### American National Standards (ANS) Process: Re-accreditation process & Audit Program

- > The webinar will start at 2pm Eastern
- > All participants are muted for the duration of the webinar
- > Slides will be distributed to all by email
- Please use the CHAT option to submit a question to "All Panelists" (Not Host)
- > This session will be recorded and the recording may be available at a later date



### Let's get started...

- On behalf of ANSI, thanks very much for joining us today
- A huge thank you to those of you who are already involved in standards...you literally make the world a better place
- Goal for the next 60-90 minutes:
  - Review the "Re-accreditation process"
  - Review the Audit Program
  - Discuss good practices
  - Answer your questions

## Just a reminder... ANS-Related ANSI Staff - psa@ansi.org

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- <u>psa@ansi.org</u> = our common email box

#### ANSI Essential Requirements: Due process requirements for American National Standards www.ansi.org/essentialrequirements

and

### **ANSI Auditing Policy & Procedures**



# Let's get started with the substance...

first "Re-accreditation" then the "ASD Audit Program"

### ASD Re-accreditation Process

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### Background

- ANSI Executive Standards Council (ExSC)
  - Accrediting body for Standards Developers
  - Current: 238 ANSI-Accredited Standards Developers
- Section 4.1 Accreditation of American National Standards Developers of the ANSI Essential Requirements
  - Application and criteria for accreditation
  - Scope
  - Maintenance of accreditation
    - Reaccreditation today's first focus
  - Withdrawal of accreditation

### **ASD Mark Available For Use**



## Accreditation by ANSI as a Developer of American National Standards (ANS)

• To be accredited by ANSI, a developer's procedures and practices for standards development shall meet the due process and consensus criteria established in the ANSI Essential Requirements.

✓ www.ansi.org/essentialrequirements

- Accreditation is a pre-condition for submitting a standard for consideration for approval as an American National Standard.
- Accreditation is a dynamic status and requires ongoing compliance and regular demonstrations of compliance.

### **Maintaining Accreditation**

 Maintain compliance with the ANSI Essential Requirements

- Submit annual ASD Compliance Forms as issued by PSA (psa@ansi.org) in January of each year
- Undergo Re-accreditation, as warranted:
  - ✓ Submit revised procedures in <u>strikethrough-underline</u> <u>format</u> for approval whenever changes are made
  - ✓ Submit explanation/list of changes

### **Maintaining Accreditation**

 Submit to regular Audits of a sample of ANS; or if "0" ANS, then a routine re-accreditation is required

 Annual payment of ANSI Membership or Maintenance of Accreditation Dues + a National Activity Assessment (NAA) based on the number of American National Standards maintained, e.g. \$2,885 for 0-3 ANS; \$6,240 for 4-54 ANS; etc. (2023)

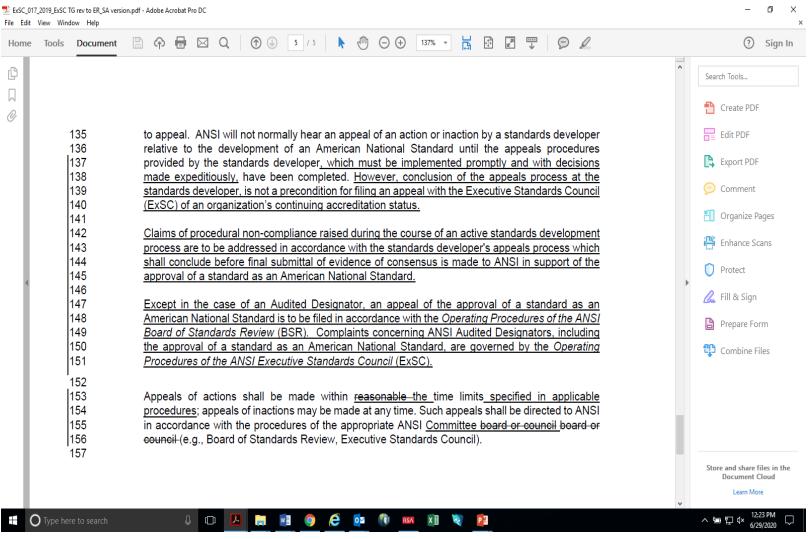
### **Maintaining Accreditation**

- ANSI-Accredited Standards Developers are required to make procedures available to any party, upon request.
  - When procedures are revised, they must be available upon request as well
  - Recommend these procedures be posted on your organization's website and easily found

## Revised Procedures = Need for Re-accreditation

- Just like ANS require review, update and maintenance actions, so do ANSI-Accredited Procedures
- Whenever any revision is made to a standards developer's procedures on record at ANSI, the ExSC shall be notified and provided with a detailed description of the changes.
  - ✓ If the changes are considered by the ExSC to be non-substantive, the standards developer will be notified and, upon such notification, may begin to operate under the revised procedures.
  - ✓ If the changes are considered by the ExSC to be substantive, notice of these changes shall appear in *Standards Action* with a call for comment.

