UNIVERSITY OF TENNESSEE BIOLOGICAL SAFETY PROGRAM
FY2016 Annual Report & Activity Summary

IBC Registration Review

The UT Institutional Biosafety Committee (IBC) conducted nine meetings during FY2016. A total of 48 categorical reviews (33 three-year renewals; 15 new projects) 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 DNA (RDNA); 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 21±18 days (including outlier; 19±14 days without). Additionally, there were 23 administrative updates/amendments and 13 terminations (experiments concluded or faculty relocation/retirement).

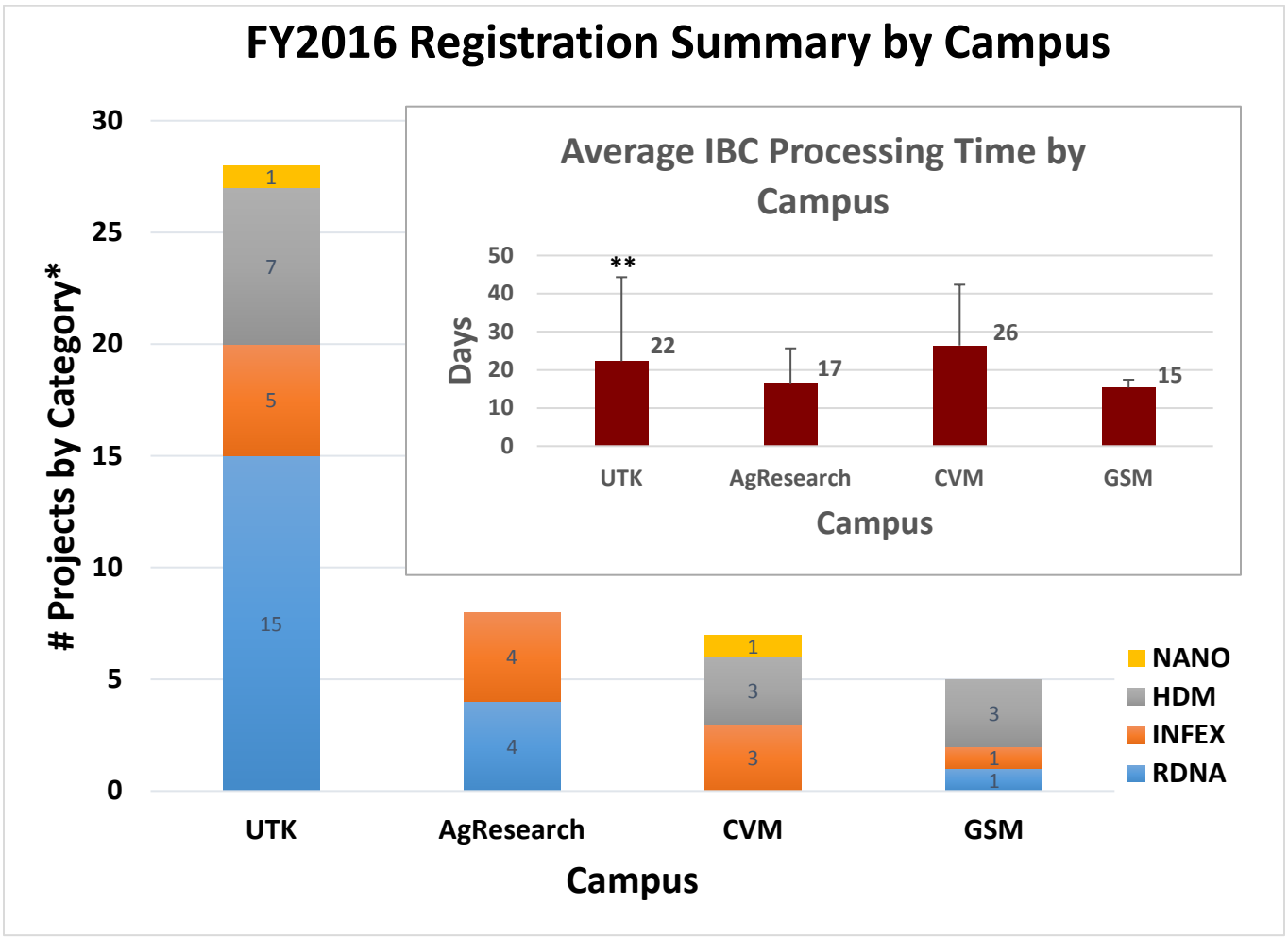

***Figure 1*: FY2016 IBC Categorical Reviews & Processing Time by Campus**
*** Registrations may include multiple project categories; reflected in data**
****Data includes one outlier due to construction/verification testing of new BSL-3 laboratory (t=86 days)**

Biosafety Training

Figure 2 highlights the number of individuals trained in various biosafety and/or research compliance subjects during FY2016. 80 in-person training sessions were conducted (643 participants), and online refresher training modules covering: the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids* and standard microbiological practices (labeled as 'Biosafety Awareness'); Biosafety Level-2 practices; the (T)OSHA Bloodborne Pathogens Standard; or biological materials shipping regulations were provided. The total number of trainees (in-class and online formats) is indicated for each category. The total number of trainees by campus is indicated in Figure 3. In total, ~1,800 individuals received either initial or annual refresher training.

