

kits. Vessels may obtain controlled substances either through the services of a medical officer who is employed by the owner or operator of the vessel and is registered with DEA as a practitioner, or, in the absence of a medical officer, through the master or first officer of the vessel personally appearing before a distributor registrant and receiving the controlled substances directly.

If a medical officer is ordering the controlled substances, he or she shall submit the order to a distributor or, when allowed pursuant to 21 CFR 1301.28(f), a pharmacy. When filling the order, the distributor or pharmacy must handle the transaction as a normal distribution subject to all of the requirements of the law and regulations regarding the distribution of controlled substances. If Schedule II controlled substances are being ordered, a properly completed and signed DEA Order Form (DEA Form-222) must be received prior to filling the order. Further, all controlled substances must be shipped directly to the medical officer at his or her registered address. The distributor or pharmacy may not ship the controlled substances to another person or address. The medical officer shall transfer the controlled substances to the vessel only at a location within the United States. The shipment of controlled substances to a foreign location can be accomplished only by a registered exporter pursuant to a valid export permit or declaration and authorization of the foreign government; to do so otherwise could be a criminal violation of the Controlled Substances Act (CSA) and U.S. International Treaty obligations.

In the absence of a registered medical officer, the master or first officer of an ocean vessel may obtain controlled substances by appearing personally before a distributor or an authorized pharmacy registrant, and by presenting proper identification and a written requisition for the controlled substances. The requisition must be prepared on the vessel's official stationery or purchase form and must contain the information required by 21 CFR 1301.28(d)(2). The distributor or pharmacy shall record the distribution in the manner required by 21 CFR 1301.28(d)(4). The master or first officer of a vessel must appear personally before the registrant to receive the controlled substances.

Issues regarding practical compliance with the regulations have arisen, including the use of contract practitioners, the shipping of controlled substances to other than a registered location, exporting controlled substances without an exporter

registration and export permit or declaration, repacking or relabelling controlled substances in violation of the CSA, and, in the absence of a medical officer, shipping controlled substances to a vessel rather than requiring a personal appearance by the master or first officer.

DEA has also received comments from wholesalers and owners/operators of vessels expressing concerns regarding the regulations and the impact they have on the delivery of controlled substances to the vessels. The primary concern is the requirement that controlled substances ordered by a medical officer must be shipped to the medical officer's registered location by the distributor. The medical officer then must ship the controlled substances to the vessel. The commentors have objected that this requirement delays the delivery of the controlled substances to the vessel and increases the potential for diversion of the substances. Comments have also been received regarding the use of medical officers, the distribution of controlled substances to vessels in foreign ports, and the use of ship's agents to help effect the delivery of controlled substances to the vessels.

In order to better understand the circumstances under which the maritime industry operates and to determine what regulatory adjustments might be possible to allow a more efficient and practical means to provide controlled substances to ocean vessels while maintaining controls against the diversion of controlled substances, DEA is requesting information and comments regarding the following:

1. What industry standards or requirements are there regarding the acquisition, storage, and dispensing of controlled substances aboard ocean vessels? If there are standards or requirements, is there a mechanism for ensuring compliance and sanctioning those that fail to comply? Further, do the standards or requirements apply to all vessels, including foreign flag vessels, or do they apply only to U.S. flag vessels?

2. Are there standardized procedures for delivering materials/supplies to vessels when they are in port? What provisions are there for the safekeeping/security of sensitive materials/supplies prior to the actual delivery to the vessel?

3. What duties do ship/port agents and ship chandlers perform? What legal responsibilities must they satisfy and to whom are they responsible? Are there specific guidelines or requirements that must be adhered to and a mechanism for enforcing compliance?

In addition to developing background information concerning the operations

of the maritime industry with respect to providing vessels with controlled substances, DEA is also seeking comments and proposals from interested parties regarding the impact of the current regulatory requirements and possible alternative procedures that might better serve the industry while preserving the necessary safeguards to prevent diversion. Areas of specific interest would include the use of contract medical officers, the shipment of controlled substances from the distributors to the vessels, and whether ship/port agents and chandlers can participate in the process. DEA also welcomes any comments and suggestions on related issues regarding the supply of controlled substances to ocean vessels.

Interested persons may, on or before November 18, 1996, submit to the Deputy Assistant Administrator, Office of Diversion Control, Attn: Federal Register Representative/CCR (address above) two copies of the written information and comments regarding this advance notice of proposed rulemaking.

