<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Voluntary Standard</td>
<td>Rationale</td>
</tr>
<tr>
<td>Four Wheel All-Terrain Vehicles - Equipment, Configuration, and Performance Requirements (ANSI/SVIA-1)</td>
<td>The CPSIA directed the Commission to publish, as a mandatory consumer product safety standard, the ANSI/SVIA-1-2007 as a mandatory standard</td>
</tr>
</tbody>
</table>


**Voluntary Standard**
ASTM Standard Consumer Safety Specification for Toy Safety (ASTM F963-08)

**Rationale**
The CPSIA made certain voluntary standards, including the ASTM F963-08, into mandatory consumer product standards.

---

**Agency:** Department of Transportation (DOT)
**Government Standard:** 63 FR 17976; April 13, 1998 - Product Safety Signs and Labels [Incorporated: 1998] [Rescinded: 2016]

**Voluntary Standard**
ANSI Z535.4 - ANSI Requirements for Color Coded Header Messages for the Different Levels of Hazard

**Rationale**
NHTSA explained in the NPRM that the American National Standard Institute (ANSI) has a standard for product safety signs and labels (ANSI Z535.4) that identifies a hierarchy of hazard levels ranging from extremely serious to moderately serious and specifies corresponding hierarchies of signal words, i.e., “danger,” “warning,” and “caution,” and of colors. For the header, the ANSI standard specifies a red background with white text for “danger,” an orange background with black text for “warning,” and a yellow background with black text for caution.”

The ANSI standard specifies that pictograms should be black on white, with occasional uses of color for emphasis, and that message text should be black on white. The agency noted in the NPRM that when it earlier updated the requirements for air bag warning labels to require the addition of color and pictograms, it had chosen not to adopt the colors specified in
the ANSI standard. NHTSA chose to use yellow instead of orange in the background of the heading for the air bag warning label, even though the word “warning” was used, because of overwhelming focus group preference for yellow. Only two of the 53 participants preferred orange. Participants generally stated that yellow was more eye-catching than orange. Participants also noted that red (stop) and yellow (caution) had meaning to them, but not orange.

NHTSA asked for comment on three color options for the revised utility vehicle rollover warning label. Proposed label 1 used the ANSI color format with the heading background in orange with the words in black. The remainder of the label had a white background with black text and drawings. Proposed label 2 used a color scheme like the air bag warning labels, which is the same as the ANSI color format except that the background color for the heading in the label is yellow. Proposed label 3 employed the color scheme used in the focus groups - the heading area had a red background with white text. The graphic areas had a yellow background with black and white drawings. The text area had a black background with yellow text.

Despite focus group preference for the signal word “danger,” the agency proposed the use of the word “warning” as more appropriate to the level of risk. The agency also noted that the word “warning” is used in the air bag warning label.

Recognizing that it might encounter additional conflicts between focus group preferences and the ANSI standard in future rulemakings, NHTSA requested comments in the NPRM on the extent to which any final choice regarding colors and signal words should be guided by the focus group preferences instead of the ANSI standard. NHTSA also requested comments on the broader issue of the circumstances in which it would be appropriate for agency rulemaking decisions to be guided by focus group results or
other information when such information is contrary to a voluntary consensus standard such as the ANSI standard.

At this time (February 22, 1999), a final decision is still pending regarding its proposal to upgrade the rollover warning label. As to the general questions it posed in the NPRM, NHTSA recognizes that ANSI’s mission differs somewhat from that of the agency’s focus groups with respect to the labeling of hazardous situations. ANSI’s mission is to develop and maintain a standard for communicating information about a comprehensive hierarchy of hazards, while the focus groups’ mission is to design an effective label for a specific hazard. The agency recognizes further that, given the difference in their missions, their conclusions about the appropriate manner of communication might differ on occasion.

