

### C. Federalism

FDA has analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects 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. Accordingly, the agency has concluded that the direct final rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

### VI. The Paperwork Reduction Act of 1995

This direct final rule contains no new collections of information. The collection of information under § 600.11(e)(4) is covered by OMB control numbers 0910-0139 (expires September 30, 2008) and 0910-0308 (expires July 31, 2008). Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) is not required.

### VII. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects in 21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 600 is amended as follows:

#### PART 600—BIOLOGICAL PRODUCTS: GENERAL

■ 1. The authority citation for 21 CFR part 600 continues to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa-25.

■ 2. Section 600.11 is amended by revising paragraph (e)(4) to read as follows:

#### § 600.11 Physical establishment, equipment, animals, and care.

\* \* \* \* \*

(e) \* \* \*

(4) *Live vaccine processing.* Live vaccine processing must be performed under appropriate controls to prevent cross contamination of other products and other manufacturing areas within the building. Appropriate controls must include, at a minimum:

(i)(A) Using a dedicated manufacturing area that is either in a separate building, in a separate wing of a building, or in quarters at the blind end of a corridor and includes adequate space and equipment for all processing steps up to, but not including, filling into final containers; and

(B) Not conducting test procedures that potentially involve the presence of microorganisms other than the vaccine strains or the use of tissue culture cell lines other than primary cultures in space used for processing live vaccine; or

(ii) If manufacturing is conducted in a multiproduct manufacturing building or area, using procedural controls, and where necessary, process containment. Process containment is deemed to be necessary unless procedural controls are sufficient to prevent cross contamination of other products and other manufacturing areas within the building. Process containment is a system designed to mechanically isolate equipment or an area that involves manufacturing using live vaccine organisms. All product, equipment, and personnel movement between distinct live vaccine processing areas and between live vaccine processing areas and other manufacturing areas, up to, but not including, filling in final containers, must be conducted under conditions that will prevent cross contamination of other products and manufacturing areas within the building, including the introduction of live vaccine organisms into other areas. In addition, written procedures and effective processes must be in place to adequately remove or decontaminate live vaccine organisms from the manufacturing area and equipment for subsequent manufacture of other products. Written procedures must be in place for verification that processes to remove or decontaminate live vaccine organisms have been followed.

\* \* \* \* \*

Dated: July 30, 2007.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

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BILLING CODE 4160-01-S

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

### 24 CFR Part 1000

[Docket No. FR-4999-F-02]

RIN 2577-AC61

### Use of Indian Housing Block Grant Funds for Rental Assistance in Low-Income Housing Tax Credit Projects

**AGENCY:** Office of the Assistant Secretary for Public and Indian Housing, HUD.

**ACTION:** Final rule.

**SUMMARY:** This final rule amends the Indian Housing Block Grant (IHBG) program regulations to specify the conditions under which IHBG funds may be used for project-based or tenant-based rental assistance. The final rule clarifies that such rental assistance may be provided in a manner consistent with assistance provided under section 8 of the United States Housing Act of 1937 on behalf of a tenant receiving assistance under the Native American Housing Assistance and Self-Determination Act of 1996 (NAHASDA). This final rule follows publication of a June 8, 2007, proposed rule, and adopts the proposed rule without change. HUD received one public comment on the June 8, 2007, proposed rule, expressing unqualified support for the proposed regulatory changes.

**DATES:** *Effective Date:* November 19, 2007.

**FOR FURTHER INFORMATION CONTACT:** Deborah Lalancette, Director, Office of Grants Management, Office of Native American Programs, Department of Housing and Urban Development, 1670 Broadway, 23rd Floor, Denver, CO 80202-4801; telephone (303) 675-1625 (this is not a toll-free number). Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Information Relay Service at (800) 877-8339.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Under the Indian Housing Block Grant (IHBG) program, HUD makes assistance available to eligible Indian tribes for affordable housing activities. The amount of assistance made available to each Indian tribe is

determined using an allocation formula, developed with the active participation of Indian tribes and using negotiated rulemaking procedures. An Indian tribe (or its tribally designated housing entity (TDHE)) may use its IHBG funds for a wide range of affordable housing activities, including the provision of project-based or tenant-based rental assistance for eligible families. The regulations governing the IHBG program are located in part 1000 of HUD's regulations in title 24 of the Code of Federal Regulations.

