

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

December 19, 2018

Dr. David J. Robertson Reactor Facility Director University of Missouri-Columbia Research Reactor Center 1513 Research Park Drive Columbia, MO 65211

SUBJECT: UNIVERSITY OF MISSOURI-COLUMBIA - ISSUANCE OF AMENDMENT NO. 38 TO RENEWED FACILITY OPERATING LICENSE NO. R-103 TO AMEND TECHNICAL SPECIFICATIONS 3.7 AND 6.2 FOR THE UNIVERSITY OF MISSOURI – COLUMBIA RESEARCH REACTOR (EPID NO. L-2018-LLA-0108)

Dear Dr. Robertson:

The U.S. Nuclear Regulatory Commission (NRC) has issued the enclosed Amendment No. 38 to Renewed Facility Operating License No. R-103 for the University of Missouri-Columbia Research Reactor (MURR). The amendment consists of changes to the facility operating license and technical specifications (TSs), in response to the MURR application dated April 17, 2018 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML18109A039), as supplemented on October 8, November 13, and December 12, 2018 (ADAMS Accession Nos. ML18283A304, ML18319A096, and ML18348A578, respectively). This amendment revises MURR TS 3.7, "Radiation Monitoring Systems and Airborne Effluents," and TS 6.2, "Review and Audit." The NRC staff's safety evaluation supporting Amendment No. 38 is enclosed.

If you have any questions, please contact me at 301-415-0893, or by electronic mail at <u>Geoffrey.Wertz@nrc.gov</u>.

Sincerely,

/RA Alexander Adams for/

Geoffrey A. Wertz, Project Manager Research and Test Reactors Licensing Branch Division of Licensing Projects Office of Nuclear Reactor Regulation

Docket No. 50-186 License No. R-103

Enclosures:

- 1. Amendment No. 38 to Renewed Facility Operating License No. R-103
- 2. Safety Evaluation

cc: See next page

University of Missouri-Columbia

cc:

Les Foyto, Associate Director Reactor and Facilities Operations University of Missouri – Columbia Research Reactor Center 1513 Research Park Drive Columbia, MO 65211

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Test, Research and Training Reactor Newsletter P.O. Box 118300 University of Florida Gainesville, FL 32611 SUBJECT: UNIVERSITY OF MISSOURI-COLUMBIA - ISSUANCE OF AMENDMENT NO. 38 TO RENEWED FACILITY OPERATING LICENSE NO. R-103 TO AMEND TECHNICAL SPECIFICATIONS 3.7 AND 6.2 FOR THE UNIVERSITY OF MISSOURI – COLUMBIA RESEARCH REACTOR (EPID NO. L-2018-LLA-0108) DATED: DECEMBER 19, 2018

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ADAMS Accession No. ML18129A347; *concurrence via e-mail				NRR-088	
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# UNIVERSITY OF MISSOURI-COLUMBIA

# DOCKET NO. 50-186

#### UNIVERSITY OF MISSOURI-COLUMBIA RESEARCH REACTOR

#### AMENDMENT TO RENEWED FACILITY OPERATING LICENSE

Amendment No. 38 License No. R-103

- 1. The U.S. Nuclear Regulatory Commission (the Commission) has found that
  - A. The application for an amendment to Renewed Facility Operating License No. R-103, filed by the University of Missouri-Columbia (the licensee) on April 17, 2018, as supplemented on October 8, November 13, and December 12, 2018, complies with the standards and requirements of the Atomic Energy Act of 1954, as amended, (the Act) and the Commission's rules and regulations set forth in Title 10 of the *Code of Federal Regulations* (10 CFR) Chapter I;
  - B. The facility will operate in conformity with the application, the provisions of the Act, and the rules and regulations of the Commission;
  - C. There is reasonable assurance that (i) the activities authorized by this amendment can be conducted without endangering the health and safety of the public, and (ii) such activities will be conducted in compliance with the regulations of the Commission set forth in 10 CFR Chapter I;
  - D. The issuance of this amendment will not be inimical to the common defense and security or to the health and safety of the public;
  - E. This amendment is issued in accordance with 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," of the Commission regulations and all applicable requirements have been satisfied; and
  - F. Prior notice of this amendment was not required by 10 CFR 2.105, "Notice of proposed action," and publication of a notice for this amendment is not required by 10 CFR 2.106, "Notice of issuance."

- 2. Accordingly, the license is amended by changes to the technical specifications as indicated in Attachment 2 to this license amendment, and paragraph 2.C.2 of Renewed Facility Operating License No. R-103 is hereby amended to read as follows:
  - B. <u>Technical Specifications</u>

The Technical Specifications contained in Appendix A, as revised by Amendment No. 38, are hereby incorporated in the license. The licensee shall operate the facility in accordance with the Technical Specifications.

3. This license amendment is effective as of the date of its issuance.

FOR THE NUCLEAR REGULATORY COMMISSION

/RA/

Alexander Adams, Jr., Chief Research and Test Reactors Licensing Branch Division of Licensing Projects Office of Nuclear Reactor Regulation

Attachments:

- 1. Changes to Renewed Facility Operating License No. R-103
- 2. Changes to Appendix A, "Technical Specifications"

Date of Issuance: December 19, 2018

# ATTACHMENT TO LICENSE AMENDMENT NO. 38

#### RENEWED FACILITY OPERATING LICENSE NO. R-103

#### DOCKET NO. 50-186

Replace the following page of the Renewed Facility Operating License No. R-103 with the revised page. The revised page is identified by amendment number and contains a marginal line indicating the area of change.

#### Renewed Facility Operating License

<u>Remove</u>

<u>Insert</u>

4

4

2. <u>Technical Specifications</u>

The Technical Specifications contained in Appendix A, as revised by Amendment No. 38, are hereby incorporated in their entirety in the license. The licensee shall operate the facility in accordance with the Technical Specifications.

#### 3. Physical Security Plan

The licensee shall maintain and fully implement all provisions of the Commission-approved physical security plan, including changes made pursuant to the authority of 10 CFR 50.54(p). The approved physical security plan, entitled "Physical Security Plan for the University of Missouri Research Reactor," dated November 15, 2016, consists of documents withheld from public disclosure pursuant to 10 CFR 73.21.

