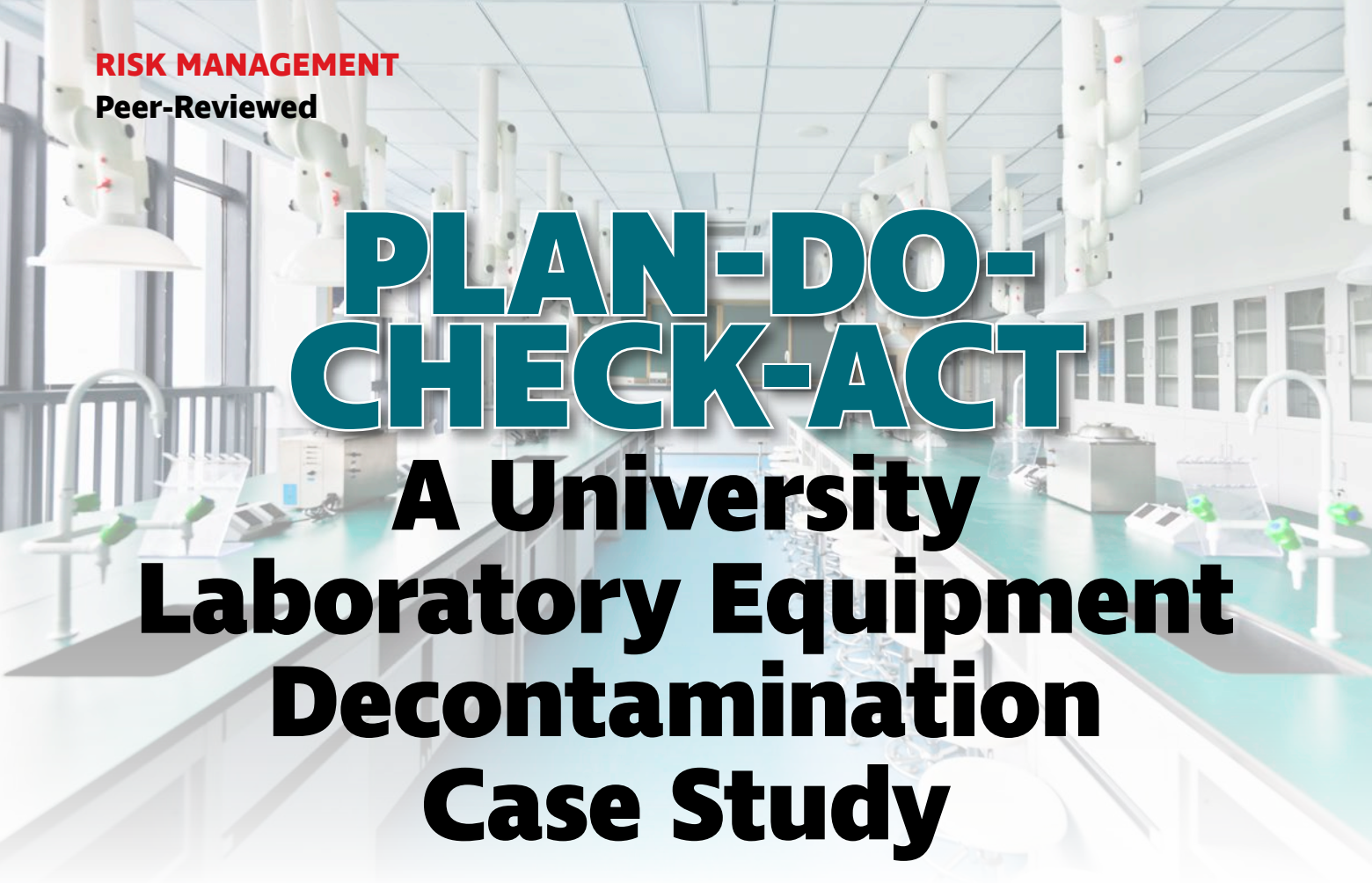

PLAN-DO-CHECK-ACT
A University Laboratory Equipment Decontamination Case Study

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THE TEXAS A&M HEALTH SCIENCE CENTER (TAMHSC) and Texas A&M University (TAMU) Environmental Health and Safety (EHS) departments are responsible for ensuring the safety of not only all faculty, staff, students and visitors to geographically dispersed campuses across the state of Texas, but also the public surrounding those campuses.

Because the university is a state entity, the preferred disposition route for all university assets is public auction administered by the Surplus department. Each research or academic department within the university determines which of its assets are no longer needed and schedules a pickup through its embedded property management team member. The removal of all unwanted assets is performed either by university personnel or by a private moving company. Although EHS had a policy in place for the decontamination of equipment prior to its release to Surplus, the process of equipment being sent to Surplus itself did not directly include EHS. Only in rare cases in which surplus or property management personnel suspected the asset to be contaminated with hazardous materials would they request EHS's involvement.

Following an institutional merger between TAMHSC and TAMU in 2013, but prior to the merger of their respective EHS departments in 2017, the TAMHSC Ethics and Compliance Committee, led by the TAMHSC risk manager, identified potentially contaminated laboratory and clinic equipment sent to public auction via the institutional surplus department as a risk. The committee was concerned due to the potential for members of the public or nonlaboratory personnel to be exposed to hazardous materials and due to the potential regulatory violations for improper transfer of protected equipment types such as laser and X-ray systems. The committee charged TAMHSC EHS with mitigating this risk.

Given the incredibly diverse selection of research materials and equipment types used at an institution of TAMHSC's size and given that all equipment to be disposed must be routed through the surplus department for sale at public auction, EHS developed a pilot program with key performance indicators (KPIs) of:

1) number of workers' compensation claims submitted before and after program implementation related to potentially contaminated equipment;

2) number of complaints before and after program implementation from members of the public who had purchased potentially contaminated equipment;

3) number of complaints submitted before and after implementation by nonlaboratory and nonclinic staff related to handling potentially contaminated equipment;

4) total number of potential regulatory violations detected related to potentially contaminated equipment being handled by nonlaboratory and nonclinic staff, and by members of the public.

