



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

April 6, 2016

Carolyn C. Haass  
Vice President  
Northwest Medical Isotopes, LLC  
815 Northwest 9th Street,  
Suite 256  
Corvallis, OR 97330

SUBJECT: ISSUANCE OF ENVIRONMENTAL SCOPING SUMMARY REPORT  
ASSOCIATED WITH THE STAFF'S REVIEW OF THE APPLICATION BY  
NORTHWEST MEDICAL ISOTOPES, LLC, FOR A CONSTRUCTION PERMIT  
FOR A RADIOISOTOPE PRODUCTION FACILITY

Dear Ms. Haass:

The U.S. Nuclear Regulatory Commission (NRC or the staff) conducted an environmental scoping process and solicited public comments from November 18, 2015, to January 4, 2016. This process determined the scope of the staff's environmental review of the application for a construction permit for the proposed Northwest Medical Isotopes, LLC, radioisotope production facility (NWMI facility). The scoping process is the first step required by Title 10 of the *Code of Federal Regulations* (10 CFR) 51.26(a) after publication of a notice of intent to prepare an environmental impact statement (EIS).

As part of the scoping process, the staff held a public meeting in Columbia, MO, on December 8, 2015, to solicit public input regarding the scope of the review. The staff also received written comments by letter, e-mail, and through the Web site <http://www.Regulations.gov>. At the conclusion of the scoping process, the staff prepared the enclosed environmental scoping summary report, which identifies comments received during the scoping period. In accordance with 10 CFR 51.29(b), the staff will send a copy of the scoping summary report to all participants in the scoping process.

The transcript of the public scoping meetings are available for public inspection in the NRC Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike, Rockville, MD 20852, or from the NRC's Agencywide Documents Access and Management System (ADAMS). The ADAMS Public Electronic Reading Room is accessible at <http://www.nrc.gov/reading-rm/adams.html>. The transcript is listed under ADAMS Accession No. ML15356A133. Persons who encounter problems in accessing documents in ADAMS should contact the NRC's PDR reference staff by telephone at 1-800-397-4209 or 301-415-4737 or by e-mail at [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov).

C. Haass

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A notice of the availability of the draft EIS and the procedures for providing comments will be published in the *Federal Register* following issuance of the draft document. If you have any questions concerning the staff's environmental review of this construction permit application, please contact Ms. Nancy Martinez, Environmental Project Manager, at 301-415-2719 or by e-mail to [Nancy.Martinez@nrc.gov](mailto:Nancy.Martinez@nrc.gov).

Sincerely,

**/RA/**

James G. Danna, Chief  
Environmental Review and Projects Branch  
Division of License Renewal  
Office of Nuclear Reactor Regulation

Docket No. 50-609

Enclosure:  
As stated

cc: See Distribution

C. Haass

- 2 -

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Sincerely,

**/RA/**

James Danna, Chief  
Environmental Review and Projects Branch  
Division of License Renewal  
Office of Nuclear Reactor Regulation

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Enclosure:  
As stated

cc: See Distribution

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**ADAMS Accession No.: ML16056A628**

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FOR A RADIOISOTOPE PRODUCTION FACILITY

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**Environmental Impact Statement  
Scoping Process**

**Summary Report**

**Proposed Northwest  
Medical Isotopes, LLC Medical  
Radioisotope Production Facility  
Columbia, MO**

**April 2016**



**U.S. Nuclear Regulatory Commission  
Rockville, Maryland**

## 1. Introduction

By letter dated November 7, 2014, Northwest Medical Isotopes, LLC (NWMI) filed with the U.S. Nuclear Regulatory Commission (NRC), pursuant to Section 103 of the Atomic Energy Act of 1954, as amended, and Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR), a portion (Part 1) of an application for a construction permit for a medical radioisotope production facility at the Discovery Ridge Research Park in Columbia, MO. By letter dated February 5, 2015, NWMI withdrew and resubmitted Part 1 (NWMI 2015a) to include a discussion of connected actions in its Environmental Report (ER) in response to a letter from the NRC (NRC 2015a). By letter dated July 20, 2015 (NWMI 2015b), NWMI submitted Part 2 of its construction permit application, which includes the integrated safety analysis summary and the remaining sections of the construction permit application, as required by 10 CFR 50.34(a).

Part 1 of the NWMI application included an ER (NWMI 2015a) prepared consistent with 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," which contains the NRC requirements for implementing the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq., herein referred to as NEPA). Guidance for the preparation and submittal of an ER for licensing radioisotope production facilities to the NRC is outlined in "Final Interim Staff Guidance Augmenting NUREG-1537, Part 1" (NRC 2012).

On November 18, 2015, the NRC initiated the scoping process for the NWMI facility by issuing a *Federal Register* notice (80 FR 72115). The *Federal Register* notice notified the public of the NRC staff's intent to prepare an environmental impact statement (EIS) related to the review of the construction permit application for the NWMI facility. The NRC staff will prepare the EIS in accordance with 10 CFR Part 51. The NRC's proposed action is to decide whether to issue a construction permit to NWMI under 10 CFR Part 50 that would allow construction of a medical radioisotope production facility.

The purpose of this report is to provide a concise summary of the determinations and conclusions the NRC staff reached, including the significant issues identified, as a result of the scoping process for the NRC's environmental review of the NWMI construction permit application.

The scoping process provides an opportunity for the public to participate to help the agency identify issues to be addressed in the EIS and to highlight public concerns. The notice of intent (80 FR 72115) identified the following objectives of the scoping process:

- a. Define the proposed action, which is to be the subject of the EIS.
- b. Determine the scope of the EIS and identify the significant issues to be analyzed in depth.
- c. Identify and eliminate from detailed study those issues that are peripheral or that are not significant.
- d. Identify any environmental assessments and other EISs that are being or will be prepared that are related to, but are not part of, the scope of the EIS being considered.

- e. Identify other environmental review and consultation requirements related to the proposed action.
- f. Indicate the relationship between the timing of the preparation of the environmental analyses and the Commission's tentative planning and decisionmaking schedule.
- g. Identify any cooperating agencies and, as appropriate, allocate assignments for preparation and schedules for completing the EIS to the NRC and any cooperating agencies.
- h. Describe how the EIS will be prepared, and include any contractor assistance to be used.

The results of the environmental review documented in the EIS will help the NRC decide whether to issue a construction permit, under 10 CFR Part 50, that would allow NWMI to construct a medical radioisotope production facility.

The scope of the EIS includes an evaluation of the environmental impacts of constructing, operating, decommissioning the facility; of the connected actions to the proposed NWMI facility; and of the reasonable alternatives to the proposed action. The Scoping Comments and Responses section of this report includes specific issues identified in the comments received. The subsequent NRC responses explain whether the issues will be addressed in the EIS and, if so, where in the report they will likely be addressed.

During the scoping process, the NRC staff received comments that were outside the scope of the environmental review. This report identifies comments that were determined to be out of the scope of this environmental review. Comments that are within the scope of the environmental review will be evaluated in detail and documented in the appropriate sections of the EIS for the proposed NWMI facility.

In accordance with 36 CFR 800.8, "Coordination with the National Environmental Policy Act," the NRC will coordinate compliance with Section 106 of the National Historic Preservation Act (NHPA) through the requirements of NEPA. NRC staff has initiated consultation with the Advisory Council on Historic Preservation and Federally recognized tribes with historic ties to the area surrounding the proposed NWMI site.

The NRC invited the applicant; Federal, State, and local government agencies; Indian Tribal governments; local organizations; and individuals to participate in the scoping process by providing oral comments at the scheduled public meeting or by submitting written comments before the end of the scoping comment period on January 4, 2016 (NRC 2015c, 2015d, 2015e; 80 FR 72115). The scoping process included a public meeting held on December 8, 2015, at the Holiday Inn Columbia-East, 915 Port Way, Columbia, MO 65201. The NRC issued press releases and purchased newspaper advertisements to advertise this meeting. Forty-three people attended. The meeting began with NRC staff members providing a brief overview of the construction permit process and the NEPA environmental review process. Following the NRC staff's prepared statements, the agency provided an opportunity for public comments. Six attendees provided separate oral comments that were recorded and transcribed by a certified

court reporter (NRC 2015f). The NRC staff issued a summary of the scoping meeting on January 20, 2016 (NRC 2016). In addition to the comments received at the meeting, the NRC also received comments by letters and e-mails. Documents associated with this scoping process are available for public inspection in the NRC Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike, Rockville, MD 20852, or from the NRC's Agencywide Documents Access and Management System (ADAMS). The ADAMS Public Electronic Reading Room is accessible at <http://www.nrc.gov/reading-rm/adams.html>. Persons who encounter problems in accessing documents in ADAMS should contact the NRC's PDR Reference staff by telephone at 1-800-397-4209 or 301-415-4737 or by e-mail at [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The ADAMS accession number for each document is listed below in Table 1.

At the conclusion of the scoping period, the staff reviewed the scoping meeting transcript (NRC 2015f) and all written material received to identify individual comments. Section 4 of this report includes a copy of the transcript, comment letters, and emails. Each comment was marked with a unique identifier consisting of the commenter identification (ID) (specified in Table 1) and a comment number. For example, Comment 12-01 refers to the first comment within the document provided by commenter ID 12. This unique identifier allows each comment to be traced back to the transcript, letter, or e-mail in which the comment was identified. Comments were consolidated and categorized according to the topic within the proposed EIS or according to the general topic if outside the scope of the EIS. After the NRC staff grouped comments according to subject area, the NRC staff determined the appropriate action for each comment. The action or resolution for each comment is described in the NRC staff's responses within this report.

