body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL ND E5 Tioga, ND [New]

Tioga Municipal Airport, ND
(Lat. 48°22′30″N., long. 102°53′51″W.)
Minot AFB, ND
(Lat. 48°24′56″N., long. 101°21′28″W.)
Williston VORTAC
(Lat. 48°15′12″N., long. 103°45′02″W.)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of the Tioga Municipal Airport and that airspace within 2 miles either side of the 133° bearing from the Tioga Municipal Airport extending from the 6.7-mile radius to 9.4 miles southeast of the airport; and that airspace extending upward from 1,200 feet above the surface bounded on the north by latitude 49°00′00″N., on the east by the 47.0-mile radius of Minot AFB, on the south by V–430, on the southwest by the 21.8-mile radius of the Williston VORTAC and on the west by the north Dakota/Montana state boundary.

* * * * *

Issued in Des Plaines, Illinois on July 29, 1998.

Richard K. Petersen,

Acting Assistant Manager, Air Traffic Division.

[FR Doc. 98–21472 Filed 8–10–98; 8:45 am]

BILLING CODE 4910–13–M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1610

Policy Statement—Reasonable and Representative Testing To Assure Compliance With The Standard for the Flammability of Clothing Textiles

AGENCY: Consumer Product Safety Commission.

ACTION: Interpretation and policy statement; final rule.

SUMMARY: The U.S. Consumer Product Safety Commission (CPSC) issues this guidance to notify manufacturers, importers, distributors, and retailers of fabric and garments of factors that the Commission considers in deciding whether to seek civil penalties for violations of the Standard for the Flammability of Clothing Textiles (General Wearing Apparel), 16 CFR part 1610.

DATES: Effective August 11, 1998.

FOR FURTHER INFORMATION CONTACT: Marilyn Borsari, Compliance Officer, Office of Compliance, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0608, extension, 1370 or e-mail mborsari@cpsc.gov.

SUPPLEMENTARY INFORMATION:

Introduction

The U.S. Consumer Product Safety Commission (CPSC) issues the following policy statement to provide guidance to manufacturers, importers, distributors, and retailers of factors the Commission considers in deciding whether to seek civil penalties for violations of the Standard for the Flammability of Clothing Textiles (General Wearing Apparel). CPSC adds this policy statement as Section 1610.62 of Subpart C of Part 1610, Chapter II, Title 16, Code of Federal Regulations. Since this document is interpretative and a general statement of policy, it is exempt from the requirement of 5 U.S.C. 553(b) for a general notice of proposed rulemaking and from the requirement of 5 U.S.C. 553(c) for an opportunity for public comments. It is also exempt from the requirement of 5 U.S.C. 553(d) for a 30-day delay in the effective date of the policy. Accordingly, the policy will become effective August 11, 1998.

Applicable Executive Orders and Statutes

This policy has been evaluated for federalism implications in accordance with Executive Order No. 12,612, and the policy raises no substantial federalism concerns.

The policy has also been evaluated under Executive Order No. 12,898, and it does not have any of the exclusionary effects specified in that order.

The policy also has been evaluated under Executive Order No. 12,988. The policy is not a ''flammability standard or other regulation for a fabric, related material, or product'' that would have a preemptive effect under 15 U.S.C. 1203.

The policy is not expected to have any environmental effects. Therefore, an environmental assessment is not required.

The policy is not a ''covered regulatory action'' as that term is defined in Executive Order No. 13,045.

This policy is not a ''rule'' as defined in 5 U.S.C. 804(3). Accordingly, 5 U.S.C. 801–808 does not require a report to Congress.

List of Subjects in 16 CFR Part 1610

Clothing, Consumer protection, Flammable materials, Reporting and recordkeeping requirements, Textiles, Warranties.

For the reasons set forth in the preamble, the CPSC amends 16 CFR part 1610 as follows:

PART 1610—STANDARD FOR THE FLAMMABILITY OF CLOTHING TEXTILES

1. The authority citation for part 1610 is amended to read as follows:

Authority: 16 U.S.C. 1191–1204.

2. Add § 1610.62 to read as follows:

§ 1610.62 Reasonable and representative testing to assure compliance with the standard for the clothing textiles.

(a) *Background.* (1) The CPSC administers the Flammable Fabrics Act (FFA), 15 U.S.C. 1191–1204. Under the FFA, among other things, the Commission enforces the Flammability Standard for Clothing Textiles (the ''general wearing apparel standard''), 16 CFR Part 1610. That standard establishes requirements for the flammability of clothing and textiles

intended to be used for clothing (hereinafter ''textiles'').

(2) The general wearing apparel standard applies both to fabrics and finished garments. The standard provides methods of testing the flammability of textiles, and sets forth the requirements that textiles must meet to be classified into one of three classes of flammability (classes 1, 2 and 3). 16 CFR 1610.2. Class 1 textiles, those that exhibit normal flammability, are acceptable for use in clothing. 16 CFR 1610.3(a)(1). Class 2 textiles, applicable only to raised fiber surfaces, are considered to be of intermediate flammability, but may be used in clothing. 16 CFR 1610.3(a)(2). Finally, class 3 textiles, those that exhibit rapid and intense burning, are dangerously flammable and may not be used in clothing. 16 CFR 1610.3(a)(3). The manufacture for sale, offering for sale, importation into the U.S., and introduction or delivery for introduction of Class 3 articles of wearing apparel are among the acts prohibited by section 3(a) of the FFA, 15 U.S.C. 1192(a).

