

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 52b

RIN 0905-AD49

National Institutes of Health Construction Grants

AGENCY: Public Health Service, Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: The National Institutes of Health (NIH) proposes to revise its regulations governing construction grants for the purpose of making them applicable to all NIH financial assistance programs with construction grant authority, including programs transferred to NIH by the ADAMHA Reorganization Act and two new programs authorized by the National Institutes of Health Revitalization Act of 1993. The regulations are also being revised for the purpose of correcting Public Health Service (PHS) Act section numbers referenced in the regulations and adding new administrative and technical requirements for the awarding of these grants and cost recovery procedures for the recovery of grant funds for facilities no longer used for biomedical research purposes.

DATES: Comments on these proposed regulations must be received on or before September 5, 1995 in order to ensure that NIH will be able to consider the comments in preparing the final rule.

ADDRESSES: Comments should be sent to: Mr. Jerry E. Moore, NIH Regulatory Affairs Officer, National Institutes of Health, Building 31, Room 1B25, 31 Center DR MSC 2075, 9000 Rockville Pike, Bethesda, Maryland 20892-2340.

FOR FURTHER INFORMATION CONTACT: Mr. Jerry E. Moore, NIH Regulatory Affairs Officer, at the address above, or telephone (301) 496-4606 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: Under the Public Health Service (PHS) Act, as amended (42 U.S.C. 201 et seq.), construction or modernization grant authority exists in sections 413(b)(6)(B) and 414(b) for the National Cancer Institute (construction grants); sections 421(b)(2)(B) and 422(c)(3) for the National Heart, Lung, and Blood Institute (construction grants); section 441(a) for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (modernization grants); section 455 for the National Eye Institute

(construction grants); section 464C(a) for the National Institute on Deafness and Other Communication Disorders (modernization grants); section 464P(b)(3) for the National Institute on Drug Abuse (construction grants); section 481A(a) for the Director of NIH, acting through the Director of the National Center for Research Resources (construction and modernization grants); section 481B(a) for the Director of NIH (construction grants); and section 2354(a)(5)(B) for NIH AIDS research programs (construction grants).

NIH proposes to revise the existing regulations at 42 CFR part 52b (National Cancer Institute Construction Grants) to make them applicable to all NIH financial assistance programs with construction or modernization grant authority. Part 52b would be retitled and the authority citation would be amended to add the additional construction and modernization grant authorities. Sections 52b.2 and 52b.3 would be revised in their entirety. Section 52b.4 would be amended by revising paragraph (d) to reference Executive Order 12372 and adding a new paragraph (e) regarding the protection of Historical Properties listed on National and State Historical Registers. Section 52b.5 would be revised in its entirety. Sections 52b.6, 52b.7, 52b.8, 52b.9, 52b.10, and 52b.11 would be revised and moved to §§ 52b.14, 52b.6, 52b.10, 52b.11, 52b.13 and 52b.12, respectively. The PHS Act sections referenced in the regulations would be corrected. Three new sections would be added to part 52b. A new § 52b.7 would be added specifying facility usage requirements; a new § 52b.8 would be added concerning NIH monitoring of the usage of biomedical research facilities constructed with Federal funds; and a new § 52b.9 would be added concerning procedures to recover Federal funds for facilities that cease to be used for biomedical research purposes. Section 52b.10 would add new requirements relating to the recording of notice of Federal interest and the purchasing of insurance. Section 52b.12 concerning minimal requirements of construction and equipment would be revised to incorporate by reference additional published standards relating to facility design, construction, and operation standards. In accordance with section 552(a) of the Freedom of Information Act (5 U.S.C. 552) and implementing regulations, 1 CFR part 51, NIH will request the approval of the Director of the Federal Register prior to incorporating by reference any new published material in the final rule.

Section 52b.14 would be revised to cite additional HHS regulations and policies that apply to part 52b. These regulations do not apply to minor alterations and renovations that are included in applications for research project grants. Minor alterations and renovations are covered under the regulations at 42 CFR part 52. These regulations also do not cover alterations and renovations under NIH center grants. These alterations and renovations are covered under the regulations at 42 CFR part 52a. The purpose of this notice is to invite public comment on these proposed changes.

