DLS ECHO Biosafety Session: September 24, 2024

Operations: Emergency Response and Contingency Plans

Benjamin Fontes, MPH, CBSP
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August Session Recap: "Operations: Planning and Maintaining "

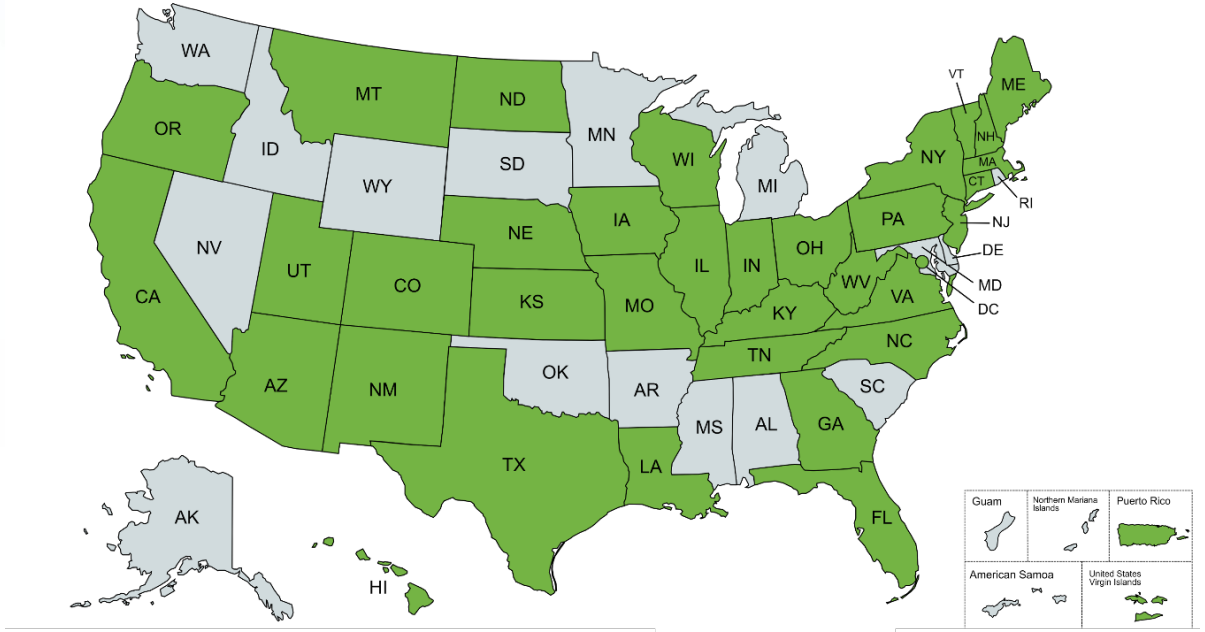
145 participants attended the session

88 organizations were represented

Tell us where you are in the implementation of biorisk management at your institution:

- Assessing risk (32%)
- Evaluating operational controls (21%)
- Getting buy-in from leadership (15%)
- Drafting SOPs (15%)
- Operationalizing SOPs (11%)

Organization Affiliation by State



Note: States shaded in green had at least one organization located in that state in attendance at this session. Attendees from at least one organization located in Belize and Canada were also present at the session. Twelve national organizations also attended this session.

Agenda

- Speaker Introduction
- Didactic and Case Presentation
- Discussion
- Summary of Discussion
- Closing Comments and Reminders

Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topic(s) covered.

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CDC ECHO Biosafety Program

September 24, 2024

ISO 35001
Emergency Response &
Contingency Plans

ISO 35001: Biorisk management for laboratories and other related organizations

- **8.9 Emergency response and contingency planning**

- Written plans covering both
- Team of individuals required to develop these
  - When planning, always ask: “Who else should be at the table?” Jim Welch
- Brainstorm to perform a “threats, risks, vulnerabilities” and “all possible incidents” scenarios
- Identify issues and response solutions

Include Local and City Emergency Response Professionals in response planning and drills

ISO 35001: Biorisk management for laboratories and other related organizations

- **8.9 Emergency response and contingency planning**

  - The organization shall establish, implement, practice, and maintain emergency response and contingency plans and procedures.

- Written incident response plans
- Train on written plans to verify competency
- Exercise to practice the plans
  - Update with any changes (new information, new agents, procedures, etc)

Key Emergency Response Messages

- BE READY
- The response for the emergency begins before the emergency occurs
- “Start with the end in mind.” Jim Welch

Key Emergency Response Messages

- Abraham Lincoln is attributed with:
  - “Give me 6 hours to chop down a tree, and I’ll spend 4 hours sharpening my axe.”
- Recommended: Book “Checklist Manifesto” by Dr. Atul Gawande
- SOP’s - simply written and understandable, e.g. Fly the plane

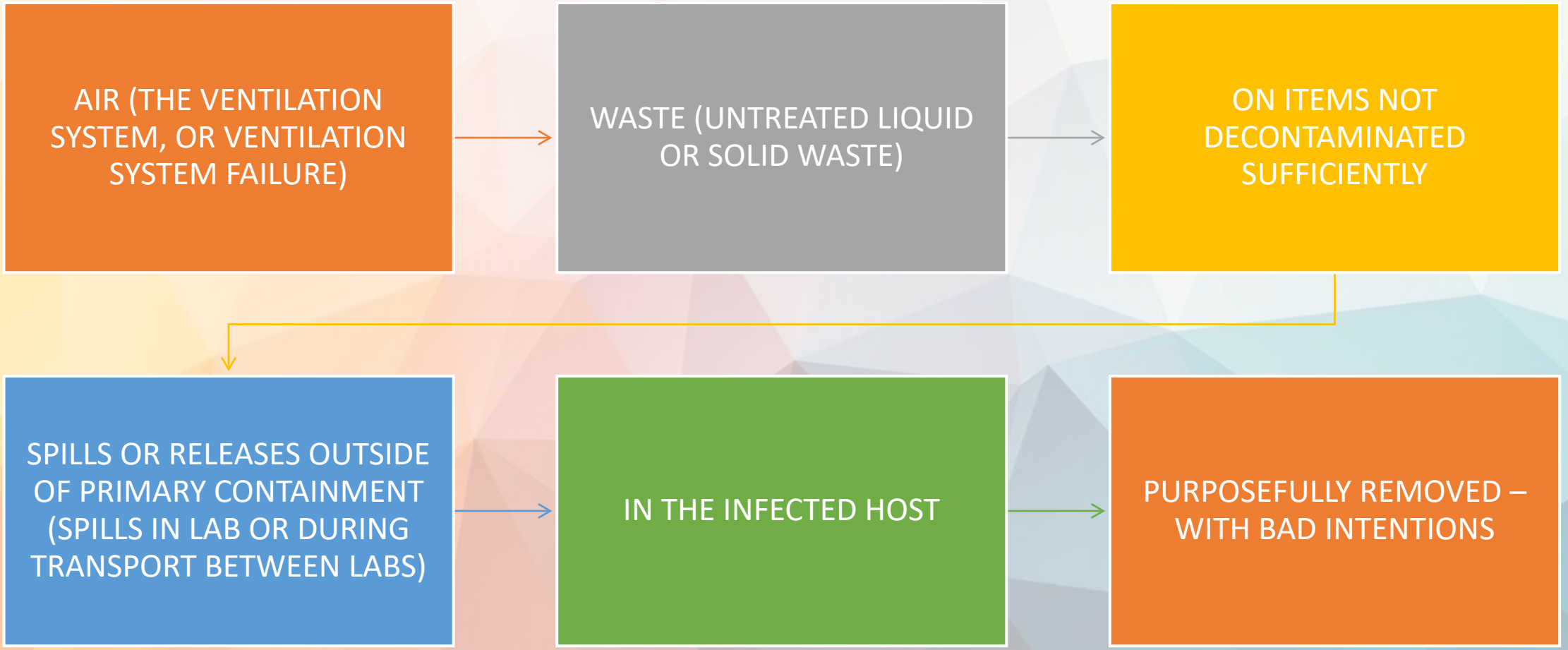
ISO 35001: Biorisk management for laboratories and other related organizations