In 1986, Congress amended the Internal Revenue Code to create the Low Income Housing Tax Credit (LIHTC) (see 26 U.S.C. 42), a tax incentive to promote the development of affordable rental housing. Eligible projects receive Federal income tax credits over a 10-year period using a formula that, in part, takes into account certain eligible costs called "eligible basis." Generally, Federal grants used with respect to a building, or for its operation thereof, result in a dollar-for-dollar decrease in eligible basis. However, the Internal Revenue Service (IRS) has recognized that certain types of Federal rental assistance payments are not Federal grants that require a reduction in a building's eligible basis. They include payments made pursuant to Section 8 of the United States Housing Act of 1937 (42 U.S.C. 1437f) (Section 8) and comparable programs or methods of rental assistance designated by the Secretary of the Treasury by publication in the **Federal Register** or in the Internal Revenue Bulletin. (See the income tax regulations at 26 CFR 1.42-16(b).)

HUD rental assistance programs (such as the project-based voucher program) address the requirements that apply when such program rental assistance is provided to tenants residing in LIHTC projects. However, the IHBG program regulations are silent with regard to the use of IHBG rental assistance in these projects. HUD has received requests from several Indian tribes and TDHEs that are IHBG recipients and wish to use their IHBG funds for LIHTC projects.

On June 8, 2007 (72 FR 31944), in response to these tribal requests, HUD published a proposed rule for public comment to specify the conditions under which IHBG funds may be used for tenant-based or project-based rental assistance.

## II. This Final Rule

This final rule follows publication of the June 8, 2007, proposed rule and adopts the proposed rule without change. The public comment period on the proposed rule closed on August 7, 2007. HUD received a single public

comment from a state housing finance agency, expressing unqualified support for the proposed regulatory changes.

The final rule adds a new § 1000.103 to clarify that IHBG funds may be used for project-based or tenant-based rental assistance. Further, the final rule clarifies that IHBG funds may be used for project-based or tenant-based rental assistance that is administered in a manner consistent with Section 8. Only the Secretary of the Treasury may make a determination that project-based or tenant-based rental assistance complies with the income tax regulations at 26 CFR 1.42-16(b) and, therefore, will not reduce the building's eligible basis. This final rule will allow for such determination to be made. This final rule does not limit the range of eligible activities that an Indian tribe or TDHE may undertake. It merely clarifies one permissible use of IHBG funds.

## III. Findings and Certifications

### *Regulatory Flexibility Act*

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. This rule would clarify that IHBG funds may be used for project-based or tenant-based rental assistance that is provided in a manner consistent with assistance provided under Section 8 of the United States Housing Act of 1937 on behalf of a tenant receiving assistance under NAHASDA. This rule would not impose new requirements on IHBG program participants. Accordingly, the undersigned certifies that this rule will not have a significant economic impact on a substantial number of small entities.

### *Environmental Impact*

A Finding of No Significant Impact (FONSI) with respect to the environment was made at the proposed rule stage in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)). The FONSI remains applicable to this final rule and is available for public inspection between the hours of 8 a.m. and 5 p.m. weekdays in the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 10276, Washington, DC 20410-0500. Due to security measures at the HUD

Headquarters building, please schedule an appointment to review the rule docket file by calling the Regulations Division at (202) 708-3055 (this is not a toll-free number).

### *Executive Order 13132, Federalism*

Executive Order 13132 (entitled "Federalism") prohibits, to the extent practicable and permitted by law, an agency from promulgating a regulation that has federalism implications and either imposes substantial direct compliance costs on state and local governments and is not required by statute, or preempts state law, unless the relevant requirements of section 6 of the Executive Order are met. This rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt State law within the meaning of the Executive Order.

### *Unfunded Mandates Reform Act*

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and on the private sector. This rule would not impose any federal mandate on any state, local, or tribal government, or on the private sector, within the meaning of UMRA.

### *Catalog of Federal Domestic Assistance*

The Catalog of Federal Domestic Assistance number applicable to the program affected by this rule is 14.862.

### **List of Subjects in 24 CFR Part 1000**

Aged, community development block grants, Grant programs—housing and community development, Grant programs—Indians, Indians, Individuals with disabilities, Public housing, Reporting and recordkeeping requirements.

■ For the reasons described in the preamble, HUD amends 24 CFR part 1000 to read as follows:

### **PART 1000—NATIVE AMERICAN HOUSING ACTIVITIES**

■ 1. The authority citation for part 1000 continues to read as follows:

**Authority:** 25 U.S.C. 1401 *et seq.* and 42 U.S.C. 3535(d).

■ 2. Add § 1000.103 to read as follows:

**§ 1000.103 How may IHBG funds be used for tenant-based or project-based rental assistance?**

(a) IHBG funds may be used for project-based or tenant-based rental assistance.

(b) IHBG funds may be used for project-based or tenant-based rental assistance that is provided in a manner consistent with section 8 of the United States Housing Act of 1937 (42 U.S.C. 1437f).

