



Quality Assurance: Best Practices in an ABSL-3 Environment

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As Animal Biosafety Level 3 (ABSL-3) suites become more prevalent within the biomedical research community, laboratory animal care professionals must increasingly meet the challenges posed by safety regulations and policy requirements. Developing the appropriate standard operating procedures (SOPs) within these environments holds the keys to achieving this.

This is, of course, a demanding task, but an efficient and well organized quality assurance (QA) program can meet these critical requirements and enhance the day-to-day operation of an ABSL-3 suite. This article provides a comprehensive overview of key QA program elements, along with practical suggestions for effective QA activities applicable in all ABSL-3 environments.

Establishing a Robust QA Program

A QA program must encompass many aspects of an ABSL-3 suite, including environmental parameters, equipment operation, staff knowledge/proficiency, SOP effectiveness, facility access, animal study proposal (ASP) review, occupational health requirements, and documentation.

Understanding the “whys” behind each practice conducted within the ABSL-3 suite allows the QA program to be tailored to each suite’s requirements. The individuals who perform QA must be knowledgeable of the ABSL-3 environment and the biohazards it contains, and capable of asking the proper questions. This brings proactive approaches to the forefront of operating the ABSL-3 facility, and ensures potential issues are noted and corrected before they engender a crisis. Therefore, facility- and position-specific training is a vital prerequisite for quality assurance.

There are several components that must be incorporated in an ABSL-3 QA program, including effective data collection and tracking; development, update, and evaluation of comprehensive SOPs; and regular reviews and observation to ensure that SOPs and best practices are consistently applied to operations.

Good data collection and tracking are critical to ensuring that occupational health requirements for each biohazardous agent are adhered to in an ABSL-3 environment. Achieving this hinges on complete and up to date information, consolidated from sources such as the biosafety office, occupational health specialist, and animal study proposals.

A database or spreadsheet must be developed and regularly reviewed/updated to capture the biohazardous agents and occupational health requirements for each animal study protocol. This helps ensure that managers and supervisors are aware of current safety and occupational health requirements for all animal care personnel and investigative staff. Similarly, the program must track inoculation requirements and due dates for all staff, since required vaccines have various administration schedules. Important information elements include:

- Each employee's name
- All occupational health requirements
- Frequency of occupational health requirements (e.g., pre-employment, yearly, semi-annually)
- Dates requirements were met

Procedural Development, Update, and Evaluation

Every ABSL-3 facility needs procedures and safeguards for access control to ensure that all personnel entering the suite are authorized users, receive proper safety training, and meet all occupational health requirements. Exit procedures are equally important; the QA team should evaluate the exit plan, and inspect emergency equipment packets for contents, expiration dates, and emergency instructions that are current, clear, and easily followed by the users.

Once these conditions are met, it is essential to ensure users can work safely within the ABSL-3 suite. The QA program must review elements such as signage that allow authorized users to adhere with established procedures and safety precautions. Effective signage reminds users of the required personnel protective equipment (PPE) to enter the suite, informs them of the biohazards within, and poses questions to force an automatic double-check of established procedures. Signs should be easy to follow, including pictures and bulleted text that outlines pertinent information.

When performing QA on the ante-rooms and donning area of the suite, the QA inspectors should challenge the posted processes. They should act as though they are new users and ensure it is possible to don the proper PPE and perform all necessary safety checks without prior knowledge, based solely on the posted instructions.

It is fairly straightforward to evaluate formal procedures. But how do you perform QA on actual practices to ensure that users consistently follow procedures? Documentation logs are one key, and must be designed with QA as an objective. Examples include user sign-in/sign-out logs to track all occupants of the suite at a given time; logs that track each Powered Air Purifying Respirator (PAPR) unit, including who is using the PAPR and acknowledgement that safety checks were performed; and logs that record when the facility checks PPE for sound operation. QA of the ante-room supply inventory is important to ensure no one is tempted to cut corners due to lack of equipment.

