FY 2007 Government Unique Standards used in lieu of Voluntary Consensus Standards

Agency: Access Board (ACCESS)

Government Standard: 36 CFR Part 1194 Electronic and Information Technology Accessibility Standards (December, 2000) [Incorporated: 2006]

Voluntary Standard	Rationale
ANSI/IEEE Standard for Hearing Aid Compatibility with Wireless Devices	A provision in the Section 508 Standards requires that interference to hearing technologies be reduced to the lowest possible level that allows a user of hearing technologies to utilize a telecommunications product. Individuals who are hard of hearing use hearing aids and other assistive listening devices, but they cannot be used if products introduce noise into the listening aids because of electromagnetic interference. The ANSI/IEEE Standard for Hearing Aid Compatibility with Wireless Devices was not completed in time for reference by the agency in its final rule published in FY 2000. However, the agency will consider using the Standard in FY 20007. In the meantime, because the requirement in the agency rule is a performance standard, the agency considers compliance with the VCS to meet the agency Standard.

Agency: Consumer Product Safety Commission (CPSC)

Government Standard: CPSC CFR Parts 1213, 1500, and 1513 [Incorporated: 2000]

Voluntary Standard	Rationale
ASTM F1427-96	The CPSC rule goes beyond the provisions of the ASTM voluntary standard to provide increased protection to children from the risk

	of death and serious injury from entrapment.

Government Standard: FR/Vol. 68, No. 75/Friday, April 18, 2003, pp. 19142-19147, Metal-Cored Candlewicks Containing Lead and Candles With Such Wicks [Incorporated: 2003]

Voluntary Standard	Rationale
Voices of Safety International (VOSI) standard on lead in candle wicks	The U.S. Consumer Product Safety Commission found that the VOSI standard is technically unsound, and thus would not result in the elimination or adequate reduction of the risk, and that substantial compliance with it is unlikely. See FR/Vol. 68, No. 75/Friday, April 18, 2003, pp. 19145-19146, paragraph H2, Voluntary Standards for further information on this finding.

Agency: Department of Labor (DOL)

Government Standard: 29 CFR 1910 Subpart S - Electrical Standard (Incorporated: 2007) [Incorporated: 2007]

Voluntary Standard	Rationale
NFPA 70 - National Electric Code NFPA 70E - Electrical Safety Requirement for Employee Workplaces. ANSI/IEEE C2 - National Electrical Safety Code ANSI/ASME B30.4 - Portal, Tower, and Pedestal Cranes NFPA 33 - Spray Application Using Flammable or Combustible Materials ANSI Z133.1 Arboricultural Operations for Pruning, Repairing, Maintaining, and Removing Trees, and Cutting Brush	Several voluntary consensus standards were relied upon for the various provisions in the final rule, however, no single VCS is available to cover all the workplace applications that are addressed by OSHA. The Agency believes that it would be less burdensome for the regulated community to use one OSHA standard rather than purchase and use the 6 individual consensus standards it used to write the rule.

Government Standard: 29 CFR 1926.1002 Roll-Over Protective Structures (Incorporated: 2006) [Incorporated: 2006]

Voluntary Standard	Rationale
SAE J1194-1999	Many consensus standards were relied upon for various provisions in the final rule. The primary VCS that applies directly to ROPS is SAE J1194-1999 which incorporates by reference several other VCSs. If SAE J1194-1999 was adopted into the OSHA provisions, the regulated community would have to consult not only the primary VCS but all of the VCSs that are incorporated into it as well. OSHA believes it is less burdensome for the regulated community to use one OSHA standard rather than require the purchase and use of several VCSs.

Government Standard: 30 CFR Part 75 - Sealing of Abandoned Areas - Emergency Temporary Standard. [Incorporated: 2007]

Voluntary Standard	Rationale
ACI 318-05 - Building Code Requirements for Structural Concrete and Commentary ACI 440.2R-02 - Design and Construction of Externally Bonded FRP Systems for Strengthening Concrete Structures ASTM E119-07 - Standard Test Methods for Fire Tests of Building Construction and Materials ASTM E162-06 - Standard Test Method for Surface Flammability of Materials Using a Radiant Heat Energy Source	Four consensus standards were relied upon for various provisions in the emergency temporary standard, but no one consensus standard is available that covered all of the topics covered by MSHA's Emergency Temporary Standard.

