

License Requirements

REASON FOR CONTROL: NS, AT, EI

Control(s)	Country chart
NS applies to entire entry.	NS Column 1.
AT applies to entire entry.	AT Column 1.

EI applies to encryption items transferred from the U.S. Munitions List to the Commerce Control List consistent with E.O. 13026 of November 15, 1996 (61 FR 58767) and pursuant to the Presidential Memorandum of that date. Refer to § 742.15 of this subchapter.

* * * * *

5D002 Information Security—"Software".

License Requirements

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EI applies to encryption items transferred from the U.S. Munitions List to the Commerce Control List consistent with E.O. 13026 of November 15, 1996 (61 FR 58767) and pursuant to the Presidential Memorandum of that date. Refer to § 742.15 of the EAR.

Note: Encryption software is controlled because of its functional capacity, and not because of any informational value of such software; such software is not accorded the same treatment under the EAR as other "software"; and for export licensing purposes, encryption software is treated under the EAR in the same manner as a commodity included in ECCN 5A002. License Exceptions for commodities are not applicable.

Note: Encryption software controlled for EI reasons under this entry remains subject to the EAR even when made publicly available in accordance with part 734 of the EAR, and it is not eligible for the General Software Note ("mass market" treatment under License Exception TSU for mass market software). After a technical review, certain encryption software may be released from EI controls and made eligible for the General Software Note treatment as well as other provisions of the EAR applicable to software. Refer to § 742.15(b)(1) of the EAR, and Supplement No. 6 to part 742 of the EAR.

* * * * *

Dated: December 23, 1998.

R. Roger Majak,

Assistant Secretary for Export Administration.

[FR Doc. 98-34669 Filed 12-30-98; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 46 and 131

[Docket No. RM99-4-000; Order No. 601]

Filing Requirements Under Parts 46 and 131 for Persons Holding Interlocking Directorates

December 18, 1998.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Federal Energy Regulatory Commission. (Commission) is revising its regulations for filings by persons holding interlocking directorates. These revisions: delete reference to a provision which no longer exists; eliminate the need for notarization; simplify and clarify a form and its instructions; reduce the number of photocopies to be filed; and permit changes to be made on an electronic version (presently a diskette) instead of by hand on a printed form. The Commission believes that, by allowing these revisions, it will improve administrative efficiency.

EFFECTIVE DATE: January 1, 1999.

FOR FURTHER INFORMATION CONTACT:

Hadas Z. Kozlowski (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426, Telephone: (202) 208-1029
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SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the **Federal Register**, the Commission also provides all interested persons an opportunity to inspect or copy the contents of this document during normal business hours in the Public Reference Room at 888 First Street, N.E., Room 2A, Washington, D.C. 20426.

The Commission Issuance Posting System (CIPS) provides access to the texts of formal documents issued by the Commission. CIPS can be accessed via Internet through FERC's Homepage (<http://www.ferc.fed.us>) using the CIPS Link or the Energy Information Online icon. The full text of this document will be available on CIPS in ASCII and WordPerfect 6.1 format. CIPS is also available through the Commission's electronic bulletin board service at no

charge to the user and may be accessed using a personal computer with a modem by dialing 202-208-1397, if dialing locally, or 1-800-856-3920, if dialing long distance. To access CIPS, set your communications software to 19200, 14400, 12000, 9600, 7200, 4800, 2400, or 1200 bps, full duplex, no parity, 8 data bits and 1 stop bit. User assistance is available at 202-208-2474 or by E-mail to cipsmaster@ferc.fed.us.

The document is also available through the Commission's Records and Information Management System (RIMS), an electronic storage and retrieval system of documents submitted to and issued by the Commission after November 16, 1981. Documents from November 1995 to the present can be viewed and printed. RIMS is available in the Public Reference Room or remotely via the Internet through FERC's Homepage using the RIMS link or the Energy Information Online icon. User assistance is available at 202-208-2222, or by E-mail to rismaster@ferc.fed.us.

Finally, the complete text on diskette in WordPerfect format may be purchased from the Commission's copy contractor, RVJ International Inc. RVJ International Inc., is located in the Public Reference Room at 888 First Street, N.E., Washington, DC 20426.

