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# Biosafety Program Annual Report

FY2018

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Prepared by: UT Biosafety Office

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## **FY2018 Biosafety Report & Activity Summary: Executive Summary**

The University of Tennessee Biosafety Program is committed to protecting faculty, staff, students, visitors, the general public and the environment from exposures (or potential exposures) to biological hazards, and to ensuring that activities involving biological hazards and the facilities used to conduct such work are in compliance with applicable U.S. Federal, Tennessee State and local laws, regulations, and guidelines. The enclosed report summarizes the FY2018 efforts of the Institutional Biosafety Committee (IBC) and Biosafety Office toward these goals, including:

- **IBC** – The IBC welcomed a new chair (Dr. David White) and vice-chair (Dr. Elizabeth Fozo). The committee implemented the iMedRIS web-based compliance management system, reviewed 40 registrations (average approval time = 25 days), revised the charter/bylaws and developed several standard operating procedures (pending distribution and implementation).
- **Training** – ~2400 individuals received biosafety-related training. More emphasis was placed on electronic/self-study training, accounting for over 60% of all trainees.
- **Biosafety support services** – The Biosafety Office provided various support services, including laboratory audits, regulatory permit reviews, autoclave validations (coordinated effort with laboratory personnel), and administrative review of IBC documents, material transfer agreements, and research proposals (700 instances, collectively).
- **Laboratory audits** – The Biosafety Office inspected nearly 80 labs, with only minor findings reported. The most frequently identified issues were insufficient eyewash functionality and/or testing documentation, training documentation, and outdated door signs.
- **Reported accidents/exposures** – Several accidents/exposures were reported to the Biosafety Office, the majority of which were sharps-related injuries. Sharps injury prevention remains a focus area of the Biosafety Program.
- **Professional engagement** – The Biosafety Office hosted and presented at the Southeastern Biological Safety Association (SEBSA) annual symposium. Additionally, the Biosafety Offices of UTK and Clemson University organized a peer exchange program review. See report for details and additional highlights.
- **FY2019 program objectives** – Future aims include, distribution and implementation of the revised IBC charter and related procedures; development and implementation of additional electronic training modules; administrative documentation of research involving exempt recombinant/synthetic nucleic acids; and enhanced communications with research stakeholders.

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Please review the report at your discretion. Questions or comments may be sent to [utbiosafety@utk.edu](mailto:utbiosafety@utk.edu).

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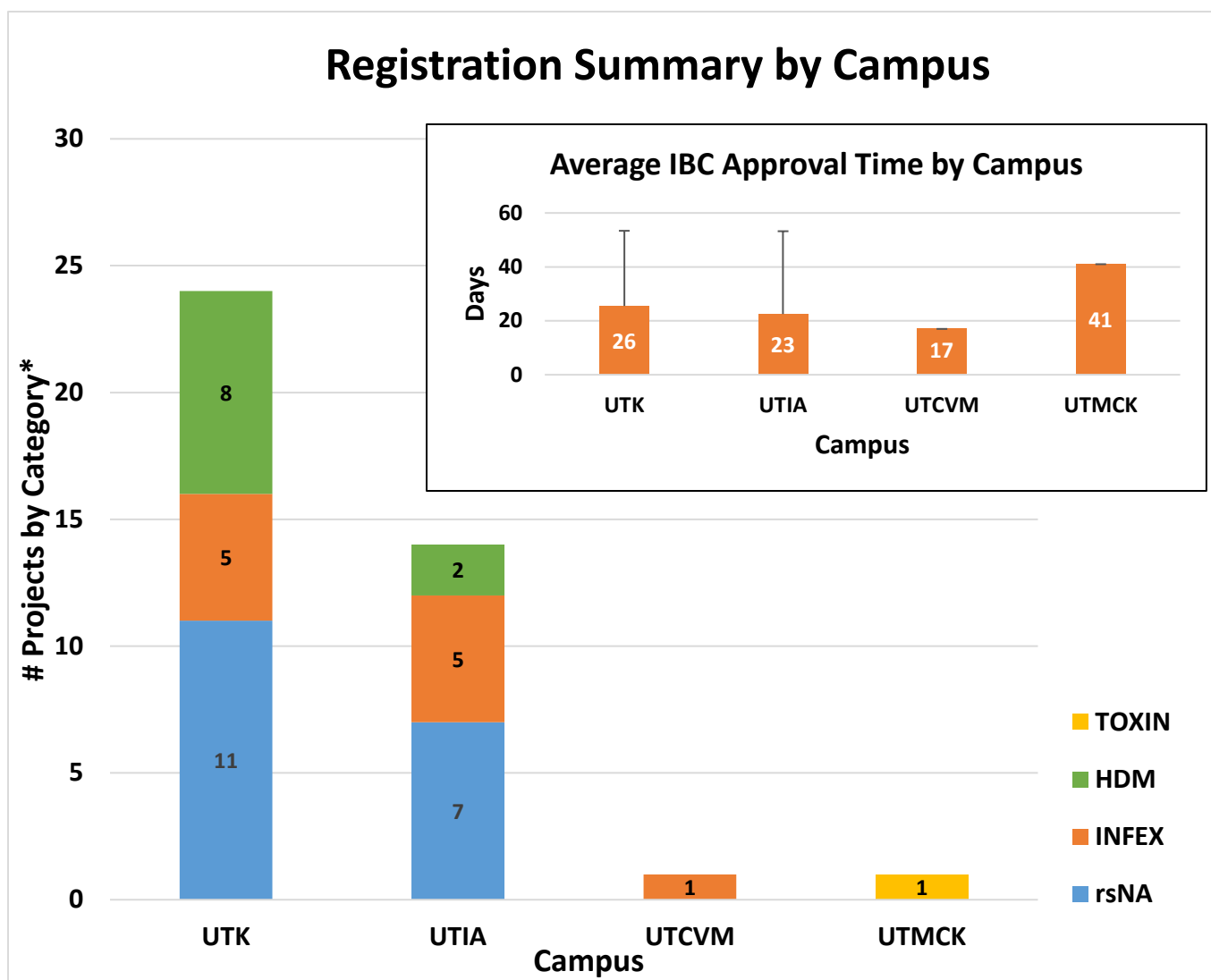
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# UNIVERSITY OF TENNESSEE BIOLOGICAL SAFETY PROGRAM FY2018 Annual Report & Activity Summary