Government Standard: Electric Motor-Drive Equipment Rule [Incorporated:

2001]

Voluntary Standard	Rationale
IEEE Standard 242-1986 Recommended Practice for Protection and Coordination of Industrial and Commercial Power Systems (IEEE Buff Book) and NFPA 70 - national Electric Code	The MSHA rule is a design-specific standards. The NFPA and IEEE standards were used as a source for the rule; however, the exact requirements of the rule were tailored to apply specifically to electric circuits and equipment used in the coal mining industry.

Government Standard: Exit Routes, Emergency Action Plans, and Fire Prevention Plans, 29 CFR 1910, Subpart E [Incorporated: 2003]

Voluntary Standard	Rationale
Life Safety Code, NFPA 101-2000	The OSHA standard addresses only workplace conditions whereas the NFPA Life Safety Code goes beyond workplaces. However, in the final rule OSHA stated that it had evaluated the NFPA Standard 101, Life Safety Code, (NFPA 101-2000) and concluded that it provided comparable safety to the Exit Route Standards. Therefore, the Agency stated that any employer who complied with the NFPA 101-2000 instead of the OSHA Standard for Exit Routes would be in compliance.

Government Standard: Fire Protection for Shipyards, 29 CFR Part 1915, Subpart P [Incorporated: 2004]

Voluntary Standard	Rationale
NFPA 312-2000 Standard for Protection of Vessels During Construction, Repair, and Lay-Up NFPA 33-2003 Standard for Spray Application Using Flammable or Combustible Materials	Many consensus standards were relied on for various provisions in OSHA's final rule, including 15 consensus standards that are incorporated by reference. However, OSHA and its negotiated rulemaking committee determined that there was no, one consensus standard available that covered all the topics in the rule.

Government Standard: Sanitary Toilets in Coal Mines, 30 CFR 71, Subpart E [Incorporated: 2003]

Voluntary Standard	Rationale
Non-Sewered Waste Disposal Systems--Minimum Requirements, ANSI Z4.3-1987	The ANSI standard was not incorporated by reference because certain design criteria allowed in the ANSI standard, if implemented in an underground coal mine, could present health or safety hazards. For instance, combustion or incinerating toilets could introduce an ignition source which would create a fire hazard. For certain other design criteria found in the ANSI standard, sewage could seep into the groundwater, or overflow caused by rain or run-off could contaminate portions of the mine.

Government Standard: Steel Erection Standards [Incorporated: 2002]

Voluntary Standard	Rationale
ANSI A10.13 - Steel Erection; ASME/ANSI B30 Series Cranes Standards	Many consensus standards were relied upon for various provisions in the final rule, but there was no one consensus standard available that covered all of the topics covered by OSHA's final rule.

Agency: Department of Transportation (DOT)

Government Standard: 63 FR 17976; April 13, 1998 - Product Safety Signs and Labels [Incorporated: 1998]

Voluntary Standard	Rationale
ANSI Z535.4 - ANSI Requirements for Color Coded Header Messages for the Different Levels of Hazard	NHTSA explained in the NPRM that the American National Standard Institute (ANSI) has a standard4 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]

Voluntary Standard	**Rationale**
ANSI ISO	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.

Government Standard: Brake Performance, 49 CFR 393.52 - FMCSA's Performance-Based Brake Testers (PBBTs) Requirement [Incorporated: 2002]

Voluntary Standard	Rationale
SAE J667 - Brake Test Code Inertia Dynamometer (cancelled February 2002) SAE J1854 - Brake Force Distribution Performance Guide - Trucks and Buses	FMCSA used government-unique standards in lieu of voluntary consensus standards when it implemented its final rule to allow inspectors to use performance-based brake testers (PBBTs) to check the brakes on large trucks and buses for compliance with federal safety standards and to issue citations when these vehicles fail (67 FR 51770, August 9, 2002). The FMCSA evaluated several PBBTs during a round robin test series to assess their functional performance and potential use in law enforcement. The standard, a specific configuration of brake forces and wheel loads on a heavy-duty vehicle, was used to evaluate the candidate PBBTs and their operating protocols. The agency's rationale for use of the government-unique standards was to verify that these measurements and new technology could be used by law enforcement as an alternative to stopping distance tests or on-road deceleration tests. PBBTs are expected to save time and their use could increase the number of commercial motor vehicles that can be inspected in a given time. Only PBBTs that meet specifications developed by the FMCSA can be used to determine compliance with the Federal Motor Carrier Safety Regulations. The final rule represents a culmination of agency

research that began in the early 1990s.

