Establishing Yale's Biosafety Stewardship Program

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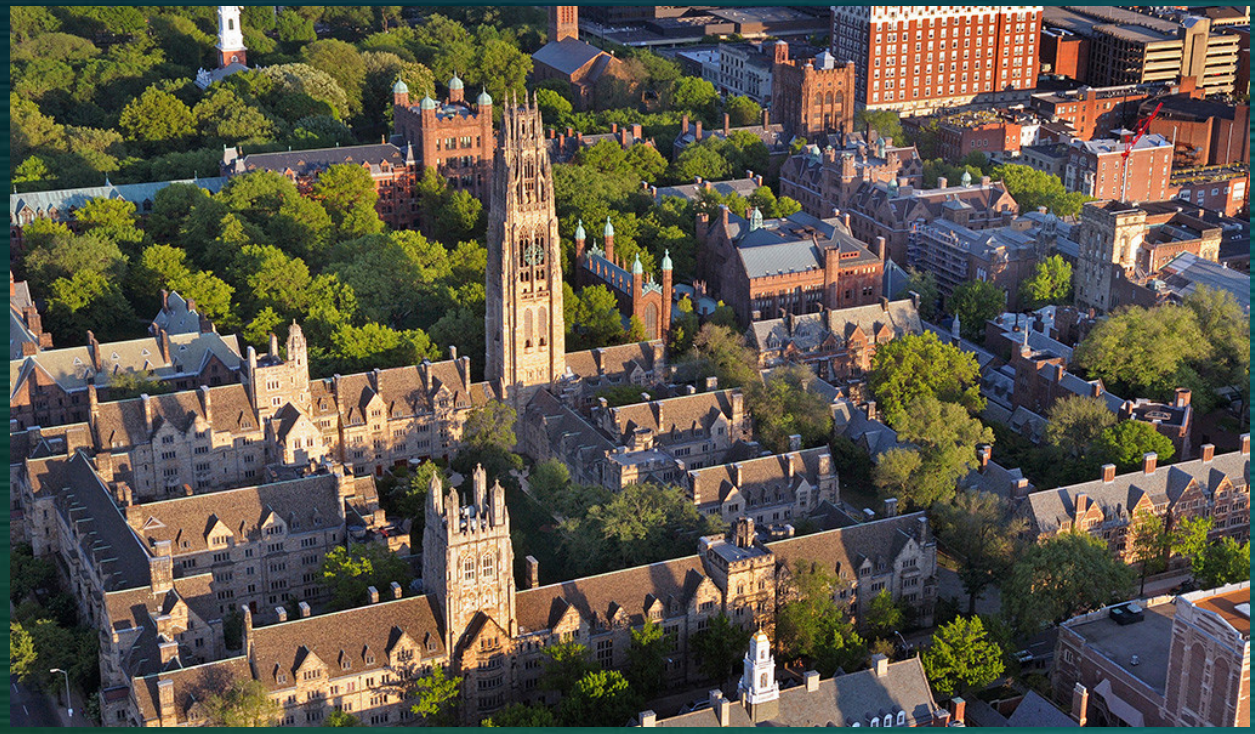
Yale University EHS, New Haven CT



ABSA 2019 Birmingham AL

Outline

1. The problem we want to address
2. Objectives of the biosafety stewardship program
3. Resources available to us
4. The freezer inventory project: Initial tasks to establish our biosafety stewardship program
5. Ongoing work in this program
6. Key outcomes