- **8.9 Emergency response and contingency planning**
  - The planning shall cover all aspects of the organization's biorisks, and include general safety, security, medical issues, and environmental emergencies.

- It will take a "village" of related parties to develop plans

- Can also use training, drills and exercises to show what can happen with poor work practices or non-conformity and provide an opportunity of teaching moments.

All must be aware that PATHOGENS CAN ESCAPE THE LABORATORY BY…..



ISO 35001: Biorisk management for laboratories and other related organizations

- **8.9 Emergency response and contingency planning**
  - The organization shall ensure provision of timely and appropriate medical care for work-related illness or injuries when preparing and implementing emergency plans.
- Identify 24/7/365 access to healthcare associated with research related events.
  - Onsite local health clinic (written medical response plans on file)
  - Arrangement with local healthcare organization
  - Contracted services, other?

Medical Surveillance

- Health history/consultation
- Baseline serum sample
- Immunization(s) if applicable
- Awareness of hazards, signs/symptoms of infection
- Knowledge of post-exposure response procedures (card?)
- Periodic testing if applicable

ISO 35001: Biorisk management for laboratories and other related organizations

- **8.9 Emergency response and contingency planning**
  - The organization shall ensure appropriate coordination with external emergency response groups when reliance is placed on them.
- Institution's police, fire, security, facilities, emergency operations, building continuity, public affairs, health officials and other related groups.
- Same listing and more from local town, city, county or state
  - Local public health office, state veterinarian, police, fire, emergency management, others?

Spill Drill: Medical Issue and Personal Contamination

Gathering info/checking health status:

ISO 35001: Biorisk management for laboratories and other related organizations

- **8.9.1 Emergency response and contingency planning**
  - The organization shall ensure that all credible and foreseeable emergency scenarios that could impact the organization's biorisks have been identified.

- Brainstorming sessions with all relevant parties
  - Create a list of all possible events that may occur at your entity
    - From within your institution, or externally
  - Develop a listing of all incidents, threats, risks and vulnerabilities

Prep of Patient for Transfer

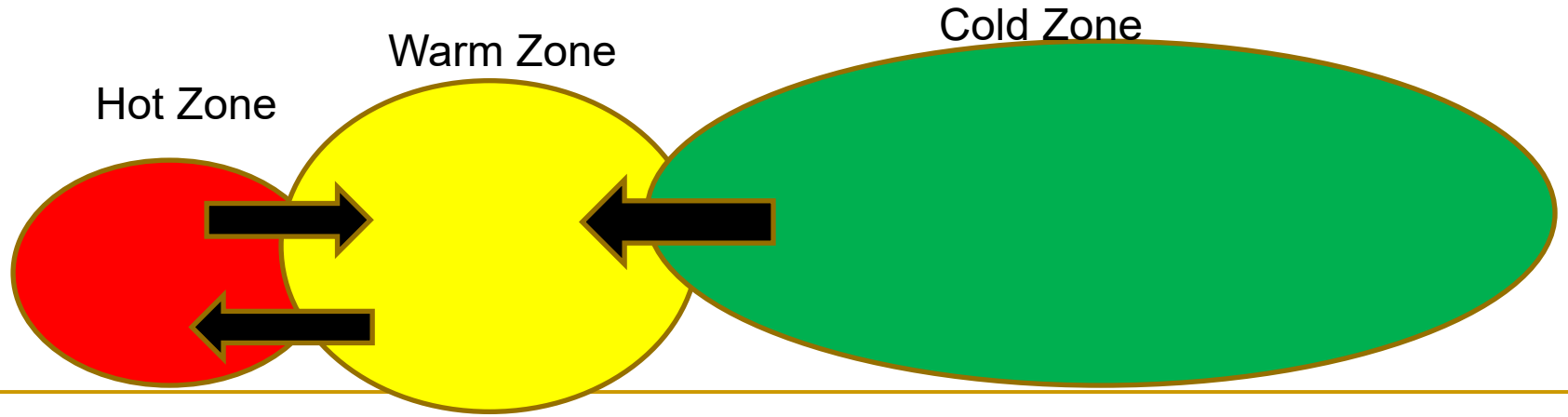
ISO 35001: Biorisk management for laboratories and other related organizations

- **8.9.2 Emergency plan training**
  - The organization shall ensure that all relevant workers are trained on the organization's emergency response plans.
- Hazardous Waste Operations and Emergency Response (HAZWOPER) training
  - Site-specific hazardous response incident training (spills, exposures, other incidents as identified)
- Training with Emergency Operations Teams
  - Incident Command Drills with local emergency responders

Prep for Patient Extraction

HazMat Work Zones

- Hot zone
  - Most hazardous area
    - Those entering wear PPE selected by the Incident Commander
    - Hazardous materials collected in this zone



ISO 35001: Biorisk management for laboratories and other related organizations

- **8.9.3 Emergency exercises and simulations**

  - The organization shall ensure that emergency exercises and simulations are conducted at regular intervals, based on risk, to test the plans, prepare workers, and learn from any good practices or deficiencies identified.

  - The organization should consider the utility of both discussion-based and operations-based exercises and simulations.

Example of access point between hot and warm zones

Biohazard Spills

- BSL-3 (spill outside containment equipment)
  - EVACUATE LAB!
  - remove PPE in anteroom (contaminated clothing)
  - wash/decon all exposed skin surfaces, face & hands
  - post sign
  - verify airflow direction
  - call safety & PI, notify Health Services
  - lab remains closed until cleared by Safety

ISO 35001: Biorisk management for laboratories and other related organizations

- **8.9.3 Emergency exercises and simulations**

- Make drills and table-top exercises as realistic as possible
- Celebrate and share actual emergency response success stories at your institution and others
  - Exposures, spills, fan failures, security systems issues
- Use near-misses or actual old events to retrain new staff

Responders Arrival and Donning Hazmat:

ISO 35001: Biorisk management for laboratories and other related organizations

- **8.9.4 Contingency plans**
  - The organization shall ensure that adequate contingency measures are in place to ensure the safety and security of continued operations in the event of an emergency.