Agency: Environmental Protection Agency (EPA)

Government Standard: EPA Method 1 – Traverse Points, Stationary Sources [Incorporated: 2001]

Voluntary Standard	Rationale
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 101 - Mercury Emissions, Chlor-Alkali Plants (Air) [Incorporated: 2001]

Voluntary Standard	Rationale
ASTM D6216-98 - Standard Practice for Opacity Monitor Manufacturers to Certify Conformance with Design and Performance Specifications.	The EPA is incorporating ASTM D6216 (manufacturers certification) by reference into EPA Performance Specification 1, Sect. 5 & 6 in another rulemaking. ASTM D6216 does not address all the requirements specified in PS-1.

Government Standard: EPA Method 101a - Mercury Emissions Sewer/Sludge Incinerator [Incorporated: 2001]

Voluntary Standard	Rationale
ASTM D6216-98 - Standard Practice for Opacity Monitor Manufacturers to Certify Conformance with Design and Performance Specifications.	The EPA is incorporating ASTM D6216 (manufacturers certification) by reference into EPA Performance Specification 1, Sect. 5 & 6 in another rulemaking. ASTM D6216 does not address all the requirements specified in PS-1.

Government Standard: EPA Method 10A – Carbon Monoxide for Certifying CEMS [Incorporated: 2001]

Voluntary Standard	Rationale
CAN/CSA Z223.21-M1978, Method for the Measurement of Carbon Monoxide: 3—Method of Analysis by Non-Dispersive Infrared Spectrometry.	1. It 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 12 – Inorganic Lead, Stationary Sources [Incorporated: 2000]

Voluntary Standard	Rationale

ASTM D4358-94 (1999), Standard Test Method for Lead and Chromium in Air Particulate Filter Samples of Lead Chromate Type Pigment Dusts by Atomic Absorption Spectroscopy	These ASTM standards do not require the use of glass fiber filters as in EPA Method 12 and require the use of significantly different digestion procedures that appear to be milder than the EPA Method 12 digestion procedure. For these reasons, these ASTM standards cannot be considered equivalent to EPA Method 12. Also, the subject ASTM standards do not require the use of hydrogen fluoride (HF) as in EPA Method 29 and, therefore, they cannot be used for the preparation, digestion, and analysis of Method 29 samples. Additionally, Method 29 requires the use of a glass fiber filter, whereas these three ASTM standards require cellulose filters and other probable nonglass fiber media, which cannot be considered equivalent to EPA Method 29.
ASTM E1741-95 (1995), Standard Practice for Preparation of Airborne Particulate Lead Samples Collected During Abatement and Construction Activities for Subsequent Analysis by Atomic Spectrometry	These ASTM standards do not require the use of glass fiber filters as in EPA Method 12 and require the use of significantly different digestion procedures that appear to be milder than the EPA Method 12 digestion procedure. For these reasons, these ASTM standards cannot be considered equivalent to EPA Method 12. Also, the subject ASTM standards do not require the use of hydrogen fluoride (HF) as in EPA Method 29 and, therefore, they cannot be used for the preparation, digestion, and analysis of Method 29 samples. Additionally, Method 29 requires the use of a glass fiber filter, whereas these three ASTM standards require cellulose filters and other probable nonglass fiber media, which cannot be considered equivalent to EPA Method 29.

ASTM E1979-98 (1998), Standard Practice for Ultrasonic Extraction of Paint, Dust, Soil, and Air Samples for Subsequent Determination of Lead	These ASTM standards do not require the use of glass fiber filters as in EPA Method 12 and require the use of significantly different digestion procedures that appear to be milder than the EPA Method 12 digestion procedure. For these reasons, these ASTM standards cannot be considered equivalent to EPA Method 12. Also, the subject ASTM standards do not require the use of hydrogen fluoride (HF) as in EPA Method 29 and, therefore, they cannot be used for the preparation, digestion, and analysis of Method 29 samples. Additionally, Method 29 requires the use of a glass fiber filter, whereas these three ASTM standards require cellulose filters and other probable nonglass fiber media, which cannot be considered equivalent to EPA Method 29.

