

State	SO ₂ Group 2 trading budget (tons) * for 2014 and thereafter	New unit set-aside (tons) for 2014 and thereafter	Indian country new unit set-aside (tons) for 2014 and thereafter
Texas	314,021	15,387	314

* Each trading budget includes the new unit set-aside and, where applicable, the Indian country new unit set-aside and does not include the variability limit.

(b) The States' variability limits for the State SO₂ Group 2 trading budgets for the control periods in 2014 and thereafter are as follows:

State	Variability limits for 2014 and thereafter
Alabama	38,386
Georgia	17,142
Kansas	7,475
Minnesota	7,557
Nebraska	11,709
South Carolina	15,952
Texas	56,524

15. Section 97.725 is amended by, in paragraph (b)(1), removing the word "2013" and adding, in its place, the word "2015".

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[EPA-HQ-OAR-2010-0750; FRL-9477-1]

RIN 2060-AQ10

New Source Performance Standards Review for Nitric Acid Plants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing revisions to the new source performance standards (NSPS) for nitric acid plants. Nitric acid plants include one or more nitric acid production units. These proposed revisions include a change to the nitrogen oxides (NO_x) emission limit, which applies to each nitric acid production unit commencing construction, modification, or reconstruction after October 14, 2011. These proposed revisions will also include additional testing and monitoring requirements.

DATES: Comments must be received on or before November 28, 2011. Under the Paperwork Reduction Act, comments on the information collection provisions are best assured of having full effect if the Office of Management and Budget (OMB) receives a copy of your

comments on or before November 14, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2010-0750, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Agency Web site:* <http://www.epa.gov/oar/docket.html>. Follow the instructions for submitting comments on the EPA Air and Radiation Docket Web site.
- *E-mail:* a-and-r-Docket@epa.gov. Include EPA-HQ-OAR-2010-0750 in the subject line of the message.
- *Fax:* Fax your comments to: (202) 566-9744, Attention Docket ID No. EPA-HQ-OAR-2010-0750.
- *Mail:* Send your comments to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, *Attention:* Docket ID No. EPA-HQ-OAR-2010-0750. Please include a total of two copies. In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *Attn:* Desk Officer for EPA, 725 17th St., NW., Washington, DC 20503.

• *Hand Delivery or Courier:* In person or by courier, deliver comments to EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC 20460. Such deliveries are only accepted during the Docket Center's normal hours of operation, (8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays), and special arrangements should be made for deliveries of boxed information. Please include a total of two copies.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise

protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means that the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to the EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and will be made available on the Internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "General Information" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available (e.g., CBI or other information whose disclosure is restricted by statute). Certain other material, such as copyrighted material, will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the EPA Docket Center, Public Reading Room, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Air Docket is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: For questions about these proposed standards for nitric acid production units, contact Mr. Chuck French, Sector

Policies and Program Division, Office of Air Quality Planning and Standards (D243-02), Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541-7912; fax number (919) 541-3207, e-mail address: French.chuck@epa.gov.

SUPPLEMENTARY INFORMATION:

The information presented in this preamble is organized as follows:

- I. General Information
 - A. Does this action apply to me?
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- V. Summary of Cost, Environmental, Energy, and Economic Impacts of These Proposed Standards
 - A. What are the impacts for new nitric acid production units?
 - B. What are the secondary impacts for new nitric acid production units?
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- VI. Statutory and Executive Order Reviews
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- C. Regulatory Flexibility Act
- D. Unfunded Mandates Reform Act
- E. Executive Order 13132: Federalism
- F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
- G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks
- H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
- I. National Technology Transfer and Advancement Act
- J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

I. General Information

A. Does this action apply to me?

Categories and entities potentially regulated by these proposed revisions include:

Category	NAICS code ¹	Examples of regulated entities
Industry	325311	Nitrogenous Fertilizer Manufacturing.
Federal government	Not affected.
State/local/tribal government	Not affected.

¹ North American Industrial Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. To determine whether your facility would be regulated by this action, you should examine the applicability criteria in 40 CFR 60.70a. If you have any questions regarding the applicability of this proposed action to a particular entity, contact the person in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. What should I consider as I prepare my comments to the EPA?

Do not submit information that you consider to be CBI electronically through <http://www.regulations.gov> or e-mail. Send or deliver information identified as CBI only to the following address: Roberto Morales, OAQPS Document Control Officer (C404-02), Office of Air Quality Planning and Standards, Environmental Protection Agency, Research Triangle Park, NC 27711, Attention Docket ID No. EPA-HQ-OAR-2010-0750. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information

claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

C. Where can I get a copy of this document?

In addition to being available in the docket, an electronic copy of the proposed action is available on the Worldwide Web (WWW) through the Technology Transfer Network (TTN) Web site. Following signature, EPA posted a copy of the proposed action on the TTN Web site's policy and guidance page for newly proposed or promulgated rules at <http://www.epa.gov/ttn/oarpg>. The TTN Web site provides information and technology exchange in various areas of air pollution control.

D. When would a public hearing occur?

If anyone contacts EPA requesting to speak at a public hearing by October 24, 2011, a public hearing will be held on October 28, 2011. Persons interested in presenting oral testimony or inquiring as to whether a public hearing is to be held should contact Mr. Chuck French, listed in the **FOR FURTHER INFORMATION CONTACT** section.

II. Background Information

A. What is the statutory authority for these proposed revisions?

New source performance standards (NSPS) implement Clean Air Act (CAA) section 111. Section 111 of the CAA requires that NSPS reflect the application of the best system of emission reductions which (taking into consideration the cost of achieving such emission reductions, any nonair quality health and environmental impact and energy requirements) the Administrator determines has been adequately demonstrated. This level of control has sometimes been referred to as "best demonstrated technology" or BDT, and will be referred to in this preamble as best system of emissions reduction (BSEER). In assessing whether a standard is achievable, EPA must account for routine operating variability associated with performance of the system on whose performance the standard is based. See *National Lime Ass'n v. EPA*, 627 F. 2d 416, 431-33 (DC Cir. 1980).

Common sources of information as to what constitutes a BSEER, and for assessing that technology's level of performance, include best available control technology (BACT) determinations made as part of new source review (NSR). Also, emissions limits that exist in state and federal permits for recently permitted sources,

and emissions test data for demonstrated control technologies collected for compliance demonstration or other purposes are evaluated during these assessments. EPA compares permit limitations and BACT determination data with actual performance test data to identify any site-specific factors that could influence general applicability of this information. Also, as part of this review we evaluate if NO_x emissions limits more stringent than those in Subpart G have been established, or if emissions limits have been developed for additional air pollutants.

The use of State permit data and BACT determination developed as part of NSR is appropriate because a BACT determination evaluates information that is similar to BSER, such as available controls, their performance, cost, and non-air environmental impacts. One important difference between BACT determinations and a BSER determination for purposes of NSPS is that BACT determinations are made on a site-specific basis. Therefore, in evaluating BACT determinations, we have to account for any site-specific factors that may not be applicable to the source category as a whole.

Section 111(b)(1)(B) of the CAA requires EPA to periodically review and revise the standards of performance, as necessary, to reflect improvements in methods for reducing emissions.

Existing affected facilities that are modified or reconstructed would also be subject to these proposed revisions for affected sources. Under CAA section 111(a)(4), "modification" means any physical change in, or change in the method of operation of, a stationary source which increases the amount of any air pollutant emitted by such source or which results in the emission of any air pollutant not previously emitted. Changes to an existing facility that do not result in an increase in emissions are not considered modifications.

Rebuilt affected facilities would become subject to the proposed standards under the reconstruction provisions, regardless of changes in emission rate.

Reconstruction means the replacement of components of an existing facility such that (1) The fixed capital cost of the new components exceeds 50 percent of the fixed capital cost that would be required to construct a comparable entirely new facility; and (2) it is technologically and economically feasible to meet the applicable standards (40 CFR 60.15).

The NSPS are directly enforceable federal regulations issued for categories of sources which cause, or contribute significantly to, air pollution which may

reasonably be anticipated to endanger public health or welfare. The primary purpose of the NSPS is to attain and maintain ambient air quality by ensuring that the best demonstrated emission control technologies are installed as the industrial infrastructure is modernized, when it is most cost effective to build in controls. Since 1970, the NSPS have been successful in achieving long-term emissions reductions in numerous industries by assuring that cost-effective controls are installed on new, reconstructed, or modified sources.

