UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

December 29, 1999

MEMORANDUM TO: Those on the Attached List

FROM: Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: POLICY AND GUIDANCE DIRECTIVE PG 83-2, REVISION 1, SUPPLEMENT 1, "RENEWAL OF MATERIALS LICENSES"

Please review and implement guidance in the attached supplement to Policy and Guidance Directive (PGD) PG 83-02, Revision 1, "Renewal of Materials Licenses." This document provides guidance for the processing of renewal applications for all materials licenses except fuel cycle licenses, Spent Fuel Project Office (SFPO) certificates, or SFPO licenses.

This guidance applies to NUREG 1556 series volumes which have been finalized. Draft NUREG volumes should not be used by either NRC or licensees in reviewing or preparing license applications. Therefore, the attached guidance should not be applied to draft NUREGs until they are finalized.

Implementation of this guidance will be included in the Integrated Materials Performance Evaluation Program review of the regions. This document supersedes those parts of PGD 83-02, Revision 1, not associated with fuel cycle licenses, SFPO's certificates, and SFPO issued licenses.

This guidance is part of a licensing streamlining initiative to focus renewal resources on licensees whose performance indicates potential programmatic weaknesses, and program areas that have undergone major changes which could affect radiation safety. Performance indicators are provided to determine the review levels necessary to renew each license. Guidelines are provided to determine when licenses (both new licenses and renewals) should be issued for less than 10 years. General guidance is also included to assist reviewers in reducing protracted interactions needed in bringing licensing actions to closure.

Attachment:
PGD 83-02, Rev. 1, Supplement 1

CONTACT: Donna-Beth Howe, NMSS/IMNS
(301) 415-7848

Enclosure 1

United States
Nuclear Regulatory Commission

Policy and Guidance Directive PG 83-2, REVISION 1, SUPPLEMENT 1, "RENEWAL OF MATERIALS LICENSES"

Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards

PREPARED BY: Donna-Beth Howe **Donna-Beth Howe, MSIB 11/ 1 /99**	**REVIEWED BY:** **Josephine M. Piccone, IMNS 11/ /99**
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APPROVED BY: **Donald A. Cool, IMNS 11/22/99**	

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ATTACHMENTS

1.0 Purpose

The Office of Nuclear Material Safety and Safeguards (NMSS) is revising its materials (excluding fuel cycle licenses, Spent Fuel Project Office (SFPO) certificates, and SFPO licenses) licensing renewal review guidance to focus resources on applications from licensees whose performance indicates potential programmatic weaknesses, and on program areas that have undergone major changes that could affect radiation safety. Performance indicators are provided to determine the level of review necessary to renew the license. A two tiered license renewal system is being introduced. Guidance is provided to assist staff in determining when licenses should be issued for less than 10 years. General guidance is included to address improved information sources, communication techniques, and licensing tools needed to bring licensing actions to closure.

The Guidance Consolidation Project initiated in 1996 resulted in a series of volumes, in the NUREG-1556 series, providing specific and consistent guidance for licensees and the U.S. Nuclear Regulatory Commission (NRC) staff to use in submitting license applications and reviewing the applications, respectively. Licensee use of this guidance should result in better and more complete submissions. Both licensee and reviewer use will enable NRC to spend less resources in reviewing renewals. This guidance should decrease the number of marginal and protracted interactions with licensees, make it easier to terminate review of inadequately supported licensing requests, and use other techniques to bring actions to closure.

2.0 Guidance

When reviewing renewals (except fuel cycle licenses, SFPO certificates, and SFPO licenses), the guidance in this Directive shall be applied. Although the licensee's use of the NUREG-1556 series is voluntary, this guidance assumes that renewal applications will be filed and reviewed in accordance with the guidance set forth in the NUREG-1556 series and that major program changes will be carefully identified by the applicants. If the licensee does not use the NUREG-1556 series, the renewal application may take longer for NRC to review. The guidance should not be used for draft NUREGs until they are finalized.

Section 2.1 describes how to determine the review status of the renewal. The performance indicators in Section 2.2 are the basis for identifying those licensees whose radioactive materials use program will need a comprehensive review. Section 2.3 describes the comprehensive review that will be used for renewals submitted by licensees triggering any of the performance indicators in Section 2.2. Section 2.4 describes the limited review that will be used for renewals submitted by licensees not triggering any of the Section 2.2 performance indicators. Guidance in Section 2.5 will be used to identify those licensees that will receive renewal of less than 10 years. Section 2.6 describes general guidance, for reviewers, that should improve communications with licensees, decrease the number of marginal and protracted interactions with licensees, make it easier to void unsupported licensing requests, and use license conditions or other techniques to bring actions to closure. All licensees will be sent the appropriate standard "Notice of License Expiration" letter (Attachment 1).

2.1. Determining Review Status of Applications for Renewal of Licenses

Each renewal application will be selected for either a comprehensive review or limited review by comparing the licensee's performance against the performance indicators in Section 2.2. Thus, the first task for the reviewer is to review the Docket and NRC data bases (such as NMED and LERs) to compare the licensee's performance against these performance indicators. An application submitted by a licensee that demonstrated the presence of one or more of these performance indicators will receive a comprehensive review, as described in Section 2.3. Applications from licensees who do not exhibit any of these performance indicators will receive the limited review described in Section 2.4. The basis for performing either a limited review or a comprehensive review will be documented as described in Attachment 2.

However, based on an evaluation of the specific circumstances associated with the presence of a performance indicator, NRC licensing management may decide that a comprehensive review is not warranted. Further, NRC licensing management may choose to perform a comprehensive review of a renewal even though the application is from a licensee that does not trigger any of the formal performance indicators but which may exhibit other characteristics warranting a comprehensive review. Such decisions must also be documented in accordance with Attachment 2.

2.2. Performance Indicators.

2.2.A. Enforcement History

A licensee that is or has been the subject of an ongoing investigation by the Office of Investigations(OI), ongoing investigation by the Office of the Inspector General (OIG), or escalated enforcement action within 5 years will be considered for a comprehensive review of the renewal application. Escalated enforcement action includes any Order, civil penalty, Notice of Violation issued at Severity Level III, II, or I.

Note: Licenses should not be renewed if they are the subject of an ongoing Office of Enforcement, OI, or OIG investigation without the written concurrence of the investigating office.

2.2.B. Loss of Material

Any licensee that has lost control of licensed material that is presumed to be in the public domain, and is reportable and/or resulted in a violation of regulatory requirements within the 5-year period immediately before the proposed renewal, will be considered for a comprehensive review of their renewal application.

2.2.C. Unauthorized Disposal or Release of Material

If the licensee has been cited with a violation regarding unauthorized disposal or release of material in the last 5-years, management control of licensed activities may be weak and a comprehensive review of the license application will be considered for a comprehensive review.

2.2.D. Overexposure

If the licensee has been cited with a violation regarding an exposure in excess of regulatory requirements in the last 5 years, management control of licensed activities may be weak and a comprehensive review of the license application will be considered. Exposures at issue would include those to members of the public as well as to occupationally exposed individuals.

