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National Science and Technology Council's Sub-Committee on Standards
c/o National Institute of Standards and Technology
100 Bureau Drive, Stop 1060
Gaithersburg, MD 20899-1060

RE: STANDARDIZATION FEEDBACK FOR SUB-COMMITTEE ON STANDARDS
Docket No. 0909100442-0563-02

The attached is a detailed response from the American Nuclear Society (ANS) addressing the Federal Register notice on "Effectiveness of Federal Agency Participation in Standardization in Select Technology Sectors for National Science and Technology Council's Sub-Committee on Standardization." The ANS Standards Committee mission is to develop voluntary consensus standards to be certified by the American National Standards Institute (ANSI) as American National Standards. The Standards Committee is responsible for the development and maintenance of standards that address the design, analysis, and operation of components, systems, and facilities related to the application of nuclear science and technology. The ANS works closely with federal agencies in the development and maintenance of our standards to gain their input and work towards their endorsement or adoption.

The responses are a compilation of comments from Standards Committee members with extensive experience in standards. These members recognize the benefit of developing voluntary consensus standards for the industry and support from federal agencies throughout the development process in staff resources and funding. This has become even more apparent as the nuclear industry prepares for the construction of new nuclear power plants after 30-years. While ANS understands the significance of federal agency support, we acknowledge the need of industry organizations to encourage their staff's participation and coordination between standards development organizations.

We very much appreciate the opportunity to provide input to this important issue and hope that the responses are found beneficial. Should you wish to discuss these responses, feel free to contact Mr. Donald J. Spellman, ANS Standards Board Vice Chair, at spellmandj@ornl.gov or 865-574-7891.

Respectfully yours,

Joe F. Colvin
ANS President

Attachment

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Specific Responses to Direct Questions Extracted from FR 2010-3086 Provided by the American Nuclear Society

A. Standards Development: Who participates in standards-setting activities?

The American Nuclear Society (ANS)[a] Standards Committee consists of the ANS Standards Board and four consensus committees that are made up of members from industry as well as government agencies [primarily the U.S. Department of Energy (DOE) and the U.S. Nuclear Regulatory Commission (NRC)]. The industry sector includes utilities; architect engineers; constructors; consultants; manufacturer/suppliers; and industry-supported organizations such as the Electric Power Research Institute (EPRI), the Institute of Nuclear Power Operations (INPO), and the Nuclear Energy Institute (NEI). Government agencies include DOE, national laboratories, NRC, and the National Institute of Standards and Technology (NIST), among others. Nuclear standards development organizations (SDOs) include the American Society of Mechanical Engineers (ASME), American Society of Testing and Materials (ASTM), Institute of Electrical and Electronics Engineers (IEEE), and many others. [The American National Standards Institute (ANSI) has hundreds of members.] Many industry consultants also participate in national consensus standards writing, balloting, and obtaining approvals.

Some nuclear industry organizations, e.g., INPO, EPRI, and NEI, do not routinely participate in national consensus standards development processes. They think that the consensus process takes too long, so they write quasi-standards for their members or develop their own "standards" as administrative procedures. Such activity has led to incongruous results. NRC may treat quasi-standards the same as true consensus standards, which may lead to higher costs, nonuse, or both. Some "standards" are not particularly clear or useful. NEI 00-04 ("10 CFR 50.69 SSC Categorization Guideline") provided the basis for 10 CFR 50.69 ("Title 10, "Energy," Part 50, "Domestic Licensing of Production and Utilization Facilities," Sec. 69, "Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Reactors"), which is a complex, confusing rule that is rarely used for light water reactors (LWRs) (use is voluntary). In addition, some utilities choose not to participate in writing consensus standards but become engaged at the review/approval stage.

1. What are the most important reasons for participation?

Standards support the general welfare by providing methods that are based on extensive professional experience of the most cost-effective, concise, risk-informed ways to ensure nuclear safety through regulation. Standards provide the "how" to safely meet federal regulations.

More-detailed reasons for participation are the following:

1) to contribute to the profession and ANS at large;

[a] The acronym "ANS" is defined as "American Nuclear Society" and is not to be confused with other definitions of "ANS" used in the industry.

