summary of the comments and the agency's response to them is provided below:

(1) One comment concurred with FDA's proposal to remove the separate regulation on IDE's for IOL's contained in part 813. However, because part 813 contains some provisions that are not reflected in part 812, the comment suggested that FDA identify what, if any, additional information FDA would require IDE submissions for IOL's to include.

Under the final rule, any requirements unique to part 813 would no longer apply. The content of IDE submissions for IOL's only need to include information required in IDE submissions for investigational devices generally. For example, with respect to institutional review boards (IRB's) (referred to in part 813 as institutional review committees), the sponsor will only be required to submit the information required by § 812.20(b)(6) and not that required by § 813.20(b)(7).

(2) Both comments recommended that FDA provide in the final rule a mechanism for IOL clinical investigations that are in progress before the final rule becomes effective to continue under part 813 until those investigations are completed or terminated. One comment also noted that, because investigators have not signed statements agreeing to conform to part 812, application of the requirements of part 812 to ongoing IOL studies would create confusion and add to the cost of the ongoing studies.

FDA does not believe that the continuation of part 813 requirements for existing studies is necessary. The differences between parts 812 and 813 are relatively minor. Investigators who are in compliance with part 813 will also generally be in compliance with part 812. Sponsors may seek a waiver under part 812, if there are any difficulties as a result of the change from part 813 to part 812. FDA, however does not anticipate any difficulties.

(3) Both comments emphasized that part 812 has certain requirements that are not included in part 813. For example, § 812.150(b)(4) requires the sponsor to submit a semi-annual investigator list to FDA; § 812.150(b)(5) requires the sponsor to submit annual progress reports to all reviewing IRB's; and § 812.150(b)(8) requires the sponsor to submit to FDA a copy of any report by an investigator under § 812.150(a)(5) within 5 working days of receipt. Both comments requested that these additional rules not be imposed on IOL studies conducted under part 812.

FDA does not believe that maintaining this type of distinction is necessary. Experience over the past 15 years has shown that the requirements of part 812 are reasonable and that sponsors of investigations under part 812 have not had undue difficulty complying with these provisions. As noted in section II (2) of this document, part 812 contains a waiver provision that can be utilized on a case-by-case basis, if needed.

(4) One comment asked how IRB's would be notified of the new rule.

FDA will send letters to sponsors of all active IOL IDE investigations, and the agency will request that sponsors inform investigators and IRB's of the change. Additionally, FDA will publicize the new rule at the regional IRB meetings and at other appropriate forums.

III. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule removes existing regulations on investigational studies of IOL's and requires such investigations to be conducted under the IDE regulations in part 812 applicable to medical devices generally, the agency certifies that the final rule will not impose any significant new burdens on sponsors and investigators of IOL's and will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 813

Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, chapter I of title 21 of the Code of Federal Regulations is amended in 21 CFR parts 812 and 813 as follows:

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

1. The authority citation for 21 CFR part 812 continues to read as follows:

Authority: Secs. 301, 501, 502, 503, 505, 506, 507, 510, 513–516, 518–520, 701, 702, 704, 721, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 353, 355, 356, 357, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381); secs. 215, 301, 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 262, 263b–263n).

§ 812.2 [Amended]

2. Section 812.2 *Applicability* is amended by removing paragraph (c)(8).

PART 813—INVESTIGATIONAL EXEMPTIONS FOR INTRAOCULAR LENSES

Part 813 [Removed and Reserved]

3. Part 813, consisting of §§ 813.1 through 813.170, is removed and reserved.

Dated: January 22, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–2169 Filed 1–28–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF EDUCATION

34 CFR Part 75

RIN 1880–AA61

Direct Grant Programs

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends the Department's regulations on direct grant programs to expand the basis for selecting applications for new grants to include a recipient's previous

performance under any Department grant program as well as its failure to submit a final performance report or submission of a report of unacceptable quality. The Secretary has decided not to amend the regulations to change the date by which applications are considered received by the Department of Education. These amendments to the final regulations are part of the Department's continuing effort to improve the discretionary grantmaking process.

EFFECTIVE DATE: These regulations take effect February 28, 1997.

FOR FURTHER INFORMATION CONTACT: Ronelle Holloman, U.S. Department of Education, 600 Independence Avenue, S.W., Room 3636, ROB–3, Washington, D.C. 20202–4248. Telephone: (202) 205–3501. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: On September 20, 1995, the Secretary published in the Federal Register (60 FR 48844) a notice of proposed rulemaking (NPRM) proposing to revise sections in the Education Department General Administrative Regulations (EDGAR) regarding the deadline date for applications and how the Secretary selects applications for new grants. These proposed amendments were expected to reduce the processing time for discretionary grants, improve the quality of the final performance report and increase the ability of the Department to ensure that qualified applicants receive grants.

