participation and accompanying information, FDA will schedule each appearance and notify each participant by mail or telephone of the time allotted to the person and the approximate time the person's presentation is scheduled to begin. Each presentation will be limited in time in order to provide sufficient time for prepared presentations by the agency followed by a discussion period. The schedule of the public meeting will be available at the meeting, and later it will be placed on file in the Dockets Management Branch (address above).

Individuals and organizations that do not submit a notice of participation but would like to testify will have the opportunity, if time permits. A transcript of the proceedings of the public meeting, as well as all data and information submitted voluntarily to FDA during the public meeting to discuss the working draft, will become part of the administrative record and will be available to the public under 21 CFR 20.111 from the Dockets Management Branch (address above).

While oral presentations from specific individuals and organizations will be limited during the public meeting, the written comments submitted as part of the administrative record may contain a discussion of any issues of concern. All relevant data and documentation should be submitted with the written comments.

There will also be a public meeting with the Device GMP Advisory Committee, established under section 520(f)(1)(B) of the act, on the working draft. That meeting will be governed by part 14 (21 CFR part 14) of FDA's administrative practices and procedures regulations, which specifies the requirements for filing notices of appearance. The tentative dates for the meeting are September 13 and 14, 1995. A notice of the exact dates, time, and place for the meeting will appear in a future issue of the **Federal Register**. After considering the written comments and the views expressed at the public meeting and at the September advisory committee meeting, FDA will publish a final rule in the **Federal Register**.

## IV. References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday:

(1) ISO 9001:1994 ''Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation, and Servicing.''

(2) ISO working draft revision of ISO/DIS 13485 ''Quality Systems—Medical Devices—Supplementary Requirements to ISO 9001.''

## V. Comments

Interested persons may, on or before October 23, 1995, submit to the Dockets Management Branch (address above), written comments regarding this working draft. 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. The working draft and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 18, 1995.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 95–18080 Filed 7–19–95; 1:36 pm]

**BILLING CODE 4160–01–F**

## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 63

**[FRL–5260–2]**

## Approval of Existing Federally Enforceable State and Local Operating Permit Programs To Limit Potential To Emit for Air Toxics; State of Alabama; Knox County, Tennessee

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA proposes approval of the State of Alabama's Federally enforceable state operating permits program (FESOP) under section 112(l) of the Clean Air Act as amended in 1990 (CAA). EPA proposes approval of the Knox County, Tennessee Federally enforceable local operating permit program (FELOP) under section 112(l) of the CAA. EPA is proposing approval of both of these requests under section 112(l) of the CAA for purposes of limiting potential to emit (PTE) for hazardous air pollutant (HAP) sources. In the final rules section of this **Federal Register**, EPA is approving Alabama and Knox County, Tennessee's submittals as a direct final rule without prior proposal because the EPA views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to that direct final rule, no further activity is contemplated in relation to this proposed rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

**DATES:** To be considered, comments must be received by August 23, 1995.

**ADDRESSES:** Written comments should be addressed to Scott Miller of the EPA Regional office listed below.

Copies of the material submitted by both agencies may be examined during normal business hours at the following 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 Programs Branch, 345 Courtland Street NE., Atlanta, Georgia 30365.

Alabama Department of Environmental Management, Air Division, 1751 Congressman W.L. Dickinson Drive, Montgomery, Alabama 36109.

Knox County Department of Air Pollution Control, City/County Building, Suite 339, 400 West Main Street, Knoxville, Tennessee 37902.

**FURTHER INFORMATION CONTACT:** Scott Miller, Air Programs Branch, Air, Pesticides & Toxics Management Division, Region 4 Environmental Protection Agency, 345 Courtland Street NE., Atlanta, Georgia 30365. The telephone number is 404/347–2864.

**SUPPLEMENTARY INFORMATION:** For additional information see the direct final rule which is published in the rules section of this **Federal Register**.

Dated: June 23, 1995.

