the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. Such an spinal implant assembly consists of a combination of anchors (e.g., bolts, hooks, and/or screws); interconnection mechanisms incorporating nuts, screws, sleeves, or bolts; longitudinal members (e.g., plates, rods, and/or plate/rod combinations); and/or transverse connectors.

(2) *Classification*. Class III (premarket approval).

(c) *Date PMA or notice of completion of a PDP is required*. An approved PMA or a declared completed PDP must be in effect before placing the device in commercial distribution. See § 888.3.

Dated: April 22, 1998,

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 98–19944 Filed 7–23–98; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IN75; FRL–6129–7]

Approval and Promulgation of Implementation Plan; Indiana

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The United States Environmental Protection Agency (USEPA) is approving Indiana's request to grant an exemption for the northwest Indiana (Lake and Porter Counties) severe ozone nonattainment area from the applicable Oxides of Nitrogen (NO_X) transportation conformity requirements. The USEPA proposed approval on January 6, 1998. The proposal was based on information the Indiana Department of Environmental Management (IDEM) submitted to the USEPA as a State Implementation Plan (SIP) revision request for an exemption under section 182(b)(1) of the Clean Air Act (Act). The technical basis for IDEM's request was the urban airshed modeling (UAM) conducted for an attainment demonstration for the Lake Michigan Ozone Study (LMOS) modeling domain.

DATES: This rule is effective August 26, 1998.

ADDRESSES: Copies of the SIP revision, public comments and USEPA's responses are available for inspection at the following address: United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604. (It is recommended that you telephone Patricia Morris at (312) 353–8656 before visiting the Region 5 Office.)

FOR FURTHER INFORMATION CONTACT: Patricia A. Morris, Regulation Development Section (AR–18J), Air Programs Branch, Air and Radiation Division, United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, Telephone Number (312) 353–8656.

SUPPLEMENTARY INFORMATION:

I. Background

Clean Air Act section 176(c)(3)(A)(iii) requires, in order to demonstrate conformity with the applicable SIP, that transportation plans and Transportation Improvement Programs (TIPs) contribute to emissions reductions in ozone and carbon monoxide nonattainment areas during the period before control strategy SIPs are approved by USEPA. This requirement is implemented in 40 CFR 93.119, which establishes what is known as the ''build/no-build test.'' The conformity requirements of 176(c)(3)(A) are more fully explained in the notice of proposed rulemaking (63 FR 456, January 6, 1998).

On July 13, 1994, the States of Illinois, Indiana, Michigan, and Wisconsin (the States) submitted to the USEPA a petition for an exemption from the requirements of section 182(f) of the Clean Air Act (Act). The States, acting through the Lake Michigan Air Directors Consortium (LADCo), petitioned for an exemption from the Reasonably Available Control Technology (RACT) and New Source Review (NSR) requirements for major stationary sources of NO_X. The petition also asked for an exemption from the transportation and general conformity requirements for NO_X in all ozone nonattainment areas in the Lake Michigan Modeling domain.

On March 6, 1995, the USEPA published a rulemaking proposing approval of the NO_X exemption petition for the RACT, NSR and transportation and general conformity requirements. A number of comments were received on the proposal. Several commenters argued that NO_X exemptions are provided for in two separate parts of the Act, in sections 182(b)(1) and 182(f), but that the Act's transportation conformity provisions in section 176(c)(3) explicitly reference section 182(b)(1). In April 1995, the USEPA entered into an agreement to change the procedural mechanism through which a NO_X exemption from transportation conformity would be granted (*EDF et al.* v. *USEPA*, No. 94–1044, U.S. Court of Appeals, D.C. Circuit). Instead of a petition under 182(f), transportation conformity NO_X exemptions for ozone nonattainment areas that are subject to section 182(b)(1) now need to be submitted as a SIP revision request. The northwest Indiana ozone nonattainment area is classified as severe and, thus, is subject to section 182(b)(1). Thus, the NO_X waiver for transportation conformity would have been granted in January 26, 1996, at the same time as the waiver for RACT, NSR and general conformity except for the technical correction to require a SIP revision request under 182(b)(1).

