



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

May 22, 2017

Ms. Cecilia Tapia  
Director, Environmental Science & Technology Division  
U.S. Environmental Protection Agency - Region 7  
11201 Renner Boulevard  
Lenexa, KS 66219

SUBJECT: FINAL ENVIRONMENTAL IMPACT STATEMENT FOR THE NORTHWEST  
MEDICAL ISOTOPE, LLC RADIOISOTOPE PRODUCTION FACILITY  
CONSTRUCTION PERMIT APPLICATION AND RESPONSE TO COMMENTS ON  
THE DRAFT ENVIRONMENTAL IMPACT STATEMENT (CAC NO. MF6135)

Dear Ms. Tapia:

This letter is in response to the U.S. Environmental Protection Agency (EPA), Region 7, letter dated December 22, 2016, that provided comments on the draft environmental impact statement (EIS) for the Northwest Medical Isotopes, LLC (NWMI), medical radioisotope production facility construction permit application. Our responses to your comments are provided as an enclosure to this letter and in Appendix A of the final EIS.

The final EIS is publicly available from the NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. The accession number for the final EIS is ML17130A862.

The final EIS was submitted to the U.S. Environmental Protection Agency via e-NEPA on May 18, 2017. Also, Mr. David Drucker of my staff provided Mr. Joe Summerlin of your staff a link to the final EIS via email on May 22, 2017.

If further information is required, please contact the NRC environmental project manager, Mr. David Drucker, at 301-415-6223 or by e-mail at [david.drucker@nrc.gov](mailto:david.drucker@nrc.gov).

Sincerely,

*/RA/*

Jeffery J. Rikhoff, Acting Chief  
Environmental Review and  
Project Management Branch  
Division of License Renewal  
Office of Nuclear Reactor Regulation

Docket No. 50-609

Enclosure: As stated

cc w/o encls: See next page

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<b>DATE</b>	5/4/17	5/3/17	5/15/17	5/22/17

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**U.S. EPA Region 7 comments and U.S. NRC responses regarding  
the Draft Environmental Impact Statement for the Construction Permit  
for the Northwest Medical Isotopes Radioisotope Production Facility**

**COMMENT:** 1 Regarding gaseous radioactive waste from routine operations, Section 2.7.1.1 Gaseous Waste: This section identifies and provides estimated annual activity of noble gas effluent expected during normal operation (See Table 2-4), but the text in this section also notes, "Radioactive iodine, particulates, and tritium could also be present in the airborne effluent exhaust." However, the draft environmental impact statement does not provide an estimation of these non-noble gas emissions, nor does it provide an estimated filtration percentage from the ventilation system.

Recommendations for the Final Environmental Impact Statement:

Please provide additional detail on the approximate total inventory, prior to and after, the gaseous waste exhaust system, including description of noble gas retention time, system efficiency with regards to iodine and particulates, and the final filtration system on radioiodines, particulates, and tritium.

**RESPONSE:** The comment asks that the EIS include additional detail on the inventories of radioactive noble gases, iodines, particulates, and tritium that could be present in the airborne effluent exhaust from the NWMI facility, both prior to and after the effluent passes through the gaseous waste exhaust and filtration systems (offgas treatment systems). The comment also asks that the EIS indicate how long noble gases are retained for decay prior to their release to the environment, and the offgas treatment system efficiencies for removal of radioactive iodines and particulates.

NWMI has not provided information regarding efficiencies for removal of radioactive iodines and particulates. NWMI has not provided non-proprietary information regarding either how long noble gases are retained for decay, or regarding inventories of gaseous radioactive material generated during facility processes. However, NWMI has provided non-proprietary information regarding the quantities of radioactive noble gases, iodines, and particulates that are actually released to the environment (i.e., that pass through the offgas treatment systems).

