
Firms are now exempt from 510(k) requirements for stairway chair lifts as long as they meet these conditions of exemption. Firms must comply with the particular mitigation measures set forth in the conditions for exemption or submit and receive clearance for a 510(k) prior to marketing.

V. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Paperwork Reduction Act of 1995

This final order contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 890

Medical devices, Physical medicine devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 890 is amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

§ 890.5150 Powered patient transport.

(a) Powered patient stairway chair lifts—(1) Identification. A powered patient stairway chair lift is a motorized lift equipped with a seat and permanently mounted in one location that is intended for use in mitigating mobility impairment caused by injury or other disease by moving a person up and down a stairway.

(2) Classification. Class II. The stairway chair lift is exempt from premarket notification procedures in subpart E of part 807 of this chapter, subject to § 890.9 and the following conditions for exemption:

(i) Appropriate analysis and nonclinical testing (such as that outlined in the currently FDA-recognized edition of American Society of Mechanical Engineers (ASME) A18.1 “Safety Standard for Platform Lifts and Stairway Chair Lifts”) must demonstrate that the safety controls are adequate to prevent a free fall of the chair in the event of a device failure;

(ii) Appropriate analysis and nonclinical testing must demonstrate the ability of the device, including armrests, to withstand the rated load with an appropriate factor of safety;

(iii) Appropriate restraints must be provided to prevent the user from falling from the device (such as that outlined in the currently FDA-recognized edition of AAMI/ANSI/IEC 60601–1–2, “Medical Electrical Equipment—Part 1–2: General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests,” and ASME A18.1 “Safety Standard for Platform Lifts and Stairway Chair Lifts”) must validate electromagnetic compatibility and electrical safety; and

(v) Appropriate analysis and nonclinical testing must demonstrate the resistance of the device upholstery to ignition.

(b) All other powered patient transport—(1) Identification. A powered patient transport is a motorized device intended for use in mitigating mobility impairment caused by injury or other disease by moving a person from one location or level to another, such as up and down flights of stairs (e.g., attendant-operated portable stair-climbing chairs). This generic type of device does not include motorized three-wheeled vehicles or wheelchairs.

2. Section 890.5150 is revised to read as follows:

The authority citation for 21 CFR § 890.5150 is revised to read

1. The authority citation for 21 CFR part 890 continues to read as follows:


2. Section 890.5150 is revised to read as follows:

§ 890.5150 Powered patient transport.

(a) Powered patient stairway chair lifts—(1) Identification. A powered patient stairway chair lift is a motorized lift equipped with a seat and permanently mounted in one location that is intended for use in mitigating mobility impairment caused by injury or other disease by moving a person up and down a stairway.

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(iv) Appropriate analysis and nonclinical testing (such as that outlined in the currently FDA-recognized editions of AAMI/ANSI/IEC 60601–1–2, “Medical Electrical Equipment—Part 1–2: General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests,” and ASME A18.1 “Safety Standard for Platform Lifts and Stairway Chair Lifts”) must validate electromagnetic compatibility and electrical safety; and

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DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 11

[Docket ID: BIA–2013–0001]

RIN 1076–AF16

Courts of Indian Offenses

AGENCY: Bureau of Indian Affairs. Interior.

ACTION: Interim final rule with request for comments.

SUMMARY: This interim final rule adds two Indian tribes to the list of tribes with Courts of Indian Offenses (also known as CFR Courts), and deletes five tribes from those under the jurisdiction of CFR Courts. The two tribes to be added are Skull Valley Band of Goshute Indians and the Seneca-Cayuga Tribe. The tribes to be removed from the list are the Seminole Nation, the Miami Tribe, the Choctaw Nation of Oklahoma, the Wyandotte Tribe, and the Quapaw Tribe.

DATES: This interim final rule is effective on March 4, 2013. Submit comments by April 3, 2013.

