wildlife resources and historic, cultural and geologic values;

2. Recreational and subsistence uses of fish and wildlife resources;

3. The protection of the natural and cultural resources of the corridors;

4. Mining and oil and gas exploration and development;

5. Water resources development projects, particularly on the Susitna River;

6. Use of the river corridors for transportation or pipeline development;

7. Public access to and across the corridors;

8. Private, State and Native corporate land holdings within corridors, and

9. Reclassification of federal lands for State selection or other disposal.

Interested parties are encouraged to review the referenced background documents and to submit any additional substantive issues relative to the proposals not addressed in this notice.

The DEIS will be released after comments have been received from this notice. The availability of the DEIS will be announced in the **Federal Register.**

The primary author of this notice is Christine Enright, U.S. Fish and Wildlife Service, 18th and C Streets, NW., Washington, D.C. 20240.

Dated: January 31, 1980.

Robert Herbst,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 80-3711 Filed 2-4-80; 8:45 am]

BILLING CODE 4310-03-M

Geological Survey

Known Recoverable Coal Resource Area; Bennie Peer, N. Dak.

Pursuant to authority contained in the Act of March 3, 1879 (43 U.S.C. 31), as supplemental by Reorganization Plan No. 3 of 1950 (43 U.S.C. 1451, note), 220 Departmental Manual 2, Secretary's Order No. 2948, and Section 8A of the Mineral Leasing Act of February 25, 1920, as added by Section 7 of the Federal Coal Leasing Amendments Act of 1976 (Pub. L. 94-377, August 4, 1976, as amended by Pub. L. 95-554, October 30, 1978), Federal lands within the State of North Dakota have been classified as subject to the coal leasing provisions of the Mineral Leasing Act of February 25, 1920, as amended (30 U.S.C. 201). The name of the area, effective date, and total acreage involved are as follows:

(34) North Dakota

Bennie Peer (North Dakota) Known Recoverable Coal Resource Area; March 6, 1979; 162,233.74 acres.

A diagram showing the boundaries of the area classified for leasing has been filed with the appropriate land office of the Bureau of Land Management. Copies of the diagram and the land description may be obtained from the Conservation Manager, Central Region, U.S. Geological Survey, Stop 609, Box 25046, Federal Center, Denver, Colorado 80225.

Dated: January 28, 1980.

H. William Menard,

Director.

[FR Doc. 80-3674 Filed 2-4-80; 8:45 am]

BILLING CODE 4310-31-M

Known Recoverable Coal Resource Area; Book Cliffs, Colo.

Pursuant to authority contained in the Act of March 3, 1879 (43 U.S.C. 31), as supplemented by Reorganization Plan No. 3 of 1950 (43 U.S.C. 1451, note), 220 Departmental Manual 2, Secretary's Order No. 2948, and Section 8A of the Mineral Leasing Act of Feburary 25, 1920, as added by Section 7 of the Federal Coal Leasing Amendments Act of 1976 (Pub. L. 94-377, August 4, 1976, as amended by Pub. L. 95-554, October 30, 1978), Federal lands within the State of Colorado have been classified as subject to the coal leasing provisions of the Mineral Leasing Act of Feburary 25, 1920, as amended (30 U.S.C. 201). The name of the area, effective date, and total acreage involved are as follows:

(6) Colorado

Book Cliffs (Colorado) Known Recoverable Coal Resource Area; June 1, 1979; 440,293 acres.

A diagram showing the boundaries of the area classified for leasing has been filed with the appropriate land office of the Bureau of Land Management. Copies of the diagram and the land description may be obtained from the Conservation Manager, Central Region, U.S. Geological Survey, Stop 609, Box 25046, Federal Center, Denver, Colorado 80225.

Dated: January 28, 1980.

H. William Menard,

Director.

[FR Doc. 80-3673 Filed 2-4-80; 8:45 am]

BILLING CODE 4310-31-M

Heritage Conservation and Recreation Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the Heritage Conservation and Recreation Service before January 25, 1980. Pursuant to § 60.13 of 36 CFR Part 60, written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, Heritage Conservation and Recreation Service, U.S. Department of the Interior, Washington, DC 20243. Written comments or a request for additional time to prepare comments should be submitted by February 15, 1980.

Sarah G. Oldham,

Acting Chief, Registration Branch.

ALABAMA

Jefferson County

Birmingham, *Birmingham, Railway, Light and Power Building,* 2100 1st Ave., North.
Birmingham, *First Christian Church Education Building,* 2100 7th Ave. N.
Birmingham, *Waters Building,* 209-211 N. 22nd St.

HAWAII

Honolulu County

Honolulu, *Canavarro, Georges de S., House,* 2756 Rooke Ave.
Honolulu, *Linekona School,* Victoria and Beretania Sts.

KENTUCKY

Newell, Beaty, James and Owens Family Buildings Thematic Resources. Reference—see individual listings under Pulaski County.

Bullitt County

Shepherdsville vicinity, *Brooks, Solomon Neill, House,* NE of Shepherdsville at Hebron Lane and KY 61.

Daviess County

Yelvington vicinity, *Riley, Amos, Plantation Site (Home of Josiah Henson)* 2 mi. N of Yelvington on U.S. 60.

Fayette County

Lexington, *Battle Row,* 159-177 N. Limestone St.
Lexington, *Lexington City National Bank Building,* 259-265 W. Main St.
Lexington, *Miller Brothers Building,* 359-361 W. Main St.

