The following statements are provided for the information of the public.

# **Regulatory Impact Statement**

Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, requires the Department to prepare an analysis for any rule that meets one of the E. O. 12866 criteria for a significant regulatory action; that is, that may—

Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866.

In addition, the Department prepares a regulatory flexibility analysis, in accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. chapter 6), if the rule is expected to have a significant impact on a substantial number of small entities.

For the reasons outlined below, we do not believe this NPRM is economically significant nor do we believe that it will have a significant impact on a substantial number of small entities. In addition, this NPRM is not inconsistent with the actions of any other agency.

This NPRM merely codifies internal policies and procedures of the Federal government used to administer non-NRSA training grants awarded by the directors of the national research institutes of NIH under the authority set forth in section 405(b)(1)(C) of the PHS Act; the Director, FIC, under the authority in section 307 of the PHS Act delegated by the Secretary: the Director, NCHGR, under the authority set forth in section 485B(b) of the PHS Act; the Secretary, acting through the Director of NIH, under the authority set forth in section 2315(a)(1) of the PHS Act; the Director of the Office of AIDS Research under the authority set forth in section 2354(a)(3)(C) of the PHS Act; and the Director of NIEHS under the authority set forth in section 103(h)(2) of the Clean Air Act. These grants do not have a significant economic or policy impact on a broad cross-section of the public. Furthermore, the proposed regulations would only affect those highly qualified

health professionals and institutions interested in participating in non-NRSA research training programs, subject to the normal accountability requirements for program participation. No individual or institution is obligated to participate in the program.

For these same reasons, the Secretary certifies that this NPRM will not have a significant economic impact on a substantial number of small entities, and that a Regulatory Flexibility Analysis, as defined under the Regulatory Flexibility Act of 1980, is not required.

# **Paperwork Reduction Act**

This NPRM does not contain any information collection requirements which are subject to Office of Management and Budget (OMB) approval under the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35).

# **Catalog of Federal Domestic Assistance**

The Catalog of Federal Domestic Assistance (CFDA) numbered program affected by these proposed regulations is:

93.837—Heart and Vascular Diseases Research

# List of Subjects in 42 CFR Part 63a

Environmental health; Grant programs—health; Health; Medical research.

Dated: November 7, 1994.

#### Philip R. Lee,

Assistant Secretary for Health.

Approved: December 27, 1994.

### Donna E. Shalala,

Secretary.

Accordingly, it is proposed to amend chapter 1 of title 42 of the Code of Federal Regulations by adding a new part 63a to read as set forth below.

# PART 63a—NATIONAL INSTITUTES OF HEALTH TRAINING GRANTS

Sec.

- 63a.1 To what programs do these regulations apply?
- 63a.2 Definitions.
- 63a.3 What is the purpose of training grants?
- 63a.4 Who is eligible for a training grant?
- 63a.5 How to apply for a training grant.
- 63a.6 How are training grant applications evaluated?
- 63a.7 Awards.
- 63a.8 How long does grant support last?
- 63a.9 What are the terms and conditions of
- awards? 63a.10 How may training grant funds be
- spent?
- 63a.11 Other HHS regulations and policies that apply.

**Authority:** 42 U.S.C. 216, 242*l*(b)(3), 284(b)(1)(C), 287c(b), 300cc–15(a)(1), 300cc–41(a)(3)(C), 7403(h)(2).

# §63a.1 To what programs do these regulations apply?

(a) The regulations of this part apply to:

(1) Grants awarded by the John E. Fogarty International Center for Advanced Study in the Health Sciences, NIH, for training in international cooperative biomedical research endeavors, as authorized under section 307(b)(3) of the Act;

(2) Grants awarded by NIH for research training with respect to the human diseases, disorders, or other aspects of human health or biomedical research, for which the institute or other awarding component was established, for which fellowship support is not provided under section 487 of the Act and which is not residency training of physicians or other health professionals, as authorized by sections 405(b)(1)(C), 485B(b), 2315(a)(1), and 2354(a)(3)(C) of the Act; and,

(3) Grants awarded by the National Institute of Environmental Health Sciences, NIH, for the education and training of physicians in environmental health, as authorized under section 103(h)(2) of the Clean Air Act, as amended.

(b) These regulations also apply to cooperative agreements awarded to support the training specified in paragraph (a) of this section. References to "grant(s)" shall include "cooperative agreement(s)."

(c) The regulations of this part do not apply to:

(1) Research training support under the National Research Service Awards Program (see part 66 of this chapter);

(2) Research training support under NIH Center Grants programs (see part 52a of this chapter);

(3) Research training support under traineeship programs (see part 63 of this chapter);

(4) Research training support under the NIH AIDS Research Loan Repayment Program (see section 487A of the Act); or

(5) Research training support under National Library of Medicine training grant programs (see part 64 of this chapter).

#### §63a.2 Definitions.

As used in this part:

"Act" means the Public Health Service Act, as amended (42 U.S.C. 201 et seq.).

- "Cooperative agreement" See § 63a.1(b).
- "HHS" means the Department of Health and Human Services.