# Accredited Standards Committee (ASC) X12

# Response to the National Institute of Standards and Technology, Federal Agency Participation

*Effectiveness of Federal Agency Participation in Standardization in Select Technology Sectors for the National Science and Technology Council's Sub-Committee on Standardization*

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**INTRODUCTION**
The Accredited Standards Committee (ASC) X12, chartered by the American National Standards Institute more than 30 years ago, develops and maintains EDI and CICA standards along with XML schemas which drive business processes globally. The diverse membership of ASC X12 includes technologists and business process experts, encompassing health care, insurance, transportation, finance, government, supply chain and other industries.

ASC X12, a cross-industry organization and leader in electronic data messaging standards, welcomes the opportunity to respond to the National Institute of Standards and Technology (NIST) regarding the *Effectiveness of Federal Agency Participation in Standardization in Select Technology Sectors for the National Science and Technology Council's Sub-Committee on Standardization*. ASC X12 will address Health Information Technology, from an Insurance perspective, and other technologies involving significant government participation, from a Transportation and then Finance perspective, in the context of these topics:

- Standards-setting Processes, Reasons for Participation and the Benefits of Standardization
- Perspectives on Government's Approach to Standards Activities
- Issues Considered During the Standards Setting Process
- Adequacy of Resources

Subject matter expertise is critical to the development and maintenance of standards. Federal agencies have valuable experience and can provide useful input on many of the operational and technological challenges addressed by private sector counterparts. Agencies' subject matter experts have provided support to develop and maintain standards and have served as useful resources in the management and leadership for some standards development work groups.

SDO success is driven by the number and caliber of volunteers who provide valuable time and expertise to create and maintain quality standards, which may affect standards that impact government operations and systems.

However, per the ANSI rules, Federal agencies and other standards stakeholders have an equal vote in the standards process, not a veto vote or a vote that supersedes other stakeholders affected by the relevant standards.

Additional, focused resources are valuable to standards development in several ways, including to improve the process of:

- Gathering critical multi-stakeholder input.
- Identifying and documenting use cases and issues.
- Expediting the development, evaluation and review process.

**INSURANCE**

The X12N (Insurance) Subcommittee respectfully addresses Health Information Technology in the context of the following topics.

***Standards-setting Processes, Reasons for Participation and the Benefits of Standardization***

1. *Who participates in standards-setting activities?*
   - Health Plans
     i. Commercial
     ii. Private
     iii. Blue Plans
   - Providers
     i. Hospitals
     ii. Physicians
     iii. Dentists
     iv. Academic Medical Centers
     v. Provider Organizations
        1. AMA
        2. AHA
        3. ADA
     vi. Pharmacies
     vii. Labs
   - Vendors
     i. HealthCare Clearinghouse
     ii. Value Added Network
     iii. Software
        1. Adjudication
        2. Billing
        3. Translator
   - Consultants
   - Federal Agencies
     i. CMS
     ii. DoD
     iii. VA
     iv. CDC
     v. SSA
   - State Agencies
     i. Medicaid
     ii. Dept of Labor/Workers' Comp
     iii. DMV
   - Other Standards Development Organizations, Data Content Committees, and Industry Associations
     i. HL7
     ii. NUCC
     iii. NUBC
     iv. NCPDP
     v. NAHDO
     vi. WEDI
     vii. IAIABC
     viii. CAQH
   - Hybrid organizations
   - Other Payer/TPA
     i. Motor Vehicle
     ii. Workers' Comp

          iii. Pharmacy Benefit Manager
- Government Contractors

2. *What are the most important reasons for participation?*
   - Ensure business process representation
   - Competitive Advantage
   - Be aware of changes
   - Discounts on education material and publications
   - Networking
   - Exchange of industry information, trends, and ideas
   - Maintain continuity of critical business practices
   - Influence outcome

3. *What are the benefits of developing standards for this sector?*
   - Administrative simplification
   - Cost savings through eCommerce
   - Consistency to promote clarity amongst trading partners
   - Expand install base
   - Interoperability

4. *How do the standards impact organizations and their competitiveness?*
   - Promote innovation
   - Reduce costs
   - Improve data quality and accuracy

5. *How has standardization spurred innovation in the technology sector(s) that is the subject of your comment?*
   - Data consistency has allowed organizations to reallocate resources to other initiatives.
   - Vendors are able to build more robust and automated systems.
   - Patient safety is enhanced through clean, accurate and rapid access to data.
   - Analytical capabilities are enhanced to provide more qualitative results.