This license is effective as of the date of issuance and shall expire at midnight, 20 years from the date of issuance.

For the Nuclear Regulatory Commission

# /RA/

William M. Dean, Director Office of Nuclear Reactor Regulation

Attachment: Appendix A, Technical Specifications

Date of Issuance: January 4, 2017

## ATTACHMENT TO LICENSE AMENDMENT NO. 38

#### **RENEWED FACILITY OPERATING LICENSE NO. R-103**

# DOCKET NO. 50-186

Replace the following pages of Appendix A, "Technical Specifications," with the revised pages. The revised pages are identified by amendment number and contain marginal lines to indicate the areas of change.

#### **Technical Specifications**

<u>Remove</u>	Insert
A-30 A-31	A-30 A-31
A-68	A-68

# UNIVERSITY OF MISSOURI RESEARCH REACTOR TECHNICAL SPECIFICATIONS Docket No. 50-186, License No. R-103

# 3.7 Radiation Monitoring Systems and Airborne Effluents – Continued

b. The maximum discharge rate through the ventilation exhaust stack shall not exceed the following:

Type of <u>Radioactivity</u>	Max. Concentration Averaged Over <u>One Year</u>
Particulates and halogens with half-lives greater than 8 days	AEC
All other radioactive isotopes	350 AEC

AEC = Air Effluent Concentration as listed in Appendix B, Table 2, Column 1 of 10 CFR 20, "Standards for Protection Against Radiation."

- c. An environmental monitoring program shall be carried out and shall include, as a minimum:
  - (1) Analysis of samples from surface waters from the surrounding areas, and vegetation or soil,

AND

(2) Placement of film badges, thermoluminescent dosimeters, or other devices at control points.

# Bases:

a. The radiation monitors provide information of an impending or existing danger from radiation so that corrective action can be initiated to prevent the spread of radioactivity to the surroundings and so that there will be sufficient time to evacuate the facility should it be necessary to do so.

Isolation of the reactor containment building at 10 times the normal previously established radiation levels is necessary to allow for sample handling within the reactor pool or when removing samples from the pool. Normal pool surface radiation levels are approximately 20 mR/h while those at the containment building exhaust plenum are around 0.15 mR/h. Operational experience has demonstrated that the 10 times factor provides sufficient margin to minimize inadvertent reactor scrams without allowing for the potential of unacceptable exposure rates to personnel in containment. Ten times the routine dose rates equate to 200 mrem at the bridge monitor and 1.5 mrem at the exhaust plenum. Dose rates at this level do not constitute an unreasonable risk and would not go unidentified for any significant period of time.

# 3.7 Radiation Monitoring Systems and Airborne Effluents - Continued

b. For the purposes of Specification 3.7.b, air effluents for particulates and halogens with half-lives greater than 8 days are limited to the Air Effluent Concentrations (AEC) without the inclusion of a dilution multiplier to minimize any chance of reconcentration at the receptor site resulting in doses in excess of the direct exposures via air concentrations. Data from Soldat, JD (Health Physics 9, p. 1170, 1963), suggest a reconcentration factor of approximately 400 for the Iodine-131 milk/man pathway; however, dilution of the stack effluent to the nearest residence due north of MURR (760 meters), the prevailing wind direction, is approximately 1900, thus giving a safety factor (ratio) of 4.75. This value is also conservative in that the wind blows from 360 degrees around MURR throughout the year and thus this value represents a worst case scenario to only the maximally exposed receptor point.

For Argon-41, the primary air effluent from MURR, dispersion calculations are based on standard reference material and experimental data obtained at the reactor showing that concentrations under average conditions will be 0.008 of the AEC limits in the unrestricted area surrounding the reactor facility. Also, dilution factors under conservative conditions are in the range of 5 x  $10^4$  under both average and stable conditions at ground level from the facility building.

c. Collecting and analyzing water, and soil or vegetation samples will provide information that environmental limits are not being exceeded. Film badges, thermoluminescent dosimeters, or other devices placed at control points provide a measurement of radiation. The continuation of the environmental program will verify that operation of the facility presents no significant risk to the health and safety of the general public.

# 6.2 **Review and Audit -** Continued

b. The RAC may appoint subcommittees consisting of knowledgeable members of the public, students, faculty, and staff of MU when it deems it necessary in order to effectively discharge its primary responsibilities. When subcommittees are appointed, these subcommittees shall consist of no less than three (3) members with no more than one (1) student appointed to each subcommittee. The subcommittees may be authorized to act on behalf of the RAC.

The RAC and its subcommittees shall maintain minutes of meetings in which the items considered and the committees' recommendations are recorded. Dissemination of the minutes to the Office of the Chancellor, the RAC and its subcommittees shall be done within four (4) months after the meetings. Independent actions of the subcommittees shall be reviewed by the parent committee at the next regular meeting. A quorum of the committee or the subcommittees consisting of at least fifty percent of the appointed members shall be present at any meeting to conduct the business of the committee or subcommittee. Additionally, reactor facility staff shall not constitute greater than fifty percent of the quorum for a meeting of the RAC. Reactor facility staff shall not constitute a majority of the RAC. The RAC shall meet at least once in each four (4) month period.

A meeting of a subcommittee shall not be deemed to satisfy the requirement of the parent committee to meet at least once in each four (4) month period.