### Sample strikethrough-underline





## Maintaining Accreditation: Use of revised procedures

If the ASD decides to implement revised procedures prior to the final approval of the ExSC, they may do so provided that

- ✓ records concerning the implementation are maintained and available for use by the ANSI Audit Program; and
- ✓ the developer certifies that the changes are in compliance with the ANSI Essential Requirements; and
- ✓ the developer accepts responsibility for all actions taken with regard to a candidate American National Standard, including resubmittal, if the ExSC does not approve a particular procedural provision

### Re-accreditation Process — General







ASD submits revised procedures in strike-through-underline format with an explanation



Re-accreditation Approval (Appeal to the ExSC then Appeals Board possible)

Public Review in Standards Action & Response to Comments by ASD





Review of Revisions, Responses to comments by ANSI ExSC; Additional comments possible

### Processing of Re-accreditations

 For most substantive revisions, full re-accreditation process, i.e., public review and ballot to the ExSC's Sub-committee on Accreditation (SC-A) is required

 Limited revisions that appear to be in compliance with ANSI's accreditation requirements may be balloted to ExSC's Sub-committee on Accreditation for approval (SC-A may decide whether or not additional public review is necessary)

## Processing of Re-accreditations: When public review is not required

- Revisions that are made at the direction of the ExSC (e.g. in response to audit recommendations, etc.) and those made expressly to bring the procedures in compliance with the current version of the ANSI ER (or excerpt text from the ANSI ER) may be administratively approved by staff on behalf of the ExSC.
  - ✓ Without public review in Standards Action

### Revisions to Scope of Accreditation

#### **During the accreditation process:**

- "The applicant shall submit its scope for informational purposes only..."
- "If, during the course of the accreditation process, the developer makes a change to their originally submitted scope or to their originally submitted operating procedures, an additional announcement shall be published in *Standards* Action..."
- ✓ Once an ASD is accredited, any change of scope should be forwarded to <a href="mailto:psa@ansi.org">psa@ansi.org</a> for publication of an informational announcement in *Standards Action*.
  - If comments are received, they must be responded to by the ASD and the response provided for the ExSC's review

## ANSI ExSC Summary Matrix: What is required in an ASD's procedures

- Guidance document: <u>7067 Matrix</u>
- Reviews every section of the *ANSI Essential Requirements* 
  - ✓ Clarifies whether explicit text to reflect each section is required to be part of a developer's accredited procedures
- Even if your procedures are silent on an issue, your organization is bound by the requirements of the ANSI Essential Requirements

## Re-accreditation - Common Comments on Revised ASD Procedures

1. Update of references to "most current version of the ANSI Essential Requirements"

2. Clarification of balance requirements (ER 1.3)

3. Inadequate definition of interest categories (ER 2.3)

## Re-accreditation - Common Comments on Revised Operating Procedures

4. Voting membership on the consensus body may not be conditional upon membership in any organization (ER 2.1)

 Recommend inclusion of text describing how comments resulting from the filing of PINS (Project Initiation Notification System) will be addressed (ER 2.5.1 and subsections)

## Re-accreditation - Common Comments on Revised ASD Procedures

- 6. Responses to views and objections; and recirculation of unresolved objections, attempts at resolution and substantive changes from vote of consensus body *and* public review (ER 2.6)
- 7. Explicit statement of numerical requirements for consensus missing or unclear (ER 2.7)
- 8. If an ANS-related vote may be taken at meeting, consensus body members who are unable to attend must be given opportunity to vote before or after meeting (ER 2.7)

## Re-accreditation - Common Comments on Revised Operating Procedures

- 9. Appeals policy should address actions and inactions, and allow for fair and impartial hearing of appeals by ASD (ER 2.8)
- 10. Missing, incomplete and/or out-of-date administrative policies, e.g. patent (ER 3.1); commercial terms & conditions (ER 3.2); antitrust (ER 3.3); records retention (ER 3.4); metric (ER 3.5); interpretations (ER 3.6)

