

paddie to neurosurgical paddie. FDA is also removing the word "cotton" from the identification of the device because many of the devices of this type are made of materials other than cotton.

## II. Environmental Impact

The agency has previously determined under 21 CFR 25.30(i) that this final rule 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 was required. The changes in these amendments do not alter this conclusion.

## III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule only changes the name of the device and does not change in any way how the device is regulated, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

## IV. Paperwork Reduction Act of 1995

FDA has determined that this final rule contains no additional collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## V. Federalism

FDA has analyzed this 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 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.

### List of Subjects in 21 CFR Part 882

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

### PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for 21 CFR part 882 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 882.4700 is amended by revising the section heading and paragraph (a) to read as follows:

#### § 882.4700 Neurosurgical paddie.

(a) A neurosurgical paddie is a pad used during surgery to protect nervous tissue, absorb fluids, or stop bleeding.

\* \* \* \* \*

Dated: February 25, 2004.

**Beverly Chernaik Rothstein,**

*Acting Deputy Director for Policy and Regulations, Center for Devices and Radiological Health.*

[FR Doc. 04–4887 Filed 3–4–04; 8:45 am]

**BILLING CODE 4160–01–S**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 69

[Region 2 Docket No. VI–5–265 D, FRL–7632–5]

### An Exemption From Requirements of the Clean Air Act for the Territory of United States Virgin Islands

**AGENCY:** Environmental Protection Agency.

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is announcing approval of a Petition, from the Governor of the Virgin Islands (US VI), which seeks an exemption of the Clean Air Act (CAA) section 165(a) requirement to obtain a

Prevention of Significant Deterioration (PSD) Permit to Construct prior to construction of a new gas turbine at the Virgin Islands Water and Power Authority (VIWAPA) St. Thomas facility. This exemption allows for construction, but not operation, of Unit 23 prior to issuance of a final PSD permit.

**EFFECTIVE DATE:** This rule will be effective March 5, 2004.

**ADDRESSES:** Copies of the Governor's Petition and submittals relied upon in the approval process are available at the following addresses for inspection during normal business hours:

Environmental Protection Agency, Region 2 Office, Air Programs Branch, 290 Broadway, New York, New York 10007–1866, Attn: Umesh Dholakia.

Environmental Protection Agency, Region 2 Office, Caribbean Field Office, Centro Europa Building, Suite 417, 1492 Ponce de Leon Avenue, Stop 22, San Juan, Puerto Rico 00907–4127, Attn: John Aponte.

The U. S. Virgin Islands Department of Planning and Natural Resources (VIDPNR), Division of Environmental Protection, Cyril E. King Airport, Terminal Building, Second Floor, St. Thomas, U.S. Virgin Islands 00802, Attn: Leslie Leonard.

#### FOR FURTHER INFORMATION CONTACT:

Umesh Dholakia, Environmental Engineer, Air Programs Branch, Division of Environmental Protection and Planning, Environmental Protection Agency, Region 2 Office, 290 Broadway, 25th Floor, New York, New York 10007–1866, (212) 637–4023 or at [Dholakia.Umesh@epa.gov](mailto:Dholakia.Umesh@epa.gov).

**SUPPLEMENTARY INFORMATION:** The following table of contents describes the format for the Supplementary Information section:

- I. What Action Is EPA Taking Today?
- II. What Comments Did EPA Receive in Response to Its Proposal?
- III. What Is EPA's Conclusion?
- IV. Statutory and Executive Order Review

#### I. What Action Is EPA Taking Today?

EPA is approving a Petition from the U.S. VI Governor seeking an exemption of the CAA requirement to obtain a PSD Permit to construct prior to commencing construction of a new gas turbine at the VIWAPA St. Thomas facility.

Pursuant to section 325(a) of the CAA, on July 21, 2003, the Governor of the U.S. VI filed a Petition with the Administrator seeking an exemption from the CAA section 165(a) PSD requirement to obtain a PSD permit to construct prior to commencing construction. The Governor requested

the exemption on behalf of VIWAPA so that it can proceed, as quickly as possible, to construct Unit 23, a 36 megawatt (MW) gas turbine at its St. Thomas facility.

This exemption will allow for construction, not operation, prior to issuance of a final PSD permit, of Unit 23 at the VIWAPA St. Thomas facility.

