Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN AF77

License Term for Medical Use Licenses

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission is proposing to amend 10 CFR part 35 to eliminate the five-year term limit for medical use licenses in 10 CFR 35.18. License terms for licenses issued pursuant to part 35 would be set, by policy up to ten years, as are the license terms for other materials licenses. The NRC would issue some licenses for shorter terms, if warranted by the individual circumstances of license applicants. The amendment would reduce the administrative burden of license renewals for both NRC and licensees, and would support NRC's goal of streamlining the licensing process.

DATES: Submit comments by October 14, 1997. Comments received after this date will be considered, if it is practical to do so, but the NRC is able to assure consideration only for comments received on or before this date.

ADDRESSES: Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Hand-deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m., Federal workdays.

Copies of any comments received may be examined at the NRC Public Document Room, 2120 L Street NW (lower level), Washington, DC.

For information on submitting comments electronically, see the discussion under Electronic Access in the Supplementary Information section.

FOR FURTHER INFORMATION CONTACT: William B. McCarthy, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–7894; e-mail WBM@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In 1995, the NRC Office of Nuclear Material Safety and Safeguards (NMSS) initiated a review to determine whether the license term for material licenses could be increased so that NRC's licensing resources could be redirected to other areas of the materials program. The resources devoted to renewals constituted over 50 percent of the total resources expended for licensing. NMSS undertook this review as a part of NRC's business process redesign efforts.

The license renewal process has been used as an opportunity for the Commission to review: (1) The history of the licensee's operating performance (e.g., the record on compliance with regulatory requirements); and (2) the licensee's program. This review is performed to ascertain if the licensee employs up-to-date technology and practices in the protection of health, safety, and the environment, and complies with any new or amended regulations. As part of a license renewal, the licensee is asked to provide information on the current status of its program as well as any proposed changes in operations (types and quantities of authorized materials), personnel (authorized users and radiation safety officers), facility, equipment, or applicable procedures. The renewal process has been perceived to benefit both the licensee and NRC because it requires both to take a comprehensive look at the licensed operation. However, in practice, most of the proposed changes are identified and requested by licensees as amendments rather than during the license renewal process.

License terms have been reviewed on numerous occasions since 1967. On May 12, 1967 (32 FR 7172), the Commission amended 10 CFR part 40 to eliminate a three-year limit on the term of source material licenses. At that time, there was no restriction on the term of byproduct licenses under 10 CFR part 30 or special nuclear material licenses, under 10 CFR part 70. In the notice of proposed rulemaking associated with this rule, dated December 22, 1966, NRC indicated that if the proposed amendment to eliminate the three-year restriction were adopted, licenses would be issued for five-year terms, except when the nature of the applicant's proposed activities indicated a need for a shorter license period. At that time, the Commission believed there was little justification for granting licenses under 10 CFR parts 30, 40, and 70 for terms of less than five years, in view of the cumulative experience up to that time and the means available to NRC to suspend, revoke, or modify such licenses if public health and safety or environment so required. Licenses have been issued for five-year terms since 1967.

In March 1978, NMSS conducted a study (SECY–78–284, ''The License Renewal Study for parts 30, 40 and 70 Licenses'') to consider changing the five-year renewal period for parts 30, 40, and 70 licenses. The study concluded, in part, that the NRC should continue its practice of issuing specific licenses for five-year terms and should retain an option to write licenses for shorter terms, if deemed necessary for new types of operations, or if circumstances warranted.

On July 26, 1985 (50 FR 30616), NRC proposed revising 10 CFR part 35, ''Medical Use of Byproduct Material.'' The proposed rulemaking indicated that the Commission had selected a term of five years for a license. It was believed that a term shorter than five years would not benefit health and safety because past experience indicated that medical programs did not generally change significantly over that period of time. The notice also indicated that a longer term may occasionally result in unintentional abandonment of the license. On October 16, 1986 (51 FR 36932), NRC issued the final rule that consolidated and clarified radiation safety requirements related to the medical use of byproduct materials, and included a license term of five years.

On June 19, 1990 (55 FR 24948), the Commission announced that the license term for major operating fuel cycle licensees (i.e., licenses issued pursuant to 10 CFR parts 40 or 70) would be increased from a five-year term to a ten-year term at the next renewal of the affected licenses. This change enabled NRC resources to be used to improve the licensing and inspection programs. The bases for this change were that major operating fuel cycle facilities had become stable in terms of significant changes to their licenses and operations,

and that licensees would be required to update the safety demonstration sections of their licenses every two years.

