

University of Tennessee- Knoxville

2013 INSTITUTIONAL BIOSAFETY COMMITTEE & BIOSAFETY OFFICE ACTIVITY SUMMARY

IBC Registration Review

The UT Institutional Biosafety Committee (IBC) conducted ten meetings during 2013. A total of 38 registrations (21 three-year renewals; 17 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 project category (recombinant DNA, infectious agent, biological toxin, or human materials) for each campus. The average processing time from submission to final approval by campus is also shown (inset). Across all registrations the average approval time was 27±20 days. Additionally, there were 5 approved amendments and 11 administrative terminations (experiments concluded or faculty relocation/retirement).

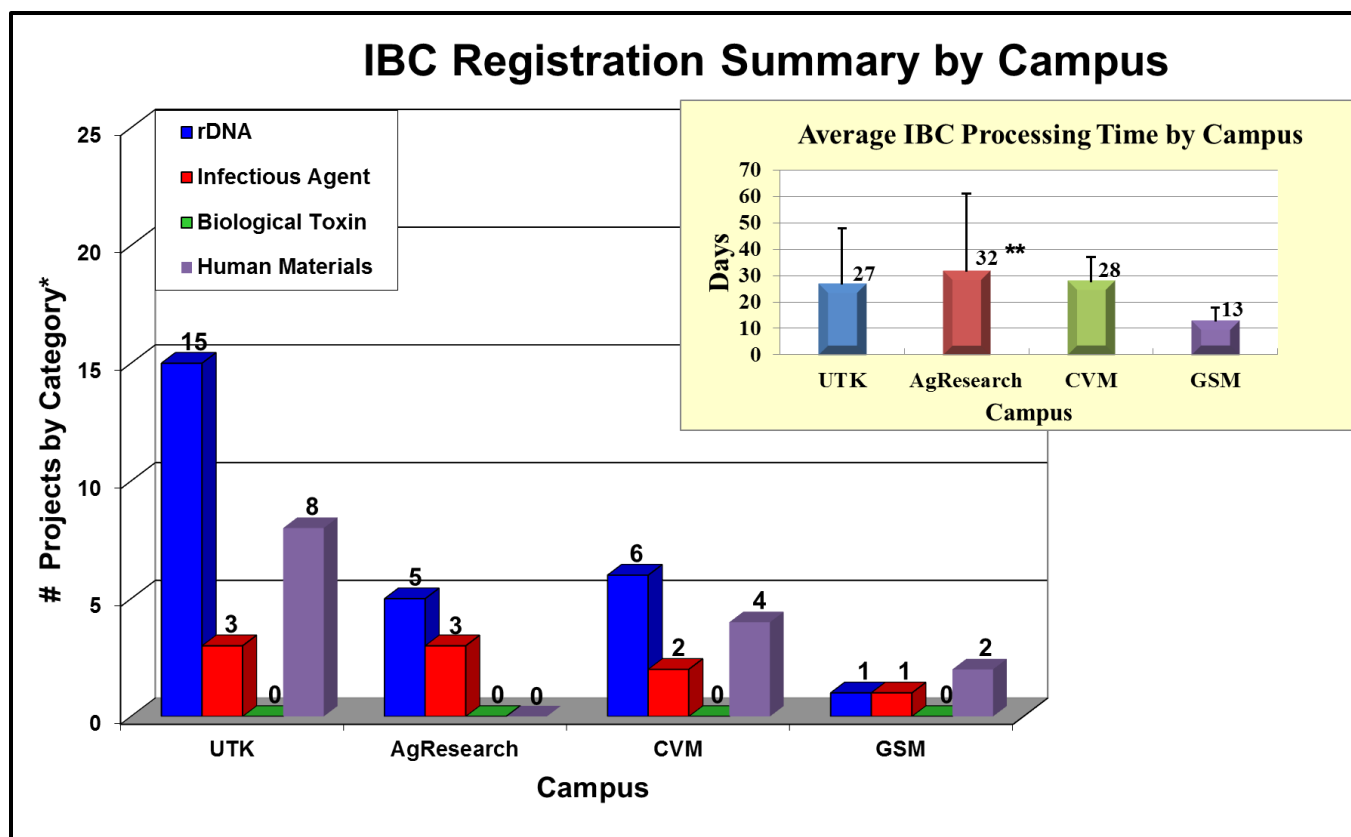


Figure 1: 2013 IBC Categorical Reviews & Processing Time by Campus

* Registrations may include multiple project categories; reflected in data

**Data excludes one outlier (t=126 days; investigator on extended international travel)

Biosafety Training

Figure 2 highlights the number of individuals trained in various biosafety and/or research compliance subjects during 2013. 121 in-person training sessions were conducted (847 participants). Additionally,

online refresher training modules were offered in standard microbiological practices (SMPs, labeled as 'Biosafety Awareness'), Biosafety Level-2 practices, the (T)OSHA Bloodborne Pathogens Standard, or biological materials shipping regulations. The total number of trainees (in-class and online formats) is indicated for each category. In total, ~1,750 individuals received either initial or annual refresher training.