2) to enhance personal professional development by gaining knowledge of new developments and by networking with industry peers;
3) to be exposed to new technology or processes;
4) to represent company interests in new technology development areas;
5) to fix historical problems; some NRC and Occupational Safety and Health Administration rules from the 1970s and 1980s have needed to be more clearly expressed;
6) to meet the requirement of organizations that their employees participate in SDOs, for reasons ranging from developing contacts for future business development to personal growth;
7) to discover how other organizations approach regulatory interests so that a common position on requirements imposed by law can be developed;
8) to support professional bodies, e.g., supporting SDOs like ANS or ASME, as professionals in the field;
9) to establish common standards for component or software interchangeability, compatibility, or related functionality;
10) to solve problems where opinions diverge on ways to meet safety requirements and regulations and in-house procedures.

2. What are the benefits of developing standards for the nuclear industry?

Benefits are derived in professional development as well as in the areas of equipment and simplified specification.

From a professional perspective, participating in standards activities broadens a participant's scope and depth of knowledge. Industry sectors have common, interfacing compatibility and interchangeability needs so that awareness of standards not only provides a participant a competitive advantage but also benefits users of his or her products.

Participants from companies that integrate huge amounts of equipment, such as architectural engineering companies, benefit from learning common formats and scopes for technical literature and other similar materials. For nuclear plants, with more than 100,000 discrete components at a single plant, standards improve how those components are used.

Citing a common standard in lieu of writing unique specifications or procedures simplifies contracts. A supplier can assess its product's applicability and fit immediately at lower cost because there is less customization.

3. How do the standards impact organizations and their competitiveness?

Standards provide nuclear suppliers, constructors, and operators with logical, consensus-based methods so that they can perform in a manner that has been judged by their peers to be acceptable and in some cases satisfy federal regulations and enhance safety.

For suppliers, having an entire industry provide input to a given standard can make supplying use-specific equipment (safety related) and services easier. Designing to proven standards reduces errors. Suppliers and individuals benefit, though in different ways. Organizations that work to continuously improve process integration need standards for guidance.

Standards development is an investment to which many companies are unable to contribute. Unless they see an immediate benefit, companies are not always willing to commit people, time, and travel expenses. The cost to send people on travel for three days two or three times a year is significant. In addition, writing standards demands focused technical time in addition to face-to-face meetings and is generally not supported during company working hours. There are also coordination demands and related administrative needs.

Some companies indirectly support standards through groups like NEI, EPRI, or owners' groups. These include the Boiling Water Reactor Owners' Group and the Pressurized Water Reactor Owners' Group. INPO rates industry participation for organizations, including support of standards. NRC "Safety Culture" measures similar criteria using consensus safety standards development participation.

4. How has standardization spurred innovation in the technology sector(s) that is the subject of your comment?

Nuclear suppliers spend millions of dollars each year to improve their products and enhance nuclear performance. For instance, fuel fabricators are constantly conducting research and development of nuclear fuel, cladding, and structural components. Pump, valve, and piping fabricators are constantly developing more efficient, longer-lasting components that meet safety criteria. Reactor designers are routinely trying to develop new, more efficient reactor heat sources and systems.

However, it is not clear that standards have actually spurred nuclear design innovation. The absence of standards may have hurt nuclear design innovation in many ways.

Nuclear design technology has not changed fundamentally for many years. Recently, ANS has begun to receive new recommendations from industry for standards development particularly for safety enhancements and cost savings.

In the past, design requirements were so complex and poorly documented that few people actually understood them. Few up-to-date nuclear design standards are available. The organizations that actually performed nuclear design seemed to develop them in direct concert with NRC regulatory changes. LWR design requirements are well known conceptually. For operating plants, however, design issues recur many times in the life of a plant. Without design process knowledge, answering specific regulatory questions on design can be difficult, especially for conceptual heat source designs. For those who perform nuclear design, wanting to know current design methods has stimulated interest in standards participation.

Construction promotes nuclear standards. Now that construction is imminent, the need for new nuclear standards is clear. New nuclear standards' needs have not been recognized for many years.

5. What is the current phase of the standards development process for this technology?

National consensus standards focus on ways to develop, clarify, and document technical information, design, and operational experience that can be used to lower nuclear costs and enhance safety, like common methods to integrate information from a number of relevant sources. Designers understand current deterministic LWR nuclear design processes very well.

They understand risk-informed LWR processes less well because of a coherent lack of source guidance to follow. Furthermore, ways to implement designs effectively, both during construction and later in operations, remain poorly understood by regulatory bodies, nuclear plant suppliers, and their operating entities. Because these areas posed such problems during nuclear construction in the 1980s, they are candidates to reexamine today. Lack of promulgation of exact requirements to the designers and engineers tends to cost much more for rework, adequacy of completed work, change control issues, and so on, as the industry addresses new construction again. Adequate consensus standards greatly simplify and provide straightforward work processes to follow. Consensus standards developers are constantly in discussions with nuclear regulators to continue to develop an understanding of where regulations are headed such that the supporting consensus standards are viable to provide an approach to meet or exceed those regulatory and safety requirements. The development process is quite adequate; the clear path forward for changing regulations is not.

