

SIP submission notes that the following State regulations and State statutes provide the Commonwealth the authority to meet the requirements of this element: 401 KAR 50:066.

*Conformity of transportation plans, programs, and projects*; 401 KAR 52:100. *Public, Affected State, and US EPA Review*; and KRS Chapter 77. *Air Pollution Control*. EPA has made the preliminary determination that Kentucky's SIP and practices adequately demonstrate consultation with affected local entities related to the 2010 1-hour SO<sub>2</sub> NAAQS when necessary.

## V. Proposed Action

With the exception of interstate transport provisions pertaining to the contribution to nonattainment or interference with maintenance in other states and visibility protection requirements of section 110(a)(2)(D)(i)(I) and (II) (prongs 1, 2, and 4) and the minor source program requirements of section 110(a)(2)(C), EPA is proposing to approve Kentucky's April 26, 2013, infrastructure SIP submission for the 2010 1-hour SO<sub>2</sub> NAAQS for the above described infrastructure SIP requirements. EPA is proposing to approve these portions of Kentucky's infrastructure SIP submission for the 2010 1-hour SO<sub>2</sub> NAAQS because these aspects of the submission are consistent with section 110 of the CAA.

## VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);

- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);

- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

**Authority:** 42 U.S.C. 7401 *et seq.*

Dated: March 25, 2016.

**Heather McTeer Toney,**

*Regional Administrator, Region 4.*

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**BILLING CODE 6560-50-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Part 88

[NIOSH Docket 094]

### World Trade Center Health Program; Petition 010—Peripheral Neuropathy; Finding of Insufficient Evidence

**AGENCY:** Centers for Disease Control and Prevention, HHS.

**ACTION:** Denial of petition for addition of a health condition.

**SUMMARY:** On January 5, 2016, the Administrator of the World Trade Center (WTC) Health Program received a petition (Petition 010) to add peripheral neuropathy to the List of WTC-Related Health Conditions (List). Upon reviewing the scientific and medical literature, including information provided by the petitioner, the Administrator has determined that the available evidence does not have the potential to provide a basis for a decision on whether to add peripheral neuropathy to the List. The Administrator finds that insufficient evidence exists to request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee (STAC), to publish a proposed rule, or to publish a determination not to publish a proposed rule.

**DATES:** The Administrator of the WTC Health Program is denying this petition for the addition of a health condition as of April 4, 2016.

#### FOR FURTHER INFORMATION CONTACT:

Rachel Weiss, Program Analyst, 1090 Tusculum Avenue, MS: C-46, Cincinnati, OH 45226; telephone (855) 818-1629 (this is a toll-free number); email [NIOSHregs@cdc.gov](mailto:NIOSHregs@cdc.gov).

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#### A. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Zadroga Act) Public Law 111-347, as amended by Public Law 114-113, added Title XXXIII to the Public Health Service Act (PHS Act)<sup>1</sup> establishing the WTC Health Program within the Department of Health and Human Services (HHS). The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville,

<sup>1</sup> Title XXXIII of the PHS Act is codified at 42 U.S.C. 300mm to 300mm-61. Those portions of the Zadroga Act found in Titles II and III of Public Law 111-347 do not pertain to the WTC Health Program and are codified elsewhere.

Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001 or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

All references to the Administrator of the WTC Health Program (Administrator) in this notice mean the Director of the National Institute for Occupational Safety and Health (NIOSH) or his or her designee.

Pursuant to section 3312(a)(6)(B) of the PHS Act, interested parties may petition the Administrator to add a health condition to the List in 42 CFR 88.1. After receipt of a petition to add a condition to the List, the Administrator must take one of the following four actions described in PHS Act, section 3312(a)(6)(B) and 42 CFR 88.17: (i) Request a recommendation of the STAC; (ii) publish a proposed rule in the **Federal Register** to add such health condition; (iii) publish in the **Federal Register** the Administrator's determination not to publish such a proposed rule and the basis for such determination; or (iv) publish in the **Federal Register** a determination that insufficient evidence exists to take action under (i) through (iii) above.

## B. Approval To Submit Document to the Office of the Federal Register

The Secretary, HHS, or her designee, the Director, Centers for Disease Control and Prevention (CDC) and Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), authorized the undersigned, the Administrator of the WTC Health Program, to sign and submit the document to the Office of the Federal Register for publication as an official document of the WTC Health Program. Thomas R. Frieden, M.D., M.P.H., Director, CDC, and Administrator, ATSDR, approved this document on March 24, 2016, for publication.

## C. Petition 010

On January 5, 2016, the Administrator received a petition to add "peripheral neuropathy" to the List (Petition 010).<sup>2</sup> The petition was submitted by a Fire Department of New York member who responded to the September 11, 2001, terrorist attacks in New York City. The petitioner indicated that he was diagnosed with peripheral neuropathy shortly after the incident. The petitioner described two studies as the medical basis for his petition: A study of the short-term effects of WTC dust on the

sciatic nerve of laboratory rats, and another concerning neuropathic symptoms in WTC responders and survivors. Both studies, as well as an initial literature search conducted by the WTC Health Program, are described below.