- c. Any additions, modifications or maintenance to the systems described in these Specifications shall be made and tested in accordance with the specifications to which the system was originally designed and fabricated or to specifications approved by the NRC.
- d. Following a favorable review by the NRC, the RAC, or the Reactor Facility Management, as appropriate, and prior to conducting any experiment, the Reactor Manager shall sign an authorizing form which contains the basis for the favorable review.
- e. Audits:
  - (1) Audits of the following functions shall be conducted by an individual or group without immediate responsibility in the area to be audited:
    - i. Facility Operations, for conformance to the Technical Specifications and license conditions, at least annually;
    - ii. Operator Requalification Program, for compliance with the approved program, at least every two (2) years;

# SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

# RELATED TO AMENDMENT NO. 38 TO

# RENEWED FACILITY OPERATING LICENSE NO. R-103

# THE UNIVERSITY OF MISSOURI-COLUMBIA

# DOCKET NO. 50-186

# 1.0 INTRODUCTION

By letter dated April 17, 2018, as supplemented by letters dated October 8, November 13, and December 12, 2018 (Agencywide Documents Access and Management System Accession Nos.: ML18109A039, ML18283A304, ML18319A096, and ML18348A578, respectively), the University of Missouri-Columbia (the licensee) submitted a license amendment request (LAR) to amend its Appendix A of Renewed Facility Operating License No. R-103, "Technical Specifications for the University of Missouri Research Reactor [MURR]." Specifically, the licensee proposed to:

- 1. revise technical specification (TS) 3.7, "Radiation Monitoring Systems and Airborne Effluents," Specification b, to delete the effluent release limits for the maximum controlled instantaneous release concentration;
- 2. revise TS 6.2, "Review and Audit," Specification b, to:
  - 2.1 extend the time allowed for the dissemination of the meeting minutes of the Reactor Advisory Committee (RAC) and its four (4) subcommittees from three (3) to four (4) months;
  - 2.2 change the requirement from "the RAC shall meet at least quarterly" to "the RAC shall meet at least once in each four (4) month period;" and,
  - 2.3 change the periodicity requirement that a meeting of a subcommittee shall not be deemed to satisfy the requirement of the parent committee from "to meet at least once during each calendar quarter" to "meet at least once in each four (4) month period."

# 2.0 REGULATORY EVALUATION

The NRC staff reviewed the licensee's LAR. The NRC staff evaluated the proposed changes based on the regulations and guidance in:

 Title 10 of the Code of Federal Regulations (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," Section 50.36, "Technical specifications," which provides the requirements for TSs to be included in facility operating licenses, including research reactor licenses. 10 CFR 50.36(a)(1) states, in part, that a summary statement of the bases or reasons for such specifications, other than those covering administrative controls, shall also be included in the application, but shall not become part of the TSs. 10 CFR 50.36(c)(2), "Limiting conditions for operation," requires that TS limiting conditions for operation specify the lowest functional capability or performance levels of equipment required for safe operation of the facility, including radiation monitoring systems for gaseous process and effluent streams. 10 CFR 50.36(c)(3), "Surveillance requirements," requires TSs to include requirements to test, calibrate, or inspect to assure that the necessary quality of systems and components is maintained, that facility operation will be within safety limits, and that the limiting conditions for operation will be met. 10 CFR 50.36(c)(5), "Administrative controls," requires TSs to include administrative controls relating to organization and management, procedures, recordkeeping, review and audit, and reporting functions necessary to assure operation of the facility in a safe manner.

- 10 CFR Part 20, "Standards for Protection against Radiation," Appendix B, "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage," Table 2, "Effluent Concentrations," Column 1, "Air," which provides effluent concentrations applicable to the assessment and control of doses to the public.
- 10 CFR 20.1101, "Radiation protection programs," which requires the licensee to develop, document, and implement a radiation protection program.
   10 CFR 20.1101(b) requires licensees to use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).
   10 CFR 20.1101(d) requires a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, be established by licensees, such that an individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent (TEDE) in excess of 10 milli-roentgen equivalent man (mrem) per year from air emissions.
- 10 CFR 20.1301, "Dose limits for individual member of the public," which provides radiation dose limits for individual members of the public. 10 CFR 20.1301(a)(1) limits the total dose to any member of the public from licensed operations not to exceed 100 mrem in a calendar year.
- 10 CFR 51.22, "Criterion for categorical exclusion; identification of licensing and regulatory actions eligible for categorical exclusion or otherwise not requiring environmental review," which identifies licensing, regulatory, and administrative actions eligible for categorical exclusion from the requirement to prepare an environmental assessment or environmental impact statement.
- NUREG-1537, Part 1, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content," Appendix 14.1, Format and Content of Technical Specifications for Non-Power Reactors;" Section 3.7.2, "Effluents;" and Section 6.2, "Review and Audit," (ADAMS Accession No. ML0424355), which provides guidance to licensees preparing research reactor applications and TSs.

- NUREG-1537, Part 2, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria," Chapter 14, "Technical Specification," (ADAMS Accession No. ML042430048), which provides guidance to the NRC staff for performing reviews of the LAR.
- American National Standards Institute/American Nuclear Society (ANSI/ANS) -15.1-1990 (Revised in 2007), "The Development of Technical Specifications for Research Reactors," Section 3.7, "Effluent," and Section 6.2, "Review and Audit," which provides guidance, used by the NRC staff, including the parameters and operating characteristics of a research reactor that should be included in the TSs. Note: since the issuance of NUREG-1537 in 1996, ANSI/ANS-15.1-1990 was revised and the current version is ANSI/ANS-15.1-2007. However, those Sections of 3.7 and 6.2 involved in this review were not changed.

# 3.0 TECHNICAL EVALUATION

# 3.1 TS 3.7, "Radiation Monitoring Systems and Airborne Effluents"

TS 3.7.a, requires radiation monitoring information regarding radiation levels be available to the reactor operator during reactor operations and TS 3.7.b, limits the release of gaseous and particulate effluents from the facility's elevated ventilation exhaust stack during normal operation.

TS 3.7, Specification b, states:

b. The maximum discharge rate through the ventilation exhaust stack shall not exceed the following:

Type of <u>Radioactivity</u>	Max. Concentration Averaged Over <u>One Year</u>	Max. Controlled Instantaneous Release <u>Concentration</u>
Particulates and halogens with half-lives greater than 8 days	AEC	AEC
All other radioactive isotopes	350 AEC	3,500 AEC

AEC = Air Effluent Concentration as listed in Appendix B, Table 2, Column 1 of 10 CFR 20, "Standards for Protection against Radiation."

