

rule) for which structure/function claims should not be permitted? If so, why and on what basis?

3. What is the potential for harm that may be associated with the use of dietary supplements during pregnancy for conditions unrelated to pregnancy?

4. Are there means to address safety concerns associated with dietary supplement use during pregnancy, for example, a requirement to conduct animal studies or collect human safety information?

5. Should dietary supplements with a specific recommended use during pregnancy be required to bear specific warnings about use during pregnancy? Should all dietary supplements be required to bear such warnings?

FDA will post any additional questions to be addressed on the Internet at <http://www.fda.gov/cder/calendar/meeting/pregsup2000/default.htm>.

Dated: February 16, 2000.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

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## DEPARTMENT OF THE INTERIOR

### Minerals Management Service

#### 30 CFR Part 250

RIN 1010-AC66

#### Oil and Gas and Sulphur Operations in the Outer Continental Shelf; Update of International Organization for Standardization Documents Incorporated by Reference

**AGENCY:** Minerals Management Service (MMS), Interior.

**ACTION:** Proposed rule.

**SUMMARY:** The MMS is proposing to remove API Specification 14A and replace it with a new document incorporated by reference in regulations governing oil and gas and sulphur operations in the Outer Continental Shelf (OCS). The addition of this document incorporated by reference will ensure that lessees use the best available and safest technologies while operating in the OCS. The proposed new document has been issued by the International Organization for Standardization (ISO) and is an international standard titled: "Petroleum and natural gas industries—Downhole equipment—Subsurface safety valve equipment" (ISO 10432:1999, otherwise known as API/ISO 10432:1999).

**DATES:** We will consider all comments we receive by May 24, 2000. We will begin reviewing comments then and may not fully consider comments we receive after May 24, 2000.

**ADDRESSES:** Mail or hand-carry comments (three copies) to the Department of the Interior; Minerals Management Service; Mail Stop 4024; 381 Elden Street; Herndon, Virginia 20170-4817; Attention: Rules Processing Team. The Rules Processing Team's e-mail address is: [rules.comments@mms.gov](mailto:rules.comments@mms.gov).

**FOR FURTHER INFORMATION CONTACT:** Fred Gray, Operations Analysis Branch, at (703) 787-1027.

**SUPPLEMENTARY INFORMATION:** We use standards, specifications, and recommended practices developed by standard-setting organizations and the oil and gas industry for establishing requirements for activities in the OCS. This practice, known as incorporation by reference, allows us to incorporate the provisions of technical standards into the regulations without increasing the volume of the Code of Federal Regulations (CFR). The legal effect of incorporation by reference is that the material is treated as if it was published in the **Federal Register**. This material, like any other properly issued regulation, then has the force and effect of law. We hold operators/lessees accountable for complying with the documents incorporated by reference in our regulations. We currently incorporate by reference 85 private sector consensus standards into the offshore operating regulations.

The regulations found at 1 CFR part 51 govern how we and other Federal agencies incorporate various documents by reference. Agencies can only incorporate by reference through publication in the **Federal Register**. Agencies must also gain approval from the Director of the Federal Register for each publication incorporated by reference. Incorporation by reference of a document or publication is limited to the specific edition or specific edition and supplement or addendum cited in the regulations.

ISO is a worldwide federation of national standards bodies (ISO member bodies). Founded in the mid 1940s, ISO is a non-profit agency based in Geneva, Switzerland, whose purpose is to promote the development of international standards and related activities to facilitate the global exchange of goods and services. The American National Standards Institute (ANSI) is the official United States member body to ISO.

The work of preparing international standards is normally carried out through an ISO technical committee (TC). Each member body interested in a subject for which a TC has been established has the right to be represented on that committee. ANSI relies on various United States trade and industry associations, such as the American Petroleum Institute (API), for support on industry specific standards. This standard was developed by ISO/TC 67, "Materials, equipment and offshore structures for petroleum and natural gas industries." API has been appointed by ANSI to administer the U.S. ISO/TC 67 delegation, known as the U.S. Technical Advisory Group (U.S.TAG). MMS has been an active participant in the U.S. TAG since August 1998.

This second edition of the international standard cancels and replaces the first edition (ISO 10432:1993) and includes the changes in the similar API standard, API Specification 14A, Ninth edition, 1994, and its supplement dated December 15, 1997. ISO 10432:1999 was released as a Final Draft International Standard (FDIS) on June 3, 1999. Voting to advance the FDIS to a full international standard occurred on August 3, 1999, and the standard was published as an international standard in November 1999.

