(4) In addition to being shown to comply with the other applicable current good manufacturing practice requirements listed under § 4.3, if the combination product includes an HCT/P, the current good manufacturing practice operating system must also be shown to implement and comply with all current good tissue practice requirements identified under § 4.3(d) that would apply to that HCT/P if it were not part of a combination product.

(c) During any period in which the manufacture of a constituent part to be included in a co-packaged or single entity combination product occurs at a separate facility from the other constituent part(s) to be included in that single-entity or co-packaged combination product, the current good manufacturing practice operating system for that constituent part at that facility must be demonstrated to comply with all current good manufacturing practice requirements applicable to that type of constituent part.

(d) When two or more types of constituent parts to be included in a single-entity or co-packaged combination product have arrived at the same facility, or the manufacture of these constituent parts is proceeding at the same facility, application of a current good manufacturing process operating system that complies with paragraph (b) of this section may begin.

(e) The requirements set forth in this subpart and in parts 210, 211, 820, 600 through 680, and 1271 of this chapter listed in § 4.3, supplement, and do not supersede, each other unless the regulations explicitly provide otherwise. In the event of a conflict between regulations applicable under this subpart to combination products, including their constituent parts, the regulations most specifically applicable to the constituent part in question shall supersede the more general.

Subpart B [Reserved]

Dated: January 15, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–01068 Filed 1–18–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Part 573

Compliance and Enforcement

AGENCY: National Indian Gaming Commission, Interior.

ACTION: Correcting amendments.

SUMMARY: On August 9, 2012, the National Indian Gaming Commission (NIGC) published a final rule amending its enforcement regulation to include a graduated pre-enforcement process for voluntary compliance. That rule referenced a rule that was later withdrawn and also incorrectly referenced an internal citation. This publication corrects the error and makes technical amendments to reference the Commission's recently finalized appeal rules contained in a new subchapter.

DATES: *Effective:* February 6, 2013.

FOR FURTHER INFORMATION CONTACT: Maria Getoff, National Indian Gaming Commission, 1441 L Street NW., Suite 9100, Washington, DC 20005. Email: *maria_getoff@nigc.gov;* telephone: (202) 632–7003.

SUPPLEMENTARY INFORMATION:

I. Background

The Indian Gaming Regulatory Act (IGRA or Act), Public Law 100–497, 25 U.S.C. 2701 *et seq.,* was signed into law on October 17, 1988. The Act establishes the National Indian Gaming Commission (''Commission'') and sets out a comprehensive framework for the regulation of gaming on Indian lands. The purposes of IGRA includes providing a statutory basis for the operation of gaming by Indian tribes as a means of promoting tribal economic development, self-sufficiency, and strong tribal governments; ensuring that the Indian tribe is the primary beneficiary of the gaming operation; and declaring that the establishment of independent federal regulatory authority for gaming on Indian lands, the establishment of federal standards for gaming on Indian lands, and the establishment of a National Indian Gaming Commission are necessary to meet congressional concerns regarding gaming and to protect such gaming as a means of generating tribal revenue. 25 U.S.C. 2702.

On August 9, 2012, the Commission published a final rule amending part 573 (Compliance and Enforcement) to include a graduated pre-enforcement process through which a tribe may come into voluntary compliance. 77 FR 47517, Aug. 9, 2012. The part also sets forth general rules governing the Commission's enforcement of the IGRA, NIGC regulations, and tribal ordinances and resolutions approved by the Chair under 25 CFR part 522.

On September 25, 2012, the Commission published a final rule consolidating all appeal proceedings before the Commission into a new subchapter H (Appeal Proceedings Before the Commission), thereby removing former parts 524, 539, and 577. 77 FR 58941, Sept. 25, 2012. Thus, any reference in part 573 to appeal rights in former part 577 is obsolete and must be revised to reference the new subchapter H.

This document amends the final rule by making two technical amendments and a correction to the final rule to accurately identify referenced regulations. Specifically, this technical amendment amends § 573.4(c)(3) and § 573.5(a) to accurately reference the new subchapter H in place of part 577. Also, this document corrects an error in § 573.2(c) by replacing a cross reference to paragraph ''(b)'' with paragraph ''(a).''

Regulatory Matters

Regulatory Flexibility Act

The rule will not have a significant impact on a substantial number of small entities as defined under the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* Moreover, Indian Tribes are not considered to be small entities for the purposes of the Regulatory Flexibility Act.

Small Business Regulatory Enforcement Fairness Act

The rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. The rule does not have an effect on the economy of $100 million or more. The rule will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, local government agencies or geographic regions. Nor will the rule have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of the enterprises, to compete with foreign based enterprises.

Unfunded Mandate Reform Act

The Commission, as an independent regulatory agency, is exempt from compliance with the Unfunded Mandates Reform Act, 2 U.S.C. 1502(1); 2 U.S.C. 658(1).

Takings

In accordance with Executive Order 12630, the Commission has determined that the rule does not have significant takings implications. A takings implication assessment is not required.

Civil Justice Reform

In accordance with Executive Order 12988, the Commission has determined that the rule does not unduly burden the judicial system and meets the

requirements of sections 3(a) and 3(b)(2) of the Order.