## IBC Registration Review

The UT Institutional Biosafety Committee (IBC) conducted nine meetings during FY2018. A total of 40 categorical reviews (9 new projects; 24 three-year renewals; 7 amendments) were reviewed and approved. Registrations were received from principal investigators spanning four university research units (hereafter referred to as 'campuses'): Knoxville (UTK); Institute of Agriculture Research (AgResearch); College of Veterinary Medicine (CVM); and UT Medical Center Graduate School of Medicine (UTMCK). Figure 1 illustrates the number of registration reviews by campus for the following project categories: recombinant/synthetic nucleic acids (rsNA); infectious agents (INFEX); human-derived materials (HDM); or acute biological toxins (TOXIN). The average processing time from submission to final approval by campus is also shown (inset). Across all registrations the average approval time was 25 days (standard deviation = 28 days). Additionally, there were 11 terminations (experiments concluded or faculty relocation/retirement).

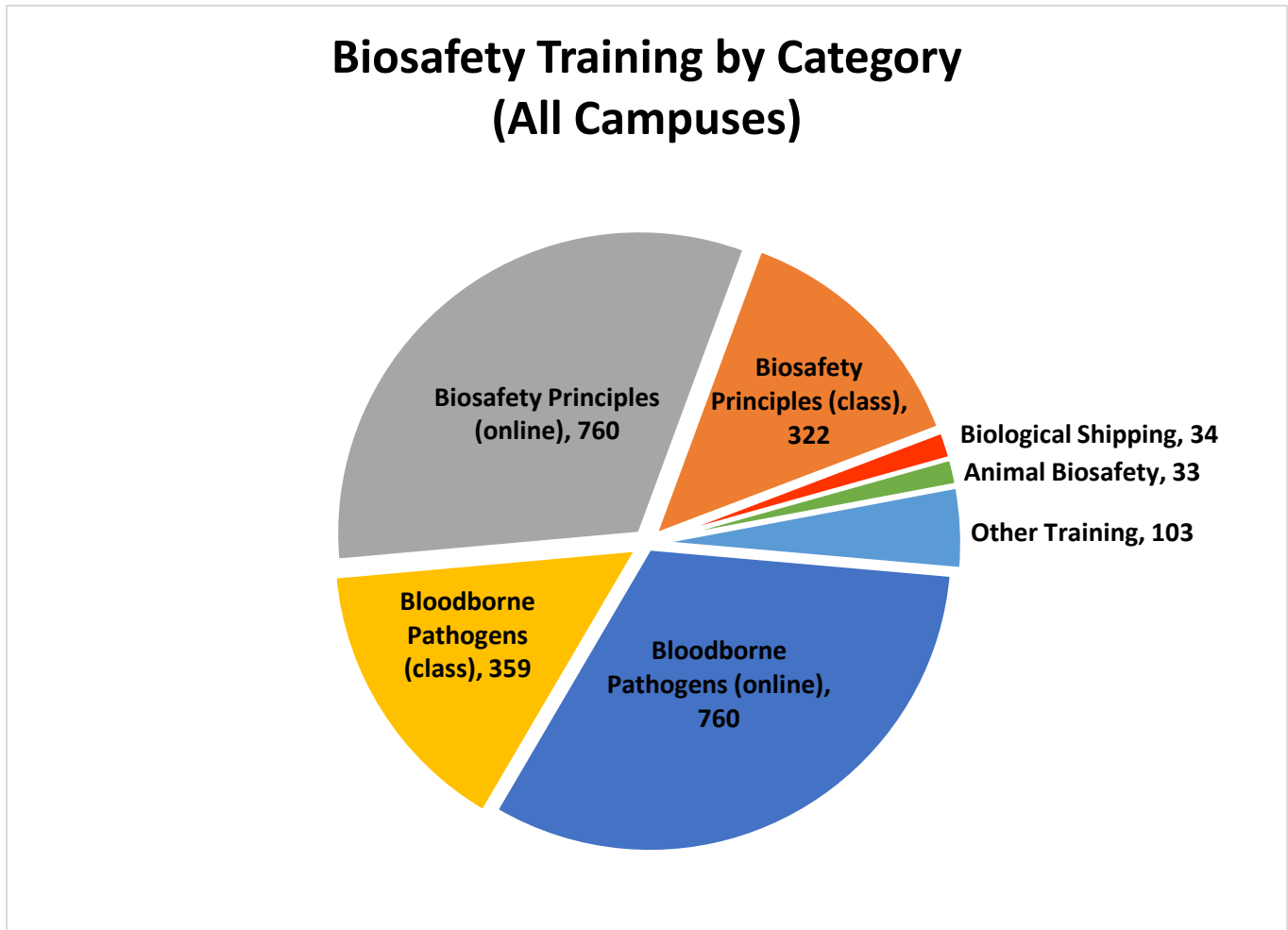


**Figure 1: FY2018 IBC Categorical Reviews & Processing Time by Campus**

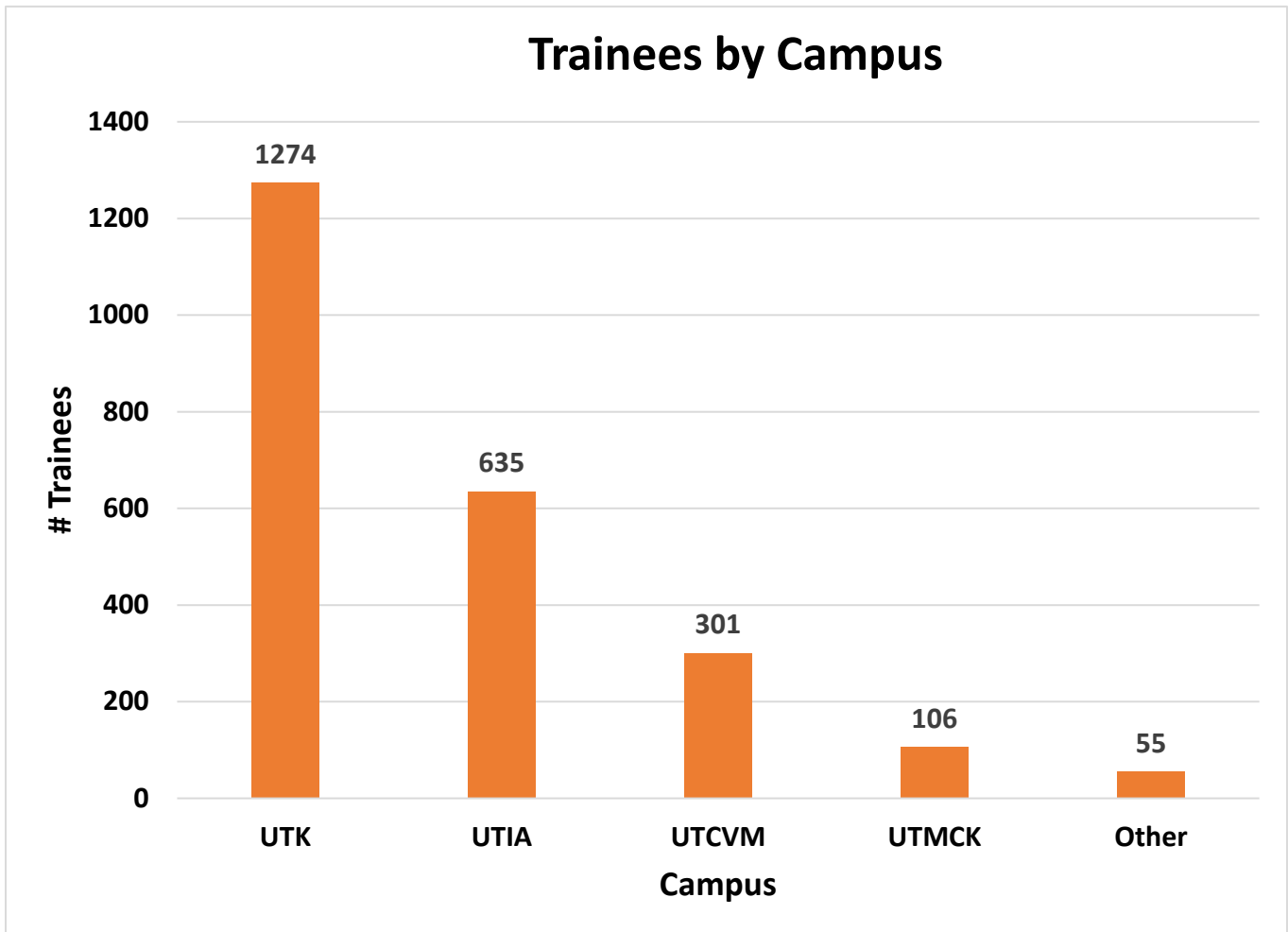
\* Registrations may include multiple project categories; reflected in data

