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, DC 20555-0001

April 24, 2013

NRC REGULATORY ISSUE SUMMARY 2013-03
PRE-APPLICATION COMMUNICATION AND SCHEDULING FOR MEDICAL RADIOISOTOPE FACILITIES INTENDING TO PRODUCE MOLYBDENUM-99

ADDRESSEES

All potential applicants for medical radioisotope utilization, production, and processing facilities intending to produce molybdenum-99 (Mo-99) under a license in accordance with the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," or 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." All Agreement State Program Directors and State Liaison Officers.

INTENT

The intent of this regulatory issue summary (RIS) is to promote early and frequent communication between the U.S. Nuclear Regulatory Commission (NRC) and addressees regarding pre-application activities, including, but not limited to, the scheduling and coordination of application submittals and reviews, associated with the licensing of proposed medical radioisotope utilization, production, and processing facilities intending to produce Mo-99. Frequent communication between the NRC and addressees promotes the submission of high-quality and complete applications. This RIS follows-up on RIS 2011-06, "Pre-application Communication and Voluntary Submittal of Schedule for Future Molybdenum-99 Facility Licensing Actions for NRC Review," dated July 1, 2011, which requested similar information.

Specifically, the NRC seeks current information regarding the scheduling of anticipated requests for licensing actions from all addressees. Providing current scheduling information in response to this RIS is strictly voluntary. Although neither specific action nor written response is required, this information will allow the NRC to better allocate resources to support the activities leading up to and including the review of a license application. Additionally, the proper allocation of NRC resources gained through accurate advanced notice of anticipated requests for licensing actions promotes the efficient and timely completion of the review of a license application.

BACKGROUND INFORMATION

The National Academy of Sciences' 2009 publication, "Medical Isotope Production without Highly Enriched Uranium," encouraged the creation of a domestic supply of Mo-99 without relying on highly enriched uranium (HEU). Following this report, the National Nuclear Security Administration (NNSA) pledged financial support to accelerate the development of technology necessary to establish a domestic commercial supply of Mo-99 using processes that do not

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utilize HEU. To date, NNSA has chosen to support four commercial entities in the development of low enriched uranium solution reactor, neutron capture, and accelerator technologies. Additional commercial entities also have expressed interest in participating in the production of a domestic Mo-99 supply without NNSA's financial support.

The amount of initial interest expressed in this initiative created uncertainty about the number of applications that the NRC would receive for new medical radioisotope utilization, production, and processing facilities intending to produce Mo-99. To ensure the timely completion of anticipated application reviews, the NRC staff issued RIS 2011-06, as mentioned above. The scheduling information submitted to the NRC in response to RIS 2011-06 helped the staff to develop application review schedules and allocate the necessary resources to support pre-application and application review activities.

SUMMARY OF ISSUE

Based on information received from potential applicants, the NRC has budgeted for the review of one application for a medical radioisotope production facility. For the NRC to continue having accurate projections of the resources necessary to ensure a timely review of all incoming applications over the next several years, it is essential that potential applicants communicate frequently with the NRC staff, providing the most current information on pre-application activities and anticipated application submission schedules.

The NRC encourages potential applicants to provide the agency with the scheduling of pre-application activities, including, but not limited to, the scheduling and coordination of application submittals, which are used to demonstrate compliance with NRC safety and environmental requirements in support of anticipated requests for licensing actions. Information from potential applicants will allow the NRC to coordinate pre-application activities better and, as appropriate, conduct vendor audits before applications are submitted. This will facilitate a more efficient licensing review. Additionally, the accuracy of the scheduling estimates provided to the agency will likely affect both the start date and the duration of the application review.

VOLUNTARY RESPONSE

The NRC staff has developed several questions regarding the scheduling of pre-application licensing activities. Based on addressees' responses to these questions, the NRC will be able to determine resource allocation better and review prioritization based, in part, on the number and complexity of applications that will be submitted for review in upcoming fiscal years.

If an addressee chooses to provide voluntary responses to the questions below, the NRC would like to receive the information within 30 days of the date of this RIS or as soon as the information requested is known. In the preparation of voluntary responses to this RIS, it may be beneficial to consult the interim staff guidance augmenting NUREG-1537, Parts 1 and 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors" (Agencywide Documents Access and Management System Accession Nos. ML12156A069 and ML12156A075). This guidance was developed to aid in the preparation of applications for radioisotope production facilities and aqueous homogeneous reactors and may help structure certain responses to the questions below.