(3) CPSC currently uses retail surveillance, attends appropriate trade shows, follows up on reports of noncompliance and previous violations, and works with U.S. Customs in an effort to find textiles that violate CPSC's standards. The Commission has a number of enforcement options to address prohibited acts. These include bringing seizure actions in federal district court against violative textiles, seeking an order through an administrative proceeding that a firm cease and desist from selling violative garments, pursuing criminal penalties, or seeking the imposition of civil penalties for ''knowing'' violations of the FFA. Of particular relevance to the latter two remedies are whether reasonable and representative tests were performed demonstrating that a textile or garment meets the flammability standards for general wearing apparel. Persons who willfully violate flammability standards are subject to criminal penalties.

(4) Section 8(a) of the FFA, 15 U.S.C. 1197(a), exempts a firm from the imposition of criminal penalties if the firm establishes that a guaranty was received in good faith signed by and containing the name and address of the person who manufactured the guarantied wearing apparel or textiles or from whom the apparel or textiles were received. A guaranty issued by a person who is not a resident of the United States may not be relied upon as a bar to prosecution. 16 CFR 1608.4. The guaranty must be based on the exempted types of fabrics or on reasonable and representative tests showing that the fabric covered by the guaranty or used in the wearing apparel covered by the guaranty is not so highly flammable as to be dangerous when worn by individuals, *i.e.*, is not a class 3 material.[1] Under 16 CFR 1610.37, a person, to issue a guaranty, should first evaluate the type of fabric to determine if it meets testing exemptions (16 CFR 1610.37(d));[2] if not, the person issuing the guaranty must devise and implement a program of reasonable and representative tests to support the guaranty. The number of tests and frequency of testing is left to the discretion of that person, but at least one test is required.

(5) In determining whether a firm has committed a ''knowing'' violation of a flammability standard that warrants imposition of a civil penalty, the CPSC considers whether the firm had actual knowledge that its products violated the flammability requirements. The CPSC also considers whether the firm should be presumed to have the knowledge that would be possessed by a reasonable person acting in the circumstances, including knowledge that would have been obtainable upon the exercise of due care to ascertain the truth of representations. 15 U.S.C. 1194(e). The existence of results of flammability testing based on a reasonable and representative program and, in the case of tests performed by another entity (such as a guarantor), the steps, if any, that the firm took to verify the existence and reliability of such tests, bear directly on whether the firm acted reasonably in the circumstances.

(b) *Applicability.* (1) When tested for flammability, a small number of textile products exhibit variability in the test results; that is, even though they may exhibit class 1 or class 2 burning characteristics in one test, a third test may result in a class 3 failure. Violative products that the Commission has discovered since 1994 include sheer 100% rayon skirts and scarves; sheer 100% silk scarves; 100% rayon chenille sweaters; rayon/nylon chenille and long hair sweaters; polyester/cotton and 100% cotton fleece/sherpa garments, and 100% cotton terry cloth robes. Since August 1994, there have been 21 recalls of such dangerously flammable clothing, and six retailers have paid civil penalties to settle Commission staff allegations that they knowingly sold garments that violated the general wearing apparel standard.

(2) The violations and resulting recalls and civil penalties demonstrate the critical necessity for manufacturers, distributors, importers, and retailers to evaluate, prior to sale, the flammability of garments made from the materials described above, or to seek appropriate guaranties that assure that the garments comply. Because of the likelihood of variable flammability in the small group of textiles identified above, one test is insufficient to assure reasonably that these products comply with the flammability standards. Rather, a person seeking to evaluate garments made of such materials should assure that the program tests a sufficient number of samples to provide adequate assurance that such textile products comply with the general wearing apparel standard. The number of samples to be tested, and the corresponding degree of confidence that products tested will comply, are to be specified by the individual designing the test program. However, in assessing the reasonableness of a test program, the Commission staff will specifically consider the degree of confidence that the program provides.

(c) *Suggestions.* The following are some suggestions to assist in complying with the general wearing apparel standard:

(1) Purchase fabrics or garments that meet testing exemptions listed in 16 CFR 1610.37(d). (If buyers or other personnel do not have skills to determine if the fabric is exempted, hire a textile consultant or a test lab for an evaluation.)

(2) For fabrics that are not exempt, conduct reasonable and representative testing before cutting and sewing, using standard operating characteristic curves for acceptance sampling to determine a sufficient number of tests.

(3) Purchase fabrics or garments that have been guarantied and/or tested by the supplier using a reasonable and representative test program that uses standard operating characteristic curves for acceptance sampling to determine a sufficient number of tests. Firms should also receive and maintain a copy of the guaranty.

(4) Periodically verify that your suppliers are actually conducting appropriate testing.

