

System. Those provisions have already been subject to a notice of proposed rulemaking, and publication of a new proposed rule is therefore unnecessary. See 58 FR 20802 (April 16, 1993). In addition, while EPA's approval/disapproval decisions described in this document do not constitute rulemaking, EPA has nonetheless received substantial public comment on these decisions. See 63 FR 10221 (March 2, 1998) (notice of receipt of State Guidance submission and request for comment); 65 FR 38830 (June 22, 2000) (notice of letter identifying inconsistencies and request for comment). EPA also believes the public interest is best served by fulfilling the CWA's requirements without further delay and publication of a notice of proposed rulemaking therefore would be contrary to the public interest. Thus, notice and public procedure are unnecessary. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B).

III. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a "significant regulatory action" and is therefore not subject to review by the Office of Management and Budget. Because the agency has made a "good cause" finding that this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, as described in Section II, above, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), or to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). In addition, because this action does not promulgate any new requirements, but only makes certain existing provisions of 40 CFR part 132 effective in Wisconsin, it does not impose any new costs. The costs of 40 CFR part 132 were considered by EPA when it promulgated that regulation. Therefore, today's rule does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of UMRA, or significantly or uniquely affect the communities of Tribal governments, as specified by Executive Order 13084 (63 FR 27655, May 10, 1998). This rule will not have substantial direct effects on the State, on the relationship between the national government and the State, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255,

August 10, 1999). This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

This action does not involve technical standards; thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. The rule also does not involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). In issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct, as required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996). This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This rule is not a major rule as defined by 5 U.S.C. 804(2). 40 CFR 132.6(f), (h)-(j) is effective on December 6, 2000. 40 CFR 132.6(g) is effective on February 5, 2001.

List of Subjects in 40 CFR Part 132

Environmental protection, Administrative practice and procedure, Great Lakes, Indian-lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water pollution control.

Dated: October 31, 2000.

Carol M. Browner,
Administrator.

For the reasons set forth above, EPA amends 40 CFR part 132 as follows:

PART 132—WATER QUALITY GUIDANCE FOR THE GREAT LAKES SYSTEM

1. The authority citation for part 132 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.*

2. Section 132.6 is amended by adding paragraphs (f) through (i) to read as follows:

§ 132.6 Application of part 132 requirements in Great Lakes States and Tribes.

* * * * *

(f) Effective December 6, 2000, the acute and chronic aquatic life criteria for copper and nickel in Tables 1 and 2 of this part and the chronic aquatic life criterion for endrin in Table 2 of this part shall apply to the waters of the Great Lakes System in the State of Wisconsin.

(g) Effective February 5, 2001, the chronic aquatic life criterion for selenium in Table 2 of this part shall apply to the waters of the Great Lakes System in the State of Wisconsin.

(h) Effective December 6, 2000, the requirements of procedure 3 in appendix F of this part shall apply for purposes of developing total maximum daily loads in the Great Lakes System in the State of Wisconsin.

(i) Effective December 6, 2000, the requirements of paragraphs D and E of procedure 5 in appendix F of this part shall apply to discharges within the Great Lakes System in the State of Wisconsin.

(j) Effective December 6, 2000, the requirements of paragraph D of procedure 6 in appendix F of this part shall apply to discharges within the Great Lakes System in the State of Wisconsin.

Dated: October 31, 2000.

Carol M. Browner,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 63

RIN 0925-AA11

Traineeships

AGENCY: National Institutes of Health, HHS.

ACTION: Final rule.

SUMMARY: The National Institutes of Health (NIH) is amending the regulations governing traineeships to add conditions under which NIH may terminate traineeship awards and revise the authorities for the awards.

EFFECTIVE DATE: This final rule is effective on December 6, 2000.

FOR FURTHER INFORMATION CONTACT: Jerry Moore, NIH Regulations Officer,

National Institutes of Health, 6011 Executive Boulevard, Room 601, MSC 7669, Rockville, MD 20852; telephone 301-496-4607 (not a toll-free number; Fax 301-402-0169; or E-mail (jm40z@nih.gov)). For information about traineeship awards contact James Alexander, Acting Director, Office of Education, Office of Intramural Research, National Institutes of Health, Building 10, Room 1C-129, 10 Center Drive, MSC 1158, Bethesda, MD 20892-1158; telephone 301-496-2427 (not a toll-free number).

