917, then southeast along State Primary Highway 917 to the Little Pee Dee River.

Done in Washington, DC, this 4th day of June 1998.

Charles P. Schwalbe,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 98–15404 Filed 6–9–98; 8:45 am]

BILLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

RIN 3150–AF77

License Term for Medical Use Licenses

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations pertaining to the medical use of byproduct material to eliminate the 5-year term limit for medical use licenses. License terms for licenses issued under these regulations will be set by policy. Other materials licenses are issued for up to 10 years. The NRC will issue some licenses for shorter terms if warranted by the individual circumstances of license applicants. The amendment reduces the administrative burden of license renewals on a 5-year cycle for both NRC and licensees and supports NRC's goal of streamlining the licensing process.

EFFECTIVE DATE: This regulation becomes effective on July 10, 1998.

FOR FURTHER INFORMATION CONTACT: Jayne M. McCausland, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415–6219, e-mail JMM2 @ nrc.gov.

SUPPLEMENTARY INFORMATION:

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I. Background

In 1995, the NRC's Office of Nuclear Material Safety and Safeguards (NMSS) initiated a review to determine whether the license term for materials licenses could be lengthened so that NRC's licensing resources could be redirected to other areas of the materials program. At that time, 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 the history of the licensee's operating performance (e.g., the record on compliance with regulatory requirements) and the licensee's overall materials safety 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, comprehensive program reviews occur when proposed changes are identified and requested by licensees as license 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 3-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 amending 10 CFR part 40, dated December 22, 1966, NRC indicated that if the proposed amendment to eliminate the 3-year restriction were adopted, licenses would be issued for 5-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 5 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.

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 5-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 5-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 5 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 5 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 5-year term to a 10-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 2 years.

On July 2, 1996, the Commission approved the NRC staff's proposal to extend the license term for uranium recovery facilities from 5 years to 10 years. Extending the license term reduces the administrative burden associated with the license renewal process for both the NRC staff and the uranium recovery licensees. Also, the extension reduces licensee fees, makes 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 that the license term for materials licenses issued pursuant to 10 CFR parts 30, 40, or 70 would be increased from a 5-year term to up to a 10-year term at the next renewal of the affected licenses. However, whereas the 10-year term for

other licenses was set by this policy, the term for licenses issued pursuant to 10 CFR part 35 was established by regulation at 5 years.

On July 31, 1997 (62 FR 40975), the NRC published a proposed rule to revise 10 CFR part 35 to eliminate the 5-year term limit in 10 CFR 35.18 for medical use licenses. The term for medical licenses could then be set by policy for up to 10 years. The NRC could issue a license for a shorter term, depending on the individual circumstances of the license applicant. The public comment period closed on October 14, 1997. A summary of the public comments is provided in Section IV, below.

II. Discussion

The change described above (i.e., increasing the license term for materials licenses issued under 10 CFR parts 30, 40, and 70 to up to 10 years) has created an inconsistency between the license terms for medical use and nonmedical use materials licenses. NRC believes that the license duration period for medical use licenses 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 a position to identify, by inspection or other means, violations of its regulations or the license conditions 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 NRC office follow-up;

(5) The NRC 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 is moving to a more performance-based regulatory approach, where emphasis is placed on the licensee's execution of commitments rather than on rereview of the details of the licensee's program.

III. Statement of Regulatory Action

The NRC is revising part 35 to eliminate the 5-year term limit in 10 CFR 35.18 for medical use licenses so that the term for medical use licenses will be set by policy.

IV. Discussion of Public Comments

Five letters of public comment were received on the proposed rule. Comments were received from National Physics Consultants, Ltd., the American Association of Clinical Endocrinologists, the Mayo Clinic, the University of Cincinnati, and the American Hospital Association.

All commenters fully supported the proposed amendment to eliminate the reference to the 5-year term limit for medical use licenses in 10 CFR 35.18. In addition, the commenters endorsed the change in license terms for licenses issued pursuant to part 35, to be set by policy for as many as 10 years, as are the license terms for other material licenses.

In general, commenters disparaged the license renewal process, on a 5-year frequency, as requiring a significant expenditure of time and fees with minimal benefit, and supported NRC's proposal to eliminate this requirement, citing a reduction of staff time and costs for both the NRC and individual licensees with no decrease in public health and safety. Commenters recognized that the NRC may issue some licenses for shorter terms if warranted by the individual circumstances of license applicants.

One commenter stated that routine license reviews by the local Radiation Safety Committee will ensure operation of a radiation safety program that protects public health and safety.

Another commenter indicated that because the NRC is in contact with the licensees on an ongoing basis, any changes in operations, personnel, facility, equipment, or applicable procedures are identified during the inspection and license amendment process.

One of the commenters agreed that the radiation safety programs at most medical facilities are very stable and pointed out that significant changes in the radiation safety program require license amendments.

Another commenter recommended that NRC extend the license term for medical use licenses from 5 years to 10 years as soon as possible to reduce the license fees and achieve further cost savings. This commenter expressed support for the NRC's ''business process redesign'' efforts to reduce both the administrative burden of license renewals and license fees. According to the commenter, this will allow that organization's members to redirect their resources to support and implement NRC's initiative to move to a more performance-based regulatory approach.

V. Agreement States Compatibility

This rulemaking will be a matter of compatibility between the NRC and the Agreement States. Compatibility Category D has been assigned to the changes in 10 CFR 35.18. Category D means the provisions are not required for purposes of compatibility. No problems have been identified regarding Agreement State compatibility implementation of this rule change.