Since agency labeling decisions are highly dependent on the facts regarding the specific hazard being addressed, NHTSA anticipates making case-by-case determinations of the extent to which it should follow voluntary standards versus information from focus groups and other sources. NHTSA will rely on its own expertise and judgement in making determinations under the NTTAA and the statutory provisions regarding vehicle safety standards.

**Government Standard:** Air Bag Warning Label (1997)  [Incorporated: 1997]  [Rescinded: 2016]

**Voluntary Standard**

**Rationale**

The Air Bag Warning Label uses yellow as the background color, instead of orange, in accordance with an ANSI standard and uses a graphic developed by Chrysler Corporation to depict the hazards of being too close to an air bag, instead of the graphic recommended by the ISO. These decisions were based on focus group testing sponsored by the agency which strongly indicated that these unique requirements would
be far more effective with respect to safety than the industry standards.


**Voluntary Standard**

SAE J2568—Intrusion Resistance of Safety Glazing Systems for Road Vehicles; BSI AU 209—Vehicle Security

**Rationale**

NHTSA studied the potential of applying these standards, but decided against adopting them for several reasons. These standards provide glazing intrusion resistance requirements from external impact (outside-in) as opposed to ejection mitigation (inside-out). Additionally, the requirements are not appropriate for vehicles with only side curtain air bags, given that there is a time dependence associated with a curtain’s ejection mitigation performance. Once deployed, the pressure in the air bag continuously decreases. The 16 km/h test is done at 6 seconds to assure that the pressure does not decrease too quickly. It does not seem that the 40 mm gap test could be done after the 6-second impact, in any timeframe which is related to rollover and side impact ejections. Further, there was no shown safety need for applying the suggested standards. We cannot show that ejections that would not be prevented by the primary 100-mm displacement requirement would be prevented by a secondary 40-mm requirement. Also, it seemed that the 40-mm requirement would indirectly require installation of advanced glazing. The costs associated with advanced glazing installations at the side windows covered by the NHTSA standard are substantial in comparison to a system only utilizing rollover curtains. For these reasons, the agency did not accept the standards.
Agency decides instead to continue to rely on procedures outlined in 40 CFR Part 90.

**Government Standard:** 40 CFR 90 - Control of Emission from Non-Road Spark Ignition Engines at or below 19KV  [Incorporated: 1999]  [Rescinded: 2007]

**Voluntary Standard**
ISO 8178 - Reciprocating Internal Combustion Engines, Exhaust Emission Measurement

**Rationale**
Procedures would be impractical because they rely too heavily on reference testing conditions. Agency decides instead to continue to rely on procedures outlined in 40 CFR Part 90.

**Government Standard:** 40 CFR 92 - Control of Air Pollution from Locomotives and Locomotive Engines  [Incorporated: 1999]  [Rescinded: 2007]

**Voluntary Standard**
ISO 8178 - Reciprocating Internal Combustion Engines, Exhaust Emission Measurement

**Rationale**
Procedures would be impractical because they rely too heavily on reference testing conditions. Agency decides instead to continue to rely on procedures outlined in 40 CFR Part 90.

**Government Standard:** EPA Method 10 - Carbon Monoxide, NDIR  [Incorporated: 1999]  [Rescinded: 2007]

**Voluntary Standard**

**Rationale**
This ASTM standard, which is stated to be applicable in the range of 0.5-100 ppm CO, does not cover the range of EPA Method 10 (20-1,000 ppm CO) at the upper end (but states that it has a lower limit of sensitivity). Also, ASTM D3162 does not provide a procedure to remove carbon dioxide interference. Therefore, this ASTM standard is not appropriate for combustion source conditions. In terms of non-dispersive infrared instrument performance specifications, ASTM D3162 has much higher maximum allowable rise and fall times (5 minutes) than EPA Method 10 (which has 30 seconds).