The NRC staff recognizes that the addressees' ability to provide responses to these questions depends, in part, on the stage of application preparation. In some cases, addressees may not be able to provide responses to all questions at this time. With this in mind, the staff also

encourages voluntary updates to initial responses to this RIS on a quarterly basis or as significant scheduling changes occur.

The NRC may share application schedules with other Federal agencies (e.g., the U.S. Department of Energy, the Food and Drug Administration, and the Office of Science and Technology Policy) to support planning efforts related to the licensing of new facilities. If a prospective applicant deems any of this information proprietary, the information must be accompanied by a request to withhold information from public disclosure in accordance with 10 CFR 2.390, "Public Inspections, Exemptions, Requests for Withholding." RIS 2004-011, "Supporting Information Associated with Requests for Withholding Proprietary Information," dated June 29, 2004, includes additional information regarding requests for withholding proprietary information from public disclosure. The NRC asks addressees to request withholding only for information the company currently treats as proprietary and, where necessary, provide the proprietary information in designated attachments to its response to this RIS.

The NRC seeks voluntary responses to the following questions:

Design and Licensing Submittal Information

(1) How many applications will be submitted to the NRC? What NRC licensing actions will the application(s) request? What will be the content of the application(s)?

(2) Under which part(s) of 10 CFR will the application(s) request licenses? In particular, will license applications be submitted under 10 CFR Part 50 for consideration as a production or utilization facility or under 10 CFR Part 70 as a processing facility? Will an exemption from any part of the regulations be sought?

(3) What consideration, if any, has been given to the applicability of other parts of 10 CFR to the application(s)? For example, a license for possession of byproduct material may be necessary in accordance with 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material."

(4) When (month and year) will the NRC receive the application(s) for review? Please provide the licensing milestones that have been established for the development, submission, and review of the application(s).

(5) Has a site been selected for each facility described in the application(s)? If so, please describe it.

(6) What design will be used for each facility? What is the current status of the development of the design(s) (i.e., conceptual, preliminary, or final)? Please provide a schedule for completing the design(s).

(7) Are vendors or consultants assisting in preparing the application(s)? If so, please describe their roles and responsibilities in the design and licensing activities.

White Papers and Technical or Topical Reports

(1) Are there current plans to submit white papers or technical or topical reports related to design features, policy resolution, or technical issues for review and approval? If so, please describe and provide a schedule for submitting the anticipated report(s).

Addressees that choose to provide responses to these questions may mail them to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001. Additionally, addressees are permitted to submit responses electronically in accordance with 10 CFR 50.4, "Written Communications." Detailed guidance can be found on the NRC's Web site at http://www.nrc.gov/site-help/e-submittals.html. If applicable, addressees should include their assigned project number in their response to this RIS.

BACKFIT DISCUSSION

This RIS requires no action or written response. Any action on the part of addressees to provide information regarding the scheduling of planned pre-application activities in accordance with the guidance contained in this RIS for the purpose of aiding the NRC in planning the use of its resources is strictly voluntary. Therefore, this RIS is not a backfit under 10 CFR 50.109, "Backfitting," and the staff did not perform a backfit analysis.

FEDERAL REGISTER NOTIFICATION

The NRC did not publish a notice of opportunity for public comment on this RIS in the *Federal Register* because it pertains to an administrative aspect of the regulatory process that involves the voluntary submission of information on the part of addressees.

CONGRESSIONAL REVIEW ACT

The NRC has determined that this action is not a rule and therefore is not subject to the Congressional Review Act.

PAPERWORK REDUCTION ACT STATEMENT

This RIS contains and references 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 (OMB), approval numbers 3150-0017, 3150-0011, 3150-0151 and 3150-0009.

The burden to the public for these voluntary information collections is estimated to average 12 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 on this burden estimate or any other aspect of these information collections, including suggestions for reducing the burden, to the Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0017, -0011, -0151 and -0009), Office of Management and Budget, Washington, DC 20503.

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CONTACT

Please direct any questions about this matter to the technical contacts listed below.

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