**Patrick M. Tobin,**

*Acting Regional Administrator.*

[FR Doc. 95–17614 Filed 7–21–95; 8:45 am]

**BILLING CODE 6560–50–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Administration for Children and Families

## 45 CFR Part 95

**RIN 0970–AB46**

## Reduction of Reporting Requirements for the State Systems Advance Planning Document (APD) Process

**AGENCY:** Administration for Children and Families, HHS.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** These proposed rules would decrease the reporting burden on States relative to the State systems advanced planning document (APD) process by increasing the threshold amounts above which APDs and related procurement documents need to be submitted for Federal approval. The APD process is the procedure by which States obtain approval for Federal financial participation in the cost of acquiring automatic data processing equipment and services. Additionally, these proposed rules would eliminate the requirement for State submittal of biennial security plans for Federal review in order to approve and ensure timely Departmental action on State funding requests.

**DATES:** Interested parties are invited to comment on these proposed rules. Comments must be received on or before September 22, 1995.

**FOR FURTHER INFORMATION CONTACT:** Bill Davis, State Data Systems Staff, 370 L'Enfant Promenade SW., Washington, DC 20447, telephone (202) 401–6404.

**ADDRESSES:** Comments should be submitted in writing to the Assistant Secretary for Children and Families, Attention: Mr. Mark Ragan, Office of Information Systems Management, room 300 E, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Comments may be inspected between 8 a.m. and 4:30 p.m. during regular business days by making arrangement with the contact person identified above.

**SUPPLEMENTARY INFORMATION:**

### Paperwork Reduction Act

These proposed rules would reduce current information collection activities and, therefore, no approvals are necessary under section 3504(h) of the Paperwork Reduction Act of 1980 (Pub. L. 96–511).

We estimate that the paperwork burden associated with advance planning document reporting requirements would be reduced by 20 percent and that a further reduction would result from the impact this regulation would have on Request for Proposals (RFP) and contract reporting requirements. Additionally, this proposed regulation would eliminate all reporting burden previously associated with submission of biennial security reports.

### Statutory Authority

These proposed regulations are published under the general authority of sections 402(a)(5), 452(a)(1), 1902(a)(4), and 1102 of the Social Security Act (the Act).

### Background and Description of Regulatory Provisions

State public assistance agencies acquire automatic data processing (APD) equipment and services for computer operations which support the Aid to Families with Dependent Children, Adult Assistance, Child Support Enforcement, Medicaid, Child Welfare, and Refugee Resettlement programs. Currently any competitive acquisition over $500,000 or any sole source acquisition over $100,000 in total State and Federal costs which will be matched at the regular Federal financial participation (FFP) rate requires written prior approval of an APD. Project cost increases of more than $300,000 require the submission of an APD Update. Also, most procurement documents (Request for Proposals (RFPs) and contracts) over $300,000, and contract amendments over $100,000 must be approved by the Federal funding agencies.

Experience since these thresholds have been in place shows that the total costs of all regular match State acquisitions under $5 million account for a small percentage of the total of all State systems development and operations costs, but that they account for a disproportionate share of the documents submitted for Federal review. In order to reduce the reporting burden on States and to better use Federal resources, we are proposing to raise the threshold amounts for regular match acquisitions. We would continue to require written prior approval for all equipment and services acquired at an enhanced matching rate.

To further the goal of reduced burden and increased efficiency, these rules also propose to eliminate the requirement for submitting biennial security reports to HHS. In the four years that biennial security reports have been required under this subpart, it has been our experience that the submission and review of these reports by HHS components has been of minimal value to assuring that States have adequate security programs. Ultimately, the adequacy of these programs rests with the States. For this reason, we are proposing to eliminate this reporting requirement, but to continue requirements that States must perform security reviews and be responsible for maintaining review reports. These reports would then be available for inspection by HHS staff during on-site reviews where their content could be compared to actual operations.

We are also proposing to change the rules to provide prompt Department action on State funding requests. On average the Department takes 30 to 60 days to respond to State submissions. Delayed responses to States can cause project delays and increased costs to all parties including the Department. From its experience, the Department has determined that response can and should be made within 60 days. In recognition of that experience and our partnership and commitment to State projects which support our programs, we are proposing to establish a provision whereby, if the Department has not provided a State written approval, disapproval, or a request for information within 60 days of issuing an acknowledgement of receipt of a State's request, the request would be deemed to have provisionally met the prior approval requirements. In this way, States would have a firmer basis upon which to establish project timeframes, including the need to obtain HHS approvals, and the incidence of increased project costs due to delays in Departmental action on State funding requests would be reduced.

