

UNIVERSITY OF TENNESSEE BIOLOGICAL SAFETY PROGRAM FY2019 Annual Report & Activity Summary

IBC Registration Review

The UT Institutional Biosafety Committee (IBC) met nine times during FY2019, conducting 49 categorical reviews. Registrations were received from principal investigators spanning four university research units (hereafter referred to as ‘campuses’): Knoxville (UTK); Institute of Agriculture (UTIA); College of Veterinary Medicine (UTCVM); 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 biologically-conjugated nanomaterials (NANO). The average processing time from submission to final approval by campus is also shown (inset). Across all registrations the average approval time was 32 days (standard deviation = 18 days). Additionally, there were 5 terminations (experiments concluded or faculty relocation/retirement).

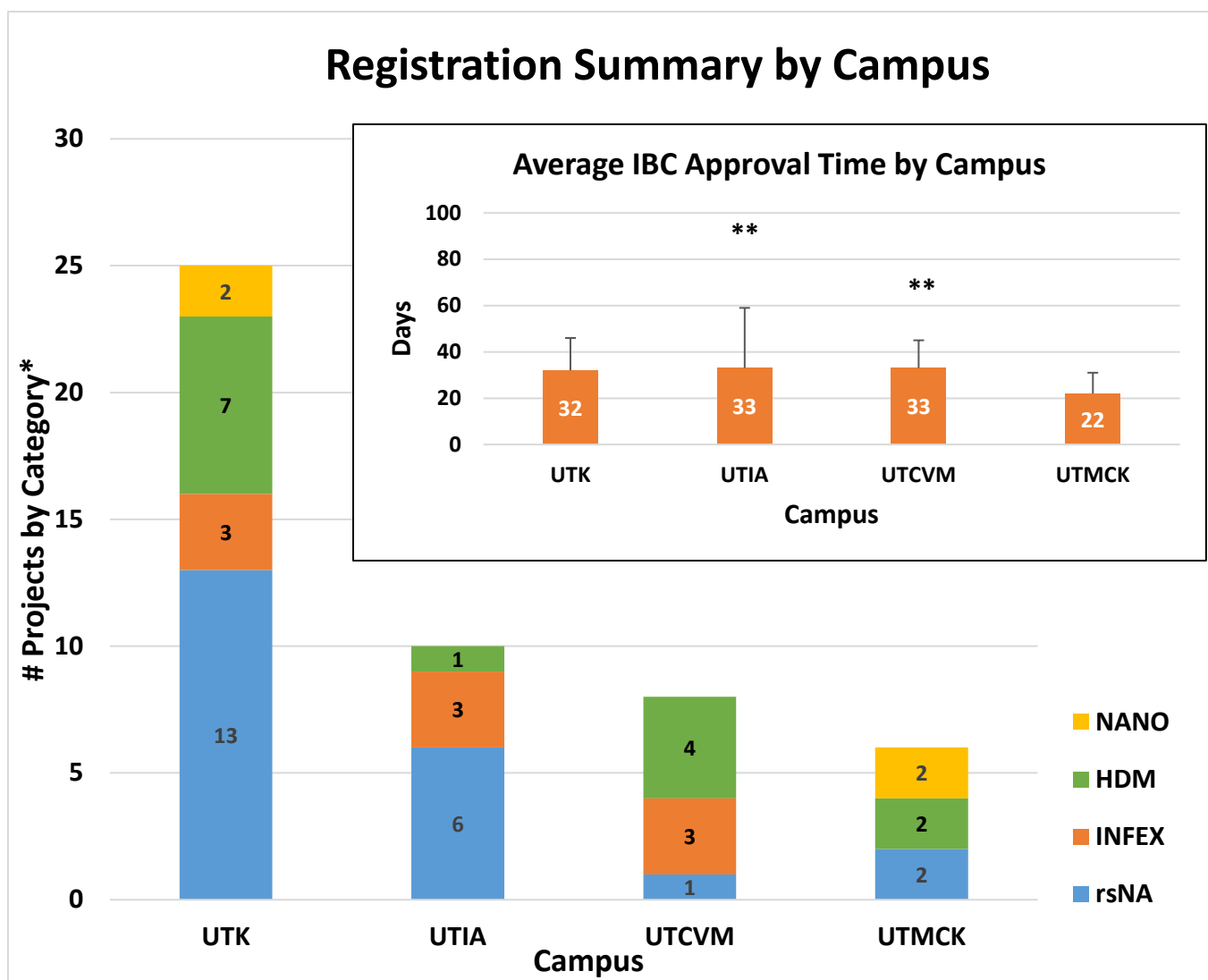


Figure 1: FY2019 IBC Categorical Reviews & Processing Time by Campus

* Registrations may include multiple project categories; reflected in data

**Statistical outliers due to delayed PI responses (UTIA = 96 days; UTCVM = 69 days)

Biosafety Training

The Biosafety Office offered classroom-based (n=97) 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, 1900 individuals received biosafety-related training.