Hart County

Munfordville, *Munfordville Multiple Resource Area (Partial Inventory).* This area includes: *Barrett, Dr. Lewis, House,* 2nd and Caldwell Sts.; *Chapline Building,* Main St.; *Cox, Alvey, House,* 1st and Washington Sts.; *Hart County Courthouse,* Town Sq.; *Hart County Deposit Bank and Trust Company Building,* Main St.; *Munford Inn,* 109 Washington St.; *Munford, Richard, House,* West and 1st Sts.; *Munford, Thomas Bolin, House,* 3rd and Washington Sts.; *Munfordville Baptist Church,* 313 S. 5th St.; *Munfordville Presbyterian Church and Green,* 3rd and Washington Sts.; *Munfordville School (Williams House)* 3rd and Washington Sts.; *Smith, F. A., House,* 204 N. Washington St.; *Wood, Gen. George T., House,* 2nd and Caldwell Sts.

Marion County

Nerinx, *Loretto Motherhouse*, Off KY 152.

Mercer County

Harrodsburg, *Daughters' College*, 638 Beaumont Dr.

Oldham County

Ballardsville vicinity, *Spring Hill*, S of Ballardsville of KY 53.

Pulaski County

Bronston, *Bronston Post Office (Newell, Beaty, James and Owens Family Buildings Thematic Resources)* Off KY 90.
Bronston, *Newell House (Newell, Beaty, James, and Owens Family Buildings Thematic Resources)*.
Bronston vicinity, *Alexander Chapel Methodist Church (Newell, Beaty, James and Owens Family Buildings Thematic Resources)* Off KY 90.
Bronston vicinity, *Newell, William O., House (Newell, Beaty, James and Owens Family Buildings Thematic Resources)* Off KY 90.
Somerset vicinity, *James-Hansford House (Newell, Beaty, James and Owens Family Buildings Thematic Resources)* KY 80.
Somerset vicinity, *James-Owens House (Newell, Beaty, James and Owens Family Buildings Thematic Resources)* Off KY 80.
Somerset vicinity, *Pisgah Presbyterian Church (Newell, Beaty, James and Owens Family Buildings Thematic Resources)* Off U.S. 27.
Somerset vicinity, *Saunders, George W., House (Newell, Beaty, James and Owens Family Buildings Thematic Resources)* Off U.S. 27.

Simpson County

Franklin, *Simpson County Courthouse*, KY 73.
Franklin vicinity, *Octagon Hall*, NE of Franklin on KY 31W.

Trigg County

Canton, *Brick Inn (Canton Hotel)* Off KY 80.

MARYLAND

Baltimore (independent city)
Benson Building, 4 E. Franklin St.
Odd Fellows Hall, 300 Cathedral St.

Talbot County

St. Michaels, *Old Inn, The*, Talbot and Mulberry Sts.

Worcester County

Berlin, *Berlin Commercial District*, Main, Broad, Williams, Bay, Pitts, and Commerce Sts.

MISSOURI

Jackson County

Kansas City, *Bellerive Hotel*, 214 E. Armour Blvd.
Kansas City, *Westminster Congregational Church*, 3600 Walnut St.
St. Louis (independent city)
Convent of the Sisters of St. Joseph of Carondelet, 6400 Minnesota Ave.

Saline County

Arrow Rock, *ARROW ROCK MULTIPLE RESOURCE AREA (Partial Inventory)*. This area includes: *Arrow Rock Historic District;* Arrow Rock vicinity, *Barger, Edwin, House*, Off MO 41; *Cole, Bill, House*, 1st St.; *Eddy, Kenneth, House*, Off MO 41; *Green, Elmer, House*, MO TT; *Hogge House*, Off MO TT; *Moseley House*, MO 41; *Murphy, Pat, House*, MO 41; *Ozias, Art, House*, Off MO 41; *Spring*, Off MO 41; *Stith, Bob, House*, Off MO 41; *Thompson House*, MO 41; *Van Winter House*, Off MO 41 and MO TT.

MONTANA

Yellowstone County

Billings, *Fire House No. 2*, 201 S. 30th St.

NEBRASKA

Buffalo County

Kearney, *Thomas, Dr. A. O., House*, 2222 9th Ave.

Sheridan County

Ellsworth vicinity, *Spade Ranch* (also in Cherry County).

NEVADA

Washoe County

Reno, *Rainier Brewing Company Bottling Plant*, 310 Spokane St.
Verdi vicinity, *1872 California-Nevada State Boundary Marker*, On California-Nevada border.

NEW YORK

Dutchess County

Fishkill vicinity, *Stony Kill Farm*, W of Fishkill on NY 9D.

New York County

New York, *East 78th Street Houses*, 157–165 E. 78th St.
New York, *East 80th Street Houses*, 116–130 E. 80th St.

Otsego County

Oneonta vicinity, *Stonehouse Farm*, E of Oneonta on NY 7.

NORTH DAKOTA

Grand Forks County

Northwood, *Linwell, Martin V., House*, 316 S. Raymond St.

OKLAHOMA

Oklahoma County

Oklahoma City, *India Temple Shrine Building*, 621 N. Robinson St.
Oklahoma City, *Oklahoma Gas and Electric Company Building*, 321 N. Harvey St.
Oklahoma City, *Ramsey Tower*, 204 N. Robinson St.
Oklahoma City, *Snyder's Super Service Station*, 1325 N. Broadway Ave.

PENNSYLVANIA

Lancaster County

Lancaster, *Lancaster County House of Employment (Old County Hospital)* 900 E. King St.

RHODE ISLAND

Providence County

Cranston, *Furnace Hill Brook Historic and Archeological District*, Phenix Ave. and Hope Rd.
Providence, *Cappelli, A. F., Block*, 263–265 Atwells Ave.

TENNESSEE

Shelby County

Memphis, *Maxwelton*, 3105 Southern Ave.