6. *What is the current phase of the standards development process for this technology?*
   - Mature

7. How has the process worked so far?
   - The ASC X12 open consensus-based process has worked well and is successful. As an organization, ASC X12 is constantly working to improve our standards to meet industry needs.

8. *When developing standards, how are the standards-setting processes managed and coordinated?*
   - ASC X12 has an open process that allows any interested stakeholder to participate in development.
   - The development life cycle includes several layers of approval before being presented to the membership and any materially-impacted party for public comment and formal ballot.

9. *Is there a strategic plan that identifies the standards needs and defines the standards development life cycle?*
   - Yes. Please see above.

*10. Are there barriers to developing high level strategies for standard-setting activities?*
- Yes. The barriers include:
    i. Resource constraints (Including: people, funding, time, etc.)
    ii. Keeping pace with a rapidly advancing Health Care Industry, Regulation, and Legislation.
    iii. Reconciliation of competing priorities
    iv. Qualified knowledge base (Both strategic and tactical)

### *Perspectives on Government's Approach to Standards Activities*
Responses to the following questions will help the Sub-Committee better understand which methods of engagement by Federal agencies are most effective and why.

1. *What methods of engagement are used by Federal agencies to participate in private sector led standards development?*
    - Method 1)
      Agency staff are among the participants at the table for both in-person meetings and conference calls.
    - Method 2)
      Agencies also hire contractors to serve as their representatives.
    - Method 3)
      Agency requirements are also represented by stakeholders who must comply with the published regulations and policies.

2. *How transparent is each method?*
    - All methods are transparent, as all work products and processes are open to all interested parties.

3. *How effective is each method?*
    - Method 1 and Method 2 effectiveness is dependent on the level of knowledge and empowerment of the representative.
        i. Representatives who are sent with the purpose of obtaining information and must consult with superiors before decisions can be made are highly ineffective.
        ii. Knowledgeable representatives who are empowered to make decisions are very effective.
        iii. Often times the representatives are from the technical areas of the agency. This results in new initiatives coming forward at the end of the process. Policy representatives not being engaged with, or consulting with, the SDO early in the process results in:
            1. Extensive delays in realizing an implementable solution.
            2. The intent of the policy and the solution to support it are incompatible.
            3. A disconnect between the policy and the standard in place.
            4. A misrepresentation and/or misunderstanding of the intent of the policy.
    - Method 3 can be effective when the policy or regulation is clear. However, when there is room for interpretation, it can be counter-productive and impedes development.
    - Method 1 and Method 2 for federally funded state agencies (For example: Medicaid) are under represented

4. *How could the methods be improved?*
    - Engage standards organizations early in the policy creation process.

- Ensure both policy and technical representatives participate (It is unrealistic to expect technical staff to be able to answer all questions as to the intent of the policy).
- Permit agency representatives to be more open during the Rule Making process, to ensure promulgated rules and the standards that support them are compatible.
- Make the Federal policy and rule-making process more transparent.
- Create a coordinated and realistic HHS-level Strategic Plan (including regulatory and statutory timelines) that provides the industry with time and resources to meet the mandates and implement their own strategic initiatives.
- Provide proper funding to enable appropriate levels of participation from both policy and technical areas of the agency.
- Require Federally-funded state agencies (Medicaid) to participate and provide adequate funding for this purpose.

5. *What other methods should the Federal agencies explore?*
- With proper funding, virtual meetings may be an opportunity to bring more individuals to the table.