## 1.1 Scoping Participants

Table 1 identifies the individuals who provided comments, their assigned commenter ID, and the affiliation stated by the commenter. Individuals are listed alphabetically, along with the source document by which the comments were submitted.

Table 1. Individuals Providing Comments during the Scoping Comment Period

<b>Commenter</b>	<b>Affiliation (if stated)</b>	<b>ID</b>	<b>Comment Source</b>	<b>ADAMS No.</b>
Lisa C. Baker	United Keetoowah Band of Cherokee Indians in Oklahoma	01	E-mail	ML16049A297
Everett Bandy	Quapaw Tribe of Oklahoma	02	Letter	ML16020A339
Dan Bague	Mallinckrodt Pharmaceuticals	03	Transcript	ML15356A133
Jerry Dowell	Columbia Chamber of Commerce	04	Transcript	ML15356A133
David Griggs	Regional Economic Development	05	Transcript	ML15356A133

Diane Hunter	Miami Tribe of Oklahoma	06	E-mail	ML16056A421
Andrew Knife Chief	Pawnee Nation of Oklahoma	07	Letter	ML16020A338
Terry Maglich	Missouri Department of Economic Development	08	Transcript	ML15356A133
Bob McDavid	Mayor, City of Columbia	09	Transcript	ML15356A133
Karen Miller	Boone County Commission, Commissioner	10	Transcript	ML15356A133
Toni M. Prawl	Missouri Department of Natural Resources	11	Letter	ML16020A340
Joshua Tapp	U.S. Environmental Protection Agency	12	Letter	ML16007A004

## 1.2 Scoping Comments

This section discusses the process for addressing the comments and suggestions received as part of the scoping process. The disposition of each comment is discussed in Section 2.

The comments received during the scoping period are grouped into the following general categories:

1. Accidents
2. Air Quality
3. Alternatives
4. Coordination
5. Cost-Benefit Comparison
6. Cumulative Impacts
7. Ecological Resources
8. Environmental Justice
9. Historical and Cultural Resources
10. Human Health
11. Purpose and Need
12. Water Resources
13. Support for the NWMI facility
14. Comments outside the scope of NRC's environmental review

In instances where a comment provided no environmental information, only a brief response is provided to the comment and no further evaluation will be performed.

The preparation of the EIS will take into account all of the relevant issues raised during the scoping process. The NRC staff expects to publish the draft EIS by December 2016. The comment period on the draft EIS will be the next opportunity for interested Federal, State, and

local government agencies; Indian Tribal governments; local organizations; the applicant; and other members of the public to provide input to the NRC's environmental review process. Comments received on the draft EIS will be considered in the preparation of the final EIS. The final EIS, along with the NRC staff's safety evaluation report, will provide much of the basis for the agency's decision on NWMI's application to construct the NWMI facility.

## **2. Proposed NWMI Medical Radioisotope Production Facility Scoping Comments and Responses**

The following sections respond to comments received during the scoping period.

### **2.1 Accidents**

**Comment 12-03:** *The increased likelihood of a transportation accident involving molybdenum-99 [...] can increase the risk of harm to sensitive populations.*

**Response:** This comment recommends that the NRC consider the increased likelihood of transportation accidents and is included in Section 4 of this report. Chapter 3 of the EIS will describe the regulatory limits that protect the public and EIS Chapter 4 will address the impacts to the public from transportation of radioactive material to and from the proposed facility. Chapter 4 of the EIS will also address the impacts to the public that result from the postulated maximum hypothetical accident at the proposed NWMI facility. An expanded response to these comments will be included in Appendix A of the EIS.

### **2.2 Air Quality**

**Comment 12-20:** *The document should also consider greenhouse gas emissions and how the preferred alternative might improve or degrade air quality based on the construction of the facility and how this facility could improve transportation GHG emissions based on reduction of imports from Canada or overseas. Information on how to comply with the President and CEQ can be found here: <https://www.whitehouse.gov/administration/eop/ceq/initiatives/nepa/ghg-guidance>.*

**Response:** This comment recommends that the EIS assess the greenhouse gas emission and air quality impacts of the proposed NWMI facility and is included in Section 4 of this report. Chapter 3 of EIS will describe air quality at and around the proposed NWMI site in Columbia, MO, and EIS Chapter 4 will address the impacts on air quality that result from construction, operation, and decommissioning of the proposed NWMI facility. Chapter 4 of the EIS will also quantify greenhouse gas emissions resulting from construction, operation, and decommissioning of the proposed NWMI facility. An expanded response to this comment will be included in Appendix A of the EIS.

### **2.3 Alternatives**

**Comment 12-01:** *Although the proposed action is only the licensing of a new low enriched uranium Medical Isotope Reactor, EPA strongly encourages NRC to consider all the significant*

*environmental impacts that would be caused by licensing this facility, both the beneficial and harmful, to human health and the environment. For example, alternatives one might consider are: 1) no-action, 2) licensing of this facility, or 3) denial of this facility to license with approval for licensing a different facility at another location.*

**Response:** This comment suggests that the NRC consider all the significant environmental impacts as a result of the no action alternative (e.g., denial of the construction permit application), the proposed action, and an alternative site and facility and is included in Section 4 of this report. In Chapter 4 of the EIS, the NRC staff will evaluate the potential environmental impacts from the proposed action. In Chapter 5 of the EIS, the NRC staff will evaluate the potential impacts to alternatives, including the no action alternative, alternative sites and alternative technologies. An expanded response to these comments will be included in Appendix A of the EIS.

## **2.4 Coordination**

**Comment 12-12:** *Has coordination between Missouri Department of Natural Resources and NRC occurred?*

**Response:** This comment recommends that the environmental review consider whether coordination has occurred between the NRC and Missouri Department of Natural Resources and is included in Section 4 of this report. In a letter dated November 19, 2015, the NRC invited the Missouri Department of Natural Resources to participate in the scoping process for the environmental review related to the proposed NWMI facility (NRC 2015c). The Missouri Department of Natural Resources did not submit comments to the NRC during the scoping period. Chapter 1 and Appendix C of the EIS will provide additional information regarding the scoping process and coordination with Federal, State, and local agencies.

**Comment 12-14:** *Will there need to be coordination for farmland conversion?*

**Response:** This comment recommends that the environmental review consider whether the NRC will need to coordinate with the U.S. Department of Agriculture regarding the conversion of prime farmland to nonagricultural uses and is included in Section 4 of this report. The proposed NWMI site, Discovery Ridge, in Columbia, MO, does not qualify as prime farmland. Discovery Ridge has been established as a research, development, and office park pursuant to Section 172.273 of Chapter 172 of Missouri Revised Statutes. Prime farmland is defined in the Farmland Protection Policy Act of 1981 (7 U.S.C. 4201 et seq.) as “land that has the best combination of physical and chemical characteristics for producing food, feed, fiber, forage, oilseed, and other agricultural crops with minimum inputs of fuel, fertilizer, pesticides, and labor, and without intolerable soil erosion, as determined by the Secretary [of Agriculture].” However, otherwise qualifying “farmland” soils do not include those on land already in, or committed to, urban development or water storage, as defined in 7 CFR 658.2, “Definitions.” Given that the Discovery Ridge site is already committed to use as a research, development, and office park, the site is not subject to the Farmland Protection Policy Act (7 CFR 658.2). Chapter 3 of the EIS will describe land use on and around the proposed NWMI site in Columbia, MO and EIS Chapter 4 will address the impacts to land use from construction, operation, and decommissioning of the proposed NWMI facility. An expanded response to these comments will be provided in Appendix A of the EIS.



**Comment 12-15:** *Has coordination occurred with the Missouri State Historic Preservation Officer?*

**Response:** This comment recommends that the environmental review consider whether coordination has occurred between the NRC and Missouri State Historic Preservation Officer and is included in Section 4 of this report. NRC staff has initiated consultation with the Missouri State Historic Preservation Officer. On September 17, 2015, NRC staff visited the State Historic Preservation Office (SHPO) in Jefferson City, MO, to discuss the NWMI construction permit application for a proposed radioisotope facility at the Discovery Ridge Research Park, NRC's environmental review of the NWMI application, and the NRC staff's approach to integrating the NEPA review process and Section 106 of the NHPA review. The SHPO indicated that it was familiar with the proposed project, having been contacted by NWMI in 2013 regarding review of the Cultural Resource Investigations Phase 1 Survey for Discovery Ridge, and concurred with the NWMI investigator's recommendation that there would be no historic properties affected (NRC 2015b). On November 19, 2015, the NRC requested scoping comments from the Missouri State Historic Preservation Officer concerning the proposed NWMI facility (NRC 2015d). On December 9, 2015, Toni M. Prawl, Deputy State Historic Preservation Officer, responded to the NRC's scoping comment request (see comment below). Chapter 1 and Appendix C of the EIS will provide additional information regarding the scoping process and coordination with Federal, State, and local agencies.

