Neurosurgical materials and devices
Report on regulatory agencies and advisory groups

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Materials and Devices Joint Committee of the American Association of Neurological Surgeons and the Congress of Neurological Surgeons

The current status of voluntary consensus standards writing procedures in neurosurgery and the current progress of government efforts to regulate materials and devices are described. A survey of the national and international standards writing bodies is presented, along with an introduction to related organizations and agencies and nomenclature. The intent of this review is to provide the neurosurgeon with a reference source regarding past and present neurosurgical activities in the materials and devices field. When President Ford signed the 1976 Medical Device Amendments on May 28, 1976, the Food and Drug Administration assumed direct legal authority to control medical devices and potentially assumed the power to regulate those professionals using them.

KEY WORDS - classification - device failure - legislation - materials - medical devices - standards - instrumentation

In 1967, American neurological surgery assumed an active role in the development of voluntary consensus standards for neurosurgical materials and devices. These endeavors, in conjunction with the various neurosurgical and other specialty societies, the established national and international standards writing societies and their coordinating bodies, the Food and Drug Administration, and many other organizations and agencies, have led neurosurgeons into a bewildering array of names and abbreviations, at times only remotely related to the practice of neurosurgery.

This article is intended to describe briefly the functions of the various interrelated committees and agencies and the nature of the 1976 Medical Device Amendments (Public Law 94-295). The agencies and committees with their abbreviations are as follows:

AAMI = Association for the Advancement of Medical Instrumentation
AAMI NS = AAMI Neurostimulation Subcommittee
AAMI NSD = AAMI Neurosurgical Committee on Devices
AANS = American Association of Neurological Surgeons
AANS M&D = AANS Materials and Devices Committee
ACS = American College of Surgeons
ACS MDC = ACS Medical Devices Committee
ANSI = American National Standards Institute
ASTM = American Society for Testing
American Society for Testing and Materials

The world's largest source of voluntary consensus standards, ASTM, was founded in 1898 as a scientific and technical organization for "the development of standards on characteristics and performance of materials, products, systems and services, and the promotion of related knowledge." More than 110 main standards committees within the society write voluntary consensus standards for almost every aspect of American science and industry. The ASTM committees related to medicine are the following:

Committee F-4 on Surgical Materials and Devices
Committee F-8 on Protective Equipment for Sports
Committee E-34 on Occupational Health and Safety Aspects of Materials, Physical and Biological Agents
Committee D-20 on Plastics
Committee E-30 on Forensic Sciences
Committee F-19 on Ortho-Orthotics and External Prosthetics
Committee F-13 on Safety and Traction for Footwear.

The F-4 Committee on Surgical Materials and Devices was originally organized in 1962 by orthopedic surgeons, and is sponsored by the major orthopedic societies of the United States. The Board of Directors of the American Association of Neurological Surgeons (AANS) sent a representative to the ASTM F-4 Committee in 1967. Stimulated by the interest of neurosurgeons and other specialty practitioners, the governing board of the F-4 Committee acquired a neurosurgical member and restructured the committee into specialty subcommittees in 1971 (Table 1). The ASTM F-4.50 Subcommittee on Neurosurgery develops voluntary consensus standards for materials and devices not having an extraneous power source.*

* A list of participating neurosurgeons responsible for various specific components is available from the authors.
of film speed. In 1966 the name was changed again, to the United States of America Standards Institute; in October, 1969, it assumed its present name. ANSI is a federation of approximately 160 national organizations and 1000 company members. The standards developed by member organizations become American national standards after ANSI determines that they have been developed in accordance with its procedures, and that consensus among interested parties has been achieved.

Association for the Advancement of Medical Instrumentation

The Association for the Advancement of Medical Instrumentation (AAMI) was organized in 1966 by physicians, engineers, and industry representatives. It is dedicated, through a multidisciplinary membership of 3000 users and producers of medical instruments, to a number of educational programs, to certification programs for biomedical equipment technicians and clinical engineers, and to the writing of standards for hospital equipment and certain device systems.

The Neurostimulation Subcommittee of AAMI was formed in 1972; additional subcommittees concerned with powered device systems were added in 1975, at which time the Committee on Neurosurgical Devices was formed.