6. *What impact have Federal agencies had on standards activities?*
- The impact is significant in many ways.
    i. Federal and state data content requirements provided the foundation for some standards.
    ii. The force of Federal Regulation and legislation has helped to drive the industry to mass adoption of the standards.
    iii. Federal programs represent a significant percentage of the business conducted by industry trading partners.
    iv. Agencies are encumbered by obsolete policies and regulations resulting in an impediment to progress and innovation.

7. *How well do Federal agencies coordinate their roles in standards activities in the sector of interest?*
- There appears to be little or no coordination.
- Some of this may be a result of policies and regulation limitations.

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?
- See Question #6, regarding impacts, above.

9. *Are Federal agencies generally receptive to input from other participants in standards setting activities?*
- The level of reception varies dependent upon the issue. Factors impacting flexibility include:
    i. Federal policies and requirements
    ii. Representative's knowledge of the policy/issue and intent
    iii. Representative's level of empowerment

10. *In those sectors where Federal agencies plays a significant role in standards activities, how valuable and timely is the work product associated with this effort?*
- Having the agencies present enables the SDO to create a higher quality product by ensuring their perspective is not omitted.

***Issues Considered During the Standards Setting Process***
The Sub-Committee is interested in understanding the types of issues (e.g., technology, competition, innovation, intellectual property rights, foreign regulations, etc.) that have been considered, and how these have been addressed/are being addressed.

1. *Has Federal agency participation in standards-setting impacted the consideration and resolution of these issues, and the standards setting processes?*
   - Competition and innovation can be handicapped by the fact that Federal agencies are highly motivated to see change based upon their needs, however, Federal agencies are resistant to change brought on by other stakeholders within a given sector that will affect all.
   - The Federal rulemaking process does not allow the industry to progress in a timely fashion. Arguments are made for voluntary adoption, but that is unrealistic due to the plethora of other mandates which must be met.

2. *With respect to foreign regulations…*
   This section is not applicable to ASC X12.

3. *With respect to intellectual property, the Sub-Committee would like to understand the approaches you have experienced or found most appropriate for handling patents and/or other types of intellectual property rights that are necessary to implement a standard.*
   a. *How does the need for access to intellectual property rights by Federal agencies factor into the use or development of standards?*
      - Not applicable

4. *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?*
   a. *How have such circumstances been addressed?*
      - Not applicable

   b. *Are there particular obstacles that either prevent intellectual property owners from obtaining reasonable returns or cause intellectual property owners to make IP available on terms resulting in unreasonable returns when their IP is included in the standard?*
      - Not applicable

   c. *What strategies have been effective in mitigating risks, if any, associated with hold-up or buyers' cartels?*
      - Not applicable

***Adequacy of Resources***
The availability and commitment of financial resources, personnel, and industry expertise may impact the success of standards development. In some instances, changing priorities or changes in an organization's budget may impact the resources an agency commits to an ongoing project. The Sub- Committee would like to better understand the resources that both private sector organizations and Federal agencies commit to standards-setting activities, constraints on those resources, and how the level of resources affects the success of the effort.
1. *What resources are needed to successfully complete the efforts?*
   - Policy/business analysts from all facets of the sector
   - Technical expertise from all facets of the sector
   - Federally funded state agencies such as Medicaid actively participating
   - Proper support from organizations that provide the volunteers to allow not only travel and meeting support, but also time for planning, documentation, and quality assurance activities

- SDO's sufficiently funded to provide administrative and documentation support

2. *Taking into account budget constraints and competing initiatives, have Federal agencies committed adequate resources?*
   - No. See "Perspectives on Government's Approach to Standards Activities," Question #1 regarding Methods, above.

3. *What resource constraints impact the successful completion of the standards efforts?*
   - See answers to previous questions.

**TRANSPORTATION**

The X12I (Transportation) Subcommittee respectfully addresses other technologies involving significant government participation in the context of the following topics.

