



## EUROPEAN QUESTIONS ABOUT THE U.S. STANDARDIZATION SYSTEM

This working document presents a list of questions prepared by the three European Standardization Organizations (ESOs)- CEN, CENELEC, and ETSI-in order to gain a better understanding of the U.S. standardization system.

It was developed in the framework of the discussion between the ESOs and ANSI about a possible formalization of their cooperation.



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NOTE: This working document initially issued on October 31, 2014 was updated in April 2015 and again in July 2018 and contains responses to a list of questions by European stakeholders addressing the U.S. standardization system.

This Q&A material is not intended to provide a comprehensive overview of the U.S. systems; an answer to a question does not imply that said answer is a complete or comprehensive explanation or response to the intended question.

# ABOUT ANSI

## 1. U.S. standardization strategy:

- a) Which are the parties involved in its development?
- b) Under what framework and through what type of process is it developed?

**Answer:** The strategy was developed through the coordinated efforts of a large and diverse group of constituents representing stakeholders in government, industry, standards developing organizations, consortia, consumer groups and academia. The strategy was developed in an open, balanced,<sup>1</sup> and transparent manner. The result represents the vision of a broad cross-section of standards stakeholders and that reflects the diversity of the U.S. standards system. The [United States Standards Strategy](#) was approved by the ANSI Board of Directors on December 8, 2005, and was updated and re-approved on December 2, 2010, and again on December 2, 2015.

## 2. Funding and fees:

- a) Are ANSI's revenues solely private funding?

**Answer:** For the most part, yes, from companies, organizations, and sale of publications.

- b) Government agencies are members of ANSI; do they pay a fee like other members?

**Answer:** Yes, government members of ANSI pay membership dues in accordance with a dues schedule based on the agency's budget.

- c) What is the share of ANSI-accredited Standards Developing Organizations (SDOs) in the membership dues?

**Answer:** ANSI-accredited standards developers pay a total annual national activity assessment of about \$1 million. In addition, they pay ANSI organizational membership dues (or the equivalent).

## 3. ANS standards:

- a) Which is, in brief, the procedure for an ANSI-accredited Standard Developing Organization (SDO) to submit standards as American National Standards?

**Answer:** Please see the *ANSI Essential Requirements: Due process requirements for American National Standards* [clause 4.1](#). The process includes an application, fee and set of proposed procedures to be used by the standards developer to develop evidence of consensus in support of a standard's approval as an American National Standard. These documents are announced for public comment, comments are responded to by the applicant and the ANSI Executive Standards Council reviews all related information and votes to accredit a standards developer. The decision to accredit is then subject to ANSI's multi-level appeals process.

1. The United States Strategy Committee consists of 22 representatives from the standards and conformity assessment community. The group's membership was selected to ensure a broad representation of diverse interests, industry sectors, small/medium and large organizations, federal and state government and more.

b) How long on average does this process last?

**Answer:** The length of time involved in the ANSI approval process for an ANS is based on the completeness of the evidence of consensus submitted by the ANSI-accredited standards developer to ANSI. The minimum amount of time would be approximately 6 months, but the length of time required to develop consensus in support of a standard's approval as an ANS is based on the nature of the standard and the procedures employed by the ANSI-accredited standards developer.

c) Does this process require any kind of validation by ANSI's governance?

**Answer:** The ANSI Board of Standards Review (BSR), which reports to the ANSI National Policy Committee, an ANSI governance body, approves individual documents as American National Standards for all but 6 ANSI-accredited standards developers, which hold the status of ANSI Audited Designator. The 6 audited designators are: ASTM International, American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE), International Association of Plumbing and Mechanical Officials (IAPMO), National Fire Protection Association (NFPA), National Science Foundation (NSF), and Underwriters Laboratories (UL).

d) Is there a mechanism ensuring that an ANS standard is regularly reviewed and updated?

**Answer:** Yes. Please refer to maintenance requirements contained in [clause 4.7 of the ANSI Essential Requirements](#) which provide three options: 1) periodic maintenance, *i.e.*, on a 5-year cycle at most; 2) continuous maintenance, *i.e.*, the entire standard is open for comment at all times; and 3) stabilized maintenance, which applies to mature standards only.

e) Are there any verification/checking procedures in the U.S. for avoiding that two standards cover the same matter or product, thus introducing conflicting requirements in the market? If yes, how it does apply in practice?

**Answer:** Yes. Please refer to related procedural requirements contained in the *ANSI Essential Requirements*. Participants in the process raise such issues, which are addressed through the relevant standards developer's procedures and the *Essential Requirements*. U.S. industry in general values competition in the market place as a means to produce a best quality standard.

