

SEP 26 1996

STATE LIAISON OFFICERS  
STATE PUBLIC UTILITY COMMISSIONS

DRAFT POLICY STATEMENT ON THE RESTRUCTURING AND ECONOMIC DEREGULATION  
OF THE ELECTRIC UTILITY INDUSTRY (SP-96-104)

The Nuclear Regulatory Commission is seeking comment on the draft statement of policy regarding its expectations for, and intended approach to, its power reactor licensees as the electric utility industry moves from an environment of rate regulation toward greater competition. The NRC is concerned that rate deregulation and disaggregation resulting from various restructuring involving power reactor licensees could have adverse effects on the protection of public health and safety. Enclosed for your review and consideration is a copy of the Federal Register notice which includes the draft policy statement. You are invited to submit comments on this draft policy statement by December 9, 1996.

Original Signed By  
RICHARD L. BANGART  
Richard L. Bangart, Director  
Office of State Programs

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UNITED STATES  
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

September 26, 1996

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(c) Any remedies permitted CCC under this part shall be in addition to any other remedy, including, but not limited to criminal remedies, or actions for damages in favor of CCC, or the United States, as may be permitted by law.

(d) Absent a scheme or device to defeat the purpose of the program, when an owner loses control of CRP acreage due to foreclosure and the new owner chooses not to continue the contract according to § 1410.51, refunds shall not be required from any participant on the contract.

(e) Crop insurance requirements in part 1405 of this chapter apply to all acreage initially enrolled after October 12, 1994, as determined by the Deputy Administrator.

(f) Land enrolled in CRP shall be classified as cropland for the time period enrolled in CRP and, after the time period of enrollment, shall be removed from such classification upon a determination by the county committee that such land no longer meets the conditions identified in part 718 of this title.

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#### § 1410.63 Permissive uses.

Unless otherwise specified by the Deputy Administrator, no crops of any kind may be planted or harvested from designated CRP acreage during the contract period.

#### § 1410.64 Special concurrence requirements for certain functions

In establishing policies, priorities, and guidelines, FSA shall obtain the concurrence of the NRCS at national, State, and local levels.

#### § 1410.65 Paperwork Reduction Act assigned numbers.

The Office of Management and Budget has approved the information collection requirements contained in these

regulations under provisions 44 U.S.C. Chapter 35 and OMB number 0560-0125 has been assigned.

Signed at Washington, DC, on September 17, 1996.

Bruce R. Weber,

Acting Administrator, Farm Service Agency,  
and Acting Executive Vice President,  
Commodity Credit Corporation.

(FR Doc. 96-24268 Filed 9-19-96; 8:45 a.m.)

BILLING CODE 3410-06-P

## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 50

#### Draft Policy Statement on the Restructuring and Economic Deregulation of the Electric Utility Industry

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft Policy Statement request for public comment.

**SUMMARY:** The NRC is seeking comment on the draft statement of policy regarding its expectations for, and intended approach to, its power reactor licensees as the electric utility industry moves from an environment of rate regulation toward greater competition. The NRC is concerned that rate deregulation and disintegration resulting from various restructurings involving power reactor licensees could have adverse effects on the protection of public health and safety.

**DATES:** The public is invited to submit comments on this draft Policy Statement by December 9, 1996. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date. On the basis of the submitted comments, the Commission will determine whether to modify the draft Policy Statement before issuing it in final form.

**ADDRESSES:** Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington DC 20555, Attention: Docketing and Service Branch.

Deliver Comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m., Federal workdays.

Examine copies of comments received at: The NRC Public Document Room, 2120 L Street NW (Lower Level), Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Robert S. Wood, Office of Nuclear Reactor Regulation, U.S. Nuclear

Regulatory Commission, Washington, DC 20555, telephone (301) 415-1255, e-mail RSW1@nrc.gov; or, for the antitrust aspects of this policy statement, William Lambe, telephone (301) 415-1277, e-mail WML@nrc.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. Purpose

The purpose of this draft policy statement is to provide a discussion of the NRC's concerns regarding the potential safety impacts on NRC power reactor licensees resulting from the economic deregulation and restructuring of the electric utility industry and the means by which NRC intends to address those concerns. This draft policy statement recognizes the changes that are occurring in the electric utility industry and the importance these changes may have for the NRC and its licensees. The NRC's principal mission is to regulate the Nation's civilian use of byproduct, source, and special nuclear materials to ensure adequate protection of the public health and safety, to promote the common defense and security, and to protect the environment. As part of carrying out this mission, the NRC must monitor licensee activities and any changes in licensee activities, as well as external factors that may affect the ability of individual licensees to safely operate and decommission licensed power production facilities.

##### II. Background

The electric utility industry is entering a period of economic deregulation and restructuring which is intended to lead to increased competition in the industry. Increasing competition may force integrated power systems to separate (or "disaggregate") their systems into functional areas. Thus, some licensees may divest electrical generation assets from transmission and distribution assets by forming separate subsidiaries or even separate companies for generation. Disaggregation may involve utility restructuring, mergers, and corporate spin-offs that lead to changes in owners or operators of licensed power reactors and may cause some licensees, including owners, to cease being an "electric utility" as defined in 10 CFR 50.2.<sup>1</sup> Such changes may affect the

<sup>1</sup> Section 50.2 defines "electric utility" as "any entity that generates or distributes electricity and which recovers the cost of this electricity, either directly or indirectly, through rates established by the entity itself or by a separate regulatory authority. Investor-owned utilities, including generation and distribution subsidiaries, public utility districts, municipalities, rural electric

Continued

licensing basis under which the NRC originally found a licensee to be financially qualified to construct, operate or own its power plant, as well as to accumulate adequate funds to ensure decommissioning at the end of reactor life.

