Paperwork Reduction Act

This policy statement does not contain new or amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing requirements were approved by the Office of Management and Budget (OMB), Approval Number 3150–0136.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

Congressional Review Act

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs, Office of Management and Budget.

Accordingly, the NRC Enforcement Policy is revised to read as follows:

NRC Enforcement Policy

* * * * *

9.2 Enforcement Discretion for the Minimum Days Off Requirements of § 26.205(d)(3)

This section sets forth the interim policy that the NRC will follow to exercise enforcement discretion for licensees who pursue the alternative approach to the minimum days off (MDO) requirements of § 26.205(d)(3). This alternative approach is consistent with the bases and objectives of 10 CFR part 26, specifically managing cumulative fatigue, and provides licensees improved simplicity and flexibility for work scheduling.

This interim policy is only applicable to licensees who inform the NRC of their intent to adopt the alternative approach. Licensees shall comply with all requirements of Subpart I, as applicable, unless explicitly replaced or amended in this interim policy. The alternative approach to the MDO requirements applies to the work hours of covered individuals [1] during normal (*e.g.,* non-outage/emergency) plant operations. This interim policy will remain in place until the implementation date of a revised final rule associated with the MDO requirements in 10 CFR part 26, subpart I.

A licensee who informs the NRC of its intent to transition to the alternative approach will receive enforcement discretion, and no enforcement action will be taken for the violation of § 26.205(d)(3). If at any time while the licensee is implementing this alternate approach it does not meet the requirements, as stated in this interim policy, the licensee may be in violation of § 26.205(d)(3) and subject to enforcement action. Once a licensee has transitioned to the alternate approach, it has the option to revert back to the requirement of § 26.205(d)(3); however, the licensee is only allowed one opportunity to do so.

A. Actions and Requirements for Transition

A licensee must inform the NRC of its intent to transition to the alternative approach. Notification shall be made via a letter to the respective Regional Administrator and shall identify the implementation date which will be set by the licensee. The hours worked prior to the implementation date, must meet the requirement of § 26.205(d)(3), or enforcement action may be taken. Once the NRC has been notified of the implementation date, the licensee can commence its transition to the alternate approach.

In order to receive continuous enforcement discretion once the alternate approach is implemented, each covered worker is limited to a weekly average of 54 hours worked, calculated using a rolling window of up to 6 weeks. This alternative is not applicable to unit outages or security system outages. Any instance of an individual's average weekly work hours exceeding the requirements for enforcement discretion may result in a violation of the MDO requirements. Typically, an instance of an isolated occurrence or occurrences with limited duration would generally be considered either a minor violation or a non-cited violation.

B. Required Actions for Transition Back to the MDO Requirement

At any time prior to the implementation date of a revised final rule associated with the MDO requirements in 10 CFR part 26, subpart I, "Managing Fatigue," the licensee has the option to transition back to the MDO requirements. However, the licensee has this option only once. The licensee must submit a written notification to the respective Regional Administrator stating that it is reverting back to compliance with the MDO requirements as specified under § 26.205(d)(3), and shall give the NRC advance notice of its transition date. There will be no enforcement action taken on any MDO violations that occurred while the licensee was implementing the alternate approach, unless the licensee failed to meet the requirements as stated in Section 9.2.A of this policy.

Dated at Rockville, Maryland, this 19th day of April 2011.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 2011–9916 Filed 4–22–11; 8:45 am]

BILLING CODE 7590–01–P

[1] The term "covered workers" refers to those individuals indentified in § 26.4(a) who are subject to the requirements in § 26.205.

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

19 CFR part 101

[CBP Dec. 11–08]

Technical Amendment to List of CBP Preclearance Offices in Foreign Countries: Addition of Dublin, Ireland

AGENCY: U.S. Customs and Border Protection, DHS.

ACTION: Final rule; technical amendment.

SUMMARY: This document amends U.S. Customs and Border Protection (CBP) regulations to reflect that U.S. Customs and Border Protection (CBP) has added a preclearance station in Dublin, Ireland. CBP officers at preclearance stations conduct inspections and examinations to ensure compliance with U.S. customs, immigration, and agriculture laws, as well as other laws enforced by CBP at the U.S. border. Such inspections and examinations prior to arrival in the United States generally enable travelers to exit the domestic terminal or connect directly to a U.S. domestic flight without undergoing further CBP processing.

DATES: *Effective Date:* April 25, 2011.

FOR FURTHER INFORMATION CONTACT: Kathleen Conway, Office of Field Operations, Preclearance Operations, (202) 344–1759.