International Sources of Standards

Two nongovernmental groups function on a global basis to coordinate and approve voluntary international standards: the International Standards Organization and the International Electrotechnical Commission.

International Standards Organization

The International Standards Organization (ISO) began as the International Federation of National Standardization Associations (ISA) in 1926. Its official work ceased in 1942 because of World War II. It was succeeded in 1944 by the United Nations Standards Coordinating Committee (UNSCC), which consisted of national organizations of 18 allied countries and functioned essentially as a wartime organization. In 1946, delegates from 25 countries created a new international organization to facilitate the international coordination and unification of industrial standards, and this organization, the ISO, began operations in 1947.

The following ISO committees are of particular interest to medicine:

ISO/TC-106 on Dentistry (Secretariat, United Kingdom)
ISO/TC-121 on Anesthetic Equipment and Medical Breathing Machines (Secretariat, United Kingdom)
ISO/TC-150 on Implants for Surgery
(Secretariat, Australia)
ISO/TC-76 on Transfusion Equipment for
Medical Use
ISO/TC-84 on Syringes for Medical Use
and Needles for Injections
ISO/TC-157 on Devices for Birth Control
ISO/TC-150, a technical committee.

The ISO/TC-150 Committee on Implants for Surgery was inaugurated in April, 1972, in London; the Secretariat of the main committee was assigned to Australia. The committee was divided into three subcommittees, with the following Secretariat assignments:

ISO/TC-150, SC-1, on Orthopedics (West Germany)
ISO/TC-150, SC-2, on Cardiovascular (United States)
ISO/TC-150, SC-3, on Neurosurgery (United States).

Each member nation can be recognized in ISO officially through only one of its standards organizations. In the United States, ANSI is recognized as the official ISO representative. The United States is the only ISO country with an entirely voluntary (non-governmental) standards system. In all other countries ISO representation is through a government agency, financed entirely with government funds.

The following bodies were organized to establish the United States' position within the ISO:

ISO/TC-150 TAG. The Technical Advisory Group (TAG) coordinates the activities and interests of orthopedic surgeons, neurosurgeons, and cardiovascular surgeons, in relation to United States Standards adaptable to global usage.

ISO/TC-150/SC-3 TAG. The Technical Advisory Group formulates the USA’s neurosurgical position to be presented at the meetings of the International Standards Organization Technical Committee, ISO/TC-150/SC-3. The membership is represented by 17 organizations, of which six are neurosurgical. The others represent science, industry, government, standards organizations, and allied professions.

The first meeting of the ISO/TC-150 Subcommittee on Neurosurgery (SC-3) was held in Miami Beach on October 20–21, 1974.

Neurosurgeons from the United Kingdom, Australia, France, Hungary, and the United States were represented. The organization of the committee was developed and work is presently underway to coordinate international standards activities.

International Electrotechnical Commission

The committee within the International Electrotechnical Commission that is of interest to medicine is Committee IEC TC-62 on Electrical Equipment in Medical Practice. Its subcommittees are:

Subcommittee 62A on common aspects of electrical equipment used in medical practice
Subcommittee 62B on x-ray equipment operating up to 400 kV and accessories
Subcommittee 62C on high energy radiation equipment and equipment for nuclear medicine
Subcommittee 62D on electromedical equipment.

Committees Representing Neurosurgical Societies

The following committees have been set up by the neurosurgical societies to coordinate standards development:

AANS Committee on Materials and Devices

This committee was established in the 1950's as the Instrument Committee of the Harvey Cushing Society. Its name was changed to Materials and Devices Committee of the AANS in 1973 to broaden its scope, to stimulate activity in legislation and standards development, and to coordinate its efforts with the Congress of Neurological Surgeons (CNS) Committee on Materials and Devices.

CNS Committee on Materials and Devices

This committee was founded by the CNS in 1972 to achieve neurosurgical representation in activities related to neurosurgical materials and devices. A primary concern was to encourage neurosurgeons to develop, on a

*A list of participating neurosurgeons responsible for various specific components is available from the authors.
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voluntary basis, those standards which were required by necessity and legislation for neurosurgery.

