

A Guide to Documentary Standards

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ABSTRACT

This Guide is intended to provide information on the U.S. standards system, entities within that system, and different types of documentary standards. It includes descriptions of performance and design standards; voluntary consensus standards; defense standards; mandatory standards; National Institute of Justice (NIJ) standards; Federal standards; *de facto* standards; industry standards; consortia standards; and, international standards. In addition, the Guide includes information on the implementation of the National Technology Transfer and Advancement Act (NTTAA) and on the link between standards and conformity assessment.

Key Words: ANSI; design standard; mandatory standard; military standard; NIJ standard; NIST; OLES; performance standard; voluntary consensus standard.

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Introduction

A documentary standard is defined by the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) as “a document, established by consensus, and approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context”.¹

The National Institute of Justice (NIJ) of the U.S. Department of Justice works cooperatively with various Federal, state and local criminal justice, public safety agencies and others through the Office of Law Enforcement Standards (OLES) at the National Institute of Standards and Technology (NIST) to develop minimum performance standards for equipment utilized by these communities (e.g., bullet resistant vests, handcuffs, ballistic helmets and communications equipment). At NIJ’s request, OLES develops voluntary national performance standards for compliance testing to ensure that equipment is suitable for use by criminal justice and public safety agencies. These standards are based on laboratory testing and evaluation of equipment samples to determine the key attributes, develop test methods, and establish minimum performance requirements for each essential attribute. OLES also publishes technical reports and user guidelines that explain the capabilities of available equipment.

In 2001, NIJ requested that OLES develop a guide to documentary, or normative, standards for use by NIJ staff. OLES subsequently asked the Office of Standards Services (OSS) at NIST to develop the guide. They asked that the following topics be included: a description of the U.S. standards system, including the role of different entities in the system; voluntary consensus standards; military standards; mandatory standards; NIJ standards; and advantages and disadvantages of each type of standard. In addition, the guide was to include information on performance and design standards; Federal standards; *de facto* standards; industry standards; consortia standards; international standards; the implementation of the National Technology Transfer and Advancement Act (NTTAA); and the link between standards and conformity assessment.

Organization of the Guide

This Guide, intended to be factual, is organized as follows: First, background information is provided on the Office of Law Enforcement Standards. Then, the U.S. standards system is described, including information on the roles of the American National Standards Institute (ANSI), NIST, standards developing organizations (SDOs), industry, consumers, and government. Next, information is provided on different types of standards. Basic descriptions of performance and design standards, Federal standards, *de facto* standards, industry standards, consortia standards, and international standards are included. A more thorough description of voluntary consensus standards, defense standards, mandatory standards and NIJ standards is offered, including initiation and development procedures, designation, review and amendment procedures, and the author’s view of potential advantages and disadvantages of each type of

standard. Last, the link between standards and conformity assessment is described. A separate Annex contains information on the implementation of the NTTAA.

The Office of Law Enforcement Standards (OLES) at NIST

The Office of Law Enforcement Standards (OLES) is part of the Electronics and Electrical Engineering Laboratory at NIST. OLES's predecessor, the Law Enforcement Standards Laboratory (LESL), was created through a Congressional Directive to the Department of Justice and established at NIST in 1971 under an agreement between the Department of Justice and the Department of Commerce. The mission of OLES is to serve as the principal agent for standards development for the criminal justice and public safety communities. OLES has been instrumental in the development of numerous standards and the issuance of various technical reports that have had significant impact on both of these communities. Through its programs, OLES helps criminal justice and public safety agencies acquire, on a cost-effective basis, the high quality resources they need to do their jobs. To accomplish this task, OLES develops methods for testing equipment performance and for examining evidentiary materials; standards for equipment and operating procedures; users' guides; and standard reference materials. OLES also performs other scientific and engineering research as required by the criminal justice and public safety communities.

OLES is active in five principal areas, namely weapons and protective systems; detection, inspection and enforcement technologies; chemical systems and materials; forensic sciences; and public safety communications standards.

Overview of the U.S. Standards System

Historical

Standards efforts in the United States began as a private-sector enterprise slightly over 100 years ago, with a sector-specific focus. A number of voluntary standards developing organizations in the United States are celebrating their 100th anniversaries. Each organization developed its own unique procedures for specifying product characteristics and means of determining if products conformed to appropriate safety standards. Gradually, manufacturers and regulators found that these standards met their needs and could be used to specify products, test methods, and even conformance requirements for products. The dominance of the United States as an economic entity immediately after World War II reinforced this sector-specific, decentralized system. Since the existing system continued to meet domestic market needs and allowed manufacturers to develop products with acceptable levels of technology and safety, the United States did not later feel the need to develop a centralized, government-run standards system. While no one agency or organization has oversight over the entire voluntary standards process, the American National Standards Institute (ANSI) serves as a coordinating body within the private sector.

Role of the American National Standards Institute (ANSI)

The American National Standards Institute (ANSI) is a private-sector, non-profit federation

founded in 1918 by several standards developing organizations (SDOs) and Federal Agencies. ANSI's goal is to enhance the global competitiveness of U.S. industry and promote the integrity of voluntary consensus standards. The federation is currently comprised of more than 1400 members, including government agencies, standards developing organizations, companies, consumers and trade associations. Representatives of these organizations participate in various ANSI fora that are, in part, responsible for determining ANSI policy and structure. ANSI receives the majority of its revenue from private-sector dues and the sale of documents. In recent years, the National Institute of Standards and Technology has also provided a small direct grant to ANSI in support of international activities.

