Appendix H.—Consensus Standards Related to International Trade in Medical Devices[1]

Introduction

The ability to market medical devices effectively outside the United States depends partly on regulatory controls imposed by the U.S. and foreign governments and on standards or specifications set by local, national, and international bodies. Most nations, including the United States, use regulations and product standards to control the sale of medical devices, both foreign and domestic. Although the need to protect public health and safety provides justification for governmental regulation, governmentally imposed requirements relating to standards, certifications, inspections and testing may create nontariff trade barriers.

Standards based on one nation's technology may by definition exclude foreign products. Testing and approval procedures, developed and required for domestic use, may be conducted in such a way as to inordinately increase importers' expenses. The internal orientation of certification systems may serve to limit access for imports or deny certification to imported products (379). These factors underscore the importance of international cooperation and coordination in standards-related activities.

The General Agreement on Tariffs and Trade (GATT) is the principal multilateral instrument that sets agreed rules for international trade. Its basic aim is to liberalize world trading practices through reduction of tariff and nontariff trade barriers. GATT, concluded in 1948 and currently subscribed to by 87 nations, provides a continuing forum for multilateral discussions and negotiations on trade matters. In contrast to earlier rounds of negotiations which focused almost exclusively on tariff issues, the "Tokyo Round, " completed in 1979, focused on reducing or removing nontariff barriers to trade and resulted in six major agreements dealing with nontariff matters. One such agreement—The Agreement on Technical Barriers to Trade (or "Standards Code'')—is of particular importance to the medical devices industry and currently has more signatories than any other GATT code (see table H-1). The Standards Code establishes international principles governing the development, adoption, or application of any standard or certification system by the signatories and thereby seeks to eliminate the use of standards and certification systems as nontariff trade barriers (379). Title IV of the Trade Agreements Act of 1979 (19 U.S.C. § 2501 et seq.) approved U.S. acceptance of the Standards Code and served to implement the code in the United States.

[1]**This appendix was drawn from a paper prepared for OTA by Lepon and Gawron (193).**

This appendix explores how established international trade agreements (such as GATT) and Federal laws (such as the Trade Agreements Act) have affected trade in medical devices, specifically as they relate to the development and application of standards. This appendix also describes organizations and agencies involved in medical device standards-setting procedures, their procedures, the effect of implementing their standards, and U.S. Government responsibilities in standards-setting.

Standards-Setting Organizations

U.S. Voluntary Consensus Organizations

Standards for medical devices in the United States have traditionally been developed in the private sector by professional organizations, trade associations, and voluntary standards organizations. These voluntary consensus standards are nonbinding standards developed by consensus among voluntary participants such as consumers, manufacturers, professional association representatives, physicians, clinical technicians, hospitals, and other users (117). Besides the organizations described below, additional ones represent specific interest groups such as hospitals, hospital sup-

Table H-1 .—Signatories to the Standards Code[a]

Argentina	Japan
Austria	Korea
Belgium[b]	Luxembourg[b]
Brazil	Netherlands[b]
Canada	New Zealand
Chile	Norway
Czechoslovakia	Pakistan
Denmark[b]	Philippines
Egypt	Romania
European Economic Community[b]	Rwanda
Finland	Singapore
France[b]	Spain
Federal Republic of Germany[b]	Sweden
Greece[c]	Switzerland
Hungary	Tunisia
India	United Kingdom[b]
Ireland[b]	Hong Kong
Italy[b]	United States
	Yugoslavia

a–As of Nov. 1, 1983.
b–The Standards Code is adhered to by the European Economic Community, in addition to being adhered to by the 10 member states of the community,

SOURCE U.S. Executive Office of the President, Office of the U.S. Trade Representative, "Status of Tokyo Round MTN Agreement Signatures and Acceptances, " Nov. 1, 1983,

pliers, health industry manufacturers, mechanical engineers, dentists, and pathologists (see table H-2). Some of these organizations develop standards for use by their own membership or have representatives on the boards and committees of other standards-setting organizations.

American National Standards Institute, Inc. (ANSI).–ANSI is a private, nonprofit federation of standards-developing organizations and standards users. Founded in 1918, ANSI has been established over the years as the primary U.S. organization for sanctioning and approving voluntary standards in many fields. ANSI approves the American National Standards, a compilation of standards widely accepted by manufacturers, product purchasers, and other professional organizations. ANSI has delegated the planning and coordination of standards in the medical device field to its Medical Devices Standards Management Board, which is composed of representatives from professional societies, trade associations, Government agencies, and general interest groups.

Through this board, ANSI has approved nearly 200 standards for medical devices, primarily by accrediting the standards developed by other organizations. These standards include many for devices used for cardiovascular surgery, neurosurgery, ophthalmology, orthopedics, dentistry, anesthesiology, thoracic surgery, respiratory assistance, and in vitro diagnostic products. ANSI also represents the United States in international standards-setting bodies, most notably the International Electrotechnical Commission (IEC).

ANSI coordinates standards to eliminate duplication among those developed by different organizations. In addition, it serves as a clearinghouse to provide standards developers with information on the procedures and activities of other standards developers.

Before a standard can receive the American National Standards designation, it must be reviewed by ANSI's appropriate committees. To this end, ANSI solicits comments from interested parties on the proposed standard in an effort to ensure that its due process requirements are met. If, as is sometimes the case, other recognized national standards already exist, ANSI will work to harmonize the standards so as to eliminate any overlap in content and ensure that a voluntary consensus can be achieved among the affected organizations.