B. What are the current NSPS for Nitric Acid Plants NSPS?

The current NSPS for Nitric Acid Plants (40 CFR part 60, Subpart G) were promulgated in the **Federal Register** on December 23, 1971 (36 FR 24881). The first review of the Nitric Acid Plants NSPS was completed on June 19, 1979 (44 FR 35265). An additional review was completed on April 5, 1984 (49 FR 13654). No changes were made to the NSPS as a result of those reviews. Minor testing and monitoring changes were made during three reviews since the original promulgation in 1971 (October 6, 1975 (40 FR 46258), April 22, 1985 (50 FR 15894), and February 14, 1989 (54 FR 6666)). The current Nitric Acid Plants NSPS (Subpart G) applies to each nitric acid production unit constructed or modified after August 17, 1971. The present NSPS has an emissions limit of 3.0 lb of NO_x per ton of 100% nitric acid produced and a 10% opacity standard as an additional method of demonstrating compliance with the NO_x emission limit. Continuous NO_x monitors are required as well as recording daily production rates.

III. Summary of Proposed Standards

A. What source category is being regulated?

Today's proposed standards would apply to new nitric acid production units. Nitric acid plants may include one or more nitric acid production units. For purposes of these proposed regulations, a nitric acid production unit is defined as any facility producing weak nitric acid by either the pressure or atmospheric pressure process. This definition has not changed from Subpart G.

A new nitric acid production unit is defined as a nitric acid production unit for which construction, modification, or reconstruction commences on or after October 14, 2011. The affected facility under the proposed NSPS is each nitric acid production unit.

B. What pollutants are emitted from these sources?

The pollutant to be regulated under section 111(b), for new nitric acid production units, is NO_x which undergo reactions in the atmosphere to form particulate matter and ozone. Nitrogen oxides, particulate matter, and ozone are all subject to national ambient air quality standards under section 109 of the Clean Air Act, based on their adverse effects to human health and welfare. NO_x is a criteria pollutant.

These nitric acid production units also emit another nitrogen compound known as nitrous oxide (N₂O), which is considered a greenhouse gas (GHG). We are not proposing an N₂O emission standard in this action. Although we have limited data from facilities in the U.S, we believe that owners/operators of nitric acid production units should consider technologies and technology combinations that would be appropriate for controlling both NO_x and N₂O. Some technologies such as selective catalytic reduction (SCR) and hydrogen peroxide injection (HPI) are effective only in controlling NO_x. However, other technologies such as nonselective catalytic reduction (NSCR) are effective in controlling both NO_x and N₂O.

The technology combinations that control both NO_x and N₂O include SCR plus secondary catalysts (located in the ammonia reactor), and SCR plus other non-NSCR types of tertiary catalysts (located after the absorption tower). We expect any controls applied to control NO_x emissions would not preclude installing cost effective N₂O control technologies in the future. We solicit relevant comments and additional information on these technologies. Nitric acid production is also one of the industrial sectors for which "white papers" were written to provide basic information on GHG control options to assist state and local air pollution control agencies, tribal authorities, and regulated entities in implementing measures to reduce GHGs, particularly in the assessment of BACT under the PSD permitting program. These papers provide basic technical information that may be useful in a BACT analysis but they do not define BACT for each sector. For more information regarding the "white papers," see <http://www.epa.gov/nsr/ghgpermitting.html>.

C. What are the proposed standards?

We are proposing to reduce the NO_x emissions limit from 3.0 pounds of NO_x per ton of nitric acid produced (lb NO_x/ton acid), expressed as NO₂, with the production being expressed as 100 percent nitric acid, to 0.50 lb NO_x/ton

acid as a 30-day emission rate calculated each operating day based on the previous 30 consecutive operating days.

The general provisions in 40 CFR part 60 provide that emissions in excess of the level of the applicable emissions limit during periods of startup, shutdown, and malfunction shall not be considered a violation of the applicable emission limit unless otherwise specified in the applicable standard. See 40 CFR 60.8(c). The general provisions, however, may be amended for individual subparts. See 40 CFR 60.8(h). Here, the EPA is proposing standards in Subpart Ga that apply at all times, including periods of startup or shutdown, and periods of malfunction.

IV. Rationale for the Proposed Standards

Section 111(a)(1) requires that standards of performance for new sources reflect the—

* * * degree of emission limitation achievable through the application of the best system of emission reduction which (taking into account the cost of achieving such reduction, and any nonair quality health and environmental impact and energy requirements) the Administrator determines has been adequately demonstrated.

A. How is EPA proposing to revise the emissions limit for affected sources?

For affected sources constructed, modified, or reconstructed after October 14, 2011, we are proposing to reduce the NO_x emissions limit from 3.0 lb NO_x/ton acid to 0.50 lb NO_x/ton acid as a 30-day emission rate calculated each operating day based on the previous 30 consecutive operating days.

The NO_x emissions limit for affected facilities constructed, modified, or reconstructed after August 17, 1971, and before October 14, 2011 remains unchanged at 3.0 lb NO_x/ton acid.

The 1971 promulgated Nitric Acid Plants NSPS were based on emission levels achieved using catalytic reduction (see 36 FR 2881, December 23, 1971). Additional reviews of the NSPS were conducted in 1979 and 1984, where EPA again concluded that catalytic reduction was the BSER considering economic, energy, and nonair environmental impacts. No changes were made to the NSPS during these reviews.

There are currently 40 nitric acid production facilities in the U.S. with a total of 67 nitric acid production units. For this review, information was collected from responses to a section 114 information collection request (ICR), through site visits and from trade associations. The information and

comments from stakeholders are contained in the docket.

The review of permits and other available information in the record revealed that SCR, NSCR, and HPI are all air pollution control technologies that are used for NO_x control in the nitric acid production source category and EPA considered all of these as candidates for BSER as we developed this proposed rule. We are not aware of any other established or emerging technologies that should be considered as candidates for BSER for this source category. SCR is used in 25 nitric acid production units in the U.S. NSCR is used in 14 nitric acid process units in the U.S. HPI is used by one facility. All of these air pollution control technologies are effective in controlling NO_x emissions. The average NO_x emission reductions for these controls are: SCR—98%; NSCR—99%, HPI—95% (for more information see Table 3.3 in the Economic Impact Analysis, which is available in the docket for this action).

The approach used for determining BSER for nitric acid production units involved reviewing the emission test data submitted in response to the section 114 ICR, recently issued state permit data, and BACT determinations developed as part of NSR. In response to clarifications of the section 114 ICRs, industry provided additional data. In determining BSER we generally look at the controls and control performance of new sources. All recent nitric acid units have installed SCR as NO_x controls. Recent BACT determinations have also identified SCR as BACT.

A 2009 BACT determination has been incorporated into the facility permit limit for a nitric acid plant in American Falls, Idaho (Southeast Idaho Energy, LLC). For this analysis, SCR was determined as BACT, and 0.60 lb NO_x/ton acid was determined as the BACT level of control. The Southeast Idaho Energy, LLC emission limit of 0.60 lb NO_x/ton acid will apply at all times during steady-state operations (no standard applies during periods of startup or shutdown, and periods of malfunction). The compliance period was not specified.

There are other recent BACT analyses at two other nitric acid production units. At Agrium in North Bend, Ohio, the BACT limit set in 2009 is 0.61 lb NO_x/ton acid on a 365-day rolling basis. At Agrium in Kennewick, Washington, the BACT limit set in 2008 is 0.60 lb NO_x/ton acid in any continuous 12-month period (including startup, shutdown and malfunction).

As part of our BSER analysis, we are proposing that the standard be stated as

a rolling 30-day limit based on 30 consecutive operating days and that the limit be met at all times. We believe that the 0.50 lb NO_x/ton acid standard, supported by existing source data and BACT determinations, is more stringent than any state BACT determination because 0.50 lb NO_x/ton acid is lower than both 0.61 lb NO_x/ton acid and 0.60 lb NO_x/ton acid.

Emissions test data were obtained from a number of sources including a section 114 ICR, trade associations, and the EPA Region 5. We received nine relative accuracy test audit (RATA) reports for 5 nitric acid production units controlled with SCR, 6 RATA reports for 6 nitric acid production units controlled with NSCR, and 1 RATA report for 1 nitric acid production unit controlled with HPI. These emissions tests are short term and are presented in the memorandum *Summary of Test Data Received from Section 114 ICR*, dated August 25, 2010 (updated December 17, 2010).

In response to the section 114 request, nitric acid plants submitted NO_x Continuous Emission Monitoring Systems (CEMS) data. These included 3 facilities using SCR and 2 facilities using NSCR.

All emission test data (short term and CEMS data) indicate that lower emissions than the current Subpart G emission limit of 3.0 lb NO_x/ton acid are being achieved, regardless of the type of NO_x control being used. We decided to further analyze the long-term CEMS data because: (1) Long term data include periods of startup and shutdown, where emissions are shown to be larger than during steady state operating conditions, (2) long term data allow the seasonal impacts of temperature and humidity on NO_x controls to be evenly distributed, as these factors often vary by the time of year and location, and (3) long term data include seasonal supply and demand cycles so that all factors that influence production are equally considered.

