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NORTHWEST MEDICAL ISOTOPES

Chapter 11.0 – Radiation Protection and Waste Management

Construction Permit Application for Radioisotope Production Facility

NWMI-2013-021, Rev. 3
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REVISION HISTORY

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CONTENTS

FIGURES

TABLES

TERMS

Acronyms and Abbreviations

^{99}Mo	molybdenum-99
^{131}I	iodine-131
ALARA	as low as reasonably achievable
ANS	American Nuclear Society
ANSI	American National Standards Institute
CAM	continuous air monitor
CFR	Code of Federal Regulations
CGA	Compressed Gas Association
COO	Chief Operating Officer
DAC	derived air concentration
DOT	U.S. Department of Transportation
EOI	end of irradiation
EPA	U.S. Environment Protection Agency
FSAR	final safety analysis report
G-M	Geiger-Mueller
HEGA	high-efficiency gas adsorption
HEPA	high-efficiency particulate air
HVAC	heating, ventilation, and air conditioning
ICRP	International Commission on Radiological Protection
Kr	krypton
LEU	low-enriched uranium
Mo	molybdenum
MURR	University of Missouri Research Reactor
NaOH	sodium hydroxide
NAVLAP	National Voluntary Laboratory Accreditation
NCRP	National Council on Radiation Protection and Measurements
NIOSH	National Institute of Occupational Safety and Health
NIST	National Institute of Standards and Technology
NRC	U.S. Nuclear Regulatory Commission
NWMI	Northwest Medical Isotopes, LLC
OSL	optically stimulated luminescence
OSTR	Oregon State University TRIGA Reactor
QAPP	Quality Assurance Program Plan
RPF	Radioisotope Production Facility
RWP	radiation work permit
SH&L	safety, health, and licensing
TEDE	total effective dose equivalent
TLD	thermoluminescent dosimeter
U.S.	United States
Xe	xenon

Units

Bq	becquerel
Ci	curie
cm	centimeter
cm^2	square centimeter
dpm	disintegrations per minute
ft	feet
ft^3	cubic feet
gal	gallon
hr	hour
in.	inch
L	liter
m	meter
m^3	cubic meter
mg	milligram
mrem	millirem
mSv	millisievert
rem	roentgen equivalent in man
Sv	sievert
wk	week
yr	year

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11.0 RADIATION PROTECTION AND WASTE MANAGEMENT

This chapter describes the Northwest Medical Isotopes, LLC (NWMI) radiation protection and waste management programs that are applied to the design of the Radioisotope Production Facility (RPF) and associated equipment and facility operations. The radiation protection program provides a complete list of all expected radiation and radioactive sources, including airborne, liquid, and solid sources. The radiation protection program also requires the development and implementation of procedures, identifies monitoring instrumentation and techniques, and specifies practices to be employed to verify compliance with the radiation dose limits and other applicable requirements. The basis and plans used to develop procedures for assessing and controlling radioactive wastes and the ALARA (as low as reasonable achievable) program are included.

This section also establishes the waste management program for radioactive wastes resulting from normal operations and maintenance of the RPF, including the required procedures to ensure that radiation exposures and releases of radioactive materials are adequately assessed and controlled. The waste management program addresses the following elements:

- Philosophy and approach to waste management
- Basis of procedures and technical specifications
- Organization, staffing, and associated training
- Document control and records management
- Review and audit committees for radioactive waste management activities
- Plans for shipping, disposal, and long-term waste storage

11.1 RADIATION PROTECTION

The section identifies the sources of radiation within the RPF, including the physical and chemical form, type (e.g., neutron, gamma), curie strength or exposure rates, energy level, encapsulation (sealed or unsealed), use, storage conditions and locations, and planned program for disposal of the radioactive material.

11.1.1 Radiation Sources

The RPF produces molybdenum-99 (^{99}Mo) from low-enriched uranium (LEU) irradiated by a network of university research reactors. The primary RPF operations will include:

- Receiving LEU from the U.S. Department of Energy
- Producing LEU target materials and fabrication of targets
- Packaging and shipping LEU targets to the university reactor network for irradiation
- Returning irradiated LEU targets for dissolution, recovery, and purification of ^{99}Mo
- Recovering and recycling LEU to minimize radioactive, mixed, and hazardous waste generation
- Treating and packaging wastes generated by RPF processes to enable transport and disposal

Along with the production of ^{99}Mo, radioactive fission and activation products and actinides are also produced.

Chapter 4.0, "Radioisotope Production Facility Description," Table 4-41, provides a summary of the estimated total radioactivity in curies (Ci) from fission products and actinides contained within each batch of irradiated LEU targets entering the RPF. The irradiated LEU targets entering the RPF provide the majority of radiation sources within the RPF.

This section identifies the source and nature of airborne, liquid, and solid radioactive materials within the RPF, including the types of radiation emitted (alpha, beta, gamma, and neutron).

11.1.1.1 Airborne Radiation Sources

Airborne radioactive sources within the RPF will consist of radioactive gases produced during recovery and purification of ^{99}Mo. Radioactive gases will originate from three areas in the RPF, which are shown in Figure 11-1:

- Target fabrication area
- Tank hot cell area, including:
  - Disassembly and dissolution of irradiated LEU targets
  - Molybdenum (Mo) recovery and purification
  - LEU recovery and recycle
- Waste management area

A description of these areas and associated processes are provided in Chapter 4.0, Section 4.1.2. Airborne radiation sources from process offgases are treated in two systems prior to discharge: the process vessel vent system, and the Zone 1 exhaust system.

Details of the process offgas system are provided in Chapter 9.0, Section 9.1.2. The process offgas system is designed to ensure that airborne radioactive releases are maintained at levels less than those defined in Table 2 of Title 10, *Code of Federal Regulations*, Part 20 (10 CFR 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."

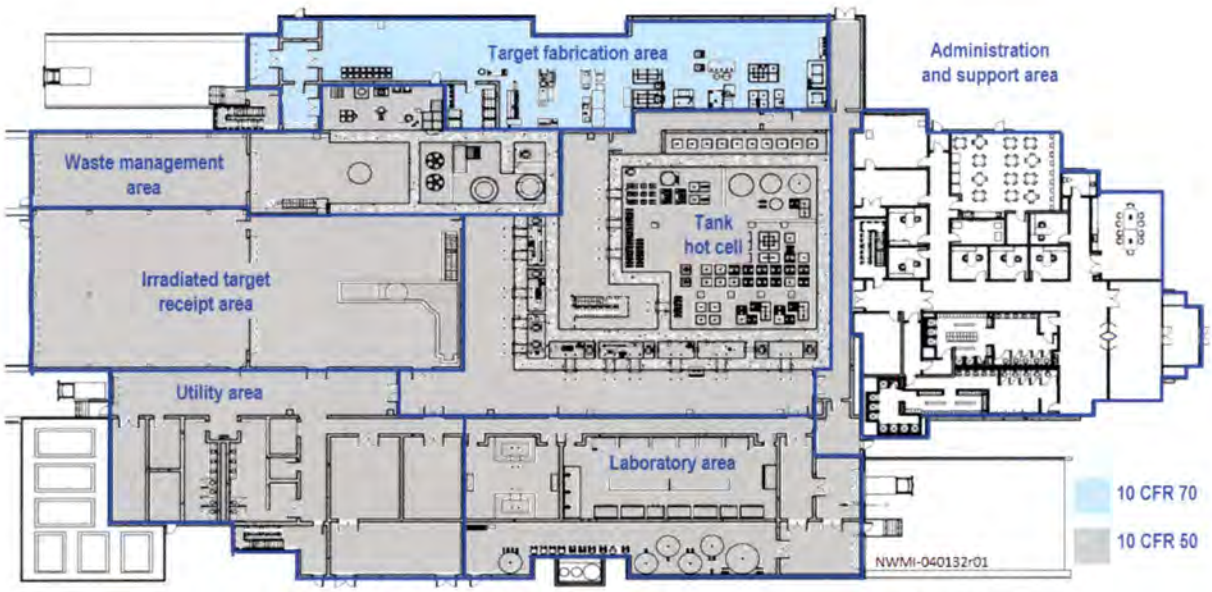

Figure 11-1. Radioisotope Production Facility Airborne Radiation Source Areas

11.1.1.1.1 Gaseous Radioactive Source

During normal operating conditions, airborne or gaseous radioactive materials will be contained within closed systems consisting of piping components and tanks. Table 11-1 provides source term information for the gaseous radioactive sources within the RPF (Barrington, 2015, and [Proprietary Information]). This source is based on the gaseous effluent prior to entering the process vessel vent system.

Table 11-1. Gaseous Radioactive Source (2 pages)

Isotope	Principal radiations	Radioactivity (Ci/wk)	Isotope	Principal radiations	Radioactivity (Ci/wk)
^{241}Am	α	[Proprietary Information]	^{240}Pu	α	[Proprietary Information]
^{136m}Ba	γ	[Proprietary Information]	^{241}Pu	β-	[Proprietary Information]
^{137m}Ba	γ	[Proprietary Information]	^{103m}Rh	γ	[Proprietary Information]
^{139}Ba	β-	[Proprietary Information]	^{105}Rh	β-	[Proprietary Information]
^{140}Ba	β-	[Proprietary Information]	^{106}Rh	β-	[Proprietary Information]
^{141}Ce	β-	[Proprietary Information]	^{106m}Rh	β-	[Proprietary Information]
^{143}Ce	β-	[Proprietary Information]	^{103}Ru	β-	[Proprietary Information]
^{144}Ce	β-	[Proprietary Information]	^{105}Ru	β-	[Proprietary Information]
^{134}Cs	β-	[Proprietary Information]	^{106}Ru	β-	[Proprietary Information]
^{134m}Cs	γ	[Proprietary Information]	^{122}Sb	β-	[Proprietary Information]
^{136}Cs	β-	[Proprietary Information]	^{124}Sb	β-	[Proprietary Information]
^{137}Cs	β-	[Proprietary Information]	^{125}Sb	β-	[Proprietary Information]
^{155}Eu	β-	[Proprietary Information]	^{126}Sb	β-	[Proprietary Information]
^{156}Eu	β-	[Proprietary Information]	^{127}Sb	β-	[Proprietary Information]
^{157}Eu	β-	[Proprietary Information]	^{128}Sb	β-	[Proprietary Information]
^{129}I	β-	[Proprietary Information]	^{128m}Sb	β-	[Proprietary Information]
^{130}I	β-	[Proprietary Information]	^{129}Sb	β-	[Proprietary Information]
^{131}I	β-	[Proprietary Information]	^{151}Sm	β-	[Proprietary Information]
^{132}I	β-	[Proprietary Information]	^{153}Sm	β-	[Proprietary Information]
^{132m}I	β-	[Proprietary Information]	^{156}Sm	β-	[Proprietary Information]
^{133}I	β-	[Proprietary Information]	^{89}Sr	β-	[Proprietary Information]
^{133m}I	γ	[Proprietary Information]	^{90}Sr	β-	[Proprietary Information]
^{134}I	β-	[Proprietary Information]	^{91}Sr	β-	[Proprietary Information]
^{135}I	β-	[Proprietary Information]	^{92}Sr	β-	[Proprietary Information]
^{83m}Kr	γ	[Proprietary Information]	^{99}Tc	β-	[Proprietary Information]
^{85}Kr	β-	[Proprietary Information]	^{99m}Tc	β-	[Proprietary Information]
^{85m}Kr	β-	[Proprietary Information]	^{125m}Te	γ	[Proprietary Information]
^{87}Kr	β-	[Proprietary Information]	^{127}Te	β-	[Proprietary Information]
^{88}Kr	β-	[Proprietary Information]	^{127m}Te	β-	[Proprietary Information]
^{140}La	β-	[Proprietary Information]	^{129}Te	β-	[Proprietary Information]

Table 11-1. Gaseous Radioactive Source (2 pages)

Isotope	Principal radiations	Radioactivity (Ci/wk)	Isotope	Principal radiations	Radioactivity (Ci/wk)
^{141}La	β-	[Proprietary Information]	^{129m}Te	β-	[Proprietary Information]
^{142}La	β-	[Proprietary Information]	^{131}Te	β-	[Proprietary Information]
^{99}Mo	β-	[Proprietary Information]	^{131m}Te	β-	[Proprietary Information]
^{95}Nb	β-	[Proprietary Information]	^{132}Te	β-	[Proprietary Information]
^{95m}Nb	β-	[Proprietary Information]	^{133}Te	β-	[Proprietary Information]
^{96}Nb	β-	[Proprietary Information]	^{133m}Te	β-	[Proprietary Information]
^{97}Nb	β-	[Proprietary Information]	^{134}Te	β-	[Proprietary Information]
^{97m}Nb	γ	[Proprietary Information]	^{232}U	α	[Proprietary Information]
^{147}Nd	β-	[Proprietary Information]	^{234}U	α	[Proprietary Information]
^{236m}Np	β-	[Proprietary Information]	^{235}U	α	[Proprietary Information]
^{237}Np	α	[Proprietary Information]	^{236}U	α	[Proprietary Information]
^{238}Np	β-	[Proprietary Information]	^{237}U	β-	[Proprietary Information]
^{239}Np	β-	[Proprietary Information]	^{238}U	A	[Proprietary Information]
^{233}Pa	β-	[Proprietary Information]	^{131m}Xe	γ	[Proprietary Information]
^{234}Pa	β-	[Proprietary Information]	^{133}Xe	β-	[Proprietary Information]
^{234m}Pa	γ	[Proprietary Information]	^{133m}Xe	γ	[Proprietary Information]
^{112}Pd	β-	[Proprietary Information]	^{135}Xe	β-	[Proprietary Information]
^{147}Pm	β-	[Proprietary Information]	^{135m}Xe	β-	[Proprietary Information]
^{148}Pm	β-	[Proprietary Information]	^{89m}Y	γ	[Proprietary Information]
^{148m}Pm	γ	[Proprietary Information]	^{90}Y	β-	[Proprietary Information]
^{149}Pm	β-	[Proprietary Information]	^{90m}Y	β-	[Proprietary Information]
^{150}Pm	β-	[Proprietary Information]	^{91}Y	β-	[Proprietary Information]
^{151}Pm	β-	[Proprietary Information]	^{91m}Y	γ	[Proprietary Information]
^{142}Pr	β-	[Proprietary Information]	^{92}Y	β-	[Proprietary Information]
^{143}Pr	β-	[Proprietary Information]	^{93}Y	β-	[Proprietary Information]
^{144}Pr	β-	[Proprietary Information]	^{93}Zr	β-	[Proprietary Information]
^{144m}Pr	β-	[Proprietary Information]	^{95}Zr	β-	[Proprietary Information]
^{145}Pr	β-	[Proprietary Information]	^{97}Zr	β-	[Proprietary Information]
^{238}Pu	α	[Proprietary Information]			[Proprietary Information]
^{239}Pu	α	[Proprietary Information]	**Total Ci**		[Proprietary Information]

Sources: Barrington, C., 2015, "NWMI Release #11 – Process Vessel Ventilation (PVV) System Estimate," (memorandum to G. Dunford, May 26), AEM Consulting, LLC, Richland, Washington, 2015, and [Proprietary Information].

α = alpha.
β = beta.
γ = gamma.

11.1.1.1.2 Release of Airborne Radionuclides

10 CFR 20.1101, "Radiation Protection Programs," paragraph (d) requires the licensee to "implement the ALARA requirements of 10 CFR 20.1101(b), and notwithstanding the requirements in 10 CFR 20.1301, a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughter products, shall be established by licensees other than those subject to 10 CFR 50.34(a), such that the 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 0.1 millisievert (mSv) (10 millirem [mrem]) per year from these emissions."

Regulatory Guide 4.20, *Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other than Power Reactors*, provides guidance on methods that the U.S. Nuclear Regulatory Commission (NRC) considers acceptable for meeting the constraint on airborne emissions of radioactive material to the environment, as described in 10 CFR 20.1101(d). In 1996, the NRC added this constraint to 10 CFR 20 to remove dual regulation by the NRC and the U.S. Environmental Protection Agency (EPA) and to provide an "ample margin of safety" to the public from airborne emissions of radioactive material to the environment. As previously noted, the defined TEDE to a member of the public is not expected to exceed 0.1 mSv (10 mrem) per year from gaseous emissions released from the RPF into the unrestricted area. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in 10 CFR 20.2203, "Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits," and promptly take appropriate corrective action to ensure against recurrence.

Regulatory Guide 4.20 notes that one method that the NRC staff considers acceptable for demonstrating compliance with 10 CFR 20.1101(d) is the use of computer codes. To evaluate the dose associated with air emissions from the RPF and to ensure rates will meet the requirements of 10 CFR 20.1101(d), the COMPLY computer model, Version 1.6, that assesses dose from airborne releases using varying amounts of site-specific information in four screening levels, was used. In Level 1, the simplest level, only the quantity of radioactive material processed during the monitoring period is entered. The calculations are based on generic parameters. Level 4 produces a more representative dose estimate and provides for a more complete treatment of air dispersion by requiring the greatest amount of site-specific information. Licensees that do not pass at the lowest level in COMPLY must move to the next higher level until they can demonstrate compliance. The bases for the methods used in COMPLY are:

- EPA 520/1-89-002, *A Guide for Determining Compliance with the Clean Air Act Standards for Radionuclide Emissions from NRC-Licensed and Non-DOE Federal Facilities*
- EPA 520/1-89-003, *Users Guide for the COMPLY Code*

Level 4 of the COMPLY code was used to demonstrate compliance with 10 CFR 20.1101(d) for the RPF. Table 11-2 provides the gaseous radionuclide stack release source term input to COMPLY. The source term was developed by combining the effluent from each of the systems that is vented to the process vessel vent system and applying decontamination factors for each of the treatment subsystems (iodine absorbers, high-efficiency particulate air [HEPA] filters, etc.) (Barrington, 2015).

The source term calculations of airborne releases are based on the processing of eight targets at University of Missouri Research Reactor (MURR) and consistent with nominal operating conditions (i.e., irradiated targets beginning to be processed in the RPF at [Proprietary Information] for systems downstream of the impure uranium lag storage tanks). The primary dose contributor is the [Proprietary Information] noble gas, and the offgas system is designed to retain [Proprietary Information] to below release limits and bound the range of target processing. These calculations will be updated and described in the final safety analysis report (FSAR) as part of the Operating License Application.

