The Society of Toxicology’s 1977 Actions on Laboratory Accreditation, Professional Certification, and Good Laboratory Practices in Toxicology

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For several years in the mid-1970s, the Society of Toxicology (SOT) had been studying the feasibility of accrediting toxicology laboratories and/or certifying the competency of individual toxicologists. Committee discussions were held, reports were issued in 1973 and 1974, and a proposal was developed by the spring of 1976. At the annual SOT business meeting in March 1976, the membership voted to establish a committee specifically to deal with the problems involved in accreditation and certification, with the mandate that it develop solid models for membership approval and implementation in these areas.

President Robert A. Scala appointed me to chair a Council committee dealing with these issues. Shortly thereafter, because of widespread concern, the Council requested that the Society develop guidelines for conducting toxicologic studies under good laboratory practices. This responsibility was added to the duties of the existing committee dealing with accreditation and certification, and resulted in the formation of a Council Committee on Accreditation, Certification, and Good Laboratory Practices in Toxicology.

The interrelationship of the three areas to be reviewed made practical their inclusion in a single committee. However, the impossibility of having one committee deal adequately with the details of each area resulted in the establishment of three separate subcommittees: Accreditation of Toxicology Facilities, Certification of Professionals in Toxicology, and Good Laboratory Practices in Toxicology. It was felt that the most expert and widely representative individuals in the Society should be called upon to serve on these subcommittees. Hence, a list of highly qualified, select individuals from within the membership was developed, and subcommittees were established granting equal representation to industry-commercial toxicology, government-regulatory affairs, and research-academia positions. Enthusiastic and experienced individuals provided leadership for each subcommittee.

Council determined that the overall committee should be given every opportunity to function efficiently and rapidly, and thus provided financial support and a target date of December 6, 1976 for the final reports. This allowed time for review by Council and submission to the membership in order to permit sufficient discussion and action at the March 1977 annual meeting. The subcommittees were organized and initiated during the late summer and early fall of 1976, and each member was provided with specific charges and copies of all documents relevant to the area under consideration. A meeting of the subcommittee chairpersons, FDA-EPA scientists, and myself was held August 31 in Rockville, Maryland, to provide interaction between the Society and the agencies. A working meeting of all subcommittees was then held during the week of September 20, 1976, at Kansas State University, Manhattan, Kansas, to develop the initial documents that would comprise the final report.

The draft documents were circulated to all members of the subcommittees and to Council for review and suggested changes. The subcommittee chairmen developed the documents into the final report, which was forwarded to President Scala on December 3, 1976. The document was reproduced by the then Office of the Executive Secretary and distributed to all members of the Society.

At the SOT annual business meeting in March 1977, the report and the recommendations of the various subcommittees were reviewed. Since many members at that meeting indicated they were unfamiliar with the report or had not received it, President Scala withheld action at that time. Comments on the various proposals were solicited from the membership and reconsideration of the report was proposed.

Concern with the educational aspects of the certification proposal prompted involvement of the Education Committee, and a special meeting of the Subcommittee on Certification of Professionals in Toxicology and members of the Education Committee was held in Kansas City, Missouri, April 27 and 28, 1977. The certification proposal was reviewed extensively at that time, with careful consideration of all the members’ comments made to the subcommittee. The Education Committee attacked the problems of defining the scope of toxicology, outlining the scientific training implicit in the education of a toxicologist, and planning for the possibility of continuing education activities so that toxicologists could maintain competence, following completion of formal ed-
ucation programs. The subcommittees on accreditation of toxicology facilities and good laboratory practices in toxicology informally reviewed their reports, and duly considered comments received, modifications, and drafts of the original reports. The Education Committee then developed a new, modified report in the late spring and summer of 1977.

Suggestions from the membership, the past presidents, and Council indicated the need for membership reaction to the finally distributed reports. Accordingly, a questionnaire-ballot was prepared by the Council of Past Presidents and the subcommittee chairmen to permit individual member reaction to the report. The questionnaire-ballot and the subcommittee reports were retyped, prefaced with a table of contents, an introduction, and a summary of individual subcommittee activities and reports, to facilitate ease in membership handling and readability. This summary report and the complete reports of the subcommittees were then distributed by the Executive Secretary to the Society membership for approval in October, 1977.

