Establishing a Culture of Care, Conscience, and Responsibility: Addressing the Improvement of Scientific Discovery and Animal Welfare Through Science-based Performance Standards

H. J. Klein and K. A. Bayne

Abstract

Science-based performance standards offer a viable means of reducing regulatory burden while ensuring that research animal welfare and high-quality research data are realized. Unlike rigid regulations, science-based performance standards evolve as new information becomes available, thereby allowing new discoveries to be implemented in a timely manner and in a way that more effectively benefits the animals and the science. The implementation of performance standards requires a well-coordinated institutional team composed of the administration, research staff, the institutional animal care and use committee, professional and technical animal care personnel, occupational health and safety staff, and physical plant staff. This animal program team is best supported in an institutional environment that reflects a culture of care, compliance, and responsibility. In such a culture, the professional judgment exercised by the team is well grounded in meeting the diverse needs of the program's customers, who include the animals, the researchers, and research stakeholders such as the public. The institutional culture of care, compliance, and responsibility fosters workplace integrity, an ethics-based decision-making paradigm, sound understanding of institutional expectations through good communication and clear lines of authority, the hiring and retention of trained and well-qualified individuals, and a system for continuous development and improvement of the program.

Key Words: animal welfare; culture of care; regulatory burden reduction; science-based performance standards

> "Animal science is about new discovery and knowledge, but is also about the international adoption and transfer of that knowledge to all aspects of human and animal life" (John P. Hearn, Ph.D., Chair, Committee on International Activities, Institute for Laboratory Animal Research (Hearn 1995, p. 55).

To facilitate the transfer of knowledge and advances in science that can be translated into benefits to humans and animals, the framework that supports and provides oversight of science must accommodate the intrinsically dynamic nature of science and its ever-evolving state. Science and the new knowledge gained from science are constantly advancing and changing. Information derived from scientific advances are verified and expanded upon through publication in the peer-reviewed scientific literature. The outcomes and progress of science will certainly be impeded if the regulation of science and the concomitant burdens placed on researchers and research administrators because of excessive albeit well-intended regulations occur. As Dr. Alan C. Rosenquist, Chair of the University of Pennsylvania Institutional Animal Care and Use Committee (IACUC[1]) has stated, "Let's regulate ourselves or someone with a ".gov" address will do it for us."

One strategy to prevent burdensome regulations is the development and implementation of a comprehensive program of animal care and use. Such a program involves an institutional team composed of the administration, research staff, animal care personnel, IACUC, occupational health and safety staff, and physical plant personnel, as well as the community at large (local, regional, national, and international). The program should be based on science, should be flexible, and should meet the needs of the scientists, the animals, and society. The success of this strategy depends on the use of performance standards in the implementation of the guidelines, policies, and regulations that pertain to animal-based research.

Our objective in this article is to make a case for the use of performance standards in creating and implementing regulations for animal-based research and to define a process for generating value to the customer. In this case, the "customer" is the combination of the animals, the scientists, and society. In addition, we suggest that the needs of these

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[1]Abbreviations used in this article: 3Rs, reduction, refinement, replacement; CTQ, critical to quality; DHHS, Department of Health and Human Services; *Guide*, *Guide for the Care and Use of Laboratory Animals*; GSK, GlaxoSmithKline; IACUC, institutional animal care and use committee; NIH, National Institutes of Health; ORI, Office of Research Integrity; RCR, responsible conduct of research; VOC, voice of the customer.

customers can best be addressed through the establishment of a culture of care, conscience, and responsibility for animal use within a research institution framework.

Implementing a Culture of Care

As noted several years ago by the National Academy of Sciences (IOM 1995), there is a changing relationship between science and society. The general public has expectations that research animals will be availed a high standard of care and use. Much of research is supported by public funds, and the public is the intended benefactor of most research. The case must be made that ethical costs do not outweigh societal benefits. This challenge is also well described by the following quotation:

> ". . . the gradual erosion of public confidence in researchers and the research process has resulted in questioning, from the public and Congress, about how human subjects in research are being protected, how institutions are handling financial conflicts of interest, how animal subjects are being treated, and how scientific misconduct can be discouraged" (Dempsey 2001).