The transportation conformity requirements are found at sections 176(c)(2), (3), and (4) of the Act. The conformity requirements apply on an areawide basis in all nonattainment and maintenance areas. The USEPA's transportation conformity rule was amended on August 29, 1995 (60 FR 44762) to reference section 182(b)(1) rather than 182(f) as the means for exempting areas subject to section 182(b)(1) from the transportation conformity NO_X requirements.

The May 24, 1996, SIP revision request from Indiana was submitted to meet the requirements in accordance with 182(b)(1). Public hearings on this SIP revision request were held on June 11, 1996.

In evaluating the 182(b) SIP revision request, the USEPA considered whether additional NO_X reductions would contribute to attainment of the standard in the northwest Indiana severe ozone nonattainment area and also in the downwind areas of the LMOS modeling domain. The USEPA granted a NO_X waiver for RACT, NSR, and general conformity based on the submitted modeling on January 26, 1996, (61 FR 2428). At the same time and using the same technical support evaluation, the USEPA would have granted the transportation conformity waiver but for the technical correction to grant the waiver under 182(b)(1) instead of 182(f). This rulemaking completes the efforts under this technical correction.

On January 6, 1998, (63 FR 456), the USEPA proposed approval of Indiana's request to grant an exemption for the northwest Indiana severe ozone nonattainment area from the applicable NO_X transportation conformity requirements.

II. Public Comments

The USEPA received two sets of comments during the public comment

period, which ended on February 5, 1998. One set was in favor of the USEPA proposal, and one set was critical. The following are the critical comments on the proposal and USEPA's responses to the comments:

Comment: Indiana has failed to establish a NO_X budget for the ozone nonattainment area. Indiana has yet to develop and submit such a budget as required by November 1994. Until the attainment demonstrations, encompassing verifiable and allocated (biogenic, point, mobile, and area) NO_X emission budgets, are submitted and complete, any determination that required control strategies are not necessary is premature and unfounded.

Response: Approval of the transportation conformity NO_X waiver does not eliminate the need for a NO_X budget determination. As described in the background section, the waiver merely removes the requirement for the build/no-build test. It is anticipated that in the future, Indiana will submit a NO_X transportation budget in its state implementation plan.

Comment: The NO_X waiver technical documentation is outdated, incomplete and inconsistent with USEPA's NO_X SIP call.

Response: USEPA's NO_X SIP call proposal published November 7, 1997, (62 FR 60317) is based on modeling conducted by the Ozone Transport Assessment Group (OTAG). OTAG used information and ozone episodes contributed by LADCo and the State of Indiana. USEPA's NO_X SIP call acknowledges the NO_X ''disbenefit'' issue and specifically mentions the Lake Michigan states as an area where the modeling shows a disbenefit. A ''disbenefit'' from NO_X is when reductions in NO_X emissions create an increase in the concentrations of ozone. USEPA's NO_X SIP call encourages local and regional modeling to determine the extent of the NO_X disbenefit; and the appropriate control strategies to deal with the disbenefit. LADCo is currently conducting modeling to refine the NO_X disbenefit and the State of Indiana, in cooperation with the other Lake Michigan states, intends to submit the modeling and analysis in response to the SIP call. Thus, there is nothing in the most recent modeling which contradicts the phenomenon of the NO_X disbenefit in the Lake Michigan area.

Comment: The Indiana submittal failed to demonstrate that low-level NO_X reductions in the northwest Indiana area would not improve air quality. While the submittal did analyze domain-wide low-level NO_X reductions, no such analysis was performed for the specific Indiana counties. The State of Indiana, in coordination with LADCo, has the capabilities to model NO_X emissions from mobile sources in these counties. Therefore, USEPA should require such a demonstration before taking final action on this rulemaking.