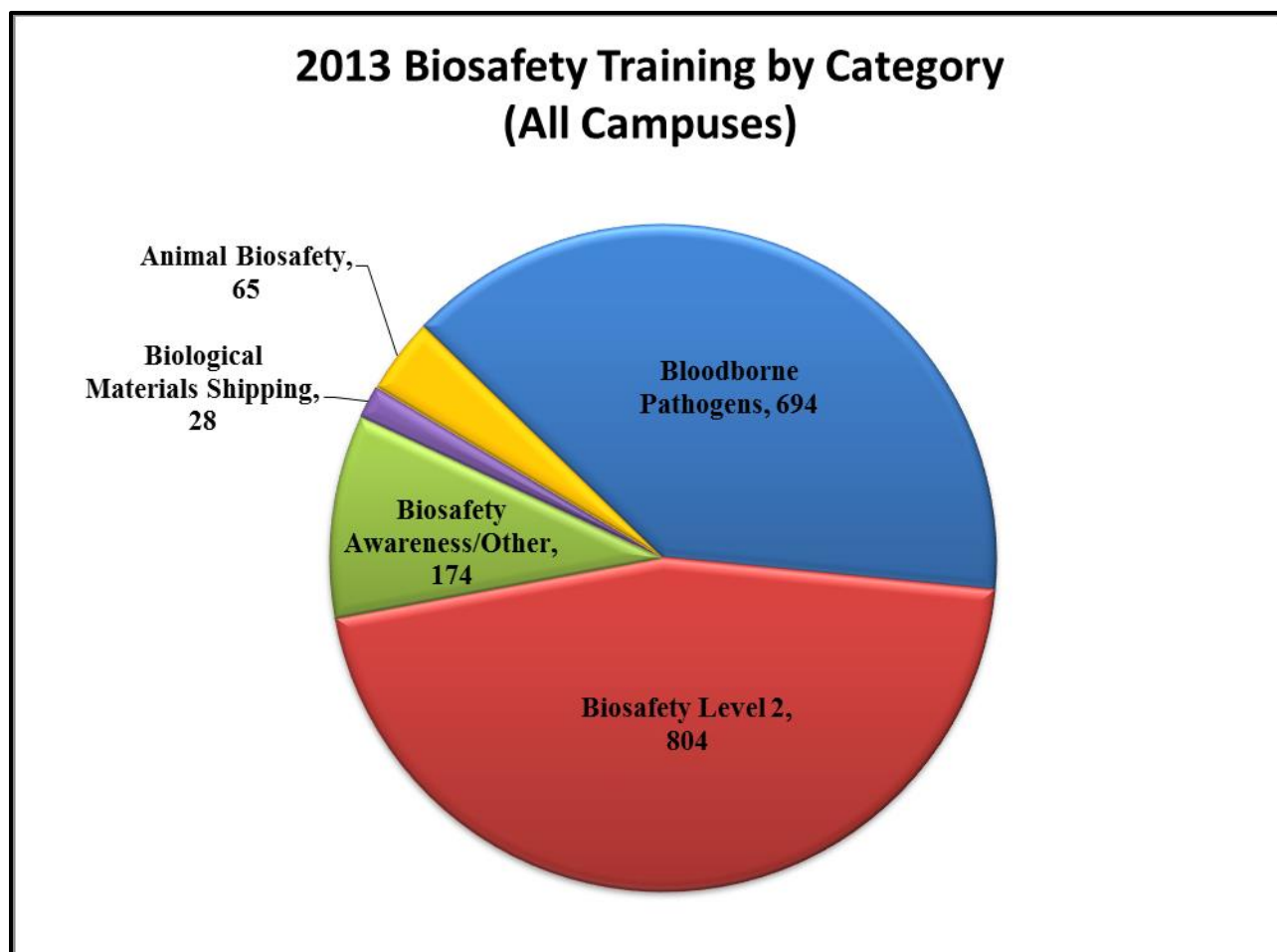


Figure 2: 2013 Biological Safety & Compliance Training by Category (All Campuses)

Other Biosafety-Related Services

Other safety and compliance services provided by the IBC/Biosafety Office are shown in Figure 3. Major efforts included:

- Administrative reviews of IBC/Biosafety registration annual updates (76; in addition to 38 processed for IBC review as described above);
- Conducting annual BSL-1 and semiannual BSL-2 lab inspections (141 total-**see Appendix A**);
- Hazard assessment and completion of Animal Hazard Control Forms for Institutional Animal Care & Use Committee (IACUC) protocols involving hazardous agents (127 protocols reviewed);
- Coordination of quarterly autoclave validations to ensure proper treatment/inactivation conditions for bagged biohazardous waste (124 total validations conducted).