- Develop a list of "what if" scenarios and identify back-up plans or "halt work / do not work" rules
  - Autoclave, Biosafety Cabinet, Exhaust Fan, keycard access failures
  - Freezer failures, failed HEPA filters, failure of back-up power
  - 2nd person of required 2-person team fails to show up, other?

NEWS: ISO Technical Specification 7446 Under Development

- **Implementation Guidance for ISO 35001, Biorisk management for laboratories and other related organisations.**
  - This document will serve as a companion guide for the ISO 35001 and provide very detailed suggestions for each section of the standard.

Preparing for Emergencies

- Be READY
- The response to the emergency begins before the emergency!

Make Sure All Know the Emergency Response Basics (the 1-2-3's and A-B-C's)

- Fire safety, fire evacuation routes and evacuation locations
  - All must know 2 ways to get out of their building
- How to use emergency showers and eye washes
  - And their location! May have impaired vision after exposures
- How to respond to an exposure (wash, notify, report to health services)

Make Sure All Know the Emergency Response Basics (the 1-2-3's and A-B-C's)

- What to do in the event of a spill or release (evacuate area, personal decons, notify EHS, etc.)
- Awareness of suspicious activities, actions and events
- Assessment of negative pressure into applicable labs -

SPILL RESPONSE STEPS

Evacuate the lab or spill area if biohazards are involved.

If spill inside a biosafety cabinet – Evacuation is not required.

Decontaminate any skin or clothing that is contaminated.

Bag any contaminated clothing items.

Wash hands, exposed skin.

Call Yale Health Acute Care and/or Employee Health

Spill Response Protocol

Use the following guidelines below for response to spills of BL3 material outside of the biosafety cabinet or any other incident that may have generated an aerosol in the containment laboratory, such as failure of physical containment devices during centrifugation.

IMMEDIATE ACTION:

- **Hold breath and leave room immediately; notify others in the room to evacuate immediately.**
- Remove personal protective equipment (PPE) in the airlock or access zone; turn potentially contaminated clothing inward; remove gloves last, and wash any exposed skin areas with antiseptic soap and warm water.

*In the event of an exposure incident:

- needlesticks/puncture wounds: wash the affected area with antiseptic soap and warm water for 15 minutes. Squeeze around the area to encourage the flow of blood out of wound.
- mucous membrane exposure: Use an eyewash for 15 minutes to flush the affected area.

- **Post a BIOHAZARD SPILL SIGN at entry to BL3 lab door.**
- Notify your Principal Investigator and EHS
- **Do not reenter laboratory until it has been cleared for reentry by the P.I. or EHS (785-3555).** In general a period of at least 30 minutes should be allowed before clean-up is attempted, but the time is contingent upon the supply and exhaust features of the lab.

EXPOSURE RESPONSE STEPS

Wash the affected area with soap and water or eye wash for 15 minutes

Notify:

Supervisor or Principal Investigator if available

(Yale EHS)

Call Yale Health Acute Care and/or Employee Health

Teaching Biohazard Emergency Response and Clean Up During Trainings:

Disinfection, Contact Time, Use of Engineering Controls

Decontamination of Equipment

Remove gown; avoid touching exterior if possible.

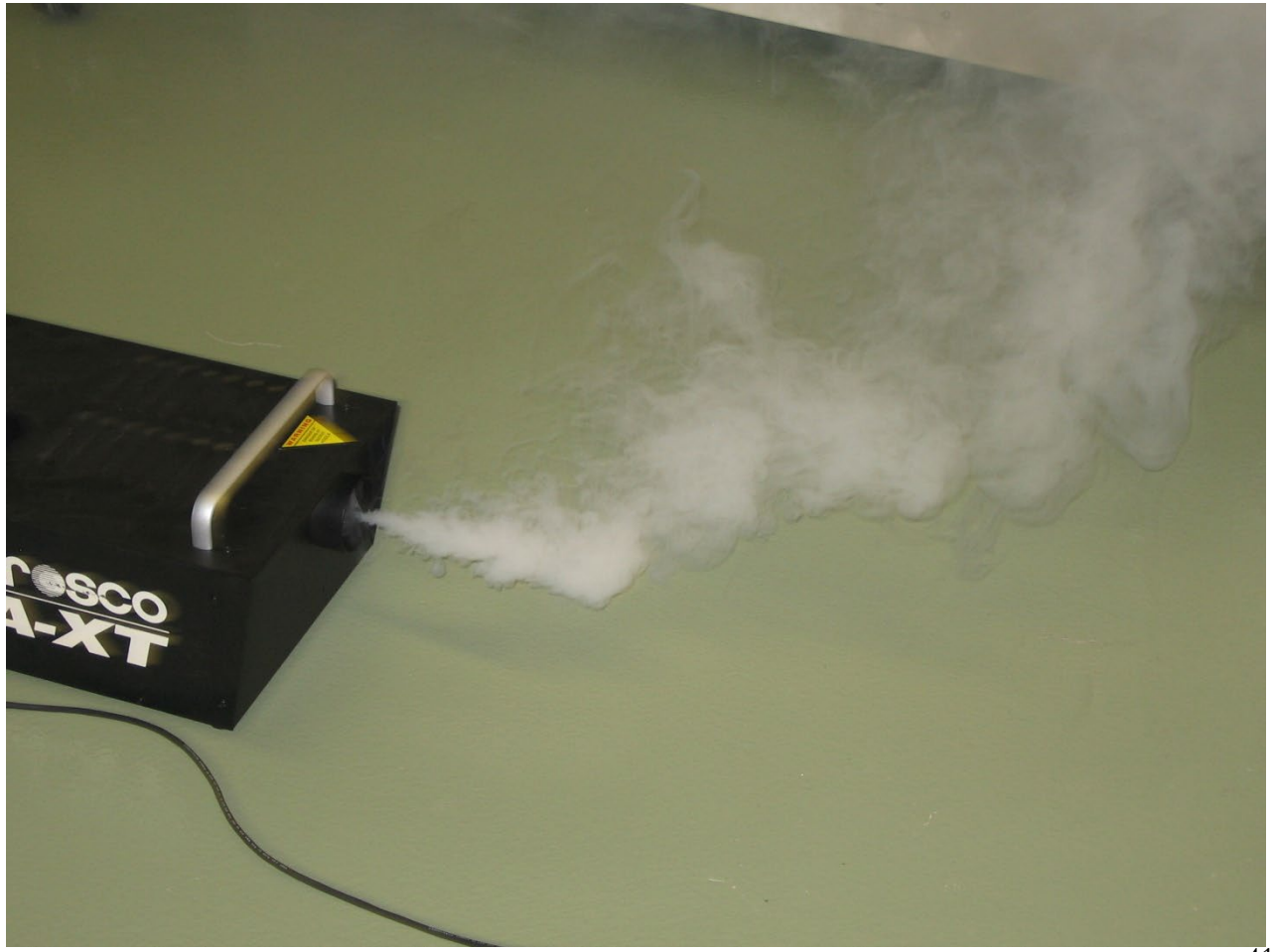
Wash hands after removing personal protective equipment