A recent Gallup Poll indicates that 81% of Americans surveyed have the opinion that the nation's moral values are in decline (Foust 2006; Spencer 2006). We therefore believe that it is imperative to develop an institutional value system that creates public trust and instills confidence in institutional staff. We believe that such trust is established and sustained through honest dialogue with all stakeholders and by having in place a decision-making process that includes an ethical component to the decision-making process. Finally, we and others have reported that establishing an attitude of care in the institutional animal care and use program can augment the mutual trust relationships that are developed in the process (Bayne 2006; Gilman 2004; Ingham 2002; Klein 2004).

The implementation of an organizational culture of care is not unique to the animal research enterprise. Indeed, other industries and elements of society have implemented a culture of care to improve service or to address specific problems. One example is the Doubletree hotel chain's culture of care, which maintains that "the key to providing excellent and uncompromising levels is to develop relationships with customers . . . " (Doubletree 2006). Doubletree considers their "caring, attentive, responsive, and empowered" ("CARE") program to be the hallmark of "total quality service" (http://doubletree.hilton.com/en/dt/promotions/dt_care/index.jhtml;jsessionid=SNNZAPLZHDRYKCSGBIW2VCQKIYFCVUUC). A similar model has been described for use in the school system (Cavanagh 2004) following the Columbine tragedy. Cavanagh draws a distinction between a culture of control that is based on fear of making mistakes and fear of punishment versus a culture of care that is not based on controlling behavior but instead uses incidences of conflict or errors in procedure as learning opportunities.

The recommendation for a culture of care has extended into animal research worldwide. For example, in New Zealand, the National Animal Ethics Advisory Committee echoes this philosophy in their *A Culture of Care*: A G*uide for People Working with Animals in Research, Testing and Teaching* (NAEAC 2002). In addition, the pharmaceutical company sanofi-aventis has established a culture of care program to inform employees about the role of animal research in the discovery and development of drugs and in improving the patients' quality of life. The sanofi-aventis program publicly affirms the company's commitment to high standards of animal care and welfare and the subsequent production of reliable data (M.D. Kastello, Vice President, Global Laboratory Animal Science and Welfare, sanofi-aventis, personal communication, 2006). Similarly, GlaxoSmithKline (GSK[1]) and Merck Research Laboratories have made a corporate commitment to maintaining high standards in research animal welfare through implementation of reduction, refinement, and replacement (the 3Rs[1]; Russell and Bruch 1959) and other programs such as the Animal Welfare Awards given to employees who develop strategies to effectively implement the 3Rs. GSK publishes a Corporate Responsibility Report, which details these achievements (GlaxoSmithKline 2005).

Implementing a Paradigm Shift away from Regulatory Burden

Research and development spending in the United States and abroad for the private sector totaled more than $39.4 billion in 2005. In response, the pharmaceutical, biotechnology, and academic/public health sectors have recently devoted considerable attention to determining the increasing cost of biomedical research. When considered along with the research and development expenditures of the US National Institutes of Health (NIH[1]) in 2005 (> $28 billion), the total expenditure in 2005 was more than $60 billion worldwide (PhRMA 2006)—a 6.5% increase over 2004 expenditures. This level of research investment on the part of the public, in a worldwide global economy, has led to expectations of a shorter period for product development and a higher yield of medicines and vaccines to address unmet medical needs more efficiently now than ever before. More recently, however, the NIH budget has not been funded at hoped-for levels; yet grant submissions have continued to escalate due in part to the congressional commitment to double the NIH budget over the 5-yr period of 1999 to 2004 with the resulting higher level of grant funding during this period. In Figure 1, the projected limited funding for biomedical research for the foreseeable future is illustrated (Waltz 2006). In contrast, the rising trajectory of expenditures for conducting medical research is demonstrated in Figure 2. This collision of increased need and fewer available funds emphasizes the need to optimize the use of lim-