2.3. Comprehensive Reviews

A comprehensive review of a renewal application is the comparison of all material, submitted by the licensee, with the requirements in the appropriate regulations, guidance in NUREG-1556, and guidance supplemented in relevant Technical Assistance Request (TAR) responses. The reviewer is to review the applicant's radiation protection program, facilities, equipment, and personnel in detail and provide additional attention to the aspects of the program that triggered the Section 2.2 performance indicators. The checklist in the appropriate NUREG 1556 volume(s) must be completed with all deficiency findings clearly annotated on the checklist.

Parts of the application that do not conform to, or fail to address, areas in this guidance, are deficiencies which must be resolved before the license is renewed. Reviewers shall apply this guidance to the extent suitable to the licensee's activities and should not apply any standards or criteria that are not contained in this guidance, or for which there is no specific regulatory basis. However, reviewers may consider program changes that are not contained in the guidance but were motivated by enforcement action (such as, the licensee's corrective actions) to be requirements for that particular licensee.

Reviewers should accept licensee procedures or proposals that result in a level of safety equivalent to that provide for in NRC guidance.

2.4. Limited Reviews

A limited review of a renewal application will only evaluate the following areas for conformance to the appropriate sections of the guidance described in Section 8 of the appropriate NUREG 1556 series:

2.4.A. Administrative Items

Review administrative items, including the licensee's name and address and other items, such as the radiation safety officer's name, which appear in the application and will be listed on the renewed license. Also ensure the renewal

application is signed and dated by an individual authorized to make binding commitments and sign official documents on behalf of the licensee.

2.4.B. Financial Assurance

For those licensees that must provide an instrument of Financial Assurance, review the license to ensure the Financial Assurance instrument is still adequate for the current scope of the program.

Note: If the licensee submitted a Decommissioning Funding Plan and the new expiration date is greater than 5 years, include the following condition on the license: "A revised Decommissioning Funding Plan must be submitted no later than 5 years from the date of issuance of this license."

2.4.C. Program Management

Review those portions of the application that address program management, including:

(1) Organizational structure (assure that appropriate elements are present and are assigned necessary authority and responsibility);

(2) The qualifications of key personnel, such as the radiation safety officer, authorized users, radiographers, well loggers, irradiator operators, authorized medical physicist, and authorized nuclear pharmacists; and

(3) The licensee's radiation safety audit program.

2.4.D. Equipment and Facilities

Review those portions of the application that address equipment and facilities.

2.4.E. Environmental Assessments

Review those portions of the application that need an environmental assessment because they do not conform to the categorical exclusions in 10 CFR Part 51.

2.4.F. Unreviewed Requests

Review any new authorizations, requested by the licensee, that have not been previously reviewed, and any major program elements which require change as a result of the new authorization. Also review the licensee's inspection reports for changes in the licensee's scope of operations that are not referred to in the renewal package. These areas should undergo a focused review as opposed to a comprehensive review of the entire application. Some examples of requests that should receive focused reviews are:

(1) New broad scope authority, introduction of iodination with millicurie quantities of iodine-131 or iodine-125 requiring major facility

additions or changes; additional research and development activities (human and non-human); additional medical therapy modalities; etc.

(2) Any new high-risk technology uses being added to an existing license, to ensure that the licensed program can safely manage and use the new technology. Specific conditions and requirements associated with new technologies may be added to the license. Examples include new license categories; use of intravascular brachytherapy; or Boron Neutron Capture Therapy in humans.

2.4.G. Change in Control

A change in control (ownership) is reviewed if it resulted in a significant change in key staff members directly responsible for the radiation safety program and which has not been previously reviewed. This condition signals that the new staff may have little operational experience in establishing a long-term performance record. In these cases a focused review of the affected areas should be done. NUREG 1556, Volume 15, may be used to assist in change of ownership issues.

2.4.H. Major Areas

A brief overview is made of the remainder of the application to determine if the major areas discussed in the guidance described in Section 8 of the appropriate NUREG-1556 series are present. If detected, an obvious failure or a deficiency in a significant area should result in a thorough review of that area. A finding that more than one area is not addressed or contains a significant deficiency could result in a comprehensive review of the license application. Change to a comprehensive review should be approved by licensing management and the reason for changing from a limited review to a comprehensive review must be clearly documented on the "Performance And Limited Review Checklist" (see Attachment 2).

Note: Each region determines from its review of the licensee's Docket file and NRC data bases whether a comprehensive review is necessary. The licensee's submission of an application that does not use the NUREG-1556 series is not a performance indicator and failure to use NUREG-1556 does not determine the level of review necessary. Although the application may take longer to review, it does not preclude a limited review with a focused review on those areas that depart from the NUREG guidance.

2.5. Establishing License expiration dates[1]

The Commission approved the extension of the terms set by policy for licenses issued under 10 CFR Parts 30 (except Part 35), 40, and 70 from 5 to 10 years in 1997. In 1998, final rulemaking was published to set the license term limit for medical use licenses at 10 years. Now all of these materials licenses have the same license term limit. The

[1] This guidance applies to both new and renewed licenses

Commission's actions approved the use of license terms shorter than 10 years on a case-specific basis.

Any license issued or renewed after July 10, 1998 (when the medical use license term limit was changed to 10 years) should have a 10-year term limit, unless management determines, on a case-by-case basis, that a license should be issued for less than 10 years. Some examples of conditions that may result in licenses issued for less than 10 years are:

2.5.A. New Technology

The license is for a new high-risk technology that the industry, the particular licensee, or NRC has not had extensive experience in using or regulating.

2.5.B. Enforcement History

The licensee, in the last inspection or 5 years (which ever is longer), had a Severity Level I, II, or III violation because of serious programmatic deficiencies and not isolated events.

2.5.C. Comprehensive Review

The licensee's renewal received a comprehensive review; or

2.5.D. Other

Other situations that would warrant increased attention, on a case-specific basis.

Note: Licenses that are in a "possession only for decommissioning" status do not need to be renewed because an expired license remains in effect until terminated by NRC (see 10 CFR 30.36, 40.42, or 70.38).

The specific expiration term for a license term shorter than 10 years should be 5 years, unless, on a case-specific basis, another time is more appropriate. NRC management may, also, decide that a license term of 10 years is warranted, based on the evaluation of specific circumstances associated with the above conditions and the licensee's commitments and program improvements made in the renewal submission.

Use Attachment 4 to document the license term, the basis for the decision, and the basis for an exemption, if appropriate.

2.6. Reviewer Guidance

2.6.A. NUREG-1556 series

Avoid requesting information not identified in the NUREGs. Use all available NUREG-1556 tools, including process, criteria, and checklists, to standardize and simplify the review process.

If the NUREG does not identify information thought to be critical to a particular licensing action, this should be identified and shared with Headquarters so that the NUREG can be revised, if necessary, to include the information.

2.6.B. Technical Assistance Request (TAR) Data Base.

When guidance is needed, staff should consult the NRC external Web page for the final versions of the NUREGs and consult the TAR database, found in Lotus Notes on the Regulatory Product Development Center servers, for existing technical guidance provided by TARs with similar issues. If the guidance exists use it; if not, develop a new TAR.