Example Methods, Means, Mechanisms for Transferring Emergency Response Protocols

- Tracking shipments (incoming and those shipped)
- Facility validations
  - Worst-case incidents (spill at time of total exhaust fan failure)
  - Exercising your facility
    - Smoke release tests
    - Smoke as surrogate for a **SP**ill **O**r **Re**lease - **O**utside **O**f **P**rimary – **C**ontainment
      - Be creative (SPORE-OOP-C) Make training memorable
    - Identify the Critical Evacuation Points (CEP)
      - Where should researchers go in the event of a SPORE-OOP-C inside their lab?
        - Testing with smoke and particle counters can identify these locations

Theatrical Smoke Generator Used for Mock Spill Release Event

Tracking where aerosols or particles will and can go in the event of an actual release incident

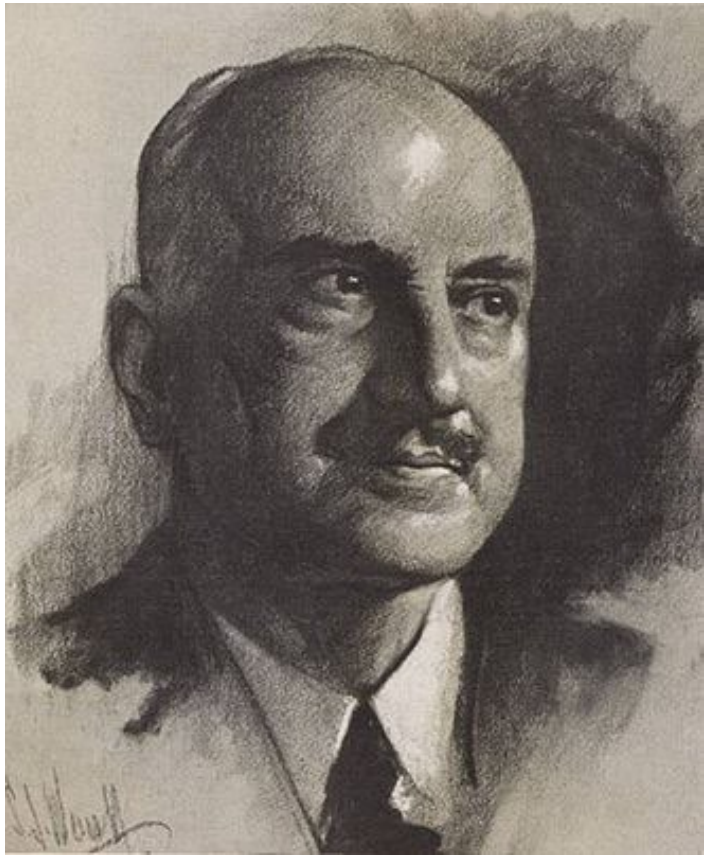


Example Methods, Means, Mechanisms for Transferring Emergency Response Protocols

- Emergency Response:
  - Manuals, Posters
  - Cards (Exposure Response and Disease agent cards)
  - Videos, Drills and exercises
  - Case Studies
- Become a student of past and recent incidents
  - At your institution, published reports, stories passed along by colleagues, networking (NEVER SAY IT CAN'T HAPPEN HERE!)
- Look at old Lab Associated Infections (LAI)
  - Invariably a spill or release (aerosol) is likely responsible for the LAI

The farther back you can look, the farther forward you are likely to see."

Winston Churchill
American Author (not "Sir" W. C.)



Those who cannot remember the past are condemned to repeat it.”

George Santayana
Spanish Philosopher

Pathogens traveling a distance!

- Sverdlovsk anthrax outbreak of 1979
  - https://pubmed.ncbi.nlm.nih.gov/7973702/
  - Science 1994 Nov 18;266(5188):1202-8. doi: 10.1126/science.7973702
- The Lanzhou Brucella Leak: The Largest Laboratory Accident in the History of Infectious Diseases?
  - https://pubmed.ncbi.nlm.nih.gov/35675697/
  - Clin Infect Dis. 2022 Nov 14;75(10):1845-1847. doi: 10.1093/cid/ciac463

Pathogens traveling a distance!

- Evidence of Long-Distance Aerial Convection of Variola Virus and Implications for Disease Control
  - https://www.mdpi.com/1999-4915/12/1/33
  - Viruses 2020, 12(1), 33; https://doi.org/10.3390/v12010033
- Long distance airborne transmission of SARS-CoV-2: rapid systematic review
  - BMJ 2022; 377 doi: https://doi.org/10.1136/bmj-2021-068743
- Airborne transmission of respiratory viruses
  - https://www.science.org/doi/10.1126/science.abd9149

