UNIVERSITY *of* MISSOURI

RESEARCH REACTOR CENTER

January 8, 2016

U.S. Nuclear Regulatory Commission
Attention: Document Control Desk
Mail Station P1-37
Washington, DC 20555-0001

REFERENCE: Docket 50-186
University of Missouri-Columbia Research Reactor
Amended Facility License No. R-103

SUBJECT: Written communication as specified by 10 CFR 50.4(b)(1) regarding responses to the "University of Missouri at Columbia - Request for Additional Information Regarding the License Amendment Request to Modify the Technical Specifications to Produce Radiochemical Sodium Iodine at the University of Missouri at Columbia Research Reactor (TAC No. MF6514)," dated November 19, 2015

By letter dated July 20, 2015, the University of Missouri-Columbia Research Reactor (MURR) submitted a request to the U.S. Nuclear Regulatory Commission (NRC) to amend the Technical Specifications (TSs), which are appended to Amended Facility License No. R-103, in order to produce the radiochemical sodium iodide (I-131).

There are currently no competing modalities for its use as a therapy for thyroid dysfunctions and no current supplier within the U.S. This license amendment would allow MURR to continue to perform a key role in the supply of critical medical radioisotopes, both domestically and internationally.

On November 19, 2015, the NRC requested additional information and clarification regarding the proposed license amendment request in the form of fourteen (14) questions. On December 30, 2015, MURR responded to those questions.

On January 7, 2016, via a conference call between MURR and NRC staff, the NRC requested additional information/clarification on three (3) of the responses, specifically Questions 5.a, 9 and 10. Below is the additional information/clarification for those questions.

If there are questions regarding this response, please contact me at (573) 882-5319. I declare under penalty of perjury that the foregoing is true and correct.

A020
NRR

1513 Research Park Drive Columbia, MO 65211 Phone: 573-882-4211 Fax: 573-882-6360 Web: www.murr.missouri.edu

Sincerely,

John L. Fruits
Reactor Manager

ENDORSEMENT:
Reviewed and Approved

Ralph A. Butler, P.E.
Director

xc: Reactor Advisory Committee
Reactor Safety Subcommittee
Dr. Garnett S. Stokes, Provost
Dr. Mark McIntosh, Vice Chancellor for Research, Graduate Studies and Economic Development
Mr. Alexander Adams Jr., U.S. Nuclear Regulatory Commission
Mr. Geoffrey A. Wertz, U.S. Nuclear Regulatory Commission
Mr. Johnny Eads, U.S. Nuclear Regulatory Commission

Attachments:

1. Newly Proposed and Revised Technical Specification Pages

JACQUELINE L. BOHM
Notary Public-Notary Seal
STATE OF MISSOURI
Commissioned for Howard County
My Commission Expires: March 26, 2019
Commission # 15634308

State of Missouri
County of Boone
Subscribed and sworn to before me this 8 day of January 2016
Jacqueline L. Bohm, Notary Public
My Commission Expires: March 26, 2019

Additional information/clarification for Question 5.a:

5. *NUREG-1537, Chapter 14, "Technical Specifications," and American Nuclear Standards Institute/American Nuclear Society (ANSI/ANS)-15.1-2007, "The Development of Technical Specifications for Research Reactors," provides guidance that tests to establish carbon filter efficiency should be performed annually to biennially, and following major maintenance. The licensee's proposed TS 5.7, Specification e states, in part, that carbon filter efficiency measurements shall be performed biennially.*

   a. *The proposed TSs do not appear to include a requirement that carbon filter efficiencies be tested following major maintenance. Provide an explanation.*

   Proposed Technical Specification 5.7.e will be revised as follows: "The efficiency of the Iodine 131 processing hot cells charcoal filter banks shall be verified biennially or following major maintenance. It shall be verified that the charcoal filter banks have a removal efficiency of 99% or greater for iodine."

   The correct revised Technical Specification 5.7.e is included in Attachment 1.

