Select Agent Ongoing Training 2021

Jay Frerotte, RO

Katy Board, ARO

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Molly Stitt-Fischer, ARO



Threat Awareness and Security

Academic research institutions and health care systems continue to be a focus for cyberthreats as well as intellectual property theft



https://www.justice.gov/opa/pr/four-chinese-nationals-working-ministry-state-security-charged-global-computer-intrusion



Threat Awareness and Security



Significant Cyber Incidents Since 2006

February 2021. A Portuguese-speaking cyber criminal group accessed computer systems at a division of Oxford University researching COVID-19 vaccines, and are suspected to be selling the data they collected to nation states.

February 2017. A suspected Russian hacker breaches at least 60 universities and US government organizations using SQL injections, including HUD, NOAA, Cornell University, and NYU, among many others. This follows up a hack by the same actor against the U.S. Electoral Assistance Commission in December 2016.

https://csis-website-prod.s3.amazonaws.com/s3fs-public/211105 SignificantCyberIncidents.pdf? Bux.NVhaioSPTAcspLrKuLx.xCZNSP3



Threat Awareness: Outsider Threats

- Social engineering attempts by contacting researchers and other personnel via social media and professional societies are increasingly common.
 - Targeted phishing (spear-phishing) using fake employment offers and/or recruiting information



Threat Awareness: Outsider Threats





Collins Aerospace is a global aerospace and defense company.

https://www.rockwellcollins.com/

I saw your profile in Linkedin and then I like your enthusiasm.

We welcomes elites like you.

I want you to work in our company.

I should be very grateful if you would accept my request.

Contact us



Myron Womack

Human Resources Manager at Rockwell Collins Washington D.C. USA

A fake LinkedIn job offer sent by a threat actor to establish contact.

Image: Kaspersky

 Example of a cyberespionage operation that resulted in installation of malware in aerospace and military companies in Europe and the Middle East, June 2020

https://www.techrepublic.com/article/dont-fall-for-linkedin-phishing-how-to-watch-for-thiscredential-stealing-attack/





Beware of phishing attacks. Don't take the bait!



- Phishing attacks use email or malicious Web sites to collect personal and financial information or to infect your computer with harmful software.
- No legitimate organization will ever ask for your password over email or on the phone.
- Phishing scams often create a sense of urgency, invoke emotions like greed or fear, or contain links that do not match legitimate resources for the organization that is contacting you.
- To report a phishing scam, forward the phishing email as an attachment to phish@pitt.edu.

technology.pitt.edu/cybersecurity



Threat Awareness for Biological Scientists: Outsider Threats

- Social engineering attempts by contacting researchers and other personnel via social media and professional societies are increasingly common.
- Avoid posting research or RBL-specific information on social media



Excerpt from RBL Manual 8: Security Plan

If in doubt, don't post it!

4.3 Social Media and Information Security for RBL

Under no circumstances should individuals in the select agent program place information on any social media platform (e.g. Facebook, Twitter) that makes reference to the RBL, select agents or animal research. Such activity is grounds for disciplinary action. The dissemination of information via social media is a security risk that places the University, its research enterprise and each employee at risk for potential activism and/or terroristic threats. It is important to remember that the audience for social media platforms has varying levels of expertise and could misinterpret information, including information that may be available in the peer-reviewed literature. The University's Image Recording Policy approved by the IACUC forbids the use of photography within animal facilities and labs, unless pre-approved. In addition, posting, tweeting, or texting information pertaining to security of select agents or research, any work with research animals, or any information regarding the University's animal facilities (which includes select agent animal facilities) is prohibited.



Threat Awareness: Pitt IT Resources



Information Technology



SECURITY

SERVICES

SOFTWARE

TRAINING

ABOUT

Best Practices: Safe Social Networking

Safety Tips for Social Networking

Social networking sites like Facebook and Twitter can be a great way to connect with friends. But there are some social networking safety tips you should always keep in mind.

- Manage your privacy settings. Learn about and use the privacy and security settings on your social
 networking sites. They help you control who sees what you post and manage your online experience
 in a positive way. You'll find some information about Facebook privacy settings at the bottom of this
 webpage.
- Remember: once posted, always posted. Protect your reputation on social networks. What you post online stays online. Think twice before posting pictures you wouldn't want your parents or future employers to see. Recent research found that 70% of job recruiters rejected candidates based on information they found online.