On July 2, 1996, the Commission approved the NRC staff's proposal to extend the license term for uranium recovery facilities from five years to ten years. Extending the license terms reduces the administrative burden associated with the license renewal process for both the NRC staff and the uranium recovery licensees. Also, the extension reduces the licensee fees, brings the license term for these facilities more commensurate with the level of risk, and supports NRC's goal of streamlining the licensing process. Licensees were informed of the extensions in July 1996.

On February 6, 1997 (62 FR 5656), the Commission gave notice of the policy that the license term for material licenses issued pursuant to 10 CFR parts 30, 40, or 70 would be increased from a five-year term to up to a ten-year term at the next renewal of the affected licenses. The term for licenses issued pursuant to 10 CFR part 35 is established by regulation at five years. The ten-year term for other licenses has been set by policy. Part 35 license terms would be set by this policy after the final rule is effective that removes the reference to a five-year license term from 10 CFR 35.18. The NRC may issue a license for a shorter term, depending on the individual circumstances of the license applicant.

II. Discussion

The change in policy under which the license term for materials licenses is up to ten years, has created an inconsistency between the license terms for medical use and non-medical use materials licenses. NRC believes that the license duration period may also be extended without adverse impacts on public health and safety, such as increases in the unintentional abandonment of licensed material, or decreases in the licensees' attention to licensed activities, for the following reasons:

(1) Licensees would continue to be required to adhere to the regulations and their license conditions, and to apply for license amendments for certain proposed changes to their programs;

(2) No changes in either the frequency or elements of the medical inspection program are being proposed;

(3) NRC would continue to be in the position to identify, by inspection or other means, violations that affect public health and safety, and to take appropriate enforcement actions;

(4) Cases of abandonment of NRC licenses would be identified through nonpayment of the annual licensing fees and regional follow-up;

(5) The staff would continue to make licensees aware of health and safety issues through the issuance of generic communications (such as information notices, generic letters, bulletins, and the *NMSS Licensee Newsletter*); and

(6) NRC efforts are moving to a more performance-based regulatory approach, where emphasis is placed on the licensee's execution of commitments rather than on re-review of the details of the licensee's program.

III. Proposed Regulatory Action

The NRC is proposing to revise Part 35 to eliminate the five-year term limit in 10 CFR 35.18 for medical use licenses, so that the term for medical licenses can be set by policy for up to ten years.

IV. Compatibility for Agreement States

No problems have been identified regarding Agreement State implementation of this rule change. Section 35.18 is a Division 3 requirement. For purposes of NRC and Agreement State compatibility requirements, Division 3 rules apply to a number of the provisions in NRC regulations that would be appropriate for Agreement States to adopt, but they do not require any degree of uniformity between NRC and State rules. Such rules are strictly matters for the regulatory agency and the regulatory community within its jurisdiction. NRC encourages states to adopt the regulatory approach taken by NRC in such rules, but states are not required to do so. Under the new Commission Policy Statement on Agreement State Compatibility, Division 3 rules will be classified as compatibility category D with the same description as Division 3.

V. Electronic Access

Comments may be submitted electronically, in either ASCII text or WordPerfect format, by calling the NRC Electronic Bulletin Board on FedWorld. The bulletin board may be accessed using a personal computer, a modem, and one of the commonly available communications software packages, or directly via Internet. Background documents on the rulemaking 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.'' Users will find the ''FedWorld Online User's Guides'' particularly helpful. 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 be accessed by a direct dial phone 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 Mall.'' At that point, a menu will be displayed that has an option ''US 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 systems.

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 description, is available. There is a 15-minute time limit for FTP access.

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

You may also access the NRC's interactive rulemaking web site through the NRC home page (http://www.nrc.gov). This site provides the same access as the FedWorld bulletin board, including the facility to upload comments as files (any format), if your web browser supports that function.

For more information on the NRC bulletin boards call Mr. Arthur Davis.

Systems Integration and Development Branch, NRC, Washington DC 20555–0001, telephone (301) 415–5780; e-mail AXD@nrc.gov. For information about the interactive rulemaking site, contact Ms. Carol Gallagher (301) 415–6215; e-mail CAG@nrc.gov.

VI. Finding of No Significant Environmental Impact: Availability

No Environmental Assessment will be needed because the rulemaking is covered by the categorical exclusion in 10 CFR 51.22(c)(3)(i) for amendments to Part 35 that relate to renewals of licenses.