KEY TAKEAWAYS

- **Texas A&M Health Science Center Risk Management identified public or nonlaboratory and nonclinic personnel exposure to potentially contaminated equipment as a risk to the institution.**
- **The university's Environmental Health and Safety department developed a process, within given constraints, to address potentially contaminated equipment leaving the institution or moving between laboratories and clinics.**
- **Following plan-do-check-act methodology, key performance indicators were evaluated, and the process was revised to improve efficiency and more appropriately assign responsibility for laboratory and clinic equipment.**

BAONA/E+/GETTY IMAGES

At launch, the program was named the Laboratory and Clinic Equipment Decontamination Program.

After TAMHSC and TAMU merged, the EHS teams from each entity were consolidated at TAMU. As part of the consolidation, all programs were integrated to ensure consistent EHS policy and service across the entire institution. The TAMHSC Laboratory and Clinic Equipment Decontamination Program was evaluated against its KPIs to determine the return on investment (ROI) before a potential consolidation between it and the existing TAMU process. The evaluation was intended to determine any value-add for a consolidated program before rollout to the entire system of campuses for which the newly merged EHS team was now responsible. Based on the KPI evaluation, revisions were made to the program that improved resource management, improved process efficiency and provided better management of institutional liability. This improved program was integrated with the existing laboratory decommissioning standard administrative procedure at TAMU.

When TAMHSC EHS performed a literature search for others who had developed similar processes, nothing could be found on which to base or against which to compare what would become the original version of the decontamination process. This article was written to add to the body of literature and discusses the original program design and implementation, the evaluation process against KPIs, the revision made to the program for rollout to the joined institutions and suggested future work based on lessons learned. In essence, this is a plan-do-check-act (PDCA) continuous improvement case study.

PCDA Method Selection

Continuous improvement "seeks to identify and implement ongoing enhancements in an organization's products, services and processes" (Reid, Koljonen & Buell, 1999). Adopting a philosophy of continuous improvement is essential in the rapidly changing world of safety and required in a research-focused university setting. By its very nature, research pushes the boundaries of what is possible and, thus, the responsible EHS team must also push to remain abreast of the emerging risks and hazards present on campus. One of the most common methods for implementing continuous improvement is the Deming Cycle, or the PDCA cycle, in which each stage of the cycle is directed toward the stated goal, in this case safety process efficiency (Reid, et al., 1999). Thinking of continuous improvement as a cycle and using the PDCA method helped EHS define what steps were needed and in what order to best revise not only the equipment decontamination policy as it existed, but also every revision thereafter.

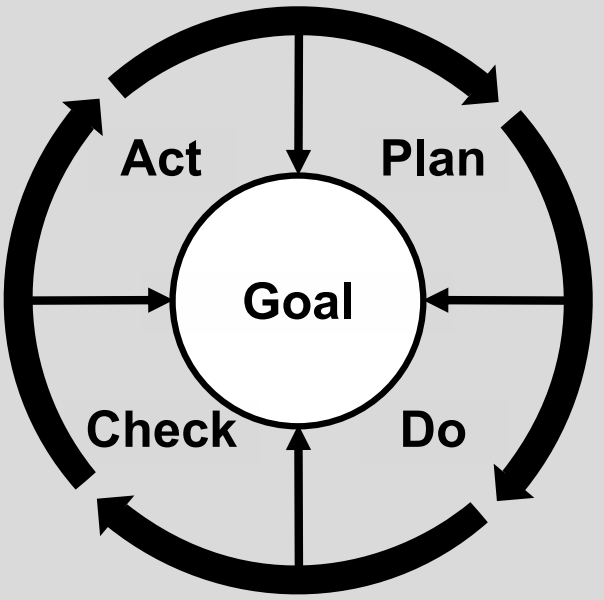
> At a high level, different types of business strategy should be able to amend to the PDCA concept. That is because, regardless of the business strategy choices, the PDCA concept emphasizes that projects must start with careful planning, must result in effective actions and must move on again to careful planning in a continuous cycle. (Srivannaboon, 2009, p. 16)

Checklists are used by many safety professionals to help with safety compliance; PDCA can be viewed as "a checklist for coordinating continuous improvement efforts" (Srivannaboon, 2009, p. 15).

PDCA Methodology

Many safety professionals are familiar with the PDCA continuous improvement methodology. Figure 1 shows its cyclical nature and highlights that the end goal of each cycle iteration must be kept at the center and as the focus of each step.

FIGURE 1
BASIC PDCA CYCLE STRUCTURE



Note. Adapted from "The Deming Cycle Provides a Framework for Managing Environmentally Responsible Process Improvements," by R.A. Reid, E.L. Koljonen and J.B. Buell, 1999, *Quality Engineering, 12*(2), pp. 199-209.

Tague (1995) describes the steps of PDCA as:

1) "Plan: Recognize an opportunity and plan the change" (Tague, 1995, p. 218). The particular areas of improvement to be measured (the KPIs) should also be determined in this step.

2) "Do: Test the change. Carry out a small-scale study" (Tague, 1995, p. 218). Due to time constraints, the EHS department did not have the opportunity to conduct a small-scale study before developing and launching the program. Once launched, the program was subjected to multiple PDCA mini-cycles and revised based on data. Data collection criteria should be wide enough to cover anything relevant to the KPIs without excluding anything. The data collection may reveal unexpected insights.

3) "Check: Review the test, analyze the results and identify learnings" (Tague, 1995, p. 219). Evaluate all data collected against the KPIs and for any additional unexpected insights. Be willing to be wrong about the initial assumptions. Perhaps the new plan is a step backward. If so, it should be immediately discarded as a less effective process regardless of the investment in the plan.