## II. What Comments Did EPA Receive in Response to Its Proposal?

### A. Background Information

On December 31, 2003, EPA announced, in proposed and direct final rules published in the **Federal Register** (68 FR 75786 and 68 FR 75782, respectively), approval of a Petition from the U.S. VI Governor seeking an exemption of the CAA requirement to obtain a PSD Permit to construct prior to commencing construction of a new gas turbine at the VIWAPA St. Thomas facility. EPA had indicated in its December 31, 2003 direct final rule that if EPA received adverse comments, it would withdraw the direct final rule. Consequently, EPA informed the public, in a withdrawal notice published in the **Federal Register** (69 FR 9216) on February 27, 2004, that EPA received an adverse comment and that the direct final rule did not take effect. EPA did not receive any other comments. EPA is addressing the adverse comment in today's final rule based upon the proposed action published on December 31, 2003. For detailed information on this action, the reader is referred to the direct final rule referenced above.

### B. A Comment Received and EPA's Response

EPA received one adverse comment on its December 31, 2003 direct final rule to approve a Petition from the U.S. VI Governor seeking an exemption of the CAA requirement to obtain a PSD Permit to construct prior to commencing construction of a new gas turbine at the VIWAPA St. Thomas facility from a concerned citizen. That comment and EPA's response follows.

*Comments:* A concerned citizen commented that he objected to any exemption from providing clean air, and that EPA should mandate the highest standards for the clean air where people live and travel.

*Response:* In order to address this concern, EPA hereby clarifies the nature of this exemption under section 325(a) of the CAA. The CAA section 165(a) of the CAA requires that an owner/operator obtain a PSD permit to construct prior to commencing construction. The petitioner in this case is seeking an exemption commencing

construction of a new gas turbine. The petitioner is not seeking any exemption from obtaining a PSD permit and meeting all emission control and air quality related obligations under the CAA prior to beginning operation of this new turbine. The CAA, under section 325(a), specifically allows for exemptions from requirements of the CAA for sources in the Virgin Islands where it can be demonstrated that either financial or geographic conditions warrant such an exemption and no air quality violations would result from such an exemption.

EPA reviewed the petitioner's request and determined that granting this exemption will not result in any adverse impact on the air quality of the islands. The Virgin Islands will continue to meet the National Ambient Air Quality Standards. This action does not allow the petitioner to begin operation of the new turbine until a final PSD permit that meets all the CAA requirements is issued.

Thus, this exemption will not affect any emission or any air quality requirements. This new turbine will be held to the same emission limitations as a similar source built in another area which is attaining the NAAQS.

### III. What Is EPA's Conclusion

The VIWAPA St. Thomas facility is unable to interconnect with a larger power supply grid. Furthermore, the distance between St. Thomas and St. Croix prohibits the interconnection between the two VIWAPA plants. Thus, St. Thomas is serviced by a single power plant that is experiencing frequent power outages. Based on these factors, EPA has determined that the petition presents unique geographic circumstances that justify the waiver.

The EPA is approving the Petition for an exemption of the CAA section 165(a) requirement to obtain a PSD permit to construct prior to commencing construction of a new gas turbine, Unit 23, at the VIWAPA St. Thomas facility. This exemption will allow for the construction, but not the operation, of Unit 23 prior to issuance of a final PSD permit.

EPA is relying on the Governor's assertion that the construction and ultimate operation of Unit 23 should provide a reliable baseload which will give VIWAPA flexibility to meet electrical demand and that the additional capacity provided by this unit would be sufficient to allow for both planned and unplanned outages of generating units at the VIWAPA St. Thomas facility. EPA believes that by accelerating the time period by which this unit can be constructed, this

rulemaking may increase VIWAPA's potential to provide more reliable power in St. Thomas.

EPA has determined that today's rule falls under the "good cause" exemption at section 553(d)(3) of the Administrative Procedures Act (APA) which allows an agency to make a rule effective immediately, upon finding "good cause," thereby avoiding the 30-day delayed effective date otherwise provided for in the APA. EPA has concluded that to delay the effectiveness of this rule for 30 days might adversely affect resolving a pending power crisis impacted by severe geographic constraints and that the entities that will be directly affected by this exemption have had ample notice of EPA's action. Therefore, EPA is making this rule effective immediately. This rule will be effective March 5, 2004.

## IV. Statutory and Executive Order Review

### A. Executive Order 12866, Regulatory Planning and Review

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order 12866, entitled "Regulatory Planning and Review."