PHS strongly encourages all grant recipients to provide a smoke-free workplace and to promote the nonuse of all tobacco products, and Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, and early childhood development services are provided to children.

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 us 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 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 would merely update internal policies and procedures of the Federal government which are used by the NIH to administer construction grants awarded under the authority set forth in section 413(b)(6)(B), 414(b), 421(b)(2)(B), 422(c)(3), 441(a), 455, 464C(a), 464P(b)(3), 481A(a), 481B(a) and 2354(a)(5)(B) of the PHS Act. These grants do not have significant economic or policy impact on a broad cross-section of the public. Furthermore, the revised regulations would only affect the limited number of public or private nonprofit agencies of institutions which are interested in participating in the construction grant program. No agency or institution is required to participate in the program. The revised regulations include no standards or requirements which would burden small entities.

For these same reasons, the Secretary certifies 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 proposed rule contains 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). The title, description, and respondent description of the information collection requirements in this proposed rule are presented below with an estimated annual burden. The information collection requirements contained in these regulations have been submitted to OMB for review. Other organizations and individuals desiring to submit comments on the information collection requirements should send their comments to (1) Dr.

Charles MacKay, Project Clearance Officer, National Institutes of Health, Building 31, Room 5B33, 9000 Rockville Pike, Bethesda, Maryland 20892-2174, and (2) the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, Room 10235, 725 17th St., N.W., Washington, D.C. 20503. Attention: Desk Officer for the National Institutes of Health, Department of Health and Human Services. After OMB approval is obtained, the OMB control number will be published in the **Federal Register**.

Title: NIH Construction Grants.

Description: The information collections will be used by NIH to evaluate grant applications, oversee the transfer of the title of a constructed facility, and monitor the use being made of a constructed facility.

Respondent Description: Public or private nonprofit agencies or institutions.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

	Annual number of respondents	Annual frequency	Average burden per response	Annual burden hours
Reporting:				
§ 52b.9(b)	1	1	.50	.50
§ 52b.10(f)	15	1	1	15
§ 52b.10(g)	30	12	1	†360
§ 52b.11(b)	100	1	1	* (100)
Subtotal				375.5
Recordkeeping:				
§ 52b.10(g)	30	260	1	†7800
Total				8175.5

* This burden is approved under OMB Approval Number 0937-0189
 † Based on an average of 30 active grants in the construction phase.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbered programs affected by these proposed regulations are:
 93.392—Cancer Construction
 93.131—Shared Research Facilities for Heart, Lung, and Blood Diseases
 93.846—Arthritis, Musculoskeletal and Skin Diseases Research

List of Subjects in Part 52b

AIDS research facilities construction; Basic biomedical research laboratory facilities construction; Cancer research facilities construction; Clinical biomedical and behavioral research facilities construction; Grants—construction; Incorporation by reference; Primate research facilities construction; Research facilities construction for AIDS; Research facilities construction for arthritis, musculoskeletal and skin diseases;

Research facilities construction for heart, lung, and blood diseases; Vision research facilities construction.

Dated: December 28, 1994.

Philip R. Lee,
Assistant Secretary for Health.

Approved: June 19, 1995.

Donna E. Shalala,
Secretary.

For reasons set out in the preamble, it is proposed to revise part 52b of title 42 of the Code of Federal Regulations to read as set forth below.

PART 52b—NATIONAL INSTITUTES OF HEALTH CONSTRUCTION GRANTS

- Sec.
- 52b.1 To what programs do these regulations apply?
- 52b.2 Definitions.
- 52b.3 Who is eligible to apply?

- 52b.4 How to apply.
- 52b.5 How will NIH evaluate applications?
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- 52b.7 How is the grantee obligated to use the facility?
- 52b.8 How will NIH monitor the use of facilities constructed with Federal funds?
- 52b.9 What is the right of the United States to recover Federal funds when facilities are not used for research or are transferred?
- 52b.10 What are the terms and conditions of awards?
- 52b.11 What are the requirements for acquisition and modernization of existing facilities?
- 52b.12 What are the minimum requirements for construction and equipment?
- 52b.13 Additional conditions.
- 52b.14 Other HHS regulations and policies that apply.