## D. Administrator's Determination on Petition 010

The Administrator has established a policy for evaluating whether to add non-cancer health conditions to the List of WTC-Related Health Conditions, published online in the Policies and Procedures section of the WTC Health Program Web site.<sup>3</sup> In accordance with the policy, the Administrator directs the WTC Health Program to conduct a review of the scientific literature to determine if the available scientific information has the potential to provide a basis for a decision on whether to add the condition to the List. The literature review includes published, peer-reviewed epidemiologic studies (including direct observational studies in the case of health conditions such as injuries) about the health condition among 9/11-exposed populations. The studies are reviewed for their relevance, quantity, and quality to provide a basis for deciding whether to propose adding the health condition to the List. Where the available evidence has the potential to provide a basis for a decision, the scientific and medical evidence is further assessed to determine whether a causal relationship between 9/11 exposures and the health condition is supported. A health condition may be added to the List if published, peer-reviewed, direct observational or epidemiologic studies, as appropriate, provide substantial support<sup>4</sup> for a causal relationship between 9/11 exposures and the health condition in 9/11-exposed populations. If the evidence assessment provides only modest support<sup>5</sup> for a causal relationship between 9/11 exposures and the health condition, the Administrator may then evaluate additional published, peer-

reviewed, epidemiologic studies, conducted among non-9/11-exposed populations, evaluating associations between the health condition of interest and 9/11 agents.<sup>6</sup> If that additional assessment establishes substantial support for a causal relationship between a 9/11 agent or agents and the health condition, the health condition may be added to the List.

In accordance with section 3312(a)(6)(B) of the PHS Act, 42 CFR 88.17, and the policy for the addition of non-cancer health conditions to the List, the Administrator reviewed the evidence presented in Petition 010. The WTC Health Program conducted a systematic literature search of the published scientific and medical literature<sup>7</sup> for evidence of a causal relationship between 9/11 exposures and peripheral neuropathy and reviewed both studies submitted in the petition.

The first study cited by the petitioner, "Analysis of Short-Term Effects of World Trade Center Dust on Rat Sciatic Nerve," by Stecker *et al.*<sup>8</sup> investigated the short-term effects of WTC dust on the sciatic nerve in laboratory rats. This study was not identified in the literature search. Because this study does not meet the policy's requirement that the decision to add a health condition to the List must be based on epidemiologic studies of 9/11-exposed populations, it was not further considered.

The systematic literature search identified only one epidemiologic study regarding peripheral neuropathy in 9/11-exposed populations, which was the second study cited by the petitioner, "Neuropathic Symptoms in World Trade Center Disaster Survivors and Responders," by Wilkenfeld *et al.*<sup>9</sup> Upon review of the study's relevance, quantity, and quality, the paper was found to have numerous limitations, including a small sample size; exclusive use of subjective self-reported outcome and exposure data; lack of information about comparability among the groups;

<sup>6</sup> 9/11 agents are chemical, physical, biological, or other agents or hazards reported in a published, peer-reviewed exposure assessment study of responders or survivors who were present in the New York City disaster area, at the Pentagon site, or at the Shanksville, Pennsylvania site, as those locations are defined in 42 CFR 88.1.

<sup>7</sup> Databases searched include: PubMed, Health & Safety Science Abstracts, Toxicology Abstracts, Toxline, Scopus, Embase, and NIOSHTIC-2.

<sup>8</sup> Mark Stecker, Jacqueline Segelnick, Marc Wilkenfeld, *Analysis of Short-Term Effects of World Trade Center Dust on Rat Sciatic Nerve*, JOEM 56(10):1024–1028, October 2014.

<sup>9</sup> Marc Wilkenfeld, Melissa Fazzari, Jacqueline Segelnick, and Mark Stecker, *Neuropathic Symptoms in World Trade Center Disaster Survivors and Responders*, JOEM 58(1):83–86, January 2016.

<sup>2</sup> See Petition 010, WTC Health Program: Petitions Received. <http://www.cdc.gov/wtc/received.html>.

<sup>3</sup> John Howard MD, Administrator of the WTC Health Program, *Policy and Procedures for Adding Non-Cancer Conditions to the List of WTC-Related Health Conditions*, October 21, 2014. [http://www.cdc.gov/wtc/pdfs/WTCHP\\_PP\\_Adding\\_NonCancers\\_21\\_Oct\\_2014.pdf](http://www.cdc.gov/wtc/pdfs/WTCHP_PP_Adding_NonCancers_21_Oct_2014.pdf).

<sup>4</sup> The substantial evidence standard is met when the Program assesses all of the available, relevant information and determines with high confidence that the evidence supports its findings regarding a causal association between the 9/11 exposure(s) and the health condition.

<sup>5</sup> The modest evidence standard is met when the Program assesses all of the available, relevant information and determines with moderate confidence that the evidence supports its findings regarding a causal association between the 9/11 exposure(s) and the health condition.

lack of objective measurements to confirm the presence of peripheral neuropathy; and absence of control for key confounders other than the comorbidities studied. Each of these limitations affect the strength of the study results, and thus the Wilkenfeld *et al.* study is not sufficient to provide the Administrator with a potential basis for deciding whether to propose adding peripheral neuropathy to the List.