2.6.C. Interaction with NRC Inspectors

Renewal reviewers are reminded to follow the guidance provided in Policy and Guidance Directive FC-90-1, Revision 1, "Guidelines for Discussions with Licensees Prior to Issuance of Renewals and Major Amendments to Fuel Cycle and Materials Licensees Authorizing Large Quantities of Hazardous Materials," when renewing materials licenses with large amounts of hazardous materials. FC-90-1, Revision 1, defines large quantities of hazardous radioactive material. This guidance instructs reviewers to, among other thing, solicit and obtain observations and comments from the inspection staff on the licensee's facilities and activities.

2.6.D. Meetings and Visits

Meet with the licensee before proceeding with complex cases, and use site visits, if necessary. As soon as NRC (i.e., the reviewer and first line supervisor) determines a request involves complex licensing issues, set up a meeting with the applicant to review and discuss the issues. Early licensee/NRC clarification interactions are important for expediting resolution and avoiding protracted correspondence exchanges. Site visits should be used to improve NRC's understanding of the applicant's facilities and program. Policy and Guidance Directive FC 84-09, "Licensing visits for byproduct material licensees," provides additional guidance on site visits.

2.6.E. Simplify Communications

Simplify licensee-staff interaction by using telephone, E-mail, and Fax. Early dialogue should be established with applicants. Once issues and deficiencies have been identified, use the simplest process available to fully communicate issues to licensees, document the request, and elicit the appropriate applicant response. Use the telephone and e-mail to communicate with licensees and reduce reliance on formal letters. The Docket must contain proper documentation of both the information requested by the reviewer (e.g., fax, telephone record, or e-mail) and the applicant's response and commitments (e.g., signed fax or letter). Draft documents from the applicant should not be used as the basis for a licensing action.

2.6.F. Request for Information

Efforts should be directed at improving, reducing, and eliminating reviewers' requests for additional Information. Ensure that each requested item for additional information is clear (i.e., provides a description of the deficiency and a statement of what is needed); is essential to protect safety; and is linked to regulatory requirements and NUREG-1556. The goal is to have no more than one request for additional information for each application. If a second request is needed, escalate it quickly to NRC and licensee management to resolve open issues. If the applicant does not provide adequate information after such an exchange, complete the licensing action that can be completed, inform the licensee of the issues that cannot be approved, and explain why not. Avoid multiple rounds of requests for additional information.

2.6.G. Custom License Conditions

With management review and approval use custom license conditions to reach closure. Where simple well-defined policy issues remain unresolved, use custom license conditions, rather than protracted negotiations with the applicant, to achieve closure .

3.0 Resources

This guidance is expected to significantly decrease resource burdens on NRC regional and Headquarters offices.

NOTICE OF EXPIRATION LETTER

Licensee Name
Address 1
Address 2
Address 3

License No. XX-XXXXX-XX
Expiration Date: XX/XX/XXXX
Program Code: XXXX

Gentlemen:

SUBJECT: NOTICE OF LICENSE EXPIRATION

Your U.S. Nuclear Regulatory Commission (NRC) license, specified above, will expire on the date shown. If you wish to continue your licensed program, you should prepare and submit a renewal application on NRC Form 313, following the instructions in the enclosed volume of NUREG 1556. If the application reflects any significant changes in your licensed program, those changes must be clearly indicated.

You must submit an application for the renewal of your license at least 30 days before the expiration date on the license. If your renewal application is filed (delivered or postmarked) before the expiration date, NRC will use discretion and your license will remain in effect until NRC takes final action on your application.

However, if your renewal application cannot be filed before the expiration date, you should contact NRC immediately to see if you can obtain a temporary extension of the expiration date. Without NRC approval of that extension request, your license expires on the expiration date stated on the license. If your license expires, you no longer have a valid license, but you are required to maintain all licensed materials in safe, locked storage until your application for a license or request for termination is submitted and approved. Use of the licensed material after the expiration of your license may subject you to criminal and/or civil sanctions.

If you do not wish to renew your license, you must dispose of or transfer all licensed radioactive material in your possession in an authorized manner (see the appropriate requirements in 10 CFR 30.36, 40.42, or 70.38); then complete the enclosed Form NRC-314, "Certificate of Disposition of Materials" and return it before the expiration date of your license, with a request that your license be terminated. If you cannot dispose of or transfer all licensed radioactive material in your license before the expiration date, you must request a license renewal, for storage-only, of the radioactive material, to avoid enforcement action for violations involving the possession of licensable material without a valid license. Enforcement action may include a substantial monetary civil penalty that could also include daily civil penalties until you achieve compliance.

This notice of your license expiration is sent for your convenience only and does not mean that similar notices will be sent in the future. The responsibility for timely submission of the license renewal remains with the licensee. If you have any questions about this notice or license expiration/renewal, please contact the NRC Regional Office that handles your license.

Enclosures
1. Form NRC 313
2. Form 314
3. (10 CFR Parts determined by program code)
4. (NUREG -1556, Volume/s determined by program code)
5. (Other appropriate documents determined by program code)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

FEBRUARY 04, 1999

MONMOUTH MEDICAL CENTER
300 SECOND AVENUE
LONG BRANCH, NJ 07740

License No. SNM-1392
Expiration Date: 05/31/1999
Program Code: 22160

Gentlemen:

SUBJECT: NOTICE OF EXPIRATION

Your NRC license specified above authorizing use of nuclear-powered pacemakers will expire on the date shown. We want to call your attention to some special conditions on your license and explain how these conditions affect your decision whether to renew the license.

In the United States, anyone who possesses and uses a nuclear pacemaker must be covered by a license. Patients in whom you have implanted pacemakers are covered by the hospital's license; see Condition 11 of your license. In Conditions 15 and 16 of your license, you are commited to following all patients with implanted pacemakers for the life of the patient or until the pacemaker is removed and returned to the manufacturer for proper disposal. Follow-up procedures must be in accordance with the protocol established by the manufacturer and approved by NRC. Termination, renewal, and fee information is included in the enclosure.

This notice of your license expiration is sent for your convenience and it should not be interpreted that similar notices will be sent in the future. The responsibiity for timely submission of an application for license renewal remains with the licensee.
If you have any questions regarding this notice or license expiration/renewal, please contact our Regional Office that handles your license.

Medical, Academic and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety

Enclosures:
1. Termination, Renewal and Fee Info. for Institutional Pacemaker Licensees
2. 10 CFR Parts 30, 70 and 170

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

JULY 01, 1997

MCKAY, JOHN H.
R. R. #5
STRATFORD, ONTARIO, CN N5A 6S6

License No. SNM-1997
Expiration Date: 10/31/97
Program Code: 22161

Gentlemen:

SUBJECT: NOTICE OF EXPIRATION

Your NRC license specified above will expire on the date shown. This license was issued to authorize your possession of an implanted nuclear-powered pacemaker while you are in the United States. United States law requires that you be covered by a license whenever you are in the United States with your pacemaker.

It would be very helpful to us if you would send a short letter, at least 30 days before the expiration of your license, telling us whether you want to renew your license or to terminate (discontinue) your license.

Information required for you to renew or terminate your license is enclosed.