Government Standard: EPA Method 17 - Particle Matter (PM) In Stack Filtration [Incorporated: 2001]

Voluntary Standard	Rationale
ASME C00049	EPA looked at this standard for both Pulp and Paper Hazardous Air Pollutant rules and for the Small Municipal Waste Combustion rule. Contains sampling options beyond which would be considered acceptable for Method 5.
ASTM D3685/3685M-95 - Standard Test method for Sampling and Determination of Particle Matter in Stack Gases	EPA looked at this standard for both Pulp and Paper Hazardous Air Pollutant rules and for the Small Municipal Waste Combustion rule. Contains sampling options beyond which would be considered acceptable for Method 5.

Government Standard: EPA Method 2 – Velocity and S-type Pitot [Incorporated: 1999]

Voluntary Standard	Rationale

ASTM D3464-96 (2001), Standard Test Method Average Velocity in a Duct Using a Thermal Anemometer	Applicability specifications are not clearly defined, e.g., range of gas composition, temperature limits. Also, the lack of supporting quality assurance data for the calibration procedures and specifications, and certain variability issues that are not adequately addressed by the standard limit EPA's ability to make a definitive comparison of the method in these areas.
ISO 10780:1994, Stationary Source Emissions-- Measurement of Velocity and Volume Flowrate of Gas Streams in Ducts	The standard recommends the use of an L-shaped pitot, which historically has not been recommended by EPA. The EPA specifies the S-type design, which has large openings that are less likely to plug up with dust.

Government Standard: EPA Method 21 - Volatile Organic Compound (VOC) Leaks [Incorporated: 2003]

Voluntary Standard	Rationale
ASTM E1211-97 - Standard Practice for Leak Detection and Location Using Surface-Mounted Acoustic Emission Sensors	This standard will detect leaks but not classify the leak as VOC, as in EPA Method 21. In addition, in order to detect the VOC concentration of a known VOC leak, the acoustic signal would need to be calibrated against a primary instrument. Background noise interference in some source situations could also make this standard difficult to use effectively.

Government Standard: EPA Method 25 – Gaseous Nonmethane Organic Emissions [Incorporated: 2001]

Voluntary Standard	Rationale
EN 12619:1999 Stationary Source Emissions--Determination of the Mass Concentration of Total Gaseous Organic Carbon at Low Concentrations	The standards do not apply to solvent process vapors in concentrations greater than 40 ppm (EN 12619) and 10 ppm carbon (ISO 14965). Methods whose upper limits are this low are

in Flue Gases--Continuous Flame Ionization Detector Method	too limited to be useful in measuring source emissions, which are expected to be much higher.
ISO 14965:2000(E) Air Quality--Determination of Total Nonmethane Organic Compounds--Cryogenic Preconcentration and Direct Flame Ionization Method	The standards do not apply to solvent process vapors in concentrations greater than 40 ppm (EN 12619) and 10 ppm carbon (ISO 14965). Methods whose upper limits are this low are too limited to be useful in measuring source emissions, which are expected to be much higher.

Government Standard: EPA Method 25A – Gaseous Organic Concentration, Flame Ionization [Incorporated: 2001]

Voluntary Standard	Rationale
EN 12619:1999 Stationary Source Emissions--Determination of the Mass Concentration of Total Gaseous Organic Carbon at Low Concentrations in Flue Gases--Continuous Flame Ionization Detector Method	The standards do not apply to solvent process vapors in concentrations greater than 40 ppm (EN 12619) and 10 ppm carbon (ISO 14965). Methods whose upper limits are this low are too limited to be useful in measuring source emissions, which are expected to be much higher.
ISO 14965:2000(E) Air Quality--Determination of Total Nonmethane Organic Compounds--Cryogenic Preconcentration and Direct Flame Ionization Method	The standards do not apply to solvent process vapors in concentrations greater than 40 ppm (EN 12619) and 10 ppm carbon (ISO 14965). Methods whose upper limits are this low are too limited to be useful in measuring source emissions, which are expected to be much higher.

Government Standard: EPA Method 28 (Section 10.1) – Wood Heaters, Certificate and Auditing [Incorporated: 2003]

Voluntary Standard	Rationale
ASME Power Test Codes, Supplement on Instruments and Apparatus, part 5,	It does not specify the number of initial calibration weights to be used nor a specific

Measurement of Quantity of Materials, Chapter 1, Weighing Scales	pretest weight procedure.
ASTM E319-85 (Reapproved 1997), Standard Practice for the Evaluation of Single-Pan Mechanical Balances	This standard is not a complete weighing procedure because it does not include a pretest procedure.