Authority: 42 U.S.C. 216, 285a-2, 285a-3, 285b-3, 285b-4, 285d-6, 285i, 285m-3, 285o-4, 287a-2, 287a-3, 300cc-41.

§ 52b.1 To what programs do these regulations apply?

The provisions of this part apply to grants authorized by: section 413(b)(6)(B) of the Act for construction or renovation of basic cancer research laboratory facilities, including clinical facilities; section 414(b) of the Act for the construction of centers for basic and clinical research into, training in, and demonstration of advanced diagnostic, prevention, control, and treatment methods for cancer; section 421(b)(2)(B) of the Act for the construction or renovation of heart, blood vessel, lung, and blood disease and blood resource laboratories, research, training, and other facilities as the Director determines necessary; section 422(c)(3) of the Act for the construction of centers for basic and clinical research into, training in, and demonstration of, the management of blood resources and advanced diagnostic, prevention, and treatment methods for heart, blood vessel, lung, or blood diseases; section 441(a) of the Act for the modernization of existing buildings to serve as centers for basic and clinical research into the cause, diagnosis, early detection, prevention, control, and treatment of and rehabilitation from arthritis and musculoskeletal diseases, including research into implantable biomaterials and biomechanical and other orthopedic procedures; section 455 of the Act for the construction of vision research facilities; section 464C(a) of the modernization of existing buildings to serve as multipurpose centers for basic and clinical research into the cause, diagnosis, early detection, prevention, control and treatment of disorders of hearing and other communication processes including research into rehabilitative aids, implantable biomaterials, auditory speech processors, speech production devices, and other otolaryngologic procedures; section 464P(b)(3) of the Act for the construction of pharmacotherapeutic research centers, laboratories, and other necessary facilities and equipment to conduct research on the development and use of medications to treat drug addiction; section 481A(a) of the Act for the expansion, remodeling or alteration of existing research facilities, or the construction of new research facilities; section 481B(a) of the Act for the construction or renovation of regional centers for research on primates; and section 2354(a)(5)(B) of the Act for the construction of facilities for acquired immunodeficiency syndrome (AIDS)

research. The provisions of this part do not apply to minor alteration and renovation that is included in the application for a research project grant. This type of alteration and renovation is covered under the regulations at 42 CFR part 52.

§ 52b.2 Definitions.

As used in this part:

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

Construction means the construction of new buildings or the modernization of, or the completion of shell space in, existing buildings (including the installation of fixed equipment), but excluding the cost of land acquisition and off-site improvements.

Construction grant means funds awarded for construction in accordance with the applicable provisions of the Act and with this part.

Director means the director of an NIH national research institute, center, or other component of NIH, authorized to award grants for construction under the applicable provisions of the Act, and any official to whom the authority involved is delegated.

Federal share with respect to any construction project means the proportion, expressed as a percentage, of the cost of the project to be paid by a grant award under the Act.

HHS, DHHS, and Department mean the Department of Health and Human Services.

Institute means any national research institute, center, or other agency of the National Institutes of Health as set forth in or established by the Secretary under section 401 of the Act.

Modernization means the alteration, renovation, remodeling, improvement, expansion, and repair of existing buildings and the provision of equipment necessary to make the building suitable for use for the purposes of the particular program.

NIH means the National Institutes of Health and its organizational components that award grants.

Nonprofit as applied to any agency or institution means an agency or institution which is a corporation or an association, no part of the net earnings of which inures or may lawfully inure to the benefit of any private shareholder or individual.

Project means the particular construction activity which is supported by a grant under this part.

Secretary means the Secretary of Health and Human Services and any official to whom the authority involved may be delegated.

§ 52b.3 Who is eligible to apply?

In order to be eligible for a construction grant under this part, the applicant must:

- (a) Be a public or private nonprofit agency or institution;
- (b) Be located in a State, the District of Columbia, Puerto Rico, the Virgin Islands, the Canal Zone, Guam, American Samoa, or the successor States of the Trust Territory of the Pacific Islands (the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau); and
- (c) Meet any additional eligibility criteria specified in the applicable provisions of the Act.

§ 52b.4 How to apply.

Applications for construction grants under this part shall be made in such form and at such times as the Secretary may specify.

§ 52b.5 How will NIH evaluate applications?