In the introduction to that report, as Chairman of the SOT Committee on Accreditation, Certification, and Good Laboratory Practices in Toxicology, I presented the report and its call for action to the membership with this admonition: “Each of the members of the subcommittees has given conscientious and deep thought to each item in the report. It is hoped that the Society members will use equal consideration and judgment in evaluating and reacting to the comments and recommendations made by each expert body. The decisions and direction (or lack of it) generated by this report will affect our profession and each one of us for many years to come. The ultimate effect will be determined by your response during these next weeks” (F. W. Oehme, 1977, Report of the Society of Toxicology Council’s Committee on Accreditation, Certification, and Good Laboratory Practices in Toxicology).

The rest is history, as the recommendations of each subcommittee were overwhelmingly approved by the membership. The resulting Toxicology Laboratory Accreditation Board made a significant impact on the quality of toxicology testing facilities during its span of influence, while the American Board of Toxicology began its highly successful and influential course of providing a statement of expertise as a peer-driven certifying body for professionals in toxicology.

Subcommittee on Accreditation and Toxicology Facilities

This subcommittee evaluated types of facilities currently in use in conducting toxicity investigations (including drug trials, biochemical studies, and other research in industry, academia, and government institutions), and made recommendations and adopted guidelines for adequately performing scientifically valid studies. Included were the review of structural plans, laboratory facility organization, animal care facilities, ventilation, safety features, floor space, instrumentation, and the presence of necessary physical items. Standards, guidelines, and recommendations on how these items should be evaluated were developed. Accreditation or inspection programs for toxicology facilities were considered and mechanisms offered.

This subcommittee was composed of the following individuals: Robert T. Drew, Chairman; Daniel Couri; William D’Aguanno; Harry W. Hays; Theodore O. King; Gordon W. Newell; Jerry M. Smith; and Robert Snyder.

Their report recognized the need for accreditation of toxicology facilities was not new. Comments about the credibility of laboratories conducting toxicity investigations had appeared in scientific communications, and public and regulatory notices of potential problems in laboratories had produced considerable controversy. The accreditation of facilities was an important factor in maintaining public confidence in laboratory test results. The report reviewed and provided guidelines for the physical facilities that should be available in toxicology laboratories, and offered comments on equipment, animal care facilities, administrative procedures, and accreditation mechanisms. It recommended that the utilization of AAALAC accreditation for animal care facilities be employed, where applicable, as an important part of overall laboratory accreditation. Although guidelines were provided for general use, the report recognized that there is no substitute for scientific judgment and that certain types of laboratories and testing procedures may require unique facilities and techniques. However, it specified that laboratories should be required to keep up with the state of the art, and recommended an inspection-accreditation procedure to assure and to document the maintenance of high quality standards by toxicology testing laboratories.

This subcommittee recommended the establishment of an Accreditation Board for Toxicology Facilities, and asked membership response in the questionnaire-ballot. It suggested that the Society recognize the need for a mechanism for the accreditation of laboratory facilities and, therefore, that it should create an organization for the purpose of establishing the specific details of such an accreditation procedure. The organization was expected to recognize the basic principles as submitted in the detailed subcommittee reports, but could alter them as deemed appropriate. It was felt that a demonstration model could precede establishment of such an accrediting body, and that membership would have ample opportunity to comment on specific details as they were developed. Before commitment to eventual establishment of an accreditation body for toxicologist facilities, it recommended that the Society establish a group to demonstrate a working model for accreditation. After several trial accreditation exercises, the committee expected to report their results to the membership for further consideration.

Subcommittee on Good Laboratory Practices in Toxicology

This subcommittee reviewed the existing practices in laboratories dealing with toxicologic studies (research, industrial, or academic) and developed recommendations, guidelines, and standards on how toxicology procedures and activities should be organized and conducted to yield meaningful results. Past experience with difficulties in laboratory practices received
heavy emphasis, and it was felt that standards for the conduct of toxicologic studies must be so documented as to assure that quality control of all aspects of laboratory procedures and research protocol were professionally and scientifically carried out. It was assumed that adequate facilities and appropriately trained and oriented technical and professional personnel were available, but the actual conduct and control measures to assure that these studies were indeed valid demanded thorough attention. Thus, a subcommittee that included members of the Society from academia, government, and industry prepared proposed guidelines for good laboratory practice as applied to toxicologic studies in animals.

