

final rule that appeared in the **Federal Register** of May 3, 2012. (77 FR 26162). The final rule provides manufacturers of biological products greater flexibility, as appropriate, and encourages use of the most appropriate and state-of-the-art test methods for assuring the safety of biological products. The rule was published with an inaccurate citation in the codified section of the rule. This notice corrects that error.

**DATES:** Effective June 4, 2012.

**FOR FURTHER INFORMATION CONTACT:** Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2012-10649, appearing on page 26162 in the **Federal Register** of Thursday, May 3, 2012, the following correction is made:

**§ 680.3 [Corrected]**

1. On page 26175, in the second column, in Part 680 Additional Standards for Miscellaneous Products, in § 680.3 Tests, paragraph (c), in line 4, “§ 601.12” is corrected to read “§ 610.12”.

Dated: May 18, 2012.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2012-12594 Filed 5-23-12; 8:45 a.m.]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF THE INTERIOR**

**Bureau of Indian Affairs**

**25 CFR Part 36**

[Docket ID: BIA-2012-0001]

RIN 1076-AF10

**Heating, Cooling, and Lighting Standards for Bureau-Funded Dormitory Facilities**

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Interim final rule with request for comments.

**SUMMARY:** As required by the No Child Left Behind Act of 2001, the Secretary of the Interior has developed regulations using negotiated rulemaking that address heating, cooling, and lighting standards for Bureau-funded dormitory facilities. These regulations also make a technical change to remove an obsolete reference.

**DATES:** This rule is effective on May 24, 2012. Please submit written comments by June 25, 2012. The incorporation by

reference of certain publications listed in the regulations is approved by the Director of the **Federal Register** as of May 24, 2012.

**ADDRESSES:** You may submit comments by any of the following methods:

—*Federal rulemaking portal:* <http://www.regulations.gov>. The rule is listed under the agency name “Bureau of Indian Affairs.” The rule has been assigned Docket ID: BIA-2012-0001. If you would like to submit comments through the Federal e-Rulemaking Portal, go to [www.regulations.gov](http://www.regulations.gov) and do the following. Go to the box entitled “Enter Keyword or ID,” type in “BIA-2012-0001,” and click the “Search” button. The next screen will display the Docket Search Results for the rulemaking. If you click on BIA-2012-0001, you can view this rule and submit a comment. You can also view any supporting material and any comments submitted by others.

—*Email:* [Regina.Gilbert@bia.gov](mailto:Regina.Gilbert@bia.gov). Include the number 1076-AF10 in the subject line of the message.

—*Fax:* (505) 563-3811. Include the number 1076-AF10 in the subject line of the message.

—*Mail:* Regina Gilbert, Office of Regulatory Affairs & Collaborative Action, U.S. Department of the Interior, 1001 Indian School Road NW., Suite 312, Albuquerque, NM 87104. Include the number 1076-AF10 in the subject line of the message.

—*Hand delivery:* Regina Gilbert, Office of Regulatory Affairs & Collaborative Action, U.S. Department of the Interior, 1001 Indian School Road NW., Suite 312, Albuquerque, NM 87104. Include the number 1076-AF10 in the subject line of the message.

We cannot ensure that comments received after the close of the comment period (see **DATES**) will be included in the docket for this rulemaking and considered. Comments sent to an address other than those listed above will not be included in the docket for this rulemaking.

**FOR FURTHER INFORMATION CONTACT:** Regina Gilbert, Office of Regulatory Affairs and Collaborative Action, Office of the Assistant Secretary—Indian Affairs, 1001 Indian School Road NW., Suite 312, Albuquerque, NM 87104; telephone (505) 563-3805; fax (505) 563-3811.