We have concluded that SCR is BSER based on data showing lower emissions rates from SCR-controlled units. For more information, see Table 1 of this preamble and the related discussion. The fact that SCR is the only known NO_x control technology being installed in new nitric acid production units, and that SCR has been determined to be BACT supports this conclusion. Further, SCR does not produce any secondary environmental impacts.

The next step in the NSPS process is to establish an achievable standard using BSER. In assessing whether a standard is achievable, the EPA must account for routine operating variability

associated with performance of the system on which the standard is based. For each plant that submitted long-term CEMS data, these data cover the entire operating period including startups, shutdowns and malfunctions. To ensure that the new NO_x standard is achievable by all properly designed and operated SCR units and covers all operating periods including startup and shutdowns, we analyzed the statistical variation by calculating the 99th percentile. When establishing an emissions limit (which is considered a never to exceed level of emissions), we

use a 99th percentile based on statistical analyses. This approach accounts for short and long-term variability in emissions associated with all normal operating conditions, including startup and shutdown (see 72 FR 54878–79, September 27, 2007). This analysis is contained in the memorandum *Statistical Evaluation of CEMS Data to Determine the NO_x Emission Standard*, dated July 18, 2011.

Using the long term CEMS data received through the ICR, the EPA determined that there were sufficient data to directly calculate the 99th percentile for the best performing

sources. The EPA determined that the CEMS represents long-term performance and accounts for long-term and day-to-day variability.

Long term CEMS data were obtained from 3 plants using SCR and 2 plants using NSCR. The plant with HPI did not submit long term CEMS data. Following is a discussion of these data—the 3 plants with SCR are discussed first followed by the 2 plants with NSCR.

The 99th percentile was directly calculated for these 5 best performing sources. A summary of the values is shown in Table 1.

TABLE 1—CEMS DATA—99TH PERCENTILE BY COMPLIANCE PERIOD
[lb of NO_x/T of 100% nitric acid]

Compliance period	Control	15 minute	hourly	3-hour rolling	daily block	7-day rolling	30-day rolling
PCS Geismar (Train 5)	SCR	0.84	0.89	1.00	1.02	0.72	0.38
Agrium North Bend	SCR	NA	0.69	0.80	1.67	0.92	0.50
El Dorado Nitrogen	SCR	NA	0.47	0.47	0.44	0.40	0.37
PCS Geismar (Train 4)	NSCR	0.97	1.25	1.74	5.58	2.41	2.41
Agrium Sacramento	NSCR	NA	2.13	NA	1.60	1.31	1.29

The Agrium-North Bend plant submitted data spanning from January 2010 through December 2010. The continuous data over the 12-month period show 0.50 lb NO_x/ton acid as the 99th percentile for each 30-day rolling time period. The 30-day periods with high NO_x emissions occurred during periods of startup and shutdown.

The PCS Geismar plant submitted 15-minute average data for Train 5 for 2007–2009. Train 5 is controlled with SCR. The period spanning January 2009 through December 2009 was analyzed. The continuous data from a 12-month period show 0.38 lb NO_x/ton acid as the 99th percentile for each 30-day rolling time period.

The El Dorado plant submitted hourly averages data for the period of July 2010–June 2011. The continuous data from a 12-month period show 0.37 lb NO_x/ton acid as the 99th percentile for each 30-day rolling time period.

We also received 15-minute average data on NO_x emissions for 2007–2009 from the PCS Geismar plant for Train 4, which is controlled with NSCR. The period spanning January 2009 through December 2009 was analyzed to be consistent with Train 5 (controlled with SCR). The continuous data from a 12-month period show 2.41 lb NO_x/ton acid as the 99th percentile emissions level for a 30-day time period for train 4. The result of this analysis is limited due to the fact that the nitric acid train was operational for approximately 65 days during the 12-month period. It is

unlikely that this short time period is representative of the NSCR performance over time.

The Agrium-Sacramento plant submitted data spanning from January 2010 through December 2010. The continuous data over the 12-month period show 1.29 lb NO_x/ton acid as the 99th percentile for a 30-day time period. The 30-day periods with high NO_x emissions occurred during periods of startup and shutdown.

As shown by Table 1, all units are meeting the current Subpart G NO_x emission standard of 3.0 lb NO_x/ton acid, regardless of the compliance period. We did not receive any long term data from the nitric acid train using HPI but the table shows that the NO_x emissions from nitric acid trains using SCR are lower than nitric acid trains using NSCR. For example, reviewing the 99th percentile on a 30-day rolling basis, SCR data range from 0.38 to 0.50 lb NO_x/ton acid and NSCR data range from 1.29 to 2.41 lb NO_x/ton acid. The lower emissions from SCR when compared to emissions from NSCR are the main reason that SCR has been determined as BSER.

Whether NSCR can meet the levels achievable by SCR over a long term, is uncertain. The long term CEMS data from 2 NSCR plants indicate difficulty in meeting the 0.50 lb NO_x/ton limit. However, we have monthly average data from 2 other facilities using NSCR. These plants with NSCR (Dyno Nobel-Deer Island and JR Simplot–Helm)

submitted monthly block averages for a three year period. For 2009, the monthly block averages for both plants were very close and range from 7 to 17 ppm or approximately 0.15–0.36 lb NO_x/ton acid. As these data are not continuous but rather block monthly averages, comparison of these with the CEMS data discussed above is not possible. These data are presented to show that NSCR may be able to achieve the proposed emission limit. Also, the data presented in the memorandum *Summary of Test Data Received from Section 114 ICR*, dated August 25, 2010 (updated December 17, 2010) show that low short-term NO_x emissions rates are possible when using NSCR and HPI.

For the units controlled by SCR, we have not been able to identify any specific factors associated with the El Dorado Nitrogen and PCS Nitrogen Train 5 units that account for the lower emission levels compared to the Agrium-North Bend unit. Thus, based on the information currently in the record, we believe that emission levels of NO_x are not only dependent on the use of SCR but also on process factors that result in variability that cannot be avoided through better or different design or through changes in operating practices.

By selecting an emission limit based on the 99th percentile of emissions data from unit with BSER (which is SCR), we ensure that this limit reflects BSER but is also achievable during all periods by facilities that have BSER equivalent

controls. The available data for units with BSER, which were used to derive the proposed NO_x emissions limit for new, modified and reconstructed units, are from existing nitric acid units that have been in operation for at least 10 years. Therefore, we believe that reconstructed, modified and new sources will be able to meet the proposed limit. We have no reason to believe that modified or reconstructed sources would not be able to meet this limit. Thus, we do not believe different standards are needed for modified or reconstructed sources.

Moreover, in the past when companies chose to increase production or replace units, it is our understanding that they would build new production units rather than modify or reconstruct existing units. In fact, to our knowledge, no existing nitric acid production unit has been reconstructed or modified since Subpart G was promulgated. Therefore, we expect no reconstructions or modifications to occur for the nitric acid industry in the foreseeable future. Nevertheless, we request comment on any reconstructions or modifications to nitric acid production units that have taken place or information about any future plans to do such modifications or reconstructions. Also, we request data on the level of NO_x emissions that these nitric acid units are able to achieve. If these emission levels are different than 0.50 lb NO_x/ton acid on a 30 day rolling basis, the commenter should include data to support the suggested emission level.

Nevertheless, we expect that growth within the industry will be limited to newly constructed nitric acid production units. We believe that new nitric acid production units will be able to meet the proposed limit which takes into consideration routine operating variability as well as variation due to weather and periods of startups and shutdowns. The proposed emission limit of 0.50 lb NO_x/ton acid is a never to exceed limit. We have not identified any specific process or technology that new nitric acid production units could employ to consistently meet an emission limit lower than 0.50 lb NO_x/ton acid. Therefore, we are proposing a limit of 0.50 lb NO_x/ton acid for Subpart Ga.

As part of our BSER analysis, we are proposing that the standard be stated as a rolling 30-day limit based on 30 consecutive operating days and that the limit be met at all times including periods of startup and shutdown. We believe that the 0.50 lb NO_x/ton acid standard is supported by existing source data. The use of a 30-day period accounts for peaks in the data that occur

during startup and shutdown. These periods occur on average about 3 to 4 hours per month and emissions during those periods are much higher than normal. Therefore, the 3 to 4 hour periods can affect average emissions beyond that 3 to 4 hour period. Setting the standard with a 30-day compliance period meets the statutory requirement that the standard reflect the degree of emission limitation that is achievable through BSER, including during periods that include startup and shutdown.

