Use of Multiple SOP Styles to Increase Personnel Compliance and Safety Within a BSL-2/BSL-3 Animal Facility

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Abstract

Biohazard training and compliance of husbandry and research staff are often complicated at the University of Arizona by the sporadic nature of the work within the BSL-2/BSL-3 suite. Projects may last for a month and then not be repeated for a significant period of time. Failure to adhere to approved safety measures and techniques for specific rooms/projects over time increased the need for clear standard operating procedures (SOPs) that were easily accessed and utilized. SOPs available only in the employee lounge are of little use when a question arises while changing cages within a BSL-2 animal room. To this end, new SOP formats and display locations were developed and instituted to increase awareness and comprehension of techniques used within the BSL-2/BSL-3 suite. Changes included the placement of plain text as well as picture-enhanced SOPs in common areas such as the employee lounge and entrance to the biohazard suite, and within the animal rooms. The introduction of SOPs containing color photographs has been instrumental in increasing compliance of in-room procedures by both native English speakers and those who do not speak English as a first language. Overall, the use of multiple styles of SOPs has been a huge success. This process has helped to reduce confusion and increase compliance by both the husbandry and research staffs working within the University Animal Care facilities.

Introduction

In 2002, a review of University Animal Care (UAC) husbandry and research staff procedures within the biohazard suite at the Central Animal Facility identified several areas of concern. Even though SOPs formalized in the late 1990s were GLP-compliant, most husbandry technicians did not have a good understanding of the SOPs or biosafety basics and were using techniques and procedures that could potentially cause the spread of contamination to personnel and/or the environment. Less than optimal processes were immediately halted and all husbandry staff were retrained based on existing versions of SOPs. Fortunately, the agents in use were primarily ABSL-2, and appropriate personal protective equipment (PPE) was being worn when the animals were handled. Research staff used appropriate technique when working with their animals, but had difficulty packaging contaminated cages appropriately for autoclaving out of the suite, often necessitating the unpacking and repacking of cages.

Data Gathering

Staff Interviews

UAC husbandry and research technicians were surveyed to establish the cause of the breakdown in technique and noncompliance with UAC SOPs. Numerous barriers were identified:

Complex or Unique Procedures. Husbandry technicians frequently used practices appropriate for sterile animal rooms instead of the required practices needed for biohazard rooms. As the bulk of their workload involved handling "clean" animals, they found it counter-intuitive to handle the "dirty" animals differently. The mindset that the animals must be protected from the technician and the environment was ingrained and using techniques to protect personnel, not animals, was reported as "feeling wrong."

Individual Variations Among Studies. Procedural differences based on the agent used confused the husbandry technicians. Often the techniques used with one study were applied to the next, without regard to the differences in agent or route of infection.

Training. Husbandry technicians were often trained by the last person to work in the animal room, with minimal emphasis on SOPs. Incorrect techniques were passed from one technician to the next, creating the "we've always done it this way" mindset. A heavy reliance was placed on expecting the technician to memorize and retain verbal information rather than to consult written documentation.

Sporadic Nature of the Studies. The sporadic nature of the biohazard studies hindered the process of knowledge "ownership" by the husbandry technicians. Often a study would last several weeks and not be repeated for 6 months to a year. It was found that husbandry technicians were trying to rely on memory rather than written documentation to refresh their memories about required processes.

Imprecise and Tedious SOPs. A review of existing husbandry SOPs showed that there were process inaccuracies, as well as contradictory statements among SOPs. Husbandry technicians complained that reading SOPs was tedious and time-consuming. The inaccuracies caused confusion, often resulting in the technician abandoning the SOP and relying on memory to complete a task.

Location of SOPs (distance to animal room). Husbandry technicians reported distance from the animal room to the employee lounge, where the GLP-compliant SOPs were kept, as an issue in the use of SOPs. They related that if a question arose while in the animal room, they did not want to waste time by removing their PPE, leaving the room, and searching out the appropriate SOP. Instead, they would rely on memory and check the SOP after their animal room work had been completed.