4) Tague (1995) describes the act step:

> Act: Take action based upon what you learned in the check step. If you were successful, incorporate the learnings from the test into wider changes. If the change did not work, go through the cycle again with a different plan. (p. 219)

The next step after act is to begin a new PDCA cycle in pursuit of continuous improvement. "Just as a circle has no end, the

FIGURE 2

PDCA CYCLE STEPS & CHARACTERISTICS AS APPLIED

Note. Adapted from "The Deming Cycle Provides a Framework for Managing Environmentally Responsible Process Improvements," by R.A. Reid, E.L. Koljonen and J.B. Buell, 1999, *Quality Engineering, 12*(2), pp. 199-209.

PDCA cycle should be repeated again and again for continuous improvement" (Tague, 1995, p. 218).

The PDCA process was applied as follows:

1) Plan: TAMHSC administration identified the process to be addressed. The EHS team met with TAMHSC administration to acquire initial constraints that were then expanded based on EHS expertise. The initial laboratory equipment decontamination policy was designed.

2) Do: EHS implemented the initial policy and began immediately collecting information related to the KPIs. Additional information acquired related to the types of equipment most often encountered, the most common signs that decontamination had or had not taken place, the questions to ask during equipment inspection that were most effective in addressing potential contamination and the most common additional potential regulatory violations detected.

3) Check: The data collected during the do step was analyzed many times. The PDCA cycle was used multiple times while the laboratory equipment decontamination policy was in effect to gradually correct inefficiencies or to address special cases of unique equipment. The program as a whole was evaluated under the check step after the merger of the EHS teams. Data on all KPIs was analyzed. Ultimately, EHS's involvement in the expanded visual inspections and verbal interviews required by TAMHSC administration as a mitigation method for the risk of releasing potentially contaminated equipment was found to provide little or no ROI.

EHS determined ROI was insufficient to support continuing the program as is. The primary concerns expressed by TAMHSC administration, namely, the number of injuries and claims against the university as a result of contaminated equipment exposing nontechnical staff or members of the public, were not affected by the expanded program. EHS determined resources could be better spent expanding existing programs that were found to already address the risks.

4) Act: As a result of the findings on ROI in the check step, the program was redesigned to improve EHS resource management, better define who is responsible for decontaminating laboratory equipment, and improve safety by correcting misconceptions and providing more clearly defined procedures and expectations of all parties and stakeholders involved.

Figure 2 shows a graphical representation of how PDCA was applied in this case and demonstrates the progression from the basic structure of PDCA as shown in Figure 1.

Plan: Original Laboratory Equipment Decontamination Program Development Design Constraints

TAMHSC EHS already had a policy in place addressing the proper decontamination of laboratory or clinic spaces and equipment. The existing policy informed equipment owners of their responsibility to decontaminate all equipment before releasing it from their ownership but did not include an EHS inspection component.

Through multiple project design meetings with TAMHSC administration, the property management office and risk management (hereafter referred to collectively as TAMHSC administration), EHS developed and launched the first version of the TAMHSC Laboratory and Clinic Equipment Decontamination Policy and supporting program.

TAMHSC administration provided the following project design constraints for the updated policy:

1) EHS was informed that the management software used by the property management office would not support integration with a digital solution and could not support modification to provide automatic notification to EHS of tracked items marked for shipment to Surplus. EHS would be notified of items needing a validation inspection directly by property managers or lab and clinic personnel.

2) In keeping with the preexisting policy, the laboratory and clinic personnel would decontaminate any equipment originating from their space. However, TAMHSC administration requested the definition of what equipment should fall under the policy be expanded to any equipment "originating from or appearing [to a layperson] to have originated from" a laboratory or clinic. Lab and clinic personnel would then take the newly added step of notifying EHS for follow up inspection.

The directive to decontaminate and inspect equipment "originating from or appearing to have originated from a laboratory or clinic" was interpreted as any equipment appearing to be of a technical nature not otherwise identified as having come from a non-lab space.

3) An in-person EHS inspection must be conducted prior to each shipment of equipment to Surplus. The inspection was meant to aid in enforcing the previous constraint and must include:

a) a validation interview for each piece of equipment to be shipped in which the person who actually performed the decontamination work would attest to and sign off on having personally decontaminated that piece of equipment according to the procedures provided in policy documentation;

b) a step in which the EHS inspector ensures the equipment is visibly clean;

c) a method to track each piece of equipment inspected with a unique ID;

d) a method to retrieve records on all inspected equipment;

e) a method to visibly and recognizably mark items having passed the EHS inspection with a green sticker or having failed with a red sticker;

f) a walkthrough of any other equipment present during validation, whether or not it was declared by the laboratory or clinic personnel as requiring validation, to ensure that no equipment appearing to have originated from within a laboratory or clinic would be transferred without completing the validation process.

4) All in-person EHS inspections must be completed within a 3-day window prior to transfer to the surplus department.

5) EHS would design and administer a training program to all TAMHSC property officers or alternates and all laboratory or clinic managers.

6) The policy must be ready to launch in 2 months with training developed and delivered to all TAMHSC property management officers by launch.

7) Documentation that the equipment had been decontaminated and had passed inspection must be present on each piece of validated equipment during transit to protect EHS and TAMHSC from liability in the event of a crash or other public contact.

Discussion of Constraints

While discussing the project constraints with TAMHSC administration, EHS raised concerns regarding the manual notification, the subjective nature of "originating from or appearing to have originated from" a lab or clinic, the verbal interview and the visual inspection. EHS believed the existing process already placed the responsibility for compliance on the lab and clinic personnel, as those were the individuals with the most knowledge about what hazardous materials were used, where within the lab or clinic space they were used and how best to clean them. EHS proposed a training program to inform necessary personnel about the existing policy and provide an opportunity to ask questions about how to decontaminate equipment in addition to a policy expansion to include accountability for those who violate the policy. However, TAMHSC administration wanted the direct involvement of EHS in the process. They expressed concerns for reputational risk and general liability in the event that an incident occurred, and they wanted EHS's involvement to mitigate those risks. EHS proceeded accordingly.