UTAH

Grand County

Moab, *Taylor, Arthur, House*, U.S. 163

Salt Lake County

Salt Lake City, *Liberty Park*, Bounded by 5th, 7th E., 9th and 13th S. Sts.
Salt Lake City, *South Temple Historic District*, S. Temple St.

Wasatch County

Heber City, *Murdoch, John, House*, 261 N. 400 West St.

VIRGINIA

Campbell County

Brookneal vicinity, *Cat Rock Sluice of the Roanoke Navigation*, W of Brookneal (also in Halifax County).

Charles City County

Rustic vicinity, *Rowe, The*, 3 mi. SW of Rustic.

Essex County

Millers Tavern vicinity, *Woodlawn*, 2.1 mi. NE of Millers Tavern.

Fairfax County

Alexandria vicinity, *Fort Hunt*, Mount Vernon Memorial Hwy.

Frederick County

Clear Brook vicinity, *Hopewell Friends Meetinghouse*, W of Clear Brook off VA 672.

Mathews County

Moon vicinity, *Billups House (Milford)* E of Moon.

Middlesex County

Urbanna, *Wormeley Cottage*, Virginia St.
Petersburg (independent city)
Folly Castle Historic District, Perry and W. Washington Sts.

Roanoke County

Roanoke vicinity, *Old Tombstone*, N of Roanoke.

Rockbridge County

Brownsburg vicinity, *New Providence Presbyterian Church*, NE of Brownsburg.

Surry County

Cabin Point vicinity, *Montpelier*, 1.4 mi. SW of Cabin Point.

Wythe County

Rural Retreat vicinity, *Kimberling Lutheran Cemetery*, NW of Rural Retreat.

WEST VIRGINIA

Fayette County

Gauley Bridge, *Gauley Bridge Railroad Station*, Off WV 16/39.

[FR Doc. 80-3495 Filed 2-4-80; 8:45 am]

BILLING CODE 4310-03-M

National Register of Historic Places; Annual Listing of Historic Properties

The Annual Listing of Historic Properties on the National Register of Historic Places, that would ordinarily appear here today, February 5, 1980, will be published in the **Federal Register** March 18, 1980.

Ronald M. Greenberg,

Acting Chief, National Register of Historic Places.

[FR Doc. 80-3739 Filed 2-4-80; 8:45 am]

BILLING CODE 4310-03-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

National Institute of Education

Assessment Policy Committee, National Assessment of Educational Progress; Meeting

Notice is hereby given that the Assessment Policy Committee of the National Assessment of Educational Progress (NAEP) will meet on February 8–9, 1980 at the Plaza Cosmopolitan Hotel, Broadway Arms Conference Room, 1780 Broadway, Denver, Colorado, 80202. The session on February 8 will commence at 8:30 a.m. and terminate at 4:30 p.m.; and the session on February 9 will commence at 8:30 a.m. and terminate at 12:00 noon.

The Assessment Policy Committee is established under section 405 (k)(2)(A) of the General Education Provisions Act, as amended by section 1242 of the Education Amendments Act of 1978. The Policy Committee is responsible for the design of NAEP, including the selection of the learning areas to be assessed, the development and selection of goal statements and assessments items, the assessment methodology, the form and content of the reporting and dissemination of results, and studies to evaluate and improve the form and utilization of NAEP.

NAEP is a periodic survey of the knowledge, skills, understandings, and attitudes of young Americans. During the meeting, the Policy Committee will review and discuss the NIE grant award for the continuation of the National Assessment and special provisions, future assessment cycles, and policy, management and other administration matters.

The entire meeting will be open to the public. Interested persons are invited to attend the meeting. In order to assure adequate seating arrangements, persons likely to attend the meeting may contact the following person: Mr. Dunlop Scott, National Assessment of Educational Progress, 1860 Lincoln Street, Denver, Colorado 80295 (303) 861–4917.

Dated: February 4, 1980.

Jeff Schiller,

Assistant Director, Testing, Assessment and Evaluation.

[FR Doc. 80-3886 Filed 2-4-80; 11:56 am]

BILLING CODE 4110-39-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Surface Coal Mining and Reclamation Operations; Permanent Regulatory Program; Correction

AGENCY: Office of Surface Mining Reclamation and Enforcement, Department of the Interior.

ACTION: Correction.

SUMMARY: This document corrects the Public Disclosure of Comments Received from Federal Agencies on the Texas Permanent Regulatory Program Submission that begins on page 7319 of the **Federal Register** of Friday, February 1, 1980.

EFFECTIVE DATE: February 5, 1980.

ADDRESS: Director, Office of Surface Mining Reclamation and Enforcement, Department of the Interior, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Carl C. Close, 202–343–4225.

SUPPLEMENTARY INFORMATION: This document corrects errors that appeared in the February 1, 1980 **Federal Register.** The following instructions will aid the user in locating referenced corrections:

page—indicates the page number that appears in the upper margin.
column—indicates the column number where the error is found.
line—indicates the number of lines down from the referenced paragraph.

Dated: February 1, 1980.

Carl C. Close,

Assistant Director, State and Federal Programs.

The following correction is made:

On page 7319, column 2, SUMMARY, lines 1–3:

"Before the Secretary of Interior may approve the Surface Mining Control and Reclamation Act of 1977," is corrected to read "Before the Secretary of the Interior may approve a State program under the Surface Mining Control and Reclamation Act of 1977,".

[FR Doc. 80-3842 Filed 2-4-80; 8:45 am]

BILLING CODE 4310-05-M

Sunshine Act Meetings

Federal Register
Vol. 45, No. 25
Tuesday, February 5, 1980

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

CONTENTS

1

FEDERAL COMMUNICATIONS COMMISSION.

