

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

December 20, 2002

NRC INFORMATION NOTICE 2002-35: CHANGES TO 10 CFR PARTS 71 AND 72
QUALITY ASSURANCE PROGRAMS

Addressees:

All holders of 10 CFR Part 71 quality assurance (QA) program approvals and all 10 CFR Part 72 licensees and certificate holders.

Purpose:

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to remind addressees of the requirement to obtain NRC approval of all changes to Parts 71 and 72 QA programs before implementation of the changes. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances:

There have been several recent instances in which holders of Parts 71 and 72 QA program approvals have implemented changes to their NRC-approved QA programs before obtaining NRC approval. Although many QA program changes have been found acceptable to NRC, after review, some changes have not satisfied the respective requirements of Part 71, Subpart H, or Part 72, Subpart G. In one instance, enforcement action was taken and the QA program approval holder had to expend considerable effort to complete corrective actions and reestablish compliance with requirements.

Discussion:

The regulations of Part 71 require that licensees and applicants for Certificates of Compliance (CoCs) have QA programs approved by the Commission as satisfying the provisions of Subpart H of Part 71. Similarly, the regulations of Part 72 require that licensees, certificate holders, and applicants for licenses or CoCs have approved QA programs satisfying the criteria of Subpart G of Part 72.

Unlike 10 CFR Part 50, there are no specific requirements, in Parts 71 and 72, addressing changes to an NRC-approved QA program. Once a Part 71 or 72 QA program is approved, no changes to the program may be made without further NRC approval, because a change would alter the program and make it an unapproved program. Thus, the regulations require that any proposed change to an NRC-approved Part 71 or 72 QA program, regardless of substance or effect on commitments, must be approved by NRC before implementation. All holders of QA

ML023520339

program approvals are reminded of, and expected to comply with, these requirements. NRC will consider enforcement actions when and as appropriate, consistent with the NRC Enforcement Policy.

The Parts 71 and 72 requirements for prior approval for all QA program changes do not apply to Part 50 licensees that apply their approved Part 50, Appendix B, QA programs as provided in 10 CFR 71.101(f) or 10 CFR 72.140(d). These licensees may continue to make changes to their QA programs, under 10 CFR 50.54. The requirements do apply to Part 50 licensees that apply separate Part 71 or 72 QA programs to Part 71 or 72 activities.

In the interests of reducing regulatory burden and increasing efficiency, NRC is considering changes to Parts 71 and 72, to provide a method similar to the provisions of 10 CFR 50.54(a)(3) and (4) for making changes to QA programs. However, until regulatory changes are developed and promulgated, Parts 71 and 72 QA program approval holders must comply with the current requirements.

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact the technical contact listed below or the appropriate regional office.

/RA/

E. William Brach, Director
Spent Fuel Project Office
Office of Nuclear Material Safety
and Safeguards

Technical Contact: Frank Jacobs, NMSS
(301) 415-3961
E-mail: fxj2@nrc.gov

Attachments:

1. List of Recently Issued NRC Information Notices
2. List of Recently Issued NMSS Information Notices

program approvals are reminded of, and expected to comply with, these requirements. NRC will consider enforcement actions when and as appropriate, consistent with the NRC Enforcement Policy.

The Parts 71 and 72 requirements for prior approval for all QA program changes do not apply to Part 50 licensees that apply their approved Part 50, Appendix B, QA programs as provided in 10 CFR 71.101(f) or 10 CFR 72.140(d). These licensees may continue to make changes to their QA programs, under 10 CFR 50.54. The requirements do apply to Part 50 licensees that apply separate Part 71 or 72 QA programs to Part 71 or 72 activities.

In the interests of reducing regulatory burden and increasing efficiency, NRC is considering changes to Parts 71 and 72, to provide a method similar to the provisions of 10 CFR 50.54(a)(3) and (4) for making changes to QA programs. However, until regulatory changes are developed and promulgated, Parts 71 and 72 QA program approval holders must comply with the current requirements.