Threat Awareness for Biological Scientists: Outsider Threats

- Social engineering attempts by contacting researchers and other personnel via social media and professional societies are increasingly common.
- Avoid posting research or RBL-specific information on social media
- Photos, videos, media requests <u>must</u> be coordinated with University Communications and RO/ARO
 - ARO will review to ensure security and other sensitive information is not present before releasing/posting



Threat Awareness: Insider Threats

- 2021 Federal Select Agent Program Inspection Update
- We are all responsible for being aware of insider threats that could compromise the safety and security of our Select Agents and Toxins, even if we do not physically have access to areas where they are used.
- We should all be familiar with some examples of concerning behavior



Some Signs that may Indicate an Insider Threat

Insider Threat Indicators

Digital

- Obtaining large amounts of data
- Sharing data with outsiders
- Seeking or saving sensitive data
- Requests for access to sensitive data not related with their job function
- Acting outside of their unique behavioral profile
- Make use of unauthorized storage devices

Behavioral

- Attempting to bypass security
- Frequently in the office during off-hours
- Displaying disgruntled behavior
- Violating any corporate policies, even those unrelated to security
- Discussing resignation or looking for new career opportunities
- Acting withdrawn or unusual





Threat Awareness: Insider Threats

Characteristics of Insiders at Risk of Becoming a Threat

Compulsive and destructive behavior

Rebellious, passive aggressive

Pattern of frustration and disappointment

History of managing crises ineffectively

Minimizing their mistakes or faults

Inability to assume responsibility for their actions

Intolerance of criticism



Threat Awareness: Insider Threats

Displaying disgruntled behavior

and

 Acting withdrawn or unusual

and

 Discussing resignation or looking for new career opportunities

and

- Violating any corporate policies, even those unrelated to security
 - = Pattern of behavior

- We should be aware of patterns of behavior
 - Anyone can have a bad day or have an isolated incident
 - If the behavior becomes a pattern it may be a concern



Threat Awareness for Biological Scientists: Potential Signs of Insider Threats

- Missing supplies. Lost or moved laboratory material.
 Equipment that appears "used" without being required by ongoing laboratory work.
- People attempting to access the laboratory who have no reason to be there.
 - Beware increased use of social engineering attempts
 - I'm a new employee; my card just stopped working and I have to save my experiment; etc.
- Personnel who work late into the evening or on weekends without experimental or project need.
- Laboratory staff who do not follow established practices.



We are a team and everyone plays a role in keeping us all safe

- If you notice a pattern of behavior or a safety or security incident you must report it to a supervisor (if you are comfortable doing so) or an ARO or the RO.
 - ARO or RO will follow up and whenever possible information will remain confidential
 - Several instances of concerns or questions reported to ARO or RO every year, and to the best of our knowledge only those persons with "need to know" may realize that a concern was mentioned



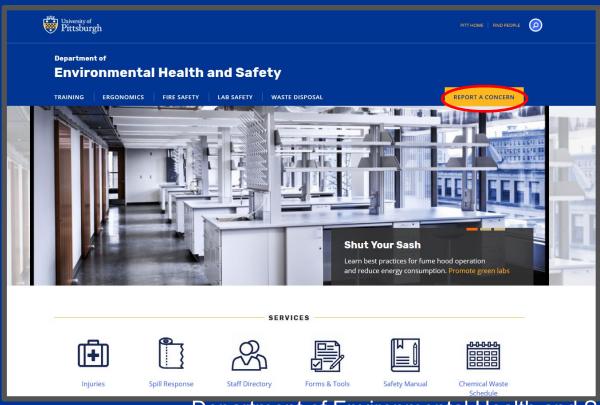
Safety Issues:

• EH&S: 412-624-9505 (business hours)