Response: The LADCo analysis demonstrated that across-the-board reductions in NO_X from point, area, and mobile sources generally showed a ''disbenefit'' in many areas of the modeling domain. Further, LADCo performed an analysis which focused on NO_X reductions from point sources. This analysis showed a small increase in ozone formation. From this result, LADCo concluded that low level NO_X controls, i.e. mobile and area sources, would be detrimental to air quality in the modeling domain. The LADCo analysis is consistent with the USEPA NO_X waiver policy which requires consideration of modeling domain wide peak ozone concentrations.

Comment: Indiana and Michigan counties now in violation of the ozone NAAQS will benefit from low-level NO_X emissions reductions.

Response: Regional modeling is currently being conducted to determine more precisely where NO_X reductions give a disbenefit. The OTAG modeling demonstrated that elevated and low-level NO_X reductions across many states will generally reduce transported ozone. The USEPA NO_X SIP call proposed on November 7, 1997, proposed statewide budgets for NO_X. The State has the ability to decide what NO_X reductions would be most beneficial, after consideration of downwind benefits and local disbenefits. The States are currently conducting additional modeling in the Lake Michigan area to determine where NO_X reductions are most beneficial. It is premature to subject transportation sources in Lake and Porter Counties to NO_X reductions until this additional modeling is completed and USEPA finalizes the SIP call notice and Indiana submits its plan for NO_X reductions.

Comment: USEPA's $PM_{2.5}$ NAAQS requires an additional net air quality benefit analysis.

Response: The USEPA timeline for implementation of the $PM_{2.5}$ NAAQS begins with setting up a monitoring network and collecting data for several years before designating areas under the new NAAQS. At this time, the USEPA does not know which areas will be designated nonattainment for $PM_{2.5}$, nor are there any control strategies currently proposed for $PM_{2.5}$. The transportation conformity requirement is to enable attainment of the one hour ozone standard. In this notice, USEPA is only waiving the transportation conformity build/no-build test, which requires reductions in NO_X in ozone nonattainment areas.

Comment: The USEPA has failed to adequately consider the net environmental benefits (such as acid rain reduction) of NO_X emissions reductions in Lake and Porter Counties.

Response: As stated above, the LADCo analysis demonstrated that across the board reductions in NO_X from point, area, and mobile sources showed both benefits and disbenefits in the modeling domain. Further, the transportation conformity rule does not require the build/no-build test for NO_X as an ozone precursor in ozone nonattainment areas where the Administrator determines that additional reductions of NO_X would not contribute to attainment of the National Ambient Air Quality Standard (NAAQS) for ozone. A net benefit analysis for all environmental benefits is not required since this requirement is specific to ozone nonattainment.

Comment: The USEPA and Indiana failed to perform the appropriate environmental justice analysis. The USEPA has failed to consider the spatial impact of where reductions could be anticipated and where increases might occur with and without NO_X conformity compliance in northwest Indiana and southeast Chicago. The USEPA is expected to address the full range of environmental implications including: (1) Will the rulemaking increase already unacceptable levels of air toxics in these communities? (2) Will this rulemaking increase already unacceptable levels of fine particulate matter in these communities? (3) Will the sprawl included by the proposal—or the elevated speed limits allowed—disproportionately impact at-risk populations? (4) Will this proposal further exacerbate the difficulty of low income and unemployed citizens in the region commuting to employment opportunities?

Response: As discussed in the January 6, 1998, proposed approval, the role that NO_X emissions play in producing ozone at any given place and time is complex. Modeling shows that controlling low level NO_X in northwest Indiana could in fact increase ozone concentrations in local urban areas particularly the minority areas in Lake County, Indiana and southeast Chicago. This disbenefit is caused by the reaction of nitrogen oxide with ozone, which locally reduces ozone concentrations, and is referred to as ozone scavenging. Since emissions of NO_X from fuel combustion sources, whether internal combustion engines or stationary combustion sources, such as industrial boilers, contain significant

amounts of NO, it is expected that ozone concentrations immediately downwind of such NO_X sources will be reduced through ozone scavenging. Therefore, reducing NO_X emissions can lead to increased ozone concentrations in the vicinity of the controlled NO_X emission sources, while causing a reduction in ozone concentrations further downwind. Reducing NO_X emissions in VOC-limited areas (areas with low VOC emissions relative to NO_X emissions) may produce minimal ozone reductions or even ozone increases. This pattern of NO_X scavenging is demonstrated in the LADCo modeling. Therefore, controlling low level NO_X in northwest Indiana could in fact increase ozone concentrations in local urban areas particularly the minority areas in Lake County, Indiana and southeast Chicago. This, in fact, is what the LADCo modeling demonstrated.