UNITED STATES OF AMERICA, FEDERAL ENERGY REGULATORY COMMISSION

Before Commissioners: James J. Hoecker, Chairman; Vicky A. Bailey, William L. Massey, Linda Breathitt, and Curt Hébert, Jr.

Filing Requirements Under Parts 46 and 131 for Persons Holding Interlocking Directorates

Docket No. RM99-4-000

ORDER NO. 601

FINAL RULE

(Issued December 18, 1998)

I. Introduction

This Final Rule revises Parts 46 and 131 of the Commission's regulations.¹ These revisions simplify and clarify both Part 46 of the regulations and FERC Form No. 561 (Form No. 561), and reduce from two to one the number of copies of this form which must be filed along with one original. In addition, the Final Rule encourages, but does not require, that changes to the so-called pre-filed Form No. 561² be made on an electronic version rather than by hand. Finally, this Final Rule deletes reference, in Part 46, to section 131.60

¹ 18 CFR Parts 46 and 131.

² Currently, the Commission sends annually to each person holding an interlocking directorate a copy of the Form No. 561 submitted by that person in the prior year, *i.e.*, a pre-filed Form No. 561.

of the Commission's regulations, which has been deleted, and eliminates the need for notarization.

II. Information Collection Statement

The Office of Management and Budget (OMB) regulations require OMB to approve certain reporting and recordkeeping (collections of information) imposed by agency rule.³ The collection of information that is the subject of this Final Rule, Form No. 561, most recently received OMB approval on December 11, 1998 for the period through December 31, 2001.

Respondents subject to the filing requirements of this Final Rule will not be penalized for failing to respond to these collections of information, unless the collections of information display a valid OMB control number.

Title: FERC No. Form 561, Annual Report of Interlocking Positions.

Action: Proposed Data Collection.

OMB Control No.: 1902-0099.

Respondents: Persons who hold certain defined positions with public utilities.

Frequency of Responses: Annually.

Reporting Burden: There are currently 1600 officers and directors of public utilities engaged in the generation, transmission, and sale of electric power who file reports with the Commission on an annual basis. The Commission estimates an average overall response rate of 0.5 hours, for a total burden of 800 hours ($1600 \times 1 \times 0.5 = 800$).

The Final Rule, if adopted, would simplify and streamline the existing reporting requirements to reduce by one half the burden on industry.

Necessity of Information: The Final Rule revises the filing requirements in 18 CFR Part 46 and 131, necessary for fulfilling the requirements of Section 211 of the Public Utility Regulatory Policies Act which amended Part III, Section 305 of the Federal Power Act. The information is collected by the Commission in order to exercise oversight of interlocking directorates involving public utilities and their related activities. This oversight is for officers and directors of public utilities who also hold an officer, director, partner, appointee, or representative position with any other delineated entity.

The Commission has submitted a copy of this Final Rule to OMB for informational purposes only.

Interested persons may obtain information on the reporting requirements by contacting the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC 20426

(Attention: Michael Miller, Office of the Chief Information Officer, (202) 208-1415), or send comments to the Office of Management and Budget, Room 10202 NEOB, Washington, DC 20503 (Attention: Desk Officer for the Federal Energy Regulatory Commission, (202) 395-3087, fax: (202) 395-7285).

III. Background

Section 305(c) of the Federal Power Act, as amended by section 211 of the Public Utility Regulatory Policies Act of 1978,⁴ provides that, on or before April 30 of each year, any person who during the previous calendar year was an officer or director of a public utility and who held, during such calendar year, the position of officer, director, partner, appointee, or representative of any other delineated entity (*i.e.*, an interlocking directorate), shall file with the Commission a written statement concerning such positions held by such person. Such statement must be available to the public.

Part 46 of the Commission's regulations sets forth these filing requirements. Section 46.4 requires that each holder of an interlocking directorate must annually file the information detailed in section 46.6, in the form specified in section 131.31, *i.e.*, Form No. 561.

This Final Rule revises sections 46.6(d) and 131.31.

IV. Discussion

As currently written, section 46.6(d)(1) provides, among other things, that the original written statement filed by the holder of an interlocking directorate shall be "verified under oath in accordance with § 131.60 of this chapter." Section 131.60, however, no longer exists. Moreover, the Commission does not believe it necessary that this statement be notarized. Accordingly, the Final Rule removes this provision.

