# UNIVERSITY OF TENNESSEE BIOLOGICAL SAFETY PROGRAM
# FY2017 Annual Report & Activity Summary

## IBC Registration Review

The UT Institutional Biosafety Committee (IBC) conducted ten meetings during FY2017. A total of 70 categorical reviews (13 new projects; 46 three-year renewals; 11 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 Graduate School of Medicine (GSM). 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-engineered 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 18±12 days. Additionally, there were 45 administrative updates and 19 terminations (experiments concluded or faculty relocation/retirement).

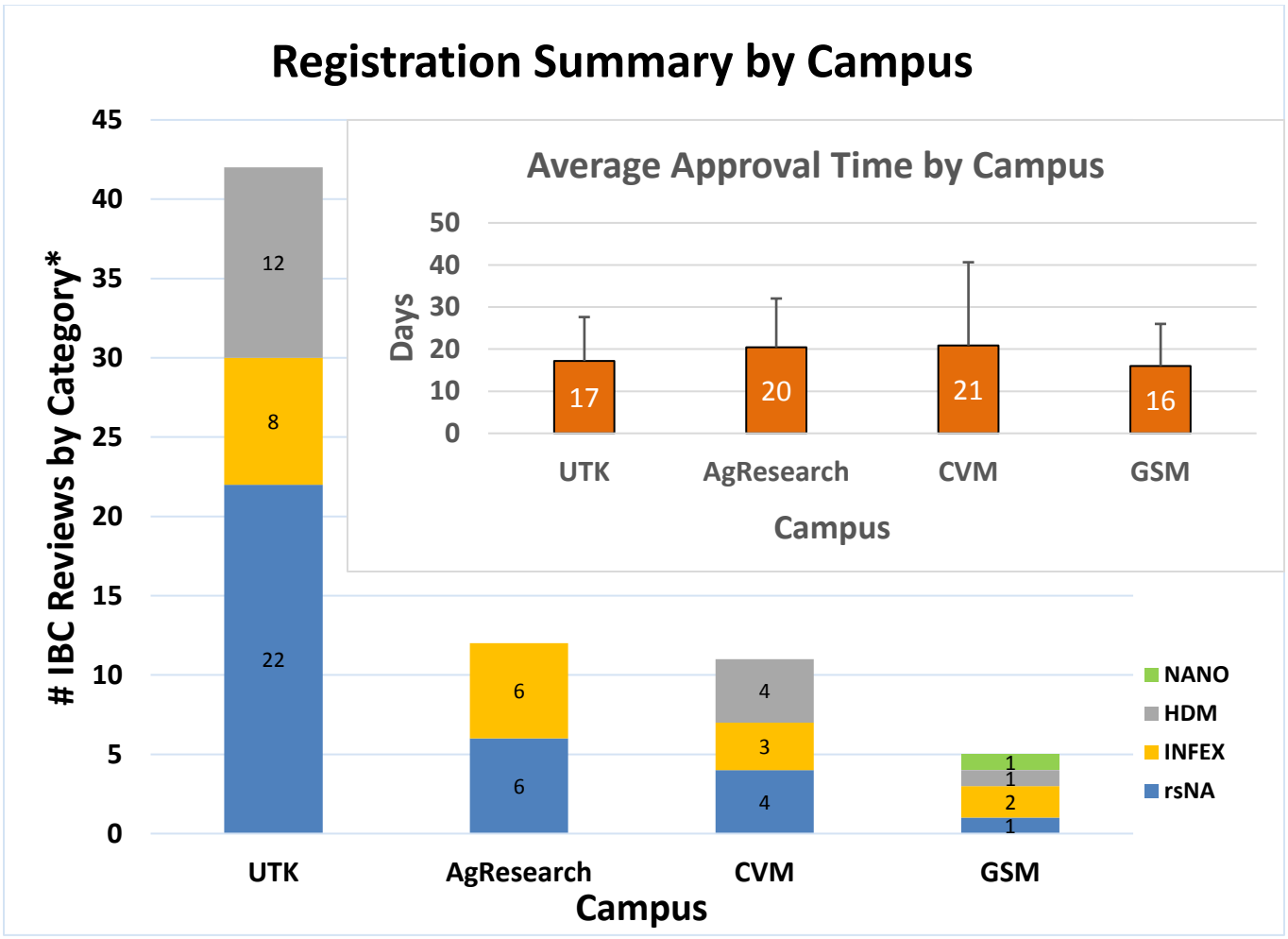


***Figure 1*: FY2017 IBC Categorical Reviews & Processing Time by Campus**
*** Registrations may include multiple project categories; reflected in data**