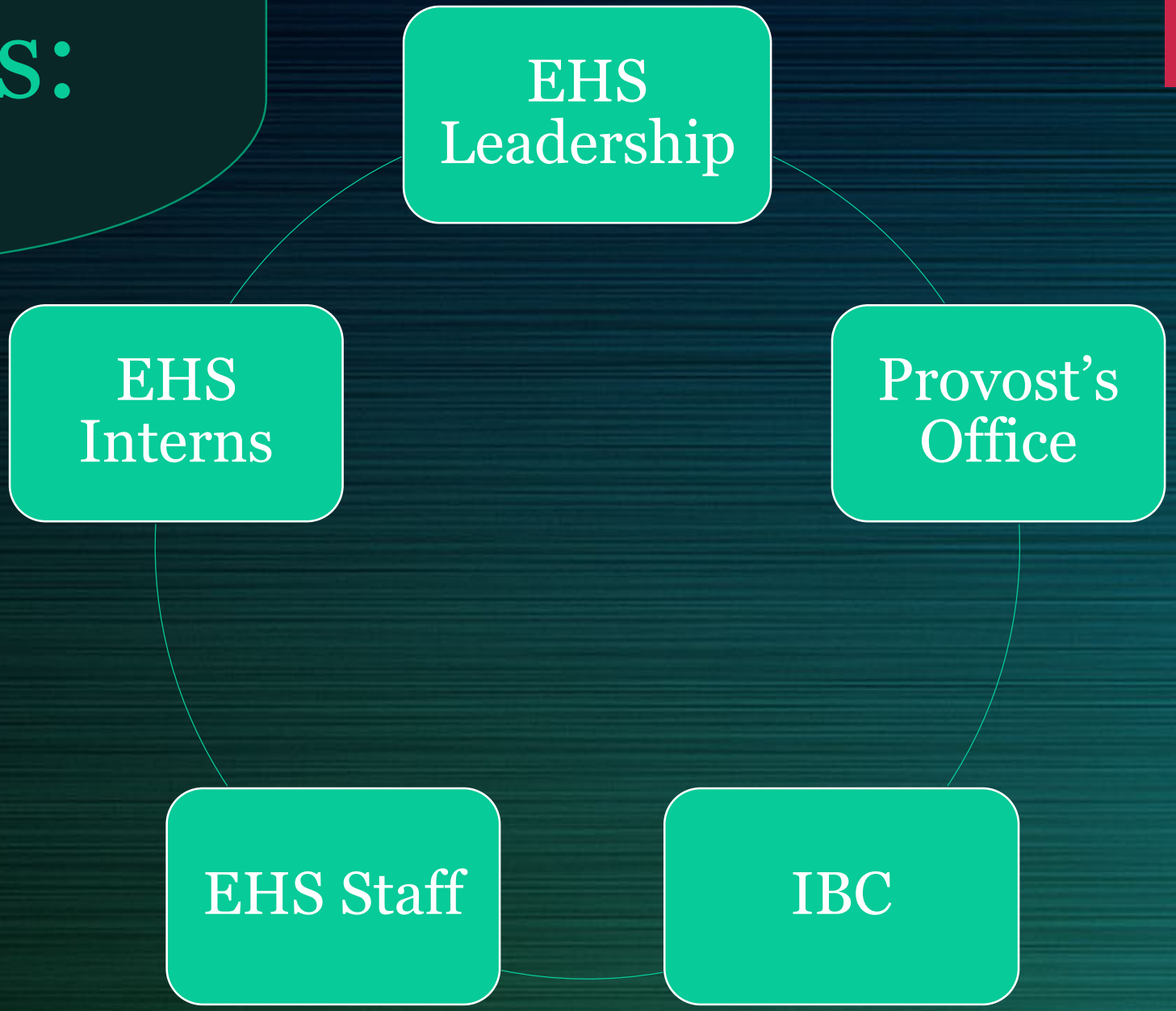
Cold Storage in Research Institutions

Do you know?

Objectives

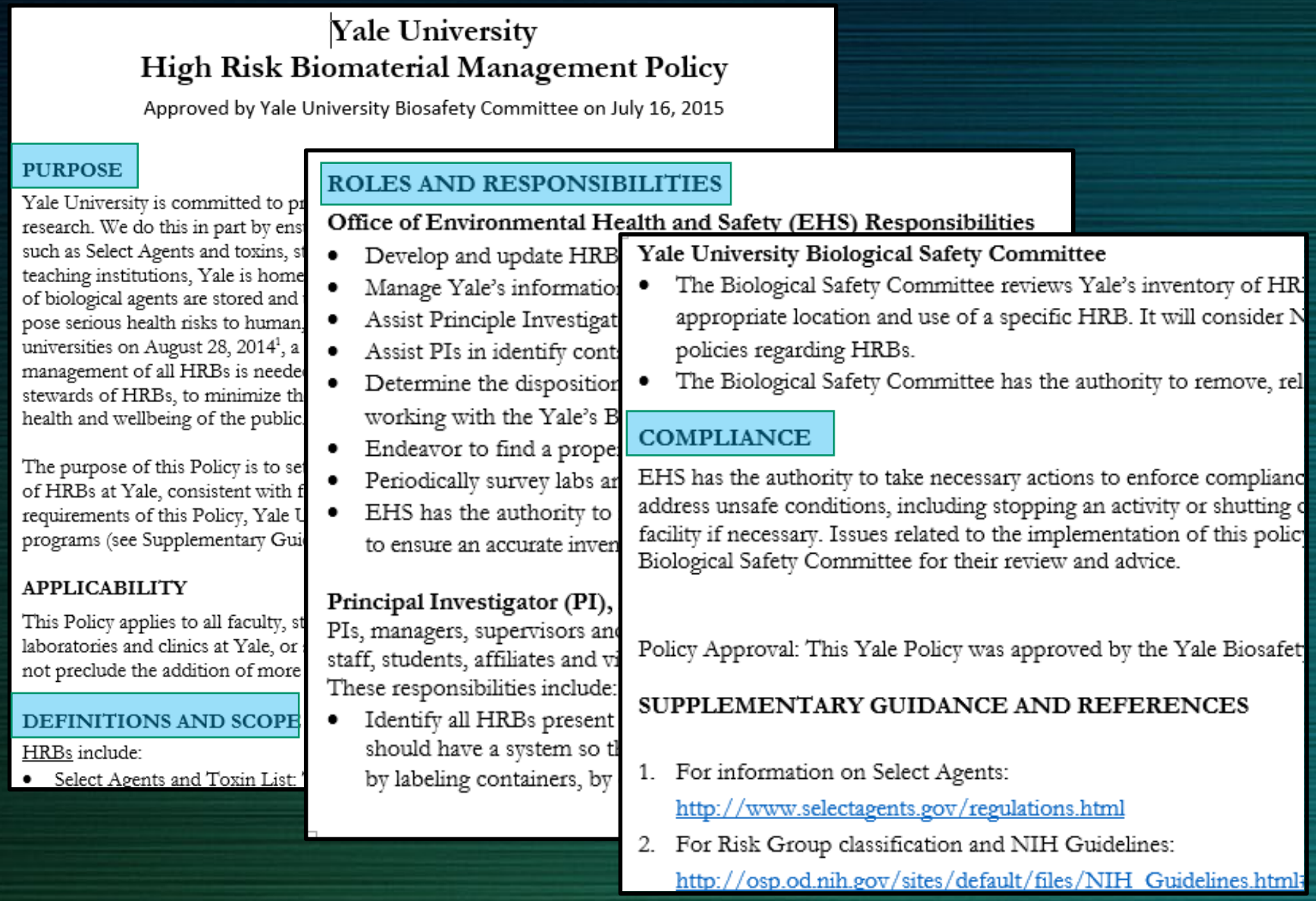
1. Establish a Yale policy for high risk biomaterial management
2. Survey and Inspect all cold storage units to identify and address unknown samples and freezers
3. Verify that all labs with high risk biomaterials have an actively updated inventory.
4. Confirm an updated inventory in the Yale Environmental Health and Safety (EHS) database for all cold storage units on campus.