This notice of your license expiration is sent for your convenience and it should not be interpreted that similar notices will be sent in the future. The responsibility for timely submission of an application for license renewal remains with the licensee. If you have any questions regarding this notice or license expiration/renewal, please contact our Regional Office that handles your license.

Medical, Academic and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety

Enclosures:
1. Renewal/Termination Info. for Individual Pacemaker Licensees
2. 10 CFR Part 70

PERFORMANCE AND LIMITED REVIEW CHECKLIST

Licensee: _____
License or Docket No: _____
Control No: _____

The following performance indicators were reviewed:

Performance Indicator	Conclusion	If YES, explain:
Enforcement History	YES ____ NO____	
Loss of Material	YES ____ NO____	
Unauthorized Disposal or Release of Material	YES ____ NO____	
Overexposure	YES ____ NO____	

If any of the above items are checked "YES", perform a Comprehensive Review using the applicable guidance contained in NUREG 1556. If all boxes are checked "NO," perform a Limited Review. An exception must be approved by a supervisor, documented on this form, or a copy of the documentation must be attached to this document for placement in the docket file.

Additional Information or Explanation of Exception

_____
_____
_____
_____

Comprehensive Review _____
Limited Review _____

_____ _____
Reviewer / Date Supervisor / Date

LIMITED REVIEW ITEMS[1]

Licensee: _____
License or Docket No: _____
Control No: _____

_____ NRC-313 or appropriate equivalent signed and dated by senior licensee representative.

_____ Place of use is a physical location (i.e., not P.O. Box, etc.)

_____ RSO and key personnel are appropriately qualified.

_____ Facilities and equipment are adequate.

_____ All uses qualify for a categorical exclusion in 10 CFR Part 51.

_____ Organizational structure conforms with applicable regulations and NUREG 1556 guidance[2] (appropriate individuals are present and are assigned necessary authority & responsibility)

_____ The audit program structure conforms with applicable regulations and NUREG 1556 guidance[2].

_____ New authorizations requested by the licensee and any major program elements which require change as a result of the new authorization structure conform with applicable regulations and NUREG 1556 guidance[2].

Major program changes, new high risk technology programs, and changes in control (ownership) normally require only a focused review of the specific changes. If these changes are so extensive that a Comprehensive Review of the entire application is needed, obtain Branch Chief approval before proceeding. Each of the following three items must be marked with NA or a check and the change briefly identified.

_____ *Major program change conforms with applicable regulations and NUREG 1556 guidance[2].*

_____ *New high risk technology program conforms with regulations for similar technologies, guidance provided for similar technologies in NUREG 1556 guidance[2], and specific licensing conditions for the new technology.*

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[1] Use either a check mark to designate a satisfactory response, "NA" to designate not applicable or "D" to designate deficiency as appropriate.

[2] Reviewers are reminded licensees have the flexibility to provide information equivalent to that requested in NUREG 1556.

_____ *Change in Control (Ownership) conforms with applicable regulations and NUREG 1556 guidance[2].*

_____ A brief overview of the remainder of the application found the major areas discussed in the guidance[2] described in Section 8 of the appropriate NUREG 1556 series are present.

_____ An obvious failure or a deficiency in a significant area resulted in a thorough review of that area.

_____ A Comprehensive Review was conducted and the reason for changing from a Limited Review to a Comprehensive Review is documented on the "Performance and Limited Review Check List."

_____ Appropriate additional information was requested (circle as appropriate: phone log / e-mail/ fax/ letter/_____)

LICENSE TERMS OF LESS THAN 10 YEARS

Licensee: _____
License or Docket No: _____
Control No: _____

The following conditions were reviewed :

Condition	Yes	NO	Basis for YES
New high risk technology without extensive use or regulation experience by industry, or licensee, or NRC;			
Enforcement History - Severity Level I, II, or III violation due to serious programmatic deficiencies and not singular events, in preceding 3-years;			
Renewal received a Comprehensive Review;			
Other			

If any of the above items are checked "YES", describe the basis above, determine the license term (usually 5 years) and document the determination below. All exceptions must be approved by a supervisor, documented, and a copy of that documentation must be attached to this document for placement in the docket.

Assigned License Term: _____ years

Additional Information or Explanation of Exception

_____

_____

_____

_____

_____

_____ _____

Reviewer / Date Supervisor / Date

Street, NW, Washington, DC 20555, and at the Local Public Document Room at the Weld Library District, Lincoln Park Branch, 919 7th Street, Greeley, Colorado 80631.

Dated at Rockville, Maryland, this 30th day of January 1997.

For the Nuclear Regulatory Commission.

Charles J. Haughney,

Acting Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 97–2979 Filed 2–5–97; 8:45 am]

BILLING CODE 7590–01–P

Proposed Generic Communication; Degradation of Steam Generator Internals

AGENCY: Nuclear Regulatory Commission.

ACTION: Extension of public comment period.

SUMMARY: On December 31, 1996 (61 FR 69116), the NRC published for public comment a proposed generic letter concerning the importance of performing comprehensive examinations of steam generator internals to ensure steam generator tube structural integrity is maintained in accordance with the requirements of Appendix B to 10 CFR part 50. The generic letter will enable the NRC to verify whether or not the condition of addressees' steam generator internals comply and conform with the current licensing basis for their respective facilities. The comment period for this proposed generic letter was originally scheduled to expire on January 30, 1997. In a letter dated January 27, 1997, the Nuclear Energy Institute requested a 45-day extension of the comment period to permit sufficient time to reach consensus on a coordinated industry response. In response to this request, the NRC has decided to extend the comment period.

DATES: The comment period has been extended 45 days and will now expire on March 15, 1997. Comments submitted after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except for comments received on or before this date.

ADDRESSES: Submit written comments to Chief, Rules Review and Directives Branch, U.S. Nuclear Regulatory Commission, Mail Stop T–6D–69, Washington, DC 20555–0001. Written comments may also be delivered to 11545 Rockville Pike, Rockville, Maryland, from 7:30 am to 4:15 pm, Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, 2120 L Street, N.W. (Lower Level), Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Stephanie M. Coffin (301) 415–2778.

Dated at Rockville, Maryland, this 30th day of January, 1997.

For the Nuclear Regulatory Commission.

Thomas T. Martin,

Director, Division of Reactor Program Management, Office of Nuclear Reactor Regulation.

[FR Doc. 97–2812 Filed 2–5–97; 8:45 am]

BILLING CODE 7590–01–P

10-Year License Terms for Materials Licensees

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Nuclear Regulatory Commission (NRC) is extending the license term for materials licenses issued pursuant to 10 CFR Part 30,[1] "Rules of General Applicability to Domestic Licensing of Byproduct Material"; Part 40, "Domestic Licensing of Source Material"; and Part 70, "Domestic Licensing of Special Nuclear Material" from the current 5-year period to a 10-year period on the next renewal of the affected licenses with the exception of licenses issued pursuant to Part 35. The license term for licenses issued pursuant to Part 35 are established by regulation and must be revised by rulemaking. The 5-year term for licenses other than those issued pursuant to Part 35 has been a matter of practice (see 31 FR 16367; December 22, 1966, and 32 FR 7172; May 12, 1967); the license term is not codified in the regulations.