## 2.5 Cost-Benefit Comparison

**Comment 12-02:** *Although the proposed action is only the licensing of a new low enriched uranium Medical Isotope Reactor, EPA strongly encourages NRC to consider all the significant environmental impacts that would be caused by licensing this facility, both the beneficial and harmful, to human health and the environment. [...] The direct effects of such facilities can be both beneficial and harmful and we encourage NRC to expand the discussion in this area.*

**Comment 12-05:** *In contrast, if such medical supplies have a pronounced effect on human health and are in short supply or are not otherwise readily available, then such considerations should also be taken into account. EPA recommends objectively analyzing both positive and negative aspects so that the decision maker can easily choose the preferred alternative.*

**Response:** The above comments suggest that the NRC staff consider the costs and benefits of the proposed action and alternatives, and are included in Section 4 of this report. In Chapter 5 of the EIS, the NRC staff will evaluate the costs and benefits for the proposed action and compare the environmental impacts of the proposed action, no action alternative, alternative sites, and alternative technologies. An expanded response to these comments will be included in Appendix A of the EIS.

## 2.6 Cumulative Impacts

**Comment 12-06:** *Cumulative impact discussions may also include transport of hazardous materials, storage of materials, national health benefits, induced development due to job creation, and reduction of GHGs due to proximity of the new facility.*

**Response:** The comment recommends that the EIS include a cumulative impact discussion that considers transportation, waste management, human health, socioeconomics, and greenhouse gas (GHG) emissions. The comment is included in Section 4 of this report. Chapter 4 of the EIS will consider the potential cumulative impacts in the associated with the construction, operation, and decommissioning of the proposed NWMI facility. An expanded response to these comments will be included in Appendix A of the EIS.

## **2.7 Ecological Resources**

**Comment 12-07:** *When developing Threatened and Endangered species, one might consider not only animal species, but also plant species if construction will occur on undisturbed land.*

**Response:** This comment recommends that the NRC consider the potential impacts to threatened and endangered animal and plants species from construction of the proposed NWMI facility and is included in Section 4 of this report. Chapter 3 of the EIS will describe the ecological resources, including threatened and endangered animal and plant species, on and around the proposed NWMI site in Columbia, MO and EIS Chapter 4 will address the impacts to ecological resources, including threatened and endangered animal and plant species, from construction, operations, and decommissioning of the proposed NWMI facility. An expanded response to this comment will be included in Appendix A of the EIS.

## **2.8 Environmental Justice**

**Comment 12-11:** *Would EJ communities be disproportionately affected by the proposed locations?*

**Response:** The comment recommends that the environmental review consider the potential human health and environmental effects of construction, operation, and decommissioning of the proposed NWMI facility on minority and low-income populations living near the proposed site. This comment is included in Section 4 of this report. The NRC staff will assess the potential for disproportionately high and adverse human health or environmental effects on minority populations and low-income populations that could result from the construction, operation, and decommissioning of the NWMI facility in Chapter 4 of the NWMI EIS. An expanded response to this comment will be included in Appendix A of the EIS.

## **2.9 Historical and Cultural Resources**

**Comment 06-01:** *In reference to the above-mentioned project, the Miami Tribe is not currently aware of existing documentation directly linking a specific Miami cultural or historic site to the project site. However, as this site is within the extended homelands of the Miami Tribe, should any human remains or Native American cultural items falling under the Native American Graves Protection and Repatriation Act (NAGPRA) or archaeological evidence be discovered during any phase of this project, the Miami Tribe requests immediate consultation with the entity of jurisdiction for the location of discovery. The Miami Tribe offers no objection to the proposed project at this time. However, should human remains and/or cultural objects be discovered,*

*regardless of initial determination as to site dating or cultural affiliation, please contact me [...] to initiate consultation.*

**Comment 01-01:** *Thank you for contacting us as a potential consulting party on this project. The UKB [United Keetoowah Band] defers consultation on this project to federally recognized tribes with more of a historic interest in this site.*

**Comment 02-01:** *This project is outside of the current area of interest for the Quapaw Tribe [of Oklahoma], therefore, the Quapaw Tribe does not desire to comment on this project at this time.*

**Comment 07-01:** *The Pawnee Nation Office of Historic Preservation has received the information and materials requested for our Section 106 Review and Consultation. Consultation with the Pawnee Nation is required by Section 106 of the National Historic Preservation Act of 1966 (NHPA), and 36 CFR Part 800. Given the information provided, you are hereby notified that the proposal project location should have no potential to adversely affect any known Archaeological, Historical, or Sacred Pawnee sites. Therefore, in accordance with 36 CFR 800.4(d)(1), you may proceed with the proposed project. However, please be advised that undiscovered properties may be encountered and must be immediately reported to us under both the NHPA and NAGPRA regulations.*

**Comment 11-01:** *The [Missouri] State Historic Preservation Office has reviewed the information submitted on the above referenced project. Based on this review, we have made the following determination: Adequate documentation has been provided (36 CFR Section 800.11). There will be "no historic properties affected" by the current project. For the above checked reason, the State Historic Preservation Office has no objection to the initiation of project activities. PLEASE BE ADVISED THAT, IF THE CURRENT PROJECT AREA OR SCOPE OF WORK ARE CHANGED, A BORROW AREA IS INCLUDED IN THE PROJECT, OR CULTURAL MATERIALS ARE ENCOUNTERED DURING CONSTRUCTION, APPROPRIATE INFORMATION MUST BE PROVIDED TO THIS OFFICE FOR FURTHER REVIEW AND COMMENT. Please retain this documentation as evidence of compliance with Section 106 of the National Historic Preservation Act, as amended.*

**Response:** The above comments express concerns relating to historical and cultural resources and are included in Section 4 of this report. The NRC staff will describe the cultural background and the known historic and cultural resources found on the proposed NWMI site in Columbia, MO, in Chapter 3 of the EIS and will address the impacts to historic and cultural resources from construction, operation, and decommissioning of the proposed NWMI facility in Chapter 4. An expanded response to these comments will be included in Appendix A of the EIS.

## **2.10 Human Health**

**Comment 12-09:** *What is the safe distance to the nearest residence?*

**Response:** The above comment recommends that the NRC consider impacts to an offsite member of the public and is included in Section 4 of this report. Chapter 4 of the EIS will assess the maximum dose to a member of the public from routine radioactive gaseous effluents and the potential radiological dose and nonradiological chemical dose from accidents that might occur at the proposed NWMI facility to an offsite member of the public at both the proposed

facility site boundary and at the nearest residence. Chapter 4 of the EIS will also evaluate whether radiological doses comply with the public dose limits in 10 CFR Part 20, "Standards for Protection against Radiation." Those dose limits will also be evaluated in the Safety Evaluation Report. An expanded response to this comment will be included in Appendix A of the EIS.

**Comment 12-18:** *Will the facility be required to conduct an annual environmental and public health radiation dose assessment similar to commercial nuclear reactors?*

**Response:** The comment recommends that the EIS consider annual environmental monitoring requirements and public dose assessment for the proposed facility. The comment is included in Section 4 of this report. If licensed to operate, the radioisotope production facility would need to comply with occupational dose limits for adults (10 CFR Part 20, Subpart C, "Occupational Dose Limits") and radiation dose limits for individual members of the public (10 CFR Part 20, Subpart D, "Radiation Dose Limits for Individual Members of the Public"). The NWMI preliminary safety analysis report (NWMI 2015b) included a proposed radiological environmental monitoring program that identifies how measurable levels of radiation from the proposed NWMI facility will be obtained and reported on to ensure compliance with 10 CFR Part 20 dose limits. The applicant's proposed radiological monitoring program will be evaluated in a separate Safety Evaluation Report related to the construction permit application based on the information in the NWMI preliminary safety analysis report (NWMI 2015b). Chapter 4 of the EIS will assess the dose to a member of the public from routine radioactive gaseous effluents and the potential radiological dose and nonradiological chemical dose from accidents that might occur at the proposed NWMI facility to an offsite member of the public at both the proposed facility site boundary and at the nearest residence. An expanded response to this comment will be included in Appendix A of the EIS.

## 2.11 Purpose and Need

**Comment 12-08:** *In reviewing the background on these type of facilities, it appears that ten letters of intent have been made recently, with one construction application already submitted in Wisconsin. If the facility in Wisconsin were to be built, would this facility and the others be necessary and viable?*

**Response:** This comment recommends that the environmental review consider if construction of the proposed NWMI facility is necessary and is included in Section 4 of this report. Chapter 1 of the EIS will describe the purpose and need for the proposed action. The purpose of the NRC's Federal action is to evaluate NWMI's proposal to construct a facility that would ultimately produce medical radioisotopes. This definition of purpose and need reflects the NRC's recognition that, unless there are findings in the safety review required by the Atomic Energy Act of 1954, as amended, or findings in the environmental analysis under NEPA that would lead the NRC to reject a construction permit application, the agency does not have a role in decisions as to whether a particular medical radioisotope production facility should be constructed and operated. An expanded response to these comments will be provided in Appendix A of the EIS.

## 2.12 Water Resources

**Comment 12-04:** *[...] or the possibility of groundwater contamination near private wells can increase the risk of harm to sensitive populations.*

**Response:** The comment recommends that the EIS assess the ground water impacts from the proposed facility and is included in Section 4 of this report. Chapter 3 of the EIS will describe the ground water resources at and around the proposed NWMI site in Columbia, MO and EIS Chapter 4 will address the impacts to ground water resources from construction, operation, and decommissioning of the proposed NWMI facility. An expanded response to this comment will be included in Appendix A of the EIS.