The U.S. Government (USG) has guidelines and mechanisms to avoid conflicting requirements in regulations (including those that may incorporate standards). See, *e.g.*, [Executive Order 12866](#). The United States has also committed to base standards, technical regulations and conformity assessment procedures on relevant international standards, except where ineffective or in appropriate (see, *e.g.*, [WTO TBT Agreement](#), see also [19 U.S.C. 2532](#)), and committed to determine whether a standard is international based on whether the standard was developed in accordance with the WTO TBT committee decision principles on international standards development which include the avoidance of "duplication of, or overlap with, the work of other international standardizing bodies" (see, *e.g.*, [United States - Korea Free Trade Agreement](#)).

f) Is there any requirement for the pricing of standards from ANSI-accredited standard developers to be proportional? Some are known to be much higher priced than others.

**Answer:** No.

- g) Which is the added value of an accredited American National Standard compared to another standard developed by a non-accredited Standard Developing Organization (SDO)?

**Answer:** Please refer to the summary contained in the [Value of an ANS](#). The value of an ANS designation may include: public and national benefit from an open and accessible process; market recognition; public confidence that the development process was fair and the resulting standard is of a high quality because all stakeholders have a voice; may increase the government's confidence that the standards development process for a particular voluntary consensus standard it is using meets the criteria for use outlined in law and policy; and some potential legal safeguards stemming from the due process requirements ANSI's procedures mandate. Certain ANSI-accredited Standards Developing Organizations (SDOs) choose to forgo submitting some or all of their standards for formal approval and designation as ANS. However, if an accredited standards developer does not maintain one or more approved American National Standards, then the developer is subject to a review of its accreditation and must submit a justification as to why they have not submitted any standards to ANSI for approval and why their accreditation remains relevant. As a result, the accreditation may be suspended or withdrawn if the justification is not provided or is otherwise unsatisfactory.

- h) What is the correct codification/designation of an American National Standard?

ANSI (e.g., ANSI 1234), or ANS (e.g., ANS 1234)

See the ANSI leaflet "[American National Standards - value of the ANS designation](#)" referring to "ANS standards."

In contrast, see American Nuclear Society website, [which also refers to ANS standards](#) and to American National Standard (as different designations):

**Answer:** The above excerpt reflects an acronym that has two separate and distinct meanings. "ANS" is the acronym utilized by the American Nuclear Society. "ANS" is also the acronym for "American National Standard". It so happens that the American Nuclear Society is also an ANSI-accredited standards developer and sponsors American National Standards (ANS). The meaning of the acronym is relevant to the context in which it is used.

Historically, going back to the 1970s and before, all American National Standards had an "ANSI" prefix to their designation, several standards developers also used their own proprietary designation (e.g., ANSI abc/UL xyz). Since then most Standards Developing Organizations (SDOs) now use only their proprietary designation; however, some standards developers who only used the ANSI prefix and an alpha-numeric designation kept this designation as it was well-known, and is still well-known, by the concerned sector.

#### 4. Is there any intent in ANSI to establish coordination activities of horizontal requirements especially related to health and safety?

**Answer:** Not at this time.

#### 5. What is ANSI's role in relation to international and European telecommunication standardization?

**Answer:** With regard to the International Telecommunication Union (ITU), the U.S. State Department is the voting member as the ITU is a treaty organization. However, ANSI and the private sector have provided recommended positions and related input on policy questions from time to time, via the State Department. The State Department also consults through an interagency process and relies on private sector organizations and advisory committees for technical input, as needed.

With regard to European telecommunication standardization, ANSI in times past has attended as a liaison/observer to the European Telecommunications Standards Institute (ETSI) General Assembly, particularly in the 1990s as ETSI was developing its patent and intellectual property policies. ANSI delegations have met with ETSI since its formation as part of the ANSI-European Standards Organizations (ESO) meetings. Concerning technical standards, ANSI has no direct role with regard to European telecommunication standards, leaving that to U.S.-based companies and organizations with telecommunication standards in their scope of activities.

#### 6. Does ANSI publish a map/list of ANSI-accredited standards developers in the U.S. (and the technology or market domains they typically cover, and contact information) at an easily accessible single location on the web? Is there any law or code of conduct requiring or recommending this?

**Answer:** Yes, ANSI provides a [list of all its accredited standards developers](#) with their contact information at one accessible single location on the web.

No, there is no law or code of conduct requiring such a listing, or recommending one.

#### 7. Relations with non-accredited Standards Developing Organizations (SDOs):

a) Does ANSI maintain any formal or informal contact with non-accredited SDOs?

**Answer:** ANSI engages all standards developers that are interested in the work of the Institute. Please see [ANSI's collaboratives](#) as examples. As well, public input and engagement is sought from all stakeholders. Some consortia, like OASIS, are also ANSI-accredited standards developers.

b) Does ANSI have a map/list of non-accredited standards developers in the U.S.?