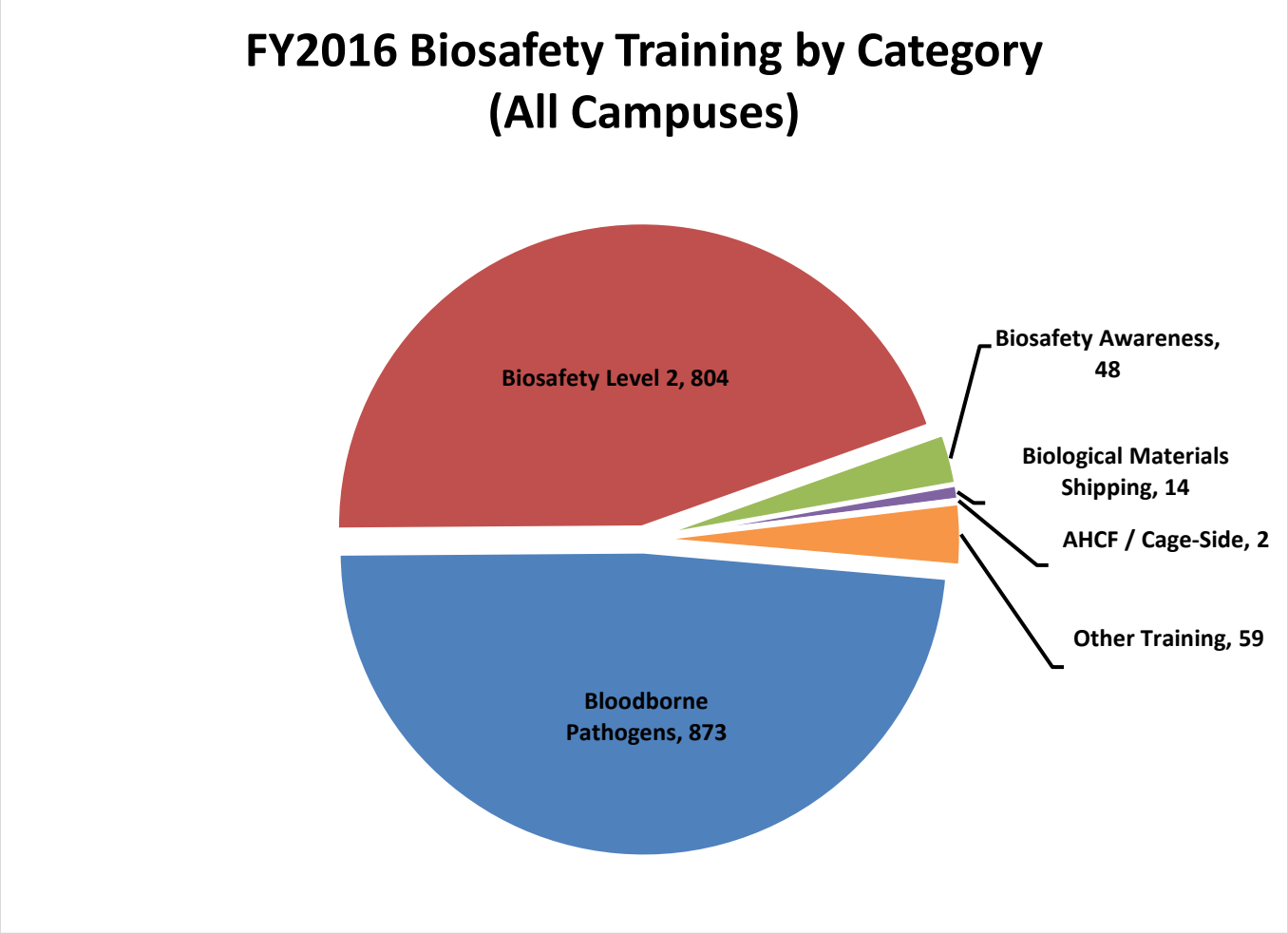

Figure 2: **FY2016 Biological Safety & Compliance Training by Category (All Campuses)**