Rate regulators have typically allowed an electric utility to recover prudently incurred costs of generating, transmitting, and distributing electric services. Consequently, in 1984, the NRC eliminated financial qualifications reviews at the operating license stage for those licensees that met the definition of "electric utility" in 10 CFR 50.2 (49 FR 35747, Sept. 12, 1984). The NRC based this decision on the assumption that "the rate process assures that funds needed for safe operation will be made available to regulated electric utilities" (49 FR at 35750). However, the NRC recognized that financial qualifications reviews for operating license applicants might be appropriate in particular cases where, for example, "the local public utility commission will not allow the total cost of operating the facility to be recovered through rates" (49 FR at 35751). The Commission also has expressed potential concern with various State proposals to implement economic performance incentive programs.<sup>2</sup>

In its 1988 decommissioning rule, the NRC again distinguished between electric utilities and other licensees by allowing "electric utilities" to accumulate funds for decommissioning over the remaining terms of their operating licenses. NRC regulations require its other licensees (with the added exception of State and Federal government licensees of certain facilities) to provide funding assurance for the full estimated cost of decommissioning, either through full up-front funding or by some allowable guarantee or surety mechanism.

A discussion of the current and future NRC review process will be contained in two Standard Review Plans that the NRC plans to issue—one for financial qualifications and decommissioning funding assurance reviews and the other for antitrust reviews. In addition, the

NRC issued an Administrative Letter on June 21, 1996, that informed power reactor licensees of their ongoing responsibility to inform, and obtain advance approval from the NRC for any changes that would constitute a transfer of the license, directly or indirectly, through transfer of control of the NRC license to any person pursuant to 10 CFR 50.80. This administrative letter also reminded addressees of their responsibility to assure that information regarding a licensee's financial qualifications and decommissioning funding assurance which may have a significant implication for public health and safety is promptly reported to the NRC.

### III. Policy Statement

The NRC is concerned with the potential impact of utility restructuring on public health and safety. The NRC has not found a consistent relationship between a licensee's financial health and general indicators of safety such as the NRC's Systematic Assessment of Licensee Performance (SALP). Thus, the NRC has traditionally relied on its inspection process to indicate when safety performance has begun to show adverse trends. Based on inspection program results, the NRC can take appropriate action, including, ultimately, plant shutdown, to protect public health and safety. However, if a plant is permanently shut down, that plant's licensee(s) may no longer have access to adequate revenues or other sources of funds for decommissioning the facility. If rate deregulation and organizational divestiture occur concurrently with the shutdown of a nuclear plant either by NRC action or by a licensee's economic decision, that licensee may not be able to provide adequate assurance of decommissioning funds. Thus, the NRC believes that its concerns with deregulation and restructuring lie primarily in the area of adequacy of decommissioning funds, although it is also concerned with the potential effect that economic deregulation may have on operational safety.

As the electric utility industry moves from an environment of substantial economic regulation to one of increased competition, the NRC is concerned about the pace of restructuring and rate deregulation. Approval of organizational and rate deregulation changes may occur rapidly without the NRC's knowledge. The pace and degree of such changes could affect the factual underpinnings of the NRC's previous conclusions that power reactor licensees can reliably accumulate adequate funds for operations and decommissioning

over the operating lives of their facilities. For example, rate deregulation could create situations where a licensee that previously qualified as an "electric utility" under 10 CFR 50.2 may, at some point, no longer qualify for such status. At that point, the NRC may require licensees to submit proof pursuant to 10 CFR 50.33(f)(4) that they remain financially qualified and will require them to meet the more stringent decommissioning funding assurance requirements of 10 CFR 50.75 that are applicable to non-electric utilities.

Although new and unique restructuring proposals will necessarily involve ad hoc reviews by the NRC, the Commission will exercise direct oversight of such reviews to maintain consistent NRC policy toward new entities. The NRC has considered mergers, the formation of holding companies, and the outright sales of facilities, or portions of facilities, to require NRC notification and prior approval in accordance with 10 CFR 50.80 in order to ensure that the transferee is appropriately qualified. For example, the NRC determines whether the surviving organization will remain an "electric utility" as defined in 10 CFR 50.2.

In consideration of these concerns, the NRC will be evaluating deregulation and restructuring activities as they evolve. The NRC will take all appropriate actions to carry out its mission to protect the health and safety of the public and, to the extent of its statutory mandate, to ensure consistency with Federal antitrust laws.