Association for the Advancement of Medical Instrumentation (AAMI).—AAMI is a nonprofit, professional association formed in 1967 and comprised of individuals, hospitals, health care facilities, professional and medical societies, Government agencies, manufacturers, and research and educational institutions concerned with the development, evaluation, and application of medical devices. Approximately 40 medical device standards, process guidelines, and recommended practices concerning such areas as critical care instrumentation are currently under development, and 11 are available in final form. AAMI carries out its work through technical committees composed of both medical device manufacturers and medical device users in an attempt to balance representation by the groups which will potentially be affected by any approved standards.

AAMI participates in the international standards-setting activities of organizations like the International Organization for Standardization (ISO) and IEC through its membership in ANSI. At the request of ISO and IEC, AAMI has placed its members on their technical committees. For instance, an AAMI participant sits on ISO's technical subcommittee for cardiovascular implants and represents the view of AAMI members.

American Society for Testing and Materials (ASTM).—ASTM, founded in 1898, is a nonprofit, nongovernmental organization involved in developing voluntary consensus standards. In medical devices, its standards primarily, but not exclusively, relate to materials used to manufacture devices. ASTM has over 30,000 individual members representing Government agencies, private physicians, hospitals, public and private laboratories, and medical device manufacturers. ASTM standards provide guidance in determining the biocompatibility of materials; define the properties and char-

Table H-2.-Additional U.S. Organizations Involved in Voluntary Standards Setting for Medical Devices

American Academy of Allergy
American Association for Clinical Chemistry
American Association of Blood Banks
American Association of Immunologists
American Dental Association
American Heart Association
American Hospital Association
American Institute for Ultrasound in Medicine
American Psychiatric Association
American Society for Artificial Internal Organs, Inc.
American Society for Microbiology
American Society of Mechanical Engineers
American Thoracic Society
College of American Pathologists
Compressed Gas Association
Health Industry Manufacturers Association
Hearing Industries Association
Illuminating Engineering Society
Institute of Electrical and Electronics Engineers
National Council on Radiation Protection and Measurements
National Electrical Manufacturers Association
National Sanitation Foundation
Pharmaceutical Manufacturers Association
Scientific Apparatus Makers Association

SOURCE: J. Lepon and E. Gawron, Kornmeier, McCarthy, Lepon, and Harris, "Medical Device Standards and International Trade," contract report prepared for the Office of Technology Assessment, 1983.

acteristics of such materials as plastics, metals, and ceramics; and establish testing methods and recommended handling practices for medical and surgical instruments. Nearly 30 technical committees are involved in reviewing and developing standards for medical surgical materials and devices.

National Fire Protection Association (NFPA).–NFPA is an independent, voluntary, nonprofit organization established in1896 to protect people and their environment from destructive fires. NFPA's membership is comprised of interested individuals and representatives of national trade and professional organizations. A primary function is the development of safety standards and codes that eventually become part of the National Fire Codes, a multivolume set of final, approved NFPA standards.

In 1975, NFPA established a health care section to assist in the development of standards that may help to prevent fires in medical facilities. NFPA also encourages safe use of medical devices, particularly electrically powered medical devices, in patient areas. It participates in many other standards-setting organizations by placing its members or organizational staff on their technical committees. For instance, NFPA is an active participant on ASTM's committee on the hazard potential of chemicals and ASTM's subcommittee on flammability and ignition testing, AAMI's subcommittees on electrical safety and monitoring devices, and the U.S. Veterans Administration (VA) Advisory Committee on structural safety of VA facilities. Through its membership in ANSI, NFPA also assists in the review and development of the American National Standards and participates in the international standards development activities of IEC.

NFPA standards for safety have been widely accepted by States and local governments in establishing regulations for licensing of medical facilities and for regular building inspections. Although NFPA standards are voluntary, their adoption by the regulatory agencies of State and local governments have made some of them mandatory.

National Committee on Clinical Laboratory Standards (NCCLS).—NCCLS is a private, nonprofit corporation devoted to upgrading health care by improving the quality of clinical laboratory methods and by providing acceptable guidelines and standards for clinical laboratories. NCCLS was founded in 1968 by representatives of the clinical laboratory services professions, the Federal and State Government agencies with responsibilities for public health, and diagnostic products companies that provide the reagents, instruments, and systems used in clinical laboratory identification and measurement. Its members work to produce voluntary consensus standards through numerous technical committees.

NCCLS coordinates the process by which national consensus on clinical laboratory standards is achieved, and thus expedites the process by which NCCLS standards become adopted as national and international standards. It works closely with its European counterpart, the European Committee on Clinical Laboratory Standards, as well as with the International Organization of Legal Metrology, and ISO in developing and harmonizing international standards.

Underwriters Laboratories, Inc. (UL)—UL is an independent not-for-profit corporation established in 1894 to help reduce or prevent bodily injury, loss of life, and property damage. UL has developed standards and requirements covering medical and dental equipment intended for professional use by personnel m hospitals, nursing homes, medical care centers, medical and dental offices, and other health care facilities.

UL's standards for safety are based on research and cooperation by engineers, manufacturers, consumers, and recognized specialists in many fields. Many UL standards for safety are recognized as American National Standards by ANSI. UL is a member of ANSI and assists in the review and development of American National Standards. Its staff members serve on technical committees and subcommittees of various domestic standards developing organizations such as ASTM and NFPA, as well as international organizations such as IEC and ISO.