Table 11-2. Radionuclide Stack Release Source Term Input to COMPLY (2 pages)

Isotope	Release rate (Ci/yr)	Isotope	Release rate (Ci/yr)	Isotope	Release rate (Ci/yr)
^{241}Am	8.67E-17	^{237}Np	1.63E-12	^{89}Sr	3.69E-02
^{136m}Ba	8.03E-08	^{238}Np	7.07E-10	^{90}Sr	3.02E-04
^{137m}Ba	2.89E-06	^{239}Np	3.49E-04	^{91}Sr	2.36E-02
^{139}Ba	1.03E-05	^{233}Pa	4.14E-13	^{92}Sr	5.57E-03
^{140}Ba	7.99E-04	^{234}Pa	1.59E-12	^{99}Tc	4.04E-08
^{141}Ce	6.02E-04	^{234m}Pa	1.23E-09	^{99m}Tc	3.29E-02
^{143}Ce	3.52E-04	^{112}Pd	7.43E-07	^{125m}Te	8.55E-07
^{144}Ce	9.87E-05	^{147}Pm	9.39E-06	^{127}Te	9.76E-04
^{134}Cs	4.92E-10	^{148}Pm	5.81E-09	^{127m}Te	1.12E-04
^{134m}Cs	2.08E-10	^{148m}Pm	4.62E-09	^{129}Te	1.89E-03
^{136}Cs	7.16E-07	^{149}Pm	6.44E-05	^{129m}Te	9.73E-04
^{137}Cs	3.06E-06	^{150}Pm	6.75E-09	^{131}Te	5.38E-04
^{155}Eu	1.03E-07	^{151}Pm	2.47E-05	^{131m}Te	2.39E-03
^{156}Eu	2.06E-06	^{142}Pr	2.22E-10	^{132}Te	2.58E-02
^{157}Eu	3.28E-07	^{143}Pr	8.15E-04	^{133}Te	1.38E-05
^{129}I	1.90E-13	^{144}Pr	9.87E-05	^{133m}Te	6.13E-05
^{130}I	7.17E-08	^{144m}Pr	1.38E-06	^{134}Te	1.78E-05
^{131}I	5.97E-04	^{145}Pr	1.14E-04	^{232}U	2.63E-12
I132	1.56E-03	^{238}Pu	1.31E-12	^{234}U	2.48E-06
^{132m}I	8.65E-08	^{239}Pu	3.56E-09	^{235}U	1.14E-07
^{133}I	2.62E-03	^{240}Pu	2.58E-12	^{236}U	3.82E-08
^{133m}I	4.36E-07	^{241}Pu	9.31E-13	^{237}U	2.40E-03
^{134}I	2.69E-05	^{103m}Rh	2.74E-04	^{238}U	7.15E-08
^{135}I	1.36E-03	^{105}Rh	6.40E-05	^{131m}Xe	1.66E+02
^{83m}Kr	3.81E-10	^{106}Rh	5.70E-06	^{133}Xe	4.98E+02
^{85}Kr	5.84E+01	^{106m}Rh	1.05E-08	^{133m}Xe	9.77E-04
^{85m}Kr	1.92E-03	^{103}Ru	2.75E-04	^{135}Xe	9.51E-20
^{87}Kr	1.80E-23	^{105}Ru	2.12E-05	^{135m}Xe	1.46E-27
^{88}Kr	1.16E-07	^{106}Ru	5.70E-06	^{89m}Y	3.43E-06
^{140}La	8.64E-04	^{122}Sb	3.89E-11	^{90}Y	2.94E-04
^{141}La	1.11E-04	^{124}Sb	6.56E-10	^{90m}Y	5.70E-09
^{142}La	1.24E-05	^{125}Sb	1.67E-07	^{91}Y	4.18E-02
^{99}Mo	3.40E-04	^{126}Sb	1.10E-07	^{91m}Y	1.50E-02
^{95}Nb	1.68E-04	^{127}Sb	1.02E-05	^{92}Y	2.03E-02
^{95m}Nb	4.64E-06	^{128}Sb	9.42E-07	^{93}Y	2.68E-02
^{96}Nb	3.06E-08	^{128m}Sb	1.05E-07	^{93}Zr	6.12E-09

Table 11-2. Radionuclide Stack Release Source Term Input to COMPLY (2 pages)

Isotope	Release rate (Ci/yr)	Isotope	Release rate (Ci/yr)	Isotope	Release rate (Ci/yr)
^{97}Nb	3.37E-04	^{129}Sb	1.14E-05	^{95}Zr	4.29E-02
^{97m}Nb	2.98E-04	^{151}Sm	6.84E-08	^{97}Zr	3.14E-02
^{147}Nd	2.81E-04	^{153}Sm	9.44E-06	**Total Ci**	**7.24E+02**
^{236m}Np	9.02E-15	^{156}Sm	6.20E-07		

Sources: Barrington, C., 2015, "NWMI Release #11 – Process Vessel Ventilation (PVV) System Estimate," (memorandum to G. Dunford, May 26), AEM Consulting, LLC, Richland, Washington, 2015, and [Proprietary Information].

The weekly radionuclides (Ci/week) generated for the maximum dose case were multiplied by 52 weeks to obtain the release rates in Ci/year (yr) The radionuclide releases were adjusted to conservatively account for one HEPA filter in the Zone I heating, ventilation, and air conditioning (HVAC) offgas treatment system (Chapter 9, "Auxiliary Systems," Section 9.1.2.2) in accordance with EPA 520/1-89-003, which recommends that radionuclide particulate releases be reduced by an adjustment factor of 0.01. The noble gases and iodine releases were not reduced in the analysis. The following radionuclides were not available in the COMPLY database: ^{136m}Ba, ^{137m}Ba, ^{133m}I, ^{97m}Nb, ^{236m}Np, ^{234m}Pa, ^{112}Pd, ^{144m}Pr, ^{106}Rh, ^{128}Sb, ^{128m}Sb, and ^{98m}Y.

The following assumptions were used in the development of the analysis:

- Meteorological data – COMPLY meteorological wind rose file for Columbia
- Stack data – Stack height 22.9 meter (m) (75 feet [ft]), diameter of 0.86 m (34 inches [in.])
- Building data – Height 19.8 m (65 ft), width 24.4 m (80 ft), length 76.2 m (250 ft)
- Receptor location – Nearest receptor locations is the RPF fence line at 9.1 m (30 ft) from the stack
- Agricultural data – Food sources (e.g., milk, meat, vegetables) assumed to be home grown at receptor location

The maximum dose to the public from the normal operational stack releases was calculated to be 0.036 mSv/yr (3.6 mrem/yr) at 9.1 m (30 ft) from the RPF. The results of the COMPLY analysis determine that the requirement of 10 CFR 20.1101(d) will be met for the RPF, such that air emissions of radioactive material to the environment will not result in a member of the public receiving a TEDE in excess of 0.1 mSv/yr (10 mrem/yr) from these emissions.

The operating conditions in the above calculations are slightly more conservative than those described in Section 4.1.2.1 and will be aligned in the FSAR as part of the Operating License Application.

11.1.1.2 Liquid Radioactive Sources

Liquid radioactive sources within the RPF will consist of process fluids created during Mo recovery and purification, liquids created during the recycling of LEU, and liquids resulting from the treatment of offgases. A detailed description of the RPF processes and associated locations are provided in Chapter 4.0, Section 4.3. Details of the process vessel vent system are provided in Chapter 9.0, Section 9.1.

During normal operating conditions, liquid radioactive materials will be contained within closed systems consisting of piping components and tanks. There will be no radioactive liquid discharges from the RPF into the sanitary sewer or the environment. Any liquid radioactive waste will be treated and/or solidified prior to being packaged and shipped to a disposal facility.

Table 11-3 provides source term information for the liquid radioactive source. This source is based on the liquid in the target dissolver based [Proprietary Information]. This source term is considered bounding ([Proprietary Information]).

Table 11-3. Liquid Radioactive Source (2 pages)

Isotope	Principal radiations	Radioactivity (Ci/wk)	Isotope	Principal radiations	Radioactivity (Ci/wk)
^{241}Am	α	[Proprietary Information]	^{240}Pu	A	[Proprietary Information]
^{136m}Ba	γ	[Proprietary Information]	^{241}Pu	β-	[Proprietary Information]
^{137m}Ba	γ	[Proprietary Information]	^{103m}Rh	γ	[Proprietary Information]
^{139}Ba	β-	[Proprietary Information]	^{105}Rh	β-	[Proprietary Information]
^{140}Ba	β-	[Proprietary Information]	^{106}Rh	β-	[Proprietary Information]
^{141}Ce	β-	[Proprietary Information]	^{106m}Rh	β-	[Proprietary Information]
^{143}Ce	β-	[Proprietary Information]	^{103}Ru	β-	[Proprietary Information]
^{144}Ce	β-	[Proprietary Information]	^{105}Ru	β-	[Proprietary Information]
^{134}Cs	β-	[Proprietary Information]	^{106}Ru	β-	[Proprietary Information]
^{134m}Cs	γ	[Proprietary Information]	^{122}Sb	β-	[Proprietary Information]
^{136}Cs	β-	[Proprietary Information]	^{124}Sb	β-	[Proprietary Information]
^{137}Cs	β-	[Proprietary Information]	^{125}Sb	β-	[Proprietary Information]
^{155}Eu	β-	[Proprietary Information]	^{126}Sb	β-	[Proprietary Information]
^{156}Eu	β-	[Proprietary Information]	^{127}Sb	β-	[Proprietary Information]
^{157}Eu	β-	[Proprietary Information]	^{128}Sb	β-	[Proprietary Information]
^{129}I	β-	[Proprietary Information]	^{128m}Sb	β-	[Proprietary Information]
^{130}I	β-	[Proprietary Information]	^{129}Sb	β-	[Proprietary Information]
^{131}I	β-	[Proprietary Information]	^{151}Sm	β-	[Proprietary Information]
I132	β-	[Proprietary Information]	^{153}Sm	β-	[Proprietary Information]
^{132m}I	β-	[Proprietary Information]	^{156}Sm	β-	[Proprietary Information]
^{133}I	β-	[Proprietary Information]	^{89}Sr	β-	[Proprietary Information]
^{133m}I	γ	[Proprietary Information]	^{90}Sr	β-	[Proprietary Information]
^{134}I	β-	[Proprietary Information]	^{91}Sr	β-	[Proprietary Information]
^{135}I	β-	[Proprietary Information]	^{92}Sr	β-	[Proprietary Information]
^{83m}Kr	γ	[Proprietary Information]	^{99}Tc	β-	[Proprietary Information]
^{85}Kr	β-	[Proprietary Information]	^{99m}Tc	β-	[Proprietary Information]
^{85m}Kr	β-	[Proprietary Information]	^{125m}Te	γ	[Proprietary Information]
^{87}Kr	β-	[Proprietary Information]	^{127}Te	β-	[Proprietary Information]
^{88}Kr	β-	[Proprietary Information]	^{127m}Te	β-	[Proprietary Information]
^{140}La	β-	[Proprietary Information]	^{129}Te	β-	[Proprietary Information]
^{141}La	β-	[Proprietary Information]	^{129m}Te	β-	[Proprietary Information]
^{142}La	β-	[Proprietary Information]	^{131}Te	β-	[Proprietary Information]
^{99}Mo	β-	[Proprietary Information]	^{131m}Te	β-	[Proprietary Information]
^{95}Nb	β-	[Proprietary Information]	^{132}Te	β-	[Proprietary Information]

Table 11-3. Liquid Radioactive Source (2 pages)

Isotope	Principal radiations	Radioactivity (Ci/wk)	Isotope	Principal radiations	Radioactivity (Ci/wk)
^{95m}Nb	β-	[Proprietary Information]	^{133}Te	β-	[Proprietary Information]
^{96}Nb	β-	[Proprietary Information]	^{133m}Te	β-	[Proprietary Information]
^{97}Nb	β-	[Proprietary Information]	^{134}Te	β-	[Proprietary Information]
^{97m}Nb	γ	[Proprietary Information]	^{232}U	α	[Proprietary Information]
^{147}Nd	β-	[Proprietary Information]	^{234}U	α	[Proprietary Information]
^{236m}Np	β-	[Proprietary Information]	^{235}U	α	[Proprietary Information]
^{237}Np	α	[Proprietary Information]	^{236}U	α	[Proprietary Information]
^{238}Np	β-	[Proprietary Information]	^{237}U	β-	[Proprietary Information]
^{239}Np	β-	[Proprietary Information]	^{238}U	α	[Proprietary Information]
^{233}Pa	β-	[Proprietary Information]	^{131m}Xe	γ	[Proprietary Information]
^{234}Pa	β-	[Proprietary Information]	^{133}Xe	β-	[Proprietary Information]
^{234m}Pa	γ	[Proprietary Information]	^{133m}Xe	γ	[Proprietary Information]
^{112}Pd	B-	[Proprietary Information]	^{135}Xe	β-	[Proprietary Information]
^{147}Pm	β-	[Proprietary Information]	^{135m}Xe	β-	[Proprietary Information]
^{148}Pm	β-	[Proprietary Information]	^{89m}Y	γ	[Proprietary Information]
^{148m}Pm	γ	[Proprietary Information]	^{90}Y	β-	[Proprietary Information]
^{149}Pm	β-	[Proprietary Information]	^{90m}Y	β-	[Proprietary Information]
^{150}Pm	β-	[Proprietary Information]	^{91}Y	β-	[Proprietary Information]
^{151}Pm	β-	[Proprietary Information]	^{91m}Y	γ	[Proprietary Information]
^{142}Pr	β-	[Proprietary Information]	^{92}Y	β-	[Proprietary Information]
^{143}Pr	β-	[Proprietary Information]	^{93}Y	β-	[Proprietary Information]
^{144}Pr	β-	[Proprietary Information]	^{93}Zr	β-	[Proprietary Information]
^{144m}Pr	β-	[Proprietary Information]	^{95}Zr	β-	[Proprietary Information]
^{145}Pr	β-	[Proprietary Information]	^{97}Zr	β-	[Proprietary Information]
^{238}Pu	α	[Proprietary Information]			
^{239}Pu	α	[Proprietary Information]	**Total Ci**		[Proprietary Information]

Source: D004, filtered dissolver product, in [Proprietary Information].

α = alpha.
β = beta.
γ = gamma.

11.1.1.3 Solid Radioactive Sources

Solid radioactive sources within the RPF will consist of fresh LEU, irradiated LEU targets, LEU target material, and solidified waste. Details on these processes are provided in Chapter 4.0. During normal operating conditions, solid radioactive sources will be contained within tanks and shielded hot cells, all within restricted areas. Table 11-4 summarizes the solid radioactive source term in the RPF. This source term is based on the cumulative total of high- and low-dose waste, encapsulated waste, and one batch of [Proprietary Information].

Table 11-4. Solid Radioactive Source (2 pages)

Isotope	Principal radiations	Radioactivity (Ci/wk)	Isotope	Principal radiations	Radioactivity (Ci/wk)
^{241}Am	α	[Proprietary Information]	^{240}Pu	α	[Proprietary Information]
^{136m}Ba	γ	[Proprietary Information]	^{241}Pu	β-	[Proprietary Information]
^{137m}Ba	γ	[Proprietary Information]	^{103m}Rh	γ	[Proprietary Information]
^{139}Ba	β-	[Proprietary Information]	^{105}Rh	β-	[Proprietary Information]
^{140}Ba	β-	[Proprietary Information]	^{106}Rh	β-	[Proprietary Information]
^{141}Ce	β-	[Proprietary Information]	^{106m}Rh	β-	[Proprietary Information]
^{143}Ce	β-	[Proprietary Information]	^{103}Ru	β-	[Proprietary Information]
^{144}Ce	β-	[Proprietary Information]	^{105}Ru	β-	[Proprietary Information]
^{134}Cs	β-	[Proprietary Information]	^{106}Ru	β-	[Proprietary Information]
^{134m}Cs	γ	[Proprietary Information]	^{122}Sb	β-	[Proprietary Information]
^{136}Cs	β-	[Proprietary Information]	^{124}Sb	β-	[Proprietary Information]
^{137}Cs	β-	[Proprietary Information]	^{125}Sb	β-	[Proprietary Information]
^{155}Eu	β-	[Proprietary Information]	^{126}Sb	β-	[Proprietary Information]
^{156}Eu	β-	[Proprietary Information]	^{127}Sb	β-	[Proprietary Information]
^{157}Eu	β-	[Proprietary Information]	^{128}Sb	β-	[Proprietary Information]
^{129}I	β-	[Proprietary Information]	^{128m}Sb	β-	[Proprietary Information]
^{130}I	β-	[Proprietary Information]	^{129}Sb	β-	[Proprietary Information]
^{131}I	β-	[Proprietary Information]	^{151}Sm	β-	[Proprietary Information]
^{132}I	β-	[Proprietary Information]	^{153}Sm	β-	[Proprietary Information]
^{132m}I	β-	[Proprietary Information]	^{156}Sm	β-	[Proprietary Information]
^{133}I	β-	[Proprietary Information]	^{89}Sr	β-	[Proprietary Information]
^{133m}I	γ	[Proprietary Information]	^{90}Sr	β-	[Proprietary Information]
^{134}I	β-	[Proprietary Information]	^{91}Sr	β-	[Proprietary Information]
^{135}I	β-	[Proprietary Information]	^{92}Sr	β-	[Proprietary Information]
^{83m}Kr	γ	[Proprietary Information]	^{99}Tc	β-	[Proprietary Information]
^{85}Kr	β-	[Proprietary Information]	^{99m}Tc	β-	[Proprietary Information]
^{85m}Kr	β-	[Proprietary Information]	^{125m}Te	γ	[Proprietary Information]
^{87}Kr	β-	[Proprietary Information]	^{127}Te	β-	[Proprietary Information]
^{88}Kr	β-	[Proprietary Information]	^{127m}Te	β-	[Proprietary Information]
^{140}La	β-	[Proprietary Information]	^{129}Te	β-	[Proprietary Information]
^{141}La	β-	[Proprietary Information]	^{129m}Te	β-	[Proprietary Information]
^{142}La	β-	[Proprietary Information]	^{131}Te	β-	[Proprietary Information]
^{99}Mo	β-	[Proprietary Information]	^{131m}Te	β-	[Proprietary Information]
^{95}Nb	β-	[Proprietary Information]	^{132}Te	β-	[Proprietary Information]
^{95m}Nb	β-	[Proprietary Information]	^{133}Te	β-	[Proprietary Information]

Table 11-4. Solid Radioactive Source (2 pages)

Isotope	Principal radiations	Radioactivity (Ci/wk)	Isotope	Principal radiations	Radioactivity (Ci/wk)
^{96}Nb	β-	[Proprietary Information]	^{133m}Te	β-	[Proprietary Information]
^{97}Nb	β-	[Proprietary Information]	^{134}Te	β-	[Proprietary Information]
^{97m}Nb	γ	[Proprietary Information]	^{232}U	α	[Proprietary Information]
^{147}Nd	β-	[Proprietary Information]	^{234}U	α	[Proprietary Information]
^{236m}Np	β-	[Proprietary Information]	^{235}U	α	[Proprietary Information]
^{237}Np	α	[Proprietary Information]	^{236}U	α	[Proprietary Information]
^{238}Np	β-	[Proprietary Information]	^{237}U	β-	[Proprietary Information]
^{239}Np	β-	[Proprietary Information]	^{238}U	α	[Proprietary Information]
^{233}Pa	β-	[Proprietary Information]	^{131m}Xe	γ	[Proprietary Information]
^{234}Pa	β-	[Proprietary Information]	^{133}Xe	β-	[Proprietary Information]
^{234m}Pa	γ	[Proprietary Information]	^{133m}Xe	γ	[Proprietary Information]
^{112}Pd	β-	[Proprietary Information]	^{135}Xe	β-	[Proprietary Information]
^{147}Pm	β-	[Proprietary Information]	^{135m}Xe	β-	[Proprietary Information]
^{148}Pm	β-	[Proprietary Information]	^{89m}Y	γ	[Proprietary Information]
^{148m}Pm	γ	[Proprietary Information]	^{90}Y	β-	[Proprietary Information]
^{149}Pm	β-	[Proprietary Information]	^{90m}Y	β-	[Proprietary Information]
^{150}Pm	β-	[Proprietary Information]	^{91}Y	β-	[Proprietary Information]
^{151}Pm	β-	[Proprietary Information]	^{91m}Y	γ	[Proprietary Information]
^{142}Pr	β-	[Proprietary Information]	^{92}Y	β-	[Proprietary Information]
^{143}Pr	β-	[Proprietary Information]	^{93}Y	β-	[Proprietary Information]
^{144}Pr	β-	[Proprietary Information]	^{93}Zr	β-	[Proprietary Information]
^{144m}Pr	β-	[Proprietary Information]	^{95}Zr	β-	[Proprietary Information]
^{145}Pr	β-	[Proprietary Information]	^{97}Zr	β-	[Proprietary Information]
^{238}Pu	α	[Proprietary Information]	Total Ci		[Proprietary Information]
^{239}Pu	α	[Proprietary Information]			

Source: [Proprietary Information] and [Proprietary Information].

α = alpha. γ = gamma.
β = beta.