1. This standard is lacking in the following areas:
   (1) Sampling procedures; (2) procedures to correct for the carbon dioxide concentration; (3) instructions to correct the gas volume if CO2 traps are used; (4) specifications to certify the calibration gases are within 2 percent of the target concentration; (5) mandatory instrument performance characteristics (e.g., rise time, fall time, zero drift, span drift, precision); (6) quantitative specification of the span value maximum as compared to the measured value.
The standard specifies that the instruments should be compatible with the concentration of gases to be measured, whereas EPA Method 10 specifies that the instrument span value should be no more than 1.5 times the source performance standard. 2. Is too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.


**Voluntary Standard**
- ASME C00031 or PTC 19-10-1981 - Part 10 Flue and Exhaust Gas Analyses
- ASTM D4323-84 (1997) - Standard Test Method for Hydrogen Sulfide in the Atmosphere by Rate of Change of Reflectance

**Rationale**
Too broad to be useful in regulatory sense. Covers Methods 3, 6, 7, and 15 with variants. ASTM D4323 only applies to concentrations of H2S from 1 ppb to 3 ppm without dilution. Many QC items are missing, such as calibration drift and sample line losses. The calibration curve is determined with only one point.

**Government Standard:**  EPA Method 1650 - Organic Halides, Absorbable (AOX)  [Incorporated: 1998] [Rescinded: 2007]

**Voluntary Standard**
- ISO, DIN, SCAN, and Standard Methods (SM 5320)

**Rationale**
EPA decided to use EPA Method 1650. This Method was developed by drawing on various procedures contained in the methods of voluntary consensus standards bodies and other standards developers, such as ISO, DIN, SCAN, and Standard Methods (SM 5320). However, none of these more narrowly focused voluntary consensus standards contained the standardized quality control and quality control compliance criteria that EPA requires for data verification and validation in its water programs. Therefore, EPA found none of these VCS standing alone to meet EPA’s needs.

**Government Standard:**  EPA Method 18 - VOC/GC  [Incorporated: 1999] [Rescinded: 2007]

**Voluntary Standard**
- ASTM D6060-96 (in review 2000) - Practice for Sampling of Process Vents with a Portable Gas Chromatography

**Rationale**
This standard lacks key quality control and assurance that is required for EPA Method 18. For example: lacks acceptance criteria for calibration, details on using other collection media (e.g. solid sorbents), and reporting/documentation requirements.
Voluntary Standard
ISO 7027 - Water Quality Determination of Turbidity

Rationale
EPA has no data upon which to evaluate whether the separate 90 degrees scattered or transmitted light measurement evaluations according to the ISO 7027 method would produce results that are equivalent to results produced by the other methods.

Voluntary Standard
ASTM 3796-90 (1998), Standard Practice for Calibration of Type S Pitot Tubes
ASTM D3154-00, Standard Method for Average Velocity in a Duct (Pitot Tube Method)
ASTM D3154-91 (1995), Standard Method for Average Velocity in a Duct (Pitot Tube Method)

Rationale
They are too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements. 1. The standard appears to lack in quality control and quality assurance requirements. It does not include the following: (1) Proof that openings of standard pitot tube have not plugged during the test; (2) if differential pressure gauges other than inclined manometers (e.g., magnehelic gauges) are used, their calibration must be checked after each test series; and (3) the frequency and validity range for calibration of the temperature sensors. 2. They are too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.

Voluntary Standard

Rationale
Is too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.

Voluntary Standard

Rationale

Measured nonvolatile matter content can vary with experimental factors such as temperature, length of heating period, size of weighing dish, and size of sample. The standard ISO 11890-1 allows for different dish weights and sample sizes than the one size (58 millimeters in diameter and sample size of 0.5 gram) of EPA Method 24. The standard ISO 11890-1 also allows for different oven temperatures and heating times depending on the type of coating, whereas EPA Method 24 requires 60 minutes heating at 110 degrees Celsius at all times. Because the EPA Method 24 test conditions and procedures define volatile matter, ISO 11890-1 is unacceptable as an alternative because of its different test conditions.


ISO 11890-2 only measures the VOC added to the coating and would not measure any VOC generated from the curing of the coating. The EPA Method 24 does measure cure VOC, which can be significant in some cases, and, therefore, ISO 11890-2 is not an acceptable alternative to this EPA method.