**Answer:** No.

# ABOUT THE ANSI-ACCREDITED STANDARDS DEVELOPING ORGANIZATIONS (SDOS) AND AUDITED DESIGNATORS

## 8. What are the basic requirements to become an ANSI-accredited Standard Developing Organizations (SDO)?

**Answer:** The requirements are listed in the [ANSI Essential Requirements, clause 4.1](#). The *ANSI Essential Requirements* include the principles of Openness, Lack of Dominance, Balance, Coordination and Harmonization, Notification, Consideration of Views and Objections (Due Process), and Consensus. In addition, to be accredited by ANSI, the developer's procedures and practices for standards development shall meet the following criteria (from 4.1):

- a) the operating procedures used for the development of evidence of consensus for approval, revision, reaffirmation, or withdrawal of standards as American National Standards shall satisfy the essential requirements contained herein;
- b) with respect to American National Standards or candidate American National Standards, including the national adoption of International Organization for Standardization (ISO) or International Electrotechnical Commission (IEC) standards as American National Standards, the applicant shall agree to:
  - 1) provide continuity of administrative oversight and support of its standards activities;
  - 2) provide for designation, publication, and maintenance of the standard(s) produced;
  - 3) provide for an appeals mechanism;
  - 4) cooperate with ANSI in standards planning and coordination activities of mutual interest;
  - 5) advise ANSI of the initiation and scope of new standards activities and revisions of existing standards expected to result in candidate American National Standards;
  - 6) submit to ANSI for public comment the requisite information concerning activities related to new candidate American National Standards and the national adoption of ISO or IEC standards as American National Standards as well as the revision, reaffirmation, or withdrawal of American National Standards;
  - 7) consider applicable international standards;
  - 8) comply with the procedures contained herein with respect to the national adoption of ISO and IEC standards as American National Standards; and
  - 9) pay to ANSI all relevant fees.
- c) as appropriate to the extent to which the applicant is involved with standardization, the applicant shall consider participation in international standards activities through ANSI; and:
- d) with respect to submitting proposed American National Standards to ANSI for Board of Standards Review (BSR) approval, the applicant shall agree to comply with the normative policies and administrative procedures (Interpretations, Patent, Metric, Commercial Terms & Conditions, Antitrust and Evidence of Compliance) outlined in the *ANSI Essential Requirements*.

ANSI's ANS-related definition of balance is below:

### 1.3 Balance

The standards development process should have a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving balance. If a consensus body lacks balance in accordance with the historical criteria for balance, and no specific alternative formulation of balance was approved by the ANSI Executive Standards Council, outreach to achieve balance shall be undertaken.

### 2.3 Balance

Historically the criteria for balance are that a) no single interest category constitutes more than one third of the membership of a consensus body dealing with safety-related standards or b) no single interest category constitutes a majority of the membership of a consensus body dealing with other than safety-related standards.

The interest categories appropriate to the development of consensus in any given standards activity are a function of the nature of the standards being developed. Interest categories shall be discretely defined, cover all materially affected parties and differentiate each category from the other categories. Such definitions shall be available upon request. In defining the interest categories appropriate to a standards activity, consideration shall be given to at least the following:

- a) producer;
- b) user;
- c) general interest.

Where appropriate, additional interest categories should be considered.<sup>2</sup>

Appropriate, representative user views shall be actively sought and fully considered in standards activities. Whenever possible, user participants shall be those with the requisite technical knowledge, but other users may also participate. User participation should come from both individuals and representatives of organized groups. There are several user categories:

1. User consumer: Where the standards activity in question deals with a consumer product, such as lawn mowers or aerosol sprays, an appropriate consumer participant's view is considered to be synonymous with that of the individual user—a person using goods and services rather than producing or selling them.
2. User industrial: Where the standards activity in question deals with an industrial product, such as steel or insulation used in transformers, an appropriate user participant is the industrial user of the product.
3. User government: Where the standards activity in question is likely to result in a standard that may become the basis for government agency procurement, an appropriate user participant is the representative of that government agency.
4. User-labor: Where the standards activity in question deals with subjects of special interest to the American worker, such as products used in the workplace, an appropriate user participant is a representative of labor.

2. Further interest categories that may be used to categorize directly and materially affected persons consist of, but are not limited to, the following: a) Consumer; b) Directly affected public; c) Distributor and retailer; d) Industrial/commercial; e) Insurance; f) Labor; g) Manufacturer; h) Professional society; i) Regulatory agency; j) Testing laboratory; k) Trade association.



9. Are ANSI-accredited Standards Developing Organizations (SDOs) non-profit organizations? If yes, is it required by ANSI's Essential Requirements to be a non-profit organization?

