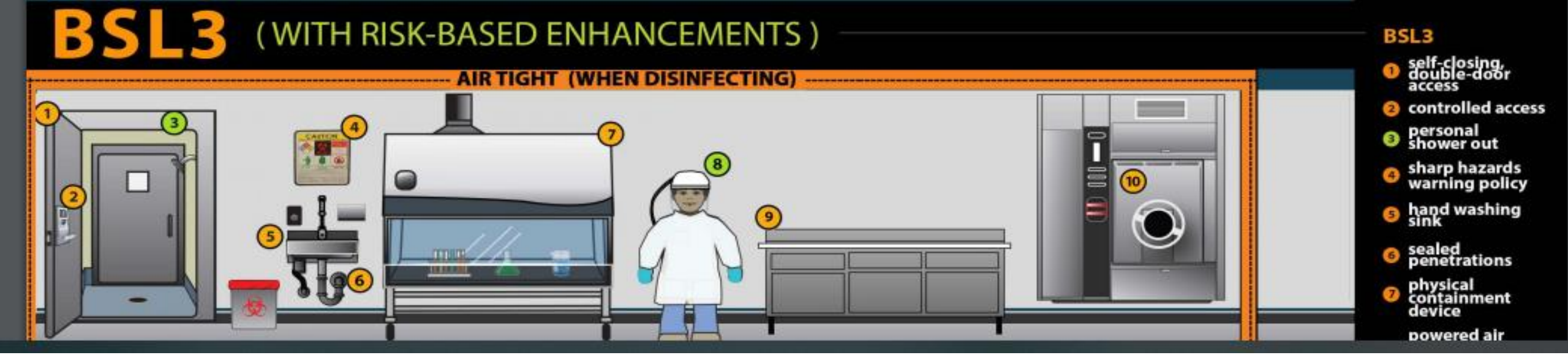
1. controlled access
2. hand washing sink
3. sharp hazards warning policy
4. personal protective equipment
5. laboratory bench
6. autoclave

Risk Group 1	Agents not associated with disease in healthy adult humans.	(No or low individual and community risk) A microorganism unlikely to cause human or animal disease.

Not known to consistently cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment. **Examples:** ***Saccharomyces cerevisiae, E. coli*** **K-12, and non-infectious bacteria**

Risk Group 2	Agents associated with human disease that is rarely serious and for which preventive or therapeutic interventions are *often* available.	(Moderate individual risk; low community risk) A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.

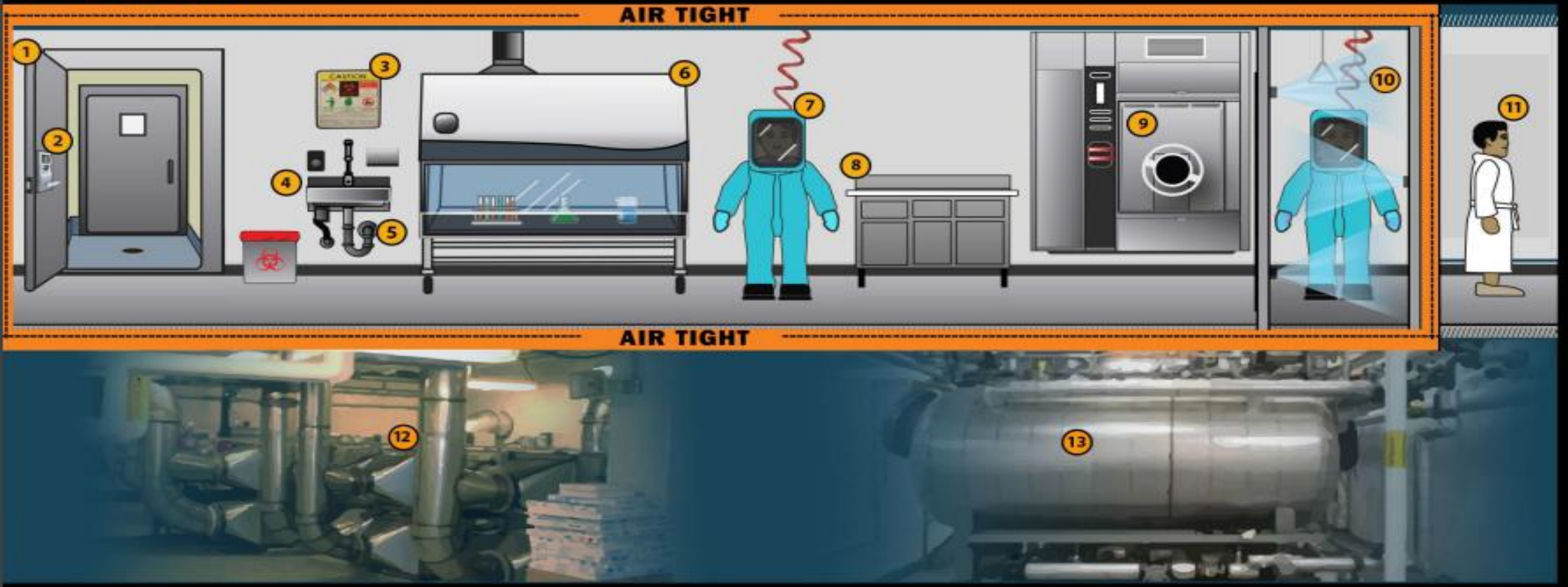
Examples: Hepatitis A virus, *Streptococcus pyogenes*, *Borrelia burgdorferi* (Lyme disease), *Salmonella* species



Risk Group 3	Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).	(High individual risk; low community risk) A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.