The NRC intends to implement policies and take action as described in this policy statement to ensure that its power reactor licensees remain responsible for safe operations and decommissioning. In summary, the NRC will:

- (1) Continue to conduct its financial qualifications, decommissioning funding and antitrust reviews as described in the Standard Review Plans being developed in concert with this policy statement;
- (2) Identify all owners, indirect as well as direct, of nuclear power plants;
- (3) Establish and maintain staff-level working relationships with State and Federal rate regulators;
- (4) Evaluate the relative responsibilities of power plant co-owners/co-licensees; and
- (5) Reevaluate its regulations for their adequacy to address changes resulting from rate deregulation.

cooperatives, and State and Federal agencies, including associations of any of the foregoing, are included within the meaning of "electric utility."

<sup>2</sup> See Possible Safety Impacts of Economic Performance Incentives: Final Policy Statement, (56 FR 33945; July 24, 1991), for the NRC's concerns relating to State economic performance incentive standards and programs. The NRC understands that States instituted many of these programs as a means of encouraging electric utilities to lower electric rates to consumers. As States deregulate electric utilities under their jurisdictions, these economic performance incentive programs ultimately may be replaced by full market competition.



#### IV. Issues Related to Restructuring and Economic Deregulation of the Electric Utility Industry

The NRC believes that its regulatory framework is generally sufficient to address many of the restructurings and reorganizations that will likely arise as a result of electric utility deregulation. In many instances, the NRC's review process will follow the current framework, or will otherwise follow policies consistent with the NRC's current regulations. However, the NRC believes that several other policy issues need to be further evaluated and options developed. Therefore, this section addresses NRC policies with respect to electric utility restructuring and economic deregulation both as these policies can be carried out under current regulations and as matters under consideration for further resolution.

##### A. NRC Responsibilities vis-a-vis State and Federal Economic Regulators

The NRC has recognized the primary role that State and Federal economic regulators serve in setting rates that include appropriate levels of funding for safe operation and decommissioning. For example, the preamble to the 1988 decommissioning rule stated: "The rule, and the NRC's implementation of it, does not deal with financial ratemaking issues such as rate of fund collection, procedures for fund collection, cost to ratepayers, taxation effects, equitability between early and late ratepayers, accounting procedures, ratepayer versus stockholder considerations, responsiveness to change and other similar concerns\* \* \*. These matters are outside NRC's jurisdiction and are the responsibility of the State PUCs and [the Federal Energy Regulatory Commission] FERC" (53 FR at 24038; June 27, 1988).

Notwithstanding the primary role of economic regulators in rate matters, the NRC has authority under the Atomic Energy Act of 1954, as amended, (AEA) to take actions that may affect a licensee's financial situation when these actions are warranted to protect public health and safety. To date, the NRC has found no significant instances where State or Federal rate regulation has led to disallowance of funds for safety-related operational and decommissioning expenses. Some rate regulators may have chosen to reduce allowable profit margins through rate disallowances, or licensees have for other reasons encountered financial difficulty.

In order for the NRC to make its safety views known and to encourage rate regulators to continue their practice of

allowing adequate expenditures for nuclear plant safety as electric utilities face deregulation, the NRC intends to take a number of actions to increase cooperation with State and Federal rate and financial regulators to promote dialogue and minimize the possibility of rate deregulation or other actions that would have an adverse safety impact. We intend to work and consult with the State PUCs through the National Association of Regulatory Utility Commissioners (NARUC), and with FERC and the Securities and Exchange Commission (SEC) to coordinate activities and exchange information.

##### B. Co-owner Division of Responsibility

Many of the NRC's power reactor licensees own their plants jointly with other, non-related organizations. Although some co-owners may be only authorized to possess the nuclear facility and its nuclear material, and not to operate it, the NRC views all co-owners as co-licensees who are responsible for complying with the terms of their licenses. Public Service Company of Indiana, Inc. (Marble Hill Nuclear Generating Station, Units 1 & 2), ALAB-459, 7 NRC 179, 200-201 (1978). The NRC is concerned about the effects on the availability of operating and decommissioning funds, and about the division of responsibility for operating and decommissioning funds, when co-owners file for bankruptcy or otherwise encounter financial difficulty.<sup>3</sup> The NRC is evaluating courses of action to ensure that operating and decommissioning costs are paid by owners.

##### C. Financial Qualifications Reviews

The NRC believes that the existing regulatory framework contained in § 50.33(f) and in the guidance in 10 CFR part 50, appendix C, is generally sufficient at this time to provide reasonable assurance of the financial qualifications of both electric utility and non-electric utility applicants and licensees under the various ownership arrangements of which the staff is currently aware. Licensees that remain "electric utilities" will not be subject to NRC financial qualifications review,

<sup>3</sup> The NRC has had experience with 3 licensees who have had much greater than de minimis shares of nuclear power plants and who filed under Chapter 11 of the U.S. Bankruptcy Code. Public Service Company of New Hampshire (PSNH), a co-owner and operator of the Seabrook plant; El Paso Electric Company (EPEC), a co-owner of the Palo Verde plant; and Cajun Electric Power Cooperative (Cajun), a co-owner of the River Bend plant. Both PSNH and EPEC continued their pro rata contributions for the operating and decommissioning expenses for their plants and successfully emerged from bankruptcy. Cajun remains in bankruptcy.

other than to determine that such licensees, in fact, remain "electric utilities." However, the NRC is evaluating the need to develop additional requirements to ensure against potential dilution of capability for safe operation and decommissioning that could arise from rate deregulation and restructuring.

