Getting to Compliant:

Personal Protective Equipment Use in the Non-Clinical Research Setting

I do not have any relevant personal, professional or financial relationships with respect to this educational activity.

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Holden Thorp Introduction to Principal Investigator Laboratory Safety Responsibilities

https://www.youtube.com/watch?v=d6AASsCEpTY&feature=youtu.be

Holden Thorp, Provost at Washington University in St. Louis, discusses standards and practices to minimize laboratory related mishaps and what lab leaders need to know and do to remain safe. The university recently won an award from the Campus Safety Health and Environmental Management

Objectives for Today's Presentation

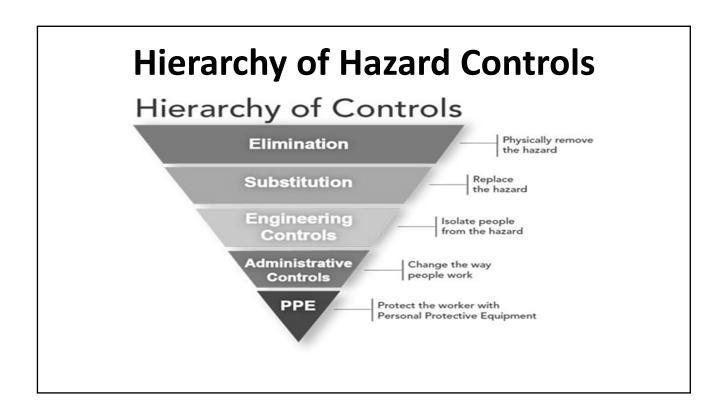
To understand the compliance concerns around personal protective equipment use in the non-clinical research lab setting



To identify compliance challenges faced by research compliance professionals in the academic medical center setting based on organizational structure and physical space

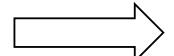


To learn strategies for PPE compliance program and policy development



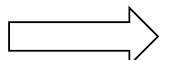
What *Are* the PPE Compliance Concerns?

Access to, and correct use of :

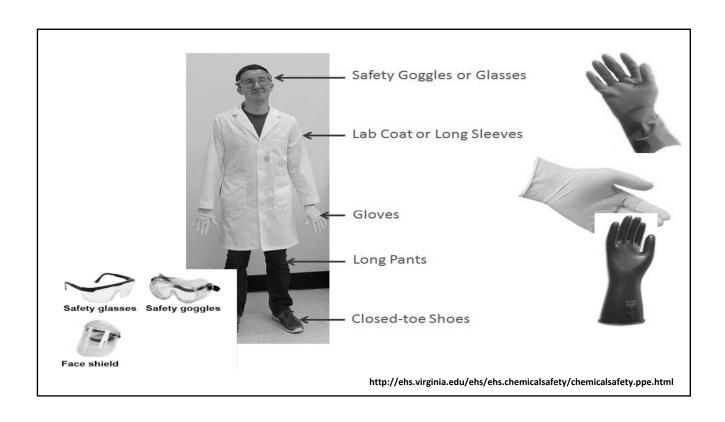


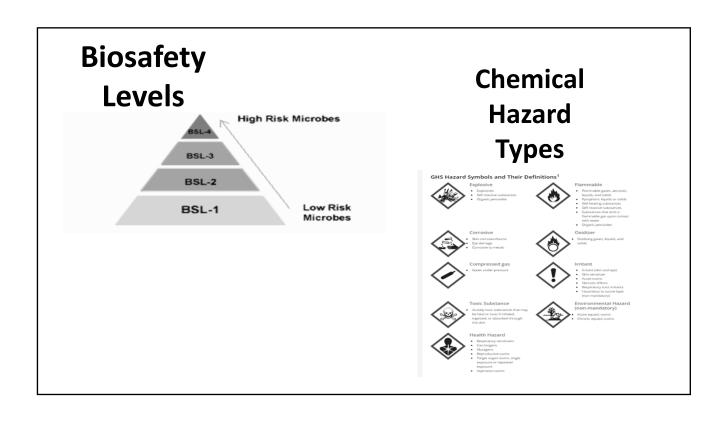
- Lab coats
- Gloves
- Eyewear
- Footwear
- Respirators