Government Standard: EPA Method 29 – Metals Emissions from Stationary Sources [Incorporated: 2001]

Voluntary Standard	**Rationale**
ASTM D4358-94 (1999), Standard Test Method for Lead and Chromium in Air Particulate Filter Samples of Lead Chromate Type Pigment Dusts by Atomic Absorption Spectroscopy	These ASTM standards do not require the use of glass fiber filters as in EPA Method 12 and require the use of significantly different digestion procedures that appear to be milder than the EPA Method 12 digestion procedure. For these reasons, these ASTM standards cannot be considered equivalent to EPA Method 12. Also, the subject ASTM standards do not require the use of hydrogen fluoride (HF) as in EPA Method 29 and, therefore, they cannot be used for the preparation, digestion, and analysis of Method 29 samples. Additionally, Method 29 requires the use of a glass fiber filter, whereas these three ASTM standards require cellulose filters and other probable nonglass fiber media, which cannot be considered equivalent to EPA Method 29.
ASTM E1741-95 (1995), Standard Practice for Preparation of Airborne Particulate Lead Samples Collected During Abatement and Construction Activities for Subsequent Analysis by Atomic Spectrometry	These ASTM standards do not require the use of glass fiber filters as in EPA Method 12 and require the use of significantly different digestion procedures that appear to be milder than the EPA Method 12 digestion procedure. For these reasons, these ASTM standards cannot be considered equivalent to EPA Method 12. Also, the subject ASTM standards

	do not require the use of hydrogen fluoride (HF) as in EPA Method 29 and, therefore, they cannot be used for the preparation, digestion, and analysis of Method 29 samples. Additionally, Method 29 requires the use of a glass fiber filter, whereas these three ASTM standards require cellulose filters and other probable nonglass fiber media, which cannot be considered equivalent to EPA Method 29.
ASTM E1979-98 (1998), Standard Practice for Ultrasonic Extraction of Paint, Dust, Soil, and Air Samples for Subsequent Determination of Lead	These ASTM standards do not require the use of glass fiber filters as in EPA Method 12 and require the use of significantly different digestion procedures that appear to be milder than the EPA Method 12 digestion procedure. For these reasons, these ASTM standards cannot be considered equivalent to EPA Method 12. Also, the subject ASTM standards do not require the use of hydrogen fluoride (HF) as in EPA Method 29 and, therefore, they cannot be used for the preparation, digestion, and analysis of Method 29 samples. Additionally, Method 29 requires the use of a glass fiber filter, whereas these three ASTM standards require cellulose filters and other probable nonglass fiber media, which cannot be considered equivalent to EPA Method 29.
CAN/CSA Z223.26-M1987, Measurement of Total Mercury in Air Cold Vapour Atomic Absorption Spectrophotometeric Method	It lacks sufficient quality assurance and quality control requirements necessary for EPA compliance assurance requirements.

Government Standard: EPA Method 306 - Chromium Emissions, Electroplating and Anodizing [Incorporated: 2002]

Voluntary Standard	**Rationale**

ASTM D4358-94 (1999) - Standard Test Method for Lead and Chromium in Air Particulate Filter Samples of Lead Chromate Type Pigment Dusts by Atomic Absorption Spectroscopy	This MACT standard (Petroleum Refineries) only cites Method 29. Therefore, the following EPA comment is only applicable for Method 29 not Method 12 and 306: Method 29 requires the use of hydrofluoric acid (HF) in its process of digestion of the sample. ASTM D4358-94 (1999) does not require the use of HF; therefore, it cannot be used in the preparation, digestion, and analysis of Method 29 samples. Additionally, Method 29 requires the use of a glass fiber filter, whereas the subject ASTM standard requires cellulose filters and other probable non-glass fiber media, and this further negates their use as Method 29 equivalent methods. (Same comment as provided for ASTM E1741 and ASTM E1979).

Government Standard: EPA Method 306a - Chromium Emissions, Electroplating -- Mason Jar [Incorporated: 2002]

Voluntary Standard	Rationale
ASTM D4358-94 (1999) - Standard Test Method for Lead and Chromium in Air Particulate Filter Samples of Lead Chromate Type Pigment Dusts by Atomic Absorption Spectroscopy	This MACT standard (Petroleum Refineries) only cites Method 29. Therefore, the following EPA comment is only applicable for Method 29 not Method 12 and 306: Method 29 requires the use of hydrofluoric acid (HF) in its process of digestion of the sample. ASTM D4358-94 (1999) does not require the use of HF; therefore, it cannot be used in the preparation, digestion, and analysis of Method 29 samples. Additionally, Method 29 requires the use of a glass fiber filter, whereas the subject ASTM standard requires cellulose filters and other probable non-glass fiber media, and this further negates their use as Method 29 equivalent methods. (Same comment as provided for ASTM E1741 and ASTM E1979).