Over the past several years, the regulatory regime applicable to materials licensees has become more stable and predictable. NRC now has extensive experience in uniform application of health and safety regulations to materials licensees. NRC has developed specific regulatory criteria for materials users in various areas. For example, NRC has revised or amended, specific regulations in the following areas: Industrial radiography, medical use, irradiators, and well-logging. In addition, NRC has recently revised its regulations regarding the standards for protection against radiation, to make them more compatible with international health and safety standards.

NRC has concluded that the term for materials licenses can be increased from 5 to 10 years, with no adverse effect on public health, safety, or the environment. This conclusion is based on the existence of the mature regulatory regime currently in place. NRC's current practice of routinely being in contact with licensees through inspections, license amendments, and annual fee-billing procedures provides further support for increasing the term of materials licenses.

Although NRC is announcing its expectation that materials licenses will be issued for 10-year terms, NRC may issue licenses for shorter terms depending on the individual circumstances of license applicants.

EFFECTIVE DATE: February 6, 1997.

FOR FURTHER INFORMATION CONTACT: Catherine Haney or Diane Flack, U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Washington, DC 20555, telephone (301) 415–7206.

Dated at Rockville, Maryland, this 31st day of January, 1997.

For the Nuclear Regulatory Commission.

Carl J. Paperiello,

Director, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 97–2978 Filed 2–5–97; 8:45 am]

BILLING CODE 7590–01–P

[1] Reference to Part 30 is intended to include 10 CFR Part 32, "Specific Domestic Licenses to Manufacture or Transfer Certain Items Containing Byproduct Material"; Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material"; Part 34, "Licenses for Radiography and Radiation Safety Requirements for Radiographic Operations"; Part 35, "Medical Use of Byproduct Material"; Part 36, "Licenses and Radiation Safety Requirements for Well Logging"; and any other regulations that are developed in the Part 30 series.

PEACE CORPS

Information Collection Requests Under OMB Review

ACTION: Notice of public use form review request to the Office of Management and Budget.

SUMMARY: Pursuant to the Paperwork Reduction Act of 1981 (44 U.S.C., Chapter 35) Peace Corps of the United States has submitted to the Office of Management and Budget a request for approval of the collection of names of groups and/or individuals which make use of the Peace Corps name or logo by Peace Corps Office of General Counsel. The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until March 3, 1997. This process is conducted in accordance with 5 CFR 1320.10; the initial notice was published in the **Federal Register** on

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:

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

OFFICE OF THE SECRETARY
CORRESPONDENCE CONTROL TICKET

To: Kane, NMSS
Appropriate Action

Date Printed: Jan 24, 2000 16:19

PAPER NUMBER: LTR-00-0048 **LOGGING DATE:** 01/24/2000

ACTION OFFICE: EDO

cys: EDO
DEDMRS
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DEDM
AO
ADM
SP

AUTHOR: ROBERT CARRETTA

AFFILIATION: SNM

SUBJECT: COMMENTS RE DRAFT NRC DOCUMENT "POLICY AND GUIDANCE DIRECTIVE PG 83-2, REV. 1, SUPPLEMENT 1, RENEWAL O MATERIALS LICENSES"

ACTION: Appropriate

ADDRESSEE:

LETTER DATE: 01/18/2000

ACKNOWLEDGED No

SPECIAL HANDLING: CHAIRMAN, COMRS, SECY/RAS

DATE DUE:

IMNS

SOCIETY OF NUCLEAR MEDICINE
1850 Samuel Morse Drive / Reston, VA. 20190-5316 / (703) 708-9000 / FAX: (703) 708-9015

January 18, 2000
Dr. Richard A. Meserve
Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Chairman Meserve

The Society of Nuclear Medicine (SNM) – a professional organization that represents over 12,000 practicing nuclear medicine health care providers – is writing to express concern about a draft NRC document: "Policy and Guidance Directive PG 83-2, Rev. 1, Supplement 1, Renewal of Materials Licenses" (PG 83-2) (May 1999, photocopy attached). Our concerns center around three points:

- PG 83-2 appears to have been written in contrast to the recent Business Process Redesign policy of consolidation and internet posting of licensing documents.
- PG 83-2 announces the creation of a two-tiered licensing system.
- PG 83-2 may represent a "desk drawer" rule.

One of the Business Process Redesign actions taken by the NRC was consolidation of materials licensing documents. This consolidation is described in NUREGs 1539 and 1541, and Commission briefings. For example, in the May 11, 1995 Commission briefing, Carl Paperiello Ph.D., then Office Director of NMSS, stated:

> "I'd like to reduce the volume, the whole team has been given a goal, cut it in half and produce for the first time a single comprehensive licensing manual. I intend to publish it in electronic format and on paper as a NUREG and this will replace all existing guidance. I'll do away with policy and guidance directives and licensing guides and we will have one document." (p. 18, NRC website, http://www.nrc.gov/NRC/COMMISSION/TRANSCRIPTS/19950511a.html).

PG 83-2 appears to be in conflict with the above policy. PG 83-2 appears, without reason, to be a stand-alone document, when it would better serve its purpose by inclusion into the NUREG 1556 series.

PG 83-2 announces a new "two tiered" licensing policy. Applicants with good performance are given ten-year licenses, while those "whose performance indicates potential programmatic weakness" may be licensed for shorter periods of time. The SNM cannot support a two tiered system of licensing. Either an applicant meets the requirements to use byproduct material or it does not. Simply shortening the license life span does not provide adequate assurance that an applicant with programmatic weakness will perform in a manner that will protect the public health and safety. Any licensee, especially one licensed with suspect programmatic

infrastructure, who fails to protect the public health and safety will negatively impact the reputation of both the NRC and the licensed community.

PG 83-2 was first published on the Agreement State website, but our members were denied access to it. The SNM then requested PG 83-2 under the Freedom of Information Act; that request was denied. Subsequently, one of our members forwarded a copy of PG 83-2 to SNM staff. After review, the SNM developed concerns that PG 83-2 might be a "desk drawer" rule, which could impact our members. Additionally, the SNM is preparing a petition and is concerned there may be other documents like PG 83-2 to be reviewed.

SNM respectfully requests that you reconsider instituting a "two tiered" licensing policy and maintain oversight of staff to insure future licensing documents are consolidated into the NUREG 1556 series in an open and public manner. We believe this would better serve the NRC and the licensed community.

Thank you for considering our comments. If you have any questions on this matter, please contact Mark Rotman, Associate Director for Public Policy, at 703-708-9000 extension 1242.