**Answer:** Nearly always, yes, but this is not a requirement in the *ANSI Essential Requirements*.

10. Can Standards Developing Organizations (SDOs) domiciled outside of the U.S. be accredited by ANSI? If yes, what are the steps to be followed?

**Answer:** Yes, using the same *ANSI Essential Requirements* as Standards Developing Organizations (SDOs) domiciled inside the U.S.

11. Funding of ANSI-accredited Standards Developing Organizations (SDOs):

- a) Does ANSI have a global view on SDOs main sources of revenue?
- b) Are some of them directly supported by public funding?

**Answers:** a) ANSI does not get involved in funding issues of individual standards developers.

b) ANSI does not get involved in funding issues of individual standards developers.

12. Does an "audited designator" have the right to develop American National Standards without any further check from ANSI or its relevant governing bodies? Or is there still a need for a formal decision from a technical and/or governing body of ANSI before granting the American National Standards status?

**Answer:** ANSI's involvement in any standards development process is procedural, not technical. ANSI audited designators are also ANSI-accredited standards developers and are bound by the *ANSI Essential Requirements* and are subject to audits just like all other accredited standards developers. Specific additional requirements are listed in clause 5 of the *ANSI Essential Requirements*, which in part state:

### 5.2 Criteria for approval of ANSI Audited Designator Status

In determining whether an accredited standards developer has achieved a "consistent record of successful voluntary standards development," the ANSI Executive Standards Council shall consider all evidence reasonably bearing on the issue, including the extent of the notice provided by the applicant concerning its development activities and the integrity of the other due process safeguards used by the applicant in conducting its work. A presumption shall exist that this test has been satisfied where a) the developer has been involved in voluntary standards development work for at least five (5) years, b) during that period, the BSR has approved at least ten of the developer's standards or if ten standards have not been approved, standard(s) totalling at least 100 pages and c) no standard submitted by the developer during the five (5)-year period was finally denied American National Standard status by ANSI due to a failure to adhere to the principles and procedures upon which the developer's accreditation was based. The inability of an applicant to make use of this presumption shall in no way preclude consideration of its application based on all the relevant evidence.

The developer shall:

- a) retain membership in ANSI and pay dues to ANSI in accordance with the policies established by ANSI's Board of Directors;
- b) conduct its activities at all times in conformity with the criteria upon which it was accredited;
- c) submit to audits of its operations by ANSI to demonstrate compliance with terms of the delegation and pay the fees associated therewith (see the *ANSI Auditing Policy and Procedures* for further details on the audit requirements);
- d) provide information required by ANSI in connection with Project Identification Number (PINS) or its equivalent, in a timely manner;
- e) provide information required by ANSI in connection with initiating the ANSI public comment period, in a timely manner;
- f) promptly notify ANSI each time that a standard is designated as an American National Standard without BSR review;
- g) not designate as an American National Standard any standard if it:
  - 1) is contrary to the public interest;
  - 2) contains unfair provisions;
  - 3) is unsuitable for national use.
- h) make a good faith effort to resolve conflicts;
- i) promptly notify ANSI of any suit or claim made against the developer arising from a standard designated as an American National Standard without Board of Standards Review (BSR) review, and provide periodic updates sufficient to apprise ANSI of the status of any such suit or claim;
- j) indemnify ANSI in connection with any suit or claim that may be made against ANSI arising from a standard designated as an American National Standard without BSR review,<sup>3</sup> which indemnity must include a commitment to advance all reasonable attorneys' fees and expenses incurred in connection with investigating or defending any such suit or claim;<sup>4</sup>
- k) consider an American National Standard designation for all of its standards; and
- l) immediately cease to apply the ANS designation to any standard approved after the developer has been notified by ANSI that its accreditation has been suspended and/or withdrawn.

In addition, the Agreement shall provide for termination by ANSI upon any material breach of its terms by the developer, following notice and an opportunity to remedy any such breach. The developer shall have the right to appeal any such decision pursuant to ANSI's appeals procedures.

3. The sufficiency of the indemnity will be evaluated on a case-by-case basis in light of the assets of the applicant. ANSI reserves the right to deny approval to any applicant should ANSI determine an offer of indemnity to be insufficient.

4. It is understood that, absent a conflict of interest, the developer may designate its own attorneys as the attorneys for ANSI as well.

# ABOUT RELATIONS BETWEEN THE U.S. STANDARDIZATION SYSTEM, INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO) AND INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC)

## 13. Adoption of International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) standards:

- a) Our understanding is that ANSI does not adopt International Organization for Standardization (ISO) or International Electrotechnical Commission (IEC) standards as such. What are the major reasons? Is it due to the fact that ANSI itself does not develop standards?