## **Biosafety Training**

The Biosafety Office offered classroom-based (n=55) and online training sessions for a variety of biosafety and/or research compliance subjects during FY2018: biosafety principles (BSL-1/BSL-2); the (T)OSHA Bloodborne Pathogens Standard; biosafety and biocontainment for animal studies; biological materials shipping regulations; and other topics (e.g. the *NIH Guidelines*; iMedRIS; Biosafety Program awareness, etc.). Figure 2 highlights the number of trainees by training category. The number of trainees by campus is indicated in Figure 3. In total, nearly 2400 individuals received biosafety-related training.



**Figure 2: FY2018 Biological Safety & Compliance Training by Category (All Campuses)**

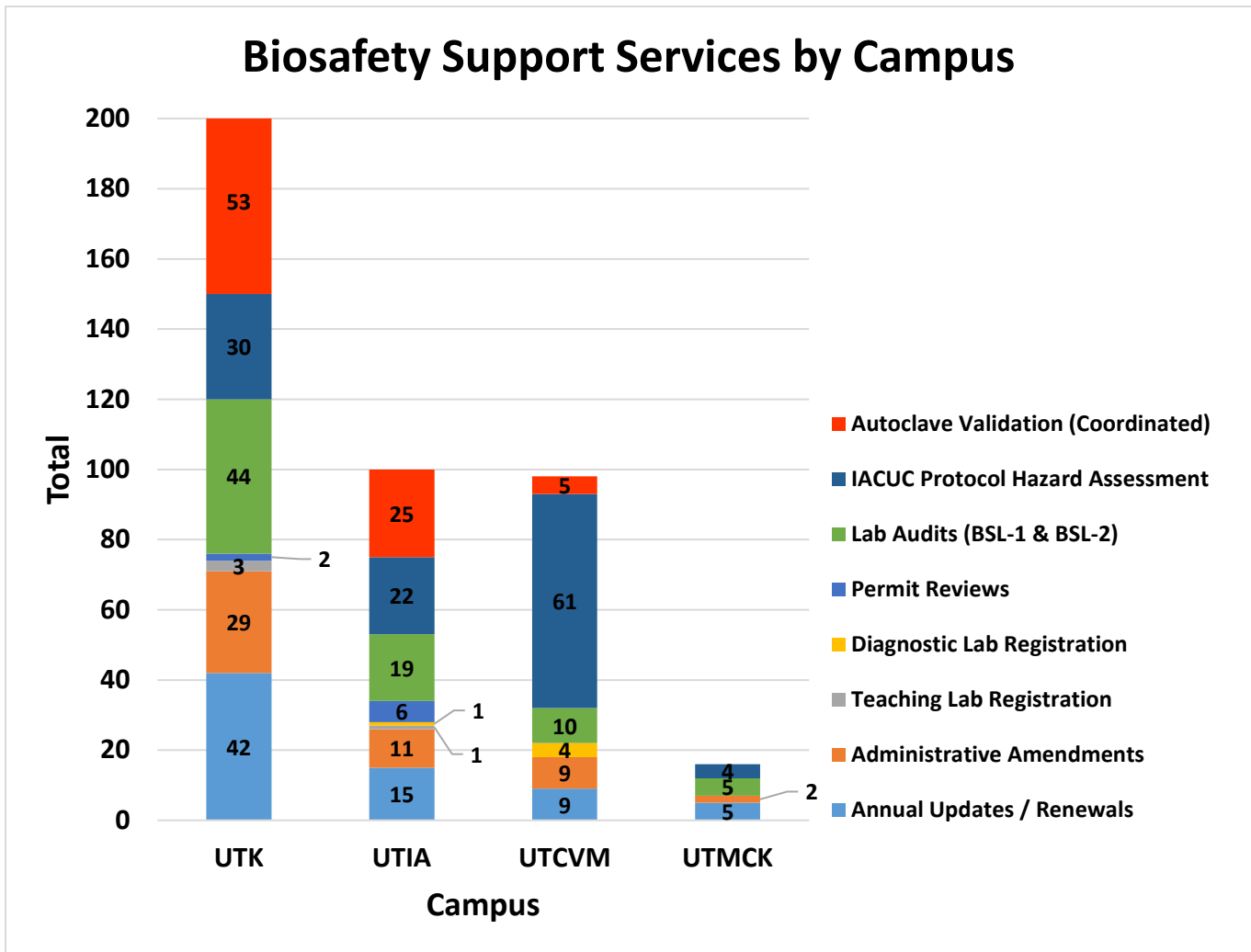


**Figure 3: FY2018 Biological Safety & Compliance Trainees by Campus**

#### **Biosafety Services**

Additional safety/compliance services provided by the Biosafety Office are shown in Figure 4. Major efforts included:

- Administrative reviews of IBC amendments, updates, and annual renewals (n=122; in addition to IBC full reviews indicated in Figure 1 above);
- Administrative registration of diagnostic (n=5) and teaching (n=4) laboratories;
- Administrative registration and consultation for regulatory permits (n=8; e.g. USDA APHIS, CDC, etc.);
- Conducting annual lab inspections (n=78; **see details below**);
- Review of Institutional Animal Care & Use Committee (IACUC) protocols (n=117) and completion of biohazard assessments for those involving biological hazards;
- Coordination of quarterly autoclave validations to ensure treatment/inactivation of bagged biohazardous waste is in accordance with Tennessee Department of Environment & Conservation requirements (n=83);
- Reviewed and verified (or followed up on) biosafety approvals for ~200 proposals submitted to Cayuse, collectively (data not shown).
- Reviewed and verified/approved ~90 material transfer agreements, collectively (data not shown).