VII. Paperwork Reduction Act Statement

This proposed rule will reduce the burden for both medical licensees and NRC, because terms could be established by policy, for up to ten years, as is the case for other material licensees. However, the reduced burden from less frequent license renewal will not be realized in the near future because the affected licenses are operating under a five-year extension of their current licenses which were granted in 1995. The impact of that one-time extension is addressed in the current supporting statement for NRC Form 313, ''Application for Material License'' which was approved by the Office of Management and Budget (OMB) under OMB clearance No. 3150–0120, and expires on July 31, 1999. The data on the reduced burden from extension of the license term for all material licenses, as well as from other actions taken to streamline the licensing process, will be included in the request for renewal of the information collection requirements on NRC Form 313, in 1999. This is appropriate because the next OMB clearance extension will cover 1999–2002, during which time the medical licenses currently under the five year extension will expire and be affected by this rulemaking.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, an information collection unless it displays a currently valid OMB control number.

VIII. Regulatory Analysis

Problem

The current rule requirement, regarding the term of medical licenses, is codified in Section 35.18 and states that, ''The Commission shall issue a license for the medical use of byproduct material for a term of five years.'' The License term of other materials licenses, as established by Commission policy, is up to ten years. There is thus an inconsistency as to duration and manner of determination of the license term of medical use licenses and all other materials licenses. Based on the above, the following options were considered.

Alternative Approaches

1. *Take no action:* Maintain the requirement that licenses issued pursuant to Part 35 would be issued for five years.

This option would continue the inconsistency between how license terms for medical licenses, and all other materials licenses, are established. Terms for medical use licenses are established in codified regulations, whereas the term for other materials licenses are set by policy. Also, this option would result in disparities in the duration of the term for material licenses, because medical use licenses would continue to be issued for five-year terms whereas the duration of the term for other materials licenses would be up to ten years.

2. *Revise 10 CFR 35.18:* Revise the regulations to delete any reference to the license term for licenses issued pursuant to Part 35.

This option would result in consistency between how license terms for medical licenses and all other material licenses are established and in the duration of such licenses. Commission decisions regarding the duration of a materials license could therefore apply uniformly to all types of material licenses. After final rulemaking action to revise 10 CFR 35.18, the license term for licenses issued pursuant to Part 35 would be set by already established policy for up to ten years.

Value and Impact

The license renewal process is resource-intensive for both the licensee and NRC. At the time of license renewal, licensees submit to NRC any changes in operations, personnel, facility, equipment, or applicable procedures. Because NRC is in contact with the licensees on an ongoing basis, many of these changes are identified during the inspection and license amendment process. Therefore, the rulemaking to remove the five-year license term for medical use of byproduct material would not change the health and safety requirements imposed on licensees.

If the reference to the five-year term in 10 CFR 35.18 is removed, and with the Commission's approval (February 1997) given to extend the license term up to ten years for all material licenses issued pursuant to Parts 30, 40, and 70, there would be a reduction in the regulatory burden for approximately 2,000 NRC licensees that use byproduct material for medical procedures. Estimated savings are based on the assumption that these licensees would only be required to submit a renewal application every ten years as opposed to every five years, resulting, on average, in a savings of 200 applications per year. However, countervailing these savings, medical licensees may need to submit an average of one additional amendment during the ten year period to account for changes in operations that would have routinely been addressed when the license was renewed on a five year cycle. Assuming that a typical license renewal application and typical amendment involves ten hours and two hours of licensee professional effort, respectively, there would be a net savings per licensee of eight hours. Based on an industry professional labor rate of $70 per hour, the annual industry-wide savings would approximate $112,000. Over a 30-year time frame, based on a 7 percent real discount rate, the present worth savings to industry would approximate $1.4 million.

Similarly, this rulemaking would also be cost effective for the NRC because fewer resources would be required to review and process renewal applications. On average, it takes approximately 14 hours of NRC professional time to renew a medical license and four hours to review an amendment. This translates to a net savings to the NRC of 10 hours per license. Assuming an NRC labor rate of $70 per hour, and on average, 200 application per year, the annual NRC savings would equal $140,000. The 30 year present worth savings to the NRC would approximate $1.7 million.