UL standards and requirements are the basis on which UL's registered certification mark may be affixed to complying products by subscribers to UL's services. This system of marking is recognized by consumers, regulatory authorities, and others who seek and rely on third-party certification of products with respect to safety. Federal, State, and municipal authorities, architects, building owners, and consumers may require listing or classification by UL as a condition of their acceptance of a device, system, or material having a bearing upon risk of fire, shock, or other injury to persons or property. Although UL standards for safety are voluntary, adoption by regulatory agencies has made some of them mandatory (109).

International Organizations

International Organization for Standardization (ISO).–ISO, formed in 1947, is an organization of national standards institutes involving over 84 countries. Its objective is to promote development of worldwide standards for the purpose of "facilitating international exchange of goods and services and to develop mutual cooperation in intellectual, scientific, technological, and economic ability" (169).

ISO recognizes ANSI as the representative member body for the United States. Other U.S. standards-

setting organizations, including various Federal Government agencies and representatives of manufacturers, participate in many of ISO's technical committees that are concerned with medical devices. These groups together comprise the U.S. delegation to the international organization. Members participate on such technical committees as dentistry, implants for surgery, mechanical contraceptives, prosthetics, and transfusion equipment.

The development of international standards, of which there are nearly 200 relating to medical devices, is a slow, deliberative process. First, draft proposals are submitted by interested national standards organizations or individuals to technical committees for study. Most of the work of reviewing these proposals is done through correspondence with its members. The process of approving a standard may take as long as 6 or 7 years, but most proposed standards take about 3 years to gain approval as an International Standard.

Once a standard has become an International Standard, many national standards institutes and governments often seek to adopt it as their national standard as well. For example, ANSI, working through its American Dental Association members, has adopted the ISO standard for dental zinc silico-phosphate as an ANSI standard (ANSI/ADA 21-1981). The reverse case has also occurred, in which a specific national or regional standard has become an International Standard. This situation is becoming more common as many aggressive national and regional standards organizations attempt to have their own standards accepted internationally. For example, AAMI has introduced its draft standard for implantable ventricular pacemakers (AAMI 1P) to ISO, which in turn accepted it as a draft International Standard (ISO 5841.1).

International Electrotechnical Commission (IEC).– IEC was formed in 1906. In accordance with a formal agreement between IEC and ISO, questions related to international standardization in the electrical and electronic engineering fields are reserved to IEC and other subject areas are the responsibility of ISO. If ISO undertakes an international standardization matter unrelated to a particular technology, it consults IEC to safeguard any electrotechnical interests that maybe involved.

The structure and process of standards development by IEC is similar to the methods employed by ISO. The recognized national standards institutes with responsibility for development of standards for electrical products are IEC members. ANSI's U.S. National Committee is the U.S. member of IEC, and other U.S. voluntary consensus organizations may participate in IEC's standards development process through its technical committees (169).

Other International Standards-Setting Organizations.—The organizations with specific areas of interest contribute their expertise to the development of those standards. Many of these international voluntary organizations maintain close liaison with their national counterparts in the United States. The governmental role in these associations is limited to the extent that an individual member of a national professional society may also be a government employee and as such have contact with her or his international counterparts in the exchange of information.

The International Committee for Standardization in Hematology develops reference materials and recommends standardized techniques in diagnostic hematology, blood transfusion practices, and related activities.

The International Union of Immunological Societies and the International Federation of Clinical Chemists develop specifications for methods of testing and materials and also receive and organize international tests to submit to the World Health Organization (WHO) for acceptance as recommended procedures. WHO also develops and promotes standards in medical devices. Expert panels and committees of WHO have worked on such topics as standardization of diagnostic equipment and quality control in health laboratories.

The International Organization for Legal Metrology (OIML) is a treaty body established in the early 1950s. It is comprised of 48 countries, including the United States, which joined in 1972. OIML works to harmonize international standards for legal measuring devices, such as gasoline pumps and weight scales, and, in the medical field, such devices as blood pressure gauges and electrocardiographs. The National Bureau of Standards represents the United States in OIML. A U.S. advisory committee for legal metrology—consisting of representatives of Government agencies concerned with legal measurements, manufacturers of measuring devices, and major standards organizations such as ASTM and ANSI—provides guidance to the National Bureau of Standards when it represents U.S. interests in OIML.

Many international and regional trade associations participate in developing their own standards, and contribute to organizations such as ISO and IEC. Some of these associations represent manufacturers of radiation equipment, surgical instruments, and clinical laboratory materials.

European Standards-Setting Organizations

Because of the large number of countries in Europe, with their varied political, social, and economic systems, the environment is a "complex scenario against

which to review standards and regulations applying to health care" (73). In addition to the government-affiliated and independent standards institutes within the various countries, there are also regional standards-related organizations.

The membership of the European Committee for Clinical Laboratory Standards represents health agencies, professional societies, and industry. Its objective is to improve clinical laboratory practices through a voluntary consensus mechanism (386).

The European Committee for Standardization (CEN) is composed of the national standards organizations of countries in the European Common Market, plus Austria, Finland, Norway, Portugal, Spain, Sweden, and Switzerland. Its major objective is to harmonize Western European implementation of ISO and IEC standards. In addition, it has developed approximately 60 "European Standards" in nonelectrotechnical fields. CEN operates certification systems, usually with respect to European Standards, and systems for recognition for test results for national certification programs where no European Standards exist (9).

The European Committee for Electrotechnical Standardization (CENELEC) is comprised of the national electrotechnical committees of its member countries. CENELEC seeks to harmonize the national electrotechnical standards of its member countries and uses IEC publications as a basis for its activities. Its major objective is to eliminate, through mutual agreement, any technical differences between the national standards and certification programs of its members that would result in trade barriers. In addition to its harmonization activities, CENELEC also develops European Standards in the electrotechnical field (9).