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact the technical contact listed below or the appropriate regional office.

/RA/

E. William Brach, Director
Spent Fuel Project Office
Office of Nuclear Material Safety
and Safeguards

Technical Contact: Frank Jacobs, NMSS
(301) 415-3961
E-mail: fxj2@nrc.gov

Attachments:

1. List of Recently Issued NRC Information Notices
2. List of Recently Issued NMSS Information Notices

C:\ORPCheckout\FileNET\ML023520339.wpd *See previous concurrence

OFC:	SFPO	C	SFPO	C	OGC		NMSS		SFPO	
NAME:	FJacobs*		MTokar*		STreby*		EKraus*		EWBrach*	
DATE:	10/8/02		10/8/02		11/19/02		11/19/02		12/6/02	

OFFICIAL RECORD COPY

LIST OF RECENTLY ISSUED
 NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
2002-34	Failure of Safety-Related Circuit Breaker External Auxiliary Switches at Columbia Generating Station	11/25/2002	All holders of operating licenses or construction permits for nuclear power reactors.
2002-33	Notification of Permanent Injunction Against Neutron Products Incorporated of Dickerson, Maryland	11/22/2002	All teletherapy and radiation processing licensees.
2002-29 (Errata)	Recent Design Problems in Safety Functions of Pneumatic Systems	11/06/2002	All holders of operating licenses or construction permits for nuclear power reactors.
2002-32	Electromigration on Semiconductor Integrated Circuits	10/31/2002	All holders of operating licenses for nuclear power reactors except those who have ceased operations and have certified that fuel has been permanently removed from the reactor vessel.
2002-31	Potentially Defective UF ₆ Cylinder Valves (1-inch)	10/31/2002	All licensees authorized to possess and use source material and/or special nuclear material for the heating, emptying, filling, or shipping of uranium hexafluoride (UF ₆) in 30- and 48-inch cylinders.
2002-30	Control and Surveillance of Portable Gauges During Field Operations	10/30/2002	All NRC licensees authorized to possess, use, transport, and store portable gauges.
2002-29	Recent Design Problems in Safety Functions of Pneumatic Systems	10/15/2002	All holders of operating licenses or construction permits for nuclear power reactors.

Note: NRC generic communications may be received in electronic format shortly after they are issued by subscribing to the NRC listserver as follows:

To subscribe send an e-mail to <listproc@nrc.gov>, no subject, and the following command in the message portion:

subscribe gc-nrr firstname lastname

LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
2002-33	Notification of Permanent Injunction Against Neutron Products Incorporated of Dickerson, Maryland	11/22/2002	All teletherapy and radiation processing licensees.
2002-31	Potentially Defective UF ₆ Cylinder Valves (1-inch)	10/31/2002	All licensees authorized to possess and use source material and/or special nuclear material for the heating, emptying, filling, or shipping of uranium hexafluoride (UF ₆) in 30- and 48-inch cylinders.
2002-30	Control and Surveillance of Portable Gauges During Field Operations	10/30/2002	All NRC licensees authorized to possess, use, transport, and store portable gauges.
2002-28	Appointment of Radiation Safety Officers and Authorized Users Under 10 CFR Part 35	09/27/2002	All medical licensees.
2002-23	Unauthorized Administration of Byproduct Material for Medical Use	07/16/2002	All medical licensees.
2002-19	Medical Misadministrations Caused By Failure to Properly Perform Tests on Dose Calibrators for Beta- and Low-Energy Photon-Emitting Radionuclides	06/14/2002	All nuclear pharmacies and medical licensees.

Note: NRC generic communications may be received in electronic format shortly after they are issued by subscribing to the NRC listserver as follows:

To subscribe send an e-mail to <listproc@nrc.gov>, no subject, and the following command in the message portion:

subscribe gc-nrr firstname lastname