**Joint Materials and Devices Committee**

In 1974, the two Materials and Devices Committees were combined to achieve a coordinated educational and advisory program related to neurosurgical materials and devices. The Joint Committee has encouraged and assisted neurosurgical standards writing working groups and task forces in existing neurosurgical subcommittees within ASTM, AAMI, and other organizations. It has monitored and testified on the federal regulation of devices, and it has advised the American Medical Association, American College of Surgeons (ACS), the Food and Drug Administration (FDA), and the United States Congress in regard to neurosurgical materials and devices. Members of the Joint Committee have also been active as members of the FDA Advisory Panel on Neurologic Devices.

**Governmental and Political Involvement**

**Food and Drug Administration**

Until May 28, 1976, the authority of the FDA was limited to the scope of the Federal Food, Drug, and Cosmetic Act of 1906, as amended in 1938 to provide authority to regulate medical devices. The intent of the 1938 amendment was to control unsafe or quack devices in the same way that the 1906 act restrained the sale of impure or fraudulent drugs.

The 1938 Act defined the term "device," and provided the same basic authority over devices as applied to drugs, with the important exception that pre-clearance authority was provided only for new drugs, and from the wording, it is clear that the term "device" was intended to include both quack machines and legitimate articles, such as surgical instruments.

Because the FDA could, until May 28, 1976, stop the manufacture and distribution of fraudulent or harmful devices only by lengthy court action, there had been a concerted effort in the Congress over the past 10 years to promote legislation empowering the FDA to impose pre-market clearance restraints on devices. Prior to the 1976 amendment, the FDA had been forced to categorize many devices as drugs, so as to gain regulatory authority over them (and unfortunately these devices have been held to the most stringent drug regulations in effect).

Historically, the Federal Food, Drug, and Cosmetic Act and each of its subsequent amendments in the interest of the public, was written as a direct result of lurid circumstances. The original Act was passed in 1906 amid a furor over conditions in the meat packing industry, as dramatized by Upton Sinclair's novel, *The Jungle*. The 1938 Act was stimulated by 75 deaths in the United States from elixir of sulfonamide, and the 1962 amendment by the thalidomide episode.

It was generally recognized that an amendment was needed to replace the current practice of classifying medical devices under the highly restrictive category of existing drug laws. Congressional hearings in 1973 on device legislation were endorsed by medicine at large as consistent with the best interests of the patient. The Joint Neurosurgical Committee provided testimony to Congressman Paul Rogers' (D., Florida) hearings held in 1975.

The 1976 amendment was initiated by Richard M. Nixon's message to Congress on consumer affairs on October 30, 1969, in which he requested that the Secretary of Health, Education and Welfare determine the scope and nature of legislative controls necessary to protect the public against unreasonable risk of injury or illness from medical devices. As a consequence, a study group on medical devices was formed under the chairmanship of Dr. Theodore Cooper, Director of the National Heart and Lung Institute.

The Cooper Committee report recommended a review of the existing medical devices, and the classification of these devices into three categories: 1) those requiring pre-marketing clearance; 2) those for which standards would be appropriate; and 3) those which should be exempt from pre-marketing review and standards.

At the request of the Secretary of Health, Education and Welfare, the FDA undertook an inventory and classification of existing medical devices from the 1100 manufacturers identified as suppliers in the USA. This task was expedited by the formation of federal advisory panels to assist the FDA. By the end of 1974, 14 panels, including a Neurological Panel, had been established,
and were working as advisors to the FDA under the guidance of a new bureau within the FDA, the Bureau of Medical Devices and Diagnostic Products (BMDDP). The Neurological Panel, which has now been functioning for over 2 years was chosen in the following manner. The FDA advertised in the Federal Register for nominations from organizations representing neurosurgery, neurology, psychiatry, neurophysiology, industrial, and consumer for the nine seats on the panel within the following categories: seven professional representatives, one industrial representative (non-voting), and one consumer representative (non-voting). Nominations for 15 neurosurgeons with significant device experience were submitted to the FDA by the ACS, AANS, CNS, Neurosurgical Society of America (NSA), ASTM, and AAMI in response to the Federal Register notice. Four neurosurgeons and three neurologists were in the group selected by the FDA. All proposed panel members successfully passed government clearance procedures and were confirmed in their positions. The panel members are as follows:

John S. Barlow, M.D., Neurology Service, Massachusetts General Hospital, Boston, Massachusetts 02114.