Section 184 of the Atomic Energy Act and 10 CFR 50.80 provide that no license shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission consents in writing. The NRC intends to review transfers to determine their potential impact on the licensee's ability both to maintain adequate technical qualifications and organizational control and authority over the facility and to provide adequate funds for safe operation and decommissioning. Such consent is clearly required where a corporate entity seeks to transfer a license it holds to a different corporate entity. See Long Island Lighting Co. (Shoreham Nuclear Power Station, Unit 1) CLI-92-4, 35 NRC 69 (1992). The NRC staff has advised licensees that agency consent should be sought and obtained under § 50.80 for the formation of a new holding company over an existing licensee. Other types of transactions, including those involving transfers of operating authority or responsibility to non-licensed organizations, have been considered by the staff on a case by case basis to determine whether § 50.80 consent is required. The NRC is evaluating what types of transfers or restructurings should be subject to § 50.80 review. Effective December 28, 1995, all orders approving § 50.80 transfers have been signed by the Director, Office of Nuclear Reactor Regulation. The NRC staff will inform the Commission of unique or unusual licensee restructuring actions.

##### D. Decommissioning Funding Assurance Compliance Reviews

The NRC believes that the existing decommissioning funding assurance provisions in § 50.75 generally provide an adequate regulatory basis for new licensees to provide reasonable assurance of decommissioning funds. However, to address this and other issues related to decommissioning funding assurance in anticipation of rate deregulation, the NRC published an advance notice of proposed rulemaking (ANPR) (61 FR 15427; April 8, 1996).

##### E. Antitrust Reviews

The NRC must be able to accurately identify all owners of its licensees to meaningfully assess whether there have been "significant changes" since the

licensing reviews. The NRC anticipates that competitive reviews over the next 5 to 10 years will arise primarily from changes in control of licensed facilities. The regulatory review addressing transfer of control of licenses under 10 CFR 50.80 will be used to determine whether new owners or operators will be subject to an NRC significant change review with respect to antitrust matters.

#### Electronic Access

Comments may be submitted electronically, in either ASCII text or WordPerfect format (version 5.1 or later), by calling the NRC electronic Bulletin Board (BBS) on FedWorld. The bulletin board may be accessed by using a personal computer, a modem, and one of the commonly available communications software packages, or directly via Internet. Background documents on the draft policy statement are also available, as practical, for downloading and viewing on the bulletin board.

If using a personal computer and modem, the NRC Rulemaking subsystem on FedWorld can be accessed directly by dialing the toll free number (800) 303-9672. Communication software parameters should be set as follows: parity to none, data bits to 8, and stop bits to 1 (N,8,1). Using ANSI or VT-100 terminal emulation, the NRC Rulemaking subsystem can then be accessed by selecting the "Rules Menu" option from the "NRC Main Menu." Many NRC subsystems and databases also have a "Help/Information Center" option that is tailored to the particular subsystem.

The NRC subsystem on FedWorld can also be accessed by a direct dial telephone number for the main FedWorld BBS, (703) 321-3339, or by using Telnet via Internet: fedworld.gov. If using (703) 321-3339 to contact FedWorld, the NRC subsystem will be accessed from the main FedWorld menu by selecting the "Regulatory, Government Administration and State Systems," then selecting "Regulatory Information Mail." At that point, a menu will be displayed that has an option "U.S. Nuclear Regulatory Commission" that will take you to the NRC Online main menu. The NRC Online area also can be accessed directly by typing "/go nrc" at a FedWorld command line. If you access NRC from FedWorld's main menu, you may return to FedWorld by selecting the "Return to FedWorld" option from the NRC Online Main Menu. However, if you access NRC at FedWorld by using NRC's toll-free number, you will have full access to all NRC systems, but you

will not have access to the main FedWorld system.

If you contact FedWorld using Telnet, you will see the NRC area and menus, including the Rules Menu. Although you will be able to download documents and leave messages, you will not be able to write comments or upload files (comments). If you contact FedWorld using FTP, all files can be accessed and downloaded but uploads are not allowed; all you will see is a list of files without descriptions (normal Gopher look). An index file listing all files within a subdirectory, with descriptions, is available. There is a 15-minute time limit for FTP access.

Although FedWorld can also be accessed through the World Wide Web, like FTP that mode only provides access for downloading files and does not display the NRC Rules Menu.

For more information on NRC bulletin boards call Mr. Arthur Davis, Systems Integration and Development Branch, NRC, Washington, DC 20555, telephone (301) 415-5780; e-mail AXD3@nrc.gov.

Dated at Rockville, Maryland, this 16th day of September 1996.

For the Nuclear Regulatory Commission.

John C. Hoyle,

Secretary of the Commission.

[FR Doc. 96-24275 Filed 9-20-96; 8:45 am]

BILLING CODE 7590-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 106 and 107

[Docket No. 95N-0309]

RIN 0910-AA04

#### Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for the Production of Infant Formula; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to December 6, 1996, the comment period on the proposed rule that published in the *Federal Register* of July 9, 1996 (61 FR 36154). The document proposed to revise FDA's infant formula regulations. The agency is taking this action in response to a request for an extension of the comment period. This extension is

intended to allow interested persons additional time to submit comments to FDA on the proposed regulations.

