UNIVERSITY OF TENNESSEE BIOLOGICAL SAFETY PROGRAM
2014 Annual Report & Activity Summary

IBC Registration Review

The UT Institutional Biosafety Committee (IBC) conducted nine meetings during 2014. A total of 46 categorical reviews (25 three-year renewals; 16 new projects; 5 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 project category (recombinant DNA, infectious agent, human materials, or biologically-engineered nanomaterials) 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 20±11 days. Additionally, there were 19 administrative terminations (projects condensed into single registration, experiments concluded or faculty relocation/retirement).

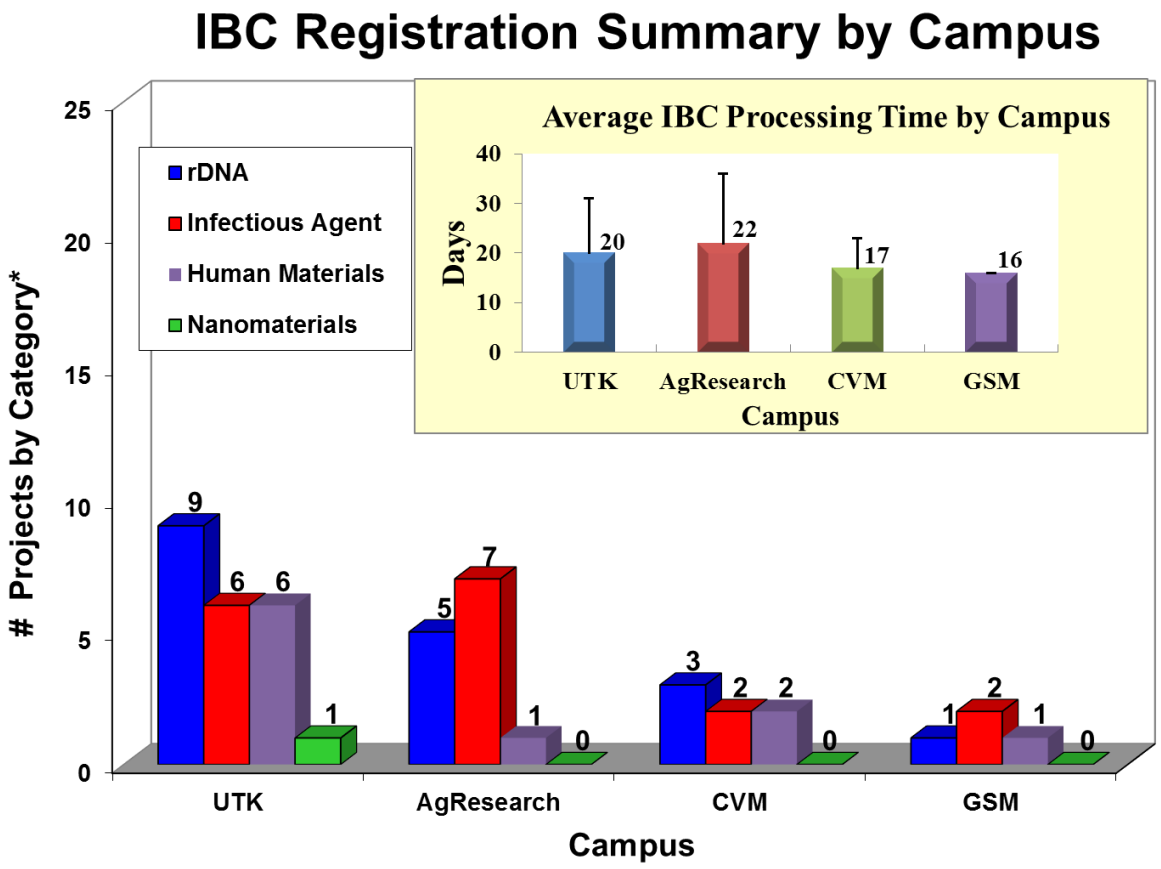

***Figure 1*: 2014 IBC Categorical Reviews & Processing Time by Campus**
*** Registrations may include multiple project categories; reflected in data**

Biosafety Training

Figure 2 highlights the number of individuals trained in various biosafety and/or research compliance subjects during 2014. 140 in-person training sessions were conducted (828 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. The total number of trainees by campus is indicated in Figure 3. In total, ~1,360 individuals received either initial or annual refresher training.