The significant difference between the NPRM and this final regulation is the deletion of the amendment that would have changed the requirement for meeting the deadline date for a competition from the postmarked date to the date the application is actually received. Most commenters opposed this change for one or both of the following reasons: (1) those applicants closest in proximity to the Washington, D.C. metropolitan area would have an unfair advantage; and (2) the change would cause additional cost burdens to recipients. Although the Department did receive several responses in support of the change, from commenters who felt that the change would not cause additional hardship and would be fair if ED allowed for reasonable exceptions to the rule, the Secretary decided not to implement this proposed change at this time.

The final regulation changes how the Secretary selects applications for new grants (34 CFR 75.217). The regulation expands the basis for selection to include a recipient's prior performance under any Department program, including use of funds and the applicant's failure to submit a final performance report or the submission of a report of unacceptable quality. The Department's motivation for this change is to promote accountability and good stewardship. The change will require a stronger commitment from a recipient to submit a final performance report and allow ED the opportunity to inform the general public and the educational community of successful project outcomes. The majority of commenters who responded agreed with the change and felt that this change would set a precedent for sound performance and accountability. Further details of the comments received are discussed below.

Analysis of Comments and Changes

In response to the Secretary's invitation in the NPRM, 44 parties submitted comments on the proposed regulations. An analysis of the comments and of the resulting changes in the regulations since the publication of the NPRM follows. Substantive issues are discussed under the section of the regulations to which they pertain. Technical and other minor changes—and suggested changes the Secretary is not legally authorized to make under the applicable statutory authority—are not addressed.

Section 75.217 How the Secretary selects applications for new grants.

Comments: The Department received a total of 11 comments on this section. The majority of commenters agreed with this change and felt that an institution that received grant funds should be held accountable for meeting the objectives of the grant.

Discussion: The Secretary agrees. Accountability is important to ensure progress and success. The submission of a final report provides opportunity for the general public to know that their tax dollars were spent wisely and provides the educational community with the opportunity to replicate a successful project. The failure to meet all of the obligations in a previous grant would alert the Department that something could be seriously wrong and ED would conduct a further review before funds could be granted in the future.

Changes: None

Comments: One commenter disagreed with the proposed change because the commenter thought it was unfair to penalize an entity for the acts of one individual and that ED does not have standards for report quality.

Discussion: This amendment broadened the range of information the Secretary could consider in selecting new grants. The criteria for selection of new grants are established in regulations of the Department. The Secretary does not agree that there need to be separate criteria for reports. In fact, the Secretary has avoided any effort to narrowly circumscribe final reports. This is consistent with the Department's new reengineered grants process that encourages a partnership with its recipients and supports flexibility in the administration of their projects. In filing an interim or final report the grantee must demonstrate that it is making substantial progress toward meeting the objectives of the grant or that it has met the objectives of the grant. A report will be considered substandard if it fails to address how the recipient met the objectives of a grant or, if it failed to meet any objectives, how it will take steps to improve the project and meet the objectives.

Changes: None

Comments: Several commenters agreed with the proposed change but expressed two similar concerns: (1) How long will a recipient's past poor performance be considered by the Department? (2) What mechanism will be used to allow applicants to receive further funding?

Discussion: Generally, in most cases where poor performance has been an issue, the Department relied on the high-risk procedures authorized under §§ 74.14 and 80.12 of the Education Department General Administrative Regulations (EDGAR). Under the high-risk regulations, ED may impose additional conditions on a recipient to help ensure proper performance. However, there are rare cases where an applicant poses such a risk of misuse of Federal funds that no award should be made. This regulation is intended to be used in those rare cases. ED is aware that recipients face unexpected challenges, some of which can cause a recipient to perform poorly on a grant; therefore, when making future funding decisions, ED will consider any extenuating circumstances on a case-by-case basis.

Paperwork Reduction Act of 1995

These regulations have been examined under the Paperwork Reduction Act of 1995 and have been found to contain no information collection requirements.

Assessment of Educational Impact

In the notice of proposed rulemaking, the Secretary requested comments on whether the proposed regulations would

require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

Based on the response to the proposed rules and on its own review, the Department has determined that the regulations in this document do not require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

List of Subjects in 34 CFR Part 75

Education Department, Discretionary grant programs—education, Continuation funding, Grant administration, Incorporation by reference, Reporting and recordkeeping requirements, Performance reports, Unobligated funds.

Dated: January 23, 1997.

