select data that shows the merger in the best possible light, and will not reveal unfavorable data.

TAPS/APPA also criticize the data we suggested applicants submit to support their screen analyses.[7] They argue that applicants themselves would never assess a potential merger based only on these data. For example:

> [t]he complete heat rates of various units * * * which change by the point of the output of the unit on the load curve, are not data which are available on EIA Form 860, and the historical fuel costs shown in FERC Form 423 are not likely to be the projected fuel costs which would be used by any executive determining whether to commit his or her company to a merger.[8]

Unless the Commission decides in its planned rulemaking[9] to require submission of all the data the company actually considered when making the real-life decision on the merger, the screen analysis may be misleading, according to TAPS/APPA.

TAPS/APPA compare this Commission's decision-making under section 203 of the Federal Power Act to that of agencies acting under the Hart-Scott-Rodino Act.[10] They claim that the Commission will not be collecting a large part of the information that these agencies examine. For instance, the agencies require submission of all information the applicants considered when deciding whether to undertake the merger. Moreover, they can make a ''second request'' for even more information. TAPS/APPA argue that the Commission should require similar information. Specific information they say should be required includes, for example, transmission studies applicants have done that show various potential solutions to transmission constraints; different ways the applicants considered calculating available and total transmission capacity; information on vertical market power; and information on power alternatives that may not be truly available in the critical area because the power can be sold at a higher price elsewhere.

TAPS/APPA are particularly concerned that the 60-day period for interventions will not be adequate if intervenors will be expected to make a full-fledged case based on the limited information available. They point out that the applicant will have had much more time than 60 days to prepare the filing and argue that it is unfair to expect a complete, detailed response in 60 days. Finally, they suggest that the Commission allow the clock to be stopped while discovery goes forward and that intervenors be required to present their case 60 days after all necessary information is submitted.[11]

Discussion

At this time, we continue to believe that 60 days will generally be enough time for adequate interventions. Intervenors are free to argue that more time is needed in a particular case, and if we think more time is needed, we will extend the comment/intervention period.[12] Moreover, the Policy Statement sets forth suggested data only; we are free to request additional data in a particular case, and have done so since the Policy Statement was issued.[13] In our upcoming rulemaking proceeding, we will consider arguments as to what information should be required for mergers, as well as arguments as to filing deadlines and other procedural matters, since it is in that proceeding that we will propose a binding rule.[14]

TAPS/APPA also ask that in light of the dynamic nature of today's industry, the Commission make it clear that we will not ignore factual changes that occur while an application is pending. We do not intend to ignore significant factual changes.

The Commission orders: The motion for reconsideration or clarification is hereby denied in part and granted in part as set forth in the body of this order.

By the Commission.

Lois D. Cashell,

Secretary.

[FR Doc. 97–16042 Filed 6–18–97; 8:45 am]

BILLING CODE 6717–01–P

[7] Policy Statement, mimeo at Appendix B.

[8] TAPS/APPA reconsideration at 8 (footnote omitted).

[9] We noted in the Policy Statement that we will be issuing a Notice of Proposed Rulemaking to set forth more specific filing requirements and additional procedures. 61 FR at 68596, n.3.

[10] Hart-Scott-Rodino Antitrust Improvement Act of 1976, 15 U.S.C. 18a (1994).

[11] TAPS/APPA argue that the Commission should make it mandatory for merger applicants who want expedited treatment to serve potential intervenors with copies of the application by overnight delivery and electronic versions as well. Potential intervenors could be identified by having the applicants file a notice of intent to file even before they file the application itself; this would allow potential intervenors to identify themselves.

[12] We have stated our intention to shorten the comment period in certain types of cases that raise minimal concerns, Enova Corporation and Pacific Enterprises, 79 FERC ¶ 61,107 (1997), and will be willing to lengthen the comment period as well when a longer period is needed. *See* Pricing Policy for New and Existing Facilities Constructed by Interstate Natural Gas Pipelines, Order Denying Rehearing, 75 FERC ¶ 61,105 at 61,344 (1996) (issues raised in requests for ''rehearing'' of Policy Statement are case-specific in nature and should be addressed in individual cases).

[13] Letter order of April 3, 1997 from Debbie Clark, Chief Accountant, Federal Energy Regulatory Commission to Ohio Edison Company, *et al.* in Docket No. EC97–5–000.

[14] TAPS/APPA may raise in the rulemaking proceeding their arguments that it should be mandatory for applicants who want expedited treatment to make special service to potential intervenors.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket No. RM94–14–001; Order No. 580–A]

Nuclear Plant Decommissioning Trust Fund Guidelines; Order on Rehearing

Issued June 12, 1997.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Order on rehearing.

SUMMARY: On rehearing, the Commission is amending its rules governing the formation, organization and operation of nuclear plant decommissioning trust funds (Fund) and Fund investments: To remove the requirement that a Fund investment manager must have a net worth of at least $100 million (although it is retaining the $100 million net worth requirement for the Trustee); and to allow public utilities with nuclear units to maintain nuclear decommissioning trust funds that include both Commission-jurisdictional and non-Commission-jurisdictional trust fund collections. The Commission is also making certain corrections and providing certain clarifications, and confirming its conclusion that a public utility may not itself make individual investment decisions.

DATES: Effective: July 21, 1997. The incorporation by reference was approved on July 31, 1995.

FOR FURTHER INFORMATION CONTACT:
Joseph C. Lynch (Legal Information), Federal Energy Regulatory Commission, Office of the General Counsel, 888 First Street, NE., Washington, DC 20426, Telephone: (202) 208–2128
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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 interest persons an opportunity to inspect or copy the contents of the document during normal business hours

in the Public Reference Room at 888 First Street, NE., Washington, DC 20426.

The Commission Issuance Posting System (CIPS), an electronic bulletin board service, provides access to the texts of formal documents issued by the Commission. CIPS is available 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. The full text of this order will be available on CIPS in ASCII and WordPerfect 6.1 format. CIPS user assistance is available at 202–208–2474.

