FY 2009 Government Unique Standards used in lieu of Voluntary Consensus Standards (Rescinded)

Agency: Consumer Product Safety Commission (CPSC)

Government Standard: All-Terrain Vehicle Standard, Consumer Product Inhancement

Act (CPSIA), Section 232(a) [Incorporated: 2009] [Rescinded: 2009]

Voluntary Standard Rationale

Four Wheel All-Terrain Vehicles -

Requirements (ANSI/SVIA-1)

The CPSIA directed the Commission to publish, as Equipment, Configuration, and Performance a mandatory consumer product safety standard, the ANSI/SVIA-1-2007 as a mandatory standard

Government Standard: Mandatory Toy Safety Standards, Consumer Product Safety

Improvement Act or 2008, Section 106 [Incorporated: 2009] [Rescinded: 2009]

Voluntary Standard Rationale

ASTM Standard Consumer Safety

Specification for Toy Safety (ASTM F963-

08)

The CPSIA made certain voluntary standards,

including the ASTM F963-08,

into mandatory consumer product standards.

Agency: Environmental Protection Agency (EPA)

Government Standard: 40 CFR 89 - Control of Emissions from New and In-Use Non-

Road Compression Ignition Engines [Incorporated: 1999] [Rescinded: 2007]

Voluntary Standard Rationale

ISO 8178 - Reciprocating Internal

Combustion Engines, Exhaust Emission

Measurement

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Engines at or below 19KV [Incorporated: 1999] [Rescinded: 2007]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 Rationale

ISO 8178 - Reciprocating Internal Combustion Engines, Exhaust Emission

Measurement

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Locomotive Engines [Incorporated: 1999] [Rescinded: 2007]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 Rationale

ISO 8178 - Reciprocating Internal

Combustion Engines, Exhaust Emission

Measurement

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[Rescinded: 2007]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 Infrared Spectrometry)

CAN/CSA Z223.21-M1978. Method for the Measurement of Carbon Monoxide: 3— Method of Analysis 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 (Continuous Measurement by Non-dispersive 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.

Government Standard: EPA Method 15 - Hydrogen Sulfide/Carbon Disulfide/Carbon

Sulfide [Incorporated: 1999] [Rescinded: 2007] **Voluntary Standard**

Reflectance

Rationale

ASME C00031 or PTC 19-10-1981 - Part 10 Too broad to be useful in regulatory sense. Covers Flue and Exhaust Gas Analyses ASTM D4323-84 (1997) - Standard Test Method for Hydrogen Sulfide in the Atmosphere by Rate of Change of

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

Rationale

ISO, DIN, SCAN, and Standard Methods (SM 5320)

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

Rationale

ASTM D6060-96 (in review 2000) - Practice This standard lacks key quality control and for Sampling of Process Vents with a Portable Gas Chromatography

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 Rationale

ISO 7027 - Water Quality Determination of **Turbidity**

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**

Rationale

Calibration of Type S Pitot Tubes

ASTM 3796-90 (1998), Standard Practice for 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** Rationale

European Committee for Standardization the Mass Concentration of PCDD'S/PCDF'S- requirements. -Part 3: Identification and Quantification

Is too general, too broad, or not sufficiently (CEN) EN 1948-3 (1997), Determination of detailed to assure compliance with EPA regulatory

Government Standard: EPA Method 24 – Surface Coatings, Volatile Matter

Content [Incorporated: 1998] [Rescinded: 2007] **Voluntary Standard** Rationale

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

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** Rationale

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 Analysis and Calculatio

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 European Text-- Part 3: Adsorption Solutions 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** Rationale

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 Analysis and Calculatio

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 European Text-- Part 3: Adsorption Solutions 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**

Rationale

ASME C00031 or PTC 19-10-1981--part 10, Is too general, too broad, or not sufficiently "Flue and Exhaust Gas Analyses"

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

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.

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

Voluntary Standard

Rationale

ASTM D6348-98, Determination of Gaseous Suggested revisions to ASTM D6348-98 were sent Compounds by Extractive Direct Interface Fourier Transform (FTIR) Spectroscopy

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

Rationale

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

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

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 Stream

1. It does not include quantitative specification for measurement system performance, most notably the calibration procedures and instrument performance characteristics. The instrument performance characteristics that are provided.

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

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

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

They are too get detailed to ass
requirements.

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

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 Rationale

ASME PTC-38-80 R85 or C00049, Determination of the Concentration of Particulate Matter in Gas Streams 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 ISO 9096:1992, Determination of Concentration and Mass Flow Rate of Particulate Matter in Gas Carrying Ducts--Manual Gravimetric Method

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

Government Standard: EPA Method 515.1 - Chlorinated Acids in Water by

CC/ECD [Incorporated: 1998] [Rescinded: 2007] **Voluntary Standard** Rationale Standard Methods 6640B

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:

Rationale

1999] [Rescinded: 2007] **Voluntary Standard**

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

ASME C00031 or PTC 19-10-1981 - Part 10 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 Concentration of Sulfur Dioxide - Hydrogen not separate SO3 from SO2 as does EPA Method Peroxide/Barium Perchlorate/ Thorin 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 - Sulpher Dioxide Emissions Stationary by IAP [Incorporated: 1999] [Rescinded: 2007]

Rationale

Voluntary Standard

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

the Continuous Measurement of Oxygen,

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.

CAN/CSA Z223.2-M86 - (1986) Method for Too general. This standard lacks in detail and quality assurance/quality control requirements. Dioxide, and Oxides of Nitrogen in Enclosed are not a required part of this method.

Combustion Flue Gas Streams

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

Carbon Doixide, Carbon Monoxide, Sulphur Appendices with valid quality control information

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** Rationale

Flue and Exhaust Gas Analyses

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

the Continuous Measurement of Oxygen, Dioxide, and Oxides of Nitrogen in Enclosed are not a required part of this method. 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.

CAN/CSA Z223.2-M86 - (1986) Method for Too general. This standard lacks in detail and quality assurance/quality control requirements. Carbon Doixide, Carbon Monoxide, Sulphur Appendices with valid quality control information

> 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 This method has been deleted from the final rule Sulfur in Natural Gas (Hyrogenation), Withdrawn

Rationale

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] Rationale Voluntary Standard

ISO 7027 - Water Quality Determination of **Turbidity**

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** Rationale

ISO 7027 - Water Quality Determination of **Turbidity**

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 Rationale

ISO 14644-1 & ISO 14644-2 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 Rationale

There are no voluntary standards none

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

Voluntary Standard Rationale

ANSI/ASQC Z1.4 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** Rationale

ANSI/AIM X5-2 & ANSI X3.182 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** Rationale

IEEE/EIA 12207.0, IEEE/EIA 12207.1, & 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 Rationale

ASTM E488 - Standard Test Methods for Strength of Anchors in Concrete and

Masonry Elements

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 Rationale

UL 768 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 Rationale None. 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 Asceptic Processing (1987) [Incorporated:

1997] [Rescinded: 2004]

Voluntary Standard

Rationale

ISO 13408-1 - Aseptic Processing of Health FDA/CBER is not using the ISO standard because Care Products, Part 1, General Requirements the applicability of these requirements is limited to only portions of aseptically manufactured biologics and does not include filtration, freezedrying, 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: 20081

Voluntary Standard

Rationale

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

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

Formulations

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

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.

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 Rationale

X12 270/271 standards

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.