

UNL's POST-APPROVAL MONITORING PROGRAM:

PARTNERING WITH RESEARCHERS TO MANAGE BIOSAFETY RESEARCH COMPLIANCE

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Background

UNL EHS is service-based department that is staffed by ~24 employees. Our department is charged with compliance oversight for multiple program areas including: hazardous waste, chemical safety, biological safety, radiation safety, occupational safety, air quality and watershed management. It is our mission to protect UNL's human resources and preserve the environment. To that end, we are dedicated to creating a partnership with the campus community and providing services to assist employees in integrating safety and compliance into their workplace culture and behavior.

Laboratory Safety Surveys

A major aspect of research compliance is laboratory safety and our office conducts a safety survey of every laboratory space annually.

Our checklist contains 75 items in 10 categories. All items on the checklist are based on regulatory guidance from multiple sources (OSHA, EPA, NRC, NIH, BMBL, etc.)

At the end of 2017, we determined that growth in biological research in combination with an overhaul of the EHS Laboratory Safety program including a robust auditor training program demanded a shift in the way we inspected biological research labs. Prior to 2018 we had a separate checklist for biosafety-related issues in addition to the standard laboratory safety checklist. We selected a subset of 8 questions from the 18 on the biosafety checklist and added 2 new sections to the lab safety checklist for these biosafety-related questions. The items that we selected to add are easily assessable (yes/no questions) and did not require in-depth knowledge of the on-going research to evaluate and answer.

Selected Checklist Items

1. Disinfectant containers are not appropriately labeled (name, made/mfg. date and expiration date). Expired disinfectants are in use.
2. A biohazardous spill kit is not available in the lab or is not appropriately stocked. Spills and contaminated surfaces and equipment are not appropriately cleaned and decontaminated.
3. Biohazardous waste is not properly or appropriately decontaminated; or waste is not properly stored or transported prior to disposal. Autoclaved waste bags are not properly prepared for disposal.
4. Furniture, chairs and other surfaces are not easily disinfected. Carpet is present.
5. Lab is unsecured. Doors left open/unlocked when unoccupied. No screens on windows that open.
6. A sign incorporating the universal biohazard symbol is not posted at the lab entrance when human materials or pathogens are present. A restricted access sign is not posted for labs working with animal pathogens, plant pathogens or plant pests.
7. Vacuum traps are not protected with liquid disinfectant traps or HEPA filters or both if an HIV/HBV laboratory.
8. Animals and plants not associated with the research are present in the lab.

The Problem

- Discontinuing use of the biosafety-specific checklist created a gap in compliance information obtained during laboratory safety surveys.
- Recent increase in NIH non-compliance incidents
- Biosafety team no longer had annual in-person contact with PIs.

Gap Analysis

- Need a means to gather information from researchers with IBC protocols related to discontinued checklist items
 - Biosafety Manual review
 - Training Needs
- Need to determine contributing factors to recent spike in NIH Non-compliance incidents.
 - Re-Training for PIs
 - Eliminate barriers to compliance
- Lab auditors do not have sufficient experience or access to the information necessary to assess and evaluate complex biosafety-related issues
 - ✦ Auditors receive robust training in standard lab safety
 - ✦ Auditors are trained in general Biosafety and Biosecurity concepts
 - ✦ Auditors lack the requisite biosafety training and research experience
 - ✦ Auditors do not have access to IBC approved research protocols