Similarly, the Commission no longer believes it necessary for the filed original written statement to be accompanied by two copies; one is sufficient. Accordingly, the Final Rule amends section 46.6(d)(1) to require only an original and one copy to be filed.

The Final Rule also amends Form No. 561, at section 131.31, similarly to eliminate the notarization section and the requirement for the filing of two copies. Additionally, there are sections on the current form that are labeled "DOE USE ONLY," which are unnecessary, and more space is provided for "FERC Docket Number"

than currently is necessary. The Final Rule also makes certain minor wording changes to Form No. 561 and the accompanying instructions to clarify them, and corrects the title of section 131.31. Consequently, the Final Rule redesigns Form No. 561 to simplify it, and modifies the accompanying instructions accordingly.

Finally, the Commission believes that it would be in the public interest to permit holders of interlocking directorates to make changes to Form No. 561 electronically, rather than by hand. To accomplish this, the Final Rule renumbers section 46.6(d)(2) as 46.6(d)(3) and adds a new section 46.6(d)(2). If this option is selected, the changes should be made to the pre-filled electronic version provided by the Commission,⁵ and filed with the Commission, along with a signed original printout of that amended form and one copy. The Commission emphasizes that filing electronic amendments will be optional, not mandatory, but will be preferred.

V. National Environmental Policy Act Analysis

The Commission concludes that promulgating this Final Rule does not represent a major Federal action having a significant adverse effect on the human environment under the Commission's regulations implementing the National Environmental Policy Act.⁶ This Final Rule is procedural in nature and does not substantially change the effect of the regulation being amended. In addition, the Final Rule involves information gathering, analysis, and dissemination. Therefore, this Final Rule falls within the categorical exemptions provided in the Commission's regulations.⁷ Consequently, neither an environmental impact statement nor an environmental assessment is required.

VI. Regulatory Flexibility Act Certification

The Regulatory Flexibility Act (RFA)⁸ generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities. Most of the persons holding interlocks required to comply with this Final Rule are not officers or directors of small entities, as defined by the RFA. Moreover, this Final Rule is procedural

³ Presently, "electronic version" means the pre-filled diskette sent annually by the Commission. In the future, however, the Commission may make alternative methods of electronic filing available.

⁴ 42 U.S.C. § 4332.

⁷ 18 CFR 380.4(a)(2)(ii), (a)(5).

⁸ 5 U.S.C. § 601-612.

³ 5 CFR 1320.12.

⁴ 16 U.S.C. § 825d(c).

and ministerial in nature and will not add any burdens to any entities; rather it will reduce the burden on all persons to whom it applies. Therefore, the Commission certifies that promulgating this Final Rule does not represent a major Federal action having a significant economic impact on a substantial number of small entities.

VII. Administrative Findings and Effective Date

Because this rule does not itself alter the substantive rights or interests of any interested persons, but rather merely reduces the burden on those persons who must file Form No. 561, the Commission finds that prior notice and comment are unnecessary under the Administrative Procedure Act.⁹

Because this rule does not alter the substantive rights or interests of any interested persons but rather relieves a restriction otherwise applicable to those persons who must file Form No. 561, and because it reduces the burden on those who must file Form No. 561, the Commission finds good cause to allow this rule to become effective upon less than 30 days' notice.¹⁰ This Final Rule therefore will be made effective January 1, 1999.

VIII. Congressional Notification

The Small Business Regulatory Enforcement Fairness Act of 1996 requires agencies to report to Congress on the promulgation of certain final rules prior to their effective dates.¹¹ That reporting requirement does not apply to this Final Rule, however. The

⁹ 5 U.S.C. § 553(b)(B).
¹⁰ 5 U.S.C. §§ 553(d)(1), (3).
¹¹ 5 U.S.C. § 801.

Commission finds that this Final Rule, which reduces the burden on persons who must file Form No. 561, does not substantially affect the rights or obligations of non-agency parties, and therefore falls within a statutory exception for rules relating to agency procedures or practices that do not substantially affect the rights or obligations of non-agency parties.¹²

List of Subjects in 18 CFR Parts 46 and 131

Antitrust, Electric utilities, Holding Companies, Reporting and recordkeeping requirements; Electric Power.