Dated: August 19, 1996.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 96-23816 Filed 9-17-96; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[AZ-030-0006; FRL-5611-8]

Approval and Promulgation of Implementation Plans; Arizona—Phoenix Nonattainment Area; Carbon Monoxide Emission Inventory

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve, as meeting the requirements of sections 172(c)(3) and 187(a)(1) of the Clean Air Act (CAA) and EPA guidance, the 1990 base year carbon monoxide (CO) emission inventory for the Phoenix CO nonattainment area. This document also discusses EPA's review of the 1995 projected year inventory for the Phoenix area.

DATES: Written comments on this proposal must be received by October 18, 1996.

ADDRESSES: Written comments should be sent to: Wienke Tax, A-2-1, U.S. Environmental Protection Agency,

Region 9, 75 Hawthorne Street, San Francisco, California 94105.

The rulemaking docket for this document, Docket No. 96-AZ-003, may be inspected and copied at the following location between 8 a.m. and 4:30 p.m. on weekdays. A reasonable fee may be charged for copying parts of the docket. U.S. Environmental Protection Agency, Region 9, Air and Toxics Division, Mobile Sources Section, A-2-1, 75 Hawthorne Street, San Francisco, California 94105.

FOR FURTHER INFORMATION CONTACT: Wienke Tax, Mobile Sources Section, Air and Toxics Division, U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, California 94105, (415) 744-1223.

SUPPLEMENTARY INFORMATION:

I. CAA Requirements and EPA Guidance for Emission Inventories

Sections 172(c)(3) and 187(a)(1) of the CAA require that a comprehensive, accurate, and current base year inventory of actual emissions be submitted to EPA as a state implementation plan (SIP) revision for each area designated as nonattainment and classified moderate or serious for carbon monoxide.¹ EPA has provided guidance to States for developing these CO inventories, most recently in *Emission Inventory Requirements for Carbon Monoxide State Implementation Plans*, (EPA-450/4-91-011) March, 1991 (*"Emission Inventory Requirements"*). While not an explicit requirement of the CAA, projected inventories are closely related to the base year inventory, and it is reasonable to review them in conjunction with the base year inventory.

A technically-sound emissions inventory is important for a number of reasons. First, it is used to identify pollutant sources for new or additional controls and so provides a basis for the control strategy. Second, the inventory provides a means of assessing progress in achieving reductions from existing

controls. Finally, both current and projected inventories are used as inputs to air quality modeling to demonstrate attainment of the national ambient air quality standards (NAAQS).

The Clean Air Act requires that emissions inventories be comprehensive, accurate, and current. To be comprehensive, the inventory must include all stationary point and area sources, non-road mobile sources, and on-road mobile sources. To be accurate, the inventory must be based on data representative of sources within the nonattainment area. To be current, the inventory must represent 1990 (the year of the CAA enactment) or later.

A. Requirements for Base Year Inventories

The base year inventory is the primary inventory from which all other CO inventories are derived. The base year inventory is defined in the CAA as a "current inventory" which EPA interprets to mean 1990. See "General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990" 57 FR 13498, 13530 (April 16, 1992). Annual emission inventory estimates are adjusted to represent the CO season weekday inventory (the "planning inventory"). EPA recommends a three month peak CO season as the basis for the planning inventory estimates. See *Emission Inventory Requirements*, page 11.

Stationary sources are grouped into point and area sources. Point sources are any stationary source emitting more than 100 tons per year of CO. Area sources generally include small stationary sources (e.g., stationary internal combustion engines) and ubiquitous emissions not associated with a permit (e.g., fireplaces). Mobile source estimates are divided into on-road and non-road categories. Emissions inventories for on-road mobile sources (e.g., automobiles, motorcycles, buses, and trucks) are generally developed using the latest version of MOBILE, EPA's mobile source emission factor model. The non-road mobile source inventory includes emissions from categories ranging from lawn mowers to marine vessels.

In documenting its on-road mobile source inventory, states must report on how on-road vehicle emission factors and vehicle miles travelled (VMT) estimates were determined. The state must fully document how the most recent MOBILE model (MOBILE5a) was used to estimate emission factors for the vehicle fleet. For VMT, the state should describe the methodology employed to generate VMT data and the key assumptions and inputs to the process.