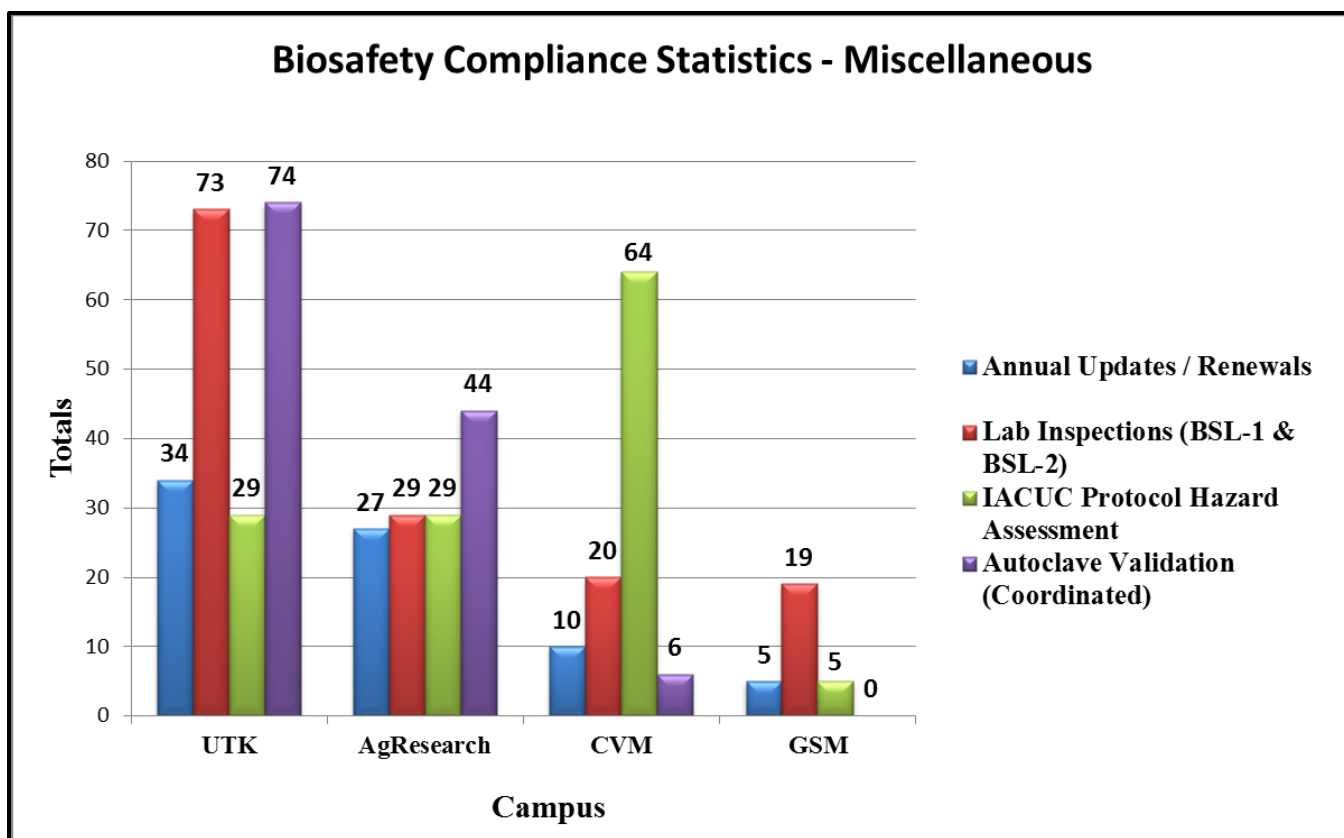


Figure 3: 2013 Additional Biological Safety/Compliance Services by Campus

2013 IBC Activity Highlights:

- Reviewed/approved 38 registrations for the research use of recombinant DNA, infectious agents, human materials (administrative-Biosafety Office), or biological toxins (Figure 1).
- Established a subcommittee to research and develop a new Charter section/purview area covering the use of nanoparticles as delivery agents of synthetic nucleic acids, cell altering peptides/proteins or other bioactive conjugates. The committee reviewed and agreed to adopt the nanoparticle section (pending official incorporation into the Charter).
- Established a subcommittee to review and amend the existing Charter. The subcommittee met and made several suggestions, including: incorporation of nanoparticles section; addition of an organization chart; expanding Biosafety Officers purview to cover accident investigations/reports; administrative review of some environmental/diagnostic materials (low-risk; minor procedures); revising reporting/posting deadlines; and minor updates and corrections. The revised Charter is pending review/discussion with the Assistant Vice-Chancellor for Research.
- The IBC SharePoint website was incorporated into the Biosafety website, and supporting information regarding IBC purview areas and registration requirements was added.

Biosafety Office Activity Highlights:

- Provided biological safety/compliance training to 1,750 faculty, staff, or students (see above).
- Performed ~140 lab inspections (see above).
- Participated in 4 USDA APHIS facility/project inspections (1 Biotechnology Regulatory Services; 1 Veterinary Services; 2 Plant Protection & Quarantine); no significant findings.