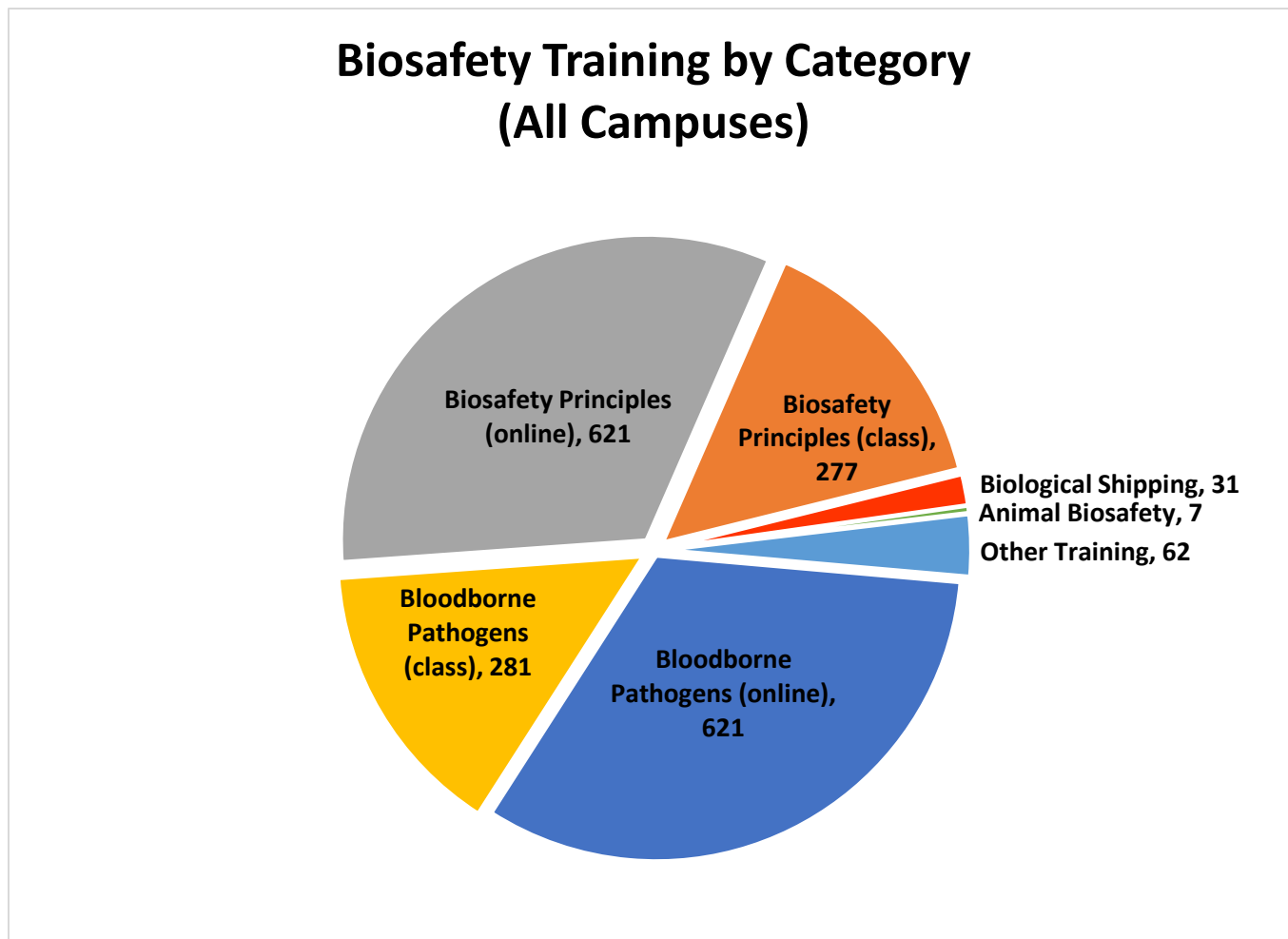


Figure 2: FY2019 Biological Safety & Compliance Training by Category (All Campuses)