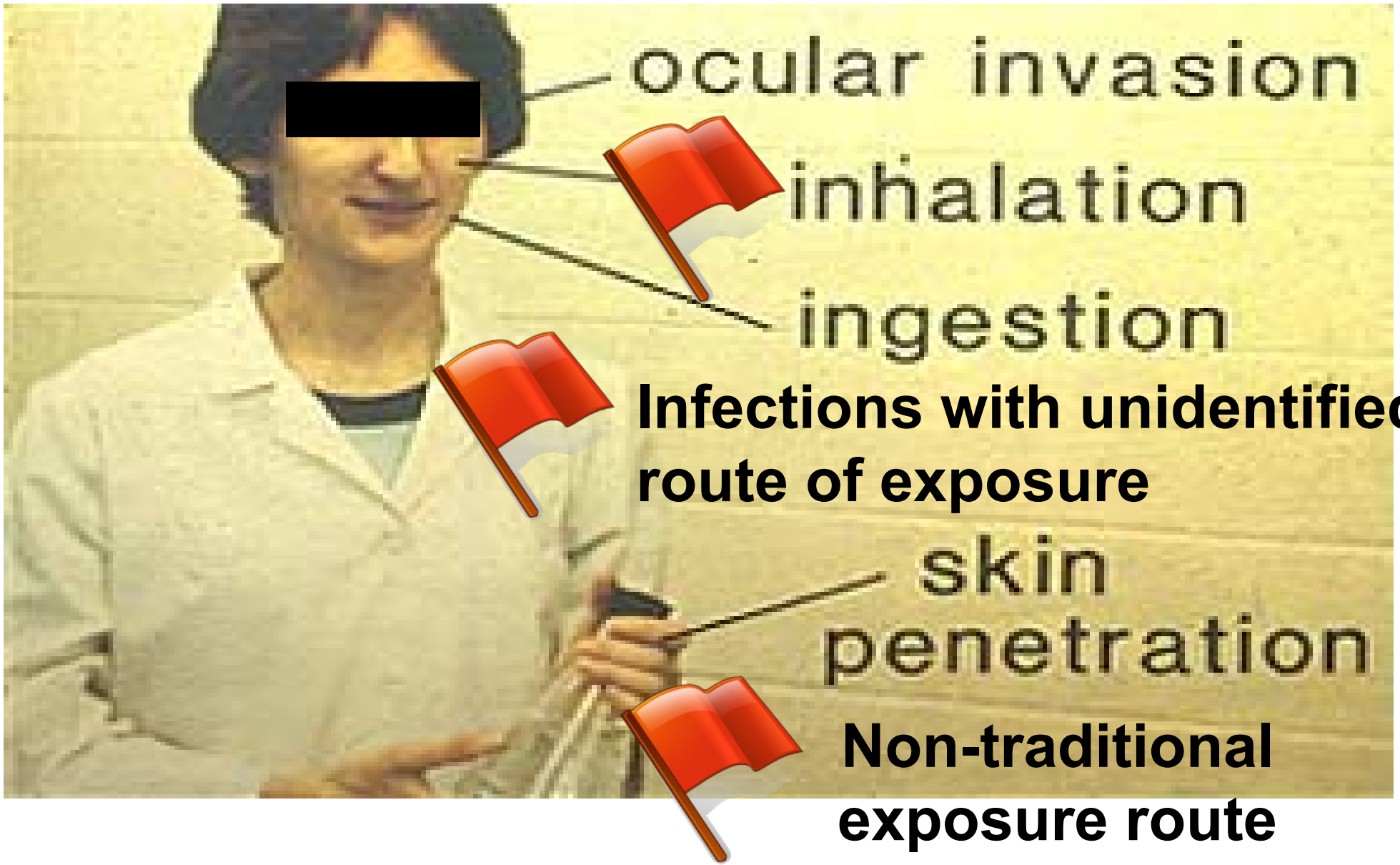
Q-Fever 7 Miles Downwind from Slaughterhouse (California)

- WELLOCK, CE, and MF PARKER. "An urban outbreak of Q fever in northern California." Ann. Conf. Am. Public Health Assoc., San Francisco. 1960.
  - 75 confirmed cases
  - Pathway from slaughterhouse 7 miles long and 1 mile wide downwind
  - Any cases outside this swath were frequent visitors to this zone
  - Sheep, goats and their placentas processed at this site
    - Aerosols generated and into prevailing winds from location at the base of the Bay Bridge to the areas downwind

Golden Age of Biosafety (1949 – 1979)

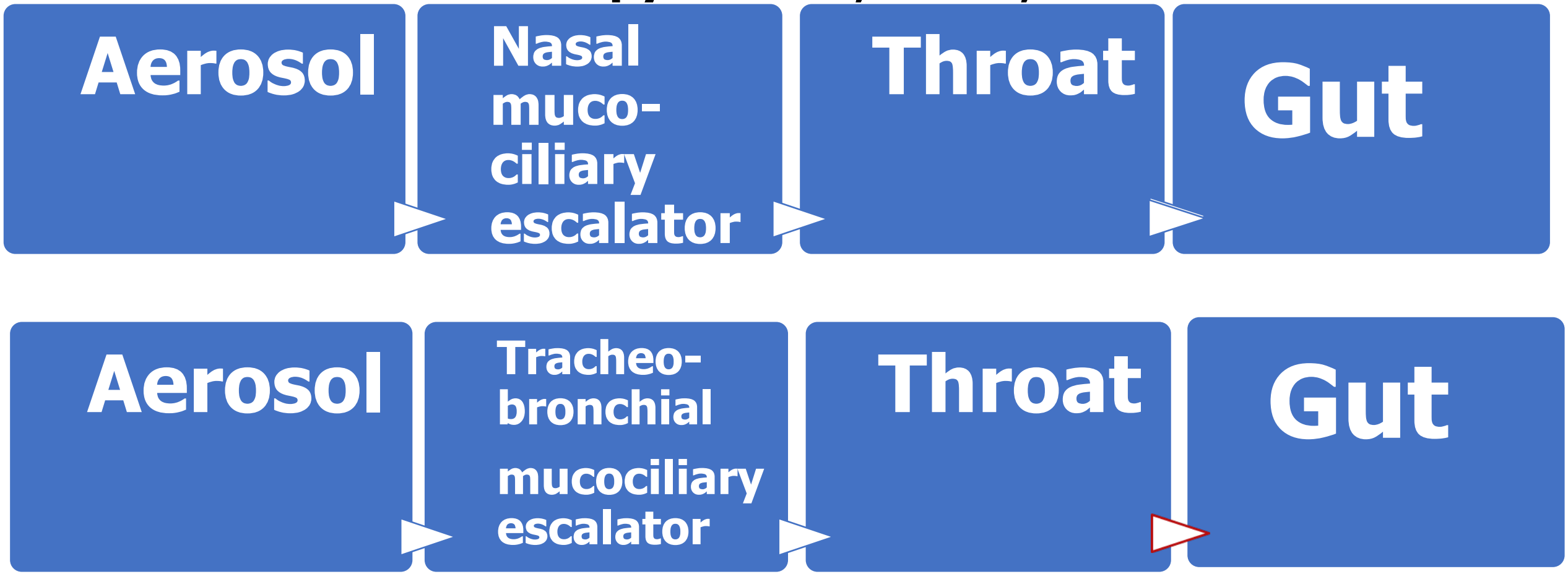
There can be **unnatural routes of exposure** in the laboratory setting that are generally not seen in nature.

(Sulkin 1960)


ocular invasion
inhalation
ingestion
Infections with unidentified route of exposure
skin penetration
Non-traditional exposure route

