FOR FURTHER INFORMATION CONTACT section by October 19, 2010. Persons may request time to make an oral presentation. Persons may also submit written comments. Written comments and requests to make oral presentations at the meeting should reach Drew Dawson at the address listed below or via the Document Management System and must be received by October 19, 2010.

All submissions received must include the docket number, NHTSA–2010–0136, and may be submitted by any one of the following methods: (1) You may submit or retrieve comments online through the Document Management System (DMS) at *http://www.regulations.gov/* under the docket number listed at the beginning of this notice. The DMS is available 24 hours each day, 365 days each year. Electronic submission and retrieval help guidelines are available under the help section of the Web site; (2) you may submit comments by E-mail to *drew.dawson@dot.gov* or *noah.smith@dot.gov;* or (3) you may submit comments by Fax to (202) 366–7149.

An electronic copy of this document may be downloaded from the **Federal Register**'s home page at *http://www.archives.gov* and the Government Printing Office's database at *http://www.access.gpo.gov/nara.*

Please note, that even after the comment closing date, we will continue to file relevant information in the docket as it becomes available.

FOR FURTHER INFORMATION CONTACT: Drew Dawson, Director, Office of Emergency Medical Services, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., NTI–140, Washington, DC 20590,Telephone number (202) 366–9966; E-mail *Drew.Dawson@dot.gov.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App. 1 *et seq.*) The NEMSAC will hold a meeting on Tuesday, October 26, 2010, via teleconference.

Agenda of Council Teleconference Meeting, October 26, 2010

The tentative agenda includes the following:

Tuesday, October 26, 2010

(1) Opening Remarks—Chair and Designated Federal Officer;
(2) Introduction of Members and all in attendance;
(3) Federal Advisory Council Act Overview;
(4) NHTSA Office of EMS Overview;
(5) Other Federal agency EMS activities;
(6) FICEMS Overview;
(7) Public Comment Period;
(8) Next Steps and Future Meetings.

While the entire meeting is open to the public, the public comment period will take place on October 26, 2010, between 4 p.m. and 4:15 p.m.

Public Attendance: The meeting is open to the public. Persons with disabilities who require special assistance should advise Drew Dawson of their anticipated special needs as early as possible. Members of the public who wish to make comments on Tuesday, October 26, between 4 p.m. and 4:15 p.m. are requested to register in advance. In order to allow as many people as possible to speak, speakers are requested to limit their remarks to 3 minutes. For those wishing to submit written comments, please follow the procedure noted above.

Individuals wishing to register for attendance in the teleconference must provide their name, affiliation, phone number, and e-mail address to Drew Dawson by e-mail at *drew.dawson@dot.gov* or by telephone at (202) 366–9966 no later than October 19, 2010. There will be limited call-in lines, so please register early. Pre-registration is necessary to enable proper arrangements.

Minutes of the NEMSAC Meeting will be available to the public online through the DOT Document Management System (DMS) at: *http://www.regulations.gov* under the docket number listed at the beginning of this notice and on *http://www.ems.gov*

Issued on: October 1, 2010.

Jeffrey P. Michael,

Associate Administrator for Research and Program Development.

[FR Doc. 2010–25164 Filed 10–5–10; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2010–0033]

Model Specifications for Breath Alcohol Ignition Interlock Devices (BAIIDs)

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice proposes revisions to the Model Specifications for Breath Alcohol Ignition Interlock Devices (BAIIDs). The Model Specifications are guidelines for the performance and testing of BAIIDs. These devices are designed to prevent a driver from starting a motor vehicle when the driver's breath alcohol concentration (BrAC) is at or above a set alcohol level. Most States currently use BAIIDs as a sanction for drivers convicted of driving while intoxicated offenses. In 1992, this technology was new. Now that it has matured, NHTSA proposes to revise the 1992 Model Specifications, to test BAIIDs for conformance and to maintain a conforming products list (CPL) of BAIIDs that have been found to meet the Model Specifications. These proposed revisions are based, in part, on input from interested parties during an open comment period.

DATES: Written comments may be submitted to this agency and must be received no later than December 6, 2010.

ADDRESSES: You may submit comments identified by DOT Docket ID Number NHTSA–2010–0033 by any of the following methods:

- *Electronic submissions:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Management Facility, M–30, U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Eastern Time, Monday through Friday, except Federal holidays.

Regardless of how you submit your comments, you should identify the Docket number of this document.

Instructions: For detailed instructions on submitting comments and additional information, *see http://www.regulations.gov.* Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the "Privacy Act" heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the complete User Notice and Privacy Notice for Regulations.gov at *http://www.regulations.gov/search/footer/privacyanduse.jsp.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* at any time or to West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Eastern Time, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: *For technical issues:* Ms. De Carlo Ciccel, Behavioral Research Division, NTI–131, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590; Telephone number: (202) 366–1694; E-mail: *decarlo.ciccel@dot.gov. For legal issues:* Ms. Jin Kim, Attorney-Advisor, Office of the Chief Counsel, NCC–113, National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590; Telephone number: (202) 366–1834; E-mail: *jin.kim@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In 1992, the National Highway Traffic Safety Administration (NHTSA) adopted and published Model Specifications for Breath Alcohol Ignition Interlock Devices (BAIIDs). (57 FR 11772.) Ignition interlocks are alcohol breath-testing devices installed in motor vehicles that require the driver to provide a breath sample in order to start the engine and to provide a breath sample periodically while the engine is running. If the breath sample provided by the driver contains more than a predetermined alcohol concentration, the ignition interlock device prevents the vehicle from starting.

Before NHTSA adopted the Model Specifications, a number of States passed laws authorizing the use of "certified" BAIIDs. However, there was no single standard or test procedure among the States for certifying BAIIDs. Manufacturers of ignition interlock devices requested that the Federal Government develop and issue standards for certifying such devices rather than leaving the industry subject to numerous State standards and test requirements. After notice and comment, NHTSA adopted the Model Specifications for BAIIDs to provide a degree of consistency.

Since the Model Specifications were adopted in 1992, many States have incorporated them or some variation into their certification requirements. Persons required to use BAIIDs are generally under the direct supervision of a court or another State agency (*e.g.,* Motor Vehicle Administration). As of March 2010, 47 States and the District of Columbia allow the use of BAIIDs for some driving while intoxicated (DWI) offenders. Of these States, 22 mandate the use of BAIIDs for repeat DWI offenders, and 13 mandate or highly incentivize the use of BAIIDs by all DWI offenders, including first-time offenders.

While many States have incorporated the Model Specifications to certify BAIIDs used by DWI offenders, there remains considerable variability among State certification requirements. Due to this variability and to rapid technological advances in the industry, States and manufacturers of BAIIDs have requested that NHTSA test the devices against the Model Specifications and maintain a conforming products list (CPL) of devices found to meet the Model Specifications, similar to CPLs that NHTSA maintains for other breath alcohol measuring devices, such as Alcohol Screening Devices, Evidential Breath Testers, and Calibrating Units for Breath Alcohol Testers.

In response to these requests, NHTSA proposes to revise and update the 1992 Model Specifications, add provisions for the agency to conduct conformance testing of BAIIDs, and maintain a CPL of BAIIDs that have been found to meet those Model Specifications. This proposal is not intended to take the place of any State certification requirements; rather, it would establish a voluntary testing and conformance program.

In advance of these proposed revisions of the 1992 Model Specifications, NHTSA published a request for comments on February 15, 2006. (71 FR 8047.) NHTSA explained that it was interested in obtaining comments from interested parties in 13 specific areas:

(1) *Accuracy and precision requirements.* Is the current set point of 0.025 grams of alcohol per 210 Liters of air (g/dL) appropriate or should it be changed? Are the current specifications for 90 percent accuracy at 0.01 g/dL above the set point in the unstressed testing conditions, and 90 percent accuracy at 0.02 g/dL above the set point in the stressed testing condition appropriate?

(2) *Sensor technology.* The 1992 Model Specifications do not address what type of sensor technology should be used to satisfy those performance requirements. Should the Model Specifications limit sensor technology to alcohol-specific sensors (such as fuel cell technology based on electro-chemical oxidation of alcohol) or other emerging sensor technologies? Or, should NHTSA not specify the sensor technology and rely on performance requirements?

(3) *Sample size requirements.* The 1992 Model Specifications set the minimum breath sampling size at 1.5 Liters. Informal comments received over the years have suggested that this requirement may be too high. Should NHTSA consider lowering the minimum breath sampling size requirement? Should NHTSA include a minimum sample size and minimum back pressure at the input-mouthpiece of the device?

(4) *Temperature extreme testing.* The 1992 Model Specifications call for testing at −40 °C, −20 °C, +70 °C and +85 °C, but allow for the removability of the alcohol sensing unit so that it may be kept at an artificial temperature when the vehicle may be subject to extremely cold or hot temperatures. Is this approach to extreme temperature testing sufficient, or should it be more stringent?

(5) *Radio Frequency Interference (RFI) or Electromagnetic Interference (EMI) Testing.* The RFI testing protocol in the 1992 Model Specifications uses power sources that are no longer commonly in use. New power sources that may interfere with the operation of BAIIDs (*e.g.,* cell phones) have output power commensurate with equipment in use today. What are the appropriate levels to measure RFI/EMI?