### Re-accreditation - Additional Policy Considerations

- If an ASD is interested in the allowing these procedural options, corresponding text describing how each will be implemented is to be incorporated into its accredited procedures:
  - Discontinuance of a Standards Project (ER 4.2.1.3.3)
  - Expedited procedures for the National Adoption of ISO/IEC Standards as ANS (ER 4.6/ANSI National Adoption Procedures – <a href="https://www.ansi.org/nationaladoption">www.ansi.org/nationaladoption</a>)
  - Stabilized Maintenance of an ANS (ER 4.7.3 and 3.3.3)
  - Registration of Technical Reports with ANSI (ANSI TR Procedures)

## Re-accreditation Requirement for ASDs with 0 ANS

- If an ASD does not maintain one or more approved American National Standards:
  - ✓ then the developer shall submit their accredited procedures for review and approval by the ExSC on a five-year cycle as well as a justification as to why they have not submitted any standards to ANSI for approval and why their accreditation remains relevant.
  - ✓ the ExSC may suspend or withdraw the accreditation if the
    justification is not provided or is otherwise unsatisfactory.

### Questions?

## ANSI Standards Developer Audit Program Governing Documents:

ANSI Essential Requirements

ANSI Auditing Policy & Procedures

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Director, ANSI Standards Developer Audit Program

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### ANS Developer Audit Program

- ANSI has conducted a total of 968 audits.
  - Regular audits: 859
  - Special audits: 109
- The vast majority of audits are closed once any required procedural updates are submitted and approved.
- Approximately 10% of standards developers have had their accreditation suspended as a result of their audit

### **ASD Audit Program Purpose**

### The Audit Program is intended to:

- ✓ strengthen the voluntary consensus standards system
- ✓ confirm adherence to the developer's, and ANSI's procedures
- ✓ increase the credibility and the effectiveness of the process
- ✓ assist developers in improving their process and detecting potential problems

### Frequency of Regular Audits

- All ASDs are required to be audited, at minimum, once every five years in accordance with the Auditing Policy and Procedures.
  - ✓ This cycle may be extended at the discretion of the ExSC.
  - ✓ ASDs who do not sponsor any approved ANS are subject to a mandatory reaccreditation of their procedures on a 5-year cycle
  - ✓ Newly accredited developers are subject to an audit of the first standard submitted to ANSI for approval

### Scheduling of Regular Audits

- Developers are notified 12-18 months in advance of the audit
- The Audit Director works with developers to establish a convenient time for the audit
- The Audit Director helps the developer prepare for the audit, including the completion of Annex B (Selfaudit) of the *Auditing Policy and Procedures* 
  - > See later slide

### Scope of Regular Audit

- 5%-10% of the American National
   Standards approved since the last audit
  - Maximum of forty (40);
  - Minimum of five (5), or
  - All, if the developer has fewer than five
    (5)

### **Audit Program Implementation**

#### **Sample** of ANS that are audited:

- ✓ American National Standards (ANS) not other standards sponsored by ASDs
- ✓ Most recently approved ANS are given priority
- ✓ ANS with objections and appeals
- ✓ ANS developed under different consensus bodies within one standards developer
- ✓ ANS sampled based on range of products or services addressed
- ✓ Other criteria, e.g., joint standards, patent issues, continuous maintenance, stabilized maintenance
- ✓ Technical Reports Registered with ANSI (not ANS, but governed by ANSI procedures),
  Provisional ANS