At discharge from the Oregon State University TRIGA[1] Reactor (OSTR) (or third) reactor, the 30 targets will have essentially the same amount of radioactivity as eight targets being discharged from MURR. Since the OSTR targets are not going to be received for 48 hr, the total radioactivity is significantly less than the eight MURR targets received in 8 hr. Therefore, other than grams of uranium, the radiation source for the 30 OSTR targets is lower.

[1] TRIGA (Training, Research, Isotopes, General Atomics) is a registered trademark of General Atomics, San Diego, California.

11.1.2 Radiation Protection Program

NWMI management is committed to protecting RPF workers, the public, and environment from unacceptable exposure to radiation sources. NWMI's policy is to conduct radiological operations in a manner that ensures the health and safety of employees, contractors, and the public. In achieving this objective, NWMI will ensure that radiation exposure to workers and the public, and releases of radioactivity to the environment, are maintained below regulatory limits. Deliberate actions will be taken to further reduce exposures and releases in accordance with a process focused on keeping exposures and releases ALARA.

NWMI is fully committed to implementing the NWMI radiation protection program to consistently reflect this policy. The NWMI radiation protection program will also meet the requirements of 10 CFR 20 and 10 CFR 19, "Notices, Instructions, and Reports to Workers: Inspection and Investigations."

The radiation protection program will be developed, documented, and implemented commensurate with the risks posed by RPF operations. NWMI will use, to the extent practicable, procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to the public that are ALARA.

The radiation protection program content and implementation will be reviewed at least annually, as required by 10 CFR 20.1101(c). In addition, in accordance with 10 CFR 20.1101(d), constraints on atmospheric releases will be established for the RPF such that no member of the public would be expected to receive a TEDE in excess of 0.1 mSv/yr (10 mrem/yr) from these releases.

The NWMI RPF administrative exposure limits have been set below the limits specified in 10 CFR 20 to ensure that regulatory radiation exposure limits are not exceeded and to emphasize ALARA principles. The administrative exposure limit (TEDE) for the RPF is defined as 0.02 Sv/yr (2 roentgen equivalent in man [rem]/yr). The ALARA goal and dose investigation level is set at 5 mSv/yr (500 mrem/yr).[2] Table 11-5 provides a conservative estimate of the dose rates during normal operations for occupied areas. The high and very high radiation areas presented in Chapter 4, Section 4.2 will not be occupied by personnel during normal operations. Dose rates outside the controlled area are anticipated to be below 0.02 mSv (2 mrem) in any 1 hr and 0.001 Sv/yr (0.1 rem/yr) in accordance with 10 CFR 20.1302, "Compliance with Dose Limits for Individual Members of the Public."

Table 11-5. Estimated Radioisotope Production Facility Controlled and Restricted Area Dose Rates

Location	Dose rate	
Target fabrication area	0.0003 mSv/hr	0.03 mrem/hr
Irradiated target receipt area	0.005 mSv/hr	0.5 mrem/hr
Hot cell operating and maintenance galleries	0.005 mSv/hr	0.5 mrem/hr
Waste management loading area	0.005 mSv/hr	0.5 mrem/hr
Utility area	0	0
Laboratory area	0.005 mSv/hr	0.5 mrem/hr
Administration and support area	0	0

[2] A dose investigation level of 5 mSv/yr (500 mrem/yr) is the TEDE above which would trigger an investigation by the Radiation Protection staff to determine why an individual received such a dose equivalent. The routine TEDE to workers is not anticipated to approach this level. An investigation might entail interviews with the individual and the immediate supervisor, review of radiation work permits (or equivalent), review of procedures, review of ALARA approaches, and providing feedback to management with recommendations on how to proceed.

The dose rates calculated for Table 11-5 are based on actual shielding calculations or were the goals/ endpoints of the shielding analysis. Table 11-5 will be updated in the FSAR as part of the Operating License Application when the final shielding design and calculations are completed. Areas identified as controlled access areas, restricted areas, radiation areas, and high radiation areas will also be designated, based on the definitions provided in 10 CFR 20, and the predicted doses rates presented by the shielding analysis. Although the Radiation Protection Plan has not yet been developed (i.e., this plan will be supplied with the Operating License Application), dosimetry is anticipated to be required in any restricted area.

In addition, although a dose rate of zero may not be achievable in the controlled areas, this is the goal. As stated in Section 11.1.5.5.2, an area monitoring program will be established in the controlled area to demonstrate compliance with public exposure limits in the FSAR as part of the Operating License Application.

To ensure that RPF personnel are protected, the radiation protection program will require surveillance of and control over the radiation exposure of personnel.

The radiation exposure policy and control measures for personnel will be established based on the requirements of 10 CFR 20 and the guidance of applicable regulatory guides. Recommendations from the International Commission on Radiological Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP) will also be used in the formulation and evolution of the RPF radiation protection program.

Details on the area monitoring program will be provided in the FSAR as part of the Operating License Application. Area monitoring is anticipated to comprise a combination of passive (e.g., TLD or optically stimulated luminescence [OSL] monitors changed out monthly or quarterly) and active (e.g., energy-compensated Geiger-Mueller (G-M) detector systems with local and remote monitoring capability) monitoring systems located at points in the controlled area that would provide reasonable assurance that radiation areas are not present in the controlled area. The selection of specific instrumentation, range of detection, and alert/alarm setpoints will be consistent with the intent to detect radiation in areas where it should not be and alert personnel to this changing condition.

11.1.2.1 Responsibilities of Key Program Personnel

This section provides the organizational structure of the NWMI radiation protection program, including the responsibilities of key personnel. Chapter 12.0, "Conduct of Operations," provides additional information on the facility management and technical organization. The NWMI Chief Operating Officer (COO) will have overall responsibility for the operation of the RPF, including radiation protection. Detailed program procedures will be provided in the Operating License Application.

11.1.2.1.1 Plant Manager

The Plant Manager will report to the COO and have direct responsibility for safe operation of the RPF, including the protection of workers and the public against radiation exposure resulting from facility operations and materials. Other responsibilities will include:

- Ensuring compliance with applicable NRC, State, and local regulations and license/permits
- Implementing the RPF conduct of operations program
- Establishing and managing the required training programs to support the operations organization

11.1.2.1.2 Safety, Health and Licensing Manager

The Safety, Health, and Licensing (SH&L) Manager will report to the COO, with overall responsibility for the development and implementation of programs addressing worker safety and health, NRC licensing, and State and local permitting (including monitoring compliance with those licenses and permits). Other responsibilities will include nuclear criticality safety, radiation protection/chemistry, environmental protection, integrated safety analysis, industrial hygiene and safety, chemical safety, fire protection, security, and emergency preparedness. With respect to operations, the SH&L Manager will be responsible to confirm the safety of those operations, and will have the authority to order facility shutdown for RPF operations that are judged to be unsafe for continued operations or noncompliant with applicable regulatory requirements and to approve restart of operations.

11.1.2.1.3 Radiation Protection Manager

The Radiation Protection Manager will report to the SH&L Manager and have responsibility for the development and implementation of programs to limit personnel radiological exposures and environmental impacts associated with facility operations, including the ALARA program. Other responsibilities include implementation of the chemistry analysis programs and procedures for the RPF. In matters involving radiological protection, the Radiation Protection Manager will have direct access to the COO. The Radiation Protection Manager, supported by his staff, will be responsible for:

- Establishing and implementing RPF radiation protection program
- Serving as Radiation Safety Officer
- Generating and maintaining procedures associated with radiation protection program
- Reviewing and auditing the efficacy of the program in complying with NRC and other government regulations and applicable regulatory guides
- Adequately staffing the Radiation Protection group to implement the radiation protection program
- Establishing and maintaining the ALARA program and ensuring personnel follow ALARA principles
- Establishing and maintaining a respirator usage program
- Monitoring worker doses, both internal and external
- Complying with radioactive materials possession limits
- Performing calibration and quality assurance of all radiological instrumentation (e.g., verification of required lower limits of detection or alarm levels)
- Establishing and maintaining a radiation safety training program
- Performing annual audits of the radiation protection program
- Establishing and maintaining the radiological environmental monitoring program
- Posting restricted areas and developing associated occupancy guidelines (e.g., radiation, airborne radioactivity, high radiation, and contaminated areas)

11.1.2.1.4 Operations Manager

The Operations Manager will report to the Plant Manager and have responsibility for day-to-day RPF operations activities. Inherent in this responsibility is the assurance that operations are conducted safely and in compliance with license conditions.

11.1.2.1.5 Employees

NWMI employees will be responsible for conducting work safely and to follow the rules, regulations, and procedures that have been established for their protection and the protection of the public. Personnel whose duties require working with radioactive material, entering radiation areas, controlling facility operations that could affect effluent releases, or directing the activities of others, are trained such that they understand and effectively carry out their responsibilities.

11.1.2.2 Staffing of the Radiation Protection Program

Only suitably trained radiation protection personnel will be employed at the RPF. For example, the Radiation Protection Manager will have a bachelor's degree (or equivalent), as a minimum, in an engineering or scientific field and 4 years of applicable nuclear experience. Other members of the radiation protection staff will be trained and qualified consistent with the guidance provided in American National Standards Institute (ANSI)/American Nuclear Society (ANS) 15.11, *Radiation Protection at Research Reactor Facilities*. NWMI management is committed to providing sufficient resources in terms of staffing and equipment to implement an effective radiation protection program.

11.1.2.3 Independence of the Radiation Protection Program

The radiation protection program will be independent of routine operations of the RPF. This independence ensures that radiation protection personnel maintain their objectivity and are focused on implementing sound radiation protection principles necessary to achieve occupational doses and doses to the public that are ALARA. As noted in Section 11.1.2.1.3, the Radiation Protection Manager has direct access to the COO for matters involving radiological protection.

11.1.2.4 Radiation Safety Committee

A Radiation Safety Committee will meet periodically to review the status of projects, measure performance, look for trends, and review radiation safety aspects of facility operations, in accordance with 10 CFR 20.1101(c). The Radiation Protection Manager will chair the Radiation Safety Committee. The other Radiation Safety Committee members come from quality assurance, operations, maintenance, and technical support, as deemed appropriate by the Plant Manager.

The objectives of the Radiation Safety Committee will be to maintain a high standard of radiation protection in all facility operations. The Radiation Safety Committee will review the content and implementation of the radiation protection program at a working level and strive to improve the program by reviewing exposure trends, the results of audits, regulatory inspections, worker suggestions, survey results, and exposure incidents. The maximum interval between meetings may not exceed 180 days. A written report of each Radiation Safety Committee meeting will be forwarded to all managers.

11.1.2.5 Training Programs

The design and implementation of the radiation protection training program will comply with the requirements of 10 CFR 19.12, "Instruction to Workers." Records will be maintained in accordance with 10 CFR 20.2110, "Form of Record." The development and implementation of the radiation protection training program will be consistent with the guidance provided in the following regulatory guidance documents:

- ASTM E1168-95, *Radiological Protection Training for Nuclear Facility Workers*
- ANSI/ANS 15.11, *Radiation Protection at Research Reactor Facilities*
- Regulatory Guide 8.10, *Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable*

- Regulatory Guide 8.13, *Instructions Concerning Prenatal Radiation Exposure*
- Regulatory Guide 8.29, *Instructions Concerning Risks from Occupational Radiation Exposure*

All personnel and visitors entering restricted areas, as described in Section 11.1.5.5, will receive training that is commensurate with the radiological hazard to which they may be exposed. Visitors will be provided with trained escorts who have received radiation protection training.

The level of radiation protection training will be based on the potential radiological health risks associated with the employee's work responsibilities and incorporate the provisions of 10 CFR 19.12. In accordance with 10 CFR 19.12, any individual working at the facility who is likely to receive a dose in excess of 1 mSv (100 mrem) in one year will be:

- Kept informed of the storage, transfer, or use of radioactive material
- Instructed in health protection problems associated with exposure to radiation and radioactive material, in procedures to minimize exposure, and in the purposes and functions of protective devices employed
- Required to observe, to the extent within the worker's control, the applicable provisions of NRC regulations and licenses for protection of personnel from exposure to radiation and radioactive material
- Instructed of the responsibility to promptly report to facility management any condition that may cause a violation of NRC regulations and licenses, or unnecessary exposure to radiation and radioactive material
- Instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and radioactive material
- Advised of the various notifications and reports to individuals that a worker may request in accordance with 10 CFR 19.13, "Notifications and Reports to Individuals."

The radiation protection training program will take into consideration a worker's normally assigned work activities. Abnormal situations involving exposure to radiation and radioactive material, which can reasonably be expected to occur during the life of the facility, will also be evaluated and factored into the training. The extent of these instructions will be commensurate with the radiological health protection considerations appropriate for the workplace.

Personnel who have previously been trained for radiological, chemical, industrial, and criticality safety will receive (retraining) refresher training at least annually. The retraining program will review procedure changes and any updates and changes in required skills. Changes to the training resulting from incidents potentially compromising safety or changes to the facility or processes will be incorporated as required.

Records of training are maintained in accordance with the NWMI records management system, which is described in the RPF Quality Assurance Program Plan (QAPP) (Chapter 12.0, Appendix C). Training programs will be established in accordance with Chapter 12.0, Section 12.10. The radiation protection sections of the training program are evaluated at least annually. The program content will be reviewed to ensure that it remains current and is adequate to ensure worker safety.

Radiation Protection Training

The radiation protection training program will emphasize the importance placed on radiological safety of workers and the public. In-depth radiation protection training will be provided for the various types of job functions (e.g., production operator, radiation protection technician, contractor personnel) commensurate with the radiation safety responsibilities associated with each position. Visitors to any of the RPF production areas will be trained commensurate with the planned activities and will be escorted by trained personnel while in those areas.

Personnel access procedures will be defined to ensure the completion of formal radiological safety training prior to being allowed unescorted access into the restricted areas. Training sessions covering safety, radiation protection, and emergency procedures will be conducted on a regular basis to accommodate new employees or those requiring retraining. Retraining will be conducted when necessary to address changes in policies, procedures, and requirements.

Specific topics covered in the training program are listed in Chapter 12.0, Section 12.10. The training provided will include the requirements of 10 CFR 19. Individuals attending these training classes must pass an initial examination covering the training contents to ensure an understanding of the requirements and to determine the effectiveness of the training. The effectiveness and adequacy of the training program curriculum and instructors will also be evaluated by audits performed by personnel responsible for safety and radiation protection.

If contractor employees are required to perform tasks in the restricted areas or controlled areas of the facility, formal training for these individuals will be designed to address the type of work being performed. In addition to applicable radiation safety topics, training contents may include radiation work permits (RWP), special bioassay sampling, and special precautions for activities performed.

Instructors approved by the Radiation Protection Manager will be responsible for conducting the radiation protection training program. The Radiation Protection Manager will be responsible for establishing and maintaining radiation protection training for all personnel, including contractor personnel who may be working at the facility. Records will be maintained by the Training Manager for each employee to document the training date, scope of the training, identity of the trainer(s), any test results, and other associated information.

Individuals requiring unescorted access to a restricted area receive annual retraining. Contents of the formal radiation protection training program will be reviewed and updated at least annually by the SH&L Manager and Radiation Protection Manager to ensure that the programs are current and adequate.

11.1.2.6 Document Control

The RPF document control program is described in the RPF QAPP (Chapter 12.0, Appendix C).

11.1.2.7 Audits

The radiation protection program will be audited annually, at a minimum, to review all functional elements of the program. This function is performed to meet the requirements of 10 CFR 20.1101(c). The audit activity is led by the Radiation Protection Manager, with the results being sent to the Radiation Safety Committee, COO, SH&L Manager, and Plant Manager for review. The corrective action program is used to address any deficiencies identified during the audit. Details on the corrective action plan are provided in the NWMI QAPP (Chapter 12.0, Appendix C).

11.1.2.8 Radiation Work Control Procedures

All work performed in restricted areas will be performed under an RWP. The procedures controlling RWPs will be consistent with the guidance provided in Regulatory Guide 8.10. An RWP may also be required whenever the Radiation Protection Manager deems that one is necessary or when activities involve licensed materials not covered by operating procedures where radioactivity levels are likely to exceed airborne radioactivity limits. Routine and nonroutine activities will be performed under an RWP that provides a description of the work to be performed (i.e., defines the authorized activities). The RWP will summarize the results of recent dose rate surveys, contamination surveys, airborne radioactivity results, and other relevant information.

Precautions to be taken by those performing the task, including personal protective equipment to be worn while working (e.g., gloves, respirators, personnel monitoring devices), stay-times or dose limits for work in the area, recordkeeping requirements (e.g., time or dose spent on job), and the attendance of a radiation protection technician during the work, will be defined in the RWP. The Radiation Protection Manager or designee will approve the RWP. The designee must meet the requirements of Section 11.1.2.2.

The RWPs will have a predetermined period of validity, with a specified expiration or termination time. Standing RWPs will be issued for routinely performed activities, such as tours of the RPF by shift personnel.

Determining the need for issuing and closing out an RWP will be the responsibility of the Radiation Protection Manager, or designee. The RWP procedures will require the following:

- Reviewing planned activities, changes to activities inside restricted areas, or work with licensed materials for the potential to cause radiation exposures that exceed action levels or produce radioactive contamination. This review is also the responsibility of the Radiation Protection Manager, or designee.
- Specifying requirements for any necessary safety controls, personnel monitoring devices, protective clothing, respiratory protective equipment, and air sampling equipment, and the attendance of radiation protection technicians at the work location
- Posting RWPs at access points to restricted areas, with copies of current RWPs posted at the work area location
- Clearly defining and limiting the work activities to which the RWPs apply
- Closing out the RWP when the applicable work activity for which it was written is completed and terminated
- Retaining the RWP as a record at least for the life of the facility

11.1.2.9 Recordkeeping

For additional program commitments applicable to records and reports, the RPF will meet the requirements of the following regulations:

- 10 CFR 20 Subpart L, "Records," and Subpart M, "Reports"
- 10 CFR 50.71, "Maintenance of Records, Making of Reports"
- 10 CFR 70.51, "Records Requirements"
- ANSI 15.8, *Quality Assurance Program Requirements for Research Reactors*
- ANSI/ANS 15.11, *Radiation Protection at Research Reactor Facilities*

The NWMI records management program is described in the NWMI QAPP (Chapter 12.0, Appendix C). NWMI will maintain records of the radiation protection program (including program provisions, audits, and reviews of the program content and implementation), radiation survey results (air sampling, bioassays, external-exposure data from monitoring of individuals, internal intakes of radioactive material), and results of corrective action program referrals, RWPs, and planned special exposures.

By procedure, NWMI will report to the NRC any event that results in an occupational exposure to radiation exceeding the dose limits in 10 CFR 20 within the time specified in 10 CFR 20.2202, "Notification of Incidents.". NWMI will prepare and submit an annual report of the results of individual monitoring to the NRC, as required by 10 CFR 20.2206, "Reports of Individual Monitoring."

11.1.3 ALARA Program

This section provides a discussion of the NWMI ALARA program, as required by 10 CFR 20.1101.

11.1.3.1 ALARA Policy

NWMI management is committed to the ALARA philosophy for radiological operations. NWMI's policy is to conduct radiological operations in a manner that will ensure the health and safety of its employees, contractors, and the public. In achieving this objective, NWMI will ensure that radiation exposure to workers and the public, and releases of radioactivity to the environment, are maintained below regulatory limits. Deliberate actions will be taken to further reduce exposures and releases in accordance with a process focused on keeping exposures or releases ALARA. NWMI is fully committed to implementing an ALARA program that consistently reflects this policy.