Resources:



The Freezer Inventory Project

1. Develop a Yale policy on High Risk Biomaterial Management.
2. Learn from other institutions (Northwestern University)



Yale University
High Risk Biomaterial Management Policy
Approved by Yale University Biosafety Committee on July 16, 2015

PURPOSE

Yale University is committed to pr
research. We do this in part by ens
such as Select Agents and toxins, s
teaching institutions, Yale is home
of biological agents are stored and
pose serious health risks to human
universities on August 28, 2014[1], a
management of all HRBs is neede
stewards of HRBs, to minimize th
health and wellbeing of the public.

The purpose of this Policy is to se
of HRBs at Yale, consistent with f
requirements of this Policy, Yale U
programs (see Supplementary Gui

APPLICABILITY

This Policy applies to all faculty, s
laboratories and clinics at Yale, or
not preclude the addition of more

DEFINITIONS AND SCOPE

HRBs include:

- Select Agents and Toxin List:

ROLES AND RESPONSIBILITIES

Office of Environmental Health and Safety (EHS) Responsibilities

- Develop and update HRB
- Manage Yale's informatio
- Assist Principle Investigat
- Assist PIs in identify cont
- Determine the dispositio
  working with the Yale's B
- Endeavor to find a prope
- Periodically survey labs ar
- EHS has the authority to
  to ensure an accurate inven

Principal Investigator (PI),
PIs, managers, supervisors an
staff, students, affiliates and v
These responsibilities include:

- Identify all HRBs present
  should have a system so t
  by labeling containers, by

Yale University Biological Safety Committee

- The Biological Safety Committee reviews Yale's inventory of HR
  appropriate location and use of a specific HRB. It will consider N
  policies regarding HRBs.
- The Biological Safety Committee has the authority to remove, rel

COMPLIANCE

EHS has the authority to take necessary actions to enforce complianc
address unsafe conditions, including stopping an activity or shutting
facility if necessary. Issues related to the implementation of this polic
Biological Safety Committee for their review and advice.

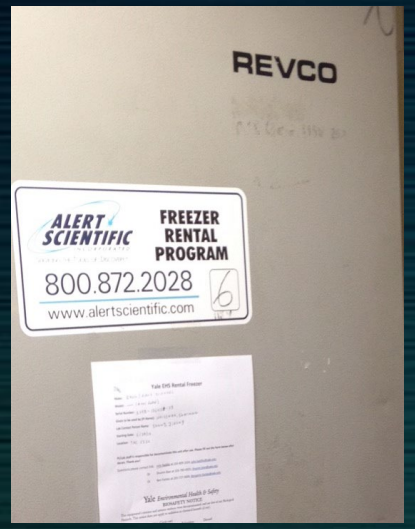
Policy Approval: This Yale Policy was approved by the Yale Biosafet

SUPPLEMENTARY GUIDANCE AND REFERENCES

1. For information on Select Agents:
   http://www.selectagents.gov/regulations.html
2. For Risk Group classification and NIH Guidelines:
   http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html