- Conducted dedicated lab animal facility inspections for compliance with biosafety standards, including: primary containment device certification confirmation; Animal Hazard Control Form and other hazard communication postings; safe sharps handling and disposal; availability of the current OSHA Bloodborne Pathogens Exposure Control Plan; biowaste removal protocols; and general housekeeping.
- Participated as a safety liaison during the AAALAC-International animal program assessment inspections/discussions.
- Commissioned 6 new BSL-2 laboratories (2 in Science & Engineering Research Facility; 4 in Brehm Animal Science).
- Directly assisted researchers with biohazardous agent shipping (7 Category A shipments; 6 Category B/Dry Ice shipments).
- Delivered IBC/Biosafety compliance awareness seminars to the Biomedical & Diagnostic Sciences and Small Animal Clinical Sciences Departments (CVM) and CASNR Fall Kickoff (Undergraduate Research and Honors Programs).
- Along with IACUC, UTK Environmental Health & Safety, Occupational Health, and Radiation Safety, coordinated and delivered the 8th Annual Division of Biology Safety Training Day.
- Provided Bloodborne Pathogens awareness training for 4-H camp counselors (Greeneville, TN).
- In collaboration with the departments of Environmental Health & Safety, UTIA Safety and Radiation Safety, provided lab safety awareness training for the UT Police Department by providing a programmatic overview and tabletop scenarios/exercises.
- In collaboration with the UTIA Safety Office, developed a guidance document highlighting protective measures for personnel exposed to or working with/around sewage and wastewater.
- 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 and trained lab animal facility personnel (emergency scenarios/tabletop exercises).
- Issued Revision 9 (2013-14) OSHA Bloodborne Pathogens Exposure Control Plan covering research programs.
- Electronic resources:
 - Authorized by the Office of Research to develop and manage the Biosafety website; reorganized content, integrated the IBC SharePoint site, developed a page outlining training module descriptions/training matrix, and developed a page outlining comprehensive biological waste segregation/treatment guidance.
 - SharePoint site created for researchers registered with the IBC/Biosafety Office-all folders populated with currently approved registrations, annual updates, training record information, and other pertinent information. Archived documents (up to 3 years) were also provided for each researcher's folder.
 - All lab inspections now documented electronically with iAuditor. Electronic inspection reports can be generated and distributed immediately following a site inspection.
- Training and professional development:
 - Brian Ranger:
 - Attended DOT/IATA Biological Hazards Shipping training (Nashville, TN; March 1, 2013);

- Attended National Center for Biomedical Research & Training's *Campus Emergencies: Prevention, Response & Recovery Management and Planning Level* (Knoxville, TN; April 24-25, 2013);
- Attended the UT/TBR System Safety Officers' meeting held at Montgomery Bell State Park (White Bluff, TN; April 30-May 2, 2013);
- Attended USDA/APHIS Biotechnology Regulatory Permitting and Compliance Educational Workshop (Knoxville, TN; May 13, 2013);
- Attended the UT System Safety Officer's Meeting (Knoxville, TN; November 5-7, 2013);
- Served on the UT CVM Occupational Safety Committee;
- Appointed to the UTK Laboratory & Workplace Safety Committee (LWSC);
- Joined the Southeastern Biological Safety Association (SEBSA);
- Renewed professional credentials through the American Society for Microbiology-National Registry of Registered Microbiologists (SM(NRCM)) and the American Biological Safety Association-Certified Biological Safety Professional (CBSP).
- Jon Phipps:
 - Attended DOT/IATA Biological Hazards Shipping training (Nashville, TN; March 1, 2013);
 - Attended *Principles and Practices of Biosafety* training course (Portland, OR; July 21-26, 2013);
 - Served on the UT CVM Occupational Safety Committee;
 - Joined SEBSA.
- Jessica Woofert:
 - Completed Word Press training for Biosafety website management (Knoxville, TN; February 1, 2013);
 - Completed Microsoft Access I, II, & III training (Knoxville, TN; April 16-17, November 7-8, & December 2-3, 2013);
 - Attended the UT Career Development Expo (Knoxville, TN; May 10, 2013);
 - Completed Web Design Fundamentals (online training; July 17-18, 2013).

Biosafety Office Program Objectives (2014):

- Conduct program gap analysis with Dr. Robert Nobles, AVCRE, and develop policies and procedures as applicable.
- Revise and issue an updated IBC Charter per endorsement by research administrators at each campus.
- Update of door sign program for all BSL-2 labs-reformat; update emergency contact numbers, etc. (in progress).
- Develop and implement a regular schedule for shipping training (quarterly?). Would also like to set up "lunch-and-learn" sessions or general Q/A sessions to allow for small group discussions of biosafety and/or other related safety concerns (monthly?). The latter would contribute to safety outreach/compliance culture initiatives.

- Use announcements (listserv and/or website) to recognize those faculty and staff who have excelled in lab safety and/or research compliance. Safety culture emerges more from rewarding what is right rather than punishing what is wrong. A recognition program may incentivize the Biosafety Office's objectives and promote a better safety culture.
- Complete a biological materials inventory in all applicable departments (periodic update). This will be done with a combination of electronic surveys and 'door-to-door' lab visits.
- Work on biological permits program to include regular training opportunities (quarterly?), permit information databasing, and permit-specific audits.
- Professional development: a) attend annual System Safety Officers' meeting and/or UT/TBR joint safety meeting (Brian Ranger); b) attend ABSA Annual Conference or ABSA-endorsed training conference (Brian Ranger/Jon Phipps); c) complete supervisory training program through Employee Organization and Development (Brian Ranger); d) continue working toward Administrative Professional certification (Jessica Woofert).