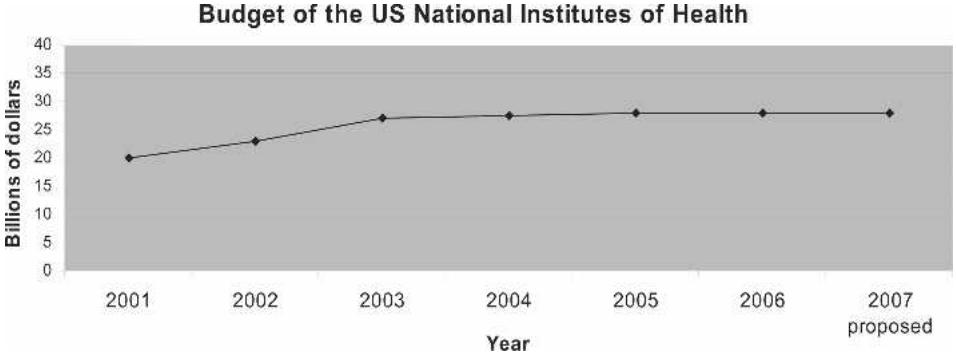

Figure 1 A significant investment has been made by the public in biomedical research, as exemplified by the National Institutes of Health budget. Reprinted by permission from Macmillan Publishers Ltd: Nature Med 12:259. Waltz E. 2006. Biomedical research faces bleak budgets.

ited resources, including those intrinsic to animal-based research.

The challenge, then, is to have a regulatory environment for animal research that is based on scientific data concerning ways to improve animal welfare that also enhances science and the public good, does not burden the cost structure of the institution or waste the public's money, and provides legitimate benefit to the animals. The literature is replete with examples in which the control of variables in an animal's environment has been essential to reproducing research (e.g., Bayne 2005; Crabbe et al. 1999). Without such control, the research is either invalidated or not reproducible, hence wasting the resources to conduct the studies or, more importantly, the animals themselves. Performance standards provide the flexibility to use science in this manner by seeking outcomes rather than stipulating the use of arbitrary and unproven processes. Hence, guidelines and regulations that provide a framework and outcome goals are a more cost-effective and beneficial way to improve animal welfare and enhance scientific productivity.

The regulatory burdens that face the research community have been clearly articulated in the recent report by Mahoney (1999). All research, and especially animal research, is affected by this challenge. The assessment of regulatory burden contained in the Mahoney report was conducted by the NIH in response to a 1998 request from the House Committee on Appropriations to "streamline and rationalize duplicative and unnecessary Federal regulations which govern the conduct of extramural scientific research." The report examined the following five specific areas: financial conflict of interest, research integrity, human subjects' protection, animal care and use, and hazardous waste disposal. In the report, "regulatory burden" is defined as "any aspect of a Federal legislation, regulation, or policy, or