11.1.3.2 Approach to ALARA Program

As stated in the ALARA policy, NWMI management is committed to the implementation of an ALARA program. The objective of the program will be to make every reasonable effort to maintain facility exposures to radiation as far below the dose limits of 10 CFR 20.1201, "Occupational Dose Limits," as practical, and to maintain radiation exposures to the public below the dose constraints of 10 CFR 20.1301, "Dose Limits for Individual Members of the Public." Annual doses to personnel will be maintained ALARA. In addition, the annual collective dose to personnel (i.e., the sum of all annual individual doses, expressed in person-Sv or person-rem) will be maintained ALARA. The dose equivalent to the embryo/fetus will be maintained below the limits of 10 CFR 20.1208, "Dose Equivalent to an Embryo/Fetus."

The goals of the ALARA program are to ensure occupational exposures and environmental releases are as far below regulatory limits as reasonably achievable. The RPF design incorporates ALARA principles. As systems, components, and process areas are designed, radiation protection staff will evaluate the potential dose to workers and the public and provide suggested approaches to reducing dose.

Areas where facility personnel are expected to spend significant time are designed so that dose rates are maintained ALARA. The areas with higher doses rates will be minimized. Radiation areas will be established to minimize the spread of contamination and reduce unnecessary exposure of personnel to radiation. The potential radiation area designations within the RPF are shown in Figure 11-2, Figure 11-3, and Figure 11-4, and discussed further in Section 11.1.5.5.

[Proprietary Information]

Figure 11-2. Radioisotope Production Facility Radiation Zones (First Floor)

[Proprietary Information]

Figure 11-3. Radioisotope Production Facility Radiation Zones (Second Floor)

[Proprietary Information]

Figure 11-4. Radioisotope Production Facility Radiation Zones (Basement)

The design and implementation of the ALARA program will be consistent with the guidance provided in:

- Regulatory Guide 8.2, *Administrative Practices in Radiation Surveys and Monitoring*
- Regulatory Guide 8.13, *Instructions Concerning Prenatal Radiation Exposure*
- Regulatory Guide 8.29, *Instruction Concerning Risks from Occupational Radiation Exposure*
- Regulatory Guide 8.37, *ALARA Levels for Effluents from Materials Facilities*

The operation of the RPF will be consistent with the guidance provided in Regulatory Guide 8.10. The guidance of Regulatory Guide 4.21, M*inimization of Contamination and Radioactive Waste Generation: Life-Cycle Planning*, will be followed to minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

The radiation protection program will ensure that a comprehensive and effective program is implemented and document that policies are established to ensure that ALARA goals are met. Facility procedures will be written to incorporate ALARA principles into routine operations of the RPF and ensure that exposures are consistent with 10 CFR 20.1201 limits.

The Radiation Protection Manager will be responsible for implementing the ALARA program and ensuring that adequate resources are committed to support an effective program. An annual ALARA program evaluation report will be prepared that summarizes (1) radiological exposure and effluent release data for trends, (2) audits and inspections, (3) use, maintenance, and surveillance of equipment used for exposure and effluent control, and (4) other issues, as appropriate, that may influence the effectiveness of the radiation protection and ALARA programs. Copies of the report will be submitted to the COO, Radiation Safety Committee, and Plant Manager.

The Radiation Safety Committee will review the effectiveness of the ALARA program at least every quarter and determine if exposures, releases, and contamination levels are in accordance with ALARA principles. The committee will also evaluate the results of assessments made by the Radiation Protection organization and reports of facility radiation levels, contamination levels, and employee exposures for identified categories of workers and types of operations. The committee will be responsible for ensuring that the occupational radiation exposure dose limits of 10 CFR 20.1201 are not exceeded under normal operations and for evaluating alternatives to improve the effectiveness of equipment used for exposure control. The committee will determine if there are any upward trends in personnel exposures, environmental releases, and/or facility contamination levels.

11.1.4 Radiation Monitoring and Surveying

Radiation monitoring and surveys will be conducted to (1) determine radiation levels, concentrations of radioactive materials, and potential radiological hazards that could be present in the facility, and (2) detect releases of radioactive material from facility equipment and operations. Radiation surveys will focus on those areas of the facility where the occupational radiation dose limits could potentially be exceeded. Measurements of airborne radioactive material and/or bioassays will be used to determine that internal occupational exposures to radiation do not exceed the dose limits specified in 10 CFR 20, Subpart C, "Occupational Dose Limits." NWMI has established written procedures to ensure compliance with the requirements of 10 CFR 20, Subpart F, "Surveys and Monitoring."

The radiation survey and monitoring programs will be consistent with the guidance provided in the following references:

- Regulatory Guide 8.2, *Administrative Practices in Radiation Surveys and Monitoring*
- Regulatory Guide 8.4, *Personnel Monitoring Device—Direct-Reading Pocket Dosimeters*

- Regulatory Guide 8.7, *Instructions for Recording and Reporting Occupational Radiation Exposure Data*
- Regulatory Guide 8.9, *Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program*
- Regulatory Guide 8.25, *Air Sampling in the Workplace*
- Regulatory Guide 8.34, *Monitoring Criteria and Methods to Calculate Occupational Radiation Doses*
- ANSI N13.1, *Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities*
- ANSI N13.6, *Practice for Occupational Radiation Exposure Records Systems*
- ANSI N13.11, *Dosimetry-Personnel Dosimetry Performance-Criteria for Testing*
- ANSI N13.27, *Performance Requirements for Pocket-Sized Alarm Dosimeters and Alarm Ratemeters*
- ANSI N323, *Radiation Protection Instrumentation Test and Calibration*
- ANSI/ANS 15.11, *Radiation Protection at Research Reactors*
- ANSI/HPS N13.22, *Bioassay Program for Uranium*
- ANSI/HPS N13.30, *Performance Criteria for Radiobioassay*
- NUREG-1400, *Air Sampling in the Workplace*

The procedures will include program objectives, sampling procedures, and data analysis methods. Equipment selection will be based on the type of radiation being monitored. The procedures will be developed for each instrument used, including the frequency and method of calibration, and the maintenance and calibration requirements. Specific types of instruments used in the facility are discussed in Section 11.1.4.1. The survey program procedures will also specify the frequency of measurements and the recordkeeping and reporting requirements. Additional information on radiation monitoring and surveys will be provided in the Operating License Application.

All personnel who enter restricted areas will be required to wear National Voluntary Laboratory Accreditation (NAVLAP)-compliant personnel dosimeters.[3] Personnel will also be required to survey themselves prior to exiting restricted areas that may have the potential for contamination.

Continuous airborne radioactivity monitors will provide indication of the airborne activity levels in the restricted areas of the facility. When deemed necessary, portable air samplers may be used to collect a sample on filter paper for subsequent analysis in the laboratory. Monitor data will be collected for regular analysis and documentation. Monitors will be equipped with alarms. The alarms activate when airborne radioactivity levels exceed predetermined limits. The limits will be set with consideration given to both toxicity and radioactivity. The volume of air sampled may have to be adjusted to ensure adequate sensitivity with minimum sampling time. The operating history of the RPF, changes in technology, changes in room functions and design, and changes in regulations may necessitate adjustment of the monitors.

[3] Personnel dosimetry will provide a means to measure, assess, and record personnel exposures to ionizing radiation from external sources. Exposure to external sources of radiation will be monitored by individual monitoring devices such as TLDs, OSL, CR-39, activation foils, or direct reading pocket dosimeters. Use of personnel dosimetry will be required for all personnel entering the "restricted areas. Use of direct-reading personnel dosimetry and criticality monitoring will be required for all personnel entering "high radiation areas" and "very high radiation areas."

Calibrations will be performed in accordance with written established procedures and documented prior to the initial use of each airflow measurement instrument (used to measure flow rates for air or effluent sampling) and each radioactivity measurement instrument. Periodic operability checks will also be performed in accordance with established written procedures.

Calibrations will be performed and documented on each airflow measurement and radioactivity measurement instrument, as follows:

- At least annually (or according to manufacturers' recommendations, whichever is more frequent)
- After failing an operability check
- After modifications or repairs to the instrument that could affect its proper response
- When the instrument is believed to have been damaged

Unreliable instruments will be removed from service until repairs are completed. Portal monitors, hand and foot monitors, and friskers will have the required sensitivity to detect alpha contamination on personnel to ensure that radioactive materials do not spread to the areas outside of the restricted areas. Instruments will be calibrated with sources that are within ±5 percent of the reference value and are traceable to the National Institute of Standards and Technology (NIST) or equivalent.

The background and efficiency of laboratory counting instruments, when used for radiation protection purposes, will be determined daily. This determination may be less frequent only if necessary due to long counting intervals.

11.1.4.1 Monitoring Equipment

The following subsections provide the procedures and equipment used at the RPF to routinely monitor and sample workplaces and other accessible locations to identify and control potential sources of radiation exposure and release.

11.1.4.1.1 Personnel Monitoring

Three basic types of personnel monitoring equipment will be used at the facility: count rate meters (friskers), hand and foot monitors, and portal monitors.

Friskers – These devices typically consist of a handheld Thermo Scientific HP 210 (or equivalent) probe connected to an RM-25 (or equivalent) count rate meter. Instructions for the use of these instruments will be posted in a prominent location near the instrument. Handheld friskers will typically be placed in locations where conditions restrict the use of other monitors or for short-term use, as necessary, to ensure effective control of the spread of contamination.

Hand and foot monitors – These devices typically consist of multiple detectors arranged to monitor only hands and feet. Instructions for the use of these monitors will be prominently posted on or near the instrument. Hand and foot monitors will be used in applications where pass-throughs are frequent and where hand and foot monitoring is the major requirement.

Portal monitors – Portal monitors can quickly scan large surface areas of the body. Portal monitors will typically use large area beta and/or gamma sensitive detectors to monitor personnel passing through. Additional detectors will be provided to monitor the hands, head, and feet. These monitors may be used where the number of personnel exiting an area, available space, etc., makes their use advantageous.

11.1.4.1.2 Air Monitoring

Continuous air monitors (CAM) will be provided within the RPF to provide indication of airborne activity. The CAMs will be operated to collect continuous samples. Portable CAMs may also be deployed when deemed necessary (e.g., non-standard maintenance activities). CAMs will be equipped with alarms. The alarm will be activated when airborne radioactivity levels exceed predetermined limits. The limits will be set with consideration given to both toxicity and radioactivity. The volume of air sampled may have to be adjusted to ensure adequate sensitivity with minimum sampling time. The operating history of the facility, along with changes in technology, room functions and design, and regulations, may necessitate adjustment of the monitors.

The exhaust stacks will be provided with continuous monitors for noble gases, particulate, and iodine. The stack monitoring system design basis is to continuously monitor the radioactive stack releases. Additional information on air monitoring will be provided in the Operating License Application.

11.1.4.1.3 Radioactive Liquid Monitoring

The RPF will not discharge radioactive liquids; therefore, the RPF will not have liquid effluent monitors. The monitoring of liquids within the RPF process systems is discussed in Chapter 4.0.

11.1.4.2 Technical Specifications

Technical specifications associated with the contamination control are provided in Chapter 14.0, "Technical Specifications" and will be developed as part of the Operating License Application.

11.1.5 Radiation Exposure Control and Dosimeter

The RPF is designed to prevent uncontrolled radiation releases to work areas or the environment during normal operations. This is accomplished through the process design and shielding discussed in Chapter 4.0 and the facility HVAC system design discussed in Chapter 9.0.

The goal of maintaining occupational internal and external radiation exposures ALARA encompasses an individual's dose and the collective dose of the entire working population. Because the TEDE is the sum of the internal and external exposures, the radiation protection program addresses both contamination control and external radiation protection. The following sections provide examples of how the RPF is designed to incorporate ALARA principles.

11.1.5.1 Process Design for ALARA

Examples of process design and operating considerations that will be implemented to reduce personnel radiation exposures include the following:

- Processing irradiated targets and purification of ^{99}Mo under subatmospheric pressure (additional details are provided in Chapter 9.0, Section 9.1)
- Limiting constant direct contact of personnel with radiological materials (additional detail provided in Chapter 4.0, Section 4.2)
- Ensuring equipment and components are designed to include reliability, availability, maintainability, inspectability, constructability, and other design features to reduce or eliminate the need for repair or preventive maintenance
- Providing design redundancy of equipment or components to reduce the need for immediate repair when radiation levels may be high or when there is no feasible method available to reduce radiation levels

- Designing equipment and piping to minimize the accumulation of radioactive materials
- Providing for draining, flushing, or, if necessary, remote cleaning or decontamination of equipment containing radioactive materials
- Designing airflow rates at exhausted enclosures and close-capture points, when in use, to preclude escape of airborne radioactive gases and particles and to minimize the potential for intake by workers. Airflow rates will be checked monthly when in use and after modification of any hood, exhausted enclosure, close-capture point equipment, or ventilation system serving these barriers. Additional detail is provided in Chapter 9.0, Section 9.1.
- Handling accidental radioactive contamination by using the personnel decontamination room. A hand-washing sink and a shower will be provided for contamination removal.

11.1.5.2 Facility Design for ALARA

Examples of facility design and operating considerations that are being implemented to reduce personnel radiation exposures include the following:

- Incorporating ease of maintenance or repair, including ease of disassembly and modularization of components for replacement or removal to a lower radiation area for repair or disposal
- Providing the ability to remotely or mechanically operate, repair, service, monitor, or inspect equipment
- Laying out the facility so that access to a given area does not require passing through a higher radiation zone area
- Providing the ability to operate equipment from accessible areas both during normal and off-normal operating conditions
- Providing areas outside of high radiation areas that equipment can be moved to for service
- Incorporating ease of decontamination of potentially contaminated areas
- Providing control systems so that process controls (e.g., essential instrumentation and controls) will be from the lowest radiation zone practicable
- Controlling HVAC system contamination by maintaining ventilation air flow patterns from areas of lower radioactivity to areas of higher radioactivity
- Requiring self-monitoring when exiting restricted areas; if contamination is detected, facility personnel will be required to notify radiation protection staff
- Training facility personnel in emergency evacuation procedures per the Emergency Preparedness Plan (Chapter 12.0, Appendix B)

All personnel whose duties require entry into restricted areas will wear individual external dosimetry devices (e.g., passive dosimeters such as thermoluminescent dosimeters [TLD] that are sensitive to beta, gamma, and neutron radiation). External dosimetry devices will be evaluated at least quarterly to ascertain external exposures.

11.1.5.3 Control of Entry

The RPF will include areas locked to limit access, and alarms and signals that alert workers to or prevent unauthorized entry into radiation areas, high radiation areas, and very high radiation areas. Additional information on control of entry will be provided in the Operating License Application.

As shown in Section 11.1.5.5.2, Figure 11-5, the entire RFP is considered a "controlled area." Figure 11-2 shows five doors from the outside of the RFP to entrances into the "restricted area." Each door will have two credential access controls (e.g., fob/PIN, fob/biometric, or biometric/PIN). The RPF radiation protection program will require personnel to access assigned dosimetry and portable survey instrumentation (as needed, based on the work authorized) from an as-yet unspecified location within the RPF administrative area before entering the restricted area. Portal survey monitoring will be in place at the exit from the restricted area into the administrative area. The specifics on the type and instrument used will be described in the FSAR as part of the Operating License Application and will either be a control that allows standing passive detection or hand and foot monitors.

11.1.5.4 Protective Equipment and Materials

Personnel working within the restricted area will be required to wear appropriate personal protective clothing. Protective clothing, as prescribed by the RWP, will be selected based on the contamination level in the work area, anticipated work activity, worker health considerations, and consideration for nonradiological hazards present. Protective clothing of the following types will be made readily available as necessary:

- Cloth and disposable coveralls
- Nonpermeable coveralls (plastic/rubberized)
- Rubber and disposable shoe covers
- Rubber and disposable gloves
- Cotton liners
- Cloth and disposable hoods
- Full-face particulate respirators
- Eye goggles
- Face shields
- Supplied-air respirators
- Self-contained breathing apparatus

Areas requiring protective clothing will be posted at each of the associated entry points. Radiation protection management and technical staff will be responsible for determining the need for protective clothing in each work area and documenting the requirements in the RWP.

Based on air sampling results and work evolutions, the Radiological Protection Manager will select the appropriate respiratory protection required. Airborne radioactivity concentrations will be minimized to the extent practical by the use of engineered controls (e.g., containment, ventilation). When establishing radiological controls for work involving potential airborne radioactivity, the first consideration will be to use techniques that help prevent or reduce the potential for airborne radioactivity and maintain loose surface contamination in controlled areas within ALARA levels. Respiratory protection equipment requirements will be specified on the area RWP.

10 CFR 20, Subpart H, "Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas," defines the required elements of the facility respiratory protection program. Additional information on implementing and maintaining the respirator program are provided in Section 11.3.

11.1.5.5 Radiological Areas

Radiological areas will be established to control (1) the spread of contamination, (2) personnel access to avoid unnecessary exposure of personnel to radiation, and (3) access to radioactive sources present in the facility. Table 11-5 lists the general dose rate estimates for the RPF. These dose estimates are based on shielding calculations (NWMI-2015-SHIELD-001, *Radioisotope Production Facility Shielding Analysis*). Areas where facility personnel spend substantial amounts of time are designed, in accordance with ALARA principles, to minimize the exposure received when routine tasks are performed.

The radiological areas within the RPF are shown in Figure 11-2 through Figure 11-4 (Section 11.1.3.2). The following subsections provide the definitions of each of these areas and a description of how the RPF radiation protection program will be implemented to protect workers and the public.

11.1.5.5.1 Restricted Areas

The NRC defines a restricted area as an area in which access is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Within the RPF, access to and egress from a restricted area will be through a radiation protection control point. Monitoring equipment will be located at these points. All personnel will be required to self-monitor prior to exiting restricted areas that have the potential for contamination. Personnel who have not been trained in radiation protection procedures will not be allowed to access a restricted area without escort by trained personnel.

Additional temporary or permanent areas may be defined within the restricted area, including radiation areas, high radiation areas, airborne radioactivity areas, and contaminated areas. The radiation areas shown in Figure 11-2, Figure 11-3, and Figure 11-4 comprise the restricted areas within the RPF. These areas are defined in 10 CFR 20.1003, "Definitions." The entire basement and second story areas will be restricted. The areas will be posted in accordance with the requirements of 10 CFR 20 to inform workers of the potential hazards in the area and to help prevent the spread of contamination.

Radiation area – A radiation area (shown in green in Section 11.1.3.2, Figure 11-2 and Figure 11-3) is where radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (5 mrem) in 1 hr at 30 centimeters (cm) (11.8 in.) from the radiation source or from any surface that the radiation penetrates.

High radiation area – A high radiation area (shown in tan in Figure 11-2 and Figure 11-3) is an area accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 1 mSv (100 mrem) in 1 hr at 30 cm (11.8 in.) from the radiation source or from any surface that the radiation penetrates. Within the RPF, these areas will not normally be accessible to individuals during routine operations.

Very high radiation area – The NRC defines very high radiation areas (shown in pink in Figure 11-2, Figure 11-3, and Figure 11-4) as areas accessible to individuals, in which radiation levels exceed 5 sievert (Sv) (500 rem) in 1 hr at 1 m from the source or from any surface that the radiation penetrates (10 CFR 20.1003). The hot cells within the RPF (not normally accessible) are an example of a very high radiation area. The hot cells will be radiologically shielded and isolated from access to individuals by the use of engineered physical barriers, including structural shield blocks and locked shield doors.

Airborne radioactivity area – An airborne radioactive area is an area, room, or enclosure where airborne radioactive materials either exist in concentrations that exceed the derived air concentrations (DAC) specified in 10 CFR 20, Appendix B, or where an individual present in the area without respiratory protection equipment could exceed, during the hours the individual is present in a week, an intake of 0.6 percent of the annual limit on intake or 12 DAC-hr. There are no identified permanent airborne radioactive areas with the RPF.

11.1.5.5.2 Controlled Area

The NRC defines a controlled area as an area outside of a restricted area but inside the site boundary, in which the licensee can limit access for any reason. For the RPF, the controlled area is the area within the perimeter fence but outside the restricted area and the Administrative Building, as shown in Figure 11-5. The area fence will limit public access to the controlled area of the site. Training for access to a controlled area will be provided commensurate with the radiological hazard.