Provisional approval would not absolve a State from meeting all Federal requirements which pertain to the computer project or acquisition. Such projects would continue to be subject to Departmental audit and review, and the determinations made from such audits and reviews. Even written prior approval by the Department does not guarantee absolutely that there will be no subsequent determination of violation of the pertinent Federal statutes and regulations. States which are confident that their project is in compliance would be able, however, to proceed after the 60-day period has expired without further delay awaiting Federal approval.

These proposed rules would revise 45 CFR 95.611(a)(1), which provides that States must obtain prior written approval for APD equipment or services anticipated to have total acquisition costs of $500,000 or more in Federal and State funds, to increase the $500,000 threshold amount to $5 million or more. Similarly, paragraph (a)(4), which requires prior written approval with respect to State plans to acquire noncompetitively from a nongovernmental source, APD equipment and services, with a total acquisition cost of greater than $100,000, is proposed to be revised to require that a State obtain prior approval of its justification for a sole source acquisition with total State and Federal costs of more than $1 million but no more than $5 million and would

provide that noncompetitive acquisitions of greater than $5 million continue to be subject to the requirements of paragraph (b), which provides specific prior approval requirements.

The Department expects that justifications for sole source acquisitions of between $1 million and $5 million would address pertinent Federal and State requirements. For example, the justification should include a description of the proposed acquisition, the circumstances identified at 45 CFR part 74, Appendix G under which a grantee may undertake a noncompetitive acquisition, and assurances that the sole source acquisition meets the requirements of State laws, regulations and other relevant guidelines. Contracts which results from sole source acquisitions of greater than $1 million are subject to prior approval in accordance with 45 CFR 95.611(b)(1)(iii).

We are also proposing to eliminate paragraph (a)(3), which provides a separate threshold amount for acquisitions in support of State Medicaid systems funded at the 75 percent FFP rate. The Health Care Financing Administration (HCFA) would apply the new thresholds of Title XIX funded projects and these rules would be described in an upcoming revision to Part 11 of the *State Medicaid Manual.* Additionally, we are proposing to modify paragraph (a)(2) to delete a reference to paragraph (a)(3) and to redesignate paragraphs (a)(4) through (a)(7) as paragraphs (a)(3) through (a)(6). We are also proposing to revise paragraph (a)(4), as redesignated, to change the reference from (a)(6) to (a)(5).

Paragraph (b)(1)(iii), which provides that unless specifically exempted by the Department, approval must be received prior to release of a Request for Proposal (RFP) or execution of a contract where costs are anticipated to exceed $300,000, is proposed to be revised to increase the threshold to $5 million with respect to competitive procurements and $1 million for noncompetitive acquisitions from nongovernment sources. As proposed, this paragraph would provide that States may be required to submit RFPs and contracts under the threshold amounts on an exception basis or if the procurement strategy is not adequately described and justified.

With respect to contract amendments, we are proposing to revise 45 CFR 95.611(b)(1)(iv) is revised to provide that prior approval is needed, unless specifically exempted by the Department, prior to execution of a contract amendment involving cost increases of greater than $1 million or time extensions of more than 120 days. In addition, States would be required to submit for approval contract amendments under these threshold amounts on an exception basis or if the contract amendment was not adequately described and justified in the APD.

As indicated, with respect to both proposed changes to paragraph (b), HHS would retain the right to review and approve all RFPs, contracts, and contract amendments, regardless of dollar amount, on an exception basis. This could include instances where new program requirements or technology are involved, as in electronic benefits transfer, or when adequate description and justification has not been provided in the APD.

Paragraph (c)(1), which provides specific approval requirements with respect to regular FFP requests, is also proposed to be revised to provide increased thresholds. First, under (c)(1)(i), the $1 million threshold with respect to the need for written approval from the Department of Annual Advanced Planning Document Updates (APDU) would be increased to $5 million. In paragraph (c)(1)(ii)(A), the threshold with respect to the requirement for approval of an ''as needed'' APDU of projected cost increases would be raised from a lesser of $300,000 or 10 percent of the project cost, to projected cost increases of $1 million or more.