**SUPPLEMENTARY INFORMATION:**

I. Background

II. Description of Changes

III. Procedural Requirements

- A. Regulatory Planning and Review (E.O. 12866)

- B. Regulatory Flexibility Act  
C. Small Business Regulatory Enforcement Fairness Act  
D. Unfunded Mandates Reform Act  
E. Takings (E.O. 12630)  
F. Federalism (E.O. 13132)  
G. Civil Justice Reform (E.O. 12988)  
H. Consultation With Indian Tribes (E.O. 13175)  
I. Paperwork Reduction Act  
J. National Environmental Policy Act  
K. Information Quality Act  
L. Effects on the Energy Supply (E.O. 13211)  
M. Clarity of This Regulation  
N. Public Availability of Comments  
O. Determination To Allow Shortened Public Comment Period

**I. Background**

The U.S. Government is responsible for educating American Indian children. This Federal duty is executed by the Bureau of Indian Affairs within the Department of the Interior. The Bureau funds 183 schools serving American Indian children. In part because of the low population densities across much of Indian country, a number of these schools include dormitory (“home-living”) facilities. Many of these schools and associated facilities are in poor physical condition.

The No Child Left Behind Act of 2001 (107 Pub. L. 110: 115 Stat. 1425) (Act) included provisions intended to improve the quality of education provided at Bureau-funded schools, and the physical condition of the school facilities. The Act directed the Secretary of the Interior to establish a negotiated rulemaking committee, in accordance with the provisions of the Negotiated Rulemaking Act, to ensure maximum contribution by the affected Indian tribes in responding to the mandates of the Act.

In 2003, the Secretary established a negotiated rulemaking committee, which held a series of meetings to address the mandates of the Act (the 2003 committee). On April 28, 2005, final rules developed by the 2003 committee were published in the **Federal Register**, addressing six components of the Act’s mandates: defining adequate yearly progress; establishing geographic attendance areas for Bureau-funded schools; establishing a formula for the minimum amount necessary to fund Bureau-funded schools; establishing a system of uniform direct funding and support for Bureau-operated schools; providing guidelines to ensure the Constitutional and civil rights of Indian students; and establishing a method for administering grants to tribally controlled schools. 70 FR 22178.

Another section of the Act, codified at 25 U.S.C. 2002, directed that:

the Secretary [of the Interior], in consultation with the Secretary of Education, Indian organizations and tribes, and Bureau-funded schools, shall revise the national standards for home-living (dormitory) situations to include such factors as heating, lighting, cooling, adult-child ratios, needs for counselors (including special needs related to off-reservation home-living (dormitory) situations), therapeutic programs, space, and privacy.

The 2003 committee promulgated rules addressing some of the components of section 2002, which were published on December 5, 2007, at 72 FR 68491. However, the 2003 committee had previously announced that:

Standards relating to heating, cooling, and lighting of dormitories for home-living situations should be deferred for later consideration by the negotiated rulemaking committee charged with negotiating school construction under section 1125 of the Act. The Committee determined that it did not have the necessary expertise to define standards for these areas.

69 FR 41773, Monday, July 12, 2004.

The section of the Act referred to by the 2003 committee in the passage quoted above directs the Secretary to form a negotiated rulemaking committee specifically to collect information on the physical condition of the Bureau-funded school facilities, and submit reports to the Secretary and to certain Congressional committees regarding the allocation of funds for the maintenance, repair, and replacement of such facilities. 25 U.S.C. 2005. To comply with that mandate, the Secretary chartered the No Child Left Behind School Facilities and Construction Negotiated Rulemaking Committee on December 8, 2009 (the 2010 committee). Membership of the 2010 committee was published at 74 FR 65784 on December 11, 2009. The 2010 committee has held seven meetings at locations around Indian country through September 2011 to complete its work responding to the mandates of 25 U.S.C. 2005. It has drafted an interim final rule to complete the work responding to the mandates of 25 U.S.C. 2002.

Responsibility for the maintenance, repair, and replacement of Indian school facilities rests with the Office of Facilities Management and Construction (OFMC), under the Assistant Secretary—Indian Affairs. In designing such facilities, OFMC complies with the criteria set out in its “School Facilities Design Handbook” (handbook) dated March 30, 2007, which can be found at [www.bia.gov/WhoWeAre/AS-IA/ORM/Rulemaking/index.htm](http://www.bia.gov/WhoWeAre/AS-IA/ORM/Rulemaking/index.htm). The handbook

identifies the building and design codes with which construction at Bureau-funded schools must comply.