## Biosafety Training

Figure 2 highlights the number of individuals trained in various biosafety and/or research compliance subjects during FY2017. Classroom-based (n=72) and online training sessions were provided covering: 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 for Research Involving Recombinant or Synthetic Nucleic Acids*). The total number of trainees is indicated for each category. The total number of trainees by campus is indicated in Figure 3. In total, over 1900 individuals received either initial (n=1240) or annual refresher (n=691) training.

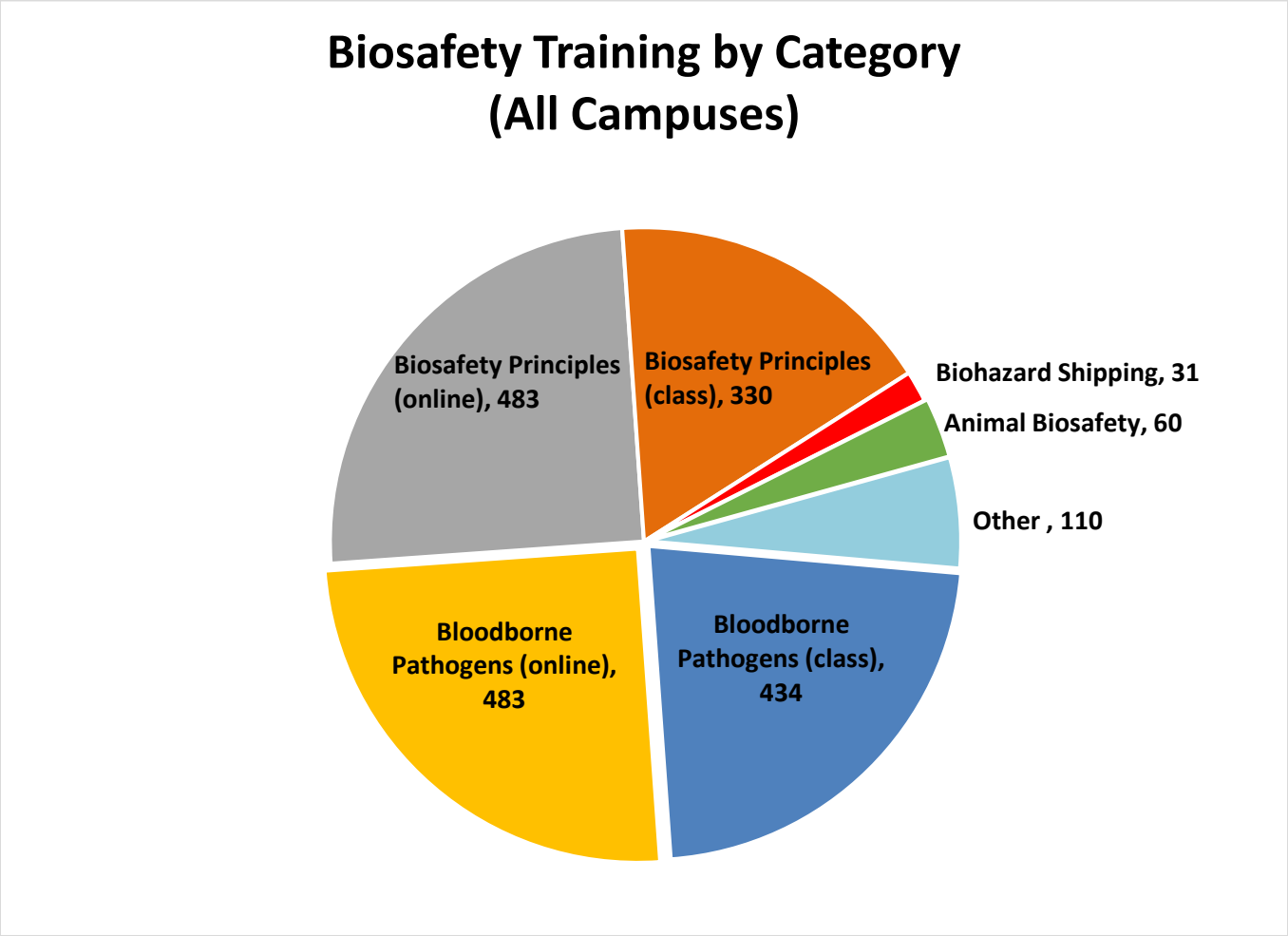


***Figure 2:*** **FY2017 Biological Safety & Compliance Training by Category (All Campuses)**

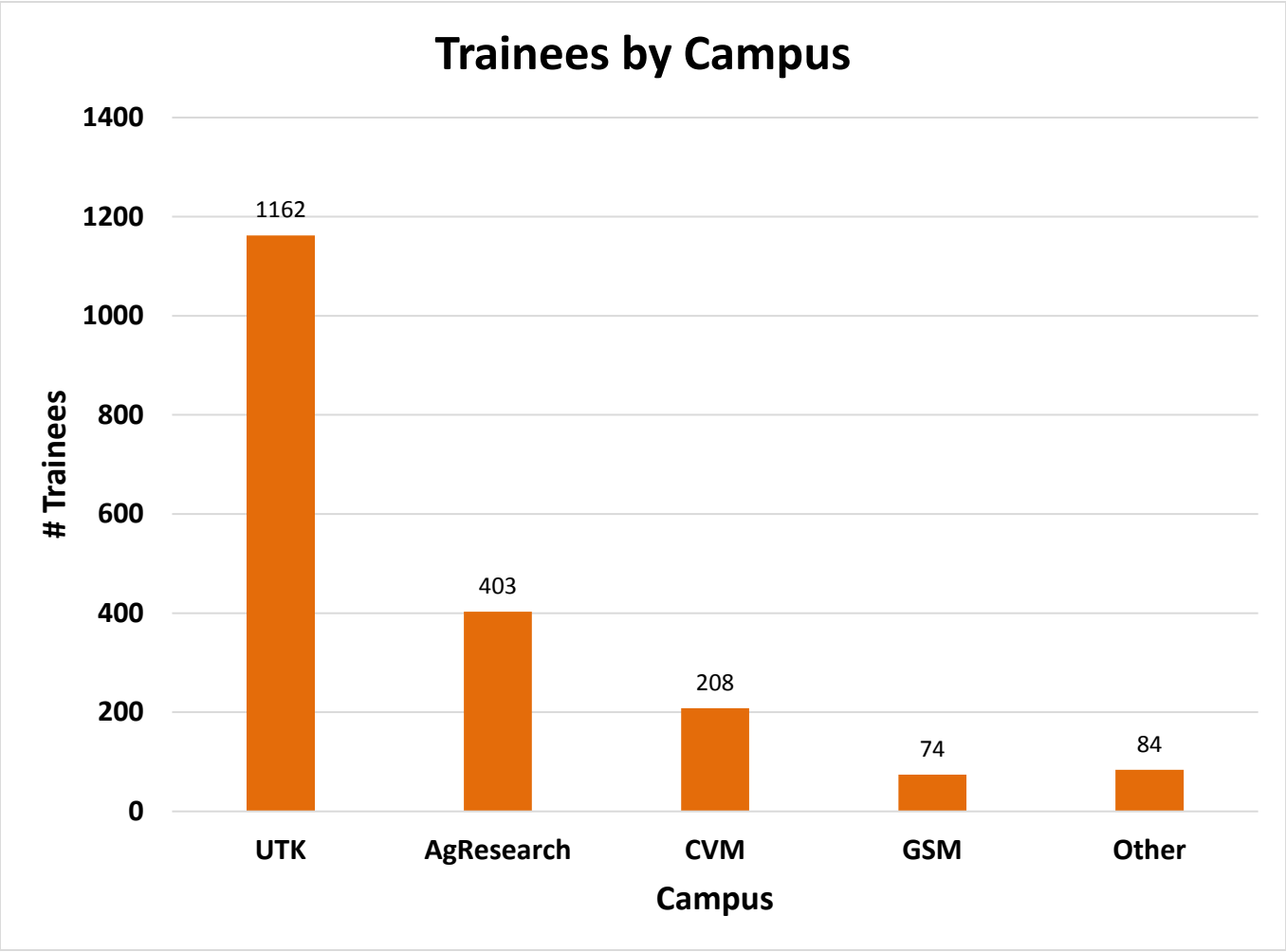


***Figure 3:*** **FY2017 Biological Safety & Compliance Trainees by Campus**

**Biosafety-Related Services**

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

- Administrative reviews of IBC/Biosafety registration annual updates (57; in addition to IBC full reviews indicated above);
- Conducting annual lab inspections (88 total; **see details below**);
- Hazard assessment and completion of Animal Hazard Control Forms for Institutional Animal Care & Use Committee (IACUC) protocols involving hazardous agents (134 protocols reviewed);
- Coordination of quarterly autoclave validations to ensure proper treatment/inactivation conditions for bagged biohazardous waste (87 total validations conducted).
- Reviewed and verified (or followed up on) biosafety approvals for ~240 proposals submitted to TERA PAMS/Cayuse, collectively (data not shown).
- Reviewed and verified/approved ~75 material transfer agreements, collectively (data not shown).

