

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(Rescinded)**

Agency: Environmental Protection Agency (EPA) – See Endnoteⁱ

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40 CFR 89 - Control of Emissions from New and In-Use Non-Road Compression Ignition Engines [Incorporated: 1999] [Rescinded: 2007]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Standard: 40 CFR 90 - Control of Emission from Non-Road Spark Ignition Engines at or below 19KV [Incorporated: 1999] [Rescinded: 2007]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Standard: 40 CFR 92 - Control of Air Pollution from Locomotives and Locomotive Engines [Incorporated: 1999] [Rescinded: 2007]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

Government Standard: EPA Method 10 - Carbon Monoxide, NDIR [Incorporated: 1999] [Rescinded: 2007]

Voluntary Standard

ASTM D3162 (1994) Standard Test Method
for Carbon Monoxide in the Atmosphere
(Continuous Measurement by Non-dispersive
Infrared Spectrometry)

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).

CAN/CSA Z223.21-M1978, Method for the
Measurement of Carbon Monoxide: 3—

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.

Government Standard: EPA Method 15 - Hydrogen Sulfide/Carbon Disulfide/Carbon Sulfide [Incorporated: 1999] [Rescinded: 2007]

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.

Government Standard: EPA Method 180.1 - Turbidity Nephelometric [Incorporated: 1999] [Rescinded: 2007]

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: EPA Method 2 – Velocity and S-type Pitot [Incorporated: 1999] [Rescinded: 2007]

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)

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.

Government Standard: EPA Method 23 – Dioxin and Furan (PCDD and PCDF) [Incorporated: 1999] [Rescinded: 2007]

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

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]

Voluntary Standard

ISO 11890-1 (2000) part 1, Paints and Varnishes--Determination of Volatile Organic Compound (VOC) Content-Difference Method

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 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.

ISO 11890-2 (2000) Part 2, Paints and Varnishes--Determination of Volatile Organic Compound (VOC) Content-Gas Chromatographic Method

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

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

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.

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 Gases Ratified European Text--Part 2: Gaseous Compounds Absorption Ratified European Text-- Part 3: Adsorption Solutions Analysis and Calculatio

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.

Government Standard: EPA Method 2C – Velocity and Flow Rate, Standard Pitot [Incorporated: 1999] [Rescinded: 2007]

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.

Government Standard: EPA Method 3 – Molecular Weight Carbon Dioxide, Oxygen [Incorporated: 1999] [Rescinded: 2007]

Voluntary Standard

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

Rationale

Is 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)

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.

Government Standard: EPA Method 320 – Vapor Phase Organic and Inorganic Emissions, FTIR [Incorporated: 1999] [Rescinded: 2007]

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 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.

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

1. It does not include quantitative specifications for measurement system performance, most notably the calibration procedures and instrument

Dioxide, and Oxides of Nitrogen in Enclosed Combustion Flue Gas Stream

performance characteristics. The instrument performance characteristics that are provided are nonmandatory and also do not provide the same level of quality assurance as the EPA methods. For example, the zero and span/calibration drift is only checked weekly, whereas the EPA methods requires drift checks after each run. 2. Is too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.

ISO 10396:1993, Stationary Source Emissions: Sampling for the Automated Determination of Gas Concentrations

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.

Government Standard: EPA Method 3B – Oxygen, Carbon Dioxide, Carbon Monoxide, Emission Rate Correction Factor [Incorporated: 1999] [Rescinded: 2007]

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.

Government Standard: EPA Method 4 – Moisture Content in Stack Gases [Incorporated: 1999] [Rescinded: 2007]

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.

ASTM E337-84 (1996), Standard Test Method for Measuring Humidity with a Psychrometer (the Measurement of Wet- and Dry-Bulb Temperatures)

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

Government Standard: EPA Method 5 – Particulate Matter, Stationary Sources [Incorporated: 1999] [Rescinded: 2007]

Voluntary Standard

ASME PTC-38-80 R85 or C00049, Determination of the Concentration of Particulate Matter in Gas Streams
ASTM D3685/D3685M-98, Test Methods for Sampling and Determination of Particulate Matter in Stack Gases
ISO 9096:1992, Determination of Concentration and Mass Flow Rate of Particulate Matter in Gas Carrying Ducts-- Manual Gravimetric Method

Rationale

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

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Government Standard: EPA Method 515.1 - Chlorinated Acids in Water by CC/ECD [Incorporated: 1998] [Rescinded: 2007]

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
Flue and Exhaust Gas Analyses

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.