Due to the substantial limitations inherent in the only available study, the Administrator has concluded that the available evidence does not have the potential to provide a basis for a decision on whether to add peripheral neuropathy to the List.

The findings described above led the Administrator to determine that insufficient evidence exists to take further action, including either proposing the addition of peripheral neuropathy to the List (pursuant to PHS Act, sec. 3312(a)(6)(B)(ii) and 42 CFR 88.17(a)(2)(ii)) or publishing a determination not to publish a proposed rule in the **Federal Register** (pursuant to PHS Act, sec. 3312(a)(6)(B)(iii) and 42 CFR 88.17(a)(2)(iii)). The Administrator has also determined that requesting a recommendation from the STAC (pursuant to PHS Act, sec. 3312(a)(6)(B)(i) and 42 CFR 88.17(a)(2)(i)) is unwarranted.

For the reasons discussed above, the request made in Petition 010 to add peripheral neuropathy to the List of WTC-Related Health Conditions is denied.

Dated: March 28, 2016.

**John Howard,**

*Administrator, World Trade Center Health Program and Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.*

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## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

#### 43 CFR Parts 3100, 3160, and 3170

[15X.LLWO300000.L13100000.NB0000]

RIN 1004-AE14

#### Waste Prevention, Production Subject to Royalties, and Resource Conservation

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Proposed rule; extension of public comment period.

**SUMMARY:** On February 8, 2016, the Bureau of Land Management (BLM) published in the **Federal Register** a proposed rule that would reduce waste of natural gas from venting, flaring, and leaks during oil and natural gas production activities on onshore Federal and Indian leases. The proposed rule would also clarify when produced gas lost through venting, flaring, or leaks is subject to royalties, and when oil and gas production used on site would be royalty-free. The proposed rule would replace existing provisions related to venting, flaring, and royalty-free use of gas contained in the 1980 Notice to Lessees and Operators of Onshore Federal and Indian Oil and Gas Leases, Royalty or Compensation for Oil and Gas Lost (NTL-4A), which is over 3 decades old. Today's **Federal Register** Notice extends the public comment period for 14 days beyond the initial comment period deadline.

**DATES:** The comment period for the proposed rule published on February 8, 2016 (81 FR 6616) is extended. Send your comments on this proposed rule to the BLM on or before April 22, 2016. The BLM need not consider, or include in the administrative record for the final rule, comments that the BLM receives after the close of the comment period or comments delivered to an address other than those listed below (see **ADDRESSES**).

**ADDRESSES:** *Mail:* U.S. Department of the Interior, Director (630), Bureau of Land Management, Mail Stop 2134 LM, 1849 C St. NW., Washington, DC 20240, Attention: 1004-AE14. *Personal or messenger delivery:* Bureau of Land Management, 20 M Street SE., Room 2134 LM, Attention: Regulatory Affairs, Washington, DC 20003. *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions at this Web site.

**FOR FURTHER INFORMATION CONTACT:** Eric Jones at the BLM Moab Field Office, 82 East Dogwood Ave., Moab, UT 84532, or by telephone at 435-259-2117; or Timothy Spisak at the BLM Washington Office, 20 M Street SE., Room 2134LM, Washington, DC 20003, or by telephone at 202-912-7311. For questions relating to regulatory process issues, please contact Faith Bremner, BLM Washington Office, at 202-912-7441. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 to contact the above individuals during normal business hours. FIRS is available 24 hours a day, 7 days a week to leave a message or question with the above individuals. You will receive a reply during normal business hours.

## SUPPLEMENTARY INFORMATION:

### Public Comment Procedures

If you wish to comment, you may submit your comments by any one of the methods listed in the **ADDRESSES** section above. Please make your comments as specific as possible by confining them to issues directly related to the content of the proposed rule, and explain the basis for your comments. The comments and recommendations that will be most useful and likely to influence agency decisions are:

1. Those supported by quantitative information or studies; and
2. Those that include citations to, and analyses of, the applicable laws and regulations.

The BLM is not obligated to consider or include in the Administrative Record for the rule comments received after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

Comments, including names and street addresses of respondents, will be available for public review at the address listed under **ADDRESSES** during regular hours (7:45 a.m. to 4:15 p.m.), Monday through Friday, except holidays.

Before including your address, telephone number, email address, or other personal identifying information in your comment, be advised that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask in your comment to withhold from public review your personal identifying information, we cannot guarantee that we will be able to do so.

### Background

The proposed rule was published on February 8, 2016 (81 FR 6616), with a 60-day comment period closing on April 8, 2016. Since publication, the BLM has received requests to extend the comment period on the proposed rule, as well as requests not to extend the comment period. Commenters requesting an extension cited the technical nature and complexity of the proposed rule; its potential interaction with the BLM's proposals to update and replace oil and gas production measurement rules currently found in Onshore Orders 3, 4, and 5; and the Environmental Protection Agency's proposed rule to establish standards for control of emissions of methane and volatile organic compounds (VOCs) from certain oil and gas production activities, which would be codified as 40 CFR part 60 subpart OOOOa.