Sincerely,

Robert F. Carretta, MD

Robert F. Carretta, MD
President
Society of Nuclear Medicine

CC: Commissioner Greta Joy Dicus
Commissioner Edward McGaffigan Jr.
Commissioner Jeffrey S. Merrifield
Commissioner Nils J. Diaz

United States
Nuclear Regulatory Commission

DRAFT

Policy and Guidance Directive PG 83-2, REV. 1 SUPPLEMENT 1

RENEWAL OF MATERIALS LICENSES

Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards

PREPARED BY: Donna-Beth Howe, MSIB 5 /99	**REVIEWED BY:** Frederick C. Combs, IMNS 5/ /99
REVIEWED BY: Frederick Sturz, MSIB 5/ /99	**CONCURRENCE:** Larry W. Camper, MSIB 5/ /99

APPROVED BY: Donald A. Cool, IMNS 5/ /99

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1.0 Purpose{tc \l1 "1.0 Purpose}

The Office of Nuclear Material Safety and Safeguards (NMSS) is revising its materials (excluding fuel cycle) licensing renewal review guidance to focus resources on applications from licensees whose performance indicates potential programmatic weaknesses and on program areas that have undergone major changes that could affect radiation safety. Performance indicators are provided to determine the level of review necessary to renew the license. A two tiered license renewal system is being introduced. Guidance is provided to assist staff in determining when licenses should be issued for less than 10 years. General guidance is included to address improved information sources, communication techniques, and licensing tools needed to bring licensing actions to closure.

The Guidance Consolidation Project initiated in 1996 resulted in a series of volumes, in the NUREG 1556 series, providing specific and consistent guidance for licensees and the U.S. Nuclear Regulatory Commission (NRC) staff to use in submitting license applications and reviewing the applications, respectively. Licensee use of this guidance should result in better and more complete submissions. Both licensee and reviewer use will enable NRC to spend less resources in reviewing renewals. This guidance should decrease the number of marginal and protracted interactions with licensees, make it easier to void unsupported licensing requests, and use license conditions or other techniques to bring actions to closure.

2.0 Guidance{tc \l1 "2.0 Guidance}

When reviewing renewals except fuel cycle renewals, the guidance in this Directive shall be applied. This guidance assumes that renewal applications will be filed and reviewed in accordance with the guidance set forth in the NUREG-1556 series and that major program changes will be carefully identified by the applicants.

Section 2.1 describes how to determine the review status of the renewal. The performance indicators in Section 2.2 are the basis for identifying those licensees whose radioactive materials use program will need a comprehensive review. Section 2.3 describes the comprehensive review that will be used for renewals submitted by licensees triggering any of the performance indicators in Section 2.2. Section 2.4 describes the limited review that will be used for renewals submitted by licensees not triggering any of the Section 2.2 performance indicators. Guidance in Section 2.5 will be used to identify those licensees that will receive renewal of less than 10 years. Section 2.6 describes general guidance, for reviewers, that should improve communications with licensees, decrease the number of marginal and protracted interactions with licensees, make it easier to void unsupported licensing requests, and use license conditions or other techniques to bring actions to closure. All licensees will be sent a standard "Notice of License Expiration" letter (Attachment 1).

Because this guidance represents a change in the renewal process, the Integrated Materials Performance Evaluation Program will be modified to address this licensing guidance.

2.1. Determining Review Status of Applications for Renewal of Licenses{tc \l1 "2.1. Determining Review Status of Applications for Renewal of Licenses}

Each renewal application will be selected for either a comprehensive review or limited review by comparing the licensee's performance against the performance indicators in Section 2.2. Thus, the first task for the reviewer is to review the Docket to compare the licensee's performance against these performance indicators. An application submitted by a licensee that demonstrated the presence of one or more of these performance indicators will receive a comprehensive review, as described in Section 2.3. Applications from licensees who do not exhibit any of these performance indicators will receive the limited review described in Section 2.4. The basis for performing either a limited review or a comprehensive review will be documented as described in Attachment 2.

Based on an evaluation of the specific circumstances associated with the presence of a performance indicator, NRC licensing management may, however, decide that a comprehensive review is not warranted. Further, NRC licensing management may have an application from a licensee that does not trigger any of the formal performance indicators but which may exhibit other characteristics warranting a comprehensive review. Such decisions must also be documented in accordance with Attachment 2.

2.2. Performance Indicators.{tc \l1 "2.2. Performance Indicators.}

2.2.A. Enforcement History{tc \l1 "2.2.A. Enforcement History}

A licensee that has been subject to escalated enforcement action within 5 years will be considered for a comprehensive review of the renewal application.

2.2.B. Loss of Material{tc \l2 "2.2.B. Loss of Material}

Any licensee that has lost control of licensed material that is presumed to be in the public domain, and is reportable and/or resulted in a violation of regulatory requirements within the 5-year period immediately before the proposed renewal, will be considered for a comprehensive review of their renewal application.

2.2.C. Unauthorized Disposal or Release of Material{tc \l2 "2.2.C. Unauthorized Disposal or Release of Material}

If the licensee has been cited with a violation regarding unauthorized disposal or release of material in the last 5-years, management control of licensed activities may be weak and a comprehensive review of the license application is necessary.

2.2.D. Overexposure{tc \l2 "2.2.D. Overexposure}

If the licensee has been cited with a violation regarding an exposure in excess of regulatory requirements since the last license renewal, management control of licensed activities may be weak and a comprehensive review of the license application is necessary. Exposures at issue would include those to members of the public as well as to occupationally exposed individuals.

2.3. Comprehensive Reviews{tc \l1 "2.3. Comprehensive Reviews}
A comprehensive review of a renewal application is the comparison of all material, submitted by the licensee, with the requirements in the appropriate regulations, guidance in NUREG-1556, and guidance supplemented in relevant Technical Assistance Request (TAR) responses. The reviewer is to review the applicant's radiation protection program, facilities, equipment, and personnel in detail and provide additional attention to the aspects of the program that triggered the Section 2.2 performance indicators. The checklist in the appropriate NUREG 1556 volume(s) must be completed with all deficiency findings clearly annotated on the checklist.

Parts of the application that do not conform to, or fail to address, areas in this guidance, are deficiencies which must be resolved before the license is renewed. Reviewers shall apply this guidance to the extent suitable to the licensee's activities and should not apply any standards or criteria that are not contained in this guidance, or for which there is no specific regulatory basis. Reviewers may consider program changes, not contained in the guidance, that were motivated by enforcement action. Reviewers should accept licensee procedures or proposals that result in an equivalent level of safety, as described in NRC guidance.

2.4. Limited Reviews{tc \l1 "2.4. Limited Reviews}

A limited review of a renewal application will only evaluate the following areas for conformance to the appropriate sections of the guidance described in Section 8 of the appropriate NUREG 1556 series:

2.4.A. Administrative Items{tc \l1 "2.4.A. Administrative Items}

Administrative items, including the licensee's name and address and other items, such as the radiation safety officer's name, which appear in the application and will be listed on the renewed license.

2.4.B. Program Management{tc \l2 "2.4.B. Program Management}

Those portions of the application that address program management, including:

(1) Organizational structure (assure that appropriate elements are present and are assigned necessary authority and responsibility);

(2) The qualifications of key personnel, such as the radiation safety officer, authorized users, radiographers, well loggers, irradiator operators, authorized medical physicist, and authorized nuclear pharmacists; and

(3) The licensee's radiation safety audit program.

2.4.C. Equipment and Facilities{tc \l2 "2.4.C. Equipment and Facilities}

Those portions of the application that address equipment and facilities.

2.4.D. Environmental Assessments{tc \l2 "2.4.D. Environmental Assessments}
Those portions of the application that need an environmental assessment because they do not conform to the categorical exclusions in 10 CFR Part 51.