6. How has the process worked so far?

So far, the process has usually worked very well, but development times are excessive. However, increased cost for participants to actively engage in standards activities has put a strain on employers to allow the required participation. Electronic systems are not developed well enough to allow online participation, nor are the standards societies funded well enough to support the necessary electronic means (i.e., online development, comment collection, and comment resolution).

7. When developing standards, how are the standards-setting processes managed and coordinated?

The standards-setting processes are managed and coordinated through consensus procedures approved by each SDO and approved and audited by ANSI.

SDOs seek the most knowledgeable experts to present and discuss various views, based on experience, related to the best and safest methods to accomplish a required task such as design of a nuclear safety-related system. Once reaching draft agreement, they document that agreement and prepare for group consensus review. Standards-setting processes vary greatly, but participants with standards development experience and writing skills provide a benefit to the timely development of standards by speeding the process. Having standards models (good and bad) with explanations and examples of what to do (and what not to do) also helps the process. The long absence of nuclear construction has been detrimental to standards development proficiency.

Writing consensus standards is a volunteer effort. Enforcing schedules and commitments is extremely difficult, if not impossible, as participants have other responsibilities. Having one or two committed persons to lead the work and development of a project plan is critical to successful standards development. The fastest approach to provide useful content is to get people to provide material in whatever form they can, put it into an appropriate format, and present it before the group. The group then evaluates the material to modify and use. Periodic face-to-face meetings are required to recalibrate the process and mark progress to the plan. Most of the actual writing is completed by working group members off-line and after normal working hours. An electronic "home" is a most useful tool for presentation of off-line material to the working group and to allow for online comments and resolutions. Only a few SDOs

have this electronic capability.

8. Is there a strategic plan that identifies the standards needs and defines the standards development life cycle?

Standards needs are developed within each SDO and generally not shared throughout the entire community for nuclear standards. The life cycle is well developed, documented, approved, and audited between the SDOs and ANSI. A recent effort has just begun through NIST and ANSI to coordinate efforts across all the nuclear SDOs, but a lack of funding for participants has severely limited any progress.

ANS uses a Project Initiation Notification System (PINS) as required by ANSI to authorize new work. A new standard requires support in addition to project approval. ANS provides the infrastructure and coordination essential to develop a standard; without this, there would be no standard.

In the 1980s, post-Three Mile Island corrective actions left little time to recognize the need and develop post-accident response standards when they were needed the most. Today, post-9/11 security issues again show the need for new standards. Both design and security could benefit from more standards development. Industry and regulators have ineffective processes to reveal where new standards are needed that can provide the most benefit. Once those standards have been identified, they should be prioritized by the national standards authority that will then assign the appropriate development efforts to the appropriate development organizations. These SDOs could then initiate development of the standards on a normal, nonemergency basis and focus available funds on higher-priority efforts.

9. Are there barriers to developing high-level strategies for standard-setting activities?

Yes, there are barriers. One barrier is adequate financial support to one top-level organizational entity. A combination of ANSI, NIST, the International Science and Technology Center, and the nuclear regulators would provide the much needed coordination and development of one strategic plan for all nuclear SDOs that could define the needs, determine the priorities, assign action plans to small groups, and develop a tracking system of completion.

Complacency and focus are significant barriers. When a need is urgent, there is no time to develop consensus standards. Once past the crisis, impetus and focus to develop standards are lost. Very often, organizations learn to live with urgently developed new rules, although at high costs. Industry should work even more closely with SDOs and regulators to improve how they select areas to develop standards. Very often, regulators perceive different needs than industry or others. Industry and SDOs may also overextend. They sometimes seek to do far more in an area than the regulator envisioned. Standards development alone does not guarantee a successful outcome. Some risk-informed standards [like NFPA 805, "Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants," or probabilistic risk assessment (PRA) standards] are so complex that their cost of implementation is high.

Here, organizations such as NEI, INPO, reactor vendor owners' groups, and even the International Atomic Energy Agency (IAEA) could, because of their paid staffs, quickly

develop a guidance document to respond to an immediate need while the SDOs were actively developing the high-priority standard to meet the identified need.