## II. Description of Changes

The 2010 committee determined, by consensus, that the codes and standards identified in the handbook respecting heating, ventilation, air conditioning, and lighting are appropriate for home-living (dormitory) situations at Bureau-funded Indian education facilities. Therefore, the regulations being published today:

- Make the building and design codes identified in the handbook mandatory for Bureau-funded Indian education dormitories;
- Require the Bureau to give the public notice and an opportunity to comment on any proposal to change which standard building codes are incorporated in the handbook; and
- Make a technical change to remove reference to subpart H, which is no longer in existence, and replace with a reference to subpart G.

## III. Procedural Requirements

### A. Regulatory Planning and Review (E.O. 12866)

This interim final rule is not a significant rule and the Office of Management and Budget has not reviewed this rule under Executive Order 12866. This rule implements statutory requirements to revise the national standards for home-living (dormitory) situations to include such factors as heating, lighting, and cooling. Such standards shall be implemented in Bureau-operated schools, and shall serve as minimum standards for contract or grant schools.

This rule also makes a technical correction. On April 28, 2005, at 70 FR 21951, subpart H was deleted, and the home-living regulations were placed in subpart G. Therefore, a technical correction is needed to correct the reference of subpart H to subpart G.

1. This rule will not have an effect of \$100 million or more on the economy or adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. This rule will have no effect on the economy because it merely establishes the minimum standards for national criteria for home-living situations.

2. This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency because the Department is the only agency with Bureau-operated schools. This rule will affect tribes that

operate schools that are contract or grant schools by following the minimum requirements for all new construction, major alterations and improvements, and minor remodeling of facilities.

3. This rule does not involve entitlements, grants, user fees, or loan programs or the rights or obligations of recipients. The revisions have no budgetary effects and do not affect the rights or obligations of any recipients.

4. These regulatory changes directly implement statutory provisions and do not raise novel legal or policy issues.

Overall, the impact of the rule is limited to Bureau-operated schools, and tribes that operate schools that are contract or grant schools. Accordingly, this rule is not a “significant regulatory action” from an economic standpoint, nor does it otherwise create any inconsistencies, materially alter any budgetary impacts, or raise novel legal or policy issues.

### B. Regulatory Flexibility Act

The Department of the Interior certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). It does not change current funding requirements or regulate small entities.

### C. Small Business Regulatory Enforcement Fairness Act

This interim final rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. It will not result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of \$100 million or more in any one year. Because the standards in this rule are already being met in practice, it will not result in a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. Nor will this rule have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of the U.S.-based enterprises to compete with foreign-based enterprises.

### D. Unfunded Mandates Reform Act

This interim final rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than \$100 million per year. The rule does not have a significant or unique effect on State, local, or tribal governments or the private sector. A statement containing the information required by the

Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

#### *E. Takings (E.O. 12630)*

Under the criteria in Executive Order 12630, this interim final rule does not affect individual property rights protected by the Fifth Amendment nor does it involve a compensable “taking.” A takings implication assessment is not required.

#### *F. Federalism (E.O. 13132)*

Under the criteria in Executive Order 13132, this interim final rule has no substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. This rule implements a statutory requirement in Public Law 107–110, which requires national standards for home-living (dormitory) situations to include such factors as heating, lighting, and cooling. This Federal rule affects Bureau-operated schools and tribes that operate schools that are contract or grant schools by following the minimum requirements for all new construction, major alterations and improvements, and minor remodeling of facilities.

Because the rule does not affect the Federal government’s relationship to the States or the balance of power and responsibilities among various levels of government, it will not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

#### *G. Civil Justice Reform (E.O. 12988)*

This interim final rule complies with the requirements of Executive Order 12988. Specifically, this rule has been reviewed to eliminate errors and ambiguity and written to minimize litigation; and is written in clear language and contains clear legal standards.

#### *H. Consultation With Indian Tribes (E.O. 13175)*

In accordance with the President’s memorandum of April 29, 1994, “Government-to-Government Relations with Native American Tribal Governments,” Executive Order 13175 (59 FR 22951, November 6, 2000), and 512 DM 2, we have evaluated the potential effects on federally recognized Indian tribes and Indian trust assets and have identified potential effects. The Department engaged tribal government representatives throughout the development of this interim final rule through the establishment of the negotiated rulemaking committee, as

required by the No Child Left Behind Act of 2001.