### B. Paperwork Reduction Act

Under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, OMB must approve all "collections of information" by EPA. The Act defines "collection of information" as a requirement for "answers to \* \* \* identical reporting or recordkeeping requirements imposed on ten or more persons \* \* \*" 44 U.S.C. 3502(3)(A). Because the exemption only applies to one company, the Paperwork Reduction Act does not apply.

### C. Regulatory Flexibility Analysis

EPA has determined that it is not necessary to prepare a regulatory flexibility analysis in connection with this final rule. For purposes of assessing the impacts of today's rule on small entities, small entity is defined as: (1) A small business that is primarily engaged in the generation and distribution of electricity as defined by NAIC code 221112 with production less than four million megawatt hours (based on Small Business Administration size standards); (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not

dominant in its field. After considering the economic impacts of today's final rule on small entities, EPA has concluded that this action will not have a significant economic impact on a substantial number of small entities. This final rule will not impose any requirements on small entities. The exemption applies to only one source and does not create any new requirements.

#### *D. Unfunded Mandates Reform Act*

Under sections 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act"), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to the private sector, of \$100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action does not include a Federal mandate that may result in estimated costs of \$100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action proposes to approve an exemption under Federal law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

#### *E. Executive Order 13132, Federalism*

Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Orders 12612 (Federalism) and 12875 (Enhancing the Intergovernmental Partnership). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations 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." Under Executive Order 13132, EPA may not issue a regulation that has federalism

implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This rule will not 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, as specified in Executive Order 13132, because it merely approves an exemption from a federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, the requirements of section 6 of the Executive Order do not apply to this rule.

#### *F. Executive Order 13175, Coordination With Indian Tribal Governments*

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." This proposed rule does not have tribal implications, as specified in Executive Order 13175.

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Thus, Executive Order 13175 does not apply to this rule.

#### *G. Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks*

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of

the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to Executive Order 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

#### *H. Executive Order 13211, Actions That Significantly Affect Energy Supply, Distribution, or Use*

This rule is not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

#### *I. National Technology Transfer and Advancement Act*

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use "voluntary consensus standards" (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical. The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

#### *J. Congressional Review Act*

The Congressional Review Act, 5 U.S.C. section 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 804 exempts from section 801 the following types of rules: (1) Rules of particular applicability; (2) Rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. section 804(3). EPA is not required to submit a rule report regarding this action under section 801 because this is a rule of particular applicability in that it exempts only one source from obtaining a PSD permit to construct.

**K. Other**

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 4, 2004. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

**List of Subjects in 40 CFR Part 69**

Environmental protection, Air pollution control.

Dated: February 27, 2004.

**Michael O. Leavitt,**  
Administrator.

■ Part 69 of chapter I, title 40 of the Code of Federal Regulations is amended to read as follows:

**PART 69—[AMENDED]**

■ 1. The authority citation for part 69 continues to read as follows:

**Authority:** 42 U.S.C. 7545(c), (g), and (i), and 7625–1.

■ 2. Section 69.41 is amended by adding paragraph (h) to read as follows:

**§ 69.41 New exemptions.**

\* \* \* \* \*

(h) Pursuant to section 325(a) of the Clean Air Act (CAA) and a petition submitted by the Governor of United States Virgin Islands on July 21, 2003, (“2003 Petition”), the Administrator of EPA conditionally exempts Virgin Islands Water and Power Authority (“VIWAPA”) from certain CAA requirements.

(1) A waiver of the requirement to obtain a PSD permit prior to construction is granted for the electric generating unit identified in the 2003 Petition as Unit 23, St. Krum Bay plant in St. Thomas with the following condition:

(i) Unit 23 shall not operate until a final PSD permit is received by VIWAPA for this unit;

(ii) Unit 23 shall not operate until it complies with all requirements of its PSD permit, including, if necessary, retrofitting with BACT;

(iii) If Unit 23 operates either prior to the issuance of a final PSD permit or without BACT equipment, Unit 23 shall be deemed in violation of this waiver and the CAA beginning on the date of

commencement of construction of the unit.