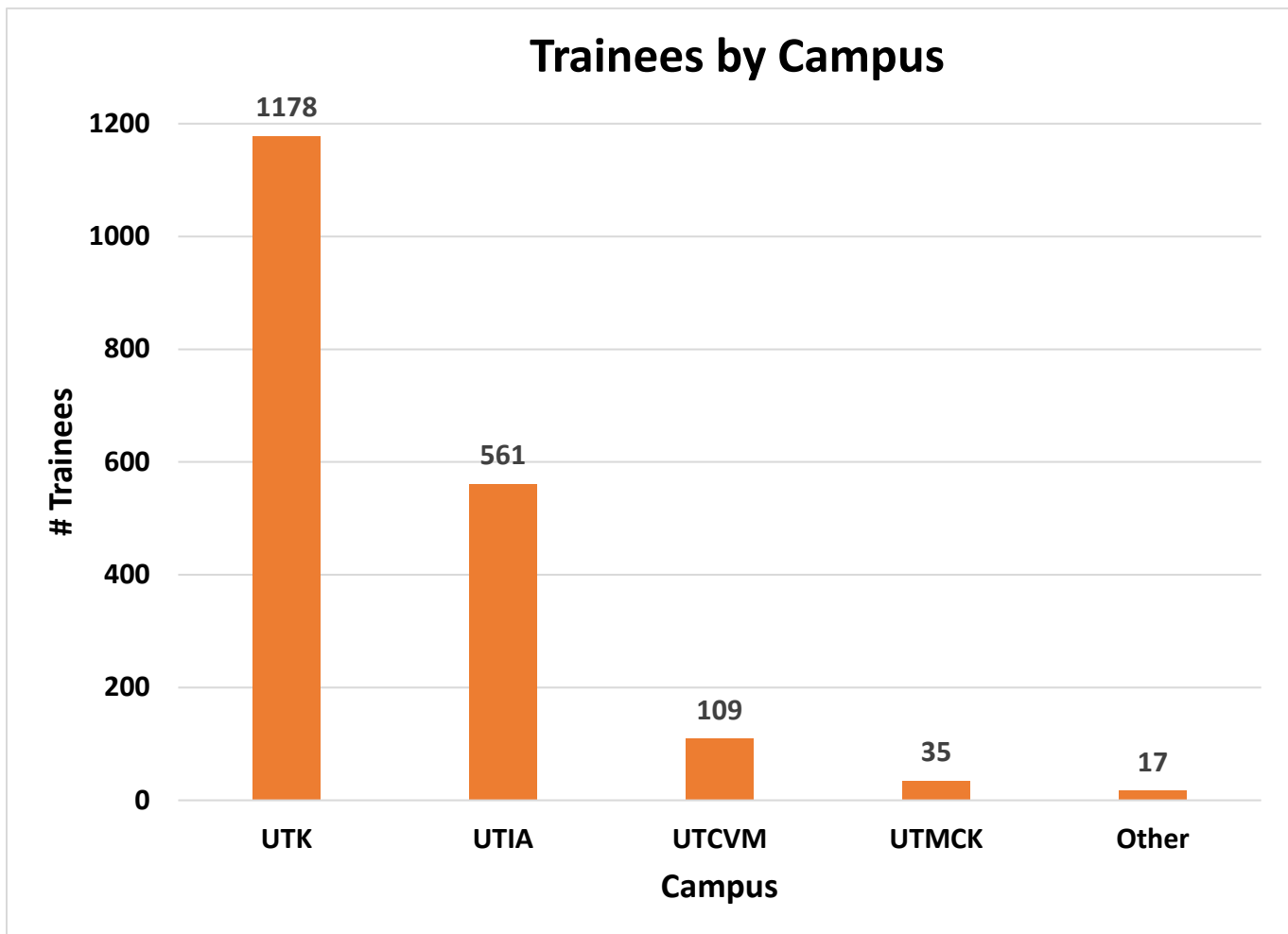


Figure 3: FY2019 Biological Safety & Compliance Trainees by Campus

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=155; in addition to IBC full reviews indicated in Figure 1 above);
- Conducting annual lab inspections (n=78; **see details below**);
- Review of Institutional Animal Care & Use Committee (IACUC) protocols (n=111) 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=136);
- Reviewed and verified (or followed up on) biosafety approvals for ~165 proposals submitted to Cayuse, collectively (data not shown).
- Reviewed and verified/approved ~50 material transfer agreements, collectively (data not shown).