**Goal** is to have broadest possible snapshot of the implementation of the ANS standards development procedures

**Focus** is on compliance with ANSI's essential requirements for consensus, including an ASD's accredited procedures

## Audit Program Implementation (Electronic)

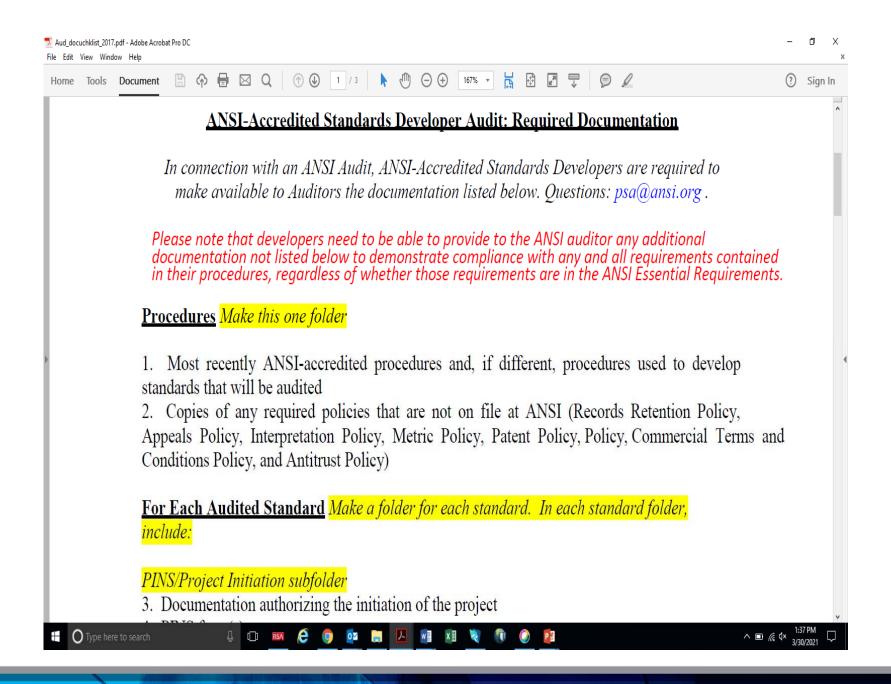
- Electronic records are deemed equivalent to hard copy records and are audited accordingly
- Some examples of ways electronic records are provided to the auditor:
  - ASD's platform
  - ftp site or similar file transfer sharing platform
  - SharePoint (including ANSI's secure Sharepoint option)
  - Other
- ✓ All Audits are conducted remotely, using electronic records and tools

### **Audit Program Implementation**

- Two documents are posted on ANSI online to help developers prepare for audits:
  - ✓ ANSI Standards Developer Audit: Required Documentation
  - ✓ ANSI Audit Guidance and Checklist for Electronic Records
- ASDs are required to provide all documentation related to the standards selected for audit per section 3.4 Evidence of compliance of the ANSI Essential Requirements

### 3.4 Evidence of compliance

- ANSI-Accredited Standards Developers shall retain records to demonstrate compliance with all aspects of these and the developer's accredited procedures.
   Such records shall be available for audit as directed by the ANSI Executive Standards Council (ExSC).
  - ➤ Periodic Maintenance
  - **→** Continuous Maintenance
  - ➤ Stabilized Maintenance

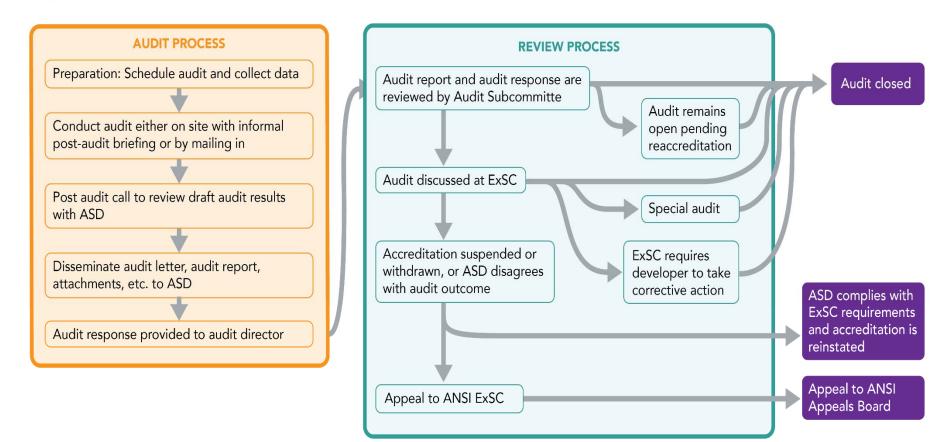


### The Audit

- The Audit process consists of the following:
  - Pre-audit conference
  - Audit (remote)
  - Post-audit conference and review of the audit results
  - Issuance of the audit report
  - Response of the developer to the audit report
  - Action by the ExSC on the audit report (subject to conflict of interest rules)
  - Right of ASD to appeal ExSC decision on audit report



#### ANSI-ACCREDITED STANDARDS DEVELOPER AUDIT PROCESS, SUMMARY FLOW



For questions, please contact Jay Moskowitz at: jmoskowitz@ansi.org or psa@ansi.org.