ANSI does not itself develop standards. Rather, it functions as a central clearinghouse and coordinating body for its member organizations, which in turn develop standards on a decentralized, consensus basis. ANSI provides guidelines for standards bodies to follow in managing their consensus standards development processes in a fair and open manner. It also accredits U.S. standards-developing organizations for compliance with these guidelines, and can approve standards submitted by accredited standards developing organizations, designating them as American National Standards. By the end of 1999, there were approximately 14,650 approved American National Standards.²

ANSI is the U.S. representative to the International Organization for Standardization (ISO) and, through the U.S. National Committee (USNC), to the International Electrotechnical Commission (IEC). The ISO and the IEC are perhaps the two best-known non-governmental standards development organizations operating in the international arena. The scope of ISO work includes all fields except electrical and electronic standards, which are the responsibility of the IEC. As the U.S. representative to these bodies, ANSI convenes delegations, approves delegation members, and appoints technical groups with a broad spectrum of experts to represent the United States in deliberations of relevant international policy Boards, individual Technical Committees, Sub-Committees and Working Groups. In this way, representatives of ANSI member organizations may serve as coordinators, through ANSI and the USNC, of U.S. technical positions within the ISO and IEC, respectively.

In 2000, members of the American National Standards Institute (ANSI) came together to create a National Standards Strategy for the United States. U.S. interests recognized that other regions of the world were promoting their own standards, technologies and practices and that the United States must promote its practices to remain competitive. The strategy establishes a framework that can be used by all interests - companies, government, non-governmental organizations, standards developers and consumers - to improve U.S. competitiveness abroad while continuing to provide strong support for domestic markets and, at the same time, addressing key quality-of-life issues such as the environment. The strategy builds on the strengths of the U.S. system by proposing a set of strategic and tactical initiatives that can be used to meet national and individual organizational objectives.³

The Role of the National Institute of Standards and Technology (NIST)

Title IV, Section 413 of the Trade Agreements Act of 1979 (19 U.S.C. 2531-2573), P.L. 96-39, authorized the implementation of all agreements negotiated during the General Agreement on Tariffs and Trade (GATT) Tokyo Round, including those relating to non-tariff barriers, such as standards-related barriers. Section 413 of the Act directs the Secretaries of Commerce and Agriculture to ensure that they are kept informed of the adequacy of representation in international standards-related activities, to identify any activities that might substantially affect the commerce of the United States, and to coordinate with the Special Representative (the Office of the United States Trade Representative, USTR) with respect to international standards-related activities. USTR is responsible for coordinating U.S. discussions and negotiations with other countries with respect to standards-related activities.

Within NIST, Technology Services's Office of Standards Services is responsible for carrying out several Title IV functions. These include maintaining: part of the "technical office" to assist with standards-related trade problems; the World Trade Organization (WTO) (formerly GATT) inquiry point; and the National Center for Standards and Certification Information (NCSCI) on standards, conformity assessment, and technical regulations. OSS also monitors the adequacy of U.S. representation in private international standards activities, particularly with regard to the potential impact on international trade.⁴ The 1994 revision of the Trade Agreements Act (P.L. 103-465), also entitled the Uruguay Round Agreements Act, did not amend these responsibilities.⁵

In addition to its responsibilities under the Trade Agreements Act, NIST serves as a coordinator of standards-related activities within the federal government. The National Technology Transfer and Advancement Act (NTTAA) and OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities," establishes policy to be followed by executive agencies in participating in activities of voluntary standards organizations and in adopting and using voluntary standards. Annex A of this Guide details NIST's responsibilities under the NTTAA and the Circular, information on the Federal Government-wide implementing body for the Circular (the Interagency Committee on Standards Policy), and issues for government agencies in implementing the Circular.

To ensure a coordinated effort between the public and private sectors in both domestic and non-treaty international standards activities, NIST and ANSI have signed (and twice revised) a Memorandum of Understanding (MoU). The current MoU recognizes the NIST and ANSI roles and how they will serve as links between private sector standards and conformity assessment interests and government interests. The objective of this cooperative effort is to enhance and strengthen the national voluntary consensus standards system of the United States while supporting continued U.S. competitiveness and economic growth.⁶

*Role of Standards Developing Organizations (SDOs)*⁷

More than 600 organizations develop voluntary standards in the United States, covering a diverse array of services, products, and systems. About 150 of them are consortia which develop *de facto* standards. Most are private sector organizations: professional and technical organizations, trade associations, research and testing bodies, building code organizations, and others.

Participants in the standards development process include representatives of government agencies, manufacturers, consumers, retailers, testing laboratories, technical experts, and other interested parties from both the United States and many other countries. The broad range of organizations developing standards and participating in the development process reflects the impact standards have on a vast spectrum of interests and disciplines.

Most formal U.S. standards developing organizations operate by the consensus process, which requires openness, balance, due process, participation of interested and affected parties, and a formal process for attempting to resolve differences of opinion. The process of developing consensus standards is open and transparent, with written procedures covering each step. As will be explained later, the entire system is known as voluntary because participation is on a voluntary basis and because compliance with the standards is usually voluntary, unless adopted or referred to by a government authority. Voluntary standards may be used by industry to build and test products and systems, or by government agencies at all levels to supplement regulations or to procure products for government use.