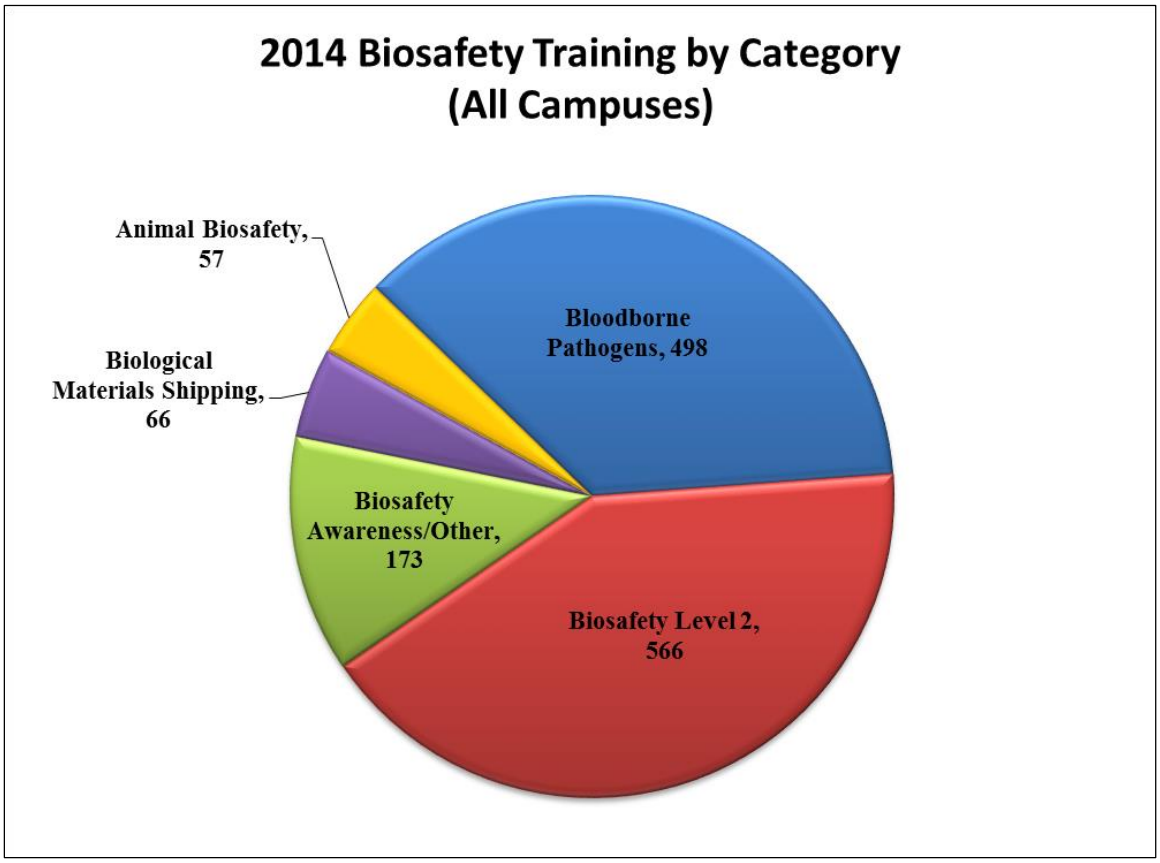

Figure 2: **2014 Biological Safety & Compliance Training by Category (All Campuses)**