(c) IHBG funds used for project-based or tenant-based rental assistance must comply with the requirements of NAHASDA and this part.

Dated: October 11, 2007.

**Orlando J. Cabrera,**

*Assistant Secretary for Public and Indian Housing.*

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**BILLING CODE 4210-67-P**

**DEPARTMENT OF THE INTERIOR**

**Office of Surface Mining Reclamation and Enforcement**

**30 CFR Part 914**

**[Docket No. IN-156-FOR, Administrative Cause No. 06-046R]**

**Indiana Regulatory Program**

**AGENCY:** Office of Surface Mining Reclamation and Enforcement, Interior.

**ACTION:** Final rule; approval of amendment.

**SUMMARY:** We, the Office of Surface Mining Reclamation and Enforcement (OSM), are approving, with certain exceptions, an amendment to the Indiana regulatory program (Indiana program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The Indiana Department of Natural Resources, Division of Reclamation (IDNR, department, or Indiana) revised its rules concerning the definition of “government-financed construction”; underground mining reclamation plans for siltation structures, impoundments, dams, embankments, and refuse piles; requirements for performance bond release; surface mining permanent and temporary impoundments; surface mining primary roads; and inspections of sites. Indiana revised its program to

be consistent with the corresponding Federal regulations, to clarify ambiguities, and to improve operational efficiency.

**DATES:** *Effective Date:* October 18, 2007.

**FOR FURTHER INFORMATION CONTACT:**

Andrew R. Gilmore, Chief, Alton Field Division—Indianapolis Area Office. Telephone: (317) 226-6700. E-mail: [IFOMAIL@osmre.gov](mailto:IFOMAIL@osmre.gov).

**SUPPLEMENTARY INFORMATION:**

- I. Background on the Indiana Program
- II. Submission of the Amendment
- III. OSM’s Findings
- IV. Summary and Disposition of Comments
- V. OSM’s Decision
- VI. Procedural Determinations

**I. Background on the Indiana Program**

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, “a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act \* \* \*; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act.” See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Indiana program effective July 29, 1982. You can find background information on the Indiana program, including the Secretary’s findings, the disposition of comments, and the conditions of approval, in the July 26, 1982, **Federal Register** (47 FR 32071). You can also find later actions concerning the Indiana program and program amendments at 30 CFR 914.10, 914.15, 914.16, and 914.17.

**II. Submission of the Amendment**

By letter dated December 11, 2006 (Administrative Record No. IND-1741), Indiana sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*) in response to a required program amendment at 30 CFR 914.16(ff) and to include changes made at its own initiative. The provisions of 312 Indiana Administrative Code (IAC) 25 that Indiana proposed to revise were: 312 IAC 25-1-57, definition of “government-financed construction”; 25-4-87, underground mining

reclamation plans for siltation structures, impoundments, dams, embankments, and refuse piles; 25-5-16, requirements for performance bond release; 25-6-20, surface mining permanent and temporary impoundments; 25-6-66, surface mining primary roads; and 25-7-1, inspections of sites.

We announced receipt of the proposed amendment in the February 6, 2007, **Federal Register** (72 FR 5374). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. We did not hold a public hearing or meeting because no one requested one. The public comment period ended on March 8, 2007. We received comments from two Federal agencies.

During our review of the amendment, we identified concerns about requirements for performance bond release. We notified Indiana of these concerns by letter dated May 9, 2007, (Administrative Record No. IND-1748). We also met with Indiana staff on June 26, 2007, to discuss the concerns regarding the amendment and corresponded with the State via email on June 23, 2007 (Administrative Record No. IND-1752). Indiana responded by email on July 24, 2007 (Administrative Record No. IND-1752), that it would not submit revisions to this portion of the amendment at this time and that we should proceed with processing the other portions of the amendment. Therefore, we are proceeding with the final rule **Federal Register** document.

**III. OSM’s Findings**

Following are the findings we made concerning the amendment under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17. We are approving the amendment with exceptions as described below. Any revisions that we do not specifically discuss below concern nonsubstantive wording or editorial changes.

*A. Minor Revisions to Indiana’s Rules*

Indiana made minor wording, editorial, punctuation, grammatical, restructuring, and recodification changes to the following previously approved rules:

Topic	State rule
Underground mining reclamation plans for siltation structures, impoundments, dams, embankments, and refuse piles.	312 IAC 25-4-87(a)(1)(B) and (a)(2)(A) and (C), (c), (e)(1) and (e)(4), and (f)(1).
Requirements for performance bond release.	312 IAC 25-5-16(b).