B. Coordination Efforts

1. What methods of engagement are used by federal agencies to participate in private sector–led standards development?

Federal agencies promote involvement in the development of standards. This development includes employing common and repeated use of rules, conditions, and guidelines for products or related processes as well as related management systems practices that are developed by these federal agencies.

An example is the DOE involvement in national nuclear energy standards. DOE has an organization called the DOE Technical Standards Program Office (HS-22) that is very involved in national standards development with all the nuclear-related SDOs. DOE writes and approves internal standards that are specifically applicable only to DOE activities. When national standards can be used, as required by Office of Management and Budget Circular A-119, DOE complies. When DOE has reliable expertise in an area where national standards are being written, it actively participates in those management committees, consensus committees, and working groups.

Other federal agencies such as the U.S. Department of Defense (DOD), U.S. Department of Commerce, and NRC likewise are heavily involved in national consensus standards activities.

When developing standards, the government agencies are often directed to take a deterministic approach rather than a design-based, risk-informed approach. This is why government standards at all levels tend to address needs or applications specific to their missions and functions rather than developing a standard for general application such as for a federal regulation. The DOD standards are primarily procurement based, and the DOE standards are process based.

NRC, DOE, and the National Energy Reliability Commission develop mandatory standards or guidelines for their specific line of responsibility. These agencies' involvement is highly visible owing to the fact that their focus is on public safety and reliability. Thus, any industry standards that are developed by these agencies have their direct or indirect involvement and are promulgated by an industry for materials, products, and services related to that industry.

Therefore, engagement is driven by the nature of the federal agency's involvement, meaning either they have a leadership role, or they are a participant. Examples of technical leadership by a federal agency is the role played by the NRC in (a) simplifying the reactor licensing process from the original two-step process of 10 CFR 50 ("Title 10, "Energy," Part 50, "Domestic Licensing of Production and Utilization Facilities") to the more efficient single-step process of 10 CFR 52 ("Title 10, "Energy," Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants") and (b) improving the technical basis for safety regulation using risk-informed and performance-based approaches.

A second avenue of engagement is in the regulatory application of voluntary consensus standards (VCSs) developed by SDOs. In some cases the standard is codified by incorporation

into regulation, such as happened with ASME's Boiler & Pressure Vessel standards. In many cases, VCSs are incorporated in parts by regulatory guidance documents. In still other cases, VCSs may not be taken note of at all within the regulatory structure. In the nuclear field, VCSs that are not given a role in the regulatory structure face the possibility of being orphaned and used in ways that may be at odds with the SDO's intent in developing the standard.

A third avenue of engagement is related to funding of standards development. A federal agency's funding decisions can make a difference relative to whether a standards project goes forward or not. With respect to ANS, DOE funding was critical to progress made with a gas-reactor standard and NRC funding with PRA methodology standards.

2. How transparent is each method?

It does not appear that decision making on standards engagement is part of a systematic and holistic process as much as it is ad hoc and "hit or miss." Hence, the level of transparency is spotty.

The process to develop a standard takes on the role "of its priority," either *mandatory* or *voluntary.* 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. When the classification of standards distinguishes between *voluntary consensus standards*, which by themselves impose no obligations regarding use, and *mandatory standard*, then the process to fulfill completion of a standard by a specified date becomes almost a moot issue. It is a known fact that a standard will take on the role of high visibility and will be completed in a timely manner when that standard must fulfill a national or international requirement, less so with a VCS.

3. How effective is each method?

Only mandated standards or requirements driving standards receive full attention and are an effective method for completing standards. Voluntary standards are voluntary regarding their use. VCSs are developed outside the federal agencies as federal standards are not subject to a consensus process. These VCSs generally do not receive the attention they need to complete within some reasonable time frame. This is probably because they are voluntary for use and do not impose a commitment. Each industry sector, government or private, sets its priorities according to the commitment upon which it must act. Cross-cooperation between government and national standards is generally very good, at least in the nuclear energy arena.

Hence, the effectiveness is unpredictable. Where a federal agency engages with technical leadership, a well-defined regulatory purpose, and funding support, the VCS process can be highly effective in meeting a national purpose or need. The caution that must be exercised in such cases is that the integrity of the consensus process should not fall victim to an overbearing government role.

4. How could the methods be improved?

Methods can be improved only if the need for the product is prioritized. Prioritization establishes involvement. Involvement means participation from all impacted parties. The time

must be taken to prioritize our industry needs both domestically and internationally; otherwise, each entity will set its own priorities, which will never achieve a common objective of standardization.