***Standards-setting Processes, Reasons for Participation and the Benefits of Standardization***

1. *Who participates in standards-setting activities?*
   - Transportation Carriers
     i. Air
     ii. Marine
     iii. Motor
     iv. Rail
   - Users of Transportation Services
     i. 3PL's
     ii. Shippers
     iii. Consignees
     iv. Government Agencies, Federal and state
     v. Other interested parties
   - Vendors
     i. Value Added Network
     ii. Software
     iii. Other
   - Consultants
   - Other Standards Development Organizations, Data Content Committees, and Industry Associations

2. *What are the most important reasons for participation?*
   - Ensure that Federal agency requirements are met by the standards that they use daily for the exchange of data with the trade
   - Exchange of industry information, trends, and ideas
   - Maintain continuity of critical business practices
   - Influence outcome

3. *What are the benefits of developing standards for this sector?*
   - Paperwork reduction
   - Meeting advance data requirements for Homeland Security
   - Cost savings through eCommerce
   - Consistency to promote clarity amongst trading partners
   - Interoperability
   - Improved supply chain visibility

4. *How do the standards impact organizations and their competitiveness?*
   - Promote Innovation
   - Cost reduction
   - Improved data quality and accuracy

5. *How has standardization spurred innovation in the technology sector(s) that is the subject of your comment?*
   - Use of ANSI ASC X12 standards has allowed the DoD to streamline their supply chain
   - Use of ASC X12 standards has allowed Homeland Security to receive advance data on shipments before they enter the United States

- Receipt of advance data has allowed Homeland Security to concentrate on shipments that require extra scrutiny

6. *What is the current phase of the standards development process for this technology?*
    - Mature, ASC X12 standards have been in use by various Federal agencies for over 20 years

7. *How has the process worked so far?*
    - ASC X12's open consensus based process has worked well and is successful. As an organization, ASC X12 is constantly working to improve our standards to meet industry needs

8. *When developing standards, how are the standards-setting processes managed and coordinated?*
    - ASC X12 has an open process that allows any interested stakeholder to participate in development, U.S. Customs and Border Protection (USCBP) and the DoD are represented at all transportation meetings
    - ASC X12's processes and procedures for standards setting are well documented and tested.
    - The development of ASC X12 standards includes several layers of approval and a vote of the entire membership. All materially impacted parties can participate in the development and approval process.

9. *Is there a strategic plan that identifies the standards needs and defines the standards development life cycle?*
    - Various agencies have differing requirements and deadlines. In the case of transportation the life cycle of the standards is defined by the agency.

10. *Are there barriers to developing high level strategies for standard-setting activities?*
    - No, there are no barriers

### *Perspectives on Government's Approach to Standards Activities*
Responses to the following questions will help the Sub-Committee to better understand which methods of engagement by Federal agencies are most effective and why.

1. *What methods of engagement are used by Federal agencies to participate in private sector led standards development?*
    - Federal agency staff is among the participants at the table for both in-person meetings and conference calls.
    - Federal agencies also hire contractors to serve as their representatives, such as the Logistics Management Institute (LMI).

2. *How transparent is each method?*
    - All methods are transparent, as all processes are open to all interested parties.

3. *How effective is each method?*
    - Both methods have worked well in transportation as both the USCBP and the DoD (U.S. Transcom, through it'ss use of LMI as a contractor) have been participating for over 20 years

4. *How could the methods be improved?*
    - Additional participation from other Federal agencies has been sporadic. Additional participation when needed would be helpful.

5. *What other methods should the Federal agencies explore?*
   - The Federal agencies that participate in the transportation subcommittee utilize all methods of participation available.

6. *What impact have Federal agencies had on standards activities?*
   - The Federal agencies participating in the Transportation Subcommittee directly impacts the data requirements and timing
   - A task group within the Transportation Subcommittee was established to meet the ongoing requirements of USCBP

7. *How well do Federal agencies coordinate their roles in standards activities in the sector of interest?*
   - There is excellent coordination between USCBP and the other agencies (OGA's) that rely on data from the trade.