TS 3.7.b provides limits for all radioactive effluent releases discharged from the ventilation exhaust stack by two types: (1) "particulates and halogens with half-lives greater than 8 days;" and, (2) "all other radioactive isotopes." The basis for the two categories is to differentiate between different dose pathways to a member of the public. "Particulates and halogens with half-lives greater than 8 days" are longer-lived radioactive isotopes that can accumulate on the soil. As such, the reconcentration of these radioactive isotopes at the receptor site provides an ingestion dose pathway (e.g., forage or cow/milk/man) which needs to be considered in addition to those doses resulting from an individual's exposure from the concentration in the air plume (i.e., submersion and/or inhalation). The second category type, "All other radioactive isotopes,"

consists of radioactive material that remains airborne and thus the ingestion pathway does not contribute significantly to dose, so the dose is considered to be entirely due to exposure from the plume (submersion and/or inhalation).

TS 3.7.b provides limits for the two (2) types of effluent concentration releases, as described above, over two (2) different release time periods. The "Max[imum] Concentration Averaged Over One Year;" provides a release limit for releases over one (1) year, which is consistent with the requirements in 10 CFR 20.1301(a)(1). The other time release period is the "Max[imum] Controlled Instantaneous Release Concentration," which provides a release limit for shorter periods of time, such as short "bursts," lasting 5 to 10 seconds in duration, that mostly consist of Ar-41, which is generated from the activation of atmospheric air in the reactor, and released from experiments associated with the operation of the pneumatic tube system or from the opening of irradiated sample cans.

For "particulates and halogens with half-lives greater than 8 days," TS 3.7.b limits the release concentrations, in micro-curies per milliliter (uCi/ml), for both the annual and instantaneous release time periods, to the Air Effluent Concentration (AEC) value provided in 10 CFR Part 20, Appendix B, Table 2, "Effluent Concentrations," Column 1, "Air."

For "all other radioactive isotopes," TS 3.7.b limits the release concentration by use of a multiplier on the AEC. For the "Max[imum] Concentration Averaged Over One Year," the TS 3.7.b limit is 350 AEC; and, for the "Max[imum] Controlled Instantaneous Release Concentration," the TS 3.7.b limit is 3,500 AEC. These multipliers increase the TS 3.7.b release concentration limits to allow the license to release radioactive effluents above the AEC limits. The multipliers (i.e., the concentration limit increase) are used because the release point, where the AEC is measured, is located within the licensee's restricted area inside the exhaust ventilation stack (i.e., not accessible by members of the public), and the effluent concentrations undergo dilution, dispersion and decay, which reduces its measured concentration (inside the ventilation stack), prior to reaching the boundary of the licensee's unrestricted are, where a member of the public could be exposed. These multipliers take into consideration the reduction in effluent concentration provided by the dilution in the licensee's exhaust ventilation flow rate. the dispersion in the licensee's elevated ventilation stack release point, and the radioactive decay provided by the time to travel from the release point (elevated stack) to boundary of the licensee's unrestricted area. These multipliers also help ensure that the concentration of any radioactive effluent released, at the location of license's unrestricted boundary, nearest residence, or highest exposure location, does not result in a radiation dose in excess of the limits in 10 CFR 20.1301 (100 mrem per year).<sup>1</sup>

The multipliers in TS 3.7.b were reviewed and approved by the NRC staff in its safety evaluation report (SER) issued with Amendment No. 12, dated July 5, 1979 (ADAMS Accession No. ML18218A256). The assumptions used by the licensee to demonstrate the continued

<sup>&</sup>lt;sup>1</sup> Exposure to the AEC value, as provided in 10 CFR Part 20, Appendix B, Table 2, Column 1, for one (1) calendar year results in an annual dose of 50 mrem, except for radioisotope effluents classified as "submersion" (external dose) in the table, such as Ar-41, where the AEC represents a dose of 100 mrem. While this difference in the annual dose from the AEC is not clearly identified in 10 CFR Part 20, Appendix B, calculations using the AEC value for submersion gases will result in a dose of 100 mrem, and ANSI/ANS-15.1-2007, Section 3.7.2, item (3), provides a description of the annual dose differences.

acceptability of the multiplier values of 350 and 3500 for the TS 3.7.b, were also reviewed and evaluated by the NRC staff during its license renewal review, completed in 2017. The multipliers were considered by the NRC staff to be acceptable to help ensure that the dose limits of 10 CFR 20.1301, were maintained by the licensee. The details of the NRC staff's review, including confirmatory dose calculations, using the maximum allowable TS 3.7.b release concentration of Ar-41, are described further below in this SER, and in more detail in the License Renewal SER, dated January 4, 2017 (ADAMS Accession No. 16124A887).

The licensee proposes to delete the "Max[imum] Controlled Instantaneous Release Concentration" limits in TS 3.7.b, in order allow MURR the capability to perform more experiments associated with its mission involving nuclear science and technology. In its LAR, the licensee states that the current TS 3.7.b, "Max[imum] Controlled Instantaneous Release Concentration," limits are very conservative and have impacted its ability to perform certain experiments targeted to produce medical isotopes.

The proposed TS 3.7, Specification b, states:

b. The maximum discharge rate through the ventilation exhaust stack shall not exceed the following:

Type of <u>Radioactivity</u>	Max. Concentration Averaged Over <u>One Year</u>
Particulates and halogens with half-lives greater than 8 days	AEC
All other radioactive isotopes	350 AEC

AEC = Air Effluent Concentration as listed in Appendix B, Table 2, Column 1 of 10 CFR 20, "Standards for Protection against Radiation."

In its LAR, the licensee indicated that of all the radioactive isotopes released from the facility in TS 3.7.b, the highest concentration of radioactive isotopes released for "particulates and halogens with half-lives greater 8 days" (with a TS 3.7.b multiplier of 1) was lodine (I)-131, with a half-life of 8.02 days; and for "all other radioactive isotopes," (with a TS 3.7.b multiplier of 350) was Ar-41, with a half-life of 1.8 hours. In order to confirm the licensee's stated radioactive isotope releases, the NRC staff reviewed the annual reports submitted by the licensee covering the last ten (10) years, as provided in Table 1 below, which lists the isotopes released from the ventilation exhaust stack with the highest effluent concentration, as a percentage of TS 3.7.b limits, for each category.<sup>2</sup>

<sup>&</sup>lt;sup>2</sup> For the category "particulates and halogens with half-lives greater 8 days," Table 1 included all isotopes released from the facility with a concentration that exceed I-131 (i.e., larger percentage of their TS 3.7.b release limit), which included Carbon-14, Osmium-191, Cerium-144, and Cobalt-60, in calendar years 2008 through 2012.