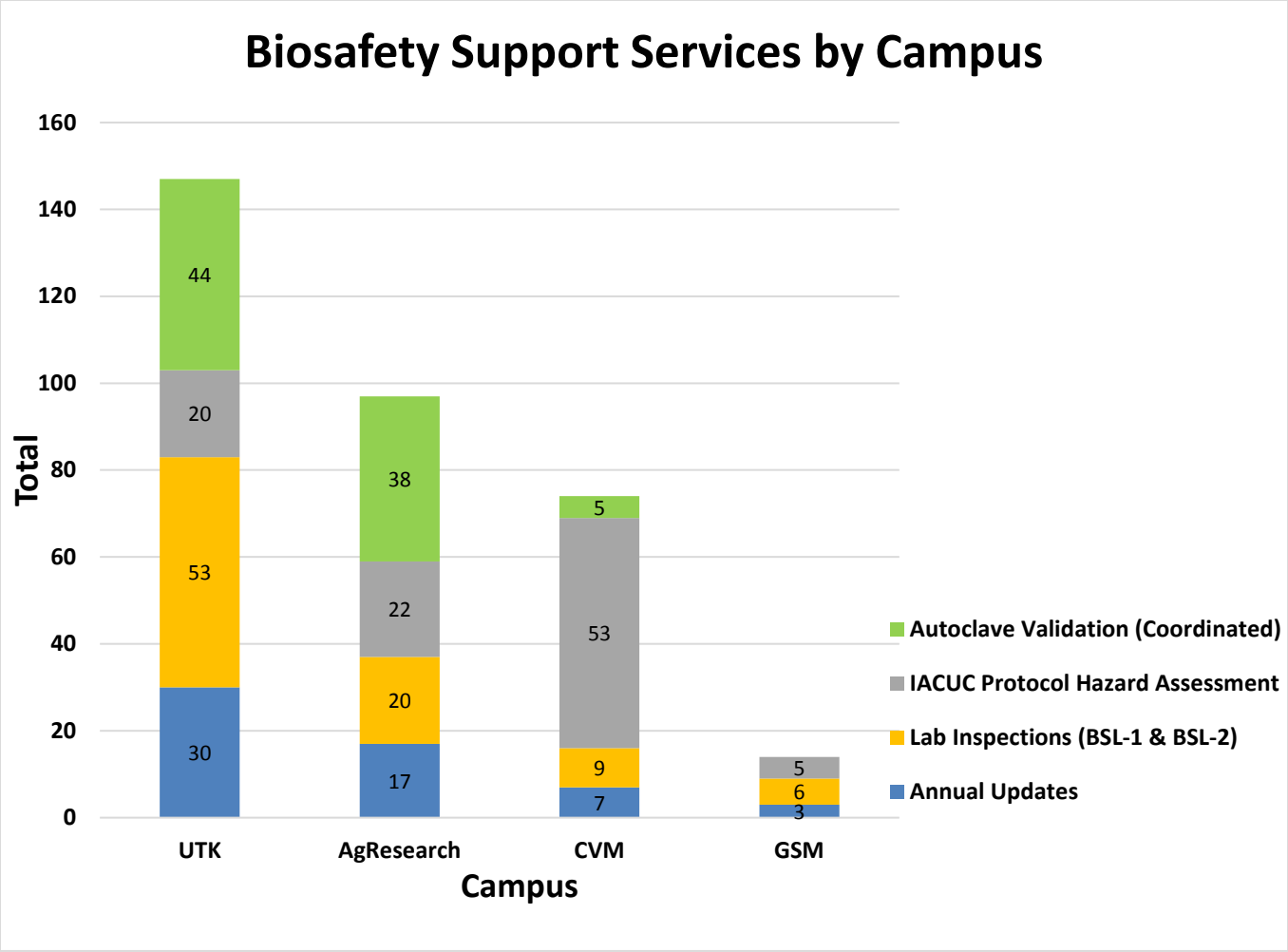


***Figure 4*: FY2017 Additional Biological Safety/Compliance Services by Campus**

**Laboratory Inspection Report:**

The first full cycle of the newly implemented two-component laboratory audit program was implemented in FY2017. Each annual cycle includes one in-person lab audit conducted by the Biosafety Office as well as an annual IBC update/lab self-assessment. 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.

The Biosafety office conducted 88 inspections, 44 were BSL-1 labs and 44 were BSL-2 labs. Laboratories were inspected based on guidelines put forth by the *Biosafety in Microbiological and Biomedical Laboratories 5th Edition* and institutional policies. None of the individual findings represented an imminent threat to life or health. 2 labs were required to be re-audited based on the cumulative risk of the findings. One lab required assistance from the UTIA Safety Office for a more comprehensive evaluation. Both labs responded satisfactorily to the findings prior to the re-audits.

Figure 5 summarizes the audit findings by campus.