Language. Some husbandry and research staff identified difficulty comprehending written instructions as one barrier to bagging contaminated caging appropriately. The individuals experiencing the most difficulty were those for whom English was not their primary language.

Communication. Instructions from research staff as to PPE and husbandry procedures used for their agent at times varied from the information included in the Institutional Animal Care and Use Committee (IACUC)-approved protocol.

Institutional Input

Next, the IACUC-approved protocols were reviewed for agents and species, PPE and equipment needed, and procedures involved in the study. This information was then compared to existing GLP-compliant UAC husbandry SOPs and the differences between the two were discussed with the University Biosafety Officer to facilitate changes needed in the SOPs to increase compliance with known industry standards for the agents used.

Materials and Methods

SOPs

Based on the data gathered from the IACUC protocols and interviews with researchers, UAC husbandry staff, research staff, and the University Institutional Biosafety Officer, it was apparent that the UAC biohazard SOPs needed revamping. The information presented in the SOPs, as well as the location and format of the SOPs, needed to be addressed. It was found that new husbandry staff needed the in-depth presentation of the GLP-compliant SOPs during initial training and for occasional review, whereas experienced staff had no need to read hundreds of pages of SOPs every time they were assigned to a biohazard animal room for the week.

To this end, all biohazard SOPs were reviewed and revised. Careful attention was paid to ensuring

that interconnecting SOPs "spoke" to each other with accuracy. Two non-GLP-compliant SOP formats were developed to distill the information presented in the GLP-compliant SOPs to an abbreviated format for use by experienced, trained husbandry staff members. SOP placement was also revised:

Employee Lounge SOP Book. University Animal Care maintains master electronic copies of GLP-compliant standard operating procedures which are available for review on a computer located in the employee lounge. Pictures were added to those SOPs where a photo could illustrate a complex issue, increase comprehension, and reduce the wordiness inherent in complex SOPs. To increase accessibility specifically to the biohazard SOPs, photocopies were organized into a three-ring binder and placed in the employee lounge.

Entrance to the Biohazard Suite SOP Binder. The biohazard suite is on a different floor from the employee lounge. Because of this, another three-ring binder containing photocopies of the GLP-compliant husbandry biohazard SOPs was placed in the entry airlock to the biohazard suite. SOPs were placed in plastic sleeves with closure flaps to keep the pages clean and facilitate updating the binder without spending excessive dollars to laminate the pages. This location allows the husbandry technicians to review procedures prior to entering the biohazard suite.

Animal Room. Several changes were implemented at the animal room level:

- A biohazard questionnaire was designed and implemented to address several of the issues identified during the data-gathering phase. The questionnaire (shown in abbreviated format in Figure 1) is completed by the PI before a new study begins (new agent or change in procedure). The Animal Facility Supervisor compares the information presented on the questionnaire with the listed IACUC protocol to determine if there are any differences in the PPE and procedures listed on the documents. Discrepancies are addressed prior to the start of the study. The Animal Facility Supervisor also searches the Web to gain third-party insight into the hazards associated with the agent. The multi-page questionnaire is converted into a single page SOP (Figure 2) for posting on the outside of the animal room door for the duration of the study. This SOP provides several key pieces of information that the husbandry technician needs prior to entering the animal room: agent used, species used, contaminated caging/dead animal/trash-processing procedures, contact name, and phone number. This SOP varies in format and length from the GLP-compliant SOPs in an attempt to increase comprehension and compliance by using a pared down, bullet-point presentation of information. The purpose of this SOP is to quickly answer the question "What do I need to do in this room?" leaving the "How do I do this task?" to the more extensive GLP-compliant SOP format. As an example, Figure 2 instructs the husbandry technician to autoclave the soiled cages. This translates roughly into 15 individual GLP-compliant SOPs and 25+ pages of material for the naïve husbandry technician to read. The experienced husbandry technician needs to know only "Do I autoclave the dirty caging?" The naïve technician needs to know how to put on the PPE, change the cages, bag the cages, operate the autoclave, etc.
- A photo-enhanced SOP (shown in abbreviated format in Figure 3) was designed to increase compliance by research and husbandry staff when bagging dirty caging for autoclaving. Including pictures with text has increased procedural compliance while decreasing the amount of caging that must be reprocessed. The laminated SOP is posted on each biosafety cabinet within the animal facility. This SOP also varies in format from the GLP-compliant SOPs in an attempt to increase comprehension and compliance by using bright, colorful, digital pictures to illuminate a process that is vital to ensure sterilization of contaminated caging. Autoclave package size limitations and autoclave operational idiosyncrasies increase the need for compliance to departmental SOPs.
- Three-ring binders containing the GLP-compliant SOPs pertaining specifically to that room were placed in the BSL-3 anterooms. These rooms vary radically in equipment, procedures, and personnel risk from the BSL-2 rooms and each other. The additional reference material has been a key component in training new personnel. Once again, SOPs were placed in plastic sleeves with closure flaps to facilitate updating the information.