Charles Burton, M.D., Department of Neuroaugmentive Surgery, Sister Kenny Institute, 2545 Chicago Avenue, Minneapolis, Minnesota 55404.

Mrs. Peter Bulkely (Consumer Representative), Association of Junior Leagues of America, 140 West Pioneer Drive, West Hartford, Connecticut 06111.

Mark Dyken, M.D., Department of Neurology, Indiana University School of Medicine, 110 West Michigan Avenue, Indianapolis, Indiana 46202.

William B. Jarzembski, Ph.D., Department of Biomedical Engineering, Texas Technical University School of Medicine, P.O. Box 4569, Lubbock, Texas 79409.

Joseph T. McFadden, M.D., Department of Neurosurgery, Eastern Virginia Medical School, Norfolk, Virginia 23507.

Blaine S. Nashold, M.D., Division of Neurosurgery, Duke Medical Center, P.O. Box 3807, Durham, North Carolina 27710.

Charles D. Ray, M.D. (Industry Representative), Neural Rehabilitation & Medical Research, Medtronic, Inc., 3055 Old Highway Eight, Minneapolis, Minnesota 55418.

Harold Stevens, Ph.D., M.D., 300 Connecticut Avenue, Washington, D.C. 20008.

At this time, the FDA Panel on Neurologic Devices (PND) has completed classification of neurological devices, and will in the future serve as a review body for scientific data on new devices. It will review and recommend medical device standards, new product development protocols, and serve as an advisory group to the FDA on device-related problems. The chairmen of the FDA medical panels, which now number 19, serve also as a separate advisory group to the FDA on policy decisions. The panels (which are required by the new law) function only in an advisory capacity, and the FDA is under no obligation to accept their recommendations. It is clear, however, that the intent of Congress is that the FDA BMDDP consult its advisory panels in all significant matters before taking any regulatory action. Prior to the passage of the recent legislation, the United States Congress was apprised by both the orthopedic and neurological advisory panels of instances in which the FDA had bypassed both advisory groups when attempting ill-conceived and untimely regulatory actions.

The Medical Device Amendment of 1976. The Cooper Report was issued in September, 1970, and congressional activity was initiated in 1973 and 1974.9,11 In April, 1975, the Senate passed its amendment to the Federal Food, Drug, and Cosmetic Act (S 510, the Kennedy Bill). The hearings and the markup on the House Bill (HR 5545, the Rogers Bill)7 were completed in October and November, 1975, following which a revised bill (HR 11124)8 was issued and passed. Under the direction of the House-Senate Compromise Committee, to whom neurosurgical recommendations were directed, the final bill was constructed and forwarded to the President for his signature. Key elements of the Rogers Device Bill that were supported by the neurosurgical profession and included in the final draft were: 1) the use of well-represented advisory panels, consisting of experts nominated by their peers, 2) adoption, when possible, of existing voluntary consensus standards, and 3) incentives to encourage future standards development by the existing voluntary consensus system.
The ultimate impact of device legislation cannot be predicted at this time. Interpretation of the law and application of regulations will determine whether many of the deleterious effects of the previous drug laws will be repeated or whether a more enlightened approach will be taken by the FDA. A clearly expressed intent of Congress in regard to this legislation is that it should serve to limit the future use of specific medical devices to physicians qualified by experience and training, and in this way exert a measure of control on the practice of medicine and neurosurgery.

Periodical Publications

Federal Register. The Federal Register is a government publication that is used as a vehicle by government agencies to present proposed regulations, final regulations, statements of policy, and general information. Regulations are first published as proposed regulations with procedures for comment by interested parties; final regulations are then published after comments are received and evaluated. Generally, instructions for challenging proposed regulations are given within the Federal Register’s statement.