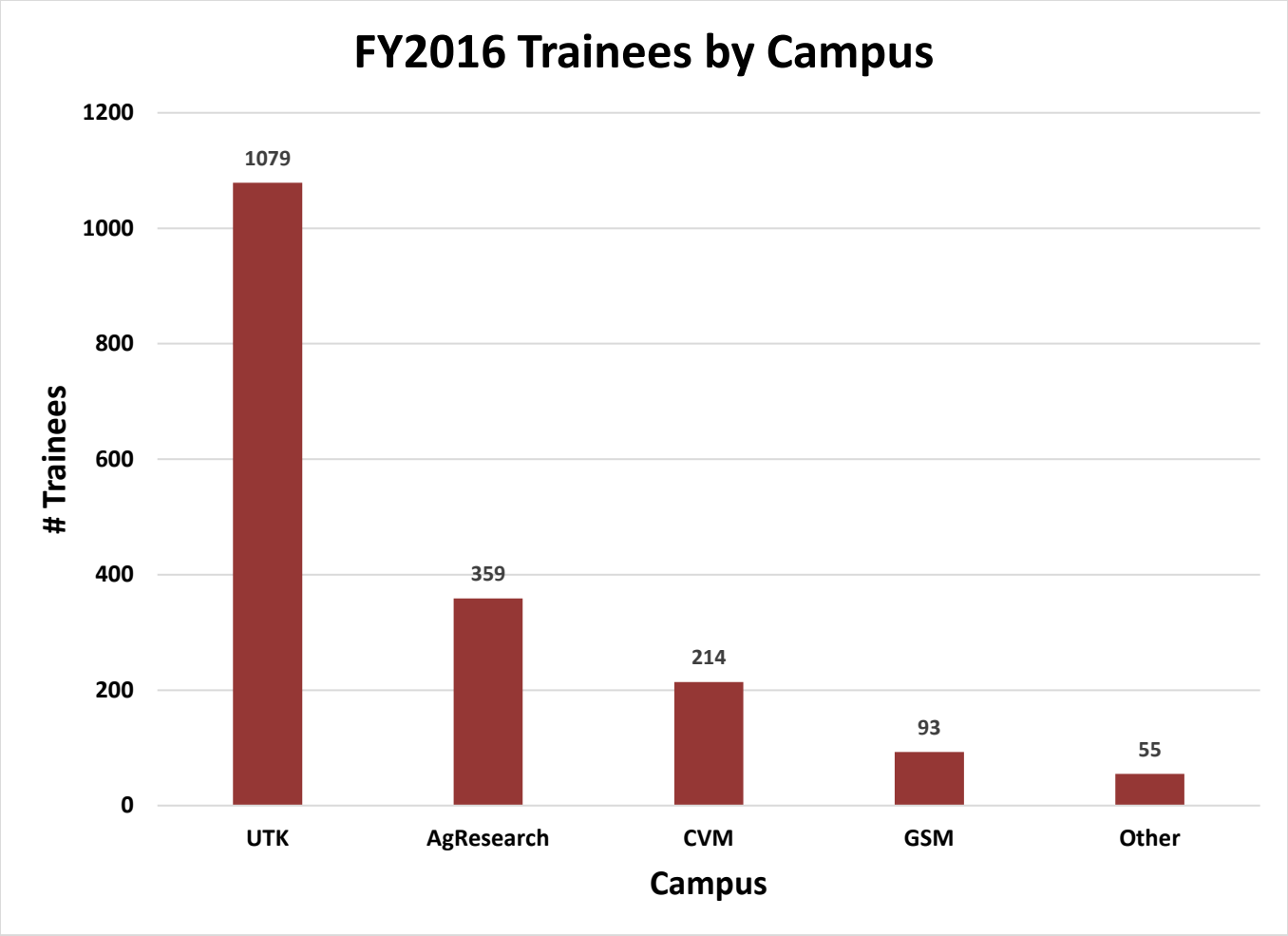

Figure 3: **FY2016 Biological Safety & Compliance Trainees by Campus**

Other 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 (60; in addition to IBC full reviews indicated above);
- Conducting annual lab inspections (41 total; **see Appendix A**);
- 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 90 proposals submitted to TERA PAMS/Cayuse, collectively (data not shown).
- Reviewed and verified/approved 76 material transfer agreements, collectively (data not shown).

