waterfowl and seabirds. While studies on waterfowl and seabird recommend the creation of a buffer to reconcile the impacts of MPWC, buffer zones will not sufficiently address the other concerns related to MPWC use throughout the sanctuary such as water pollution, user conflicts, and other wildlife and human disturbance outside of the zones.

Comment 22: MPWC use in the Sanctuary is decreasing.

Response: NOAA disagrees. With the closure of other areas within and around the Sanctuary, such as GGNRA and PRNS, it is unlikely that use in the Sanctuary will decrease. NOAA is not aware of any data indicating that MPWC use is decreasing in GFNMS, other than statements from MPWC users and use trends nationally, which are documented in the United States Coast Guard report (1999).

Comment 23: NOAA's proposed regulation is arbitrary because it would prohibit MPWC operation because of their speed.

Response: NOAA disagrees. As stated in earlier responses, MPWCs have not been proposed to be banned in the Sanctuary because of any single reason such as speed. Speed is one of many aspects of MPWCs, including water quality effects, noise disturbance to humans and wildlife, and user conflicts, that NOAA considered.

III. Summary of Regulations

The regulations for the GFNMS are amended as follows:

The addition to 15 CFR 922.82(a) prohibits operation of MPWC in the Sanctuary. The prohibition includes an exception for the use of MPWC for emergency search and rescue and law enforcement (other than training activities) by Federal, State and local jurisdictions.

The addition to 15 CFR 922.81 provides a definition of ''motorized personal watercraft.'' ''Motorized personal watercraft'' will be defined as ''a vessel which uses an inboard motor powering a water jet pump as its primary source of motive power and which is designed to be operated by a person sitting, standing, or kneeling on the vessel, rather than the conventional manner of sitting or standing inside the vessel''.

IV. Miscellaneous Rulemaking Requirements

Executive Order 12866: Regulatory Impact

This rule has been determined to be not significant for purposes of Executive Order 12866.

Regulatory Flexibility Act

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration when this rule was proposed that if it was adopted as proposed it would not have a significant economic impact on a substantial number of small entities. No comments were received on the economic impact of the proposed rule on small entities and, therefore, the basis for the certification has not changed.

Accordingly, a Regulatory Flexibility Analysis was not prepared.

Paperwork Reduction Act

This rule would not impose an information collection requirement subject to review and approval by OMB under the Paperwork Reduction Act of 1980, 44 U.S.C. 3500 *et seq.*

National Environmental Policy Act

NOAA has concluded that this regulatory action does not constitute a major federal action significantly affecting the quality of the human environment. Therefore, an environmental impact statement is not required. A draft environmental assessment has been prepared. It is available for comment from the address listed at the beginning of this notice.

List of Subjects in 15 CFR Part 922

Administrative practice and procedure, Coastal zone, Education, Environmental protection, Marine resources, Penalties, Recreation and recreation areas, Reporting and recordkeeping requirements, Research.

Alan Neuschatz,

Chief Financial Officer/Chief Administrative Officer, Ocean Services and Coastal Zone Management.

Accordingly, for the reasons set forth above, 15 CFR Part 922, Subpart H, is amended as follows:

PART 922, NATIONAL MARINE SANCTUARY PROGRAM REGULATIONS

1. The authority citation for Part 922 continues to read as follows:

Authority: 16 U.S.C. 1431 *et seq.*

2. Section 922.81 is amended by adding the following definition, in the appropriate alphabetical order.

§ 922.81 Definitions.

* * * * *

Motorized personal watercraft means a vessel which uses an inboard motor powering a water jet pump as its primary source of motive power and which is designed to be operated by a person sitting, standing, or kneeling on the vessel, rather than the conventional manner of sitting or standing inside the vessel.

3. Section 922.82 is amended by adding new paragraph (a)(7) as follows:

§ 922.82 Prohibited or otherwise regulated activities.

(a) * * *

(7) Operation of motorized personal watercraft, except for the operation of motorized personal watercraft for emergency search and rescue mission or law enforcement operations (other than routine training activities) carried out by National Park Service, U.S. Coast Guard, Fire or Police Departments or other Federal, State or local jurisdictions.

