UNIVERSITY OF TENNESSEE BIOLOGICAL SAFETY PROGRAM
2020 Annual Report & Activity Summary

Note: The information in this report reflects a transition from reporting based on the fiscal year to reporting based on the calendar year. 2020 reporting for the calendar year contains additional irregularities due to the SARS-CoV-2 pandemic and the use of BioRAFT for integrated audits on the main campus.

IBC Registration Review

The UT Institutional Biosafety Committee (IBC) met ten times during calendar year 2020, conducting 64 categorical reviews. Registrations were received from principal investigators spanning four university research units (hereafter referred to as 'campuses'): Knoxville (UT); The Herbert College of Agriculture (Herbert); 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 20 days with a standard deviation of 23 days. There were 11 terminations (experiments concluded or faculty exit).

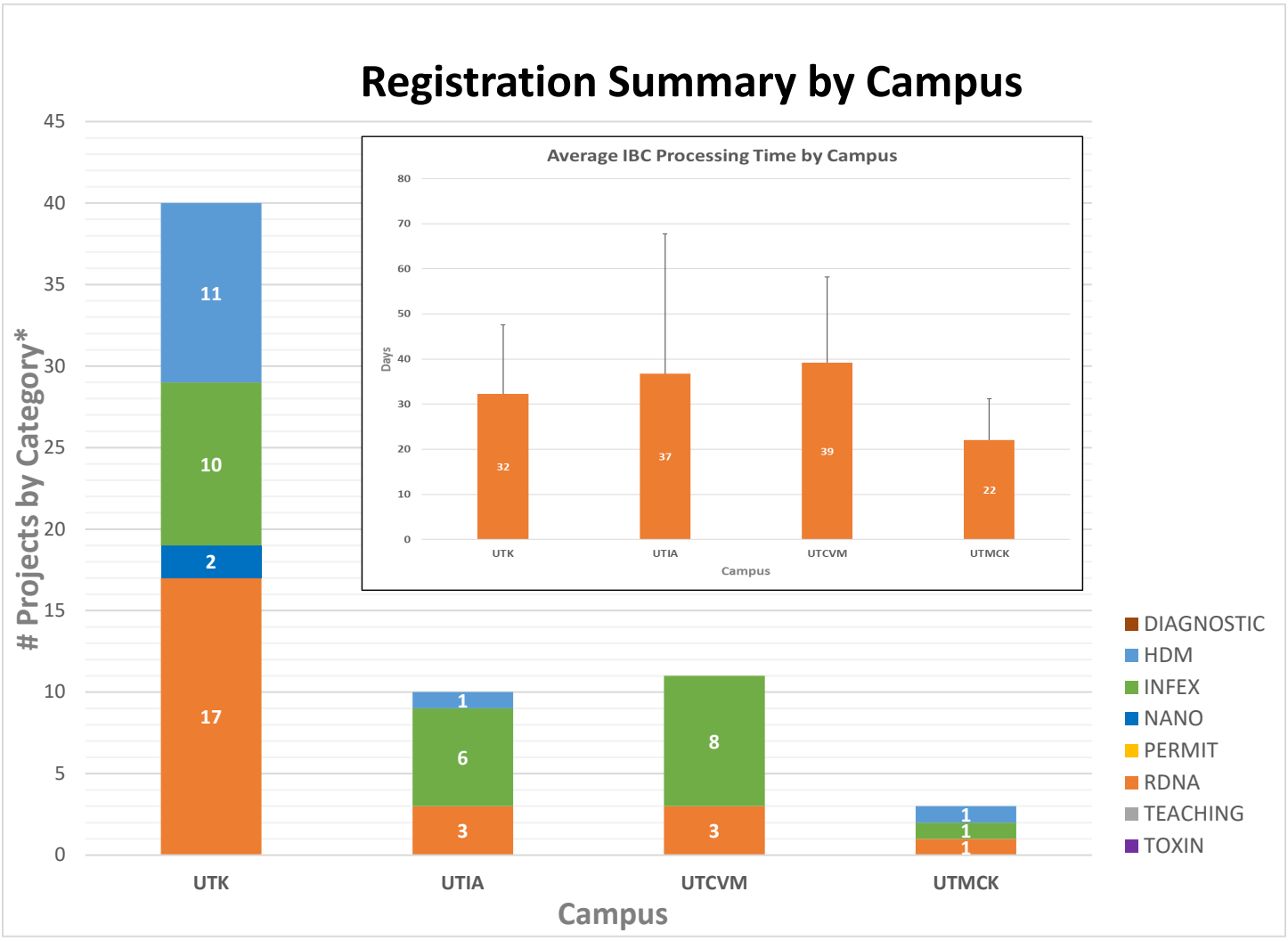

***Figure 1*: CY2020 IBC Categorical Reviews & Processing Time by Campus**
*** Registrations may include multiple project categories; reflected in data**

Biosafety Training

EHS Biosafety offered classroom based (n=10) and online training sessions for a variety of biosafety and/or research compliance subjects during CY2020: 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, 1492 individuals received biosafety-related training.