To protect from exposure to:



- Biologics
- Chemicals
- Laser lights & radiation
- Animal bites





Regulatory Compliance

Federal Regulations and Guidelines in the lab:

- OSHA Standards
 - Bloodborne pathogens
 - PPE requirements
 - Respiratory Protection
 - Surveillance of exposure to certain chemicals
 - Hazardous waste operations/Emergency response
- CDC biosafety in biomedical research lab guidelines
- Dept of Homeland Security lab security/safety
- US Drug Enforcement Agency controlled substances
- FDA GLP (21CFR58)
- NIH rDNA
- PHS & USDA (animal research activities)
- NFPA



State & Municipal Requirements:

- Local Fire Dept
- · Regional or State water authorities
- Departments of Health

What Does Non-Compliant Look Like?

- √ "One glove policy"
- ✓ Soiled lab coats
- ✓ No access to lab coats
- ✓ Improper lab coat use
- √ Wrong gloves e.g. dry ice or liquid nitrogen necessitate cryo gloves
- ✓ Lack of or inadequate eye protection
- ✓ Seasonal issues e.g. summer clothing
- ✓ Using unapproved equipment e.g. personal respirator equipment without fit testing

Any examples to Share?

What are the challenges to improving compliance?

The Various Challenges to Improving Compliance....

- Breadth and depth of technical expertise required
- Physical space
- Physical plant/maintenance
- Training a transient, international workforce
- Lab activities perceived as low risk
- Lack of clear and / or enforceable compliance for behavior
- Accurately and adequately compliance determinations
- Financial limitations
- Lack of centralization of processes
- Lack of institutional continuity in policy

What are Some Strategies for Improvement?

Engaging Key Stakeholders

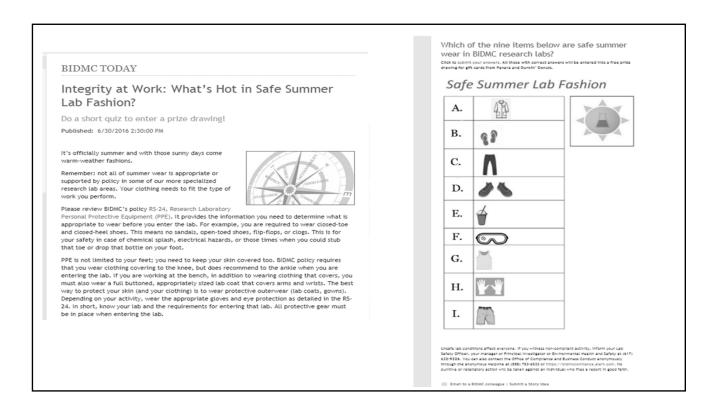
- Environmental Health & Safety Staff
- IACUC staff
- Animal research facility staff/vet
- Biosafety officer
- Employee health
- Research facilities
- Research faculty
- Research staff

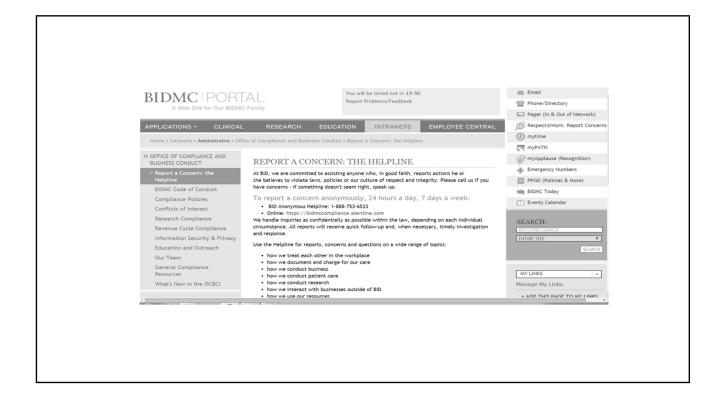
Presence/Involvement in Operations

- Attending meetings on a regular basis
- Committee membership if possible
- Presentations to stakeholder groups
- Participation in ongoing activities –updates, website improvements, training updates
- Involvement in policy development and revision