Government Standard: EPA Method 26 – Hydrogen Chloride, Halides, Halogens

Emissions [Incorporated: 1999] [Rescinded: 2007]

Voluntary Standard

Rationale
Part 3 of this standard cannot be considered equivalent to EPA Method 26 or 26A because the sample absorbing solution (water) would be expected to capture both HCl and Cl2 gas, if present, without the ability to distinguish between the two. The EPA Methods 26 and 26A use an acidified absorbing solution to first separate HCl and Cl2 gas so that they can be selectively absorbed, analyzed, and reported separately. In addition, in EN 1911 the absorption efficiency for Cl2 gas would be expected to vary as the pH of the water changed during sampling.


Voluntary Standard
EN 1911-1,2,3 (1998), Stationary Source Emissions-- Manual Method of Determination

Rationale
Part 3 of this standard cannot be considered equivalent to EPA Method 26 or 26A because

the sample absorbing solution (water) would be expected to capture both HCl and Cl2 gas, if present, without the ability to distinguish between the two. The EPA Methods 26 and 26A use an acidified absorbing solution to first separate HCl and Cl2 gas so that they can be selectively absorbed, analyzed, and reported separately. In addition, in EN 1911 the absorption efficiency for Cl2 gas would be expected to vary as the pH of the water changed during sampling.

Voluntary Standard
ASTM D3154-00, Standard Method for Average Velocity in a Duct (Pitot Tube Method)

Rationale
1. The standard appears to lack in quality control and quality assurance requirements. It does not include the following: (1) Proof that openings of standard pitot tube have not plugged during the test; (2) if differential pressure gauges other than inclined manometers (e.g., magnehelic gauges) are used, their calibration must be checked after each test series; and (3) the frequency and validity range for calibration of the temperature sensors. 2. They are too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.

Voluntary Standard
ASME C00031 or PTC 19-10-1981--part 10, "Flue and Exhaust Gas Analyses"

ASTM D3154-00, Standard Method for Average Velocity in a Duct (Pitot Tube Method)

Rationale
Is too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.
1. The standard appears to lack in quality control and quality assurance requirements. It does not include the following: (1) Proof that openings of standard pitot tube have not plugged during the test; (2) if differential pressure gauges other than inclined manometers (e.g., magnehelic gauges) are used, their calibration must be checked after each test series; and (3) the frequency and validity range for calibration of the temperature sensors. 2. They are too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.
Voluntary Standard
ASTM D6348-98, Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform (FTIR) Spectroscopy

Rationale
Suggested revisions to ASTM D6348-98 were sent to ASTM by the EPA that, would allow the EPA to accept ASTM D6348-98 as an acceptable alternative. The ASTM Subcommittee D22-03 is currently undertaking a revision of ASTM D6348-98. Because of this, we are not citing this standard as an acceptable alternative for EPA Method 320 in the final rule today. However, upon successful ASTM balloting and demonstration of technical equivalency with the EPA FTIR methods, the revised ASTM standard could be incorporated by reference for EPA regulatory applicability. In the interim, facilities have the option to request ASTM D6348-98 as an alternative test method under 40 CFR 63.7(f) and 63.8(f) on a case-by-case basis.

Government Standard: EPA Method 3A – Carbon Dioxide and Oxygen Concentrations, IAP  [Incorporated: 1999] [Rescinded: 2007]
Voluntary Standard
ASTM D5835-95, Standard Practice for Sampling Stationary Source Emissions for Automated Determination of Gas Concentration

Rationale
1. They lack in detail and quality assurance/quality control requirements. Specifically, these two standards do not include the following: (1) Sensitivity of the method; (2) acceptable levels of analyzer calibration error; (3) acceptable levels of sampling system bias; (4) zero drift and calibration drift limits, time span, and required testing frequency; (5) a method to test the interference response of the analyzer; (6) procedures to determine the minimum sampling time per run and minimum measurement time; and (7) specifications for data recorders, in terms of resolution (all types) and recording intervals (digital and analog recorders, only). 2. Is too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.