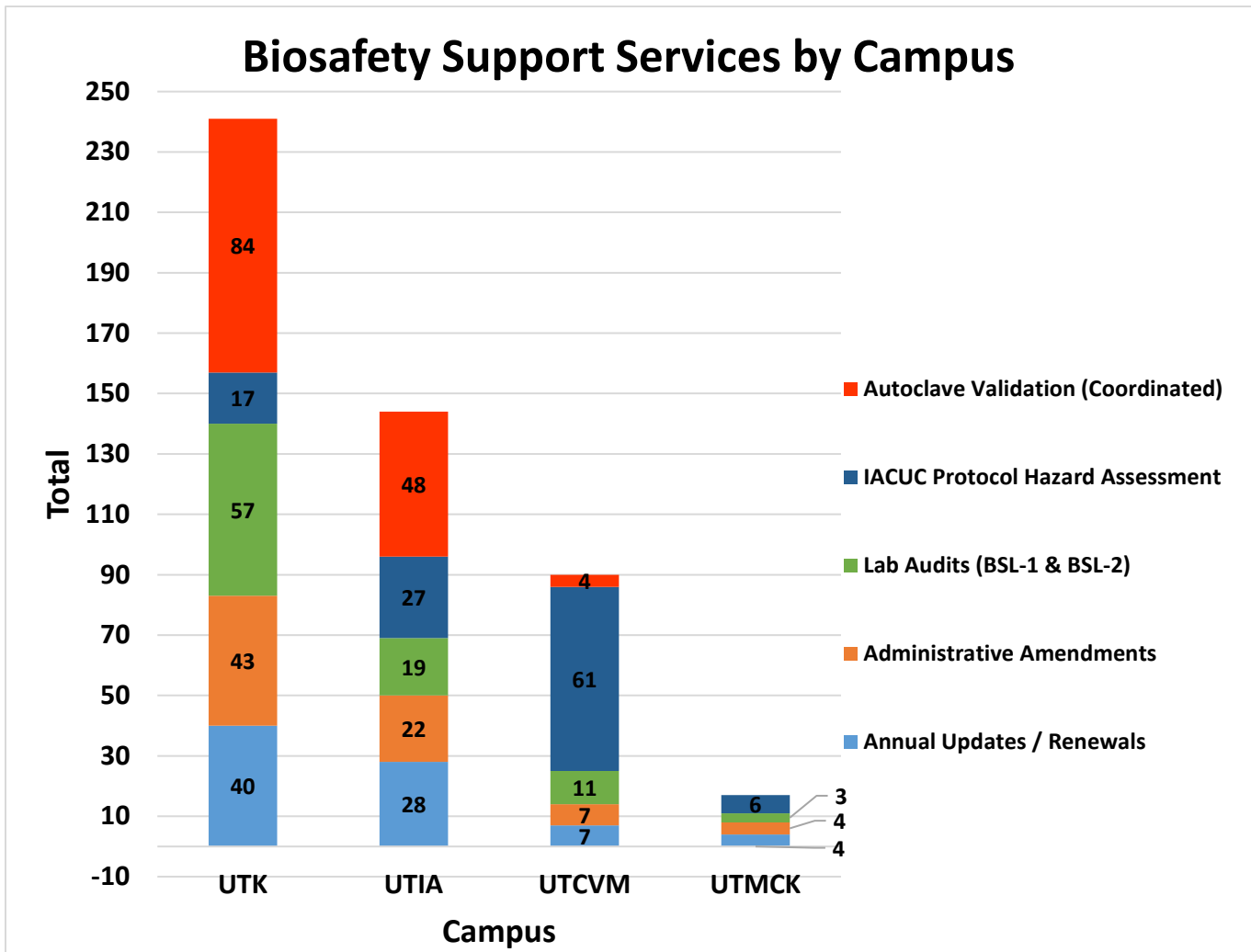


Figure 4: FY2019 Additional Biological Safety/Compliance Services by Campus

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. Additionally, the Biosafety Office fully implemented a coordinated lab audit-refresher training program in FY2019, whereby those attending the lab audit/findings discussion are given credit for annual refresher training.

In FY2019, the Biosafety office conducted 90 inspections by registered principal investigator (PI) or supervised teaching laboratory (31 BSL-1 labs and 59 BSL-2 labs). Laboratories were inspected based on guidelines put forth by the *Biosafety in Microbiological and Biomedical Laboratories 5th Edition, NIH Guidelines*, and institutional policies. None of the individual findings represented an imminent threat to life or health or significant compliance deficiency. However, due to excessive or repeated minor findings, two UTK labs were re-inspected (findings resolved upon re-inspection).

Figure 5 summarizes the audit findings by campus.

