FY 2008 Government Unique Standards used in lieu of Voluntary Consensus Standards
(Rescinded)

Agency: Environmental Protection Agency (EPA) – See Endnote¹

Government Standard: 40 CFR 89 - Control of Emissions from New and In-Use Non-Road Compression Ignition Engines [Incorporated: 1999] [Rescinded: 2007]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Standard: 40 CFR 90 - Control of Emission from Non-Road Spark Ignition Engines at or below 19KV [Incorporated: 1999] [Rescinded: 2007]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Government Standard: 40 CFR 92 - Control of Air Pollution from Locomotives and Locomotive Engines [Incorporated: 1999] [Rescinded: 2007]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.


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
Method of Analysis by Non-Dispersive Infrared Spectrometry 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
- 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.
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

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

ASTM D3154-00, 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.

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


Voluntary Standard
European Committee for Standardization (CEN) EN 1948-3 (1997), Determination of

Rationale
Is too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.
the Mass Concentration of PCDD’S/PCDF’S- requirements.
-Part 3: Identification and Quantification

**Government Standard:** EPA Method 24 – Surface Coatings, Volatile Matter Content  [Incorporated: 1998] [Rescinded: 2007]

<table>
<thead>
<tr>
<th>Voluntary Standard</th>
<th>Rationale</th>
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<tbody>
<tr>
<td>ISO 11890-1 (2000) part 1, Paints and Varnishes--Determination of Volatile Organic Compound (VOC) Content-Difference Method</td>
<td>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 Celcius 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.</td>
</tr>
<tr>
<td>ISO 11890-2 (2000) Part 2, Paints and Varnishes--Determination of Volatile Organic Compound (VOC) Content-Gas Chromatographic Method</td>
<td>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.</td>
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<th>Voluntary Standard</th>
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<td>EN 1911-1,2,3 (1998), Stationary Source Emissions-- Manual Method of Determination of HCl--Part 1: Sampling of Gases Ratified European Text--Part 2: Gaseous Compounds Absorption Ratified European Text-- Part 3: Adsorption Solutions Analysis and Calculatio</td>
<td>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.</td>
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**Government Standard:** EPA Method 26A – Hydrogen Halide and Halogen,
Isokinetic  [Incorporated: 1999] [Rescinded: 2007]
Voluntary Standard
EN 1911-1,2,3 (1998), Stationary Source Emissions-- Manual Method of
Determination of HCl--Part 1: Sampling of Gaseous Ratified European Text--Part 2:
Gaseous Compounds Absorption Ratified European Text-- Part 3: Adsorption Solutions Analysis and Calculation

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.

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<tr>
<td>Voluntary Standard</td>
<td>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 a 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.</td>
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<tr>
<td>ASTM D6348-98, Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform (FTIR) Spectroscopy</td>
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<td>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.</td>
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<tr>
<td>ASTM D5835-95, Standard Practice for Sampling Stationary Source Emissions for Automated Determination of Gas Concentration</td>
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Dioxide, and Oxides of Nitrogen in Enclosed Combustion Flue Gas Stream


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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 work with the Standard Methods committee to resolve this issue prior to the next publication.


Voluntary Standard
ASME C00031 or PTC 19-10-1981 - Part 10

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.


Voluntary Standard
ASTM D5835-95 - Standard Practice for Sampling Stationary Source Emissions for Automated Determination of Gas Concentration
ISO 10396:1993 - Stationary Source Emissions: Sampling for the Automated Determination of Gas Concentrations

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.


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.

Voluntary Standard
ASTM D5835-95 - Standard Practice for Sampling Stationary Source Emissions for Automated Determination of Gas Concentration
ISO 10396:1993 - Stationary Source Emissions: Sampling for the Automated Determination of Gas Concentrations

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 GG – (Title not found in index)  [Incorporated: 2003] [Rescinded: 2007]
Voluntary Standard
ASTM D3031-81 – Method of Test for Total Sulfur in Natural Gas (Hyrogenation), Withdrawn

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.

Voluntary 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.
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<tr>
<td>[Incorporated: 2008] [Rescinded: 2008]</td>
<td>Rationale</td>
<td>There are no voluntary standards</td>
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<tr>
<td>ANSI/ASQC Z1.4</td>
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<td>Quality Assurance. Cited in small number of contracts due to editing errors. These are being corrected and phased out.</td>
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<td>ANSI/AIM X5-2 &amp; ANSI X3.182</td>
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<td>IEEE/EIA 12207.0, IEEE/EIA 12207.1, &amp;</td>
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| Agency: General Services Administration (GSA) |
| Voluntary Standard | ASTM E488 - Standard Test Methods for Strength of Anchors in Concrete and Masonry Elements | Rationale | This government-unique standard is prepared & maintained by the Defense Logistics Agency (DLA). Both the GSA & 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. |

| Agency: Department of Health and Human Services (HHS) |
| Voluntary Standard | None. | Rationale | None available. |

| Agency: Department of Health and Human Services (HHS) |
| Voluntary Standard | HL7 Dosage Form and Route of Administration | Rationale | 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.

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<tr>
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<tr>
<td>ISO 13408-1 - Aseptic Processing of Health Care Products, Part 1, General Requirements</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>
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<tr>
<td>ASTM Standard E1115 - Test Method for Evaluation of Surgical Hand Scrub Formulations</td>
<td>Sensitivity and bias of the ASTM Standard has not been established.</td>
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<tr>
<td>ASTM Standard E1173-93 - Standard Test Method of an Evaluation of Preoperative, precatheterization, or Preinjection Skin Preparations</td>
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<td>Sensitivity and bias of the ASTM Standard has not been established.</td>
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<tr>
<td>ASTM Standard E1174-00 - Standard Test method for the Evaluation of the Effectiveness of Health Care Personnel or Consumer Handwash Formulations</td>
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<td>X12 270/271 standards</td>
<td>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</td>
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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.

**Government Standard:** National Standard Format  [Incorporated: 1997]  [Rescinded: 2004]

**Voluntary Standard**

ANSI X12 837

**Rationale**

The NSF is used widely across the health care payment industry and has become a de facto 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.

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1 NOTE- EPA Standards listed were recategorized as *not in lieu of existing voluntary standards* and are therefore not subject to NTTAA reporting.