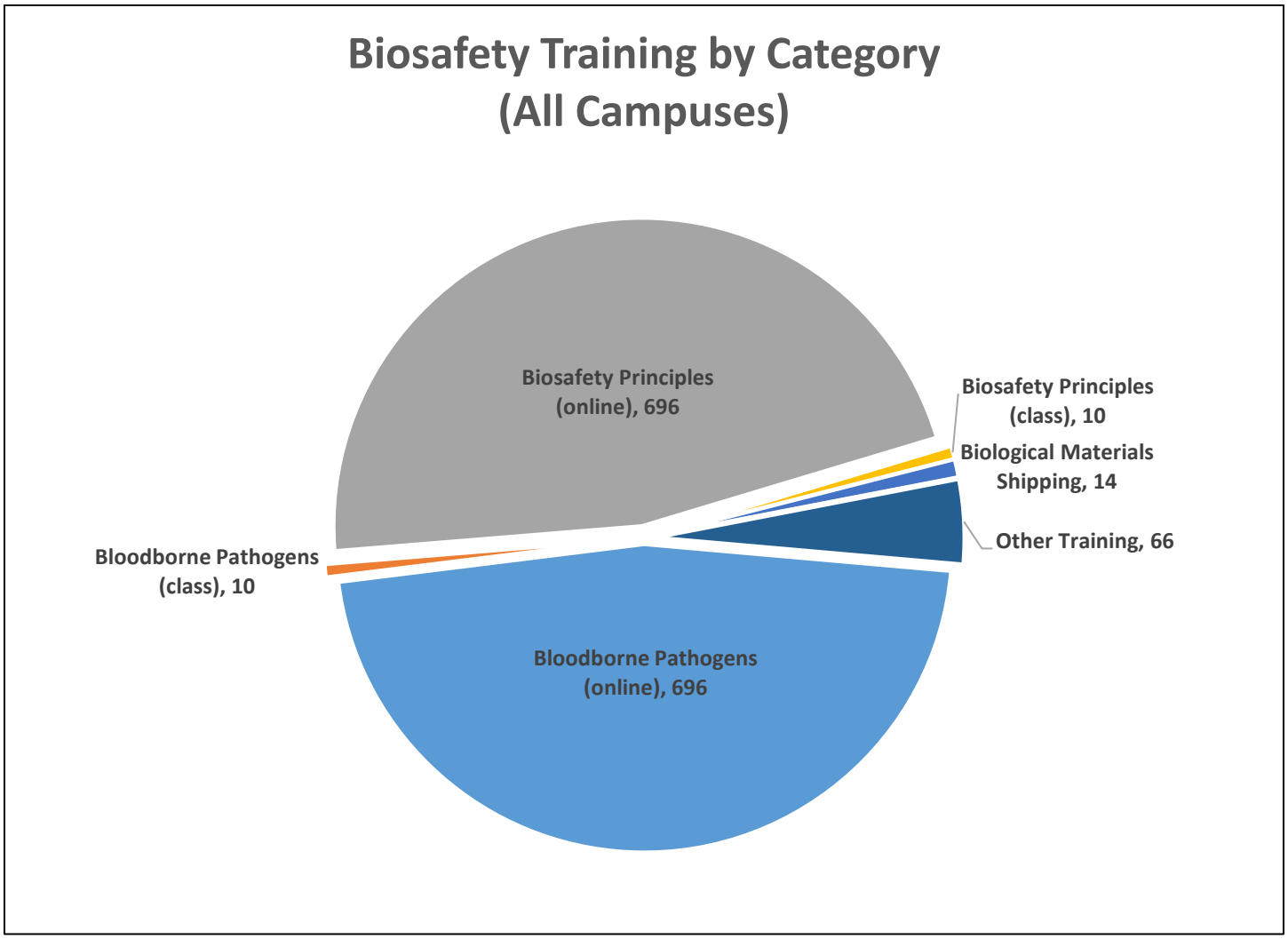

Figure 2: **CY2020 Biological Safety & Compliance Training by Category (All Campuses)**