Although the proposed limit of 0.50 lb NO_x/ton acid is based on the data for SCR, NSPS do not require the use and installation of a specific control device. We request additional long-term data (in units of the standard) to determine whether NSCR and HPI can achieve the proposed limit.

For all of the reasons discussed above, we are proposing 0.50 lb NO_x/ton acid as the revised standard for Nitric Acid Plants to be established in Subpart Ga.

Periods of Startup or Shutdown. In proposing the standards in this rule, the EPA has taken into account startup and shutdown periods and, for the reasons explained below, has not proposed different standards for those periods.

According to information received from industry in the section 114 ICR, NO_x emissions during startup and shutdown are higher than during normal operations. Due to the relatively short duration of startup and shutdown events (generally a few hours) compared to normal steady-state operations, we believe that a 30-day emission rate calculated based on 30 consecutive operating days will allow affected sources to meet the 0.50 lb NO_x/ton acid at all times, including periods of startup and shutdown. We request comment on the use of a 30-day emission rate calculated based on 30 consecutive operating days. Further, we request comment on whether the standard should be set with a compliance period that is shorter (such as 24 hours). For any comment suggesting a shorter time period, the comment should explain why that different period is appropriate and include data supporting the different compliance period and how startup and shutdown would be factored into a shorter term limit.

If you believe that the EPA's conclusion is incorrect, or that the EPA has failed to consider any relevant information on this point, we encourage you to submit comments. In particular, we note that the general provisions in Part 60 require facilities to keep records of the occurrence and duration of any startup, shutdown or malfunction (40 CFR 60.7(b)) and either report to the

EPA any period of excess emissions that occurs during periods of startup, shutdown or malfunction (40 CFR 60.7(c)(2)) or report that no excess emissions occurred (40 CFR 60.7(c)(4)). Thus, any comments that contend that sources cannot meet the proposed standard during startup and shutdown periods should provide data and other specifics supporting their claim.

Periods of Malfunction. Periods of startup, normal operations, and shutdown are all predictable and routine aspects of a source's operations. However, by contrast, malfunction is defined as a "sudden, infrequent, and not reasonably preventable failure of air pollution control and monitoring equipment, process equipment or a process to operate in a normal or usual manner * * *" (40 CFR 60.2). The EPA has determined that malfunctions should not be viewed as a distinct operating mode. Further, nothing in section 111 or in case law requires that the EPA anticipate and account for the innumerable types of potential malfunction events in setting emission standards. See, *Weyerhaeuser v. Costle*, 590 F.2d 1011, 1058 (DC Cir. 1978) ("In the nature of things, no general limit, individual permit, or even any upset provision can anticipate all upset situations. After a certain point, the transgression of regulatory limits caused by 'uncontrollable acts of third parties,' such as strikes, sabotage, operator intoxication or insanity, and a variety of other eventualities, must be a matter for the administrative exercise of case-by-case enforcement discretion, not for specification in advance by regulation.")

Further, it is reasonable to interpret section 111 as not requiring the EPA to account for malfunctions in setting emissions standards. For example, we note that section 111 provides that the EPA will set standards of performance which reflect the degree of emission limitation achievable through "the application of the best system of emission reduction" that the EPA determines is adequately demonstrated. Applying the concept of "the application of the best system of emission reduction" to periods during which a source is malfunctioning presents significant difficulties. The "application of the best system of emission reduction" is more appropriately understood to include operating in such a way as to avoid malfunctions of their units.

Moreover, even if malfunctions were considered a distinct operating mode, we believe it would be impracticable to take malfunctions into account in setting CAA section 111 standards for the nitric acid production units that will

be covered in the proposed Subpart Ga. As noted above, by definition, malfunctions are sudden and unexpected events and it would be difficult to set a standard that takes into account the myriad different types of malfunctions that can occur across all sources in the category. Moreover, malfunctions can vary in frequency, degree, and duration, further complicating standard setting.

If the standard is stated as a 30-day emission rate calculated based on 30 consecutive operating days, or some other time period, we believe that sources will be able to operate their plants in compliance with the standard even if they experience malfunctions. Also, excess emissions from a nitric acid production unit during a malfunction can frequently be mitigated or avoided by shutting the plant down if a key component fails.

In the event that a source fails to comply with the applicable CAA section 111 standards as a result of a malfunction event, the EPA would determine an appropriate response based on, among other things, the good faith efforts of the source to avoid malfunctions and to minimize emissions during malfunction periods, including preventative and corrective actions, as well as root cause analyses to ascertain and rectify excess emissions. The EPA would also consider whether the source's failure to comply with the CAA section 111 standard was, in fact, "sudden, infrequent, not reasonably preventable" and was not instead "caused in part by poor maintenance or careless operation." 40 CFR 60.2 (definition of malfunction).

Finally, the EPA recognizes that even equipment that is properly designed and maintained can sometimes fail and that such failure can sometimes cause an exceedance of the relevant emission standard. (See, e.g., *State Implementation Plans: Policy Regarding Excessive Emissions During Malfunctions, Startup, and Shutdown* (Sept. 20, 1999); *Policy on Excess Emissions During Startup, Shutdown, Maintenance, and Malfunctions* (Feb. 15, 1983)). The EPA is therefore proposing to add an affirmative defense to civil penalties for exceedances of emission limits that are caused by malfunctions. See 40 CFR 60.71a (defining "affirmative defense" to mean, in the context of an enforcement proceeding, a response or defense put forward by a defendant, regarding which the defendant has the burden of proof, and the merits of which are independently and objectively evaluated in a judicial or administrative

proceeding). We also are proposing other regulatory provisions to specify the elements that are necessary to establish this affirmative defense; the source must prove by a preponderance of the evidence that it has met all of the elements set forth in 60.74a. (See 40 CFR 22.24). The criteria ensure that the affirmative defense is available only where the event that causes an exceedance of the emission limit meets the narrow definition of malfunction in 40 CFR 60.2 (sudden, infrequent, not reasonably preventable and not caused by poor maintenance and/or careless operation). For example, to successfully assert the affirmative defense, the source must prove by a preponderance of the evidence that excess emissions "[w]ere caused by a sudden, infrequent, and unavoidable failure of air pollution control and monitoring equipment, process equipment, or a process to operate in a normal or usual manner * * *." The criteria also are designed to ensure that steps are taken to correct the malfunction, to minimize emissions in accordance with section 60.72a(b) and to prevent future malfunctions. For example, the source must prove by a preponderance of the evidence that "[r]epairs were made as expeditiously as possible when the applicable emission limitations were being exceeded * * *" and that "[a]ll possible steps were taken to minimize the impact of the excess emissions on ambient air quality, the environment and human health * * *." In any judicial or administrative proceeding, the Administrator may challenge the assertion of the affirmative defense and, if the respondent has not met its burden of proving all of the requirements in the affirmative defense, appropriate penalties may be assessed in accordance with section 113 of the Clean Air Act (see also 40 CFR part 22.77).

B. How is the EPA proposing to revise the testing and monitoring requirements?

The current NSPS requires an initial performance test, the installation of a continuous NO_x monitor and the recording of the daily production rate and hours of operations. We are proposing that the new Subpart Ga also require the installation, operation, and maintenance of an exhaust gas flow rate monitor. The capital cost of this monitor is \$39,000 and the total annualized cost for this monitor for a new nitric acid production unit is estimated to be \$15,000. The gas flow rate monitor provides data on the volume of gas emitted per unit of time, and this information combined with the data from the NO_x monitor will result in

more accurate measurements of the total NO_x being emitted.

Subpart G currently requires that owners/operators of nitric acid production units conduct an initial performance test to demonstrate initial compliance with the NO_x emission limit. The initial performance test is based on three one-hour test runs for NO_x using manual testing methods; specifically, Method 7 (or, alternatively, Method 7A, 7B, 7C, or 7D) for NO_x concentration, and Method 2 for volumetric flow rate (40 CFR 60, appendix A-4). The nitric acid production rate also must be determined during the initial performance test so that the emissions can be calculated in terms of the emissions limit, lb NO_x per ton of acid produced (100 percent acid basis). The current rule does not provide specific procedures or criteria for determining the production rate or concentration.

The current NSPS also requires the owner/operator to install, calibrate, maintain and operate a CEMS for measuring NO_x concentration (40 CFR 60, appendix B, Performance Specification 2) to demonstrate continuing compliance. The owner/operator is required to establish a conversion factor expressed as lb NO_x per ton acid produced per ppm NO_x by comparing the CEMS data (ppm NO_x) obtained during the performance test to the performance test results (lb NO_x per ton of acid). The conversion factor is used to convert the CEMS concentration data into units of the emissions standard on an on-going basis. Subsequently, the owner/operator must report periods of excess emissions defined as any 3-hour period during which the average nitric acid emissions (arithmetic average of three contiguous 1-hour periods) as measured by the CEMS exceed the emissions standard. The owner/operator must reestablish the conversion factor during any subsequent performance test.