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?*
   - Due to the need for rapid implementation of standards by various Federal agencies, the speed at which the standards have been developed has increased

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

10. *Does receptiveness tend to depend on whether the Federal agency is a regulator or a customer?*
    - No

11. *In those sectors where Federal agencies plays a significant role in standards activities, how valuable and timely is the work product associated with this effort?*
    - Participation by the Federal agencies is invaluable.

**Issues Considered During the Standards Setting Process**
The Sub-Committee is interested in understanding the types of issues (e.g., technology, competition, innovation, intellectual property rights, foreign regulations, etc.) that have been considered, and how these have been addressed/are being addressed.

1. *Has Federal agency participation in standards-setting impacted the consideration and resolution of these issues, and the standards setting processes?*
   - The Federal agencies that participate in the Transportation Subcommittee have a positive affect on the standards. (See Appendix, USTRASCOM Role)

2. *With respect to foreign regulations…*
   a. *how are foreign technical regulations are considered and addressed during standards setting or conformity assessment activities?*
      - N/A

   b. *Are efforts made to determine whether there is potential for overlap or duplication with existing international standards?*
      - N/A

       *c.   How are other appropriate international standards that may be of interest identified?*
- N/A

       *d.   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 international standard being considered by the committee?*
- N/A

3. *With respect to intellectual property, the Sub-Committee would like to understand the approaches you have experienced or found most appropriate for handling patents and/or other types of intellectual property rights that are necessary to implement a standard.*
    *a.   How does the need for access to intellectual property rights by Federal agencies factor into the use or development of standards?*
- N/A

4. *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?*
    a.   *How have such circumstances been addressed*?
- N/A

    *b.   Are there particular obstacles that either prevent intellectual property owners from obtaining reasonable returns or cause intellectual property owners to make IP available on terms resulting in unreasonable returns when their IP is included in the standard?*
- N/A

    *c.   What strategies have been effective in mitigating risks, if any, associated with hold-up or buyers' cartels?*
- N/A

### *Adequacy of Resources*
The availability and commitment of financial resources, personnel, and industry expertise may impact the success of standards development. In some instances, changing priorities or changes in an organization's budget may impact the resources an agency commits to an ongoing project. The Sub- Committee would like to better understand the resources that both private sector organizations and Federal agencies commit to standards-setting activities, constraints on those resources, and how the level of resources affects the success of the effort.

1. *What resources are needed to successfully complete the efforts?*
- Representation from the Federal agencies is required at all meetings

2. *Taking into account budget constraints and competing initiatives, have Federal agencies committed adequate resources?*
- Yes

3. *What resource constraints impact the successful completion of the standards efforts?*
- Lack of knowledgeable representation from Federal Agencies

**FINANCE**

The X12F (Finance) Subcommittee respectfully addresses other technologies involving significant government participation in the context of the following topics.

***Standards-setting Processes, Reasons for Participation and the Benefits of Standardization***

1. *Who participates in standards-setting activities?*
   - Financial Institutions, Clearing House members, and Corporations actively participate in standards-setting activities.

2. *What are the most important reasons for participation?*
   - Participation helps insure that standards are being developed to meet the broader needs of the industry.

3. *What are the benefits of developing standards for this sector?*
   - Some of the benefits of developing standards for this sector include:

     - Ensuring the standards developed can help meet your specific business needs
     - Provide a better understanding of the issues facing other entities in your industry
     - Establish contacts with other entities in your industry to discuss issues and possible solutions to address those issues

4. *How do the standards impact organizations and their competitiveness?*
   - In some respects, the standards helps to "level the playing field" for basic, core offerings while creating opportunities to be more competitive by offering additional or ancillary products/services.

5. *How has standardization spurred innovation in the technology sector(s) that is the subject of your comment?*
   - Standardization has spurred integration of multiple applications that previously existed in stand-alone "silos." Standardization has also helped rapid adaptation of new technology.