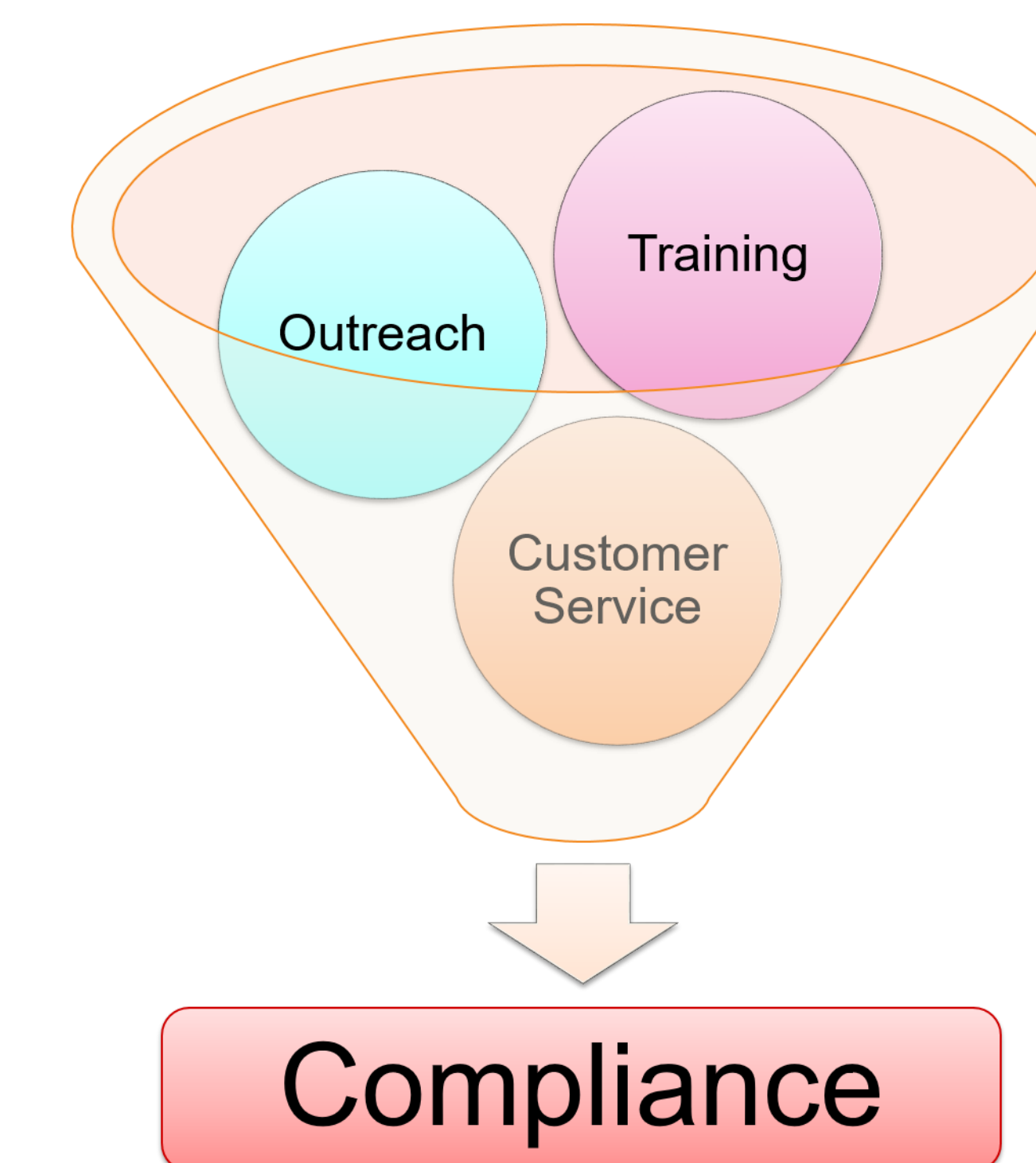
- ✦ Infrequent contact with PIs
- ✦ Several NIH Non-compliance incidents each year
- ✦ Limited outreach and on-campus training opportunities
- ✦ Strong relationships with PIs
- ✦ Infrequent NIH Non-compliance
- ✦ Visible outreach and regular on-campus training

The Solution

Establish new program dubbed **Post-Approval Monitoring (PAM)** for all PIs who have active IBC protocols (~180)

Goals:

- Further build relationships with PIs
- Offer outreach about training and EHS resources
- Assist with IBC compliance



PAM Visit Summary

Brief (30-60 min), informal discussion with the PI about current and future work pertinent to their IBC protocol.

- Biosafety Compliance Items
 - Training
 - Last Safety Survey Issues
 - Biosafety Manual
 - Exposures/Injuries
- Discuss Current and future projects
- Inform PIs about new policies and procedures
- Customer Satisfaction Feedback from PIs