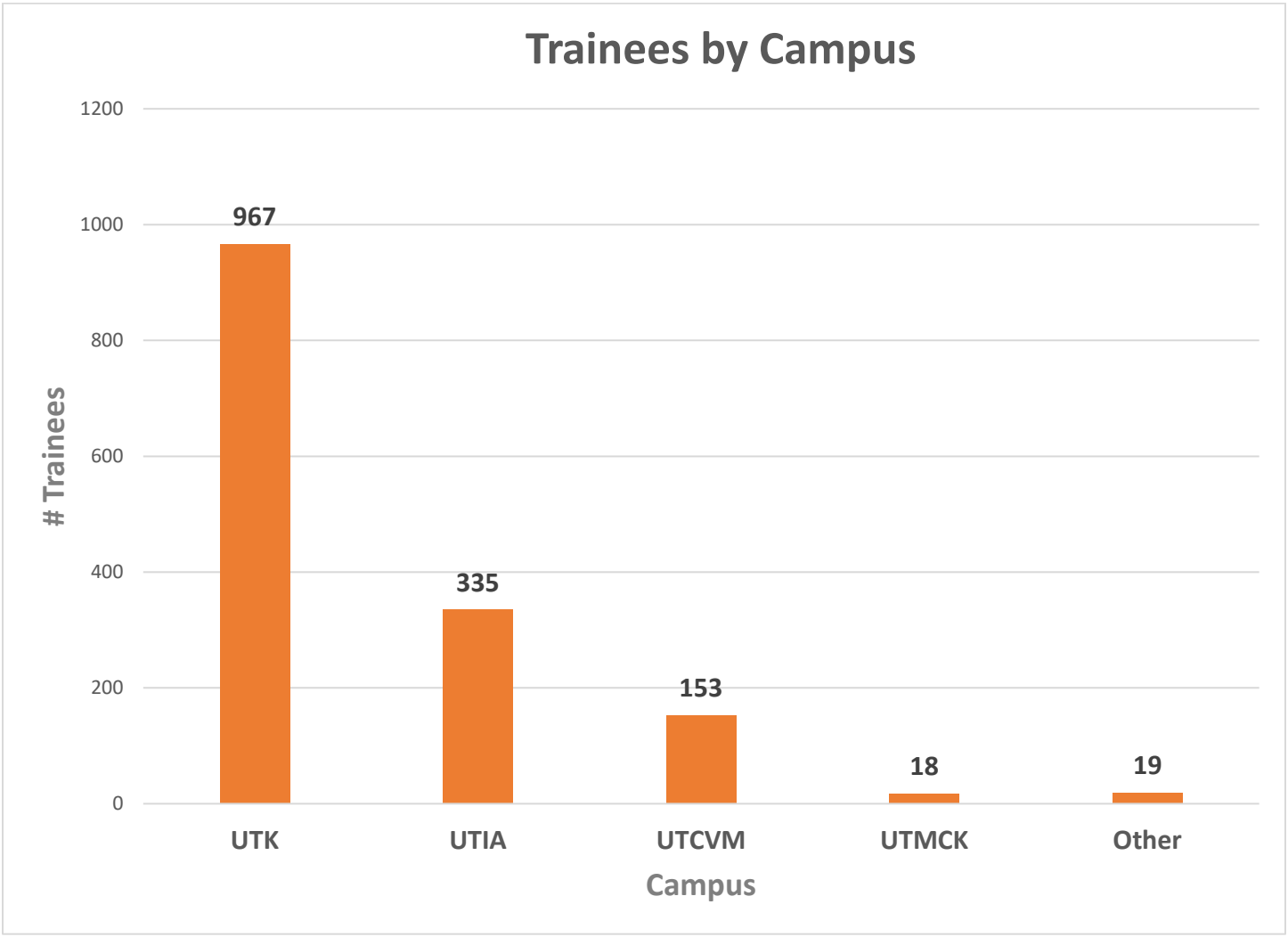

Figure 3: **CY2020 Biological Safety & Compliance Trainees by Campus**

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=109; in addition to IBC full reviews indicated in Figure 1 above);
- Conducting annual lab inspections (n=83; **see details below**);
- Review of Institutional Animal Care & Use Committee (IACUC) protocols (n=114) 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=23);
- Reviewed and verified (or followed up on) approvals for biosafety-related proposals submitted to Cayuse, collectively (data not shown).
- Reviewed and verified/approved ~45 material transfer agreements, collectively (data not shown).