Annual Report	Isotope	TS 3.7.b multiplier	TS 3.7.b limit (percent)	ADAMS Accession No.	
2047	Ar-41	350	56.9	ML18058A747	
2017	I-131	1	1.68		
2046*	Ar-41	350	33.7		
2016*	I-131	1	2.91	ML17095A937	
2045	Ar-41	350	48.8		
2015	I-131	1	0.95	ML16060A211	
0044	Ar-41	350	74.2	MI 150614000	
2014	I-131	1	0.20	- ML15061A293	
0010	Ar-41	350	78.1		
2013	I-131	1	0.02	ML14063A044	
	Ar-41	350	68.0		
2012	Carbon-14**	1	0.72	ML13058A025	
	I-131	1	0.05		
	Ar-41	350	45.1		
2011	Carbon-14**	1	0.47	ML12059A368	
	I-131	1	0.05		
	Ar-41	350	58.1		
2010	Carbon-14**	1	0.58	ML110270073	
	I-131	1	0.04		
	Ar-41	350	70.3		
2000	Osmium-191**	1	4.17	MI 100560444	
2009	Carbon-14**	1	0.61	ML100560441	
	I-131	1	0.60		
	Ar-41	350	77.4		
	Carbon-14**	1	0.78	]	
2008	Cerium-144**	1	0.08	ML090570540	
	Cobalt-60**	1	0.07	]	
	I-131	1	0.07	]	

Table 1 Stack Effluent Released at MURR 2013-2017

\* corrected report – airborne effluents released.
\*\* higher release concentration than I-131.

Based on its review of the data in Table 1, above, the NRC staff finds that Ar-41 was the isotope released annually in the highest concentration and was the highest isotope released annually in the "all other radioactive isotopes" category. I-131 (along with Carbon-14, Osmium-191, Cerium-144, and Cobalt-60) was among the higher effluent concentrations released annually in the "particulates and halogens with half-lives greater 8 days" category, but at much lower concentrations than Ar-41. As such, the NRC staff finds that the majority of the dose from effluents released from the facility are associated with Ar-41.

The proposed change to TS 3.7.b would delete the "Max[imum] Controlled Instantaneous Release Concentration" limits for both "particulates and halogens with half-lives greater than 8 days" and "all other radioactive isotopes."

If approved, the licensee would be able to release isotopes in concentrations above the current TS 3.7.b, "Max[imum] Controlled Instantaneous Release Concentration" limits of the AEC and 3,500 AEC, respectively. However, the requirements of TS 3.7.b, for the "Max[imum] Concentration Averaged Over One Year," would remain unchanged to help ensure that the dose to any member of the public is limited to the requirements in 10 CFR 20.1301, a TEDE of 100 mrem per year. As such, the license would have to continue to monitor and account for its radioactive effluent releases in order to ensure that the annual TEDE limit of 100 mrem is maintained in accordance with 10 CFR 20.1301. Additionally, the NRC regulations require the licensee to continue to implement an ALARA program that keeps the air emissions consistent with the constraint in 10 CFR 20.1101(b) of 10 mrem per year to any member of the public.

Based on the information described above, the NRC staff focused its review of the acceptability of removing the limits in TS 3.7.b, associated with the "Max[imum] Controlled Instantaneous Release Concentration," by considering the licensee's ability to control its routine effluent releases, and by reviewing the licensee's facility's past effluent releases and the associated radiological doses to any members of the public. The NRC staff also reviewed the licensee's administrative controls for evaluating and limiting the releases of radioactive effluents during routine operation.

In its LAR, the licensee provided the calculated maximum total effective dose equivalent (TEDE) in mrem, to the maximally exposed member of the public (annual dose), for the past 5 years. The information provided is reproduced in Table 2 below.

Year	TEDE (mrem)	10 CFR 20.1301 Annual Limit (mrem)
2017	3.0	
2016	1.7	
2015	2.4	100
2014	3.8	
2013	4.0	

 Table 2

 Calculated Dose to the Maximally Exposed Member of the Public

The NRC staff reviewed and approved current TS 3.7.b, as part of its review of MURR's license renewal (LR) application. In its LR SER Section 11.1.1, "Radiation Sources," the NRC staff documented its review of the doses to members of the public from the airborne radiation sources released. The licensee indicated in its safety analysis report, Section 11.1.1.1, provided in support of its LR review, that the MURR airborne sources mainly consist of Ar-41, which accounts for ninety-nine (99) percent of the radioactivity released through the facility ventilation exhaust stack at an elevation which is required to be a minimum of fifty-five (55) feet above the containment building (which houses the reactor) grade level, in accordance with TS 5.5.b. In the NRC LR SER Table 11-1, "Annual Ar-41 Doses to Members of the Public," the NRC staff listed the results of the licensee's and NRC staff's dose calculations of the maximum annual Ar-41 doses calculated to the nearest resident as being 2.35 mrem and 4.15 mrem, respectively. As noted in the LR SER, the NRC staff found its results in close agreement with the results of the licensee's dose calculations. The NRC staff also confirmed, by review of the licensee's annual reports, that Ar-41 was the largest contributor to dose isotope released. By activity level (uCi/ml), Ar-41 releases were several orders of magnitude over the activity level other all other isotopes released. The NRC staff considered the difference between the two dose calculations to be due to the choice of the dose conversion factors. However, as stated in LR SER Section 11.1.1, the NRC staff found the licensee's dose calculations used conservative assumptions and the calculation methodology used guidance consistent with industry practices. Based on the close agreement between the licensee's maximum annual Ar-41 doses and the NRC staff's independent confirmatory calculations, the NRC staff found the licensee's dose calculation methodology acceptable.