Non-Traditional Exposure routes

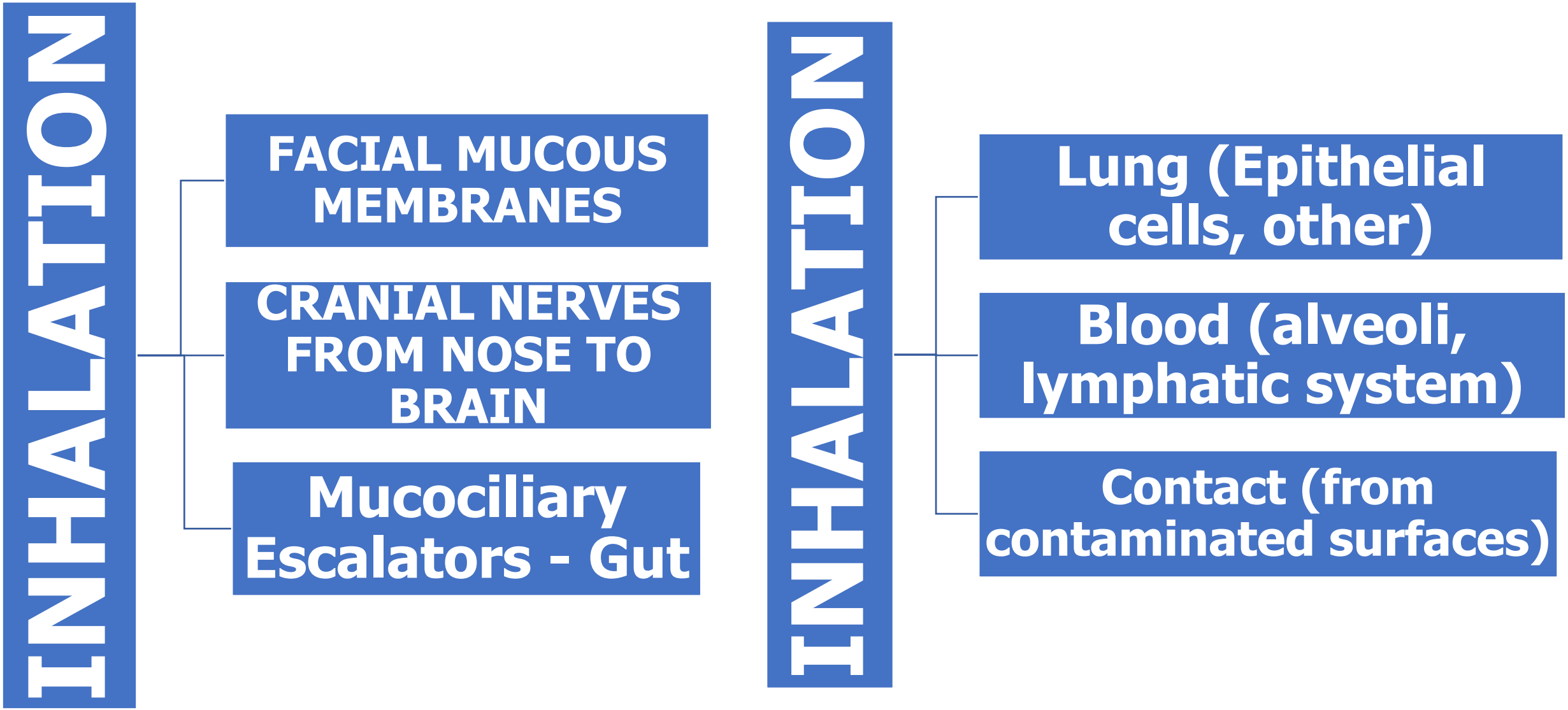
GI Pathogens: Salmonella, Listeria, Shigella, Campylobacter, E. coli, etc.



Non-Traditional Exposure routes

West Nile Virus, Yellow Fever Virus, Rabies Virus, Influenza Virus, Neisseria meningitidis, Streptococcus pneumoniae

ROUTE OF EXPOSURE TREES



Glove - Leak Rate - Facts

Glove Leak Rates	Exam Gloves	Surgical Gloves
Before Use (FDA)	2.5%	1.5%
After Use	*21 – 35%	**15.2%

****Double gloving: leak rates for inner gloves when double gloved - 1.17% (98.83% Effective!)**

*Boyle, B & Boyle, T, "Loss of Glove Integrity During Laboratory Animal Care Providers Daily Tasks," Lenape Regional High School, Medford NJ, Science Fair Poster Presentation, 2017

**Makama, J.G. et al, "Glove Perforation Rate in Surgery: A Randomized, Controlled Study to Evaluate the Efficacy of Double Gloving," Surgical Infections, Vol. 17 No. 4, pp 436-442, March 16, 2016

PPE for Nigerian Airport Ebola Screening (Reuters photo) . . . anything odd?

PPE Used by U.S. Ebola Physician: How did he get infected?

Photo: Sally Ezra, CDC Public Health Photo Library

Golden Age of Biosafety (1949 – 1979)

The **laboratory can be more dangerous than nature** due to the ability to **amplify** and concentrate pathogens to levels not seen in nature. Also, the growth and propagation of infectious agents in laboratory settings are **conducted repeatedly** within the laboratory as part of the research effort, enhancing the potential exposure.

(Langmuir 1960)

Pathogen Survival (examples)

Pathogen	Survival
Yellow Fever virus 17D	Likely not very long
Vesicular Stomatitis virus	3 to 4 days
HIV	42 days in blood in syringes, 7 days dried on cover slip
Salmonella	**3 months in wet feces, 13 months in dry feces, 6 years on surfaces, 231 days in soil**
Rhinovirus	Up to 3 hours
Sindbis virus	Long periods of time
Staphylococcus aureus	Carcasses – 42 days, floors – 7 days Skin – up to 38 days, fabrics – up to months
Mycbocterium (BCG)	**Weeks to months on inanimate surfaces**
Pseudomonas aeruginosa	Months on dry surfaces
Adenovirus	**7 days – 3 months on dry surfaces**
Borrelia burgdorferi	28 – 35 days at room temperature
Campylobacter jejuni	Can enter a viable but not culturable state to enhance survival
Chlamydia psittici	24 hours – 120 days on surfaces, 45 minutes on hands

Rank Order of Microorganisms by Disinfection Difficulty

Most Difficult to Inactivate
Prions or Transmissible Spongiform Encephalopathies (Creutzfeldt-Jakob Disease agent) Low Molecular Weight Toxins (Saxitoxin, Tetrodotoxin, Brevetoxins, Conotoxins, T-2 Mycotoxin, Polytoxin)
Very Difficult to Inactivate
Bacterial and Fungal Spores Parasitic Cysts (other stages) Giardia, Hookworm, Cryptosporidium
Difficult to Inactivate
Mycobacteriae Non-lipid viruses (Norovirus, Coxsackie virus, poliovirus, caliciviruses, rhinoviruses, enteroviruses)
Easier to Inactivate
Fungi, vegetative bacteria and lipid or enveloped viruses (SARS-CoV-2, HIV, Influenza)

Facilitated Discussion - Biosecurity

- A containment facility staff member called EHS to report a suspicious person who obscured their identity with a hoodie, hat, sunglasses, and a surgical mask.

- The report indicated that the person went onto the laboratory floor and down the lab access corridor with a back-pack, but the person left very shortly after without the backpack.

Questions

- What do you do?
  - First steps?
- Who needs to be informed?
- What other resources may exist to assist you with this response?
- Is this scenario already in your emergency response or contingency plans?
  - If yes, how well did your written plans work?
    - Update accordingly
  - If no, then update your plans to include this scenario.