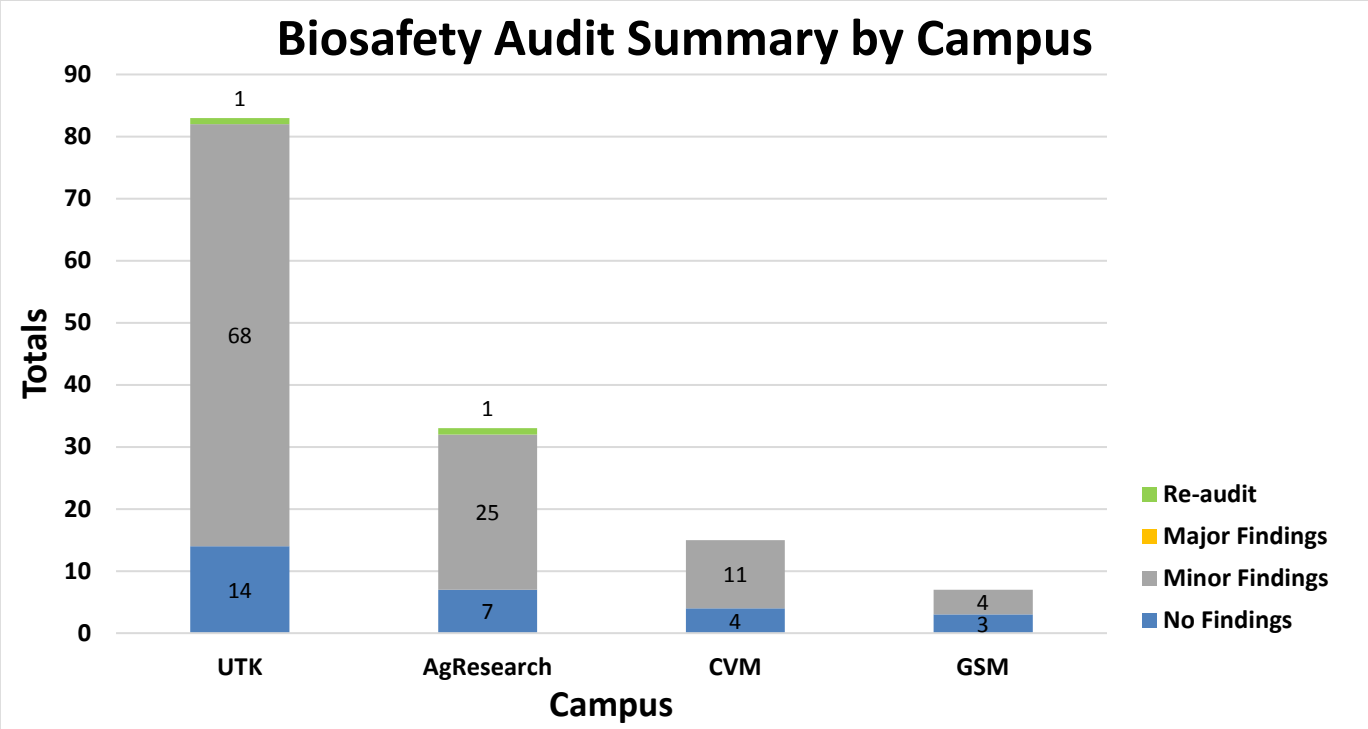


***Figure 5*: FY2017 Lab Audit Findings by Category**

Figure 6 categorizes the findings as follows:

- **No findings:** 28 audited labs had no findings to record.
- **Training management:** Incomplete performance/recording of SMP training in the BSL-1 labs, site specific training and initial/refresher training in BSL-2 labs.
- **Eyewash management:** Eyewash function deficiencies and failure to record weekly or monthly flushes. All eyewashes that were determined to have functionality issues were reported to Facilities Services or CVM Hospital Operations.
- **Sharps management:** Improper handling and/or disposal of laboratory sharps.
- **Housekeeping and disinfection:** Concerns related to lab hygiene and absorptive furniture used in "wet work" areas.
- **Biohazardous waste management:** Deficiencies in biohazardous waste collection practices.
- **Biohazard signage:** Missing, incorrect, or outdated biohazard signage for BSL-2 labs.
- **Vacuum line waste trap management:** Improper labeling and secondary containment of vacuum traps containing biohazardous waste.
- **Biosafety cabinet certification:** Denotes biosafety cabinets that were not certified in the 12 months prior to the audit.
- **Aerosol control:** Indicates a concern regarding aerosol generation outside of the biosafety cabinet and/or recommendations for minimizing aerosols.
- **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.
- **Personal protective equipment (PPE) practices:** Unavailability of or improper use of protective equipment.

- **Handwashing practices:** Inadequate handwashing procedures and/or lack of a handwashing policy in place that requires lab personnel to wash their hands after procedures and prior to leaving the lab.