Site visitors will include delivery people, site visitors, and service personnel who are temporary, transient occupants of the controlled area. Area monitoring will demonstrate compliance with public exposure limits for such visitors. All NWMI personnel or contractor employees who work only in the controlled area will be subject to the exposure limits for the public, as stated in 10 CFR 20.1301.

Figure 11-5. Controlled and Unrestricted Areas

Details on the area monitoring program will be provided in the FSAR as part of the Operating License Application. Area monitoring is anticipated to comprise a combination of passive (e.g., TLD or OSL monitors changed out monthly or quarterly) and active (e.g., energy-compensated G-M detector systems with local and remote monitoring capability) monitoring systems located at points in the controlled area that will provide reasonable assurance that radiation areas are not present in the controlled area. The selection of specific instrumentation, range of detection, and alert/alarm setpoints will be consistent with the intent to detect radiation in areas where it should not be and alert personnel to this changing condition.

11.1.5.5.3 Unrestricted Areas

The NRC defines an unrestricted area as an area that is not controlled or limited by the licensee. For the RPF, the areas not specifically included within the definition of restricted and controlled areas will be considered unrestricted areas, as shown in Figure 11-5. These areas can be accessed by facility personnel and by the public. The unrestricted area is governed by the limits in 10 CFR 20.1301, with the TEDE to individuals from the licensed operation not to exceed 1 mSv (100 mrem) in a year (exclusive of background radiation) nor exceed 0.02 mSv (2 mrem) in any one hour.

11.1.5.6 Personnel Monitoring and Assessment of Internal and External Dose

The following subsections describe personnel monitoring and provide an assessment of internal and external dose.

11.1.5.6.1 Internal Dose

Internal exposures for selected personnel are evaluated via direct bioassay (e.g. in vivo body counting), indirect bioassay (e.g., urinalysis), or an equivalent technique.

For soluble (Class D) uranium, 10 CFR 20.1201(e) limits worker intake to no more than 10 milligrams (mg) of soluble uranium in a week. This limit is to protect workers from the toxic chemical effects of inhaling Class D uranium. The RPF annual administrative limit for the TEDE will be 0.02 Sv (2 rem). Internal doses will be evaluated at least annually.

Continuous air monitoring in airborne radioactivity areas may be performed to complement the bioassay program. Alarm setpoints on the CAMs in the airborne radioactivity areas may be used to provide an indication that internal exposures may be approaching the action limit.

If the facility annual administrative limit is exceeded, as determined from bioassay results, an investigation will be performed to determine what types of activities may have contributed to the worker's internal exposure. The action limit is based on ALARA principles. This investigation may include procedural reviews, efficiency studies of the air-handling system, and work practices, and the results will be documented.

11.1.5.6.2 External Dose

External dose will primarily be received from the fission products produced from irradiated targets and associated processing. The radionuclides of significance are identified in Section 11.1.1. All personnel whose duties require entry into restricted areas will wear individual external dosimetry devices (e.g., passive dosimeters such as TLDs that are sensitive to beta, gamma, and neutron radiation). External dosimetry devices will be evaluated at least quarterly to ascertain external exposures. The ALARA goal on radiation exposure is set at 5 mSv/yr (500 mrem/yr) based on an administrative limit of 10 percent of the NRC limit of 0.05 Sv/yr (5 rem/yr) given in 10 CFR 20.1201.

If 25 percent of the ALARA goal (1.25 mSv [125 mrem]) is exceeded in any quarter, an investigation will be performed to determine what types of activities may have contributed to the worker's external exposure. This investigation may include procedural reviews, efficiency studies of the air-handling system, cylinder storage protocol, and work practices, and the results will be documented.

The Radiation Protection Manager will be informed whenever an administrative limit is exceeded. The Radiation Protection Manager will be responsible for determining the need for and recommending investigations or corrective actions to the responsible manager(s). Copies of the Radiation Protection Manager's recommendations will be provided to the Radiation Safety Committee.

11.1.6 Contamination Control

Contamination will consist of two types:

- **Loose (removable) contamination**, which can be removed from surfaces by smears and may contribute to airborne radioactivity and/or personnel contamination from routine activities. Loose contamination poses both an internal and external radiation hazard.
- **Fixed contamination**, which is not smearable and may only be reduced by using approved decontamination techniques, procedures, and equipment. Fixed contamination does not readily contribute to airborne radioactivity and/or personnel contamination from routine activities. Fixed contamination poses an external radiation hazard.

When establishing radiological controls for work involving potential loose or airborne contamination, the first consideration is to use techniques that will help prevent or reduce the potential for airborne radioactivity and to maintain loose surface contamination in controlled areas within ALARA levels.

11.1.6.1 Routine Monitoring to Detect Contamination

Contamination survey monitoring will be performed for all process areas and areas in which radioactive materials are handled or stored. Surveys will include routine checks of non-process areas, including areas normally not contaminated. Monitoring will include direct radiation and removable contamination measurements. Survey procedures will be based on the potential for contamination of an area and operational experience. All restricted areas will be surveyed at least weekly.

The change rooms will be surveyed at least daily. Various instruments (e.g., proportional counters and thin window G-M tubes) will be used at the RPF to evaluate contamination levels. Additional information on routine contamination survey monitoring will be provided in the Operating License Application.

11.1.6.2 Access Control to Contaminated Areas

The access control program will be established to ensure that:

- Signs, labels, and other access controls are properly posted and operative
- Restricted areas prevent spread of contamination and have appropriate signage
- Step-off pads, change facilities, protective clothing facilities, and personnel monitoring instruments are provided in sufficient quantities and locations

For other areas, access control will be managed by administrative methods. Access to certain areas may be physically prevented for security reasons. Personnel who have not been trained in radiation protection procedures will not be allowed access to a restricted area without escort by other trained personnel.

Access to and egress from a restricted area will be through one of the monitor stations at the particular restricted area boundary. Access to and egress from each radiation area, contaminated area, or airborne radioactivity area within the restricted area may also be individually controlled. A contamination monitor (e.g., frisker, hand and foot monitor, or portal monitor), step-off pad, and container for any discarded protective clothing may be provided at the egress point from certain areas to prevent the spread of contamination.

Action levels for skin and personal clothing contamination at the point of egress from restricted areas and any additional designated areas within the restricted area (e.g., a contaminated area that is provided with a step-off pad and contamination monitor) will not exceed 2.5 becquerel (Bq)/100 square centimeter (cm^2) (150 disintegrations per minute [dpm]/100 cm^2) alpha or beta/gamma contamination (corrected for background).

Clothing contaminated above egress limits will not be released unless laundered to within these limits. If skin or other parts of the body are contaminated above egress limits, reasonable steps that exclude abrasion or other damage will be undertaken to effect decontamination.

Areas that are designated as high radiation and very high radiation areas will not be accessible to individuals during routine operation of the RPF. These areas will be radiologically shielded and isolated from access to individuals by the use of engineered physical barriers that include structural shield blocks and/or locked shield doors.

11.1.6.3 Anti-Contamination Techniques

The RPF is designed to limit contamination, with processes and equipment that contain radioactive material designed to require as little maintenance as possible to ensure personnel radiation exposures are ALARA. Additional exposure reductions will be achieved by:

- Removing as much radioactive material as possible from equipment and area prior to maintenance, thereby reducing the intensity of the radiation field
- Providing adequate space for ease of maintenance to reduce the length of time required to complete the task, thereby reducing time of exposure
- Preparing and using procedures that include specifications for tools and equipment needed to complete assigned work activities
- Conducting proper job planning, including practice on mockups

- Reviewing previous similar jobs
- Identifying highest contamination areas and communicating that information to workers prior to start of work.

11.1.6.4 Monitoring and Handling Contaminated Equipment and Components Outside Contaminated Areas

The RPF processes and equipment that contain radioactive material are designed to require as little maintenance as possible to ensure that personnel radiation exposures are ALARA. Additional contamination controls are described in Section 11.1.6.3.

11.1.6.5 Criteria for Classification of Contaminated Material, Equipment, and Working Areas

Contaminated material and equipment that are removed from a restricted area will be appropriately packaged in preapproved containers, inventoried, and monitored prior to release. The specific criteria for classifying contaminated materials and equipment will be provided in the Operating License Application. Classification of the working areas is provided in Section 11.1.5.5.

11.1.6.6 Training Programs

Details on the training program associated with the radiation protection program are discussed in Section 11.1.2.5.

11.1.6.7 Recordkeeping

Recordkeeping requirements associated with the radiation protection program are discussed in Section 11.1.2.9.

11.1.6.8 Technical Specifications

As determined in Chapter 13.0, "Accident Analysis," the RPF is designed to control contamination consistent with occupational safety and protection of the public and environment. Contamination control will likely not require a technical specification.

11.1.7 Environmental Monitoring

The RPF radiological environmental monitoring program will meet 10 CFR 20.1302. The radiological environmental monitoring program will be used to verify:

- Effectiveness of plant measures are used to control release of radioactive material
- Measurable concentrations of radioactive materials and levels of radiation are not higher than expected based on effluent measurements and modeling of environmental exposure pathways.

Methods for establishing and conducting environmental monitoring are provided in Regulatory Guide 4.1, *Radiological Environmental Monitoring for Nuclear Power Plants*. Regulatory Guide 4.1 refers to NUREG-1301, *Offsite Dose Calculation Manual Guidance: Standard Radiological Effluent Controls for Pressurized Water Reactors*, for detailed guidance on conducting effluent and environmental monitoring. Although Regulatory Guide 4.1 and NUREG-1301 are written for nuclear power plants, due to the similarities between airborne releases of radioactivity from nuclear power plants and those released from the RPF, the guidance provided in Regulatory Guide 4.1 and NUREG-1301 was considered when developing radiological environmental monitoring for the RPF. Specifically, guidance provided in Figure 1 of Regulatory Guide 4.1 and Table 3.12-1 of NUREG-1301 was considered when determining which exposure pathways to sample, sample locations, types of samples, and sample frequencies for the RPF.

11.1.7.1 Verification of Compliance

Environmental monitoring data will be compared against permits and environmental reports, as appropriate, to ensure compliance. As described above, methods for establishing and conducting environmental monitoring are provided in Regulatory Guide 4.1. Regulatory Guide 4.1 refers to NUREG-1301 for detailed guidance on conducting effluent and environmental monitoring.

11.1.7.2 Identification of Potential Impacts

Potential impacts of the RPF on the environment are addressed in Chapter 19.0, "Environmental Review."

11.1.7.3 Establishment of Baseline Environmental Quality

Background radiation values will be obtained during the baseline environmental survey by monitoring TLDs at multiple locations (Section 11.1.7.4.2). This survey will be conducted prior to construction and prior to RPF operation.

11.1.7.4 Environmental Surveillance Program

The following radiation exposure pathways will be considered for monitoring under the NWMI radiological environmental monitoring program:

- Waterborne exposure pathway
- Direct radiation exposure pathway monitoring using TLDs
- Airborne exposure pathway monitored using continuous air samples
- Ingestion exposure pathway

11.1.7.4.1 Waterborne Exposure Pathway Monitoring

The proposed RPF is designed to have zero liquid discharge from the radiologically controlled area, with no release of water from the facility to the adjacent environment that would affect surface water (e.g., Gans Creek). As such, surface water sampling will not be included in the radiological environmental monitoring plan. Similarly, aquatic life in the rivers is not expected to accumulate detectable levels of radioactivity, and sampling of fish or other aquatic creatures for the ingestion pathway will not be included in the radiological environmental monitoring plan.

The groundwater aquifer beneath the proposed RPF site is the Mississippian aquifer (also referred to as the Kimmswick-Potosi aquifer), which is discussed in detail in Chapter 19.0, Section 19.3.4.2. There are no defined liquid effluent release pathways, and the groundwater is not expected to be contaminated due to operation of the RPF. Therefore, groundwater sampling will not be included in the radiological environmental monitoring plan.

11.1.7.4.2 Direct Exposure Pathway Monitoring

TLDs will provide measurements of direct radiation from radioactive materials located at the RPF, radioactivity in airborne effluent, and deposition of airborne radioactivity onto the ground. NUREG-1301 recommends 40 TLD locations, consisting of an inner ring and outer ring of TLDs, with one TLD located in each ring at each of the 16 meteorological sectors (i.e., a total of 32 TLDs) and the remainder located at special interest areas. NUREG-1301 also recommends that at least one TLD be located a significant distance from the facility as a control station to measure background radiation dose.

At the RPF, seven TLDs will be located outside at entry points to the building where personnel may congregate or spend time outside of the RPF building. An additional TLD will be located on the outside wall near the target fabrication area to evaluate direct radiation from the hot cells and waste management area. The location of the on-site TLDs is shown in Figure 11-6.

Figure 11-6. Location of On-Site Environmental Thermoluminescent Dosimeters and Continuous Air Monitors

TLDs will also be located at the site boundary (the perimeter of the lot) to evaluate the direct radiation dose. Sixteen TLDs will be placed on the lot line, with a TLD placed at all four corners of Lot 15, and the remaining TLDs placed at approximately equal distances from each other. The sixteen TLDs will provide adequate coverage to ensure that direct doses to neighboring facilities on adjoining lots can be monitored and evaluated. The location of the perimeter TLDs is shown in Figure 11-6.

An additional TLD will serve as a control and will be located offsite at a significant distance from the RPF such that it represents a background dose. One TLD location will be provided with two TLDs so that data quality can be determined.

11.1.7.4.3 Airborne Exposure Pathway Monitoring

Airborne effluent releases from the RPF will contribute to off-site doses. The airborne effluent exhaust from the vent stacks is expected to contain measurable quantities of noble gas radioactivity (e.g., Xe and Kr). Radioactive iodine, radioactive particulates, and tritium could also be present in the airborne effluent exhaust. However, most of the off-site exposure due to airborne effluent releases will be associated with noble gas and radioactive iodine releases. The tritium release rate would be a small fraction of the noble gas rates provided in Table 11-2 (several orders of magnitude less). The dose contribution from tritium would be a small fraction of the dose contributions, and the total public dose from all routine gaseous releases including tritium would remain well below 10 CFR 20 limits.

The final facility design strategy is to route the air stream from the evaporation tanks into the Zone I exhaust system. The Zone I exhaust stack will have continuous monitoring.

Environmental airborne sampling will be performed to identify and quantify particulates and radioactive iodine in airborne effluents. Regulatory Position C.3.b of Regulatory Guide 4.1 indicates that airborne sampling should always be included in the environmental monitoring programs for nuclear power plants. Since the RPF includes airborne effluent releases and radioactivity in the airborne effluent can result in measurable off-site doses, the radiological environmental monitoring program will include airborne sampling.

The guidance provided in Table 3.12-1 of NUREG-1301 was used to establish locations for airborne sample acquisition, sampling frequency, and type of sample analysis. Continuous air sample locations will be specified in accordance with the guidance provided in Table 3.12-1 of NUREG-1301. The CAMs that are used to obtain continuous air samples will include a radioiodine canister for weekly iodine-131 (^{131}I) analysis, and a particulate sampler that is analyzed for gross beta activity and for quarterly isotopic analysis.

Four CAMs (air samplers) will be located near the facility fence line, with one CAM being located in the direction of the prevailing wind (e.g., north-northwest) and the other three CAMs being located in the remaining cardinal directions (e.g., 90 degrees) from the first CAM location (i.e., west-southwest, south-southeast, and east-northeast). The CAM locations are shown in Figure 11-6. An additional CAM will be located a sufficient distance from the RPF, in the least prevalent wind direction, to provide background information for airborne activity.

11.1.7.4.4 Ingestion Exposure Pathway Monitoring

NUREG-1301 suggests sampling of various biological media (biota monitoring) to indirectly assess doses due to particulate and iodine ingestion. This type of monitoring may include sampling of soils and broad-leafed plants, fish, meat, or milk. Considering that particulates and iodine radionuclides are not expected to be present in measurable quantities within the RPF airborne effluent releases, biota monitoring will not be performed. In the event that environmental airborne sample results indicate the presence of iodine or particulates in measurable quantities, or if the effluent monitor sample results indicate the presence of iodine or particulates in quantities large enough to result in a calculated dose at the property line that exceeds 10 percent of the dose constraint (i.e., 1 mrem/yr), a sampling campaign will be undertaken.

Milk is an important food product that contributes to the radiation dose to people, most notably from radioactive iodine. If biota sampling is determined to be required as a result of radioactive iodine and particulate activity measured during effluent monitoring or air sampling, milk sampling will be performed following the guidance provided in Table 3.12-1 of NUREG-1301 (e.g., sampling frequency and type of sample analysis). Cow and/or goat milk samples will be obtained from dairy production sites on a semi-monthly basis (when animals are on pasture) and on a monthly basis (at other times). A gamma isotopic analysis and ^{131}I analysis will be performed on the samples. Since milk samples are considered a better indicator of radioactive iodine in the environment than vegetation, as long as milk samples are obtained, vegetation sampling (e.g., broad leaf vegetation) is not expected to be included in the exposure pathway sampling, in accordance with guidance provided in Table 3.12-1 of NUREG-1301.

11.2 RADIOACTIVE WASTE MANAGEMENT

Radioactive waste management activities associated with the RPF liquid, gaseous, and solid waste systems will be performed in accordance with approved written procedures. A detailed description of the sources, types, and approximate quantities of waste within the proposed RPF is provided in Chapter 19.0, Section 19.2.7.

The Plant Manager will have responsibility for preparation and implementation of the radioactive waste management procedures.

11.2.1 Radioactive Waste Management Program

The following subsections provide a description of the radioactive waste management program, including the philosophy and objectives. Organizational information is provided relative to the Waste Management organization. A detailed NWMI organization chart is provided in Chapter 12.0, Section 12.1.

The waste management program will be coordinated with the radiation protection program, and program management will report to the Plant Manager. Section 11.1 describes the program and procedures for controlling and assessing radioactive exposures associated with radioactive sources, including radioactive waste streams.

The goal of the waste management program is to minimize waste generation, minimize exposure of personnel, and to protect the public and environment. An official charter describing the authority, duties, and responsibilities of personnel in the Waste Management organization will be described in the FSAR as part of the Operating License Application.

11.2.1.1 Waste Management Policy

NWMI management is committed to the ALARA philosophy for radioactive waste management. NWMI's policy is to conduct waste management operations in a manner that ensures the health and safety of employees, contractors, and the public, and to comply with all Federal, State, and local laws and regulations for generation, storage, packaging, transportation, and disposal of wastes generated at the RPF.

11.2.1.2 Waste Management Procedures

Radioactive waste management procedures will be developed and reviewed in accordance with the RPF procedure program, as discussed in Chapter 12.0, Section 12.3. These procedures will provide for the efficient and safe conduct of operations of the waste management program. Additional information on waste management procedures will be provided in the Operating License Application.

11.2.1.3 Organizational Responsibilities

11.2.1.3.1 Plant Manager

The Plant Manager will report to the COO and have direct responsibility for the safe operation of the RPF, including the protection of workers and the public against radiation exposure resulting from facility operations and materials. Other responsibilities will include:

- Ensuring compliance with applicable NRC, State, and local regulations and license/permits
- Implementing the RPF conduct of operations program
- Establishing and managing the required training programs to support the operations organization

11.2.1.3.2 Waste Management Manager

The Waste Management Manager will report to the Plant Manager and have responsibility for the following:

- Implementing waste management policy
- Developing waste management procedures for the processing, packaging, and shipment of radioactive waste from the facility
- Processing, packaging, and shipping radioactive waste from the facility
- Providing technical input to the design of equipment and processes
- Providing technical input to the waste management training program
- Establishing and maintaining contractual relationships with waste disposal sites and radioactive waste carriers
- Maintaining working knowledge of the waste acceptance criteria, standards, guides, and codes with respect to waste disposal
- Conducting self-assessments of waste management practices and ensuring compliance with procedures in accordance with the waste management self-assessment program

11.2.1.4 Training

The radioactive waste management training program will be closely coordinated with the radiation protection training program to emphasize the importance placed on radiological safety of RPF personnel and the public. In-depth waste management training will be provided for the various types of job functions (e.g., operator, waste technician, and waste shipper) commensurate with responsibilities associated with each position and conducted in accordance with the procedures defined in Chapter 12.0. Additional information on training will be provided in the Operating License Application.