Facilitated Discussion – Medical Surveillance

- An animal technician just notified their manager that they have signs and symptoms of infection with one of the pathogens used in the room they service, Middle-Eastern Respiratory Syndrome Coronavirus (MERS-CoV). The researcher had just reviewed his MERS-CoV pathogen card after falling ill.
- Symptoms include respiratory illness, fever, chills, sore throat, headache, muscle pains, with diarrhea and vomiting.

Questions

- What do you do?
  - First steps?
- Who needs to be informed?
- What other resources may exist to assist you with this response?
- Is this scenario already in your emergency response or contingency plans?
  - If yes, how well did your written plans work?
    - Update accordingly
  - If no, then update your plans to include this scenario.

Facilitated Discussion – Combined Medical and Biohazard Emergency

- Security dispatch just phoned the EHS emergency line to report that a researcher just contacted them to indicate while working with a co-worker handling Rabies virus, his co-worker collapsed while transferring flasks from the biosafety cabinet to the incubator.
- The co-worker is not responding and the flasks released virus when hitting the floor and contaminated the fallen researcher with Rabies virus.
- Security has already called 911 to request immediate medical assistance

Questions

- What do you do?
  - First steps?
- Who needs to be informed?
- What other resources may exist to assist you with this response?
- Is this scenario already in your emergency response or contingency plans?
  - If yes, how well did your written plans work?
    - Update accordingly
  - If no, then update your plans to include this scenario.

Facilitated Discussion – Contingencies and Biosecurity

- Two researchers just contacted Security separately to indicate that there are problems with the lab access doors into the BSL-3 research facility. The first call at 10:30 AM, indicated that the door to his lab was not locked, and she was able to push the door open without using a keycard.
- Security also noted that they had received a call about 10 minutes earlier from a researcher who noted that they could not gain entry to their research lab. Security contacted the Facilities group and asked them to send assistance.

Questions

- What do you do?
  - First steps?
- Who needs to be informed?
- What other resources may exist to assist you with this response?
- Is this scenario already in your emergency response or contingency plans?
  - If yes, how well did your written plans work?
    - Update accordingly
  - If no, then update your plans to include this scenario.

Facilitated Discussion Contingencies

- A researcher phoned EHS with her sealed bagged enclosed cell phone to indicate that the biosafety cabinet she was just using for research with SARS-CoV-2 just stopped working during her experiment.

Questions

- What do you do?
  - First steps?
- Who needs to be informed?
- What other resources may exist to assist you with this response?
- Is this scenario already in your emergency response or contingency plans?
  - If yes, how well did your written plans work?
    - Update accordingly
  - If no, then update your plans to include this scenario.

Facilitated Discussion Contingencies

- A researcher notified EHS to indicate that she had to leave the Animal BSL-3 room after noticing a significant build up of vapor on the interior of her Powered-Air-Purifying-Respirator hood. She was only in the room for 5 minutes before she couldn’t see very well so left.
- She also reported that none of the respirator alarms triggered.

Questions

- What do you do?
  - First steps?
- Who needs to be informed?
- What other resources may exist to assist you with this response?
- Is this scenario already in your emergency response or contingency plans?
  - If yes, how well did your written plans work?
    - Update accordingly
  - If no, then update your plans to include this scenario.

Do what you can

With what you have

In the place that you are

In the time that you have

Nkosi Johnson

From book "We Are All The Same" by Jim Wooten

Thank you

Ben Fontes

Yale University EHS

Benjamin.fontes@yale.edu

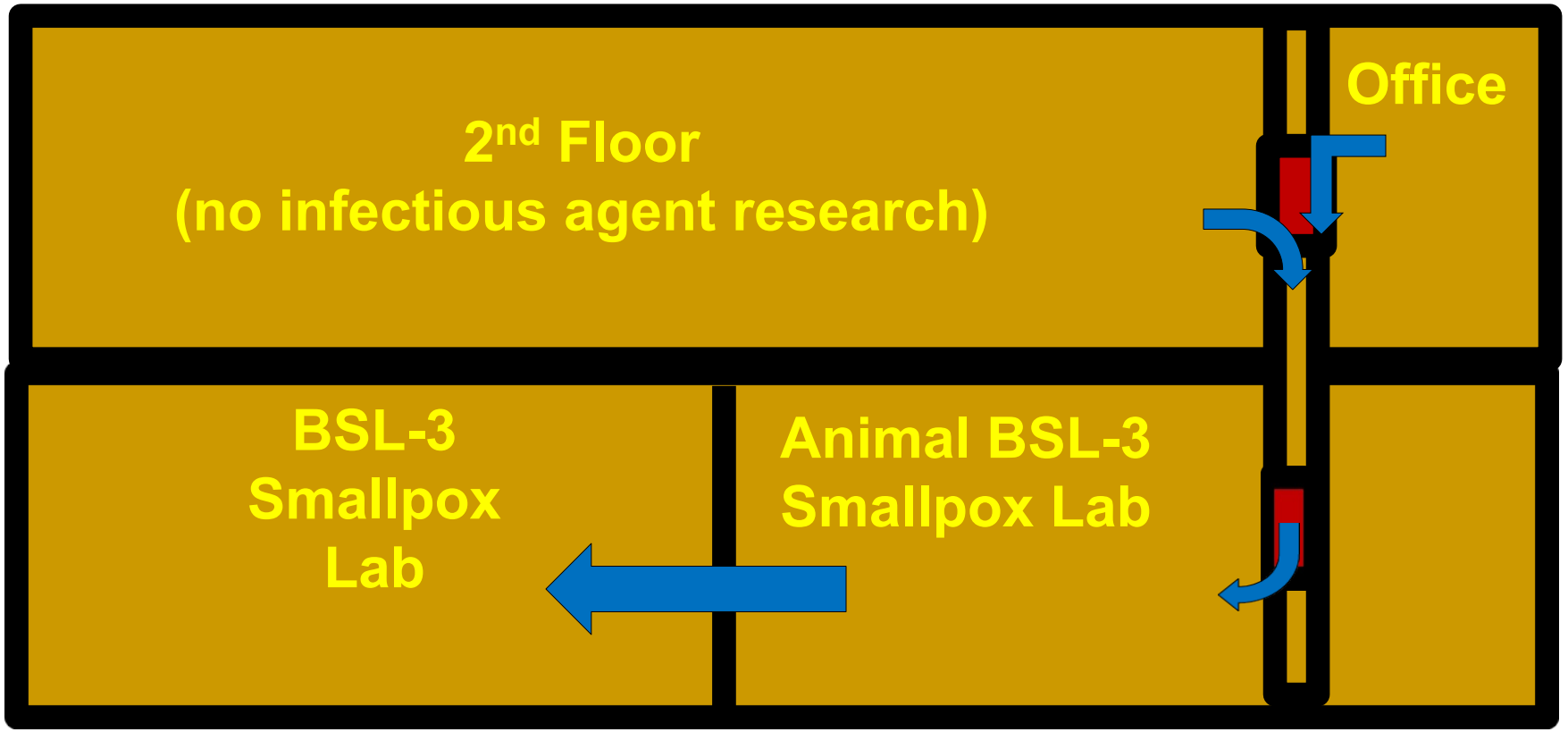
IF TIME
BONUS CASE STUDY FROM THE PAST

Fatal Smallpox virus infection: Support Staff Worker at High-Containment Facility