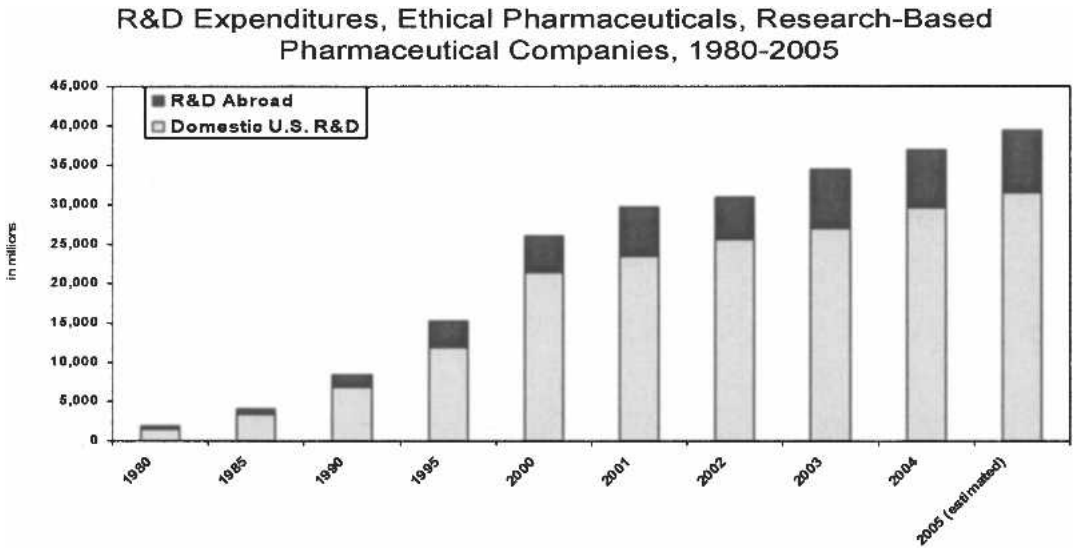

Figure 2 Biomedical research faces a weak budget. Adapted from Pharmaceutical Industry Profile 2006, Table 1, p 44. Washington DC: Pharmaceutical Research and Manufacturers of America (PhRMA). Available online (www.phrma.org/publications).

Federal/research institution practices that can be made more efficient without diminishing the intended level of protections." Some of the factors associated with regulatory burden include regulations that emphasize processes that often limit flexibility without enhancing results and the concern that multiple agencies (e.g., US Department of Agriculture, Food and Drug Administration, Environmental Protection Agency, Nuclear Regulatory Commission, and the Occupational Safety and Health Administration) potentially impose inconsistent and redundant requirements. Furthermore, the regulation of science has often resulted in additional burden to the research community, although it is now agreed that better communication among oversight agencies can help to reduce regulatory burden (NIH 2002, 2006).

Moving from Noncompliance to a Culture of Conscience

The Department of Health and Human Services (DHHS[1]) Office of Research Integrity (ORI[1]) oversees and directs activities within the DHHS to promote the responsible conduct of research (RCR[1]). The ORI promotes RCR by developing policy, monitoring research misconduct investigations, and providing educational resources regarding both human and animal research. RCR resources for research animal welfare can be found on the ORI's Web site (http://ori.dhhs.gov/). A 2004 review of research misconduct reported from 1992 to 2001 (Rhoades 2004) highlights several key points that illustrate the critical need for institutions to embrace a culture of conscience. The report specifically notes that the number of institutions that conducted investigations into allegations of research misconduct has increased "steadily, and is expected to continue to do so."

Of the institutions that reported incidences of misconduct, 89% can be classified into the following three categories: higher education (61%), research organizations (17%), and independent hospitals (11%). Institutions in these three categories made up 90% of the research misconduct findings. Fortunately, most allegations were not upheld; however, 248 institutions initiated investigations into 703 cases. Of these, 110 (44.3%) confirmed instances of research misconduct were reported by 76 (10.8%) institutions. Falsification of information was the most frequently reported allegation. Notably, more than half of the reported research misconduct occurred in the top 75 funded institutions.

Reports on research integrity by the National Academies of Science (IOM 1995, 2002) also underscore the need for integrity in research, including animal subjects. These reports have confirmed that leadership at the institutional level must be accountable and responsible for the integrity of new information generated from its research programs. Potential causes of noncompliance should be recognized by the institution and steps should be taken to prevent their occurrence. Examples of causes of noncompliance include the following: a lack of institutional commitment; inadequate resources (funding, personnel, and time); an Institutional Official who is not adequately empowered to address identified problems; inconsistencies in procedures between the centralized animal resource and satellite facilities; unclear lines of authority; and inadequate systems of oversight of the program. Allowing such institutional flaws to persist or inadequately addressing noncompliance can result in a loss of public trust not only in the institution but also in the research enterprise, in increased regulatory burden, in increased costs to conduct research, or in delays in accomplishing research goals. It is critically important for authorities to investigate incidences of noncompliance to determine whether the noncompliance was an honest error in procedure due to a lack of understanding, a case of inadequate training or lack of attention to detail, or a simple disregard for the rules.