**Comment 12-13:** *Would there be a need for a 404/401 permit?*

**Response:** The comment recommends that the environmental review consider whether the proposed NWMI facility will require a Section 401 water quality certification and Section 404 permit under the Clean Water Act of 1972, as amended (33 U.S.C. 1251 et seq). This comment is included in Section 4 of this report. Chapter 3 of the EIS will describe the water resources on and around the proposed NWMI site in Columbia, MO and EIS Chapter 4 will address the impacts to water resources from construction, operation, and decommissioning of the proposed NWMI facility. Chapter 4 of the EIS will also discuss the Clean Water Act certification and permits that are expected to be required for construction and operation the proposed facility. The permits, approvals, and associated regulatory requirements will also be summarized in Appendix B of the EIS. An expanded response to this comment will be included in Appendix A of the EIS.

## 2.13 Support for the NWMI Facility

**Comment 10-01:** *I am here to testify in support of Northwest Medical Isotopes, LLC's proposed project. Because of our wide array of community assets, we believe that Boone County is an excellent location for the proposed facility. One of our community's premier assets is the University of Missouri's nuclear reactor. The physical proximity of the reactor, as well as its history of excellence in performance, combine to make this a perfect partnership between the University of Missouri and Northwest Medical Isotopes.*

*Through this partnership we will be -- which will produce 99-Mo, cancer patients throughout the United States will have more opportunities for a better outcome. The proposed location of the facility at University of Missouri's Discovery Ridge Park will provide access to Mid-Missouri Regional Airport. This too is an enormous benefit to the project, since reducing the time between production of the drug and delivery to healthcare professionals will effectively increase the efficacy of the drug needed by the patients and doctors throughout the United States. Another asset that our community brings to the table is Boone County's ability to utilize our economic development tool, as Chap -- known as Chapter 100 Bond. With this tool, in cooperation with our taxing entities, we can make this project successful. This is a community-wide partnership, which has the potential to grow ever stronger through the collaboration created by effectively utilizing our community assets, the University's research reactor, Mid-Missouri Regional Airport, and our ability to utilize the economic tool Chapter 100*

*Bond. Our community directly benefits from this partnership because this project will bring good-paying jobs and capital investment, and it creates the possibility of pharmaceutical companies joining the research hub of Discovery Ridge, with that enhanced tax base benefiting all citizens. Please accept this testimony made on behalf of the Boone County Commission in support of the Northwest Medical Isotopes, LLC facility location.*

**Comment 09-01:** *I appreciate the opportunity to testify before the NRC in support of the Northwest Medical Isotopes proposal. This is an important initiative for obviously several different reasons. One is that we have a highly-skilled workforce in Boone County and can easily support the 80-plus jobs that will be required in the production of technetium.*

*Secondly, obviously for Boone County, the 1,600 workers that will be required to construct the building is very important to the economy here in Mid-Missouri and in the whole state of Missouri.*

*Second -- next, you know, I have -- in my former life I was a physician and have been on staff of both the University of Missouri Hospital and Boone Hospital; and I know how important, you know how important the use of radioisotopes is to the healthcare community, to the men and women who do diagnostic and therapeutic intervention, and you know how important this tool is to continue. And it's -- it's -- I know there are a lot of healthcare providers that are uncomfortable with the prospect that Technetium may be in short supply in the pending near future. And, last, and really most important in my opinion is the fact that so many of us may be requiring this tool. You know, whether there's -- of the 18 million doses of Technetium a year, which, obviously, do the math, is 50,000 a day, many of us will need this diagnostic tool for heart disease, bone, skin, and other emerging technologies. And it means so much if we're able to bring the production of this very essential radioisotope back into the United States where we can produce it here and deliver it to the 300-plus citizens of the United States who continue to need this and will need this in the future.*

**Comment 04-01:** *I wanted to put on record the Columbia Chamber of Commerce's support of the Northwest Medical Isotopes application. I wanted to highlight a couple of items that we are supportive of. Missouri and Columbia is the home to world-class medical research resources, and Columbia is at the strategic central location of that access point, and it accesses to other critical markets across the country. So we're supportive of that effort. Also, the Discovery Ridge site utilizes the proximity nourished Missouri and its proximity to transport access at the intersections of two major highways and our access to a regional airport. Also, we have an ample workforce available for the construction phase through the decommissioning phase of this facility. So, once again, the Columbia Chamber of Commerce wants to be on record in support of the Northwest Medical Isotopes application.*

**Comment 05-01:** *I mention that simply to reinforce the point that this project, Northwest Medical Isotopes, has from the start been the perfect example of a private-public or a public-private partnership. Much like REDI, which is also a public-private partnership, this project is a prime example of a company in the city of Columbia, county of Boone, state of Missouri, and our great native University working together to do whatever's necessary to bring a great project to fruition.*

*You will hear some more and have heard from several folks tonight about more specific information relating to this project. My role is to discuss the overall economic pro-- economic impact of the project and how it will impact our community and state.*

*REDI's worked with Northwest for over two years by assisting Northwest and bringing together the right organizational leadership to help move this project to this point. I mentioned many of them just a second ago, but must stress the critical role of the University and the University team at the research reactor. This is simply an amazing opportunity for Columbia, the University, Missouri and, in fact, the United States and our citizens.*

*There are approximately 50,000 doses of this drug that will be produced at this proposed facility administered every day in North America. There's no other producer in the United States for this credible diagnostic medical pharmaceutical. Our research reactor, in collaboration between Northwest and the University, are the critical components for this project.*

*It's estimated that construction of this \$70 million radioisotope production facility in fully operational state will require over 180 full-time skilled construction personnel from Central Missouri and take longer than a year. When the facility's in operation, it's estimated to employ 98 full-time employees. I will tell you those positions will range from extremely highly-skilled technical jobs to those tasked with maintenance of equipment in the facilities. I make that point to note the variety of employment opportunities this project brings to our community. Not included in these construction and operational employment and cost estimates are the ancillary jobs this project will create. Obviously these radiopharmaceuticals require very rapid delivery to the medical facilities that administer them around the country.*

*This project will be located at University's Discovery Ridge Research Park on 7.4 acres. Discovery Ridge is another great example of great public-private partnerships, as it houses ABC Laboratories, which is an environmental testing organization serving the pharmaceutical industry, and other clients like IDEXX, a bioscience company serving veterinary and the animal health research industry. This site is critically located within a few miles of Interstate Highway 70, sets immediately adjacent to U.S. Highway 63. This location provides critical north, south, east, west transportation assets from the center of the United States and is only about six miles from Columbia Regional Airport.*

*All necessary utilities and street infrastructures, including an adjacent overpass providing access to Highway 63, is already in place at the lot line for a fast timeline for this project. That fact simply demonstrates our community's long-term commitment to support this very type of development at Discovery Ridge. In addition to the investment and employment opportunities I've mentioned, it's also anticipated over the life of this project this project will produce over \$76 million in tax revenues to support our school, our city, our county, and our state. In closing, on behalf of REDI and myself, our community, our county, our state, and the thousands of U.S. citizens whose lives will be positively impacted by this project on a daily basis, I give our support and approval.*

**Comment 08-01:** *The opportunities that we look forward to are those that allow for the growth of employment as well as investment. We're very, very pleased to have provided an assistance proposal to Northwest Isotopes approximately a year and a half ago that does just that; creates a number of great jobs, a great deal of investment in one of our targeted industries of life*

*sciences. It also does something that I consider very important; it creates an opportunity to save lives.*

**Comment 03-01:** *Large-scale production of moly-99 is currently only completed at five facilities worldwide. Moly-99 has not been produced domestically since 1991. These five facilities rely on aging research reactors, which are periodically subject to planned and unplanned maintenance. Some of these unplanned maintenance outages have led to shortages of moly-99, frequently impacting patient access to technetium for these important diagnostic procedures.*

*Mallinckrodt is also a major producer of moly-99 at our facility in the Netherlands, so we are very familiar with what is needed to produce commercial quantities of this isotope. As the world's largest consumer of moly-99, Mallinckrodt closely follows new efforts to produce this critical isotope and supports construction of new facilities for its production. We are very familiar with Northwest Medical Isotopes' plan to license and construct a facility in Columbia, Missouri for the production of moly-99 and the recycling of their target material. As we understand it, they intend to utilize a network of two to three university research reactors and build a new moly-99 production facility, all of which should provide additional moly-99 capacity.*

*We believe their technology offers distinct advantages because it is based on the well-proven fission method of moly-99 production and uses existing reactors. Their operation will, importantly, also be based upon low-enriched uranium, which meets the objectives of the U.S. Government's nonproliferation policy, as stated at the 2012 Nuclear Security Summit in Seoul, South Korea and in 2014 in the Netherlands.*

*Nuclear medicine procedures performed in the U.S. consume half of the world's supplies of moly-99. A domestic moly-99 production facility will reduce radioactive decay losses in transit from the current suppliers in Europe, South Africa, and Australia. A U.S. supply, if robust enough to supply the entire market, will also eliminate or reduce transport problems we've had in the past relying on shipments from Europe, incidents including volcanic activity in Iceland and flood destructions due to terrorist concerns. Discussions leading up to the passage of the American Medical Isotope Production Act of 2012 cited all of these issues as a reason to encourage domestic production of moly-99.*

*Mallinckrodt applauds Northwest Medical Isotopes' efforts to build its facility in Columbia and encourages the NRC to provide the necessary resources for an expedient review of their construction permit and operating license applications.*

**Response:** These comments generally support the application and note the medical and socioeconomic benefits of constructing and operating the proposed NWMI facility at the University of Missouri's Discovery Ridge Park in Columbia, MO. The comments are included in Section 4 of this report. The commenters cite the use of a proven technology, the benefit of providing a domestic supply of molybdenum-99 for medical use, public-private partnership, and the proximity of the proposed NWMI facility site to transportation infrastructure.