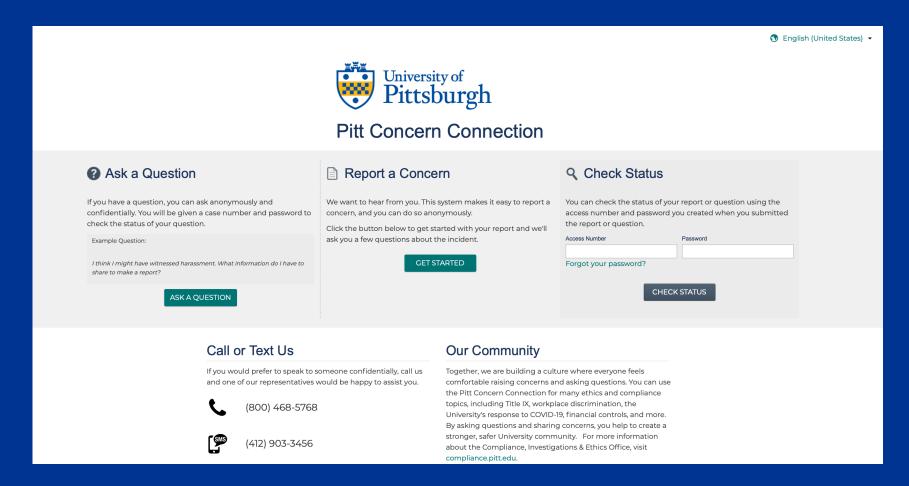
EH&S: Anonymous reporting via Pitt

Concern Connection app

www.ehs.pitt.edu

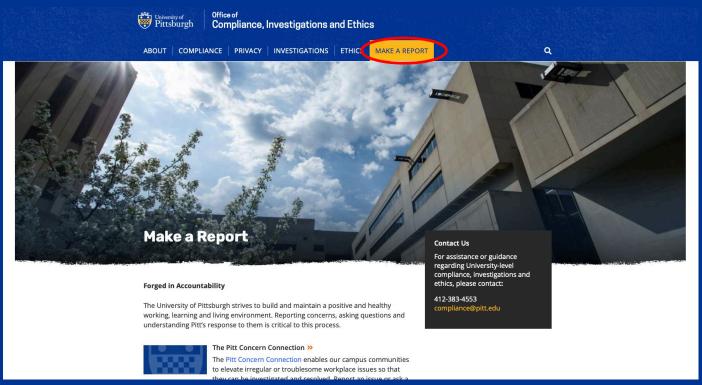




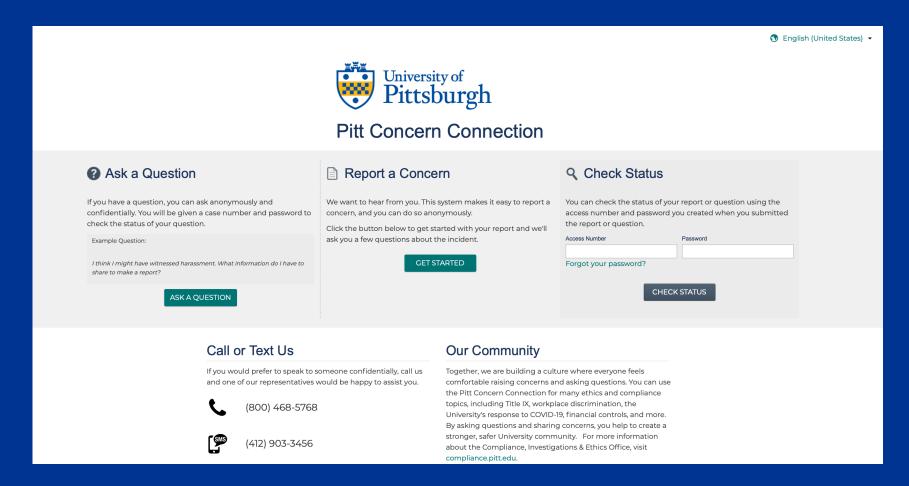




- AlertLine replaced with Pitt Concern Connection
- https://compliance.pitt.edu/make-report









Reporting Outside the University

- We hope that personnel will feel comfortable sharing any concerns with the AROs or RO
- If you are uncomfortable reporting concerns within the University, the Federal Select Agent Program does provide a reporting capability



Reporting Outside the University



www.selectagents.gov

Anonymous Reporting

To report safety, security, or other concerns associated with select agents and toxins, please use the Office of Inspector General (OIG)'s confidential hotline. When reporting these issues to OIG, please ensure that you indicate it is a "Select Agent Complaint" issue.