**DATES:** Written comments by December 6, 1996.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Carolyn W. Miles, Center for Food Safety and Applied Nutrition (HFS-456), 200 C St. SW., Washington, DC 20204, 202-401-9858.

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of July 9, 1996 (61 FR 36154), FDA issued a proposed rule to revise its infant formula regulations to establish requirements for quality factors and current good manufacturing practice (CGMP); to amend its requirements on quality control procedures, notification, and records and reports; to require that infant formulas contain, and be tested for, certain nutrients, be tested for any nutrients added by the manufacturer throughout their shelf life, and be produced under strict microbiological controls; to require that manufacturers implement the CGMP and quality control procedure requirements by establishing a production and in-process control system of their own design; and to implement certain notification requirements in the Federal Food, Drug, and Cosmetic Act. Interested persons were given until October 7, 1996, to comment on the proposed rule.

FDA received a request for an extension of the comment period on its proposed rule to revise its infant formula regulations. After careful consideration, FDA has decided to extend the comment period to December 6, 1996, to allow additional time for the submission of comments on the proposed revisions to its infant formula regulations.

Interested persons may, on or before December 6, 1996, submit to Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

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NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

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Signed at Washington, DC, on September 17, 1996.

Bruce R. Weber,

Acting Administrator, Farm Service Agency,  
and Acting Executive Vice President,  
Commodity Credit Corporation.

[FR Doc. 96-24268 Filed 9-19-96; 8:45 am]

BILLING CODE 3410-06-P

## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 50

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**SUMMARY:** The NRC is seeking comment on the draft statement of policy regarding its expectations for, and intended approach to, its power reactor licensees as the electric utility industry moves from an environment of rate regulation toward greater competition. The NRC is concerned that rate deregulation and disaggregation resulting from various restructurings involving power reactor licensees could have adverse effects on the protection of public health and safety.

**DATES:** The public is invited to submit comments on this draft Policy Statement by December 9, 1996. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date. On the basis of the submitted comments, the Commission will determine whether to modify the draft Policy Statement before issuing it in final form.

**ADDRESSES:** Mail comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington DC 20555, Attention: Docketing and Service Branch.

Deliver Comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m., Federal workdays.

Examine copies of comments received at: The NRC Public Document Room, 2120 L Street NW (Lower Level), Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Robert S. Wood, Office of Nuclear Reactor Regulation, U.S. Nuclear

Regulatory Commission, Washington, DC 20555, telephone (301) 415-1255, e-mail RSW1@nrc.gov; or, for the antitrust aspects of this policy statement, William Lambe, telephone (301) 415-1277, e-mail WML@nrc.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. Purpose

The purpose of this draft policy statement is to provide a discussion of the NRC's concerns regarding the potential safety impacts on NRC power reactor licensees resulting from the economic deregulation and restructuring of the electric utility industry and the means by which NRC intends to address those concerns. This draft policy statement recognizes the changes that are occurring in the electric utility industry and the importance these changes may have for the NRC and its licensees. The NRC's principal mission is to regulate the Nation's civilian use of byproduct, source, and special nuclear materials to ensure adequate protection of the public health and safety, to promote the common defense and security, and to protect the environment. As part of carrying out this mission, the NRC must monitor licensee activities and any changes in licensee activities, as well as external factors that may affect the ability of individual licensees to safely operate and decommission licensed power production facilities.

##### II. Background

The electric utility industry is entering a period of economic deregulation and restructuring which is intended to lead to increased competition in the industry. Increasing competition may force integrated power systems to separate (or "disaggregate") their systems into functional areas. Thus, some licensees may divest electrical generation assets from transmission and distribution assets by forming separate subsidiaries or even separate companies for generation. Disaggregation may involve utility restructuring, mergers, and corporate spin-offs that lead to changes in owners or operators of licensed power reactors and may cause some licensees, including owners, to cease being an "electric utility" as defined in 10 CFR 50.2.<sup>1</sup> Such changes may affect the

<sup>1</sup> Section 50.2 defines "electric utility" as "any entity that generates or distributes electricity and which recovers the cost of this electricity, either directly or indirectly, through rates established by the entity itself or by a separate regulatory authority. Investor-owned utilities, including generation and distribution subsidiaries, public utility districts, municipalities, rural electric

Continued

licensing basis under which the NRC originally found a licensee to be financially qualified to construct, operate or own its power plant, as well as to accumulate adequate funds to ensure decommissioning at the end of reactor life.

Rate regulators have typically allowed an electric utility to recover prudently incurred costs of generating, transmitting, and distributing electric services. Consequently, in 1984, the NRC eliminated financial qualifications reviews at the operating license stage for those licensees that met the definition of "electric utility" in 10 CFR 50.2 (49 FR 35747; Sept. 12, 1984). The NRC based this decision on the assumption that "the rate process assures that funds needed for safe operation will be made available to regulated electric utilities" (49 FR at 35750). However, the NRC recognized that financial qualifications reviews for operating license applicants might be appropriate in particular cases where, for example, "the local public utility commission will not allow the total cost of operating the facility to be recovered through rates" (49 FR at 35751). The Commission also has expressed potential concern with various State proposals to implement economic performance incentive programs.<sup>2</sup>

In its 1988 decommissioning rule, the NRC again distinguished between electric utilities and other licensees by allowing "electric utilities" to accumulate funds for decommissioning over the remaining terms of their operating licenses. NRC regulations require its other licensees (with the added exception of State and Federal government licensees of certain facilities) to provide funding assurance for the full estimated cost of decommissioning, either through full up-front funding or by some allowable guarantee or surety mechanism.