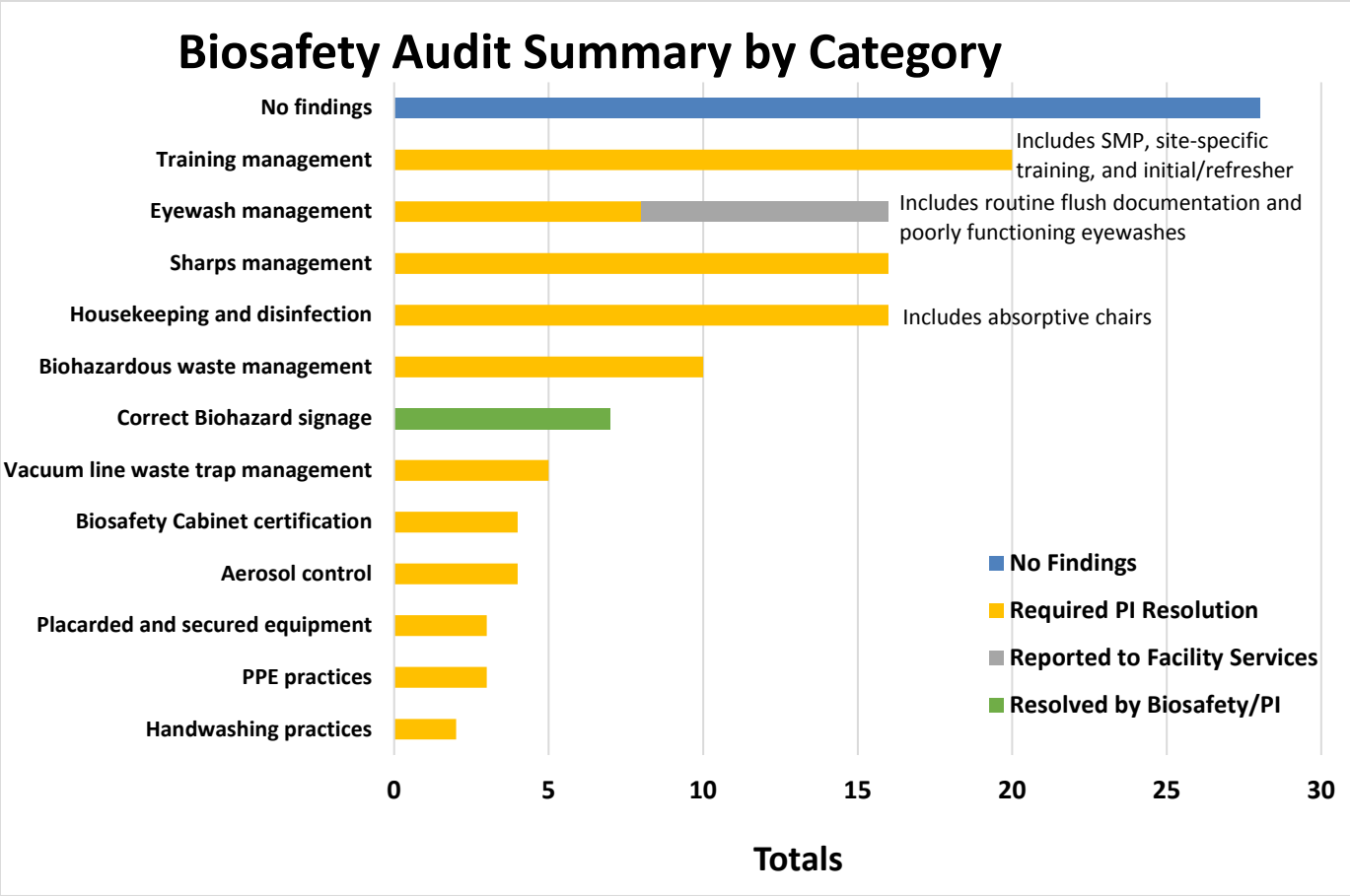


***Figure 6*: FY2017 Lab Audit Findings by Category**

**<u>Reported Accidents, Exposures, & Releases</u>:**

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

- UTK: 1 puncture from scalpel used for cleaning human bone; 2 cuts/scrapes from wire grate used to cover human tissues. All involved the presence of unfixed tissue (from individuals with documented health history). None of the injuries caused significant damage (beyond first aid treatments) or secondary infections/complications. All incidents were investigated. Recommendations were made for rounded scalpel blades, improved sharps handling, and eliminating or reducing sharp edges associated with 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 will be a focus area for FY2018 (see below).
- CVM: 1 environmental release of a recombinant vaccine agent. Notifications, risk assessments, and corrective actions were sent to the NIH Office of Science Policy and USDA Center for Veterinary Biologics as required. Corrective actions included: a new policy covering the use of recombinant/synthetic nucleic acids and recombinant organisms in veterinary clinical trials (more details in the following section); a supporting appendix in the IACUC protocol form; and a revised hazard review workflow for IACUC amendments. No adverse events from the release were observed. The corrective actions were deemed acceptable, and no regulatory citations were issued.

**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); and 4th year CVM clinical rotation students (joint effort with Dr. Amy Knowles, CVM Occupational Health).