National Environmental Policy Act

The Commission has determined that the rule does not constitute a major federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4321, *et seq.*

Paperwork Reduction Act

This rule does not require information collection under the Paperwork Reduction Act of 1995, 44 U.S.C. 2501, *et seq.,* and is therefore not subject to review by the Office of Management and Budget.

List of Subjects in 25 CFR Part 573

Enforcement, Enforcement actions, Gambling, Gaming, Indians, Indian gaming.

Text of the Rules

For the reasons discussed in the Preamble, the Commission corrects its regulations at 25 CFR part 573 as follows:

PART 573—COMPLIANCE AND ENFORCEMENT

■ 1. The authority citation for part 573 continues to read as follows:

Authority: 25 U.S.C. 2706(b)(1); 2713; E.O. 13175, 65 FR 67249, 3 CFR 2000 Comp., p. 304.

■ 2. In § 573.2, revise paragraph (c) to read as follows:

§ 573.2 When may a letter of concern be issued?

* * * * *

(c) A letter of concern issued under paragraph (a) of this section must provide a time period for the respondent to respond. If the letter of concern is resolved without enforcement action, NIGC staff may send an investigation completion letter pursuant to § 571.4 of this chapter.

* * * * *

■ 3. In § 573.4, revise paragraph (c)(3) to read as follows:

§ 573.4 When may the Chair issue an order of temporary closure?

* * * * *

(c) * * *

(3) Whether or not a respondent seeks informal expedited review under this paragraph, within thirty (30) days after the Chair serves an order of temporary closure the respondent may appeal the order to the Commission under subchapter H of this chapter. Otherwise, the order shall remain in effect unless rescinded by the Chair for good cause.

■ 4. In § 573.5, revise paragraph (a) to read as follows:

§ 573.5 When does and enforcement action become final agency action?

* * * * *

(a) A respondent fails to appeal the enforcement action as provided for in subchapter H of this chapter and does not enter into a settlement agreement resolving the matter in its entirety; or

* * * * *

Dated: January 14, 2013, Washington, DC.

Tracie L. Stevens,

Chairwoman.

Daniel J. Little,

Associate Commissioner.

[FR Doc. 2013–00946 Filed 1–18–13; 8:45 am]

BILLING CODE 7565–01–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

Occupational Exposure to Hazardous Chemicals in Laboratories (Non-Mandatory Appendix); Technical Amendment

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Technical amendment.

SUMMARY: This document updates a non-mandatory appendix in OSHA's Occupational Exposure to Hazardous Chemicals in Laboratories Standard. The non-mandatory appendix is being updated to include the contents of the latest National Academy of Sciences publication entitled, ''Prudent Practices in the Laboratory: Handling and Management of Chemical Hazards,'' 2011 edition. All revisions being made are minor and non-substantive.

DATES: The effective date of this technical amendment to the standard is January 22, 2013.

FOR FURTHER INFORMATION CONTACT:

Press inquiries: Frank Meilinger, Director, Office of Communications, OSHA, U.S. Department of Labor, Room N–3647, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–1999.

General and technical information: Andrew Levinson, OSHA Directorate of Standards and Guidance, Office of Biological Hazards, Room N–3718, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone: (202) 693–1950.

SUPPLEMENTARY INFORMATION:

Background

When the OSHA Laboratory Standard was published in 1990, the non-mandatory Appendix A was based on the 1981 edition of ''Prudent Practices for Handling Hazardous Chemicals in Laboratories'' and the 1983 edition of ''Prudent Practices for Disposal of Chemicals from Laboratories,'' both published by National Academy Press. Since then, there have been many changes in the culture of safety in laboratories. The National Academies of Science (NAS) recognized these changes and has revised and updated its earlier ''Prudent Practices,'' reflected in the 2011 edition of ''Prudent Practices in the Laboratory: Handling and Management of Chemical Hazards'' (National Academies Press). The 2011 edition of ''Prudent Practices'' is being used by OSHA as the basis for non-mandatory Appendix A because of its wide distribution and acceptance and because of its preparation by recognized authorities in the laboratory community. OSHA has reviewed the 2011 edition and collaborated with the NAS to revise non-mandatory Appendix A. This new revision addresses current laboratory practices, security, and emergency response, as well as promoting safe handling of highly toxic and explosive chemicals and their waste products.

Inapplicability of Public Notice and Delayed Effective Date Requirements

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(3)(B), provides that, when an Agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the Agency may issue a final rule without providing notice and an opportunity for public comment. OSHA has determined that there is good cause, pursuant to 5 U.S.C. 553(b)(3)(B), Section 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655(b)), and 29 CFR 1911.5, for making this technical amendment final without prior proposal and opportunity for comment because the amendment does not modify or revoke existing rights or obligations, and does not establish new rights or obligations. Its revisions are non-mandatory and disseminated for informational purposes only. For the same reasons, the Agency finds good cause under 5 U.S.C. 553(d)(3) to make the amendments effective upon publication.

List of Subjects in 29 CFR Part 1910

Occupational safety and health, Laboratories.