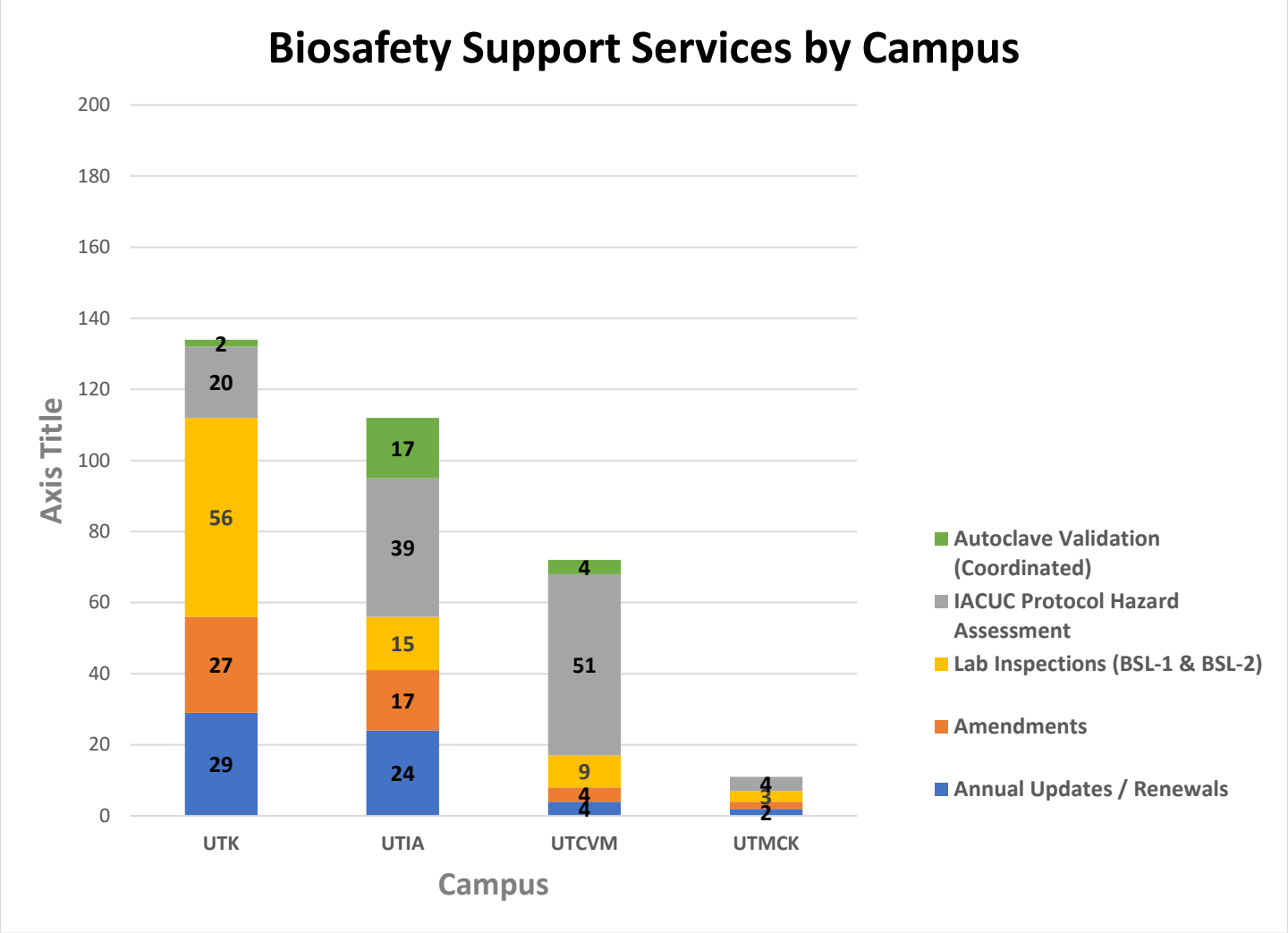

***Figure 4*: CY2020 Additional Biological Safety/Compliance Services by Campus**

Laboratory Audit Report:

During calendar year 2020, a number of process changes/extenuating circumstances resulted in changes to the methods used to evaluate biosafety practices in registered labs. The consolidation of Biosafety with EHS and the use of the BioRAFT platform resulted in biosafety audits being included in the general lab safety audits on the main campus. UTIA does not use the BioRAFT inspection platform so UTIA audits were stand-alone audits utilizing iAuditor. Due to the pandemic biosafety walk-throughs were conducted for registered labs at UTIA and CVM and self-assessments were provided by the CVM diagnostic labs.

Lab audits were conducted without lab personnel being present for questions and clarifications and the in-person refresher training sessions were suspended due to the pandemic.

In CY2020, EHS Biosafety conducted 19 biosafety walk-throughs of registered labs at UTIA including CVM and there were 5 self-assessments completed by diagnostic labs. There were 83 total inspections by registered principal investigator (PI) or supervised teaching/diagnostic laboratory. 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. There were no repeat audits.

Reported Accidents, Exposures, & Releases:

None

Biosafety in Teaching Laboratories:

Due to the multi-modal nature of teaching laboratories in 2020 and other extenuating circumstances of the pandemic, there was no focused audit of teaching laboratories. Where main campus EHS walk-through included laboratories, a cursory review of biosafety was performed.

CY2020 Programmatic Highlights (Other):

- Worked on the EOC Research Contingency Planning Team that oversaw the pandemic response for research laboratories, instructional science laboratories, and field research. Utilized the checklist developed by the IBC to develop the safety checklist for shutdowns and research curtailments.