Market the PPE compliance message

- Articles
 - "Integrity at Work" series
- Promote reporting noncompliance and 'near misses'
 - Hotline/helpline promotion
 - Dedicated email mailbox address





PPE Workplan Item: A Case Example

Personal Protective Equipment (PPE)/ Research Safety Audits	Workplan Audit	Audit for PPE Compliance in BIDMC labs in collaboration with EH&S to improve overall compliance with RS-24 and research safety.	1. 2. 3. 4. 5.	Tasks Audit labs quarterly for PPE compliance and other research safety issues. Document findings. Keep statistical records. Educate on-the-spot for policy and safety violations. Notify other individuals and departments as appropriate (e.g. Lab Manager, PI, facilities, etc.). Report statistical findings at least	Regulatory Driver RS-24 Research Laboratory Personal Protective Equipment (PPE) Policy
			6.	Report statistical findings at least yearly.	

Beth Israel Deaconess Medical Center BIDMC Manual

Title: Research Laboratory Personal Protective Equipment (PPE) Policy

Policy#: RS-24

Purpose:
The purpose of the Research Laboratory Personal Protective Equipment (PPE) fi is to outline the basic requirements for clothing and personal protective equipment worn in the laboratory and the PPE requirements for working with specific hazard well as outlines procedures for appropriate selection, use, and maintenance of P

Scope:
This policy applies to all laboratory research spaces in properties and facilities or occupied, or managed by Beth Israel Deaconess Medical Center (BIDMC), inclu the main campus and at off-site locations. In some cases, certain responsibilities under the Research Laboratory PPE Policy are shared with or delegated to local managers and/or outside parties such as landlords, tenants, or contractors. As applicable to particular locations, this policy covers BIDMC and HMFP employee research staff, and visitors present in these locations.

Policy Statement:
In a continuing effort to provide a safe work environment, it is the policy of BIDM all individuals are provided proper training and proper PPE to protect against inju or illiness from known workplace hazards. This policy incorporates current BIDM practices, standard precautions, and those requirements set forth by the Occupant Safety and Health Administration (OSHA) Personal Protective Equipment Stands (29 CFR 1910 132). In addition to BIDMC is institutional PPE Program (EOC-30), PPE practices, individuals are equired to wear andor use inspection of the PPE as mandated by this policy. PPE shall be properly worn and used as a condition of employment. Non-compliance with this policy will subject the employee to correct action, as outlined in policy PM-04 and vendors will be subject to the breach of p clause in Section J of policy ADM-02, Industry Representative Code of Conduct.

Personal Protective Equipment (PPE): Equipment or clothing/apparel design prevent or reduce injury by acting as a barrier of last resort to potential hazard See Appendix A for PPE Expectations. Work Place Hazard: An item, material, or condition in the workplace capable causing injury and/or illness.

causing injury and/or illness.

Chemical Hazard: A solid, liquid or gaseous material that may cause acute or chronic health effects and/or physical harm upon exposure. Chemicals covere this definition include, but are not limited to, carcinogens, toxic or highly toxic agents, reproductive toxins, flammables, reactives, corrosives, oxidizers, sensitizers, and agents that irritate or damage the lungs, skin, eyes, or mucous

RS-24, Appendix A

PPE Expectations

A.1. Entering a research laboratory: Required:

Shoes with a closed toe & heel
Clothing covering at least to the knees
Recommended:
Clothing covering to the ankle

A.2. Working at laboratory bench:

All above requirements for entering lab
 Laboratory coat (appropriately sized, buttoned to full length, sleeves fully covering arms & wrists)
 Nitrile or other non-latex gloves*
 Eye & face protection for work posing a splash/particle

