of FCLAA (15 U.S.C. 1333) to require that nine new health warning statements appear on cigarette packages and in cigarette advertisements. Section 201 also states that “the Secretary of Health and Human Services shall issue regulations that require color graphics depicting the negative health consequences of smoking” to accompany the nine new health warning statements.

On November 12, 2010, FDA published a proposed rule seeking comment on these new requirements (75 FR 69524). The proposed rule provides a 60-day comment period, which ends January 11, 2011. FDA proposed several options for color graphics that could accompany each of the nine health warning statements required by FCLAA. These documents are available in the docket and on FDA’s Web site (http://www.fda.gov/cigarettewarnings). FDA seeks comment on these proposed images.

II. Experimental Study

In considering and developing appropriate color graphics depicting the negative health consequences of smoking to accompany the textual warning statements specified in section 4(a)(1) of FCLAA (15 U.S.C. 1333(a)(1)), FDA assessed the graphic warnings that other countries have required for tobacco products, as well as scientific literature studying the impact of graphic warnings on smoking behavior and evaluating the communication effectiveness of such images. FDA worked with various experts in the fields of health communications, marketing research, graphic design, and advertising to develop the required warnings published with the proposed rule. The proposed rule explained that FDA was conducting research to: (1) Measure consumer attitudes, beliefs, and intended behaviors related to cigarette smoking in response to the proposed color graphics and their accompanying textual warning statements; (2) determine whether consumer responses to the proposed color graphics and their accompanying textual warning statements differ across various groups based on smoking status, age, or other demographic variables; and (3) evaluate the relative effectiveness of the proposed color graphics and their accompanying textual warning statements at conveying information about various health risks of smoking, and additionally, at encouraging smoking cessation and discouraging smoking initiation (75 FR 7604 (February 22, 2010); 75 FR 52352 (August 25, 2010)). The proposed rule stated that once the research is complete and final analyses of the results are available, FDA planned to place a report of the results of the analyses in the docket so the public has an opportunity to comment on it.

FDA has now completed this research and analyzed the results. The Experimental Study Report describes FDA’s findings and analysis. FDA has placed the Experimental Study Report in the docket for the proposed rule and is providing notice and an opportunity to comment on it.

III. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding the Experimental Study Report and the related rulemaking documents. It is only necessary to send one copy of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.


Margaret A. Hamburg, Commissioner of Food and Drugs.

[FR Doc. 2010–30685 Filed 12–3–10; 8:45 am]

BILLING CODE 4160–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63


RIN 2060–AP36

National Emission Standards for Hazardous Air Pollutants for Reciprocating Internal Combustion Engines

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of reconsideration of final rule; request for public comment; notice of public meeting.

SUMMARY: On March 3, 2010, EPA published final national emission standards for hazardous air pollutants for existing compression ignition stationary reciprocating internal combustion engines. Subsequently, the Administrator received two petitions for reconsideration concerning one particular issue arising from the final rule. EPA is announcing our reconsideration of and requesting public comment on that one issue. Specifically, while EPA is not proposing at this time any specific changes to our regulations, EPA is requesting comment on our decision to amend the limitations on operation of emergency stationary engines to allow emergency engines to operate for up to 15 hours per year as part of an emergency demand response program. EPA plans to issue a final decision on this issue as expeditiously as possible. EPA is seeking comment only on this issue. EPA will not respond to any comments addressing any other issue or any other provisions of the final rule or any other rule.

DATES: Comments. Comments must be received on or before February 7, 2011, or 30 days after date of public meeting if later.

Public Meeting. If anyone contacts us requesting to speak at a public meeting by December 27, 2010, a public meeting will be held on January 6, 2011. If you are interested in attending the public meeting, contact Ms. Pamela Garrett at (919) 541–7966 to verify that a meeting will be held.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2008–0708, by one of the following methods:

• http://www.regulations.gov: Follow the on-line instructions for submitting comments.

• E-mail: a-and-r-docket@epa.gov.

• Fax: (202) 566–1741.