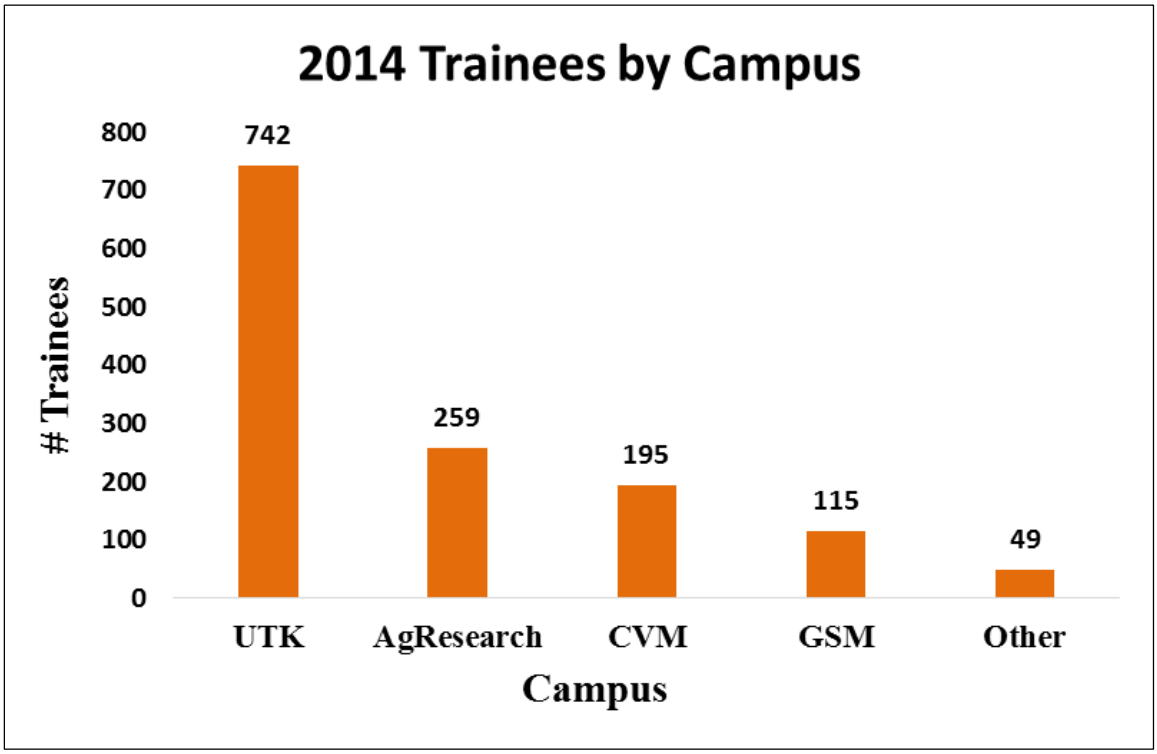

Figure 3: **2014 Biological Safety & Compliance Trainees by Campus**

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 (89; in addition to IBC full reviews indicated above);
- Conducting annual BSL-1 and semiannual BSL-2 lab inspections (160 total; **see Appendix A**);
- Hazard assessment and completion of Animal Hazard Control Forms for Institutional Animal Care & Use Committee (IACUC) protocols involving hazardous agents (119 protocols reviewed);
- Coordination of quarterly autoclave validations to ensure proper treatment/inactivation conditions for bagged biohazardous waste (118 total validations conducted).