Government Standard: EPA Method 3A – Carbon Dioxide and Oxygen Concentrations, IAP [Incorporated: 1999]

Voluntary Standard	Rationale
ISO 12039:2001, Stationary Source Emissions-- Determination of Carbon Monoxide, Carbon Dioxide, and Oxygen--Automated Methods	This ISO standard is similar to EPA Method 3A, but is missing some key features. In terms of sampling, the hardware required by ISO 12039:2001 does not include a 3-way calibration valve assembly or equivalent to block the sample gas flow while calibration gases are introduced. In its calibration procedures, ISO 12039:2001 only specifies a two-point calibration while EPA Method 3A specifies a three-point calibration. Also, ISO 12039:2001 does not specify performance criteria for calibration error, calibration drift, or sampling system bias tests as in the EPA method, although checks of these quality control features are required by the ISO standard.

Government Standard: EPA Method 515.4 – Chlorinated Acids in DW by LL Fast CG/ECD [Incorporated: 2003]

Voluntary Standard	Rationale
ASTM D5317-98 -- Standard Test Method For Determination of Chlorinated Organic Acid Compounds in Water by Gas Chromatography With an Electron Capture Detector	ASTM D5317-98 specifies acceptance windows for the initial demonstration of proficiency for laboratory fortified blank samples that are as small as 0 percent to as large as 223 percent recovery for picloram, with tighter criteria for other regulated contaminants. Therefore, this method permits unacceptably large control limits, which include 0 percent recovery.
Standard Method 6640 B for the chlorinated acids	The use of this voluntary consensus standard would have been impractical due to significant shortcomings in the sample preparation and

	quality control sections of the method instructions. Section 1b of Method SM 6640 B states that the alkaline wash detailed in section 4b2 is optional. The hydrolysis that occurs during this step is essential to the analysis of the esters of many of the analytes. Therefore, this step is necessary and cannot be optional. In addition, the method specifies that the quality control limits for laboratory-fortified blanks are to be based upon plus or minus three times the standard deviation of the mean recovery of the analytes, as determined in each laboratory. Therefore, this method permits unacceptably large control limits, which may include 0 percent recovery.

Government Standard: EPA Method 531.2 – N-Methylcarbamoylozimes/ates, Aqueous In/HPLC [Incorporated: 2003]

Voluntary Standard	**Rationale**
Standard Method 6610, 20th Edition	Standard Method 6610, 20th Edition has recently been approved for compliance monitoring. Standard Method 6610, 20th Supplemental Edition permits the use of a strong acid, hydrochloric acid (HCL), as a preservative. The preservatives in all of the other approved EPA and Standard Methods procedures for these analytes are weak acids that adjust the pH to a specific value based upon the pKa of the preservative. The use of HCL would require accurate determinations of the pH of the sample in the field and could be subject to considerable error and possible changes in pH upon storage. Although not specifically observed for oxamyl or carbofuran during the development of similar methods, structurally similar pesticides have been shown

	to degrade over time when kept at pH 3. Therefore, approval of this method is impractical because it specifies the use of a strong acid (HCL) when positive control of the pH is critical.
Standard Method 6610, 20th Supplemental Edition	Standard Method 6610, 20th Edition has recently been approved for compliance monitoring. Standard Method 6610, 20th Supplemental Edition permits the use of a strong acid, hydrochloric acid (HCL), as a preservative. The preservatives in all of the other approved EPA and Standard Methods procedures for these analytes are weak acids that adjust the pH to a specific value based upon the pKa of the preservative. The use of HCL would require accurate determinations of the pH of the sample in the field and could be subject to considerable error and possible changes in pH upon storage. Although not specifically observed for oxamyl or carbofuran during the development of similar methods, structurally similar pesticides have been shown to degrade over time when kept at pH 3. Therefore, approval of this method is impractical because it specifies the use of a strong acid (HCL) when positive control of the pH is critical.