Chapter 3 of the EIS will describe the environment around the proposed NWMI site as it relates to the socioeconomic and transportation impacts and EIS Chapter 4 will address the impacts from construction, operation, and decommissioning of the proposed NWMI facility. The NRC staff will evaluate the costs and benefits of the proposed action and alternatives to the proposed



action in Chapter 5 of the EIS. Substantive information provided in these comments will be used in the referenced EIS chapters. An expanded response to these comments will be provided in Appendix A of the EIS.

## **2.14 Comments Outside the Scope of the NRC's Environmental Review**

**Comment 12-10:** *Is there adequate emergency response infrastructure in place to address unforeseen events at the proposed locations? Are there any prohibitions to evacuation or sheltering from the proposed facility location?*

**Response:** This comment recommends that the environmental review consider whether there is adequate emergency response, infrastructure, and planning for the proposed NWMI facility and is included in Section 4 of this report. This comment is outside the scope of the environmental review and will not be evaluated further in the development of the EIS. NWMI submitted an emergency response plan in its preliminary safety analysis report (NWMI 2015b). The NWMI plan discusses provisions for responding to radiological and other emergencies and minimizing the consequences of accidents at the proposed NWMI radioisotope production facility. The NRC staff safety review of the operating license application will include an evaluation of the sufficiency of emergency response plan and the staff review will be documented in a Safety Evaluation Report.

**Comment 12-17:** *Are there any US Food and Drug Administration issues with the LEU method of producing molybdenum-99?*

**Response:** This comment recommends that the environmental review consider whether the U.S. Food and Drug Administration (FDA) has concerns about low-enriched uranium (LEU)-based Mo-99 production and is included in Section 4 of this report. This comment is outside the scope of the environmental review and will not be evaluated further in the development of the EIS. Under the Atomic Energy Act of 1954, as amended, the NRC regulates the civilian possession and use of nuclear materials. The NRC's Federal action is to consider whether to issue NWMI a permit to construct a facility that would ultimately produce medical radioisotopes, and includes a determination of whether there is reasonable assurance the facility can be safely operated and of the environmental impacts of that activity. The FDA is responsible for assuring the safety, effectiveness, and proper labeling of medical products (i.e., drugs, devices, and biological products) and reviews new drug applications supporting radiopharmaceutical use, including technetium-99m generated from LEU-produced molybdenum-99. The producer of the medical isotope will have to separately submit an application to the FDA for approval.

**Comment 12-19:** *Is there adequate financial assurance for decommissioning? Is there a maximum time requirement between facility shutdown and decommissioning?*

**Response:** This comment recommends that the environmental review consider whether there is adequate financial assurance for decommissioning of the facility and whether decommissioning time requirements for the proposed facility. The above comment can be found in Section 4 of this report. This comment is outside the scope of the environmental review and will not be evaluated further in the development of the EIS. In accordance with 10 CFR Part 50, an applicant for an operating license of a production or utilization facility must submit a decommissioning funding report. The regulation at 10 CFR 50.33(k) requires that a

report indicate how reasonable assurance will be provided that funds will be available to decommission the facility. If NWMI submits the report required by 10 CFR 50.33(k), the NRC staff will evaluate the adequacy of the decommissioning report in its Safety Evaluation Report that documents its review of the operating license application.

**Comment 12-16:** *Does FAA need to establish a restricted zone around this facility and if so, has coordination been conducted?*

**Response:** This comment recommends that the environmental review consider whether the Federal Aviation Agency (FAA) needs to restrict the airspace zone around the proposed facility and whether coordination has occurred between FAA and the NRC. The comment is included in Section 4 of this report. This comment is outside the scope of the environmental review. As such, this comment will not be evaluated further in the development of the EIS. FAA is responsible for airspace designations in accordance with its regulations in 14 CFR Part 73, "Special Use Airspace," and 14 CFR Part 77, "Safe, Efficient Use, and Preservation of the Navigable Air Space." Coordination between FAA and the NRC has not occurred. The NRC Safety Evaluation Report will consider siting factors such as proximity to airports and will evaluate structures, components, equipment, and systems designed to ensure safe operation, performance, and shutdown of the proposed NWMI facility in the event they are subjected to aircraft impacts.

### 3. References

*U.S. Code of Federal Regulations*, “Domestic Licensing of Production and Utilization Facilities,” Part 50, Title 10, Energy.

*U.S. Code of Federal Regulations*, “Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,” Part 51, Title 10, Energy.

*U.S. Code of Federal Regulations*, “Special Use Airspace,” Part 73, Title 14, Aeronautics and Space.

*Code of Federal Regulations*, “Safe, Efficient Use, and Preservation of the Navigable Airspace,” Part 77, Title 14, Aeronautics and Space.

*U.S. Code of Federal Regulations*, “Coordination with the National Environmental Policy Act,” 800.8, Title 36, Parks, Forests, and Public Property.

U.S. Nuclear Regulatory Commission, “Northwest Medical Isotopes, LLC—Intent To Conduct Scoping Process and Prepare an Environmental Impact Statement; Public Meeting and Request for Comment,” *Federal Register* Vol. 80, No. 222, November 18, 2015, pp. 72115–72117.

Atomic Energy Act of 1954, as amended. 42 U.S.C. §2011 et seq.

Clean Water Act of 1972, as amended. 33 U.S.C. §1251 et seq.

Endangered Species Act of 1973, as amended. 16 U.S.C. §1531 et seq.

Farmland Protection Policy Act of 1981, 7 U.S.C. §4201 et seq.

National Environmental Policy Act of 1969, as amended (NEPA). 42 U.S.C. §4321 et seq.

National Historic Preservation Act of 1966. 16 U.S.C. §470 et seq.

Missouri Revised Statutes, Chapter 172, Section 172.273, Missouri General Assembly, Jefferson City, Missouri, as amended, August 28, 2012.

[NRC] U.S. Nuclear Regulatory Commission. 2012. Final Interim Staff Guidance Augmenting NUREG-1537, Part 1, “Guidelines for Preparing and Reviewing Applications for the Licensing of Non- Power Reactors: Format and Content,” for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors. Washington, DC. October 17, 2012. Agencywide Documents Access and Management System (ADAMS) Accession No. ML12156A069.

[NRC] U.S. Nuclear Regulatory Commission. 2015a Northwest Medical Isotopes, LLC - Status of the Acceptance Review of Part One of the Application for Construction Permit. January 23, 2015. Accession No. ML14349A501.

[NRC] U.S. Nuclear Regulatory Commission. 2015b. Summary of the Environmental Site Audit Related to the Review of Construction Permit Application. Washington, DC, October 13, 2015. ADAMS Package Accession No. ML15266A139.

[NRC] U.S. Nuclear Regulatory Commission. 2015c. Request for Scoping Comments Concerning the Northwest Medical Isotopes, LLC Radioisotope Production Facility Application Environmental Review. Washington, DC, November 17, 2015. Package available at ADAMS Accession No. ML15308A362.

[NRC] U.S. Nuclear Regulatory Commission. 2015d. Request for Scoping Comments Concerning the Northwest Medical Isotope, LLC, Radioisotope Production Facility Application Review. Washington, DC, November 19, 2015. Package available at ADAMS Accession No. ML15314A686.

[NRC] U.S. Nuclear Regulatory Commission. 2015e. Request for Scoping Comments Concerning the Northwest Medical Isotope, LLC, Radioisotope Production Facility Application Review. Washington, DC, November 20, 2015. Package available at ADAMS Accession No. ML15316A036.

[NRC] U.S. Nuclear Regulatory Commission. 2015f. Official Transcript Proceedings, Public Scoping Meeting for Northwest Medical Isotopes, LLC. December 8, 2015 (NRC 2015f). ADAMS Package Accession No. ML15356A133

[NRC] U.S. Nuclear Regulatory Commission. 2016. Summary of the Public Scoping Meeting Conducted Related to the Review of the Proposed Northwest Medical Isotopes, LLC Radioisotope Production Facility. Washington, DC, 2016. Package available at ADAMS Accession No. ML15356A096.

[NWMI] Northwest Medical Isotopes, LLC. 2015a. Submittal of Part 1 Construction Permit Application for a Radioisotope Production Facility. Corvallis, OR. Package available at ADAMS Accession No. ML15086A261.

[NWMI] Northwest Medical Isotopes, LLC. 2015b. Submittal Part 2 Construction Permit Application for a Radioisotope Production Facility. Corvallis, OR. Package available at ADAMS Accession No. ML15210A182.