Instilling a Culture of Responsibility in the Institution

A key way to minimize the occurrence of noncompliance is to ensure that the institutional team (administration, IACUC, researchers, veterinarian(s), environmental health and safety office, facilities maintenance staff, and others) are working in a coordinated manner and have a common goal of a high quality program. (Ingham et al. 2002) The Institutional Official should be both well informed about and engaged in the program, and should provide "sustained and visible support" (DHHS 1988). The IACUC should clearly articulate policies and procedures so that everyone understands the institutional expectations. Policies should be implemented using scientifically sound, performance-based standards. There should be an interface between the animal program and other key institutional components such as the Environmental Health and Safety office. The institution should establish and support effective internal training programs, and the institution should engage in outreach to assure the public of quality animal care and use. The veterinarian and animal care staff should work in concert and as a partner with the IACUC and investigators, should ensure adequate care of the animals, and should exercise professional judgment to facilitate the science in the context of animal welfare. Signs indicating that the institution does not have a functioning team include the following: (1) one person bears most of the responsibility for the program; (2) there is a sense that it is simply "easier" if one person at the institution handles the program; (3) there is evidence that other individuals involved in the program (e.g., animal users, physical plant staff) either are not knowledgeable about the program or are simply not interested in it; and (4) there is a lack of an institutional policy for "zero tolerance" for noncompliance.

Although recent polls indicate that the majority of Americans support animal research (Foust 2006; McGinn Group 2005), one sector of the public presents a serious

detractor to the animal research enterprise. Specifically, actions by extremists against institutions conducting research have been costly in terms of animal life, research progress, and steps taken by institutions to protect their animal use programs from terrorist attacks (e.g., through increased security). A strong research program and a well-developed animal care and use program are predicated on performance standards that are based on a culture of ethical conscience and responsibility, on science, and on a commitment to compliance with applicable standards. It is apparent that simple assurances from the research community are insufficient in engendering the public's trust that research is done responsibly. However, we believe that open communication with both internal and external constituents, sound training programs, a top-down institutional attitude of caring and conscience, and being accountable will protect and preserve the privilege to conduct research with animals and demonstrate to the public that responsible animal-based research is compatible with societal values.

Determination of the Value Proposition to Science and to Animal Welfare

The research community has been presented with the difficult challenge of defining the true value and benefit of using performance standards based on science versus using prescriptive engineering standards. Although prescriptive engineering standards are often clear cut, they are adynamic or static; and it is not always possible to apply those standards to the multiple and complex scenarios that are often encountered in biomedical research. The complexity of animal-based biomedical research is amplified by the variety of species, the type or areas of research (e.g., pharmacology, neuroscience, oncology, and infectious disease), the facilities, the equipment, and the level of knowledge and training of personnel who are involved.

The question of whether to use a performance standards approach to compliance instead of engineering standards has been difficult for either the performance standards advocates or the engineering standards advocates to answer. Both approaches have the potential to provide "value" to the animals, the scientific community, and the public; however, the difficulty lies in making that determination of value objectively and using the same methodology.

The process that is outlined below is used by the business community in determining value and the value proposition as it relates to a particular business problem (Curtis 2006; George et al. 2005; Reidenback 2006). We believe that this methodology may prove useful in making comparisons for animal research. By determining the value that performance standards have over engineering standards as a result of creating more objective measures (qualitatively and quantitatively) using the same process, it becomes possible to create a more meaningful comparison in the context of animal-based biomedical research.

Critical to Quality (CTQ[1]) Needs

The methodology defining what is known as "Critical to Quality Needs" is a customer-based value analysis process that identifies customers and the factors they deem critical to quality. In the first stage of the value analysis, it is necessary to define the "customers" because it is they who identify the factors that are CTQ in the determination of value (or benefit). As mentioned above, we believe that the "customer" in this context is an integrated combination of the animals, the scientists, and society. The customers such as the scientists or the public may define the value or benefits of animal research in a straightforward way because they are able to articulate or explain what is critical to quality or has maximal value from their perspective. However, the other customers—the animals—do not have that ability. Thus, when the animals are viewed as the customers in the research process, it becomes much more challenging to define value or what is critical to quality from their perspective.