As part of an ongoing effort to improve compliance with various federal air emission regulations, we are proposing to require use of a continuous compliance determination method (CCDM) for NO_x for nitric acid production units subject to Subpart Ga. The proposed CCDM is a continuous emissions rate monitoring system (CERMS) comprised of the NO_x CEMS and a continuous exhaust gas flow rate monitoring system. The CERMS would be required to meet the requirements of performance specification 6 (40 CFR 60, appendix B).

Performance Specification 6 (PS6) provides performance criteria for the flow rate monitoring system and stipulates the overall performance

criteria for the monitoring system in terms of pollutant emissions rate (*i.e.*, lb NO_x/hour). PS6 refers to the criteria of performance specification 2 (PS2) for the NO_x CEMS. Extractive Fourier Transform Infrared Spectroscopy (FTIR) is capable of measuring NO_x through the requirements in Performance Specification 15 (PS15). The proposed regulation allows use of the FTIR CEMS for determining compliance with the NO_x emissions limit, in lieu of a monitor meeting the requirements of PS2, at the discretion of the owner/operator.

This proposed rule would require the acid production rate to be determined on a daily basis. The daily NO_x emissions rate measured by the CERMS (lb) and the daily production rate (tons of acid per day) are used to calculate the emissions rates in units of the standard, lbs NO_x per ton of acid. This proposed rule would provide options for measuring the production rate and stipulates a minimum accuracy requirement for the measurement equipment. This proposed rule also requires that the concentration of the produced nitric acid be tested daily.

We are proposing that nitric acid production units subject to Subpart Ga will not be subject to an opacity standard; consequently no test or monitoring method for opacity is included in this proposed rule. Using the nitric acid production rate and concentration of the nitric acid, the NO_x concentration from the NO_x CEMS, and the flow rate from the proposed flow monitor, the NO_x emission rate in units of the standard (lb NO_x/ton acid) can be determined at any point in time. Therefore, an opacity standard is not required as an additional method of demonstrating compliance with a NO_x emission limit.

C. How is the EPA proposing to revise the notification, reporting, and recordkeeping requirements?

The only recordkeeping requirements in the existing Subpart G are of daily production rate and hours of operation. The reporting requirements in the existing subpart G include reports of excess emissions and production rate. The frequency of reporting is semiannually as specified in 60.7(c).

Reporting and recordkeeping requirements are being proposed as separate sections for Subpart Ga. Owners/operators subject to Subpart Ga must keep records of all performance tests and results; and dated daily records of hours of operation, nitric acid production rate, and nitric acid concentration; explanations for periods of noncompliance and corrective actions

taken; span exceedances; and any modifications to CERMS which could affect the ability of the CERMS to comply with applicable performance specifications.

Owners/operators must report all performance tests and results; dated daily records of NO_x emission rates that exceed the standard, explanations for periods of noncompliance and corrective actions taken, span exceedances, and any modifications to CERMS which could affect the ability of the CERMS to comply with applicable performance specifications; and RATA (*i.e.*, from the initial certification) and performance test data. The frequency of reporting for Subpart Ga is the same as for Subpart G.

V. Summary of Cost, Environmental, Energy, and Economic Impacts of These Proposed Standards

In setting standards, the CAA requires us to consider alternative emission control approaches, taking into account the estimated costs as well as impacts on energy, solid waste, and other effects.

A. What are the impacts for new nitric acid production units?

We are presenting estimates of the impacts for the proposed 40 CFR part 60, Subpart Ga that change the performance standards for new nitric acid production units. The cost, environmental, and economic impacts presented in this section are expressed as incremental differences between the impacts of nitric acid production units complying with the proposed Subpart Ga and the current NSPS requirements of Subpart G (*i.e.*, baseline). The impacts are presented for future nitric acid production units that commence construction, reconstruction, or modification over the 5 years following promulgation of the revised NSPS. Costs are based on 2nd quarter of 2010. The analyses and the documents referenced below can be found in Docket ID No. EPA-HQ-OAR-2010-0750.

In order to determine the incremental impacts of this proposed rule, we first estimated the number of new nitric acid production units that would become subject to regulation during the five year period after promulgation of subpart Ga. Based on existing nitric acid production units and estimated future growth rates, 6 new nitric acid production units are expected to be required to meet the nitric acid production demand in that five year period. For further detail on the methodology of these calculations, see memorandum *Impacts of Nitric Acid NSPS Review—NO_x*, dated December 15, 2010, in Docket ID No. EPA-HQ-OAR-2010-0750.

The proposed Subpart Ga NO_x emission limit reflects the use of control technologies currently in use by the industry and reflects an adjustment of the limit to more accurately reflect the performance of these control technologies. The current Subpart G NSPS NO_x emissions limit can be achieved using a number of control techniques including NSCR, SCR and HPI. In many cases, the air pollution control systems used to meet the current NSPS could be used to meet the proposed revised NO_x emission limit for future affected facilities. The potential nationwide emission reduction associated with lowering the NO_x limit from 3.0 to 0.50 lb NO_x/ton acid (100 percent acid basis) is estimated to be 2,000 tons per year (tpy) NO_x. This potential emission reduction may be overestimated because the majority of control systems installed on future affected facilities would likely result in emissions at or below the proposed emissions limit even in the absence of these proposed revisions.

There are many existing nitric acid production units currently meeting 0.50 lb NO_x/ton acid. Therefore, there is no increase in control costs of meeting the proposed emission limit of 0.50 lb NO_x/ton acid for new nitric acid production units compared to the control costs to comply with subpart Ga. The only costs incurred would be the installation of an air flow monitor, which is discussed below.

There are differences in notification, testing, monitoring, reporting, and recordkeeping (MRR) between Subpart G and the new Subpart Ga that result in increased costs. We are proposing the use of a CERMS for monitoring compliance with Subpart Ga. The CERMS requires the installation of both a continuous NO_x monitor and continuous exhaust gas flow rate monitor. The current NSPS (subpart G) requires only the installation of a continuous NO_x monitor. The installation, operation, and maintenance of an exhaust gas flow rate monitor will increase the cost to nitric acid production units over what would be incurred to comply with subpart G. We estimate that the total increase in nationwide annual cost associated with this proposed monitoring revision is \$90,110 for all six of the new production units projected to be built from 2011 to 2016.

The estimated nationwide incremental 5-year NO_x emissions reductions and cost impacts for these proposed revisions are summarized in Table 2 of this preamble. The methodology is detailed in the memorandum *Impacts of Nitric Acid*

NSPS Review—NO_x, dated December 13, 2010 (updated July 27, 2011). The overall cost effectiveness is about \$45 per ton of NO_x removed.

TABLE 2—NATIONAL INCREMENTAL NO_x EMISSION REDUCTIONS AND COST IMPACTS FOR NEW NITRIC ACID PRODUCTION UNITS SUBJECT TO PROPOSED STANDARDS UNDER 40 CFR PART 60, SUBPART GA (FIFTH YEAR AFTER PROMULGATION)

Proposed revisions for future affected facilities	Total annualized cost [\$1,000/yr]	Potential annual NO _x emission reductions [tons NO _x /yr]	Potential cost effectiveness [\$ /ton NO _x]
Revisions to NO _x emission limit	\$0	2,000	\$0.00
Revisions to MRR requirements	90		
Total	90	2,000	45

B. What are the secondary impacts for new nitric acid production units?

Indirect or secondary air quality impacts are impacts that would result from the increased electricity usage associated with the operation of control devices (i.e., increased secondary emissions of criteria pollutants from power plants). Energy impacts consist of the electricity and steam needed to operate control devices and other equipment that would be required under this proposed rule. In most cases, to comply with the current Subpart G NO_x emission limit or this Subpart Ga NO_x emission limit, the same control system (SCR, NSCR, or HPI) would have been installed. These proposed revisions only require the addition of exhaust gas flow monitors, which would result in minimal secondary air impacts or increase in overall energy demand.

C. What are the economic impacts for new nitric acid production units?

We performed an economic impact analysis that estimates changes in prices and output for nitric acid production units nationally using the annual compliance costs estimated for this proposed rule. All estimates are for the fifth year after promulgation since this is the year for which the compliance cost impacts are estimated. The impacts to producers and consumers affected by this proposed rule are slightly higher product prices and slightly lower outputs. Prices for products (nitric acid) from affected plants should increase by less than 0.07 percent for the fifth year. The output of nitric acid should decrease by less than 0.50 percent for the fifth year. Hence, the overall economic impact of this proposed NSPS should be low on the affected industries and their consumers. For more information, please refer to the Economic Impact Analysis for this proposed rulemaking in the public docket.