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[1] The person proffering a guaranty to the Commission must also not, by further processing, have affected the flammability of the fabric, related material or product covered by the guaranty that was received.

[2] Some textiles never exhibit unusual burning characteristics and need not be tested. 16 CFR 1610.37(d). Such textiles include plain surface fabrics, regardless of fiber content, weighing 2.6 oz. or more per sq. yd., and plain and raised surface fabrics made of acrylic, modacrylic, nylon, olefin, polyester, wool, or any combination of these fibers, regardless of weight.

Dated: August 5, 1998.

Sadye Dunn,

Secretary to the Commission.

[FR Doc. 98–21387 Filed 8–10–98; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 814

[Docket No. 98N–0168]

Medical Devices; 30–Day Notices and 135–Day PMA Supplement Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) published, in the **Federal Register** of April 27, 1998 (63 FR 20530), a direct final rule to implement the amendments to the premarket approval provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). The comment period closed on July 13, 1998. FDA is withdrawing the direct final rule because the agency received significant adverse comment.

DATES: The direct final rule published at 63 FR 20530, April 27, 1998, is withdrawn on August 11, 1998.

FOR FURTHER INFORMATION CONTACT: Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the direct final rule published on April 27, 1998, at 63 FR 20530 is withdrawn.

Dated: August 5, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–21470 Filed 8–10–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Parts 250 and 253

RIN 1010–AC33

Oil Spill Financial Responsibility for Offshore Facilities

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Final rule.

SUMMARY: This final regulation establishes new requirements for demonstrating oil spill financial responsibility (OSFR) for removal costs and damages caused by oil discharges and substantial threats of oil discharges from oil and gas exploration and production facilities and associated pipelines. This rule applies to the Outer Continental Shelf (OCS), State waters seaward of the line of ordinary low water along that portion of the coast that is in direct contact with the open sea, and certain coastal inland waters. This rule implements the authority of the Oil Pollution Act (OPA) of 1990.

DATES: This final regulation is effective October 13, 1998. However, the information collection aspects of this rule will not become effective until approved by the Office of Management and Budget (OMB). MMS will publish a document at that time in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Steve Waddell, Adjudication Unit Supervisor, at (504) 736–1710.

SUPPLEMENTARY INFORMATION: Title I of OPA (33 U.S.C. 2701 *et seq.*), as amended by section 1125 of the Coast Guard Authorization Act of 1996 (Pub. L. 104–324), provides at section 1016 that parties responsible for offshore facilities must establish and maintain OSFR for those facilities according to methods determined acceptable to the President. Section 1016 supersedes the OSFR provisions of the Outer Continental Shelf Lands Act (OCSLA). The Executive Order (E.O.) implementing OPA (E.O. 12777; October 18, 1991) assigned the OSFR certification function to the Department of the Interior (DOI). The Secretary of the Interior, in turn, delegated this function to MMS.

This regulation replaces the current OSFR regulation at 33 CFR part 135, which was written to implement the OCSLA. The OCSLA regulation is limited to facilities located in the OCS and sets the amount of OSFR that must be demonstrated by responsible parties at $35 million. The regulation published today covers both the OCS and certain State waters. The regulation requires responsible parties to demonstrate as much as $150 million in OSFR if MMS determines that it is justified by the risks from potential oil spills from covered offshore facilities (COFs).

The minimum amount of OSFR that must be demonstrated is $35 million for COFs located in the OCS and $10 million for COFs located in State waters. The regulation provides an exemption for persons responsible for facilities having a potential worst case oil-spill discharge of 1,000 barrels (bbls) or less, unless the risks posed by a facility justify a lower threshold volume.

Background

The existing OSFR program for offshore facilities was developed under Title III of the OCSLA and initially administered by the U.S. Coast Guard (USCG). OPA replaced and rescinded the OCSLA OSFR requirements. However, section 1016(h) of OPA provides that any regulation relating to OSFR remains in force until superseded by a new regulation issued under OPA. The OSFR regulations for offshore facilities in the OCS (33 CFR part 135) will be phased out according to the timetable specified in § 253.44.

The Secretary of Transportation has authority for vessel oil pollution financial responsibility, and the USCG regulates the oil-spill financial responsibility program for vessels. A mobile offshore drilling unit (MODU) is classified as a vessel. However, a well drilled from a MODU is classified as an offshore facility under this rule.

Upon request from the USCG, MMS will provide available information for any COF involved in an oil pollution incident (i.e., oil-spill discharge or a substantial threat of a discharge) including:

(1) The lease, permit, or right-of-use and easement (RUE) for the area in which the COF is located;

(2) The designated applicant and guarantors and their contacts for claims;

(3) U.S. agents for service of process;

(4) Amounts indemnified; and

(5) List of all responsible parties.

Analysis of Comments on the Proposed Rule and Changes for the Final Rule

A Notice of Proposed Rulemaking (NPR) was published on March 25, 1997 (62 FR 14052–14079). We received 28 written comments. We also received oral comments during a public workshop on the proposed rule that MMS sponsored in New Orleans, Louisiana, on June 5, 1997. All of the comments were considered in developing this final regulation. The