Training to the SOPs

After the GLP-compliant SOPs were revised, the additional SOP designs formalized, and both styles put in place, departmental training packets were updated to reflect the changes in procedures and processes. Husbandry staff members were retrained and a "one size fits all" mindset was discouraged. Emphasis was placed on recognizing the differences in procedures in their daily routine. Husbandry staff members are now formally trained using all styles of biohazard SOPs and are fully aware of where to find the information they need to work safely in the animal rooms.

Conclusion

Compliance with standard operating procedures is a crucial step in ensuring the safety of husbandry and research technicians working in areas housing animals exposed to biohazards. It is vital to identify barriers to comprehension of SOPs by the technicians. Physical location, language, and accuracy are all important factors to consider when reviewing SOPs. Is the SOP in an area where the technician can review it when actually performing the task? If not, is it possible to place the information where it will be readily accessible? Is it important that all of the information is presented in its entirety or can the SOP be abbreviated and the format changed to present a more readily comprehended and consumed product? Will using pictures reduce confusion and wordiness? Do all interrelated SOPs speak to one another accurately? By answering these questions, University Animal Care was able to produce stronger SOPs and a safer working environment for its technicians and research staff.

FIGURE 1
UAC Biohazard Information Questionnaire

This worksheet has been prepared to aid in the establishment of investigator specific Standard Operating Procedures (SOPs) for biohazard studies. Completing this worksheet will better enable UAC to care for your biohazardous animals and assist you in meeting your research goals.

This form must be filled out and submitted to the UAC Facility Supervisor prior to initiation of animal experiments.

P.I. _____ Office Phone #_____Research Tech:_____

Lab Phone # _____ Weekend/Holiday Contact Name and Phone #:_____

Species used:_____ ***Protocol #:***_____

Agent used: *Please check all that apply and list agent (s). (Note: This form must be filled out in addition to the Authorization Form for Radioactive Material.)*

☐ Carcinogenic agent(s):
☐ Radioactive agent(s):
☐ Human Infectious Agent(s):
☐ Animal Infectious Agent(s):

Study size and duration:
How many cages of animals do you expect to have in use at a time?
How long will the animals be in the room?
If using a radioactive compound, can the animals be housed in a general animal room?

Husbandry Tasks. *Please check one:*

☐ UAC staff will do all husbandry tasks for the room. This includes changing the cages, removing dead animals, servicing the cages by adding food and water as needed and changing flooded cages.
☐ Investigator will perform all husbandry tasks. (***Note***-This includes packaging the used caging/bedding/trash for autoclaving.)
☐ Investigator and UAC staff will share husbandry tasks. *Please explain:*

Diets: *Please check one*

☐ All mice will be fed Teklad NIH-31 diet
☐ All rats will be fed Teklad 4% Mouse/Rat diet
☐ Other, *Please explain*:

Protective Equipment Needed:
All personnel entering this room need to wear the following: *Please check all that apply:*
☐ Bonnet ☐ N95 Respirator ☐ Eye protection ☐ Yellow gown ☐ Jump suit ☐ Shoe covers ☐ Gloves
☐ Other:_____