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

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–2013–0001. If you would like to submit comments through the Federal e-Rulemaking Portal, go to www.regulations.gov and do the following. Go to the box entitled “Enter Keyword or ID,” type in “BIA–2013–0001,” and click the “Search” button. The next screen will display the Docket Search Results for the rulemaking. If you click on BIA–2013–0001, you can view this rule and submit a comment. You can also view any supporting material and any comments submitted by others.

—Email: consultation@bia.gov. Include the number 1076–AF16 in the subject line of the message.


Email: consultation@bia.gov. Include the number 1076–AF16 in the subject line of the message.

Mail: Elizabeth Appel, Office of Regulatory Affairs & Collaborative Action, U.S. Department of the Interior, 1849 C Street NW, MS
I. Summary of Rule

This rule revises a section of 25 CFR part 11 to add the following Indian tribes to the list of tribes with established Courts of Indian Offenses (also known as CFR Courts): The Seneca-Cayuga Tribe and the Skull Valley Band of Goshute Indians. This rule inserts these tribes into 25 CFR 11.100. The tribes’ names were inserted where they will appear in the list of tribes alphabetically, therefore necessitating redesignation of some of the paragraph numbers in the regulatory text, and placing the tribes in alphabetical order, where they were not.

The rule also revises a section of 25 CFR 11.100(c) to remove five tribes from the list of those with established CFR Courts. The tribes to be removed from the list are the Seminole Nation, the Miami Tribe, the Wyandotte Tribe, the Choctaw Nation of Oklahoma, and the Quapaw Tribe of Indians. This rule removes these tribes from 25 CFR 11.100(c). The tribes’ names will no longer appear in the list of tribes alphabetically, therefore necessitating re-designation of some of the paragraph numbers in the regulatory text, and placing the tribes in alphabetical order, where they were not. Adding these tribes will allow for the administration of justice until the added tribes put into effect a law-and-order code that establishes a court system that meets regulatory requirements or until the tribe adopts a legal code and establishes a judicial system in accordance with its constitution and bylaws or other governing documents.

Courts of Indian Offenses operate in those areas of Indian country where tribes retain jurisdiction over Indians that is exclusive of State jurisdiction but where tribal courts have not been established to exercise that jurisdiction. The Skull Valley Band of Goshute Indians and the Seneca-Cayuga Tribe have limited resources and are in need of a judicial forum. The Eastern Seneca Tribe was once listed as being under the jurisdiction of the CFR Court, was removed from the list, and now is again in need of a judicial forum. The Wyandotte Tribe of Oklahoma, Seminole Nation of Oklahoma, Choctaw Nation of Oklahoma, the Miami Tribe, and the Quapaw Tribe of Indians were previously listed as being within the jurisdiction of the CFR Court and have, or are in the process of establishing, tribal courts; and are therefore no longer in need of an extra-tribal judicial forum.

Two tribes left the jurisdiction of the CFR Court to form their own courts since 25 CFR 11.100 was last revised, but are now seeking to come back under the jurisdiction of the CFR Court: the Delaware Nation and the Eastern Shawnee Tribe. Because no change was made to the rule to remove these tribes from list of CFR Courts, no revision is necessary now. This rule confirms that both the Delaware Nation and Eastern Shawnee Tribe are on the list of tribes with CFR Courts.

The following table lists the changes made to § 11.100:

<table>
<thead>
<tr>
<th>Current § 11.100</th>
<th>Interim final rule § 11.100</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)(1) Te-Moak Band of Western Shoshone Indians (Nevada)</td>
<td>Moved to (a)(3).</td>
</tr>
<tr>
<td>(a)(2) Ute Mountain Ute Tribe (Colorado)</td>
<td>Moved to (a)(5).</td>
</tr>
<tr>
<td>(a)(3) Tribes located in the former Oklahoma Territory (Oklahoma) that are listed in paragraph (b) of this section.</td>
<td>Moved to (a)(4).</td>
</tr>
<tr>
<td>(a)(4) Tribes located in the former Indian Territory (Oklahoma) that are listed in paragraph (c) of this section.</td>
<td>Moved to (a)(1).</td>
</tr>
<tr>
<td>(a)(5) Winnemucca Indian Tribe; and</td>
<td>Added Skull Valley Band of Goshute Indians (Utah) to (a)(2).</td>
</tr>
<tr>
<td>(a)(6) Santa Fe Indian School property, including Santa Fe Indian Health Hospital, and the Albuquerque Indian School Property (land held in trust for the 19 Pueblos of New Mexico).</td>
<td>No change.</td>
</tr>
<tr>
<td>(b)(1) Apache Tribe of Oklahoma</td>
<td>No change.</td>
</tr>
<tr>
<td>(b)(2) Caddo Nation of Oklahoma</td>
<td>No change.</td>
</tr>
<tr>
<td>(b)(3) Comanche Nation (except Comanche Children’s Court)</td>
<td>No change.</td>
</tr>
<tr>
<td>(b)(4) Delaware Nation</td>
<td>No change.</td>
</tr>
<tr>
<td>(b)(5) Fort Sill Apache Tribe of Oklahoma</td>
<td>No change.</td>
</tr>
<tr>
<td>(b)(6) Kiowa Tribe of Oklahoma</td>
<td>No change.</td>
</tr>
<tr>
<td>(b)(7) Otoe-Missouria Tribe of Oklahoma</td>
<td>No change.</td>
</tr>
<tr>
<td>(b)(8) Wichita and Affiliated Tribes of Oklahoma</td>
<td>No change.</td>
</tr>
<tr>
<td>(c)(1) Choctaw Nation</td>
<td>Deleted.</td>
</tr>
<tr>
<td>(c)(2) Seminole Nation</td>
<td>No change.</td>
</tr>
<tr>
<td>(c)(3) Eastern Shawnee Tribe</td>
<td>Moved to (c)(1).</td>
</tr>
<tr>
<td>(c)(4) Miami Tribe</td>
<td>Deleted.</td>
</tr>
<tr>
<td>(c)(5) Modoc Tribe</td>
<td>Moved to (c)(2).</td>
</tr>
<tr>
<td>(c)(6) Ottawa Tribe</td>
<td>Moved to (c)(3).</td>
</tr>
<tr>
<td>(c)(7) Potawatomi Tribe</td>
<td>Moved to (c)(4).</td>
</tr>
<tr>
<td>(c)(8) Quapaw Tribe; and</td>
<td>Deleted.</td>
</tr>
</tbody>
</table>
II. Procedural Requirements

A. Regulatory Planning and Review (E.O. 12866 and 13563)

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget (OMB) will review all significant rules. OIRA has determined that this rule is not significant.

E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the Nation’s regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The E.O. directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements. This rule is also part of the Department’s commitment under the Executive Order to reduce the number and burden of regulations.

B. Regulatory Flexibility Act

The Department of the Interior certifies that this rule 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.).

C. Small Business Regulatory Enforcement Fairness Act

This 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. The rule’s requirements 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 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 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 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.

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

This 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. During development of the rule, the Department discussed the rule with the affected tribes.

I. Paperwork Reduction Act

This rule does not contain any information collections requiring approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq.

J. National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment because it is of an administrative, technical, and procedural nature.

K. Effects on the Energy Supply (E.O. 13211)

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

L. 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.

M. 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.
N. 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). Under 553(b), we find that prior notice and comment are unnecessary and would be contrary to the public interest. This rule is necessary to ensure that these tribes have courts to administer justice on land under their jurisdiction. Prior notice and comment are unnecessary and would be contrary to the public interest because access to judicial process may be impeded or interrupted to a degree that the governmental function of providing justice for all tribal members is impaired.

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 the delay in publishing this rule would inhibit access to justice for tribal members and likely obstruct speedy trial rights for members of those tribes seeking to come under the jurisdiction of CFR Courts, and would diminish the sovereign right of those tribes to establish their own tribal courts and to assume personal and subject-matter jurisdiction now asserted by CFR Courts.

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 11

Courts, Indians-law.