# Transmittal Letter (Accompanies Audit Report)

- Provides suggestions for ways in which the developer may be able to improve their process
  - ✓ Suggestions are not binding on the standards developer, but most find them useful to consider or incorporate in SOP (standard operating procedures)
- Opportunity for developer to identify members of the ExSC who have a conflict of interest

## The Audit Report

- The audit report consists of the following sections:
  - Introduction
  - Background
  - Scope of Audit
  - Audit Objectives
  - Conduct of the Audit
  - Summary of the Examination of Records and Documents
  - Development of Audit Findings, Recommendations and Comments
    - Findings and Recommendations
    - Auditor's Notes
    - Previous audit findings (if applicable) and auditor's observations as to whether those findings have been addressed and if any previous findings are repeat findings

### What if non-compliances are identified?

- If the developer is found to be not in compliance with the ANSI Essential Requirements (or its accredited procedures) in one or more areas, such information will be contained in the audit report
- The developer will have an opportunity to respond to allegations of non-compliance
  - ✓ During the course of the audit, an ASD may be given an opportunity to take corrective actions
- The ExSC will determine what action, if any, shall be taken as a result of non-compliance

## Consequences of Non-Compliance

- Potential Actions Taken by the ExSC
  - 1. Close the audit
  - 2. Keep the audit open until specific corrective actions are taken by the developer, e.g., submittal and approval of revised procedures, other required actions
  - 3. Require a special audit (paid for by the developer)
  - 4. Suspend accreditation
  - Withdraw accreditation
  - 6. Remand an ANS to the ANSI BSR for review with the audit report, to determine whether the approval shall stand or be withdrawn (*Withdrawal for cause*)

## Right to Appeal

 Process, findings or outcome of the Audit may be appealed first to the ANSI ExSC and then finally to the ANSI Appeals Board

## Sample Serious Audit Findings

- ASD did not report unresolved objections along with attempts at resolution and/or substantive changes to the consensus body members in order to provide them with an opportunity to respond, revise or reaffirm their vote
- ASD did not ensure that all substantive changes underwent additional public review
- ASD did not notify unresolved objectors in writing of their right to appeal
- PINs (Project Initiation Notification) forms were not submitted in a timely manner
- Overage ANS and Discrepancies in ASD's records vs. ANSI records of standards approved as ANS
- Entire ANS not open for full review and comment during the five (5) year review period

## Sample Serious Audit Findings

- ASD did not provide a proper written disposition with reasons therefor
- ASD did not consider and/or respond to comments promptly (e.g. responding many months or longer after a comment is submitted)
- ASD used a comment resolution vote as a vote to approve the standard or as a recirculation opportunity
- ASD did not conduct targeted outreach for underrepresented interest categories
- ASD limited solicitation of consensus body members to members of the ASD (not the broader public)

## **Special Audits**

- Serious Audit Findings may result in an ExSC decision to require a Special Audit
- Special Audit procedures were updated in 2022

## **Updates re: Special Audits**

### **5.2 Scheduling special audits**

In determining whether a special audit is appropriate (either on its own initiative or at the request of the BSR), the ExSC shall consider all evidence it deems relevant. The ExSC may choose to give specific instructions as part of the next regular audit, or direct the scheduling of a separate special audit sooner, as circumstances warrant. When conducting a special audit, the audit team may be provided with instructions specific to the special audit in addition to the regular audit procedures. Such special instructions might include, for example, instructions to review a particular development committee, to review how a particular standard was developed, or to review a particular aspect of the standards-development process, etc.



## **Updates re: Special Audits**

### 5.3 Special audit implementation

An ANSI-Accredited Standards Developer that has not developed a proposed ANS within five (5) years from the date of the ExSC's decision to require a special audit shall submit their accredited procedures for review by the ExSC along with reasons why they have not developed a proposed ANS and why they believe their accreditation nevertheless remains relevant. In addition, thereafter, and on an annual basis, the developer must submit updated comparable information until a subsequent special audit takes or withdraw place. The ExSC may suspend the accreditation if the requested information is not provided or is deemed unsatisfactory.