CIPS is also available on the Internet through the Fed World system. Telnet software is required. To access CIPS via the Internet, point your browser to the URL address: http//www.fedworld.gov and select the ''Go to the FedWorld Telnet Site'' button. When your Telnet software connects you, log onto the FedWorld system, scroll down and select FedWorld by typing: 1 at the command line then typing: /go FERC. FedWorld may also be accessed by Telnet at the address fedworld.gov.

Finally, the complete text on diskette in WordPerfect format may be purchased from the Commission's copy contractor, La Dorn Systems Corporation. La Dorn Systems Corporation is also located in the Public Reference Room at 888 First Street, NE., Washington, DC 20426.

Before Commissioners: Elizabeth Anne Moler, Chair; Vicky A. Bailey, James J. Hoecker, William L. Massey, and Donald F. Santa, Jr.

[Docket No. RM94–14–001]

Nuclear Plant Decommissioning Trust Fund Guidelines; Order No. 580–A; Order on Rehearing

Issued June 12, 1997.

In this order the Commission is: (a) Deleting from its regulations the requirement that a nuclear decommissioning trust fund investment manager must have a net worth of at least $100 million (although it is retaining the $100 million net worth requirement for the Trustee); and (b) allowing public utilities with nuclear units to maintain nuclear decommissioning trust funds that include both Commission-jurisdictional and non-Commission-jurisdictional decommissioning collections. It is also making certain corrections and providing certain clarifications,[1] and confirming its conclusion that a public utility may not itself make individual investment decisions.

Background

On June 16, 1995, the Commission issued a Final Rule in Nuclear Plant Decommissioning Trust Fund Guidelines,[2] setting forth requirements for the formation, organization and operation of nuclear decommissioning trust funds (Fund) and for Fund investments. The Final Rule provided, among other things, that:

A. The Trustee and any other Fiduciary shall have a net worth of at least $100 million; [3] and

B. The Fund must be an external trust fund in the United States, established pursuant to a written trust agreement that is independent of the utility, its affiliates or associates.[4]

The Commission received motions for stay and/or requests for rehearing and for clarification of the Final Rule from: Commonwealth Edison Company (Commonwealth Edison); Edison Electric Institute (EEI); a group of investment/trust companies and a group of public utilities (together: Investment/Trust/Utility Companies); [5] Indiana Michigan Power Company (I&M); Maine Yankee Atomic Power Company (Maine Yankee); New England Public Power Nuclear Customers; and Strong Capital Management Inc. (Strong). The requests for rehearing of Commonwealth Edison, EEI, Investment/Trust/Utility Companies and Strong ask the Commission to eliminate the requirement that a Fund investment manager must have a net worth of at least $100 million. Most of those requesting rehearing also oppose the Commission's requirement of a separate Fund for Commission-jurisdictional decommissioning collections.

Effective July 31, 1995, the Commission, pending further action on rehearing, stayed the requirement in 18 CFR 35.32(a)(4) that a Fund investment manager have a net worth of at least $100 million. In that same order, the Commission also stayed the requirement in 18 CFR 35.32(a)(1) and (f) that public utilities establish a separate nuclear decommissioning trust fund for Commission-jurisdictional Fund collections.[6] Following issuance of the stay, a number of entities filed comments.[7]

Discussion

A. One Hundred Million Dollar Net Worth Requirement for Investment Managers

1. Background

The Commission first imposed a $100 million net worth requirement in *System Energy Resources, Inc.*,[8] where the Commission directed that ''[t]he trustee [of a Fund] shall have a net worth of at least $100 million.'' [9] Following passage of section 1917 of the Energy Policy Act of 1992,[10] the Commission reaffirmed its then-existing guidelines for Fund organization and investment, including the requirement that a trustee have a net worth of $100 million.[11] In the Final Rule, the Commission extended the $100 million net worth requirement to Fund investment managers.[12]

The $100 million net worth requirement originally arose from the

[1] Among the changes and clarifications are the following: (a) the Commission is correcting the address references in 18 CFR 35.33(a)(3) to reflect that the Commission's library is in Room 95–01, 888 First Street, NE; (b) the Commission is deleting the ''Effective Date Note'' found at the end of 18 CFR 35.32 (this order on rehearing moots the stay referred to in that note); and (c) the Commission is clarifying the number of copies of the financial report required to be filed with the Commission.

[2] Nuclear Plant Decommissioning Trust Fund Guidelines, Order No. 580, 60 FR 34109 (June 30, 1995), FERC Stats. & Regs. Regulations Preambles 1991–96 ¶ 31,023 (1995).

[3] 18 CFR 35.32(a)(4); *see* FERC Stats. & Regs. Regulations Preambles 1991–96 at 31,360. In the Final Rule, the Commission used the term ''Fiduciary'' to refer to the ''person(s) or institutions(s) that perform the trustee and investment management functions * * * .'' 60 FR at 34116, FERC Stats. & Regs. Regulations Preambles 1991–96 at 31,359. Because a Fund investment manager performs an ''investment management function[],'' the Final Rule effectively required it to have a net worth of $100 million.

[4] 18 CFR 35.32(a)(1) and (f); *see* FERC Stats. & Regs. Regulations Preambles 1991–96 at 31,360.

[5] These two groups essentially filed identical pleadings. Citations to their pleadings will track the page numbers of the investment/trust companies' filing.

[6] Nuclear Plant Decommissioning Trust Fund Guidelines, 60 FR 39251–52 (August 2, 1995); FERC Stats. & Regs. Regulations Preambles 1991–96 ¶ 31,024 (1995).