Finally, the state must describe how the VMT data were combined with the emission factors to produce mobile source emissions estimates. See *Emission Inventory Requirements*, page 54.

In its emissions inventory submittal, a state is also required to describe the implementation of the state's emission inventory quality assurance (Q/A) program and the results achieved by that program. For all source category types, the Q/A discussion must address the completeness of the inventory, reasonableness of the emissions estimates, and relative accuracy of the data. See *Emission Inventory Requirements*, page 55.

A detailed discussion of EPA's emission inventory requirements can be found in the Technical Support Document (TSD) for this rulemaking as well as in the cited guidance documents. The TSD and all cited documents can be requested from the contact person listed at the beginning of this notice.

B. Guidance on Projected Emissions Inventories

Future year inventories are needed for projecting and modeling attainment. Future year inventories are developed using base year inventory estimates adjusted using growth and control factors. EPA's guidance for developing projected year inventories is found in *Procedures for Preparing Emissions Projections*, (EPA-450/4-91-019) July, 1991.

Inventory projections attempt to project how the combination of future emission controls and changes in source activity will influence future emission rates. Growth factors are developed using socioeconomic forecasts (i.e., population, housing, employment, and motor vehicle activity) and Standard Industrial Classification data. Growth rates for motor vehicles consider projected changes in vehicle miles traveled, trips, and vehicles in use. Control factors are used to adjust future year inventory estimates to account for reductions from adopted and scheduled measures. All growth and control factors and their derivation should be thoroughly documented.

All emissions projected for future years should be based on the same inventory methodologies and computational principles as the base year emissions. For example, if a travel demand model is used for estimating travel in the base year, the same model should be applied to estimate travel demand for projected years. Using the same methodology ensures consistency in format and content between base year

¹ At the time of the SIP submittals that are the subject of today's notice, Phoenix was classified as moderate and, because its design value is under 12.7 ppm, was considered a low moderate area. EPA has recently found that the Phoenix area failed to attain the CO NAAQS by the statutory deadline. See 61 FR 39343 (July 29, 1996). As a consequence of this finding, the area has been reclassified to "serious" under section 186(b)(2). As a result, the area is now subject to the section 187(b) requirements for serious CO areas. These requirements include those applicable to CO areas with design values between 12.7 ppm and 16.4 ppm (high moderate areas) in section 187(a). For the purpose of today's action, however, the relevant CAA requirements are those that apply to low moderate CO nonattainment areas.

and projection year emissions estimates and prevents possible spurious inventory differences due to changes in methodology.

For further information on requirements for emission inventory projections, see the TSD.

II. The Maricopa CO Emissions Inventory Submittal

The Arizona Department of Environmental Quality (ADEQ) initially submitted the 1990 base year (annual and average daily emissions) as well as projected 1995 and 2005 CO inventories for the entire Phoenix nonattainment area on November 15, 1993 as part of the Maricopa Association of Governments (MAG) 1993 *Carbon Monoxide Plan for the Maricopa County Area (CO Plan)*. On April 4, 1994, ADEQ submitted updated and improved inventories as part of MAG's 1993 *Carbon Monoxide Plan for the Maricopa County Area—Addendum (Addendum)*.² These revised inventories reflected adjustments to growth factors and the impact of measures in Arizona House Bill 2001. Both submittals became complete by operation of law under CAA section 110(k)(1)(B) on May 15, 1994 and October 8, 1994, respectively.

The Maricopa County Division of Air Pollution Control (MCAPC) prepared the stationary (point and area) and non-road mobile source portions of the inventories, while MAG Transportation and Planning Office prepared the transportation data and the on-road mobile sources emissions estimates. Quality assurance/quality control procedures were performed by MCAPC and ADEQ.

A. Baseline (1990) Emissions Inventory

Because CO violations in Phoenix occur primarily from November through January, November and December of 1989 and January of 1990 were chosen as the basis for the planning inventory, as per EPA guidance. See *Emission Inventory Requirements*, page 11. The emissions data section of the inventories contains a summary of 1990 emissions data by source type (point, area and mobile), for both average daily

emissions and annual emissions. See "1990 Base Year Carbon Monoxide Emission Inventory for the Maricopa County, Arizona Nonattainment Area," MCAPC, August 1993 (located in Appendix B, Exhibit 1 of the *CO Plan*) ("EI Documentation") at page 1–6. Inventory development procedures are discussed separately for point, area, non-road mobile and on-road mobile sources in the EI Documentation.