OIG Hotline contact information:

Voice: 1-800-HHS-TIPS (800-447-8477)

Fax: 1-800-223-8164

Web:

https://oig.hhs.gov/fraud/report-fraud/index.asp

Mail:

Office of Inspector General

Department of Health & Human Services

Attn: Hotline P.O. Box 23489 Washington, DC 20026

USDA OIG Hotline contact information:

Voice: 1-800-424-9121 Fax: 1-202-690-2474

Mail:

United States Department of Agriculture

Office of Inspector General

P.O. Box 23399

Washington, DC 20026-3399



Biosafety: Choosing an appropriate disinfectant in the lab and at home



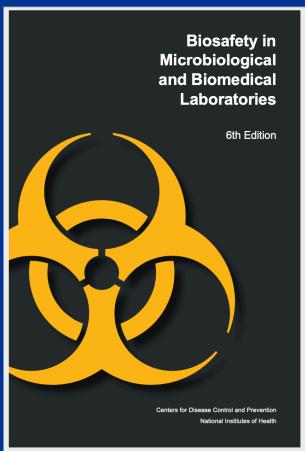








 The new edition of the BMBL has an appendix dedicated to decontamination that can be a resource



Appendix B—Decontamination and Disinfection of Laboratory Surfaces and Items

Purpose and Scope

Appendix B provides basic guidance for the decontamination or disinfection of environmental surfaces and items in the laboratory with antimicrobial substances and other practices to mitigate the possibility of transmission of pathogens to laboratory workers, the public, and the environment. The selection of an appropriate antimicrobial product and adherence to the product label instructions are critical to ensuring the product's performance against the target microorganism. Regulatory oversight, terminology, factors necessary for environmentally-mediated transmission of infection (e.g., aerosol generation, contact, indirect contact), methods for sterilization and disinfection, and the levels of antimicrobial activity associated with liquid chemical disinfectants are reviewed in this appendix. One must remember that aerosol-generating procedures should be conducted in containment. Accidents involving infectious aerosols have been a source of contamination within the laboratory setting and may impact the method chosen for decontamination. General approaches are emphasized instead of detailed protocols and methods. It is important to follow the manufacturer's instructions for use when performing decontamination practices in the laboratory.

Antimicrobial Products—U.S. Regulations

Antimicrobial pesticides (e.g., disinfectants) are classified as pesticides and are regulated by both the United States Environmental Protection Agency under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)^{1,2}



- Is disinfectant effective against organism in use?
 - Spores are more resistant to disinfectants than viruses
- In areas where multiple organisms in use = prefer disinfectant effective against all

Figure 1. Descending Order of Relative Resistance to Disinfectant Chemicals

Prions



Bacterial Spores

Bacillus subtilis, Clostridium sporogenes, Clostridium difficile



Mycobacteria

Mycobacterium bovis, M. terrae, and other Nontuberculous mycobacteria



Non-enveloped or Small Viruses

Poliovirus, Coxsackievirus, Rhinovirus



Fungi

Trichophyton spp., Cryptococcus spp., Candida spp.



Vegetative Bacteria

Pseudomonas aeruginosa, Staphylococcus aureus, Salmonella choleraesuis, Enterococci