As noted in the comment, Table 2-4 in Section 2.7.1.1 of the EIS provides the estimated annual activity releases for three radioactive noble gases (krypton-85, metastable xenon-131, and xenon-133). As discussed in Section 2.7.1.1 of the EIS, radioactive iodines, particulates, and tritium could also be present in the airborne effluent exhaust. As a result of this comment, Section 2.7.1.1 of the EIS has been revised to additionally clarify that noble gases other than krypton-85, metastable xenon-131, and xenon-133 could also be present in the airborne effluent exhaust. However, Section 2.7.1.1 of the EIS has also been revised to clarify that of all the radionuclides that could be present in the exhaust, krypton-85, metastable xenon-131, and xenon-133, are the primary radionuclides of interest in the gaseous effluent from a public dose standpoint. Section 2.7.1.1 of the EIS has been revised to clarify that, although smaller amounts of other radionuclides besides krypton-85, metastable xenon-131, and xenon-133 (radioactive iodines, particulates, tritium, and noble gases other than krypton-85, metastable xenon-131, and xenon-133) would also be released, because the quantities released for these other radionuclides would be small, the public dose contribution from these radionuclides would also be small. A reference to the NWMI RAI response (NWMI 2016), which lists quantities of

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radioactive noble gases, iodines, and particulates released to the environment, and shows that except for krypton-85, metastable xenon-131, and xenon-133, the quantities are small, has also been added to Section 2.7.1.1 of the EIS. The quantities of radioactive iodines, particulates, and noble gases other than krypton-85, metastable xenon-131, and xenon-133 are provided in the NWMI RAI response (NWMI 2016), but are not discussed in detail in the EIS because they are not expected to contribute significantly to the public dose. (NWMI has not provided a non-proprietary estimate of the quantity of tritium released to the environment, but, as stated in Section 4.8.2.1 of the EIS, and also added to Section 2.7.1.1 of the EIS, NWMI determined that the dose from tritium would be negligible relative to the dose from other radionuclides released.)

As discussed in Section 1.2 of the EIS, the NRC staff is conducting a safety review of NWMI's construction permit application that is separate from the environmental review that has resulted in this EIS. Additionally, NWMI cannot operate its facility unless it submits, and the NRC approves, an application for an operating license as well as a license to receive and possess special nuclear material for processing. The issuance of a construction permit is a separate licensing action from the issuance of an operating license for a facility, and both include environmental and safety reviews. The NRC staff safety reviews will further evaluate the radionuclide source terms for the proposed facility, as well as facility design features used to minimize radiation exposures. The safety reviews will include the information discussed in the comment, including proprietary information, as appropriate, and will determine whether radiation exposures associated with operation meet NRC requirements. The environmental review for the operating license application will also consider additional information provided by NWMI in its operating license application, as appropriate. The results of the safety reviews for the construction permit application and the operating license application will be documented in the NRC staff Safety Evaluation Reports, and the environmental review for the operating license application will be documented in an EIS supplement prepared by the NRC staff. As a result of this comment, the NRC staff revised Section 2.7.1.1 of the EIS as discussed above.

**COMMENT:** 2. Regarding the Waste Management Building, Section 2.1 Site Location and Layout, Section 2.7.1.2 Liquid and Solid Waste, and Section 19.2.8.1.2 Treatment and Temporary Storage of Waste Onsite of the Construction Permit Application for Radioisotope Production Facility (ML15086A265): These sections refer to a "Waste Management Building" and certain waste that will be collected prior to shipment off-site, but it is unclear in the draft environmental impact statement what radionuclides and activities will be stored in the detached waste building? Is it anticipated that routine operational exposures from these wastes will occur? Are fire protection safety systems considered? Is there any special filtration considered as part of the ventilation system, and is shielding from direct gamma exposure in this building and wastes considered for occupational and public exposures?

Recommendation for the Final Environmental Impact Statement:

Please provide additional information on these items in the final environmental impact statement, as well as, whether an accidental release of these wastes was considered as part of the design basis accident assessment.

**RESPONSE:** The comment asks what types and activities of radioactive waste will be stored in the detached waste management building, whether routine occupational exposures from wastes in this building will occur, and whether fire protection, filtration, or shielding are considered in the design of this building. The comment also asks whether an accidental release of radioactive waste in this building was considered as part of the accident assessment for the NWMI facility.