(a) In evaluating and approving applications for construction grants under this part, the Director shall take into account, among other pertinent factors, the following:

- (1) The priority score,
- (2) The relevance of the project for which construction is proposed to the objectives and priorities of the particular statutory program under the Act,
- (3) The scientific merit of the research program activities which will be carried out in the proposed facility,
- (4) The scientific or professional standing or reputation of the applicant and of its existing or proposed officers and research staff,
- (5) The availability, by affiliation, or other association, of other scientific or health personnel and facilities to the extent necessary to carry out effectively the program proposed for the facility, including the adequacy of an acceptable biohazard control and containment program when warranted,
- (6) The need for the facility and its total effects on similar or related facilities in the locale, and the need to accomplish appropriate geographic distribution of similar facilities, and
- (7) The financial need of the applicant.

(b) The priority score of the application shall be based, among other pertinent factors, on the following criteria:

- (1) The scientific merit of the total program and its component parts to be carried out in the facility,
- (2) The administrative and leadership capabilities of the applicant's officers and staff,

(3) The organization of the applicant's research program and its relationship with the overall institutional settings,

(4) The anticipated effect of the project on other relevant research programs and facilities in the geographic area, and nation-wide,

(5) The need for the project or additional space, and

(6) The project cost and design.

§ 52b.6 What is the rate of Federal financial participation?

(a) Unless otherwise specified in statute, the rate of Federal participation in a construction project supported by a grant under this part shall not be more than 50 percent of the necessary allowable costs of construction as determined by the Director, except that when the Director finds good cause for waiving this limitation, the amount of the construction grant may be more than 50 percent of the necessary allowable costs of construction.

(b) Subject to paragraph (a) of this section, the Director shall set the actual rate of Federal financial participation in the necessary allowable costs of construction taking into consideration the most effective use of available Federal funds to further the purposes of the applicable provisions of the Act.

§ 52b.7 How is the grantee obligated to use the facility?

(a) The grantee shall use the facility (or that portion of the facility supported by a grant under this part) for its originally authorized purpose so long as needed for that purpose, unless that grantee obtains advance written approval from the Director to use the facility for another purpose. Use for other purposes shall be limited to, in order of priority:

(1) Projects or programs supported by other Federal grants or assistance agreements,

(2) Activities not supported by other Federal grants or assistance agreements, but whose purposes are consistent with those of the legislation under which the original grant was made.

(b) The Director, in determining whether to approve an alternative use of the facility, shall take into consideration the extent to which:

(1) the facility will be devoted by the grantee or other owner to a use described in paragraph (a)(1) or (2) of this section; or

(2) there are reasonable assurances that for the remainder of the useful life of the facility, alternative facilities not previously used for NIH supported research will be utilized for this purpose and are substantially equivalent in nature and extent for these purposes.

(c) *Sale, transfer, or change in use; general.* Approval may be requested from the Director to transfer title to a third party eligible under § 52b.3 for continued use for authorized purposes in accordance with paragraphs (a) and (b) of this section. If approval is permissible under the Act or other Federal statute and is granted, the terms of the transfer shall provide that the transferee shall assume all the rights and obligations of the transferor set forth in 45 CFR part 74, subpart O, or other terms of the grant.

§ 52b.8 How will NIH monitor the use of facilities constructed with Federal funds?

NIH may monitor the use of each facility constructed with funds awarded under this part to ensure its continued use for the original authorized research purpose, by means of requesting periodic facility use certifications or reports, site visits, and other appropriate means.

§ 52b.9 What is the right of the United States to recover Federal funds when facilities are not used for research or are transferred?

(a) If, during its useful life, a facility supported by a construction grant under this part ceases to be used for the particular biomedical research or training purposes for which it was constructed (or alternate use authorized under § 52b.7(a)), or the grantee sells or decides to sell or transfer title to an entity ineligible for a grant under § 52b.3, the grantee shall request disposition instructions from NIH. Those instructions will provide for one of the following alternatives:

(1) The facility may be sold and the grantee or transferee shall pay to the United States an amount computed by multiplying the Federal share of the facility times the proceeds from the sale (after deducting the actual and reasonable selling and fix-up expenses, if any, from the sales proceeds), plus interest, if any, as may be allowed by law. Proper sales procedures shall be used that provide for competition to the extent practicable and result in the highest possible return.