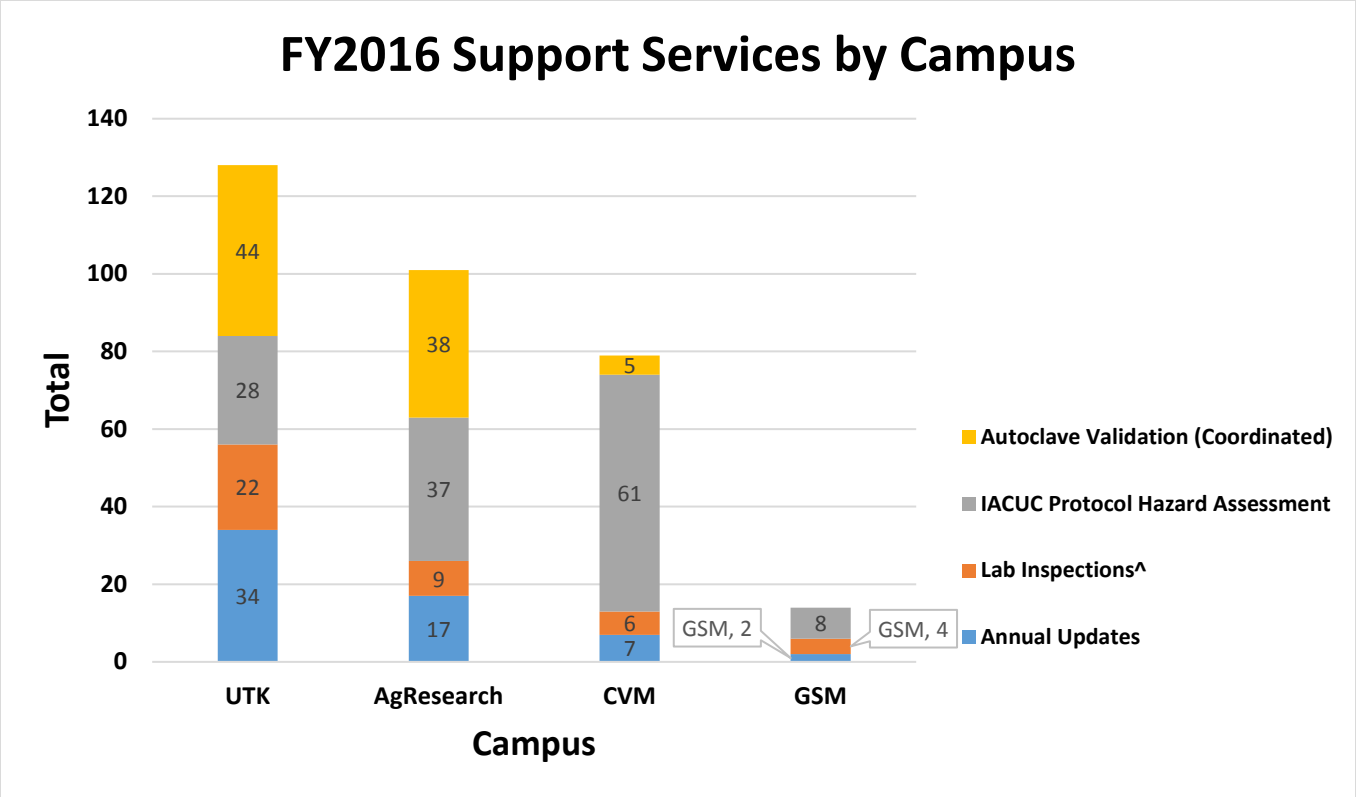

***Figure 4*: FY2016 Additional Biological Safety/Compliance Services by Campus**
^Reduced lab Inspection totals based on new 1 inspection/year procedure (see Appendix A below)

Reported Accidents, Exposures, & Releases:

The Biosafety Office was notified of 4 accidents involving biological materials as follows:

- UTK: 3 cuts/punctures from dental instruments used for cleaning human bone. Two involved the presence of primary 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 and attributed to improper bracing/securing of the specimens while working with a sharp device. A follow-up training session on sharps handling/safety was provided by the Biosafety Office and included examples of bracing/gripping pads, Kevlar cut-resistant gloves, and other engineering controls, and instruction on hand-positioning while holding/bracing the specimen.
- UTK: 1 laboratory spill and superficial exposure to recombinant HEK293 (human) cells stably transduced with replication-incompetent lentiviral vectors carrying bioluminescence reporter genes. Medical evaluation deemed that the exposure involved only intact skin and was otherwise insignificant. The incident was investigated and determined to be caused by improper handling/viewing techniques. Personnel were retrained on flask handling and cell viewing techniques, including ensuring that caps are tightened and that cells are viewed with a suitable microscope (e.g. inverted microscope) on a stable platform. The incident was reported to NIH Office of Biotechnology Activities per requirements for exposures involving recombinant Risk Group 2 agents/materials (no additional information or follow-up required from NIH OBA).