As a result of this comment and Comment 3 below, the NRC staff revised Section 2.8.1.1 of the EIS to clarify that only Class A radioactive wastes (which generally contain mostly short-lived

radionuclides at relatively low activity concentrations) would be handled and stored in the detached waste management building, and no processing of waste would be performed in that building. As discussed in Section 2.7.1.2 of the EIS, a total of about 232,000 kg (511,472 lbs) of Class A waste would be generated at the proposed facility per year, and as discussed in Section 2.8.1.1 of the EIS, Class A waste could be stored at the facility for approximately 12 weeks before shipment offsite for disposal. The type (Class A) of the waste stored in the detached waste management building, along with the rate of Class A waste generation and the storage duration for Class A waste, bound the total activities of radioactive waste that could be present in the building. Additionally, NWMI estimated in its construction permit application (NWMI 2015) that the total activity in Class A solidified process waste (which, by mass, comprises most of the Class A waste produced) that would be produced at the proposed facility would be approximately 0.14 curies per week.

Routine occupational exposures, including exposures from wastes stored in this building, would occur during operation of the NWMI facility. However, as discussed in Section 2.8.1.1 of the EIS, radioactive waste, including wastes stored in the detached waste management building, would be stored in a manner that would ensure that personnel exposures to radiation would be as low as is reasonably achievable and within 10 CFR Part 20 limits. As discussed in Section 4.8.2.1 of the EIS, the combination of shielding within the NWMI facility (including the detached waste management building) and the distance from the NWMI facility buildings to the site boundary would ensure that the direct radiation dose to members of the public at the site boundary would be negligible. The NRC staff expects that shielding provided by the detached waste management building structure would also help reduce occupational doses.

NWMI has not identified any specific fire protection and filtration systems for the detached waste management building. However, as discussed in Section 2.8.1.1 of the EIS, radioactive waste, including wastes stored in the detached waste management building, would be stored in a manner that would help ensure that no uncontrolled release of radioactive materials from the waste would occur, and if any release did occur, resulting doses would be within 10 CFR Part 20 limits. As a result of this comment, the NRC staff revised Section 2.8.1.1 of the EIS to clarify this discussion. Additionally, as a result of this comment and Comment 3 below, the NRC staff revised Section 2.8.1.1 of the EIS to state that because only Class A (low activity concentration) wastes would be stored and no waste would be processed in the detached building, any activity available for release would be limited.

As discussed in Section 4.11.1 of the EIS, NWMI considered a variety of potential nuclear criticality or radioactive material accidents for evaluation of the radiological consequences for members of the public from potential accidents at the proposed NWMI facility. NWMI did not specifically consider a fire in the detached waste management building in the construction permit application. However, as discussed in Section 4.11.1 of the EIS, events that were not specifically considered in NWMI's construction permit application were either determined by NWMI to be bounded by the accidents considered; were determined by NWMI to pose an acceptably low level of risk, based on low likelihood and/or consequences; or they have not yet been fully evaluated by NWMI.

As discussed in Section 4.11.1 of the EIS, the NRC staff is conducting an independent review of the radiological consequences of accidents at the proposed NWMI facility as part of its separate safety review of the construction permit application for the facility. If NWMI submits an operating license application for the proposed facility, the NRC staff will conduct an additional and separate safety review, which will further evaluate accident consequences. These reviews will evaluate NWMI's analyses of the full range of accidents that could occur at the facility, including the assumptions used for the analyses, to ensure that the proposed NWMI facility would comply with 10 CFR 70.61 and any other NRC regulations applicable to radiological

accident consequences. Additionally, a separate environmental review will be conducted if an operating license application is submitted and docketed, and that review will also consider any additional information submitted by NWMI in its operating license application. The results of the safety reviews for the construction permit application and the operating license application (if submitted) will be documented in separate NRC staff Safety Evaluation Reports. The environmental review for the operating license application will be documented in an EIS supplement prepared by the NRC staff.

As a result of this comment, the NRC staff revised Section 2.8.1.1 of the EIS as discussed above.