In general, each country has a national standards institute that produces or sanctions standards, much as does ANSI. These institutes also have technical committees comprised of government officials, manufacturers, and end-product users. For the most part, standards established by these institutes are voluntary; however, since each country has its own method of administering and monitoring compliance with these standards, the line between voluntary standards and mandatory regulations is often blurred (73). Therefore, it is useful to describe briefly key aspects of the standards setting and administering processes for several major European nations, namely the Federal Republic of Germany, the United Kingdom, and France.

In 1981, a group of international medical device manufacturers formed the European Regulatory-Technical Affairs Study Committee, and conducted a study in the major nations of Europe on the state of regulatory affairs in the field of medical devices, including the diagnostic field. The resulting six-volume report contains a listing of government regulatory agencies, as well as information on certifying and testing organizations and on national standards-setting. This report indicates that there is an increasing trend for development of standards in Europe *(102).*

Federal Republic of Germany .—Two national laws govern most of the Federal Republic of Germany's governmental involvement in standards-related activity: the Drug Law of August 24, 1976; and the Law on Technical Equipment and Devices of June *24, 1968,* as amended August 13, 1979 (163). Although the Drug Law is directed primarily to the pharmaceutical industry, it defines "drugs" to include certain surgical dressings, surgical sutures, and diagnostic products within the term "fictitious drugs" (164,174). In addition, implantables are brought within the scope of the legislation once they are actually implanted (163).

The Drug Law is comprehensive and contains sections on manufacture, licensing and registration, clinical trials, recording of adverse effects, inspections, labeling, and advertising (174). The Ministry of Health has statutory responsibility when problems with regulated products are reported and corrective action is necessary (163).

The Technical Equipment and Devices Law, administered by the Ministry for Labor and Social Affairs, sets forth standards for equipment safety. Special provisions require that a manufacturer certify that technical medical equipment is in proper condition and that either the manufacturer or an officially designated expert has subjected the equipment to final inspection. Equipment controls and operating instructions must incorporate use of the German language or utilize standard symbols (164).

There are two principal standards-setting organizations in West Germany. The Verband Deutscher Elektrotechniker (VDE) develops standards and provides certification testing and listing services for electrical components and systems. The other, the Deutsches Institut für Normung (DIN), is a voluntary consensus standards organization that has developed standards in a number of areas. Standards involving electrical aspects are often published jointly by DIN and VDE. In addition, there is a major testing-certification organization called the Technischer Uberwachungs Verein (TÜV) which deals primarily with complete products, rather than their component parts. TUV issues a "GS" (Geprüfte Sicherheit) mark that, although not mandatory, carries with it the same sort of prestige as the UL mark in the United States (293, 135).

[2]Becton-Dickinson-France, **S. A.; Beiersdorf A. G.; Cordis Dow, B. V.; Johnson & Johnson, Ltd.;** Medtronic **France, S. A.; Miles Laboratories, Ltd.; 3M Europe, S. A.; Travenol International Services, Inc.; and Welcome Reagents, Ltd.**

United Kingdom.—In the United Kingdom, with its national health system, the Government is the primary user of medical devices. The Medicines Act of 1968 requires full premarket evaluation for drugs and medicines and sets forth requirements for licensing, manufacturing, inspecting, testing, and labeling. Certain medical devices, such as surgical sutures, dental filling substances, contact lenses, intrauterine contraceptive devices, and certain radioactive medicinal products, have been brought within the regulatory framework of the Medicines Act (174).

The British Standards Institution (BSI) is a voluntary standards-setting organization that was formed in 1901. In addition to its standards-developing activities, BSI also provides testing and certification services. Although the standards developed by BSI are voluntary, the Department of Health and Social Security (DHSS) has issued a recommendation that governmental purchases of medical devices comply with existing BSI standards (149). Therefore, medical devices manufacturers regard BSI standards as mandatory in practice, as they must be met in order to market devices effectively in the United Kingdom.

As BSI standards cover only a relatively small number of medical devices, DHSS general specifications, technical requirements, and voluntary "good manufacturing practices" have been developed to fill this void. Through its Scientific and Technical Services Branch, DHSS has also established a registration scheme for manufacturers. The role of that branch is to develop, in conjunction with various trade associations, suitable standards for quality assurance or good manufacturing practices, to assess the manufacturers' compliance with those general standards, and to publish a register of manufacturers complying with the good manufacturing practices (149). In the event that this voluntary scheme proves ineffective, the Medicines Act provides for residual authority to extend its scope to cover all medical devices (163).

France.—In France, the authority to control medical devices is derived from the Ministry of Health and Family and the Ministry of Industry. The two major mechanisms for control are the French Pharmacopoeia and a "homologation" system (a system of official approval) *(174).*

The Ministry of Health and Family publishes Pharmacopoeia monographs that contain specifications and descriptions for many sterile products, a variety of plastic products, surgical dressings, sutures, various tubing, and absorbent cotton. Requirements dictated by the Pharmacopoeia are technically applicable only to products sold to public institutions (which account for over 90 percent of all medical facilities in France) or to products that claim to conform to the Pharmacopoeia (164,293).

The homologation system is a process of obtaining official government approval applicable to a listing of devices that is periodically reviewed and updated. Although approval is mandatory only for products purchased by public institutions, the homologation system is linked to reimbursement procedures under the French social security system. Therefore, approval is necessary whenever a purchaser wishes to apply for reimbursement *(164).* Until recently, approval had been granted by an interdepartmental commission, and product-specific requirements, specifications, and procedures for testing were stipulated by decree.