(2) The grantee may retain title and shall pay to the United States an amount computed by multiplying the market value of the facility by the Federal share of the facility.

(3) The grantee shall transfer the title to either the United States or to an eligible non-Federal party approved by the Director. The grantee shall be entitled to be paid an amount computed by multiplying the market value of the facility by the non-Federal share of the facility.

(b) The transferor of a facility which is sold or transferred, or the owner of a facility the use of which has changed, as described in paragraph (a) of this section, shall provide the Director written notice of the sale, transfer, or change not later than 30 days from the date on which the sale, transfer, or change occurs.

(c) The Secretary may waive the recovery rights of the United States set forth in paragraph (a) of this section with respect to a facility if the Secretary determines that there is good cause for waiving the rights with respect to the particular facility. In determining whether there is good cause, the Secretary shall take into consideration the extent to which (and the grantee or transferee provides reasonable assurances that):

(1) the facility will be utilized for the remainder of its useful life, in order of priority:

(i) For other health related activities consistent with the purposes of one or more of the activities of the awarding Institute authorized under title IV of the Act,

(ii) To provide training or instruction in the health fields for health professionals or health related information programs for the public, or

(iii) Other health related purposes consistent with one or more purposes authorized under the Act; or,

(2) facilities of substantially comparable value or utility will be utilized for the remainder of the facility's useful life to carry out the biomedical research or training purpose for which the grant was awarded.

Alternative facilities (and the grantee) shall be subject to the same use obligation and the other requirements imposed on the grantee by this part.

(d) The right of recovery of the United States set forth in paragraph (a) of this section shall not, prior to judgment, constitute a lien on any facility with respect to which funds have been paid under this part.

(e) Any amount recovered under this section will be paid to the awarding institute for disposition as required by law.

§ 52b.10 What are the terms and conditions of awards?

In addition to any other requirement imposed by law or determined by the Director to be reasonably necessary with respect to any particular grant to fulfill the purposes of the grant, each construction grant shall be subject to the terms and conditions, and the grantee shall provide the assurances, required by this section, supported by such documentation as the Director may

reasonably require. The Director may, by general policy or for good cause shown by an applicant, approve exceptions to these terms and conditions or assurances where the Director finds that the exceptions are consistent with the applicable provision of the Act and the purposes of the particular program:

(a) *Title.* That the applicant has a fee simple or such other estate or interest in the site, including necessary easements and rights-of-way sufficient to assure for the estimated useful life of the facility, as determined by the Director, undisturbed use and possession for the purpose of the construction and operation of the facility.

(b) *Plans and specifications.* That approval by the Director of the final working drawings, specifications, and cost estimate shall be obtained before the project is advertised or placed on the market for bidding. The approval shall include a determination by the Director that the final plans and specifications conform to the minimum standards of construction and equipment as set forth in § 52b.12 of this part.

(c) *Relocation assistance.* That in the case of a public applicant with an approved project which involves the displacement of persons or businesses on or after January 4, 1971, the applicant will comply with the provisions of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (42 U.S.C. 4601 et seq.) and the applicable regulations issued under that Act (45 CFR part 15).

(d) *Approval of changes in estimated cost.* That the applicant will not enter into any construction contract or contracts for the project or a part thereof, the cost of which is in excess of the estimated cost approved in the terms of an award for that portion of the work covered by the plans and specifications, without the prior approval of the Director.

(e) *Completion responsibility.* That the applicant will construct the project, or cause it to be constructed, to final completion in accordance with the grant application, the terms of award, and the approved plans and specifications.

(f) *Construction inspection.* Prior to the start of construction, the grantee shall submit an approved copy of the construction schedule (critical path method) to the Director.

(g) *Construction management.* That the applicant will provide and maintain competent and adequate construction management services for inspection at the construction site to ensure that the completed work conforms with the

approved plans and specifications. Construction management services will also include daily construction logs and monthly status reports which will be maintained at the job site and shall be submitted to the Director at the time and in the form and manner as the Director may prescribe.

(h) *Non-Federal share.* That sufficient funds are available to meet the non-Federal share of the costs of constructing the facility.