For the reasons stated in the preamble, the Department of the Interior, Bureau of Indian Affairs, amends part 11 in Title 25 of the Code of Federal Regulations as follows:

PART 11— COURTS OF INDIAN OFFENSES AND LAW AND ORDER CODE

1. The authority for part 11 continues to read as follows:


2. Revise § 11.100 to read as follows:

§ 11.100 Where are Courts of Indian Offenses established?
(a) Unless indicated otherwise in this title, these Courts of Indian Offenses are established and the regulations in this part apply to the Indian country (as defined in 18 U.S.C. 1151) and by Federal court precedent) occupied by the following tribes:
(1) Santa Fe Indian School Property, including the Santa Fe Indian Health Hospital, and the Albuquerque Indian School Property (land held in trust for the 19 Pueblos of New Mexico);
(2) Skull Valley Band of Goshutes Indians (Utah);
(3) Te-Moak Band of Western Shoshone Indians (Nevada);
(4) Tribes located in the former Oklahoma Territory (Oklahoma) that are listed in paragraph (b) of this section;
(5) Tribes located in the former Indian Territory (Oklahoma) that are listed in paragraph (c) of this section;
(6) Ute Mountain Ute Tribe (Colorado); and
(7) Winnemucca Indian Tribe.
(b) This part applies to the following tribes located in the former Oklahoma Territory (Oklahoma):
(1) Apache Tribe of Oklahoma;
(2) Caddo Nation of Oklahoma;
(3) Comanche Nation (except Comanche Children’s Court);
(4) Delaware Nation;
(5) Fort Sill Apache Tribe of Oklahoma;
(6) Kiowa Indian Tribe of Oklahoma;
(7) Otoe-Missouria Tribe of Indians; and
(8) Wichita and Affiliated Tribe of Indians.
(c) This part applies to the following tribes located in the former Indian Territory (Oklahoma):
(1) Eastern Shawnee Tribe of Oklahoma;
(2) Modoc Tribe of Oklahoma;
(3) Ottawa Tribe of Oklahoma;
(4) Peoria Tribe of Indians of Oklahoma; and
(5) Seneca-Cayuga Tribe of Oklahoma.


Kevin K. Washburn,
Assistant Secretary—Indian Affairs.

BILLING CODE 4310–6W–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

Approval and Promulgation of Air Quality Implementation Plans; Delaware; the 2002 Base Year Emissions Inventory for the Delaware Portion of the Philadelphia Nonattainment Area for the 1997 Annual Fine Particulate Matter National Ambient Air Quality Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving a revision to the Delaware State Implementation Plan (SIP) submitted by the State of Delaware, through the Delaware Department of Natural Resources and Environmental Control (DNREC) on April 3, 2008. The SIP revision pertains to the 2002 base year emissions inventory for the Delaware portion of the Philadelphia-Wilmington, Pennsylvania-New Jersey-Delaware (PA-NJ-DE) nonattainment area. The 2002 base year emissions inventory was submitted to meet nonattainment requirements related to the Delaware nonattainment area for the 1997 annual fine particulate matter (PM2.5) national ambient air quality standard (NAAQS). EPA is approving the 2002 base year emissions inventory in accordance with the requirements of the Clean Air Act (CAA).

DATES: This final rule is effective on April 3, 2013.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2010–0141. All documents in the docket are listed in the www.regulations.gov Web site. Although listed in the electronic docket, some information is not publicly available, i.e., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Delaware Department of Natural Resources and Environmental Control, 89 Kings Highway, P.O. Box 1401, Dover, Delaware 19903.

FOR FURTHER INFORMATION CONTACT: Rose Quinto, (215) 814–2182, or by email at quinto.rose@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On November 19, 2012 (77 FR 69399), EPA published a notice of proposed rulemaking (NPR) for the State of Delaware. The NPR proposed approval of the 1997 annual PM2.5 attainment demonstration, analysis of reasonably available control measures (RACM) and reasonably available control technology (RACT), the 2002 base year emissions