(6) *Circumvention testing.* The 1992 Model Specifications offer a number of procedures for evaluating whether existing devices can be easily circumvented. Are these procedures sufficient or should new or modified procedures be incorporated into the Model Specifications?

(7) *The Vehicle-Interlock Interface.* Anecdotal reports from ignition interlock manufacturers have suggested that it is sometimes difficult to install existing interlock systems in some of the newer electronic ignition systems. Should NHTSA establish any guidelines regarding the vehicle-interlock interface?

(8) *Calibration stability.* Is the duration of calibration stability testing sufficient? Should ignition interlocks be required to hold their calibration for a longer period of time, thereby requiring less frequent calibration checks?

(9) *Ready-to-use Times.* Should NHTSA establish a "ready-to-use" time period for extreme cold temperatures, such that devices must operate within a given period of time under extreme cold conditions?

(10) *NHTSA testing.* Should NHTSA undertake the responsibility to evaluate ignition interlocks against its Model Specifications and publish a Conforming Products List (CPL) of devices meeting those specifications?

(11) *International Harmonization.* Is it important to harmonize the ignition interlock Model Specifications with standards in other parts of the world, such as the European Union, Canada, and Australia?

(12) *Specifications for Ignition Interlock Programs.* Does the ignition interlock community (users, manufacturers, States, etc.) favor NHTSA development of an interlock program, in addition to Model Specifications for devices?

(13) *Acceptance Testing.* NHTSA's current Model Specifications involve "type-testing" (*i.e.,* testing particular models of BAIIDs for conformance) of various models of BAIIDs. Should NHTSA establish standardized acceptance-testing procedures (*i.e.,* testing each individual device for conformance), instead of the current type-testing guidelines? What testing should be included in such Model Specifications? Who should conduct the testing?

In addition to the above 13 specific areas, NHTSA's 2006 notice solicited comments on other areas that might enhance the revisions of the Model Specifications. Comments were received from five manufacturers of interlock devices, five State government representatives, two automobile manufacturers, one association of interlock installers and the European Committee for Electrotechnical Standardization (CENELEC). Today's notice responds to these comments in setting forth the agency's proposal.

In addition, this notice sets forth the proposed procedures for submitting BAIIDs for NHTSA testing (Appendix A) and re-examination of BAIIDs that have been tested (Appendix B).

II. Response to Comments

The comments were supportive of the agency's proposal to revise the Model Specifications, noting that they had served well in organizing the interlock field but that some adjustments were warranted to assure more consistency in the quality of equipment in use today.

A. Set Point, Accuracy and Precision Requirements

There was a lot of variability among comments on the alcohol set point (i.e., Breath Alcohol Concentration (BrAC) at which a BAIID is set to lock the ignition). Two commenters stated that the 1992 Model Specification requirements for set point was appropriate and should not be changed. One State representative recommended a 0.025 g/dL set point for adults and a 0.02 g/dL set point for minors. Other State representatives commented that the alcohol set point could be more stringent. One commenter stated that several States already use a 0.02 g/dL set point.

NHTSA proposes to lower the set point for testing BAIIDs from 0.025 g/dL to 0.02 g/dL. This is the critical point that is used in the Breath Alcohol Screening Devices to indicate the presence of alcohol. Accordingly, for listing on the Conforming Products List (CPL), NHTSA proposes to test BAIIDs that are capable of locking out at a set point of 0.02 g/dL. NHTSA believes that 0.02 g/dL is an appropriate set point because it is an appropriate level to test the presence of alcohol among offenders using ignition interlocks and it is our understanding that the technology is available for BAIIDs to have a set point at 0.02 g/dL.

A few commenters stated that the 1992 Model Specifications for accuracy and precision were appropriate. Most commenters indicated that with improved technology, a greater degree of accuracy was possible, but did not specify to what degree. One interlock manufacturer advocated 95 percent accuracy with a precision of 19 out of 20 test trials at 0.01 g/dL above the set point for unstressed conditions (*i.e.,* normal) and 100 percent accuracy and with a precision of 20 out of 20 test trials at 0.02 g/dL above the set point for stressed conditions (*i.e.,* atypical, such as extreme temperatures).

Accuracy is the degree to which a BAIID measures the BrAC correctly. For example, for a BAIID to be accurate, a breath sample with no alcohol present (0.000 g/dL) must not lock the ignition. Precision is the degree to which that same measure can be repeated. In the previous example, for that BAIID to be precise, that same alcohol free breath sample should not lock the ignition 20 out of 20 test trials.

NHTSA agrees with the commenters that because of improved technology, BAIIDs should be subject to a higher degree of accuracy and precision. NHTSA proposes to define the accuracy and precision requirements for BAIIDs by testing at ±0.012 g/dL above and below the nominal set point of 0.02 g/dL, i.e., 0.032 g/dL and 0.008 g/dL, respectively. At 0.032 g/dL, not more than 1 ignition unlock in 20 trials would be allowed. At 0.008 g/dL, not more than 1 ignition lock in 20 trials would be allowed. No ignition locks in 20 trials would be allowed at 0.000 g/dL. This increases the accuracy from 90 percent to 95 percent at ±0.012 g/dL above and below the nominal set point of 0.02 g/dL, and 100 percent at 0.000 g/dL. NHTSA determined these proposed test levels by using standard statistical techniques for small samples.

B. Sensor Technology

Most commenters stated that it is important to require alcohol-specific technology in the Model Specifications, but that the particular sensor design should not be specified. A small group, including States, favored the use of a particular sensor design (*e.g.,* fuel cell). One interlock manufacturer stated that a non-alcohol-specific technology, such as a semi-conductor that senses alcohol differently and costs about 50 percent less than a fuel cell, was an economic alternative to the fuel cell.

While alcohol-specific sensor technologies have made great advances, this proposal does not limit the sensor technology used in the BAIIDs as long as the BAIID meets the performance requirements of the Model Specifications. We believe that this approach will allow a wider variety of options, including the use of emerging technologies as they become available.

C. Sample Size Requirement

Most commenters advocated lowering the current 1.5 Liters (L) minimum sample size (to either 1.2 L or 1.0 L). A subset of these commenters felt that anything lower than 1.2 L should be set only on recommendation of a physician. One commenter thought that a 1.5 L air sample was not enough to ensure an accurate measure of the alcohol content. NHTSA agrees with the recommendation to lower the minimum sample size to 1.2 L and proposes a minimum 1.2 L sample size. NHTSA believes that, at this level, accuracy can be attained and that users will be able to deliver this smaller sample size.

Some commenters felt that a minimum back pressure, which controls the force of the air entering the BAIID, was not necessary if the sample size was not lower than 1.0 L. One commenter suggested requiring 1.2 L sample size with a minimum back pressure and a flow rate of 0.2 L/second. A manufacturer suggested requiring 1.2 L sample size with a back pressure of 20 hectoPascal (hPa) (e.g., 2 kiloPascals (kPa)) and a flow rate of 0.1 L/sec. One State suggested an exhale-inhale-exhale pattern as an alternative to setting a standard. Two States suggested a 1.2 L sample size with back pressure, temperature and time requirements. Two commenters felt that NHTSA should only set the minimum sample size, and should not prescribe the means by which the sample delivery would be accomplished.

In addition to lowering the minimum sample size to 1.2 L as discussed above,

NHTSA proposes to require a minimum flow rate of 0.1 L/sec. Flow rate is the length of time that a sample breath is delivered into the BAIID. NHTSA believes that a 0.1 L/sec minimum flow rate is a level that will enable more people to deliver an adequate sample. By lowering the minimum sample size and adding a minimum flow rate, NHTSA does not believe that specifying a minimum back pressure is necessary. NHTSA believes that this proposal will make the BAIID available to a larger population of users.

D. Extreme Temperature Testing, Removable Sensing Heads or Units

One interlock manufacturer suggested that NHTSA test for extreme temperature at −45 °C, as temperatures reach that level in high latitudes and high altitudes. Another interlock manufacturer suggested that NHTSA leave the testing temperature unchanged and continue to allow the sensing unit to be removed from the vehicle. Most commenters felt that the current testing temperature extremes of −40 °C and +85 °C were appropriate, but did not object to tests at more extreme temperatures. The CENELEC suggested that the component of the device that is mounted in the engine compartment be tested for +125 °C in addition to −45 °C. CENELEC further suggested that the −45 °C temperature test be conducted at 75 percent of nominal battery voltage because extreme temperatures can reduce available voltage from a vehicle battery.

NHTSA proposes to retain the current extreme temperature tests at −40 °C and +85 °C. The agency believes that the current temperature range is reasonably representative of the environments encountered in the United States. However, NHTSA proposes to conduct additional high temperature tests for components of the BAIID installed in the passenger compartment (at +49 °C) and in the engine compartment (at +85 °C), and to specify the humidity level for these high temperature tests. Further, NHTSA proposes to discontinue testing at −20 °C and +70 °C because our experience indicates that testing at the extreme temperatures is sufficient.