**Answer:** ANSI is not a standards developer and so does not adopt any International Organization for Standardization (ISO) or International Electrotechnical Commission (IEC) standards. ANSI-accredited standards developers may adopt ISO or IEC standards as American National Standards. The procedures that govern the national adoption of ISO and IEC standards as ANS are contained in [ANSI Procedures for the National Adoption of ISO and IEC standards as American National Standards](#) and by reference, the *ANSI Essential Requirements*.

- b) Is there any ANSI policy paper promoting the adoption of International Organization for Standardization (ISO) or International Electrotechnical Commission (IEC) standards as American National Standard through their accredited Standards Developing Organizations (SDOs)?

**Answer:** This is no overarching ANSI policy paper promoting the adoption of International Organization for Standardization (ISO) or International Electrotechnical Commission (IEC) standards. The United States National Committee of International Electrotechnical Commission (USNC/IEC) has a formal policy on the subject of adoption/adaptation of IEC standards as American National Standards. It basically states that the USNC encourages the adoption/adaptation of IEC standards if the cognizant industry deems that action is appropriate and beneficial.

- c) Is there any paper or guideline establishing the process and conditions for ANSI-accredited Standard Developing Organizations (SDO) to adopt an International Organization for Standardization (ISO) or International Electrotechnical Commission (IEC) standard in their catalogue? What does it cover? For instance, degree of equivalence, format, and so on.

**Answer:** Yes, the document laying out the process and conditions for ANSI-accredited Standards Developing Organizations (SDOs) to adopt International Organization for Standardization (ISO) or International Electrotechnical Commission (IEC) standards is detailed in the following document: [ANSI Procedures for the National Adoption of ISO and IEC standards as American National Standards](#).

- d) How are International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) standards weighted in domestic use?

**Answer:** ANSI does not weight any standard by designation for domestic use. With respect to use by federal agencies, U.S. law requires federal agencies to consider and where appropriate base standards on relevant international standards (see [19 U.S.C. 2532](#)) and U.S. law and policy requires federal agencies to use voluntary consensus standards in lieu of government unique standards in regulations and procurement documents, except where contrary to law or otherwise impracticable (see [Office of Management and Budget \(OMB\) Circular A-119](#) and the [National Technology Transfer Advancement Act, NTTAA](#)).

#### 14. Technical Advisory Groups (TAGs):

- a) Our understanding is that U.S. Technical Advisory Groups (TAGS) could be considered as potentially equivalent to European national mirror committees. Are all of them hosted by ANSI?

**Answer:** We sometimes use the term “mirror” committee to help explain to non-U.S. nationals what a U.S. Technical Advisory Group (TAG) actually is in practice, but they are not mirror committees as such as they do not develop standards, but only develop recommended positions for ANSI to take into International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC). In the case of ISO, nearly all the U.S. TAGs are hosted by ANSI-accredited Standards Developing Organizations (SDOs) and in the case of the IEC, all the United States National Committee (USNC) TAGs are hosted by ANSI-accredited SDOs.

- b) Who are their members and what role do they have (establishing U.S. positions? Appointing U.S. delegation members?)?

**Answer:** The members of our technical advisory groups vary by interest area. They come from all parts of the ANSI federation, namely from industry, organizations, government (local, state, federal), consumer organizations, academia, etc. Their role is to provide ANSI with recommended positions on International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) documents where a position is required (when ANSI is a participating member). The U.S. and United States National Committee (USNC) TAGs are responsible for appointing U.S. delegates to ISO and IEC TC and SC meetings and for naming experts to working groups.

The procedures that govern ANSI’s participation in ISO are contained in the [ANSI International Procedures](#). The United States National Committee of International Electrotechnical Commission’s (USNC/IEC’s) governing document for participation in the IEC is its [Model Operating Procedures for USNC Technical Advisory Groups](#).

- c) Are U.S. TAGs the only form of representation of U.S. experts in International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) technical committees?

**Answer:** Yes, but U.S. representatives could also be part of organizations that are in liaison with International Organization for Standardization (ISO) or International Electrotechnical Commission (IEC) technical committees.

**15. Do U.S. experts in International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) Technical Committees (TCs) and Subcommittee (SCs) have national mandates? To whom do they report?**

**Answer:** There are no national mandates given to U.S. experts to International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) Technical Committees (TCs) and Subcommittee (SCs). They report back to their respective U.S. or United States National Committee (USNC) Technical Advisory Group (TAG).

# ABOUT CONFORMITY ASSESSMENT CLAUSES IN STANDARDS

16. Is there any internal guide/policy on how to include conformity assessment requirements in standards developed by ANSI-accredited standards developing Organizations (SDOs)?

**Answer:** The *ANSI Essential Requirements* include [clause 3.2 Commercial terms and conditions](#), which addresses the inclusion of conformity assessment requirements in an American National Standard.

17. Is it possible for an ANSI-accredited Standard Developing Organization (SDO) to introduce specific clauses requiring third party certification in their standards? Is there any guideline or policy document framing or banning this practice?