#### *I. Paperwork Reduction Act*

This interim final rule does not require any information to be collected. Therefore, the Paperwork Reduction Act is not required.

#### *J. National Environmental Policy Act*

This interim final rule does not constitute a major Federal action significantly affecting the quality of the human environment.

#### *K. Information Quality Act*

In developing this interim final rule we did not conduct or use a study, experiment, or survey requiring peer review under the Information Quality Act (Pub. L. 106–554).

#### *L. Effects on the Energy Supply (E.O. 13211)*

This interim final rule is not a significant energy action under the definition in Executive Order 13211. A Statement of Energy Effects is not required.

#### *M. Clarity of This Regulation*

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

- (a) Be logically organized;
- (b) Use the active voice to address readers directly;
- (c) Use clear language rather than jargon;
- (d) Be divided into short sections and sentences; and
- (e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the “COMMENTS” section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you believe lists or tables would be useful, etc.

#### *N. Public Availability of Comments*

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying

information from public review, we cannot guarantee that we will be able to do so.

#### *O. Required Determinations Under the Administrative Procedure Act*

We are publishing this interim final rule with a request for comment without prior notice and comment, as allowed under 5 U.S.C. 553(b)(B).

Under section 553(b)(B), we find that prior notice and comment are unnecessary and would be contrary to the public interest. This rule codifies standards applicable to school facilities. The 2010 committee wrote this rule after consultation with tribes and to meet the needs of the Bureau-funded dormitory facilities. Delay in publishing this rule could lead to uncertainty about which standards are appropriate for heating, cooling, and lighting in residential facilities, which could lead to substandard living conditions, health problems, and other serious consequences. Delaying the rule by publication of a proposed rule would therefore be contrary to the public interest.

As allowed under 5 U.S.C. 553(d)(3), the effective date of this rule is the date of publication in the **Federal Register**. Good cause for an immediate effective date exists because immediate availability of the standards that the rule requires will eliminate uncertainty about facility requirements and will avoid problems that could result from substandard facilities, as discussed above.

We have requested comments on this interim final rule. We will review any comments received and, by a future publication in the **Federal Register**, address any comments received and either confirm the interim final rule with or without change or initiate a proposed rulemaking.

#### **List of Subjects in 25 CFR Part 36**

Educational facilities, Incorporation by reference, Indians—education, School construction.

For the reasons given in the preamble, the Department of the Interior amends 25 CFR part 36 as follows:

#### **PART 36—MINIMUM ACADEMIC STANDARDS FOR THE BASIC EDUCATION OF INDIAN CHILDREN AND NATIONAL CRITERIA FOR DORMITORY SITUATIONS**

■ 1. The authority for part 36 continues to read as follows:

**Authority:** Section 502, 25 U.S.C. 2001; section 5101, 25 U.S.C. 2001; Section 1101, 25 U.S.C. 2002; 5 U.S.C. 301; 25 U.S.C. 2 and 9; 25 U.S.C. 2901, Title I of Pub. L. 101–477.

- 2. Revise § 36.2 to read as follows:

**§ 36.2 Applicability.**

The national criteria for dormitory situations established under subpart G serve as a minimum requirement and are mandatory for all Bureau-operated and Indian-controlled contract schools.

- 2. Add § 36.104 to read as follows:

**§ 36.104 What are the requirements for heating, ventilation, cooling and lighting at dormitories?**

(a) All dormitories must be designed to meet or exceed the standards for heating, ventilation, cooling, and lighting set out in the building codes in the Bureau of Indian Affairs "School Facilities Design Handbook," dated March 30, 2007, written and published by the Bureau of Indian Affairs Office of Facilities Management and Construction. The Director of the Federal Register has approved this incorporation by reference in accordance with 5 U.S.C. 552(a). To enforce any edition other than that specified in this section, the Bureau of Indian Affairs must publish notice of change in the **Federal Register** and the material must be available to the public.

(1) You may obtain a copy of the Handbook at <http://www.bia.gov/cs/groups/xraca/documents/text/idc008030.pdf>. You can get answers to your questions from the Bureau of Indian Affairs Office of Facilities Management and Construction at: 1011 Indian School Road NW., Suite 335, Albuquerque, NM 87103; email: [OFECT@bia.gov](mailto:OFECT@bia.gov); Web site: <http://www.bia.gov/WhoWeAre/AS-IA/OFECR/index.htm>.