The scientists comprising this subcommittee were Emil A. Pfitzer, Chairman; John L. Emmerson; Harold C. Grice; Francis N. Marzulli; Paul A. Mattis; Stata Norton; Carrol S. Weil; and Hanspeter R. Witschi.

The report’s guidelines stated the basic principles and practices that should provide the basis for an objective review, with tangible evidence to assure the scientific reliability of data. There were two major features to the proposed guidelines: the basic principles and practices must be presented in sufficient generality to be equally applicable to all types of toxicological studies; and a mechanism should be described for providing a technical review for specific subjects, requiring (a) further detail, (b) a listing of acceptable procedures, and/or (c) a consideration of controversial issues. This feature allowed flexibility for scientifically sound improvements and advancements in methodologies without compromising reliability.

The recommendation that the Society establish panels of scientific experts who would be available to review aspects of and/or make judgments on specific subjects relating to accreditation and good laboratory practices was presented to the membership for comment on the questionnaire-ballot. When there are external reviews of a toxicology laboratory, controversial issues about specific practices may arise. It was suggested that the SOT provide leadership for resolution when such issues are of importance relative to the public good or the advancement of the profession. Certain of these issues could best be resolved by a group of scientific experts. It was envisioned that the panels would include experts from disciplines other than toxicology, as needed. Examples of controversial issues were differences of opinion about the impact of certain “errors” in data collection affecting the validity of the conclusions of the study, or the scientific suitability of a technical procedure utilized in a toxicity study. This panel could poll toxicologists to obtain views describing current practices regarding technical subjects (see examples below). In addition, it was suggested that a master list should be compiled of those practices that are considered scientifically acceptable, and these should be compiled with. Certain other specific procedures that would be considered as unacceptable could be listed when necessary. The panel would be responsible for descriptions of procedures providing sufficient flexibility so that they allowed for improved and creative innovations. A mechanism to provide prompt updating of new, acceptable procedures would be needed.

When there was sufficient scientific interest in the report of this panel, such as via recommendations for technical procedures in the laboratory, the findings would be considered potentially acceptable for publication as brief communications in one of the Society’s journals or in the Newsletter, or made otherwise available as documents from the SOT.

Following are some examples of subjects that required technical review by such a panel:

- Methods of statistical analysis of data for incidence of tumors, including a definition of the population at risk and the appropriate denominator for the tumor index
- A definition of the term “original data,” which should include use of nonwritten records, e.g., those from computer or recorder
- Methods for recording and securing original data, including use of bound books, pens, and worksheets
- Disposal of animals found dead or killed on test, particularly for those that could not be necropsied immediately; what are acceptable methods for optimal preservation of the tissues prior to necropsy? What is an acceptable time that animals can be held when so preserved?
- What criteria should be used to determine when sick or moribund test animals should be killed, so that tissues would not be lost for subsequent examination?
- Criteria for the protection of female technicians of childbearing age when exposed to potential carcinogens, mutagens, or teratogens.
- Procedures of clinical examination of small laboratory animals
- Procedures to train toxicology technicians
- What data should be available to a pathologist when he performs gross and histopathologic examinations?
- Effective identification systems for rodents, e.g., ear tags
- Criteria for decisions to treat extraneous disease of, or injury to, animals on study
- Schedules for time of retention of specimens and records

Coordination of Reports on Accreditation of Toxicology Facilities and Good Laboratory Practices in Toxicology

The initial separation of the Accreditation of Toxicology Facilities and the Good Laboratory Practices (GLP) in Toxicology subcommittees was necessary to address each topic suitably. However, upon completion of the respective reports, the subcommittee chairs met for the purpose of integrating the two reports. They agreed that facilities and GLPs must be addressed by the same accreditation organization. Thus, while the initial subcommittee reports were not combined, it became our intention that they be coordinated.

There was much overlap in the two reports. The subcommittee on GLPs, for example, addressed facilities and equipment on a philosophical basis, whereas these subjects were treated in much greater detail in the Accreditation of Facilities report. The subjects of specific protocols, conduct of studies,
quality assurance, and standard operating procedures, which were addressed individually by the subcommittee on GLPs, were collectively dealt with in the section on administrative procedures in the Accreditation of Facilities report.

