UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
WASHINGTON, DC 20555-0001

July 1, 2011

NRC REGULATORY ISSUE SUMMARY 2011-06
PRE-APPLICATION COMMUNICATION AND VOLUNTARY SUBMITTAL OF SCHEDULE FOR FUTURE MOLYBDENUM-99 FACILITY LICENSING ACTIONS FOR NRC REVIEW

ADDRESSEES

All potential applicants for molybdenum-99 isotope utilization, production, and processing facilities seeking a license under 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."

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 the scheduling of application submissions, environmental reviews, construction plans, and other pre-application activities. Frequent communication between the NRC and addressees helps to ensure the submission of high-quality and complete applications.

Specifically, the NRC seeks updated information regarding the scheduling of upcoming licensing actions from all addressees. Providing updated 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 for the review of license applications. Additionally, accurate advanced notice of licensing actions will aid NRC staff in the development of an effective prioritization system for incoming applications, allowing for the timely completion of reviews.

BACKGROUND INFORMATION

The National Academy of Sciences' 2009 publication "Medical Isotope Production without Highly Enriched Uranium" encouraged the creation of a domestic supply of molybdenum-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 molybdenum-99 using processes that do not 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 have also expressed interest in participating in the production of a domestic molybdenum-99 supply without NNSA's financial support. The amount of interest expressed in this initiative has created uncertainty as to the number of applications that the NRC will receive for new molybdenum-99 isotope utilization, production, and processing facilities. To ensure the timely completion of application reviews, it is essential that the potential applicants and the NRC communicate frequently regarding pre-application scheduling activities.

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Previous licensing experiences throughout the agency have clearly established the need for pre-application communication between the NRC and potential applicants. On January 13, 2006, the NRC staff issued RIS 2005-27, Rev. 1, "NRC Timeliness Goals, Prioritization of Incoming License Applications and Voluntary Submittal of Schedule for Future Actions for NRC Review," to stress the value of pre-application meetings and regular updates on anticipated licensing activities. In the years following the issuance of this RIS, the importance of verbal and written communication has been reiterated to potential applicants seeking licenses under the provisions of 10 CFR Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants." Additionally, the NRC began requesting that potential applicants submit scheduling information. RIS 2007-08, "Updated Licensing Submittal Information to Support the Design-Centered Licensing Review Approach," dated April 16, 2007, solicited information from potential applicants regarding the anticipated date of application submittal, the status of environmental reports, vendors and consultants involved in the preparation of the application, and the timing of construction activities. Since the issuance of RIS 2007-08, the NRC has made similar requests for information to other 10 CFR Part 52 applicants, including potential small modular reactor applicants (see RIS 2010-03, "Licensing Submittal Information for Small Modular Reactor Designs," dated February 25, 2010).

SUMMARY OF ISSUE

The NRC anticipates multiple applications for molybdenum-99 isotope utilization, production, and processing facilities within the next several years. To ensure timely and thorough reviews of all incoming applications, it is essential that applicants keep the NRC staff up to date on pre-application activities through frequent communication.

The NRC encourages potential applicants to provide the agency with the scheduling of application submissions, environmental reviews, construction plans, and other pre-application activities used to demonstrate compliance with NRC safety and environmental requirements. Information received from potential applicants will allow the NRC to better coordinate pre-application activities and, as appropriate, conduct vendor audits before the submission of applications, which 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 acceptance review.

VOLUNTARY RESPONSE

The NRC staff has developed several questions regarding the scheduling of pre-application licensing activities. Responses to these questions will allow the NRC to better determine resource allocation and review prioritization based, in part, on the number and complexity of applications to be submitted for review in fiscal years 2012 and 2013.

If an addressee chooses to provide voluntary responses to the questions below, the NRC is interested in obtaining the information within 30 days of the date of this RIS or as soon as the information requested is known. The NRC staff recognizes that the ability of applicants to provide responses to these questions depends, in part, on the stage of application preparation, and, in some cases, applicants 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 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, NNSA, 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 that potential applicants request withholding only for information the company currently treats as proprietary and, where necessary, provide the proprietary information in designated attachments to their 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? When (month and year) will the NRC receive these application(s) for review? What NRC licensing actions will the application(s) request? What are the project milestones for the applicant and the NRC (i.e., review length)?

  (2) Under which part(s) of 10 CFR will the application(s) seek licenses? In particular, will license applications for processing facilities be submitted under 10 CFR Part 50 for consideration as a production facility or under 10 CFR Part 70 as a processing facility? Will an exemption from any part of the regulations be sought? If so, has the applicant accounted for the increase in time for the licensing process (a possible six month increase in time should be allotted).

  (3) Has a location been selected for each proposed unit at the site? If so, please describe.

  (4) When will the environmental report be submitted for review?

  (5) What design will be used for each facility? What is the current status of the development of this design? Please provide a schedule for completing the design.

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

  (7) What actions, if any, have you taken or propose to take regarding 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," license for possession of byproduct material (or a State byproduct materials license if in an Agreement State)?

- White Papers and Technical/Topical Reports

    1. Are there current plans to submit for review and approval white papers or technical/topical reports related to design features, policy resolution, or technical issues? Please provide a schedule for submitting future anticipated reports.

Addressees choosing to provide responses to the above 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 per 10 CFR 50.4. Detailed guidance can be found on the NRC's Website 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 the RIS 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) under OMB control numbers 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 regarding 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 by e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0011, -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 contact listed below.

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Note: NRC generic communications may be found on the NRC public Web site, http://www.nrc.gov, under Electronic Reading Room/Document Collections.

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