[7] These entities are: Association for Investment Management and Research (AIMR); Sanford C. Bernstein & Co. (Bernstein); Capital Guardian Trust Company (Capital Guardian); Carolina Power & Light Company (CP&L); Florida Power & Light Company (FP&L); Loomis, Sayles & Company, L.P.; NISA Investment Advisors, L.L.C. (NISA); Nuveen • Duff & Phelps Investment Advisors (Nuveen); RCM Capital Management (RCM Capital); W.H. Reaves & Company; Southern Companies; Union Electric Company.

This decision takes into consideration all pleadings filed, both before and after the Commission issued the stay.

[8] 37 FERC ¶ 61,261 (1986) (*SERI I*), *clarified*, 65 FERC ¶ 61,083 (1993), *order on reh'g*, 67 FERC ¶ 61,228 (1994).

[9] *SERI I*, 37 FERC at 61,727.

[10] Pub. L. No. 102–486, 106 Stat. 2776, 3024–25 (1992); *see* 26 U.S.C. 468(A)(e).

[11] System Energy Resources, Inc., 65 FERC ¶ 61,083 (1993) (*SERI II*), *order on reh'g*, 67 FERC ¶ 61,228 (1994).

[12] *See supra* n.2 and accompanying text.

Commission's ''overriding concern about the security of a decommissioning fund,'' [13] and its intention ''to ensure that ratepayer-contributed funds will, in fact, be available when decommissioning occurs.'' [14] The intent of the $100 million net worth requirement adopted in the Final Rule was to ''ensure[] that the fiduciary [in this case, the Fund investment manager] will have the necessary assets to adequately self-insure its performance.'' [15] The ''performance'' to which the Commission referred was not market performance, but rather adherence to the prudent investor standard (set forth in Restatement (Third) of Trusts) that the Commission in the Final Rule laid down as the guiding fiduciary standard for Fund investment managers. [16] By imposing a $100 million net worth requirement, we sought to ensure that a utility would have assets to turn to should an investment manager's performance fall below the prudent investor standard. As represented by the comments and requests for rehearing (discussed below), the public utility and investment communities seem willing to do without this safeguard, which they find unduly costly and burdensome.

2. Comments and Requests for Rehearing

(a) *The $100 million net worth requirement.* Almost all commenters oppose the imposition of the $100 million net worth requirement for Fund investment managers; none support it. They observe that most investment managers do not have a net worth of $100 million. They submit that the $100 million net worth requirement will not only disqualify many investment advisors currently managing Fund assets, but also will pose a serious obstacle to firms that would otherwise seek to participate in Fund investment management. They argue that, if the Commission insists upon the $100 million net worth requirement, utility companies will lose a substantial body of experience *and* expertise. They further maintain that the requirement will force utilities to choose new investment managers from a small universe: those that have *both* $100 million in net worth *and* expertise in managing Fund assets. They contend that investment management fees will likely rise, since less robust competition and concentration of market power ordinarily leads to higher prices.[17]

The commenters fear that with management of Commission-jurisdictional decommissioning collections concentrated in the hands of a relatively few institutions, there will be a diminution of investment flexibility for Fund assets.[18] They further raise the possibilities of: (a) ''large investment losses'' [19] resulting from entry into the market of investment managers who have the requisite net worth but who are not experienced with the unique features of Fund investment management; [20] and (b) a ''forced liquidation effect'' if replacement investment managers change the composition of the Funds' investment portfolios. [21] Commonwealth Edison argues that, although ''the $100 million net worth requirement, as it relates to nuclear decommissioning trustees, is appropriate[,] * * * this requirement is unnecessary with respect to investment managers who direct the investment of the assets, but who do not exercise control over these assets as the trustees do.'' [22]

(b) *Alternative proposals.* Several commenters suggest that, in lieu of the $100 million net worth requirement, the Commission might insist that utilities select to manage their Fund investments only investment managers that conform to certain criteria. Among the criteria that these commenters suggest are: (a) A certain minimum amount of assets (for example, $1 billion) under management; (b) a minimum number of years (for example, ten) in the investment-management field; (c) a fidelity bond and errors and omissions insurance (for example, $1 million of insurance for every $5 million of Commission-jurisdictional funds under management); [23] registration with the Securities and Exchange Commission (SEC) under the Investment Advisors Act of 1940; (d) membership in a recognized investment industry organization; and (e) conformance with that organization's rules.[24] The commenters' believe that insistence upon these criteria may provide sufficient assurance that utilities will select responsible Fund investment managers.

3. Commission Response

(a) *$100 million net worth requirement.* While we do not agree with everything that they have said, the Commenters have raised an important issue. Were we to insist on the $100 million net worth requirement for Fund investment managers, public utilities with nuclear units would have to replace those investment managers currently in place who do not have the requisite net worth. Obviously, there would be a cost associated with searching for a new investment manager. This cost would affect a Fund's future compound earnings. And it is true, as earlier observed, that a change in investment managers could well result in a redirection in portfolio investment strategy (which, in turn, could have tax ramifications [25]).

Also, there is much force to the argument that utilities should not be forced to forego Fund investment managers who otherwise are capable, experienced and well-regarded, whom they have carefully selected, with whom they have worked for many years and who understand the regulatory environment in which Funds exist, simply because those investment managers do not have a particular stated net worth. The argument that the $100 million net worth requirement would result in a lack of flexibility in Fund

[13] *SERI II,* 65 FERC at 61,513.

[14] *Id.*

[15] 60 FR at 34117; FERC Stats. & Regs. Regulations Preambles 1991–96 at 31,360.

[16] 60 FR at 34122; FERC Stats. & Regs. Regulations Preambles 1991–96 at 31,369–70.

[17] *E.g.,* AIMR Comments at 2; Bernstein Comments at 2; Capital Guardian Comments at 2; Investment/Trust/Utility Companies Request for Rehearing at 9; Maine Yankee Request for Reconsideration at 3; NISA Comments at 4; Southern Company Comments at 8–9; Strong Comments at 3; Strong Request for Rehearing at 10–11.

[18] Investment/Trust/Utility Companies Request for Rehearing at 9; Strong Request for Rehearing at 10.