SUPPLEMENTARY INFORMATION:

Background

CBP preclearance operations have been in existence since 1952. Preclearance facilities are established through the cooperative efforts of CBP, foreign government representatives, and the local facility authorities and are evidenced with signed preclearance agreements. Each facility is staffed with CBP officers responsible for conducting

inspections and examinations in connection with preclearing passengers, crew, and their goods bound for the United States. Generally, travelers who are inspected at a preclearance facility are permitted to arrive at a U.S. domestic facility and exit the U.S. domestic terminal upon arrival or connect directly to a U.S. domestic flight without further CBP processing. Preclearance facilities primarily serve to facilitate low risk travelers, relieve passenger congestion at federal inspection facilities in the United States, and enhance security in the air environment through the screening and inspection of travelers prior to their arrival in the United States. In Fiscal Year 2010, over 14 million aircraft travelers were processed at preclearance locations. This figure represents more than 16 percent of all commercial aircraft travelers cleared by CBP in FY 2010.

The Agreement Between the Government of the United States of America and the Government of Ireland on Air Transport Preclearance was signed on November 17, 2008. Preclearance operations began in Dublin, Ireland on January 19, 2011. The Dublin preclearance station is open for use by commercial flights.

Section 101.5 of the CBP regulations (19 CFR 101.5) sets forth a list of CBP preclearance offices in foreign countries. This document amends this section to add Dublin, Ireland to the list of preclearance offices.

Inapplicability of Public Notice and Delayed Effective Date Requirements

This amendment reflects the addition of a new CBP preclearance office that was established through a signed agreement between the United States and the Government of Ireland. Accordingly, pursuant to 5 U.S.C. 553(b)(B), notice and public procedure are unnecessary. For the same reason, pursuant to 5 U.S.C. 553(d)(3), a delayed effective date is not required.

The Regulatory Flexibility Act and Executive Order 12866

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) do not apply. This amendment does not meet the criteria for a "significant regulatory action" as specified in Executive Order 12866.

Signing Authority

This document is being issued in accordance with 19 CFR 0.2(a).

List of Subjects in 19 CFR Part 101

Customs duties and inspection, Customs ports of entry, Foreign trade statistics, Imports, Organization and functions (Government agencies), Shipments, Vessels.

Amendments to Regulations

For the reasons set forth above, Part 101 of the Code of Federal Regulations (19 CFR part 101), is amended as set forth below.

PART 101—GENERAL PROVISIONS

■ 1. The general authority citation for part 101 and the specific authority citation for section 101.5 continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 2, 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1623, 1624, 1646a.

* * * * *

Section 101.5 also issued under 19 U.S.C. 1629.

* * * * *

■ 2. Revise § 101.5 to read as follows:

§ 101.5 CBP preclearance offices in foreign countries.

Listed below are the preclearance offices in foreign countries where CBP officers are located. A Director, Preclearance, located in the Office of Field Operations at CBP Headquarters, is the responsible CBP officer exercising supervisory control over all preclearance offices.

Country	CBP office
Aruba	Orangestad.
The Bahamas	Freeport.
	Nassau.
Bermuda	Kindley Field.
Canada	Calgary, Alberta.
	Edmonton, Alberta.
	Halifax, Nova Scotia.
	Montreal, Quebec.
	Ottawa, Ontario.
	Toronto, Ontario.
	Vancouver, British Columbia.
	Winnipeg, Manitoba.
Ireland	Dublin.
	Shannon.

Dated: February 11, 2011.

Alan D. Bersin,

Commissioner, U.S. Customs and Border Protection.

[FR Doc. 2011–9883 Filed 4–22–11; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2006–N–0045] (Formerly Docket No. 2006N–0109)

Medical Devices; Reclassification of the Topical Oxygen Chamber for Extremities

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying the topical oxygen chamber for extremities (TOCE) from class III to class II. This device is intended to surround a patient's limb and apply humidified oxygen topically at a pressure slightly greater than atmospheric pressure to aid healing of chronic skin ulcers, such as bedsores. This reclassification is on the Secretary of Health and Human Services's own initiative based on new information. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) as amended by the Medical Device Amendments of 1976 (the 1976 Amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document entitled "Class II Special Controls Guidance Document: Topical Oxygen Chamber for Extremities," which will serve as the special control for this device.

DATES: This rule is effective May 25, 2011.

FOR FURTHER INFORMATION CONTACT: Charles N. Durfor, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3555.

SUPPLEMENTARY INFORMATION:

I. Background

The FD&C Act (21 U.S.C. 301 *et seq.*), as amended by the 1976 Amendments (Pub. L. 94–295), the SMDA (Pub. L. 101–629), and the FDAMA (Pub. L. 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and