This standard was formulated to provide the minimum acceptable requirements for subsurface safety valve (SSSV) equipment—the SSSV is a downhole safety device used to shut off flow of hydrocarbons in the event of an emergency. MMS views this important piece of equipment as the last line of defense in securing the well and/or preventing pollution of the environment. The standard covers SSSVs, safety valve locks, safety valve landing nipples, and all components that establish tolerances and/or clearances that may affect performance or interchangeability of the SSSV equipment.

We have reviewed this document and have determined that the new edition should be incorporated into the regulations to ensure the use of the best and safest technologies. We currently incorporate by reference the ninth edition (July 1994) of API Specification 14A, without Supplement 1. Until now we have not included API Specification 14A, Supplement 1, in the documents incorporated by reference in our regulations. API Specification 14A, Supplement 1, includes editorial corrections, changes, and revisions approved by the API Subcommittee on Valves and Wellhead Equipment. The revisions strengthened guidelines for

equipment changes that affect requalification testing, added new definitions to clarify the revised design change language, and deleted a 3-year requalification testing requirement for SSSVs.

MMS has been analyzing the potential impacts of deleting the 3-year requalification testing requirement for SSSVs and specifically requests public comment on this issue. MMS has been involved in a series of meetings and discussions with oil and gas operating companies, representatives of oil and gas associations, equipment manufacturers, quality assurance auditors, independent third-party testing and research facilities, and MMS offshore inspectors to consider the relative merits of the 3-year requalification testing requirement. Our data gathering indicates that manufacturers of SSSVs perform functional testing of each valve manufactured and each valve must pass all test criteria before shipment to a purchaser. Functionally testing every valve produces volumes of data and is a good indicator of product conformity, design efficiency, quality procedures, and safety effectiveness. The requalification testing process, conducted on a single valve once every 3 years, provides significantly less data and does not address safety considerations in each manufactured valve.

It is anticipated that API will adopt ISO 10432:1999 as the API/ISO standard. Since maintaining one standard is more resource efficient than maintaining two in parallel, it is also anticipated that all future revisions to the SSSV standard will be made to API/ISO 10432:1999. MMS sees value in developing international standards and is supportive of harmonization of technical standards worldwide where practical. If MMS issues a final rulemaking to incorporate by reference ISO 10432:1999 (API/ISO 10432:1999) into our regulations, we will simultaneously remove API Specification 14A from the documents we incorporate by reference.

Comments are sought on the suitability of including the international standard among the documents incorporated by reference in our regulations.

#### **Procedural Matters**

This is a very simple rule to add one additional document incorporated by reference. The addition of the new document, ISO 10432:1999 (API/ISO 10432:1999), will not have a significant effect on any entity (small or large). One entity which serves as a third party

independent testing facility for initial design verification testing and subsequent 3-year requalification design testing will be affected. Therefore, this regulation's impact on the entire industry is minor.

#### **Public Comment Procedure**

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the rulemaking record, which we will honor to the extent allowable by law. There may be circumstances in which we would withhold from the rulemaking record a respondent's identity, as allowable by the law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses available for public inspection in their entirety.

#### **Federalism (Executive Order 13132)**

According to Executive Order 13132, this rule does not have Federalism implications. This rule does not substantially and directly affect the relationship between the Federal and State governments because it concerns the manufacturing requirements for specific equipment used in offshore oil and gas wells. The rule only affects manufacturers and users of such equipment. This rule does not impose costs on States or localities, as it only affects manufacturers and users of specific equipment used in offshore oil and gas wells.

#### **Takings Implication Assessment (Executive Order 12630)**

According to Executive Order 12630, this rule does not have significant Takings Implications.

#### **Regulatory Planning and Review (Executive Order 12866)**

This document is not a significant rule and is not subject to review by the Office of Management and Budget under Executive Order 12866.

(1) This rule will not have an effect of \$100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

The rule would have no significant economic impact because the document does not contain any significant revisions that will cause lessees or operators to change their business practices. The document will not require the retrofitting of any facilities.

(2) This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

(3) This rule does not alter the budgetary effects or entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients.

(4) This rule does not raise novel legal or policy issues.

#### **Civil Justice Reform (Executive Order 12988)**

According to Executive Order 12988, the Office of the Solicitor has determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

#### **National Environmental Policy Act (NEPA) of 1969**

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the NEPA is not required.

#### **Paperwork Reduction Act of 1995**

There are no information collection requirements associated with this rule.