TIME AND DATE: 2 p.m., Thursday, January 31, 1980.

PLACE: Room 856, 1919 M Street NW., Washington, D.C.

STATUS: Emergency closed meeting.

MATTERS TO BE CONSIDERED:

Internal Personnel Matters

The prompt and orderly conduct of Commission business did not permit announcement of this meeting prior to the meeting.

Additional information concerning this meeting may be obtained from Edward Dooley, FCC Public Affairs Office, telephone (202) 632-7260.

Issued: February 1, 1980.

[S-226-80 Filed 2-1-80; 1:50 pm]

BILLING CODE 6712-01-M

2

FEDERAL ELECTION COMMISSION.

TIME AND DATE: 10 a.m., Tuesday, February 5, 1980.

PLACE: 1325 K Street NW., Washington, D.C.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Compliance, Personnel, Audit Policy—Threshold Audits.

TIME AND DATE: 10 a.m., Wednesday, February 6, 1980.

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED: Special meeting for discussion of regulations.

TIME AND DATE: 10 a.m., Thursday, February 7, 1980.

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED:

Setting of dates for future meetings.
Correction and approval of minutes.
Certifications.
Advisory Opinions: Draft AO 1979-81—Larry Winn, Jr. (Member of Congress) and Draft AO 1979-82—Ronald M. Mottl (Member of Congress).
1980 Election and related matters.
Impact of H.R. 5010.
Interim enforcement procedures.
Appropriations and Budget—November Management Report.
Pending legislation.
Classification actions.
Routine administrative matters.
Discussion of regulations (continued).

PERSON TO CONTACT FOR INFORMATION: Mr. Fred Eiland, Public Information Officer, Telephone: 202-523-4065.

Marjorie W. Emmons,

Secretary to the Commission.

[S-219-80 Filed 2-1-80; 9:59 am]

BILLING CODE 6715-01-M

3

FEDERAL ENERGY REGULATORY COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 45 FR 6686, January 29, 1980.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: January 30, 1980, 10 a.m.

CHANGE IN THE MEETING: The following item has been added:

Item Number, Docket Number and Company

EL80-9, *Operation Overcharge Complainant* v. *Virginia Electric & Power Co.*, Respondent

Kenneth F. Plumb,

Secretary.

[S-216-80 Filed 1-31-80; 4:57 pm]

BILLING CODE 6450-01-M

4

FEDERAL ENERGY REGULATORY COMMISSION. Meeting.

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

TIME AND DATE: Approximately 12 noon, January 31, 1980.

PLACE: Room 9306, B25 North Capital Street, NE., Washington, D.C. 20426.

STATUS: Closed.

CONTACT PERSON FOR MORE INFORMATION: Kenneth F. Plumb, Secretary, telephone (202) 357-8400.

The following members of the Commission voted that agency business requires the holding of a closed meeting on less than the one week's notice required by the Government in the Sunshine Act:

Chairman Curtis.
Commissioner Sheldon.
Commissioner Holden.

Kenneth F. Plumb,

Secretary.

[S-217-80 Filed 1-31-80; 4:57 pm]

BILLING CODE 6450-01-M

5

FEDERAL ENERGY REGULATORY COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: To be published February 4, 1980.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 10 a.m., February 6, 1980.

Item Number, Docket Number, and Company

CP-3. CP77-363, Columbia Gas Transmission Corporation and National Fuel Gas Corporation.

Kenneth F. Plumb,

Secretary.

[S-225-80 Filed 2-1-80; 1:09 pm]

BILLING CODE 6450-01-M

6

January 30, 1980.

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION.

TIME AND DATE: 10 a.m., Wednesday, February 6, 1980.

PLACE: Room 600, 1730 K Street NW., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following:

1. Ottawa Silica Company, WILK 79-69-PM (Petition for Discretionary Review; issues include interpretation and application of 30 CFR § 56.12-68)

2. Davis Coal Company, HOPE 78-627-P, etc., HOPE 79-195-P, HOPE 79-233-P, etc., WEVA 79-25, WEVA 79-130, etc. (Issues include whether certain proposed penalty settlements were appropriately approved.)

CONTACT PERSON FOR MORE INFORMATION: Jean Ellen 202–653–5632.

[S–218–80 Filed 2–1–80; 9:53 am]

BILLING CODE 6820–12–M

7

NATIONAL CREDIT UNION ADMINISTRATION.

TIME AND DATE: 10 a.m., Thursday, February 7, 1980.

PLACE: Board room, seventh floor, 1776 G Street NW., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Review of Central Liquidity Facility Lending Rates.
2. Applications for charters, amendments to charters, bylaw amendments, mergers as may be pending at that time.
3. Report of actions taken under delegated authorities.

CONTACT PERSON FOR MORE INFORMATION: Beatrix Fields, Acting Secretary of the Board, telephone (202) 357–1030.

[S–220–80 Filed 2–1–80; 11:21 am]

BILLING CODE 7535–01–M

8

NATIONAL CREDIT UNION ADMINISTRATION.

TIME AND DATE: 2 p.m., Friday, February 8, 1980.

PLACE: Board room, seventh floor, 1776 G Street, NW., Washington, D.C.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Requests from federally insured credit unions for special assistance under Section 208 of the Federal Credit Union Act in order to prevent their closing. Closed pursuant to exemption (8) and (9)(A)(ii).
2. Administrative Actions under Section 120 of the Federal Credit Union Act. Closed pursuant to exemptions (8), (9)(A)(ii), and (10).
3. Special Reserve Actions Under Sections 116 of the Federal Credit Union Act. Closed pursuant to exemptions (8), and (9)(A)(ii).
4. Merger. Closed pursuant to exemptions (8), and (9)(A)(ii).
5. Final order to place a Federal credit union into liquidation under Section 207 of the Federal Credit Union Act. Closed pursuant to exemptions (8), and (9)(A)(ii).
6. Personnel Actions. Closed pursuant to exemptions (2) and (6).