The next stage of the value analysis process defines customer needs (what is important) and wants (how the result is achieved). Customer needs and wants can be translated into specific and measurable requirements that are critical to determining value. It is possible to create a matrix that ranks or weights a want and a need based on each customer's perspective. By scoring each need versus want (usually on a 1-5 basis), a ranking or weighting can be performed for each desired outcome (i.e., performance standard or engineering standard). To determine the value wanted by specific customers, one can use scientific outcomes with measurable benefits to the public. Examples of value wanted by specific customers include new medicines and vaccines, reduction of pain or distress, lower numbers of animal used for a research procedure, and an increased number of data points gathered per animal. In terms of the process, these requirements can be translated to a needs statement so that once the needs are identified, it will be possible to begin measuring them through determination of the CTQ requirements. Once the most highly ranked or scored wants and needs are identified through creation of a weighted matrix, it will be possible to identify the key elements that are critical to quality in the value analysis. In general terms, they are described as an output, a y metric, a target (result expected), and a specification or tolerance limit. A schematic example of a "critical to quality" analysis using environmental enrichment for any given animal species is shown in Figure 3.

By using the process described above—identifying those elements that are needs ("whats") and wants ("how") from the perspective of the customer ranking, and generating a CTQ analysis for each of these elements—it is possible to perform an overall value analysis. This analysis will allow an objective comparison of the outcomes derived from either performance-based standards or engineering standards for animal-based biomedical research.

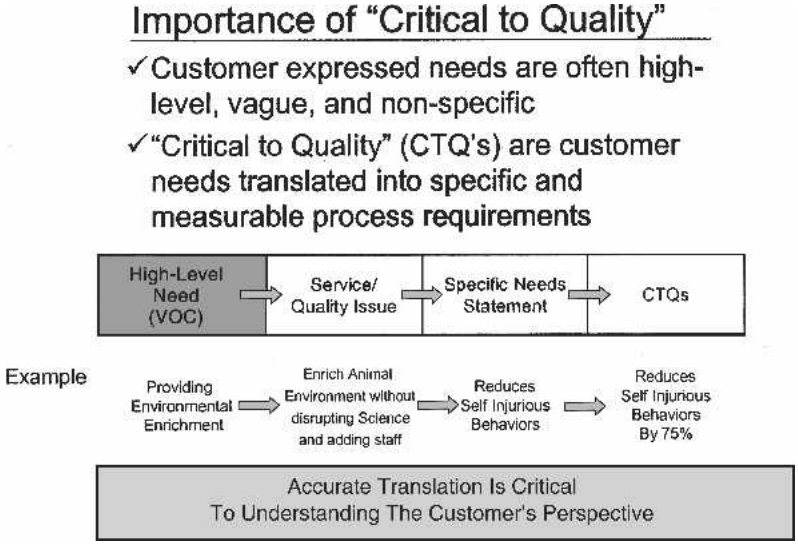

Figure 3 The process of defining "Critical to Quality" using environmental enrichment as an example.

Voice of the Customer (VOC[1])

By using the VOC process, it is possible to generate data that can then be used in the following contexts: for validation and reproduction, for scrutiny under peer review, and for help in settling the argument of whether performance standards have more or less value in the eyes of all customers compared with engineering standards. These data may also be used to help resolve arguments, encourage debate, and set forward-looking direction to improve animal welfare and scientific progress, especially when performance standards are employed. An example of translating VOC needs into specific requirements is shown in Figure 4.

Use of Performance Standards to Frame Institutional Culture

The term "performance standard" was first introduced to the laboratory animal science community in the seventh edition

