UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF FEDERAL AND STATE MATERIALS AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
OFFICE OF NUCLEAR REACTOR REGULATION
WASHINGTON, D.C. 20555

June 27, 2007

NRC REGULATORY ISSUE SUMMARY 2006-27, SUPPLEMENT 1, AVAILABILITY OF NRC 313A SERIES OF FORMS AND GUIDANCE FOR THEIR COMPLETION

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees, commercial nuclear pharmacy licensees, and NRC Master Material Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.

INTENT

The NRC is issuing this supplement to Regulatory Information Summary (RIS) 2006-27, "Availability of NRC 313A Series of Forms and Guidance For Their Completion," dated December 13, 2006, to inform addressees that revisions have been made to three of the NRC 313A Forms and to the guidance for completion of the forms. No specific action or written response is required. NRC is providing this RIS supplement to the Agreement States for their information and for distribution to their medical licensees as appropriate.

BACKGROUND

The NRC RIS 2006-27 was issued to inform addressees of the availability of NRC 313A series of forms and the guidance for the completion of these forms. The following three forms and associated guidance have been revised since the RIS-2006-27 was issued on December 13, 2006, to more clearly reflect the documentation of training and experience (T&E) required for applicants seeking to become authorized users (AU) for the medical use of byproduct material.

NRC FORM 313A (AUD), "AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.100, 35.200, and 35.500) [10 CFR 35.190, 35.290, and 35.590]";

NRC FORM 313A (AUT), "AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.300) [10 CFR 35.390, 35.392, 35.394, and 35.396]"; and

NRC FORM 313A (AUS), "AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.400 and 35.600) [10 CFR 35.490, 35.491, and 35.690]."

"Licensing Guidance for using the NRC FORM 313A Series of Forms - Documentation of Training and Experience to Identify Individuals on a License as Authorized User, Radiation Safety Officer, Authorized Nuclear Pharmacist, or Authorized Medical Physicist."

SUMMARY OF ISSUE

10 CFR 35.290, "Training for imaging and localization studies," and 10 CFR 35.390, "Training for use of unsealed byproduct material for which a written directive is required," establish the training and experience requirements for physicians who are seeking to become AUs of unsealed byproduct material for the uses authorized under §35.200, and §35.300 respectively. Physicians seeking to become AUs under these regulations are required to complete 700 hours of T&E. NRC received inquiries about the interpretation of the type of work experience that could be credited toward the required 700 hours of T&E in 10 CFR 35.290 and 35.390 for physicians seeking to become AUs.

As explained in the Supplementary Information accompanying the final rule revising the T&E requirements (70 FR 16336, March 30, 2005), the regulatory requirements in these sections refer to two categories of training: (a) classroom and laboratory training, and (b) supervised work experience. All hours credited to "classroom and laboratory training" must relate directly to radiation safety and safe handling of byproduct material. NRC will broadly interpret "classroom and laboratory training" to include various types of instruction, including online training, as long as it meets the specific clock hour requirements and the subject matter relates to radiation safety and safe handling of byproduct material for the uses for which authorization is being requested.

The "supervised work experience" must include, but is not limited to, the subject areas listed in the applicable T&E requirements in 10 CFR 35.290 and 35.390. The NRC recognizes that physicians in training may not dedicate all of their "supervised work experience" time specifically to the subject areas listed in these regulatory requirements and will be attending to other clinical matters involving the medical use of byproduct material (e.g., in these cases reviewing case histories or interpreting scans). Even though these clinical activities are not specifically required by the NRC, this type of supervised clinical experience may be credited toward the "supervised work experience" category to obtain the required total of 700 hours of T& E, but not to the "classroom and laboratory training" category.

Although the issue initially identified focused on 10 CFR 35.290 and 35.390, this interpretation of the type of work experience that may be credited toward the required hours of T&E is also applicable to the supervised work experience requirements in 10 CFR 35.392 "Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)," 10 CFR 35.394, "Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries), 10 CFR 35.396, "Training for the parenteral administration of unsealed byproduct material requiring a written directive," 10 CFR 35.490,

"Training for use of manual brachytherapy sources," and 10 CFR 35.690, "Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units."

The NRC Form 313A (AUD), NRC Form 313A (AUT), and NRC Form 313A (AUS) are used to document the T&E for medical uses in 10 CFR 35.200, 35.300, 35.400 and 35.600. These forms and the guidance for completion of the forms were revised to more clearly reflect the documentation of T&E required for applicants seeking to become AUs for the medical use of byproduct material. The forms have been revised to reflect that the regulations do not require the supervised work experience to be restricted to just the elements named in the regulations. In addition, the forms were revised to remove the section for documenting the number of clock hours of supervised work experience in each of the required categories and replace it with a single space for documenting the total number of supervised work experience hours. The forms now request that the applicant indicate whether the work experience was obtained for each category.