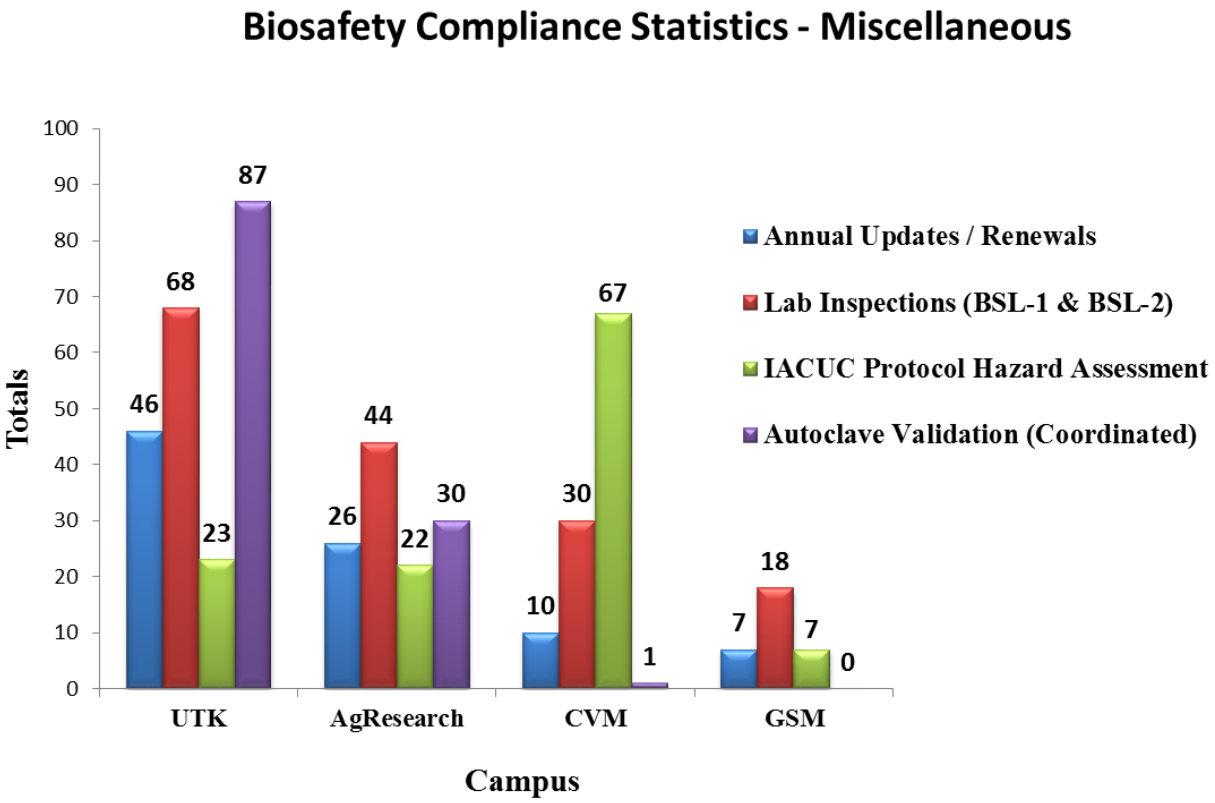

***Figure 4*: 2014 Additional Biological Safety/Compliance Services by Campus**

Accidents, Exposures, & Releases:

The Biosafety Office was notified of 10 accidents involving biological materials as follows:

- 8 sharps injuries from CVM—4 cuts/lacerations from scalpels, 3 needlesticks, and 1 cut from broken cover slip. All involved the presence of primary animal blood/tissue (with the exception of one injury caused by a clean scalpel blade). None of the injuries caused significant damage (beyond first aid treatments) or secondary infections/complications.
- 1 sharps injury/pathogen exposure from AgResearch—cut on arm with pipet tip. The pipet tip had been used to transfer cell culture containing lab-adapted hepatitis A virus (non-recombinant). The injury was immediately flushed as prescribed for Risk Group 2 pathogen exposures. Follow-up medical evaluation indicated that injury as superficial. First aid was given and topical antibiotic applied (to prevent secondary infection). Given the individual's health history and route of exposure, a prophylactic hepatitis A vaccine was not administered. There were no secondary complications.

- 1 superficial exposure to human blood (UTK teaching laboratory)—small drop of student blood (finger pricks for blood glucose testing) landed on exposed wrist of teaching assistant while collecting biowaste from the teaching benches. The drop was immediately flushed off per prescribed response for human blood exposures. Follow-up medical evaluation ruled out any risk of potential bloodborne pathogen transmission (low risk individual; type of exposure deemed insignificant for potential transmission).

In all cases, root causes were generally related to hurried behaviors and inattention. Standard microbiological practices and sharps safety precautions were reiterated.