Government Standard: EPA Method 5i - Low Level Particulate Matter, Stationary Sources [Incorporated: 2001]

Voluntary Standard	**Rationale**
ASTM D6331-98	This standard does not have paired trains as specified in method 5 and does not include some quality control procedures specified in the EPA method and which are appropriate to

use in this rule.

Government Standard: EPA Method ALT 004 [Incorporated: 2002]

Voluntary Standard	Rationale
ASTM D5835-95 - Standard Practice for Sampling Stationary Source Emissions for Automated Determination of Gas Concentration	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.
ISO 10396:1993 - Stationary Source Emissions: Sampling for the Automated Determination of Gas Concentrations	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 CTM 022 [Incorporated: 2002]

Voluntary Standard	Rationale
ASTM D5835-95 - Standard Practice for Sampling Stationary Source Emissions for Automated Determination of Gas Concentration	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.
ISO 10396:1993 - Stationary Source Emissions: Sampling for the Automated Determination of Gas Concentrations	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 Performance Specification 2 (nitrogen oxide portion only) [Incorporated: 2001]

Voluntary Standard	Rationale
ISO 10849:1996, Determination of the Mass Concentration of Nitrogen Oxides--Performance	Is too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.

Government Standard: EPA Performance Specification 2 (sulfur dioxide portion only) [Incorporated: 2001]

Voluntary Standard	Rationale

ISO 7935:1992, Stationary Source Emissions--Determination of the Mass Concentration of Sulfur Dioxide--Performance Characteristics of Automated Measuring Methods"	Is too general, too broad, or not sufficiently detailed to assure compliance with EPA regulatory requirements.

Government Standard: SW846-6010b [Incorporated: 2002]

Voluntary Standard	Rationale
ASTM C1111-98 (1998) - Standard Test Method for Determining Elements in Waste Streams by Inductively Coupled Plasma-Atomic Emission Spectrometers	This standard lacks details for instrument operation QA/QC, such as optimizing plasma operating conditions; upper limit of linear dynamic range; spectral interference correction; and calibration procedures, which include initial and continuous calibration verifications. Also lacks internal standard and method of standard addition options for samples with interferences.
ASTM D6349-99 (1999) - Standard Test Method for Determining Major and Minor Elements in Coal, Coke, and Solid Residues from Combustion of Coal and Coke by Inductively Coupled Plasma-Atomic Emission Spectrometers	This standard lacks details for instrument operation QA/QC, such as optimizing plasma operating conditions, upper limit of linear dynamic range, spectral interference correction, and calibration procedures, that include initial and continuous calibration verifications. Also lacks details for standard preparation, and internal standard and method of standard addition options for samples with interferences.

Agency: General Services Administration (GSA)

Government Standard: Federal Specification KKK-A-1822E - Federal Specification for Ambulances [Incorporated: 2003]

Voluntary Standard	Rationale
ASTM F2020 - Standard Practice for	The ASTM Standard Practice for Design,

Design, Construction, and Procurement of Emergency Medical Services Ambulances	Construction, and Procurement of Emergency Medical Services (EMSS) Ambulances (ASTM F2020) is not practical for use, and therefore GSA uses the Federal Specification for Ambulances (KKK-A-1822E). GSA has determined the ASTM document is not practical for use for the following reasons: 1) GSA has determined that ASTM F2020 contains specific practices that are technically and economically impractical to use for the acquisition of commercial based vehicles because the document is financially burdensome and technically ineffective. Specifically at issue is the ASTM Standard Specification for Medical Oxygen Delivery Systems for EMS Ground Vehicles, F1949-99 which is inclusive to ASTM F2020. 2) GSA has determined that ASTM F2020 is impractical because it is defined as a standard practice which is ambiguous and an ineffective substitution for specifications or requirements for use in GSA contract documents. ASTM F1949-99, a Standard Specification for Medical Oxygen Delivery Systems for EMS Ground Vehicles is included in ASTM F2020. ASTM F1949-99 is defined as a “standard specification”. 3) GSA has determined that ASTM F2020 is impractical because ASTM International does not provide interpretations and written guidance to their publications which is inadequate and less useful. ASTM members may only offer personal opinions. ASTM offers

no mechanism to support timely resolution of conflicts between contractor and procurement organizations on technical subject matter. GSA provides interpretations, clarifications and engineering determinations when required. This is one of the most important concerns presented by the Ambulance Manufacturers Division (AMD).