3. Preparations:

- Supplies to laboratories
- Inventory templates



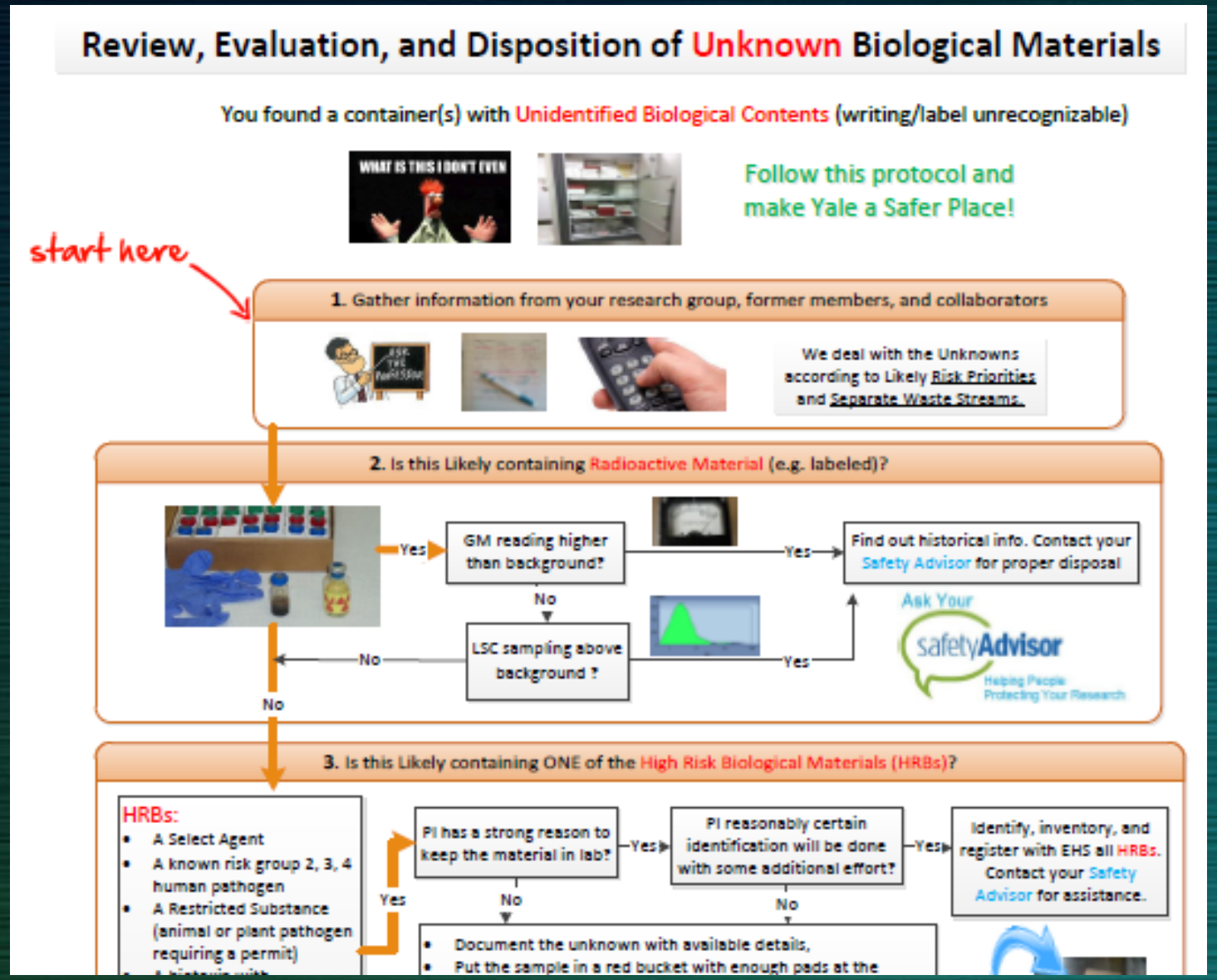
High Risk Biomaterial Inventory

Dept/Organization: **Principle Investigator:** **Most Recent Update:**

	Agent Information								Physical Location						Owner Info	
Entry #	Species	Strain	Cell Line or Oranism	Construct	Storage media	Titer Passage Volume	Medical Surveil. Vaccine	BSL	Building/ Room #	Freezer fridge #	Shelf #	Rack #	Box #	Tube in box	Owner ID	Date Inventory or Removal
1																
2																
3																
4																
5																

3. Preparations (cont.)

- Supplies to labs
- Inventory templates
- Unknown disposal procedure



3. Preparations (cont.)

- Supplies to labs
- Inventory templates
- Unknown disposal procedure
- Compliance Status stickers

Freezer Inventory Complete

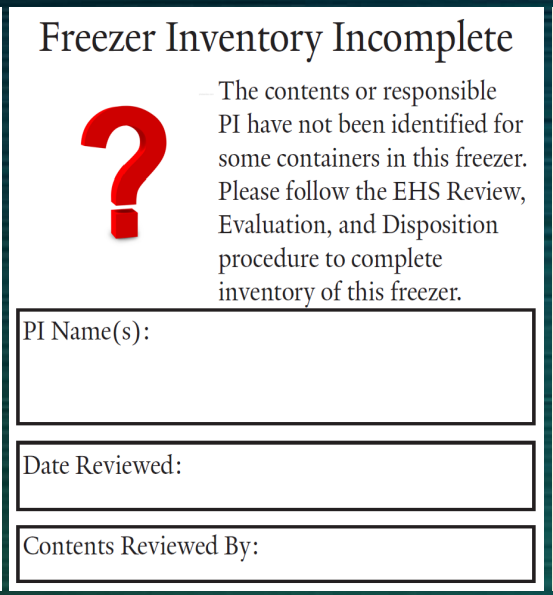
The contents of this freezer have been reviewed.

The contents of each container and PI responsible for each container have been identified.

PI Name(s):

Date Reviewed:

Contents Reviewed By:



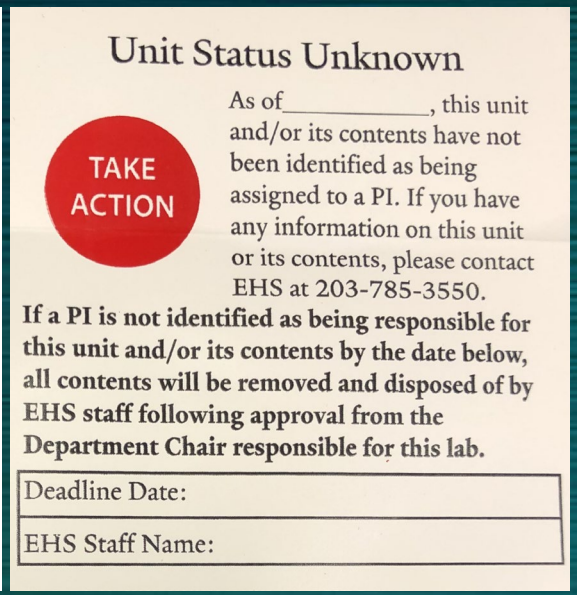
Freezer Inventory Incomplete

The contents or responsible PI have not been identified for some containers in this freezer. Please follow the EHS Review, Evaluation, and Disposition procedure to complete inventory of this freezer.

PI Name(s):

Date Reviewed:

Contents Reviewed By:



Unit Status Unknown

TAKE ACTION

As of_____, this unit and/or its contents have not been identified as being assigned to a PI. If you have any information on this unit or its contents, please contact EHS at 203-785-3550.

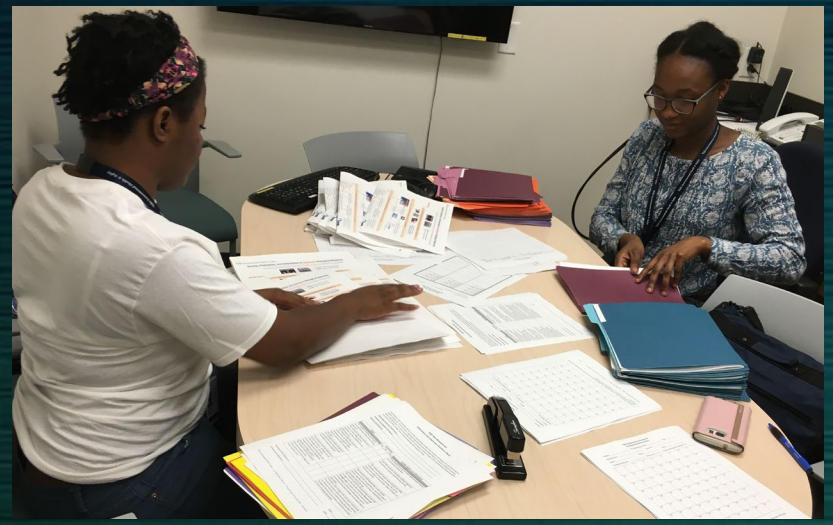
If a PI is not identified as being responsible for this unit and/or its contents by the date below, all contents will be removed and disposed of by EHS staff following approval from the Department Chair responsible for this lab.