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

2014 Programmatic Highlights:

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

- Appointment of a new IBC Chair (Dr. Jun Lin, Animal Science), Vice-Chair (Dr. Patti Coan, Office of Lab Animal Care), and 2 new voting members (Dr. Liz Fozo, Microbiology; Dr. Deidra Mountain, GSM Department of Surgery).
- Worked closely with principal investigators, UTK/CVM administration, project designers and facility engineers to establish basic infrastructure and operational criteria for a retrofitted BSL-3 laboratory (non-select agent research). The new containment lab is projected to be completed by May, 2015.
- Drafted a general biosafety policy for the UT-Knoxville area campuses (pending final approval and implementation).
- Conducted survey to determine the use/scope of biological hazards in teaching laboratories. A framework for biosafety oversight in teaching laboratories was developed and the pros/cons discussed. An *ad hoc* faculty task force, headed by Dr. Jun Lin, Animal Science, was created to draft a set of recommendations for the framework, implementation, and maintenance of the teaching lab biosafety program (pending).
- Began populating information for migration to an online registration and data management system, iMedRIS. To date, the registration form, annual update form, and several letters have been provided and are pending development. The beta-testing is projected for March~April, 2015, with rollout to the research community projected for ~June, 2015.
- Determination of a designated-member review (DMR) process; categorized project submission types as either IBC (full committee), designated member, or administrative review/approval. This mechanism will be fully adapted upon iMedRIS implementation.
- Surveyed the research community for general customer satisfaction and/or recommendations for improvement. Responses were generally positive, and only minor programmatic adjustments were recommended.
- Participated in 3 USDA APHIS facility/compliance inspections (1 Plant Protection & Quarantine, 1 Biotechnology Regulatory Services, and 1 Veterinary Services). No significant concerns reported.
- Revised and strengthened the *Biosafety Principles* (BSL-2) training module. The updated version includes more detailed examples and operational instructions. Trainee feedback has been positive.
- Worked with laboratory investigators and staff to cut eyewash operation/maintenance concerns by >80%.
- Provided information for and encouraged participation in Biosafety Stewardship Month (September), as requested by U.S. Federal agencies.
- In collaboration with the Office of Emergency Management, and in response to domestic Ebola cases, assisted in updating and revising the UT Pandemic Preparedness Plan to ensure campus preparedness and continuity of operations.

- 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 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.
- Issued Revision 10 (2014-15) OSHA Bloodborne Pathogens Exposure Control Plan covering research programs.
- Updated website to include a lab coat laundering standard operating procedure and information on the safe storage, handling, and disposal of biological toxins.
- Biosafety Office staff attended the 2015 American Biological Safety Association Conference (San Diego, CA) and the 2015 Southeastern Biological Safety Association Symposium (Nashville, TN).

Biosafety Office Program Objectives (2015):

- Complete final approval, implementation, and dissemination of UT-Knoxville area biosafety policy.
- Complete and implement program for biosafety in teaching laboratories with the goal of having all applicable teaching laboratories/courses identified and covered by the end of 2015.
- Finalize standard operating procedures for BSL-3 laboratory. Work with PI and other stakeholders to ensure facility passes commissioning.
- Complete iMedRIS module for biosafety, test, and rollout to research community by the beginning of the fall semester.
- Revise and reissue an updated IBC Charter to reflect the general policy, changes in teaching oversight, and iMedRIS submission procedures/requirements.
- Update biological materials inventory in all applicable departments (periodic update) coincident with Biosafety Stewardship Month. This will be done with a combination of electronic surveys and 'door-to-door' lab visits.
- Contribute to Office of Research & Engagement compliance publications and/or distribute monthly/bimonthly biosafety/compliance blurbs through the Biosafety listserv.
- 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

Annual inspections of BSL-2 laboratory spaces were conducted in late June and early November of 2014. From these site visits, 28 items were found to be deficient or in violation of 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. In one instance, a re-inspection was required to ensure that noted issues were properly addressed.

For this report, individual questions found on the inspection form were grouped into 8 categories, each of which cover the following:

- **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;
- **Signage and Practices:** category covers restricted lab access/lab security, prohibition of food and drink, and standard microbiological practices;
- **Housekeeping:** assessment of the general state of the lab in regards to excessive clutter or other issues that might present a safety concern;
- **Personal Protective Equipment:** evaluates personnel access to lab coat, gloves and eye protection when working with infectious or recombinant agents;
- **Biosafety Cabinet:** confirmation that a functional biosafety cabinet available and has it been properly certified within the last year;
- **Handwashing and eyewash:** confirmation that soap, hand towels and functional sinks are present, and availability and routine maintenance of eyewashes (as required);
- **Waste Management:** assurance that biohazardous wastes (solids, liquids, and sharps) are properly segregated and neutralization practices are in place prior to disposal;
- **Shared storage and other resources**: confirmation that materials stored outside of the lab are properly secured and labeled.

