

**SUMMARY:** The Food and Drug Administration (FDA) is reopening for 90 days the comment period for the submission of comments regarding 3 of the 38 devices proposed for reclassification from class III into class II. The proposed rule was published in the **Federal Register** of March 15, 1999 (64 FR 12774). The agency is taking this action in order to allow more time to submit comments to FDA regarding the guidance documents that were not made available when the March 15, 1999, proposed rule was published. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability for comment of two guidance documents that are special controls for three devices.

**DATES:** Submit written comments on the proposed rule by February 20, 2001.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-827-2974.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of March 15, 1999 (64 FR 12774), FDA published a proposed rule to reclassify 38 preamendments class III devices into class II and to establish special controls for these devices. Interested persons were given until June 14, 1999, to comment on the proposed rule.

A trade association requested that FDA reopen the comment period for 6 of the 38 devices. The request noted that FDA had not made the guidance documents that were proposed as special controls for these six devices available for comment through the agency's good guidance practices (GGP's). The request further noted that it was impossible to comment on the proposed reclassification without the guidance documents being available. Therefore, the trade association requested that FDA extend the comment period until at least 90 days after the guidance documents became publicly available for comment. In the **Federal Register** of April 19, 2000 (65 FR 20933), FDA reopened the comment period on the proposed reclassification of those six devices.

FDA also identified an additional three devices for which the agency had not issued the guidance documents proposed as special controls for

comment in accordance with the GGP policy. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability for comment of two guidance documents that are special controls for three devices. Accordingly, FDA is reopening the comment period for the March 15, 1999, proposed rule to allow additional time for interested persons to comment on the following three devices:

- Indwelling blood carbon dioxide partial pressure (P<sub>co2</sub>) analyzer (21 CFR 868.1150),
- Indwelling blood hydrogen ion concentration (pH) analyzer (21 CFR 868.1170), and
- Indwelling blood oxygen partial pressure (P<sub>o2</sub>) analyzer (21 CFR 868.1200).

**II. Comments**

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the proposed rule only with respect to the three devices listed above by February 20, 2001. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 31, 2000.

**Linda S. Kahan,**

*Deputy Director for Regulations Policy, Center for Devices and Radiological Health.*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 81**

[NV-032-FON; FRL-6905-6]

**Clean Air Act Reclassification; Nevada—Reno Planning Area; Particulate Matter of 10 Microns or Less (PM-10)**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** In this action EPA proposes to find that the Reno (Washoe County) Planning Area (RPA) has not attained the PM-10 national ambient air quality standards (NAAQS) by the Clean Air Act (CAA) mandated attainment date for moderate nonattainment areas. Section 188(c)(1) of the Act established an

attainment date of no later than December 31, 1994 for areas classified as moderate nonattainment areas under section 107(d)(4)(B) of the CAA. This proposed finding is based on monitored air quality data for the PM-10 NAAQS during the years 1992-1994. If EPA takes final action on this proposed finding, the RPA will be reclassified by operation of law as a serious nonattainment area under section 188(b)(2)(A) of the CAA.

**DATES:** Comments on this proposed finding must be received in writing by December 7, 2000.

**ADDRESSES:** Comments should be addressed to Manny Aquitania, U.S. Environmental Protection Agency, Region 9, Air Division, Planning Office (AIR-2), 75 Hawthorne Street, San Francisco, California 94105.

**FOR FURTHER INFORMATION CONTACT:** For monitoring data questions contact Manny Aquitania, U.S. EPA, Region 9, Air Division, Technical Support Office (AIR-7), 75 Hawthorne Street, San Francisco, California 94105; (415) 744-1299, aquitania.manny@epa.gov. For other questions contact Doris Lo, U.S. Environmental Protection Agency, Region 9, Air Division, Planning Office (AIR-2), 75 Hawthorne Street, San Francisco, California 94105, (415) 744-1287, lo.doris@epa.gov.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

*A. CAA Requirements and EPA Actions Concerning Designation and Classification*

On November 15, 1990, the date of enactment of the 1990 Clean Air Act Amendments, PM-10 areas meeting the qualifications of section 107(d)(4)(B) of the Act were designated nonattainment by operation of law. Once an area is designated nonattainment, section 188 of the Act outlines the process for classification of the area and establishes the area's attainment date. Pursuant to section 188(a), all PM-10 nonattainment areas were initially classified as moderate by operation of law upon designation as nonattainment. These nonattainment designations and moderate area classifications were codified in 40 CFR part 81 in a **Federal Register** notice published on November 6, 1991 (56 FR 56694). The Reno Planning Area (RPA) was designated nonattainment and classified as moderate. See 40 CFR 81.329.