VI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a significant regulatory action because it could raise novel legal or policy issues. Accordingly, the EPA submitted this action to the Office of Management and Budget for review under Executive Order 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

B. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document prepared by the EPA has been assigned the EPA ICR number [2445.01].

These proposed revisions to the existing new source performance standards for nitric acid production units would add monitoring requirements for future affected facilities. We have revised the ICR for the existing rule.

These proposed revisions to the new source performance standards for nitric acid production units for future affected facilities include a change to the emission limit and additional continuous monitoring requirements. The monitoring requirements include installing a continuous flow monitor and monitoring the nitric acid concentration. These monitoring requirements are in addition to a CEMS for NO_x concentration which is required under the current subpart G. These requirements are based on specific requirements in Subpart Ga which are mandatory for all operators subject to

NSPS. These recordkeeping and reporting requirements are specifically authorized by section 114 of the CAA (42 U.S.C. 7414). All information submitted to the EPA pursuant to the recordkeeping and reporting requirements for which a claim of confidentiality is made is safeguarded according to the EPA policies set forth in 40 CFR part 2, subpart B.

The annual burden for this information collection averaged over the first 3 years of this ICR is estimated to total 968 labor-hours per year at a cost of \$91,808 per year. The annualized capital costs are estimated at \$19,288 per year. The annualized operation and maintenance (O&M) costs are \$23,488. The total annualized capital and O&M costs are \$42,776 per year. Burden is defined at 5 CFR 1320.3(b).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

To comment on the agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, the EPA has established a public docket for this rule, which includes this ICR, under Docket ID number EPA-HQ-OAR-2010-0750. Submit any comments related to the ICR to the EPA and OMB. See **ADDRESSES** section at the beginning of this notice for where to submit comments to the EPA. Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, *Attention:* Desk Office for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after October 14, 2011, a comment to OMB is best assured of having its full effect if OMB receives it by November 14, 2011. The final rule will respond to any OMB

or public comments on the information collection requirements contained in this proposal.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that this rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This certification is based on the economic impact of this action to all affected small entities. Only four small entities may be impacted by this proposed rule. We estimate that all affected small entities will have annualized costs of less than 0.3 percent of their sales. We conclude that there is no significant economic impact on a substantial number of small entities (SISNOSE) for this rule.

For more information on the small entity impacts associated with this proposed rule, please refer to the Economic Impact and Small Business Analyses in the public docket. Although this proposed rule would not have a significant economic impact on a substantial number of small entities, the EPA nonetheless tried to reduce the impact of this proposed rule on small entities. When developing the revised standards, the EPA took special steps to ensure that the burdens imposed on small entities were minimal. The EPA conducted several meetings with industry trade associations to discuss regulatory options and the corresponding burden on industry, such as recordkeeping and reporting. We continue to be interested in the potential impacts of the proposed rule

on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

This rule does not contain a federal mandate that may result in expenditures of \$100 million or more for state, local, and tribal governments, in the aggregate, or to the private sector in any one year. This rule is not expected to impact state, local, or tribal governments. The nationwide annualized cost of this proposed rule for affected industrial sources is \$90,010/yr. Thus, this rule is not subject to the requirements of sections 202 and 205 of the Unfunded Mandates Reform Act (UMRA).

This rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. This rule will not apply to such governments and will not impose any obligations upon them.

E. Executive Order 13132, Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Nitric acid plants are privately owned companies and there will be no direct impact on states and other federal offices. Thus, Executive Order 13132 does not apply to this proposed rule. In the spirit of Executive Order 13132, and consistent with the EPA policy to promote communications between the EPA and state and local governments, the EPA specifically solicited comment on this proposed rule from state and local officials.

F. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It will not have substantial direct effects on tribal governments, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, as specified in Executive Order 13175. This proposed rule imposes requirements on owners and operators of nitric acid production units and not tribal governments. We do not know of any nitric acid production units owned

or operated by Indian tribal governments. However, if there are any, the effect of this proposed rule on communities of tribal governments would not be unique or disproportionate to the effect on other communities. Thus, Executive Order 13175 does not apply to this action. The EPA specifically solicits additional comment on this proposed rule from tribal officials.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

The EPA interprets Executive Order 13045 (62 FR 19885, April 22, 1997) as applying to those regulatory actions that concern health or safety risks, such that the analysis required under section 5-501 of the Executive Order has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it is based solely on technology performance.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law No. 104-113 (15 U.S.C. 272 note), directs the EPA to use voluntary consensus standards (VCS) in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. VCS are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs the EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable VCS.

This proposed rulemaking involves technical standards. The EPA proposes to use: ASTM D6348-03, Standard Test Method for Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform Infrared (FTIR) Spectroscopy, and ASTM E1584, Standard Test Method for Assay of Nitric Acid, which have been incorporated by reference.

The EPA welcomes comments on this aspect of the proposed rulemaking and specifically invites the public to identify

potentially applicable voluntary consensus standards and to explain why such standards should be used in this regulation.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

The EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. The EPA has also determined that a proximity-based demographic study comparing populations in closest proximity to the regulated sources to the general population is not appropriate for this rulemaking due to lack of pollutants with localized effects.

List of Subjects in 40 CFR Part 60

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements, Incorporation by reference.

Dated: September 30, 2011.

Lisa P. Jackson,
Administrator.

For the reasons stated in the preamble, title 40, chapter I, of the Code of Federal Regulations is amended as follows:

PART 60—[AMENDED]

1. The authority citation for part 60 continues to read as follows:

Authority: 42 U.S.C. 7401.

Subpart A—[Amended]

2. Section 60.17 is amended by revising paragraph (a)(82) and adding paragraph (a)(93) to read as follows:

§ 60.17 Incorporations by reference.

* * * * *

(a) * * *

(82) ASTM D6348–03, Standard Test Method for Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform Infrared (FTIR) Spectroscopy, IBR approved for § 60.73a(f)(2) of subpart Ga, table 7 of subpart IIII of this part, and table 2 of subpart JJJJ of this part.

* * * * *

(93) ASTM E1584–00(2005)e1, Standard Test Method for Assay of Nitric Acid, IBR approved for § 60.73a(b)(2) of subpart Ga.

* * * * *

3. Section 60.70 is amended by revising paragraph (b) to read as follows:

§ 60.70 Applicability and designation of affected facility.

* * * * *

(b) Any facility under paragraph (a) of this section that commences construction or modification after August 17, 1971, and on or before October 14, 2011 is subject to the requirements of Subpart G. Any facility that commences construction or modification after October 14, 2011 is subject to Subpart Ga.

* * * * *

4. Add Subpart Ga to read as follows:

Subpart Ga—Standards of Performance for Nitric Acid Plants for Which Construction, Reconstruction, or Modification Commenced After October 14, 2011

Sec.

60.70a Applicability and designation of affected facility.

60.71a Definitions.

60.72a Standards.

60.73a Emissions testing and monitoring.

60.74a Affirmative Defense for Exceedance of Emission Limit During Malfunction.

60.75a Calculations.

60.76a Recordkeeping.

60.77a Reporting.

Subpart Ga—Standards of Performance for Nitric Acid Plants for Which Construction, Reconstruction, or Modification Commenced After October 14, 2011

§ 60.70a Applicability and designation of affected facility.

(a) The provisions of this subpart are applicable to each nitric acid production unit, which is the affected facility.

(b) This subpart applies to any nitric acid production unit that commences construction or modification on or after October 14, 2011.

§ 60.71a Definitions.

As used in this subpart, all terms not defined herein shall have the meaning given them in the Act and in subpart A of this part.

(a) *Affirmative defense* means, in the context of an enforcement proceeding, a response or defense put forward by a defendant, regarding which the defendant has the burden of proof, and the merits of which are independently and objectively evaluated in a judicial or administrative proceeding.

(b) *Nitric acid production unit* means any facility producing weak nitric acid by either the pressure or atmospheric pressure process.

(c) *Operating day* means a 24-hour period beginning at 12:00 a.m. during which the nitric acid production unit at any time during this period.

(d) *Weak nitric acid* means acid which is 30 to 70 percent in strength.

§ 60.72a Standards.

(a) *Nitrogen oxides.* On and after the date on which the performance test required to be conducted by § 60.73a(a) is completed, you may not discharge into the atmosphere from any affected facility any gases which contain NO_x, expressed as NO₂, in excess of 0.50 pounds (lb) per ton of nitric acid produced, as a 30-day emission rate calculated based on 30 consecutive operating days, the production being expressed as 100 percent nitric acid. The emission standard applies at all times.