Spring 2014

As shown in Figure A.1, only a few concerns were cited (15 total: 6 UTK; 3 AgResearch; 5 CVM; and 1 GSM). Eyewashes were the most often identified problem among all campuses. This was due to a combination of faulty equipment and failure to conduct flush/check activities within the proscribed one month time-frame. In addition to this, two laboratories from AgResearch were found to have Bloodborne Pathogen Exposure Control Plan documents which were out of date. Another lab was found to have biohazardous waste bins and biohazardous sharps bins that were overfilled, creating a potential safety concern. Finally, two laboratories on the UT Knoxville campus and one laboratory at the UT College of Veterinary Medicine were found to be unsecured at the time of inspection. In the case of the laboratory on the main campus, the main door to the lab was equipped with a non-functional lock. This issue had been reported to the maintenance staff prior to the inspection, but had been unresolved for a number of months. The door has since been repaired.

(Note: BSL-1 lab inspections were also conducted in June, with no significant concerns noted).

Fall 2014

As with the spring laboratory visits, the number of documented concerns was generally low (12 total: 8 UTK; 1 AgResearch; 1 CVM; and 2 GSM). Again, the most common problem identified in the fall inspection process was either non-functional or non-flushed eyewash stations. As noted in Figure A.2, these instances occurred across all campuses with the UT main campus having the most number of infractions in this category. Following this, there were three instances of laboratory groups which were found to be in violation of standard practices which included both eating and drinking in the lab space, and labs that were found to be unlocked at the time of the inspection. Of note during the fall inspection cycle, one laboratory received a failing score on the inspection upon the initial inspection due to a combination

of bad housekeeping, unsecured lab spaces, improper waste handling, and expired documentation (BBP Exposure Control Plan). In this case, the principal investigator was notified and a time was arranged to re-inspect the lab space. Upon this re-inspection the condition of the lab was found to be much improved, and was able to achieve a passing score. In addition to the re-inspection, the students and post-doctoral personnel were required to attend training sessions for working in a Biosafety Level-2 environment and for working with human derived materials (Bloodborne Pathogen Training).