NHTSA also agrees that the −40 °C temperature test should be performed at 9 volts, which is representative of 75 percent of the nominal battery voltage (i.e., 12-volt automobile battery). NHTSA believes that the test should be conducted at this voltage because vehicles often do not operate at the optimal battery voltage. Accordingly, NHTSA proposes to test BAIIDs using a 9-volt direct current (DC) power source, simulating a 12-volt DC battery operating at low temperatures.

Many commenters stated that NHTSA should not allow the removal of the sensing unit because BAIIDs are expected to operate at a variety of ambient temperature conditions. One State favored a removable mouthpiece (to protect users' lips from extreme temperatures), rather than a removable sensing unit, and another State favored a prescribed warm-up period. NHTSA agrees with the commenters that the sensing unit should not be removable because it can more easily be damaged or mishandled, leading to frequent repairs and increased cost. Accordingly, NHTSA proposes to test only BAIIDs without removable sensing heads or units. (The agency does not object to BAIIDs with a removable mouthpiece.)

E. RFI or EMI Testing

Commenters noted that appropriate power for RFI testing should be considered because an increasing number of electronic devices are being operated in close proximity to BAIIDs, such as gaming, remote keyless entry, portable medical and Bluetooth-capable devices. Two BAIID manufacturers suggested that the European Standard for EMI be adopted because it describes electromagnetic compatibility of vehicles for broadband and narrowband interference and shielding. Two commenters noted that CB radios were more relevant sources of interference and that the CENELEC standard is unnecessarily restrictive on EMI. A State government commenter suggested that the Society of Automotive Engineers (SAE) J551 Vehicle Electromagnetic Immunity-Bulk Current Injection Standard be applied to BAIIDs.

NHTSA agrees that the current specifications do not adequately define or describe RFI/EMI tests. NHTSA proposes to test BAIIDs for emissions and transmissions of RFI/EMI and immunity to RFI/EMI using the SAE Surface Vehicle Standard J1113 series for Class C devices (devices essential to the operation or control of the vehicle) and the International Special Committee on Radio Interference (CISPR), Subcommittee of International Electrotechnical Committee (IEC), specifically CISPR 25, for RFI/EMI testing. NHTSA proposes these tests because we believe that they represent a broad consensus in the industry.

F. Tampering and Circumvention Testing

There was some criticism that the 1992 Model Specifications for tampering and circumvention testing are confusing and lack specificity. One BAIID manufacturer felt that the U.S. should adopt the CENELEC standards for charcoal filters, water bubbler, condensation through a long cool tube and pressurized air, and interlock bypass. Another BAIID manufacturer commented that there are aspects of the circumvention detection specifications that are difficult to quantify because different companies develop their own proprietary anti-circumvention strategies (*e.g.,* a learned hum code or toot sequence). This manufacturer commented that program standards should address this by imposing consequences for tampering with devices. Three State government commenters suggested that NHTSA should set higher anti-circumvention standards and have a counter system or data log that records attempts to start the vehicle by bypassing the ignition. One State thought that the use of time, pressure, differing blow patterns and breath temperature should help prevent circumvention. States believed that device design should not present challenges to the user, and that the individual's breath signature should be used as the basis for anti-circumvention efforts.

Although NHTSA believes that an individual's breath signature (i.e., a person's unique breath pattern) is a good goal for the future, NHTSA's proposal does not include individual breath signature as an anti-circumvention measure. NHTSA does not believe that technology is sufficiently advanced to warrant including individual breath signature in this proposal. However, NHTSA agrees with commenters that the circumvention requirements are confusing. Accordingly, the agency proposes to clarify and specify the requirement for circumvention and tampering tests and to specify that the BAIID must have tamper proof seals to indicate when a BAIID has been disconnected from the ignition.

G. Vehicle-interlock interface

Interlock manufacturers and providers supported a standard interlock-vehicle interface, and recommended that NHTSA require all vehicles to have either a communications bus interface or another hard-wired interface connector for specific use for any ignition interlock device. Other commenters suggested that a common interface would be a great convenience since it would make installation easier. However, two automobile manufacturers commented that although there may be benefits, requiring all vehicles to have a common interface for BAIIDs presented significant challenges

that could compromise vehicle ignition security systems and anti-theft immobilizing technologies.

While we understand the installation convenience that would be afforded by a common vehicle interlock interface, such a requirement goes beyond the scope of this proposal, which is limited to the BAIID itself and not to changes to the vehicle.

H. Calibration Stability and Service Interval

NHTSA received comments regarding both calibration stability and service interval requirements. Some manufacturers commented that NHTSA should establish separate requirements for the minimum period of calibration stability and the service interval. NHTSA notes that these two requirements are interrelated. If a BAIID's calibration remains stable for a given period of time, it follows that service will be required after that period to verify the calibration of the BAIID. For clarity, NHTSA proposes to define calibration stability as the ability of the BAIID to hold its accuracy and precision over a defined time period and calibration interval as the maximum time period that a BAIID may be used without a calibration check, after which the ignition must lock. NHTSA proposes to define the service interval as the maximum time period that a BAIID may be used without maintenance.

For both the calibration interval and the service interval, most commenters stated that the BAIID should enter a lockout countdown to notify the BAIID user that the BAIID needs a calibration check or maintenance, service or data download, and the BAIID should prevent the vehicle from starting at the end of the lockout countdown period. In response to these comments, NHTSA proposes to incorporate a 7-day lockout countdown for both calibration interval and service interval. NHTSA believes that requiring a lockout countdown for both the calibration interval and the service interval is important to ensure that the BAIID is accurately reading breath samples and is properly working. NHTSA further proposes that during the lockout countdown period, the BAIID should notify the user of the time remaining before the ignition locks. However, NHTSA declines to impose any countdown or lockout requirement for downloading data, as this decision should properly be left to the States or the courts for decision.

NHTSA proposes to revise the calibration stability requirements. The 1992 Model Specifications called for calibration stability for 7 days beyond the manufacturer's designated calibration stability period of 30, 45, or 60 days. For example, if the manufacturer required that the calibration of BAIIDs be checked after 60 days, the BAIID would need to hold the calibration for 67 days. NHTSA now proposes that BAIIDs must hold calibration for a minimum 30 days plus the 7-day lockout countdown described previously (i.e., 37 days) in order to conform to the Model Specifications. Although some manufacturers have BAIIDs that are claimed to hold calibration for a longer time period, NHTSA proposes to test the calibration stability at 37 days (i.e., 30 days plus the 7-day lockout countdown) and to require lockout after 37 days. Accordingly, NHTSA proposes that only BAIIDs that meet both the 37-day calibration stability test and the 30+ 7-day lockout countdown function will be listed on the CPL.

NHTSA also proposes to add service interval requirements. The 1992 Model Specifications did not specifically require a service interval period. Although the term "service interval" is used in the 1992 Model Specifications, that term was used only in relation to calibration stability. It is our understanding that some States use this term to denote the time period for maintenance and data download as well as calibration stability checks. Commenters from State governments recommended that NHTSA require that BAIIDs have a service interval not greater than 30 days, plus a 7-day lockout countdown. NHTSA agrees with these comments and proposes to incorporate this requirement in the Model Specifications because requiring regular maintenance checks is important to ensure that the BAIID is properly working. As noted above, we do not specify a lockout requirement for data download.

I. Ready-to-Use Times and Retest

Commenters stated that a quicker ready-to-use time is possible with newer technology. A commenter stated that one of the biggest complaints with users of BAIIDs is the waiting time for the breath test, and that reducing the waiting time may increase the acceptance of BAIIDs. Several manufacturers indicated that a faster ready time of 3 minutes at low temperatures was achievable.

NHTSA agrees that with current technology, BAIIDs can be ready for use faster than the times provided under the 1992 Model Specifications. NHTSA proposes that at temperatures above −40 °C (−40 °F), BAIIDs should be ready for use in 1 minute or less and be ready to retest in 1 minute or less. For temperatures at −40 °C (−40 °F), NHTSA proposes that the BAIID should be ready for use in 3 minutes or less and ready to retest in 3 minutes or less. NHTSA proposes to test this performance.

NHTSA does not intend that retests be conducted while the vehicle is moving, but rather while the engine is running with the vehicle stopped in a safe location on the side of the road. The proposed Model Specifications make this point clear.

J. NHTSA Testing

Commenters favored a certified testing laboratory program. Most advocated a NHTSA test program and the development of a Conforming Products List (CPL) based on the Model Specifications. One commenter favored having a single private testing laboratory certified by NHTSA for this purpose. Several manufacturers noted significant problems with State certification requirements leading to questionable test results for some products. In general, both manufacturers and States favored a NHTSA test program because it would organize and standardize the industry and exclude less effective BAIIDs. One commenter suggested that NHTSA require BAIID re-certification in the event of an instrument design change and/or at some reasonable interval.