One way to improve may be by SDOs and agencies working together to assure that no VCSs are ignored. It should be a matter of simple fairness to the volunteers who labor to produce a standard that the SDO ensure that agencies and industry take note of a VCS and that some feedback is forthcoming so that it can serve to inform future standards development efforts. If a new VCS that incorporates latest technology is ignored, there can be adverse safety and cost implications.

5. What other methods should the federal agencies explore?

Federal agencies must establish a single department, if not already in place, with a mission and charter established to support standards for their focused area(s). Without such an infrastructure, developing standards for the industry will never become transparent. In the past, the Interagency Committee on Standards Policy at NIST has done a very poor job of this.

6. What impact have federal agencies had on standards activities?

For the federal agencies noted in B1 above, support for standards has been mixed. Some standards are completed in a timely manner; some are completed beyond a targeted due date. This completion date is based on the priority and need for that standard. Standards that are not given a priority will probably never receive the attention they need to complete the product.

7. How well do federal agencies coordinate their roles in standards activities in the sector of interest?

Federal agencies need to be more involved in projecting the needs of the future. In addition, federal agencies do not appear to be proactive in implementing the policies, procedures, and programs that they develop. The industry knows that every agency has a strategic and tactical plan, but implementing and monitoring those plans seem to fall short.

8. When federal agencies have been involved in standards-setting efforts in a technology sector, how has the progress of standards-setting efforts in this technology sector changed after federal agencies became involved?

When federal agencies become involved, the process of developing a standard, for the most part, appears to run more smoothly. This positive impact is for two reasons:

1) Other participants tend to look to the federal agency for its input since it is the "keeper" of items of which the other industry participants may not be aware;
2) Federal agencies can provide leverage on others to set criteria and schedules for targeted completion dates.

However, agency involvement can also have detrimental effects if it is not properly managed. Agency endorsement of a VCS may "fossilize" development by creating a disincentive to bring in technology improvements that occur with time.

9. Are federal agencies generally receptive to input from other participants in standards-setting activities?

Generally speaking, the answer is "yes." But, being receptive to ideas is one thing; budget and personnel support are quite another. National consensus standards would definitely benefit by greater federal budget and personnel involvement.

10. Does receptiveness tend to depend on whether the federal agency is a regulator or a customer?

No, as a regulator, the federal agency generally moves forward with the proposed regulation based primarily on input from the industry. Regulators then depend on the standards community to follow draft regulations with the "how to" to meet those regulations in a safe, efficient manner based on years of technical experience in that area. Different SDOs respond to different regulations depending on the charter of the SDO.

As a customer, federal agencies have routinely participated in national standards at a level so that needs of the agencies are generally included as the standards are drafted. If not, the standards maintenance process allows for periodic updates to approved standards to include those needs based upon a consensus of the industry (i.e., balance of interest). However, it should be noted that regulatory language may not be subjected to any updating requirements resulting in regulatory obsolescence. This can be a source of significant disconnection between federal agencies and SDOs.

11. In those sectors where federal agencies play a significant role in standards activities, how valuable and timely is the work product associated with this effort?

If the work is a priority especially if it benefits public safety, the federal agencies will play a significant role in both the quality of the product and the timing for completion of that standard. Their participation will be visible.

Credibility of all participants and the priority of the standard appear to be the key factors in completing a "quality" standard by the targeted date.

C. International Cooperation

1. Are efforts made to determine whether there is potential for overlap or duplication with existing international standards?

Such efforts are limited to those U.S. experts that participate in the initiation, review, comment, and balloting of International Organization for Standardization (ISO) standards through the ANSI Technical Advisory Groups (TAGs). For nuclear issues, the Nuclear TAG provides a direct link between ISO Technical Committee 85 on Nuclear Energy and ANSI. However, because of lack of any direct funding, the U.S. NTAG is not very active. Very little information is passed routinely among ISO, ANSI, and the U.S. SDOs. Evaluation of overlaps is nearly nonexistent.

2. How are other appropriate international standards that may be of interest identified?

International standards that may be of interest are nearly nonexistent. ISO has a project identification notice that allows an international standard to be developed or revised based on member country approvals. The U.S. Nuclear TAG receives these notices, but they are not routinely passed to SDOs.

3. Are efforts made to identify existing or planned regional or national standards that may be considered for use as the basis for foreign technical regulations, rather than the committee considering the international standard?