(i) *Funds for operation.* That sufficient funds will be available when construction is completed for effective use of the facility for the purposes for which it is being constructed.

(j) *Inspection.* That the Director and the Director's representatives shall have access at all reasonable times to all work during any stage of construction and the contractor shall provide proper facilities for this access and inspection.

(k) *Accessibility to handicapped.* That the facility shall be designed to comply with the Federal Accessibility Standards (41 CFR subpart 101-19.6), as modified by other standards prescribed by the Director or the Administrator of General Services. The applicant will be responsible for conducting inspections to insure compliance with these specifications by the contractor.

(l) *Notice of Federal interest.* The grantee shall record a Notice of Federal Interest in the appropriate official records of the jurisdiction in which the property is located.

(m) *Title insurance.* The grantee shall purchase a title insurance policy unless a legal opinion has been provided which certifies that the grantee institution has fee simple title to the site free and clear of all liens, easements, rights-of-way, and any other adverse interests which would encumber the project. A waiver to this requirement may be obtained if the grantee is adequately self-insured against the risks involved.

(n) *Physical destruction insurance.* At the time construction is completed or at the time of beneficial occupancy, whichever comes first, the grantee shall purchase an insurance policy which insures the facility at the full appraised value of the property using State certified appraisers. The insurance policy must protect the property from total or partial physical destruction and must be maintained throughout the period of Federal interest. A waiver to this requirement may be obtained if the grantee is adequately self-insured against the risks involved.

§ 52b.11 What are the requirements for acquisition and modernization of existing facilities?

In addition to the other requirements of this part, the following requirements are applicable to the acquisition and modernization of existing facilities.

(a) *Minimum standards of construction and equipment.* A determination by the Director that the facility conforms (or upon completion of any necessary construction will conform) to the minimum standards of construction and equipment as set forth in § 52b.12 of this part, shall be obtained before entering into a final or unconditional contract for the acquisition and/or remodeling of facilities. Where the Director finds that exceptions to or modifications of construction or equipment would be consistent with the purposes of the applicable section of the Act under which the acquisition is supported, the Director may authorize the exceptions or modifications.

(b) *Estimated cost of acquisition and remodeling: Suitability of facility.* Each application for a project involving the acquisition of existing facilities shall include in the detailed estimates of the costs of the project, the cost of acquiring these facilities, and any cost of remodeling, renovating or altering the facilities to serve the purposes for which they are acquired. The application shall demonstrate to the satisfaction of the Director that the architectural, mechanical, electrical, plumbing, structural, and other pertinent features of the facility, as modified by any proposed expansion, remodeling, renovation, or alteration, will be clearly suitable for the purposes of the applicable sections of the Act.

(c) *Bona fide sale.* Grant awards for the acquisition of existing facilities shall be subject to the condition that the acquisition constitutes a bona fide sale involving an actual cost to the applicant and will result in additional or improved facilities for purposes of the applicable provisions of the Act.

(d) *Facility which has previously received a Federal grant.* No grant for the acquisition or modernization of a facility which has previously received a Federal grant for construction, acquisition, or equipment shall serve either to reduce or restrict the liability of the applicant or any other transferor or transferee from any obligation of accountability imposed by the Federal Government by reason of the prior grant.

§ 52b.12 What are the minimum requirements for construction and equipment?

In addition to being subject to other regulations and policies referred to in § 52b.14, the standards set forth in this section have been determined by the Director to constitute minimum requirements for construction and equipment, including the expansion, remodeling, renovation, or alteration of existing buildings, and these standards as may be amended, or any revisions or successors of these standards, shall apply to all projects for which Federal assistance is requested under the applicable sections of the Act. In accordance with 5 U.S.C. 552(a)(1), the publications to which reference is made in this section, unless otherwise indicated, are hereby incorporated by reference and made a part of the regulations in this part. The Director may for good cause shown approve plans and specifications which contain deviations from the requirements prescribed, if the Director is satisfied that the purposes of the requirements have been fulfilled. In addition to these requirements, each project shall meet the requirements of State and/or local codes and ordinances relating to construction.