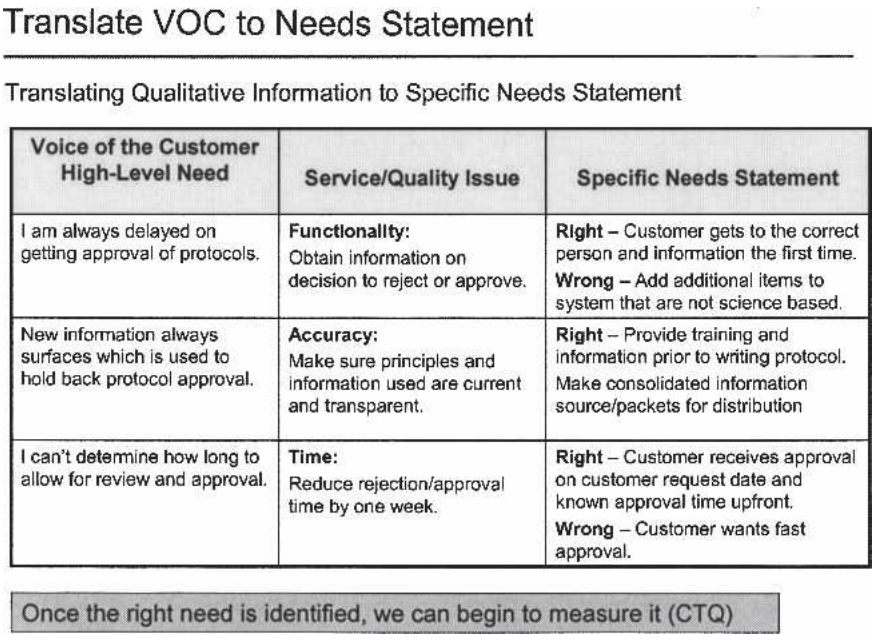

Figure 4 An example of translating the voice of the customer (VOC) into specific requirements using institutional animal care and use (IACUC) protocol review as an example. CTQ, critical to quality.

of the *Guide for the Care and Use of Laboratory Animals* (*Guide*[1]) (NRC 1996). The six preceding editions of the *Guide* had modeled the same approach but had not specifically used the new term. As opposed to more inflexible engineering standards, performance standards are predicated on sound professional judgment, and they facilitate science through an outcome-driven approach, rather than using prescribed processes that are difficult to define or rigid standards that may not fit each institution's circumstances. Performance standards provide criteria for assessing the desired outcome but do not limit the methods by which to achieve that outcome. However, the successful application of performance standards requires that IACUCs, veterinarians, research scientists, and animal producers utilize sound professional judgment in making specific decisions regarding the animal care and use program (see NRC 2004). Standards must be applied in a harmonized and cohesive manner by the various institutional representatives that have responsibility for different aspects of the program. Clearly, science-based references such as the following are central to defining the foundation for the use of professional judgment and the implementation and interpretation of guidelines and standards: the *Guide* (NRC 1996); Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations, and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (Directive 86/609EEC 1986); the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes (ETS 123 1986); national legislation and other science-based resources (e.g., the AVMA's 2000 Report of the Panel on Euthanasia [AVMA 2001]; pertinent issues of *ILAR Journal*; and AAALAC International's list of Reference Resources, which it uses for a science-based performance approach to its animal care and use accreditation program [AAALAC 2006]).

The application of performance standards should include a mechanism to audit and evaluate whether the institution continues to conform to appropriate policies and regulations while providing the scaffolding for quality science and animal welfare. One way to conduct this audit is to ensure sound internal methods of oversight such as through the IACUC (Ingham et al. 2000) or self-directed audits conducted by internal committees or panels of experts, as well as by external methods, such as audits by the International Organization for Standardization ("ISO") or accreditation by AAALAC International. Although IACUC members may formulate position statements, institutional policies, and guidelines that may be above and beyond those promulgated by the government agencies, AAALAC International, as an example, does not formulate additional policies. Rather, AAALAC International relies on the scientific literature to augment the recommendations of the *Guide* and federal requirements.

To ensure that performance standards are clearly understood by all involved parties at the institutional level, it is important to employ effective and efficient tools for communication. These tools may include but should not be limited to meetings, seminars, surveys, outreach activities, electronic bulletins, and various forms of training, and should also make reference material available to those who would benefit. Surveys and retrospective reviews have been particularly useful tools for objectively determining whether an outreach or training program for animal-based research has been implemented effectively (Ingham 2003; Ingham et al. 2000). Because scientific standards and information are used to define them, one clear advantage of performance standards is that, by definition, they evolve and are refined as new information about animal biology, laboratory animal science, and laboratory animal medicine is discovered.