#### **Regulatory Flexibility Act**

The Department certifies that this document 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.*). In general, the entities that engage in offshore activities are not considered small due to the technical and financial resources and experience necessary to safely conduct such activities. Incorporating the new document into MMS regulations would allow SSSVs with design verification approval to be manufactured and placed into service without the need for requalification testing every 3 years. Thus, incorporating the new document will not impose new cost on the offshore oil and gas industry but rather the new document will reduce the costs to the offshore oil and gas industry by decreasing the costs of the newly manufactured SSSVs, in that manufacturers of SSSVs will not incur the costs of requalification testing every 3-years. The Department also determined that the indirect effects of this rule on small entities that provide

support for offshore activities are small (in effect zero).

Your comments are important. The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small business about Federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the enforcement actions of MMS, call toll-free (888) 734-3247.

**Small Business Regulatory Enforcement Fairness Act (SBREFA)**

This rule is not a major rule under 5 U.S.C. 804(2), SBREFA. This rule:

(a) Does not have an annual effect on the economy of \$100 million or more. The proposed rule will not cause any significant costs to lessees or operators. The only costs will be the purchase of the new document and revisions to some operating procedures. The revisions to operating procedures will actually result in significant costs savings, in that manufacturers of SSSVs will not incur the costs of requalification testing every 3-years.

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises.

**Unfunded Mandates Reform Act (UMRA) of 1995**

This rule does not impose an unfunded mandate on State, local, and 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 UMRA (2 U.S.C. 1531 *et seq.*) is not required.

**List of Subjects in 30 CFR Part 250**

Continental shelf, Environmental impact statements, Environmental protection, Government contracts, Incorporation by reference, Investigations, Mineral royalties, Oil and gas development and production, Oil and gas exploration, Oil and gas

reserves, Penalties, Pipelines, Public lands—mineral resources, Public lands—rights-of-way, Reporting and recordkeeping requirements, Sulphur development and production, Sulphur exploration, Surety bonds.

Dated: February 8, 2000.

**Sylvia V. Baca,**  
*Acting Assistant Secretary, Land and Minerals Management.*

For the reasons stated in the preamble, the MMS proposes to amend 30 CFR Part 250 as follows:

**PART 250—OIL AND GAS AND SULPHUR OPERATIONS IN THE OUTER CONTINENTAL SHELF**

1. The authority citation for part 250 continues to read as follows:

**Authority:** 43 U.S.C. 1331, *et seq.*

2. In § 250.198, in the table in paragraph (e), the entry for “API Spec 14A” is removed and a new entry is added in alphanumerical order to read as follows:

**§ 250.198 Documents incorporated by reference.**

\* \* \* \* \*

(e) \* \* \*

Title of documents					Incorporated by reference at
*	*	*	*	*	*
ISO/FIS 10432 (1999), Petroleum and natural gas industries—Downhole equipment—Subsurface safety valve equipment ...					§ 250.806(a)(3).
*	*	*	*	*	*

3. In § 250.806, the last sentence in paragraph (a)(3) is revised to read as follows:

**§ 250.806 Safety and pollution prevention equipment quality assurance requirements.**

(a) \* \* \*

(3)\* \* \* All SSSVs must meet the technical specifications of ISO/FIS 10432 (1999) (API/ISO 10432:1999).

\* \* \* \* \*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 165**

**[OPP-190001C; FRL-6495-4]**

**RIN 2070-AB95**

**Standards for Pesticide Containers and Containment; Reopening of Comment Period**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule; reopening of comment period.

**SUMMARY:** On October 21, 1999 (64 FR 56918), EPA reopened the comment period on the proposed rule “Standards for Pesticide Containers and Containment” (59 FR 6712, February 11, 1994) to obtain comment on four specific issues. On December 21, 1999, EPA published a notice in the **Federal Register** to extend the comment period

by 60 days until February 19, 2000. EPA is now reopening the comment period for an additional 30 days until March 20, 2000. The October 21, 1999 notice solicited comments on potential changes that would reduce the scope of the container standards, add an exemption for certain antimicrobial pesticides, and adopt some of the Department of Transportation (DOT) hazardous materials regulations. That notice also requested comments on the definition for small business used to identify small pesticide formulators, agrichemical dealers and commercial pesticide applicators in the small entity impact analysis. These potential changes, if adopted in the final rule, would support EPA's goal of pollution prevention by promoting the use of refillable containers and would harmonize and promote consistency within the Federal packaging standards by adopting the DOT standards. In addition, the changes would decrease