Richard W. Riley,

Secretary of Education.

(Catalog of Federal Domestic Assistance Number does not apply)

The Secretary amends Part 75 of Title 34 of the Code of Federal Regulations as follows:

PART 75—DIRECT GRANT PROGRAMS

1. The authority citation for Part 75 continues to read as follows:

Authority: 20 U.S.C. 1221e–3 and 3474, unless otherwise noted.

2. Section 75.217 is amended by revising paragraph (d)(3) to read as follows:

§ 75.217 How the Secretary selects applications for new grants.

* * * * *

(d) * * *

(3) Any other information—

(i) Relevant to a criterion, priority, or other requirement that applies to the selection of applications for new grants;

(ii) Concerning the applicant's performance and use of funds under a previous award under any Department program; and

(iii) Concerning the applicant's failure under any Department program to submit a performance report or its submission of a performance report of unacceptable quality.

* * * * *

[FR Doc. 97–2196 Filed 1–28–97; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[PA 055–4038; FRL–5653–7]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Approval of a NO_X RACT Determination for International Paper Company—Hammermill Papers Division—Lockhaven

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the Commonwealth of Pennsylvania. This revision establishes and requires reasonably available control technology (RACT) on International Paper Company—Hammermill Papers Division, a major source of nitrogen oxide (NO_X) emissions. Additionally, it limits the volatile organic compound (VOC) emissions at this facility to no more than 50 tons per year; thereby making this facility a synthetic minor VOC source. The intended effect of this action is to approve a source-specific operating permit for the emission units at International Paper—Hammermill Division—Lockhaven, located in Clinton County, Pennsylvania. This action is being taken under section 110 of the Clean Air Act.

EFFECTIVE DATE: This final rule is effective on February 28, 1997.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air, Radiation, and Toxics Division, U.S. Environmental Protection Agency, Region III, 841 Chestnut Building, Philadelphia, Pennsylvania 19107; the Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and Pennsylvania Department of Environmental Protection, Bureau of Air Quality, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Cynthia H. Stahl, (215) 566–2180, at the EPA Region III office or via e-mail at stahl.cynthia@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On April 9, 1996 (61 FR 15709), EPA published a direct final rulemaking notice and the accompanying notice of proposed rulemaking (NPR) (61 FR 15744) for the Commonwealth of Pennsylvania pertaining to the VOC and NO_X RACT determinations for 21 sources. One of these sources was International Paper Company—Hammermill Papers Division—Lockhaven (IP—Lockhaven), located in Clinton County, Pennsylvania. On June 28, 1996, adverse comments were submitted to EPA by the New York Department of Environmental Conservation (NYDEC) pertaining to the RACT determination for IP—Lockhaven. The formal SIP revision for IP—Lockhaven was submitted by Pennsylvania on April 19, 1995. Pennsylvania Department of Environmental Protection (PADEP) also submitted comments to EPA on the IP—Lockhaven RACT determination.

NYDEC Comments

New York Department of Environmental Conservation commented that while they agreed with EPA's determination that RACT for the two 350 mmBTU/hr coal-fired stoker boilers was the operation and maintenance of the boilers in accordance with manufacturer's specifications and good air pollution control practices, they disagreed with the accompanying emission limit of 0.7 lbs NO_X/mmBTU, averaged over a 30 day period, that was also determined to be RACT for these boilers. NYDEC stated that since the AP–42 emission factor estimates NO_X emissions for this type of unit at 0.56 lbs/mmBTU, the limit of 0.7 lbs/mmBTU was too high. NYDEC concludes that in the absence of supporting data, the AP–42 emission rate should become the SIP emission rate for these boilers.

Pennsylvania Comments

Pennsylvania Department of Environmental Protection submitted comments to EPA on July 16, 1996 stating that the proposed RACT emission limits of 0.7 lbs NO_X/mmBTU for the two boilers at IP—Lockhaven were established based on actual emissions data. The 30 day average CEM data recorded for boiler #1 was 0.61 lbs/mmBTU with the range as 0.52 to 0.67 lbs/mmBTU. The 30 day average CEM data recorded for boiler #2 was 0.58 lbs/mmBTU with the range as 0.53 to 0.60 lbs/mmBTU. Since a year's worth of certified data was not available at the time that DEP issued the permit to IP—Lockhaven (December 1995, OP 18–0005), DEP established the limit of 0.7 lbs/mmBTU to allow a buffer to account for the limited emission data. DEP also states that condition #6 of the IP permit allows the Department to revise the NO_X emission limits based on future CEM data. Furthermore, DEP states that since the permit was issued, the IP boilers have recorded exceedances and were