Applicants are encourage to go to the NRC public web site for the most recent versions of the NRC Form 313A series of forms and guidance for completing these forms at http://www.nrc.gov/materials/miau/med-use-toolkit.html

FEDERAL REGISTER NOTIFICATION

A notice of opportunity for public comment on this RIS was not published in the *Federal Register* because this RIS is informational, and does not represent a departure from current regulatory requirements.

CONGRESSIONAL REVIEW ACT

This RIS is not a rule as designated by the Congressional Review Act (5 U.S.C. §§ 801-886) and, therefore, is not subject to the Act.

PAPER REDUCTION ACT STATEMENT

This Regulatory Issue Summary contains information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These information collections were approved by the Office of Management and Budget, approval number 3150-0120, which expires October 31, 2008.

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.

CONTACT

This RIS supplement requires no specific action or written response. If you have any questions about this summary, please contact the individual listed below or the appropriate regional office.

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Enclosure: Recently Issue FSME/NMSS Generic Comminications

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Recently Issued FSME/NMSS Generic Communications

Date	GC No.	Subject	Addressees
02/02/07	IN-07-03	Reportable Medical Events Involving Patients Receiving Dosages of Sodium Iodide Iodine-131 less than the Prescribed Dosage Because of Capsules Remaining in Vials after Administration	All U.S. Nuclear Regulatory Commission medical use licensees and NRC Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
02/28/07	IN-07-08	Potential Vulnerabilities of Time-reliant Computer-based Systems Due to Change in Daylight Saving Time Dates	All U. S. Nuclear Regulatory Commission licensees and all Agreement State Radiation Control Program Directors and State Liaison Officers.
03/13/07	IN-07-10	Yttrium-90 Theraspheres® and Sirspheres® Impurities	All U.S. Nuclear Regulatory Commission (NRC) Medical Licensees and NRC Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.
04/04/07	IN-07-13	Use of As-Found Conditions to Evaluate Criticality-related Process Upsets at Fuel Cycle Facilities	All licensees authorized to possess a critical mass of special nuclear material.
05/02/07	IN-07-16	Common Violations of the Increased Controls Requirements and Related Guidance Documents	All licensees who are implementing the U.S. Nuclear Regulatory Commission (NRC) Order Imposing Increased Controls (EA-05-090), issued November 14, 2005 and December 22, 2005.
05/21/07	IN-07-19	Fire Protection Equipment Recalls and Counterfeit Notices	All holders of operating licenses for nuclear power reactors and fuel cycle facilities; except those licensees for reactors that have permanently ceased operations and who have certified that fuel has been permanently removed from the reactor vessel; and except those licensees for decommissioned fuel cycle facilities.
06/11/07	IN-07-20	Use of Blank Ammunition	All power reactors, Category I fuel cycle facilities, independent spent fuel storage installations, conversion facility, and gaseous diffusion plants.

Date	GC No.	Subject	Addressees
03/01/07	RIS-07-03	Ionizing Radiation Warning Symbol	All U.S. Nuclear Regulatory Commission licensees and certificate holders. All Radiation Control Program Directors and State Liaison Officers
03/09/07	RIS-07-04	Personally Identifiable Information Submitted to the U.S. Nuclear Regulatory Commission	All holders of operating licenses for nuclear power reactors and holders of and applicants for certificates for reactor designs. All licensees, certificate holders, applicants, and other entities subject to regulation by the U.S. Nuclear Regulatory Commission (NRC) of the use of source, byproduct, and special nuclear material
03/20/07	RIS-07-05	Status and Plans for Implementation of NRC Regulatory Authority for Certain Naturally-occurring and Accelerator-produced Radioactive Material	All NRC materials licensees, Radiation Control Program Directors, State Liaison Officers, and NRC's Advisory Committee on the Medical Uses of Isotopes
04/05/07	RIS-07-07	Clarification of Increased Controls for Licensees That Possess Collocated Radioactive Material During Transportation Activities	All U.S. Nuclear Regulatory Commission (NRC) licensees issued NRC's Order Imposing Increased Controls and all Radiation Control Program Directors and State Liaison Officers
05/04/07	RIS-07-09	Examples of Recurring Requests for Additional Information (RAIs) for 10 CFR Part 71 and 72 Applications	All holders of, and applicants for, a: (1) 10 CFR Part 71 certificate of compliance (CoC) for a radioactive material transportation package; (2) 10 CFR Part 72 CoC for a spent fuel storage cask; and (3) 10 CFR Part 72 specific license for an independent spent fuel storage installation (ISFSI).
05/15/07	RIS-07-10	Subscriptions To New List Server For Automatic Notifications Of Medical-Related Generic Communications, *Federal Register* Notices And Newsletters	All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC Master Materials licensees. All Radiation Control Program Directors and State Liaison Officers.

Note: A full listing of generic communications may be viewed at the NRC public website at the following address: http://www.nrc.gov/Electronic Reading Room/Document Collections/Generic Communications.