NHTSA proposes to test BAIIDs for conformance with the Model Specifications. See Appendix A for proposed BAIID submission procedures. NHTSA also proposes to maintain and publish periodically a CPL with BAIIDs that have been tested and found to conform to the Model Specifications. NHTSA proposes to manage this new program as it does its other breath alcohol instrument testing programs, including the re-examination of BAIIDs at its sole discretion (Appendix B) and requiring manufacturers to inform NHTSA of any changes or modifications to a tested BAIID. As with NHTSA's other testing programs, NHTSA also proposes to require manufacturers to submit a quality assurance plan (QAP) for BAIIDs being tested. A QAP is a manufacturer's plan for maintaining the integrity and the calibration of a BAIID. NHTSA proposes that the QAP include the following information: instructions for checking the calibration of the BAIID (*i.e.,* recommended calibrating unit, BrAC of 0.02 g/dL, agreement not greater than ±0.005 BrAC, verification of accuracy of readout, actions to take for failed calibration check), instructions for downloading the data from the data logger, instructions to maintain the BAIID, instructions on checking for

tampering, and any other information regarding quality assurance unique to the instrument. See Appendix C, the proposed sample QAP template.

Testing of BAIIDs will be subject to the availability of Federal funds. If Federal funds are not available, NHTSA will discontinue testing BAIIDs until funds become available.

K. International Harmonization

There was considerable variability from commenters on this issue. Those favoring harmonization with the CENELEC standards argued that in an increasingly global marketplace, common standards would benefit both economic and safety concerns. Some against harmonization stated that aspects of the CENELEC standard are potentially restrictive and costly. Others opposed harmonization because the U.S. organized the BAIID industry by emphasizing safety and design flexibility in a way that encouraged the domestic industry and avoided costly requirements.

NHTSA believes that there are some benefits to harmonizing some standards, and has proposed to incorporate aspects of CENELEC standards as identified elsewhere in this proposal.

L. Interlock Program Specifications

Some commenters stated that interlock program specifications or interlock program guidelines (*i.e.,* programs to implement the use of BAIIDs) have been and should remain a function of State government. Others largely expressed support for NHTSA development of interlock program guidelines, especially in the areas of installation requirements, monitoring and recalibration of devices, and recognizing device tampering. While NHTSA believes that such a program is important, today's notice addresses only BAIID performance criteria and testing of BAIIDs. NHTSA may explore interlock program guidelines in a future action.

M. Acceptance Testing

Some commenters stated that acceptance testing is being performed by some States, but that the criteria vary among those States. These commenters stated that NHTSA should establish standardized acceptance-testing procedures in addition to the 1992 Model Specifications. Several commenters requested that the term "acceptance testing" be more clearly defined. One commenter recommended that NHTSA establish enforceable guidelines, mandatory audits and periodic re-examinations.

NHTSA defines "acceptance testing" as the pass-fail evaluation of each individual device performed before placing that device into service. Because of limited resources, NHTSA proposes to conduct "type-testing" (*i.e.,* testing of a sample of a particular model of BAIID, rather than every device manufactured).

N. Additional Comments

1. Two commenters suggested that BAIID manufacturers make available the operating software codes of the BAIIDs, including disclosure of how the BAIIDs monitor their own malfunctions and the criteria the devices use to trigger recalls. NHTSA does not believe that making a manufacturer's proprietary software publicly available is desirable or necessary, as the agency's proposal sets forth performance specifications, not design specifications. Moreover, making such information public may lead to increased circumvention and tampering.

2. Commenters suggested that data loggers distinguish calibration tests from user samples. NHTSA agrees that distinguishing such information would be useful for monitoring the BAIID user. Accordingly, NHTSA proposes that the BAIID must include a data logger that will distinguish calibration tests from user samples as well as record all start attempts and outcomes, such as emergency override, circumvention, tampering, and BrAC for each start attempt. The data must be presented in chronological order (*i.e.,* by date and time of event). See Appendix D for a sample format for downloaded data from the data logger. The audit trail should also indicate the version of the metrological software (*i.e.,* the BAIID's operating system) in use. All printed and downloaded reports should indicate the software version. NHTSA proposes to test these features.

The agency understands that some customers (such as States) request certain changes to the BAIID, so that read-out data is presented in a particular format. Such customization is generally accomplished through software modifications. Testing customer-driven software modifications is beyond the scope of this program. Moreover, if such modifications were permitted to be performed to the internal software of the BAIID at a customer's behest, the integrity of the CPL would be compromised as the BAIID tested could then differ from customized devices in production. However, NHTSA is aware that States (and local jurisdictions) use different set points in their interlock programs. Therefore, we do not believe that changes to the set point, alone, should be deemed impermissible modifications. Accordingly, the agency's proposal does not allow any modifications of internal BAIID software at the behest of customers, except for adjustments to the set point. (We note that for testing purposes, NHTSA proposes to test BAIIDs with an alcohol set point of 0.02 g/dL.) Manufacturers wishing to accommodate a customer's interest in data formatting options should do so by providing a port that allows connection of a peripheral device with its own formatting software. Manufacturers are advised that, when submitting a BAIID to NHTSA for testing, they must submit the basic model without any customized or add-on software.

3. Commenters suggested that the BAIID memory should be located in a fixed control box. NHTSA agrees with these commenters and proposes to add this to the General Requirements and BAIID Features because a fixed control box provides less opportunity for potential damage to the BAIID memory.

4. Commenters suggested that restarts should be allowed only if a vehicle stalls, but not if the ignition is intentionally turned-off or if a BAIID malfunctions or is awaiting a retest. NHTSA proposes that a restart (*i.e.,* without a breath sample) should be allowed when the vehicle stalls, provided the restart is accomplished in no more than 20 seconds. NHTSA also proposes that in all other situations where the vehicle malfunctions, the vehicle should be prevented from starting without a breath test.

Commenters further suggested that if a BAIID malfunctions or fails, the device should default to preventing the vehicle from starting. NHTSA agrees with the commenters and proposes that if a BAIID malfunctions or fails (*e.g.,* improper voltage, temperature exceeding operating range, dead sensor, etc.), the BAIID should prevent the vehicle from starting.

5. Some commenters stated that an emergency override was a useful feature. NHTSA declines to propose that BAIIDs be required to have an emergency override feature (*i.e.,* the ability to start the vehicle without a breath test) in order to conform with the Model Specifications. However, should a BAIID be equipped with an emergency override feature, NHTSA proposes to allow its activation to start the vehicle only once. After that, the BAIID must indicate the need for service and record the use of the emergency override. No additional emergency overrides would be allowed during the lifetime of the BAIID installation. The agency proposes to test this feature. NHTSA also proposes that this emergency override feature have a default to prevent an

override from being used when the BAIID malfunctions or fails. *See* Section II, N, 4 above.

6. A commenter suggested that the BrAC test results be displayed to the driver. NHTSA declines to propose that BAIIDs display the BrAC test results to the driver and does not propose to add this requirement in the Model Specifications. NHTSA believes that the role of the BAIID is to detect the presence of alcohol and to prevent the driver from operating the vehicle if alcohol is present. We believe that displaying the BrAC goes beyond the purpose of the BAIID. Accordingly, NHTSA does not propose to test BAIIDs for the accuracy of the BrAC display. NHTSA proposes to test only the accuracy of the notifications to a BAIID user that are related to the features tested by NHTSA, such as warm-up time, retest, calibration check and service interval.

In addition, NHTSA proposes to remove a number of tests for optional features identified in the 1992 Model Specifications.

7. A commenter suggested that an interlock-specific tone (other than a honking horn) be used to alert outsiders to BAIID violations. At this time, NHTSA does not believe that audible sounds or lights to alert the public to interlock violations are necessary, and does not include the suggestion in this proposal.

8. A commenter suggested that several CENELEC standards be adopted into the Model Specifications, including a dust test, a drop test for removable sensor heads, vibration tests, and protection against reverse polarity on all circuits. That commenter also suggested that instruction guides or manuals be provided to the interlock installers and user.

In two decades of experience, NHTSA has received no reports suggesting that dust is an issue or source of concern in BAIIDs installed in vehicles. Therefore, we are not proposing a dust standard. As the agency's proposal does not allow the removal of the sensor head, we are not proposing a drop test. NHTSA proposes to update the vibration and cigarette smoke tests from the 1992 Model Specifications to incorporate aspects of the CENELEC standard (*see* Test 7 and Test 12, respectively). NHTSA agrees with the commenter that electrical properties of the vehicle (contact safety, etc.) must not adversely affect or be affected by a properly installed BAIID. NHTSA also agrees that instruction guides or manuals should be made available to interlock installers and users.

O. Other Proposed Revisions

The agency proposes to re-organize the Model Specifications to improve clarity. NHTSA also proposes to delete the commentary sections of the 1992 Model Specifications because these sections are no longer necessary. Also, we have not retained the previous organization of sections on safety and utility, and we have specified in more detail the tests for humidity, cigarette smoke, retest, and circumvention and tampering. In addition, the proposed Model Specifications no longer include a separate test for user displays, but rather incorporate the test for user display under other tests (*e.g.,* warm up time, retest, calibration interval, service interval). The proposed Model Specifications delineate conformance tests and performance requirements.