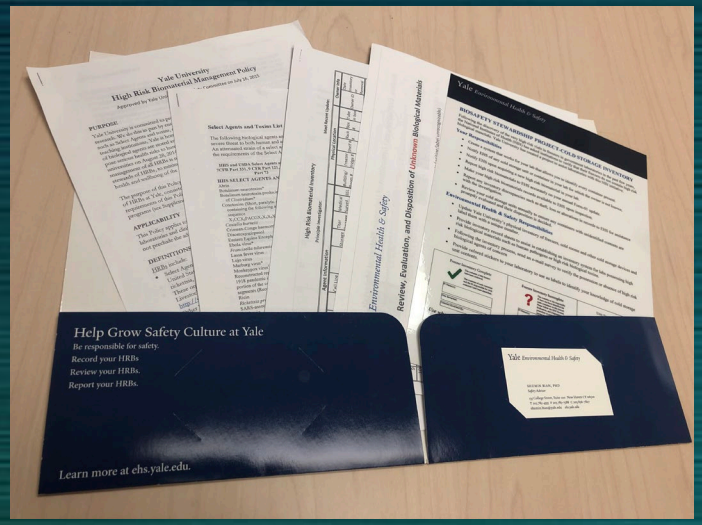
Deadline Date:

EHS Staff Name:

4. Outreach:

- Seminars
- Flyers and announcements
- Information folder for safety advisors prep visits





5. Trial Run

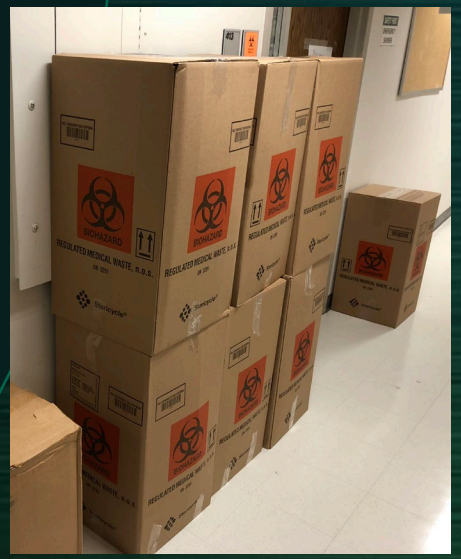
Lab visits :

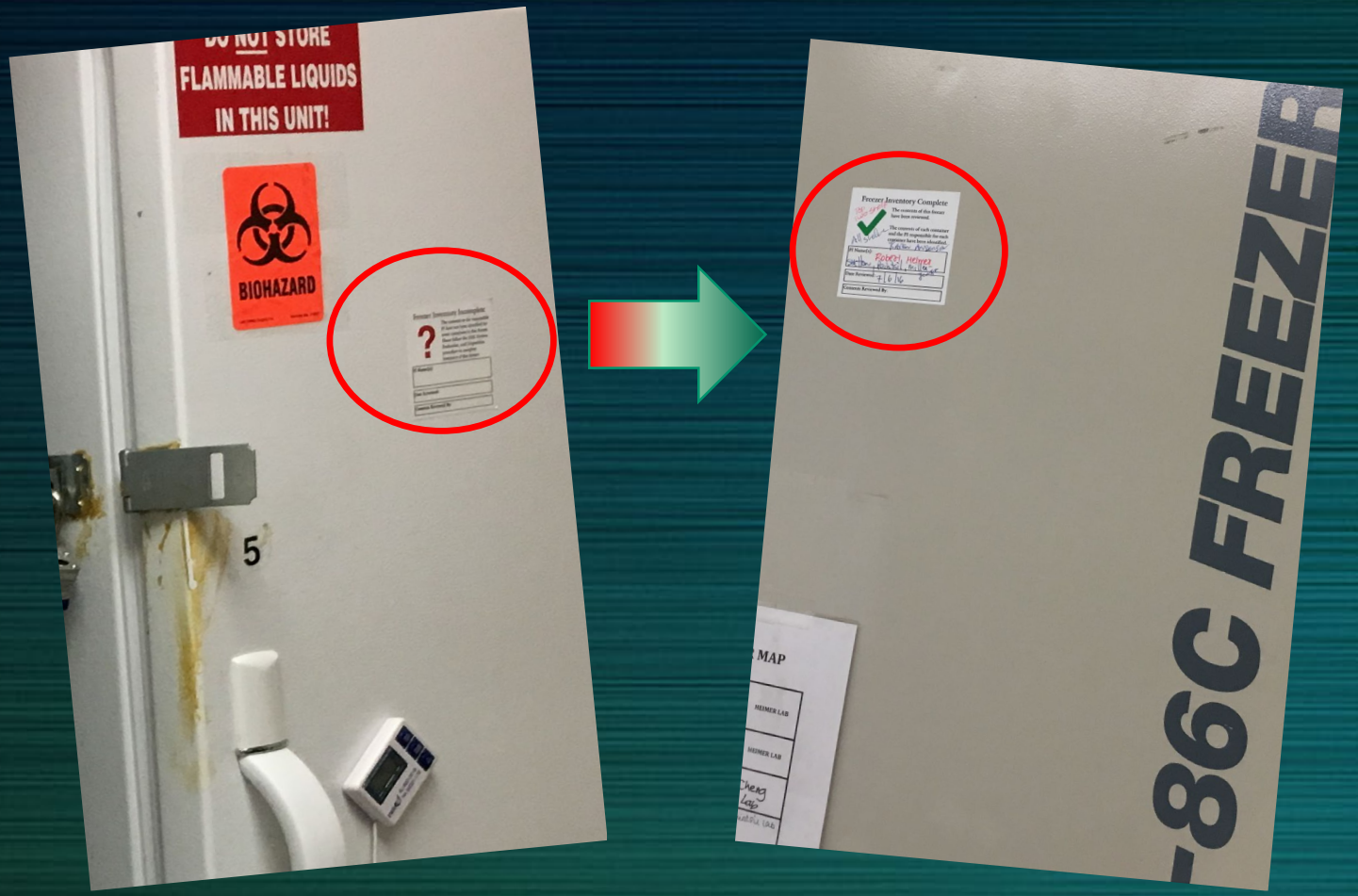
How big is the task?