Additional information/clarification for Question 9:

9. *Accidental airborne releases of any radioactive materials other than I-131 (such as other isotopes of iodine, or activation products of target impurities), or toxic materials, inside or outside the hot cells do not appear to be discussed in the amendment request. Discuss whether other failures exist that could cause these releases to occur at any point during the experiment.*

   The following discussion is in addition to what was previously submitted to the NRC regarding this question:

   <u>Part 3: Tellurium Activation Products</u>

   Hypothetically, some trace amount of the activated target could be converted to the vapor state during the dry-distillation process which occurs at the melting point of the target material. If so, the vapor would be entrained in the air flow along with the molecular iodine product sweeping both the desired I-131 and undesirable radioactive tellurium isotopes into the aqueous product-collection traps contaminating the intended I-131 radiopharmaceutical product. To avoid radio-impurities of tellurium, a quartz separator is installed just outside the furnace between the molten target material and the product-collection traps. This separator operates in a temperature range sufficiently cool to condense any tellurium vapor that might have been produced while sufficiently high to maintain the molecular iodine in the gaseous state. From our experience, this quartz separator functions as-designed preventing the release of any radioactive tellurium vapor beyond the separator in measurable amounts. Furthermore, as discussed below, we have analyzed the aqueous and solid-filter media in the 3-component trap installed on the processing-line downstream from the product-collection traps detecting no tellurium radionuclides at sub-microcurie levels. Therefore, we conclude that there are no significant tellurium radionuclides released to the PHC or beyond the PHC.

When naturally occurring tellurium is subjected to neutron activation, ten (10) tellurium radionuclides are produced having half-lives ranging from 25 minutes (Te-131) to 154 days (Te-121m). All of these radionuclides can be quantitatively measured at different determination limits using high-resolution gamma-ray spectroscopy (HRGRS). Of these ten (10) tellurium radionuclides, Te-123m (half-life = 119.7 days), based on its gamma-ray energy, branching ratio and detection efficiency, can be measured with the highest sensitivity (≈5E-5 microcuries) by HRGRS on a filter medium in service during the dry-distillation processing of a maximum-activity target. When this experiment was undertaken subsequent to the dry-distillation production and capture of 24.3 Curies of I-131, there was no Te-123m detected in the 3-component trap above a detection-limit of 1E-4 microcuries under the measurement parameters used. Therefore, no measureable release of tellurium radioisotopes to the environment is anticipated under normal operations or from any credible accident scenario. Consequently, the release limits imposed by Technical Specifications 3.6.c or 3.7.a. are satisfied for the ten (10) tellurium radionuclides produced in the maximum-activity target subsequently processed by dry-distillation.

Additional information/clarification for Question 10:

10. *The NRC staff noted that the proposed MURR TS 3.6, Specification p, limits the I-131 inventory of a non-fueled experiment to 150 curies. However, the current MURR TS 3.6, Specification c, appears to limit non-fueled experiments to "that amount of material such that the airborne concentration of radioactivity averaged over a year will not exceed the limits of Appendix B, Table I of 10 CFR Part 20. Exception: Fueled experiments (See Specification 3.6a)." Explain how the limits of TS 3.6, Specification c, and proposed TS 3.6, Specification p, are satisfied for the proposed Iodine production.*

    Current MURR Technical Specification 3.6.c will be revised to read, "Where the possibility exists that the failure of an experiment could release radioactive gases or aerosols to the reactor bay or atmosphere, the experiment shall be limited to that amount of material such that the airborne concentration of radioactivity averaged over a year will not exceed the limits of Appendix B, Table I of 10 CFR Part 20. Exception: Fueled experiments that produce iodine 131 through 135 and non-fueled experiments that produce iodine 131 (See Specifications 3.6.a and 3.6.p)."

    This revision to TS 3.6.c will satisfy the radioactive airborne concentration limits of the proposed iodine processing facility.

    The revised Technical Specification 3.6.c is included in Attachment 1.

Additionally, an error was noted in the bases of Technical Specification 3.6.c (Page 4 of 5 of Technical Specification 3.6). The words "...specification 3.5.c..." were corrected to "... specification 3.6.c...".