2.4.E. Unreviewed Requests{tc \l2 "2.4.E. Unreviewed Requests}

Any new authorizations, requested by the licensee, that have not been previously reviewed, and any major program elements which require change as a result of the new authorization. These areas should undergo a focused review as opposed to a comprehensive review of the entire application. Some examples of requests that should receive focused reviews are:

(1) New broad scope authority, introduction of iodination with millicurie quantities of iodine-131 or iodine-125 requiring major facility additions or changes; additional research and development activities (human and non-human); additional medical therapy modalities; etc.

(2) Any new high-risk technology uses being added to an existing license, to ensure that the licensed program can safely manage and use the new technology. Specific conditions and requirements associated with new technologies may be added to the license. Examples include new license categories for Department of Energy activities converted to commercial facilities; use of intravascular brachytherapy; or Boron Neutron Capture Therapy in humans.

2.4.F. Change in Control{tc \l2 "2.4.F. Change in Control}

A change in control (ownership) that has resulted in a significant change in key staff members directly responsible for the radiation safety program and which has not been previously reviewed. This condition signals that the new staff may have little operational experience in establishing a long-term performance record. In these cases a focused review of the affected areas should be done. NUREG 1556, Volume 15, may be used to assist in change of ownership issues.

2.4.G. Major Areas{tc \l2 "2.4.G. Major Areas}

A brief overview of the remainder of the application to determine if the major areas discussed in the guidance described in Section 8 of the appropriate NUREG 1556 series are present. If detected, an obvious failure or a deficiency in a significant area should result in a thorough review of that area. A finding that more than one area is not addressed or contains a significant deficiency could result in a comprehensive review of the license application. Change to a comprehensive review should be approved by licensing management and the reason for changing from a limited review

to a comprehensive review must be clearly documented on the "Performance And Limited Review Checklist" (see Attachment 2).

2.5. Establishing License expiration dates{tc \l1 "2.5. Establishing License expiration dates}[1]

The Commission approved the extension of the terms set by policy for licenses issued under 10 CFR Parts 30 (except Part 35), 40, and 70 from 5 to 10 years in 1997. In 1998, final rulemaking was published to set the license term limit for medical use licenses at 10 years. Now all materials licenses have the same license term limit. The Commission's actions approved the use of license terms shorter than 10 years on a case-specific basis.

Any license issued or renewed after July 10, 1998 (when the medical use license term limit was changed to 10 years) should have a 10-year term limit, unless management determines, on a case-by-case basis, that a license should be issued for less than 10 years. Some examples of conditions that may result in licenses issued for less than 10 years are:

2.5.A. New Technology{tc \l1 "2.5.A. New Technology}

The license is for a new high-risk technology that the industry, the particular licensee, or NRC has not had extensive experience in using or regulating.

2.5.B. Enforcement History{tc \l2 "2.5.B. Enforcement History}

The licensee had a Severity Level I, II, or III violation because of serious programmatic deficiencies and not isolated events, during the 3-year period immediately before the proposed renewal.

2.5.C. Comprehensive Review{tc \l2 "2.5.C. Comprehensive Review}

The licensee's renewal received a comprehensive review; or

2.5.D. Other{tc \l2 "2.5.D. Other}

Other situations that would warrant increased attention, on a case-specific basis.

[1] This guidance applies to both new and renewed licenses

Note: Licenses that are in a "possession only for decommissioning" status do not need to be renewed because an expired license remains in effect until terminated by NRC (see 10 CFR 30.36, 40.42, or 70.38).

The specific expiration term for a license term shorter than 10 years should be 5 years, unless, on a case-specific basis, another time is more appropriate. NRC management may, however, decide that a license term of 10 years is warranted, based on the evaluation of specific circumstances associated with the above conditions and the licensee's commitments and program improvements made in the renewal submission.

Use Attachment 4 to document the license term, the basis for the decision, and the basis for an exemption, if appropriate.

2.6. Reviewer Guidance{tc \l1 "2.6. Reviewer Guidance}

2.6.A. NUREG-1556 series{tc \l1 "2.6.A. NUREG-1556 series}

Avoid requesting information not identified in the NUREG. Use all available NUREG-1556 tools, including process, criteria, and checklists, to standardize and simplify the review process.

If the NUREG does not request information thought to be critical to a particular licensing action, this should be identified and shared with Headquarters so that the NUREG can be revised, if necessary, to include the information.

2.6.B. Technical Assistance Request (TAR) Data Base{tc \l2 "2.6.B. Technical Assistance Request (TAR) Data Base}.

When guidance is needed, staff should consult the NUREG Web page site on NRC's Intranet and then the TAR database, found in Lotus Notes on the Regulatory Product Development Center servers, for existing technical guidance provided by TARs with similar issues. If the guidance exists use it; if not, develop a new TAR. If a TAR response provides new licensing guidance, the response will be added to the electronic NUREG Web page site as an addendum to the appropriate volume of NUREG-1556.

2.6.C. Interaction with NRC Inspectors{tc \l2 "2.6.C. Interaction with NRC Inspectors}

Renewal reviewers are reminded to follow the guidance provided in Policy and Guidance Directive FC-90-1, Revision 1, "Guidelines for Discussions with Licensees Prior to Issuance of Renewals and Major Amendments to Fuel Cycle and Materials Licensees Authorizing Large Quantities of Hazardous Materials," when renewing materials licenses with large amounts of hazardous materials. FC-90-1, Revision 1, defines large quantities of hazardous radioactive material.

2.6.D. Meetings and Visits{tc \l2 "2.6.D. Meetings and Visits}

Meet with the licensee before proceeding with complex cases, and use site visits, if necessary. As soon as NRC (i.e., the reviewer and first line supervisor) determines a request involves complex licensing issues, set up a meeting with the applicant to review and discuss the issues. Early licensee/NRC clarification interactions are important for expediting resolution and avoiding protracted correspondence exchanges. Site visits should be used to improve NRC's understanding of the applicant's facilities and program. Policy and Guidance Directive FC 84-09, "Licensing visits for byproduct material licensees," provides additional guidance on site visits.

2.6.E. Simplify Communications{tc \l2 "2.6.E. Simplify Communications}

Simplify licensee-staff interaction by using telephone, E-mail, and Fax. Early dialogue should be established with applicants. Once issues and deficiencies have been identified, use the simplest process available to fully communicate issues to licensees, document the request, and elicit appropriate applicant response. Use the telephone and e-mail to communicate with licensees and reduce reliance on formal letters. The Docket must contain proper documentation of both the information requested by the reviewer (e.g., fax, telephone record, or e-mail) and the applicant's response and commitments (e.g., signed fax or letter). Draft documents from the applicant should not be used as the basis for a licensing action.

2.6.F. Request for Information{tc \l2 "2.6.F. Request for Information}

Efforts should be directed at improving, reducing, and eliminating reviewers' requests for additional Information. Ensure that each requested item for additional information is clear (i.e., provides a description of the deficiency and a statement of what is needed); is essential to protect safety; and is linked to regulatory requirements and NUREG-1556. The goal is to have no more than one request for additional information for each application. If a second request is needed, escalate it quickly to NRC and licensee management to resolve open issues. If the applicant does not provide adequate information after such a exchange, complete the licensing action that can be completed, inform the licensee of the issues that cannot be approved, and explain why not. Avoid multiple rounds of requests for additional information.