***Perspectives on Government's Approach to Standards Activities***

Responses to the following questions will help the Sub-Committee to better understand which methods of engagement by Federal agencies are most effective and why:

1. *What methods of engagement are used by Federal agencies to participate in private sector led standards development?*
   - Historically, some of the Federal agencies have become ASC X12 members and have actively participated in the development of the standards.

2. *What impact have Federal agencies had on standards activities?*
   - When the Federal agencies are part of the standards-development activities, the resulting standard tends to address a broader range of business needs. When the Federal agencies are not part of the standards-development activities, the resulting standard may or may not be adopted by the Federal agency and create exception processing in the transaction life cycle.

***Issues Considered During the Standards Setting Process***

With respect to foreign regulations, the Subcommittee is interested in understanding how foreign technical regulations are considered and addressed during standards setting or conformity assessment activities.

1.  *Are efforts made to determine whether there is potential for overlap or duplication with existing international standards?*
    - There are a number of ways of determining if there is potential for overlap/duplication with existing international standards.  For example:

        - A number of ASC X12 members are actively involved, or are aware of other associates within their company that are involved, with other developing or existing international standards.
        - Harmonization efforts between ASC X12 and other standard-setting organizations have been undertaken

### Adequacy of Resources
The Sub-Committee would like to better understand the resources that both private sector organizations and Federal agencies commit to standards-setting activities, constraints on those resources, and how the level of resources affects the success of the effort.

1.  *What resources are needed to successfully complete the efforts?*
    - Typically the best resources for standard-setting activities are those that have a deep understanding of the business practices as well as those that have a strong technology background.

2.  *Taking into account budget constraints and competing initiatives, have Federal agencies committed adequate resources?*
    - ASC X12 has implemented virtual meetings to help address the budget constraints that were limiting member participation in the standard-setting activities.  Hopefully, as more Federal agencies become aware of the virtual meetings, more Federal agencies and their resources can be committed.

3.  *What resource constraints impact the successful completion of the standards efforts?*
    - Without input from the Federal agencies, the standards solution may not meet the business needs of the Federal agencies.

**FOR ADDITIONAL INFORMATION**
For more information about the positions outlined above, please contact:

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**APPENDIX**

## USTRANSCOM ROLE IN STANDARDS DEVELOPMENT

The United States Transportation Command (USTRANSCOM) mission is to develop and direct the Joint Deployment and Distribution Enterprise, to globally project strategic national security capabilities; accurately sense the operating environment; provide end-to-end distribution process visibility and responsive support of Joint, US Government, and Secretary of Defense approved multinational and non-governmental logistical requirements.

USTRANSCOM established the Defense Transportation Electronic Business (DTEB) Committee, comprising the military services, DLA, DFAS, GSA, and USTRANSCOM. The committee provides a forum where the Defense transportation activities can coordinate the development of their e-business projects. It also serves as the DoD and Federal functional working groups for transportation.

DTEB publishes implementation conventions for the USTRANSCOM EDI transactions that are based upon ASC X12 EDI standards. In support of those standards, USTRANSCOM actively participates in ASC X12 meetings, with a representative serving as a voting member of X12I-Transportation Sub-Committee, where he actively participates in new transaction development and data maintenance in traditional EDI and in emerging XML data formats. The representative also serves as the secretary to the X12I – Transportation Sub-Committee, X12I/TG1 – XML Development and X12I-TG3 – Motor task groups.

The USTRANCOM representative also monitors work undertaken by the X12C – Communications and Control, X12G – Government, and X12M – Supply Chain subcommittees and participates in those subcommittees as needed.

USTRANSCOM continues to modernize its business processes and improve its ability to exchange information via electronic means. DTEB through its collaboration with X12 will continue to progress initiatives that will directly contribute to the success of several DoD logistics programs, including the Electronic Transportation Payment Program, Intransit Visibility, Total Asset Visibility, Defense Logistics Management Standards, and the DoD Logistics Strategic Plan.