NHTSA proposes to delete the following terms as no longer applicable: Safety and Utility (Safety Feature, Utility Feature, and Optional Feature), Stress Tests, Certification Tests, Clearance Rates, Device, Fail-safe, False-negative, False-positive, High end and Low end. NHTSA also proposes to add three terms—calibration stability, calibration interval, and service interval. *See* Section II, H.

NHTSA proposes to delete the Certification Test Summary and the Equipment List that appeared in Appendices A and B because these provisions are obsolete, and relevant information is incorporated in the Tests.

NHTSA proposes to add two tests to the Model Specifications—High Altitude (Test 11) and Acetone (Test 13). NHTSA believes that because high altitudes may affect semi-conductor type alcohol sensors, this condition should be tested. NHTSA believes that acetone should be tested because it is the most common interfering substance for BAIIDs. Finally, of the tests listed, Test 17 (Data Integrity and Format) must be performed last as this test checks the integrity of the downloaded data. See also Appendix D for a sample format for downloaded data from the data logger.

In addition, NHTSA proposes that in order to be listed on the CPL, manufacturers must submit a self-certification, certifying that the manufacturer meets the requirements of the U.S. Department of Health and Human Services Public Health Services, Food and Drug Administration's (FDA) Good Manufacturing Practices regulations for devices used for medical purposes (21 CFR Part 820), and that the device's label meets the requirements contained in FDA's Labeling regulations for devices used for medical purposes (21 CFR 809.10), even if the devices are not to be used for medical purposes. If NHTSA becomes aware that a manufacturer of a BAIID on the CPL is not in compliance with the requirements in FDA's Good Manufacturing Practices regulations for devices used for medical purposes or that the device's label does not comply with the requirements in FDA's labeling regulations for devices used for medical purposes, NHTSA may remove the manufacturer's BAIID from the CPL.

The agency encourages interested parties to review carefully this notice and the Model Specifications set forth below, and to submit comments in the manner identified in Addresses above.

These proposed Model Specifications, if adopted in final, would not have the force of regulations and are not binding. States and others may adopt these Model Specifications and rely on NHTSA's type-test results or they may conduct their own tests according to their own procedures and specifications.

After consideration of the comments, the agency proposes the Model Specifications for Breath Alcohol Ignition Interlock Devices as set forth below.

Authority: 23 U.S.C. 403; 49 CFR 1.50; 49 CFR part 501.

Model Specifications for Breath Alcohol Ignition Interlock Devices (BAIID)

A. Purpose and Scope

1. In General

The purpose of these specifications is to establish performance criteria and test methods for breath alcohol ignition interlock devices (BAIIDs), commonly referred to as alcohol interlocks or ignition interlocks. BAIIDs are breath alcohol sensing instruments designed to be connected to the ignition system in a way that prevents the motor vehicle from starting unless the driver first provides a breath sample whose alcohol concentration is below the set point into the BAIID. If the measured breath alcohol concentration (BrAC) is at or above a set level, the ignition is locked and the vehicle will not start. BAIIDs are currently being used as court sanctions as well as administrative conditions of licensure. Drivers convicted of Driving While Intoxicated (DWI) may be required to use BAIIDs in their vehicle under court supervision or as part of a required path to full reinstatement of driving privileges. These specifications are intended for use in conformance testing of BAIIDs installed in vehicles. BAIIDs found to conform to these specifications will be placed on a conforming products list

(CPL) published in the **Federal Register**. NHTSA will periodically update this CPL. These specifications are voluntary and do not impose any compliance obligations on BAIID manufacturers or others.

2. Limitations

NHTSA will test BAIIDs for conformance with these Model Specifications on a first-come, first-served basis, subject to the manufacturer submission requirements of Appendix A. Any re-examination of BAIIDs will be conducted at the agency's sole discretion, in accordance with the provisions of Appendix B. All tests are subject to the availability of Federal funds.

B. Terms

Alcohol—Ethanol or ethyl alcohol (C_2H_5OH).

Alcohol set point—Breath Alcohol Concentration (BrAC) at which a BAIID is set to lock the ignition.

Breath Alcohol Concentration (*BrAC*)—The amount of alcohol in a given amount of breath, expressed in weight per volume (w/v) based upon grams of alcohol per 210 liters (L) of breath, in accordance with the Uniform Vehicle Code, Chapter 11, Section 11–903.4 and 5.[1]

Breath alcohol ignition interlock device (BAIID)—A device that is designed to allow a driver to start a vehicle if the driver's BrAC is below the set point and to prevent the driver from starting the vehicle if the driver's BrAC is at or above the set point.

Breath Sample – Normal expired human breath primarily containing air from the deep lung.

Calibration Interval—The maximum time period that a BAIID may be used without a calibration check, after which the ignition must lock.

Calibration Stability—The ability of a BAIID to hold its accuracy and precision over a defined time period.

Circumvention—An attempt to bypass the correct operation of a BAIID, whether by use of an altered breath sample, by starting the vehicle without using the ignition switch, or by any other means without first providing a breath sample.

Filtered air sample—Any human breath sample that has intentionally been altered so as to remove alcohol from it.

Interlock Data Logger—A device within a BAIID that records all pertinent events, dates, and times during the period of installation and use of a BAIID.

Retest—A breath test that is required after the initial engine start-up breath test and while the engine is running with the vehicle stopped in a safe location on the side of the road. This is also referred to as a running retest or a rolling retest.

Service Interval—The maximum time period that a BAIID may be used without maintenance or data download, after which the ignition must lock.

Simulator—A device that produces an alcohol-in-air test sample of known concentration (*e.g.,* a Breath Alcohol Sampling Simulator (BASS))[2] or a device that meets the NHTSA Model Specifications for Calibrating Units (72 FR 34742)).

Tampering—An attempt to physically disable, disconnect, adjust, or otherwise alter the proper operation of a BAIID.

C. General Requirements and Features of BAIIDs

In order to be listed on NHTSA's Conforming Products List (CPL), a BAIID must meet the following requirements:

The BAIID must pass each of the conformance tests 1 through 17 in Section D, unless explicitly excluded from a test by the specific terms of these specifications.

Installation and service of the BAIID in a vehicle must not compromise any normal function of the vehicle, including anti-theft functions, on-board computer functions, or vehicle safety features required by the Federal Motor Vehicle Safety Standards, and must not cause harm to the vehicle occupants. Care should be taken to protect against reverse polarity and damage to other circuits and to ensure that the BAIID does not drain the vehicle's battery while in sleep mode (*i.e.,* power save mode).

The BAIID must not have a removable sensing head or unit, but may include the use of a detachable mouthpiece for breath sample delivery.

The BAIID memory must be in a fixed control box.

The BAIID must have tamper proof seals to indicate when a BAIID has been disconnected from the ignition.

The BAIID must be capable of locking out at a specified breath alcohol concentration. The submitted BAIID will be tested at an alcohol set point of 0.02 g/dL with a minimum flow rate of 0.1 L/sec. Upon detecting an alcohol concentration at or above that set point, the BAIID must lock the ignition for a period of time before another test can be performed.

If the vehicle is equipped with a remote start device, the BAIID must be installed so that the remote start function is bypassed or disabled so that a valid breath test must be performed before the vehicle may be started.

The BAIID must include clear instructions to the driver (*e.g.,* when to blow, when to wait, when to start the vehicle, when to retest, when a lockout countdown occurs, including the time remaining before the BAIID locks the vehicle's ignition, and when to seek service).

Manufacturers must submit the operator's manual (user's guide or instructions to the user), the maintenance manual, and specifications and drawings fully describing the BAIID to the Volpe Center.

In addition, manufacturers must submit the quality assurance plan (QAP) to NHTSA for approval. The QAP must include the following information: instructions for checking the calibration of the BAIID (*i.e.,* recommended calibrating unit, BrAC of 0.02 g/dL, agreement not greater than ±0.005 BrAC, verification of accuracy of readout, actions to take for failed calibration check), instructions for downloading the data from the data logger, instructions to maintain the BAIID, instructions on checking for tampering, and any other information regarding quality assurance unique to the BAIID. *See* Appendix C for sample QAP template.

Manufacturer must also submit a self-certification to NHTSA, certifying that the manufacturer meets the requirements of the U.S. Department of Health and Human Services Public Health Services, Food and Drug Administration's (FDA) Good Manufacturing Practices regulations for devices used for medical purposes (21 CFR Part 820), and that the device's label meets the requirements contained in FDA's Labeling regulations for devices used for medical purposes (21 CFR 809.10), even if the devices are not to be used for medical purposes. (If NHTSA becomes aware that a manufacturer of a BAIID on the CPL is not in compliance with the requirements in FDA's Good Manufacturing Practices regulations for devices used for medical purposes or that the device's label does not comply with the requirements in FDA's labeling regulations for devices used for medical purposes, NHTSA may remove the manufacturer's BAIID from the CPL.)

The design of the BAIID must include a data logger that will record all start

[1] Available from the National Committee on Uniform Traffic Laws and Ordinances, 107 South West Street, #110, Alexandria, VA 22314 (*http://www.ncutlo.org*).