2.6.G. Custom License Conditions{tc \l2 "2.6.G. Custom License Conditions}

Utilize custom conditions to reach closure. Where simple well-defined policy issues remain unresolved, use custom license conditions, rather than protracted negotiations with the applicant, to achieve closure .

3.0 Resources{tc \l1 "3.0 Resources}

This guidance is expected to significantly decrease resource burdens on NRC regional and Headquarters offices.

NOTICE OF EXPIRATION LETTER{tc \l2 "NOTICE OF EXPIRATION LETTER}

Licensee Name
Address 1
Address 2
Address 3

License No. XX-XXXXX-XX
Expiration Date: XX/XX/XXXX
Program Code: XXXX

Gentlemen:

SUBJECT: NOTICE OF LICENSE EXPIRATION

Your U.S. Nuclear Regulatory Commission (NRC) license, specified above, will expire on the date shown. If you wish to continue your licensed program, you should prepare and submit a renewal application on NRC Form 313, following the instructions in the enclosed volume of NUREG 1556. If the application reflects any significant changes in your licensed program, those changes must be clearly indicated.

You must submit an application for the renewal of your license at least 30 days before the expiration date on the license. If your renewal application is filed at least 30 days before the expiration date, your license will remain in effect until NRC takes final action on your application.

However, if your application is filed less than 30 days before the expiration date, you should contact NRC immediately to see if you will need a temporary extension of the expiration date. If your license expires, you no longer have a valid license, but you are required to maintain the safety of all licensed materials until your application for a license or request for termination is submitted and approved. Your use of the licensed material after the expiration of your license will subject you to enforcement action.

If you do not wish to renew your license, you must dispose of or transfer all licensed radioactive material in your possession in an authorized manner (see the appropriate requirements in 10 CFR 30.36, 40.42, or 70.38); then complete the enclosed Form NRC-314, "Certificate of Disposition of Materials" and return it before the expiration date of your license, with a request that your license be terminated. If you cannot dispose of or transfer all licensed radioactive material in your license before the expiration date, you must request a license renewal, for storage-only, of the radioactive material, to avoid enforcement action for violations involving the possession of licensable material without a valid license. Enforcement action may include a substantial monetary civil penalty that could also include daily civil penalties until you achieve compliance.

This notice of your license expiration is sent for your convenience only and does not mean that similar notices will be sent in the future. The responsibility for timely submission of the license renewal remains with the licensee. If you have any questions about this notice or license expiration/renewal, please contact the NRC Regional Office that handles your license.

Enclosures
1. Form NRC 313
2. Form 314
3. NUREG -1556, Volume as appropriate
4. 10 CFR Parts as appropriate

5. Other appropriate documents

LETTER TO PACEMAKER MEDICAL USE LICENEE

** Not available electronically **

LETTER TO PACEMAKER RECIPIENT LICENSEE

** Not available electronically **

PERFORMANCE AND LIMITED REVIEW CHECKLIST{tc \l2 "PERFORMANCE AND LIMITED REVIEW CHECKLIST}

Licensee: _____
License or Docket No: _____
Control No: _____

The following performance indicators were reviewed:

Performance Indicator	Conclusion	If YES, explain:
Enforcement History	YES ____ NO____	
Loss of Material	YES ____ NO____	
Unauthorized Disposal or Release of Material	YES ____ NO____	
Overexposure	YES ____ NO____	

If any of the above items are checked "YES", perform a Comprehensive Review using the applicable guidance contained in NUREG 1556. If all boxes are checked "NO," perform a Limited Review. An exception must be approved by a supervisor, documented, and a copy of that documentation must be attached to this document for placement in the docket.

Additional Information or Explanation of Exception

_____
_____
_____
_____

Comprehensive Review _____
Limited Review _____

_____ _____
Reviewer / Date Supervisor / Date

LIMITED REVIEW ITEMS{tc \l2 "LIMITED REVIEW ITEMS}[1]

Licensee: _____
License or Docket No: _____
Control No: _____

_____ NRC-313 or appropriate equivalent signed and dated by senior licensee representative.

_____ Place of use is a physical location (i.e., not P.O. Box, etc.)

_____ RSO and key personnel are appropriately qualified.

_____ Facilities and equipment are adequate.

_____ All uses qualify for a categorical exclusion in 10 CFR Part 51.

_____ Organizational structure conforms with applicable regulations and NUREG 1556 guidance[2] (appropriate individuals are present and are assigned necessary authority & responsibility)

_____ The audit program structure conforms with applicable regulations and NUREG 1556 guidance[2].

_____ New authorizations requested by the licensee and any major program elements which require change as a result of the new authorization structure conform with applicable regulations and NUREG 1556 guidance[2].

Major program changes, new high risk technology programs, and changes in control (ownership) normally require only a focused review of the specific changes. If these changes are so extensive that a Comprehensive Review of the entire application is needed, obtain Branch Chief approval before proceeding. Each of the following three items must be marked with NA or a check and the change briefly identified.

_____

[1] Use either a check mark to designate a satisfactory response, "NA" to designate not applicable or "D" to designate deficiency as appropriate.

[2] Reviewers are reminded licensees have the flexibility to provide information equivalent to that requested in NUREG 1556.

_____ Major program change conforms with applicable regulations and NUREG 1556 guidance[2].

_____ New high risk technology program conforms with regulations for similar technologies, guidance provided for similar technologies in NUREG 1556 guidance[2], and specific licensing conditions for the new technology.

_____ Change in Control (Ownership) conforms with applicable regulations and NUREG 1556 guidance[2].

_____ A brief overview of the remainder of the application found the major areas discussed in the guidance[2] described in Section 8 of the appropriate NUREG 1556 series are present.

_____ An obvious failure or a deficiency in a significant area resulted in a thorough review of that area.

_____ A Comprehensive Review was conducted and the reason for changing from a Limited Review to a Comprehensive Review is documented on the "Performance and Limited Review Check List."

_____ Appropriate additional information was requested (circle as appropriate: phone log / e-mail/ fax/ letter/_____)

LICENSE TERMS OF LESS THAN 10 YEARS{tc \l2 "LICENSE TERMS OF LESS THAN 10 YEARS}

Licensee: _____
License or Docket No: _ _____
Control No: _____

The following conditions were reviewed :

Condition	Yes	NO	Basis for YES
New high risk technology without extensive use or regulation experience by industry, or licensee, or NRC;			
Enforcement History - Severity Level I, II, or III violation due to serious programmatic deficiencies and not singular events, in preceding 3-years;			
Renewal received a Comprehensive Review;			
Other			

If any of the above items are checked "YES", describe the basis above, determine the license term (usually 5 years) and document the determination below. All exceptions must be approved by a supervisor, documented, and a copy of that documentation must be attached to this document for placement in the docket.

Assigned License Term: _____ years

Additional Information or Explanation of Exception

_____

_____

_____

_____

_____

Reviewer / Date

Supervisor / Date