

Letters to the Editor

Is it Time to Redefine “Major Operative Procedures?”

Dear Editor,

I read with interest the Editorial entitled, *Is it Time to Redefine “Major Operative Procedures?”*³ As one who has been involved in the regulatory process for over 30 y, my answer would be no. I believe that the current definition is straightforward and allows those who have expertise in various surgical methodologies to use their professional judgment to properly classify operative procedures as either major or minor. If IACUCs are grappling with this definition, I do not think that a reevaluation of the current definition is the approach to take. I believe a better approach for minimizing confusion is to have individuals with the appropriate expertise prepare a definitive guideline; not to change the existing definition. Groups such as the Academy of Surgical Research, the American College of Laboratory Animal Medicine, the American Society of Laboratory Animal Practitioners, and the Association for Primate Veterinarians have the expertise to develop such guidelines and AALAS could serve as the facilitator for such a process. Those who participate in formulating such guidelines should do so with knowledge of the regulatory history that led to the current definition.

Knowledge of a current rule’s regulatory history is important because it helps us understand the concerns of the research community at the time a rule was proposed and the thinking of the federal agency in developing the Final Rule. When an IACUC attempts to classify an operative procedure as major or minor, this knowledge could help it put things in perspective and make the proper classification. On p 36, 116 of the 31 August 1989 *Federal Register*,² the USDA reported they had received 193 comments from the research community concerning their proposed definition of “major operative experiment” and as a result of those comments revised the definition. In so doing they explained,

...we stated that the potential for causing physical disability would be sufficient to consider an experiment to be within the proposed definition, and that we were not concerned with the intended effect of the principal investigator in performing the experiment. Upon further consideration of the comments we received, we have determined that determining whether a procedure is a major operative procedure can best be done retrospectively rather than prospectively, and that doing so will satisfy the Act’s prohibition against using an animal in a second major operative experiment. It is clear from a research proposal whether the research will involve surgical intervention that penetrates and exposes a body cavity. However, the permanent effects of the procedures can best be determined afterwards.²

The alternative approach suggested in the editorial is in effect developing a definition that is based upon the expectations of what a procedure might produce and is, in my opinion, far more subjective than the current definition. In fact, during the rule making process that led to the current definition, the USDA stated, “The intended effect in performing a procedure cannot be relied upon to determine whether a procedure should be termed “major” or “minor” since the effect may or may not be accomplished.”¹ Thus, the USDA anticipated that the postoperative effects of the procedure should be considered in classifying the procedure as minor or major.

I would recommend that in developing the guidelines suggested above we consider the current definition to consist of 2

parts. First, does the procedure penetrate and expose a body cavity? If the answer to this is yes, the procedure should be considered a major operative procedure. Second, if the procedure does not penetrate and expose a body cavity, then the animal should be evaluated after the procedure to determine if it produced any permanent impairment of physical or physiological functions. If the answer to this is yes, the procedure should be considered a major operative procedure. However, if the answers to both question are no, the procedure should be classified as a minor procedure.

Thank you for the opportunity to comment on the editorial and should AALAS elect to facilitate the development of the guidelines proposed above, I would be glad to participate in that process.

Sincerely yours,
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References

1. **Animal and Plant Health Inspection Service.** 1989. Docket no. 88-013. 54 FR §10827.
2. **Final Rules: Animal Welfare.** 1989. 9 CFR Parts 1 and 2. (54 FR 36112-36163).
3. **Yates B, Toth L.** 2010. Is it time to redefine “major operative procedures?” *J Am Assoc Lab Anim Sci* 49:8.

Response to Dr Bennett’s Letter to the Editor:

Dr Bennett’s letter addressing our editorial⁴ raises a number of interesting points. We agree that an operative procedure can often be easier to classify as major or minor based on the outcome. We also agree that procedures producing a broad opening of a body cavity that is subsequently penetrated (for example, an abdominal surgery requiring a large incision) should be classified as a major operative procedure. Dr Bennett did not object to the major tenet of our article: that an overly-conservative definition of what constitutes a “major operative procedure” contradicts the principle of reduction because it can result in an overall increase in the number of animals required for biomedical research. Animals used in surgical studies that do not require euthanasia as part of the study design may nonetheless undergo euthanasia due to regulatory limitations on future use, rather than to meet either scientific or humane objectives. In our experience, this situation is particularly common with, but by no means exclusive to, animals subject to regulation under the *Animal Welfare Act*.² Our position is that minimizing animal pain and distress should be pursued in balance with the complementary objective of limiting the number of animals used in experimentation. The comments received by the United States Department of Agriculture (USDA) in response to its 1989 query in the *Federal Register* suggest that the research community broadly holds the same viewpoint.¹

Dr Bennett claims that the current definition of a major operative procedure is sound because an IACUC and the regulatory community can easily understand what is meant by “any surgical intervention that penetrates and exposes a body cavity.” We agree with allowing individual IACUCs to develop internal policies and assess individual protocols to determine whether any particular procedure “exposes a body cavity.” The Office of Laboratory Animal Welfare (OLAW) of the National Institutes of Health recently expressed a similar opinion as a response to frequently asked questions: “OLAW recognizes the authority of the IACUC to determine whether specific manipulations used in