At the national level, the United States maintains about 100,000 standards in an active status. This figure includes Federal Government standards developed to meet procurement and regulatory needs. In recent years, the number of government-unique standards has been declining in accordance with the National Technology Transfer and Advancement Act (NTTAA), which requires government agencies to rely on voluntary standards to meet their needs instead of developing government-unique standards, whenever feasible and consistent with law and regulation.

Trade associations represent the largest category of non-government standards developers. Trade associations are organizations of manufacturers, suppliers, customers, service providers and other firms active in a given industry sector. These associations promote their own industries and products. Many trade associations develop standards for the products manufactured by their members or for products used by the entire industry. Funding for these standards development activities is primarily through member dues, while members of technical committees typically participate as representatives of their firms, not as individuals.

Scientific and professional societies are individual membership organizations that support the practice and advancement of a particular profession. Several of these, particularly those in the engineering disciplines, develop technical standards. Participants in standards committees serve as individual professionals, rather than as representatives of their firms. Funding for standards

development activities is principally from publication and sale of standards, as well as through direct services to industry.

Still other types of voluntary standards developing organizations are membership organizations, specifically founded to develop standards. Membership is not limited to a particular industry or profession. Membership fees are generally low, facilitating participation by individuals not sponsored by an employer. Publishing and selling standards accounts for the majority of revenues for these organizations. Some organizations may also provide other services such as testing products to their standards.

It should also be noted that ANSI maintains an Organizational Member Council (OMC) which allows standards developing organization members of ANSI to discuss common issues of interest to them.

Role of Industry

U.S. industry plays a vital role in the standards development process by ensuring that standards meet economic needs and incorporate new technologies. Many manufacturers participate in the standards development process, either through ANSI, through industry associations, or on their own. Some firms may not participate directly, but may still choose to submit input on issues of interest to them.

ANSI also maintains a Company Member Council (CMC) that, similar to the Organizational Member Council, serves as a forum for ANSI's company members to discuss issues of interest.

Role of Consumers

Consumers play an active and important role in all stages of U.S. standards development activities. ANSI's Board of Directors includes representatives of consumer organizations and the National Standards Strategy advocates responsiveness to consumer interests as one of its core initiatives.

Role of the Federal Government

The U.S. Federal Government plays an important role in the U.S. voluntary standards system as a purchaser, regulator and active participant in the development of specific standards. The Federal Government itself is directly concerned with setting and implementing standards through legislation, regulation or contractual obligations for sales to government purchasers. While most standards-setting activities in the Federal Government are carried out by the Department of Defense (DOD) and the General Services Administration (GSA), numerous other agencies also adopt and set standards in various fields.

It is important to note that many government personnel participate in the development of voluntary consensus standards, primarily in the role of technical experts. As such, they can

convey their agency's needs to the standards developers to facilitate the agency's potential later use of the standards.

ANSI also maintains a Government Member Council (GMC) to serve as a forum for government members to discuss issues of mutual interest.

Types of Standards

Now that a basic overview of the U.S. standards system has been provided, it is important to understand similarities and differences among types of standards. A standard may be either a performance or design standard, or may incorporate both performance and design characteristics. A description of performance and design standards is therefore provided first. Following this brief description, this section will discuss voluntary consensus standards, defense standards, mandatory standards, and standards developed by the National Institute of Justice. For each type of standard, the standards development, designation, review and amendment processes are described. The author's own opinion presents some possible advantages and disadvantages of each type of standard. Finally, a basic description of other types of standards is provided, including Federal, *de facto*, consortia, industry, and international standards.

Performance and design standards

One distinction among standards is the manner in which they specify requirements. Standards that describe a product's intended function, but without stating how it might achieve that function, are called performance standards. In contrast, design standards define the product's characteristics, or how it is to be built. The distinction between these two types of standards is not always clear. Within a standard, one requirement may be stated in terms of performance while another is in terms of design. For example, in a standard for tires, some requirements may be specified in terms of performance (such as the ability to withstand a specified amount of pressure, or wear and tear), but the tire's dimensions may be required to meet specific designs.

Design standards are often appropriate, such as in testing methods where the need for comparability outweighs other considerations. However, in general, performance standards tend to be less restrictive than design standards and are more likely to encourage innovation.⁸ For that reason, standardizing bodies that have accepted Annex 3, the Code of Good Practice for the Preparation, Adoption and Application of Standards of the WTO Agreement on Technical Barriers to Trade are encouraged to write standards in terms of performance, rather than design, characteristics.⁹

Voluntary Consensus Standards

The definition of consensus developed by the ISO/IEC is, "General agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments."¹⁰

As mentioned earlier, major U.S. standards developing organizations (SDOs) operate by a consensus process, characterized by openness, transparency, and mechanisms for ensuring adherence to organizational processes, including provision for appeals. The standards produced by these SDOs are usually called voluntary consensus standards because both participation in the standards development process and compliance with the standards are voluntary, except where government regulatory agencies have adopted or referred to the standards.