### Characteristics of a Positive Audit

- ✓ All necessary evidence of compliance with ANSI's requirements and the developer's accredited procedures is available and organized
- ✓ Implementation of the developer's procedures/requirements is efficient and effective
- ✓ Audit findings are minimal and for the most part considered not serious. In addition, there are few or no repeat findings from the previous audit

### Characteristics of a Well-prepared Auditee

- ✓ Records are available, well organized and related documents are clearly labeled/identified for the auditor
- ✓ Established deadlines are met including timely responses to questions and requests for information by the auditor
- ✓ Staff are familiar with their ANSI-accredited procedures and available during the audit

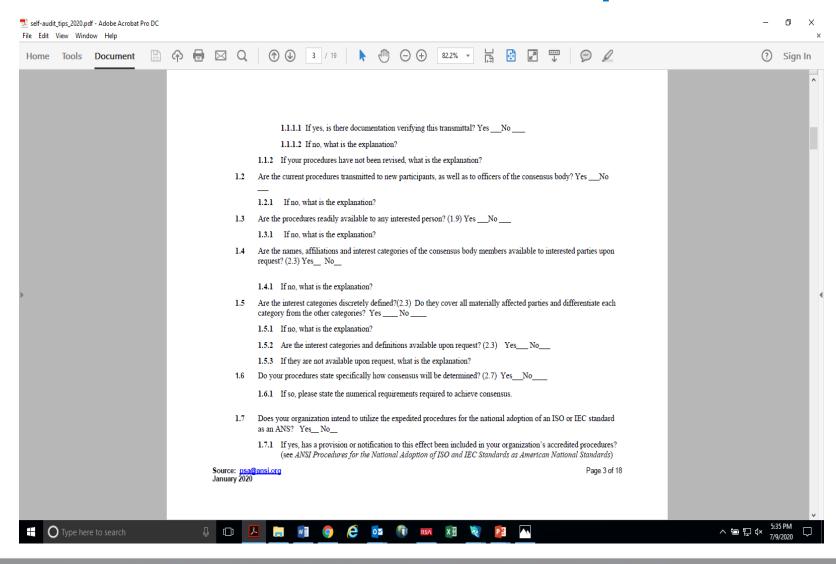
### Characteristics of a Well Prepared Auditee

- ✓ Staff are prepared: they have reviewed the previous audit and findings and provide evidence that such findings have been addressed
- ✓ All internal guidelines and SOPs are well documented and consistent with ANSI's procedural requirements and their own accredited procedures
- ✓ Developer has already performed a self-audit based on Annex B of the Audit Procedures — a number of developers are proactive in response to issues that they identify via this mechanism and are accordingly commended in the Audit for taking corrective actions

## Recommendation: Use the Audit Report as a Tool

- ✓ Refer to the most recent audit report between audits and ensure that the audit findings have been corrected and are not repeated.
  - Why does this matter?
- ✓ Implement all suggestions from the most recent audit that are practical to help achieve efficiencies.
- ✓ Conduct Self Audits using Annex B of the *ANSI*Auditing Policy and Procedures and be proactive in addressing any deficiencies identified.