SUPPLEMENTARY INFORMATION: Section 405(b)(1)(C) of the Public Health Service (PHS) Act, as amended, authorizes the Secretary, acting through the directors of the national research institutes of NIH, to conduct and support research training for which fellowship support is not provided under section 487 of the PHS Act, and which is not residency training of physicians or other health professionals. The Director, NIH, has similar authority under section 402(b)(13) of the PHS Act. Additionally, section 485D(a) of the PHS Act authorizes the Director of the National Center for Complementary and Alternative Medicine to support research training; section 472 of the PHS Act authorizes the award of traineeships in medical library science and related fields; and section 413(b)(3) of the PHS Act authorizes the Director of the National Cancer Institute (NCI), in carrying out the National Cancer Program, to support appropriate programs of education and training (including continuing education and laboratory and clinical research training). Unlike the NIH authority set forth in section 405(b)(1)(C) of the PHS Act, the NCI authority does not exclude residency training. Under these authorities, NIH awards research traineeships to qualified individuals. The regulations codified at 42 CFR part 63 govern these traineeships. NIH revised the regulations in their entirety, February 27, 1995 (60 FR 10718).

NIH proposed amendments to Part 63 in a notice of proposed rulemaking (NPRM) published in the **Federal Register**, October 30, 1998 (63 FR 58336). The NPRM provided for a 60-day comment period. The comment period expired December 29, 1998. NIH received no comments. Consequently, except for minor clarifying and editorial changes, the final regulations described below are the same as those proposed in October 1998.

In these final regulations, NIH is revising § 63.9 by amending paragraph (b) to add scientific misconduct as a ground for termination and by adding

new paragraphs (c) and (d), which add conviction of a felony and certain other criminal offenses and programmatic changes or lack of funds, respectively, as grounds for termination.

Additionally, NIH is amending the authority citation by adding a reference to section 413(b)(3) of the PHS Act pertaining to the National Cancer Program that was inadvertently excluded from the proposed rule and removing the reference to section 485B(b) of the PHS Act and the parallel U.S. Code citation to reflect the renaming of the National Center for Human Genome Research as the National Human Genome Research Institute (NHGRI), effective January 27, 1997 (62 FR 3900). As a result of the establishment of this new research institute, the current reference to section 485B is redundant and unnecessary. The current references to the National Center for Human Genome Research and section 485B of the PHS Act in § 63.1 and § 63.2 are also redundant and unnecessary as a result of the renaming. Consequently, NIH is removing the references to the National Center for Human Genome Research and section 485B of the PHS Act in paragraph (a) of § 63.1 and in the definitions set forth in § 63.2 of the terms "award," "awardee," "director," and "traineeship." Also NIH is adding to § 63.2 the definition of "misconduct in science," as set forth in the PHS regulations governing the responsibility of awardees and applicants for dealing with misconduct in science, 42 CFR part 50, subpart A.

Finally, NIH is revising the references set forth in unnumbered paragraphs 8, 9, and 10 of § 63.10 to comply with **Federal Register** format requirements.

NIH provides the following statements as public information.

Executive Order 12866

The Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) reviewed this rule as required under Executive Order 12866, Regulatory Planning and Review. The OMB deemed it to be not significant, as defined under the Order.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. chapter 6) requires that regulatory actions be analyzed to determine whether they will have a significant impact on a substantial number of small entities. The Director, NIH, certifies that the changes in the traineeship regulations will not have a significant economic impact on a substantial number of small entities and, therefore, a regulatory flexibility analysis, as defined under the

Regulatory Flexibility Act, is not required.

Executive Order 13132

Executive Order 13132, Federalism, requires that Federal agencies consult with State and local government officials in the development of regulatory policies with federalism implications. We reviewed the rule as required under the Order and determined that it does not have any federalism implications. The Director, NIH, certifies that the changes in the traineeships regulations will not have an effect on the States or on the distribution of power and responsibilities among the various levels of government.

Paperwork Reduction Act

This rule does not contain any information collection requirements that are subject to OMB approval under the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance (CFDA) numbered program affected by this rule is: 93.140—Intramural Research Training Award.