In the United States, many SDOs follow ANSI criteria to have the consensus standards they develop approved as American National Standards (ANS). As previously mentioned, there were approximately 14,650 approved American National Standards in 1999. However, many consensus standards developed by U.S. SDOs are not submitted for designation as American National Standards. Procedures for development, designation, and review differ according to the organization that is in charge of the development process. This section does not attempt to cover all the different types of processes followed to develop non-ANS designated voluntary consensus standards. Instead, this section focuses on the development of ANSs, as outlined in the ANSI Procedures for the Development and Coordination of American National Standards. The full Procedures document may be found on the ANSI homepage at <http://www.ansi.org>.¹¹

Initiation and Development Procedures

Any standards developer whose procedures meet the requirements of due process and criteria for approval and withdrawal of ANS, as outlined in the ANSI Procedures, may apply to ANSI for accreditation. Due process means that any person with a direct and material interest has a right to participate in standards development activities by expressing a position, having that position considered, and having the right to appeal. ANSI Procedures stipulate that the minimum acceptable due process requirements for the development of consensus include, among others, openness, balance, interest categories, written procedures, appeals, and notification of standards development. The full list of ANSI's due process requirements for the development of consensus may be found in Section 1.2 of the ANSI Procedures. Similarly, the description of criteria for approval and withdrawal of ANSs may be found in Section 1.3 of the ANSI Procedures.¹²

ANSI accredits standards developers to one or more of three recognized methods of developing evidence of consensus. Below is a brief description of each of these three accepted methods:¹³

Accredited organization method

Under this method, the standards developer must develop its own operating procedures and submit a copy to ANSI. The procedures must meet the requirements outlined in ANSI Procedures. These include: ensuring due process; providing administrative oversight and support for its standards development activities; providing an appeals mechanism; designating, maintaining, and publishing standards produced; advising ANSI of the initiation and scope of

potential new ANSs; and advising ANSI of the revision, reaffirmation, or withdrawal of ANSs. Please see Section 2.2 of the ANSI Procedures for a full list of accreditation criteria.

Accredited standards committee method

Accredited standards committees are administered by a secretariat. The secretariat is maintained by an organization that has offered to be responsible for providing administrative oversight of the committee's activities and ensuring compliance with relevant operating procedures. The committee may choose to develop its own operating procedures in accordance with the accreditation requirements outlined in ANSI Procedures or to follow Annex A, Model Procedures for an Accredited Standards Committee, of the ANSI Procedures.

Accredited canvass method

A standards developer using the canvass method develops a draft standard and then relies on due process to determine consensus. This is accomplished by identifying those who are directly and materially affected by the standards development activity and determining consensus on the draft standard through a letter ballot or canvass. The canvass process must be carried out in accordance with Annex B, Procedures for Canvass by an Accredited Sponsor, of the ANSI Procedures. Annex B includes procedures on developing and populating an appropriate canvasee list, conducting the canvass, resolution of objections, appeals, and submission of standards for ANSI approval.

Designation

Standards are approved as American National Standards after ANSI determines they have been developed in accordance with its consensus procedures. Those standards must have an approved logo furnished by ANSI or the words "an American National Standard" on their cover or title page. Any portion of the document that is not part of the American National Standard must be identified.

Standards that are not designated as American National Standards may carry different logos or titles, depending on the procedures of the organization that has developed the standard.

Procedures for Review and Amendments

To ensure that ANSs are current and relevant, standards developers must follow either a periodic or continuous maintenance cycle to reaffirm, revise, or withdraw standards. Under the periodic cycle, the process to reaffirm, revise or withdraw standards must begin within four years of the date of the standard's approval as an ANS. If the standards developer cannot complete this process within five years of the date of approval, the developer must request an extension of the review date from ANSI. Extensions with rationale may be granted. However, no extension of time is granted beyond 10 years of the date of the standard's approval as an ANS.

Alternatively, a standards developing organization may also follow a cycle of continuous

maintenance, under which it maintains its own program for periodic publication of revisions, not to exceed four years. If no action has been taken to revise the standard after four years, action will be taken to reaffirm or revise the standard in accordance with the procedures outlined under the periodic maintenance cycle.¹⁴

Opinion: Advantages and Disadvantages

The ANSI Procedures ensure that all standards designated as American National Standards have been developed in a consensus manner and incorporate due process and openness. As a result, all parties, including regulators and consumers, can have a high level of confidence in the standards developed. Also, the standards typically incorporate the highest level of technology at the lowest cost.

One disadvantage to the ANSI process is the length of time allowed for revision of ANSs. Upon request, and with rationale, a standards developer may take up to ten years to revise, reaffirm or withdraw an ANS from its original date or approval. For regulators and consumers who require that standards incorporate the latest, safest technologies and practices as soon as possible, an additional possible five-year delay in updating beyond the regular five-year period is a lengthy one.

Military Standards and Specifications

The Department of Defense (DOD) is the largest developer and user of standards in the United States. In recent years, former Secretary of Defense Perry pioneered the effort to reduce the DOD practice of writing new specifications instead of taking advantage of voluntary standards already on the books. The Department of Defense has since undertaken the Military Specifications (MilSpecs) Reform initiative, which emphasizes replacement of military-unique documents with voluntary consensus standards wherever there is a dual-use application. As a result of this initiative, DOD has reviewed all of its Military Specifications and standards. Also, the Department has put into place a system to review new requirements for military-unique documents to determine if existing voluntary consensus documents would be more appropriate. If so, DOD reviews all available sources to locate appropriate voluntary consensus standards rather than create military-unique documents. DOD maintains a five-year review process to identify documents that did not have a voluntary consensus standard counterpart at one time, but for which an appropriate document may have since been created.¹⁵

For areas for which no other standard or specification is readily available, the Department develops and uses military standards and specifications, otherwise known as defense standards and defense specifications. A defense standard is defined as a document that establishes uniform engineering and technical requirements for military-unique or substantially modified commercial processes, procedures, practices, and methods. Types of defense standards include interface standards, design criteria standards, manufacturing process standards, standard practices, and test method standards. Content and format for defense standards are outlined in MIL-STD-962C.