• Mail: Air and Radiation Docket and Information Center, Environmental Protection Agency, Mailcode: 6102T, 1200 Pennsylvania Ave., NW., Washington, DC 20460. Please include a total of two copies. EPA requests a separate copy also be sent to the contact person identified below (see FOR FURTHER INFORMATION CONTACT).

• Hand Delivery: Air and Radiation Docket and Information Center, U.S. EPA, Room B102, 1301 Constitution Avenue, NW., Washington, DC. Such deliveries are only accepted during the Docket’s normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OAR–2008–0708. EPA’s policy is that all comments received will be included in the public docket without change and may be made available on-line at 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
This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. To determine whether your engine is regulated by this action, you should examine the applicability criteria in 40 CFR 63.6585. You should contact the person listed in the preceding FOR FURTHER INFORMATION CONTACT section.

### Category

<table>
<thead>
<tr>
<th>Category</th>
<th>NAICS 1</th>
<th>Examples of regulated entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any industry using a stationary reciprocating internal combustion engine</td>
<td>2211</td>
<td>Electric power generation, transmission, or distribution.</td>
</tr>
<tr>
<td></td>
<td>622110</td>
<td>Medical and surgical hospitals.</td>
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<tr>
<td></td>
<td>48211</td>
<td>Natural gas transmission.</td>
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<tr>
<td></td>
<td>211111</td>
<td>Crude petroleum and natural gas production.</td>
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<td></td>
<td>211112</td>
<td>Natural gas liquids producers.</td>
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<tr>
<td></td>
<td>92811</td>
<td>National security.</td>
</tr>
</tbody>
</table>

1 North American Industry Classification System.

### C. What should I consider as I prepare my comments for EPA?

1. Submitting CBI

Do not submit this information to EPA through http://www.regulations.gov or e-mail. 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 so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. Send or deliver information identified as CBI to only the following address: Ms. Melanie King, c/o OAQPS Document Control Officer (Room C404–02), U.S. EPA, Research Triangle Park, NC 27711, Attention Docket ID No. EPA–HQ–OAR–2008–0708.
2. Tips for Preparing Your Comments

When submitting comments, remember to:
(a) Identify the action by docket number and other identifying information (subject heading, Federal Register date and page number).
(b) Follow directions. EPA may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations part or section number.
(c) Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
(d) Describe any assumptions and provide any technical information and/or data that you used.
(e) If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
(f) Provide specific examples to illustrate your concerns, and suggest alternatives.
(g) Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
(h) Make sure to submit your comments by the comment period deadline identified.

Docket. The docket number for this action is Docket ID No. EPA–HQ–OAR–2008–0708.
World Wide Web (WWW). In addition to being available in the docket, an electronic copy of this action will be posted on the WWW through the Technology Transfer Network Website (TTN Web). Following signature, EPA will post a copy of this action on the TTN’s policy and guidance page at http://www.epa.gov/tnn/oarpg. The TTN provides information and technology exchange in various areas of air pollution control.

II. Background

On March 3, 2010, EPA promulgated national emission standards for hazardous air pollutants (NESHAP) for existing stationary compression ignition (CI) reciprocating internal combustion engines (RICE) (75 FR 9648). The final NESHAP for stationary RICE were promulgated under 40 CFR part 63, subpart ZZZZ, which already contained pollution control. The final CI RICE NESHAP is available at http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480a0ab3523.

Following promulgation of the March 3, 2010, final rule, the EPA Administrator received a petition for reconsideration, dated April 30, 2010, from the Delaware Department of Natural Resources and Environmental Control (DE DNREC) pursuant to section 307(d)(7)(B) of the CAA. The EPA Administrator also received a petition for reconsideration, dated May 27, 2010, from CPower Inc., EnergyConnect Inc., EnerNOC Inc., and Innovative Power LLC (EnerNOC, et al.) pursuant to section 307(d)(7)(B) of the CAA. On August 2, 2010, EPA issued a letter to the council for the DE DNREC and EnerNOC, et al. granting the petitions for reconsideration and indicating that the Agency would issue a Federal Register notice regarding the reconsideration process. This action requests comment on issues raised in the petitions for reconsideration.