VI. Environmental Impact: Categorical Exclusion

The Commission has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(3)(i) for amendments to Part 35 that relate to renewals of licenses. Therefore, neither an environmental statement nor an environmental assessment has been prepared for this final regulation.

VII. Paperwork Reduction Act Statement

This final rule reduces the burden for both medical licensees and the NRC because license terms for Part 35 licensees could be established by policy, for as many as 10 years, as is the case for other materials 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 5-year extension of current licenses 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 which expires on July 31, 1999. The data on reduced burden from extension of the license term for all material licenses and 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, when the medical licenses currently under the 5-year extension will expire and will be affected by this rulemaking. Send comments on any aspect of this information collection, including suggestions for further reducing the burden, to the Information and Records Management Branch (T–6F33), U.S. Nuclear Regulatory

Commission, Washington, DC 20555–0001, or by Internet electronic mail at BJS1@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150–0014), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

If a document used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

VIII. Regulatory Analysis

Problem

The current rule requirement, regarding the term of medical licenses, is codified in 10 CFR 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 10 years. There is an inconsistency as to duration and manner of specifying the license terms 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 5 years.

This option would continue the inconsistencies between medical licenses and all other materials licenses as to the duration and specification of license terms. Terms for medical use licenses are established in codified regulations, whereas the term for other materials licenses is now set by policy. Also, this option would result in disparities in the duration of the term for materials licenses. Medical use licenses would continue to be issued for 5-year terms whereas the duration of the term for other materials licenses is up to 10 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 materials licenses are established and in the duration of these licenses. Commission decisions regarding the duration of a materials license could therefore apply uniformly to all types of materials 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 the already established policy for as many as 10 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 5-year license term for medical use of byproduct material would not change the health and safety requirements imposed on licensees.

By removing the reference to the 5-year term in 10 CFR 35.18 and, with the Commission's February 1997 extension of the license term for as many as 10 years for all materials licenses issued pursuant to parts 30, 40, and 70, there is a reduction in the regulatory burden for approximately 1,900 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 10 years as opposed to every 5 years, resulting, on average, in a savings of 190 applications per year. However, offsetting these savings, medical licensees may need to submit an average of one additional amendment during the 10-year period to account for changes in operations that would have routinely been addressed when the license was renewed on a 5-year cycle. Assuming that a typical license renewal application and typical amendment involves 19 hours and 4 hours of licensee professional effort, respectively, there would be a net savings per licensee of 15 hours. Based on an industry professional labor rate of $125 per hour, the annual industry-wide savings would approximate $356,000. Over a 30-year time frame, based on a 7-percent real discount rate, the present worth savings to industry would approximate $4.4 million.

Similarly, this rulemaking is also 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 4 hours to review and issue a license amendment. This means a net savings to the NRC of 10 hours per licensee. Assuming an NRC labor rate of $125 per hour, and on average, 190 applications per year, the annual NRC savings would equal $237,000. The 30-year present worth savings to the NRC would approximate $2.9 million.

Conclusion

This rulemaking, to remove the 5-year license term for medical use of byproduct material, is promulgated so the term for medical licenses will be consistent with that of other materials licenses (set by policy to be as many as 10 years). The extension will reduce the administrative burden of license renewals for both NRC and licensees 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 desire to reduce burden whenever it is possible to do so without reducing protection of public health and safety, to maintain consistency among license terms for materials licensees, and the cost effectiveness of longer license terms, the NRC is amending 10 CFR part 35 to eliminate the 5-year term limit for medical use licenses and allow the license term to be set by policy, as is the case for other materials licenses.

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 will not have a significant economic impact on a substantial number of small entities. By removing the reference to the 5-year license term in 10 CFR 35.18, the duration of medical use licenses will be set by policy, resulting in a reduction in the regulatory burden for NRC medical use licensees.

X. Backfit Analysis

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

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a ''major rule'' and has verified this determination with the Office of Information and Regulatory Affairs, Office of Management and Budget.

List of Subjects in 10 CFR Part 35

Byproduct material, Criminal penalties, Drugs, Health facilities, Health professions, Medical devices, Nuclear materials, Occupational safety and health, Radiation protection, Reporting and recordkeeping 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 amendment 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, Md., this 20th day of May 1998.

For the Nuclear Regulatory Commission.

L. Joseph Callan,

Executive Director for Operations.

[FR Doc. 98–15400 Filed 6–9–98; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–NM–97–AD; Amendment 39–10582; AD 98–12–28]

RIN 2120–AA64

Airworthiness Directives; CASA Model C–212 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to all CASA Model C–212 series airplanes, that requires repetitive inspections for cracking in the false spar of the wing, and repair, if necessary. This amendment is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by this AD are intended to detect and correct cracking in the false spar, which could result in reduced structural integrity of the wing.

DATES: Effective July 15, 1998.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the **Federal Register** as of July 15, 1998.

ADDRESSES: The service information referenced in this AD may be obtained from Construcciones Aeronauticas, S.A., Getafe, Madrid, Spain. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the **Federal Register**, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to all CASA Model C–212 series airplanes was published in the **Federal Register** on April 9, 1998 (63 FR 17341). That action proposed to require repetitive inspections for cracking in the false spar of the wing, and repair, if necessary.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Conclusion

The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Cost Impact

The FAA estimates that 41 airplanes of U.S. registry will be affected by this AD, that it will take approximately 30 work hours per airplane to accomplish the required inspection, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the inspection required by this AD on U.S. operators is estimated to be $73,800, or $1,800 per airplane, per inspection cycle.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

98–12–28 Construcciones Aeronauticas, S.A. (CASA): Amendment 39–10582. Docket 98-NM–97-AD.

Applicability: All Model C–212 series airplanes, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area