CAN/CSA Z223.2-M86(1986), Method for the Continuous Measurement of Oxygen, Carbon Dioxide, Carbon Monoxide, Sulphur Dioxide,

Rationale
1. It does not include quantitative specifications for measurement system performance, most notably the calibration procedures and instrument performance characteristics. The
and Oxides of Nitrogen in Enclosed Combustion Flue Gas Stream


1. They lack in detail and quality assurance/quality control requirements. Specifically, these two standards do not include the following: (1) Sensitivity of the method; (2) acceptable levels of analyzer calibration error; (3) acceptable levels of sampling system bias; (4) zero drift and calibration drift limits, time span, and required testing frequency; (5) a method to test the interference response of the analyzer; (6) procedures to determine the minimum sampling time per run and minimum measurement time; and (7) specifications for data recorders, in terms of resolution (all types) and recording intervals (digital and analog recorders, only). 2. Is too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.


Voluntary Standard

ASTM D3154-00, Standard Method for Average Velocity in a Duct (Pitot Tube Method)

Rationale

1. The standard appears to lack in quality control and quality assurance requirements. It does not include the following: (1) Proof that openings of standard pitot tube have not plugged during the test; (2) if differential pressure gauges other than inclined manometers (e.g., magnehelic gauges) are used, their calibration must be checked after each test series; and (3) the frequency and validity range for calibration of the temperature sensors. 2. They are too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.

ASTM D3154-91 (1995), Standard Method for Average Velocity in a Duct (Pitot Tube Method)

Is too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.

Voluntary Standard

ASTM D3154-00, Standard Method for Average Velocity in a Duct (Pitot Tube Method)

Rationale

1. The standard appears to lack in quality control and quality assurance requirements. It does not include the following: (1) Proof that openings of standard pitot tube have not plugged during the test; (2) if differential pressure gauges other than inclined manometers (e.g., magnehelic gauges) are used, their calibration must be checked after each test series; and (3) the frequency and validity range for calibration of the temperature sensors. 2. They are too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.

ASTM D3154-91 (1995), Standard Method for Average Velocity in a Duct (Pitot Tube Method)

Rationale

Is too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.


Rationale

They are too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.


Voluntary Standard

ASME PTC-38-80 R85 or C00049, Determination of the Concentration of Particulate Matter in Gas Streams

Rationale

It lacks sufficient quality assurance and quality control requirements necessary for EPA compliance assurance requirements.

ASTM D3685/D3685M-98, Test Methods for Sampling and Determination of Particulate Matter in Stack Gases

Rationale

It lacks sufficient quality assurance and quality control requirements necessary for EPA compliance assurance requirements.


Rationale

It lacks sufficient quality assurance and quality control requirements necessary for EPA compliance assurance requirements.


Voluntary Standard

Standard Methods 6640B

Rationale

Standard Methods 6640B for acid herbicides was tentatively deemed impractical for EPA’s needs because its sample preparation and quality control procedures were not similar enough to EPA Method 515.1 to ensure that there would not be underreporting of acid herbicide
contamination. EPA plans to offer to work with the Standard Methods committee to resolve this issue prior to the next publication.

**Government Standard:** EPA Method 6 - Sulphur Dioxide Emissions  [Incorporated: 1999] [Rescinded: 2007]

**Voluntary Standard**
- ASME C00031 or PTC 19-10-1981 - Part 10
- ISO 11632:1998 - Stationary Source Emissions
  - Determination of the Mass Concentration of Sulfur Dioxide - Ion Chromatography
- ISO 7934:1998 - Stationary Source Emissions
  - Determination of the Mass Concentration of Sulfur Dioxide - Hydrogen Peroxide/Barium Perchlorate/ Thorin Method

**Rationale**
- Too broad to be useful in regulatory sense. Covers Methods 3, 6, 7, and 15 with variants.
- This standard is only applicable to sources with 30 mg/m³ SO₂ or more. In addition, this method does not separate SO₃ from SO₂ as does EPA Method 6; therefore, this method is not valid if more than a negligible amount of SO₃ is present. Also, does not address ammonia interferences.