(a) *Mandatory design and construction standards.* The facility design and construction shall comply with the following standards:

- (1) "Guidelines for Construction and Equipment for Hospital and Medical Facilities" (current edition). American Institute of Architects, 1735 New York Avenue, NW., Washington, DC 20006.
- (2) "Laboratories Chapter, American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE) Handbook" (current edition). ASHRAE, 1791 Tullie Circle, NE., Atlanta, Georgia 30329.
- (3) "Uniform Federal Accessibility Standards," Federal Standard 795 (current edition). General Services Administration.
- (4) Seismic safety for federally assisted construction—Earthquake Hazards Reduction Act of 1977, as amended (42 U.S.C. 7701 et seq.) and Executive Order 12699, "Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction," dated January 5, 1990. The Executive Order requires that, effective January 5, 1993, new federally assisted or regulated buildings are to be designed and constructed using appropriate seismic standards. The latest edition of the model codes listed below provide a level of seismic safety that is considered appropriate for implementing E.O. 12699 and are applicable to all federally

assisted construction, depending on geographical location. State, county, or local jurisdictional building ordinances adopting and enforcing these model codes in their entirety, without significant revisions in the direction of less seismic safety, are also acceptable.

- (i) 1991 International Conference of Building Officials (ICBO) Uniform Building Code;
- (ii) 1992 Supplement to the Building Officials and Code Administrators International (BOCA) National Building Code;
- (iii) 1992 Amendments to the Southern Building Code Congress (SBCC) Standard Building Code; and
- (iv) "Recommended Lateral Force Requirements and Commentary" of the Seismology Committee, Structural Engineers Association of California.
- (5) "Life Safety Code" (current edition). National Fire Protection Association (NFPA) Publication 101. NFPA, 1 Batterymarch Park, Quincy, Massachusetts 02269.
- (6) "Standards on Fire Protection for Laboratories Using Chemicals" (current edition). National Fire Protection Association (NFPA) Publication No. 45. NFPA, 1 Batterymarch Park, Quincy, Massachusetts 02269.
- (7) "Prudent Practices for Handling Hazardous Chemicals in Laboratories." (National Academy Press (1981)) National Research Council, 2001 Wisconsin Avenue, NW., Washington, DC 20007.
- (8) "National Sanitation Foundation Standard No. 49 for Class II (Laminar Flow) Biohazard Cabinetry" (current edition). National Sanitation Foundation (NSF), 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106.
- (9) "Industrial Ventilation" (current edition). American Conference of Governmental Industrial Hygienists, 6500 Glenwood Avenue, Cincinnati, Ohio 45211.
- (10) "Health Care Facilities Handbook" (current edition). National Fire Protection Association, 1 Batterymarch Park, Quincy, Massachusetts 02269.
- (11) "Standards for Nonflammable Medical Gas Systems" (current edition). National Fire Protection Association (NFPA) Publication No. 99. NFPA, 1 Batterymarch Park, Quincy, Massachusetts 02269.
- (12) "National Electric Code" (current edition). National Fire Protection Association (NFPA) Publication No. 70. NFPA, 1 Batterymarch Park, Quincy, Massachusetts 02269.
- (13) "Guide for the Care and Use of Laboratory Animals" (current edition). DHHS Publication No. (NIH) 85-23.

(14) "Laboratory Ventilation" standards, ANSI/AIHA (current edition).

(15) "Design Policy and Guidelines" (current edition). Division of Engineering Services, National Institutes of Health.

(b) [Reserved]

§ 52b.13 Additional conditions.

The Director may with respect to any grant award impose additional conditions consistent with the regulations of this part prior to or at the time of any award when in the Director's judgment the conditions are necessary to assure or protect advancement of the approved project, the purposes of the applicable provisions of the Act, or the conservation of grant funds.

§ 52b.14 Other Federal regulations and policies that apply.