Defense standard requirements must be written in performance terms to the maximum extent possible.¹⁶

A defense specification is defined as a document that describes the essential technical requirements for purchased materiel that is military-unique or substantially modified commercial items. Content and format for all defense specifications are covered in MIL-STD-961D. Defense specifications must be written in performance terms to the maximum extent possible. An alternative to defense specifications are guide specifications, which identify performance characteristics for subsystems, equipment, or components.¹⁷

Initiation and Development Procedures

As mentioned earlier, DOD reviews all available sources to locate an appropriate voluntary consensus standard rather than create military-unique documents. Should a voluntary consensus standard not exist, defense handbooks may be developed to provide guidance on the use or application of commercial products and practices, as well as for military products and practices. Defense specifications or standards may be developed for items with military-unique requirements.

To determine whether development of a defense standard or specification will proceed, the project proponents within DOD must answer a series of questions about the document. The questions focus on determining the need for the document, whether an existing document could be used instead of developing a new document, whether the document will cover a process or product that is commercial or military-unique, and if the document requires the use of hazardous materials.

Drafting of any defense standard or specification must be coordinated with appropriate interests. The extent of coordination depends on the type of document being developed. This section of the publication will discuss only the process undertaken for coordinated documents. Coordinated documents are those that are to be used by more than one department or agency within the Department of Defense. Under the coordinated process, draft standards or specifications are developed by project proponents within DOD and distributed for comment to appropriate representatives of industry, civilian interests, DOD users, and any other appropriate users. If the draft is distributed electronically, a 45-day response time is allowed. If drafts are distributed by mail, a 60-day response time is allowed.

Any comments received during the comment period shall be considered. However, only essential comments must be resolved or incorporated. Essential comments are those that are critical to ensuring that mission needs are met. Resolution of essential comments can be accomplished by acceptance of the comments, modification, rejection, discussions on comments via working groups, or arbitration.¹⁸

Designation

After essential comments have been resolved, defense standards and specifications are considered approved and are dated. An appropriate Standardization Executive must approve new defense standards. New defense specifications must be certified in accordance with procedures established by military departments or defense agencies.

After approval, a document number is assigned to the new standard or specification. All draft and final standardization documents have a cover that includes any applicable security classification, title, document identifier, date of issue, the DOD seal, and any relevant numbers assigned to the document.

Procedures for Review and Amendment

Originating offices are responsible for maintaining documents up to date. All documents must be reviewed every five years for update, inactivation, or cancellation. If no action has been taken after an additional year, the originating office will be notified of pending cancellation and after thirty days, if no action has still been taken, the document will be cancelled. The originating offices may also request to reinstate a cancelled document. An appropriate Standardization Executive must approve any reinstatement.

If a document is revised or amended, the same procedures are followed as those already outlined for development of a new standard or specification. If no revisions are necessary, originating offices issue a validation notice that states the requirements outlined in the document are current and meet users' needs. Updates of defense standards may be approved by the originating office without the approval of the Standardization Executive. Similarly, updates of defense specifications may be approved without certification.¹⁹

Opinion: Advantages and Disadvantages

One advantage of defense specifications and standards is that they serve as a source of information for items with military-unique purposes. DOD contractors, suppliers and users of the military-unique item do not have to develop the standards or specifications for the item themselves. Instead, they may draw upon existing standards and specifications that have been developed by experts and through consultations. In addition, thanks to DOD's efforts to reduce the number of military-unique standards and specifications and to rely on voluntary consensus standards wherever possible to meet DOD's procurement needs, DOD has ensured that the military is able to enhance efficiency, reduce costs, use commercial products and practices, and rely on the latest technologies.

One disadvantage of defense specifications and standards is that when DOD develops a military-unique standard or specification, input is not solicited on a broad basis nor is anyone outside DOD directly involved in developing the draft standard. In addition, there is no mechanism for

appeals or for ensuring that non-essential comments are resolved or taken into account.

Mandatory Standards

“A mandatory standard is a standard the application of which is made compulsory by virtue of a general law or exclusive reference in a regulation.”²⁰ A mandatory standard is generally published as part of a code, rule or regulation by a regulatory government body and imposes an obligation on specified parties to conform to it. Voluntary consensus standards may be referenced in government regulations or procurement specifications, effectively rendering them mandatory for the indicated purposes. Voluntary consensus standards may also become quasi-mandatory due to conditions in the marketplace.

Government-unique standards are those developed by the government for its own uses. Should these standards be referenced in regulations, they become mandatory. However, the number of these mandatory government-unique standards has been decreasing as more U.S. Government agencies look to existing, voluntary consensus standards to meet their needs.

The basic process by which U.S. Government agencies develop a rule or regulation is described below. Approaches to incorporate standards into those rules or regulations are also described.