B. Work-type Specific PPE Expectations

B.1. Biological hazards

B.1.b. Biosafety Level 2+ (BL2 with stipulations*):

Required:

- Base requirements for Biosafety Level 1 & 2, plus:

- Disposable, liquid-impervious gown (cated of lab coat) or liquid-impervious sleeves

- Double inflitie or other non-latex gloves

PPF Expectations

PPE Research Safety Audits

- > Assess baseline compliance with specific PPE categories
- > Have both technical expertise and enforcement authority
- Provide on the spot education
- ➤ In-person visibility/resource
- Collect and report out data
- Identify educational gaps

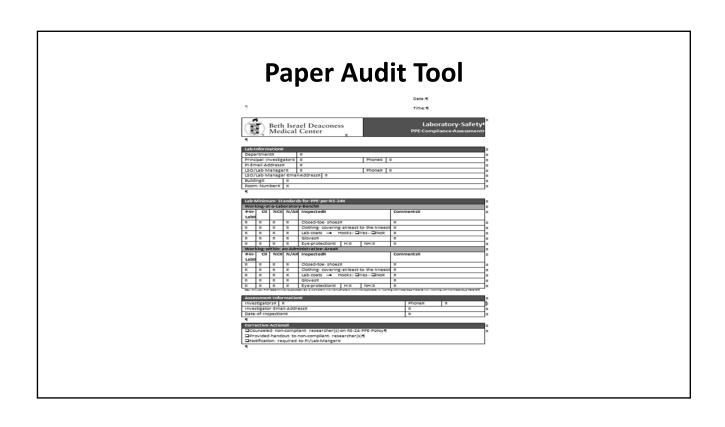
Audit Tips & Tools

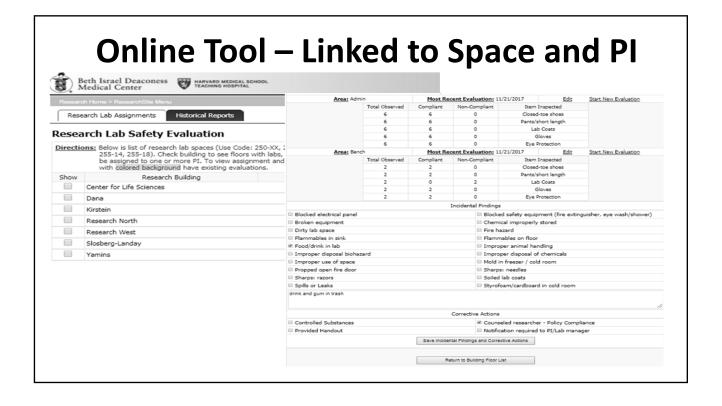
- Vary day and time of audits
- Practice your own safe behavior
- Stay out of the way
- Take advantage of face-to-face
- If possible have satellite space (for coats, bags, etc) travel light

"Toolkit"

- Business cards
- Educational materials
- Cell phone
- 'a smile' 'kill them with kindness'... to a point

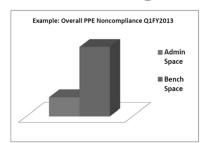


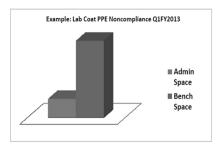




Audit Findings Data Sharing

- Where to present data
 - Various key audiences
 - Other Departments may present and use data for related purposes
- How to present data
 - Breaking up information to focus on risk areas, for example:





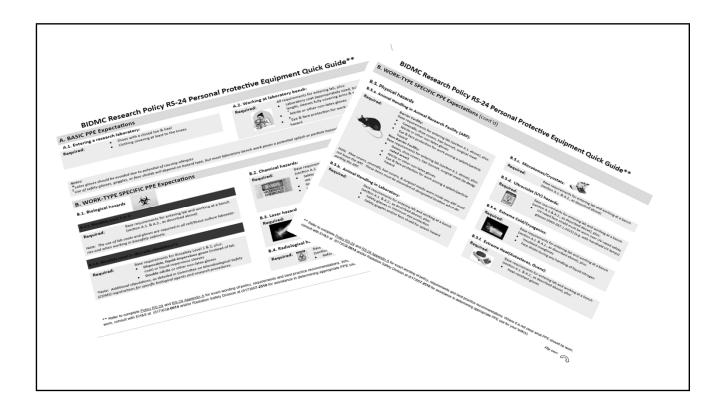
Incidental Findings

- Be prepared: You'll have your 'compliance hat' on, be aware that there are other things you may find:
- Use incidental findings to prompt discussion about needs for additions/revisions to policy

- Improper disposal of hazardous substances
- > Children in the lab
- Food and drink in the lab
- Fire code violations (doors propped open, items stored improperly
- Possible IACUC violations/animal welfare concerns

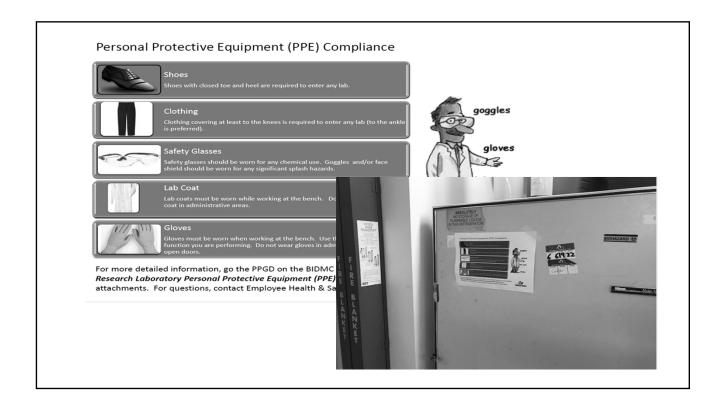
Educational Efforts

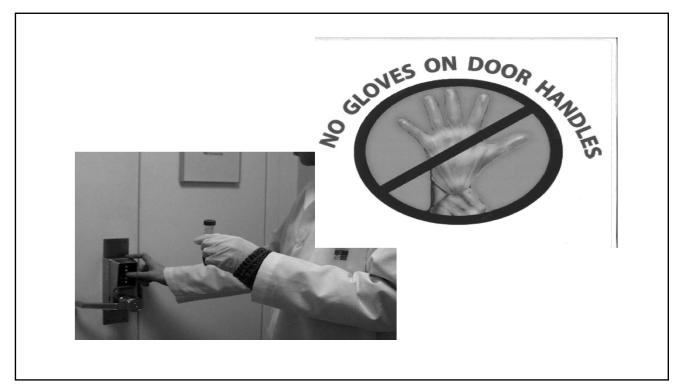
- Integrity at Work articles
- Presentations on audit findings
- Involvement in training material development



Educational Efforts

- Education materials for various audiences
 - Limited English speakers
 - Role specific materials
- Signage e.g. stickers 'no gloves on handles'
- Videos (produced in-house, You Tube)





Enforcement & Consequences

Use institutional authority and follow the Escalation policy:

> "... The ReSC has the authority to stop any BIDMC laboratory operations in which the health and safety of faculty and/or staff may be compromised or may result in non-compliance with applicable laws or policies."

- Targeted emails from leadership
 - **Notice**
 - Warning
 - Suspension
 - **Appeal**

Beth Israel Deaconess Medical Center Policy Manual

Title: Research Safety Management Policy

Policy #: RS-22 Purpose:

This policy defines the safety management program for Research at the Beth Israel Deaconess Medical Center ("BIDMC") which is in place to protect individuals from potential hazards associated with the work that occurs in research laboratories

Policy Sta

RS-22 Appendix A:
Research Safety Enforcement and Escalation Procedure

BIDMC is C Research Safety Committee (ReSC) Authority applicable f As described below, the ReSC has the authority to stop any BIDMC laboratory operations in which the health and safety of faculty and/or staff may be compromised or may result in non-compliance with applicable laws or policies.