As for the other environmental and social implications, this rulemaking addresses NO_X reduction for meeting the ozone standard and merely waives the build/no-build reduction requirement for transportation sources. NO_X from the transportation plan is not expected to increase significantly and thus will not increase air toxics or fine particulates. It is through the transportation planning process that transportation decisions are made.

This transportation conformity waiver is not expected to adversely affect the transportation options of minority populations in northwest Indiana. In fact, letters from IDEM and Indiana Department of Transportation and the Northwestern Indiana Regional Planning Commission indicate that the NO_X transportation waiver, will allow transportation planning to be simplified and allow federal funding of transportation improvements to proceed.

Comment: The Indiana request utilizes the BEIS–I inventory for biogenic emissions. OTAG concluded that the BEIS–II inventory is the preferred inventory for UAM analyses.

Response: The BEIS–I was the approved and most appropriate biogenic emissions inventory available to LADCo when the NO_X modeling analysis was performed. Any subsequent modeling performed by LADCo will utilize the BEIS–II biogenic emissions inventory.

Comment: OTAG concluded that both elevated and low level NO_X reductions are effective in reducing ozone levels. These conclusions were based extensively on OTAG modeling, and are significant and relevant to USEPA's action on this rule. The modeling clearly demonstrated the efficacy of reducing low-level (mobile source) NO_X in controlling ozone. The conclusions of the policy group were that such reductions were cost effective, and beneficial to reduce transport to downwind areas.

Response: It should be noted that OTAG concluded that States must have the opportunity to conduct additional local and subregional modeling to assess appropriate, type, and timing of controls. OTAG further concluded that States can work together, in coordination with USEPA, toward developing local SIPs including an evaluation of possible local NO_X disbenefits. In addition, OTAG modeling results demonstrated a significant potential for NO_X control disbenefits in the Lake Michigan area.

Comment: OTAG concluded that disbenefit analyses found ozone increases to be less frequent and severe than USEPA concluded based on the July 13, 1994 LADCo 182(f) NO_X waiver submittal.

Response: The OTAG fine grid analysis utilized a 12 km grid as compared to the LADCo fine grid of 4 km. This disparity in fine grid size can de-emphasize the NO_X disbenefit at the local urbanized area. OTAG concluded that some areas will experience local NO_X disbenefits at more frequent pronounced levels when finer grids are considered.

Comment: In previous rulemakings on similar NO_X waiver requests, USEPA committed to incorporate the OTAG findings in future USEPA rulemakings. OTAG recommendations are now complete, OTAG findings are clear, and USEPA has validated these OTAG findings in proposing its NO_X SIP call. This proposal is inconsistent with and even undermines the USEPA NO_X SIP call.

Response: The summary of OTAG findings states that NO_X reductions decrease and increase ozone: decreases occur domain wide; increases are confined to a few days in a few urban areas.

The USEPA's recently proposed regional NO_X rulemaking uses the OTAG findings to identify States which contribute significantly to ozone problem areas in other states. In addition, the proposed rulemaking establishes State wide NO_X budgets for the year 2007.

A section of the rulemaking also solicits comments on approaches that can be used to address the disbenefit issue in areas such as Lake Michigan. Subsequent modeling by the LADCo States will need to address the disbenefit issue as it pertains to the NO_X budget, ozone transport, and attainment. It is premature at this time to require NO_X reductions from transportation sources in northwest Indiana before completion of modeling, finalization of the NO_X SIP call and preparation of the State implementation plan to address state NO_X reductions.