By the Commission.
David P. Boergers,
Secretary.

In consideration of the foregoing, the Commission amends Parts 46 and 131, Chapter I, Title 18, *Code of Federal Regulations*, as set forth below.

PART 46—PUBLIC UTILITY FILING REQUIREMENTS AND FILING REQUIREMENTS FOR PERSONS HOLDING INTERLOCKING POSITIONS

1. The authority citation for Part 46 continues to read as follows:

Authority: Federal Power Act, as amended, 16 U.S.C. 792–828c; Public Utility Regulatory Policies Act of 1978, 16 U.S.C. 2601–2645; Department of Energy Organization Act; 42 U.S.C. 7101–7352; E.O. 12009, 3 CFR 142 (1978).

2. In § 46.6, paragraph (d)(1) is revised, paragraph (d)(2) is redesignated as (d)(3), and a new paragraph (d)(2) is added to read as follows:

¹² 5 U.S.C. § 804(3)(C).

§ 46.6 Contents of the written statement and procedures for filing.

* * * * *

(d)(1) Each person shall file an original and one copy of such written statement with the Office of Secretary of the Commission on or before April 30 of each year immediately following the calendar year during any portion of which such person held a position described in § 46.4. The original of such statement shall be dated and signed by such person. The copy shall bear the date that appeared on the original; the signature on the copy may be stamped or typed on the copy.

(2) Instead of submitting changes to the Commission on the pre-printed Form No. 561 sent annually by the Commission, a person may choose to make changes to the pre-filled electronic version provided by the Commission. This electronic version, along with the signed original and one copy (as required by Paragraph (d)(c)) shall also be filed with the Commission.

* * * * *

PART 131—FORMS

1. The authority citation for Part 131 continues to read as follows:

Authority: 16 U.S.C. 791a–825r, 2601–2645; 31 U.S.C. 9701, 42 U.S.C. 7101–7352.

2. Section 131.31 is revised to read as follows:

§ 131.31 FERC Form No. 561, Annual report of interlocking positions.

(See section 46.4 of this chapter.)

Form Approved
OMB No. 1902-0099

**FEDERAL ENERGY REGULATORY COMMISSION
ANNUAL REPORT OF INTERLOCKING POSITIONS**

This report is mandatory under Section 305(c)(1) of the Federal Power Act. Failure to report may result in criminal fines, civil penalties and other sanctions as provided by law. The Federal Energy Regulatory Commission does not consider this report to be of a confidential nature. PLEASE READ THE INSTRUCTIONS ATTACHED BEFORE COMPLETING THIS FORM.

RESPONDENT INFORMATION

1 Full Name (Last, First, and Middle Initial) 2 Business Address (Street, City, State, and Zip Code)

3 Reporting Year

5 Latest Date Authorized

6 Mail to Company

PUBLIC UTILITY DATA

(1) Name of Public Utility (2) Position Code(s) (1) Name of Public Utility (2) Position Code(s)

INTERLOCKING ENTITY DATA

(3) Name of Entity (4) Position Code(s) (5) Type Code (6) Total Revenue(\$)

Signature: _____ Date: _____

Format Number FERC 561 (REVISED 12/98)

INSTRUCTIONS FOR COMPLETING ANNUAL REPORT OF INTERLOCKING POSITIONS

GENERAL INFORMATION:

Purpose of Report

The data collected by this report will be used by the Federal Energy Regulatory Commission's staff for the review and oversight of interlocking positions between public utilities and certain other entities as described below.

Who Must Submit

This report must be completed by all persons holding interlocking positions between public utilities and certain other entities (described in the specific instructions) during any portion of the calendar year.

When to Submit

Submit this report on or before April 30 of each year for the preceding calendar year. (For example, the report for the year 1999 would be filed on or before April 30, 2000.)

What and Where to Submit

Submit an original and one (1) copy of this report to: Federal Energy Regulatory Commission, Office of the Secretary, Attention FERC 561, 888 First Street NE, Washington, DC 20426

Sanctions

This report is mandatory and is prescribed by Section 305(c)(1) of the Federal Power Act and 18 CFR 46.4. Failure to report may result in certain penalties and other sanctions as provided by law.