All personnel handling the animals in this room need to use the following when opening the cages:
☐ Biosafety Cabinet ☐ Glove Box ☐ Chemical Fume Hood ☐ Other:_____

Check all that apply*:*

☐ All animal cages and bedding must be autoclaved after use in the animal room.
☐ All animal bedding must be disposed of in yellow radioactive bags and the label filled out.
☐ All trash must be autoclaved prior to disposal from the animal room.
☐ Trash may be disposed in the red barrels without autoclaving.
☐ All animal carcasses must be autoclaved prior to disposal.
☐ All animal carcasses must be disposed of in yellow radioactive bags and the label filled out.
☐ Animal carcasses may be disposed of in the red barrels without autoclaving.
☐ Other: _____

FIGURE 2

UAC Biohazard SOP (Completed Sample)

P.I. John Jones, DVM, PhD P.I. E-mail: jjones@u.arizona.edu Office Phone # 555-1234

Research Technician: Jane Smith E-mail: jsmith@u.arizona.edu Fax # 555-2345

Lab Phone # 555-3456 Weekend/Holiday Contact Name and Phone #: Jane 555-9023

Species used: ***Mouse*** ***Protocol #:*** ***04-555***

Agent used: Human and Animal Infectious Agent: *Cryptosporidium parvum*

Study size and duration: Approximately 10-12 cages will be in the room for 7-10 days.

Husbandry Tasks.

☒ UAC staff will do all husbandry tasks for the room. This includes changing the cages, removing dead animals, servicing the cages by adding food and water as needed and changing flooded cages.

Diets: All mice will be fed Teklad NIH-31 non-irradiated mouse chow.

Protective Equipment Needed:

All personnel entering this room need to wear the following: *Please check all that apply:*

☒ Bonnet ☒ N95 Respirator ☒ Yellow gown ☒ Impervious shoe covers x 2 ☒ Gloves x 2

All personnel handling the animals in this room need to use the following when opening the cages: Biosafety cabinet

Check all that apply*:*

☒ All animal cages, bedding and trash must be autoclaved after use in the animal room.

☒ Animal carcasses may be disposed of in the red barrels without autoclaving.

☒ Personnel must ungown in the ante room.

☒ The PI will be responsible for terminating all moribund animals.

Notification of Death: Death slips will be filled out and mailed as usual. Investigators will be notified **immediately** upon finding dead animals in order for them to harvest tissues or necropsy.

P.I._____ UAC Supv. _____

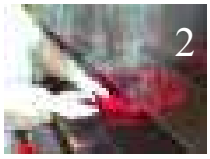
Signature Date Signature Date

FIGURE 3

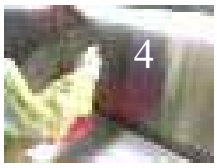
Bagging animal caging using a biosafety cabinet with a dump station:

1. Gown up before entering the animal room. See door SOP for specific PPE worn.

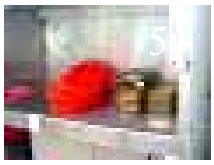
2. Line the dump station barrel with a red, or orange biohazard bag – see door SOP.



3. Turn the biosafety cabinet on.



4. Clean cabinet with Clidox. Spray directly on all surfaces except "ceiling" and wipe down with paper towels. Follow the same process with alcohol.



5. Place clean cages, water bottles, etc. in the biosafety cabinet if changing cages.

Join a Committee

Have you ever considered joining a committee? When you choose to serve on a volunteer committee, you open up a world of possibilities for networking, professional growth, and career opportunities while serving your profession. Volunteer member groups are the backbone of the association because they:

- Serve as a forum for exchange of information
- Advance the science in all specialties of biosafety
- Develop guidelines and standards
- Provide education and training
- Link ABSA to many other institutions

You should explore committees in areas of the profession where you are active or have an interest. There is a great variety; you can be sure to find one of interest to you. Please review the list of committees and identify those areas in which you would like to participate or contact the chair of the committee (http://www.absa.org/abocommittees.html) that interests you to find out more information about the committee's goals. You are also invited to attend the committee's meeting during our national conference or at any other time (all committee meetings are open).