[19] *Id.*

[20] The commenters state that Fund investment management is very different from managing tax-sheltered assets for pensions funds, or even taxable assets for individuals. It involves a complicated investment problem: assuring the funding of an unusual liability while contending with complex tax, regulatory and legal constraints. For example, a Fund manager must not only comply with the requirements of the Securities and Exchange Commission, but also with the requirements of this Commission, the Nuclear Regulatory Commission, and state public service commissions. The Fund manager must also correctly interpret and comply with section 468A of the Internal Revenue Code. *See* NISA Comments on Rehearing at 4; Nuveen Comments on Rehearing at 2–3.

[21] *E.g.,* Investment/Trust/Utility Companies Request for Rehearing at 9; Strong Request for Rehearing at 10.

[22] Commonwealth Edison Request for Rehearing at 4. *See also* Maine Yankee Request for Rehearing at 2; Union Electric Comments at 2–3.

[23] Several parties, most notably RCM Capital, mentioned such insurance. A fidelity bond protects against theft of assets; errors and omissions insurance protects against a breach of fiduciary duty.

[24] *See e.g.,* AIMR Comments at 3; Bernstein Comments at 1–2; Loomis Sayles Comments at 1; Maine Yankee Comments at 2–3; NISA Comments at 5; RCM Capital Comments at 6, 11–14; Southern Companies Comments at 3; Strong Comments at 4–5. The criteria discussed above are a composite from the comments; not every commenter suggested each criterion.

[25] One would expect an investment manager to take such tax consequences into account when making decisions to sell Fund investments such as stock.

market investments also carries some weight. Having a greater number of investment fund managers available would allow a utility to employ several investment managers to manage various asset classes and to blend investment strategies for optimum Fund performance.[26]

We also recognize, as Commenters observe, that the $100 million net worth requirement reduces the number of available investment managers based on a net worth calculation that is not necessarily related to a manager's skill and performance.[27] Reducing the number of investment managers and concentrating Fund investments in the hands of a comparatively few institutions would reduce competition for the opportunity to manage Funds. Also, it could force several nuclear utilities to use the same investment manager, with the result that poor performance by one investment manager could affect a number of utilities with nuclear units.[28]

Nor is there an obvious correlation between the $100 million figure and sufficient assurance that a utility will be able to fund the decommissioning of its nuclear unit. In certain instances, a lesser net worth might well be adequate.[29] On balance, then, the commenters have persuaded us that the disadvantages attendant upon a $100 million net worth requirement for Fund investment managers outweigh its benefit as a recourse in the event of an investment manager's failure to adhere to the prudent investor standard. We will, therefore, delete this requirement. However, we will continue to impose this requirement for the Trustee. As we stated in the Final Rule, the Trustee's primary duty is custodial.[30] We continue to believe it appropriate that the individual who holds the funds have a net worth requirement of $100 million.

(b) *Other proposed requirements.* While we agree with commenters that the alternative criteria they propose may be useful and we encourage public utilities to consider them (and others that they believe are appropriate) in their selection of Fund managers, we decline to incorporate them into the Final Rule, because each criterion may not be appropriate in every instance. We prefer instead to rely on public utilities to choose their investment managers with the care and caution that the situation demands and to allow them flexibility in choosing the appropriate investment manager(s) in each individual case.

Although we are granting public utilities greater freedom in selecting their Fund investment managers than we initially adopted in the Final Rule, we, nevertheless, will hold public utilities to their duty to protect the ratepayers who are contributing the underlying principal that makes Fund investments possible. We will continue to insist that public utilities with nuclear units ensure that all of their fiduciaries, including their Fund investment managers, adhere to the prudent investor standard that we established in the Final Rule.

B. Requirement of Separate Fund for Commission-Jurisdictional Collections

1. The Final Rule

To ensure that Fund assets would not be available to creditors in the event of the bankruptcy of a utility, the Final Rule provided that:

> [T]he Trust assets must be segregated from those of the utility and outside the utility's administrative control. There must be a written trust agreement and the fiduciary or fiduciaries, in fulfilling the various duties, must be completely separate and apart from the utility. The utility may provide general investment policies, but it may do so only in writing and it may not engage in the day-to-day management of the Fund * * *.[31]

The Commission noted that these criteria accord with the regulations and guidelines that the Nuclear Regulatory Commission uses to ensure the availability of funds for decommissioning nuclear reactors.

2. Comments and Requests for Rehearing

Several commenters explain that, in most cases, public utilities that have nuclear generating units have already established for each generating unit both a qualified Fund (to which the public utility can make currently-deductible contributions under section 468A of the Internal Revenue Code (Tax Code)), and a non-qualified Fund. They further state that most of these public utilities have deposited in each Fund monies that they have collected from both interstate, wholesale (Commission-jurisdictional) sales and intrastate, retail (State-jurisdictional) sales and that in most (but not all) cases they have established separate accounts within each Fund to identify the different jurisdictional components (Commission- or state-jurisdictional) of the contributions to the Fund.[32]

These commenters argue that, if, as they believe we intended, we were to force public utilities to transfer assets from an existing, qualified Fund, containing both wholesale (Commission-jurisdictional) and retail (State-jurisdictional) collections, to a new Fund containing only Commission-jurisdictional collections, they may suffer adverse tax consequences.[33]

Various commenters also note that, in general, a public utility can maintain only one qualified Fund with respect to a nuclear unit.[34] There is an exception for nuclear units that are:

> Subject to the ratemaking jurisdiction of two or more public utility commissions * * * [when] any such * * * commission requires a separate fund to be maintained for the benefit of ratepayers whose rates are established or approved by the public utility commission * * *.[35]

Under this exception, ''the separate funds maintained for such a plant (whether or not established and maintained pursuant to a single trust agreement) * * * [are] considered a single [qualified Fund] for purposes'' of Tax Code section 468A and the underlying Treasury regulations.[36]

Several commenters contend that the exception does allow public utilities to establish a new, separate Fund to hold Commission-jurisdictional decommissioning collections, but only from the effective date of the Commission's Final Rule (July 31, 1995) and to treat the resulting two Funds (the existing Fund and the new, Commission-jurisdictional-only Fund) as a single qualified Fund for Federal income tax purposes only from that date forward. For example, Investment/Trust/Utility Companies submit that the exception allows public utilities to establish a separate Fund for Commission-jurisdictional collections only on a ''going-forward'' basis.[37]

Since the exception does not explicitly permit the transfer of assets from an existing qualified Fund to a

[26] *See* Capital Guardian Comments at 3; FP&L Comments at 4.