There were no reports of accidental loss or release of biological hazards.

FY2016 Programmatic Highlights:

In addition to the metrics detailed above, programmatic highlights included:

- Linda Hamilton, MPH, was hired as the Biosafety Specialist (October), filling the position previously held by Dr. Jonathan Phipps.
- Appointment of 2 new IBC members: Dr. M. Reza Hajimorad (Entomology & Plant Pathology) and Ms. Brittany Isabell (East Tennessee Regional Health Office; non-affiliated representative).
- Worked closely with principal investigators, UTK/CVM administration, project designers and facility engineers to bring a new BSL-3 laboratory online at CVM, the first for the UTK-area campuses. Efforts included: HEPA filter certifications; coordination of performance verification testing by an external, third-party consultant (Mr. Paul Jennette, PE, RBP; AHA Consulting Engineers); coordination of facility improvements; and preparation of written BSL-3 biosafety and emergency response plans.
- Finalized, communicated and implemented UTK-area *Biosafety Program Policy*. This policy covers the use of biological hazards in research, teaching, and diagnostic testing. It defines the purpose, purview, scope of the Biosafety Program; roles and responsibilities of program stakeholders, including administrators and end users; and general programmatic requirements. This policy was vetted by the Institutional Biosafety Committee (IBC); UTK Laboratory Safety Committee; UTK Safety Committee; Associate Deans of Research; Associate Deans of Academic Affairs; Research Council; Executive Committee of the Faculty Senate; and Institutional Compliance Committee. The policy can be found on the Biosafety website at: http://biosafety.utk.edu/policies/.