Several other Federal regulations and policies apply to grants under this part. These include, but are not necessarily limited to:

(a) *Regulations.*

- 9 CFR part 3—Animal welfare; standards.
- 29 CFR part 1910—Occupational safety and health standards; § 1910.1450—Occupational exposure to hazardous chemicals in laboratories.
- 36 CFR part 1190—Minimum guidelines and requirements for accessible design.
- 42 CFR part 50, subpart A—Responsibility of PHS awardee and applicant institutions for dealing with and reporting possible misconduct in science.
- 42 CFR part 50, subpart D—Public Health Service grant appeals procedure.
- 45 CFR part 16—Procedures of the Departmental Grant Appeals Board.
- 45 CFR part 46—Protection of human subjects.
- 45 CFR part 74—Administration of grants.
- 45 CFR part 75—Informal grant appeals procedures.
- 45 CFR part 76—Governmentwide debarment and suspension (nonprocurement) and governmentwide requirements for drug-free workplace (grants).
- 45 CFR part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—effectuation of title VI of the Civil Rights Act of 1964.
- 45 CFR part 81—Practice and procedure for hearings under part 80 of this title.
- 45 CFR part 84—Nondiscrimination on the basis of handicap in programs and activities receiving Federal financial assistance.
- 45 CFR part 86—Nondiscrimination on the basis of sex in education programs and activities receiving or benefiting from Federal financial assistance.
- 45 CFR part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance.
- 45 CFR part 93—New restrictions on lobbying.

45 CFR part 92—Uniform administrative requirements for grants and cooperative agreements to State and local governments.

(b) *Policies.*

(1) 51 FR 16958 (May 7, 1986)—NIH Guidelines for Research Involving Recombinant DNA Molecules. [Note: this policy is subject to changes, and interested persons should contact the Office of Recombinant DNA Activities, NIH, Suite 323, 6006 Executive Blvd., MSC 7052, BETHESDA, MD 20892-7052 (301-496-9838; not a toll-free number) to obtain the current version and any amendments. There may be a charge for materials provided.]

(2) 59 FR 14508 (March 28, 1994)—NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. [Note: this policy is subject to changes, and interested persons should contact the Office of Research on Women's Health, NIH, Room 201, Building 1, MSC 0161, BETHESDA, MD 20892-0161 (301-402-1770; not a toll-free number) to obtain the current version and any amendments. There may be a charge for materials provided.]

(3) "Public Health Service Policy on Humane Care and Use of Laboratory Animals," Office for Protection from Research Risks, NIH (Revised September

1986). [Note: this policy is subject to changes, and interested persons should contact the Office for Protection from Research Risks, NIH, Suite 3B01, 6100 Executive Blvd., MSC 7507, ROCKVILLE, MD 20852-7507 (301-496-7005; not a toll-free number) to obtain the current version and any amendments. There may be a charge for materials provided.]

(4) "PHS Grants Policy Statement," DHHS Publication No. (OASH) 94-50,000 (Rev.) April 1, 1994. [Note: this policy is subject to changes, and interested persons should contact the Grants Policy Branch, OASH, Room 17A45, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857 (301-443-1874; not a toll-free number) to obtain the current version and any amendments. There may be a charge for materials provided.]

(5) "Biosafety in Microbiological and Biomedical Laboratories." Centers for Disease Control and Prevention (CDCP). DHHS Publication No. (CDC) 88-8395. [Note: this policy is subject to changes, and interested persons should contact the Division of Safety, Occupational Safety and Health Branch, NIH, Room 3K04, 13 South Drive, MSC 5760, BETHESDA, MD 20892-5760 (301-496-2960; not a toll-free number) to obtain

the current version and any amendments. There may be a charge for materials provided.]

(6) "NIH Guidelines for the Laboratory Use of Chemical Carcinogens." DHHS Publication No. (NIH) 81-2385. [Note: this policy is subject to changes, and interested persons should contact the Division of Safety, Occupational Safety and Health Branch, NIH, Room 3K04, 13 South Drive, MSC 5760, BETHESDA, MD 20892-5760 (301-496-2960; not a toll-free number) to obtain the current version and any amendments. There may be a charge for materials provided.]

(7) "Guide for the Care and Use of Laboratory Animals." DHHS Publication No. (NIH) 85-23. Office for Protection from Research Risks, NIH (Revised September 1986). [Note: this policy is subject to changes, and interested persons should contact the Office for Protection from Research Risks, NIH, Suite 3B01, 6100 Executive Blvd., MSC 7507, ROCKVILLE, MD 20852-7507 (301-496-7005; not a toll-free number) to obtain the current version and any amendments. There may be a charge for materials provided.]

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