We are also proposing to revise 45 CFR 95.611 to provide prompt Federal action on State funding requests. Accordingly, paragraph (d) would be revised to provide that, if the Department has not provided written approval, disapproval, or a request for information within 60 days of issuing an acknowledgement of receipt of a State's request, the request would be provisionally deemed to have met the prior approval requirements.

Finally, we are proposing to amend 45 CFR 95.621(f)(6), which requires States to submit biennial security reports for Federal review and approval, to require that such reports be maintained by States for on-site review by HHS in the future.

**Regulatory Impact Analysis**

Executive Order 12866 requires that regulations be reviewed to ensure that they are consistent with the priorities and principles set forth in the Executive Order. The Department has determined that this rule is consistent with these priorities and principles. No costs are associated with this rule as it merely decreases reporting burden on States.

**Regulatory Flexibility Act**

Consistent with the Regulatory Flexibility Act (Pub. L. 96–354), which requires the Federal government to anticipate and reduce the impact of rules and paperwork requirements on small businesses and other small entities, the Secretary certifies that this rule has no significant effect on a substantial number of small entities. Therefore, a regulatory flexibility analysis is not required.

**List of Subjects in 45 CFR Part 95**

Claims, Computer technology, Grant programs—health, Grant programs, Social programs, Social Security.

(Catalog of Federal Domestic Assistance Program Numbers 93.645 Child Welfare Services-State Grants; 93.658, Foster Care Maintenance; 93.659, Adoption Assistance; 93.563, Child Support Enforcement Program; 93.174, Medical Assistance Program; 93.570, Assistant Payments-Maintenance Assistance)

Dated: November 29, 1994.

**Mary Jo Bane,**

*Assistant Secretary for Children and Families.*

Approved: March 30, 1995.

**Donna E. Shalala,**

*Secretary.*

For the reasons set forth in the preamble, 45 CFR is proposed to be amended as follows:

## PART 95—GENERAL ADMINISTRATION—GRANT PROGRAMS (PUBLIC ASSISTANCE AND MEDICAL ASSISTANCE)

1. The authority citation for part 95, subpart F continues to read as follows:

Authority: Secs. 402(a)(5), 452(a)(1), 1102, and 1902(a)(4) of the Social Security Act, 42 U.S.C. 602(a)(5), 652(a)(1), 1302, 1396a(a)(4); 5 U.S.C. 301 and 8 U.S.C. 1521.

2. Section 95.611 is amended by revising paragraphs (a)(1), (a)(2), (b)(1)(iii), (b)(1)(iv), (c)(1)(i), (c)(1)(ii) (A) and (d) and by removing paragraph (a)(3) and redesignating paragraphs (a)(4) through (a)(7) as (a)(3) through (a)(6) and revising newly redesignated paragraphs (a)(3) and (a)(4) to read as follows:

**§ 95.611 Prior approval conditions.**

(a) * * * (1) A State shall obtain prior written approval from the Department as specified in paragraph (b) of this section, when the State plans to acquire APD equipment or services with proposed FFP at the regular matching rate that it anticipates will have total acquisition costs of $5,000,000 or more in Federal and State funds.

(2) A State shall obtain prior written approval from the Department as specified in paragraph (b) of this

section, when the State plans to acquire APD equipment or services with proposed FFP at the enhanced matching rate authorized by 45 CFR 205.35, 45 CFR part 307 or 42 CFR part 433, subpart C, regardless of the acquisition cost.

(3) A State shall obtain prior written approval from the Department of its justification for a sole source acquisition, when it plans to acquire noncompetitively from a nongovernmental source APD equipment or services, with proposed FFP at the regular matching rate, that has a total State and Federal acquisition cost of more than $1,000,000 but no more than $5,000,000. Noncompetitive acquisitions of more than $5,000,000 are subject to the provisions of paragraph (b) of this section.

(4) Except as provided for in paragraph (a)(5) of this section, the State shall submit requests for Department approval, signed by the appropriate State official, to the Director, Administration for Children and Families, Office of Information Management Systems. The State shall send to ACF one copy of the request for each HHS component, from which the State is requesting funding, and one for the State Data Systems Staff, the coordinating staff for these requests. The State must also send one copy of the request directly to each Regional program component and one copy to the Regional Director.