A discussion of the current and future NRC review process will be contained in two Standard Review Plans that the NRC plans to issue—one for financial qualifications and decommissioning funding assurance reviews and the other for antitrust reviews. In addition, the

NRC issued an Administrative Letter on June 21, 1996, that informed power reactor licensees of their ongoing responsibility to inform, and obtain advance approval from the NRC for any changes that would constitute a transfer of the license, directly or indirectly, through transfer of control of the NRC license to any person pursuant to 10 CFR 50.80. This administrative letter also reminded addressees of their responsibility to assure that information regarding a licensee's financial qualifications and decommissioning funding assurance which may have a significant implication for public health and safety is promptly reported to the NRC.

### III. Policy Statement

The NRC is concerned with the potential impact of utility restructuring on public health and safety. The NRC has not found a consistent relationship between a licensee's financial health and general indicators of safety such as the NRC's Systematic Assessment of Licensee Performance (SALP). Thus, the NRC has traditionally relied on its inspection process to indicate when safety performance has begun to show adverse trends. Based on inspection program results, the NRC can take appropriate action, including, ultimately, plant shutdown, to protect public health and safety. However, if a plant is permanently shut down, that plant's licensee(s) may no longer have access to adequate revenues or other sources of funds for decommissioning the facility. If rate deregulation and organizational divestiture occur concurrently with the shutdown of a nuclear plant either by NRC action or by a licensee's economic decision, that licensee may not be able to provide adequate assurance of decommissioning funds. Thus, the NRC believes that its concerns with deregulation and restructuring lie primarily in the area of adequacy of decommissioning funds, although it is also concerned with the potential effect that economic deregulation may have on operational safety.

As the electric utility industry moves from an environment of substantial economic regulation to one of increased competition, the NRC is concerned about the pace of restructuring and rate deregulation. Approval of organizational and rate deregulation changes may occur rapidly without the NRC's knowledge. The pace and degree of such changes could affect the factual underpinnings of the NRC's previous conclusions that power reactor licensees can reliably accumulate adequate funds for operations and decommissioning

over the operating lives of their facilities. For example, rate deregulation could create situations where a licensee that previously qualified as an "electric utility" under 10 CFR 50.2 may, at some point, no longer qualify for such status. At that point, the NRC may require licensees to submit proof pursuant to 10 CFR 50.33(f)(4) that they remain financially qualified and will require them to meet the more stringent decommissioning funding assurance requirements of 10 CFR 50.75 that are applicable to non-electric utilities.

Although new and unique restructuring proposals will necessarily involve ad hoc reviews by the NRC, the Commission will exercise direct oversight of such reviews to maintain consistent NRC policy toward new entities. The NRC has considered mergers, the formation of holding companies, and the outright sales of facilities, or portions of facilities, to require NRC notification and prior approval in accordance with 10 CFR 50.80 in order to ensure that the transferee is appropriately qualified. For example, the NRC determines whether the surviving organization will remain an "electric utility" as defined in 10 CFR 50.2.

In consideration of these concerns, the NRC will be evaluating deregulation and restructuring activities as they evolve. The NRC will take all appropriate actions to carry out its mission to protect the health and safety of the public and, to the extent of its statutory mandate, to ensure consistency with Federal antitrust laws.

The NRC intends to implement policies and take action as described in this policy statement to ensure that its power reactor licensees remain responsible for safe operations and decommissioning. In summary, the NRC will:

- (1) Continue to conduct its financial qualifications, decommissioning funding and antitrust reviews as described in the Standard Review Plans being developed in concert with this policy statement;
- (2) Identify all owners, indirect as well as direct, of nuclear power plants;
- (3) Establish and maintain staff-level working relationships with State and Federal rate regulators;
- (4) Evaluate the relative responsibilities of power plant co-owners/co-licensees; and
- (5) Reevaluate its regulations for their adequacy to address changes resulting from rate deregulation.

cooperatives, and State and Federal agencies, including associations of any of the foregoing, are included within the meaning of "electric utility."

<sup>2</sup> See Possible Safety Impacts of Economic Performance Incentives: Final Policy Statement, (56 FR 33945; July 24, 1991), for the NRC's concerns relating to State economic performance incentive standards and programs. The NRC understands that States instituted many of these programs as a means of encouraging electric utilities to lower electric rates to consumers. As States deregulate electric utilities under their jurisdictions, these economic performance incentive programs ultimately may be replaced by full market competition.

#### IV. Issues Related to Restructuring and Economic Deregulation of the Electric Utility Industry

The NRC believes that its regulatory framework is generally sufficient to address many of the restructurings and reorganizations that will likely arise as a result of electric utility deregulation. In many instances, the NRC's review process will follow the current framework, or will otherwise follow policies consistent with the NRC's current regulations. However, the NRC believes that several other policy issues need to be further evaluated and options developed. Therefore, this section addresses NRC policies with respect to electric utility restructuring and economic deregulation both as these policies can be carried out under current regulations and as matters under consideration for further resolution.