States containing areas which were designated as moderate nonattainment by operation of law under section 107(d)(4)(B) were to develop and submit state implementation plans (SIPs) to

provide for the attainment of the PM-10 NAAQS. Pursuant to section 189(a)(2), those SIP revisions were to be submitted to EPA by November 15, 1991.

*B. Reclassification as Serious Nonattainment*

EPA has the responsibility, pursuant to sections 179(c) and 188(b)(2) of the Act, of determining within 6 months of the applicable attainment date, whether PM-10 nonattainment areas have attained the NAAQS. Section 179(c)(1) of the Act provides that these determinations are to be based upon an area's "air quality as of the attainment date", and section 188(b)(2) is consistent with this requirement. EPA makes the determinations of whether an area's air quality is meeting the PM-10 NAAQS based upon air quality data gathered at monitoring sites in the nonattainment area. These data are reviewed to determine the area's air quality status in accordance with EPA guidance at 40 CFR part 50, appendix K.

Pursuant to appendix K, attainment of the annual PM-10 standard is achieved when the annual arithmetic mean PM-10 concentration is equal to or less than 50 µg/m<sup>3</sup>. Attainment of the 24-hour standard is determined by calculating the expected number of exceedances of the 150 µg/m<sup>3</sup> limit per year. The 24-hour standard is attained when the expected number of exceedances is 1.0 or less. A total of 3 consecutive years of clean air quality data is generally necessary to show attainment of the 24-hour and annual standards for PM-10. A complete year of air quality data, as referred to in 40 CFR part 50, appendix K, is comprised of all 4 calendar quarters with each quarter containing data from at least 75 percent of the scheduled sampling days.

Under section 188(b)(2)(A), a moderate PM-10 nonattainment area must be reclassified as serious by operation of law after the statutory attainment date if the Administrator

finds that the area has failed to attain the NAAQS. Pursuant to section 188(b)(2)(B) of the Act, EPA must publish a notice in the **Federal Register** identifying those areas that failed to attain the standard and the resulting reclassifications.

**II. Today's Action**

EPA is, by today's action, proposing to find that the RPA did not attain either the 24-hour or annual PM-10 NAAQS by the required attainment date of December 31, 1994. As discussed below, this proposed finding is based upon air quality data which revealed violations of the PM-10 NAAQS during 1992-1994.<sup>1</sup>

*A. Ambient Air Monitoring Data*

The following table lists each of the monitoring sites in the RPA where the 24-hour and annual PM-10 NAAQS were violated during 1992-1994:

SITES VIOLATING PM-10 NAAQS<sup>2</sup>

Site	24-hour exceedances (micrograms per cubic meter, µg/m <sup>3</sup> )		Annual averages (micrograms per cubic meter)		
	Concentration	Date	1992	1993	1994
Reno—N. Lake St. ....	167 48 µg/m <sup>3</sup>	1/25/93.	48 µg/m <sup>3</sup> .....	55 µg/m <sup>3</sup> .....	52 µg/m <sup>3</sup>
Reno—Galetti Way .....	.....	.....			

The Reno—N. Lake St. monitoring site in the RPA violated the 24-hour PM-10 NAAQS during 1992-1994. This site recorded a concentration of 167 micrograms per cubic meter on January 25, 1993.

The Reno—N. Lake St. monitoring site operates on a one-in-six day sampling schedule. Generally, if PM-10 sampling is scheduled less than every day, EPA requires the adjustment of observed exceedances to account for incomplete sampling. In the case of the Reno—N. Lake St. site, one exceedance of the 24-hour NAAQS was observed in 1993. After adjusting for incomplete sampling, the number of exceedances of the NAAQS in 1993 at this site was 6.4.

According to 40 CFR part 50, the 24-hour NAAQS is attained when the expected number of days per calendar year with a 24-hour average concentration above 150 µg/m<sup>3</sup> is equal to or less than one. In the simplest case, the number of expected exceedances at a site is determined by recording the

number of exceedances in each calendar year and then averaging them over the past three calendar years. Therefore from 1992-1994, the number of expected exceedances at the the Reno—N. Lake St. monitoring site was 2.1. This exceedance causes the Reno—N. Lake St. site to be in violation of the 24-hour PM-10 NAAQS.

In addition, the annual PM-10 NAAQS was violated at the Reno—Galetti Way site in RPA. Based on the monitoring data collected during 1992-1994, the Reno—Galetti site had an annual average of 52 µg/m<sup>3</sup>.

*B. SIP Requirements for Serious Areas*

PM-10 nonattainment areas reclassified as serious under section 188(b)(2) of the CAA are required to submit, within 18 months of the area's reclassification, SIP revisions providing for the implementation of best available control measures (BACM) no later than four years from the date of reclassification. The SIP also must

contain, among other things, a demonstration that the implementation of BACM will provide for attainment of the PM-10 NAAQS no later than December 31, 2001.<sup>3</sup> See CAA sections 188(c)(2) and 189(b). EPA has provided specific guidance on developing serious area PM-10 SIP revisions in an addendum to the General Preamble to Title I of the Clean Air Act. See 59 FR 41998 (August 16, 1994).