MCAPC was the lead agency responsible for developing the point source inventory. All methods for collecting point source data and estimating emissions were documented, and detailed emissions information was provided (see Chapter 2 of the EI Documentation) and entered into EPA's Aerometric Information Retrieval System (AIRS). Point source base year emissions totalled 1299 tons CO per year (<1% of the inventory, without accounting for on-road mobile source emissions) and 8.7 tons CO per average CO season day (<1% of the inventory). See EI Documentation, page 1–6.

MCAPC evaluated all area sources included in EPA's guidance document³ for their significance in Maricopa County except residential incineration; open burning at industrial, commercial/institutional, and residential sources; and charcoal grilling. The first two categories are prohibited by law; charcoal grilling was not addressed because suitable emission factors and activity data were not available and because emissions contributions from this category were judged to be negligible. See EI Documentation, page 3–1. A rule effectiveness (RE) factor of 80 percent was applied to source categories subject to regulation, as recommended by EPA for all categories except woodburning. Rule penetration was estimated per EPA guidance. See EI Documentation, page 3–1. While EPA recommends a 50 percent RE factor for woodburning, woodburning is only a small fraction of the Maricopa CO inventory, so the assumption of a 80 percent RE factor is insignificant in this instance. Total CO base year emissions from area sources were 13,337.8 tons per year in 1990 (7.3% of inventory, without accounting for on-road mobile source emissions), and 87.65 tons per average CO season day (7.7% of inventory). See EI Documentation, page 1–6.

Non-road source categories inventoried in the *CO Plan* include aircraft, locomotives, and non-road equipment sources. EPA's Office of

Mobile Sources prepared the emissions estimates for the non-road equipment source categories. See Chapter 3 of the EI Documentation. These categories included recreational vehicles, construction equipment, industrial/commercial equipment, lawn and garden equipment, and farm equipment. Emissions calculations were presented for aircraft (commercial, military, general aviation) and locomotives, per EPA guidance. See *Procedures for Emission Inventory Preparation, Volume IV: Mobile Sources* (EPA-450/4-81-026d Revised) 1992. (*Procedures, Mobile Sources*). Non-road CO emissions for 1990 totalled 167,303 tons (91.9% of inventory, without accounting for on-road mobile sources), while average daily CO season emissions totalled 238 tpd (20.8% of inventory). See EI Documentation, page 1–6.

On-road mobile sources were inventoried per EPA guidance found in *Procedures, Mobile Sources*. MAGTPO prepared the 1990 VMT estimates, using the Highway Performance Monitoring System (HPMS) data for 1990 collected by the Arizona Department of Transportation (ADOT). The HPMS data were supplemented by traffic count data and estimates of total street mileage in the CO nonattainment area from MAGTPO. The *CO Plan* contains an extensive discussion of the conversions performed on the HPMS data to produce inventory-compatible VMT estimates. See EI Documentation, Chapter 5.

The version of the MOBILE model used to develop on-road mobile emission factors for the November 1993 and March 1994 submittals was MOBILE5. The *CO Plan* fully documents the inputs to the model. See EI Documentation, Chapter 5. On-road mobile source emission factors and emissions are presented by vehicle class and roadway type. Total CO baseline emissions from on-road mobile sources totalled 807.7 tons per CO season day (70.7% of inventory). See EI Documentation, Chapter 5.

Chapter 6 of the EI Documentation contains a discussion of quality assurance and quality control (QA/QC) procedures used by the various agencies in developing the inventory. The QA/QC procedures included checks for accuracy, reasonableness, and completeness, including reviews by independent parties. More detailed procedures included reviewing the descriptive information contained in each section to assure completeness, clarity, and correctness; examining formulae, calculations and conversions to assure freedom from errors and inconsistencies; evaluating data quality to assure the worth and usefulness of

² On August 9, 1993, EPA issued a SIP call under section 110(k)(5) of the CAA that required Arizona to submit a plan to EPA that demonstrated attainment of the CO NAAQS in the Phoenix area by December 31, 1995. As an area with a design value under 12.7 ppm, the State would not otherwise have been required to submit an attainment plan for the Phoenix area. See section 187(a). CAA section 187(a)(1) requires the submittal of a comprehensive, accurate, current inventory of actual emission for all CO nonattainment areas whether or not they have a separate requirement to submit an attainment demonstration.