* * * * *

[FR Doc. 01–22637 Filed 9–7–01; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 872, 878, 880, 882, 884, and 892

[Docket No. 01N–0073]

Medical Devices; Exemption From Premarket Notification Requirements; Class I Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: In the **Federal Register** of July 25, 2001 (66 FR 38786), the Food and Drug Administration (FDA) amended its medical device classification regulations for class I devices to specifically add a reference to the general limitations on exemptions from premarket notification requirements from each generic device classified as exempt in each section. As published, an exemption from the premarket notification requirements and a reference to the general limitations language was inadvertently added to 12 device classifications that should not include the reference. These devices are not exempt from the requirements of premarket notification. This document corrects those errors.

DATES: This rule is effective September 10, 2001.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

Provisions under section 206 of the Food and Drug Administration Modernization Act (FDAMA) exempt certain class I devices from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (the act). To implement the new law, FDA evaluated all class I devices to determine which device types should become exempt under the new provisions and which device types should remain subject to the requirements of 510(k) of the act (21 U.S.C. 360(k)). FDA then amended its classification regulations through a series of publications in the **Federal Register** (63 FR 63222, November 12, 1998; 65 FR 2296, January 14, 2000; 63 FR 5387, February 2, 1998; and 66 FR 38786). The most recent amendment (66 FR 38786) revised statutory citations for over 500 devices in order to reference the limitation provisions found in each device classification regulation for devices that were exempt from the premarket notification requirements for clarity and convenience. During preparation of the final rule, however, certain devices were inadvertently included in a list of devices to be amended, and were erroneously changed by adding the limitations language and an exemption from premarket notification. This document corrects those errors.

II. 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.

III. Analysis of Impacts

FDA has examined the impact of this rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), 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 rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, this 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 does not change the status quo for these devices, the agency certifies that this final rule will not have a significant negative economic impact on a substantial number of small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed $100 million.

IV. Paperwork Reduction Act of 1995

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

List of Subjects

21 CFR Parts 872, 878, 880, 882, and 884

Medical devices.

21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 872, 878, 880, 882, 884, and 892 are amended as follows:

PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR part 872 continues to read as follows:

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

2. Section 872.6710 is amended by revising paragraph (b) to read as follows:

§ 872.6710 Boiling water sterilizer.

* * * * *

(b) *Classification.* Class I (general controls).

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

3. The authority citation for 21 CFR part 878 continues to read as follows:

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

4. Section 878.4460 is amended by revising paragraph (b) to read as follows:

§ 878.4460 Surgeon's glove.

* * * * *

(b) *Classification.* Class I (general controls).

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

5. The authority citation for 21 CFR part 880 continues to read as follows:

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

6. Section 880.5680 is amended by revising paragraph (b) to read as follows:

§ 880.5680 Pediatric position holder.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

7. Section 880.6250 is amended by revising paragraph (b) to read as follows:

§ 880.6250 Patient examination glove.

* * * * *

(b) *Classification.* Class I (general controls).

8. Section 880.6375 is amended by revising paragraph (b) to read as follows:

§ 880.6375 Patient lubricant.

* * * * *

(b) *Classification.* Class I (general controls).

9. Section 880.6760 is amended by revising paragraph (b) to read as follows:

§ 880.6760 Protective restraint.

* * * * *

(b) *Classification.* Class I (general controls).

PART 882—NEUROLOGICAL DEVICES

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

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

11. Section 882.1030 is amended by revising paragraph (b) to read as follows:

§ 882.1030 Ataxiagraph.

* * * * *

(b) *Classification.* Class I (general controls).

12. Section 882.1420 is amended by revising paragraph (b) to read as follows:

§ 882.1420 Electroencephalogram (EEG) signal spectrum analyzer.

* * * * *

(b) *Classification.* Class I (general controls).

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

13. The authority citation for 21 CFR part 884 continues to read as follows:

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

14. Section 884.2980 is amended by revising paragraph (a)(2) to read as follows:

§ 884.2980 Telethermographic system.