- > 50 research and clinical buildings
- > 500 principal investigators (PIs)
- > 5000 cold storage units in use

6. Yale-wide lab visits: Building-by-building, Floor-by-floor, Lab-by-lab.

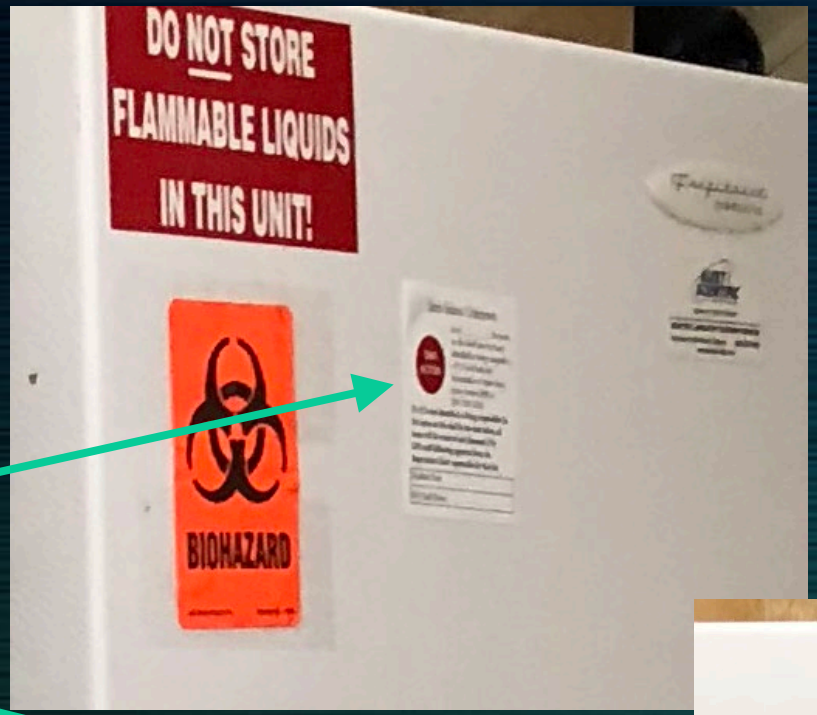
7. Return visits

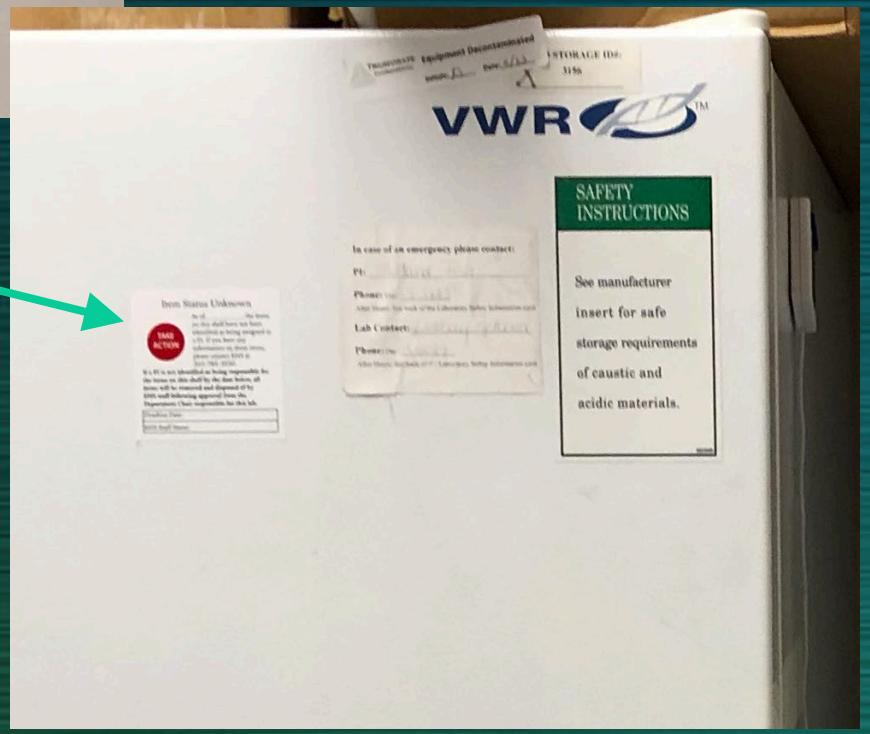




8. Identify "Take Action" units:

   Orphan
   Abandoned
   Unknown

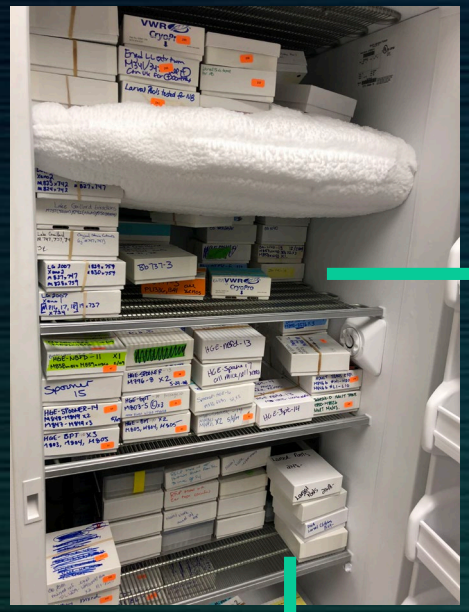




(Contracted with TEI)