**Government Standard:** EPA Method 6c - Sulphur Dioxide Emissions Stationary by IAP  [Incorporated: 1999] [Rescinded: 2007]

**Voluntary Standard**

**Rationale**
- Similar to Methods 3a, 6c, 7e, 10, ALT 004, CTM 022. Lacks in detail and quality assurance and quality control requirements. Very similar to ISO 10396.
- Too general. This standard lacks in detail and quality assurance/quality control requirements. Appendices with valid quality control information are not a required part of this method.
- Duplicates Method 3a, 6c, 7e, 10, ALT 004, CTM 022. Lacks in detail and quality assurance plus quality control requirements. Similar to ASTM D5835.

**Government Standard:** EPA Method 7 - Nitrogen Oxide Emissions Stationary Sources  [Incorporated: 1999] [Rescinded: 2007]

**Voluntary Standard**
- ASME C00031 or PTC 19-10-1981 - Part 10
- Flue and Exhaust Gas Analyses

**Rationale**
- Too broad to be useful in regulatory sense. Covers Methods 3, 6, 7, and 15 with variants.

**Government Standard:** EPA Method 7e - Nitrogen Oxide, Instrumental  [Incorporated: 1999] [Rescinded: 2007]

**Voluntary Standard**

**Rationale**
Similar to Methods 3a, 6c, 7e, 10, ALT 004, CTM 022. Lacks in detail and quality assurance and quality control requirements. Very similar to ISO 10396.

Too general. This standard lacks in detail and quality assurance/quality control requirements. Appendices with valid quality control information are not a required part of this method.

Duplicates Method 3a, 6c, 7e, 10, ALT 004, CTM 022. Lacks in detail and quality assurance plus quality control requirements. Similar to ASTM D5835.

Rationale
This method has been deleted from the final rule because it was discontinued by the ASTM in 1990 with no replacement. If the total sulfur content of the fuel being fired in the turbine is less than 0.4 weight percent, we are adding a provision that the following methods may be used to measure the sulfur content of the fuel: ASTM D4084-82 or 94, D5504-01, D6228-98, or the Gas Processors Association Method 2377-86. This provision is consistent with the provision in 40 CFR 60.13(j)(1) allowing alternatives to reference method tests to determine relative accuracy of CEMS for sources with emission rates demonstrated to be less than 50 percent of the applicable standard.

Rationale
This international standard is only applicable on a site specific basis by direct correlation with the manual method ISO 9096 (which does not produce particulate matter measurements like EPA Method 5). This appears to be a PM CEMS performance specification similar to EPA Performance Specification 11, but does not contain detailed RATA procedures. Also, EPA doesn’t have a final performance specification to compare this to.
**Government Standard**: GLI Method 2  
**Voluntary Standard**: ISO 7027 - Water Quality Determination of Turbidity

**Rationale**: EPA has no data upon which to evaluate whether the separate 90 degrees scattered or transmitted light measurement evaluations according to the ISO 7027 method would produce results that are equivalent to results produced by the other methods.

**Government Standard**: Standard Method 2130B  
**Voluntary Standard**: ISO 7027 - Water Quality Determination of Turbidity

**Rationale**: EPA has no data upon which to evaluate whether the separate 90 degrees scattered or transmitted light measurement evaluations according to the ISO 7027 method would produce results that are equivalent to results produced by the other methods.