As noted, EHS hoped to automate notification out of concern that equipment would be overlooked or missed if property managers, or lab and clinic personnel were relied on to remember to send notification to EHS every time equipment was to be moved or sent to Surplus. The automatic notification would serve the additional purpose of simplifying the property management and surplus personnel's workload, and possibly improve buy-in for the new process. Access to the FAMIS software in use by property management was denied on grounds it did not support modification to satisfy EHS's request. To address this issue, EHS was asked instead to include and emphasize the notification requirement in the new policy training for property managers and other responsible parties.

EHS suggested that updating the definition of equipment covered in the policy scope to "equipment originating from or appearing to have originated from a lab or clinic" was difficult to enforce given its subjectivity. EHS further stated that labs frequently use equipment not obviously originating from a lab, as would be the case with microwave ovens and other similar items. Thus, anyone outside of the originating lab may not recognize which pieces of equipment appear to be lab related. However, TAMHSC administration wanted to place the onus of compliance on lab and clinic personnel, and created this constraint as a catch-all to be enforced by EHS during the visual inspection.

EHS explained that interviewing the person who signed as having performed the decontamination was not a quantitative assessment of the decontamination work or even definitive proof that it had happened at all. As such, the interview seemed to add little value to the overall process, because it was not quantitative proof that decontamination had occurred and was redundant, as those individuals had already attested by signature that they had performed the work. TAMHSC administration still maintained it was necessary for the individual to be present, interviewed and to sign the documentation attesting to the equipment's cleanliness.

EHS reiterated that a visual inspection added little value, as most biohazards, chemicals and radioactive material contaminants are invisible to the naked eye and allowed for misinterpretation of the equipment cleanliness and, thus, a false sense of security. EHS stressed the visual inspection would be qualitative at best and could not be construed as any guarantee of the equipment cleanliness. EHS recommended a third-party decontamination service provider be retained to perform scientific tests for a quantitative assessment. TAMHSC administration maintained the position that visual inspection be conducted by EHS.

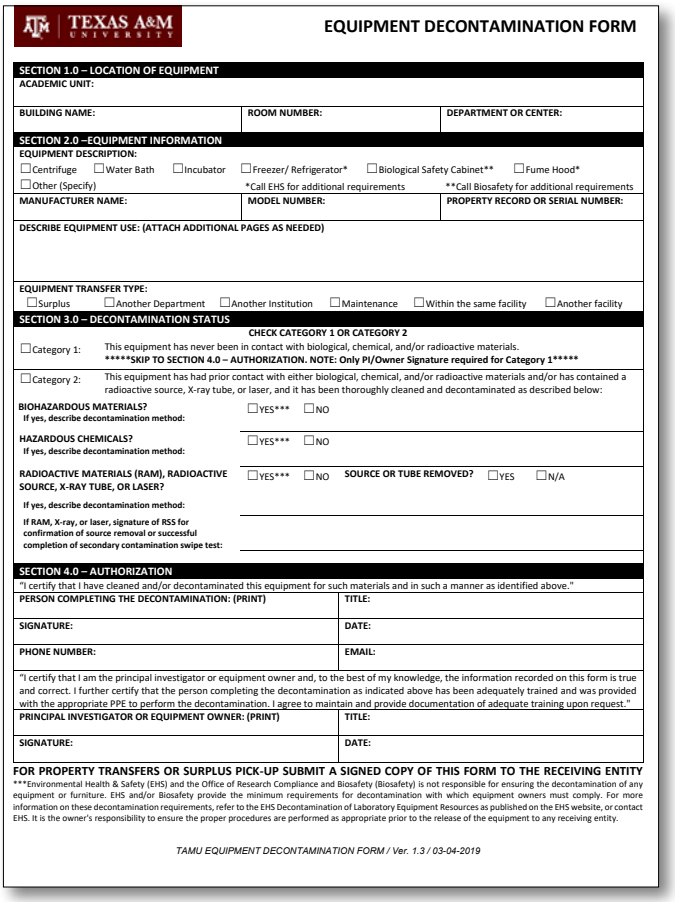
On the matter of how to enforce the policy, EHS suggested an escalation schedule for noncompliant labs and clinics including suspending the rights of noncompliant labs and clinics to send anything to Surplus. TAMHSC administration initially agreed, but later decided in favor of leaving enforcement to EHS. Because property managers reported to the management structure within their academic departments and not to TAMHSC administration, central administration felt they had little or no ability to enforce compliance with Surplus shipping suspension. Surplus personnel claimed they were unable to screen equipment at the origination point or reject any equipment arriving at their facility even when it did not meet their own requirements or those of the EHS policy. As a result, it was suggested that EHS be tasked with providing the screening function at the loading docks of any facility initiating a Surplus shipment, although that was ultimately deemed unnecessary. EHS relied on the notification process existing within the laboratory and fire and life safety inspection escalation schedule for noncompliant items in which higher-level supervisors including the respective vice president of the department would be notified when instances of noncompliance were not addressed.

Constraint Implications

EHS realized the design constraints received from TAMHSC administration essentially created an employee class of nonlaboratory or nonclinic workers who were assumed to lack the technical expertise of laboratory or clinic staff. They were now included in the group of laypersons who may not recognize types of equipment and their associated potential hazards, and who would be coming in contact with potentially contaminated equipment needing validation. This employee class would include maintenance personnel, surplus personnel and auctioneers, custodial staff, office staff and departmental property management officers.