[27] *See* Carolina Power & Light Comments at 5; FP&L Comments at 2; Southern Companies Comments at 3 (''there is no established link between performance and net worth.'').

[28] *See* FP&L Comments at 3.

[29] *See* Commonwealth Edison Comments at 4 (its annual Commission-jurisdictional decommissioning collections are currently $340,000).

[30] 60 FR at 34116; FERC Stats. & Regs. Regulations Preambles 1991–1996 at 31,359.

[31] 60 FR at 34117; FERC Stats. & Regs. Regulations Preambles 1991–96 at 31,360 (footnote omitted).

[32] *E.g.,* Investment/Trust/Utility Companies Request for Rehearing at 3; Strong Request for Rehearing at 3.

[33] *E.g.,* Investment/Trust/Utility Companies Request for Rehearing at 2–4; Strong Request for Rehearing at 4.

[34] *See* 26 CFR 1.468–A–5(a)(iii).

[35] *Id.*

[36] *Id.*

[37] Investment/Trust/Utility Companies Request for Rehearing at 5. *See also* Strong Request for Rehearing at 5.

newly-established, separate Fund, commenters are concerned that the Internal Revenue Service (IRS) might treat the transfer of assets as a withdrawal, and as a taxable event. They point out that, should the IRS treat the transfer of assets as a withdrawal, and as a taxable event, the IRS would recognize gains or losses on the transferred assets, include the value of the transferred assets in the public utility's income in the current year for Federal income tax purposes and deny a current deduction for the contribution of the transferred assets to the newly-established, separate Fund. [38]

3. Commission response

Having considered the commenters' concerns, we agree that a separate Fund for Commission-jurisdictional collections is not necessary to our properly monitoring Commission-jurisdictional collections for decommissioning, so long as public utilities establish clearly identifiable separate accounts within a single Fund to identify Commission-jurisdictional and state-jurisdictional components of the Fund. This accounting would allow decommissioning collections to remain consolidated in a single trust, while separately identifying Commission- and state-jurisdictional assets. It would also avoid the additional expenses associated with establishing and maintaining separate trusts.[39]

The Final Rule provides that the Trustee or Investment Manager shall keep accurate and detailed accounts of all investments, receipts, disbursements and transactions of the Fund. [40] This requirement incorporates the necessity of distinguishing between Commission- and state-jurisdictional collections, and we shall carefully monitor Funds' compliance with this requirement. Consistent with this discussion, we also are modifying 18 CFR 35.32(a)(1) to expressly provide that if a Fund includes monies collected in both Commission-jurisdictional and non-Commission-jurisdictional rates, then a separate account of the Commission-jurisdictional monies shall be maintained.

C. Other matters

1. Fund Balances

a. *Request for rehearing.* I&M asks that we modify the Final Rule to allow a public utility to: (a) completely decommission *all* of its nuclear plants before making any refunds to ratepayers of excess balances and (b) to use a surplus from one Fund to make up for a shortfall in another Fund. I&M argues that forcing each Fund to stand entirely on its own may result in excessive Fund balances to ensure that each Fund is adequate to support the decommissioning of the nuclear unit to which it relates. [41]

b. *Commission response.* We decline to make this change in the Final Rule. I&M is correct when it observes that, ''a rule that requires refunds from individual Funds * * * is a requirement that each Fund must stand entirely on its own.'' [42] As we noted in the Final Rule, Funds are not generic. Each Fund does stand on its own. Public utilities with multiple nuclear units must collect unit-by-unit amounts to decommission *each* unit and must meet deficiencies on a unit-by-unit basis. [43] To do otherwise would allow utilities to speculate with the solvency of individual Funds through a form of risk management, ''offsetting favorable and unfavorable assumptions regarding each plant or unit * * * [and so obtaining] the advantage of diversification of risk through aggregation * * * .'' [44] Such risk balancing could put individual funds at risk.

What I&M also overlooks is that Fund investment managers are fiduciaries. Each Fund is unit-specific because the fiduciary duty of each Fund investment manager is to the ratepayers who have contributed to the cost of decommissioning the specific unit for which it manages the Fund. While a particular fiduciary may administer more than one Fund, it has a separate fiduciary responsibility to the ratepayers contributing to each Fund. A fiduciary should not be allowed to violate its duty to the ratepayers who contributed to the Fund it manages in order to make available monies for the decommissioning of other units.

We will not allow public utilities with multiple nuclear units to use excesses in one Fund to offset deficiencies in another Fund and so force one set of ratepayers to subsidize another. I&M, however, speculates that the same customer group may be associated with both Funds.[45] Even were this the case, and I&M has not demonstrated that it is, still, the customer group is contributing to the decommissioning of two units and has the right to be secure that the separate collections for *each* unit will be used to decommission *that* unit. As we stated in the Final Rule:

> The remedy for a Fund deficiency is not to take a surplus from another Fund, but to adjust the collections for the Fund that is deficient.[46]

2. Audits and Inspections of Accounts

a. *Request for rehearing.* I&M challenges our authority to direct a public utility with nuclear units to conduct an audit or inspection of the accounts, books and/or records of a Fund and to participate in such an audit or inspection.[47] It asks that we delete the following language from the Final Rule:

> The utility or its designee must notify the Commission prior to performing * * * [an] inspection or audit. The Commission may direct the utility to conduct an audit or inspection.[48]

b. *Commission response.* Our authority to order public utilities to audit or inspect the accounts, books and records and to forward the results of that examination to us, (and our authority to participate in those audits should we choose to do so) derives from our authority to ensure that public utilities' accounts are correct and conform to the Commission's Uniform System of Accounts.[49] It also derives from our authority to determine, under sections 205 and 206 of the Federal Power Act (FPA),[50] whether, how, and to what extent a public utility may recover decommissioning funds through wholesale rates, just as we have the authority to regulate the recovery of all other costs of service through wholesale rates.