ATTACHMENT 1

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ATTACHMENT 1

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TECHNICAL SPECIFICATION

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SUBJECT: Experiments (continued)

airborne concentration of radioactivity averaged over a year will not exceed the limits of Appendix B, Table I of 10 CFR Part 20. Exception: Fueled experiments that produce iodine 131 through 135 and non-fueled experiments that produce iodine 131 (See Specifications 3.6.a and 3.6.p)."

d. Explosive materials shall not be irradiated or allowed to generate in any experiment in quantities over 25 milligrams.

e. Only movable experiments in the center test hole shall be removed or installed with the reactor operating. All other experiments in the center test hole shall be removed or installed only with the reactor shut down. Secured experiments shall be rigidly held in place during reactor operation.

f. Experiments shall be designed and operated so that identifiable accidents such as loss of reactor coolant flow, loss of experiment cooling, etc., will not result in a release of fission products or radioactive materials from the experiment.

g. Experiments shall be designed such that a failure of an experiment will not lead to a direct failure of other experiments, a failure of reactor fuel elements, or to interference with the action of the reactor control elements or other operating components.

h. Cooling shall be provided to prevent the surface temperature of a submerged irradiated experiment from exceeding the saturation temperature of the cooling medium.

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SUBJECT: Experiments (continued)

o. Fueled experiments containing inventories of Iodine 131 through 135 greater than 1.5 Curies or Strontium 90 greater than 5 millicuries shall be in irradiation containers that satisfy the requirements of specification 3.6.i or be vented to the exhaust stack system through HEPA and charcoal filters which are continuously monitored for an increase in radiation levels.

p. Each non-fueled experiment shall be limited such that the inventory of Iodine 131 is not greater than 150 Curies.

q. Non-fueled experiments that are intended to produce Iodine 131 shall be processed in hot cells that are vented to the exhaust stack system through charcoal filters which are continuously monitored for an increase in radiation levels.

Bases

a. Specification 3.6.a restricts the generation of hazardous materials to levels that can be handled safely and easily. Analysis of fueled experiments containing a greater inventory of fission products has not been completed, and therefore their use is not permitted.

b. Specification 3.6.b is intended to reduce the likelihood of accidental voiding in the core or water annulus surrounding the center test hole by restricting materials which could generate or accumulate gases or vapors.

c. The limitation on experiment materials imposed by specification 3.6.c assures that the limits of Appendix B of 10 CFR 20 are not exceeded in the event of an experiment failure.

d. Specification 3.6.d is intended to reduce the likelihood of damage to reactor or pool components resulting from detonation of explosive materials.

e. Specification 3.6.e is intended to limit the experiments that can be moved in the center test hole while the reactor is operating, to those that will not introduce reactivity transients more severe than one that can be controlled without initiating safety system action (Ref. Add. 5 to HSR).

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f. Specifications 3.6.f and 3.6.g provide guidance for experiment safety analysis to assure that anticipated transients will not result in radioactivity release and that experiments will not jeopardize the safe operation of the reactor.

g. Specification 3.6.h is intended to reduce the likelihood of reactivity transients due to accidental voiding in the reactor or the failure of an experiment from internal or external heat generation.

h. Specification 3.6.i is intended to reduce the likelihood of damage to the reactor and/or radioactivity releases from experiment failure.

i. Specification 3.6.j provides assurance that no chemical reaction will take place to adversely affect the reactor or its components.

j. Specification 3.6.k provides assurance that the integrity of the beamports will be maintained for all loop-type experiments.

k. Specification 3.6.l assures that corrosive materials which are chemically incompatible with reactor components, highly flammable materials and toxic materials are adequately controlled and that this information is disseminated to all reactor users.

l. The extremely low temperatures of the cryogenic liquids present structural problems which enhance the potential of an experiment failure. Specification 3.6.m provides for the proper review of proposed experiments containing or using cryogenic materials.

m. Specifications 3.6.p and 3.6.q provide assurance that the processing of Iodine 131 can be performed safely and that equipment necessary for accident mitigation has been installed.

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SUBJECT: Iodine 131 Processing Hot Cells

Applicability

This specification shall apply to the limiting conditions of operation on the equipment needed to safely process Iodine 131.