Therefore, in addition to external design constraints, EHS took steps to close additional gaps by adding the following constraints to the overall program:

- This policy would apply to all equipment needing maintenance, being moved or handled, or in any way coming into contact with nonlaboratory and nonclinic personnel.
- The term *equipment* would need to include any furniture or materials within the same airspace in a lab or clinic in which hazardous materials were employed and on which airborne contaminants could settle, as well as computer equipment used within a lab or clinic that could collect contaminated dust in internal fans or components or could be used with contaminated gloves (e.g., keyboards, mice, trackballs).
- Anyone performing the decontamination work should be properly trained and that training should be documented for inspection and attested to by the responsible equipment owner.
- Documentation created during validation should include photographs of the exterior and interior of any equipment at the time of validation to prove the thoroughness of each equipment inspection.
- TAMHSC EHS must take steps to ensure that equipment remained as inspected after validation until it reached the central surplus department (through shipping) and to thus somehow seal or prevent tampering with the equipment once validation was complete.



TEXAS A&M UNIVERSITY

EQUIPMENT DECONTAMINATION FORM

SECTION 1.0 – LOCATION OF EQUIPMENT

ACADEMIC UNIT:

BUILDING NAME: | ROOM NUMBER: | DEPARTMENT OR CENTER:

SECTION 2.0 –EQUIPMENT INFORMATION

EQUIPMENT DESCRIPTION:

☐Centrifuge ☐Water Bath ☐Incubator ☐Freezer/ Refrigerator* ☐Biological Safety Cabinet** ☐Fume Hood*

☐Other (Specify) *Call EHS for additional requirements **Call Biosafety for additional requirements

MANUFACTURER NAME: | MODEL NUMBER: | PROPERTY RECORD OR SERIAL NUMBER:

DESCRIBE EQUIPMENT USE: (ATTACH ADDITIONAL PAGES AS NEEDED)

EQUIPMENT TRANSFER TYPE:

☐Surplus ☐Another Department ☐Another Institution ☐Maintenance ☐Within the same facility ☐Another facility

SECTION 3.0 – DECONTAMINATION STATUS

CHECK CATEGORY 1 OR CATEGORY 2

☐Category 1: This equipment has never been in contact with biological, chemical, and/or radioactive materials.
*****SKIP TO SECTION 4.0 – AUTHORIZATION. NOTE: Only PI/Owner Signature required for Category 1*****

☐Category 2: This equipment has had prior contact with either biological, chemical, and/or radioactive materials and/or has contained a radioactive source, X-ray tube, or laser, and it has been thoroughly cleaned and decontaminated as described below:

BIOHAZARDOUS MATERIALS? ☐YES*** ☐NO
If yes, describe decontamination method:

HAZARDOUS CHEMICALS? ☐YES*** ☐NO
If yes, describe decontamination method:

RADIOACTIVE MATERIALS (RAM), RADIOACTIVE SOURCE, X-RAY TUBE, OR LASER? ☐YES*** ☐NO SOURCE OR TUBE REMOVED? ☐YES ☐N/A
If yes, describe decontamination method:
If RAM, X-ray, or laser, signature of RSS for confirmation of source removal or successful completion of secondary contamination swipe test:

SECTION 4.0 – AUTHORIZATION

"I certify that I have cleaned and/or decontaminated this equipment for such materials and in such a manner as identified above."

PERSON COMPLETING THE DECONTAMINATION: (PRINT) | TITLE:

SIGNATURE: | DATE:

PHONE NUMBER: | EMAIL:

"I certify that I am the principal investigator or equipment owner and, to the best of my knowledge, the information recorded on this form is true and correct. I further certify that the person completing the decontamination as indicated above has been adequately trained and was provided with the appropriate PPE to perform the decontamination. I agree to maintain and provide documentation of adequate training upon request."

PRINCIPAL INVESTIGATOR OR EQUIPMENT OWNER: (PRINT) | TITLE:

SIGNATURE: | DATE:

FOR PROPERTY TRANSFERS OR SURPLUS PICK-UP SUBMIT A SIGNED COPY OF THIS FORM TO THE RECEIVING ENTITY

***Environmental Health & Safety (EHS) and the Office of Research Compliance and Biosafety (Biosafety) is not responsible for ensuring the decontamination of any equipment or furniture. EHS and/or Biosafety provide the minimum requirements for decontamination with which equipment owners must comply. For more information on these decontamination requirements, refer to the EHS Decontamination of Laboratory Equipment Resources as published on the EHS website, or contact EHS. It is the owner's responsibility to ensure the proper procedures are performed as appropriate prior to the release of the equipment to any receiving entity.

TAMU EQUIPMENT DECONTAMINATION FORM / Ver. 1.3 / 03-04-2019

TAMU Equipment Decontamination Form developed by the team.

Do: Original Policy Features

The existing TAMHSC EHS equipment decontamination policy was updated to include the new requirements and scope. The policy was published on the EHS website and the training, after the initial classroom sessions, was placed on the TAMHSC's online training repository.

The program continued to evolve as new scenarios were discovered requiring specific handling. When mature, the process worked as follows:

1) Laboratory or clinic personnel would identify those pieces of equipment they wished to transfer to another department or institution, or to Surplus.

2) The identified equipment would be decontaminated as appropriate for the known hazards with which the equipment was used, or for those hazards present in the laboratory or clinic environment.

a) Recommendations for decontamination methods and materials were included in the program documentation with an encouragement to consult EHS and Biosafety in the event of questions.

3) An equipment decontamination form (EDF) would be completed describing the location of the equipment, who

owned it, what the equipment was, whether any hazardous materials were used with the equipment, how it was decontaminated, who performed the decontamination, and who authorized the decontamination and assumed responsibility for the equipment. In the case of lasers or radioactive materials, documented approval from the laser safety officer or radiation safety officer, respectively, was required.

4) The EDF would be scanned and submitted to EHS through an online portal that would route the form to the appropriate campus safety officer (based on equipment location), the laboratory safety manager (for oversight and workload balancing) and the receiving entity.

5) Upon receipt of the EDF, EHS would contact the person listed as having performed the decontamination and would schedule the verbal interview to occur within 3 days prior to the shipping or transfer date.