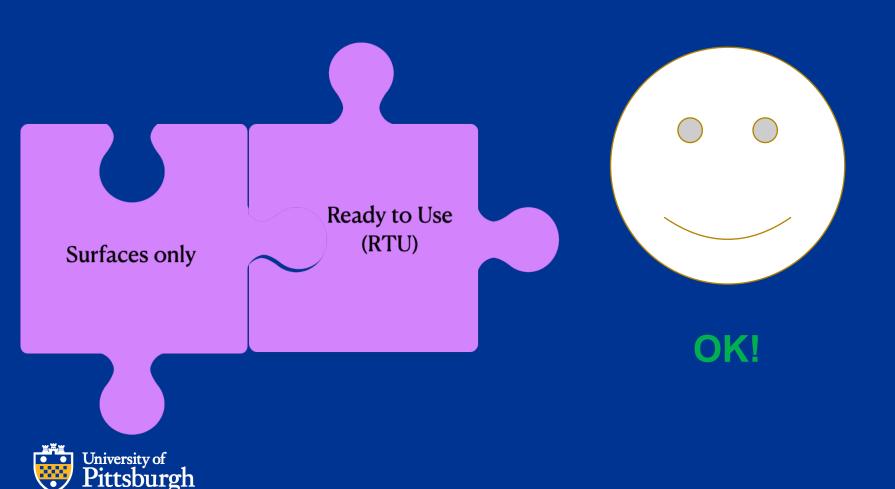


Enveloped or Medium-size Viruses

Herpes simplex virus, CMV, Respiratory syncytial virus, HBV, HCV, HIV, Hantavirus, Ebola virus



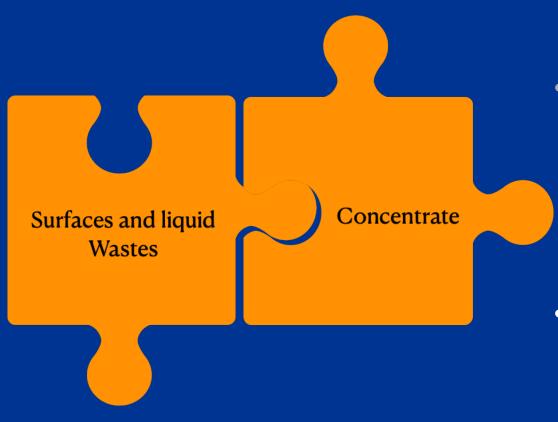
 What do you need to decontaminate? Not all disinfectants can be used for all circumstances.





- Using a ready to use disinfectant to decontaminate liquid wastes dilutes active ingredient
 - No longer effective

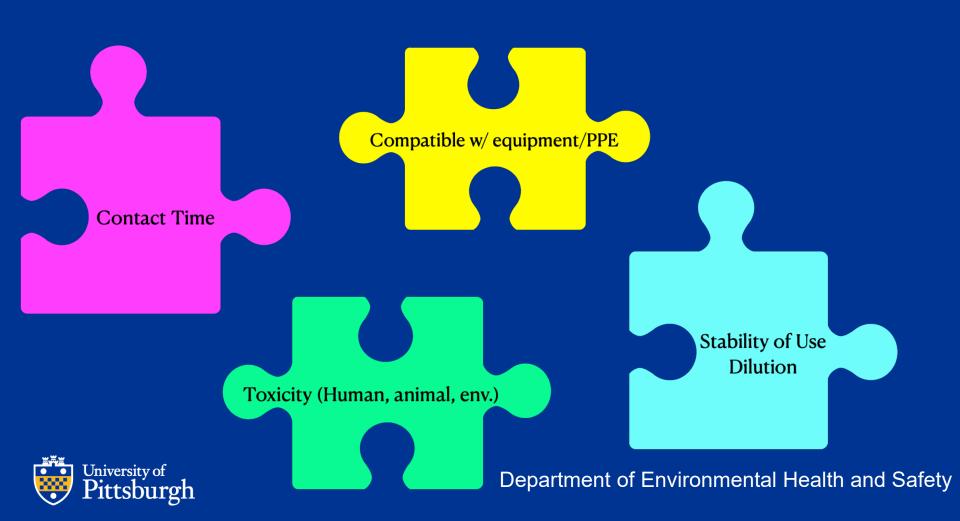




- Using a ready to use disinfectant to decontaminate liquid wastes dilutes active ingredient
 - No longer effective
- A concentrated disinfectant must be used to decontaminate liquid wastes



Other factors to consider include:



How does choosing a disinfectant impact Incident Response?

Why does EH&S recommend use of a single disinfectant whenever possible?