(b) *General Duty to minimize emissions.* At all times, the owner or operator must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions. Determination of whether such operation and maintenance procedures are being used will be based on information available to the Administrator which may include, but is not limited to, monitoring results, review of operation and maintenance procedures, review of operation and maintenance records, and inspection of the source.

§ 60.73a Emissions testing and monitoring.

(a) *Nitric acid production monitoring.*

(1) For any affected facility, you must determine the daily nitric acid production parameters (production rate and concentration) by installing, calibrating, maintaining, and operating a permanent monitoring system (e.g., weigh scale, volume flow meter, mass flow meter, tank volume) to measure

and record the weight rates of nitric acid produced in tons per day. You must verify that each component of the monitoring system has an accuracy and precision of no more than ± 5 percent of full scale.

(2) You may analyze product concentration via titration or by determining the temperature and specific gravity of the nitric acid. You may also use ASTM E1584–00(2005)e1 (incorporated by reference, see § 60.17), for determining the concentration of nitric acid in percent. You must determine product concentration daily.

(3) For any affected facility, you must use the acid concentration to express the daily nitric acid production as 100 percent nitric acid.

(4) For any affected facility, you must record the daily nitric acid production, expressed as 100 percent nitric acid, and the hours of operation.

(b) *Nitrogen oxides continuous emissions monitoring system.* (1) You must install, calibrate, maintain, and operate a continuous emission rate monitoring system (CERMS) for measuring and recording the mass emissions of NO_x in accordance with the provisions of 60.13 and Performance Specifications 2 and 6 of appendix B of this part. The CERMS must consist of equipment for measuring NO_x concentration and stack gas volumetric flow rate monitoring equipment for measuring the volumetric flow rate and for calculating and reporting hourly and daily NO_x mass emissions rates in units of lb/hour and lb NO_x/ton of 100% nitric acid.

(2) As applicable, use a span value, as defined in Performance Specification 2 § 3.11, for all NO_x concentration monitoring equipment equal to 125 percent of the maximum estimated NO_x emission concentration.

(3) You must conduct performance evaluations of the NO_x CERMS according to the requirements in § 60.13(c) and Performance Specifications 2 and 6 of appendix B of this part. For conducting the relative accuracy evaluations, per § 8.4 of the Performance Specification 2, use either EPA Reference Method 7, 7A, 7C, 7D, or 7E of appendix A–4 of this part; EPA Reference Method 320 of appendix A of part 63 of this chapter; or ASTM D6348–03 (incorporated by reference, see § 60.17).

(4) If you use EPA Reference Method 7E of Appendix A–4 of this part, you must mitigate loss of NO₂ in water according to the requirements in paragraphs (a)(4)(i), (ii), or (iii) of this section and verify performance by conducting the system bias checks required in § 8 of EPA Reference

Method 7E of appendix A–4 of this part according to (b)(4)(iv) of this section, or follow the dynamic spike procedure according to paragraph (b)(4)(v) of this section.

(i) For a wet-basis measurement system, you must measure and report temperature of sample line and components (up to analyzer inlet) to demonstrate that the temperatures remain above the sample gas dew point at all times during the sampling.

(ii) You may use a dilution probe to reduce the dew point of the sample gas.

(iii) You may use a refrigerated-type condenser or similar device (e.g., permeation dryer) to remove condensate continuously from sample gas while maintaining minimal contact between condensate and sample gas.

(iv) If your analyzer measures nitric oxide (NO) and nitrogen dioxide (NO₂) separately, you must use both NO and NO₂ calibration gases. Otherwise, you must substitute NO₂ calibration gas for NO calibration gas in the performance of system bias checks.

(v) You must conduct dynamic spiking according to § 16.1 in EPA Reference Method 7E of appendix A–4 of this part using NO₂ as the spike gas.

(5) You must use stack gas flow rate measurement equipment with a full scale output of at least 125 percent of the maximum expected exhaust volumetric flow rate (see § 8 of Performance Specification 6, Appendix B, of this part).

(d) CERMS Quality Assurance and Quality Control.

(1) The CERMS must comply with the quality assurance requirements in Procedure 1 of Appendix F of this part. You must use cylinder gas audits to fulfill the quarterly auditing requirement at Appendix F, Procedure 1, § 5.1 of this part only on the NO_x concentration measurement equipment. You must conduct relative accuracy testing to provide for calculating the relative accuracy for RATA and RAA determinations in units of lb/hour and lb NO_x/ton nitric acid.

(2) You must determine daily calibration drift assessments separately for each analyzer in terms of its specific measurement. You must perform the daily assessments in accordance with the procedures specified in §§ 8.1 and 13.1 of Performance Specification 6 of appendix B of this part.

(3) Should you apply an FTIR CEMS meeting the requirements of Performance Specification 15, Appendix B of this part, you must replace the Relative Accuracy Test Audit requirements of Procedure 1 of appendix F of this part with the validation requirements and criteria of

§§ 11.1.1 and 12.0 of Performance Specification 15 of appendix B of this part.

(e) For each CERMS, including NO_x concentration measurement, volumetric flow rate measurement, and nitric acid production measurement equipment, you must meet the requirements in paragraphs (e)(1) through (3) of this section.

(1) You must operate the CERMS and collect data at all required intervals at all times the affected source is operating except for periods of monitoring system malfunctions or out-of-control periods as defined in Appendix F, §§ 4 and 5, repairs associated with monitoring system malfunctions or out-of-control periods, and required monitoring system quality assurance or quality control activities including, as applicable, calibration checks and required zero and span adjustments. A monitoring system malfunction is any sudden, infrequent, not reasonably preventable failure of the monitoring system to provide valid data.

Monitoring system failures that are caused in part by poor maintenance or careless operation are not malfunctions. You are required to affect monitoring system repairs in response to monitoring system malfunctions or out-of-control periods, and to return the monitoring system to operation as expeditiously as practicable.

(2) You may not use data recorded during monitoring system malfunctions or out-of-control periods, repairs associated with monitoring system malfunctions or out-of-control periods, or required monitoring system quality assurance or control activities in calculations used to report emissions or operating levels. You must use all the data collected during all other periods in calculating emissions and the status of compliance with the applicable emissions limit in accordance with § 60.72a(a).

(3) Except for periods of monitoring system malfunctions or out-of-control periods, repairs associated with monitoring system malfunctions or out-of-control periods, and required monitoring system quality assurance or quality control activities including, as applicable, calibration checks and required zero and span adjustments, failure to collect required data is a violation of the monitoring requirements.

(f) *Initial Performance Testing.* You, as the owner or operator of a new unit, must conduct an initial performance test to demonstrate compliance with the NO_x emissions limit under § 60.72a(a) beginning in the calendar month following initial certification of the NO_x

and flow rate monitoring CEMS. The initial performance test consists of collection of hourly NO_x average concentration, mass flow rate (SCFH) recorded with the certified NO_x concentration and flow rate CEMS and the corresponding acid generation (tons) data for all of the hours of operation for the first 30 days beginning on the first day of the first month following completion of the CEMS installation and certification as described above. You must assure that the CERMS meets all of the data quality assurance requirements as per § 60.13 and appendix F, procedure 1 of this part and you must use the data from the CERMS for this compliance determination.

§ 60.74a Affirmative Defense for Exceedance of Emission Limit During Malfunction.

In response to an action to enforce the standards set forth in paragraph § 60.72a, you may assert an affirmative defense to a claim for civil penalties for exceedances of such standards that are caused by malfunction, as defined at 40 CFR 60.2. Appropriate penalties may be assessed, however, if you fail to meet your burden of proving all of the requirements in the affirmative defense. The affirmative defense shall not be available for claims for injunctive relief.