[2] *See* NBS Special Publication 480–41, July 1981. Available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

attempts and outcomes, including an emergency override, delineation of calibration checks, circumvention, tampering, operator attempts to start the vehicle, and BrAC for each start attempt. The data must be presented in chronological order (*i.e.,* by date and time of event). *See* Appendix D for a sample format for downloaded data from the data logger. The manufacturer must provide NHTSA with a means of downloading the data from the data logger.

The BAIID must track all changes to the metrological software and indicate the software version and date on all printed and downloaded reports. The BAIID must not include any add-on or specialized software to meet the needs of a specific customer. Manufacturers wishing to accommodate a customer's interest in data formatting options should do so by providing a port that allows connection of a peripheral device with its own formatting software. We are aware that States (and local jurisdictions) use different set points in their interlock programs, and such changes to the set point, alone, would not be deemed impermissible. However, NHTSA will test BAIIDs at an alcohol set point of 0.02 g/dL.

D. BAIID Test Procedures

General Test Conditions

Unless otherwise specified in the conformance test, the following conditions apply to each test:

- Number of trials at each alcohol level = 20
- Ambient temperature: 22 °C ± 3 °C (71.6 °F ± 5.4 °F).
- Ambient atmospheric pressure: 97.5 kPa ± 10.5 kPa (25.7 and 31.9 inches Hg).
- Sample parameters: volume 1.2 liters; ambient flow rate 0.3 Liters per second; maximum delivery pressure 2.5 kPa; temperature 34 °C (93.2 °F)
- Simulated breath samples will be generated by the BASS[3] or by a wet bath type calibrating unit that is listed on the NHTSA Conforming Products List for such devices. Solutions used in the calibrating device will be prepared as described in the NHTSA Model Specifications for Calibrating Units published June 25, 2007 (72 FR 34742).

Performance Requirements

Unless otherwise specified in the conformance test, the BAIID must meet the following performance requirements in each test:

- Tests at 0.032 g/dL BrAC (grams alcohol/210 liters of air): not more than 1 ignition unlock in 20 trials is allowed.
- Test at 0.008 g/dL BrAC: not more than 1 ignition lock in 20 trials is allowed.
- Tests at 0.000 g/dL BrAC: no ignition lock in 20 trials is allowed.
- A BAIID must be ready for use 1 minute after it is turned on. A BAIID must be ready for a second test within 1 minute of a preceding test.

Conformance Tests

Unless otherwise specified in a test, these conformance tests need not be conducted in any particular order. Except when a test or portion of a test specifically requires the use of a motor vehicle, NHTSA may elect to use either a motor vehicle or a bench test set-up that simulates the relevant functions of a motor vehicle.

Test 1. Precision and Accuracy

Test the BAIID at the following alcohol concentrations:

a. 0.000 g/dL BrAC,
b. 0.008 g/dL BrAC, and
c. 0.032 g/dL BrAC.

Test 2. Breath Sample Volume and Flow Rate

Use a mass flow meter to monitor sample volume. Conduct each test (a–d) five times.

a. Test at 0.000 g/dL BrAC with sample volume 1.0 liter. The BAIID must lock the ignition and indicate insufficient volume 5 out of 5 times.

b. Test at 0.000 g/dL BrAC with sample volume 1.5 liters. The BAIID must not lock the ignition 5 out of 5 times.

c. Test at 0.000 g/dL BrAC with sample volume 1.2 liters at 0.1 L/s. The BAIID must not lock the ignition 5 out of 5 times.

d. Test at 0.000 g/dL BrAC with sample volume 1.2 liters at 0.7 L/s. The BAIID must not lock the ignition 5 out of 5 times.

Test 3. Calibration Interval and Calibration Stability

Initialize the BAIID to begin the calibration stability test. A BAIID must not be re-calibrated after the start of Test 3. Conduct Test 1. Repeat Test 1 at 37 days. Test 2 and Tests 4–15 may be performed between these two Precision and Accuracy tests.

After 30 days, the BAIID must prominently indicate a 7-day lockout countdown, *i.e.,* an indication that the BAIID must be taken to a designated facility for a calibration check within 7 days or the ignition will lock and the event will be logged. Over the course of the 7-day lockout countdown, the BAIID must prominently indicate that the BAIID needs a calibration check, the time remaining until ignition lockout, but the ignition must not lock. At the end of this 7-day lockout countdown, the BAIID must prominently indicate that the BAIID needs a calibration check and the ignition must lock.

Test 4. Input Power

Conduct Test 1b and Test 1c at the following input power conditions:

a. Test at 11 VDC input power.
b. Test at 16 VDC input power.

Test 5. Extreme Temperature and Humidity

Using a temperature/humidity chamber:

a. Soak the BAIID at −40 °C (−40 °F) for 1 hour, then conduct Test 1b and Test 1c at that temperature using 9 VDC input power.

b. Soak the BAIID at 49 °C (120 °F), 95 percent relative humidity for 1 hour, then conduct Test 1b and Test 1c at that temperature and humidity using 16 VDC input power.

c. This part of the test applies only to BAIIDs with components installed in the engine compartment. Soak the components of the BAIID that are installed in the engine compartment at 85 °C (185 °F), 95 percent relative humidity for 1 hour, then conduct Test 1b and Test 1c at that temperature and humidity using 16 VDC input power. The components that are installed in the passenger compartment should remain at ambient temperature and humidity conditions (see General Test Conditions).

Test 6. Warm Up Time at −40 °C

Using a temperature chamber, soak the BAIID for 1 hour at −40 °C. With input power set at 9 VDC, the BAIID must be ready to test in 3 minutes, and ready to retest in 3 minutes after being turned on. Conduct Test 6 five times. The BAIID must indicate that it is ready to test or ready to retest in 3 minutes all five times. This test may be conducted in conjunction with Test 5 Extreme Temperature and Humidity.

Test 7. Vibration

Vibrate the BAIID in simple harmonic motion on each of three main axes uniformly through the frequency schedule specified below. For components not intended to be mounted on the engine, vibrate according to Test 7a; for components intended to be mounted on the engine, vibrate according to Test 7b. If a BAIID consists of several components connected by electrical wires or connected wirelessly,

[3] *See* NBS Special Publication 480–41, July 1981. Available from Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

vibrate these components separately. After completion of the vibration, remove the BAIID from the shake table and conduct Test 1b and Test 1c.

VIBRATION FREQUENCY SCHEDULE

Test 7	Frequency range, Hz	Number of cycles	Sweep rate, octave/min	Amplitude, inches 0 to peak	Acceleration, gravity (g), 0 to peak
a	10 to 500	10	1	0.2	3
b	10 to 500	10	1	0.08	15

Test 8. Retest

If a BAIID includes a feature designed to detect whether the vehicle is moving, conduct Test 8 using a motor vehicle. If a BAIID does not include a feature designed to detect whether the vehicle is moving, conduct Test 8 using a motor vehicle or a bench test set-up that simulates the relevant functions of a motor vehicle. Retests must not be conducted while the vehicle is moving, but must be conducted while the engine is running with the vehicle stopped in a safe location on the side of the road.

a. Within an interval of 5 to 7 minutes after a successful ignition unlock, using a 0.000 g/dL BrAC test sample, and while the ignition remains unlocked and the engine is running, the BAIID must indicate that a second breath sample is required. Conduct Test 1b five times. The ignition must remain unlocked all 5 times.

b. Within an interval of 5 to 7 minutes after a successful ignition unlock, using a 0.000 g/dL BrAC test sample, and while the ignition remains unlocked and the engine is running, the BAIID must indicate that a second breath sample is required. Conduct Test 1c five times. The ignition must remain unlocked, but the BAIID must prominently indicate the need for a service call (i.e., this is an indication of a failed retest).

A failed retest must be identified as an alert condition and flagged on the data logger. A missed retest must be flagged on the data logger. After the driver is alerted to retest, if the engine is accidentally or intentionally powered off, the BAIID must not unlock without a service call. If a BAIID includes a feature designed to detect whether the vehicle is moving, perform the above tests with and without vehicle movement.

Test 9. Tampering and Circumvention

Attempt to start the ignition as indicated below. Conduct each test (a through f) five times. Each attempt to start the engine must be logged by the data logger.

a. "*Hot wiring*". Start the engine by electrically bypassing the BAIID. The data logger must record the ignition on with no breath test.

b. *Push start.* A motor vehicle must be used for this part of Test 9. Use a vehicle equipped with a manual transmission. Start the engine by pushing the vehicle with another vehicle or by coasting the vehicle downhill before engaging the clutch. The data logger must record the ignition on with no breath test.

c. *Un-warmed air sample.* Deliver an alcohol-free air sample of at least 2 liters into the BAIID using an air filled plastic bag which is fitted to the sampling tube and squeezed in a manner that mimics a person blowing into the BAIID. The ignition must remain locked.

d. *Warmed air sample.* Prepare a 12-ounce foam coffee cup fitted with a bubble tube inlet and a vent tube (rubber or tygon tubing) attached through the plastic lid. Fill the cup with 8 ounces of water warmed to 36 °C and attach the lid. Attach the vent tube to the BAIID and pass an air sample of at least 2 liters through the bubble tube into the heated water and thence into the BAIID. The flow rate must not be high enough to cause a mechanical transfer of water to the BAIID. The ignition must remain locked.

e. *Cooled 0.032 BrAC sample.* Attach a 4 foot long tygon tube of ⅜ inch inside diameter which has been cooled to ice temperature to the inlet of the BAIID, then test at 0.032 BrAC. The ignition must remain locked.

f. *Filtered 0.032 BrAC sample.* Prepare a 1 to 2 inch diameter 3 to 5 inches long paper tube loosely packed with an active absorbent material. Use loose cotton plugs to retain the absorbent in the paper tube. Pack the tube so that a person can easily blow 2 liters of air through the assembly within 5 seconds. Test the absorbent by passing a 2 liter 0.032 BrAC sample though the assembly within 5 seconds. If the air passing out of the BAIID is found to have a concentration of 0.006 BrAC or less, prepare 5 tubes packed in the same manner, fit separately to the BAIID and test at 0.032 BrAC. The ignition must remain locked.