As we noted in the Final Rule, the inclusion in rates of amounts to cover future decommissioning expenditures would not be just and reasonable if we did not concomitantly provide the necessary safeguards to ensure that

[38] Investment/Trust/Utility Companies Request for Rehearing at 5–6; Strong Request for Rehearing at 5–7. Tax Code section 468A(b) limits the amount that a public utility may contribute to a qualified Fund and currently deduct in a given year to the amount of decommissioning costs that the public utility includes in its cost of service for ratemaking purposes for that year. Were the IRS to consider a transfer from a previously-established Fund to a new Fund a withdrawal, and a taxable event, the IRS would deny a current deduction to the extent that the transferred assets exceed the amount of allowable contribution to the new Fund in the current year.

[39] *See* Union Electric Company Comments at 2.

[40] 18 CFR 35.32(a)(5).

[41] I&M Request for Rehearing at 2–5.

[42] Id. at 3.

[43] 60 FR at 34,117; FERC Stats. & Regs. Regulations Preambles 1991–96 at 31,361.

[44] I&M Request for Rehearing at 3–4.

[45] *Id.* at 3.

[46] 60 FR at 34117; FERC Stats. & Regs. Regulations Preambles 1991–96 at 31,361.

[47] I&M Request for Rehearing at 5.

[48] 18 CFR 35.32(a)(5).

[49] The Commission's authority to prescribe a uniform system of accounts and to require jurisdictional utilities to keep accounts is well settled. *See* Kansas City Gas and Electric Company, 43 FERC ¶61,248 at 61,675 (1988) and cases there cited.

[50] 16 U.S.C. 824d, 824e.

public utilities will use the collections for their intended purpose.[51] One of these necessary safeguards is our ability to order public utilities to audit or inspect Fund accounts, books and records and to forward the results to us for our inspection (and for us to participate in those audits if we choose). In the Final Rule we stated that:

> By allowing public utilities with nuclear units to collect decommissioning funds in advance of decommissioning expenditures, the Commission has allowed the utilities to become fiduciaries for their ratepayers. The Commission did not have to allow this fiduciary relationship to form. But, having allowed the relationship to develop, the Commission undoubtedly has the authority to impose appropriate conditions upon the fiduciaries' use of ratepayers' funds to ensure that Fund monies will be available for their intended purpose, *i.e.* to cover the cost of decommissioning.[52]

Accordingly, we will not delete the challenged language from the regulations.

3. Reports

a. *Request for clarification.* New England Public Power Nuclear Customers ask the Commission to specify whether Fund annual reports will be public documents. They also ask the Commission to direct that public utilities serve Fund annual reports on all wholesale customers. They reason that directing public utilities to serve Fund annual reports on all wholesale customers would be consistent with the Commission's requirements at 18 CFR 35.2(d), 35.3(a) and 35.8(a), that public utilities serve changes in rate schedules on all wholesale customers, and

> would enable wholesale customers to keep themselves and their customers informed, to bring problems to the Commission's attention when necessary, and to negotiate more effectively with public utilities over decommissioning rates and related matters.[53]

b. *Commission response.* A Fund annual report is not a rate schedule. Nevertheless, we agree that ratepayers and other interested entities should have access to Funds' annual reports. These reports are public documents and will, of course, be available in the Commission's Public Reference Room at 888 First Street, NE., Washington, DC 20426. In addition, we will require Funds to mail a copy of their annual report to anyone who requests it. This will make the information available to anyone who requests it, while at the same time avoiding the needless expense of mailing copies of the annual report to those who have no wish to see them.[54]

4. Investments

a. *Request for clarification.* Maine Yankee inquires whether the provision in the Final Rule prohibiting a utility from ''engag[ing] in day-to-day management of the Fund or mandat[ing] individual investment decisions'' [55] would prohibit Maine Yankee from itself investing a portion of its Fund in an equity index mutual fund that replicates the Standard & Poor 500 index. Maine Yankee submits that the decision to select a mutual fund is akin to a decision regarding general investment objectives and the selection of an investment manager. Maine Yankee maintains that:

> In selecting a mutual fund, the utility is adopting an investment policy of paralleling market performance and is achieving this performance at a low cost. The utility engages in no individual fund management and no investment decision. The mutual fund manager serves in the role of investment manager.[56]

b. *Commission response.*

In the Final Rule we stated that:

> The utility may provide general investment policies, but * * * may not engage in the day-to-day management of the Fund or * * * itself make individual investment decisions.[57]

We disagree with Maine Yankee that the decision to invest a portion of Maine Yankee's Fund in a specific mutual fund is akin to the selection of a Fund investment manager. The mutual fund manager manages the mutual fund on behalf of all of the customers of the mutual fund; it does not make investment decisions solely on Maine Yankee's behalf. We also disagree with Maine Yankee that in selecting a mutual fund ''[t]he utility engages in * * * no investment decision.'' [58] The decision to invest a portion of Maine Yankee's Fund in a mutual fund would be an individual investment decision, and a ''utility may not * * * itself make individual investment decisions.'' [59]

Individual investment decisions are solely the province of the Fund investment manager, who ''directs and implements the Fund's investment program * * *.'' [60] Maine Yankee has the responsibility to select ''trained, experienced, professional investment managers who are skilled in the art of offsetting risk,'' [61] but the Fund manager makes individual Fund investment decisions. Maine Yankee may not itself invest a portion of its Fund portfolio in a mutual fund.