In January 1983, France introduced an entirely new scheme of approval. Although it is unclear how the new scheme will operate in practice, the interdepartmental commission has been abolished, and a National Committee of Homologation, which has full responsibility for the approval process, has been created within the Ministry of Health and Family. The National Committee has five subcommittees, composed of experts drawn from the ministries, hospitals, and universities, and charged with defining the homologation procedures. The subcommittees operate in the areas of: imaging, operating theaters, artificial organs and prostheses, anesthesia and reanimation, and diagnostic equipment and monitoring (163).

In general, approval requests must be presented to the Ministry of Health and Family by an authorized agent established in France, and a testing laboratory will then be assigned. In practice, only laboratories within the Groupment des Laboratoires des Materiels de Technique Medicale are adequately equipped and staffed to do the work. For an electrically powered product, the French Electrical Code is applied as the minimum standard. If a particular product standard exists, it is also applied. Clinical testing may be required by physicians assigned by the ministry (293).

The Association Francaise de Normalisation (AFNOR) is France's primary standards organization. AFNOR is a private, public service association that centralizes and coordinates all work and studies concerning standardization, much as does ANSI. Formed in 1926, AFNOR is a voluntary organization of manufacturers, consumers, professional associations, and government representatives. Standards developed by AFNOR are voluntary; however, they may become mandatory if adopted for use within the homologation system. In *1943,* AFNOR was given governmental authority to develop public standards and to administer the mark "NF" as indicating conformity with a standard.

Other Foreign Organizations

Japan.—The Ministry of Health and Welfare regulates the importation and sale of medical devices pur-

suant to the Pharmaceutical Affairs Law. In July 1983, an omnibus bill was passed making extensive changes in Japan's standards and certification system. The omnibus bill is the culmination of over 4 years of bilateral discussions between the United States and Japan (121).

Standards in Japan are normally developed through advisory committees to Japanese Government ministries (359). The Japanese Industrial Standards Committee (JIS) within the Ministry of International Trade and Industry is of particular importance to the medical devices industry. Products conforming to JIS standards and testing requirements are entitled to bear the "JIS" mark, which is the most prominent and widely used certification mark in Japan.

Prior to passage of the recent amendments, only JIS standardized medical devices were exempt from the approval process. The new legislation permits certain non-JIS standardized devices to bypass the approval process. The devices exempted are those for which the utility, efficiency, and safety is generally acknowledged, including such items as surgical knives, tweezers, medical scissors, sterilizers, operating tables, and stethoscopes (121).

Canada.—In Canada, the Department of National Health and Welfare's Bureau of Medical Devices (BMD) is the central point for mandatory standards. Under the Food and Drug Act of 1953, the department was granted authority to adopt standards and create regulations for medical devices. To date, BMD, which was created in 1975, has developed seven medical device regulations: 1) contraceptives, 2) cardiovascular pacemakers, 3) hearing aids (revoked in 1979, but the bureau is working to have them reestablished), 4) mobile oxygen inhalators, 5) blood collection tubes, 6) disposable insulin syringes, and *7)* electromedical devices. In developing these standards, BMD examined existing national voluntary standards and other international and foreign standards which could be adopted or modified, and then based its standards upon a synthesis of them.

The Canadian Standards Association (CSA) is a voluntary, nonprofit, autonomous organization that provides standards-writing and certification services. Its members are drawn from the industrial, governmental, private, and educational sectors. In the mid-1970s, CSA initiated a Health Care Technology Program, whose goal is to develop consensus standards in the medical engineering field and to implement those standards throughout Canada through education, professional societies, and provincial or federal legislation (90). CSA is also a testing house for certification of medical devices. Manufacturers can pay to have their products certified as complying with CSA standards and certain other relevant standards.

The majority of Canadian medical device standards are not mandatory. However, since almost all of Canada's hospitals are public, various provincial governments require that certain medical devices meet CSA's standards or some other national, international, or foreign standard, such as those of AAMI or ISO.

This requirement has the effect of making many voluntary standards mandatory in operation. For example, all electromedical equipment sold or used in any Canadian province must be "approved," which in effect means that the product must be shown to conform to CSA standard C.22.2 No. 125 (90). Although certain CSA standards are substantially similar to UL standards in the United States, CSA does not automatically certify products certified by UL, but conducts its own testing (463).

Like ANSI (the American National Standards Institute), the Standards Council of Canada, a nonprofit organization, coordinates other standards-setting organizations and sanctions the standards developed by these bodies.

Mexico.—The Mexican Government has no uniform system of standards development that affects medical devices (301). The importation of medical products is governed only by the customs law and not by medical device or pharmaceutical legislation as in other developed countries. Entry requires a certificate of origin and description of the product. If a product bears a certification of compliance with the standards of the producing country, such as a UL mark, this certification is generally accepted by customs officials.

Change in the enforcement of customs laws in Mexico can generally be traced to national and international economic policy issues, such as the effect of imports on Mexican employment and other such economic concerns. These reasons usually are not directed at control of the quality, safety, or effectiveness of the products (301).

U.S. Government Agencies Involved in Standards-Setting Related to International Trade

The GATT Standards Code establishes new international ground rules in the area of technical (nontariff) barriers to trade. It sets forth international rules among governments for regulating the procedures by which standards and certification systems are prepared, adopted, and applied and by which products are tested for conformity with standards (359,380). The basic premise of the code is that standards-related activities should not be used as mechanisms to restrict unnecessarily international trade *(46).*

Although the code is directly binding only on the central governments of its signatories, these governments are obliged to take reasonable measures to ensure that regional, State, local, and private organizations also comply with the code's provisions (359). Therefore, the code provisions affect governmental and nongovernmental standards, whether voluntary or mandatory, and whether developed by central, regional, State, or local governments or private sector standards organizations.