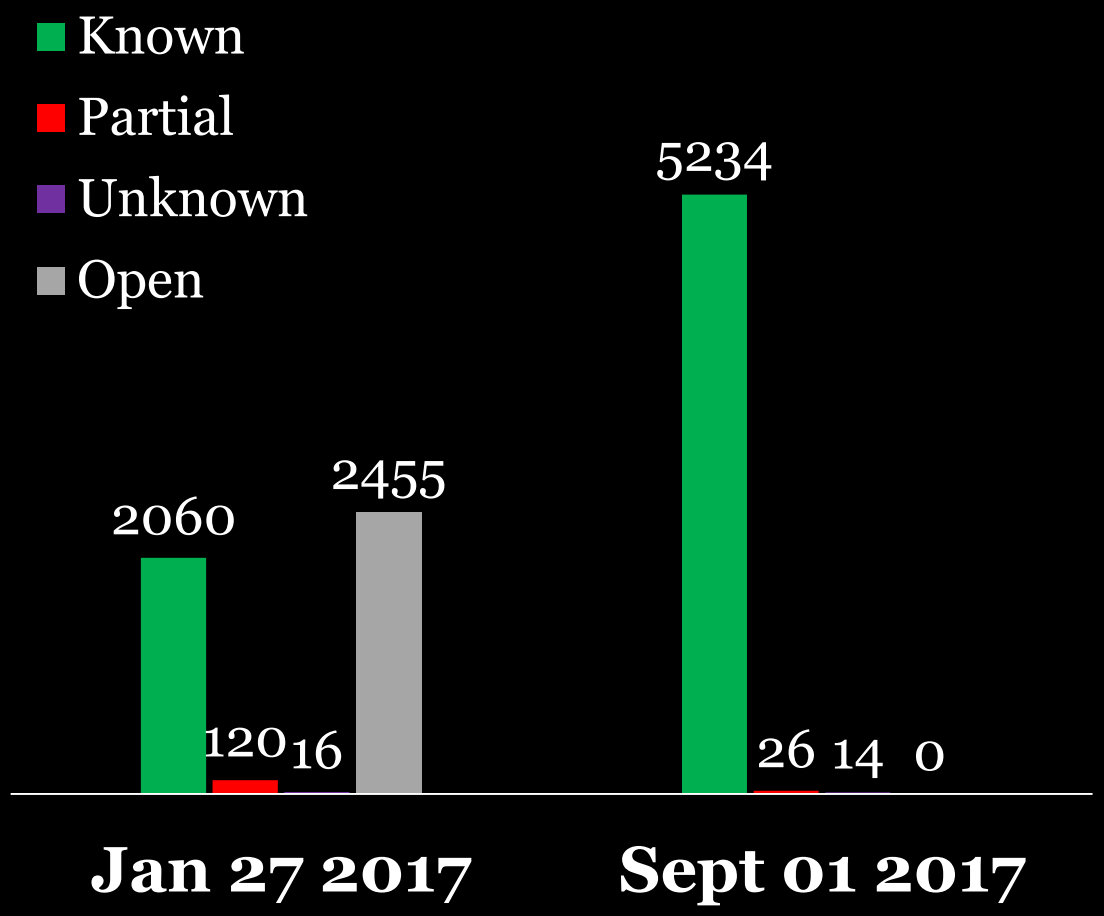
9. Disposal of "Action Required" units:

!!! Researchers DO NOT want to throw away THEIR samples!!!