Regulatory Flexibility Act Certification

The Regulatory Flexibility Act [62] requires rulemakings to either contain a description and analysis of the effect that the proposed rule will have on small entities or to contain a certification that the rule will not have a substantial economic impact on a substantial number of small entities. Most public utilities to which the proposed rule would apply do not fall within the definition of small entity.[63] Consequently, the Commission certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

Effective Date and Congressional Notification

This rule is effective July 21, 1997. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget, that this order on rehearing is not a major rule within the meaning of section 351 of the Small Business Regulatory Enforcement Act of 1996.[64] The Commission is submitting the order on rehearing to both Houses of Congress and to the Comptroller General.

List of Subjects in 18 CFR Part 35

Electric power rates, Electric utilities, Incorporation by reference, Reporting and recordkeeping requirements.

By the Commission.

Lois D. Cashell,

Secretary.

In consideration of the foregoing, the Commission amends Part 35, Chapter I, Title 18, *Code of Federal Regulations,* as set forth below.

PART 35—FILING OF RATE SCHEDULES

1. The authority citation for Part 35 continues to read as follows:

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[51] 60 FR 34112–13; FERC Stats. & Regs. Regulations Preambles 1991–96 at 31,352–353.

[52] 60 FR 34113; FERC Stats. & Regs. Regulations Preambles 1991–96 at 31,353.

[53] New England Public Power Customers at 4.

[54] We will also revise 18 CFR 35.33(d) to provide that the utility submit to the Commission each year an original and 3 conformed copies of the financial report furnished to the utility by the Fund's Trustee.

[55] 18 CFR 35.32(a)(2).

[56] Maine Yankee Request for Clarification at 4.

[57] 60 FR at 34117; FERC Stats. & Regs. Regulations Preambles 1991–96 at 31,360.

[58] Maine Yankee Request for Clarification at 4.

[59] 60 FR at 34117; FERC Stats. & Regs. Regulations Preambles 1991–96 at 31,360.

[60] 60 FR at 34116; FERC Stats. & Regs. Regulations Preambles 1991–96 at 31,359.

[61] 60 FR at 34122; FERC Stats. & Regs. Regulations Preambles 1991–96 at 31,369.

[62] 5 U.S.C. 601–612.

[63] *See* 5 U.S.C. 601(3), citing to section 3 of the Small Business Act, 15 U.S.C. 632, which defines ''small business concern'' as a business that is independently owned and operated and that is not dominant in its field of operation.

[64] 5 U.S.C. 804(2).

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

2. Sections 35.32 and 35.33 are revised to read as follows:

§ 35.32 General provisions.

(a) If a public utility has elected to provide for the decommissioning of a nuclear power plant through a nuclear plant decommissioning trust fund (Fund), the Fund must meet the following criteria:

(1) The Fund must be an external trust fund in the United States, established pursuant to a written trust agreement, that is independent of the utility, its subsidiaries, affiliates or associates. If the trust fund includes monies collected both in Commission-jurisdictional rates and in non-Commission-jurisdictional rates, then a separate account of the Commission-jurisdictional monies shall be maintained.

(2) The utility may provide overall investment policy to the Trustee or Investment Manager, but it may do so only in writing, and neither the utility nor its subsidiaries, affiliates or associates may serve as Investment Manager or otherwise engage in day-to-day management of the Fund or mandate individual investment decisions.

(3) The Fund's Investment Manager must exercise the standard of care, whether in investing or otherwise, that a prudent investor would use in the same circumstances. The term ''prudent investor'' means a prudent investor as described in Restatement of the Law (Third), Trusts § 227, including general comments and reporter's notes, pages 8–101. St. Paul, MN: American Law Institute Publishers, (1992). ISBN 0–314–84246–2. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Law Institute, 4025 Chestnut Street, Philadelphia, PA 19104, and are also available in local law libraries. Copies may be inspected at the Federal Energy Regulatory Commission's Library, Room 95–01, 888 First Street, NE. Washington, DC or at the Office of the Federal Register, 800 North Capitol St., NW., Room 700, Washington, DC.

(4) The Trustee shall have a net worth of at least $100 million. In calculating the $100 million net worth requirement, the net worth of the Trustee's parent corporation and/or affiliates may be taken into account only if such entities guarantee the Trustee's responsibilities to the Fund.

(5) The Trustee or Investment Manager shall keep accurate and detailed accounts of all investments, receipts, disbursements and transactions of the Fund. All accounts, books and records relating to the Fund shall be open to inspection and audit at reasonable times by the utility or its designee or by the Commission or its designee. The utility or its designee must notify the Commission prior to performing any such inspection or audit. The Commission may direct the utility to conduct an audit or inspection.

(6) Absent the express authorization of the Commission, no part of the assets of the Fund may be used for, or diverted to, any purpose other than to fund the costs of decommissioning the nuclear power plant to which the Fund relates, and to pay administrative costs and other incidental expenses, including taxes, of the Fund.

(7) If the Fund balances exceed the amount actually expended for decommissioning after decommissioning has been completed, the utility shall return the excess jurisdictional amount to ratepayers, in a manner the Commission determines.

(8) Except for investments tied to market indexes or other mutual funds, the Investment Manager shall not invest in any securities of the utility for which it manages the funds or in that utility's subsidiaries, affiliates, or associates or their successors or assigns.

(9) The utility and the Fiduciary shall seek to obtain the best possible tax treatment of amounts collected for nuclear plant decommissioning. In this regard, the utility and the Fiduciary shall take maximum advantage of tax deductions and credits, when it is consistent with sound business practices to do so.

(10) Each utility shall deposit in the Fund at least quarterly all amounts included in Commission-jurisdictional rates to fund nuclear power plant decommissioning.

