

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, DC 20555

December 1, 2004

**NRC REGULATORY ISSUE SUMMARY 2004-18
EXPIRATION DATE FOR 10 CFR PART 71 QUALITY ASSURANCE
PROGRAM APPROVALS**

ADDRESSEES

All holders of U.S. Nuclear Regulatory Commission (NRC) - approved 10 CFR Part 71 Quality Assurance Programs (QAPs).

INTENT

NRC is issuing this regulatory issue summary (RIS) to notify affected parties of a change to the renewal period for 10 CFR Part 71 QAPs. The intent is to reduce the unnecessary regulatory burden of some administrative actions. No specific action nor written response is required.

BACKGROUND

Currently, after review and approval of the applicant's 10 CFR Part 71 QAP, an expiration date of 5 years is entered on NRC Form 311, "Quality Assurance Program Approval Form For Radioactive Material Packages." The use of an expiration date requires the QAP to be renewed in accordance with 10 CFR 71.38, "Renewal of a certificate of compliance or quality assurance program approval," should the holder of an NRC-approved 10 CFR Part 71 QAP elect to continue regulated activities pursuant to 10 CFR Part 71.

SUMMARY OF ISSUES

10 CFR 71.38 does not specify a QAP duration. The NRC staff notes that the 5-year QAP approval period was established to provide an opportunity for NRC staff to periodically review QAPs and to maintain periodic contact with the QAP holders. The 5-year renewal period also facilitated NRC record keeping in terms of points of contact, package fabrication, use activities, and other administrative activities.

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In the case where a previously approved QAP, from an Appendix B, 10 CFR Part 50 program, is used to satisfy the requirements of 10 CFR Part 71, the NRC staff notes that a 5-year QAP approval period is also entered in Block 3 of the QAP Approval For Radioactive Material Packages form - NRC Form 311.

The NRC staff notes that the need to maintain an opportunity for NRC staff review of QAPs and periodic contact with the holders of NRC-approved 10 CFR Part 71 QAPs, by way of the 5-year renewal period, is less important now than in the past. Staff contact now occurs more frequently with the annual billing process required to maintain a QAP approval pursuant to 10 CFR Part 171. At this time NRC is made aware of any changes to points of contact, organizational changes, and termination of QAPs. In addition, the NRC inspection program provides reasonable assurance that QAP requirements and commitments are effectively implemented. For these reasons the use of a 5-year expiration date is no longer justified and burdens QAP holders with arbitrary renewal dates that require resubmittal of their QAPs, in accordance with 10 CFR 71.38, even when there have been no changes nor reductions in commitment to the QAPs.

Conclusion: Effective immediately, NRC will be entering an expiration date on Form 311 of 10 years in order to reduce unnecessary regulatory burden. In the interest of efficiency, existing QAP's will not be revised -- that is, upon the next regular renewal or amendment, NRC will issue a 10-year expiration. Further, the regulations of 10 CFR Part 71 continue to provide reasonable assurance that QAP holders will adequately maintain and implement their NRC-approved QAPs. Further, staff will assess whether a rulemaking change is appropriate to codify the effective term of a QAP approval, or whether any expiration date for the QAP is needed. The NRC staff notes that before implementation of any change to its NRC-approved 10 CFR Part 71 QAP, the licensee or certificate holder is required to submit any and all QAP changes to NRC for review and approval.

BACKFIT DISCUSSION

This RIS does not require any action that would implicate a backfit; therefore, the staff did not perform a backfit analysis.

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment on this RIS was not published in the *Federal Register* because the RIS is informational and clarifies the guidance on the QAP approval expiration date.

PAPERWORK REDUCTION ACT STATEMENT

This Regulatory Issue Summary modifies information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.) by extending the term for Quality Assurance Program renewals. These information collections were approved by the Office of Management and Budget, approval number 3150-0008.

The burden reduction to the public for these mandatory information collections is estimated to result in an average reduction of 15 responses annually at 40 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments regarding this burden estimate or any other aspect of these information collections, including suggestions for reducing the burden, to the Records and FOIA/Privacy Services Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet electronic mail to INFOCOLLECTS@NRC.GOV; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0008), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

This RIS requires no specific action nor written response. If you have any questions about this summary, please contact the technical contact listed below.

/RA/
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Attachment: List of Recently Issued NRC Regulatory Issue Summaries

LIST OF RECENTLY ISSUED
NRC REGULATORY ISSUE SUMMARIES

Regulatory Issue Summary No.	Subject	Date of Issuance	Issued to
2004-17	Revised Decay-In-Storage Provisions for the Storage of Radioactive Waste Containing Byproduct Material	11/23/2004	All licensees regulated under 10 CFR Parts 30, 32, 33, and 50.
2004-16	Use of Later Editions and Addenda to ASME Code Section XI For Repair/Replacement Activities	10/19/2004	All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.
2004-15	Emergency Preparedness Issues: Post 9/11	10/18/2004	All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.
2004-14	Focusing Resources in the Office of Nuclear Reactor Regulation as a Result of Review of Security Plan Changes	09/20/2004	All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.

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