11.2.1.5 Document Control and Recordkeeping

Document control and recordkeeping will be in accordance with the procedures defined in the QAPP (Chapter 12.0, Appendix C) and will include waste manifests, audits, and program reviews. Additional information on document control and recordkeeping will be provided in the Operating License Application.

11.2.1.6 Reviews and Audits

Audits of the RPF radioactive waste management program will be conducted, at a minimum, on an annual basis to review the functional and safety elements of the waste management program. An additional component of these audits will be to evaluate efforts to minimize the production of radioactive wastes. Additional detail on the NWMI review and audit function is provided in Chapter 12.0.

11.2.1.7 Technical Specifications

As discussed in Chapter 13.0, the RPF waste management processes are designed with a focus on occupational safety and protection of the public and the environment. The technical specifications associated with waste management area, if applicable, will be discussed in Chapter 14.0 as part of the Operating License Application.

11.2.2 Radioactive Waste Management Controls

The NRC divides low-level radioactive waste into three different classes: A, B, and C. These classes are based on waste concentration and the half-lives and types of radionuclides in the waste.

- **Class A** – Waste consisting of radionuclides with the shortest half-lives and lowest concentrations, with radioactivity levels that return to background levels within 100 years
- **Classes B and C** – Waste containing greater concentrations of radionuclides with longer half-lives, fading to background levels in less than 500 years (must meet stricter disposal requirements than Class A waste)
- **Greater than Class C** – Waste exceeds the requirements for Class C waste and is the responsibility of the U.S. Department of Energy under Federal law

Descriptions of the RPF processes that will produce radioactive waste are provided in Chapter 4.0. NWMI will implement pollution prevention and waste minimization activities that review associated processes and procedures to ensure that the kinds and amounts of waste generated are minimized.

Waste management control will include methods to:

- Avoid inadvertent exposure of personnel or uncontrolled escape of the radioactive materials
- Maintain continuous control of radioactive materials that require treatment and management as waste

11.2.2.1 Waste Designation

The RPF will generate class A, B, and C low-level radioactive waste. Greater than Class C waste will not be produced in the RPF. The Class A waste is low-dose waste, while Class B and C wastes are high-dose waste. The solidified high-dose liquid waste from the RPF will be either Class B or Class C waste. As a result of reducing the waste volume and minimizing disposal costs, the liquid waste concentration endpoint may result in a change in the final waste classification from Class B to Class C.

The waste handling system for the generated wastes is discussed in Chapter 9.0, Section 9.7.4. High-dose liquids will be designated as waste once the liquids are collected in the waste concentrate collection tank. The low-dose condensate from the high-dose concentrator held in the condensate collection tank will be used as much as practical by the uranium recovery process. Low-dose liquids will be designated as waste once the liquids are collected in the low-dose evaporation tank. Solids will be designated as waste once the solid materials are loaded into waste drums.

11.2.2.2 Waste Management Procedures

Radioactive waste management operating procedures are discussed in Section 11.2.1.2. These procedures ensure proper identification, characterization, and separate treatment of radioactive wastes. Additional information on waste management procedures will be provided in the Operating License Application.

11.2.2.3 Airborne Radioactive Waste Management

The RPF will not directly produce airborne radioactive waste. Chapter 9.0, Section 9.1, provides a detailed description of the process vessel vent system and the Zone I and Zone II HVAC treatment systems. Liquid waste resulting from these processes will be directed to the high-dose waste collection tank and processed through the high-dose waste treatment system, where the waste will be solidified.

11.2.3 Release of Radioactive Waste

This section discusses the methods used to identify, characterize, package, and transport waste offsite from the RPF. The majority of the radioactive waste being shipped from the RPF will require special containers to provide for the protection of the public and environment. Each of these containers is designed to meet applicable NRC and U.S. Department of Transportation (DOT) standards. In general, waste released from the RPF will be processed and packaged to meet the waste acceptance criteria of an established disposal facility. The processing and packaging of routine waste is described in Chapter 9.0, Section 9.7.4. Table 11-6 summarizes the types waste generated and annual generation rate for the RPF.

Table 11-6. Waste Produced in the Radioisotope Production Facility

Description[a]	Matrix	Class	Annual generation
High-dose[b,c,d]	Solid	B or C	200,000 L (52,834 gal)
Low-dose[b,c]	Solid	A	150,000 L (39,625 gal)
Target cladding materials from disassembly encapsulated in cement	Solid	C	1,100 L (290 gal)
Exchange resins and other solid waste	Solid	C	1,370 L (365 gal)
Solid wastes encapsulated in cement	Solid	A	8,000 L (2,113 gal)
HEPA filters	Solid	A or C	28 m^3 (977 ft^3)
Carbon	Solid	A or C	0.14 m^3 (5.1 ft^3)[e]
Iodine absorption	Solid	C	0.06 m^3 (2.1 ft^3)[f]
Facility support waste (non-rad)	Solid	N/A	26,000 L (6,868 gal)
Facility support waste (rad)	Solid	A	40,000 L (10,566 gal)
Silicone oil	Liquid	A	100 L (26 gal)
Lab pack	Liquid	A	10 L (2.6 gal)
Solvent	Liquid	A	200 L (53 gal)

[a] Special nuclear material is not considered a waste. SNM will be returned to the U recovery and recycle system, purified, and reused. In addition, waste volume projections are based on the composite values from the MURR and OSTR mass balance calculations that assume an eight-target/week MURR processing rate plus a 30-target/week OSTR processing rate and will bound the planned operations.

[b] Caustic soda (NaOH) is included in the waste volume estimates.

[c] Waste solidification agents are included in the waste volume estimates.

[d] Nongaseous long-lived radioisotopes are contained in the high-dose liquid waste stream that is solidified and eventually sent offsite for disposal.

[e] Volume represents changeout of carbon beds every two years (1/2).

[f] Volume represent changeout of iodine absorption beds every five years (1/5).

HEPA = high-efficiency particulate air.
MURR = University of Missouri Research Reactor.
N/A = not applicable.
NaOH = sodium hydroxide
OSTR = Oregon State University TRIGA Reactor
SNM = special nuclear material.
U = uranium.

11.2.3.1 Solid Radioactive Waste

The majority of solid waste produced in the RPF will be the high- and low-dose waste discussed in Chapter 9.0. Samples of this waste will be analyzed in the RPF laboratory to ensure that the waste meets the disposal facility waste acceptance criteria. This waste will be stored for radioactive decay to meet shipping and disposal requirements, and then packaged in approved transportation casks for transport to the disposal facility.

The RPF will also produce intermittent waste that includes HEPA filters, carbon absorption beds, and zeolite absorption beds. Samples of these wastes will be analyzed within the RPF laboratory to ensure that the waste meets the disposal facility waste acceptance criteria. These wastes will be encapsulated and packaged in appropriate waste containers for disposal. Depending on the location and use, HEPA filters are anticipated to have a changeout frequency from monthly to every 2 years. The iodine adsorber beds are designed to last 5 years before requiring changeout. Carbon beds have a 2-year design life.

Table 11-7, Table 11-8, and Table 11-9 list the low-dose radioactive waste sources, high-dose radioactive waste sources, and encapsulated solid radioactive waste sources, respectively.

11.2.3.2 Liquid Radioactive Waste

The RPF does not release any radioactive liquid waste. As discussed in Chapter 9.0, Section 9.7, high- and low-dose liquid waste will be solidified prior to release.

11.2.3.3 Gaseous Radioactive Waste

Gases from the RPF process and HVAC system will be processed as described in Chapters 4.0 and 9.0, respectively. The offgas system is designed to filter and/or retain these isotopes in the facility until the resulting release is at levels less than those defined in Table 2 of 10 CFR 20, Appendix B. The gaseous radioactive emissions will be released through the RPF's three exhaust stacks. Monitoring of the effluent is described in Section 11.1.4.1.2.

Table 11-7. Low-Dose Radioactive Waste Sources

Isotope	Radioactivity (Ci/wk)	Isotope	Radioactivity (Ci/wk)	Isotope	Radioactivity (Ci/wk)
^{241}Am	2.26E-15	^{239}Np	6.92E-04	^{89}Sr	8.91E-03
^{136m}Ba	1.77E-06	^{233}Pa	1.08E-11	^{90}Sr	7.44E-05
^{137m}Ba	7.11E-05	^{234}Pa	4.10E-11	^{91}Sr	2.00E-17
^{140}Ba	1.75E-02	^{234m}Pa	3.15E-08	^{99}Tc	1.06E-08
^{141}Ce	1.44E-02	^{112}Pd	2.45E-11	^{99m}Tc	7.06E-04
^{143}Ce	4.29E-06	^{147}Pm	2.42E-04	^{125m}Te	2.29E-07
^{144}Ce	2.42E-03	^{148}Pm	8.17E-08	^{127}Te	9.62E-05
^{134}Cs	1.21E-08	^{148m}Pm	1.11E-07	^{127m}Te	2.93E-05
^{136}Cs	1.58E-05	^{149}Pm	3.96E-05	^{129}Te	1.53E-04
^{137}Cs	7.52E-05	^{151}Pm	5.56E-08	^{129m}Te	2.39E-04
^{155}Eu	2.54E-06	^{142}Pr	1.41E-15	^{131}Te	2.31E-08
^{156}Eu	4.67E-05	^{143}Pr	1.89E-02	^{131m}Te	1.03E-07
^{157}Eu	1.95E-14	^{144}Pr	2.42E-03	^{132}Te	1.09E-03
^{129}I	7.96E-12	^{144m}Pr	3.39E-05	^{232}U	7.85E-12
^{130}I	2.36E-18	^{238}Pu	3.37E-11	^{234}U	7.40E-06
^{131}I	4.17E-03	^{239}Pu	9.06E-08	^{235}U	3.38E-07
I132	7.61E-04	^{240}Pu	6.41E-11	^{236}U	1.14E-07
^{133}I	6.88E-09	^{241}Pu	2.31E-11	^{237}U	5.34E-03
^{85}Kr	2.94E-10	^{103m}Rh	6.77E-03	^{238}U	2.13E-07
^{140}La	2.01E-02	^{105}Rh	1.63E-06	^{131m}Xe	3.87E-09
^{99}Mo	3.12E-05	^{106}Rh	1.44E-04	^{133}Xe	2.58E-07
^{95}Nb	4.47E-03	^{103}Ru	6.78E-03	^{133m}Xe	3.20E-10
^{95m}Nb	1.21E-04	^{106}Ru	1.44E-04	^{89m}Y	8.29E-07
^{96}Nb	5.04E-12	^{122}Sb	7.32E-11	^{90}Y	7.43E-05
^{97}Nb	2.02E-10	^{124}Sb	1.63E-08	^{90}Y	1.02E-02
^{97m}Nb	1.78E-10	^{125}Sb	4.28E-06	^{91m}Y	1.27E-17
^{147}Nd	5.95E-03	^{126}Sb	2.46E-06	^{93}Y	1.80E-16
^{236m}Np	1.89E-18	^{127}Sb	7.36E-05	^{93}Zr	1.51E-09
^{237}Np	7.04E-11	^{151}Sm	1.71E-06	^{95}Zr	1.04E-02
^{238}Np	7.23E-10	^{153}Sm	2.26E-06	^{97}Zr	1.87E-10
				Total Ci	**1.44E-01**

Source: W017, solidified low-dose concentrate, in [Proprietary Information].

Table 11-8. High-Dose Radioactive Waste Sources

Isotope	Radioactivity (Ci/wk)	Isotope	Radioactivity (Ci/wk)	Isotope	Radioactivity (Ci/wk)
^{241}Am	2.52E-10	^{233}Pa	1.20E-06	^{89}Sr	9.93E+02
^{136m}Ba	1.97E-01	^{234}Pa	4.57E-06	^{90}Sr	8.30E+00
^{137m}Ba	7.92E+00	^{234m}Pa	3.51E-03	^{91}Sr	2.22E-12
^{139}Ba	1.95E+03	^{112}Pd	2.73E-06	^{99}Tc	1.18E-03
^{140}Ba	1.60E+03	^{147}Pm	2.70E+01	^{99m}Tc	7.87E+01
^{141}Ce	4.78E-01	^{148}Pm	9.10E-03	^{125m}Te	2.55E-02
^{143}Ce	2.70E+02	^{148m}Pm	1.24E-02	^{127}Te	1.07E+01
^{134}Cs	1.35E-03	^{149}Pm	4.41E+00	^{127m}Te	3.27E+00
^{136}Cs	1.76E+00	^{151}Pm	6.19E-03	^{129}Te	1.71E+01
^{137}Cs	8.39E+00	^{142}Pr	1.57E-10	^{129m}Te	2.66E+01
^{155}Eu	2.83E-01	^{143}Pr	2.11E+03	^{131}Te	2.58E-03
^{156}Eu	5.20E+00	^{144}Pr	2.70E+02	^{131m}Te	1.14E-02
^{157}Eu	2.18E-09	^{144m}Pr	3.78E+00	^{132}Te	1.22E+02
^{129}I	8.87E-07	^{238}Pu	3.71E-06	^{232}U	2.88E-11
^{130}I	2.63E-13	^{239}Pu	9.97E-03	^{234}U	2.71E-05
^{131}I	4.65E+02	^{240}Pu	7.06E-06	^{235}U	1.24E-06
I132	8.48E+01	^{241}Pu	2.54E-06	^{236}U	4.17E-07
^{133}I	7.67E-04	^{103m}Rh	7.54E+02	^{237}U	1.96E-02
^{85}Kr	3.27E-05	^{105}Rh	1.82E-01	^{238}U	7.80E-07
^{140}La	2.24E+03	^{106}Rh	1.61E+01	^{131m}Xe	4.31E-04
^{99}Mo	3.47E+00	^{103}Ru	7.56E+02	^{133}Xe	2.87E-02
^{95}Nb	4.98E+02	^{106}Ru	1.61E+01	^{133m}Xe	3.57E-05
^{95m}Nb	1.35E+01	^{122}Sb	8.16E-06	^{135}Xe	5.24E-17
^{96}Nb	5.61E-07	^{124}Sb	1.82E-03	^{89m}Y	9.23E-02
^{97}Nb	2.25E-05	^{125}Sb	4.77E-01	^{90}Y	8.28E+00
^{97m}Nb	1.98E-05	^{126}Sb	2.74E-01	^{90}Y	1.13E+03
^{147}Nd	6.63E+02	^{127}Sb	8.20E+00	^{91m}Y	1.41E-12
^{236m}Np	3.51E-17	^{128}Sb	1.15E-15	^{93}Y	2.01E-11
^{237}Np	1.30E-09	^{151}Sm	1.90E-01	^{93}Zr	1.68E-04
^{238}Np	1.34E-08	^{153}Sm	2.52E-01	^{95}Zr	1.16E+03
^{239}Np	1.28E-02	^{156}Sm	3.68E-15	^{97}Zr	2.09E-05
				Total Ci	**1.42E+04**

Source: W015, solidified high-dose concentrate, in [Proprietary Information].

Table 11-9. Encapsulated Solid Radioactive Waste Sources

Isotope	Radioactivity (Ci/wk)	Isotope	Radioactivity (Ci/wk)	Isotope	Radioactivity (Ci/wk)
^{241}Am	4.07E-12	^{233}Pa	7.37E-08	^{89}Sr	1.60E+01
^{136m}Ba	3.18E-03	^{234}Pa	5.67E-05	^{90}Sr	1.34E-01
^{137m}Ba	1.28E-01	^{234m}Pa	4.40E-08	^{91}Sr	3.59E-14
^{139}Ba	3.14E+01	^{112}Pd	4.35E-01	^{99}Tc	1.90E-05
^{140}Ba	2.58E+01	^{147}Pm	1.47E-04	^{99m}Tc	1.27E+00
^{141}Ce	7.72E-03	^{148}Pm	2.00E-04	^{125m}Te	4.12E-04
^{143}Ce	4.36E+00	^{148m}Pm	7.12E-02	^{127}Te	1.73E-01
^{134}Cs	2.18E-05	^{149}Pm	1.00E-04	^{127m}Te	5.28E-02
^{136}Cs	2.84E-02	^{151}Pm	2.53E-12	^{129}Te	2.76E-01
^{137}Cs	1.35E-01	^{142}Pr	3.40E+01	^{129m}Te	4.30E-01
^{155}Eu	4.57E-03	^{143}Pr	4.36E+00	^{131}Te	4.16E-05
^{156}Eu	8.40E-02	^{144}Pr	6.10E-02	^{131m}Te	1.85E-04
^{157}Eu	3.51E-11	^{144m}Pr	5.99E-08	^{132}Te	1.97E+00
^{129}I	1.47E-08	^{238}Pu	1.61E-04	^{232}U	8.92E-10
^{130}I	4.35E-15	^{239}Pu	1.14E-07	^{234}U	8.40E-04
^{131}I	7.69E+00	^{240}Pu	4.11E-08	^{235}U	3.84E-05
I132	1.40E+00	^{241}Pu	1.22E+01	^{236}U	1.29E-05
^{133}I	1.27E-05	^{103m}Rh	2.94E-03	^{237}U	6.07E-01
^{85}Kr	1.13E-02	^{105}Rh	2.59E-01	^{238}U	2.42E-05
^{140}La	3.62E+01	^{106}Rh	1.22E+01	^{131m}Xe	1.49E-01
^{99}Mo	1.31E+00	^{103}Ru	2.59E-01	^{133}Xe	9.90E+00
^{95}Nb	8.04E+00	^{106}Ru	1.32E-07	^{133m}Xe	1.23E-02
^{95m}Nb	2.17E-01	^{122}Sb	2.94E-05	^{135}Xe	1.81E-14
^{96}Nb	9.06E-09	^{124}Sb	7.70E-03	^{89m}Y	1.49E-03
^{97}Nb	3.63E-07	^{125}Sb	4.43E-03	^{90}Y	1.34E-01
^{97m}Nb	3.20E-07	^{126}Sb	1.32E-01	^{90}Y	1.83E+01
^{147}Nd	1.07E+01	^{127}Sb	1.85E-17	^{91m}Y	2.28E-14
^{236m}Np	1.53E-15	^{128}Sb	3.07E-03	^{93}Y	3.24E-13
^{237}Np	5.68E-08	^{151}Sm	4.07E-03	^{93}Zr	2.72E-06
^{238}Np	5.83E-07	^{153}Sm	5.94E-17	^{95}Zr	1.87E+01
^{239}Np	5.58E-01	^{156}Sm	7.37E-08	^{97}Zr	3.37E-07
				Total Ci	**2.42E+02**

Source: W022 encapsulated waste in [Proprietary Information].

Note: This table does not include carbon beds, iodine absorption beds, or HEPA filters.

HEPA = high-efficiency particulate air.

11.3 RESPIRATORY PROTECTION PROGRAM

10 CFR 20, Subpart H, defines the required elements of the RPF respiratory protection and ventilation programs. The use of engineering controls is preferred over the use of respirators to minimize radioactive materials in the air. However, there may be a need for the following to control the concentrations of radioactive material in the air to maintain the TEDE ALARA.