Three U.S. Government agencies play a significant role in the implementation of the Standards Code in the United States: the Office of the U.S. Trade Representative, the Department of Commerce, and the Department of Agriculture (380). The Department of Agriculture's role, while important with respect to overall implementation of the code, is beyond the scope of this paper. Activities within the Department of Health and Human Services are outlined below.

U.S. Department of Health and Human Services

The National Center for Devices and Radiological Health in the Food and Drug Administration (FDA) frequently interacts with domestic and international voluntary standards-setting organizations. Domestically, the national center contributes to the review and development of standards by organizations such as ANSI, AAMI and ASTM.[3] FDA also participates in development of international standards through its work on the technical committees of both ISO and IEC. However, U.S. Government agencies have neither control over nor any official leadership role in the domestic or international private voluntary standards-setting process.

Recently, U.S. Government agencies—specifically FDA—have increased their participation in voluntary standards-setting activities because of two Federal policy initiatives: the GATT Standards Code, as implemented in the Trade Agreements Act of 1979 (19 U.S.C. § 2531-2573) and Office of Management and Budget (OMB) Circular A-119, Both of these policy initiatives establish guidelines for and encourage Federal Government agency participation in domestic and international voluntary standards-setting activities.

The Trade Agreements Act recommends the use, where appropriate, of international standards as the basis for developing domestic standards. FDA's work with voluntary organizations is important, therefore, to ensure that the U.S. view is expressed and that internationally developed standards are consistent with U.S. national standards in terms of product safety and effectiveness.

OMB Circular A-119 sets forth as Federal policy that the U.S. Government will rely on voluntary standards, both domestic and international, where appropriate, in lieu of governmentally developed standards. Circular A-119 also specifies that Federal employee participation should not in any way attempt to dominate the voluntary process (21).

The Centers for Disease Control (CDC) has also been active in voluntary standards-setting activities in the medical devices field. CDC provides technical assistance to organizations such as the National Committee on Clinical Laboratory Studies through CDC's work with various professional societies and through information received from State health departments and other public and private medical laboratories.

Office of the U.S. Trade Representative

In connection with its responsibility for setting and administering overall trade policy, the U.S. Trade Representative (USTR) coordinates the development and execution of the U.S. standards-related trade policy (419). USTR is responsible for resolving standards-related trade disputes between the U.S. and foreign governments, overseeing the general implementation of the Standards Code in the United States and coordinating the international trade activities of other U.S. Government agencies that engage in standards-related activities that may significantly affect trade, and negotiating bilateral standards arrangements (380).

Under the Standards Code, any signatory may question another signatory's compliance with code provisions. Bilateral or multilateral consultations are encouraged to resolve disputes. In the United States, a private party may informally raise with USTR a foreign practice that appears to be inconsistent with the code or otherwise denies benefits to the United States under the code (380). USTR will then pursue the resolution of problems, keeping the complainant apprised of its activities. Problems arising under the code usually involve: failure by signatories to provide adequate information on their standards-setting activities, failure by importing governments to adopt standards set by international organizations, nonacceptance by importing countries of test data generated in the United States, and denial of access to certification systems (359).

U.S. Department of Commerce

National Bureau of Standards (NBS) .—NBS has been delegated the responsibility for establishing and

[3] FDA's activities regarding mandatory performance standards are discussed in ch. 5.

maintaining the U.S. inquiry point for Standards Code matters, the central repository for standards and certification information, and a technical office for nonagricultural products. The responsibilities delegated to NBS are carried out through the Office of Product Standards Policy's Standards Code and Information program.

As the U.S. inquiry point mandated by the Standards Code, staff of the Standards Code and Information program notify the GATT Secretariat of proposed U.S. regulations potentially having an effect on trade. They receive notices and information on proposed foreign regulations and disseminate the information through several media and directly to interested U.S. parties. A primary objective of the notification program is to encourage review and comment on proposed foreign regulations. Foreign notifications are routed through various Government agencies, such as the Bureau of Industrial Economics in the Department of Commerce (DOC); agency members of the Interagency Committee on Standards Policy; private standards organizations; and industry groups.

This program also operates the National Center for Standards and Certification Information, which is the national repository for standards documents. The center responds to general inquiries about the existence of specific standards and regulations and maintains a reference collection of voluntary and mandatory U.S. standards, as well as major foreign and international ones. The technical office within the program provides assistance in the areas of exchange of information and dispute settlement.

To market products in foreign countries, U.S. exporters must be informed of the testing procedures, approval programs, and certification rules in effect in those countries. To date, there are no centralized or accessible reference collections that can provide exporters with this essential information (359). Current funding and staff resources within the Standards Code and Information program are insufficient to allow it to expand effectively into this area (1,91). However, the center has begun to collect certification information on an informal basis through its collection of materials on foreign and international standards activities and through information provided by U.S. trade and professional organizations.

International Trade Administration (ITA).—The Trade Agreements Act directs the USTR and the Secretaries of Commerce and Agriculture to consult with the private sector for technical and policy advice on the implementation of the Trade Agreements Act and the Standards Code (46,359). In order to meet its responsibilities, DOC has established an Industry Functional Advisory Committee (IFAC) on Standards for Trade and Policy Matters. IFAC, administered by ITA in DOC, is composed of approximately 20 members drawn from Industry Sector Advisory Committees within DOC and an approximately equal number drawn from private sector groups involved in standards-related activities (359).