**Agency**: Government Publishing Office (GPO)

**Government Standard**: FED-STD 209  
**Voluntary Standard**: ISO 14644-1 & ISO 14644-2


**Government Standard**: Federal Information Standards Publication 201 (FISP 201)  
**Voluntary Standard**: unknown

**Rationale**: To compete as a GSA approved supplier with graphical certification.

**Government Standard**: Government Paper Specifications Standards, QATAP and Microfilm Attributes

**Voluntary Standard**: none

**Rationale**: There are no voluntary standards

**Government Standard**: MIL-STD 105  
**Voluntary Standard**: ANSI/ASQC Z1.4

**Rationale**: Quality Assurance. Cited in small number of contracts due to editing errors. These are being corrected and phased out.

**Government Standard**: MIL-STD 1189  
**Voluntary Standard**: none

**Rationale**: None
<table>
<thead>
<tr>
<th>Standard</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANSI/AIM X5-2 &amp; ANSI X3.182</td>
<td>Quality Assurance. Cited in small number of contracts due to editing errors. These are being corrected and phased out.</td>
</tr>
<tr>
<td><strong>Government Standard:</strong> MIL-STD 498</td>
<td><strong>Rationale</strong></td>
</tr>
<tr>
<td><strong>Voluntary Standard</strong></td>
<td><strong>Quality Assurance. Cited in small number of contracts due to editing errors. These are being corrected and phased out.</strong></td>
</tr>
<tr>
<td>IEEE/EIA 12207.0, IEEE/EIA 12207.1, &amp; IEEE/EIA 12207.2</td>
<td></td>
</tr>
<tr>
<td><strong>Agency:</strong> General Services Administration (GSA)</td>
<td><strong>Government Standard:</strong> Federal Specification A-A-1925 - Shield, Expansion (Nail Anchors)</td>
</tr>
<tr>
<td><strong>Voluntary Standard</strong></td>
<td><strong>Rationale</strong></td>
</tr>
<tr>
<td>ASTM E488 - Standard Test Methods for Strength of Anchors in Concrete and Masonry Elements</td>
<td>This government-unique standard is prepared &amp; maintained by the Defense Logistics Agency (DLA). Both the GSA &amp; DLA contract for products that reference A-A-1925. In order to maintain product continuity in the Federal marketplace, we must cite the standard as the DLA.</td>
</tr>
<tr>
<td><strong>Government Standard:</strong> FF-L-2740</td>
<td><strong>Rationale</strong></td>
</tr>
<tr>
<td><strong>Voluntary Standard</strong></td>
<td><strong>These government specifications cover products used for the protection of national security information. The standards were developed after government review and testing determined that the commercial standards did not provide the required level of protection, or those commercial products that did provide the level of protection significantly exceeded the price of products meeting the government standards.</strong></td>
</tr>
<tr>
<td>UL 768</td>
<td></td>
</tr>
<tr>
<td><strong>Agency:</strong> Department of Health and Human Services (HHS)</td>
<td><strong>Government Standard:</strong> CDC/NIOSH use of 42CFR Part 84 in their mandated respirator certification program</td>
</tr>
<tr>
<td><strong>Voluntary Standard</strong></td>
<td><strong>Rationale</strong></td>
</tr>
<tr>
<td>None.</td>
<td>None available.</td>
</tr>
<tr>
<td><strong>Government Standard:</strong> FDA Dosage Form and Route of Administration</td>
<td><strong>Rationale</strong></td>
</tr>
<tr>
<td><strong>Voluntary Standard</strong></td>
<td></td>
</tr>
</tbody>
</table>
FDA uses some government-unique standards such as 'dosage form' and 'route of administration' in lieu of voluntary consensus standards. FDA had considered using HL7's 'dosage form' and 'route of administration' voluntary standards, but rejected such voluntary standards for several reasons, including (1) pre-coordination of disparate terms, (2) cumbersome and untimely terminology maintenance, and (3) inadequate terminology coding and versioning. The government-unique standards (developed by FDA and jointly maintained by FDA and NCI) for 'dosage form' and 'route of administration' adequately address all of these HL7 'deficiencies'. These particular government-unique standards were chosen as a CHI standard and mandated throughout the federal government, which is yet another compelling reason why FDA chose to continue to use them.