(2) You may inspect the Handbook at the Department of the Interior Library, Main Interior Building, 1849 C Street NW., Room 1151, Washington, DC 20240; telephone: (202) 208-3796. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741-6030 or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(b) If an existing dormitory does not comply with the standards in paragraph (a) of this section, we will classify the discrepancy as "deferred capital maintenance" for purposes of prioritizing correction of the discrepancy.

(c) The Bureau must publish in the **Federal Register** any proposal to change which building codes are included in the Bureau of Indian Affairs "School Facilities Design Handbook" or any

successor document, and allow 120 days for public comment and consultation.

Dated: February 3, 2012.

**Larry Echo Hawk,**

*Assistant Secretary—Indian Affairs.*

[FR Doc. 2012-12678 Filed 5-23-12; 8:45 a.m.]

**BILLING CODE 4310-W7-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 100**

[Docket No. USCG-2009-0996]

**Hydroplane Races Within the Captain of the Port Puget Sound Area of Responsibility**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of enforcement of regulation.

**SUMMARY:** The Coast Guard will enforce the Special Local Regulation for Hydroplane Races within the Captain of the Port Puget Sound Area of Responsibility for the Tustin' n' Racin' hydroplane event in Lake Sammamish, WA on June 9th and 10th, 2012. This action is necessary to restrict vessel movement in the vicinity of the race courses thereby ensuring the safety of participants and spectators during these events. During the enforcement period non-participant vessels are prohibited from entering the designated race areas. Spectator craft entering, exiting or moving within the spectator area must operate at speeds which will create a minimum wake.

**DATES:** The regulations in 33 CFR 100.1308 will be enforced from 9 a.m. through 6 p.m. on June 9, 2012 and from 9 a.m. through 6 p.m. on June 10, 2012.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this notice, call or email Ensign Anthony P. LaBoy, Sector Puget Sound Waterways Management Division, Coast Guard; telephone 206-217-6323, email [SectorPugetSoundWWM@uscg.mil](mailto:SectorPugetSoundWWM@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Coast Guard is providing notice of enforcement of the Special Local Regulation for Hydroplane Races within the Captain of the Port Puget Sound Area of Responsibility 33 CFR 100.1308. The Lake Sammamish area, 33 CFR 100.1308(a)(3) will be enforced on June 9, 2012, from 9 a.m. to 6 p.m. and on June 10, 2012 from 9 a.m. to 6 p.m. These regulations can be found in the March 29, 2011 issue of the **Federal Register** (76 FR 17341).

Under the provisions of 33 CFR 100.1308, the regulated area shall be closed for the duration of the event to all vessel traffic not participating in the event and authorized by the event sponsor or Coast Guard Patrol Commander.

When this special local regulation is enforced, non-participant vessels are prohibited from entering the designated race areas unless authorized by the designated on-scene Patrol Commander. Spectator craft may remain in designated spectator areas but must follow the directions of the designated on-scene Patrol Commander. The event sponsor may also function as the designated on-scene Patrol Commander. Spectator craft entering, exiting or moving within the spectator area must operate at speeds which will create a minimum wake.

**Emergency Signaling:** A succession of sharp, short signals by whistle or horn from vessels patrolling the areas under the discretion of the designated on-scene Patrol Commander shall serve as a signal to stop. Vessels signaled shall stop and shall comply with the orders of the patrol vessel. Failure to do so may result in expulsion from the area, citation for failure to comply, or both.

This notice is issued under authority of 33 CFR 100.1308 and 5 U.S.C. 552(a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners. If the Captain of the Port determines that the regulated area need not be enforced for the full duration stated in this notice, he may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: May 13, 2012.

**S.J. Ferguson,**

*Captain, U.S. Coast Guard, Captain of the Port, Puget Sound.*

[FR Doc. 2012-12595 Filed 5-23-12; 8:45 a.m.]

**BILLING CODE 9110-04-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Parts 100 and 165**

[Docket No. USCG-2012-0350]

**Special Local Regulations and Safety Zones; Recurring Events in Northern New England**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of enforcement of regulations.