Initiation and Development Procedures²¹

The basic rulemaking process to be followed by all agencies of the U.S. Government is set out in the Administrative Procedures Act (APA). The APA requires that in issuing a substantive rule (as distinguished from a procedural rule or statement of policy), an agency must at a minimum:

- Publish a notice of proposed rulemaking in the Federal Register setting forth the text or the substance of the proposed rule, the legal authority for the rulemaking proceeding, and applicable times and places for public participation;
- Ensure that all interested persons have an opportunity to participate in the rulemaking by providing written data, views, or arguments on a proposed rule. This public comment process serves a number of purposes, including giving interested persons an opportunity to provide the agency with information that will enhance the agency’s knowledge of the subject matter of the rulemaking. The public comment process also gives interested persons an opportunity to challenge the factual assumptions on which the agency is proceeding, and to show in what respect such assumptions may be in error; and
- Publish a notice of final rulemaking at least thirty days before the effective date of the rule. This notice must include a statement of the basis and purpose of the rule and respond to all substantive comments received. Exceptions to the 30-day rule are provided for in the APA if the rule makes an exemption or relieves a restriction, or if the agency concerned makes and publishes a finding that an earlier effective date is required “for good cause”. In general,

however, exceptions to the APA are limited and must be justified.

As mentioned earlier, the National Technology Transfer and Advancement Act (NTTAA) directs Federal agencies to participate in voluntary standards development activities and to use voluntary consensus standards to meet their regulatory or procurement needs in lieu of developing government-unique standards, except where inconsistent with law or otherwise impractical. This is in recognition that many voluntary consensus standards are appropriate or adaptable for the Government's purposes. In response to the Act, Federal agencies regularly review and incorporate appropriate voluntary consensus standards into their regulations, either directly or through reference, thereby rendering the standards mandatory. In 1999, Federal agencies reported 542 voluntary consensus standards were substituted for government-unique standards.²²

Designation

Once a regulation has been established, it becomes part of the Code of Federal Regulations. If a voluntary standard is referenced in the regulation, it may be referenced in whole or in part. Many regulations that reference voluntary standards will provide contact information on how the standard may be purchased so that interested parties may fully understand and comply with the regulation. Similarly, if government-unique requirements are incorporated into the regulation, information on how to comply with those requirements will be made available.

Procedures for Review and Amendment

It is up to individual agencies to determine when a regulation will be reviewed or amended. Individuals may write to an agency at any time to request that a regulation be reviewed or amended. Appropriate rationale must be provided.

One issue that has arisen as Federal agencies rely more on voluntary consensus standards is that of updating out-of-date standards in their regulations. As mentioned earlier, many standards developing organizations update and review their standards at a minimum of once every five years. If a Federal agency references that standard in its regulation, the agency must be sure that it is referencing the most recent version or language. In cases where the agency only references the standard by name and number, the regulation does not necessarily need to be updated at the same time as the standard is. However, should portions of the standard's text be included in the regulation, and that text change, the regulation must also be updated to reflect the new text. Federal agencies are working closely with appropriate standards developing bodies to address this issue.

Opinion: Advantages and Disadvantages

One advantage of mandatory standards is that they help protect the environment and human, plant, and animal health and safety. If a regulatory agency decides to incorporate voluntary consensus standards in its regulations, the resulting regulations can take advantage of and incorporate the latest technologies at a relatively low cost to the regulator. In addition, the

voluntary consensus standard will have been developed in an open manner, through discussions with a broad range of users and through resolution of comments using the consensus process.

One disadvantage to government-unique mandatory standards is that parties that need to comply with them may need to develop new processes or manufacturing methods in order to comply. This may lead to increased costs and reduced competitiveness for the complying parties.

National Institute of Justice Standards

The Law Enforcement and Corrections Standards and Testing Program is sponsored by the Office of Science and Technology of the National Institute of Justice (NIJ). The Program is an applied research effort that determines the technological needs of Federal, state, and local criminal justice and public safety agencies, develops technical reports, sets minimum performance standards for specific devices, tests commercially available equipment against those standards, and disseminates the standards and the test results to criminal justice and public safety agencies nationally and internationally.

Initiation and Development Procedures

Development of equipment standards is a collaborative effort among Federal, state and local criminal justice and public safety agencies and others. NIJ cooperates with various public and private sector entities to develop the best standards possible. The NIJ program operates through a system of regional centers. OLES serves as one of these centers, working closely with the National Law Enforcement and Corrections Technology Center (NLECTC) in Rockville, Maryland, who manages, on behalf of the National Institute of Justice, all the equipment test programs. The NLECTC maintains an Advisory Board known as the Law Enforcement and Corrections Technology Advisory Council (LECTAC). LECTAC is composed of several subcommittees that cover specific equipment and technology areas. Members of LECTAC and of LECTAC subcommittees are nationally recognized criminal justice practitioners from Federal, State, and local agencies that are appointed for specific terms based on their distinguished service records. LECTAC recommends research and development priorities and advises the NLECTC on equipment testing and the creation of standards, user guides, and technical reports. LECTAC also reviews and analyzes the present and future technological needs of the criminal justice system, particularly at the State and local levels.

The NIJ standards development work is carried out by OLES and responds directly to identified needs. After OLES staff develops the draft standard, it is sent to the LECTAC for review and comments. The draft may also be sent to appropriate manufacturers. All comments received on the draft standard are seriously considered but the final decision to issue a standard is made by NIJ.

Designation

Most NIJ minimum-performance standards take 2 to 3 years to develop. Once they are

completed, they are issued as NIJ voluntary national standards.