4) The AMD has determined through consensus that it is impractical to replace the Federal Specification for Ambulances, KKK-A-1822E with the ASTM Standard Practice, F2020. GSA initiated a survey to collect public responses from a wide range of constituent users of the Federal Ambulance Specification. The National Association of Emergency Medical Technicians (NAEMT), the International Association of Fire Chiefs (IAFC), the National Association of State EMS Directors (NASEMSD) and the National Association of EMS Physicians universally accept and support the continued use of the Federal Specification. The AMD and constituent users have determined that it is impractical to replace the Federal Specification for Ambulances, KKK-A-1822E with the ASTM Standard Practice, F2020 because rule promulgation is burdensome and costly. Staff and administration resources would need to be diverted in each state EMS office to implement the change in statutes, public health codes, rules and regulations.

5) GSA has determined that ASTM F2020 is impractical because it is burdensome to GSA procurement efforts. While the current ASTM

	document recites many of the requirements from the Federal Specification, a future ASTM document would likely have diverging requirements unacceptable to the Government. This was verified by a member of the ASTM F2020 subcommittee at the September 4, 2003 meeting of the Federal Interagency Committee on Emergency Medical Services.

Government Standard: FF-L-2937 [Incorporated: 2006]

Voluntary Standard	**Rationale**
UL 768	Federal Specification FF-L-2937 – Combination Lock, Mechanical used in lieu of UL 768 Combination Locks. The lock covered by the GUS is used for the protection of classified information and weapons. The UL specification did not meet identified government needs for dialing tolerance and bolt end pressure.

Government Standard: MIL-G-9954 - Glass Beads for Cleaning and Peening [Incorporated: 2000]

Voluntary Standard	**Rationale**
SAE/AMS 2431 - Peening Media, General Requirements	This government-unique standard contains specific size & performance required for Air Force critical applications that are not present in the voluntary standards.

Agency: Department of Health and Human Services (HHS)

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

Voluntary Standard	**Rationale**
HL7 Dosage Form and Route of Administration	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 (2004) [Incorporated: 2004]

Voluntary Standard	Rationale
ISO 13408-1 Asceptic Process ing of Health Care Products, Part 1, General Requirements	FDA 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]

Voluntary Standard	Rationale

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

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.

Agency: Department of Housing and Urban Development (HUD)

Government Standard: 24 CFR 200.935 - Administrator qualifications and procedures for HUD building products and certififcation programs [Incorporated: 2000]

Voluntary Standard	Rationale
ANSI A119.1 N - Recreation Vehicles	HUD Building-Product Standards & Certification

	Programs. HUD was required by legislation to "establish Federal construction and safety standards for manufactured homes and to authorize manufactured home safety research and development". Recently, HUD retained a private consensus body (NFPA) to update and modernize the Manufactured Home Standards. At the conclusion of the development process, NFPA will submit the revised standard to HUD for regulatory adoption.

Government Standard: 24 CFR 3280 - Manufactured Home Construction and Safety Standards [Incorporated: 2000]

Voluntary Standard	Rationale
ANSI A119.1 - Recreation Vehicles and NFPA 501C - Standard on Recreational Vehicles	HUD-Unique Manufactured Home Construction & Safety Standards. HUD was required by legislation to "establish Federal construction and safety standards for manufactured homes and to authorize manufactured home safety research and development". Recently, HUD retained a private consensus body (NFPA) to update and modernize the Manufactured Home Standards. At the conclusion of the development process, NFPA will submit the revised standard to HUD for regulatory adoption.

Agency: National Archives and Records Administration (NARA)

Government Standard: NARA data standard [Incorporated: 2000]

Voluntary Standard	Rationale
Archives, Personal Papers, and Manuscripts (APPM); General International Standard Archival Description (ISAD(G));	These voluntary standards do not meet the precise needs of the agency.

International Standard Archival
Authority Record for Corporate Bodies,
Persons, and Families (ISAAR(CPF));
Encoded Archival Description (EAD);
Machine Readable Cataloging (MARC)

Agency: Department of Agriculture (USDA)
Government Standard: Name: WILDLAND FIRE FOAM Number: USDA Forest Service Specification 5100-307; July, 2000 Title: International Specification for Fire Suppressant Foam for Wild land Fires, Aircraft or Ground Application) [Incorporated: 2005]

Voluntary Standard	**Rationale**
NFPA 1150 - Standard on Fire-Fighting Foam Chemicals for Class A Fuels in Rural, Suburban, and Vegetated Areas.	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.