PAM Program Details

PAM Questionnaire Topics



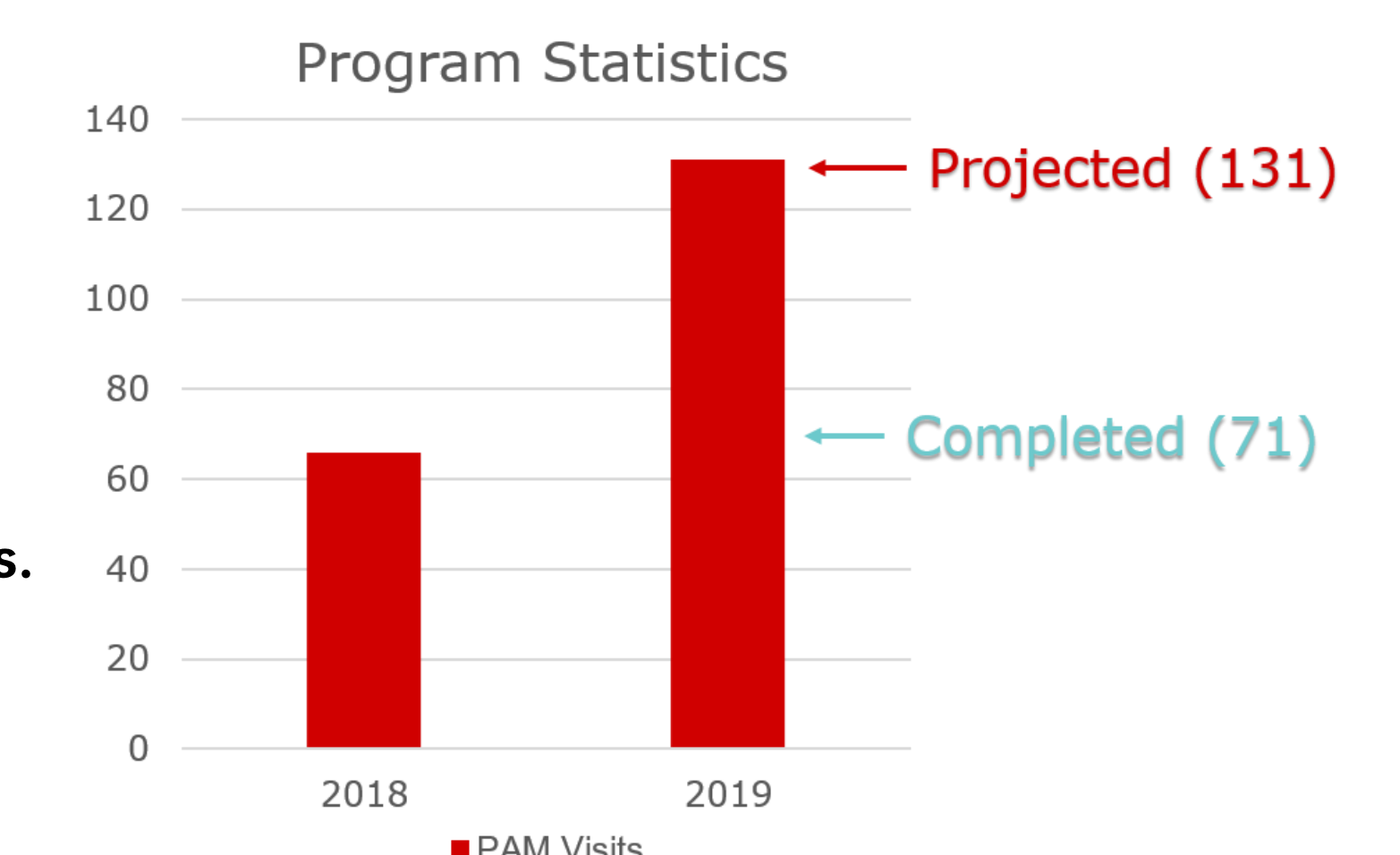
How often do we visit each PI?

- It is not feasible to visit every PI each year.
- We created a tiered classification system based on the risk assessment of the work and other factors like safety record and IBC compliance history.

Frequency Rationale

6 months	New researcher or chronic safety issues or recent non-compliance incident or infrequent protocol updates
1 year	r/sNA research and Infrequent protocol updates or medical surveillance concerns or non r/sNA research with safety concerns
2 years	r/sNA research and regular protocol updates along with good lab safety record
3 years	Non r/sNA research (e.g. field collections, human subject studies)

- Visits are divided between 3 biosafety team members.
- 66 visits the first year
- Will visit all active PIs at least once by the end of 2020.
- Reports are kept as internal records.
- Follow up with PIs for resource requests and training outreach



Summary

- Very positive feedback from faculty;
- Increased our presence on campus and strengthened our relationships;
- Emphasizes the importance of providing resources to PIs and helping maintain compliance.



Actual PI Feedback!

"(submitting an amendment) goes much faster when members of the Biosafety team are present."

"I really appreciate the outreach and expertise from the EHS Biosafety Staff."

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