Procedures for Review and Amendment

NIJ standards are usually reviewed every 3 to 4 years for revision or update. Standards may be reviewed more frequently if there are changes to a particular technology or if interested parties request a review and submit corresponding appropriate rationale. If a standard is amended, the NIJ will issue a notice of change to Federal, state, and local law enforcement and public safety agencies. Typically, when a standard is amended, there is a transition period between the old and new standards. At the end of the transition period, all users of the old standard should have begun using the new standard.

Opinion: Advantages and Disadvantages²³

There are currently more than 3,000 police departments in the United States. 90% of them are small in size and do not have the money or resources to develop their own standards. Prior to the development of minimum-performance standards for equipment, law enforcement and public safety agencies were required to rely on the untested claims of product manufacturers and the opinions of consumers when purchasing equipment. NIJ standards provide independent and accurate information on cost-effective, reliable equipment standards that incorporate the latest advances in life-saving technologies.

The biggest disadvantage of NIJ standards is that they are voluntary. Police departments do not have to buy equipment that meets NIJ standards if they choose not to. However, some Congressional Grants to local police departments require grant recipients to use equipment that complies with NIJ standards.

Other Types of Standards

Federal Standards

Federal standards are developed and issued by the General Services Administration (GSA) to meet procurement needs of Federal Government agencies.

De Facto

In a number of industrial sectors, standards developed through means other than formal standards organizations have become increasingly important. Such *de facto* standards need to be considered in the overall context of standardization.

De facto standards are developed in a number of ways and are typically open to participation from any interested individuals or organizations. A single company with great market power may sometimes introduce a product that becomes a *de facto* standard by virtue of its widespread adoption in the market. Microsoft's Windows operating system, Hewlett Packard's printer control language, and Sun Microsystem's JAVA programming language are a few examples. Sometimes such standards may eventually be introduced into formal standards and become *de*

jure standards. For example, the C programming language originally developed by Bell Laboratories was eventually adopted as an ANS and ISO/IEC standard.

Consortia

Very few companies have the market power to create a standard on their own. However, it is becoming increasingly common for groups of like-minded companies that collectively have significant market power to develop a standard through a consortium, outside the formal standards process. These are often motivated by the need to rapidly develop a specification for a new technology that the promoters wish to bring to market quickly. In many cases the market being addressed is new or rapidly evolving, and the basis for competition is the technology itself. If the proponents attempted to move such specifications through the formal system, the process would be much slower. Recent examples of standards developed by consortia include Bluetooth (a standard for wireless connectivity) and Wireless Application Protocol, among others.

Some view the formation of such consortia as a failure of the formal standards system. Another view is that this approach provides a complementary vehicle that satisfies an important industry needs to create partial-consensus standards in rapidly moving, high technology fields.

There is now a growing recognition of the need to combine the consortia development process with the formal standards development process. For example, the Institute of Electrical and Electronics Engineers (IEEE) formed a new organization, called the IEEE Industry Standards and Technology Organization (ISTO), to provide a flexible structure to support the formation and operation of consortia-like groups in IEEE-related fields. This structure allows a participant group to develop an IEEE-ISTO standard to address a specific market need more rapidly than would be possible through the full consensus process. It also provides a means by which the specification can subsequently go through the process of the IEEE Standards Association, if appropriate, to become a full consensus standard. This flexibility provides an effective way for specifications for new technologies to be rapidly developed and introduced to market, while providing a path for those that become proven and accepted in the market to become full, consensus standards.

Industry

Within the category of industry standards, there are both company standards and industry standards. Company standards are those developed for use by a single company or organization for its own products or for the products it purchases, while industry standards may be developed and used within a particular industry. Members of industry standards development groups are typically representatives of a particular company or industry.

International

International standards are developed and promulgated by governmental and non-governmental international organizations. International standards may be voluntary or mandatory in nature.

The best known non-governmental standards development organizations operating in the international arena are the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), where ISO covers all fields except electrical and electronic standards, which are the responsibility of the IEC. In addition, the International Telecommunication Union (ITU) is a treaty organization which develops Recommendations in the area of telecommunications standardization. The U.S. State Department coordinates U.S. participation in the ITU.

During the Second Triennial Review of the Operation and Implementation of the WTO Agreement on Technical Barriers to Trade (TBT), the WTO Committee on Technical Barriers to Trade developed Annex 4 to the Agreement, entitled 'Decision of the Committee on Principles for the Development of International Standards, Guides And Recommendations'. The Annex lays out specific principles and procedures that should be observed when developing international standards, guides and recommendations. These principles and procedures relate to transparency, openness, impartiality and consensus, effectiveness and relevance, coherence, and the concerns of developing countries.²⁴ Annex 4 was developed partially in response to a long-standing debate about what types of bodies should be considered international standardizing bodies.

Relationship between Standards and Conformity Assessment

Because standards and conformity assessment activities have an impact on one another, it is important for readers to have some familiarity with conformity assessment procedures.

Standards can cover many aspects of the conformity assessment process. They can describe characteristics of the product for which conformity is sought; the methodology (e.g., test, inspection or other assessment methods) used to assess conformity; or even the conformity assessment process itself (e.g., how a certification program should be operated). Standards used in conformity assessment should be clearly and concisely written, readily understood, precise, technically credible, and contain only unambiguous requirements - the absence or presence of which can be objectively verified. The use of well-written standards in a conformity assessment process lends credibility and validity to the process, increasing its usefulness. In addition, standards for conformity assessment methods (e.g., test methods) used in the conformity assessment process should be capable of evaluating the conformity of a product to the specified requirements in a manner that produces test results that are within an acceptable accuracy range. The results should also be consistent with results produced by the same laboratory when it repeats the test using the same or a similar test method. The results should also be reproducible, i.e., capable of being duplicated by other testing bodies using the same or similar test methods.