**Answer:** The *ANSI Essential Requirements* include [clause 3.2 Commercial terms and conditions](#), which addresses the inclusion of conformity assessment requirements in an American National Standard. An American National Standard (ANS) could contain a generic requirement for 3<sup>rd</sup> party certification (*i.e.*, requiring that a product or service be subject to "third-party certification" but not explicitly naming the organizations that may perform such certification.)

# ABOUT THE USE OF STANDARDS IN TECHNICAL REGULATIONS AT FEDERAL LEVEL

## 18. What are the possible linkages between standards and regulation in the U.S., apart from incorporation by reference?

**Answer:** Federal and state regulators may incorporate standards in regulation, for example, by making compliance with a voluntary standard mandatory through a regulation. Regulators may also use standards in voluntary programs. Standards may be incorporated in regulation by reference or otherwise and as incorporated may relate e.g., to product performance or production methods or conformity assessment. Standards may also be referenced as one acceptable means of compliance, meaning that following the standard will meet the intent of the regulation but that the standard is not the only way to comply and an individual or organization is free to choose and defend an alternate standard or method to comply with the regulation. [National Technology Transfer Advancement Act \(NTTAA\)](#) and [Office of Management and Budget \(OMB\) Circular A-119](#) direct federal agencies to use voluntary consensus standards in lieu of government unique standards in their regulations (and procurement), except where contrary to law or otherwise impracticable.

## 19. Do federal agencies only use American National Standards developed by ANSI-accredited Standards Developing Organizations (SDOs) in support of technical regulations or can any standard be used by regulators and executive agencies?

**Answer:** No, federal agencies use of standards is not limited to American National Standards. [National Technology Transfer Advancement Act \(NTTAA\)](#) and [Office of Management and Budget \(OMB\) Circular A-119](#) direct federal agencies to use voluntary consensus standards in lieu of government unique standards in their regulations (and procurement), except where contrary to law or otherwise impracticable, and the [Trade Agreements Act of 1979](#) requires federal agencies to consider and where appropriate use international standards. Certain laws may also require use of a particular standard in certain instances. Other than the need to meet these statutory requirements, federal agencies may generally use any standard that meets its regulatory or procurement needs. Under this flexible policy, agencies and departments have chosen to use thousands of non-ANS standards from ANSI-accredited Standards Developing Organizations (SDOs), consortia, and other standards bodies such as International Organization for Standardization (ISO), International Electrotechnical Commission (IEC), International Maritime Organization (IMO), Deutsches Institut für Normung e.V. (German Institute for Standardization) (DIN), and British Standards Institution (BSI).

## 20. Are standards incorporated by reference in U.S. federal regulations mandatory?

**Answer:** The language contained in the specific regulation would determine the status of the standard. Some standards are used in voluntary programs and some are referenced in technical regulations; however, the standard may be mandatory or not, depending on the specific way it is referenced.

## 21. In the U.S. Code of Federal Regulations, some products or product categories are required to be “listed” under a specific third party certification body. Is there any ANSI official policy paper, guidelines or document framing such practice?

**Answer:** No, however please see the *ANSI’s United States Conformity Assessment Principles*.

## 22. In U.S. federal regulations, is it possible to find references to several standards (potentially developed by different Standards Developing Organizations (SDOs) to support the same regulatory requirements?

**Answer:** Yes, three examples are provided below:

- a) The Environmental Protection Agency (EPA), under authority of the Clean Air Act, released the prepublication of its *Federal Register* on, “[New Source Performance Standards for Residential Wood Heaters](#),” in February 2015. The EPA states, “For hydronic heaters, we are requiring emission testing, reporting and certification based on crib wood to demonstrate compliance with Step 1 and Step 2 emissions limits. The final rule requires crib wood emission testing of hydronic heaters by one of the following methods: EPA Method 28 WHH in its entirety or EPA Method 28 WHH-PTS (with approved adjustment for crib wood versus cord wood) or ASTM E2618-13 with conditions or European National (EN) test method EN 303-5 with conditions.”
- b) In October 2009, DHS published a notice in the *Federal Register* announcing its intent to adopt three preparedness standards. Following a series of public meetings and the incorporation of public comments, the three standards, listed below, were approved in June 2010 based on scalability, balance of interest and relevance to [PS-Prep™](#).

[ASIS International](#)

[British Standards Institution \(BSI\)](#)

[National Fire Protection Association \(NFPA\)](#)

These standards provided a comprehensive management systems approach to organizational resilience, preparedness and business continuity widely applicable for private and non-profit organizations.

- c) See 2009 document [US-EU High Level Regulatory Cooperation Forum Report on the Use of Voluntary Standards in Support of Regulation in the United States](#).