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Voluntary Standard</td>
<td>ISO 13408-1 - Aseptic Processing of Health Care Products, Part 1, General Requirements</td>
</tr>
<tr>
<td>Rationale</td>
<td>FDA/CBER is not using the ISO standard because the applicability of these requirements is limited to only portions of aseptically manufactured biologics and does not include filtration, freeze-drying, sterilization in place, cleaning in place, or barrier-isolator technology. There are also significant issues related to aseptically produced bulk drug substance that are not included in the document</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Voluntary Standard</td>
<td>ASTM Standard E1115 - Test Method for Evaluation of Surgical Hand Scrub Formulations</td>
</tr>
<tr>
<td>Rationale</td>
<td>Sensitivity and bias of the ASTM Standard has not been established.</td>
</tr>
<tr>
<td></td>
<td>ASTM Standard E1173-93 - Standard Test Method of an Evaluation of Preoperative, precatheterization, or Preinjection Skin Preparations</td>
</tr>
<tr>
<td>Rationale</td>
<td>Sensitivity and bias of the ASTM Standard has not been established.</td>
</tr>
<tr>
<td></td>
<td>ASTM Standard E1174-00 - Standard Test method for the Evaluation of the Effectiveness</td>
</tr>
<tr>
<td>Rationale</td>
<td>Sensitivity and bias of the ASTM Standard has not been established.</td>
</tr>
</tbody>
</table>
of Health Care Personnel or Consumer Handwash Formulations


Voluntary Standard
X12 270/271 standards

Rationale
Pending completion of a system to support real-time use of the X12 270/271, CMS has permitted providers and our contractors to continue to use government eligibility inquiry and response standards. Use of these GUSs is not in lieu of, but in addition to the X12 270/271 standards to avoid industry disruption prior to full transition to use of the HIPAA X12 270/271 standards with Medicare via the Internet and an Intranet.


Voluntary Standard
ANSI X12 837

Rationale
The NSF is used widely across the health care payment industry and has become a defacto national standard. However, the Centers for Medicare and Medicaid Services (CMS) have directed their contractors to discontinue use of the NSF standard and replace it with ANSI X12 837 by the beginning of FY 2003.

Agency: National Archives and Records Administration (NARA)


Voluntary Standard
Archives, Personal Papers, and Manuscripts (APPM);
General International Standard Archival Description (ISAD(G));
International Standard Archival Authority Record for Corporate Bodies, Persons, and Families (ISAAR(CPF));
Encoded Archival Description (EAD);
Machine Readable Cataloging (MARC)

Rationale
These voluntary standards do not meet the precise needs of the agency.

Agency: Department of Agriculture (USDA)

Rationale
Foam fire suppressants contain foaming and wetting agents. The foaming agents affect the accuracy of an aerial drop, how fast the water drains from the foam and how well the product clings to the fuel surfaces. The wetting agents increase the ability of the drained water to penetrate fuels. Foam fire suppressants are supplied as wet concentrates.

This standard was developed with international cooperation for Class A Foam used in wildland fire suppression situations and equipment. Standard created by the USDA Forest Service in cooperation with the Department of Interior (DOI), the State of California, Department of Forestry and Fire Protection and the Canadian Interagency Forest Fire Center.

The National Fire Protection Association (NFPA) does have a standard for Class A Foam, (NFPA 1150 - Standard on Fire-Fighting Foam Chemicals for Class A Fuels in Rural, Suburban, and Vegetated Areas). The Forest Service has not chosen to utilize NFPA 1150 as it is designed specifically for application by municipal fire agencies in the wildland-urban interface, utilizing apparatus and situations that they are likely to encounter. The Forest Service’s GUS for foam products is specific to use by wildland fire equipment and situations that are unique, e.g. helicopter use of foams, remote storage situations, and varied quality of water sources in the wildland settings. The agency feels this standard more accurately reflects the needs and mission of the federal wildland fire suppression agencies.