- Finalized and communicated the UTK-area *Framework for Biological Hazards in Teaching Laboratories*. This document establishes a new framework for the use of biological hazards in teaching laboratories or other experiential learning environments as recommended by an appointed task force of instructional faculty and staff. It was vetted by the same groups indicated above. The framework, which follows the guidance of the American Society for Microbiology's *Guidelines for Biosafety in Teaching Laboratories* (2012), outlines the applicability and scope, administrative roles and responsibilities, and covers:

    - Hazard awareness/communication;
    - Training;
    - Medical evaluation considerations;
    - Personal protective equipment;
    - Emergency response and notification procedures spills and exposures;
    - Laboratory/site inspections; and
    - Documentation

    This policy can be found on the Biosafety website at: http://biosafety.utk.edu/policies/. Collection of course information and full implementation pending.

- Implemented a new two-phase laboratory audit program with the goal of bolstering lab biosafety practices and compliance awareness. Each annual cycle will now include 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 are conducted roughly 6 months apart (see Appendix A below for audit cycle results).
- Completed online submission form for the iMedRIS IBC/Biosafety module. Next steps include establishing routing procedures, developing instructional videos/guides, and a limited roll-out for testing. Full implementation is projected to be Fall, 2016.

- IBC self-assessment was completed by a designated subcommittee. Recommendations for improvement included IBC Charter revision, creation of decision tree tools to instruct IBC applicability to research protocols/programs, and improved methods of training. Recommendations were reported to the IBC and the Associate Vice-Chancellor for Research (pending resolution).
- Liaised 6 USDA APHIS facility/compliance inspections (5 Plant Protection & Quarantine, 1 Veterinary Services). No significant concerns reported.
- Presented seminars covering the *NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acids* requirements as well as other aspects of the Biosafety Program to the Biochemistry, Cellular & Molecular Biology department and the Graduate School of Medicine; also provided Biosafety Program module for Responsible Conduct of Research Lunch & Learn seminar series.
- Developed and launched the annual refresher training covering the *NIH Guidelines*, biosafety principles/practices, and the OSHA Bloodborne Pathogens standard.
- Issued Revision 11 (2015-16) OSHA Bloodborne Pathogens Exposure Control Plan covering research programs.
- In collaboration with the Office of Laboratory Animal Care, the IACUC Director of Animal Compliance Support, the IACUC Institutional Official, and the UTK Emergency Manager, updated the dedicated lab animal facility emergency response plans.
- Participated in AAALACi site-visit for laboratory animal care/use program accreditation.
- Professional Development & Training:
    - Coordinated, hosted (UT Conference Center) and participated in the EHS Academy training course provided by Dr. Robert Emery, Southwest Center for Occupational and Environmental Health. Nearly 40 people from 8 states the southeastern region participated.
    - Biosafety staff participated in the IBC 101 and Best Practices symposium (State College, PA).
    - Biosafety staff completed a 'train-the-trainer' course for shipping biological hazards in commerce in accordance with DOT and IATA regulations (Nashville, TN).
    - Biosafety staff attended the annual symposium of the Southeastern Biological Safety Association (SEBSA) in Auburn, AL.