### 23. Is there any policy or guidance including mechanisms to withdraw U.S. standards conflicting with another or conflicting references to standards in regulation?

**Answer:** There is no such broad policy or guidance on this matter from ANSI. With respect to American National Standards, the *ANSI Essential Requirements* address possible conflict. The World Trade Organization (WTO) Code of Good Practice ([Annex III](#) of the World Trade Organization (WTO) Technical Barriers to Trade Agreement (TBT) and the WTO TBT Committee Decision on international standards both provide that Standards Developing Organizations (SDOs) shall avoid duplication of, and overlap with, the work of other standardizing bodies. ANSI has accepted the Code of Good Practice on behalf of ANSI-accredited SDOs, and the United States is committed to determine whether a standard is international based on whether the standard was developed in accordance with the WTO TBT Committee Decision. For regulations, the U.S. Government (USG) has policies and mechanisms in place to avoid and address conflicts in regulation. See, e.g., Executive Orders [12866](#), [13563](#), and [13610](#) and the [Administrative Procedures Act, section 553\(e\)](#). Federal agencies and SDOs work together where possible to address such circumstances described above.

### 24. Is there a system in place enabling U.S. regulators or executive agencies to update a reference to a standard incorporated in regulation without going to a full process of revising the regulation itself?

**Answer:** Every agency controls its response to updating Incorporated by Reference (IBR) standards. Executive Orders [13563](#) and [13610](#) require federal agencies to periodically review their regulations to determine whether they should be modified or repealed, and such reviews provide an opportunity for agencies to update references to standards incorporated by reference, including in response to public input. Many agencies have formal rulemaking processes to ratify and reference an updated standard. Some agencies—for some standards—will place a notice for comment in the *Federal Register* when an IBR standard is updated by the relevant Standard Developing Organization (SDO). If significant adverse comments are not received, the agency, after a stated amount of time, will accept the updated standard as a revised IBR.

### 25. Is there any public notice or mechanism for stakeholders (in particular Small- and Medium-sized Enterprises (SMEs) to know in advance that a particular standard is intended to be used in support of Federal technical regulations, allowing them to contribute to its development?

**Answer:** Yes. All proposed standards intended to be incorporated by reference or otherwise used in federal technical regulations are published in the *Federal Register* and [regulations.gov](#), which are available to all who wish to access it for review and comment. The United States also notifies all proposed technical regulations to the World Trade Organization (WTO) for comment by other members.

**26. Is there any single place where economic actors can find pointers to all standards referenced by U.S. federal regulations? (Pointer would include at least title, ID/ number, source of legal requirement (e.g., law ID), scope of requirement as to products/services types, contact information of copyright owner and/or distributors).**

**Answer:** Yes, the [Code of Federal Regulation](#), which is the U.S. compilation of federal regulations organized by regulatory area/subject/topic. It is electronically searchable by key word. Where a standard is incorporated by reference the regulation must state where a copy of the standard can be obtained. The National Institute of Standards and Technology (NIST) maintains a [database of standards incorporated by reference](#).

**27. Are any free-of-charge abstracts of standards referenced by U.S. federal regulations published so that economic operators can identify which standards apply to their products? Is there any law or code of conduct requiring or recommending this?**

**Answer:** [1 CFR part 51](#) addresses requirements associated with incorporating standards by reference, including that the standard is “reasonably available to and usable by the class of persons affected.” Some ANSI-accredited Standards Developing Organizations (SDOS) offer the full text of standards that have been referenced in regulation (read only) available for free on their websites.

**28. Does any party assemble and publish bundles of standards that jointly relate to or cover the legal requirements for certain classes of products? Is there any law or code of conduct requiring or recommending this?**

**Answer:** To the best of our knowledge, we know of no Standard Developing Organization (SDO) or commercial reseller who assembles and publishes bundles of standards specifically related to or covering the legal requirements for certain classes of products. But some SDOs, given the needs of their constituencies, may have assembled bundles in certain sectors. We also do not know of any law or code of conduct requiring or recommending this.

# ABOUT THE USE OF STANDARDS IN TECHNICAL REGULATIONS AT SUB-FEDERAL LEVEL

## 29. Generalities:

- a) Compared with the federal level (and referring here to the [Office of Management and Budget \(OMB\) Circular A-119](#)), what are the main commonalities and/or differences in the way sub-federal-level authorities and executive agencies use standards in support of regulatory requirements?

**Answer:** Any commonalities and/or differences in the way sub-federal-level authorities and executive agencies use standards in support of regulatory requirements depend on the local jurisdiction.

- b) Is there any common policy or guidance regarding standards, applied in a similar way by all U.S. states?

**Answer:** Not that ANSI is aware of. However, states and other local jurisdictions can and do reference the same standards as the federal government, particularly in the areas of safety and health, as needed.

