

Creating A Comprehensive Training Program

This paper summarizes the major points presented in the “Training and Certification Documentation – Tips and Ideas” session at the 2003 Laboratory Animal Welfare Training Exchange Conference by Dr. Pritt, Ms. Samalonis, and Ms. Bindley.

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As members of the laboratory animal science community, we are acutely aware of the need to provide accurate and adequate training to animal facility personnel. By providing training to staff members, we improve the level of research and animal welfare for the animals we care for. While several resources exist for training materials within the research community and many laboratory animal science regulatory bodies require training, little has been done to formerly address how to document the training.

For example, the *Guide for the Care and Use of Laboratory Animals* states, “...AWRs and the PHS Policy require institutions to ensure that people caring for or using animals are qualified to do so...” and “Personnel caring for animals should be appropriately trained...”¹. The *Education and Training in the Care and Use of Laboratory Animals* states, “...Regulations that implement the Animal Welfare Act specifically require that institutions provide training...”². However, these regulations do not provide a standard outline for training documentation.

When asked about what should be included in a facility’s training documentation program at an IACUC 101 session, representatives from the Public Health Service, the USDA, and AAALAC, International responded that they had no particular requirements for a training program except that the training and documentation program be consistent throughout an institution and that it document all relevant material³.

The Federal Drug Administration’s Good Laboratory Practice regulations covering preclinical testing of pharmaceuticals and medical devices presents a more comprehensive view of what to document while still leaving the specifics up to the institution. The regulations state “...Each individual engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions. Each testing facility shall maintain a current summary of training and experience and job description for each individual



engaged in or supervising the conduct of a nonclinical laboratory study...”⁴.

Other international regulatory bodies including the Organization for Economic Co-operation and Development and AAALAC, International, have guidelines requiring training for the individuals working with research animals, but again, do not impart specific details with respect to training documentation^{5,6}.

In essence, to demonstrate compliance to the various regulations and guidelines, a facility must document its training program as well as experience personnel have gathered prior to their current position and in any external training situations. Additionally, training documentation would be needed to enable IACUCs to effectively monitor animal care and use programs^{7,8}; meet continuing education requirements for laboratory animal technicians; help with employee performance reviews; meet the expectations of client or other audits (for contract labs or other similar organizations), regulatory inspectors, and organizational management;

help justify a training budget; and help the facility if legal situations involving training and/or animal use were to arise. As a special note to those in industry or contract laboratory situations, the need to demonstrate adequate, even above-average training is a necessity during client audits. Clients will many times base a decision on placing business with a specific facility

in part on employee training as demonstrated by the facility’s training documentation system. Maintaining a well-organized and easily accessible system can facilitate such reviews of employee training records and create a favorable impression on the auditors.

Basic areas to cover when creating a training documentation system or evaluating an existing one for improvement include determining which staff positions require training documentation, what system will be employed to document the training, who will maintain the documentation and who will have access the records. From a legal standpoint, all staff positions should have training documentation requirements. The level of documentation for each job type should be defined.

Positions

In “Creating a Training Coordinator Position”, Kennedy provides some basic employee positions that should have their training documented⁹. These positions include animal care providers, research and veterinary technicians, students with animal contact, interns, summer students, post-doctorates, visiting scientists, IACUC members¹⁰, administrative staff, and physical plant personnel⁹. Additionally, veterinarians, principle investigators, quality assurance personnel, and regulatory affairs personnel staff should be included.

Programs

The obvious answer is to document what you are currently doing. However, other references and ideas in the field should be incorporated to make a training program as comprehensive as possible. For example, GLP training documentation includes the experience of the individual. To truly document experience, training documentation would need to start before a person is hired. This would include documenting degrees, college transcripts if necessary, certifications, resumes/curriculum vitae, licenses, USDA accreditation for veterinarians, and DEA registrations. As part of an ongoing security program, verification of all or some of these items may be performed. Also, consider any research awareness or public relations training in your documentation program.



Documentation of the following subjects would be needed as part of an overall training program

- core laboratory animal modules for technical and non-technical staff
- company/facility policies and procedures
- orientation programs
- facility tours
- re-training
- in-house certifications
- species specific and procedure specific training¹¹
- GLP training
- other regulatory training (i.e. International Organization of Standards)
- Standard Operating Procedure training
- OSHA and other safety training including equipment and radiation training, ongoing external continuing education (i.e. AALAS seminars, research related sources)
- training materials read during the course of employment
- data handling
- project specific training
- buddy or one-on-one training
- bilingual training

Details to be included for didactic and other training include the title of the course, date or dates given, duration, outline and/or course abstract, qualifications of the instructor(s), and acknowledgement by the employee and employee's supervisor of training attendance. For standard classroom training courses, a sign-in sheet or other acknowledgement of training with a signature of the employee should be arranged.

Documentation Systems & Maintenance

The process of documenting and maintaining the documentation is again specific to an institution. Smaller institutions may find that maintaining paper records with a standard training program check-off list and paper attendance records in a file for each employee is sufficient. However, larger institutions with multiple locations and a combination of formal class, informal one-on-one, and online training programs may find computer-based systems, either purchased or developed in-house, easier to manage. In-house programs typically utilize database management or spreadsheet programs. An important decision with the implementation of any type of system is the determination of who will maintain and update the system. A Training Coordinator usually assumes those responsibilities⁹. In the absence of a Training Coordinator, other departments or individuals can successfully maintain the records. These positions include the IACUC (Chair, Coordinator, other member), Human Resources, Regulatory Affairs/Quality Assurance, Supervisors, Safety Office, employees, and others. Again, larger institutions will many times have parts of their training programs administered by different departments, with those departments maintaining the actual documentation. Ideally, a central location should be utilized to maintain a complete documentation of an employee's entire training record. The system should allow for accessibility of records in a timely manner to



accommodate unannounced regulatory inspections. As previously discussed, the system should maintain a consistent format throughout the institution³.

Documentation Access

Since an employee's training record contains specific information related to job performance, the record should be kept in a secure location and have limited access. An institutional system should be implemented to determine who has access to the information, and the employee should be made aware of who is able to view the training record. This is not only considerate, but may help in possible legal situations. Examples of individuals who would have access to the information would be IACUC members, human resources, managers and supervisors, attorneys, the FDA, the USDA, clients, and other inspectors.

Employee health-related information should be kept separate from training records. Such health-related information is considered confidential according to various laws and regulations.¹²

Training Effectiveness

As the *Education and Training in the Care and Use of Laboratory Animals* points out, the effectiveness of the training program should also be documented². This allows the employees to express their feelings about the program in order to provide guidance for future training². While informal verbal feedback should always be appreciated and encouraged, surveys will usually suffice². More comprehensive ways

More comprehensive ways to document the effectiveness of a training program may include quizzes and exams, progression in AALAS certification by employees, auditing by outside groups, and monitoring for trends and deficiencies in employee performance.

Also, an employee should never feel that they are being forced to sign-off on their training. They should always feel that they have been sufficiently training.

Conclusions

Several reasons exist to document training including regulatory oversight, IACUC or managerial mandates, and business concerns. While required, the details of training documentation are left up to institutions to determine on their own. A thorough examination of the regulations as well as other aspects of a training program can ensure that documentation is adequate and will help a facility maintain a high level of research and animal welfare. By answering and addressing basic questions about training documentation, a training program can be assured of its success in the long-run.

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