Appendix A: Biosafety Level-2 Laboratory Inspection Report

Introduction

In November 2012, the Office of Biosafety adopted a new electronic system for performing laboratory inspections. This software application, iAuditor, offers freeform template design capabilities alongside the ability to generate inspection reports in the form of PDF and word documents which are made immediately available to both faculty and the Office of Biosafety using either email or dropbox.

The inspection cycle for Fall 2013 represents the first full year of use for the iAuditor program. In general this new format has been well received. The benefits to our office come from the ease in which forms can be generated and revised based on changing needs. This approach also reduces errors associated with transcribing inspection results from paper evaluations to electronic forms, as was required prior to the adoption of the new system. Further, the generation of completed inspection forms as PDF files has the added advantage of allowing our office to retain reports indefinitely without generating storage concerns associated with paper files. While a full satisfaction survey has yet to be performed, anecdotal responses from faculty have also been positive regarding the switch to the iAuditor system. Comments thus far have indicated that completed forms are concise and easily understandable. In addition, faculty has also expressed an appreciation of the email delivery of completed reports.

Results

The inspection form itself was generated from the guidelines put forth within the Biosafety in Microbiological and Biomedical Laboratories 5th edition and can be found in attachment 1. A summary of items along with the total number of deficiencies noted, system wide, in 2013 are found in table 1.

During 2013, 115 BSL-2 site visits were conducted by the office of Biosafety. Of these, 56 took place in the spring semester, while 61 occurred in the fall (Fig. 1a, 1b). Due to lab closures (SERF 108, 205) and the addition of the one lab (SERF 331) the number of site visits on the UT Knoxville Main Campus demonstrated a net loss of 1 lab over the inspection periods. In contrast, the completion of the new Brehm Animal Sciences building along with the addition of new faculty and laboratories in the Plant Biotech Building resulted in a net gain of 6 new BSL-2 sites on the UT Institute of Agriculture campus. The number of inspection sites for both the UT College of Veterinary Medicine and UT Medical Center remained steady over the course of the year.

Regarding the deficiencies in compliance, the most common citation was due to a lack of documentation for eyewash flushes (41), followed by biowaste disposal issues (6) and laboratory spaces being unsecured (6). Of the remaining issues, 5 were due to outdated exposure control plans, 4 lab groups were cited for recapping needles or other inappropriate sharps disposal practices, there were 2 instances of food being found in the lab, two other groups were found without the appropriate training and spill control documents present, and finally one biosafety cabinet was still in use past the posted certification date.

Table 1. Summary of items found on the current Biosafety Level-2 laboratory inspection form along with the number of violations, systemwide, for UT main, UTIA, UTCVM, and UTMCK campuses.

Inspection item	Number of incidents	Inspection item	Number of Incidents
Access to lab area restricted?	6	Biowaste containers labeled, lined, leak proof and lidded?	6
Biohazard signage present at entrance?	0	Handwashing sinks available with soap and towels?	0
Benchtops impervious to heat/water/chemicals?	0	Eyewash stations (functional, checked)	41
No carpets or porous materials?	0	Biosafety cabinets (certified, clean, liquid waste housed properly)?	1
Food or drink in lab?	2	Gloves available?	0
Emergency response proc. Posted?	0	Lab coats available?	0
Lab in clean/sanitary condition?	0	Eye protection available?	0
Pest management issue?	0	New personnel added who need training?	0
Non-work related animals or plants?	0	Biosafety manual available?	2
Lab equipment decontaminated routinely?	0	Biological spills procedure available?	2
Shared equipment?	0	Site specific training documented?	2
Needles and sharps disposed of appropriately?	2	Bloodborne pathogens (training, Exposure control plan available, etc)	5
Needles not bent, broken or recapped?	4		