##### A. NRC Responsibilities vis-a-vis State and Federal Economic Regulators

The NRC has recognized the primary role that State and Federal economic regulators serve in setting rates that include appropriate levels of funding for safe operation and decommissioning. For example, the preamble to the 1988 decommissioning rule stated: "The rule, and the NRC's implementation of it, does not deal with financial ratemaking issues such as rate of fund collection, procedures for fund collection, cost to ratepayers, taxation effects, equitability between early and late ratepayers, accounting procedures, ratepayer versus stockholder considerations, responsiveness to change and other similar concerns" \* \* \*. These matters are outside NRC's jurisdiction and are the responsibility of the State PUCs and [the Federal Energy Regulatory Commission] FERC" (53 FR at 24038; June 27, 1988).

Notwithstanding the primary role of economic regulators in rate matters, the NRC has authority under the Atomic Energy Act of 1954, as amended, (AEA) to take actions that may affect a licensee's financial situation when these actions are warranted to protect public health and safety. To date, the NRC has found no significant instances where State or Federal rate regulation has led to disallowance of funds for safety-related operational and decommissioning expenses. Some rate regulators may have chosen to reduce allowable profit margins through rate disallowances, or licensees have for other reasons encountered financial difficulty.

In order for the NRC to make its safety views known and to encourage rate regulators to continue their practice of

allowing adequate expenditures for nuclear plant safety as electric utilities face deregulation, the NRC intends to take a number of actions to increase cooperation with State and Federal rate and financial regulators to promote dialogue and minimize the possibility of rate deregulation or other actions that would have an adverse safety impact. We intend to work and consult with the State PUCs through the National Association of Regulatory Utility Commissioners (NARUC), and with FERC and the Securities and Exchange Commission (SEC) to coordinate activities and exchange information.

##### B. Co-owner Division of Responsibility

Many of the NRC's power reactor licensees own their plants jointly with other, non-related organizations. Although some co-owners may be only authorized to possess the nuclear facility and its nuclear material, and not to operate it, the NRC views all co-owners as co-licensees who are responsible for complying with the terms of their licenses. Public Service Company of Indiana, Inc. (Marble Hill Nuclear Generating Station, Units 1 & 2), ALAB-459, 7 NRC 179, 200-201 (1978). The NRC is concerned about the effects on the availability of operating and decommissioning funds, and about the division of responsibility for operating and decommissioning funds, when co-owners file for bankruptcy or otherwise encounter financial difficulty.<sup>3</sup> The NRC is evaluating courses of action to ensure that operating and decommissioning costs are paid by owners.

##### C. Financial Qualifications Reviews

The NRC believes that the existing regulatory framework contained in § 50.35(f) and in the guidance in 10 CFR part 50, appendix C, is generally sufficient at this time to provide reasonable assurance of the financial qualifications of both electric utility and non-electric utility applicants and licensees under the various ownership arrangements of which the staff is currently aware. Licensees that remain "electric utilities" will not be subject to NRC financial qualifications review,

<sup>3</sup> The NRC has had experience with 3 licensees who have had much greater than de minimis shares of nuclear power plants and who filed under Chapter 11 of the U.S. Bankruptcy Code: Public Service Company of New Hampshire (PSNH), a co-owner and operator of the Seabrook plant; El Paso Electric Company (EPEC), a co-owner of the Palo Verde plant; and Cajun Electric Power Cooperative (Cajun), a co-owner of the River Bend plant. Both PSNH and EPEC continued their pro rata contributions for the operating and decommissioning expenses for their plants and successfully emerged from bankruptcy. Cajun remains in bankruptcy.

other than to determine that such licensees, in fact, remain "electric utilities." However, the NRC is evaluating the need to develop additional requirements to ensure against potential dilution of capability for safe operation and decommissioning that could arise from rate deregulation and restructuring.

Section 184 of the Atomic Energy Act and 10 CFR 50.80 provide that no license shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission consents in writing. The NRC intends to review transfers to determine their potential impact on the licensee's ability both to maintain adequate technical qualifications and organizational control and authority over the facility and to provide adequate funds for safe operation and decommissioning. Such consent is clearly required where a corporate entity seeks to transfer a license it holds to a different corporate entity. See Long Island Lighting Co. (Shoreham Nuclear Power Station, Unit 1) CLI-92-4, 35 NRC 69 (1992). The NRC staff has advised licensees that agency consent should be sought and obtained under § 50.80 for the formation of a new holding company over an existing licensee. Other types of transactions, including those involving transfers of operating authority or responsibility to non-licensed organizations, have been considered by the staff on a case by case basis to determine whether § 50.80 consent is required. The NRC is evaluating what types of transfers or restructurings should be subject to § 50.80 review. Effective December 28, 1995, all orders approving § 50.80 transfers have been signed by the Director, Office of Nuclear Reactor Regulation. The NRC staff will inform the Commission of unique or unusual licensee restructuring actions.