Test 10. Restart of Stalled Motor Vehicle

Conduct Test 10 using a motor vehicle.

Using a 0.000 g/dL BrAC sample, turn on the ignition. Turn off the ignition. Attempt to restart the ignition without a breath sample in less than 20 seconds—the ignition must not lock. Turn off the ignition. Attempt to restart the ignition without a breath sample between 20 to 25 seconds after turning off the ignition—the ignition must lock. Conduct Test 10 five times.

Test 11. High Altitude

This test applies only to BAIIDs with a semiconductor-type alcohol sensor. Conduct Test 1b and Test 1c each at pressures of 80 kPa and 110 kPa (600 mmHg and 820 mmHg). Conduct Test 11 five times at each indicated pressure. At indicated pressure levels, for Test 1b, the ignition must remain unlocked; for Test 1c, the ignition must remain locked.

Test 12. Cigarette Smoke

Direct a cigarette smoker, who is alcohol-free, to smoke approximately ½ of a cigarette. The smoker must wait 1 minute or a period specified by the BAIID manufacturer before testing. Conduct Test 12 three times. The ignition must not lock. (A simulator may be used in lieu of a smoker.)

Test 13. Acetone

Test the BAIID for acetone interference. Conduct Test 1b by adding 230 microliters of acetone [4] to the 500 milliliters of .008 g/dL BrAC alcohol simulator solution. Conduct Test 1b three times. The ignition must not lock.

Test 14. Emergency Override

This test applies only to BAIIDs equipped with an emergency override feature. Follow the BAIID manufacturer's instructions to activate the emergency override feature without providing a breath sample. Upon a first

[4] The amount of acetone specified is experimentally determined based on water to air partition factor of 365 to 1 at 34 °C to yield an acetone concentration in the air sample of 0.5 mg/liter.

activation, verify that the BAIID allows the vehicle to start. Attempt to activate the emergency override feature two additional times without providing a breath sample. Verify that the BAIID does not allow the vehicle to start on either of those subsequent attempts. The ignition must not lock on the first attempt, and must lock on both subsequent attempts. All other functions of the BAIID should operate normally, including the running retest and data logging.

Test 15. Radiofrequency Interference/ Electromagnetic Interference

The Society of Automotive Engineers (SAE) Surface Vehicle Standard J1113 series, Required Function Performance Status, as defined in Surface Vehicle Standard J1113–1 for Class C devices (devices essential to the operation or control of the vehicle), and the International Special Committee on Radio Interference (CISPR), Subcommittee of International Electrotechnical Committee (IEC), specifically CISPR 25, will be used to evaluate BAIID electromagnetic immunity and compatibility. The test severity levels are specified below. The tests must be performed while the BAIID is in the drive and standby modes.

a. *J1113–1* 2006–10 General and definitions. Electromagnetic Compatibility Measurement Procedures and Limits for Vehicles, Boats, and Machines (Except Aircraft) (16.6 Hz to 18 GHz).

b. *J1113–2* 2004–07 Conducted immunity 30 Hz to 250 kHz—Power leads.

Level	Severity (volts, peak to peak)	Status
1	0.15	I.
2	0.50	I.
3	1.0	I.
4	3.0	II.

c. *J1113–4* 2004–08 Conducted immunity—Bulk Current Injection (BCI) Method.

Level	Severity (milliamps)	Status
1	25 to 60	I.
2	60 to 80	II.
3	80 to 100	III.
4	100	IV.

d. *J1113–11* 2007–06 Immunity to Conducted Transients on Power Leads.

Pulse (12 v sys)	Level	Severity (volts)	Status
	1	−25	I.
1	2	−50	II.
	3	−75	II.
	4	−100	IV.
	1	25	I.
2a	2	40	II.
	3	50	II.
	4	75	IV.
2b	1	10	I.
	1	−35	I.
3a	2	−75	II.
	3	−112	II.
	4	−150	IV.
	1	25	I.
3b	2	50	II.
	3	75	II.
	4	100	IV.
	1	−4	I.
4	2	−5	II.
	3	−6	II.
	4	−7	IV.
5	1	87	IV.

e. *J1113–13* 2004–11 Part 13: Immunity to Electrostatic Discharge.

Severity	Status
Contact discharge	
0–4 kV	I.
4–8 kV	II.
8 kV	IV.
Air discharge	
0–4 kV	I.
4–15 kV	II.
15 kV	IV.

f. *J1113–21* 2005–10 Immunity to Electromagnetic Fields, 30 MHz to 18 GHz.

Severity (V/M)	Status
Up to 60	I.
60–80	II.
80–100	III.
100–150	IV.

g. *J1113–22* 2003–11 Immunity to magnetic fields.

Severity (uT)	Status
40	I.
40–50	II.
50–80	III.
80	IV.

h. *IEC CISPR 25* Limits of Radio Disturbance.

RADIATED DISTURBANCE LIMITS

[1 M test distance, 120 kHz bandwidth]

30–75 MHz	75–400 MHz	400–1000 MHz
a: 62 − 25.13 × log(F/30)	52 + 15.13 × log(F/75)	63
b: 52 − 25.13 × log(F/30)	42 + 15.13 × log(F/75)	53

a: Broadband, quasi-peak detector.
b: Narrowband, average detector.
Limit in dB (uV/M) at frequency F.

CONDUCTED TRANSIENT EMISSIONS

Pulse polarity	Maximum pulse amplitude (12 volt system) (V)
Positive	75

CONDUCTED TRANSIENT EMISSIONS—Continued

Pulse polarity	Maximum pulse amplitude (12 volt system) (V)
Negative	−100

LIMITS FOR BROADBAND CONDUCTED DISTURBANCES (MHZ)

	0.15–0.3		0.53–2.0		5.9–6.2		30–54		68–108	
	P	QP	P	QP	P	QP	P	QP	P	QP
a	93	80	79	66	65	52	65	52	49	36

LIMITS FOR BROADBAND CONDUCTED DISTURBANCES (MHz)—Continued

	0.15–0.3		0.53–2.0		5.9–6.2		30–54		68–108	
	P	QP	P	QP	P	QP	P	QP	P	QP
b	80	67	76	63	62	49	62	49	56	43

a: Power lines, limit in dB (uV).
b: Control lines, limit in dB (uA).
P: Peak detector.
QP: Quasi-Peak detector.

LIMITS FOR NARROWBAND CONDUCTED DISTURBANCES (MHz)

	0.15–0.3	0.53–2.0	5.9–6.2	30–54	68–87	76–108
a	70	50	45	40	30	36
b	60	50	45	40	40	46

a: Power lines, limit in dB (uV).
b: Control lines, limit in dB (uA).
Limits by peak detection.

Test 16. Service Interval

Initialize the BAIID to begin the service interval period. After thirty (30) days, the BAIID must prominently indicate that it must be taken to a designated maintenance facility for maintenance and data downloads within 7 days or the ignition will lock and the event will be logged. Over the course of the 7-day lockout countdown, the BAIID must prominently indicate that the BAIID is in need of service, the time remaining until ignition lockout, but the ignition must not lock. At the end of this 7-day lockout countdown, the BAIID must prominently indicate that the BAIID is in need of service and the ignition must lock. Other tests (except Tests 15 and 17) may be performed during this 37-day period.

Test 17. Data Integrity and Format

Complete all other tests before performing Test 17. Download the data from the data logger and compare it to the data recorded for each test. Disconnect, then reconnect the power to the data logger. Download the data again and compare it to the first data download. No lost or corrupted data is allowed. Check the data format (*i.e.,* date and time of event) to verify conformance with the sample format in Appendix D.

Appendix A—Submission Procedures for Conformance Testing of Breath Alcohol Ignition Interlock Devices (BAIID)

NHTSA will test Breath Alcohol Ignition Interlock Devices (BAIIDs) at the DOT Volpe National Transportation Systems Center (Volpe Center). Testing of BAIIDs will be subject to the availability of Federal funds. If Federal funds are not available, NHTSA will discontinue testing BAIIDs until funds become available.