**COMMENT:** 3. Regarding accident assessment, Section 4.11.1 Radiological Accidents: This section refers to an accident scenario evaluation within the radioisotope production facility with effluents vented out the elevated ventilation stack. An elevated release would cause additional dispersal of a plume, as noted by the maximum projected dose to a member of the public calculated at nearly a mile downwind. The draft environmental impact statement does not indicate if other accident scenarios were evaluated. For example, a situation where a fire involving lesser amounts of activity but released at ground level may have a comparable dose impact to nearby off-site receptors. What was the basis for the accident assessment to assume all radionuclide effluents would be entrained through the ventilation system and out the elevated release point? Did other accident scenarios postulate varying conditions where a fire would lead to a radionuclide release at ground level as a comparison to the noted design-basis accident? Does the design-basis accident represent the highest plausible public dose accident, and did an accident scenario consider a fire in the detached waste management building (assuming this building as noted in Figure 2-3, Proposed NWMI Facility Site Boundary and Site Layout, stores radioactive waste material)?

Recommendation for the Final Environmental Impact Statement:

The reference, NWMI, 2016a, includes an accession number, ML16053A212, with source term information and updated accident assessment modeling that does not appear to be fully explained in the draft environmental impact statement. Please provide an additional summary of this reference in the final document.

**RESPONSE:** The comment asks whether other accidents, such as those that could result in radioactive material being released at ground level rather than from the elevated ventilation stack (for example, a fire in the detached waste management building), could result in consequences that exceed the hypothetical radioactive material accident (a fire-related gross failure of the target dissolution offgas treatment system) discussed in EIS Section 4.11.1. The comment also recommends that the EIS include additional detail regarding the source term information and accident assessment modeling for the accident discussed in EIS Section 4.11.1.

As discussed in Section 4.11.1 of the EIS, NWMI stated that it determined that a fire-related gross failure of the target dissolution offgas treatment system accident resulting in a release of radioactive material from the stack could result in radiological consequences for members of the public that would bound those of any credible radiological accident at the NWMI facility.

As also discussed in Section 4.11.1 of the EIS, NWMI considered a variety of different potential nuclear criticality or radioactive material accidents, including offgas treatment system accidents and other accidents, for evaluation of the radiological consequences for members of the public from potential accidents at the proposed NWMI facility. At this time, NWMI has not provided information regarding whether any of the accident scenarios it evaluated specifically considered the maximum public doses resulting from a ground release of radioactive material. However, as

discussed in Section 2.7.1.1 of the EIS, the ventilation system of the NWMI Radioisotope Production Facility building (in which target processing is performed, and which contains the target dissolution offgas treatment system) is designed such that air leaving the facility is exhausted through an elevated vent stack. Therefore, the ventilation system would help ensure that any radioactive material released into the Radioisotope Production Facility building from a fire, spill, or other event would be released to the environment at an elevated release point.

NWMI did not specifically consider a fire in the detached waste management building in the construction permit application. However, as discussed in Section 4.11.1 of the EIS, events that were not specifically considered in NWMI's construction permit application were either determined by NWMI to be bounded by the accidents considered; were determined by NWMI to pose an acceptably low level of risk, based on low likelihood and/or consequences; or they have not yet been fully evaluated by NWMI. NWMI may provide additional postulated accident information in its operating license application that will be submitted separately for NRC review.

As a result of this comment and Comment 2 above, the NRC staff revised Section 2.8.1.1 of the EIS to state that only Class A (low activity concentration) waste would be stored in the detached waste management building, and no processing of waste would be performed in that building, so any activity available for a potential release from the building would be limited. The NRC staff also notes that, as discussed in Section 2.8.1.1 of the EIS, all radioactive waste at the NWMI facility, including waste in the detached waste management building, would be stored in a manner that would help ensure that no uncontrolled release of radioactive materials from the NWMI facility could occur. If any release did occur, any resulting public or occupational dose would be within 10 CFR Part 20 limits.

Section 4.11.1 of the EIS summarizes the source term basis and other assumptions used in NWMI's analysis of the hypothetical radioactive material accident involving a fire-related gross failure of the target dissolution offgas treatment system. The summary provided in Section 4.11.1 is consistent with the information in the NWMI RAI response referenced in the comment (NWMI 2016). As discussed in Section 4.11.1, the source term for NWMI's analysis is based on the assumption that all radioactive iodine and noble gas isotopes retained in the target dissolution offgas treatment system (following 12 weeks of facility operation, with 12 targets processed per week, and all targets processed directly upstream of the offgas treatment system) are released, without mitigation, from the facility stack. NWMI also applied a safety margin of 1.32 to account for uncertainty in its source term. Although the RAI response referenced in the comment (NWMI 2016) provides some additional information regarding the source term and assumptions for NWMI's accident analysis, this information is beyond the scope of the discussion in Section 4.11.1 of the EIS, which provides a basic summary of the accident analysis.