CONTACT PERSON FOR MORE INFORMATION: Beatrix Fields, Acting Secretary of the Board, telephone (202) 357–1030.

[S–227–80 Filed 2–1–80; 2:43 pm]

BILLING CODE 7535–01–M

9

NUCLEAR REGULATORY COMMISSION.

TIME AND DATE: February 7, 1980.

PLACE: Commissioners conference room, 1717 H Street NW., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Thursday, February 7

2 p.m.

1. Briefing on Impact of Special Inquiry Group Report on Action Plan (approx. 2 hours, public meeting).
2. Affirmation Session (approx. 5 minutes, public meeting) (items are tentative):
   a. Protection of Individuals Providing Information to NRC.
   b. Access Controls to Power Plant Vital Areas.
   c. Re-appointment of ACRS Member.
   d. CEQ–NEPA Regulations.
   e. Revisions to Part 20.

CONTACT PERSON FOR MORE INFORMATION: Roger Tweed (202) 634–1410.

Roger M. Tweed,

Office of the Secretary.

January 31, 1980.

[S–221–80 Filed 2–1–80; 1:03 pm]

BILLING CODE 7590–01–M

10

[Form 1]

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION:

TIME AND DATE: 1 p.m., February 7, 1980.

PLACE: Room 1101, 1825 K Street NW., Washington, D.C.

STATUS: Because of the subject matter, it is likely that this meeting will be closed.

MATTERS TO BE CONSIDERED: Discussion of specific cases in the Commission adjudicative process.

CONTACT PERSON FOR MORE INFORMATION: Ms. Patricia Bausell (202) 634–4015.

Dated: February 1, 1980.

[S–222–80 Filed 2–1–80; 1:03 pm]

BILLING CODE 7600–01–M

11

[Form 1]

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION.

TIME AND DATE: 10 a.m., February 13, 1980.

PLACE: Room 1101, 1825 K Street NW., Washington, D.C.

STATUS: Because of the subject matter, it is likely that this meeting will be closed.

MATTERS TO BE CONSIDERED: Discussion of specific cases in the Commission adjudicative process.

CONTACT PERSON FOR MORE INFORMATION: Ms. Patricia Bausell (202) 634–4015.

Dated: February 1, 1980.

[S–223–80 Filed 2–1–80; 1:03 pm]

BILLING CODE 7600–01–M

12

[Form 1]

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION.

TIME AND DATE: 10 a.m., February 21, 1980.

PLACE: Room 1101, 1825 K Street NW., Washington, D.C.

STATUS: Because of the subject matter, it is likely that this meeting will be closed.

MATTERS TO BE CONSIDERED: Discussion of specific cases in the Commission adjudicative process.

CONTACT PERSON FOR MORE INFORMATION: Ms. Patricia Bausell (202) 634–4015.

Dated: February 1, 1980.

[S–224–80 Filed 2–1–80; 1:03 pm]

BILLING CODE 7600–01–M

federal register

Tuesday
February 5, 1980

Part II

Department of Health, Education, and Welfare

Food and Drug Administration

Cardiovascular Devices; Classification and Development of General Provisions

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 870

[Docket No. 78N-1406]

Cardiovascular Devices; General Provisions

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule regarding general provisions applicable to the classification of cardiovascular devices. The preamble to this rule responds to general comments received on the proposals regarding classification of cardiovascular devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: March 6, 1980.

FOR FURTHER INFORMATION CONTACT: John L. Ely, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 9, 1979 (44 FR 13284), FDA published a proposed regulation containing general provisions applicable to the classification of cardiovascular devices. The preamble to the regulation described the development of the proposed regulations classifying cardiovascular devices and the activities of the Cardiovascular Device Classification Panel, an FDA advisory committee that makes recommendations to FDA concerning the classification of cardiovascular devices. FDA also published in that issue of the **Federal Register** individual proposed regulations to classify 141 cardiovascular devices. FDA provided a period of 60 days for interested persons to submit written comments on these proposals.

Comments on Classification Proposals

Elsewhere in this issue of the **Federal Register**, FDA is issuing final regulations classifying 138 individual cardiovascular devices. FDA is responding to specific comments regarding the classification of individual cardiovascular devices in the final regulations for these devices.

No written comments were received on proposed § 870.1 (21 CFR 870.1), which concerns general provisions for all cardiovascular devices. Accordingly, FDA is promulgating § 870.1 with one change: The agency is adding an explanation that references in Part 870 to other regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 of the Code of Federal Regulations, unless otherwise noted.

FDA received one general comment regarding classification proposals for cardiovascular devices. The comment asked whether a manufacturer of a device with more than one use, one or more of which would require it to be placed in class III, and one or more of which would require it to be subject to class II controls, could, by astute device listing, avoid complying with the requirements of class III. The comment referred to a cardiac monitor with arrhythmia detection capability as an example of a device that could present a manufacturer with such an opportunity.

If a device performs the functions of two or more generic types of devices, each with a different classification, the manufacturer of that device is subject to the controls applicable to all of the generic types of devices involved. In the example given, a cardiac monitor device with arrhythmia detection capability is required to conform to any performance standard applicable to a class II cardiac monitor device, and the manufacturer of the device is also subject to the premarket approval requirements applicable to a class III arrhythmia detector device.