As described in the LR SER Section 10.3, "Experiment Review," and the licensee's responses to NRC requests for additional information, Nos.10.3 and 10.4 (ADAMS Accession No. ML110740249), the licensee provided a description of its process for review and approval of experiments, which could potentially release radioactive effluents through the exhaust ventilation stack to the environment. The review process is required by TS 6.5, "Experimental Review and Approval," and controlled by administrative procedure AP-RO-135, "Reactor Utilization Requests," which requires that a safety analysis be prepared, reviewed and approved prior to implementation. The AP-RO-135 safety analysis includes a review and evaluation of potential credible accidents, transients, and off-gassing in order to ensure that the experiment does not constitute a hazard to the safety of the facility staff or member of the public. The review criteria used for evaluation of the experiment includes the applicable TSs, and other limitations based upon sound operating, engineering and health physics practices, which are reviewed and approved by both the Reactor Manager and the Reactor Health Physics Manager before an experiment can be conducted. Furthermore, if an experiment request is determined to be a new class of experiment or to have safety significance, the review is also submitted to the Reactor Safety Subcommittee, which reports to the RAC. TS 6.2.a.(3) requires a review of any experiments which are significantly different from any previously reviewed or which involve a question pursuit to the requirements of 10 CFR 50.59. Additional controls for experiments are provided in TS 3.8, "Experiments," which specify limits for all experiments conducted at the facility.

As part of its LR review, the NRC staff reviewed the licensee's process for conducting new experiments, including experiments associated with the development of medical isotopes. As described in the LR SER, the NRC staff found that the licensee's review of new experiments appears effective to ensure that any potential radioactive effluent releases, including the potential for any "instantaneous bursts," are clearly understood and adequately controlled. Based on its review of the effluent releases documented in the licensee's annual reports from

the past ten (10) years of operation of the facility, as summarized in Table 1 above, the NRC staff finds that the licensee has effectively managed effluent releases at the facility.

The requirements of 10 CFR 20.1301 limit the TEDE to any member of the public to less than or equal to 100 mrem in any calendar year. In its LAR, the licensee indicates that it will continue to comply with the requirements in 10 CFR 20.1101, "Radiation protection programs," and the requirements in 10 CFR 20.1302, "Compliance with dose limits for individual members of the public." The licensee also states that its management, along with the Isotope Use Subcommittee, a subcommittee of the RAC, routinely and periodically (monthly) monitor the aggregate of radioactive effluents released from MURR, and the subsequent dose contributions to any members of the public, throughout the year. A MURR staff health physicist prepares a monthly effluent release summary report that is distributed through the MURR Senior Leadership Team for review and then reviewed by the Isotope Use Subcommittee. This administrative review process ensures continual engagement by MURR management to properly oversee and manage the effluents released, as needed to maintain MURR effluents ALARA in accordance with the requirements of 10 CFR 20.1101. Additionally, MURR TS 6.6, "Reportable Events and Required Actions," item e, "Annual Report," Specification (6) requires the licensee to "provide a summary of the nature and amount of radioactive effluents released or discharged to the environs beyond the effective control of the licensee as measured at or prior to the point of such release or discharge." The NRC staff finds that TS 6.6.e.(6) helps ensure the licensee's compliance with the effluent release limits in 10 CFR 20.1301. Based on the licensee's management oversight of its radiation protection program, as well as the recent history of effluent releases, provided in Table 2, which shows that the calculated potential public doses have remained well below 100 mrem, as described above, the NRC staff finds that the licensee has implemented both review and reporting processes that are effective to maintain awareness of the cumulative radioactive effluents released from the facility, as well as to ensure compliance with annual dose limits of 10 CFR 20.1301.

The regulation, 10 CFR 20.1101, "Radiation protection programs," paragraph (b), requires the licensee to use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA. Furthermore, 10 CFR 20.1101(d) imposes a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, by licensees, such that an individual member of the public likely to receive the highest dose will not be expected to receive a TEDE in excess of 10 mrem per year from air emissions. In its LAR, the licensee indicated that it would continue to comply with the limits in 10 CFR 20.1101. As part of its LR review, the NRC staff evaluated the licensee's radiation protection programs, including radiation monitoring and surveying, and environmental monitoring, in Chapter 11, "Radiation Protection Program and Waste Management," of the LR SER. The NRC staff concluded that the MURR Radiation Protection Program complied with the requirements of 10 CFR Part 20, was acceptably implemented, and provided reasonable assurance that the facility staff, the public, and the environment would be protected from unacceptable radiation exposures. Based the information described above, including the dose information associated with past operation of the facility, the NRC staff finds that the licensee's control of airborne radioactive releases from the facility should continue to remain within the regulatory limits provided in 10 CFR Part 20 for members of the public.

In summary, the NRC staff reviewed the proposed change to TS 3.7.b and finds that eliminating the TS limits associated with the "Max[imum] Controlled Instantaneous Release Concentration," is acceptable, for the following reasons. The license maintains dose limits on experiments, as provided by TS 3.8, and has effective management programs designed to ensure that annual

effluent release doses to members of the public will remain below the limits in 10 CFR Part 20. The proposed change to TS 3.7.b does not alter the limit for the annual radiation exposure to any members of the public, and 10 CFR 20.1101(c) requires the license to review (a least annually) both the control and implementation of its Radiation Protection Program. Management procedure AP-RO-135 provides experimental review requirements to help ensure that any potential releases are understood in advance of the performance of any new experiment. A subcommittee of the RAC, along with an assigned health physicist, maintains continual awareness of the cumulative doses to any member of the public from the radioactive isotopes released from the facility, during its monthly review, to ensure that the annual release limit is controlled and limited to the requirements in 10 CFR 20.1101 and 10 CFR 20.1301. The NRC staff review of the licensee's past effluent releases, as documented in recent licensee annual reports, and the NRC staff's confirmatory dose calculations done during the LR review, also support the conclusion that the licensee can maintain any potential doses to the public below the 10 CFR Part 20 limit. Based on the information provided above, the NRC staff finds that the proposed change to TS 3.7.b, is acceptable.

Consistent with 10 CFR 50.36(a)(1), the licensee submitted corresponding TS Bases changes for TS 3.7.b that reflect the new bases for the proposed change. The NRC staff concludes that the TS Bases changes describe the bases for the affected TSs.