(a) * * *

(2) *Classification.* Class I (general controls).

* * * * *

15. Section 884.2982 is amended by revising paragraph (a)(2) to read as follows:

§ 884.2982 Liquid crystal thermographic system.

(a) * * *

(2) *Classification.* Class I (general controls).

* * * * *

PART 892—RADIOLOGY DEVICES

16. The authority citation for 21 CFR part 892 continues to read as follows:

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

17. Section 892.1100 is amended by revising paragraph (b) to read as follows:

§ 892.1100 Scintillation (gamma) camera.

* * * * *

(b) *Classification.* Class I (general controls).

18. Section 892.1110 is amended by revising paragraph (b) to read as follows:

§ 892.1110 Positron camera.

* * * * *

(b) *Classification.* Class I (general controls).

Dated: August 23, 2001.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 01–22577 Filed 9–7–01; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[PA–4152a; FRL–7050–1]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; VOC and NO_X RACT Determinations for 14 Individual Sources in the Philadelphia-Wilmington-Trenton Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve revisions to the Commonwealth of Pennsylvania's State Implementation Plan (SIP). The revisions were submitted by the Pennsylvania Department of Environmental Protection (PADEP) to establish and require reasonably available control technology (RACT) for 14 major sources of volatile organic compounds (VOC) and/or nitrogen oxides (NO_X). These sources are located in the Philadelphia-Wilmington-Trenton ozone nonattainment area (the Philadelphia area). EPA is approving these revisions to the SIP in accordance with the Clean Air Act (CAA).

DATES: This rule is effective on October 25, 2001, without further notice, unless EPA receives adverse written comment by October 10, 2001. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Written comments should be mailed to David L. Arnold, Chief, Air Quality Planning & Information Services Branch, Air Protection Division, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available 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; the Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and the Pennsylvania Department of Environmental Protection, Bureau of Air Quality Control, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Ray Chalmers at (215) 814–2061, the EPA Region III address above or by e-mail at *chalmers.ray@epa.gov.* Please note that while questions may be posed via telephone and e-mail, formal comments must be submitted, in writing, as indicated in the **ADDRESSES** section of this document.

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to sections 182(b)(2) and 182(f) of the Clean Air Act (CAA), the Commonwealth of Pennsylvania (the Commonwealth or Pennsylvania) is required to establish and implement RACT for all major VOC and NO_X sources. The major source size is determined by its location, the classification of that area and whether it is located in the ozone transport region (OTR). Under section 184 of the CAA, RACT as specified in sections 182(b)(2) and 182(f) applies throughout the OTR. The entire Commonwealth is located within the OTR. Therefore, RACT is applicable statewide in Pennsylvania.

State implementation plan revisions imposing reasonably available control technology (RACT) for three classes of VOC sources are required under section 182(b)(2). The categories are: (1) All sources covered by a Control Technique Guideline (CTG) document issued between November 15, 1990 and the date of attainment; (2) All sources covered by a CTG issued prior to November 15, 1990; (3) All other major non-CTG rules were due by November 15, 1992. The Pennsylvania SIP has approved RACT regulations and requirements for all sources and source categories covered by the CTGs.

On February 4, 1994, PADEP submitted a revision to its SIP to require major sources of NO_X and additional major sources of VOC emissions (not covered by a CTG) to implement RACT. The February 4, 1994 submittal was amended on May 3, 1994 to correct and clarify certain presumptive NO_X RACT requirements. In the Philadelphia area, a major source of VOC is defined as one having the potential to emit 25 tons per year (tpy) or more, and a major source of NO_X is also defined as one having the potential to emit 25 tpy or more. Pennsylvania's RACT regulations require sources, in the Philadelphia area, that have the potential to emit 25 tpy or more of VOC and sources which have the potential to emit 25 tpy or more of NO_X to comply with RACT by May 31, 1995. The regulations contain technology-based or operational ''presumptive RACT emission limitations'' for certain major NO_X sources. For other major NO_X sources, and all major non-CTG VOC sources (not otherwise already subject to RACT under the Pennsylvania SIP), the