* * * * *

(b) * * *

(1) * * *

* * * * *

(iii) For the Request for Proposal and Contract, unless specifically exempted by the Department, prior to release of the RFP or prior to the execution of the contract when the contract is anticipated to or will exceed $5,000,000 for competitive procurement and $1,000,000 for noncompetitive acquisitions from nongovernmental sources. States will be required to submit RFPs and contracts under these threshold amounts on an exception basis or if the procurement strategy is not adequately described and justified in an APD.

(iv) For contract amendments, unless specifically exempted by the Department, prior to execution of the contract amendment involving contract cost increases exceeding $1,000,000 or contract time extensions of more than 120 days. States will be required to submit contract amendments under these threshold amounts on an exception basis or if the contract amendment is not adequately described and justified in an APD.

* * * * *

(c) * * *

(1) * * *

(i) For an annual APDU for projects with a total acquisition cost of more than $5,000,000, when specifically required by the Department.

(ii) For an ''As Needed APDU'' when changes cause any of the following:

(A) A projected cost increase of $1,000,000 or more.

* * * * *

(d) *Prompt action on requests for prior approval*. The ACF will promptly send to the approving components the items specified in paragraph (b) of this section. If the Department has not provided written approval, disapproval, or a request for information within 60 days of the date of the Departmental letter acknowledging receipt of a State's request, the request will automatically be deemed to have provisionally met the prior approval conditions of paragraph (b) of this section.

3. Section 95.621 is amended by revising paragraph (f)(6) to read as follows:

**§ 95.621 APD reviews.**

* * * * *

(f) * * *

(6) The State agency shall maintain reports of their biennial APD system security reviews, together with pertinent supporting documentation, for HHS on-site review.

[FR Doc. 95–18070 Filed 7–21–95; 8:45 am]

BILLING CODE 4184–01–M

## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

### 49 CFR Part 531

**[Docket No. 95–51; Notice 1]**

### Passenger Automobile Average Fuel Economy Standards; Proposed Decision To Grant Exemption

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), DOT.

**ACTION:** Proposed decision.

**SUMMARY:** This proposed decision responds to a petition filed by Rolls-Royce Motors, Ltd. (Rolls-Royce) requesting that it be exempted from the generally applicable average fuel economy standard of 27.5 miles per gallon (mpg) for model year 1997, and that a lower alternative standard be established. In this document, NHTSA proposes that the requested exemption be granted and that an alternative standard of 15.1 mpg be established for MY 1997 for Rolls-Royce.

**DATES:** Comments on this proposed decision must be received on or before September 7, 1995.

**ADDRESSES:** Comments on this proposal must refer to the docket number and notice number in the heading of this notice and be submitted, preferably in ten copies, to: Docket Section, Room 5109, National Highway Traffic Safety Administration, 400 Seventh Street, S.W., Washington, DC 20590. Docket hours are 9:30 a.m. to 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Mr. Orron Kee, Office of Market Incentives, NHTSA, 400 Seventh Street, SW, Washington, DC 20590. Mr. Kee's telephone number is: (202) 366–0846.

**SUPPLEMENTARY INFORMATION:**

#### Statutory Background

Pursuant to 49 U.S.C. section 32902(d), NHTSA may exempt a low volume manufacturer of passenger automobiles from the generally applicable average fuel economy standards if NHTSA concludes that those standards are more stringent than the maximum feasible average fuel economy for that manufacturer and if NHTSA establishes an alternative standard for that manufacturer at its maximum feasible level. Under the statute, a low volume manufacturer is one that manufactured (worldwide) fewer than 10,000 passenger automobiles in the second model year before the model year for which the exemption is sought (the affected model year) and that will manufacture fewer than 10,000 passenger automobiles in the affected model year. In determining the maximum feasible average fuel economy, the agency is required under 49 U.S.C. 32902(f) to consider:

(1) Technological feasibility

(2) Economic practicability

(3) The effect of other Federal motor vehicle standards on fuel economy, and

(4) The need of the Nation to conserve energy.

The statute at 49 U.S.C. 32902(d)(2) permits NHTSA to establish alternative average fuel economy standards applicable to exempted low volume manufacturers in one of three ways: (1) A separate standard for each exempted manufacturer; (2) a separate average fuel economy standard applicable to each class of exempted automobiles (classes would be based on design, size, price, or other factors); or (3) a single standard for all exempted manufacturers.