#### 3.2 TS 6.2, "Review and Audit"

The licensee proposed changes to TS 6.2.b that would increase the period for the dissemination of the RAC and RAC subcommittee meeting minutes to the Office of the Chancellor, the RAC and its subcommittees from "three (3)" to "four (4)" months; and change the RAC meeting frequency from "quarterly" to "at least once in each four (4) month period;" and similarly, change the periodicity requirement that a meeting of a subcommittee shall not be deemed to satisfy the requirement of the parent committee from "to meet at least once during each calendar quarter" to "meet at least once in each four (4) month period," to be consistent with the previous change in the RAC meeting frequency.

As stated in its LAR, as supplemented, the RAC and its four (4) active subcommittees, Reactor Safety Subcommittee, Isotope Use Subcommittee, Reactor Safety Procedure Review Subcommittee, and Isotope Use Procedure Review Subcommittee, currently meet at least quarterly. The licensee stated that the dissemination of the twenty (20) committee and subcommittee meeting minutes within the three (3) month period after meetings, as is currently required by TS 6.2.b, has become an administrative burden. In addition, the licensee stated that the previous meeting minutes are always presented to the RAC and the subcommittee at the next regular meeting, but the next meeting might not fall with the three (3) month window.

The NRC staff evaluation of the proposed change for dissemination of meeting minutes to a four (4) month period using the guidance provided in Part 1, Format and Content, and Part 2, Standard Review Plan and Acceptance Criteria, of NUREG-1537. Specifically, NUREG-1537, Part 1, Chapter 14, Appendix 14.1, Section 6.2, provides guidance to the applicant, which accepts the criteria provided in ANSI/ANS-15.1-1990, Section 6.2.2, "Charter and rules," item (4), which states, "Dissemination, review, and approval of minutes [shall be done] in a timely

manner."<sup>3</sup> NUREG-1537, Part 2, Chapter 14, provides acceptance criteria to follow the format and content of ANSI/ANS-15.1-1990.

Based on its review, the NRC staff finds that the dissemination of meeting minutes in a four (4) month period is timely as it would allow the licensee the flexibility to prepare and distribute the meeting minutes at the next scheduled meeting, which is consistent with the guidance in NUREG-1537 and ANSI/ANS-15.1-2007. On this basis, the NRC staff concludes that the proposed change to dissemination of meeting minutes to a four (4) month period in TS 6.2.b is acceptable.

The NRC staff also reviewed the licensee's other proposed changes to TS 6.2.b: 1) to change the RAC meeting frequency to meet at least "once in each four (4) month period;" and 2) to change the description of the periodicity of the parent committee (i.e., the RAC) meetings to at least once "in each four (4) month period," using the guidance in NUREG-1537, Part 1, Chapter 14, Appendix 14.1, Section 6.2, which accepts the criteria provided in ANSI/ANS-15.1-1990, Section 6.2.2, "Charter and rules," which states: in item "(1) meeting frequency: not less than once per calendar year and more frequently as circumstances warrant."<sup>4</sup>

In its letter dated December 12, 2018, the licensee stated that the proposed changes represent a reduction in the stated periodicity of the RAC from "quarterly" and "during each calendar quarter," to "once in a four (4) month period." In its LAR, the licensee indicated that it had difficulty scheduling the RAC with the membership quorum requirements satisfied, once during each calendar quarter given the varied workload of the committee members in a university academic calendar. The licensee indicated that having the flexibility to schedule meetings at least once in each four (4) month period will increase the licensee's ability to accommodate the majority of committee members (i.e., individuals not employed at MURR, but whom work primarily in an academic environment). In addition, the flexibility provided by increasing the period for conducting the RAC meetings to at least once in each four (4) month period will help ensure greater attendance and participation by the committee's members, and will thus enhance the committee's review and audit function in matters that support the safe operation of the facility.

The NRC staff finds that the changes proposed will result in a reduction in the number of required RAC meetings in a given calendar year from four (4) to three (3). However, the proposed changes will allow the licensee the flexibility to schedule the RAC meetings at times that will support an increase in meeting attendance by individuals that do not work at the MURR facility. Further, the NRC staff finds that any potential reduction in the effectiveness of the audit and review function, due to one (1) fewer meetings conducted each year, would be offset by the increased attendance of non-MURR committee members who would bring greater independence in the oversight of the review and audit function, and would help to ensure the continued safety of the MURR facility. The NRC staff also finds that the new periodicity for the RAC meetings is greater than once per calendar year, and thus is more than the minimum periodicity recommended in the guidance in NUREG-1537 and ANSI/ANS-15.1-2007.

<sup>&</sup>lt;sup>3</sup> Since the issuance of NUREG-1537 in 1996, ANSI/ANS-15.1-1990 has been revised. The current version is ANSI/ANS-15.1-2007 and Section 6.2.2, item (4) was not changed.

<sup>&</sup>lt;sup>4</sup> Since the issuance of NUREG-1537 in 1996, ANSI/ANS-15.1-1990 has been revised. The current version is ANSI/ANS-15.1-2007 and Section 6.2.2, item (1) was not changed.

On this basis, the NRC staff finds that the proposed change in the RAC committee and subcommittee meetings periodicity in TS 6.2.b is acceptable.

# 3.3 <u>Conclusion</u>

The NRC staff reviewed the proposed changes to TS 3.7.b and TS 6.2.b, and finds them acceptable. The licensee provided information in its LAR to demonstrate that the proposed TS 3.7.b remains consistent with the requirements in 10 CFR Part 20, and the proposed TS 6.2.b remains consistent with the guidance in NUREG-1537 and ANSI/ANS-15.1-2007.

# 4.0 ENVIRONMENTAL CONSIDERATION

Pursuant to 10 CFR 51.22(b), no environmental assessment or environmental impact statement is required for any action within the category of actions listed in 10 CFR 51.22(c), for which the Commission has declared to be a categorical exclusion by finding that the action does not individually or cumulatively have a significant effect on the human environment.