No, this in not routinely done. No consideration is routinely made for use of any U.S. standards as potential input for foreign country regulations.

However, inclusion of U.S. national consensus standards has been considered as a baseline for development of adoption as ISO standards. On one occasion, ASTM proposed that a number of ASTM standards be adopted directly by ISO Technical Committee 85 and published as joint ISO/ASTM standards. This project was completed for nine ASTM standards.

D. Intellectual Property

1. How does the need for access to intellectual property rights by federal agencies factor into the use or development of standards?

Intellectual property rights are not divulged in national consensus standards. To do so would unbalance competition between vendors who hold these rights. All national consensus standards are unclassified in any form except for copyright laws of the individual SDOs.

An intellectual property issue often overlooked is the value to an SDO of the contents of a VCS. Especially in the international arena where enforcement is difficult, use of U.S. SDO intellectual property without appropriate compensation is a problem that should be given attention.

2. To what extent, if any, has the development, adoption, or use of a standard by federal agencies in this technology sector been affected by holders of intellectual property?

The principal holders of intellectual property are the members of the working groups that create national consensus standards. These members are charged with protecting any intellectual property of their companies and organizations. Since all national consensus standards are openly available to the public, intellectual property is protected by not having been included in the consensus standard in the first place.

Mandatory standards that are developed by a specific company such as Caterpillar or Boeing do, in general, contain intellectual property but are not releasable to the general public by internal rules and regulations. Federal agencies often have access to these proprietary company standards under special disclosure agreements between federal agencies such as DOD and Boeing for protection of these rights.

How a federal agency deals with a VCS can affect the value of the intellectual property asset that an SDO possesses in any given standard. It should be incumbent on an agency to be appropriately concerned about protecting an SDO's intellectual property value.

3. How have such circumstances been addressed?

It is not clear that these circumstances have been addressed systematically and consistently in national consensus standards. NRC is trying to create new guidance for digital controls for nuclear plant safety applications where these issues will certainly arise. NRC is attempting to resolve intellectual property issues that other industries have kept company internal through mandatory company standards. No guidance has been promulgated as yet.

4. Are there particular obstacles that either prevent intellectual property owners from obtaining reasonable returns or cause such owners to make intellectual property available on terms resulting in unreasonable returns when their intellectual property is included in the standard?

Inclusion of company intellectual property information in national consensus standards would impose an undue burden on the SDO. Methods to compensate a company for a small amount of intellectual property that was included in a national standard may be difficult. These issues are most likely much more prevalent in DOD standards because of their ability to apply security classifications to their standards.

One action that should be considered for implementation is that proper attribution should be required when the content of a VCS is used in any way by industry or a federal agency. This should be seen as a matter of fairness to the volunteers involved as well as creating the right incentives for SDOs to pursue their useful work.

5. What strategies have been effective in mitigating risks, if any, associated with hold-up or buyers' cartels?

This issue does not occur in national consensus standards because of their open public approval process and balance of interest.

E. Adequacy of Resources

1. What resources are needed to successfully complete the efforts?

Successfully scoping the accurate number of new nuclear standards that is needed will require a survey, a priority assignment, and a cost estimate based on the relative breadth of the standards work proposed. NIST should conduct this survey through the Nuclear Energy Standards Coordination Collaborative. Once needed standards are identified and prioritized, SDO assignments should be made with funding provided to support an expedited development schedule.

2. Taking into account budget constraints and competing initiatives, have federal agencies committed adequate resources?

No, very minimal budget resources have been allocated, from time to time, by the DOE Office of Nuclear Energy and NRC. DOE and NRC do provide in-kind services to populate working groups to develop standards as well as service on consensus committees.

Resource requirements vary by agency. NIST resources should identify and prioritize new standards that need to be developed or revised. Industry should share responsibility for helping identify the scope of the work needed for new and revised standards. Events like Constellation's Calvert Cliffs 3 cancellation due to inability to predict capital costs stress this point. The most important standards should specify requirements that would allow control of nuclear project costs. These standards would be used to define currently vague regulatory requirements, such as reliability assurance program requirements, and provide a path for compliance with those regulations. This would remove a large amount of risk to help control new nuclear project costs.

3. What resource constraints impact the successful completion of the standards efforts?

The major impact comes from an inability of many of the standards working group members to meet at least four times a year. Face-to-face meetings are a necessity to ensure a proper dialog between experts on the group, resolve complex issues, and provide somewhat of an incentive to participate. Working group meetings generally require two to four days at a central, inexpensive travel location.