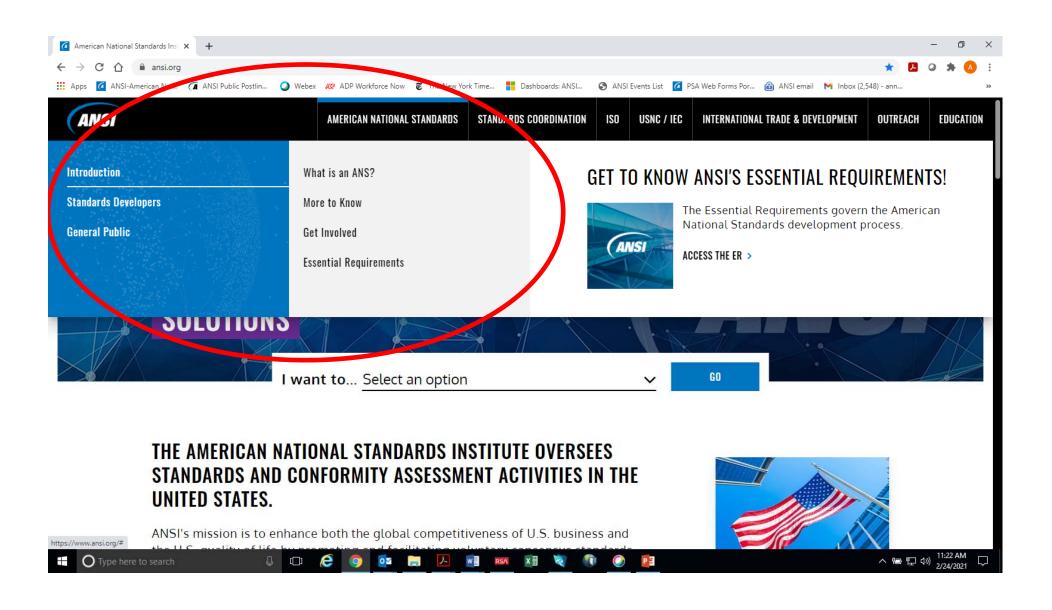
## Self-Audit: Annex B, Sample





## Questions?

Then, a quick look at ANSI's website



## Enhanced ANSI Website (www.ansi.org)

### **✓** ANS - Background:

https://www.ansi.org/american-national-standards/ans-introduction/overview#introduction

### ✓ ASD – Developer focused:

https://www.ansi.org/american-national-standards/info-for-standards-developers/standards-developers

### **✓** General Public - participation:

https://www.ansi.org/american-national-standards/info-for-the-general-public/general-public

### ✓ Standards Action page with resources

https://www.ansi.org/resource-center/standards-action

www.ansi.org/standardsaction

### Where else can I find ANS information?

### www.ansi.org/asd

- 1. List of ANSI-Accredited Standards Developers (ASD) with a scope and contact
- 2. List of **proposed** ANS (point-in-time)
- 3. List of **approved** ANS (point-in-time)

### www.ansi.org/StandardsAction

- > ANSI's free public notice vehicle for ANS
- ➤ Published weekly on Friday afternoon
- > Includes proposed ANS and open public comment opportunities

### Subscribe online to ANSI Standards Action and more

https://www.ansi.org/resource-center/publications-subscriptions#

## **Upcoming ANS-Related Webinars**

• April 19, 2023 (Wednesday at 2pm Eastern): ANS Process: Key Forms

https://goansi.webex.com/weblink/register/ra114c5026af96254f7afc2d1efaa4f3e

• April 27, 2023 (Thursday at 2pm Eastern): Overview of the ANSI Essential Requirements (www.ansi.org/essentialrequirements): Sections 1.0 & 2.0

https://goansi.webex.com/weblink/register/rc782116081117e59c5b7100d4f2a9264

 June 15, 2023 (Thursday at 2pm Eastern): ANS Process: National Adoption of ISO and IEC standards as American National Standards (ANS)

https://goansi.webex.com/weblink/register/r4e1be9c33abeaeafa89a852a8adf5ba3

 June 22, 2023 (Thursday at 2pm Eastern): ANS Process: Focus on Votes & Public Comments

https://goansi.webex.com/weblink/register/r74fb8180025a6ca1bc86e3e8f51dde57

 June 29, 2023 (Thursday at 2pm Eastern): ANS Process - Procedural Appeals Requirements

https://goansi.webex.com/weblink/register/r998210947953d9f8bad6108aa8887218

### Helpful Resources...

- ANSI FAQ: https://www.ansi.org/standards-faqs
- ANSI Glossary: <a href="https://www.ansi.org/standards-faqs/acronym-glossary">https://www.ansi.org/standards-faqs/acronym-glossary</a>
- ANS Forms: <a href="https://www.ansi.org/portal/psawebforms/">https://www.ansi.org/portal/psawebforms/</a>
- ANSI Essential Requirements: <u>www.ansi.org/essentialrequirements</u>
- List of approved ANS and proposed ANS: <u>www.ansi.org/asd</u> or <u>www.ansi.org/standardsaction</u>
- List of ANSI-Accredited Standards Developers: <a href="www.ansi.org/asd">www.ansi.org/asd</a>
- ANSI Standards Action (weekly information about proposed and approved ANS): www.ansi.org/standardsaction
- Summary of ANS process steps: <a href="www.ansi.org/anskeysteps">www.ansi.org/anskeysteps</a>
- ANS Value Brochure: www.ansi.org/ansvalue
- ANSI Membership: www.ansi.org/membership
- Standards Boost Business: www.standardsboostbusiness.org
- ANSI online training: www.standardslearn.org
- Staff are available via psa@ansi.org

# Thanks for joining us today and stay well...

- ✓ Please complete the quick exit survey that follows
- ✓ Please join us to celebrate World Standards Week 2023 October 10-13, 2023

https://www.ansi.org/events/standards-events/world-standards-week

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