IFAC is responsible for advising USTR on matters concerning trade, the operation of existing trade agreements, and other matters connected with U.S. trade policy. IFAC provides detailed policy and technical advice, information, and recommendations concerning standards and their effect on trade and the implementation of the Standards Code (359).

Although the mandates of the Standards Code are technically applicable only to the Federal Government, the Trade Agreements Act legislation calls on the President to promote adherence to the code principles by State and private sector bodies (19 U.S.C. § 2533). To this end, ITA has issued voluntary procedural guidelines for State and local governments and private sector organizations engaged in standards development, product testing, and certification systems (314).

Representation of U.S. Interests in International Standards Organizations.—The Trade Agreements Act directs the U.S. Secretaries of Commerce and Agriculture to keep adequately informed of international standards-related activities, to identify those activities that may have a substantial effect on U.S. commerce, and to coordinate those efforts with USTR. Although the act does not designate any specific private organization as the "official" representative of U.S. interests, it confirms the role of U.S. member bodies in private international standards organizations, such as the ANSI/ISO relationship.

The Secretary of Commerce has authority to determine that a member body is not adequately representing U.S. interests and to make arrangements for adequate representation (380). For any governmental international standards organizations in which U.S. interests are represented by one or more Federal agencies, the Secretary is directed to encourage cooperation among the agencies to seek a uniform position. In addition, the Secretary is directed to encourage such Federal agencies to seek information from and cooperate with any affected domestic industries (380).

The Standards Code and Information program fulfills DOC's obligations with respect to ensuring adequate representation of U.S. interests in international standards-setting through two major activities. First, the program's technical office responds to any information, complaints, or criticisms concerning participation in international standardization activities. Second, the program maintains statistics and information on U.S. participants in international standards-related activities (359).

Problem Areas for Medical Devices Standards in International Trade

At an OTA workshop in August 1983, representatives of selected members of the Health Industry Manufacturers' Association (HIMA) identified certain problems related to standards and international trade. All the participants came from large companies that engage in foreign trade. Although their views may not be generalizable to the medical devices industry as a whole, they do indicate the experiences and perspectives of companies from several areas of medical devices (see app. B for a list of workshop participants). It should also be borne in mind that a complete examination of standards-setting would require consideration of the benefits to purchasers and users of devices. This section discusses issues raised at the workshop as well as information from Government agencies and other industry representatives.

Development of Standards

Rationale or Need for Standards.—Workshop participants commented that insufficient attention is given to the rationale for developing standards. Developing medical device standards may proceed with little or no demonstration of concerns related to clinical safety and effectiveness (118). For safety standards that are engineering- or technology-based, much time and effort may go into creating standards important from an engineering point of view but of limited concern from a medical point of view. One way to demonstrate that a standard is reasonable is to include a rationale that defines the standard's purpose and limitations (118).

A related comment was that many standards are developed without any attempt to examine costs and benefits. Highly restrictive, costly, hardware-oriented standards are produced where adequate nonhardware alternatives (such as education, training, and preventive maintenance) for resolving the problem may exist. Publication of a rationale would facilitate public review and comment and would permit more appropriate application of standards (89).

The workshop participants advocated greater clinical input into standards development. Recently, a trend to involve medical professionals has been developing, particularly in the United States and in Canada, but many medical professionals appear reluctant to take the time away from their practices (or other responsibilities) or incur the expenses connected with participation. Consequently, standards may contain requirements that differ from those necessary to assure the safety and effectiveness of medical devices (145).

There was speculation that some foreign countries have reacted to the 1976 Medical Device Amendments by promulgating their own standards, both voluntary and mandatory. The question was raised of whether or not standards are needed, considering that many manufacturers produce devices to specific internal corporate standards based on current scientific and technical information, the marketability of the devices, and protection of the company from personal injury liability.

Access to Information.—When standards—domestic, foreign, and international—are being developed, it is often difficult for an individual or company to gain timely access to information so that comments can be submitted. A major objective of the Standards Code is to make standards-setting and certification activities open to all interested parties, and code signatories must follow certain procedures for new or amended mandatory standards and certification system rules (380). However, few foreign countries have detailed specific requirements regarding public notice, and the Standards Code requirements speak only in terms of reasonableness. Although none of the code signatories maintain notice procedures that actually violate the code, U.S. manufacturers have encountered difficulties in obtaining the timely, adequate information necessary for making meaningful comments (359).

FDA's notices of proposed standards development may not give enough information about the purpose or rationale to determine the scope or need for comments (21 CFR pt. 866). At the local level, users of standards, manufacturers, or consumers are not all members of national organizations and do not all subscribe to the publications (such as the *Federal Register* for domestic notices and the *Commerce Business Daily* for foreign notices) in which notices are published. Consequently, they may not take part in the comment process.

In January 1980, HIMA surveyed its membership to obtain information regarding members' international marketing activities, monitoring of regulations and product standards, and participation in foreign industry organizations. According to the survey results, manufacturers typically rely on foreign agents and distributors for information on changes in foreign regulations and product standards, and many have designated a specific employee, stationed either in the United States or abroad, to monitor standards-related developments.

Whereas over 70 percent of the manufacturers responding to the survey relied on distributors, agents, and employees as information sources, 35 percent of the respondents obtained information directly from U.S. Government sources and 21 percent obtained the

information directly from foreign governments or foreign industry organizations (146).