6) EHS would complete the verbal interview to validate that the decontamination as documented was appropriate for the hazards described and to visually inspect the equipment for cleanliness. Upon satisfactory completion of all previous steps, the equipment would be sealed with tamper-evident tape and a green sticker with a unique ID number would be placed on the equipment for approval and tracking purposes. Issues with the equipment or documentation that were discovered during the interview could be corrected immediately by the owner or representative at the EHS inspector's discretion.

7) In iForms software on a mobile device, EHS would record the unique ID for each item validated. Pictures of both the final EDF (as updates may have been required as a result of the interview) and the equipment with all doors, drawers or other areas that are accessible during normal use open would also be attached. Any items failing validation were marked with a red tag.

8) The green-tagged equipment could then be transferred. However, per policy it was the responsibility of the departmental property officers to prevent any items not green-tagged from being moved, and it was the responsibility of Surplus to reject items brought to them without green tags.

LESSONS LEARNED

A true need was identified: A potential risk existed for improperly decontaminated items being sent to Surplus and the general population, but difficulties arose when planning a mitigation method, as competing interests often exist in policy development. The political environment sometimes plays a larger role in policy development than technical information.

Buy-in at all levels and of all stakeholders or parties involved (including EHS) is paramount to the success of any new initiative. Buy-in was gained for this policy with upper-level management support, announcements to all affected by the policy, training sessions with required attendance, Q&A sessions and minimizing burden of compliance wherever possible. Leveraging technology (e.g., online submission forms) is a good and often simple way to minimize the compliance burden. The easier it is to comply, the easier it is to get buy-in.

The assumption was made that lab personnel had the knowledge to properly decontaminate their own equipment, which turned out to not be true in all cases. It was discovered that some research faculty had even tasked their nontechnical office administration staff with performing the decontamination work. EHS stepped in, but it was a surprise that lab personnel would involve untrained administrative staff.

Known Process Gaps

Based on the design constraints, EHS knew gaps remained in the process. Measures were taken to minimize the impact of those gaps. Two examples of gaps and their mitigation efforts were:

1) EHS still relied on the laboratory personnel to inform them of upcoming surplus shipments or equipment moves. In the absence of any possibility for automation on the property management software side, EHS could not guarantee all surplus shipments or equipment moves would be detected before they happened. The education campaign and efforts of campus safety officers to inform campus constituents of the policy were the primary means of controlling this gap.

2) The verbal interview and visual inspection of equipment were not quantitative. Given the nature of many hazardous materials employed in a university research environment, a visual inspection is inadequate to determine whether equipment has been effectively decontaminated. A visual inspection may catch instances of gross negligence in decontamination if the equipment is visibly dirty or covered in dust and thus not recently cleaned at all, but, without more extensive testing, visual inspection remained qualitative and relied on the attestation of the interviewee. A method used to control this gap was that EHS inspectors would look closely for signs of dried cleaning materials (e.g., smears from bleach and water wipes, soap scum, streaks that may indicate recent cleaning) and would question those who performed the decontamination specifically about which decontamination method and materials they had used in an attempt to determine whether they had chosen the correct method for the contaminants either present in the lab or attested to on the form.

Tools

EHS had already selected the iFormBuilder mobile platform (Zerion Software) deployed on Apple iPads for the general laboratory safety, and fire and life safety inspections. That software aids the inspectors in the performance of their duties by dramatically improving their efficiency over the previous paper process. This software is a completely customizable form generator that can be used on iOS and Android mobile devices. Once an inspection is completed, the software synchronizes data to a hosted server making the resultant data accessible from anywhere an Internet connection is available. EHS personnel are able to use a web-based control panel through which forms can be created, modified and assigned to the appropriate inspector. The control panel also allows for data modification, filtering, report generation and data export in multiple file formats. An extensive support community aids in the design of forms with more complex requirements such as data retrieval and logic in entry field display.

EHS had already issued iPads to its personnel, as the devices improved mobile work and communication capabilities. These devices, already in use for the general laboratory, and fire and life safety inspections, were used for the implementation of the new equipment inspection process. All TAMHSC campuses were already supplied with Wi-Fi, enabling the devices to be used to their full potential and allowing a persistent connection to the hosted iFormBuilder server from anywhere an EHS inspection would be conducted. However, a continuous Wi-Fi connection was not required throughout

the inspection. As long as the mobile app has already downloaded the most recent version of the inspection form, it can function independently of the hosted server by storing the inspection results in memory for upload to the hosted server once an Internet connection is available.

An online software, MachForms, acted as the portal through which all EDFs were routed via skip logic to the appropriate recipients (e.g., Surplus personnel, campus-specific EHS personnel, and whoever would receive the equipment after validation if not Surplus). This software is also a customizable form generation tool, similar to iFormBuilder in many respects. However, where iFormBuilder forms are exclusively accessible from mobile devices via an app, MachForms forms may be embedded into web pages. Since MachForms was a TAMHSC-wide asset, EHS did not incur any additional cost to use it. For this reason, and for its ability to make the forms available on the Internet and, thus, accessible by all TAMHSC faculty and staff, MachForms was selected as the EDF submission system.

Cost of Implementation & Cost-Effectiveness

The cost of implementation was limited to the time and effort of two full-time EHS employees. Development took approximately 2 months before the launch of the first version. All software, mobile devices and other equipment employed to perform the required tasks were already owned by TAMHSC and were in use for other purposes, thus, those costs are not included. The only additional supplies needed to complete the tasks required under the new process were color-printable labels for the green- and red-tag process, and tamper-evident tape.

Once the visual inspection and interview were complete and appropriate documentation was attached, equipment was still removed by university personnel or shipped via moving van operated by a third-party moving company to central Surplus for auction as before. Any decontamination work was performed by lab or clinic personnel or, in rare cases, by EHS staff without the need for a third-party decontamination company. Since the disposal route was not changed and no additional decontamination costs were incurred due to the work being performed by university staff, there was no change in equipment disposal costs.