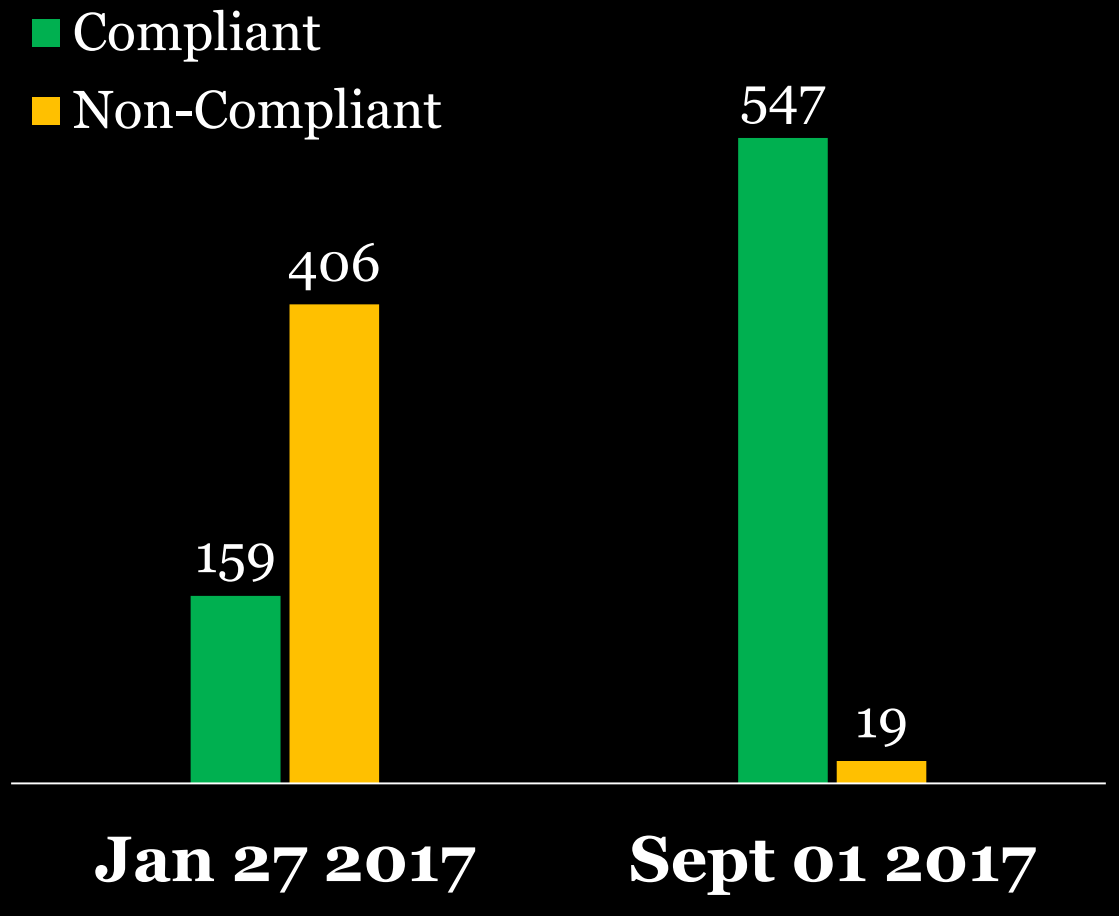


Project progress monitoring

Cold Storage Inventory Status

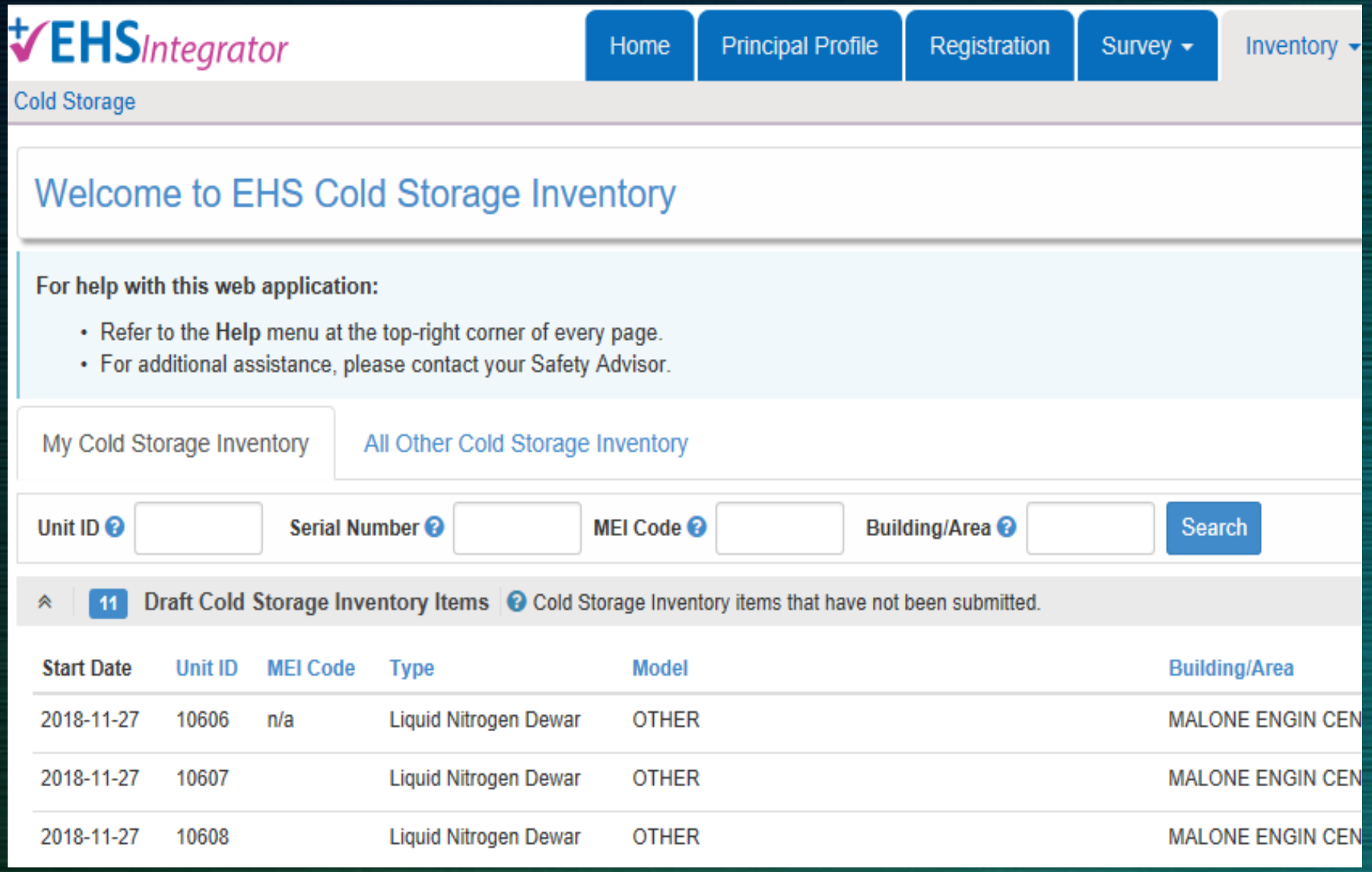


Principal Investigator Status



Ongoing Work

1. Cold storage inventory updates online
2. High risk biomaterial inventory updates online
3. Regular surveys by EHS



Key Outcomes

1. We have a High Risk Biomaterial Management policy in place,
2. Identified and disposed unknown/unwanted biomaterials; identified and cleaned up orphan/abandoned freezers,
3. Ensured labs with high risk biomaterials have updated active inventory,
4. Set up online cold storage database that can be updated easily.
5. Freed up freezer spaces, streamlined cold storage in labs.

Thank You!

- Yale EHS Director Peter Reinhardt
- BSO Ben Fontes and Associate BSO Deb Ferry
- Deputy Director: Kevin Charbonneau
- EHS staff and interns: Rob Davis, Donique Haynes, Kole Sheriff, Julio Badillo, Ray Charles Capanzana, Taylor Gainey, Tamara Gray