- Control of access
- Limitation of exposure times
- Use of respiratory protection equipment
- Other controls

The RPF facility design and analysis of the RPF ventilation system ensures that no uncontrolled release of airborne radioactive material to the unrestricted environment could occur during normal operational states and to mitigate the consequences of design basis accidents (e.g., maintaining a series of cascading pressure zones to draw air from the cleanest area to the most contaminated area of the RFP). In addition, the preliminary design indicates that the distribution and concentrations of any airborne radionuclides are limited by operation of the ventilation system so that during the full range of facility operations, no potential occupation exposures would exceed the design bases (e.g., 10 CFR 20), as described in this chapter. The pressure relationship between the four ventilation zones and ambient atmospheric pressure is presented below.

Zone IV will be the cleanest zone and is slightly positively pressurized with respect to atmosphere. Zone IV is independent of the other three ventilation zones. Zones I, II, and III will potentially be contaminated areas, with Zone III being the cleanest of the potentially contaminated areas, and each subsequent zone being more contaminated and having lower pressures, as shown below:

$$P_{\text{Zone I}} < P_{\text{Zone II}} < P_{\text{Zone III}}$$

The irradiated target receipt area and the irradiated target truck bay are two different areas in the RPF. The truck bay is where trailers will be rinsed before entering the receipt area, and where the cask will be removed from the trailer. The irradiated target truck bay is Zone IV, while the irradiated target receipt area is normally Zone III. Details of how the irradiated target receipt area will transition between Zone II and III during operating/maintenance activities will be provided in the FSAR as part of the Operating License Application.

Section 3.1 provides the codes and standards to which the ventilation system will be designed. The detailed ventilation system criteria, including minimum flow velocity at openings in each zone, maximum differential pressure across filters, and types of filters to be used (e.g. HEPA, high-efficiency gas adsorption [HEGA]), will be provided in the FSAR as part of the Operating License Application.

NWMI's radiological respiratory protection program is designed to comply with the requirements of ANSI Z-88.2, *American National Standard for Respiratory Protection*; 10 CFR 20, Subpart H; and 29 CFR 1910.134, "Respiratory Protection." Respirators will only be issued if the Radiation Protection Manager determines that engineering controls may be ineffective, the total effective dose will be reduced by wearing respirators, and/or the physical stress of wearing a respirator will not interfere with workers' health and safety.

If the decision is made to permit the use of respiratory protection equipment to limit the intake of radioactive and hazardous materials, only National Institute of Occupational Safety and Health (NIOSH)-certified equipment will be used.

The respiratory protection program will include the following elements:

- Air sampling to identify the potential hazard, select proper equipment, and estimate doses
- Surveys and when necessary, bioassays, to evaluate actual intakes
- Performance testing of respirators for operability (user seal-check for face-sealing devices and functional check for others) immediately prior to each use
- Limitations on periods of respirator use and relief from respirator use
- Determination by a physician that the individual user is medically fit to use respiratory protection equipment. This evaluation will be done prior to initial fitting of a face sealing respirator, before the first field use of non-face sealing respirators, and either every 12 months thereafter, or periodically at a frequency determined by a physician.
- A respirator fit test will require a minimum fit factor of at least 10 times the assigned protection factor for negative pressure devices, and an overall fit factor of at least 500 for any positive pressure, continuous flow, and pressure-demand devices. The fit testing will be performed before the first field use of tight-fitting, face-sealing respirators. Subsequent testing will be performed at least annually thereafter. Fit testing must be performed with the face-piece operating in the negative pressure mode.

Personnel using respirators will be informed that they may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief. Respirator used within the RPF will provide for vision correction and adequate communication and allow for concurrent use of other safety or radiological protection equipment. Radiological protection equipment will be used in such a way as to not interfere with the proper operation of the respirator.

Standby rescue personnel will be used whenever one-piece, atmosphere-supplying suits are in use. Standby rescue personnel will also be available when any combination of supplied air respiratory protection device and personnel protective equipment is in use that presents difficulty for the wearer to remove the equipment. The standby personnel will be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue personnel will observe and maintain continuous communication with the workers (e.g., visual, voice, signal line, telephone, radio, or other suitable means). The rescue personnel will be immediately available to assist the workers in case of a failure of the air supply or for any other emergency. The Radiation Protection Manager, in consultation with the SH&L Manager, will specify the number of standby rescue personnel that must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

Atmosphere-supplying respirators will be supplied with respirable air of a quality that meets or exceeds the specifications of Compressed Gas Association (CGA) G-7, "Compressed Air for Human Respiration," and G-7.1, "Commodity Specification for Air," and the requirements included in the regulations of the Occupational Safety and Health Administration, 29 CFR 1910.134(i)(1)(ii)(A) through (E).

No objects, materials, or substances (e.g., facial hair), or any conditions that interfere with the face-to-face-piece seal or valve function, and that are under the control of the respirator wearer, will be allowed between the skin of the wearer's face and the sealing surface of a tight-fitting respirator face-piece. The dose to individuals from the intake of airborne radioactive material will be estimated by dividing the ambient air concentration outside the respirator by the assigned protection factor. If the actual dose is later found to be greater than that estimated initially, the corrected value will be used. If the dose is later found to be less than the estimated dose, the lower corrected value may be used.

Records of the respiratory protection program (including training for respirator use and maintenance) will be maintained in accordance with the NWMI records management program, as described in Section 11.1.6.7.

The radiological respiratory protection program will include written procedures for each of the following:

- Monitoring, including air sampling and bioassays
- Supervision and training of respirator users
- Fit testing
- Respirator selection
- Breathing air quality
- Inventory and control
- Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment
- Recordkeeping

Respiratory protection procedures will be revised as necessary whenever changes are made to the facility, processing, or equipment.

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NWMI
NORTHWEST MEDICAL ISOTOPES

Chapter 12 – Conduct of Operations

Construction Permit Application for Radioisotope Production Facility

NWMI-2013-021, Rev. 3
September 2017

Prepared by:
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Chapter 12 – Conduct of Operations

Construction Permit Application for Radioisotope Production Facility

NWMI-2013-021, Rev. 3

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***Title*: Chapter 12 – Conduct of Operations Construction Permit Application for Radioisotope Production Facility**	
***Approved by*: Carolyn Haass**	***Signature*:** Carolyn C Haass

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REVISION HISTORY

Rev	Date	Reason for Revision	Revised By
0	6/29/2014	Initial Application	Not required
1	8/5/2017	Incorporate changes based on responses to NRC Requests for Additional Information	C. Haass
2	N/A		
3	9/5/2017	Incorporate final comments from NRC Staff and ACRS; full document revision	C. Haass

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CONTENTS

APPENDICES

FIGURES

TERMS

Acronyms and Abbreviations

ALARA	as low as reasonably achievable
ANS	American Nuclear Society
ANSI	American National Standards Institute
CEO	Chief Executive Officer
CFO	Chief Financial Officer
CFR	Code of Federal Regulations
COO	Chief Operating Officer
IROFS	items relied on for safety
MC&A	material control and accountability
NRC	U.S. Nuclear Regulatory Commission
NWMI	Northwest Medical Isotopes, LLC
QA	quality assurance
QAPP	Quality Assurance Program Plan
RPF	Radioisotope Production Facility
SH&L	safety, health, and licensing
SNM	special nuclear material
U.S.	United States

Units

mrem	millirem

12.0 INTRODUCTION

12.1 ORGANIZATION

This section describes the Northwest Medical Isotopes, LLC (NWMI) operational structure, functional responsibilities, levels of authority, and interfaces for establishing, executing, and verifying the organizational structure for the Radioisotope Production Facility (RPF). The organizational structure identifies internal and external functions for NWMI, including interface responsibilities for multiple organizations. The organizational structure facilitates the execution of the conduct of operations program. Conduct of operations is a philosophy of working in a formalized, disciplined manner to achieve operational excellence. The conduct of operations program emphasizes safety in every aspect of plant operations. The organizational aspects of the RPF radiation protection program, safety program, staffing, and selection and training of personnel are also discussed in this section.

12.1.1 Structure

Functional levels and assignments of responsibility have been developed by NWMI for the RPF. The functional levels and titles used in the Quality Assurance Program Plan (QAPP) are not intended to define a specific organization or to completely define the responsibilities of each level of organization. Responsibilities for various levels of the NWMI organization will be described in the administrative section of Chapter 14.0, "Technical Specifications," and will comply with American National Standards Institute/American Nuclear Society (ANSI/ANS)-15.1, *The Development of Technical Specifications for Research Reactors*.

The NWMI RPF organization consists of personnel responsible for design, construction, operation, and maintenance of the RPF. The significant functional levels of the organization are presented in Figure 12-1 and are described below. Additional detail of the NWMI organization will be provided in the Operating License Application.

12.1.2 Responsibility

NWMI has the legal responsibility for holding the RPF operating license. The responsibilities of NWMI management are identified in the following subsections.

12.1.2.1 Chief Executive Officer

The President and Chief Executive Officer (CEO) will report directly to the NWMI Board of Managers and will be responsible for overall management and leadership, promoting continuous improvement of the company, and establishing company policies to ensure that customer and company expectations are fully met. The CEO will also provide direction to the COO and CFO to fulfill the organization's responsibilities.

12.1.2.2 Level 1

12.1.2.2.1 Chief Operating Officer

The Chief Operating Officer (COO) will report directly to the President and CEO for operational aspects of the company, including safety, quality, security and safeguards, environmental stewardship, and regulatory licensing and affairs. The COO will be responsible for ensuring the availability of appropriately trained and skilled personnel to successfully meet the needs of NWMI projects and that appropriate resources are allocated. The COO will assign priorities and responsibilities, and will maintain personal involvement in all aspects of NWMI's operations.

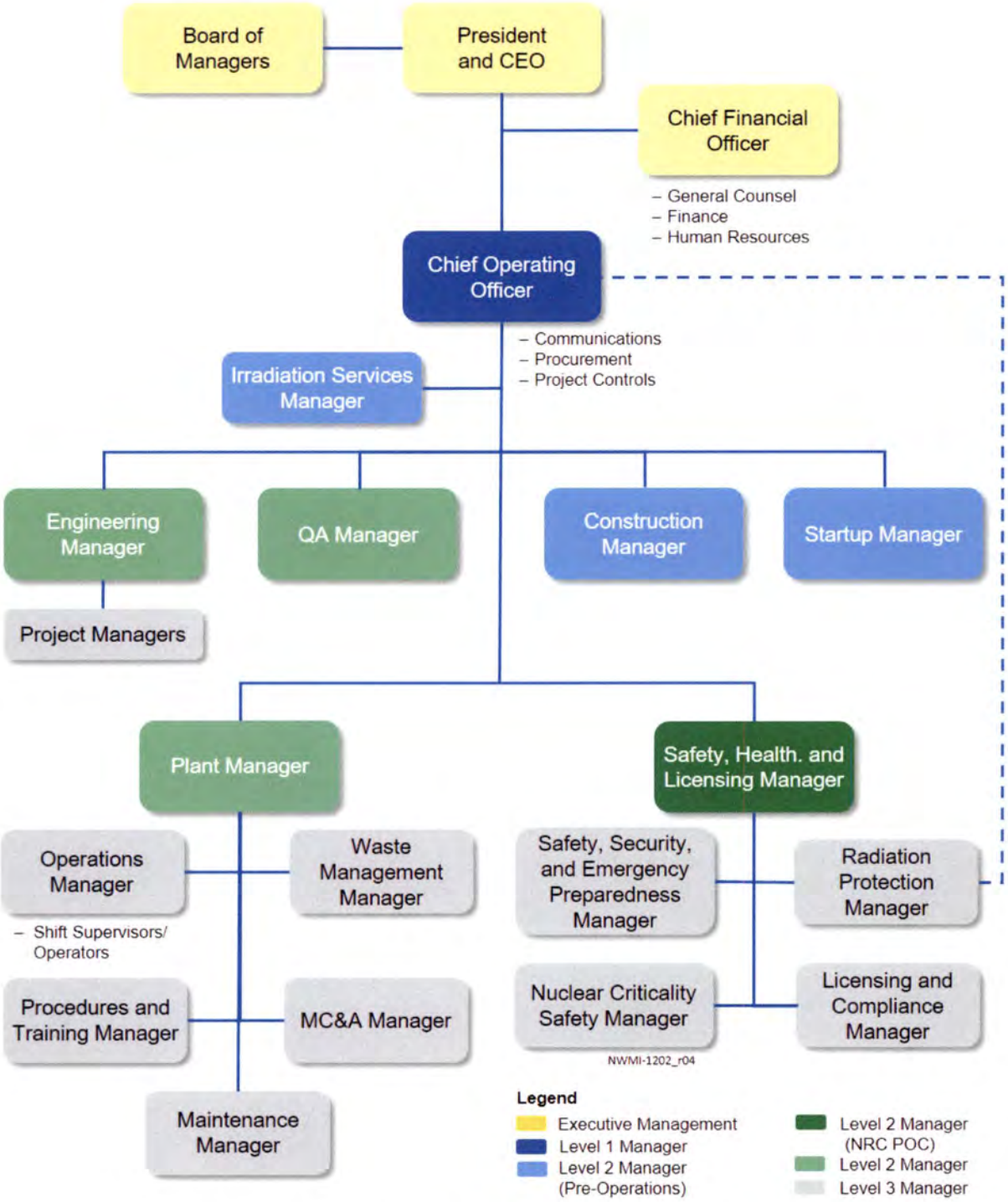

Figure 12-1. Northwest Medical Isotopes, LLC Organization Chart

12.1.2.2.2 Chief Financial Officer

The Chief Financial Officer (CFO) will report to the CEO and have responsibility for all financial matters for NWMI. The CFO will partner with senior leadership and the Board of Directors to develop and implement financial strategies across the organization. Additional responsibilities will include legal, finance, and human resources in support of NWMI projects.

12.1.2.3 Level 2

12.1.2.3.1 Safety, Health, and Licensing Manager

The Safety, Health, and Licensing (SH&L) Manager will report to the COO, with overall responsibility for the development and implementation of programs addressing worker safety and health, U.S. Nuclear Regulatory Commission (NRC) licensing, and State and local permitting (including monitoring compliance with those licenses and permits). Other responsibilities will include nuclear criticality safety, radiation protection/chemistry, environmental protection, integrated safety analysis, industrial hygiene and safety, chemical safety, fire protection, security, and emergency preparedness. With respect to operations, the SH&L Manager will be responsible to confirm the safety of those operations, and will have the authority to order facility shutdown for RPF operations that are judged to be unsafe for continued operations or noncompliant with applicable regulatory requirements and to approve restart of operations.

12.1.2.3.2 Engineering Manager

The Engineering Manager will report directly to the COO, with responsibility for site characterization, facility design and the design control process, configuration management, engineering, and acceptance test coordination, including test control of facility modifications. Other responsibilities will include:

- Ensuring that common design processes (e.g., standardization of work processes, design methodologies, technologies, and systems and equipment) meet company and project needs
- Ensuring that each project managers is trained to the appropriate requirements prior to assuming the role of project manager and performing such duties
- Developing and revising engineering procedures and project procedures
- Overseeing records management and document control activities
- Approving the disposition of nonconforming items when dispositioned as "repair" or "use-as-is" during operations

12.1.2.3.3 Quality Assurance Manager

The QA Manager will report directly to the COO and will have independent oversight responsibility for implementation of the QAPP. The QA Manager will be responsible for:

- Auditing for compliance with regulatory requirements and procedures through assessments and technical reviews
- Monitoring organizational processes to ensure conformance to commitments and licensing document requirements
- Maintaining sufficient independence from other priorities to identify issues affecting safety and quality

- Serving as a focal point for matters involving quality, with the authority to identify, initiate, recommend, or provide solutions to those problems, verify implementation of the solutions, and resolve any related concerns reported to employees, management, and/or NWMI customers
- Implementing training of all assigned project personnel

12.1.2.3.4 Plant Manager

The Plant Manager will report to the COO and have direct responsibility for the safe operation of the RPF, including the protection of workers and the public against radiation exposure resulting from facility operations and materials. Other responsibilities will include:

- Ensuring compliance with applicable NRC, State, and local regulations and license/permits
- Implementing the RPF conduct of operations program
- Establishing and managing the required training programs to support the operations organization

12.1.2.3.5 Construction Manager

The Construction Manager will report to the COO and have responsibility for managing construction and future modifications to the RPF. This responsibility will include managing the activities of qualified contractors who are tasked with the preparation of construction documents and construction of the facility, including modifications and expansion.

12.1.2.3.6 Startup Manager

The Startup Manager will report to the COO and have responsibility for the overall preoperational and startup test program for the RPF. Other responsibilities will include:

- Developing preoperational, startup, and operational test procedures
- Providing technical advice to personnel conducting the tests
- Briefing personnel responsible for RPF operations during the tests
- Ensuring that tests are performed in accordance with applicable procedures
- Preparing test reports

12.1.2.4 Level 3

12.1.2.4.1 Operations Manager

The Operations Manager will report to the Plant Manager and have responsibility for day-to-day RPF operations activities. Inherent in this responsibility is the assurance that operations are conducted safely and in compliance with license conditions.

12.1.2.4.2 Waste Management Manager

The Waste Management Manager will report to the Plant Manager and have responsibility for the following:

- Implementing waste management policy
- Developing waste management procedures for the processing, packaging, and shipment of radioactive waste from the facility
- Processing, packaging, and shipping radioactive waste from the facility
- Providing technical input to the design of equipment and processes

- Providing technical input to the waste management training program
- Establishing and maintaining contractual relationships with waste disposal sites and radioactive waste carriers
- Maintaining working knowledge of the waste acceptance criteria, standards, guides, and codes with respect to waste disposal
- Conducting self-assessments of waste management practices and ensuring compliance with procedures in accordance with the waste management self-assessment program

12.1.2.4.3 Procedure and Training Manager

The Procedure and Training Manager will report to the Plant Manager, with responsibility for the development, implementation, and administration of the RPF training programs, including maintenance of the RPF training database. The training programs provided and/or coordinated by the Training Manager will address qualifications of workers to perform work and identify safety training requirements. In addition, the Procedure and Training Manager will be responsible for maintaining and updating facility procedures.

12.1.2.4.4 Material Control and Accountability Manager

The Material Control and Accountability Manager will report to the Plant Manager, with responsibility for ensuring the proper implementation of the Nuclear Material Control and Accountability Plan. This position will be separate from and independent of other departments to ensure a definite division between the safeguards group and the other departments. In matters involving safeguards, the Safeguards Manager will have direct access to the COO.

12.1.2.4.5 Maintenance Manager

The Maintenance Manager will be responsible for safe and reliable performance of preventive and corrective maintenance and support services on structures, systems, and components (including items relied on for safety [IROFS]). Other responsibilities include integrated planning and scheduling.

12.1.2.4.6 Safety, Security, and Emergency Preparedness Manager

The Safety, Security, and Emergency Preparedness Manager will report to the SH&L Manager, with responsibility for and maintenance of the integrated safety analysis, industrial hygiene and safety, chemical safety, fire protection, security, and emergency preparedness programs.

12.1.2.4.7 Radiation Protection Manager

The Radiation Protection Manager will report to the SH&L Manager and have responsibility for the development and implementation of programs to limit personnel radiological exposures and environmental impacts associated with facility operations, including the as low as reasonably achievable (ALARA) program. Other responsibilities include implementation of the chemistry analysis programs and procedures for the RPF. In matters involving radiological protection, the Radiation Protection Manager will have direct access to the COO.

12.1.2.4.8 Nuclear Criticality Safety Manager

The Nuclear Criticality Safety Manager will report to the SH&L Licensing Manager and have responsibility for the development and implementation of the nuclear criticality safety program. Other responsibilities will include:

- Performing nuclear criticality safety analyses and evaluations of applicable operations involving special nuclear material (SNM) and changes to those operations
- Establishing limits and controls based on those analyses and evaluations
- Ensuring the proper incorporation of limits and controls into applicable procedures and instructions
- Monitoring plant compliance with nuclear criticality safety requirements

12.1.2.4.9 Licensing and Compliance Manager

The Licensing and Compliance Manager reports to the SH&L Manager, with responsibility for regulatory oversight functions, regulatory and licensing/permitting compliance, facility change process, and commitment management.