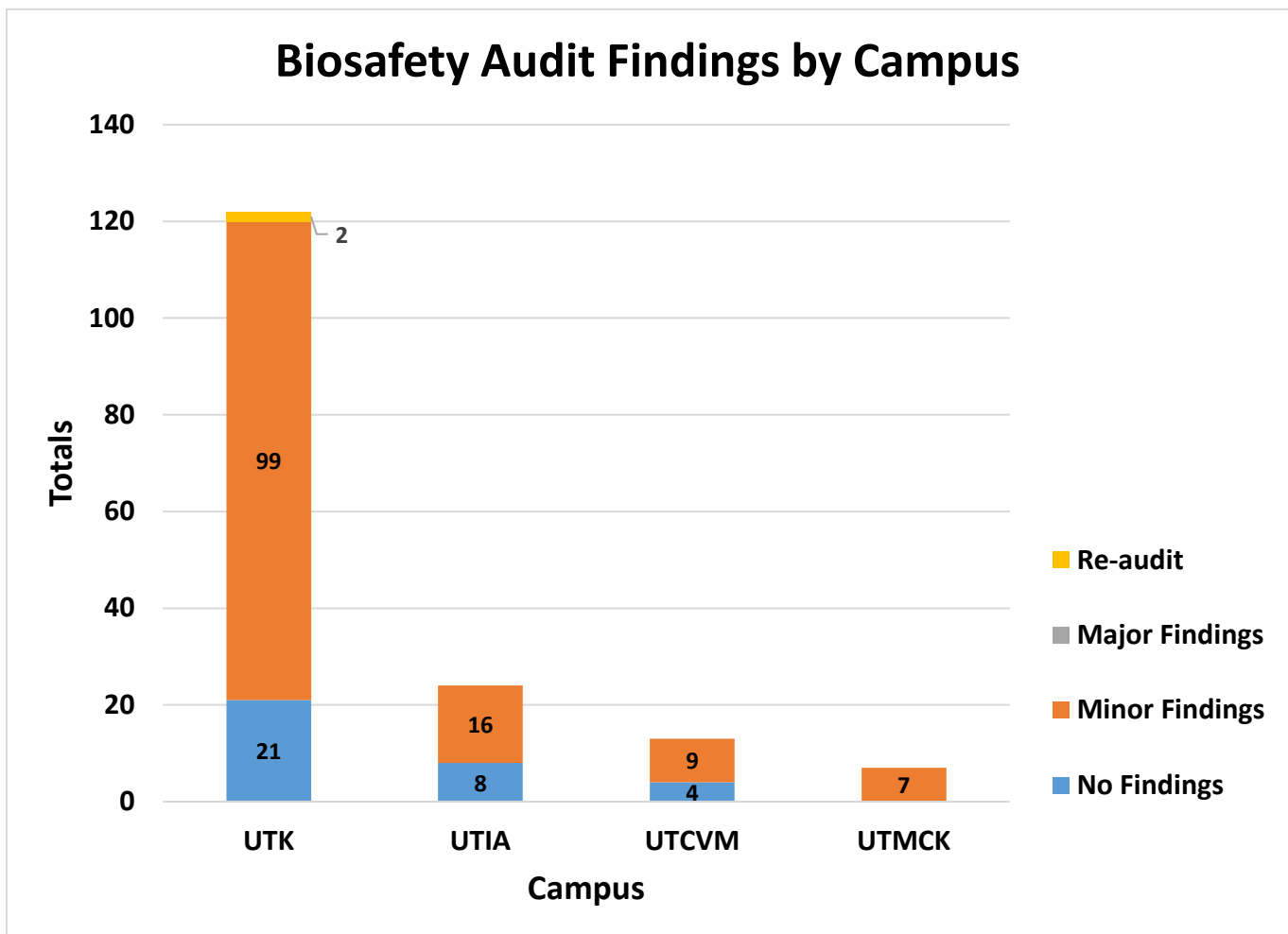


Figure 5: FY2019 Lab Audit Findings by Category

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.
- **Facilities management/signage:** Concerns related to lab hygiene including laboratory clutter, surface disinfection, absorptive furniture used in bench areas, and missing/incorrect biohazard signage for BSL-2 lab.
- **Training management:** Incomplete performance/documentation of initial, refresher or site-specific biosafety training.
- **Biohazardous waste management:** Deficiencies in biohazardous waste collection practices.
- **Spills management:** Missing spill response postings and/or unfamiliarity with spill clean-up/disinfection process.
- **Sharps management:** Improper handling and/or disposal of laboratory sharps.
- **Aerosol management:** Indicates a concern regarding aerosol generation outside of the biosafety cabinet and/or recommendations for minimizing aerosols.

- **Bloodborne pathogen compliance:** Missing or incomplete bloodborne pathogens training and/or hepatitis B offer documentation.
- **Laboratory security:** Findings related to security of and emergency response for laboratories or equipment holding Risk Group 2 agents located in unsecured common areas or shared spaces.
- **Personal protective equipment (PPE) management:** Unavailability of or improper use of protective equipment.
- **Sample transport:** Inadequate secondary containment of biohazards moved outside of the laboratory.