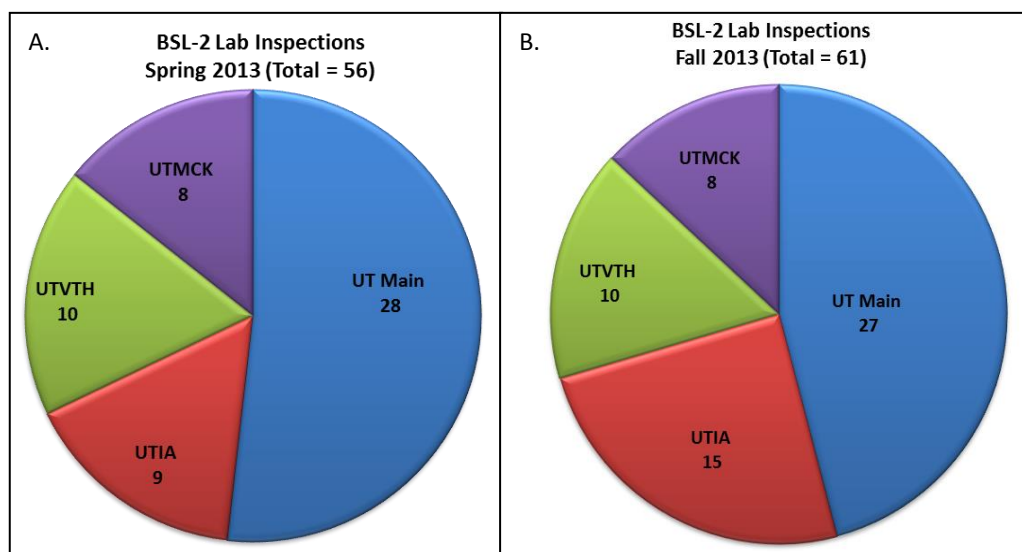


Figure 1. Number of lab inspections by site. The number of inspections for each campus are shown for **A.)** Spring and **B.)** Fall 2013.

Main Campus

During the Spring inspection cycle on the main campus 25 labs passed the initial site visit, 3 received provisional pass recommendations, while 1 lab failed the initial visit (Figure 2). With the labs receiving provisional pass recommendations included, the overall score for the main campus groups was still high (96.42%). A comparison of scores for all units across both semesters can be found in Figure 3.

The failure of the individual lab from this group was due to lack of security (the door was found open with no personnel present during the entire period of the visit), and that the inspector was unable to locate the biosafety manual. Due to the lack of personnel present neither of these issues could be addressed onsite, and when taken with the fact that this was the second inspection in a row in which the lab was found unsecured and empty following previous notifications to the PI the decision was made to fail the lab and schedule a follow-up visit. During the second inspection, the issues from the first report were addressed with the lab supervisor and remedied.

Results were improved for the main campus during the fall semester with 27 labs passing the initial inspection with only a single provisional pass cited due to poor handling of biowaste and lack of training material present in the biosafety manual. In this case, a follow-up visit was scheduled with the PI and lab supervisor and the issues were resolved. The average score of the labs for the main campus was also improved to 98.03% (Figure 3).

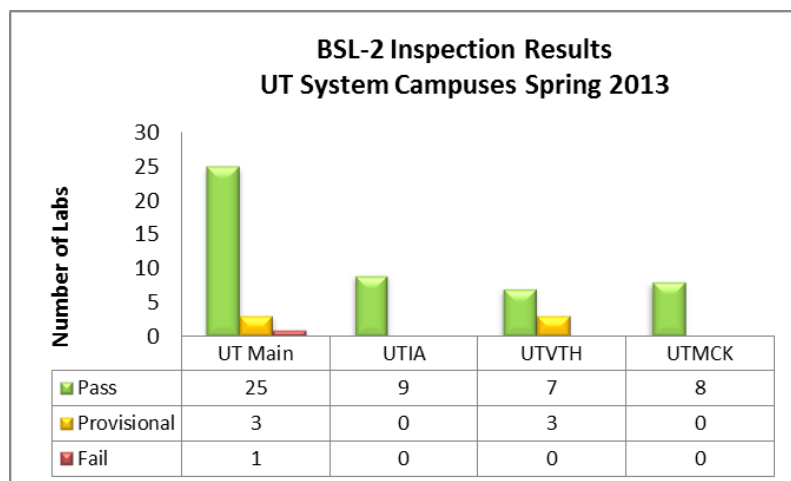
UTIA

Relatively few problems were identified in laboratories located on the UT Agricultural campus for either the fall spring semesters. In general, the problems that were identified during the fall inspection cycle were related to eyewash flush documentation. In all of these cases the problems were addressed with laboratory staff at the time of the inspection and the issue was considered to be resolved. The one exception was that a BSL-2 facility was found unlocked in the Brehm Animal Sciences Building. In this case, the lab supervisor was emailed immediately following the inspection and the problem was addressed. The average scores for labs on the agricultural campus were very high at 97.8% and 98%, respectively for each semester.