It was important that the membership recognize these reports as drafts of models for accreditation procedures and guidelines for criteria that would be included in the various steps leading to accreditation. Assuming an accrediting body would be established, it was expected that it would adhere to the basic philosophy of the reports, but the accrediting body would be responsible for all the specific details of the accreditation process and the requirements set forth as part of that process.

Subcommittee on Certification of Professionals in Toxicology

This committee studied certification in various specialty boards in toxicology and developed models of a toxicology specialty board. It examined the qualifications deemed necessary for professional toxicologists and especially those involved in laboratories performing toxicologic studies. Standards, guidelines, and recommendations on how the expertise and capability of these personnel should be evaluated and the type of certification and examination mechanisms necessary to assure that individuals making judgments on toxicologic matters are appropriately qualified were all considered. Requirements for certification, areas of competency, and methods and types of examination were reviewed.

The toxicologists comprising this subcommittee were Robert B. Forney, Chairman; Robert V. Blanke; Herbert Blumenthal; Ted A. Loomis; Orville E. Paynter; Verald K. Rowe; and Anne M. Wolven.

In its report, the Subcommittee recognized that there were many sub-specialties in toxicology, as exemplified by the diversity, background, and interests of the Society’s membership; therefore, the subcommittee chose to address, initially, the certification of a toxicologist in the most general sense. It was recognized that the Society might have wished to recognize the five established certification programs then in existence as subspecialties in the general classification of toxicology. It was pointed out that the Department of Health, Education, and Welfare (DHEW) issued a policy statement in June of 1976, for “a proposal for credentialing health manpower.” Since the proposed Society-sponsored certification program was undoubtedly to be health-related, the provisions of the DHEW policy statement had to be considered.

The subcommittee further pointed out that, if a certification program were adopted, a key factor in organizing the certifying board would be that the public interest must remain supreme. Therefore, it would have to be organized as a not-for-profit corporation, meeting the pertinent IRS criteria. The organization of such a corporation would be a highly specialized field, and therefore, competent legal counsel, professional accounting advice, and appropriate insurance coverage would be indispensable. The organization and operation of such a board was seen as expensive. The SOT would have to underwrite the costs involved in establishing and incorporating such a board and its operation for at least a three-year period on a renewable basis, or until, possibly, the board becomes financially self-sustaining. The need to establish a certification program for professional toxicologists may not have been readily apparent to all members of the Society, but it was necessary that those who were in favor of it understood that it would be an expensive, time-consuming effort if it were to succeed.

It was recommended that the subcommittee’s report be carefully reviewed by the membership and that opinions be provided on the questionnaire-ballot.

The Education Committee

The Education Committee was asked to contribute to the Committee on Accreditation, Certification, and Good Laboratory Practices in Toxicology report, because of the membership’s concern at the 1977 annual business meeting regarding the scope and training of individuals working in toxicology, and because of the obvious interaction between continuing education programs and any developing certification programs. The Education Committee was asked to offer their collective expertise in providing a definition of toxicology, a workable definition of a toxicologist, a proposed curriculum model for training toxicologists, a listing of areas of current specialization in toxicology with additional areas that the committee felt would develop within the next ten years, and a listing of continuing education programs in toxicology that should be developed to assist the membership in maintaining competency standards in the rapidly developing toxicology specialties. Although the other groups had addressed several of these items, the Education Committee discussed and considered how the Society could relate to the educational needs in toxicology.

Since the Education Committee was in the midst of a membership change, President Scala asked the two recently elected members to meet with the individuals still comprising the Committee. The expanded Education Committee was composed of Carl C. Smith, Chairman, James E. Gibson, James E. Long, Stata Norton, Andrew L. Reeves, and Joseph C. Street.

The Education Committee’s report provided a basis upon which future educational efforts could be developed. Definitions of the terms toxicology and toxicologist were given, and curricula for undergraduate and graduate programs in toxicology were formulated. Maintaining competency in toxicology was encouraged, and a review of the Society’s existing continuing education program was provided. Organizers of workshops, symposia, and short courses were advised to inform the Society of their programs as soon as possible, so that this information could be made available to members. The interaction of continuing education programs and their relevance to the certification and maintenance of certification for toxicologists was emphasized. Future education committees were encouraged to stress the necessity for providing appropriate continuing education opportunities for Society members.