# 4.1 Proposed Change to TS 3.7.b

The regulation in 10 CFR 51.22(c)(9), states, in part, that issuance of an amendment that changes a requirement with respect to installation or use of a facility component located within the restricted area, as defined by 10 CFR Part 20, meets the definition of a categorical exclusion, provided that, the proposed change satisfies each of 10 CFR 51.22(c)(9) criteria listed below:

## (i) The amendment or exemption involves no significant hazards consideration; [10 CFR 51.22(c)(9)(i)]

Pursuant to 10 CFR 50.92(c), the Commission may make a final determination that a license amendment involves no significant hazards consideration if operation of the facility, in accordance with the amendment, would not:

# (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or [10 CFR 50.92(c)(1)]

As discussed in Section 3.1 of this safety evaluation, the proposed change to TS 3.7.b would delete the effluent release limits associated with the "Max[imum] Controlled Instantaneous Release Concentration," but retains the TS 3.7.b limits for the "Maximum Concentration Averaged Over One Year," which helps ensure that the annual effluents released by the facility do not exceed the dose limits to any member of the public as provided in 10 CFR 20.1301. TS 3.7.b would still limit effluent releases that occur during the conduct of experiments and the potential dose consequences to any member of the public would continue to be evaluated prior to conducting the experiment and monitored annually. As such, the NRC staff finds that the proposed change does not significantly affect the probability or consequences (doses) of any accident previously evaluated in the licensee's SAR since the limits in 10 CFR Part 20 must be met. Therefore, the NRC staff concludes that the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) create the possibility of a new or different kind of accident from any accident previously evaluated; or [10 CFR 50.92(c)(2)]

As discussed in Section 3.1 of this safety evaluation, the proposed change to TS 3.7.b would delete the effluent release limits associated with the "Max[imum] Controlled Instantaneous Release Concentration," but retains the TS 3.7.b limits for the "Maximum Concentration Averaged Over One Year." The proposed change to TS 3.7.b does not affect any accident scenarios, including the maximum hypothetical accident. The proposed change to TS 3.7.b would allow more flexibility to conduct experiments, but does not involve any hardware changes or significant changes to the operation of the facility. Therefore, the NRC staff finds that the proposed change to TS 3.7.b does not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) involve a significant reduction in a margin of safety. [10 CFR 50.92(c)(3)]

As discussed in Section 3.1 of this safety evaluation, the proposed change to TS 3.7.b would delete the effluent release limits associated with the "Max[imum] Controlled Instantaneous Release Concentration," but retains TS 3.7.b limits for the "Maximum Concentration Averaged Over One Year," which helps ensure that any member of the public will not receive doses from the annual radioactive effluents released by the facility that exceed the 100 mrem limit in 10 CFR 20.1301. TS 3.7.b would still limit effluent releases that occur during the conduct of experiments and the potential dose consequences to any member of the public would continue to be evaluated prior to conducting the experiment and monitored annually. As required by TS 6.5, the licensee will continue to implement both review and reporting processes that are effective to maintain awareness of the cumulative radioactive effluents released from the facility, as well as ensure compliance with annual dose limits provided by 10 CFR 20.1301 (100 mrem). Additionally, 10 CFR 20.1101(d) requires a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, such that an individual member of the public likely to receive the highest dose will not be expected to receive an annual dose in excess of 10 mrem from air emissions. Further, if a licensee exceeds the 10 mrem annual dose constraint, 10 CFR 20.1101(d) requires the licensee to report the exceedance to the NRC, and promptly take appropriate corrective action to prevent recurrence. Therefore, the NRC staff finds that this amendment does not involve a significant reduction in a margin of safety.

Based on the above, the NRC staff concludes that the amendment authorizing the change to TS 3.7.b involves no significant hazards consideration.

(ii) There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite; and [10 CFR 51.22(c)(9)(ii)]

There are no significant changes in the type and the amounts of radionuclide effluents released by the facility resulting from the proposed change to TS 3.7.b to delete the release limits associated with the "Max[imum] Controlled Instantaneous Release Concentration." Although deleting the instantaneous release limits would allow the licensee the flexibility in performing experiments, the requirements for the "Max[imum] Concentration Averaged Over One Year," would remain unchanged. These limits will continue to help ensure that any member of the public does not receive a radiation dose in excess of the annual dose limits in 10 CFR 20.1101 (10 mrem) and 10 CFR 20.1301 (100 mrem).

(iii) There is no significant increase in individual or cumulative occupational radiation exposure. [10 CFR 51.22(c)(9)(iii)]

The proposed change to TS 3.7.b to eliminate the "instantaneous" limits for the release of radioactive isotopes from the main facility exhaust stack does not impact the individual or cumulative occupational radiation exposure at the facility. The main facility exhaust stack releases radioactive effluents to the environment, so occupational exposures, which would occur within the confines of the facility, are not affected. The proposed changes neither impact any of the previously evaluated accidents nor create a new accident. The proposed change does not alter the existing TS 3.7.b for the annual radioactive effluent releases, which helps ensure that any exposures from the facility are maintained within the air emission limits in 10 CFR 20.1101, and, as required by 10 CFR 20.1301, less than 100 mrem per year limit for doses to individual members of the public. Therefore, the NRC staff finds that there is no significant increase in individual or cumulative occupational radiation exposure.

#### 4.2 Proposed Change to TS 6.2.b

The NRC staff determined that proposed changes to TS 6.2.b changes recordkeeping, reporting, or administrative procedures in Section 6, "Administrative Controls," of the TSs. Accordingly, the proposed changes meet the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(10)(ii).

# 4.3 Conclusion

Accordingly, the NRC staff has determined that issuance of this amendment changes a requirement with respect to the installation or use of a facility component located within the restricted area under 10 CFR Part 50 and the NRC staff has determined that amendment involves no significant hazards consideration as well as no significant increase in the amounts, and no significant increase in the types, of any effluents that may be released offsite, and there is no significant increase in individual or cumulative occupational radiation exposure. Also, the amendment changes recordkeeping and administrative procedures or requirements. Therefore, the amendment meets the eligibility criteria for a categorical exclusion set forth in 10 CFR 51.22(c)(9) and 10 CFR 51.22(c)(10)(ii), respectively. Pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the issuance of this amendment.

## 5.0 <u>CONCLUSION</u>

The Commission has concluded, based on the considerations discussed above, that: (1) there is reasonable assurance that the health and safety of the public will not be endangered by operation in the proposed manner, (2) there is reasonable assurance that such activities will be conducted in compliance with the Commission's regulations, and (3) the issuance of the amendment will not be inimical to the common defense and security or to the health and safety of the public.

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