(2) [Reserved]

[FR Doc. 04–4987 Filed 3–4–04; 8:45 am]

BILLING CODE 6560–50–P

**DEPARTMENT OF THE INTERIOR****Fish and Wildlife Service****50 CFR Part 17**

RIN 1018–AI28

**Endangered and Threatened Wildlife and Plants; Listing the San Miguel Island Fox, Santa Rosa Island Fox, Santa Cruz Island Fox, and Santa Catalina Island Fox as Endangered**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Final rule.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), determine endangered status pursuant to the Endangered Species Act (Act) of 1973, as amended (16 U.S.C. 1531 *et seq.*), for four subspecies of island fox (*Urocyon littoralis*): San Miguel Island fox (*U. l. littoralis*), Santa Rosa Island fox (*U. l. santarosae*), Santa Cruz Island fox (*U. l. santacruzae*), and Santa Catalina Island fox (*U. l. catalinae*). This final rule extends the Federal protection and recovery provisions of the Act to these subspecies.

**DATES:** This final rule is effective April 5, 2004.

**ADDRESSES:** The complete file for this rule is available for inspection, by appointment, during normal business hours at the U.S. Fish and Wildlife Service, Ventura Fish and Wildlife Office, 2493 Portola Road, Suite B, Ventura, CA 93003.

**FOR FURTHER INFORMATION CONTACT:** Field Supervisor, U.S. Fish and Wildlife Service, Ventura Fish and Wildlife Office, at the address above (telephone 805/644–1766; facsimile 805/644–3958).

**SUPPLEMENTARY INFORMATION:****Background**

The island fox was first described as *Vulpes littoralis* by Baird in 1857 from the type locality of San Miguel Island, Santa Barbara County, California. Merriam (1888, in Hall and Kelson 1959) reclassified the island fox into the genus *Urocyon* and later described island foxes from Santa Catalina, San Clemente, and Santa Cruz Islands as three separate taxa (*U. catalinae*, *U. clementae*, and *U. littoralis santacruzae*) (Merriam 1903). Grinnell *et al.* (1937) revised Merriam’s classification, placing

foxes from all islands under the species *U. littoralis* and assigning each island population a subspecific designation (*U. l. catalinae* on Santa Catalina Island, *U. l. clementae* on San Clemente Island, *U. l. dickeyi* on San Nicolas Island, *U. l. littoralis* on San Miguel Island, *U. l. santacruzae* on Santa Cruz Island, and *U. l. santarosae* on Santa Rosa Island). Recent morphological and genetic studies support the division of the *U. littoralis* complex into six subspecies that are each limited in range to a single island (Gilbert *et al.* 1990; Wayne *et al.* 1991; Collins 1991a, 1993; Goldstein *et al.* 1999). Each subspecies is reproductively isolated from the others by a minimum of 5 kilometers (3 miles) of ocean waters. The island fox is closely related to the mainland gray fox, *U. cinereoargenteus*, but is smaller in size and darker in coloration (Moore and Collins 1995).

The island fox is a very small canid, weighing approximately 3 to 6 pounds (1.4 to 2.7 kilograms) and standing approximately 1 foot (0.3 meter) tall. The tail is conspicuously short. Dorsal coloration is grayish-white and black. The base of the ears and sides of the neck and limbs are cinnamon-rufous in color, and the underbelly is a dull white. Island foxes display sexual size dimorphism (males being larger and heavier than females) (Moore and Collins 1995).

Island foxes inhabit the six largest islands (San Miguel, Santa Rosa, Santa Cruz, San Nicolas, Santa Catalina, and San Clemente Islands) off the coast of southern California. Genetic evidence suggests that all island foxes are descended from one colonization event (Gilbert *et al.* 1990), possibly from chance overwater dispersal during which foxes rafted on floating debris (Moore and Collins 1995). Fossil evidence indicates that island foxes inhabited the northern Channel Islands (San Miguel, Santa Rosa, and Santa Cruz) between 10,000 to 16,000 years ago (Orr 1968). However, island foxes are thought to have existed on the northern Channel Islands even before that time, during a period when Santa Cruz, Santa Rosa, and San Miguel were one land mass referred to as “Santarosae,” last known to have been united 18,000 years ago (Johnson 1978, 1983). The island fox was thought to have reached the southern Channel Islands (San Nicolas, San Clemente, and Santa Catalina) much more recently (2,200 to 3,800 years ago), most likely introduced to these islands by Native Americans as pets or semidomesticates (Collins 1991a, b). However, island fox remains recently recovered from San Nicolas Island suggest this introduction