Devices and Diagnostics Letter. This is a weekly newsletter on medical devices and diagnostic products.

The Gray Sheet. This is a weekly newsletter on medical devices and diagnostic products (Medical Devices, Diagnostics and Instrumentation).

The Pink Sheet. This newsletter deals with FDA reports on drugs.

Washington Drug and Device Letter. This weekly newsletter pertains to both devices and drugs.

Industrial Organizations

As interest and activity in neurosurgical materials and devices has increased in recent years, the larger manufacturing and distributing companies have joined the Health Industries Manufacturers Association (HIMA). Smaller companies are in the process of forming a Neurosurgical Manufacturers and Distributors Organization (NMDO).

Areas of Present Concern

Device Failure and Adverse Reactions

The FDA has indicated an intent to base regulatory actions on device failure and adverse result data. The system by which the FDA proposed to collect data was recently reviewed by the 14 advisory panel chairmen; the system was unanimously rejected as invalid.

A mechanism for reporting neurosurgical device failure and data on adverse results was created by the CNS Materials and Devices Committee in 1974, modeled on a similar program previously created by the American Society of Internal Medicine (ASIM). The ASIM program was started in cooperation with AAMI, and the Emergency Care Research Institute (ECRI) of Philadelphia, as a means by which a medical specialty could collect valid data on its failures and adverse reactions.

Biocompatibility

Although many tests are used to establish biocompatibility, until the present, there have been no valid short term screening methods to separate toxic new materials from those that show promise of biocompatibility, and therefore qualify for investigational status for long-term testing.

To overcome this deficiency, the CNS Materials and Devices Committee (under the auspices of the ASTM F-4.50 Subcommittee and the Joint Neurosurgical Materials and Devices Committee, with the aid of neurosurgeons, biomedical scientists, and standards, industrial, and government representatives) on June 19, 1974, drafted a proposal for a “cell cultural spectrum analysis” screening test.

It was soon evident that although the test was intended for neurosurgical implants, its non-specificity made it potentially applicable to all body systems. Since its inception, the screening method has been reviewed and supported by the ISO/TC-150/SC-3, and has received the unanimous support of the FDA Panel on Neurological Devices.
The FDA agreed to fund the testing and development of the cell cultural spectrum analysis method, and a supporting contract has been awarded to Travenol Laboratories. An ad hoc FDA committee on biocompatibility (under the auspices of the Neurological Advisory Panel) is now evaluating the data being generated by this project.

Editorial Policies

Reviews conducted by Materials and Devices Committee members for standards development have frequently found references to materials in medical journals to be by generic name only. For example, in over 500 references on clinical use of methylmethacrylate, less than 5% provided specific chemical identity under the generic terminology. Thus, 95% of the clinical studies were valueless in documenting long-term use and safety. This waste of scientific effort could have been prevented by editorial policies requiring specific identification of referenced materials. The Joint Neurosurgical Materials and Devices Committee recommends publication of the following basic information: full non-proprietary name as well as brand name, recommended dosage or use, batch number or lot number of all devices and chemicals, identification of source, and a list of additives. Recently, the Committee on Materials and Devices of the American College of Surgeons recommended to the Board of Regents that surgeons be asked to record in their operative notes specific identification of any implanted medical devices; this applies to neurosurgery as well as the other specialties.

Summary of Neurosurgical Standards Developments

The ASTM F4.50 Subcommittee on neurosurgical materials and devices and the AAMI Subcommittee on neurostimulation and powered device systems now have numerous draft standards in various stages of development. The ultimate publication of a consensus standard requires a relatively long period of processing through several voting stages. After a period barren of productivity, it appears that several standards will be published almost simultaneously. The opinions and the contributions of the neurosurgical community are invited in the formulation of these standards.

References

4. Association for the Advancement of Medical Instrumentation: AAMI membership brochure. Published by AAMI, 1901 North Fort Meyer Drive, Arlington, Virginia, 1976
6. National Technical Information Service: Medical devices: a legislative plan. Published by NTIS, 5285 Port Royal Road, Springfield, Virginia, September 1970


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