IV. USEPA Action

In this final action, USEPA is approving the transportation conformity NO_X waiver SIP revision for the State of Indiana. In light of the modeling completed thus far and considering the importance of the Ozone Transport Assessment Group process and attainment plan modeling efforts the USEPA notes that it may reexamine the impact of this NO_X waiver as future modeling becomes available. In the near future, USEPA intends to require appropriate States to submit SIP measures to achieve emissions reductions of ozone precursors needed to prevent significant transport of ozone. The USEPA will evaluate the States' submitted SIP measures and available refined modeling to determine whether the NO_X waiver should remain in place, or whether USEPA will require a new plan revision.

The USEPA also reserves the right to require NO_X emission controls for transportation sources under section 110(a)(2)(D) of the Act if future ozone modeling demonstrates that such controls are needed to achieve the ozone standard in downwind areas.

Nothing in this action should be construed as permitting, allowing or establishing a precedent for any future request for revision to any SIP. Each request for 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.

V. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget has exempted this regulatory action from Executive Order 12866 review.

B. Executive Order 13045

This final rule is not subject to Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks,'' because it is not an ''economically significant'' action under Executive Order 12866.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements 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 not-for-profit enterprises, and small governmental jurisdictions.

This final rule will not have a significant impactr on a substantial number of small entities because SIP approvals under section 110 and subchapter I, part D of the Act do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities. Moreover, due to the nature of the Federal-State relationship under the Act, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of the State action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *EPA.*, 427 U.S. 246, 256–66 (1976); 42 U.S.C. 7410(a)(2).

D. Unfunded Mandates

Under section 202 of the Unfunded Mandates Reform Act of 1995, signed into law on March 22, 1995, EPA must undertake various actions in association with 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. This federal action does not impose any new federal requirements. Accordingly, no additional costs to state, local, or tribal governments, or the private sector, result from this action.

E. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective.

F. Petitions for Judicial Review

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 25, 1998. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Oxides of Nitrogen, Ozone, Transportation-air quality planning, Transportation conformity.

Authority: 42 U.S.C. 7401–7671q.

Dated: July 15, 1998.

David A. Ullrich,

Acting Regional Administrator.

Part 52, Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart P—Indiana

2. Section 52.777 is amended by adding paragraph (t) to read as follows:

§ 52.777 Control strategy: Photochemical Oxidants (hydrocarbons).

* * * * *

(t) Approval—On May 24, 1996, the Indiana Department of Environmental Management submitted a revision to the ozone State Implementation Plan for Lake and Porter Counties. The submittal pertained to a plan for the implementation of the Federal transportation conformity requirements in accordance with 40 CFR part 51 subpart T—Conformity to State or Federal Implementation Plans of Transportation Plans, Programs, and Projects Developed, Funded or Approved Under Title 23 U.S.C. or the Federal Transit Act.

* * * * *

[FR Doc. 98–19931 Filed 7–24–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[KY–90–1–9735a: FRL–6130–3]

Approval and Promulgation of Implementation Plans Kentucky: Adoption of General Conformity Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: On November 10, 1995, the Commonwealth of Kentucky, through the Kentucky Natural Resources and Environmental Protection Cabinet (KNREPC), submitted revisions to EPA concerning the adoption of general conformity rules into the Kentucky State Implementation Plan (SIP). Since general conformity rules are required by Section 176 of the Clean Air Act (CAA) in all nonattainment and maintenance areas and the Kentucky submittal is consistent with EPA requirements, these revisions are being incorporated into the Federally approved Kentucky SIP.

DATES: This direct final rule is effective on September 25, 1998 without further notice, unless EPA receives adverse comment by August 26, 1998. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Written comments on this action should be addressed to Gregory O. Crawford at the Environmental Protection Agency, Region 4 Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303. Copies of documents relative to this action are available for public inspection during normal business hours at the locations below. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day. Reference file KY–90–9735. The Region 4 office may have additional background documents not available at the other locations.

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

Environmental Protection Agency, Region 4 Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303, Gregory O. Crawford, 404/562–9046.

Commonwealth of Kentucky, Natural Resources and Environmental