In addition to the petitions for reconsideration, one petition for judicial review of the March 3, 2010, final NESHAP for existing stationary CI RICE was filed with the U.S. Court of Appeals for the District of Columbia Circuit by EnerNOC, et al. (Doc. No. 10–1090, D.C. Cir). On June 3, 2010, EPA filed an unopposed motion to hold the case in abeyance while the Agency considers the pending administrative petitions for reconsideration. On June 4, 2010, the Court granted EPA’s motion and ordered the case held in abeyance pending further order from the Court. The petitions for reconsideration are available for review at http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480af3dd6 and http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480afedbd.

III. Discussion of the Issue

On March 5, 2009, EPA proposed NESHAP for several categories of existing stationary RICE (74 FR 9698). That proposed rule made revisions to 40 CFR part 63, subpart ZZZZ. The pre-existing subpart ZZZZ stated that emergency stationary RICE did not include engines that supply power to an electric grid or otherwise provide power as part of a financial arrangement with another entity. The proposed rule did not change the definition, but specified certain use requirements for existing emergency stationary RICE.

EPA received comments on the proposed rule recommending that emergency stationary RICE be allowed to participate in emergency demand response programs to ensure stability of the electric grid. Based on the comments, EPA determined that it would be appropriate to allow emergency engines to operate as part of emergency demand response programs for a limited number of hours of operation per year in situations where grid failure and a blackout are imminent. EPA included a provision in the March 3, 2010, final rule specifying that emergency engines could be operated for a maximum of 15 hours per year as part of a demand response program if the regional transmission organization or equivalent balancing authority and transmission operator has determined there are emergency conditions that could lead to a potential electrical blackout, such as unusually low frequency, equipment overload, capacity or energy deficiency, or unacceptable voltage level.

Following promulgation of the final rule, EPA received two petitions for reconsideration regarding the allowance for operation of emergency engines in emergency demand response programs. The petition from DE DNREC requested that EPA reconsider the decision to allow 15 hours of emergency demand response operation for emergency engines because of the adverse impacts of the increased emissions from these engines. According to the DE DNREC, the emergency demand response operation would likely occur on high ozone days, and would undercut the progress Delaware has made in reducing emissions of hazardous air pollutants, nitrogen oxides, volatile organic compounds, and ozone. The DE DNREC also stated that there was insufficient notice that EPA would amend the provisions for stationary emergency engines.

The petition from EnerNOC, et al., requested that EPA revise the allowance for emergency demand response operation in the final rule to allow the engines to be operated for a maximum of 60 hours per year or the minimum hours required by the Independent System Operator (ISO) tariff, whichever is less. In the opinion of EnerNOC, et al., the final rule may prevent emergency engines from participating in emergency demand response programs since the engines may not be able to meet ISO tariff requirements that specify minimum hours of availability to participate. According to the petition from EnerNOC, et al., emergency engines have historically been called to operate for emergency demand response on a very limited basis. The EnerNOC, et al., petition provided a summary of the historical usage of engines in emergency demand response programs. The petitioners were of the opinion that emergency demand response programs provide a benefit to the environment by preventing rotating or wholesale blackouts, which would result in the operation of all emergency engines in the affected area.
IV. Solicitation of Public Comment and Participation