(a) To establish the affirmative defense in any action to enforce such a limit, you must timely meet the notification requirements in paragraph (b) of this section, and must prove by a preponderance of evidence that:

(1) The excess emissions:

(i) Were caused by a sudden, infrequent, and unavoidable failure of air pollution control and monitoring equipment, process equipment, or a process to operate in a normal or usual manner, and

(ii) Could not have been prevented through careful planning, proper design or better operation and maintenance practices; and

(iii) Did not stem from any activity or event that could have been foreseen and avoided, or planned for; and

(iv) Were not part of a recurring pattern indicative of inadequate design, operation, or maintenance; and

(2) Repairs were made as expeditiously as possible when the applicable emission limitations were being exceeded. Off-shift and overtime labor were used, to the extent practicable to make these repairs; and

(3) The frequency, amount and duration of the excess emissions (including any bypass) were minimized to the maximum extent practicable during periods of such emissions; and

(4) If the excess emissions resulted from a bypass of control equipment or a process, then the bypass was unavoidable to prevent loss of life, personal injury, or severe property damage; and

(5) All possible steps were taken to minimize the impact of the excess emissions on ambient air quality, the environment and human health; and

(6) All emissions monitoring and control systems were kept in operation if at all possible consistent with safety and good air pollution control practices; and

(7) All of the actions in response to the excess emissions were documented by properly signed, contemporaneous operating logs; and

(8) At all times, the facility was operated in a manner consistent with good practices for minimizing emissions; and

(9) A written root cause analysis has been prepared, the purpose of which is to determine, correct, and eliminate the primary causes of the malfunction and the excess emissions resulting from the malfunction event at issue. The analysis shall also specify, using best monitoring methods and engineering judgment, the amount of excess emissions that were the result of the malfunction.

(b) *Notification.* The owner or operator of the facility experiencing an exceedance of its emission limit(s) during a malfunction shall notify the Administrator by telephone or facsimile (FAX) transmission as soon as possible, but no later than two business days after the initial occurrence of the malfunction, if it wishes to avail itself of an affirmative defense to civil penalties for that malfunction. The owner or operator seeking to assert an affirmative defense shall also submit a written report to the Administrator within 45 days of the initial occurrence of the exceedance of the standard in § 60.72a to demonstrate, with all necessary supporting documentation, that it has met the requirements set forth in paragraph (a) of this section. The owner or operator may seek an extension of this deadline for up to 30 additional days by submitting a written request to the Administrator before the expiration of the 45 day period. Until a request for an extension has been approved by the Administrator, the owner or operator is subject to the requirement to submit such report within 45 days of the initial occurrence of the exceedance.

§ 60.75a Calculations.

(a) The 30-day rolling NO_x emission rate is calculated as the sum of all daily NO_x mass emissions recorded by the

CERMS for 30 consecutive operating days divided by the sum of nitric acid production for these 30 consecutive operating days. Calculate and record the daily mass emissions of NO_x according to the procedures in paragraphs (a)(1) through (4) of this section.

(1) You must calculate the daily mass emissions according to Equation 1:

$$M_d = \sum_{i=1}^n C_i * Q_i \quad (\text{Eq. 1})$$

Where:

M_d = daily mass emissions of NO_x as NO₂, lb NO_x.

C_i = concentration of NO_x for hour i, lb/standard cubic foot (scf).

Q_i = volumetric flow rate of effluent gas for hour i, scf/hour.

n = number of operating hours in the operating day.

(2) For any operating day where monitoring data are only available for part of the hours where nitric acid is produced during that day due to CERMS malfunctions, out-of-control periods, or repairs associated with monitoring system malfunctions or out-of-control periods, you must calculate M_d for the periods where monitoring data are available using Equation 1 in (a)(1) above, and then adjust upwards overall operating hours on a *pro rata* basis.

(3) You must ensure appropriate corrections for moisture are made when measuring flow rates.

(4) Following each calendar day on which the affected facility was operated, you must calculate the 30-day NO_x emission rate according to Equation 2:

$$E_{30\text{-day}} = \frac{\sum_{d=1}^m M_d}{\sum_{d=1}^m P_d} \quad (\text{Eq. 2})$$

Where:

E_{30-day} = emission rate of NO_x as NO₂ calculated based on 30 consecutive operating days, lb NO_x/ton of 100 percent nitric acid.

M_d = daily mass emissions of NO_x as NO₂ for operating day d, lb NO_x

P_d = daily nitric acid production for operating day d, tons of 100 percent nitric acid.

m = number of days in the 30-day compliance period for which CERMS data is available.

§ 60.76a Recordkeeping.

(a) For the NO_x emissions rate, you must keep records of the performance test data from the initial and subsequent performance tests and from the performance evaluation of the continuous monitors.

(b) You must maintain records of the following information for each 30 day period:

- (1) Hours of operation.
- (2) Production rate of nitric acid, expressed as 100 percent nitric acid.
- (3) NO_x mass emissions.

(c) You must maintain records of the following time periods:

- (1) Times when you were not in compliance with the emissions standards.
- (2) Times when the pollutant concentration exceeded full span of the NO_x pollutant monitoring equipment.
- (3) Times when the volumetric flow rate exceeded the high value of the volumetric flow rate monitoring equipment.

(d) You must maintain records of the reasons for any periods of noncompliance and description of corrective actions taken.

(e) You must maintain records of any modifications to CERMS which could affect the ability of the CERMS to comply with applicable performance specifications.

(f) For each malfunction, you must maintain records of the following information:

(1) Records of the occurrence and duration of each malfunction of operation (*i.e.*, process equipment) or the air pollution control and monitoring equipment.

(2) Records of actions taken during periods of malfunction to minimize emissions in accordance with section 60.72a(b), including corrective actions to restore malfunctioning process and air pollution control and monitoring equipment to its normal or usual manner of operation.

§ 60.77a Reporting.

(a) The performance test data from the initial and subsequent performance tests and from the performance evaluations of the continuous monitors must be submitted to the Administrator at the appropriate address as shown in 40 CFR 60.4.

(b) The following information must be reported to the Administrator for each 30 day period where you were not in compliance with the emissions standard:

- (1) Time period.
- (2) NO_x emission rates (lb/ton of acid produced).
- (3) Reasons for noncompliance with the emissions standard; and description of corrective actions taken.

(c) You must also report the following whenever they occur:

(1) Times when the pollutant concentration exceeded full span of the NO_x pollutant monitoring equipment.

(2) Times when the volumetric flow rate exceeded the high value of the volumetric flow rate monitoring equipment.

(d) You must report any modifications to CERMS which could affect the ability of the CERMS to comply with applicable performance specifications.

(e) As of December 31, 2011 and within 60 days after the date of completing each performance evaluation or test required under this subpart, you must submit the relative accuracy test audit data and performance test data by successfully submitting the data electronically to EPA's Central Data Exchange (CDX) by using the Electronic Reporting Tool (ERT) (see http://www.epa.gov/ttn/chief/ert/ert_tool.html).

(f) If a malfunction occurred during the reporting period, you must submit a report that contains the following:

(1) The number, duration, and a brief description for each type of malfunction which occurred during the reporting period and which caused or may have caused any applicable emission limitation to be exceeded.

(2) A description of actions taken by an owner or operator during a malfunction of an affected source to minimize emissions in accordance with 60.72a(b), including actions taken to correct a malfunction.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 71

[Docket No. CDC-2011-0007]

RIN 0920-AA37

Foreign Quarantine; Etiological Agents, Hosts, and Vectors

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the U.S. Department of Health and Human Services (HHS) is issuing this Notice of Proposed Rulemaking (NPRM) to revise the regulations that cover the importation of etiological agents and the hosts and vectors of human disease. The changes are proposed to improve CDC's ability to prevent the introduction, transmission, or spread of communicable diseases into the United States.

DATES: To be assured consideration, comments must be received on or before

December 13, 2011. Comments received after the close of the comment period will be considered to the fullest extent possible.

ADDRESSES: You may submit comments, identified by Regulatory Information Number (RIN) 0920-AA37 in the heading of this document, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *E-mail:* SAPcomments@cdc.gov. Please include the RIN number in the subject line of the message.

- *Fax:* 404-718-2093.

- *Mail:* Division of Select Agents and Toxins, Centers for Disease Control and Prevention, ATTN: Importation Regulations, 1600 Clifton Road, NE., MS A-46, Atlanta, Georgia 30333.

- *Hand Delivery/Courier:* Division of Select Agents and Toxins, Centers for Disease Control and Prevention, ATTN: Importation Regulations, 1600 Clifton Road, NE., MS A-46, Atlanta, Georgia 30333.

Instructions: All submissions received must include the agency name and RIN for this rulemaking. All relevant comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received or to download an electronic version of the NPRM, go to <http://www.regulations.gov>. Comments will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m. at 1600 Clifton Road, NE., Atlanta, GA 30333. Please call ahead to 1-866-694-4867 and ask for a representative in the Division of Select Agents and Toxins to schedule your visit. Our general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet as they are received and without change.

FOR FURTHER INFORMATION CONTACT: Robbin Weyant, PhD, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road, NE., MS A-46, Atlanta, GA 30333. Telephone: 404-718-2000.

SUPPLEMENTARY INFORMATION: The Preamble to this notice of proposed rulemaking is organized as follows:

- I. Background
 - A. HHS/CDC Authority
- II. Proposed Changes to 42 CFR 71.54
 - A. Section Heading & Definitions
 - B. Biosafety and Inspection Provisions