Changes in Classification Proposals

FDA is continuing its efforts to consolidate panel recommendations concerning similar devices. FDA has attempted to identify these devices before publication of classification proposals and to ensure that each panel's recommendation is considered and published for comment before FDA promulgates final classification regulations for devices reviewed by more than one panel. In the **Federal Register** of March 6, 1979 (44 FR 12269), FDA published a notice of the availability of an index of classification regulations for medical devices. The index may be used by interested persons to determine the specific classification regulation for a device that was classified by more than one classification panel and to determine with which panel's classification regulations it will be published.

With respect to several cardiovascular device classification proposals, FDA has made minor changes in nomenclature and grammar to clarify the regulation, change the device's name from plural to singular, correct spelling, etc. In several proposals, FDA has changed the identification or name of the device to make clear that the regulation applies only to the cardiovascular uses of the device. The devices are: Catheter introducers (Docket No. 78N-1427), impedance plethysmographs (Docket No. 78N-1466), vascular clips (Docket No. 78N-1479), and arterial embolization devices (Docket No. 78N-1481).

FDA is not publishing the final regulation for electrocardiograph conducting media (Docket No. 78N-1455) and pH catheter probes (Docket No. 78N-1419) because these devices were found to be similar to other devices classified by other panels. Electrocardiograph conducting media were classified in the regulation classifying electroconductive media (Docket No. 78N-1005), published with the final classification regulations for neurological devices in the **Federal Register** of September 4, 1979 (44 FR 51726). The pH catheter probes will be classified by the final regulation based on the proposal to classify indwelling blood hydrogen ion concentration (pH) analyzer (Docket No. 78N-1659), published with the proposed classification regulations for anesthesiology devices in the **Federal Register** of November 2, 1979 (44 FR 63292).

In response to a comment, FDA has determined that catheter guide holders (Docket No. 78N-1425) are not sold separately for use in resterilization of catheter guide wires and are designed to serve only as protective packaging. FDA has determined that catheter guide holders are not devices; and, therefore, the agency is not publishing a final regulation for catheter guide holders.

Based on the comments received and on additional consideration of the information before the agency, FDA has placed several devices in different classes from those originally proposed. Changes in classification were made in each of the following regulations with respect to all or some devices subject to the regulation: Cardiopulmonary bypass accessory equipment (Docket No. 78N-1509), cardiovascular surgical instruments (Docket No. 78N-1535), and DC defibrillator (including paddles) (Docket No. 78N-1543). FDA does not believe that it is necessary to issue a new proposal concerning these decisions. The purpose of publishing a proposal and soliciting comments is to enable the agency to determine whether its proposed classification of a device was correct. After reviewing the comments submitted on a proposal, the agency may be persuaded that its proposed classification is incorrect. Persons interested in the classification process should therefore anticipate that in a final regulation a device may be

placed in a class different from the one originally proposed. This possibility was specifically identified in the proposed general regulation on cardiovascular devices (see 44 FR 13286). Persons who disagree with a final classification for a device may petition for reclassification of the device under Subpart C of Part 860 (21 CFR Part 860).

List of Cardiovascular Devices

The following is a list of cardiovascular devices being classified in final regulations published elsewhere in this issue of the **Federal Register.** The list shows the section in the Code of Federal Regulations under which the regulation classifying the device is being codified, the docket number of the classification regulation, and the classification of each device.

Section	Device	Docket No.	Class
	Subpart B—Cardiovascular Diagnostic Devices		
870.1025	Arrhythmia detector and alarm	78N-1407	III
870.1100	Blood pressure alarm	78N-1408	II
870.1110	Blood pressure computer	78N-1409	II
870.1120	Blood pressure cuff	78N-1410	II
870.1130	Noninvasive blood pressure measurement system	78N-1411	II
870.1140	Venous blood pressure manometer	78N-1412	II
870.1200	Diagnostic intravascular catheter	78N-1413	II
870.1210	Continuous flush catheter	78N-1414	II
870.1220	Electrode recording catheter or electrode recording probe	78N-1415	II
870.1230	Fiberoptic oximeter catheter	78N-1416	II
870.1240	Flow-directed catheter	78N-1417	II
870.1250	Percutaneous catheter	78N-1418	II
870.1270	Intracavitary phonocatheter system	78N-1420	II
870.1280	Steerable catheter	78N-1421	II
870.1290	Steerable catheter control system	78N-1422	II
870.1300	Catheter cannula	78N-1423	II
870.1310	Vessel dilator for percutaneous catheterization	78N-1424	II
870.1330	Catheter guide wire	78N-1426	II
870.1340	Catheter introducer	78N-1427	II
870.1350	Catheter balloon repair kit	78N-1428	III
870.1360	Trace microsphere	78N-1429	III
870.1370	Catheter tip occluder	78N-1430	II
870.1380	Catheter stylet	78N-1431	II
870.1390	Trocar	78N-1432	II
870.1425	Programmable diagnostic computer	78N-1433	II
870.1435	Single-function, preprogrammed diagnostic computer	78N-1434	II
870.1450	Densitometer	78N-1435	II
870.1650	Angiographic injector and syringe	78N-1436	II
870.1660	Indicator injector	78N-1437	II
870.1670	Syringe actuator for an injector	78N-1438	II
870.1750	External programmable pacemaker pulse generator	78N-1439	II
870.1800	Withdrawal-infusion pump	78N-1440	II
870.1875	Stethoscope	78N-1441	I, II
870.1915	Thermodilution probe	78N-1442	II
	Subpart C—Cardiovascular Monitoring Devices		
870.2050	Biopotential amplifier and signal conditioner	78N-1443	II
870.2060	Transducer signal amplifier and signal conditioner	78N-1444	II
870.2100	Cardiovascular blood flowmeter	78N-1445	II
870.2120	Extravascular blood flow probe	78N-1446	II
870.2300	Cardiac monitor (including cardiotachometer and rate alarm)	78N-1447	II
870.2310	Apex cardiograph (vibrocardiograph)	78N-1448	II
870.2320	Ballistocardiograph	78N-1449	II
870.2330	Echocardiograph	78N-1450	II
870.2340	Electrocardiograph	78N-1451	II
870.2350	Electrocardiograph lead switching adaptor	78N-1452	II
870.2360	Electrocardiograph electrode	78N-1453	II
870.2370	Electrocardiograph surface electrode tester	78N-1454	II
870.2390	Phonocardiograph	78N-1456	II
870.2400	Vectorcardiograph	78N-1457	II
870.2450	Medical cathode-ray tube display	78N-1458	II
870.2600	Signal isolation system	78N-1459	II
870.2620	Line isolation monitor	78N-1460	II
870.2640	Portable leakage current alarm	78N-1461	II
870.2675	Oscillometer	78N-1462	II
870.2700	Oximeter	78N-1463	II
870.2710	Ear oximeter	78N-1464	II
870.2750	Impedance phlebograph	78N-1465	II
870.2770	Impedance plethysmograph	78N-1466	II
870.2780	Hydraulic, pneumatic, or photoelectric plethysmograph	78N-1467	II
870.2800	Medical magnetic tape recorder	78N-1468	II
870.2810	Paper chart recorder	78N-1469	II
870.2840	Apex cardiographic transducer	78N-1470	II
870.2850	Extravascular blood pressure transducer	78N-1471	II
870.2860	Heart sound transducer	78N-1472	II
870.2870	Catheter tip pressure transducer	78N-1473	II
870.2880	Ultrasonic transducer	78N-1474	II
870.2890	Vessel occlusion transducer	78N-1475	II
870.2900	Patient transducer and electrode cable (including connector)	78N-1476	II
870.2910	Radiofrequency physiological signal transmitters and receivers	78N-1477	II
870.2920	Telephone electrocardiograph transmitters and receivers	78N-1478	II