#### **4. Comment Letters and Meeting Transcript**

The following pages contain the comments, identified by the commenter ID and comment number. The comments are from letters, emails, and the transcript of the public scoping meeting. The comment letters and emails are presented first followed by the scoping meeting transcript.

Comments received are presented in the following order:

##### Letters and Emails

- Lisa C. Baker, Commenter ID: 01
- Everett Bandy, Commenter ID: 02
- Diane Hunter, Commenter ID: 06
- Andrew Knife Chief, Commenter ID: 07
- Toni M. Prawl, Commenter ID: 11
- Joshua Tapp, Commenter ID: 12

##### Scoping Meeting Transcript

- Karen Miller, Commenter ID: 10
- Bob McDavid, Commenter ID: 09
- Jerry Dowell, Commenter ID: 04
- David Griggs, Commenter ID: 05
- Terry Maglich, Commenter ID: 08
- Dan Brague, Commenter ID: 03

Comment of Lisa C. Baker

From: UKB Historic Preservation  
[<mailto:ukbthpo-towers@yahoo.com>]

Sent: Wednesday, December 09, 2015 3:59 PM

To: Hoffman, Robert <Robert.Hoffman@nrc.gov>

Cc: ebird@unitedkeetoowahband.org

Subject: [External\_Sender] Northwest Medical Isotopes, LLC,  
Boone County, MO

Thank you for  
contacting us as a potential consulting party on this  
project. The UKB defers consultation on this project to  
federally recognized tribes with more of a historic interest  
in this site.



01-01

Thank you,

Lisa C. Baker

Acting THPO  
United Keetoowah Band  
of Cherokee Indians in Oklahoma PO Box 746 Tahlequah, OK  
74465

Comment of Everett Bandy

<b>QUAPAW TRIBE OF OKLAHOMA</b>	
	
P.O. Box 765 Quapaw, OK 74363-0765	(918) 542-1853 FAX (918) 542-4694
<i>11/18/2015</i> <i>80 FR 72115</i>	
December 7, 2015	<div style="border: 1px solid black; border-radius: 50%; width: 40px; height: 40px; display: flex; align-items: center; justify-content: center; margin: 0 auto;">3</div>
<div style="writing-mode: vertical-rl; transform: rotate(180deg);">RECEIVED</div> <div style="writing-mode: vertical-rl; transform: rotate(180deg);">2015 JUN 13 PM 4:42</div> <div style="writing-mode: vertical-rl; transform: rotate(180deg);">RULES, ANNOUNCEMENTS AND DIRECTIVES BRANCH</div>	
Cindy Bladley, Chief Rules, Announcements and Directives Branch (RADB) Office of Administration, Mail Stop: OWFN-12-H08 U.S. Nuclear Regulatory Commission Washington, DC 20555-0001	
Re: Scoping comments concerning the Northwest Medical Isotopes, LLC Radioisotope Production Facility Application Review	
Dear Ms. Bladley:	
This project is outside of the current area of interest for the Quapaw Tribe; therefore, the Quapaw Tribe does not desire to comment on this project at this time. Thank you for your efforts to consult with us on this matter.	
Sincerely,	
	
Everett Bandy, THPO Quapaw Tribe of Oklahoma P.O. Box 765 Quapaw, OK 74363 (p) 918-542-1853	
<div style="border: 1px solid red; padding: 2px; display: inline-block;">02-01</div>	
<b>SUNSI Review Complete</b> Template = ADM - 013 E-RIDS= ADM -03 Add= <i>W. Maltinez (rxms)</i>	

Comment of Diane Hunter

**From:** [Diane Hunter](#)  
**To:** [Hoffman, Robert](#)  
**Subject:** [External\_Sender] Northwest Medical Isotopes, LLC Radioisotope Production Facility  
**Date:** Thursday, December 10, 2015 10:58:30 AM

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Dear Mr. Hoffman:

Aya, kikwehsitoole. My name is Diane Hunter, and I am the Acting Tribal Historic Preservation Officer for the Federally Recognized Miami Tribe of Oklahoma. In this capacity, I am the Miami Tribe's point of contact for all Section 106 issues.

In reference to the above-mentioned project, the Miami Tribe is not currently aware of existing documentation directly linking a specific Miami cultural or historic site to the project site. However, as this site is within the extended homelands of the Miami Tribe, should any human remains or Native American cultural items falling under the Native American Graves Protection and Repatriation Act (NAGPRA) or archaeological evidence be discovered during any phase of this project, the Miami Tribe requests immediate consultation with the entity of jurisdiction for the location of discovery.

06-01

The Miami Tribe offers no objection to the proposed project at this time. However, should human remains and/or cultural objects be discovered, regardless of initial determination as to site dating or cultural affiliation, please contact me at 918-541-8966, by email at [dhunter@miamination.com](mailto:dhunter@miamination.com), or by mail at the address listed below to initiate consultation.

Sincerely,

Diane Hunter  
Acting Tribal Historic Preservation Officer  
Miami Tribe of Oklahoma  
P.O. Box 1326  
Miami, OK 74355  
[dhunter@miamination.com](mailto:dhunter@miamination.com)  
918-541-8966



Comment of Andrew Knife Chief

**Pawnee Nation of Oklahoma**

P.O. Box 470  
Pawnee, Oklahoma  
74058

Phone: 918.762.2180  
Fax: 918.762.3662  
E-mail: [aknifechief@pawneenation.org](mailto:aknifechief@pawneenation.org)



11/18/2015  
80 FR 79115

(2)

December 1, 2015

Cindy Bladey, Chief  
RULES, ANNOUNCEMENTS AND DIRECTIVES BRANCH (RADB)  
Office of Administration, Mail Stop: OWFN-12-H08  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

**RE: Request for Section 106 Consultation and Review for proposed construction located Discovery Ridge Park, Columbia, Boone County, MO.**

Dear Cindy,

The Pawnee Nation Office of Historic Preservation has received the information and materials requested for our Section 106 Review and Consultation. Consultation with the Pawnee Nation is required by Section 106 of the National Historic Preservation Act of 1966 (NHPA), and 36 CFR Part 800.

Given the information provided, you are hereby notified that the proposal project location should have no potential to adversely affect any known Archaeological, Historical, or Sacred Pawnee sites. Therefore, in accordance with 36 CFR 800.4(d) (1), you may proceed with your proposed project. However, please be advised that undiscovered properties may be encountered and must be immediately reported to us under both the NHPA and NAGPRA regulations.

This information is provided to assist you in complying with 36 CFR Part 800 for Section 106 Consultation procedures. Please retain this correspondence to show compliance. Should you have any questions, please do not hesitate to contact me at [aknifechief@pawneenation.org](mailto:aknifechief@pawneenation.org). Thank you for your time and consideration.

Should you have questions, please do not hesitate to contact me at [aknifechief@pawneenation.org](mailto:aknifechief@pawneenation.org). Thank you for your time and consideration.

Sincerely,

*Andrew Knife Chief*  
Andrew Knife Chief, B.A., J.D.

SUNSI Review Complete  
Template = ADM - 013  
E-RIDS = ADM-03  
Add = *m. mullins (xms)*

07-01

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RULES, ANNOUNCEMENTS  
AND DIRECTIVES  
BRANCH

Comment of Toni M. Prawl

**CULTURAL RESOURCE ASSESSMENT**

**Section 106 Review**

**CONTACT PERSON/ADDRESS**

**C:**

Cindy Bladey, Chief  
Rules, Announcements & Directives Branch (RADB)  
Office of Administration, Mail Stop: OWFN-12-H08  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

Chad Massman, DED  
Paul Mohr, HUD

**PROJECT:**

Northwest Medical Isotopes, LLC Radioisotope Production Facility, Columbia

**FEDERAL AGENCY**

CDBG

**COUNTY:**

BOONE

The State Historic Preservation Office has reviewed the information submitted on the above referenced project. Based on this review, we have made the following determination:

- ☐ After review of initial submission, the project area has a low potential for the occurrence of cultural resources. A cultural resource survey, therefore, is not warranted.
- ☒ Adequate documentation has been provided (36 CFR Section 800.11). There will be "no historic properties affected" by the current project.
- ☐ An adequate cultural resource survey of the project area has been previously conducted. It has been determined that for the proposed undertaking there will be "no historic properties affected".

11-01

For the above checked reason, the State Historic Preservation Office has no objection to the initiation of project activities. PLEASE BE ADVISED THAT, IF THE CURRENT PROJECT AREA OR SCOPE OF WORK ARE CHANGED, A BORROW AREA IS INCLUDED IN THE PROJECT, OR CULTURAL MATERIALS ARE ENCOUNTERED DURING CONSTRUCTION, APPROPRIATE INFORMATION MUST BE PROVIDED TO THIS OFFICE FOR FURTHER REVIEW AND COMMENT. Please retain this documentation as evidence of compliance with Section 106 of the National Historic Preservation Act, as amended.