Examples: *Yersinia pestis* (plague), *Mycobacterium tuberculosis*, SARS, rabies virus, West Nile Virus, hantaviruses

BSL4



BSL4

1. self-closing, double-door access
2. controlled access
3. sharp hazards warning policy
4. hand washing sink
5. sealed penetrations
6. physical containment device
7. positive pressure protective suit
8. laboratory bench
9. autoclave
10. chemical shower out
11. personal shower out
12. supply and exhaust HEPA filters
13. effluent decontamination system

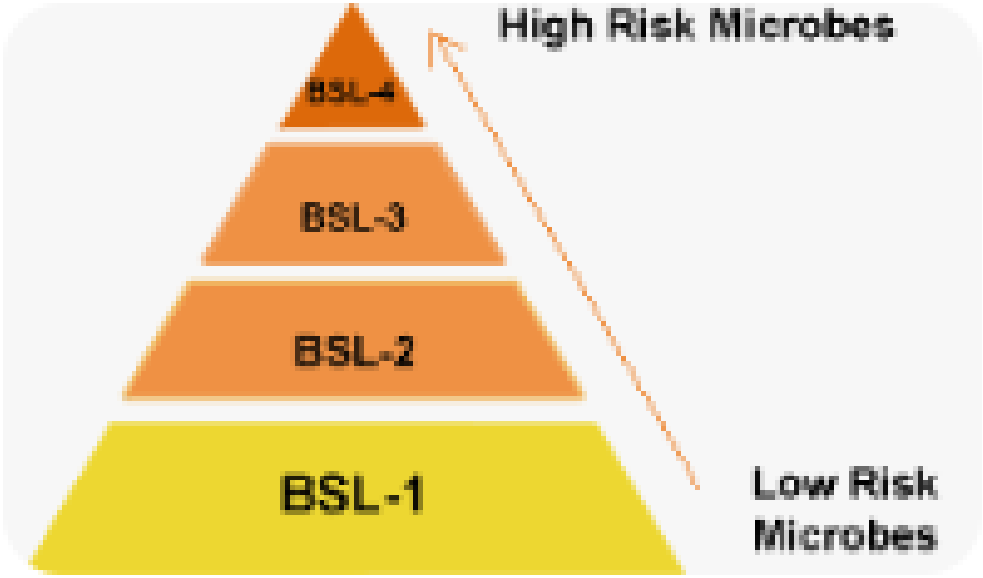
● Required safety equipment ● Risk-based enhancements

www.cdc.gov/24-7

Risk Group 4	Agents likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk).	(High individual and community risk) A pathogen that usually causes serious human or animal disease and can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.[3]	Examples: Ebola virus, smallpox virus

Draft Biosafety Policy:

- CDC NIH guidance
- Requirements to protect public health and safety of businesses, employees, residents, general public.
- Based on Boxborough and Somerville
- Drafted with DEC legal Counsel (working with Devens Fire and Health Inspectors)
- DEC Legal Counsel and DEC IPS Peer Review Consultants, and MD
- Maintain Devens commitment to support sustaianble economic development – in a safe and responsible manner



Draft Biosafety Policy Outline:

SECTION 1: AUTHORITY

Boards of Health MGL, Chapter 111, Section 3

SECTION 2: PURPOSE

To safeguard the health and welfare of the residents, general population at large, visitors, staff and employees of businesses in Devens
Specifying the practices to be used for constructing and handling biological agents
Following NIH Guidelines
Keeping track of biological agents in Devens
Prohibiting BSL-4

SECTION 3: APPLICABILITY

Any business within the DREZ

Healthcare or veterinary services exemption

Educational institutions teaching kits exempt

SECTION 4: DEFINITIONS

Draft Biosafety Policy Outline:

SECTION 5: PROFESSIONAL ADVISORY ASSISTANCE

SECTION 6: GENERAL REQUIREMENTS

Procedures, protocols, annual reports.

SECTION 7: INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) REQUIREMENTS

Formation of Institutional Biosafety Committee (IBC), (DEC's Consultant the Fire Chief or their designees plus one community representative).

Meetings, Review Assessment and oversight

SECTION 8: REGISTRATION AND PERMITTING REQUIREMENTS

Low Risk Facilities (BSL-1) registration process

SECTION 9: ADMINISTRATIVE APPROVAL AND FORMAL APPROVAL

Administrative approval provided that there are no significant deficiencies. A

Formal approval if deficiencies ID'd in registration process

Draft Biosafety Policy Outline:

Section 10: AMENDMENTS AND THE "THREE YEAR RULE"

Any expansion of lab space within current facilities, increase in the containment level (BSL), new agents requires an amendme

Three year rule for minor (BSL 1) may be handled administratively.

SECTION 11: PROHIBITIONS AND EXEMPTIONS

BSL-4 or higher containment shall not be permitted in Devens.

NIH Guidelines for guidance on issues not addressed in Policy

SECTION 12: ENFORCEMENT

testing, evaluation or other procedure to demonstrate conditions are in compliance with the health and safety needs of the c

SECTION 13: OTHER APPLICABLE PERMITS AND APPROVALS

Compliance with all required federal, state, and local permits

SECTION 14: PENALTIES

Fines, Permit suspension,Appeal Process

Draft Biosafety Policy Outline:

SECTION 14: PENALTIES

Fines, Permit suspension,Appeal Process

SECTION 15: SEVERABILITY

Each provision of this policy shall be construed as separate (if one is invalidated).

SECTION 16: WAIVERS

Discretionary