In addition to the general QA of animal and procedure rooms of a facility, the QA program within an ABSL-3 suite must include additional signage and more frequent environmental parameter checks. Signage within the suite must be detailed and ensure that all users entering each area are informed of additional PPE requirements and potential hazards for the animal or procedure room being entered. The QA inspection needs to challenge and review these additional PPE requirements and the procedures

listed at each animal and procedure room door with regard to the biohazards within the room. If additional disinfectant or PPE procedures are required, ready availability of the disinfectants and additional PPE supplies ensures that the requirements can be easily met.

Documentation within an ABSL-3 suite must be more frequent than in most laboratory environments, and rigorously accurate. For example, accurate airflow monitoring and records are essential, and should be completed daily. The airflow log must be in a user friendly format with no room for error or misinterpretation. It can be helpful to annotate the ABSL-3 suite's floor plan with arrows indicating the airflow at each point.

General documentation QA of the ABSL-3 suite should include inspection of biohazardous material labeling for animal caging, carcasses, tissues, and containment vessels. The labeling must be clear and concise to ensure there is no potential user misinterpretation. Documentation should include a daily animal census – including reporting of census fluctuations (e.g., animals received and euthanized) – and the QA team should review and evaluate them regularly as part of the overall inspection.

The QA team must also inspect all physical areas, including the presence and disposal of all sharp and glass items within the suite, ensuring these objects are limited and determining whether they could be replaced with plastic or dull implements. They should verify that the room is well organized, neat, and clutter-free, allowing users to move freely within the suite without risk of PPE damage or user injury.

Another area of concern is the removal of materials such as medical pathological waste, dirty caging, etc. The QA program must monitor these processes to ensure biohazard exposure will not occur, and the staff must inspect all areas in which materials could exit from inside the ABSL-3 suite.

Autoclave procedures play a key role with QA. It is important to be able to easily confirm that items have been properly autoclaved before leaving the suite, which can be accomplished through environmental QA. The assessment should include steam, pressure, and sterilization processes, and can be accomplished through daily QA monitoring utilizing steam integrators with each load and performing periodic vacuum and microbiological testing. The QA team should evaluate the documentation for these processes and monitor daily operation by ensuring that each autoclave load's steam integrator is attached to the autoclave print-out to indicate that sterilization occurred and autoclave time and temperature requirements were met. It is also important to inspect the preparation of equipment before it goes into the autoclave, such as verifying that water is placed in autoclave bags to generate steam for the sterilization process, and proper placement of steam integrator strips throughout the load to monitor surface temperature as well as temperature inside the caging.

Ensuring the knowledge and proficiency of employees working within the suite is a critical aspect of QA. It is essential to question employees on autoclave procedures (including why each procedure is in place) and have them demonstrate the processes themselves. This approach should be applied to QA for all procedures within the ABSL-3 suite; staff attention to detail and understanding of the "whys" behind each procedure help employees take more ownership of their job responsibilities and enhance quality and safety.

Conclusion

This article has provided a snapshot of general QA factors for a typical ABSL-3 suite. The actual QA program must be tailored and customized specifically for each suite to ensure procedures match the infrastructure and biohazards. Thorough QA inspections can be facilitated by developing a comprehensive series of check-off sheets for each area of the specific suite, including elements such as the following example for an ante-room:

Ante-room check off sheet

- Door signs and PPE requirements correct
- Sign-in and sign-out log properly utilized
- PAPR units plugged into battery charger when not in use
- HEPA filters in working order
- PAPR units signed out and tested for functional operation
- Biohazards listed on the door sign coincide with biohazards within the suite
- Supplies stocked
- All documentation reviewed

The key to effective QA is to consistently challenge the processes, perform rigorous inspections, follow up promptly on any deficiencies or potential issues, and continuously train and educate suite users. The ultimate goal is to prevent problems by identifying a potential hazard or risk, and take appropriate action before it becomes the source of a crisis or exposure.

A solid QA program will ensure the protection of individuals working within the ABSL-3 suite, as well as the safety of the greater community surrounding the facilities.

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