Some European countries with only a few manufacturers in specialized fields such as medical devices have developed standards swiftly. These standards are often based on locally manufactured products and may, in fact, serve to restrain import trade. The standards-setting government may justify its standards by asserting that they are based on international standards "with qualifications," but the qualifications may be substantial and belie the original standard. Because these standards are often quickly enacted, U.S. standards organizations and interested manufacturers often have difficulty submitting comments in a timely manner. Once these standards are finalized, U.S. manufacturers may have difficulty in having their products conform to the foreign standards.

Suitable Representation.—The expense of analyzing drafts, preparing comments, and attending international meetings often makes it particularly difficult for small companies to participate, since the cost of participation is the burden of the individual committee members. In the private sector, it is usually the manufacturer who pays the expenses of the employee representative. The review and comment work of committees usually takes place over a period of months, or years in some cases. As a result, the interests of small manufacturers (and others unable to attend international meetings) in international standards-setting are often not taken into account.

Although 98 percent of the manufacturers responding to the HIMA survey were involved in the export or foreign manufacture of medical products, only 27 percent indicated membership in foreign industry organizations and only 25 percent reported active direct involvement in international standards organizations. The manufacturers that did participate in international standards development reported employee participation in various technical committees of organizations such as IEC, ISO, NCCLS, and OIML—as well as the national standards organizations of Australia, France, West Germany, and the United Kingdom (146).

Even with improved representation in international standards setting, U.S. interests may be unable to influence decisionmaking at the international level. European countries involved in the regional standards setting activities of organizations such as CEN and CENELEC often vote as a bloc in ISO or IEC to establish European technology as the basis for international standards (249).

Application of Standards

Cost of Conforming to Standards.—In the United States, UL or NFPA standards are often specified in public municipal codes, such as building and safety codes, or in purchasing specifications. Products must then bear a UL mark or other form of approval to be used within those jurisdictions. A device may be subject to design and performance standards as well as installation and use standards. Each time a test is conducted, additional costs are incurred. For example, some electrical devices require a UL mark as well as conformity to NFPA fire and safety codes. In addition, a foreign government might require different or additional tests and markings for the same product.

Although manufacturers consider some medical devices standards, such as those developed under the 1968 Radiation Control for Health and Safety Act, to have significantly improved the safety and quality of the products, they also maintain that the improvements have raised the cost of research, development, and final products.

In foreign countries, the cost to a U.S. manufacturer of complying with foreign standards that differ from domestic standards must be built into the price of its products. This can make U.S. products more expensive than local foreign ones, and thus less cost competitive. To minimize the costs of additional testing or procedures related to meeting foreign and domestic standards, as well as for other reasons, U.S. manufacturers have set up overseas operations. Establishment of foreign manufacturing subsidiaries by U.S. companies diminishes the balance-of-trade advantage for the United States.

Interpretation and Reliability of Information.—The existence of an international or foreign standard, and knowledge of its existence by a U.S. manufacturer, has only limited value. It is more important to the manufacturer to know how that standard will be interpreted by local or national officials, or other certifying bodies such as testing laboratories, government reimbursement agencies, or insurance providers.

In the Federal Republic of Germany, for example, there are DIN standards for medical device components, but within the country the officials of the various states interpret these standards differently. Differing interpretations can result in costly delays in supplying products or in cancellations of orders and contracts. In Germany, U.S. importers also face problems relating to insurance coverage. For example, although not legally required, a customer's insurance carrier asked the importer of an ultrasound imaging device to certify that the product met radiofrequency interference standards (235). This action caused considerable expense to the manufacturer in legal fees and delayed introduction of the product.

This situation occurs in other countries as well where the ultimate legal responsibility for radiofrequency interference (or any other responsibility for equipment

safety or performance) rests with the user as opposed to the manufacturer. In order to obtain insurance coverage in these situations, the user's case is much stronger if it can be shown that the product meets, or has been certified to, the requirements of an applicable standard (293).

Most companies doing business internationally must rely on their market researchers to identify standards or other requirements that they must meet or on local distribution agents for their knowledge of local administrative procedures. Obtaining information through these sources is costly and time-consuming. It is all the more difficult for those companies that cannot afford researchers or local agents.

Once manufacturers have obtained information regarding foreign standards-related practices, they often encounter difficulties in confirming the accuracy of that information and determining its practical implications. A major difficulty in foreign standardization activities is determining what is required versus what is customary or desirable in certain markets. Manufacturers report that certain foreign standards requirements that appear to be mandatory may in practice be negotiable with the inspector.

For example, in the United Kingdom, one manufacturer succeeded in overcoming a seemingly mandatory DHSS radiation protection standard for X-ray equipment that contained an unworkable limit on fluoroscopic exposure. Through negotiations with the inspector involved, the manufacturer was able to obtain approval of its product (235).

Effect of Standards on Innovation.—The interpretation of standards by foreign governments and the reliability y of information can be linked to the issue of how standards keep pace with new technologies. Some countries, such as Mexico, reportedly use out-of-date standards and have rejected products not meeting these standards. A recent example involved implantable pacemakers (301.).

Although some standards have provisions for assessing new or improved products, others are written to preclude newly developed or improved products, such as the replacement of digital monitors for analog equipment. If standards are not written to accommodate product changes, introduction of new technologies will be restricted by existing standards and will serve as a barrier to trade.

The process of changing standards, especially international standards, is often as long and cumbersome as the initial development process. New technological innovations in medical devices may thus be barred from certain countries, either voluntarily or involuntarily, because the standards for the devices have not evolved so quickly as the products themselves.