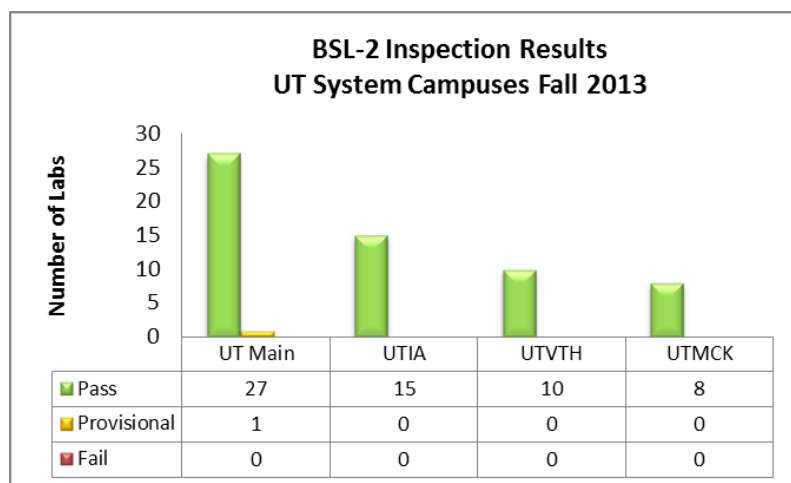
UTCVM

During the spring inspection cycle only a few deficiencies were noted in labs housed in the Veterinary Teaching Hospital Facilities. The majority of these were in the form of outdated Bloodborne Pathogen Exposure Control Plan documents found within the Biosafety manuals, with the remainder being either non-functional eyewash stations, eyewash stations that had not been flushed regularly, or issues with overflowing sharps containers. In the instances of outdated documentation, lab personnel were directed to the biosafety website where updated copies of the Exposure control plans are located. In the case of the sharps container, the lab supervisor was notified and asked to arrange for disposal of the waste using the contracted vendor. The overall scores for these labs were lowest during the spring inspection cycle (95.8%), owing mainly to 2 labs which reduced the average significantly. Of note, between the two groups, one was a previously established laboratory while the other was only recently opened. In the case of the former, the issues were addressed with both the PI and lab supervisor to correct the deficiencies onsite. In the case of the latter, the PI and lab supervisor were both notified of the deficiencies and given a grace period to correct the problems that were noted as no actual experiments had begun at the time of the inspection.

A.



B.



C.

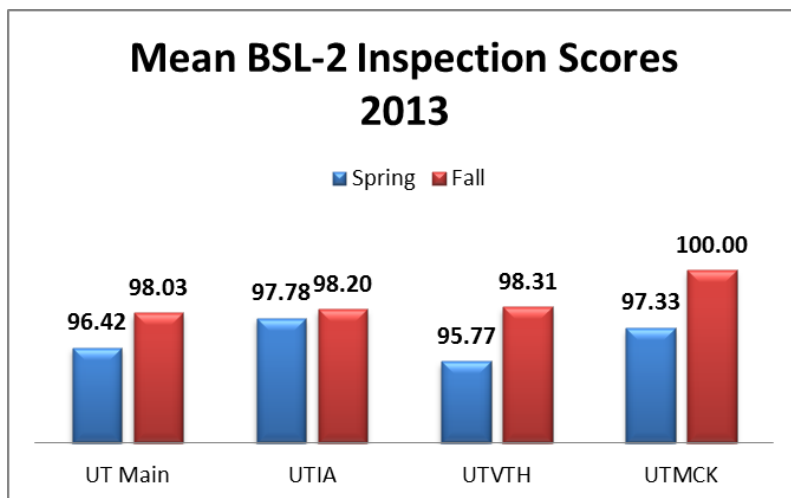


Figure 2. Outcomes of individual lab inspections and mean scores for each campus. Based on the overall score and severity of non-compliance issues laboratories received either pass, provisional pass, or fail ratings for both **A.)** spring and **B.)** fall inspections. **C.)** The average scores for each campus was calculated for both spring and fall semester.