(b) The establishment, organization, and maintenance of the Fund shall not relieve the utility or its subsidiaries, affiliates or associates of any obligations it may have as to the decommissioning of the nuclear power plant. It is not the responsibility of the Fiduciary to ensure that the amount of monies that a Fund contains are adequate to pay for a nuclear unit's decommissioning.

(c) A utility may establish both qualified and non-qualified Funds with respect to a utility's interest in a specific nuclear plant. This section applies to both ''qualified'' (under the Internal Revenue Code, 26 U.S.C. 468A, or any successor section) and non-qualified Funds.

(d) A utility must regularly supply to the Fund's Investment Manager, and regularly update, essential information about the nuclear unit covered by the Trust Fund Agreement, including its description, location, expected remaining useful life, the decommissioning plan the utility proposes to follow, the utility's liquidity needs once decommissioning begins, and any other information that the Fund's Investment Manager would need to construct and maintain, over time, a sound investment plan.

(e) A utility should monitor the performance of all Fiduciaries of the Fund and, if necessary, replace them if they are not properly performing assigned responsibilities.

§ 35.33 Specific provisions.

(a) In addition to the general provisions of § 35.32, the Trustee must observe the provisions of this section.

(b) The Trustee may use Fund assets only to:

(1) Satisfy the liability of a utility for decommissioning costs of the nuclear power plant to which the Fund relates as provided by § 35.32; and

(2) Pay administrative costs and other incidental expenses, including taxes, of the Fund as provided by § 35.32.

(c) To the extent that the Trustee does not currently require the assets of the Fund for the purposes described in paragraphs (b)(1) and (b)(2) of this section, the Investment Manager, when investing Fund assets, must exercise the same standard of care that a reasonable person would exercise in the same circumstances. In this context, a ''reasonable person'' means a prudent investor as described in Restatement of the Law (Third), Trusts § 227, including general comments and reporter's notes, pages 8–101. St. Paul, MN: American Law Institute Publishers, 1992. ISBN 0–314–84246–2. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Law Institute, 4025 Chestnut Street, Philadelphia, PA 19104, and are also available in local law libraries. Copies may be inspected at the Federal Energy Regulatory Commission's Library, Room 95–01, 888 First Street, NE. Washington, DC or at the Office of the Federal Register, 800 North Capitol St., NW., Room 700, Washington, DC.

(d) The utility must submit to the Commission by March 31 of each year, one original and three conformed copies of the financial report furnished to the utility by the Fund's Trustee that shows for the previous calendar year:

(1) Fund assets and liabilities at the beginning of the period;

(2) Activity of the Fund during the period, including amounts received

from the utility, purchases and sales of investments, gains and losses from investment activity, disbursements from the Fund for decommissioning activity and payment of Fund expenses, including taxes; and

(3) Fund assets and liabilities at the end of the period. The report should not include the liability for decommissioning.

(e) The utility must also mail a copy of the financial report provided to the Commission pursuant to paragraph (d) of this section to anyone who requests it.

(f) If an independent public accountant has expressed an opinion on the report or on any portion of the report, then that opinion must accompany the report.

[FR Doc. 97–16043 Filed 6–18–97; 8:45 am]
BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Office of the Commissioner

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority by adding a new authority from the Assistant Secretary for Health (ASH), Office of Public Health and Science (OPHS), Office of the Secretary (OS), to the Commissioner of Food and Drugs (the Commissioner), delegating all the authorities vested in the Secretary under section 601 of Effective Medication Guides of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1997, as amended hereafter. The delegation excludes the authority to issue reports to Congress.

EFFECTIVE DATE: June 19, 1997.

FOR FURTHER INFORMATION CONTACT: Loretta W. Davis, Division of Management Systems and Policy (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4809.

SUPPLEMENTARY INFORMATION: On October 7, 1996, the Secretary of Health and Human Services delegated to the ASH, OPHS, with authority to redelegate as appropriate, the authorities vested in the Secretary under section 601 of Effective Medication Guides of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1997 (Pub. L. 104–180), as amended hereafter. In a memorandum dated January 27, 1997, the ASH delegated to the Commissioner all of the authorities delegated to the ASH under section 601 of Effective Medication Guides of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1997 (Pub. L. 104–180), as amended hereafter.

Further redelegation of the authority delegated may only be authorized with the Commissioner's approval. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591.

2. Section 5.10 is amended by adding a new paragraph (a)(39) to read as follows:

(a) * * *

(39) Functions vested in the Secretary under section 601 of Effective Medication Guides of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act of 1997 (Pub. L. 104–180), as amended hereafter. The delegation excludes the authority to issue reports to Congress.

* * * * *

Dated: June 12, 1997.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

[FR Doc. 97–16065 Filed 6–18–97; 8:45 am]
BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 85N–0285]

Medical Devices; Reclassification of the Infant Radiant Warmer

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to reclassify the infant radiant warmer from class III (premarket approval) into class II (special controls). The infant radiant warmer is a device intended to maintain the infant's body temperature by means of radiant heat. The special controls are the Association for the Advancement of Medical Instrumentation (AAMI) Voluntary Standard for the Infant Radiant Warmer, a prescription statement, and labeling. This reclassification is based on new information regarding the device contained in a reclassification petition submitted by the Health Industries Manufacturers Association (HIMA). This action is taken under the Medical Device Amendments of 1976 as amended by the Safe Medical Devices Act of 1990.

EFFECTIVE DATE: July 21, 1997.

FOR FURTHER INFORMATION CONTACT: Patricia M. Cricenti, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 24, 1979 (44 FR 49873), FDA published a proposed rule to classify the infant radiant warmer into class III. The preamble included the classification recommendation of the General Hospital and Personal Use Devices Panel (the Panel). The Panel's recommendation included a summary of the reasons why the device should be subject to premarket approval and identified certain risks to health presented by the device, including electric shock, possible eye damage due to long-term exposure to infrared radiation, patient