Standards used in conformity assessment should also be chosen so that they specify all essential characteristics of a product necessary for achieving the objective of the conformity assessment

activity. For example, if the objective is to ensure the electrical safety of a microwave oven, a standard that covers only the electrical safety of the oven's cord but not the oven's heating element would fail to meet that objective. Knowing what aspects of the product will be evaluated in a conformity assessment process and whether there are other aspects which might impinge on quality, safety, or performance allows the user of the conformity assessment data to evaluate the data's significance.²⁵

Conclusion

As can be seen from the overview provided in this Guide, the U.S. standards system is highly decentralized. A large number of different groups within the United States develop and/or participate in developing various types of standards. Participation and development procedures and practices depend on the area of standardization, resource considerations, and potential use of the standard. Examples of standards developers include trade associations, technical organizations, and scientific and professional societies. The Federal Government, including the National Institute of Justice, also develops standards for its own use. Users of standards include consumers, retailers, manufacturers, companies, Federal, state and local level governments, among others. In short, standards have an impact on almost every aspect of daily life in the United States. That impact is reflected in the breadth and diversity of use of standards and participation in the development process.

While the U.S. system is decentralized, it is also highly effective. ANSI Procedures ensure that SDOs accredited by ANSI operate in a consensus manner. Similarly, increased government participation in voluntary standards development, combined with the passage of the NTTAA, has led to greater reliance on voluntary standards to meet procurement and regulatory needs. There has also been increased recognition of the impact of standards on trade, as evidenced by the development of Annex 4 on International Standards within the WTO Committee on Technical Barriers to Trade.

In the United States, all of these factors have come together to create safe, reliable standards that incorporate the latest technologies at the lowest cost.

Annex A - OMB Circular A-119

“Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities”

Implementation of the National Technology Transfer and Advancement Act (NTTAA) through OMB Circular A-119

Responsibilities of NIST

Under the Circular, which serves as implementation guidance for the National Technology Transfer and Advancement Act of 1995 (P.L. 104-113), NIST is directed to:

- Coordinate and foster executive branch implementation of the Act and, as appropriate, provide administrative guidance to assist agencies in implementing the Act including guidance on identifying voluntary consensus standards bodies and voluntary consensus standards;
- Sponsor, chair and support the Interagency Committee on Standards Policy (ICSP), which considers agency views and advises agency heads on the Act;
- Report to the Director of the Office of Management and Budget (OMB) concerning the implementation of the policy provisions of the Act;
- Establish procedures for agencies to use when developing directories and establish procedures to make these directories available to the public; and,
- Issue guidance to other agencies to improve coordination on conformity assessment.

Interagency Committee on Standards Policy (ICSP)

The Interagency Committee on Standards Policy (ICSP) advises the Secretary of Commerce and other Executive Branch agencies in standards policy matters. The Committee reports to the Secretary of Commerce through the Director of the National Institute of Standards and Technology (NIST). The Committee's authority is set out in Section 13 of OMB Circular A-119.²⁶

The ICSP Membership consists of one principal representative from each Federal Executive Agency. The representative is an official appointed to serve as the Agency Standards Executive. The objectives of the ICSP are to promote effective and consistent standards policies in furtherance of U.S. domestic and foreign goals and, to this end, to foster cooperative participation by the Federal government and U.S. industry and other private organizations in standards activities, including the related activities of product testing, quality system registration, certification, and accreditation.

One of the key activities undertaken to implement the Circular is the compilation of the OMB Annual Report. The reports address the Federal government's use of voluntary consensus standards during each fiscal year. At the time of this writing, the Annual Reports for 1997, 1998, and 1999 are available on the Internet at <http://ts.nist.gov/ts/htdocs/210/nttaa/pubs.htm>.

Issues for Government Agencies

Since the 1996 revision of OMB Circular A-119, a number of reporting issues have arisen for Federal agencies. Most Federal agencies have continued to progress in their use of voluntary consensus standards for agency programs and missions for both procurement and regulatory activities. However, for many agencies, resources for participation in standards activities appear to be diminishing, thereby making it difficult for agencies to ensure adequate representation on appropriate committees. There has also been a corresponding decrease in resources for participation in standards-development activities by industry.

Some agencies are also having difficulty knowing when to report instances of government standards being used in lieu of voluntary consensus standards. Some agencies also report difficulty in updating out-of-date standards in their regulations. Current standards reflect new technology; new products; more precise methods of testing; and faster, cheaper, and better ways of doing things. It is important that regulations incorporate these new approaches. The time and effort required for agencies to conduct reviews to ensure that voluntary standards address regulatory concerns, combined with the resources needed to promulgate rules, can require the commitment of substantial agency resources-- resources which may not be available given other agency priorities. The ICSP is focusing on procedures for improving the timeliness of updates of standards used in regulations.

As a result of the Law and the Circular, there is increased use of voluntary standards by Federal agencies in both regulation and procurement, and conformity assessment activities are now receiving greater attention than before passage of the Law.

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