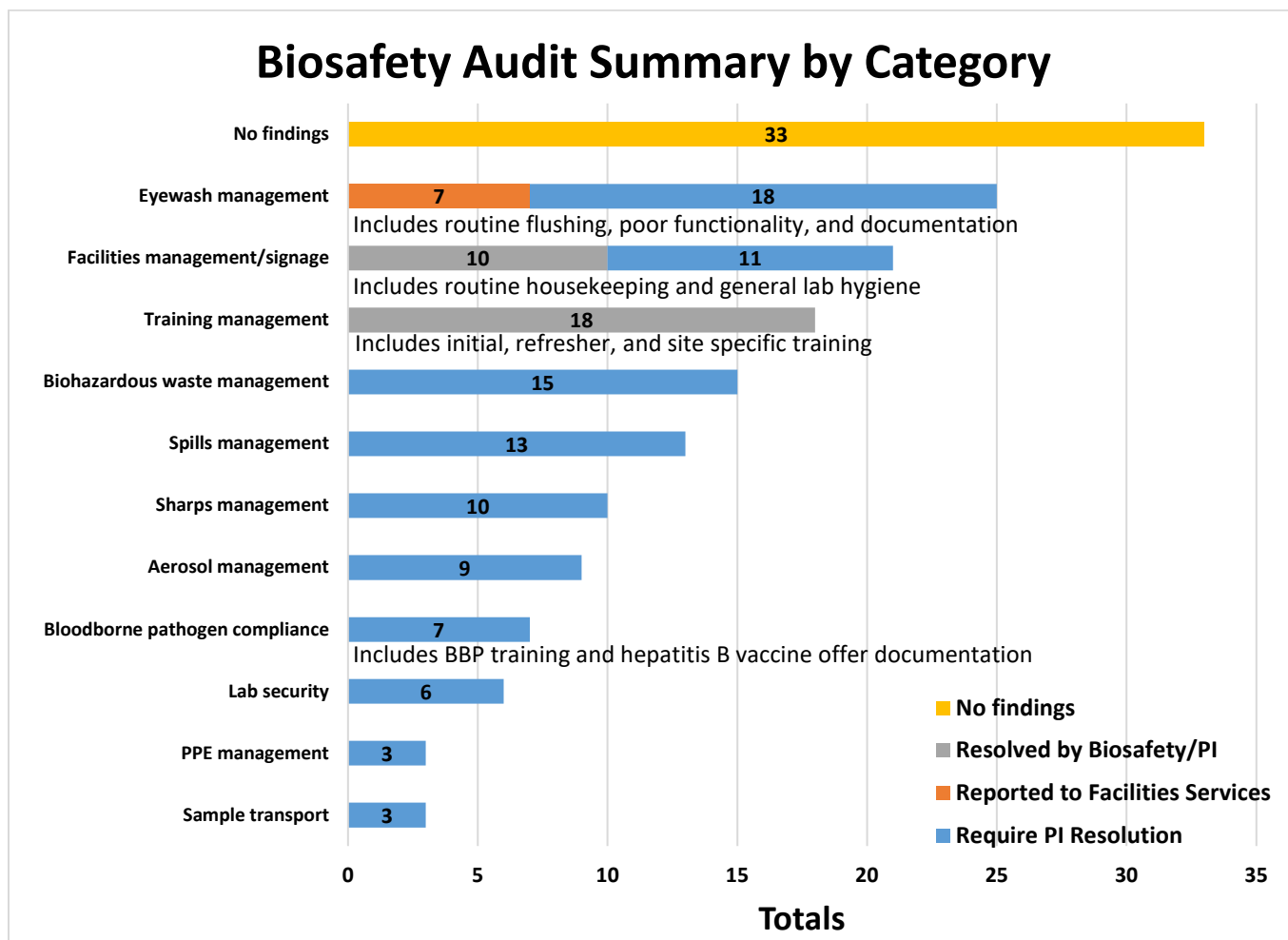


Figure 6: FY2019 Lab Audit Findings by Category

Reported Accidents, Exposures, & Releases:

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

- UTK: One puncture from hypodermic needle used on low-risk transgenic rodent. Improper sharps management/disposal were identified as causative factors. The individual was retrained in sharps safety (in-person and electronic training).
- CVM: Several sharps injuries involving unfixed tissues, most occurring in Necropsy. None caused significant damage (beyond first aid treatments) or resulted in infection/illness. Although focused training and risk awareness campaigns did reduce the occurrence of CVM sharps injuries by 50% (relative to FY2018), sharps safety remains a focus area of the Biosafety Office and CVM Occupational Health & Safety Committee.

- CVM: Anecdotal (unreported) student exposure to *Cryptosporidium parvum* resulting in signs/symptoms of infection. The Biosafety Office worked with faculty to identify the source of infection, review preventative practices in the field (diligent hand hygiene, elimination/reduction/containment of potential fomites, and enhanced PPE including mouth/nose-covering masks), particularly for high-risk/suspected cases. The importance of reporting all suspected exposures/illnesses was reiterated.
- CVM: Biosafety Office was notified of a *potential* exposure to *Francisella tularensis* (tularemia) per downstream diagnostic testing on pathological samples. There were no signs/symptoms of infection or disease manifestations. Public health and regulatory officials were notified as required.

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 482; and 4th year CVM clinical rotation students (joint effort with CVM Occupational Health).