³ Procedures for the Preparation of Emission Inventories for Precursors of Ozone, Volume I, (EPA 450/4-88-021) December 1988.

the inventory; and assessing, where possible, the significance of the calculated quantities to assure accuracy and justifiable precision.

EPA has concluded that the baseyear emission inventories in the MAG *CO Plan* and *Addendum* conform to EPA's guidance and the CAA requirements for CO inventories and are therefore proposed for approval.

B. Projected Emissions Inventory

The *CO Plan* contained a 1995 attainment year projected emission inventory. See *Addendum*, Exhibit 3. This inventory was prepared by MAG using the methodologies in EPA's guidance.⁴ The *Addendum* modified the projected inventory in several respects. First, in response to comments received during the public hearing on the Plan, MCAPC revised the growth factors used to project 1990 emissions to 1995. Secondly, in November 1993, the Arizona legislature passed H.B. 2001 which included additional commitments for measures designed to bring the region into attainment for CO. A few minor additional adjustments to modeling inventories were also made and the effects of the existing oxygenated fuels program on non-road emissions was included. Overall, these changes resulted in slight decreases (1–4 percent) in projected CO emissions for future years.

EPA has concluded from its review of the 1995 projected year emission inventory in the MAG *CO Plan* and *Addendum* that it conformed EPA's guidance for CO projected inventories.

III. Summary of EPA Actions

Because EPA has concluded that it conforms to EPA guidance for base year emission inventories, EPA is proposing to approve, pursuant to sections 172(c)(3) and 187(a)(1) of CAA, the 1990 CO base year inventory for the Maricopa CO nonattainment area. EPA is also finding that the 1995 projected year inventory conforms to EPA guidance.

Nothing in this proposed action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any SIP. Each request for a revision to the SIP shall be considered separately in light of specific technical, economic and environmental factors and in relation to relevant statutory and regulatory requirements.

⁴ While the *CO Plan* and *Addendum* include a year 2005 CO projected emission inventory, EPA did not review that inventory. Neither the Clean Air Act nor EPA guidance requires states to demonstrate maintenance after the applicable attainment date until an area requests redesignation to attainment under section 175A(a).

IV. Administrative Requirements

A. Executive Order 12866

This action has been classified as a Table 3 action for signature by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214–2225), as revised by a July 10, 1995 memorandum from Mary Nichols, Assistant Administrator for Air and Radiation. The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small business, small not-for-profit enterprises and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under subchapter I, part D of the Clean Air Act, do not create any new requirements, but simply approve requirements that a state is already imposing. The action proposed today is simply the approval of technical information required to be developed under the CAA and imposes no state or federal requirements on any entity. Therefore, the Administrator certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the CAA, preparation of a flexibility analysis would constitute federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. U.S.E.P.A.*, 427 U.S. 246, 256–66 (S.Ct. 1976); 42 U.S.C. 7410(a)(2).

C. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995 ('Unfunded Mandates Act'), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a federal mandate that may result in estimated costs to state, local, or tribal governments in the aggregate; or to the private sector, of \$100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves that objectives of the rule and is consistent with

statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by this rule.

EPA has determined that the approval action proposed does not include a federal mandate that may result in estimate costs of \$100 million or more to either state, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under state or local law, imposes no new federal requirements. Accordingly, no additional costs to State, local or tribal governments, or to the private sector, results from this action. Accordingly, no costs to State, local, or tribal governments, or to the private sector, result from this action.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations.

Authority: 42 U.S.C. 7401–7671q.

Dated: September 9, 1996.

Felicia Marcus,

Regional Administrator.

[FR Doc. 96–23822 Filed 9–17–96; 8:45 am]

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40 CFR Parts 52

[FL–60–1–6929b; FRL–5609–4]

Approval and Promulgation of Lead State Implementation Plan for the State of Florida

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA proposes to approve the state implementation plan (SIP) revision submitted by the State of Florida on August 18, 1994, through the Florida Department of Environmental Protection. The revision includes amendments to the rules in the Florida Administrative Code, Chapters 17–275, Air Quality Areas, and 17–296, Stationary Sources—Emission Standards. These revisions provide for the control of lead emissions from facilities in the State of Florida, and will replace the Federal Implementation Plan requirements codified in 40 CFR 52.535.

In the final rules section of this Federal Register, the EPA is approving the State of Florida's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no adverse comments. A