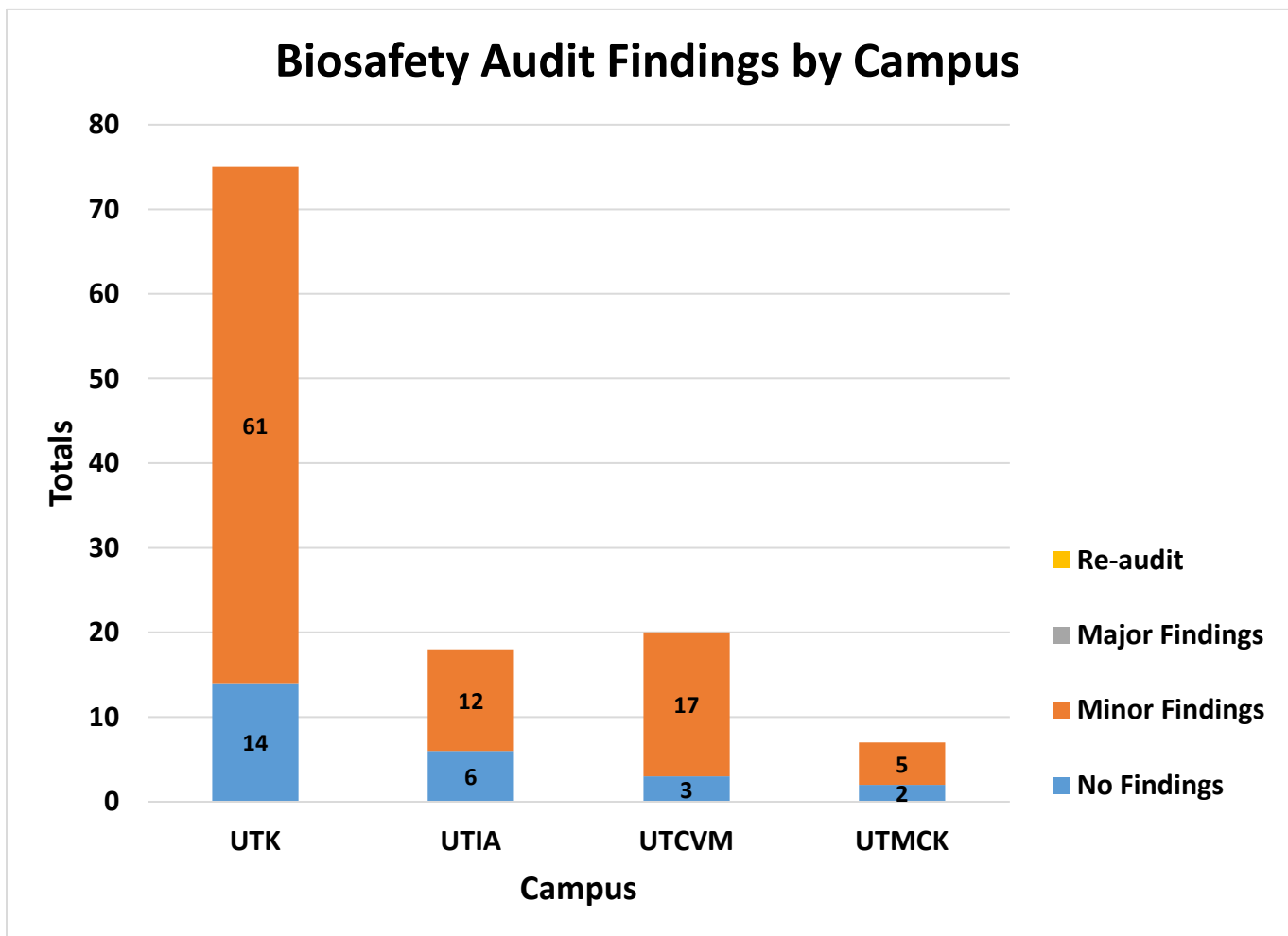
**Figure 4: FY2018 Additional Biological Safety/Compliance Services by Campus**

**Laboratory Audit Report:**

The Biosafety Office uses a two-component laboratory audit program, including one in-person lab audit and one IBC update/lab self-assessment per year. The two elements are conducted roughly 6 months apart. The annual in-person lab audits are scheduled with the principal investigator and/or designated research staff in advance. Lab audits will not be conducted unless lab personnel are present for questions and clarifications. This mechanism allows for better communication of expectations, engages the research staff, and bolsters safety awareness through dialogue and practical review/training.

In FY2018, the Biosafety office conducted 78 inspections (28 BSL-1 labs and 50 BSL-2 labs). Laboratories were inspected based on guidelines put forth by the *Biosafety in Microbiological and Biomedical Laboratories 5<sup>th</sup> Edition* and institutional policies. None of the individual findings represented an imminent threat to life or health, and no labs had to be re-audited.

Figure 5 summarizes the audit findings by campus.