- c) Is there any ANSI or U.S. government policy or guidance supporting the coordination of the way standards are used in support of regulatory requirements among federal and sub-federal levels?

**Answer:** There is no overarching policy or guidance to coordinate use of standards among federal and sub-federal levels.

## 30. What are the possible linkages between standards and regulation at the sub-federal level in the U.S., apart from incorporation by reference?

**Answer:** See answer to question 18.

## 31. Are standards incorporated by reference in U.S. sub-federal regulations mandatory?

**Answer:** See answer to question 18.

## 32. In U.S. sub-federal level regulations, is it possible to find references to several standards (potentially developed by different Standards Developing Organizations (SDOs) to support the same regulatory requirements?

**Answer:** Yes.

**33. Is there any public notice or mechanism for stakeholders (in particular SMEs) to know in advance that a particular standard is intended to be used in support of sub-federal level technical regulations, allowing them to contribute to its development?**

**Answer:** Each state has its own Administrative Procedures Act (APA)-like procedures providing the public notice and comment on proposed regulations including those incorporating standards. The United States also notifies state-level technical regulations to the WTO.

**34. Is there any single place where economic actors can find pointers to all standards referenced by sub-federal-level regulations? (Pointer would include at least title, ID/number, source of legal requirement (e.g., law ID), scope of requirement as to products/services types, contact information of copyright owner and/or distributors).**

**Answer:** Not that we know of, however, most states maintain searchable compilation of regulations.

# ABOUT SMES AND SOCIETAL STAKEHOLDERS<sup>5</sup>

35. Within ANSI's governance, is representation of Small- and Medium-sized Enterprises (SMEs), environmental Non-Governmental Organizations (NGOs), consumer associations and/or trade unions foreseen and organized?

**Answer:** The ANSI Board of Directors, and all of its governance committees and councils, allows for representation from all aspects of our membership, including SMEs, consumer interests, labor and environmental stakeholders. Specifically, ANSI does have consumer representation on its Board of Directors.

36. Is there any ANSI guidance or policy paper regarding the access of representatives of SMEs and societal stakeholders to standards and standardization activities of ANSI-accredited Standards Developing Organizations (SDOs)?

**Answer:** There is no specific guidance for access of Small- and Medium-sized Enterprises (SMEs) and other stakeholders except that the process of standards development within the ANSI-accredited procedures requires that the process be open to all interests who are directly and materially affected.

37. Is the participation of Small- and Medium-sized Enterprises (SMEs) and societal stakeholders in standardization activities in the U.S. measured? Is there any publicly available information in this respect and where?

**Answer:** Individual Standards Developing Organizations (SDOs) may measure and track Small- and Medium-sized Enterprises (SMEs) and societal stakeholders within their standards development activities, but we are not aware of where such information can be found.

38. Does ANSI have regular contacts with the U.S. Small Business Administration (SBA) in order to promote the use of standards amongst Small- and Medium-sized Enterprises (SMEs) and their involvement in standardization activities?

**Answer:** No. However, all of ANSI's panels and collaboratives are open to engage all stakeholders. In addition, ANSI's *Standards Action* is available to all at no cost, and facilitates participation by Small- and Medium-sized Enterprises (SMEs). Finally, trade associations are very active in ANSI and facilitate SME involvement in standardization.

5. Societal stakeholders are understood in Europe as those organizations representing "societal interests," for instance organizations representing consumers, employees and workers, environmental interests. See the dedicated [CEN-CENELEC webpage](#).

39. In the U.S., do Small- and Medium-sized Enterprises (SMEs) and societal stakeholders benefit from any (financial or other) mechanism facilitating their involvement in standardization activities of ANSI-accredited Standards Developing Organizations (SDOs) (e.g., free participation in technical bodies, etc.)?

**Answer:** There is no ANSI policy regarding financial assistance to Small- and Medium-sized Enterprises (SMEs) and societal stakeholders. However, individual Standards Developing Organizations (SDOs) may have relevant policies and practices.

40. What is the role of trade associations or federations within ANSI?

**Answer:** Trade associations and other federations of members are organizational members of ANSI. They can and do participate at all levels of ANSI governance as meets their specific sector's needs. They may be ANSI-accredited Standards Developing Organizations (SDOs), and may serve as administrators of U.S. and United States National Committee (USNC) Technical Advisory Group (TAGs) in relevant subject areas.

# ABOUT THE USE OF STANDARDS IN FEDERAL OR STATE PUBLIC PROCUREMENT

41. Is there any reference (or preference) to compliance with American National Standards or U.S.-domiciled Standards Developing Organizations (SDOs') standards in federal acquisition regulation and/or "Buy American" Act or other relevant public procurement regulations in the U.S. at federal or state level?

**Answer:** We are not aware of such a reference or preference.