As discussed in Section 4.11.1 of the EIS, the NRC staff is conducting an independent review of the radiological consequences of accidents at the proposed NWMI facility as part of its separate safety review of the construction permit application for the facility. If NWMI submits an operating license application for the proposed facility, the NRC staff will conduct an additional and separate safety review, which will further evaluate accident consequences. These reviews will evaluate NWMI's analyses of the full range of accidents that could occur at the facility, including the assumptions used for the analyses, to ensure that the proposed NWMI facility would comply with 10 CFR 70.61 and any other NRC regulations applicable to radiological accident consequences. Additionally, a separate environmental review will be conducted if an operating license application is submitted and docketed, and that review will also consider any additional information submitted by NWMI in its operating license application. The results of the safety reviews for the construction permit application and the operating license application (if submitted) will be documented in separate NRC staff Safety Evaluation Reports. The

environmental review for the operating license application will be documented in an EIS supplement prepared by the NRC staff.

As a result of this comment, the NRC staff revised Section 2.8.1.1 of the EIS as discussed above.

**COMMENT:** 4. Regarding public dose limits, Section 3.8.2.3 Regulations Governing Dose from Human-Made Sources of Radiation: This section references the 10 millirem per year public dose standard for airborne releases under 10 CFR 20.1101(d). Does the U.S. Nuclear Regulatory Commission anticipate additional "As Low As Reasonably Achievable" objectives for gaseous effluent control below 10 millirem? Does Appendix I of 10 CFR 50, which includes numerical guides for these objectives, stipulate any additional considerations to the Northwest Medical Isotopes facility in regards to iodine or other air effluents?

Recommendations for the Final Environmental Impact Statement:

If additional objectives or concerns are anticipated, please include them in the final environmental impact statement.

**RESPONSE:** The comment asks whether the NRC anticipates that NWMI would use additional "as low as is reasonably achievable" (ALARA) objectives for public doses from gaseous effluents other than the 10 millirem constraint of 10 CFR 20.1101(d), for example, objectives based on 10 CFR Part 50, Appendix I. The comment also recommends that any additional ALARA objectives or Appendix I based concerns be included in the EIS.

For public doses from gaseous effluents, NWMI has not committed to additional ALARA objectives beyond the 10 millirem constraint of 10 CFR 20.1101(d). Additionally, the NRC staff notes that the proposed facility would not be subject to 10 CFR Part 50, Appendix I, because that regulation is only applicable to light-water-cooled nuclear power reactors. Therefore, the NRC staff does not currently expect that NWMI would use any additional ALARA objectives for public doses from gaseous effluents. As discussed in Section 4.8.2.1 of the EIS, NWMI estimates that the maximum dose to the public from gaseous effluents would be 3.6 millirem per year. This estimated dose is well below the annual public dose limit of 100 millirem in 10 CFR 20.1301, and is also within the 10 millirem constraint of 10 CFR 20.1101(d). The NRC staff did not revise the EIS as a result of this comment.

**COMMENT:** 5. Does the U.S. Nuclear Regulatory Commission anticipate the University of Missouri Research Reactor to increase radionuclide emissions due to the Northwest Medical Isotopes target irradiation? And if so, what is the estimated increase in effluent and anticipated changes to both the annual projected dose under normal operating conditions as well as accident conditions?

Recommendation for the Final Environmental Impact Statement:

Include any additional emissions from the University of Missouri Research Reactor, as well as, accident conditions. A reference to the University of Missouri Research Reactor's accident plan would be sufficient.

**RESPONSE:** The comment asks whether the target irradiation at the University of Missouri Research Reactor (MURR) would result in possible increases in public doses from routine operation of, or potential accidents at, the research reactor; and, if so, what amount of increases would occur.