##### D. Decommissioning Funding Assurance Compliance Reviews

The NRC believes that the existing decommissioning funding assurance provisions in § 50.75 generally provide an adequate regulatory basis for new licensees to provide reasonable assurance of decommissioning funds. However, to address this and other issues related to decommissioning funding assurance in anticipation of rate deregulation, the NRC published an advance notice of proposed rulemaking (ANPR) (61 FR 15427; April 8, 1996).

##### E. Antitrust Reviews

The NRC must be able to accurately identify all owners of its licensees to meaningfully assess whether there have been "significant changes" since the



licensing reviews. The NRC anticipates that competitive reviews over the next 5 to 10 years will arise primarily from changes in control of licensed facilities. The regulatory review addressing transfer of control of licenses under 10 CFR 50.80 will be used to determine whether new owners or operators will be subject to an NRC significant change review with respect to antitrust matters.

#### Electronic Access

Comments may be submitted electronically, in either ASCII text or WordPerfect format (version 5.1 or later), by calling the NRC electronic Bulletin Board (BBS) on FedWorld. The bulletin board may be accessed by using a personal computer, a modem, and one of the commonly available communications software packages, or directly via Internet. Background documents on the draft policy statement are also available, as practical, for downloading and viewing on the bulletin board.

If using a personal computer and modem, the NRC Rulemaking subsystem on FedWorld can be accessed directly by dialing the toll free number (800) 303-9672. Communication software parameters should be set as follows: parity to none, data bits to 8, and stop bits to 1 (N,8,1). Using ANSI or VT-100 terminal emulation, the NRC Rulemaking subsystem can then be accessed by selecting the "Rules Menu" option from the "NRC Main Menu." Many NRC subsystems and data bases also have a "Help/Information Center" option that is tailored to the particular subsystem.

The NRC subsystem on FedWorld can also be accessed by a direct dial telephone number for the main FedWorld BBS, (703) 321-3339, or by using Telnet via Internet: fedworld.gov. If using (703) 321-3339 to contact FedWorld, the NRC subsystem will be accessed from the main FedWorld menu by selecting the "Regulatory, Government Administration and State Systems," then selecting "Regulatory Information Mail." At that point, a menu will be displayed that has an option "U.S. Nuclear Regulatory Commission" that will take you to the NRC Online main menu. The NRC Online area also can be accessed directly by typing "go nrc" at a FedWorld command line. If you access NRC from FedWorld's main menu, you may return to FedWorld by selecting the "I turn to FedWorld" option from the NRC Online Main Menu. However, if you access NRC at FedWorld by using NRC's toll-free number, you will have full access to all NRC systems, but you

will not have access to the main FedWorld system.

If you contact FedWorld using Telnet, you will see the NRC area and menus, including the Rules Menu. Although you will be able to download documents and leave messages, you will not be able to write comments or upload files (comments). If you contact FedWorld using FTP, all files can be accessed and downloaded but uploads are not allowed; all you will see is a list of files without descriptions (normal Gopher look). An index file listing all files within a subdirectory, with descriptions, is available. There is a 15-minute time limit for FTP access.

Although FedWorld can also be accessed through the World Wide Web, like FTP that mode only provides access for downloading files and does not display the NRC Rules Menu.

For more information on NRC bulletin boards call Mr. Arthur Davis, Systems Integration and Development Branch, NRC, Washington, DC 20555, telephone (301) 415-5780; e-mail AXD3@nrc.gov.

Dated at Rockville, Maryland, this 16th day of September 1996.

For the Nuclear Regulatory Commission.  
John C. Hoyle,  
Secretary of the Commission.  
[FR Doc. 96-24275 Filed 9-20-96; 8:45 am]  
BILLING CODE 7590-01-2

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 106 and 107

[Docket No. 95N-0309]

RIN 0910-AA04

#### Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for the Production of Infant Formula; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is extending to December 6, 1996, the comment period on the proposed rule that published in the *Federal Register* of July 9, 1996 (61 FR 36154). The document proposed to revise FDA's infant formula regulations. The agency is taking this action in response to a request for an extension of the comment period. This extension is

intended to allow interested persons additional time to submit comments to FDA on the proposed regulations.

**DATES:** Written comments by December 6, 1996.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Carolyn W. Miles, Center for Food Safety and Applied Nutrition (HFS-456), 200 C St. SW., Washington, DC 20204, 202-401-0858.

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of July 9, 1996 (61 FR 36154), FDA issued a proposed rule to revise its infant formula regulations to establish requirements for quality factors and current good manufacturing practice (CGMP); to amend its requirements on quality control procedures, notification, and records and reports; to require that infant formulas contain, and be tested for, certain nutrients, be tested for any nutrients added by the manufacturer throughout their shelf life, and be produced under strict microbiological controls; to require that manufacturers implement the CGMP and quality control procedure requirements by establishing a production and in-process control system of their own design; and to implement certain notification requirements in the Federal Food, Drug, and Cosmetic Act. Interested persons were given until October 7, 1996, to comment on the proposed rule.

FDA received a request for an extension of the comment period on its proposed rule to revise its infant formula regulations. After careful consideration, FDA has decided to extend the comment period to December 6, 1996, to allow additional time for the submission of comments on the proposed revisions to its infant formula regulations.

Interested persons may, on or before December 6, 1996, submit to Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.