By: Toni M. Prawl  
Toni M. Prawl, Ph.D., Deputy State Historic Preservation Officer

December 9, 2015  
Date

MISSOURI DEPARTMENT OF NATURAL RESOURCES  
STATE HISTORIC PRESERVATION OFFICE  
P.O. Box 176, Jefferson City, Missouri 65102

For additional information, please contact Judith Deel, (573) 751-7862. Please be sure to refer to the project number:  
017-BO-16

Comment of Joshua Tapp



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 7

11201 Renner Boulevard  
Lenexa, Kansas 66219

JAN 4 2016

Ms. Cindy Bladey  
Office of Administration  
U.S. Nuclear Regulatory Commission  
Mail Stop: OWFN-12-H08  
Washington, D.C. 20555

11/18/2015  
80FR 72115

①

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2016 JAN -5 AM 9:34

RULES AND RECORDS  
DIVISION  
10-20-15

Dear Ms. Bladey:

The U.S. Environmental Protection Agency, Region 7, has reviewed the scoping documents and public hearing comments prepared for and by the U.S. Nuclear Regulatory Commission and community stakeholders. In accordance with our responsibilities under Section 309 of the Clean Air Act, the National Environmental Policy Act, and the Council on Environmental Quality regulations for implementing NEPA, EPA is providing the following comments:

Although the proposed action is only the licensing of a new low enriched uranium Medical Isotope Reactor, EPA strongly encourages NRC to consider all of the significant environmental impacts that would be caused by licensing this facility, both beneficial and harmful, to human health and the environment. For example, alternatives one might consider are: 1) no-action, 2) licensing of this facility, or 3) denial of this facility to license with approval for licensing a different facility at another location.

12-01

The direct effects of such facilities can be both beneficial and harmful and we encourage NRC to expand the discussion in this area. The increased likelihood of a transportation accident involving molybdenum-99, or the possibility of groundwater contamination near private wells can increase the risk of harm to sensitive populations. In contrast, if such medical supplies have a pronounced effect on human health and are in short supply or are not otherwise readily available, then such considerations should also be taken into account. EPA recommends objectively analyzing both positive and negative aspects so that the decision maker can easily choose the preferred alternative.

12-02

12-03

12-04

12-05

Cumulative impact discussions may also include transport of hazardous materials, storage of materials, national health benefits, induced development due to job creation, and reduction of GHGs due to proximity of the new facility.

12-06

When developing Threatened and Endangered species, one might consider not only animal species, but also plant species if construction will occur on undisturbed land.

12-07

In reviewing the background on these type of facilities, it appears that ten letters of intent have been made recently, with one construction application already submitted in Wisconsin. If the facility in Wisconsin were to be built, would this facility and the others be necessary and viable?

12-08

Other issues that should be examined in the environmental review include:

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E-RIDS= ADM-03

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- What is the safe distance to the nearest residence? 12-09
- Is there adequate emergency response infrastructure in place to address unforeseen events at the proposed locations? 12-10
- Are there any prohibitions to evacuation or sheltering from the proposed facility location? 12-11
- Would EJ communities be disproportionately affected by the proposed locations? 12-12
- Has coordination between Missouri Department of Natural Resources and NRC occurred? 12-13
- Would there be a need for a 404/401 permit? 12-14
- Will there need to be coordination for farmland conversion? 12-15
- Has coordination occurred with the Missouri State Historic Preservation Officer? 12-16
- Does FAA need to establish a restricted zone around this facility and if so, has coordination been conducted? 12-17
- Are there any US Food and Drug Administration issues with the LEU method of producing molybdenum-99? 12-18
- Will the facility be required to conduct an annual environmental and public health radiation dose assessment similar to commercial nuclear reactors? 12-19
- Is there adequate financial assurance for decommissioning?
- Is there a maximum time requirement between facility shutdown and decommissioning?

The document should also consider greenhouse gas emissions and how the preferred alternative might improve or degrade air quality based on the construction of the facility and how this facility could improve transportation GHG emissions based on reduction of imports from Canada or overseas. Information on how to comply with the President and CEQ can be found here: <https://www.whitehouse.gov/administration/eop/ceq/initiatives/nepa/ghg-guidance>. 12-20

Again, we appreciate the opportunity to participate in the public meeting and provide early comments on this project. As discussed above, there are a number of issues that we would like to see addressed in the forthcoming environmental review would likely warrant an Environmental Impact Statement. We look forward to working with you on this project. If you have questions, please call me at 913-551-7606 or contact Joe Summerlin at 913-551-7029 or [summerlin.joe@epa.gov](mailto:summerlin.joe@epa.gov).

Sincerely,



Joshua Tapp

Deputy Director

Environmental Sciences and Technology Division

## Scoping Meeting Transcript

24

1 First I would like to invite Karen Miller  
2 to the podium.

3 MS. MILLER: Good evening. My name's  
4 Karen Miller, and I'm associate commissioner here  
5 in Boone County. I am here to testify in support of  
6 Northwest Medical Isotopes, LLC's proposed project.  
7 Because of our wide array of community assets, we  
8 believe that Boone County is an excellent location for  
9 the proposed facility.

10 One of our community's premier assets is  
11 the University of Missouri's nuclear reactor. The  
12 physical proximity of the reactor, as well as its  
13 history of excellence in performance, combine to make  
14 this a perfect partnership between the University of  
15 Missouri and Northwest Medical Isotopes.

16 Through this partnership we will  
17 be -- which will produce 99-MO, cancer patients  
18 throughout the United States will have more  
19 opportunities for a better outcome. The proposed  
20 location of the facility at University of Missouri's  
21 Discovery Ridge Park will provide access to  
22 Mid-Missouri Regional Airport. This too is an  
23 enormous benefit to the project, since reducing the  
24 time between production of the drug and delivery to  
25 healthcare professionals will effectively increase the

10-01

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1 efficacy of the drug needed by the patients and doctors  
2 throughout the United States.

3 Another asset that our community brings  
4 to the table is Boone County's ability to utilize our  
5 economic development tool, as Chap -- known as Chapter  
6 100 Bond. With this tool, in cooperation with our  
7 taxing entities, we can make this project successful.

8 This is a community-wide partnership,  
9 which has the potential to grow ever stronger through  
10 the collaboration created by effectively utilizing our  
11 community assets, the University's research reactor,  
12 Mid-Missouri Regional Airport, and our ability to  
13 utilize the economic tool Chapter 100 Bond.

14 Our community directly benefits from this  
15 partnership because this project will bring  
16 good-paying jobs and capital investment, and it creates  
17 the possibility of pharmaceutical companies joining  
18 the research hub of Discovery Ridge, with that enhanced  
19 tax base benefiting all citizens.

20 Please accept this testimony made on  
21 behalf of the Boone County Commission in support of the  
22 Northwest Medical Isotopes, LLC facility location.

23 Thank you.

24 MS. HAUSMAN: Thank you.

25 Next I would like to invite Bob McDan

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1 (sic).

2 MR. MCDAVID: Thank you. My name is Bob  
3 McDavid. I'm mayor of the City of Columbia. I  
4 appreciate the opportunity to testify before the NRC  
5 in support of the Northwest Medical Isotopes proposal.

6 This is an important initiative for  
7 obviously several different reasons. One is that we  
8 have a highly-skilled workforce in Boone County and can  
9 easily support the 80-plus jobs that will be required  
10 in the production of Technetium.

11 Secondly, obviously for Boone County, the  
12 1,600 workers that will be required to construct the  
13 building is very important to the economy here in  
14 Mid-Missouri and in the whole state of Missouri.

15 Second -- next, you know, I have -- in my  
16 former life I was a physician and have been on staff  
17 of both the University of Missouri Hospital and Boone  
18 Hospital; and I know how important, you know how  
19 important the use of radioisotopes is to the healthcare  
20 community, to the men and women who do diagnostic and  
21 therapeutic intervention, and you know how important  
22 this tool is to continue. And it's -- it's -- I know  
23 there are a lot of healthcare providers that are  
24 uncomfortable with the prospect that Technetium may be  
25 in short supply in the pending near future.

09-01

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1 And, last, and really most important in  
2 my opinion is the fact that so many of us may be  
3 requiring this tool. You know, whether there's -- of  
4 the 18 million doses of Technetium a year, which,  
5 obviously, do the math, is 50,000 a day, many of us will  
6 need this diagnostic tool for heart disease, bone,  
7 skin, and other emerging technologies. And it means  
8 so much if we're able to bring the production of this  
9 very essential radioisotope back into the United States  
10 where we can produce it here and deliver it to the  
11 300-plus citizens of the United States who continue to  
12 need this and will need this in the future.

13 Thank you for your consideration.

14 MS. HAUSMAN: Thank you.

15 Next, Matt McCormick.

16 MR. DOWELL: Actually, Matt is on his  
17 way. So I'm going to speak on behalf of our  
18 organization, if that's all right.

19 MS. HAUSMAN: Sure. No problem.

20 MR. DOWELL: I'm Jerry Dowell. I'm the  
21 director of government affairs for the Columbia Chamber  
22 of Commerce, and I wanted to put on record the Columbia  
23 Chamber of Commerce's support of the Northwest Medical  
24 Isotopes application.

25 I wanted to highlight a couple of items

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1 that we are supportive of. Missouri and Columbia is  
2 the home to world-class medical research resources, and  
3 Columbia is at the strategic central location of that  
4 access point, and it accesses to other critical markets  
5 across the country. So we're supportive of that  
6 effort.

04-01  
cont.

7 Also, the Discovery Ridge site utilizes  
8 the proximity nourished Missouri and its proximity to  
9 transport access at the intersections of two major  
10 highways and our access to a regional airport. Also,  
11 we have an ample workforce available for the  
12 construction phase through the decommissioning phase  
13 of this facility.