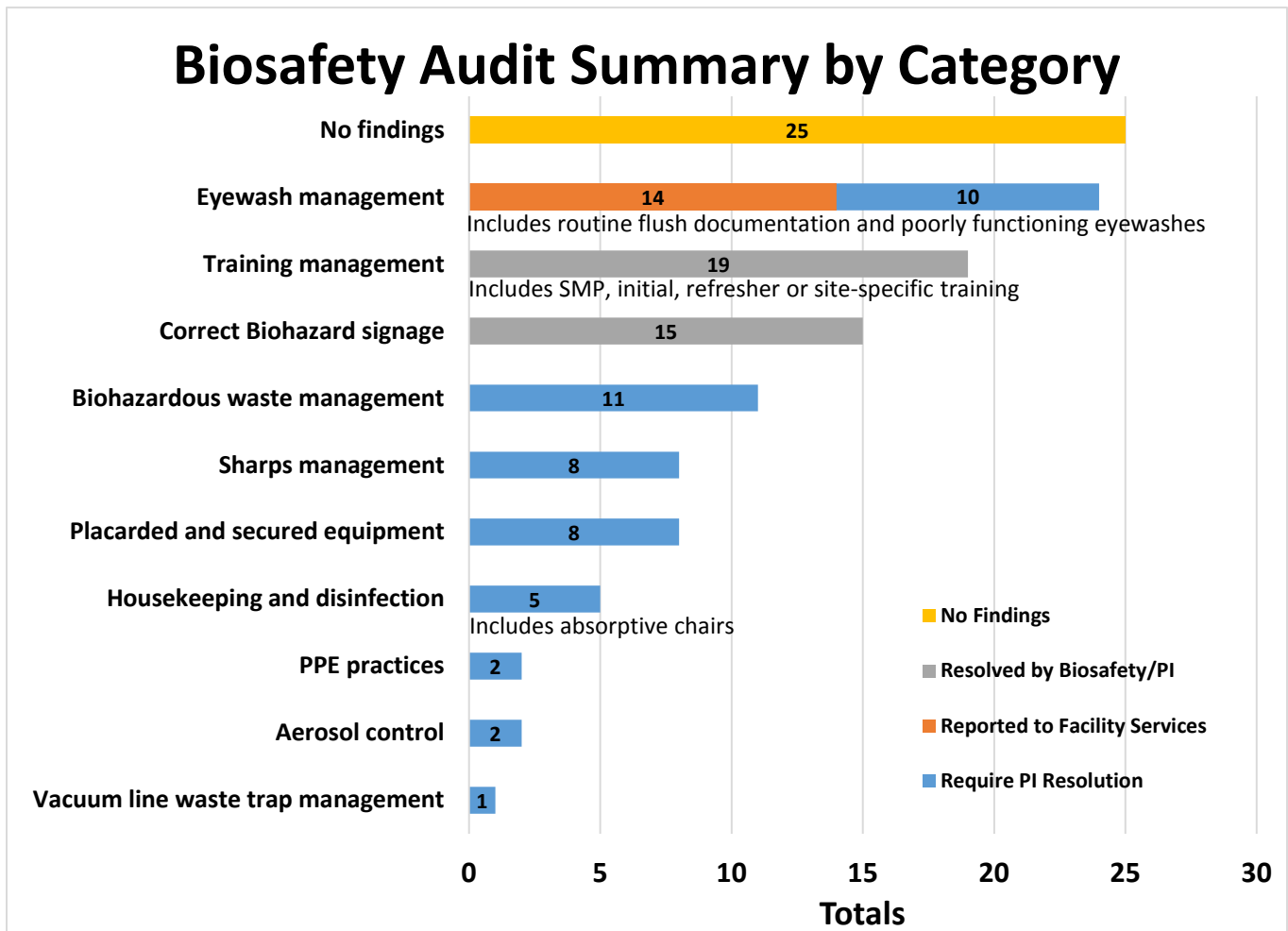
**Figure 5: FY2018 Lab Audit Findings by Category**

Figure 6 categorizes the findings as follows:

- **No findings:** Audited labs had no findings to record.
- **Eyewash management:** Eyewash function deficiencies and failure to record weekly flushes. All eyewashes that were determined to have functionality issues were reported to Facilities Services or CVM Hospital Operations.
- **Training management:** Incomplete performance/recording of standard microbiological practices (SMP) training in the BSL-1 labs, site specific training and initial/refresher training in BSL-2 labs.
- **Biohazard signage:** Missing, incorrect, or outdated biohazard signage for BSL-2 labs.
- **Biohazardous waste management:** Deficiencies in biohazardous waste collection practices.
- **Sharps management:** Improper handling and/or disposal of laboratory sharps.
- **Placarded and secured equipment:** Findings related to security of and emergency response for equipment holding RG2 or higher agents that are located in unsecured common areas or in shared spaces.
- **Housekeeping and disinfection:** Concerns related to lab hygiene and absorptive furniture used in “wet work” areas.
- **Personal protective equipment (PPE) practices:** Unavailability of or improper use of protective equipment.



- **Aerosol control:** Indicates a concern regarding aerosol generation outside of the biosafety cabinet and/or recommendations for minimizing aerosols.
- **Vacuum line waste trap management:** Improper labeling and secondary containment of vacuum traps containing biohazardous waste.



**Figure 6: FY2018 Lab Audit Findings by Category**

**Reported Accidents, Exposures, & Releases:**

The Biosafety Office was notified of the following accidents/incidents involving biological materials:

- UTK: 1 puncture from wire grate used to cover human tissues. Injury involved the presence of unfixed tissue (from individuals with documented health history). The accident did not cause significant injury or secondary infections/complications. The incident was investigated, and recommendations were made for eliminating, reducing, or folding sharp edges (with mechanical device) prior to placing over human tissues.
- CVM: Several sharps injuries involving unfixed tissues, most occurring in Necropsy. None caused significant damage (beyond first aid treatments). Improving safety procedures in Necropsy remains a focus area. The Biosafety Office will continue to work closely with the CVM Occupational Health & Safety Committee to reduce sharps injuries.
- CVM: 4 suspected student exposures to *Cryptosporidium parvum* resulting in signs/symptoms of infection. The Biosafety Office worked with faculty to identify the source of infection (client farm). Emphasis will be put on diligent hand hygiene, elimination/reduction/containment of potential fomites, and enhanced PPE, including mouth/nose-covering masks, for high-risk/suspected cases.