Where to Send Comments on Public Reporting Burden

The public reporting burden for this collection of information is estimated to average 0.25 hours per response, including the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to: Federal Energy Regulatory Commission, Attn: Federal Energy Regulatory Commission Information Clearance Officer, 888 First Street NE, Washington, DC 20426.

You shall not be penalized for failure to respond to this collection of information unless the collection of information displays a valid OMB control number.

GENERAL INSTRUCTIONS

1. Prepare this report in conformity with the requirements prescribed in 18 CFR 46.4.
2. Leave blank any columns that are not applicable.

SPECIFIC INSTRUCTIONS

Item and Instruction

Respondent Information

- 1 and 2 Enter your full name and your business address.
- 3 Enter the calendar year for which this report is filed.

4 and 5 If you are authorized by this Commission to hold the position of officer or director in accordance with Part 45 of the Commission's regulations: enter in space 4 the complete FERC docket number of such authorization; enter in space 5 the latest date of such authorization. Otherwise, leave these spaces blank.

6 Enter the public utility or public utility holding company to which you want next year's Form 561 sent.

Public Utility Data

Col (1) and Col (2) Enter in column (1) the name of each public utility in which you hold an executive position. In column (2) enter the appropriate code for each such position, according to the list below:

Code and Name

- Dir Director
- CEO Chief Executive Officer
- PRES President
- VP Vice President
- SEC Secretary
- TREA Treasurer
- GM General Manager
- COMP Comptroller
- PURA Chief Purchasing Agent
- OEP Other Executive Position

Interlocking Entity Data

Col (3) and Col (4) Enter in Column (3) the name of each entity in which you hold an interlocking position. Enter the appropriate code for each executive position you hold in the entity named in Column (3), using the list below:

Code and Name

- DIR Director
- CEO Chief Executive Officer
- PRES President
- VP Vice President
- SEC Secretary
- TREA Treasurer
- GM General Manager
- COMP Comptroller
- PURA Chief Purchasing Agent
- PART Partner
- APPT Appointee
- REP Representative
- OEP Other Executive Position

Col (5) Enter in Column (5) the appropriate code type for each entity listed in Column (3), using the list below:

Code and Name

- FIN Investment bank; bank holding company; foreign bank or subsidiary thereof doing business in the United States; other organization primarily engaged in the business of providing financial services or credit; mutual savings bank; or savings and loan association
- FINI Insurance company
- SECU Entity authorized by law to underwrite or participate in the marketing of securities of a public utility
- ELEQ Entity which produces/supplies electric equipment for the use of any public utility
- FUEL Entity which produces/supplies coal, natural gas, nuclear fuel, or other fuel for the use of any public utility

20CL Entity specified in 18 CFR 46.3 (one of the 20 largest purchasers of electric energy from a utility)

CNEN Entity which is controlled by any one of the above named entities

305B Entity referred to in Section 305(b) of the Federal Power Act (not otherwise identified above)

Col (6) For each entity that supplies electric equipment (ELEQ) named in Column (3) enter the aggregate amount of revenues from producing or supplying electrical equipment to any public utility named in column (1) in the subject calendar year, rounded to the nearest \$100,000. Otherwise, leave this column blank.

Signature The original of this report must be dated and signed. The copy must bear the date that appeared on the original. The signature on the copy may be stamped or typed on the copy.

[FR Doc. 98-34131 Filed 12-30-98; 8:45 am]
BILLING CODE 6717-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 54

[Docket No. 93N-0445]

RIN 0910-AB77

Financial Disclosure by Clinical Investigators

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; action on petition for reconsideration.

SUMMARY: The Food and Drug Administration (FDA) is revising the requirements regarding financial disclosure by clinical investigators in order to add material to the codified language that was inadvertently omitted and to clarify the compliance dates to, in some cases, restrict the retroactive application of certain requirements of the rule. FDA is making these changes in order to respond to concerns raised by the Pharmaceutical Research Manufacturers Association (hereinafter referred to as "PhRMA"). By making these changes, FDA will be reducing the administrative burden for manufacturers and other affected parties while, at the same time, ensuring that the agency obtains the information that is most relevant to its review of clinical data submitted in marketing applications.

DATES:

Effective Date: This regulation becomes effective February 2, 1999.

Comment Date: Submit written comments on the information collection provisions in the rule published on