Biosafety Office Program Objectives (FY2017):

- Fully implement the biosafety in teaching laboratories framework, with the goal of having all applicable teaching laboratories/courses identified and covered by January 1, 2017.
- Complete iMedRIS module for biosafety, test, and rollout to research community. A limited rollout is projected for September, 2016, with full implementation by January 1, 2017.
- Revise and reissue an updated IBC Charter to reflect the general policy, changes in teaching oversight, and iMedRIS submission procedures/requirements. Other recommendations generated during the IBC self-assessment will be addressed as applicable. Tentative release is late 2016/early 2017.
- Laboratory safety focus areas:

- Coordinate with other UTK-area safety offices and the UTK Laboratory Safety Committee to ensure congruence of laboratory safety requirements, and where possible, eliminate laboratory safety audit redundancies.
- 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.
- Review biological safety cabinets (BSC) for associated physical hazards including non-interlocked UV germicidal lamps and plumbed natural gas. The Biosafety Office will work with research staff to significantly reduce or eliminate these hazards. Guidance documents and/or policies will be generated as necessary.
- Prioritize the removal of fabric furniture (or furniture in disrepair) from research laboratories.

- Prepare and implement electronic training modules for selected biosafety and compliance topics, e.g. *NIH Guidelines* awareness, biosafety principles, bloodborne pathogens, etc.
- 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.

Appendix A: Biosafety Level-2 Laboratory Inspection Report

The Biosafety Office implemented a new two-phase laboratory audit program with the goal of bolstering lab biosafety practices and compliance awareness. Each annual cycle includes 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 are conducted roughly 6 months apart. The annual in-person lab audits are now scheduled with the principal investigator and/or designated research staff in advance. 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 41 inspections of (primarily) BSL-2 laboratory spaces in April-June, 2016. Laboratories were inspected relative to the guidelines put forth by the *Biosafety in Microbiological and Biomedical laboratories 5th Edition.* In the majority of cases, deficiencies were addressed with laboratory personnel and resolved on site. Three laboratories (one each from UTK, AgResearch and CVM) required re-inspection due to numerous findings. All three labs had adequately addressed the concerns upon re-inspection and subsequently passed.

Figure A.1 summarizes the audit findings by category as follows:

- **Personal protective equipment:** evaluates personnel access to lab coats, gloves and eye protection when working with infectious or recombinant agents;
- **Shared storage, equipment and other resources:** confirmation that materials stored outside of the lab are properly secured and labeled;
- **Emergency procedures:** ensures that exposure/injury response and spill control/clean-up procedures are documented and properly communicated to lab staff;
- **Sharps & biological waste disposal practices:** assurance that biohazardous wastes (solids, liquids, and sharps) are properly segregated and neutralization practices are in place prior to disposal;
- **Practices and procedures:** assessment of availability standard operating procedures and evaluation of biological safety and containment practices;
- **Housekeeping:** assessment of the general state of the lab in regards to excessive clutter or other issues that might present a safety concern;
- **Biosafety resources and documentation:** category covers the presence of an up to date biosafety notebook and Bloodborne Pathogen Exposure Control Plan (if required) and on-site record of training;
- **Hygiene and primary containment measures:** confirmation that soap, hand towels and functional sinks are present, availability and routine maintenance of eyewashes, and proper installation and certification of biological safety cabinets and other containment equipment (as applicable);
- **Facility signage and practices:** category covers restricted lab access/lab security, prohibition of food and drink, updated door placards and emergency response postings, and labeling of equipment used to store or process biohazards.

As indicated, the Biosafety Office worked closely with laboratory staff to update door placards, emergency response postings, and biosafety manuals. Additionally, the Biosafety Office reported several non- or poorly-functioning eyewashes to Facilities Services (some of which were recently resolved). Other recurring deficiencies included: failure to document lab-specific training; poor housekeeping/lab hygiene to include improper cleaning and disinfection of work surfaces; improper waste management, including overfilled sharps containers and biowaste cans; and conducting procedures with aerosol-generating potential without primary containment measures (e.g. outside of a biosafety cabinet). To address these

issues the Biosafety Office will bolster didactic and practical training, create guidance documents or policies as necessary, and broadly communicate expectations through the Biosafety listserv, newsletters, or safety bulletins.