FY2019 Programmatic Highlights (Other):

- Drafted and revised a new IBC charter and bylaws and related procedures (roles & responsibilities, training, event escalation, registration/review/recordkeeping, and laboratory audits). Documents were vetted by the UT Office of the General Counsel prior to distribution to the UTK research community and posting to the Biosafety website (see <https://biosafety.utk.edu/biosafety-program/policies/>).
- Prepared and implemented electronic self-study modules for selected biosafety and compliance topics, e.g. *NIH Guidelines* awareness, biosafety principles, bloodborne pathogens, biological materials shipping, USDA/CDC regulatory permit compliance awareness, etc. Training modules were adapted for the Qualtrics survey tool, but they can be made available in other e-learning platforms (e.g. K@TE, Canvas, CITI, etc.) as necessary.
- Completed, socialized, and posted an electronic biosafety manual, available at <https://biosafety.utk.edu/biosafety-program/biosafety-manual/>.
- Participated in peer review of UTK-area health and safety programs conducted by Dr. Robert Emery, professor and vice president, University of Texas Health Science Center at Houston. Subsequently, worked with UTK Environmental Health & Safety (EHS), the UTK Radiation Safety Department, and UTIA Safety to address Dr. Emery's recommendations for improvement.
- Facilitated laboratory moves from Jessie Harris and Walters Life Sciences (lab decommissioning) to the new Ken & Blair Mossman Building (lab commissioning). Assisted with updates of IBC registrations to reflect the new lab locations.
- Worked with architects, engineers, EHS, UTK Facilities Services, and departmental faculty on Mossman facility HVAC evaluations and improvements.
- Collaborated with EHS on a risk assessment framework for food/drink allowances in Mossman lab write-up areas. Framework reviewed and approved by the IBC and UTK Laboratory Safety Committee.

- Collaborated with UTIA Safety and the CVM Occupational Health & Safety Committee on comprehensive walkthrough and review of CVM facilities (laboratories and clinics) and policies/procedures. Findings were tabulated, ranked by risk, and submitted to the CVM executive committee for follow-up.
- Worked with UTK-area safety offices to define parameters and begin implementation of BioRAFT, a web-based platform for laboratory hazard management.
- Collaborated with safety officers from UTK, UTIA, UTC, and UTHSC to develop a safety escalations policy and associated procedures. Policy/procedures presented at the UT System Safety Officers' meeting (Franklin, TN); pending final implementation.
- Worked with the IACUC institutional official and attending veterinarian to revise the standard operating procedure for IACUC protocol review, hazard identification, and safety awareness training.
- Worked with the UT Office of Emergency Management on a principal investigator emergency/research asset protection guide.
- Worked with EHS to create a unified OSHA bloodborne pathogens exposure control plan covering affected research and non-research units; implementation pending.
- Liaised one USDA APHIS (Plant Protection & Quarantine) and Tennessee Department of Agriculture facility/compliance inspection; no findings.
- Professional Development & Training:
 - Completed various training courses or workshops covering: genome editing, synthetic biology, biocontainment in agricultural research, biological agent inactivation methods, safety culture development, behavioral safety, and emergency/incident response
 - FBI Fraud Prevention (Knoxville, TN)
 - FBI biosecurity workshop (Nashville, TN)
 - Annual conference of the American Biological Safety Association (Charleston, SC)
 - Annual SEBSA symposium (Clemson, SC)
 - Annual UT System Safety Officers' meeting (Knoxville, TN) and TN Higher Education Safety Officers' meeting (Franklin, TN)

Program Objectives (FY2020):

- Work with EHS, Radiation Safety, UTIA Safety and campus administration to create an integrated safety program; begin implementation.
- Finalize, distribute, and implement unified bloodborne pathogens exposure control plan.
- Work with the IACUC and Office of Laboratory Animal Care to identify and resolve safety and safety compliance gaps in dedicated laboratory animal facilities. Effort may coincide with upcoming AAALACi animal care and use program accreditation.
- Use BioRAFT laboratory profiles or other surveillance tools to identify and resolve gaps in biosafety and research compliance.
- Participate in at least one national and/or regional conference on biosafety.