Let's think through a quick case study:

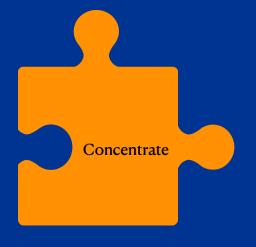


A Leaking Ice Machine on the Lab Side causes a flood

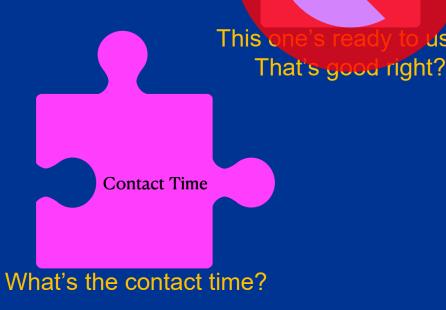
 What information do we need to consider in our response?



Which suite?



What's the dilution factor?



What pathogen(s)?



to Use

Ideal = Single Facility-Wide Disinfectant



Grab the Vesphene and go! This makes incident response and daily operations much more simple.

We don't have to stop and think about which disinfectant we should use during an incident.



Practical considerations led to addition of approved disinfectant.

 Bleach is more cost effective and EH&S approval for use was requested









Practical considerations led to addition of approved disinfectant.

- While cost is an important consideration, our primary concern is to ensure effective decontamination of agents in use.
- Changes in disinfectant use, preparation, and storage MUST be reviewed and approved by EH&S
- Why?



EH&S Disinfectant Review

 Some disinfectants must be made up at specific concentrations to be effective against certain microorganisms

For Use as a One-Step Bactericide and *Virucide Cleaner/Disinfectant: Dilute at 2.0 oz. of product per gallon of water (1:64).

- Pre-clean heavily soiled areas.
- 2. Spray 6-8 inches from surface until surface is thoroughly wet.
- **3.** Allow surface to remain wet for 10 minutes as a bactericide and 5 minutes as a *virucide.
- **4.** Wipe surfaces dry and let air dry.

1 excluding Canine Parvovirus, FMDv and Minute Virus of Mice.

To Kill *Canine Parvovirus: Dilute at 4.0 oz. of product per gallon of water (1:32).

- 1. Pre-clean heavily soiled areas.
- 2. Apply Use Solution until thoroughly wet.
- 3. Let stand for 10 minutes.
- 4. Wipe surfaces and let air dry.

To Kill *Foot and Mouth Disease Virus (FMDv): Dilute at 2.0 oz of product per gallon of water (Dilute at 1:64).

- 1. Pre-clean heavily soiled areas.
- 2. Apply Use Solution until thoroughly wet.
- 3. Let stand for 10 minutes.
- 4. Wipe surfaces and let air dry.



EH&S Disinfectant REview

Once prepared, disinfectants have a specific shelf-life

PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS: Corrosive; Causes eye and skin damage. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. **CLEANING AND DISINFECTING WASHABLE, HARD, NON-POROUS SURFACES:** Add 1 fl. oz. (30 cc) to each measured gallon of water used. Always add this product to pre-measured water. Thoroughly mix solution until uniform. Apply solution with a cloth, sponge, mop, or brush using normal cleaning methods. Allow treated surfaces to soak for 10 minutes. Then remove excess solution with a wrung-out applicator.

Remove gross filth mechanically by sweeping before cleaning begins. Discard solution daily or when it becomes dirty and replace with a fresh solution. A properly prepared solution of **Vesphene lise** intended for use as a hard surface disinfectant has a shelf life of 14 days

(use life) when stored in a closed container such as a spray bottle. This is a complete product. Do not add other chemicals. If frozen, thaw and re-mix. Use only as directed.



Practical considerations led to addition of approved disinfectant.

- While cost is an important consideration, our primary concern is to ensure effective decontamination of agents in use.
- Changes in disinfectant use, preparation, and storage MUST be reviewed and approved by EH&S
- Bleach is an effective disinfectant for microorganisms in use in the RBL and when prepared fresh daily is approved for use



- Regulations require access to Select Agents be restricted
- It is <u>critical</u> that supervisors and PIs promptly notify the RO/AROs when personnel no longer need to be registered for access to Select Agents
 - Notify RO/ARO BEFORE personnel are scheduled for last day so that inactivation of access credentials and removal from our registration can be coordinated



- Regulations require all personnel to have annual refresher and insider threat awareness training
- Annual means within a calendar year. Personnel who are not on approved absence or leave must complete 2021 annual training by December 31, 2021.