Section	Device	Docket No.	Class
	Subpart D—Cardiovascular Prosthetic Devices		
870.3250	Vascular clip	78N-1479	II
870.3260	Vena cava clip	78N-1480	II
870.3300	Arterial embolization device	78N-1481	III
870.3375	Cardiovascular intravascular filter	78N-1482	III
870.3450	Vascular graft prosthesis of less than 6 mm diameter	78N-1483	III
870.3460	Vascular graft prosthesis of 6 mm and greater diameter	78N-1484	II
870.3470	Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene.	78N-1485	II
870.3535	Intra-aortic balloon and control system	78N-1487	III
870.3545	Ventricular bypass (assist) devices	78N-1488	III
870.3600	External pacemaker pulse generator	78N-1489	III
870.3610	Implantable pacemaker pulse generator	78N-1490	III
870.3620	Pacemaker lead adaptor	78N-1491	III
870.3630	Pacemaker generator function analyzer	78N-1492	II
870.3640	Indirect pacemaker generator function analyzer	78N-1493	II
870.3650	Pacemaker polymeric mesh bag	78N-1494	II
870.3670	Pacemaker charger	78N-1496	II
870.3680	Permanent and temporary pacemaker electrode	78N-1497	II, III
870.3690	Pacemaker test magnet	78N-1498	II
870.3700	Pacemaker programmer	78N-1499	III
870.3710	Pacemaker repair or replacement materials	78N-1500	III
870.3720	Pacemaker electrode function tester	78N-1501	II
870.3730	Pacemaker service tools	78N-1502	I
870.3800	Annuloplasty ring	78N-1503	III
870.3850	Carotid sinus nerve stimulator	78N-1504	III
870.3925	Replacement heart valve	78N-1505	III
870.3935	Prosthesis heart valve holder	78N-1506	II
870.3945	Prosthesis heart valve sizer	78N-1507	II
	Subpart E—Cardiovascular Surgical Devices		
870.4075	Endomyocardial biopsy device	78N-1508	II
870.4200	Cardiopulmonary bypass accessory equipment	78N-1509	I
870.4205	Cardiopulmonary bypass bubble detector	78N-1378	II
870.4210	Cardiopulmonary bypass vascular catheter, cannula, or tubing	78N-1510	II
870.4220	Cardiopulmonary bypass heart-lung machine console	78N-1511	II
870.4230	Cardiopulmonary bypass defoamer	78N-1512	III
870.4240	Cardiopulmonary bypass heat exchanger	78N-1513	II
870.4250	Cardiopulmonary bypass temperature controller	78N-1514	II
870.4260	Cardiopulmonary bypass arterial line blood filter	78N-1515	III
870.4270	Cardiopulmonary bypass cardiotomy suction line blood filter	78N-1516	II
870.4280	Cardiopulmonary pre-bypass filter	78N-1517	II
870.4290	Cardiopulmonary bypass fitting, manifold, stopcock and adaptor	78N-1518	II
870.4300	Cardiopulmonary bypass gas control unit	78N-1519	II
870.4310	Cardiopulmonary bypass coronary pressure gauge	78N-1520	II
870.4320	Cardiopulmonary bypass pulsatile flow generator	78N-1521	III
870.4330	Cardiopulmonary bypass on-line blood gas monitor	78N-1522	II
870.4340	Cardiopulmonary bypass level sensing monitor and/or control	78N-1523	II
870.4350	Cardiopulmonary bypass oxygenator	78N-1524	III
870.4360	Nonroller type cardiopulmonary bypass blood pump	78N-1525	III
870.4370	Roller-type cardiopulmonary bypass blood pump	78N-1526	II
870.4380	Cardiopulmonary bypass pump speed control	78N-1527	II
870.4390	Cardiopulmonary bypass pump tubing	78N-1528	II
870.4400	Cardiopulmonary bypass blood reservoir	78N-1529	II
870.4410	Cardiopulmonary bypass in-line blood gas sensor	78N-1530	II
870.4420	Cardiopulmonary bypass cardiotomy return sucker	78N-1531	II
870.4430	Cardiopulmonary bypass intracardiac suction control	78N-1532	II
870.4450	Vascular clamp	78N-1533	II
870.4475	Surgical vessel dilator	78N-1534	II
870.4500	Cardiovascular surgical instruments	78N-1535	I
870.4875	Intraluminal artery stripper	78N-1536	II
870.4885	External vein stripper	78N-1537	II
	Subpart F—Cardiovascular Therapeutic Devices		
870.5050	Patient care suction apparatus	78N-1538	II
870.5150	Embolectomy catheter	78N-1539	II
870.5175	Septostomy catheter	78N-1540	II
870.5200	External cardiac compressor	78N-1541	III
870.5225	External counter-pulsating device	78N-1542	III
870.5300	DC-defibrillator (including paddles)	78N-1543	II, III
870.5325	Defibrillator tester	78N-1544	II
870.5550	External transcutaneous cardiac pacemaker (noninvasive)	78N-1545	III
870.5800	Compressible limb sleeve	78N-1546	II
870.5900	Thermal regulating system	78N-1547	II
870.5925	Automatic rotating tourniquet	78N-1548	II