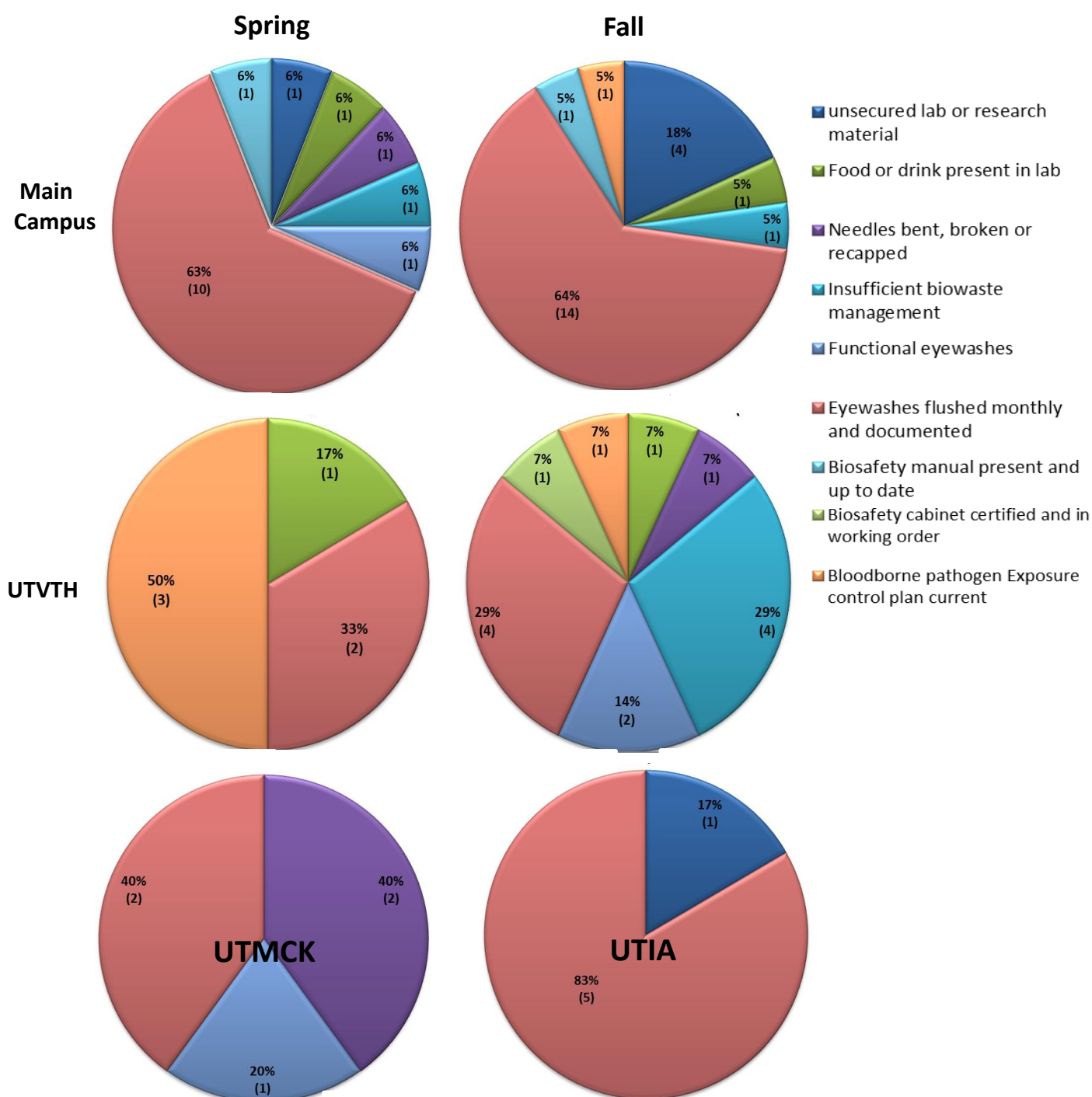


Figure 3. Compliance deficiencies for each campus during fall and spring inspection cycles. Deficiencies that were noted for each campus are represented here for spring (Left Column) and fall (right column). Likewise, campuses are divided into labs located on the UT main campus (top), UT Veterinary Teaching Hospital (Middle) and the UT Institute of Agriculture and UT Medical Center campuses (bottom). Note: For UTIA and UTMCK, only semesters in which compliance issues were noted are shown.

The total number of citations that were noted were increased during the Fall inspection cycle and varied more in scope as compared with those noted in the spring. In addition to the problems previously noted, several more eyewash stations were out of order with several more having not been recently tested or flushed. A lab was found to have a sharps container with re-capped syringes, sharps disposal continued to be an issue with one of the groups and several instances of overflowing biowaste containers were noted. In addition, one biosafety cabinet was found to be out of certification by a few weeks. Despite the increasing variety of issues, most labs were diligent in updating the exposure control plan documents during this time. As these issues were spread across more groups as compared with the spring evaluations, the overall score of the vet school was improved to 98%.

UTMCK

The University of Tennessee Medical Center houses nine research laboratories that fall under the administrative review of the Office of Biosafety. From these facilities, relatively few deficiencies were noted during the spring inspection. These issues included: two instances of eyewash flush checks being out of date, two instances of re-capped needles being found in the sharps waste cans, and one instance of a non-functional eyewash. In each instance, personnel were consulted at the time of the report and arrangements were made to address both the scheduling of eyewash flushes and for the remediation of the practice of re-capping needles. As for the non-functional eyewash, the principal investigator was advised of the issue and requested a repair by hospital maintenance staff. Despite these issues, the overall score for the medical center facility was 97% for this inspection cycle.

To the credit of the faculty and staff at the medical center facilities, none of the deficiencies that were noted from the spring inspection were present during the fall visitation. In addition, no new issues were noted. The overall score for the fall inspection was 100%.

Summary

Overall, most academic units performed well, as evidenced by the high scores among all campuses for both inspection cycles. In total, more deficiencies were identified in laboratories located on the main campus as compared with the other units (16 in the spring; 22 in the fall); however as these were broken up among more lab groups the incidence per lab remained low (0.5 and 0.8 violation/lab). Comparatively, groups within the veterinary teaching hospital facility 6 non-compliance issues were identified in the spring semester which rose sharply to 14 incidences by the fall inspection cycle. This resulted in the Veterinary Teaching Hospital having the highest violation to lab ratios among each of the academic units (0.6 and 1.4 violations/laboratory for the spring and fall inspection cycles, respectively). Groups from the Institute of Agriculture had the lowest incidence per lab ratio of 0.0 and 0.4 violations/lab for the spring and fall inspection cycles respectively, while the Medical Center campus demonstrated the highest level of improvement with their ratio of incidence per lab dropping from 0.6 to 0 violations/lab between the inspection cycles.

Report prepared by: Brian Ranger, UTK/UTIA/GSM Biosafety Officer