- Regulations require compliance with all biosafety best practices
- A note for laboratory personnel/PIs: at the time of inspection several o-rings on centrifuge safety cups and/or rotors were found to be showing signs of deterioration (small cracks in surface)
 - Please immediately review your equipment and replace any o-rings or gaskets that appear to be dried out or deteriorating
 - Recommend having extra o-rings on hand for proactive replacement as repeated exposure to disinfectant is known to accelerate deterioration

- Noted as concern during exit review:
- A reminder for PIs with personnel approved to inactivate Select Agents:
 - PIs MUST NOT pre-sign inactivation certificates
 (e.g. pre-sign inactivation certificates before traveling etc.
 - Recommend using electronic signatures via DocuSign
 - Access via MyPitt.edu
 - Web-enabled process improved and more user friendly (drag and drop document for signing; no more setting up envelopes)



- Noted as concern during exit review:
 - PIs MUST NOT pre-sign inactivation certificates (e.g. pre-sign inactivation certificates before traveling etc.
 - Pls may designate (in writing in PI RBL-specific biosafety manual) a senior laboratory member who has appropriate scientific expertise and experience to sign inactivation certificates
 - Only when PI is not able to electronically sign certificates and only for a specified time period (recommend documenting via memo with dates of travel/return and storing this information with inactivation certificates)



- Noted as concern during exit review:
- Please remember to sign yourself and your visitor out of the visitor logs when serving as an escort
 - This is a safety procedure so that all personnel can be accounted for in an emergency
 - We can check personnel and visitor sign in/out logs to ensure that we don't have anyone "stuck" unaware inside containment



- Noted as concern during exit review:
- Laboratory personnel performing inactivation procedures
 - Please <u>print</u> your name so it is legible on the inactivation certificate
 - A signature isn't required and we must be able to identify the individual who performed the inactivation procedure as long as the sample is retained
 - Several years from now new personnel might not recognize your signature



You Must Complete a Quiz via the EH&S Website by December 15, 2021!



Training

Per University guidance, all EH&S live training sessions are currently suspended. Online training options are available. Questions regarding training can be directed to EH&S at 412-624-9505 or safety@ehs.pitt.edu.

EH&S develops and maintains records for environmental and safety training for all faculty, staff, and students. Training requirements are determined by your occupation and exposure risks. Training may be offered online or as a live training session. Click on the training module link on this page to learn more about the training and how it is offered. Contact EH&S to arrange group training or specialty training.



Training Calendar for Live Training Sessions >>

No pre-registration required. Bring your Pitt ID to ensure proper credit.



Research Training Requirements >>

Those conducting research at Pitt are required to complete training prior to starting a project, regardless of funding source. Training requirements vary based on the nature of the research.

Training for the Non-Pitt Community >>

Training designated for visitors, UPMC employees, contractors, or users with sponsored accounts.

TRAINING

Overview

- BBP Exposure Control for a Facility Worker
- Asbestos Awareness - BBP for Lab Personnel
- BBP for Resident Assistants
- Chemical Hygiene
- Class C Refresher
- Compressed Gas Safety
- Confined Space Entry
- Dangerous Goods Shipping
- Dual Use Research of Concern
- Electrical Safety Awareness
- Fire Safety
- Fall Protection
- Formaldehyde Awareness
- Hazard Communication
- Hearing Conservation
- Hydrofluoric Acid Safety
- Lab Safety for Chemistry Students
- Lab Safety for Facility Workers
- Laboratory Security Training
- Ladder Safety
- Laser Safety
- Lock Out/Tag Out
- NFCF Cleanroom
- NFCF General Training
- Personal Protective Equipment
- Select Agent Refresher Quiz

Maccinia Virus Awareness Training



You Must Complete a Quiz via the EH&S Website!

You will use your Pitt credentials to log in.

Your completion of the short quiz is your proof of training and it must be completed by Wednesday, December 15, 2021.

If you don't complete the quiz by December 15 we will be forced to pester you with e-mail reminders.







In the closing meeting the FSAP inspectors complimented our excellent program in a complex, cutting-edge research environment and extremely active facility. This is a direct reflection of your excellent work every day.

Your RO and AROs thank each of you for your daily commitment to the Select Agent Program.