It is difficult to quantify the cost-effectiveness of any risk mitigation effort when the potential adverse event being mitigated is injury or legal action, as the costs resulting from those events or actions can vary widely. However, the updated laboratory and clinic equipment decontamination process resulted in the elimination of the complaints and concerns that TAMHSC administration and EHS were receiving from the surplus department. As this was one of the KPIs to measure program success, EHS was encouraged that the program was working as hoped.

Check: Evaluation of Laboratory Equipment Decontamination Program Development

Since implementation on July 30, 2015, the laboratory equipment decontamination policy resulted in the completion of 3,832 decontamination validations by EHS personnel of equipment and material originating or appearing to originate from within a laboratory or clinic. These decontamination validations could be either large individual pieces of equipment or a moving box full of smaller items, equipment or supplies.

The average time spent per validation was determined to be 8.4 minutes by calculating the time interval between the unique time stamps generated by the iForms software at the beginning of each validation. Time intervals less than 1 minute and greater than 8 hours per validation were removed as outliers. Intervals of less than 1 minute were removed because completing the iForm and taking the required two pictures of each item took longer than 1 minute to complete. Upon subsequent investigation, it was found that some EHS personnel generated all of the unique IDs at their desks so they could print out all of the needed green or red stickers before the validations as an efficiency method. Intervals greater than 8 hours were removed because EHS procedure required that any equipment unable to pass the validation during the inspection be red-tagged for cleaning and resubmission at a later date, and validation inspections did not extend past a normal 8-hour workday. Thus, all intervals greater than 8 hours were more likely the result of errors in assigning the date of the validation due to the difference between the time zone in which the server clock determined the unique ID and the time zone in which the validation was taking place.

Total time spent to date by all EHS personnel performing validations was 537.6 person-hours in the 35 months since implementation. The total postimplementation labor cost is $14,708 in aggregate or $5,043 on average per year not including time spent on program development, training, travel time to remote sites, reviewing submitted documentation or scheduling the validation inspections. Total cost is calculated using a weighted average of total validations per person and salaries adjusted to an average hourly rate.

A simple method to estimate the cost per year to expand the original program to all of the now combined TAMU and TAMHSC locations was to tally the total lab spaces at each institution. It is reasonable to assume that all lab space contains at least some laboratory equipment, and that all of this lab equipment would fall under the jurisdiction of the equipment decontamination program based on original constraints. Therefore, a comparison of total lab spaces is a reasonable method to estimate the cost of program expansion. In 2017, the TAMHSC counted 665 active lab spaces and TAMU counted 4,798 lab spaces for which TAMU EHS was responsible. This results in a new total of 5,463 active spaces and an estimated expansion of cost by a factor of approximately 8.2, thus potentially increasing costs from $5,043 to $41,425 per year.

Cost alone is not a proper method of determining whether a safety program is worth continuing. As stated by Reid, Koljonen and Buell (1999), "the idea [of PDCA] is to determine if the planned changes were successful in addressing the core problem and whether the symptoms have been diminished." The original KPIs were the symptoms that prompted the initial revisions to the equipment decontamination program. Thus, they would be evaluated to determine the efficacy of the revisions.

The first two KPIs chosen to determine program success were 1) whether a reduction occurred in the number of workers' compensation claims or first report of injury forms filed from exposures to contaminated lab equipment; and 2) the number of complaints submitted by members of the public who had purchased potentially contaminated equipment at auction before and after program implementation. As of the date the program reevaluation was conducted, the TAMHSC risk management team reported no change in the number of workers' compensation claims, first report of injury forms filed or complaints from auction participants.

Furthermore, when TAMHSC EHS integrated with the TAMU EHS team in 2017, policy standardization was a priority

to ensure that all campus constituents across the newly merged institutions were protected to the same degree. The merger process between TAMHSC and TAMU also included merging the respective surplus departments. TAMU Surplus had a more mature program and an established relationship with TAMU EHS allowing them to deal with potentially contaminated equipment on a case-by-case basis and thus addressing the third KPI.

In collecting data related to the fourth KPI, potential regulatory violations detected related to potentially contaminated equipment being handled by nonlaboratory and nonclinic staff and by members of the public, EHS had found multiple instances of hazardous materials packaged in regular moving boxes with miscellaneous office supplies or not packaged at all. An example case was an unlabeled capped glass jar of 70% ethanol, which, had it been shipped, would be in potential violation of the 2015-2016 version of 49 CFR §172.102(c)(1) Special Provision 24; §173.150(b)(2); §173.202(a); §172.702 and 704; §172.300, 400 and 500; §173.24(b), 25(a)(4); §177.817(a); §178.601 and possibly more as described in 49 CFR §107 Subpart D, Appendix A. Those hazardous materials identified as improperly packaged were subsequently repackaged appropriately and shipped according to all applicable transport regulations. These potential 49 CFR violations were only detected during large lab moves, not individual equipment decontamination.

To address this problem, EHS already had a dedicated hazardous shipping subject-matter expert and an inspection team that performed walkthrough evaluations of all labs being decommissioned prior to move or shutdown. These teams were already intercepting potential regulatory issues of this nature and, now equipped with better data to target their efforts in detecting where and how improperly packaged hazardous materials may be appropriately addressed, would continue to do so. Laboratory staff were also retrained by the respective campus safety officers to ensure that they were aware of their responsibilities and were reminded of the support systems in place to facilitate compliant hazardous materials shipping.

The decontamination validation program had not demonstrated a measurable improvement in constituent safety based on the first two of its original KPIs. In addition, the third KPI was no longer applicable given the surplus department merger, and the fourth KPI was addressed through other already established means (although now with improved data derived from scrutiny of so many lab moves). It was therefore unreasonable to expand the program to all TAMU and TAMHSC campuses. Thus, this program was a prime candidate for reinvention to become more efficient.