**FY2017 Programmatic Highlights (Other):**

- Fully implemented the iMedRIS web-based compliance platform for IBC submissions and data maintenance. Implementation included: full migration of existing IBC registrations, amendments and updates into the system (many thanks to the UTHSC iMedRIS technical staff for their assistance with the migration); compilation of response letters for auto-notifications; creation of several guidance documents to assist faculty, staff, and the IBC with system and workflow navigation; and classroom-based training sessions.
- The IBC, in cooperation with the IACUC, finalized and communicated a policy covering the use of recombinant molecules or microbes in veterinary clinical trials. The policy emphasizes that IBC purview is limited only to those trials conducted in containment (as defined by the *NIH Guidelines*). Trials involving environmental release, including client animals released to owners and/or adoptions, must be approved by the appropriate federal authority such as the USDA or FDA (in addition to institutional approvals). The policy can be found on the Biosafety website at: http://biosafety.utk.edu/policies/.
- Served on a task force to evaluate safety practices and safety culture at the College of Veterinary Medicine. The task force, comprised of Biosafety, UTIA Safety, Occupational Health, and CVM faculty and staff, evaluated the physical facilities, operational policies and procedures, and accident/injury/exposure trends from the past 5 years. The findings and recommended remedial actions were presented to the CVM Dean and Executive Committee. Notable resolutions included improved accident/injury/exposure reporting, updated policies and procedures (particularly in clinical isolation and other high-impact areas), and a facility-wide policy on secondary containment of clinical specimens for transport/delivery.
- Liaised a CDC Import Permit Program inspection of affected BSL-2 and BSL-3 laboratories. Preparation included submission of ventilation testing (re-verified prior to the inspection), standard operating procedures, and other related records. The facilities were approved with only minor recommendations for improvement (implemented and administratively approved by the CDC Import Permit Program inspection team).
- Liaised 3 USDA APHIS & Tennessee Department of Agriculture facility/compliance inspections (2 Plant Protection & Quarantine, 1 Biotechnology Services). No significant findings.
- Completed the first annual cycle of the revised lab audit program, including one in-person lab audit conducted by the Biosafety Office as well as an annual IBC update/lab self-assessment joint report submitted by the principal investigator or lab supervisor. The two elements were conducted roughly 6 months apart.
- Served as the technical review chair and point-of-contact for Procurement Services for a regulated medical waste RFP (awarded to Advantra, Inc.). The Biosafety Office also liaised the transition to the new contractor and will continue to be the point-of-contact for pick-up scheduling, supply requests, manifest tracking, and resolution of any contractor-related concerns.
- Presented seminar (module) covering the *NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acids* requirements as well as other aspects of the Biosafety Program for the UTIA Responsible Conduct of Research Lunch & Learn seminar series.

- Developed and launched a Qualtrics-based self-study for initial biosafety principles/practices and OSHA Bloodborne Pathogens Standard training.
- Developed and launched the annual refresher training covering biosafety principles/practices and the OSHA Bloodborne Pathogens Standard.
- Issued Revision 12 (2016-17) OSHA Bloodborne Pathogens Exposure Control Plan covering research programs.
- Dr. David Bemis and Mr. Al Iannacone stepped down from the IBC at the end of FY2017. Each received special recognition for his 14 years and 10 years (respectively) of excellent service.
- 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), laboratory safety (and safety culture improvement), accident investigation/mitigation, and various e-management programs and tools
    - Biosafety and Biosecurity Training Course (Ft. Collins, CO)
    - Annual conference of the American Biological Safety Association (ABSA International) in Grapevine, TX
    - Annual symposium of the Southeastern Biological Safety Association (SEBSA) at Central Florida University in Orlando, FL
    - Annual UT System Safety Officers' meeting (Memphis, TN) and TN Higher Education Safety Officers' meeting (Franklin, TN)

**Program Objectives (FY2018):**

- Revise and reissue an updated IBC Charter to reflect the general policy, teaching oversight, iMedRIS submission and workflow, and other applicable policies and procedures. Tentative release is January 2018.
- Update biological materials inventory in all applicable departments (periodic update). This will be done with a combination of electronic surveys and in-person laboratory visits/audits.
- Prepare and implement electronic training modules for selected biosafety and compliance topics, e.g. *NIH Guidelines* awareness, biosafety principles, bloodborne pathogens, etc. Platforms that interface with iMedRIS are preferred for training delivery.
- Work with CVM Necropsy to improve safety awareness and practices in the necropsy suite (emphasis programs on training, sharps handling/management, and accident/exposure follow-up procedures).
- Provide at least 3 biosafety/compliance awareness seminars to academic departments or administrative units.
- Participate in at least one national and/or regional conference on biosafety.