Strategies and tactical approaches to developing an institutional culture that uses performance standards create an environment that facilitates the conduct of high-quality animal-based research. One major success strategy that has been used by many institutions has been to link program needs and structure to sound institutional policies for occupational health and safety, veterinary care, and the operation of the IACUC, as well as to inform and involve administrative leaders within the institution and other key personnel who are customers or stakeholders. These individuals form a team that works together to provide oversight, thereby ensuring a responsible and effective program. For some institutions, this approach may seem easy; however, transitioning institutional oversight from a system based on rigid and strict processes to one based on outcomes (i.e., performance standards) has intrinsic challenges. The following four elements, which are described below briefly, are key to an effective strategy: (1) organizational commitment to the animal program, (2) communication of expectations, (3) collection and use of objective data, and (4) implementation of effective training programs.

Element #1: Organizational Commitment to the Animal Program

The upper administration's recognition of the importance and necessary empowerment of the IACUC and the other animal program team members (e.g., the veterinary care team, the occupational health and safety team, and the training team) is a crucial first step toward establishing its visible support for the animal research program. The desired strength of the organization's commitment to the animal program may require educating the administration about the activities and value of the program, and conveying information about external forces that may have an impact on the program.

Element #2: Communication of Expectations

It is critically important to clearly delineate the strategy that the institution will use and to define the rules and roles of

the team members who will work together to provide effective oversight. Each individual or group is charged with the responsible conduct of a functional or programmatic component and is held accountable to deliver on a previously agreed-upon set of objectives. These deliverables and objectives are often defined and shaped by the customers at the institution (e.g., the researchers, animals) or by the public.

Element #3: Collection and Use of Objective Data

Institutional responsibility for conducting an assessment of the animal care and use program should be based in part on observations that will then be used to further define and improve the program. To ensure success, we recommend creating complete and well-organized documentation and a data collection infrastructure to accurately record and utilize this information. These data can then be used to provide valid and timely information as requested by different interested parties, whether they are internal institutional components, regulatory agencies, or the public. Surveys and Value Determination are examples of ways to obtain objective data effectively (Ingham 2003; Ingham et al. 2000).

Element #4: Implementation of Effective Training Programs

The institution must develop and implement a sound training program that is offered at defined intervals. The program should fulfill the following objectives: to encompass a variety of staff, students, and visiting scientists who are affiliated with the program; to be tailored to meet the responsibilities of all of these different individuals; and to provide frequent and/or regular updates on changes in the program.

Other strategies such as assessing oversight processes for errors (e.g., surveys to look at error reduction of protocol review) and developing process maps for robust improvements are excellent tools that can be used by an institution to further define the quality. This information should be made available to and be reviewed by key institutional representatives to determine whether the program conforms to the established standards of animal care and use.

Summary and Conclusions

A culture of care, conscience, and responsibility relies on the establishment of an effective program of self-monitoring. This process entails building a trust relationship with oversight bodies (e.g., US Department of Agriculture, Office of Laboratory Animal Welfare, and AAALAC International); the application of sound ethical principles, which will ensure an appropriate level of resources for the program; and establishing and sustaining an appropriate institutional organization that includes vigilant monitoring of the program. We believe it will be helpful to conduct a gap analysis to define currently available resources and to identify those areas in the program that need additional buttressing to ensure that program weaknesses are corrected in a prioritized manner. We also recommend strong leadership of the institution, which provides vision and direction to the program; establishing an institutional attitude that every person bears ownership of the program; and developing action plans that are achievable, are measurable, and provide feedback to allow adjustment of the plan.

The recognition of successful outcomes may be based on thorough analysis of data, rational conclusions, and working together in a team-like manner. Ultimately, we believe that the hallmarks of a strong framework for a culture of care, conscience, and responsibility will include the following important components: the use of performance standards, science-based standards, and analysis of value and value propositions; solid mechanisms for continuous development improvement methods; and an overarching endeavor to provide for animal welfare and high-quality science.

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