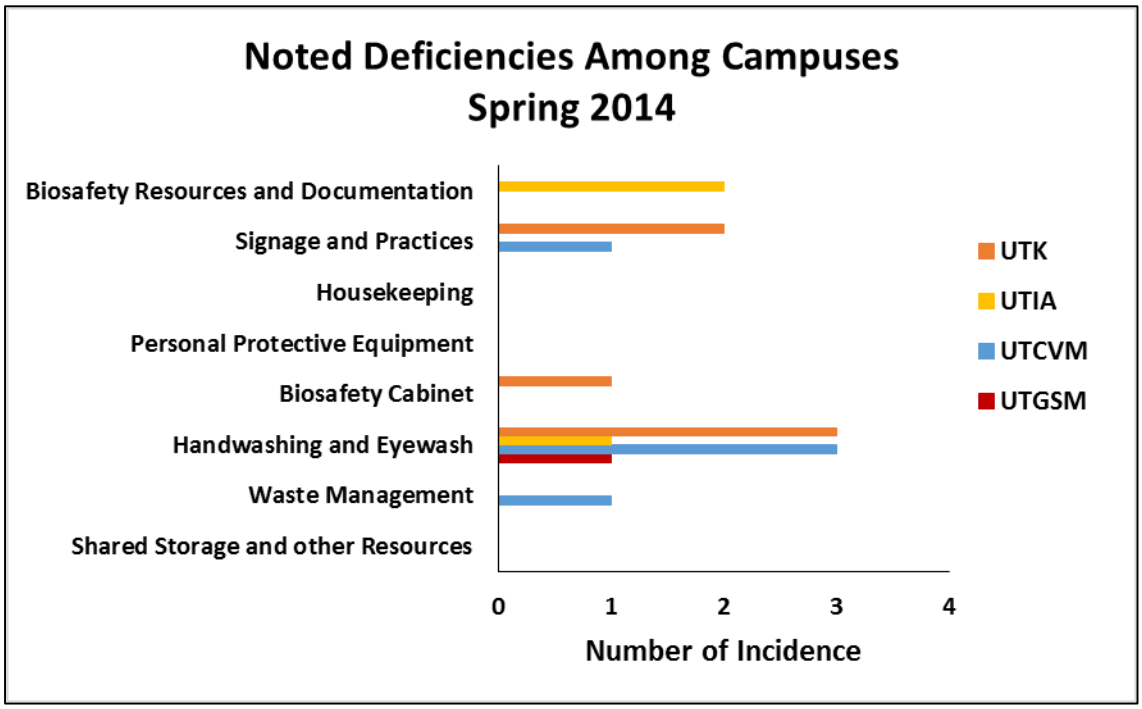

***Figure A.1*: Spring 2014 BSL-2 Lab Inspection Summary by Campus**

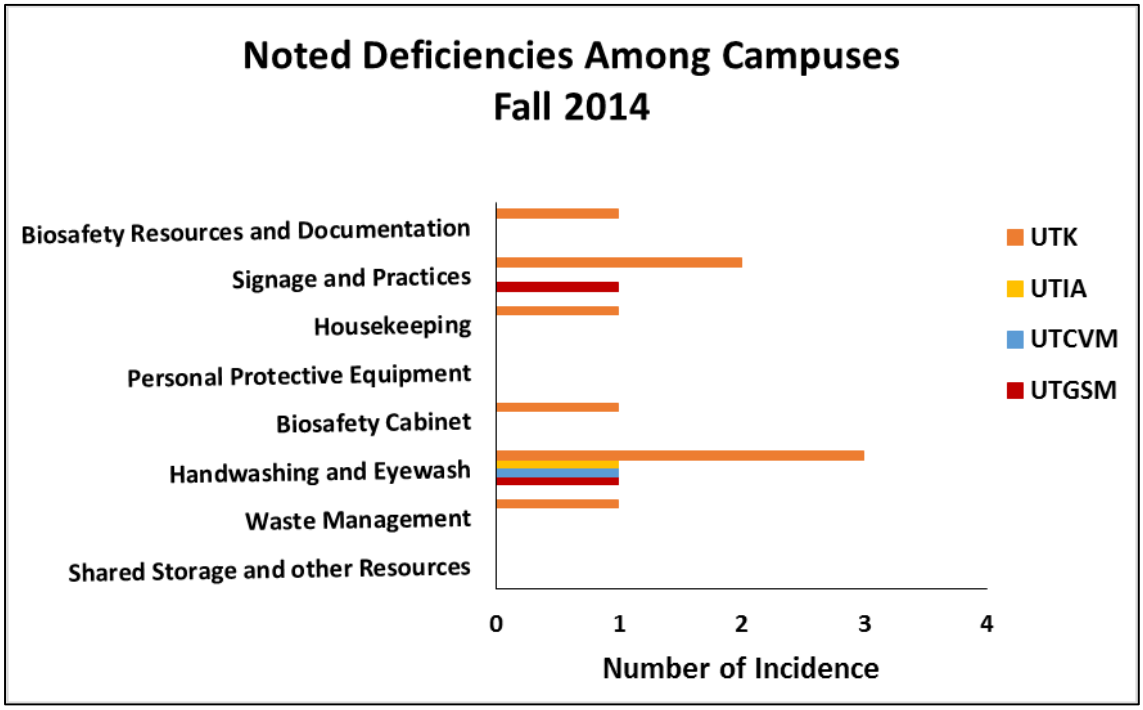

***Figure A.2*: Fall 2014 BSL-2 Lab Inspection Summary by Campus**

Report prepared by: Brian Ranger, Biosafety Officer