EPA seeks full public participation in arriving at its final decisions. At this time EPA is not proposing any specific revisions to our regulations allowing 15 hours for emergency stationary RICE in emergency demand response programs in the final NESHAP for stationary RICE. However, EPA requests public comment on the regulations delineating the allowance to assess whether those regulations should be revised. EPA requests comment on whether or not engines should be allowed to participate in emergency demand response programs, while keeping their status as emergency engines under the regulations, and if they are allowed to participate, what, if any, limitations should be placed on the operation of emergency engines in emergency demand response programs. EPA specifically requests comment on whether emergency engines in emergency demand response programs should be limited to use during periods in which the regional transmission organization or equivalent balancing authority and transmission operator directs the implementation of operating procedures for voltage reductions of 5 percent of normal operating voltage requiring more than 10 minutes to implement, voluntary load curtailments by customers, or automatic or manual load-shedding, in response to, or to prevent the occurrence of, unusually low frequency, equipment overload, capacity or energy deficiency, unacceptable voltage levels, or other such emergency conditions. EPA also requests comment on whether the limitation on use should be for periods in which the regional transmission authority or equivalent balancing authority has declared an Energy Emergency Alert Level 2 (EEA Level 2) as defined in the North American Electric Reliability Corporation Reliability Standard EOP–002–3, Capacity and Energy Emergency. EPA is also requesting information on whether the operation of these engines in emergency demand response programs is needed to ensure the stability of the electric grid. EPA is seeking comment on whether the costs for meeting the requirements for non-emergency engines would prevent these engines from taking part in emergency demand response programs. In addition, EPA is requesting information on the environmental impact of the operation of these engines. EPA is interested in information on the typical frequency and duration of the operation of these engines in emergency demand response programs and whether their operation tends to occur on high ozone days.

EPA recently published a notice of proposed rulemaking to revise portions of the New Source Performance Standards for Stationary Compression Ignition and Stationary Spark Ignition Internal Combustion Engines. 75 FR 32612 (June 8, 2010). In that action, EPA proposed revising the definition and use restrictions on emergency stationary internal combustion engines in 40 CFR part 60, subparts III and IJJJ, to correspond to the definition of emergency RICE and the restrictions on emergency RICE finalized in the March 3, 2010, final NESHAP for existing stationary CI RICE. Therefore, the comments received on this issue in both proceedings may be relevant to one another.

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

This action is not a “significant regulatory action” under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under the Executive Order.

B. Paperwork Reduction Act

This action does not impose any new information collection burden. EPA is not proposing any new information collection activities (e.g., monitoring, reporting, recordkeeping) as part of this action. With this action, EPA is seeking additional comments on one aspect of the final NESHAP for existing stationary CI RICE (75 FR 9648, March 3, 2010). The Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., and has assigned OMB control number 2060–0548. The OMB control numbers for EPA’s regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act 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 the 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 action 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 action on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This action seeks comment on one aspect of the final NESHAP for existing stationary CI RICE without proposing any changes to the rule, and it does not impose any new requirements.

D. Unfunded Mandates Reform Act of 1995

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for State, local, or tribal governments or the private sector. The action imposes no enforceable duty on any State, local or tribal governments or the private sector. Therefore, this action is not subject to the requirements of sections 202 or 205 of the UMRA.

This action 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 action requests comment on one aspect of the final NESHAP for existing stationary CI RICE without proposing any changes to the rule.

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. This action seeks comment on one aspect of the final NESHAP for existing stationary CI RICE without proposing any changes to the rule. Thus, Executive Order 13132 does not apply to this action.
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). This action 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. Thus, Executive Order 13175 does not apply to this action.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the 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 and not on health or safety risks.

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 (NTTAA) of 1995 (Pub. L. 104–113, Section 12(d), 15 U.S.C. 272 note) directs EPA to use voluntary consensus standards (VCS) in its regulatory activities, unless to do so would be inconsistent with applicable law or otherwise impractical. The VCS are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by VCS bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency does not use available and applicable VCS.

This action does not involve technical standards. Therefore, EPA did not consider the use of any VCS.

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

Executive Order 12898 (59 FR 7629 (Feb. 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 on minority or low-income populations.

EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. This action seeks comment on one aspect of the final NESHAP for existing stationary CI RICE without proposing any changes to the rule.

List of Subjects in 40 CFR Part 63

Administrative practice and procedure, Air pollution control, Hazardous substances, Intergovernmental relations.

Dated: November 30, 2010.

Lisa P. Jackson, Administrator.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–4064, or (e-mail) luis.rodriguez1@dhs.gov.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) proposes to make determinations of BFEs and modified BFEs for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed BFEs and modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These proposed elevations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in those buildings.