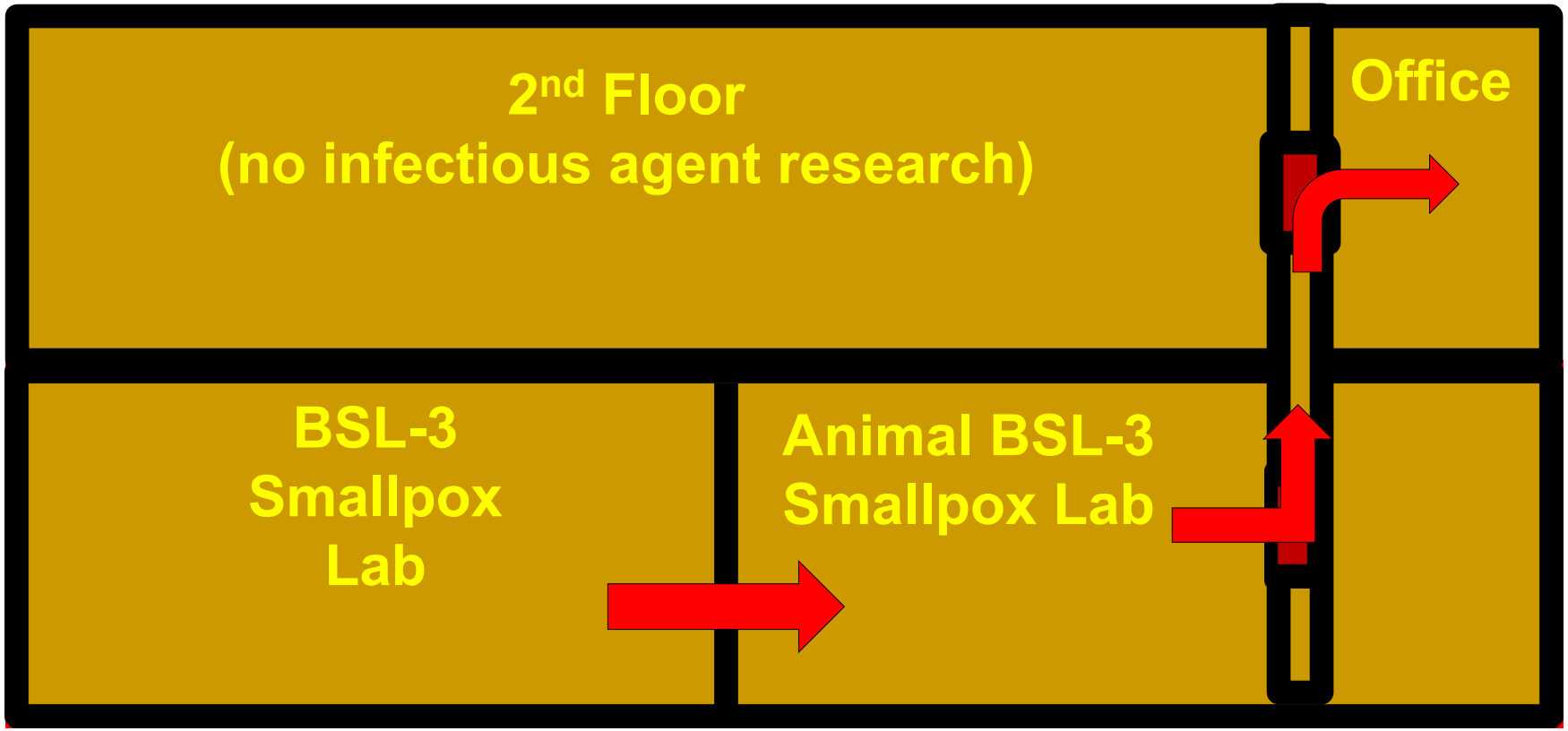
- BSL-3 Smallpox virus lab (Birmingham, UK) - 1979
  - Smallpox reclassified as RG4 (will require BSL-4 in 6 months)
- Photographer/Administrative support employee infected
  - Never handled virus, not vaccinated
  - Orders supplies using phone in 2nd floor office
- Race to conduct as much research as possible
- Facility aging, doesn't meet modern specifications
  - Exhaust fan old, shuts off periodically, not interlocked to shut off supply
  - No visible tell-tales, no alarms for fan failures

1978 Fatal Smallpox Virus Lab Acquired Infection (LAI)

1978 Fatal Smallpox LAI: (Airflow direction with lab exhaust fan ON)



1978 Fatal Smallpox LAI: (Airflow direction with lab fans "OFF")



Post-session Survey

- Takes 2 minutes to complete and helps improve ECHO Biosafety Program and CoP
- Participation is voluntary
- Responses are anonymous and feedback will be summarized in aggregate
- Questions? Contact DLSbiosafety@cdc.gov

Scan here to take the September survey

International Organization for Standardization (ISO) 35001:2019 Biorisk Management

CDC's Division of Laboratory Systems (DLS) is offering free access to the **ISO 35001:2019 - Biorisk management for laboratories and related organizations** for clinical and public health laboratories

ISO 35001:

- ISO 35001 defines a process to identify, assess, control, and monitor the risks associated with hazardous biological materials.
- The standard applies to laboratories or organizations that work with, store, transport, and/or dispose of hazardous biological materials.
- The offer is currently limited to interested laboratories and organizations within the United States.

International Organization for Standardization (ISO) 35001:2019 Biorisk Management (cont.)

Process Overview:

- Select a point of contact responsible for biorisk management (e.g., Laboratory Director, Biosafety Officer).
- Point of contact email DLSBiosafety@cdc.gov
  - Name and physical address of the institution
  - Name and work e-mail address
  - Role in the organization
- DLS notifies the approved point of contact with details on how to access the standard.

DLS supports the enhancement of biorisk management in laboratories and encourages your institution to participate. For questions, contact DLSBiosafety@cdc.gov.

Biosafety & Biosecurity Month

Upcoming Webinars

- Wednesday, 10/9, at 1 PM ET
  - *Safe Handling and Reporting of Highly Pathogenic Microorganisms in the Laboratory*
- Wednesday, 10/16, at 1 PM ET
  - *Lab Safety in the Age of AI: Evaluating Multimedia Options*

DLS ECHO Biosafety Session: October 22, 2024

Biosecurity Aspects of Biorisk Management

Cristine C. Lawson, Ph.D., RBP, CBSP

Deputy Director for Biosecurity

Biological Select Agent and Toxin (BSAT) Biorisk Program Office,
U.S. Department of Defense

Frederick, MD