14 So, once again, the Columbia Chamber of  
15 Commerce wants to be on record in support of the  
16 Northwest Medical Isotopes application.

17 MS. HAUSMAN: Thank you.

18 David Griggs.

19 MR. GRIGGS: I must say that a third of  
20 my speech has already been given, so I'm going to spare  
21 you in giving it.

22 My name is David Griggs. I reside at 6420  
23 North Highway VV in Columbia. Tonight I'm here to  
24 represent Regional Economic Development, or REDI,  
25 about this great project.

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1 Just a little bit of background on where  
2 I'm coming from. I'm a former Boone County  
3 Commissioner, a past president of the Columbia Chamber  
4 of Commerce, two-time former chair of REDI, and I've  
5 operated a business in Columbia for over 40 years. I  
6 mention that simply to reinforce the point that this  
7 project, Northwest Medical Isotopes, has from the start  
8 been the perfect example of a private-public or a  
9 public-private partnership. Much like REDI, which is  
10 also a public-private partnership, this project is a  
11 prime example of a company in the city of Columbia,  
12 county of Boone, state of Missouri, and our great native  
13 University working together to do whatever's necessary  
14 to bring a great project to fruition.

15 You will hear some more and have heard  
16 from several folks tonight about more specific  
17 information relating to this project. My role is to  
18 discuss the overall economic pro-- economic impact of  
19 the project and how it will impact our community and  
20 state.

21 REDI's worked with Northwest for over two  
22 years by assisting Northwest and bringing together the  
23 right organizational leadership to help move this  
24 project to this point. I mentioned many of them just  
25 a second ago, but must stress the critical role of the

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1 University and the University team at the research  
2 reactor. This is simply an amazing opportunity for  
3 Columbia, the University, Missouri and, in fact, the  
4 United States and our citizens.

5 There are approximately 50,000 doses of  
6 this drug that will be produced at this proposed  
7 facility administered every day in North America.  
8 There's no other producer in the United States for this  
9 credible diagnostic medical pharmaceutical. Our  
10 research reactor, in collaboration between Northwest  
11 and the University, are the critical components for  
12 this project.

13 It's estimated that construction of this  
14 \$70 million radioisotope production facility in fully  
15 operational state will require over 180 full-time  
16 skilled construction personnel from Central Missouri  
17 and take longer than a year. When the facility's in  
18 operation, it's estimated to employ 98 full-time  
19 employees. I will tell you those positions will range  
20 from extremely highly-skilled technical jobs to those  
21 tasked with maintenance of equipment in the facilities.  
22 I make that point to note the variety of employment  
23 opportunities this project brings to our community.

24 Not included in these construction and  
25 operational employment and cost estimates are the

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1 ancillary jobs this project will create. Obviously  
2 these radiopharmaceuticals require very rapid delivery  
3 to the medical facilities that administer them around  
4 the country.

5 This project will be located at  
6 University's Discovery Ridge Research Park on 7.4  
7 acres. Discovery Ridge is another great example of  
8 great public-private partnerships, as it houses ABC  
9 Laboratories, which is an environmental testing  
10 organization serving the pharmaceutical industry, and  
11 other clients like IDEXX, a bioscience company serving  
12 veterinary and the animal health research industry.

13 This site is critically located within a  
14 few miles of Interstate Highway 70, sets immediately  
15 adjacent to U.S. Highway 63. This location provides  
16 critical north, south, east, west transportation  
17 assets from the center of the United States and is only  
18 about six miles from Columbia Regional Airport.

19 All necessary utilities and street  
20 infrastructures, including an adjacent overpass  
21 providing access to Highway 63, is already in place at  
22 the lot line for a fast timeline for this project. That  
23 fact simply demonstrates our community's long-term  
24 commitment to support this very type of development at  
25 Discovery Ridge.

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1 In addition to the investment and  
2 employment opportunities I've mentioned, it's also  
3 anticipated over the life of this project this project  
4 will produce over \$76 million in tax revenues to support  
5 our school, our city, our county, and our state.

05-01  
cont.

6 In closing, on behalf of REDI and myself,  
7 our community, our county, our state, and the thousands  
8 of U.S. citizens whose lives will be positively  
9 impacted by this project on a daily basis, I give our  
10 support and approval. And thank you very much.

11 MS. HAUSMAN: Thank you, David.

12 Terry Maglich.

13 MR. MAGLICH: Good evening. I'm Terry  
14 Maglich. I am a project manager with the Department  
15 of Economic Development with the State of Missouri.  
16 The role of myself and the Department is to provide  
17 assistance to business and communities that create  
18 opportunities. The opportunities that we look forward  
19 to are those that allow for the growth of employment  
20 as well as investment.

21 We're very, very pleased to have provided  
22 an assistance proposal to Northwest Isotopes  
23 approximately a year and a half ago that does just that;  
24 creates a number of great jobs, a great deal of  
25 investment in one of our targeted industries of life

08-01

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1 sciences. It also does something that I consider very  
2 important; it creates an opportunity to save lives.

3 Thank you for allowing me to testify.

4 MS. HAUSMAN: Thank you, Terry.

5 Next, Dan Brague.

6 MR. BRAGUE: Thank you. My name is Dan  
7 Brague. I'm the vice president and general manager of  
8 global medical imaging for Mallinckrodt  
9 Pharmaceuticals. I'm responsible for the commercial  
10 activities for Mallinckrodt's nuclear medicine  
11 business globally, and I have been interested in the  
12 supply of moly-99.

13 Mallinckrodt is the world's largest  
14 producer of technetium generators for use of nuclear  
15 medicine. These generators use moly-99 with a three-day  
16 half-life to provide sterile, pyrogen-free  
17 technetium-99 medicine with a six-hour half-life.

18 Mallinckrodt has generator manufacturing  
19 operations in Missouri, as well as the Netherlands,  
20 which rely on a steady supply of moly-99. Technetium  
21 is used in roughly 80 percent of all nuclear medicine  
22 procedures nearly 30 million times each year globally  
23 to diagnose heart disease, diagnose and stage cancer,  
24 and examine organ functions in kidneys, lungs and  
25 brain. More than 100 diagnostic procedures are

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1 available to patients using technetium-99  
2 radiopharmaceuticals.

3 Large-scale production of moly-99 is  
4 currently only completed at five facilities worldwide.  
5 Moly-99 has not been produced domestically since 1991.  
6 These five facilities rely on aging research reactors,  
7 which are periodically subject to planned and unplanned  
8 maintenance. Some of these unplanned maintenance  
9 outages have led to shortages of moly-99, frequently  
10 impacting patient access to technetium for these  
11 important diagnostic procedures.

12 Mallinckrodt is also a major producer of  
13 moly-99 at our facility in the Netherlands, so we are  
14 very familiar with what is needed to produce commercial  
15 quantities of this isotope. As the world's largest  
16 consumer of moly-99, Mallinckrodt closely follows new  
17 efforts to produce this critical isotope and supports  
18 construction of new facilities for its production. We  
19 are very familiar with Northwest Medical Isotopes' plan  
20 to license and construct a facility in Columbia,  
21 Missouri for the production of moly-99 and the  
22 recycling of their target material. As we understand  
23 it, they intend to utilize a network of two to three  
24 university research reactors and build a new moly-99  
25 production facility, all of which should provide

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1 additional moly-99 capacity.

2 We believe their technology offers  
3 distinct advantages because it is based on the  
4 well-proven fission method of moly-99 production and  
5 uses existing reactors. Their operation will,  
6 importantly, also be based upon low-enriched uranium,  
7 which meets the objectives of the U.S. Government's  
8 nonproliferation policy, as stated at the 2012 Nuclear  
9 Security Summit in Seoul, South Korea and in 2014 in  
10 the Netherlands.

11 Nuclear medicine procedures performed in  
12 the U.S. consume half of the world's supplies of  
13 moly-99. A domestic moly-99 production facility will  
14 reduce radioactive decay losses in transit from the  
15 current suppliers in Europe, South Africa, and  
16 Australia. A U.S. supply, if robust enough to supply  
17 the entire market, will also eliminate or reduce  
18 transport problems we've had in the past relying on  
19 shipments from Europe, incidents including volcanic  
20 activity in Iceland and flood destructions due to  
21 terrorist concerns. Discussions leading up to the  
22 passage of the American Medical Isotope Production Act  
23 of 2012 cited all of these issues as a reason to  
24 encourage domestic production of moly-99.

25 Mallinckrodt applauds Northwest Medical

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1 Isotopes' efforts to build its facility in Columbia and  
2 encourages the NRC to provide the necessary resources  
3 for an expedient review of their construction permit  
4 and operating license applications.

03-01  
cont.

5 Thank you for the opportunity to provide  
6 these comments today.

7 MS. HAUSMAN: Thank you, Dan.

8 Does anybody else have a comment that they  
9 would like to make this evening?

10 Okay. Going once, twice.

11 We would like to thank everyone for coming  
12 to and participating in the meeting this evening, for  
13 openness and transparency.

14 The transcript of this meeting will be  
15 available publicly on NRC's web page. And the NRC  
16 staff will be available for a short time after. If you  
17 have questions or comments for us, we will be here.

18 Thank you.

19 (Whereupon, at 6:45 p.m., the proceedings  
20 went off the record.)  
21  
22  
23  
24  
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