**III. Request for Public Comment**

The EPA is requesting comment on all aspects of today's proposal. As indicated at the outset of this notice, EPA will consider any comments received by December 7, 2000.

**IV. Administrative Requirements**

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget.

<sup>1</sup> The RPA is also not currently attaining the PM-10 NAAQS. A summary of more recent air quality data can be found in the docket.

<sup>2</sup> All violating PM-10 samplers in RPA operated on a 1-in-6 day sampling schedule. Since sampling

is not performed every day, any exceedance of the 24-hour NAAQS is adjusted such that the exceedance is now considered a violation. The procedures for calculating the number of violations is specified in 40 CFR part 50, appendix K.

<sup>3</sup> If certain conditions are met, EPA may extend this attainment deadline to no later than December 31, 2006. CAA section 188(e).

Under section 188(b)(2) of the CAA, findings of failure to attain is based solely upon air quality considerations and the subsequent nonattainment area reclassification must occur by operation of law in light of those air quality conditions. These actions do not, in-and-of themselves, impose any new requirements on any sectors of the economy. In addition, because the statutory requirements are clearly defined with respect to the differently classified areas, and because those requirements are automatically triggered by classifications that, in turn, are triggered by air quality values, findings of failure to attain and reclassification cannot be said to impose a materially adverse impact on State, local, or tribal governments or communities.

Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Similarly, because the proposed finding of failure to attain is a factual determination based on air quality considerations and the resulting reclassification must occur by operation of law and, do not impose any federal intergovernmental mandate, these actions do not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). For the same reason, this proposed rule also does not significantly or uniquely affect the communities of Indian tribal governments, as specified by Executive Order 13084 (63 FR 27655, May 10, 1998).

For the same reasons, this proposed finding of failure to attain and resulting reclassification 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 (64 FR 43255, August 10, 1999). These proposed actions are also not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because they are not economically significant. Finally, for the same reason that this proposed finding of failure to attain is a factual determination based on air quality considerations and the resulting reclassification must occur by operation of law, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply.

As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this proposed finding of failure to attain, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the "Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings" issued under the executive order. This proposed finding of failure to attain does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

#### List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

**Authority:** 42 U.S.C. 7401-7671q.

Dated: November 13, 2000.

**Felicia Marcus,**

*Regional Administrator, Region 9.*

[FR Doc. 00-29879 Filed 11-21-00; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 300

[FRL-6859-2]

#### National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List

**AGENCY:** Environmental Protection Agency.

**ACTION:** Proposed deletion of the John Deere Ottumwa Works Site (Site) from the National Priorities List (NPL).

**SUMMARY:** The Environmental Protection Agency (EPA) Region VII proposes to delete the John Deere Ottumwa Works site from the National Priorities List (NPL) and requests public comment on this action. The NPL constitutes Appendix B to Part 300 of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA), as amended. The EPA has determined that the site poses no significant threat to public health or the environment, as defined by CERCLA, and therefore, further

remedial measures pursuant to CERCLA are not appropriate.

We are publishing this rule without prior proposal because the Agency views this as a noncontroversial revision and anticipates no dissenting comments. A detailed rationale for this approval is set forth in the direct final rule. If no dissenting comments are received, no further activity is contemplated. If EPA receives dissenting comments, the direct final action will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period. Any parties interested in commenting should do so at this time.

**DATES:** Comments concerning this Action must be received by December 22, 2000.

**ADDRESSES:** Comments may be mailed to Debra Kring, Environmental Protection Specialist, Superfund Division, U.S. Environmental Protection Agency, Region VII, 901 North 5th Street, Kansas City, KS 66101. Comprehensive information on this site is available through the public docket which is available for viewing at the Site information repository at U.S. EPA Region VII, Superfund Division Records Center, 901 North 5th Street, Kansas City, KS 66101.

**FOR FURTHER INFORMATION CONTACT:** Debra Kring, Environmental Protection Specialist, U.S. Environmental Protection Agency, 901 North 5th Street, Kansas City, KS 66101, fax (913) 551-7063.

**SUPPLEMENTARY INFORMATION:** For additional information, see the Direct Final Action which is located in the Rules Section of this **Federal Register**.

Dated: August 17, 2000.

**William Rice,**

*Acting Regional Administrator, Region VII.*

[FR Doc. 00-29643 Filed 11-21-00; 8:45 am]

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 679

[I.D. No. 111500B]

#### Fisheries of the Exclusive Economic Zone Off Alaska; Commencement of Groundfish Fisheries in 2001

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.