Patient Information

FDA is considering requiring the development and dissemination of information for patients and consumers about the uses, benefits, and risks of medical devices. For example, patient information has already been required or approved by FDA for intrauterine devices and hearing aids. In addition, the Bureau of Radiological Health is conducting a consumer education program on x-rays that includes posters on the effects of radiation during pregnancy and the distribution of x-ray record cards.

FDA believes that patient information is needed if: (1) There is a choice among alternatives of which the patient should be aware; (2) there are substantial risks or discomforts associated with the product; (3) the cost of the product is significant; (4) there is a need for the patient to strictly adhere to a specific treatment regimen; or (5) there is substantial public or professional controversy about the device or its related procedures.

FDA can require that manufacturers make medical device information available to providers for their use and the use of their patients through the premarket approval or standards-setting processes as well as the general control provisions of the Federal Food, Drug, and Cosmetic Act. The mechanisms available to FDA to provide patient information for devices include: (1) Labeling for restricted and nonrestricted devices; (2) patient package inserts and provider information; and (3) consumer and patient education programs.

FDA has tentatively identified several cardiovascular devices for which patient information may be required. Other cardiovascular devices may be identified in the future, after the criteria for selection of devices needing patient information have been further refined. The devices that have been identified so far are listed below:

1. Home-use devices in these categories: blood pressure cuffs (Docket No. 78N–1410), noninvasive blood pressure measurement systems (Docket No. 78N–1411), stethoscopes (Docket No. 78N–1441).

2. Monitoring equipment for home use, in the following categories: Arrhythmia detectors and alarms (Docket No. 78N–1407), electrocardiographs (Docket No. 78N–1451), electrocardiograph electrodes (Docket No. 78N–1453), medical magnetic tape recorders (Docket No. 78N–1468).

3. Home-use heart rate monitors in one of the following categories: Cardiac monitors (including cardiotachometers and rate alarms) (Docket No. 78N–1447), impedance plethysmographs (Docket No. 78N–1466), hydraulic, pneumatic, or photoelectric plethysmographs (Docket No. 78N–1467).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs amends Chapter I of Title 21 of the Code of Federal Regulations by adding new Part 870, Subpart A, to read as follows:

PART 870—CARDIOVASCULAR DEVICES

Subpart A—General Provisions

Sec.

870.1 Scope.

Authority: Secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 701(a)).

Subpart A—General Provisions

§ 870.1 Scope.

(a) This part sets forth the classification of cardiovascular devices intended for human use.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 may not show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a cardiovascular device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed in the subpart representing one use of the device, rather than in two or more subparts.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

Effective date. This regulation is effective March 6, 1980.

(Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. (360c, 371(a))))

Dated: January 14, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

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21 CFR Part 870

[Docket No. 78N–1407]

Cardiovascular Devices; Classification of Arrhythmia Detectors and Alarms

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying arrhythmia detectors and alarms into class III (premarket approval). The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning the safety and effectiveness tests of the device. Each application must be submitted to FDA on or before September 30, 1982, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: March 6, 1980.

FOR FURTHER INFORMATION CONTACT: John L. Ely, Bureau of Medical Devices (HFK–450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7559.

SUPPLEMENTARY INFORMATION: FDA published in the Federal Register of March 9, 1979 (44 FR 13284), a proposed regulation explaining the development of the proposed regulations classifying cardiovascular devices, the medical device classification procedures, and the activities of the Cardiovascular Device Classification Panel. FDA also published in that issue of the Federal Register (44 FR 13291) a proposed regulation to classify arrhythmia detectors and alarms into class III (premarket approval). A period of 60 days was provided for interested persons to submit written coments to FDA.

One comment was received regarding arrhythmia detectors and alarms. The comment suggested that the device should be in class II rather than class III as proposed. The comment said that "standards do exist and that determinations of effectiveness are available and recognized." The comment provided information showing one institution's purchasing specifications indicating the accuracy level and types of algorithm considered acceptable by that institution. The comment also presented data showing the means for comparison of accuracy of detection programs (Ref. 1).