F. Lessons Learned

1. What lessons about standards development in complex technologies has ANS learned so far, as pertaining to ANS work?

The following approaches are the most important for standards development:

1) *technical expertise*: agency support with technical expertise;
2) *identification*: agency coordinating identification of standards needed;
3) *relevance*: agency efforts to keep regulatory requirements updated and to reference only up-to-date standards;
4) *participation*: focus brought by those who use standards;
5) *communication*: telephone conversations and online access to perform work;
6) *technical writing*: agency support for technical writing for new standards publication;
7) *funding*: agency trip funding for periodic face-to-face workshops.

The following approaches are secondarily important in standards development:

1) *project management*: performing better project management to do the work effectively;
2) *writing skills/pride of authorship*: getting effective standards written with no technical writers available;
3) *schedules*: completing standards to fixed schedules; applying project management techniques for getting standards published expediently;
4) *brainstorming*: developing workarounds to break through impasses;

5) *perfection versus adequate*: writing good standards, not perfect ones; avoiding obsessive focus (minutia on details);
6) *focus*: prioritizing the right work to do, maintaining effort, and sustaining projects to timely completion;
7) *industry support*: giving industry people assigned to standards the time to develop them;
8) *duplication*: avoiding duplication through appropriate allocation;
9) *review and resolution*: providing fair reviews and comment resolution to reach consensus.

The following approaches are suggested to speed and improve standards development:

1) Assign section technical content providers early in the process;
2) Get a draft out quickly, rough as it may be;
3) Provide assets so technical writers can assemble content between group meetings;
4) Limit meeting discussion per topic;
5) Monitor processes online;
6) Ensure that reviewers follow ANSI guidance.

2. How have these lessons learned been implemented?

The lessons have been partially and inconsistently implemented. These approaches need further discussion and evaluation. For the secondarily important approaches, the status is the following:

1) *Project management*: ANS leadership is evaluating methods to improve project management through the use of a project plan;
2) *Writing skills/pride of ownership*: Better methods of controlling pride of ownership are being discussed; how to assign company sponsorship and/or professional writer support for each new or revised standard (potential pride of ownership) is being addressed;
3) *Schedules*: ANS regularly informs government agencies and other stakeholders of standards developments and follows up with information dissemination;
4) *Brainstorming*: Meeting control and preparation are being implemented;
5) *Perfection versus adequate*: A proposed authorization commitment has been proposed to address this situation; the authorization relates to project management and how committee leaders are selected;
6) *Focus*: ANS has been discussing how to change the focus to emphasize value, which needs to be built into the structure of development of standards by all SDOs;
7) *Industry support*: An organizational sponsor should be developed for each standard;
8) *Duplication*: ANSI needs to strengthen its support to provide standards allocation to organizations using PINS forms to avoid duplication.
9) *Review and resolution*: Standards need to be consistent with the ANS standards policy guide and the PINS form.

3. Have there been any impediments to implementing these lessons?

The primary impediment is that there is insufficient knowledge and appreciation for the structures, processes, and value of the U.S. VCS system. This extends to the management and staff of the various institutional stakeholders. In addition, there are issues related to past practice, resources (those with available skills), and impetus to improve standards processes. Until the recent nuclear renaissance, there has been little perceived need to improve standards processes.

4. How has this information been documented or disseminated, and implemented?

Within ANS, the Standards Board and the consensus committees have discussed methods to improve processes as presented here. Participation by the industry coordinating body, NEI, has been significantly improved. Information exchange between the Standards Committee leadership and institutions such as NRC, DOE, INPO, and IAEA has significantly increased. The documented proceedings of the Standards Committee meetings reflect ongoing improvements.

5. What kinds of performance metrics are appropriate to measure the effectiveness of the standards-setting process?

Project and process performance metrics would be appropriate. These include total numbers of projects; percentage completion of each; percentage completion to schedule; active projects in progress; active projects completed in the year; projects with scopes defined; projects approved; percentage schedule adherence, overall.

In addition, federal agencies should be required to document any beneficial use of the contents of VCSs, which should be noted even if the standard is not explicitly reviewed and endorsed. The reporting requirements should include some kind of tally of the useful contributions made by standards use.

Modern information technology tools should also be employed to track industry use of the contents of standards, even if only parts of the standard are used. However, this should be done judiciously, without adding significantly to the cost of using a standard.