ISO 11632:1998 - Stationary Source Emissions -
Determination of the Mass Concentration of Sulfur
Dioxide - Ion Chromatography

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

ASTM D5835-95 - Standard Practice for
Sampling Stationary Source Emissions for
Automated Determination of Gas
Concentration

CAN/CSA Z223.2-M86 - (1986) Method for
the Continuous Measurement of Oxygen,
Carbon Dioxide, Carbon Monoxide, Sulphur
Dioxide, and Oxides of Nitrogen in Enclosed
Combustion Flue Gas Streams

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 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

ASTM D5835-95 - Standard Practice for Sampling Stationary Source Emissions for Automated Determination of Gas Concentration

CAN/CSA Z223.2-M86 - (1986) Method for the Continuous Measurement of Oxygen, Carbon Dioxide, Carbon Monoxide, Sulphur Dioxide, and Oxides of Nitrogen in Enclosed Combustion Flue Gas Streams

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 (Hydrogenation), 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.

Government Standard: EPA Performance Specifications 11 - Particulate Matter Continuous Monitoring System [Incorporated: 1999] [Rescinded: 2007]

Voluntary Standard

ISO 10155:1995 - Stationary source emissions. Automated monitoring of mass concentration of particles - Performance characteristics, test methods and specifications.

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 [Incorporated: 1999] [Rescinded: 2007]

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 [Incorporated: 1999] [Rescinded: 2007]

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 Printing Office (GPO)

Government Standard: FED-STD 209 [Incorporated: 2000] [Rescinded: 2005]

Voluntary Standard

ISO 14644-1 & ISO 14644-2

Rationale

Quality Assurance. Second ISO standard not issued until end of FY 2000. Being phased out.

Government Standard: Government Paper Specifications Standards, QATAP and Microfilm Attributes [Incorporated: 2008] [Rescinded: 2008]

Voluntary Standard

none

Rationale

There are no voluntary standards

Government Standard: MIL-STD 105 [Incorporated: 2000] [Rescinded: 2005]

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 [Incorporated: 2000] [Rescinded: 2005]

Voluntary Standard

ANSI/AIM X5-2 & ANSI X3.182

Rationale

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

Government Standard: MIL-STD 498 [Incorporated: 2000] [Rescinded: 2005]

Voluntary Standard

IEEE/EIA 12207.0, IEEE/EIA 12207.1, &

Rationale

Quality Assurance. Cited in small number of

IEEE/EIA 12207.2

contracts due to editing errors. These are being corrected and phased out.

Agency: General Services Administration (GSA)

Government Standard: Federal Specification A-A-1925 - Shield, Expansion (Nail Anchors) [Incorporated: 2000] [Rescinded: 2004]

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.

Government Standard: FF-L-2740 [Incorporated: 2000] [Rescinded: 2001]

Voluntary Standard

UL 768

Rationale

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.

Agency: Department of Health and Human Services (HHS)

Government Standard: CDC/NIOSH use of 42CFR Part 84 in their mandated respirator certification program [Incorporated: 2007] [Rescinded: 2007]

Voluntary Standard

None.

Rationale

None available.

Government Standard: FDA Dosage Form and Route of Administration [Incorporated: 2006] [Rescinded: 2008]

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.

Government Standard: FDA Guidelines on Aseptic Processing (1987) [Incorporated: 1997] [Rescinded: 2004]

Voluntary Standard

ISO 13408-1 - Aseptic Processing of Health Care Products, Part 1, General Requirements

Rationale

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

Government Standard: FR Notice dated June 17, 1994 Tentative Final Monograph for Health Care Antiseptic Drug Products; Proposed Rule [Incorporated: 1997] [Rescinded: 2008]

Voluntary Standard

ASTM Standard E1115 - Test Method for Evaluation of Surgical Hand Scrub Formulations

Rationale

Sensitivity and bias of the ASTM Standard has not been established.

ASTM Standard E1173-93 - Standard Test Method of an Evaluation of Preoperative, precatheterization, or Preinjection Skin Preparations

Sensitivity and bias of the ASTM Standard has not been established.

ASTM Standard E1174-00 - Standard Test method for the Evaluation of the Effectiveness of Health Care Personnel or Consumer Handwash Formulations

Sensitivity and bias of the ASTM Standard has not been established.

Government Standard: Government eligibility inquiry and response standards [Incorporated: 2006] [Rescinded: 2008]

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.

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 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.

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