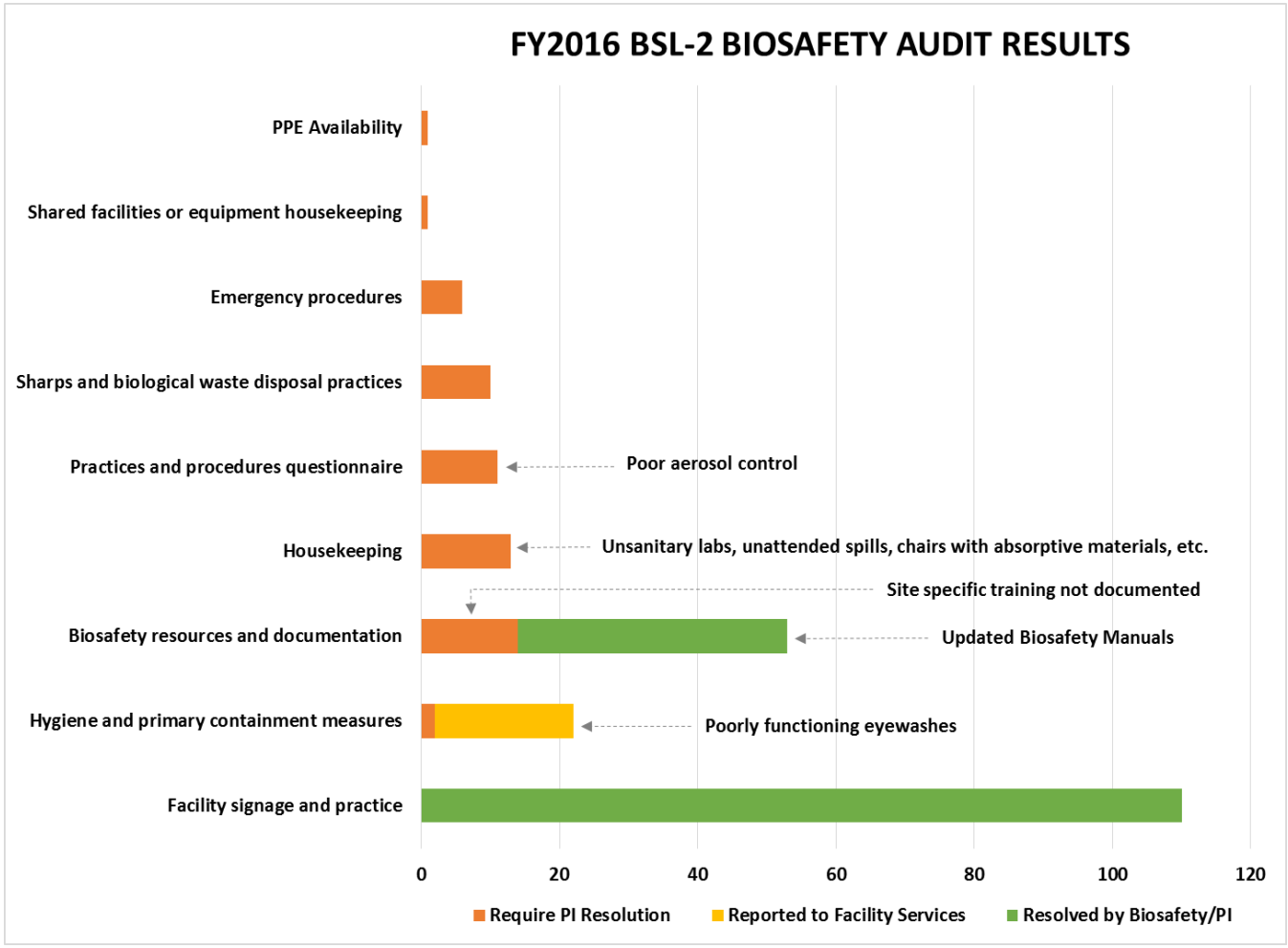

***Figure A.1*: FY2016 BSL-2 Lab Audit Findings Summary**