- Worked closely with the Hazen lab and the Loeffler lab to stand up wastewater and saliva testing laboratories to assist in the campus COVID-19 surveillance testing programs. The IBC expedited the reviews to meet the timeline of the EOC and the Chancellor's policy group directives.
- The initial draft and review by the committee was made on the new iMedRIS form for registrations. This project is ongoing and will be completed in FY2022.
- Completed the assembly and stakeholder review of the unified OSHA bloodborne pathogens exposure control plan covering affected research and non-research units. The unified plan is posted on the Biosafety web page.
- Professional Development & Training:
  - Completed various training courses or workshops covering: animal biosafety and risk assessment, biosafety critical task analysis, SARS CoV-2/COVID-19, and industrial hygiene
  - 16th CDC International Symposium on Biosafety
  - Eagleson Institute Course: *Large or Small the Challenges are the Same: 5 Key Areas Where Biosafety Programs Break Down; and Animal Biosafety and Risk Assessment*
  - ABSA 63rd Annual Biosafety and Biosecurity Conference
  - Various webinars delivered by ABSA, SEBSA, FRaBSA (Front Range Biological Safety Association), and CSHEMA
  - Registered Biosafety Professional credentials earned for staff member

Program Objectives (CY2021):

- Successfully re-start the BSL-3 laboratory.
- Continue work with EHS, Radiation Safety, UTIA Safety and campus administration to create an integrated safety program.
- Complete the new iMedRIS form for IBC registrations.
- Transition away from the use of BioRAFT for laboratory safety reviews and begin the implementation of an integrated template in iAuditor.
- Conduct and document a comparative review of the new 6th Edition of the BMBL, the WHO Laboratory Biosafety Manual, and the ISO 35001 Biosafety standard.
- Participate in at least one national and/or regional conference on biosafety.