As discussed in Section 4.13.1.2 of the EIS, no radiological gaseous emissions are expected from the targets themselves during routine target irradiation. Routine gaseous releases from the operation of the reactor (which would occur regardless of whether targets are being irradiated) can change based on how often and at what power level the reactor is operated. At



MURR, however, no change in radiological gaseous effluents would be expected because the operating tempo (frequency and power level) of the reactor would not change. Therefore, there would be no increase in radiation doses to the public from routine gaseous effluents. Additionally, no changes in the source, types, or quantities of routine radiological liquid effluents from MURR are expected. Gaseous and liquid radiological effluents from MURR would continue to be required to remain within NRC regulatory limits.

The consequences of potential accidents at research reactors must comply with NRC regulations, including the public dose limits in 10 CFR Part 20. When research reactors are licensed by the NRC, applicants must evaluate the consequences of potential accidents at the research reactor facility. Research reactor license applicants must provide analyses that demonstrate that the consequences of accidents are within 10 CFR Part 20 dose limits. If the accident doses are within 10 CFR Part 20 limits, then the environmental impacts of accidents at the research reactor are small. As discussed in Section 4.13 of the EIS, research reactors that irradiate NWMI's targets will need to submit a request for a separate NRC license amendment to provide irradiation services to NWMI. The NRC must issue each reactor facility a license amendment before NWMI's targets can be irradiated at the reactor. The license amendment requests will need to include an analysis of potential accidents that could occur at the research reactors in conjunction with target irradiation, and address whether research reactor accidents associated with target irradiation could potentially have dose consequences that exceed those of accidents previously evaluated for each research reactor facility. The NRC will conduct a separate review of each license amendment request submitted to the NRC to ensure that the consequences of any potential accident associated with target irradiation are within 10 CFR Part 20 dose limits. If the consequences of any new, credible accident that could occur at MURR, OSTR, or the third research reactor site in conjunction with target irradiation remain within 10 CFR Part 20 dose limits, then there would be no significant additional environmental impact from accidents at the facilities, because the environmental impact would still be small.

Sections 4.13.1.2, 4.13.2.2, and 4.13.3.2 of the EIS do not include a discussion of possible increases in doses from potential accidents related to target irradiation at research reactors, because these accidents have not yet been evaluated, and also because no significant change in impacts from research reactor accidents is anticipated as discussed above. As a result of this comment, the NRC staff revised Sections 4.13.1.2, 4.13.2.2, and 4.13.3.2 of the EIS to clarify that the NRC staff will perform a detailed review of potential accidents related to target irradiation at the research reactor facilities as part of its review of the research reactor license amendment requests, and that if the consequences of potential accidents remain below 10 CFR Part 20 dose limits, then no significant additional environmental impact is expected from accidents at the MURR, OSTR, and third research reactor. Additionally, as a result of this comment, the NRC staff revised Section 3.10 of the EIS to clarify that existing research reactor accident dose analyses (for previously evaluated accidents, not related to target irradiation) are not discussed in Section 3.10 of the EIS because activities related to target irradiation at the research reactors are not anticipated to result in a significant change in impacts of potential research reactor accidents. The NRC staff will perform an additional, separate environmental review and safety review for each research reactor license amendment and it will also prepare a supplemental EIS in conjunction with its safety review of NWMI's operating license application. These additional environmental reviews for each license amendment, and the supplemental EIS for the NWMI operating license application, would provide additional details as appropriate regarding impacts from research reactor accidents.

As a result of this comment, the NRC staff revised Sections 3.10, 4.13.1.2, 4.13.2.2, and 4.13.3.2 of the EIS as discussed above.

## REFERENCES:

[NWMI 2015] Northwest Medical Isotopes, LLC. 2015. Preliminary Safety Analysis Report (PSAR), Chapter 9 “Auxiliary Systems,” Chapter 10, “Experimental Facilities” Chapter 11, “Radiation Protection and Waste Management” and Chapter 12, “Conduct of Operations.” June 2015. ADAMS No. ML15210A118.

[NWMI 2016] Northwest Medical Isotopes, LLC. 2016. Northwest Medical Isotopes, LLC Responses to the U.S. Nuclear Regulatory Commission Regarding the Preliminary Safety Analysis Report Request for Additional Information (Letter dated September 29, 2016). ADAMS No. ML16344A049.

The references provided above are publicly available from the NRC’s Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>.