Objective

The objective of this specification is to reasonably assure that the health and safety of the staff and public is not endangered as a result of processing Iodine 131.

Specification

a. The facility ventilation exhaust system shall be operable when processing Iodine 131 in the Iodine 131 processing hot cells.

b. The facility ventilation exhaust system shall maintain the Iodine 131 processing hot cells at a negative pressure with respect to the surrounding areas when processing Iodine 131.

c. Processing of Iodine 131 shall not be performed in the Iodine 131 processing hot cells unless the following minimum number of radiation monitoring channels are operable.

	Radiation Monitoring Channel	Number
1.	Stack Radiation Monitor	1
2.	Iodine-131 Processing Hot Cells Radiation Monitor	1

Exception: When the required radiation monitoring channel becomes inoperable, then portable instruments may be substituted for the normally installed monitor in specification 3.11.c.2 within one (1) hour of discovery for a period not to exceed one (1) week.

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SUBJECT: Iodine 131 Processing Hot Cells (continued)

d. At least three (3) charcoal filter banks each having an efficiency of 99% or greater shall be operable when processing Iodine 131 in the Iodine 131 processing hot cells.

Bases

a. Operation of the facility ventilation exhaust system when processing Iodine 131 in the Iodine 131 processing hot cells ensures proper dilution of effluents to prevent exceeding the limits of 10 CFR 20 Appendix B.

b. Maintaining the Iodine 131 processing hot cells at a negative pressure with respect to the surrounding areas ensures safety for the facility staff.

c. The radiation monitors provide information to operating personnel regarding routine release of radioactivity and any impending or existing danger from radiation. Their operation will provide sufficient time to take the necessary steps to prevent the spread of radioactivity to the surroundings. The Stack Radiation Monitor continuously monitors the air exiting the facility through the exhaust stack for airborne radioactivity. The Iodine-131 Processing Hot Cells Radiation Monitor is a six (6) detector system; two (2) detectors serving each one of the three (3) hot cells. For each hot cell, one (1) detector is located at the processor's work area where the hot cell manipulators are installed and the other is located in the bay above the hot cell next to the exhaust charcoal filters.

d. The potential radiation dose to staff and individuals at the Emergency Planning Zone boundary and beyond have been calculated following an accidental release of Iodine 131 activity. These calculations are based on the facility ventilation exhaust system directing all Iodine 131 processing hot cell effluents through charcoal filtration with an efficiency of 99% or greater prior to being released through the facility exhaust stack.

ATTACHMENT 1

TECHNICAL SPECIFICATION

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Amendment No.__________

SUBJECT: Iodine 131 Processing Hot Cells

Applicability

This specification shall apply to the surveillance of the equipment needed to safely process Iodine 131.

Objective

The objective of this specification is to reasonably assure proper operation of the equipment needed to safely process Iodine 131.

Specification

a. An operability test of the facility ventilation exhaust system shall be performed monthly.

b. The operability of the facility ventilation exhaust system to maintain the Iodine 131 processing hot cells at a negative pressure with respect to the surrounding areas shall be verified daily prior to any process (channel check).

c. The radiation monitors as required by specification 3.11.c shall be calibrated on a semi-annual basis.

d. The radiation monitors as required by specification 3.11.c shall be checked for operability with a radiation source at monthly intervals.

e. The efficiency of the Iodine 131 processing hot cells charcoal filter banks shall be verified biennially or following major maintenance. It shall be verified that the charcoal filter banks have a removal efficiency of 99% or greater for iodine.

Bases

a. Experience has shown that monthly tests of the facility ventilation exhaust system are sufficient to assure proper operation.

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SUBJECT: Iodine 131 Processing Hot Cells (continued)

b. Verifying that the Iodine 131 processing hot cells are at negative pressure with respect to the surrounding areas prior to use ensures personnel safety.

c. Semiannual channel calibration of the radiation monitoring instrumentation will assure that long-term drift of the channels will be corrected.

d. Experience has shown that monthly verification of operability of the radiation monitoring instrumentation is adequate assurance of proper operation over a long time period.

e. Biennial verification of filter banks ensures that the filters will perform as analyzed.