Conclusion

This rulemaking, to remove the five-year license term for medical use of byproduct material, is proposed so the term for medical licenses will be consistent with that of other materials licenses (set by policy to be up to 10 years). The extension will reduce the administrative burden of license renewals for both NRC and the licensee and will support NRC's goal of streamlining the licensing process without any reduction in health and safety. NRC may issue some licenses for shorter terms, if warranted by the individual circumstances of license applicants.

Decisional Rationale

Based on the consistency which is created between license terms for medical licenses and all other material licenses by the rulemaking, and the cost effectiveness of a license term of up to ten years, the NRC is proposing to amend 10 CFR part 35 to eliminate the five-year term limit for medical use licenses and allow the license term to be set by the established policy for up to ten years.

IX. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule, if adopted, will not have a significant impact on a substantial number of small entities. If any small entity subject to this regulation determines that, because of its size, it is likely to bear a disproportionate adverse economic impact, the entity should notify the Commission of this in a comment that indicates the following:

(a) The licensee's size and how the proposed regulation would result in a significant economic burden upon the license compared to the economic burden on a larger licensee;

(b) How the proposed regulation could be modified to take into account the licensee's differing needs and capabilities;

(c) The benefits that would accrue, or the detriments that would be avoided, if the proposed rule were modified as suggested by the licensee;

(d) How the proposed regulation, as modified, would more closely equalize the impact of NRC regulations or create more equal access to the benefits of Federal programs, as opposed to providing special advantages to any one individual or group; and

(e) How the proposed regulation, as modified, would still adequately protect public health and safety.

X. Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this rule, and therefore a backfit analysis is not required because the amendment does not involve any provisions that would impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects in 10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and record requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR part 35.

PART 35—MEDICAL USE OF BYPRODUCT MATERIAL

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

Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

2. The introductory text of § 35.18 is revised to read as follows:

§ 35.18 License issuance

The Commission shall issue a license for the medical use of byproduct material if:

* * * * *

Dated at Rockville, Maryland, this 10th day of July, 1997.

For the Nuclear Regulatory Commission.

Hugh L. Thompson, Jr.,

Acting Executive Director for Operations.

[FR Doc. 97–20189 Filed 7–30–97; 8:45 am]

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NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50 and 73

[PRM 50–59 and PRM 50–60]

RIN 3150–AF63

Frequency of Reviews and Audits for Emergency Preparedness Programs, Safeguards Contingency Plans, and Security Programs For Nuclear Power Reactors

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is proposing to amend its regulations to change the frequency of licensees' independent reviews and audits of their emergency preparedness programs, safeguards contingency plans, and security programs. This amendment is being proposed in response to petitions for rulemaking submitted by Virginia Power Company. Specifically, instead of conducting reviews every 12 months, as is currently required, the proposed amendment would require nuclear power reactor licensees to conduct program reviews and audits in response to program performance indicators, or after a significant change in personnel, procedures, equipment, or facilities, but in no case less frequently than every 24 months.

DATES: Submit comments October 14, 1997. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Comments may be sent to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Attention: Rulemakings and Adjudications Staff.

Deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:30 a.m. and 4:15 p.m. on Federal workdays.

For information on submitting comments electronically, see the discussion under Electronic Access in the Supplementary Information Section.

Certain documents related to this rulemaking, including comments received, may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. These documents may also be viewed and downloaded electronically via the Electronic Bulletin Board established by NRC for this rulemaking as discussed under Electronic Access in the Supplementary Information section.

FOR FURTHER INFORMATION CONTACT: Dr. Sandra D. Frattali, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–6261, e-mail sdf@nrc.gov.

SUPPLEMENTARY INFORMATION:

Background

On January 7, 1994, the Commission docketed a petition for rulemaking from Virginia Power, dated December 30, 1993, (PRM–50–59) to change the required audit frequency for safeguards contingency plans and security programs at nuclear power reactors. On January 19, 1994, the Commission docketed, as a separate petition for rulemaking (PRM–50–60), Virginia Power's request that the NRC change the required audit frequency for emergency preparedness programs at nuclear power reactor facilities. NRC published these two petitions for public comment in the **Federal Register**. PRM–50–59 was published on May 6, 1994 (59 FR 23641). PRM 50–60 was published on April 13, 1994 (59 FR 17449).

The Commission's regulations currently require power reactor licensees to conduct independent reviews and audits of each of these programs at least every 12 months. Virginia Power requested that the frequency be changed to nominally every 24 months. This rulemaking addresses the issues raised in these petitions.