

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 will relieve a burden and simplify the marketing of these devices, 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.

VI. Paperwork Reduction Act of 1995

FDA concludes that 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.

VII. 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 order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 876

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 876 is amended as follows:

PART 876—GASTROENTEROLOGY—UROLOGY DEVICES

1. The authority citation for 21 CFR part 876 continues to read as follows:

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

2. Section 876.5980 is amended by revising paragraph (b)(1) to read as follows:

§ 876.5980 Gastrointestinal tube and accessories.

(b) *Classification.* (1) Class II (special controls). The barium enema retention catheter and tip with or without a bag that is a gastrointestinal tube and accessory is exempt from the premarket notification procedures in subpart E of

this part subject to the limitations in § 876.9.

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Dated: December 3, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8889]

RIN 1545-AV10

Guidance Regarding Claims for Certain Income Tax Convention Benefits; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final regulations.

SUMMARY: This document contains corrections to final regulations (TD 8889) which were published in the **Federal Register** on Monday, July 3, 2000 (65 FR 40993). The final regulations relate to claims for certain income tax convention benefits.

DATES: This correction is effective July 3, 2000.

FOR FURTHER INFORMATION CONTACT: Shawn R. Pringle (202) 622-3850 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are subject to these corrections are under section 894 of the Internal Revenue Code.

Need for Correction

As published, final regulations (TD 8889) contains errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of final regulations (TD 8889), which was the subject of FR Doc. 00-16761, is corrected as follows:

1. On page 40996, column 2, in the preamble under the paragraph heading "D. Treatment of Complex Trusts", paragraph 2, line 13 from the bottom of the paragraph, the language "the hands of the interest holder are" is corrected to read "the hands of the interest holder are not".

2. One page 40997, column 1, in the preamble under the paragraph heading "Special Analyses", paragraph 1, line 2,

the language "treasury decision not a significant" is corrected to read "Treasury decision is not a significant".

§ 1.894-1 [Corrected]

3. On page 40997, column 1, correct the amendatory instruction for Par. 2. to read as follows:

Par. 2. Section 1.894-1 is amended as follows:

1. Paragraph (d) is redesignated as paragraph (e), and a new paragraph (d) is added.

2. In newly designated paragraph (e), add a sentence at the end of the paragraph.

The additions read as follows:

4. On page 40999, column 2, § 1.894-1(d)(5), paragraph (i) of *Example 7.*, line 10, the language "legal personality of the arrangement, A is not" is corrected to read "legal personality in Country X of the arrangement, A is not".

5. On page 40999, column 2, § 1.894-1(d)(5), paragraph (i) of *Example 7.*, lines 11 and 12, the language "liable to tax at the entity level of Country X and is not a resident within the meaning of" is corrected to read "liable to tax as a person at the entity level in Country X and is thus not a resident within the meaning of".

6. On page 40999, column 2, § 1.894-1(d)(5), paragraph (ii) of *Example 7.*, line 9, the language "is not considered a resident of Country X" is corrected to read "is not considered a person in Country X and thus not a resident of Country X".

7. On page 40999, column 2, § 1.894-1(d)(5), paragraph (ii) of *Example 7.*, line 12, the language "derive the income for purposes of the U.S.-" is corrected to read "derive the income as a resident of Country X for purposes of the U.S.-".

8. On page 41000, column 1, § 1.894-1(d)(5), paragraph (i) of *Example 11.*, the last line of the paragraph, the language "subject to tax by Country X." is corrected to read "taxed by Country X."

9. On page 41000, column 2, § 1.894-1, after paragraph (d)(6), add a sentence at the end of paragraph (e) to read as follows:

§ 1.894-1 Income affected by treaty.

* * * * *

(e) * * * See paragraph (d)(6) of this section for applicability dates for paragraph (d) of this section.

10. On page 41000, column 2, a new amendatory instruction Par. 3. is added to read as follows:

§ 1.894–1T [Removed]

Par. 3. Section 1.894–1T is removed.

Cynthia E. Grigsby,

Chief, Regulations Unit, Office of Special Counsel (Modernization & Strategic Planning).

[FR Doc. 00–31255 Filed 12–7–00; 8:45 am]

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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 Documents Incorporated by Reference—API Specification 14A, Tenth Edition

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Final rule.

SUMMARY: MMS is updating one document incorporated by reference in regulations governing oil and gas and sulphur operations in the Outer Continental Shelf (OCS). The new edition of this document incorporated by reference will ensure that lessees use the best available and safest technologies while operating in the OCS. The updated document, issued by the American Petroleum Institute (API), is API Specification 14A, Tenth Edition, November 2000, ISO 10432:1999, Petroleum and natural gas industries—Downhole equipment—Subsurface safety valve equipment, Stock No. G14A09.

DATES: This rule is effective January 8, 2001. The incorporation by reference of publications listed in the regulation is approved by the Director of the Federal Register as of January 8, 2001.

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. The regulations found at 1 CFR part 51 govern how MMS 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.

The International Organization for Standardization (ISO) is a worldwide federation of national standards bodies (ISO member bodies). Founded in the mid-1940's, 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 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 US ISO/TC 67 delegation, known as the US Technical Advisory Group (US TAG). MMS has been an active participant in the US 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.

ISO permits a national adoption of its international standards with or without the inclusion of regional-specific annexes to account for regional or local conditions. The API procedures to effect the adoption of this international standard with a regional annex included a balloting and comment period to ensure consensus among users, manufacturers, regulatory agencies, and other interested parties. API balloting of the international standard with U.S. annexes, including an annex addressing the API quality specification and an independent test agency, occurred on June 9, 2000, and the API version of the international standard was published in October 2000.

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 oil and gas in the event of an emergency. MMS views this important piece of equipment as the last opportunity to secure the well and/or prevent 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 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. Among other things, API Specification 14A, Supplement 1, deleted a 3-year requalification test requirement for SSSVs.

We have 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 test requirement. We specifically requested public comment on the potential impacts of deleting the 3-year requalification testing requirement for SSSVs in the Notice of Proposed Rulemaking (65 FR 9232) published in the **Federal Register** on February 24, 2000. Comments were also sought on the suitability of including an international standard among the documents incorporated by reference in our regulations.

In response to our request for public comment on the 3-year requalification test requirement, we received five comments supportive of deleting the 3-