Manufacturers that wish to submit a BAIID for testing must apply in writing to the Office of Behavioral Safety Research, NTI–130, NHTSA, 1200 New Jersey Avenue, SE., Washington, DC 20590. Manufacturers must apply separately for each BAIID. NHTSA will test BAIIDs on a first-come, first-served basis. NHTSA will contact manufacturers with a test date and instructions for BAIID delivery to the Volpe Center. Manufacturers should not send devices until NHTSA has scheduled a test date.

When NHTSA has scheduled a test date, the manufacturer must submit one BAIID. If the BAIID is designed with special features, the BAIID must be submitted with instructions explaining how to turn each feature on and off. The manufacturer must also submit the operator's manual (user's guide or instructions to the user), the maintenance manual, quality assurance plan (QAP) (Appendix C), including recalibration and service requirements that are provided to the installation providers with the purchase or lease of the BAIID, self-certification as to the FDA's good manufacturing practices and device labeling requirements, as well as specifications and drawings fully describing the BAIID and its use. Manufacturers seeking confidential treatment for submitted information must follow the procedures set out in 49 CFR part 512.

The manufacturer is responsible for ensuring that the BAIID is operating properly and calibrated prior to the initiation of the test. Once testing begins, the manufacturer will not be allowed access to the BAIID or to the test site.

BAIIDs that are tested by the Volpe Center and determined to conform to the Model Specifications will be listed on a Conforming Products List (CPL). NHTSA will not accept test results from other sources. Except as specifically noted under a test procedure, BAIIDs must conform to the specifications in all 17 tests in order to be listed on the CPL.

Any malfunction of a BAIID resulting in failure to complete any of the required tests satisfactorily will result in a determination that the BAIID does not conform to the Model Specifications. If a BAIID fails any one of the tests, the agency at its own discretion may stop any further tests. If a BAIID fails to conform to the Model Specifications, NHTSA will notify the manufacturer in writing, and provide the reasons for the failure.

NHTSA will publish and update the CPL periodically in the **Federal Register**.

Appendix B—Re-Examination* of Breath Alcohol Ignition Interlock Devices (BAIID)

*Re-examination of a BAIID is at the sole discretion of NHTSA and subject to the availability of Federal funds.

1. Re-Examination of Nonconforming BAIID

If test results reveal that a BAIID does not meet the Model Specifications, a manufacturer may resubmit the BAIID for re-examination after appropriate corrections have been made to the BAIID. The manufacturer must follow the submission procedures in Appendix A. In addition, the manufacturer must provide written documentation of the changes or corrections that have been made to the BAIID to bring the device into conformance with the Model Specifications.

2. Changes to BAIID Listed on the Conforming Products List (CPL)

Manufacturers contemplating changes to a BAIID listed on the CPL (other than modification of the set point) are advised that any change may affect the status of the BAIID on the CPL. The manufacturer should inform NHTSA of the contemplated change(s) to determine whether re-examination of the BAIID is necessary. The manufacturer should submit the following information to NHTSA:

- Model name of the changed device.
- Nature and reason for change.
- Scope of change (*e.g.,* Will existing BAIIDs or BAIIDs in the marketplace be retrofitted? Will the change apply to some users but not others?)
- Will the change affect performance of the BAIID under the Model Specifications? (Precision and accuracy, temperature operations, vibrations, other laboratory readings, etc.)
- How will the change(s) be documented for the benefit of the user? (e.g., Will the

change(s) be documented in service bulletins and/or service manuals? If not, why not?)

• Drawings of the changed BAIID.

If NHTSA determines that the changes to the BAIID may affect the conformance of the BAIID with the Model Specifications, NHTSA will request that the changed BAIID be sent for testing. Refusal to provide the changed BAIID for testing may result in the removal of the BAIID from the CPL.

3. Re-Examination of BAIID Listed on the CPL

If available information indicates that a BAIID on the CPL may not perform in accordance with the Model Specifications, NHTSA may direct the Volpe Center to re-examine the BAIID. To assist in this effort, NHTSA may request manufacturers to send another BAIID sample for testing. (Refusal to provide another BAIID sample may result in the removal of the BAIID from the CPL.) Based on the new tests, NHTSA will determine whether the BAIID continues to conform to the Model Specifications. If the BAIID does not meet the Model Specifications, the BAIID will be removed from the CPL.

Appendix C—Quality Assurance Plan Template

[Manufacturer name], Quality Assurance Plan for [Interlock name AND Model number] [date]

Under the National Highway Traffic Safety Administration (NHTSA) Breath alcohol ignition interlock testing program, interlocks are evaluated according to the NHTSA Model Specifications for Breath Alcohol Ignition Interlocks (BAIIDs). Those models that conform to the Model Specifications are added to the Conforming Products List for Breath Alcohol Ignition Interlocks. This Quality Assurance Plan (QAP) and the operating instructions for the [Interlock name] provide step-by-step instructions for checking the accuracy of the calibration of a BAIID and the maintenance of the BAIID. (As noted in the Model Specifications, BAIIDs must hold calibration for 37 days (30 days + 7 day lockout countdown) and must have a service interval of 37 days (30 days + 7 day lockout countdown).

1. Provide step-by-step instructions for checking the calibration of the BAIID. These instructions must include:

• Recommended calibrating unit(s) (listed on NHTSA's Conforming Products List of Calibrating Units for Breath Alcohol Testers) and instructions for using the calibrating unit(s);

• Breath alcohol concentration to be used in the calibration check(s): 0.02 g/dL BrAC;

• Agreement of the calibration check with the breath alcohol concentration of the calibrating unit: Not greater than ±0.005 BrAC;

• Description of how to verify the accuracy of the BAIID reading of BrAC (e.g., from an instrument read out, printout, data logger, etc.);

• Description of actions that must be taken if the BAIID fails the calibration check.

2. Provide instructions on downloading the data from the data logger.

3. Provide instructions on how to maintain the BAIID (i.e., what must be examined at the 30 day service interval; any functions that require less frequent checks). Such instructions must detail any corrective action to be taken if the BAIID fails to perform as well as any events that would require a BAIID to be taken out of service and returned to the manufacturer.

4. Provide instructions on how to check for tampering.

5. Other information regarding quality assurance unique to this instrument, if any:

Contact information for the BAIID manufacturer regarding calibration and maintenance issues:

Appendix D—Sample Format for Downloaded Data From Data Logger

Date	Time	Start attempts (engine activity)
Example 1. Acceptable start and drive cycle		
4/21/07	0951	start attempt.
		sample accepted.
		BrAC (alcohol absent, *e.g.,* 0.000, 0.008).
		unlock.
		ignition keyed.
		starter active.
		0952 engine on.
		0956 rolling retest.
		sample accepted.
		BrAC (alcohol absent, *e.g.,* 0.000, 0.008).
		1032 engine off.
Example 2. Acceptable start but fail rolling re-start		
4/22/07	2316	start attempt.
		sample accepted.
		BrAC (alcohol absent, *e.g.,* 0.008).
		unlock.
		ignition keyed.
		starter active.
	2317	engine on.
	2319	rolling retest.
		BrAC (alcohol present, *e.g.,* 0.025).
		warning given.
4/23/07	0047	engine off.
Example 3. Push start		
4/23/07	2054	ignition keyed.
		warning given.
		starter not active.
	2055	engine on.
		warning given.
	2120	engine off.
Example 4. Start attempted but alcohol detected. Retry		
4/21/07	1652	start attempt.

Date	Time	Start attempts (engine activity)
		sample accepted.
		BrAC (alcohol present, *e.g.,* 0.030).
		lock.
	1653	warning given.
	1656	start attempt.
		sample accepted.
		BrAC (alcohol absent, *e.g.,* 0.015).
		unlock.
		ignition keyed.
		starter active.
	1657	engine on.
	1702	rolling retest.
		sample accepted.
		BrAC (alcohol absent, *e.g.,* 0.010).
	1850	engine off.
Example 5. Start attempted using filtered sample. Retry		
4/15/07	2016	start attempt.
		low temp.
		warning given.
	2205	start attempt.
		sample accepted.
		BrAC (alcohol absent, 0.000).
		unlock.
		ignition keyed.
		starter active.
	2206	engine on.
	2352	engine off.
Example 6. Calibration Check		
4/28/07	0900	start attempt.
		sample accepted.
		BrAC (alcohol absent, 0.000 or 0.008).
		unlock.
		ignition keyed.
		starter active.
	0903	engine on.
	0926	rolling retest.
		sample accepted.
		BrAC (alcohol absent, 0.000 or 0.008).
	1032	engine on.
	1045	Calibration check.

Issued on: October 1, 2010.

Jeff Michael,

Associate Administrator for the Office of Research and Program Development, National Highway Traffic Safety Administration.

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BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2010–0161]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 17 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs). The exemptions will enable these individuals to operate commercial motor vehicles (CMVs) in interstate commerce without meeting the prescribed vision standard. The Agency has concluded that granting these exemptions will provide a level of safety that is equivalent to, or greater than, the level of safety maintained without the exemptions for these CMV drivers.

DATES: The exemptions are effective October 6, 2010. The exemptions expire on October 8, 2012.

FOR FURTHER INFORMATION CONTACT: Dr. Mary D. Gunnels, Director, Medical Programs, (202)–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue, SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-