List of Subjects in 42 CFR Part 63

Grant programs—health, Health professions, Libraries, Manpower training programs, Medical research, Students.

Dated: August 3, 2000.

Ruth L. Kirschstein,

Principal Deputy Director, National Institutes of Health.

Accordingly, part 63 of title 42 of the Code of Federal Regulations is amended as set forth below.

PART 63—TRAINEESHIPS

1. The authority citation for part 63 is revised to read as follows:

Authority: 42 U.S.C. 216, 282(b)(13), 284(b)(1)(C), 285a-2(b)(3), 286b-3, 287c-21(a).

2. Section 63.1 is revised to read as follows:

§ 63.1 To what programs do these regulations apply?

(a) The regulations in this part apply to research traineeships awarded by the Director, NIH, each director of a national research institute of NIH, the Director of the National Library of Medicine, and the Director of the National Center for Complementary and Alternative Medicine, or their designees, pursuant to sections 402(b)(13), 405(b)(1)(C), 413(b)(3), 472, and 485(D)(a) of the Act, respectively.

(b) The regulations of this part do not apply to research training under the National Research Service Award Program governed by 42 CFR part 66 or to the Mental Health Traineeship Program governed by 42 CFR part 64a.

(c) Except as otherwise permitted under section 413(b)(3) of the Act, the regulations of this part do not apply to residency training of physicians or other health professionals.

3. Section 63.2 is amended by revising the definitions of "Award," "Awardee," "Director," and "Traineeship," and adding in alphabetical order a new definition of "Misconduct in science," to read as follows:

§ 63.2 Definitions.

* * * * *

Award means an award of funds under sections 402(b)(13), 405(b)(1)(C), 413(b)(3), 472, 485D(a), or other sections of the Act which authorize research training or traineeships.

Awardee means an individual awarded a traineeship under sections 402(b)(13), 405(b)(1)(C), 413(b)(3), 472, 485D(a), or other sections of the Act which authorize research training or traineeships.

Director means the Director, NIH, the director of a national research institute of NIH, the Director of the National Library of Medicine, and the Director of the National Center for Complementary and Alternative Medicine, or any

official of NIH to whom the authority involved has been delegated.

* * * * *

Misconduct in science shall have the same meaning as prescribed in § 50.102 of this chapter.

* * * * *

Traineeship means an award under the regulations of this part to a qualified individual for that person's subsistence and other expenses during the period that person is participating in the research training approved under the award.

4. Section 63.9 is revised to read as follows:

§ 63.9 How may NIH terminate awards?

The Director may terminate a traineeship at any time:

(a) Upon written request of the awardee; or

(b) If it is determined that the awardee has committed misconduct in science, is ineligible, or has materially failed to comply with the terms and conditions of the award or to carry out the purpose for which the award was made; or

(c) If the awardee is convicted of a felony, or an offense involving any illegal drug or substance, or any offense involving a lack of financial integrity or business honesty; or

(d) Because of programmatic changes or lack of funds.

5. Section 63.10 is amended by removing the last three entries in the list of policies and regulations and adding three new entries in their place to read as follows:

§ 63.10 Other HHS regulations and policies that apply.

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59 FR 14508 (March 28, 1994)—NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. (**Note:** Interested persons should contact the Office of Research on Women's Health, NIH, Room 201, Building 1, MSC 0161, Bethesda, MD 20892-0161; telephone 301-402-1770 (not a toll-free number) to obtain copies of this policy.)

59 FR 34496 (July 5, 1994)—NIH Guidelines for Research Involving Recombinant DNA Molecules. (**Note:** Interested persons should contact the Office of Biotechnology Activities, NIH, Suite 323, 6000 Executive Boulevard, MSC 7010, Bethesda, MD 20892-7010; telephone 301-496-9838 (not a toll-free number) to obtain copies of the policy.)

"Public Health Service Policy on Humane Care and Use of Laboratory Animals" (Revised September 1986), Office of Laboratory Animal Welfare, NIH. (**Note:** Interested persons should contact the Office of Laboratory Animal Welfare, NIH, Rockledge Building I, 6705 Rockledge Drive, Suite 1050, MSC 7982, Bethesda, MD 20892-7982; telephone 301-496-7163 (not a toll-free number) to obtain copies of the policy.)

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