ACT: Method of Implementation

TAMU EHS had been handling laboratory decommissioning through a process defined in a standard administrative procedure (SAP). Although thorough, the laboratory decommissioning SAP did not include a process for the decommissioning and decontamination of equipment when it was only the equipment within a lab being decommissioned and not the lab itself. TAMU EHS had a policy that required certain types of equipment (e.g., refrigerators, freezers, chemical fume hoods) to be inspected and cleared before those items were sent to Surplus. The TAMU EHS radiological safety team had also deployed special red stickers to prompt either lab or surplus staff to contact EHS for all equipment known to have been used with radioactive materials, or for equipment containing lasers or radiation-producing devices. However, the surplus office had not been instructed to refuse any equipment that was missing the clearance form or the special red stickers, and other types of lab equipment that could potentially be contaminated were not included in this policy.

A new version of the equipment decontamination policy was incorporated into the laboratory decommissioning SAP, which places the newly merged EHS in an appropriate advisory role and directs campus constituents to additional resources to aid in their decontamination efforts.

All components of the validation process (e.g., verbal interview, visual inspection, sealing equipment with tamper tape), while still within the rights of EHS to conduct, are no longer required. This change is a tremendous improvement in the efficiency of the process, as EHS was only ever confirming information already attested to by signature on the EDF and inspecting at a qualitative level at best. The EDF is still required to be completed and attached to each piece of equipment being serviced by nonlaboratory personnel or released to members of the public. The revised EDF still provides locations for lab personnel to describe the specific steps taken to decontaminate the equipment and provides space for EHS to document confirmation surveys in the case of equipment used with radioactive materials or containing an X-ray tube or laser. The EDF also contains a thorough explanation of the ramifications of signing and attesting to proper decontamination, namely, that all responsibility lies with the signer.

Assigning all responsibility to the equipment owner was determined to be the best possible path forward, since the lab staff are in the best position to know which potential contaminants may be on each piece of equipment. Thus, they are best suited to perform the appropriate decontamination and document their steps. EHS remains in an advisory role to consult on best practices for decontamination, but without the extra unnecessary step of confirming verbally what has already been confirmed in writing. Additionally, since the visual inspection previously required was not a quantitative certification of cleanliness, it could not be relied on as a means to judge whether decontamination has actually occurred. Furthermore, the visual inspection and the tamper tape may have offered a false sense of security, as they were no guarantee of decontamination. Removal of the EHS validation process and the placement of the responsibility for the status of equipment clearly on the lab staff and equipment owners eliminated a commonly expressed misperception by campus constituents that EHS had "certified" the equipment as free of contamination.

Cost of Implementation for Revised Policy

The cost to revise the program was limited to the time and effort of two full-time EHS employees who drafted the new SAP governing the equipment decontamination and laboratory decommissioning processes. Development took approximately 1 month.

Cost-Effectiveness

As noted, the total cost for the validations alone, not including process development, implementation, material (e.g., tamper tape, stickers to link equipment to ID record, scissors), submitted documentation review, scheduling validation inspections and travel to remote sites, was approximately $5,043 per year when limited to only the TAMHSC campuses. Eliminating the validation process results in an immediate and ongoing savings of that amount per year. Additionally, restructuring the program allows for the expansion of the new laboratory

and equipment decommissioning SAP to the entirety of TAMU without added cost.

Scope of Revised Program

The scope of the revised program was to merge existing TAMU and TAMHSC SAPs to develop a streamlined equipment decontamination process and to place responsibility for ensuring cleanliness on those most appropriate to bear that responsibility: the lab personnel releasing the equipment.

Streamlining in this way greatly improves the efficiency of the process and eliminates several points of misperception that may have given rise to a false sense of safety. These improvements have allowed the program to expand and cover a larger number of labs at the university and, thus, safeguard campus constituents and members of the public who may interact with lab and clinic equipment. The result of the SAP merger also improves the original TAMU SAP by adding greater detail regarding proper equipment decontamination when not included in a lab decommissioning, which closes a program gap given how often equipment is serviced or transferred. An additional improvement now that equipment decontamination is handled separately in the SAP is that all those who interact with lab equipment are now explicitly directed to contact EHS should they feel they need assistance.

Results & Conclusions

Through the development, implementation, review and revision of the laboratory equipment decontamination process, the team learned that, while a risk, there are more effective means of mitigating that risk than an expansive visual inspection and interview process. A major improvement is the much greater specificity provided in policy documentation to define what must be decontaminated, who is responsible and what resources are available to assist. Having institutional policy as support for EHS efforts greatly enhances EHS effectiveness when dealing with lab and clinic personnel.

Every institution should author a procedure to determine the steps they require to be completed before lab and clinic equipment is decommissioned and potentially released to the public via auction or disposal, or released to nonlaboratory personnel for maintenance. As the lab and clinic personnel best know which materials have been used with which equipment, it is their responsibility to appropriately decontaminate that equipment. EHS should always be available in an advisory role, but it is not practical for EHS to take on more responsibility in this process as demonstrated by the ROI determined at KPI reevaluation. Automated solutions could be leveraged to minimize EHS labor and, thus, make a process similar to the original policy described less burdensome, but, without lab and clinic personnel participation, any equipment decontamination process will struggle to improve over baseline.

Suggested Future Work

Given the rapid expansion in low-cost technology solutions for tracking nearly anything and the growing interest among many research industry vendors in developing the connected lab in which all assets communicate with each other, a potential solution to tracking lab and clinic equipment might be RFID, Bluetooth beacon, QR code technology or vendor-specific connected lab solutions. These tags could be affixed once the equipment is received by the institution or when the equipment is noted on a laboratory or clinic inspection, then be detected when the equipment is sent to surplus, public auction or waste handling teams to prevent it from leaving the institution before someone can follow up. Additionally, if software integration were possible, property management systems may be able to alert whomever the institution deems appropriate when certain types of equipment are flagged in the system for movement or disposal. **PSJ**

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