

[JALAS Committee Symposium 2]

Performance Standards and Defaults in the ILAR Guide 8th edition

CS2-1

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ILAR Guide is aiming at well-being of laboratory animals involved in research, testing and teaching. The balance between ethical and science-based practice is the basis of the Guide. ILAR believes that professional judgement supports the central notion of performance standards and avoids more stringent regulations.

Performance standards describe a desired outcome, provides flexibility in achieving the outcome by granting discretion to those responsible for managing the animal care and use program. However, developing and implementing performance standards are not easy compared to the engineering standard. The latter specifies a method, technology, or technique for achieving a desired outcome not allowing modification, whereas it is useful to establish a baseline and relatively easy in evaluating compliance.

To prevail the concept of the performance standard, the Guide describes recommendations such as minimum spaces, temperature and humidity,

ventilation, illumination and noise so that research institutions can develop their self-regulations using the recommendations as default standards. Personnel can take alternative strategies with the review of IACUC and the approval of Institutional Official. The latest edition of the Guide focused on the behavior and management of social spaces. It describes that single housing of social species should be the exception and judged based on experimental requirements or veterinary concerns about animal well-being.

The presenter will introduce some examples of performance standard-based institutional regulations in a breeder, a pharmaceutical company and a research institute. Also, she will refer to regulatory and advisory perspectives on performance standards. The policy of international assessment and accreditation bodies on the performance standards may be of interesting for audiences.

The Role, Responsibilities, and Duties of the Attending Veterinarian in the US Institutions

CS2-2

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In the US, the role of the attending veterinarian (AV) was first officially defined in animal welfare regulations in 1970. Since then, the role continually expanded, and the AV is now recognized to be the person responsible for the veterinary care program in the Guide for the Care and Use of Laboratory Animals, 8th ed., and the "well-being and clinical care of animals" in the AAALAC position statement. The AV is also responsible for provision of guidance to those involved in the care and use of animals including investigators, and guidance and oversight to the surgical programs and peri-operative care of animals.

Actual duties of the AV differ depending on multiple factors, such as the size of the program, number and type of species used, nature of experiments, and availability of resources. However, as a leader of the animal care and use program, the AV is expected to have skills and knowledge on all aspects

of the program, including but not limited to: clinical medicine, husbandry, facility management, regulatory requirements, research, training, and finances.

To fulfill above responsibilities and duties, AAALAC position statement notes that the AV should be provided with sufficient authority to make decisions and adequate resources. Collaborative attitude and strong leadership are essential qualifications for the AV. Additionally, training in clinical medicine is necessary for managing veterinary care program; thus, ACLAM board certification, or eligibility is strongly desired, or often required at institutions. Finally, true "passion" to ensure animal well-being is a requirement from institutions and the laboratory animal community. In this presentation, the AV's roles, responsibilities, duties, challenges and their approaches will be discussed, with examples from different institutions.

The Promotion of Self-Management of Animal Experimentation through External Validation and Authentication

CS2-3

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The purpose of external validation is to promote animal welfare based on the international principle of 3Rs and to enhance transparency of animal experimentation. In order to attain the goal, it is necessary for external organizations to validate animal care and use programs at each institution from the viewpoints of science and ethics, and its results should be disclosed. In Japan, it is stipulated in the “Guidelines for Proper Conduct of Animal Experiments” (Science Council of Japan, 2006) that external organizations should validate animal experimentation at each institution. In the “Basic Guidelines” established by the Ministry of Education, Culture, Sports, Science and Technology (MEXT), the Ministry of Health, Labor and Welfare (MHLW), and the Ministry of Agriculture, Forestry and Fisheries (MAFF), respectively, it is stipulated that the results of self-inspection and self-assessment of animal experimentation should be validated by external organizations. And also in the “The Standard for Care and Management of Laboratory Animals and Alleviation of Pain” (Ministry of the Environment, 2013), it is stipulated that each institution should undergo self-inspection and external validation as well as disclose the information about animal experimentation.

In Japan, there are three systems whereby institutions undergo external validation of animal experimentation: (1) The University Federation: This was started in 2009, and they perform evaluation of animal care and use programs including facility inspection, but do not offer accreditation. So far about 114 institutions

have been evaluated. (2) The Japan Health Sciences Foundation: Their activities were initiated in 2008 and they assess and accredit animal care and use programs and also perform facility inspection. So far about 117 institutions have been evaluated. (3) The Japanese Society for Laboratory Animal Resources: They started their activities in 2004. Initially, they had only reviewed animal care programs of laboratory animal breeding companies and given suggestions for improvement as needed. Thereafter, they started accreditation as well as assessment of laboratory animal care in 2013. They have so far accredited about 40 institutions. These three assessment and accreditation systems are not mutually exclusive, but there exist subtle differences among the three accreditation systems. In addition to above three domestic organizations, AAALAC International also performs assessment and accreditation of animal care and use programs here in Japan. It would be necessary to further enhance the coordination among the three domestic organizations.

It is urgently needed to train personnel in order to promote external validation of animal care and use programs. The Japanese Association for Laboratory Animal Science (JALAS) has recently launched an AMED’s National Bioresource Project “Training of Personnel for the Promotion of External Validation of Animal Experimentation”. It is expected that this Project will further promote external validation here in Japan.