6. If any such performance metrics have been used, what are the results?

Although ANS keeps track of the progress of projects, ANS does not report progress against performance metrics. Guidelines are provided in the standard development project plan. Because the writing group members are volunteers, many factors can affect the timing of completion of the standard. Additional travel funding for working group members to meet at least four times per year would greatly improve the schedule of completion. A note of caution is that such monitoring should not be allowed to reflect poorly on the tremendous value of the volunteer's work.

G. General Assessments

1. Effectiveness of the methods federal agencies have used to engage in standards-setting activities by identifying which methods have enhanced or limited the public-private standards-setting processes

The first step revealing candidate standards as available for use requires an effective method for cataloging standards to present to potential users. Given Office of Management and Budget Circular A-119 and the mandate of the National Technology Transfer Act of 1995, this should be a first step. In the past, available applications (MS Word, Excel, printed catalogs, etc.) limited the identification of available standards that could interest potential users. To a large degree, hard-copy catalogs presented standards sorted by title and simple topical content descriptions. Now, newer technologies allow keyword sorts. Recognition that the Web can also access, present, and disseminate standards information supersedes those capabilities. Even updated to PDF formats, those methods are now obsolete. Standards content can vary tremendously, for example, from addressing offshore petroleum production to electric grid reliability applications to new nuclear design. To develop and present standards that could apply in many areas requires a common approach.

2. Effectiveness of Federal agencies' coordination with the private sector

In nuclear design, standards development with the private sector has been limited. In risk-informed design, private-sector participation has been passive. Since the Three Mile Island accident, for all practical purposes, NRC has dictated design, and private industry has followed its lead. As a result, tedious highly complex probabilistic methods are required to certify nuclear designs today. Nuclear digital controls provide a good example. Although the absence of nuclear construction contributed, the lack of nuclear design innovation reflects (in part) failure to develop effective standards. Attempting to apply complex risk methods to digital circuits, NRC has yet to license digital controls. The U.S. commercial nuclear industry lags behind other industries; for example, it is now decades behind commercial aviation. It is widely recognized that digital controls are substantially safer than analog ones. Foreign designers are developing newer, more innovative ways of performing nuclear safety design. Many have already licensed nuclear digital controls.

Ineffective design processes result in very high new nuclear design costs. Westinghouse cites excess of $400 million developing the AP-1000 design, today. Obviously, prohibitive costs block small modular reactor development. Consequently, nuclear design innovation is moving offshore. To reverse this trend requires improving design standards, devising better rules, or both.

It should be noted that NRC is only now developing a database to identify regulatory reference to standards content. This effort recognizes that similar cataloging by industry is also needed. However, the schedules associated with this activity are so long drawn out that the usefulness is foreseen only for a long time from now.

3. Adequacy and availability of federal resources

The single greatest resource lack within agencies is leadership to promote innovative approaches to the development and application of standards. Ideally, standards would simplify ways to achieve important goals and lower costs by identifying acceptable, effective approaches for regulatory approval. In nuclear design, they do not.

New nuclear plants require solutions, today. The primary missing resource is timely and appropriate agency leadership. Other high-risk industries—aerospace, for example—solved

the technical problems of licensing digital controls decades ago. To build a new nuclear generation and maintain older nuclear plants safely at reasonable cost, agencies need to resolve nuclear digital controls application. (Digital controls exhibit much lower drift and fewer intrinsic failures. The resulting safety improvements and cost savings are substantial.) Federal agencies should support, but not control, nuclear standards development.

4. Other issues that arise and are considered during the standards-setting process that impact the process, and the timeliness, adoption, and use of the resulting standards

The single greatest issue among federal agencies that affects the timely development, adoption, and use of standards is the capacity to tolerate innovative thinking. For example, for nuclear work can other safety design processes provide "risk-informed" design control (NRC code words)? There are no logical reasons to exclude other methods for licensing digital controls, although NRC's regulatory position is to apply traditional PRA. The question of acceptability of other design processes (other than PRA-based design) hampers U.S. nuclear development. The challenge is to produce safer designs, regardless of the safety process. The application of LWR PRA processes to other non-LWR designs significantly hampers U.S. nuclear design of new, innovative reactors. Therefore, the design of these innovative small modular reactors will move offshore. For example, Bill Gates envisions licensing the traveling wave reactor in China, first.

The principal strategic goal for federal standards support should be finding better, more innovative methods of doing work. They should help open markets and cut costs, rather than promote restrictive, inefficient processes originating from past regulatory efforts. Promoting innovative standards thinking needs more federal support.