## **Biosafety in Teaching Laboratories:**

The Biosafety Office worked with instructional faculty and supervisors of teaching and experiential learning laboratories involving biohazards to ensure coverage of: hazard/risk awareness, prudent safety practices, personal protective equipment, and accident/injury reporting. Covered programs included: Microbiology 210, 319, 329, 429; Food Science & Technology 429; Biomedical Engineering 430; Nutrition 450; the Forensic Anthropology Center (FAC); Civil & Environmental Engineering 310, 482; and 4<sup>th</sup> year CVM clinical rotation students (joint effort with Dr. Amy Knowles, CVM Occupational Health).

## **FY2018 Programmatic Highlights (Other):**

- Appointment of new IBC members, including: Dr. David White (Associate Dean of UTIA AgResearch) as Chair; Dr. Elizabeth Fozo (Associate Professor, Microbiology) as Vice-Chair; Dr. Marc Caldwell (Assistant Professor, Large Animal Clinical Sciences) as a voting member; and Dr. George Dizikes (Director, Tennessee Department of Health, Knoxville Laboratory) as a non-affiliated voting member.
- Full implementation of the iMedRIS web-based compliance platform for IBC submissions and data maintenance, including classroom-based training sessions and the purchase of Bomgar™ for remote assistance.
- Drafted and revised a new IBC Charter and related policies/procedures (roles & responsibilities, training, event escalation, registration/review/recordkeeping, and laboratory audits); pending final approvals, distribution, & implementation.
- Completed peer review exchange with the Clemson Biosafety Program; no significant findings, though recommendations were made for streamlining laboratory safety and developing a comprehensive occupational health program (under discussion).
- Hosted the Southeastern Biological Safety Association's (SEBSA) annual symposium, which featured current topics in pathogen research, field safety/biosafety, large animal containment, biosafety in teaching laboratories, collaborative communication techniques, facility design, and biosafety program management. UTK Biosafety staff delivered 2 presentations at the symposium, one on the value of collaborative communication during laboratory audits (Hamilton), and one on planning and completion of a biosafety program peer exchange (Ranger). Over 50 people from 10 states attended the event.
- Liaised 3 USDA APHIS & Tennessee Department of Agriculture facility/compliance inspections (1 Plant Protection & Quarantine, 2 Biotechnology Services); no findings.
- Presented seminar (module) covering various aspects of the Biosafety Program for the UTK Responsible Conduct of Research workshop.
- Issued Revision 13 (2017-18) OSHA Bloodborne Pathogens Exposure Control Plan covering research programs.
- Professional Development & Training:
  - Completed various training courses or workshops covering: virology, molecular biology, genome editing technologies (e.g. CRISPR/Cas9), synthetic biology, IBC compliance and management (best practices), biosecurity, and various e-management programs and tools
  - *NIH Guidelines: Honoring the Past, Charting the Future* workshop (Bethesda, MD)
  - Annual conference of the American Biological Safety Association (ABSA International) in Albuquerque, NM
  - CDC International Symposium on Biosafety: *Biosafety in the Era of One Health* (Atlanta, GA)
  - ORAU Council of Sponsoring Institutions on *Public Health Security and Biological Threats* (Oak Ridge, TN)

- Annual SEBSA symposium (Knoxville, TN)
- Annual UT System Safety Officers' meeting (Chattanooga, TN) and TN Higher Education Safety Officers' meeting (Franklin, TN)

**Program Objectives (FY2019):**

- Finalize, distribute, and implement revised IBC Charter and associated policies/procedures.
- Prepare and implement electronic self-study modules for selected biosafety and compliance topics, e.g. *NIH Guidelines* awareness, biosafety principles, bloodborne pathogens, biological materials shipping, autoclave safety, etc. Training modules will be constructed so that they can be adapted to various online learning platforms (K@TE, Canvas, CITI, etc.).
- Identify, review, and administratively register (or log) the research use of exempted recombinant/synthetic nucleic acids.
- Work with CVM Occupational Health & Safety Committee to improve safety awareness and practices in the necropsy unit (emphasis programs on training, sharps handling/management, and accident/exposure follow-up procedures).
- Enhance Biosafety Program communications with end-users by sending out brief announcements, reminders, and blurbs at least monthly.
- Participate in at least one national and/or regional conference on biosafety.