- 1. <u>Lab Safety Enforcement:</u> To safeguard the requirements set forth in regulations, audits of each laboratory will be made by the BIDMC SO (Safety Officer) or a designee annually and/or at his/her discretion. Audit findings will be sent to the Principal Investigator ((P) and the Lab Safety Officer (LSO) of the laboratory. Audits may range from a walk through visit to an in-depth audit to insure that protocol information (such as users) and trainings are up to date. In addition, the SO also responds to emergencies (e.g. code red, crange) in the research lab areas, and generates an after action summary. This report is sent to the responsible parties for action.
- General Safety Escalation: This section outlines procedures for responding to safety concerns which
 are identified during day to day operations. Examples include: audit findings, compliance issues identified
 during routine rounds, or violations of safe practice standards/policies that may not pose an immediate
 thread to life or safety.
 - ReSC or the appropriate representative will follow-up verbally and in written format with all those

Focused Monitoring

- Repeat offenders
- High risk behaviors
- Developing a monitoring/auditing plan
 - Outline scope and frequency
 - Include clear milestones to prompt step down or escalation
 - Use institutional policy to ensure authority

Have a "Wish List"

- Better engineering controls
- Increased \$\$\$ resources
- Centralization of responsibility for specific tasks – lab coats, eye protection and specific vendors
- Additional/better signage



What's on your wish list?

References, Related Regulations and Guidance

- Holden Thorp Introduction to Principal Investigator Laboratory Safety Reps

- https://www.youtube.com/watch?v=d6AASsCEpTY&feature=youtu.be
 OSHA Standards https://www.osha.gov/SLTC/laboratories/standards.html
 OSHA Hierarchy of Hazard Concerns: https://www.osha.gov/shpguidelines/hazard-prevention.html
 https://www.osha.gov/shpguidelines/hazard-prevention.html

- "A research university's rapid response to a fatal chemistry accident: Safety changes and outcomes"

 "https://www.sciencedirect.com/science/article/pii/S1871553214000048

 Safety in Academic Chemistry Laboratories 8TH EDITION

 https://www.acs.org/content/dam/acsorg/about/governance/committees/chemicalsafety/publications/safety-in-academic-chemistry-laboratories students aff
- laboratories-students.pdf
 Department of Homeland Security, Appendix A: Chemicals of Interest (COI) List https://www.dhs.gov/appendix-a-chemicals-interest-listDEA
- Controlled substances
- Environmental Protection Agency Federal Clean Water Act 33 U.S.C. §1251 et seq. (1972)

- CDC biosafety in biomedical research lab guidelines https://www.cdc.gov/biosafety/publications/bmbl5/
 CDC Federal Select Agent Program Biosafety / Biocontainment Plan Guidance: https://www.selectagents.gov/bbp-requirements.html
 Title 21 Part 58 Good Laboratory Practice for NonClinical Laboratory Studies
 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=58
 The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

 https://osp.od.nih.gov/biotechnology/nih-guidelines The NIH Guidelines for Nesearch informs, incoming incoming guidelines/
 guidelines/
 EPA Resource Conservation and Recovery Act (RCRA) Laws and Regulations https://www.epa.gov/rcra
 Title 49 of the Code of Federal Regulations (49 CFR), Subchapter C, "Hazardous Materials Regulations."

 NFPA 45 Standard on Fire Protection for Laboratories Using Chemicals https://www.nfpa.org/codes-and-standards/all-codes-and-standards/list-of-codes-and-standards/all-

- - RS-22 "Research Safety Management Policy"
 - RS-22 Appendix A "Research Safety Enforcement and Escalation Procedure" RS-24 "Research Lab PPE Policy"

 - RS-24 Appendix "PPE Expectations"

THANK YOU AND ENJOY THE **REST OF THE CONFERENCE!**