12.1.2.4.10 Project Managers

Project managers will report directly to the Engineering Manager and have overall responsibility for providing planning, management, and execution of NWMI projects in accordance with this QAPP and established requirements. Project managers will be responsible for:

- Ensuring that all project personnel are properly trained and indoctrinated to perform their intended duties
- Ensuring that all project personnel are provided with the proper information and tools, support, and motivation to carry out their assigned duties
- Ensuring that quality is integrated into daily work activities at the earliest time consistent with established schedules, and periodically assessing their respective organizations to ensure adequate and effective implementation of the QAPP
- Planning and accomplishing work affecting quality under suitably controlled conditions, including the use of appropriate equipment and environmental conditions, and ensuring that the prerequisites for the given activity have been satisfied
- Identifying opportunities for improvement and initiating actions to fully realize these opportunities
- Periodically conducting management assessments of their respective organizations and projects to ensure that company objectives and customer expectations are fully satisfied
- Verifying the achievement of quality by performing audits, assessments, or surveillances of ongoing or completed activities

12.1.2.5 Other

12.1.2.5.1 Shift Supervisors

The shift supervisors will report to the Operations Manager. The shift supervisors will be responsible for the safe operation of the RPF and will authorize day-to-day site activities, including:

- Control of access to the facility
- Work activities (e.g., work permits and execution of specific operations procedures)
- Deliveries and shipments
- Decisions to start or shutdown equipment
- Directing abnormal or emergency actions, including notifications

12.1.2.5.2 Operators

Senior operators and operators will be responsible for conforming to applicable rules, regulations, and procedures for RPF operations. All operators will accept responsibility for safe and efficient operation of an area of the facility when designated by the shift supervisor.

12.1.2.5.3 Employees

NWMI employees will be responsible for conducting work in accordance with the QAPP, company policies, and implementing procedures. Employees will be encouraged to measure their own performance and recommend quality improvements. Each NWMI employee working on a project will also be responsible for the achievement and maintenance of quality within their assigned area of responsibility by following the requirements of this QAPP and its implementing procedures.

12.1.3 Staffing

NWMI will provide sufficient resources in personnel and materials to safely conduct operations. Facility staffing considerations, including minimum staffing levels, allocation of control functions, overtime restrictions, facility status updates during turnover between shifts, procedures, training, and availability of senior operators during routine operations, will be defined in the Operating License Application.

12.1.4 Selection and Training of Personnel

NWMI will establish and maintain formal and informal indoctrination and training programs for personnel performing, verifying, or managing facility operation activities to ensure that suitable proficiency is achieved and maintained. The Procedures and Training Manager will be responsible to the Plant Manager for development and implementation of training that ensures satisfactory operational behavior and performance in the areas of nuclear, industrial, and radiological safety. ANSI/ANS 15.4, *Selection and Training of Personnel for Research Reactors*, will be used in the selection and training of personnel, as applicable. All records of personnel training and qualification will be maintained.

Personnel who are likely to receive an occupational dose in excess of 100 millirem (mrem) per year (in accordance with Title 10, *Code of Federal Regulations*, Part 19.12, "Instruction to Workers," [10 CFR 19.12], paragraph [b]) will be kept informed, advised, and instructed per the requirements of 10 CFR 19.12(a)(1) through (6). Details of the training programs for facility personnel to meet the requirements of 10 CFR 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," will be provided in the Operating License Application. The operator selection and training program will conform to 10 CFR 50.54, "Conditions of Licenses," paragraphs (i) and (i-1), as appropriate for the RPF.

Required minimum qualifications for the RPF staff will be developed and provided in the Operating License Application.

12.1.5 Radiation Safety

The radiation protection program will meet the requirements of 10 CFR 19 and 10 CFR 20, "Standards for Protection Against Radiation," and be consistent with the guidance provided in Regulatory Guide 8.2, *Guide for Administrative Practice in Radiation Surveys and Monitoring*. NWMI will develop, document, and implement the radiation protection program commensurate with the risks posed by the RPF.

Procedures and engineering controls will be developed, to the extent practicable, based on sound radiation protection principles, to achieve occupational doses to workers and doses to members of the public that are ALARA.

The radiation protection staff will report to the Radiation Protection Manager, who in turn will implement the radiation protection program in support of ongoing RPF activities. The radiation protection program content and implementation will be reviewed at least annually, as required by 10 CFR 20.1101, "Radiation Protection Programs," paragraph (c). NWMI will have sufficient staffing and equipment resources to implement an effective radiation protection program.

Further details of the radiation protection program are provided in Chapter 11.0, "Radiation Protection and Waste Management." The authority of the radiation safety staff will be defined in the Operating License Application.

12.1.6 Production Facility Safety Program

The RPF safety program will be developed and integrated with the radiological safety and other facility safety programs and will use the methods described in 10 CFR 50, "Domestic Licensing of Production and Utilization Facilities;" 10 CFR 70.61, "Performance Requirements;" and 10 CFR 70.62, "Safety Program and Integrated Safety Analysis," as appropriate. Further details of the facility safety program will be provided in the Operating License Application. Details will address the following:

- Complying with 10 CFR 50, 10 CFR 70.61, and 10 CFR 70.62
- Establishing a records management program
- Establishing criticality program and measures
- Identifying process safety information
- Identifying radiological, chemical, and facility hazards
- Establishing management measures
- Identifying potential accident sequences
- Applying radiological and chemical consequence and likelihood scenarios
- Designating IROFS
- Establishing and maintaining records

12.2 REVIEW AND AUDIT ACTIVITIES

The Plant Manager will establish the Review and Audit Committee and ensure that the appropriate technical expertise will be available for review and audit activities. Committee activities will be summarized and reported to the COO. Independent audits of the RPF will be conducted periodically and will be specified in the Operating License Application.

12.2.1 Composition and Qualifications

The Review and Audit Committee will be established with participants having the appropriate expertise and experience. The committee will be designated by the Plant Manager and will provide NWMI management an independent assessment of RPF operations. The minimum number and qualifications of the committee members and the potential use of members from outside the organization will be identified in the Operating License Application.

12.2.2 Charter and Rules

The charter and rules for the Review and Audit Committee will address the required meeting interval (at least one per year), quorum required for meetings (not less than one-half the committee membership), issuance of meeting minutes, and voting methods (e.g., facility personnel may never have a majority vote). The details of the charter and rules will be developed for the Operating License Application.

12.2.3 Review Function

At a minimum, the following items will be reviewed by the Review and Audit Committee:

- Determinations that proposed changes in equipment, systems, test, experiments, or procedures are allowed without prior authorization by the responsible authority
- New procedures and major revisions having safety significance, or proposed changes in production facility equipment or systems having safety significance
- New experiments or classes of experiments that could affect reactivity or result in the release of radioactivity
- Proposed changes in technical specifications or the operating license
- Violations of technical specifications or license, and internal procedures or instructions having safety significance
- Changes of the RPF under 10 CFR 50.59, "Changes, Tests and Experiments"
- Radiation protection program
- Operating abnormalities having safety significance
- Reportable occurrences
- Audit reports

Upon completion of a review, a written report of any findings and recommendations of the committees will be provided to the COO.

12.2.4 Audit Function

All aspects of facility operations (e.g., radiation protection and laboratory programs, emergency preparedness plan, physical security plan, operator requalification plan) will be audited every two years, at a minimum. Not all areas have to be audited at the same time, but all will be audited within the designated intervals. Each audit will have a plan prepared and implemented. Discussions with personnel and observation of operations will be used as appropriate. Individuals with immediate responsibility for an area cannot perform an audit in their area of responsibility. NWMI will establish relationships with outside expertise to participate in RPF audits. The following items are examples of potential audit activities:

- Facility operations for conformance to technical specifications and operating license conditions
- Retraining and requalification program for RPF operating staff
- Results of action taken to correct those deficiencies that may occur in RPF equipment, systems, structures, or methods of operations that affect nuclear safety
- Emergency preparedness plan and implementing procedures

Deficiencies identified during the audit will be entered into the NWMI corrective action program. The details of the audit function will be provided in the Operating License Application.

12.3 PROCEDURES

Operating procedures will provide appropriate direction to ensure that the RPF is operated within its design basis and in compliance with technical specifications. The Procedure and Training Manager will be responsible for NWMI implementing procedures.

Operating procedures will be written, reviewed, approved by appropriate management, controlled, and monitored to ensure that the content is technically correct and the wording and format are clear and concise. Procedures will be prepared, approved, revised, canceled, and implemented in accordance with the NWMI procedure program. Procedure changes, including substantive and minor changes and temporary deviations to deal with special or unusual circumstances during RPF operations, will comply with ANSI/ANS 15.1 requirements.

Document control will maintain the master procedures list and ensure that revisions are documented appropriately, approved for release by authorized personnel, and distributed for use at the location where the prescribed activity is performed. Document control will also retain and distribute procedures in accordance with NWMI document control procedures.

The NWMI policy on use of procedures will be documented and clearly understood by NWMI personnel. The extent of detail in a procedure will be dependent on the complexity of the task; experience, education, and training of the users; and potential significance of the consequences of error. The process for making changes and revisions to procedures will be documented. A controlled copy of all operations procedures will be maintained in the control room or other designated area. All RPF activities will be performed in accordance with approved implementing procedures.

The details of the RPF operating procedures function will be specified in the Operating License Application.

12.4 REQUIRED ACTIONS

Required actions to be taken in the event of an RPF safety limit violation or the occurrence of a reportable event will be provided in the Operating License Application.

12.5 REPORTS

A list of reports to be submitted to the NRC, and associated frequency, will be provided in the Operating License Application. At a minimum, an annual report is anticipated to be required that will supply information relative to changes made to the facility and procedures under the 10 CFR 50.59 process. Other items discussed in the annual report may include:

- Results of environmental monitoring
- Personnel exposures
- Generic operational parameters

12.6 RECORDS

The records management program will define the process for managing RPF records and will be consistent with the requirements of the applicable regulations. The records management program will include the identification, generation, authentication, maintenance, and disposition of records and will be provided in the Operating License Application.

12.7 EMERGENCY PLANNING

The RPF Emergency Preparedness Plan will follow the guidance provided in ANSI/ANS 15.16, *Emergency Planning for Research Reactors*, and Regulatory Guide 2.6, *Emergency Planning for Research and Test Reactors*. NWMI will also use NUREG-0849, *Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors*, for guidance on emergency planning. Details about the RPF will be included in the Operating License Application, per the guidelines provided in NUREG-1520, *Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility*. A draft Emergency Preparedness Plan is provided in Appendix A to this chapter and will be updated in the Operating License Application.

12.8 SECURITY PLANNING

The RPF physical security plan will be developed using the guidance provided in Regulatory Guide 5.59, *Standard Format and Content for a Licensee Physical Security Plan for the Protection of Special Nuclear Material of Moderate or Low Strategic Significance*. A draft physical security plan is provided in Appendix B to this chapter and will be updated in the Operating License Application.

12.9 QUALITY ASSURANCE

This corporate QAPP describes the policies and requirements necessary to meet applicable federal regulations and provides a description of the NWMI quality assurance (QA) program in a controlled document based on 10 CFR 50.34, "Contents of Applications; Technical Information." and associated ANSI/ANS 15.8, *Quality Assurance Program Requirements for Research Reactors*; Regulatory Guide 2.5, *Quality Assurance Program Requirements for Research and Test Reactors*; 10 CFR 70.64(a)(1), "Quality Standards and Records;" and ISO-9001, *Quality Assurance Requirements*. This QAPP will apply to all nuclear, quality-related projects and activities that require conformance to a nuclear QA program and will be the standard for all NWMI personnel to follow for compliance to those requirements.

The QAPP is further intended to ensure that reliability and performance of NWMI products and services are maximized through the application of effective and prudent business management practices commensurate with the risk to workers, the public, and environment. NWMI has adopted a graded approach to quality such that the level of analysis, verification/validation, documentation, and actions are determined based on safety, quality, and/or project risk. This graded approach will determine the appropriate level of effort necessary to attain and document the technical and quality requirements.

A draft QAPP is provided in Appendix C and will be updated for the Operating License Application.

12.10 RADIOISOTOPE PRODUCTION FACILITY OPERATOR TRAINING AND REQUALIFICATION

As set forth in 10 CFR 50.54(h) and (i), the license is subject to the provisions of the Act, and the licensee may not permit the manipulation of the controls of any facility by anyone who is not authorized pursuant to the regulations in 10 CFR 55, "Operator's Licenses." Although 10 CFR 55 only specifies the licensing requirements for facility operators, without specifically addressing production facilities, the NRC has determined that the same technical and safety considerations apply to operators of production facilities and will apply the relevant 10 CFR 55 requirements to production facility operators by a license condition.

The general and specific training requirements for licensing an RPF and facility operators will conform to 10 CFR 50.54 and 10 CFR 55, as applicable. NWMI's training program will define the knowledge and skills required for workers conducting safety-related operations with SNM. This training program will address the following topics:

- Theory and principles of the radioisotope production processes involving SNM
- Theory and principles of radioisotope extraction and purification processes
- RPF design and operating characteristics
- Instrumentation and control systems
- Engineered safety features
- Technical specifications
- Criticality control features and management measures required for each process involving SNM
- Normal and emergency operating procedures

ANSI/ANS 15.4 provides additional guidance on training and qualification of personnel that may be applicable to the RPF. In 10 CFR 50.54(i-1), the NRC requires the licensee to have an operator requalification program in effect, which at a minimum meets the requirements of 10 CFR 55.59, "Requalification," paragraph (c), within 3 months after the operating license is issued. The regulations in 10 CFR 55 apply specifically to reactor operating licenses. With regard to production facilities, the proposed operator training license conditions should comply with the same requirements of 10 CFR 50.54(i) and (i-1). NUREG-1537, *Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors – Format and Content*, Part 2, Section 12.10b, presents specific information about the content of a RPF training and qualification program. This RPF operator training and requalification program will be described in the Operating License Application.

12.11 STARTUP PLAN

Startup operations involving SNM in liquid or solid form, as appropriate, will be described in this section. Operations with SNM may be subject to the requirements of 10 CFR 70, "Domestic Licensing of Special Nuclear Material." Applicable paragraphs of 10 CFR 70 may be incorporated into the 10 CFR 50 license as license conditions.

Startup operations will be included in the safety program and integrated safety analysis, and IROFS will be identified if necessary to meet integrated safety analysis performance requirements and to provide assurance of adequate safety. The startup plan will be developed and described in the Operating License Application.

12.12 VACATED

This section has been vacated, per the final interim staff guidance augmenting NUREG-1537 (NRC, 2012).

12.13 MATERIAL CONTROL AND ACCOUNTING PROGRAM

NWMI will present information about the material control and accountability (MC&A) program. The description should be sufficient to ensure that the program can fulfill its functions per NUREG-1065, *Acceptable Standard Format and Content for the Fundamental Nuclear Material Control (FNMC) Plan Required for Low-Enriched Uranium Facilities*.

The information in this section will address the following:

- MC&A organization
- Measurements
- Measurement control program
- Statistics
- Physical inventories
- Item control
- Shipper-receiver comparisons
- Assessment and review of the MC&A program
- Resolving indications of missing uranium or other SNM of significance
- Data to assist in the investigation and recovery of missing uranium
- Recordkeeping

The MC&A program will be described in the Operating License Application.

12.14 REFERENCES

10 CFR 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," *Code of Federal Regulations*, Office of the Federal Register, as amended.

10 CFR 19.12, "Instruction to Workers," *Code of Federal Regulations*, Office of the Federal Register, as amended.

10 CFR 20, "Standards for Protection Against Radiation," *Code of Federal Regulations*, Office of the Federal Register, as amended.

10 CFR 20.1101, "Radiation Protection Programs," *Code of Federal Regulations*, Office of the Federal Register, as amended.

10 CFR 50, "Domestic Licensing of Production and Utilization Facilities," *Code of Federal Regulations*, Office of the Federal Register, as amended.

10 CFR 50.34, "Contents of Applications; Technical Information," *Code of Federal Regulations*, Office of the Federal Register, as amended.

10 CFR 50.54, "Conditions of Licenses," *Code of Federal Regulations*, Office of the Federal Register, as amended.

10 CFR 50.59, "Changes, Tests and Experiments" *Code of Federal Regulations*, Office of the Federal Register, as amended.

10 CFR 55, "Operators' Licenses," *Code of Federal Regulations*, Office of the Federal Register, as amended.

10 CFR 55.59, "Requalification," *Code of Federal Regulations*, Office of the Federal Register, as amended.

10 CFR 70, "Domestic Licensing of Special Nuclear Material," *Code of Federal Regulations*, Office of the Federal Register, as amended.

10 CFR 70.61, "Performance Requirements," *Code of Federal Regulations*, Office of the Federal Register, as amended.

10 CFR 70.62, "Safety Program and Integrated Safety Analysis," *Code of Federal Regulations*, Office of the Federal Register, as amended.

10 CFR 70.64, ""Quality Standards and Records," *Code of Federal Regulations*, Office of the Federal Register, as amended.

ANSI/ANS 15.1, *The Development of Technical Specifications for Research Reactors*, American National Standards Institute/American Nuclear Society, La Grange Park, Illinois, 2007.

ANSI/ANS 15.4, *Selection and Training of Personnel for Research Reactors*, American National Standards Institute/American Nuclear Society, La Grange Park, Illinois, 2007.

ANSI/ANS 15.8, *Quality Assurance Program Requirements for Research Reactors*, American National Standards Institute/American Nuclear Society, La Grange Park, Illinois, 1995 (R2005).

ANSI/ANS 15.16, *Emergency Planning for Research Reactors*, American National Standards Institute/American Nuclear Society, La Grange Park, Illinois, 2008.

ISO-9001, *Quality Assurance Requirements*, International Organization for Standardization, Geneva, Switzerland, 2008.

NRC, 2012, *Final Interim Staff Guidance Augmenting NUREG-1537, "Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors," Parts 1 and 2, for Licensing Radioisotope Production Facilities and Aqueous Homogeneous Reactors*, Docket ID: NRC-2011-0135, U.S. Nuclear Regulatory Commission, Washington, D.C., October 30, 2012.

NUREG-0849, *Standard Review Plan for the Review and Evaluation of Emergency Plans for Research and Test Reactors*, U.S. Nuclear Regulatory Commission, Office of Inspection and Enforcement, Washington, D.C., September 1983.

NUREG-1065, *Acceptable Standard Format and Content for the Fundamental Nuclear Material Control (FNMC) Plan Required for Low-Enriched Uranium Facilities*, Rev. 2, U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Washington, D.C., December 1995.

NUREG-1520, 2010, *Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility*, Rev. 1, U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Washington, D.C., May 2010.

NUREG-1537, *Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors – Format and Content*, Part 2, U.S. Nuclear Regulatory Commission, Office of Nuclear Reactor Regulation, Washington, D.C., February 1996.

Regulatory Guide 2.5, *Quality Assurance Program Requirements for Research and Test Reactors*; Title 10, *Code of Federal Regulations*, Rev. 1, U.S. Nuclear Regulatory Commission, Office of Nuclear Regulatory Research, Washington, D.C., June 2010.

Regulatory Guide 2.6, *Emergency Planning for Research and Test Reactors*, Rev. 1, U.S. Nuclear Regulatory Commission, Office of Nuclear Regulatory Research, Washington, D.C., March 1983.

Regulatory Guide 5.59, *Standard Format and Content for a Licensee Physical Security Plan for the Protection of Special Nuclear Material of Moderate or Low Strategic Significance*, Rev. 1, U.S. Nuclear Regulatory Commission, Office of Nuclear Regulatory Research, Washington, D.C., March 1983.

Regulatory Guide 8.2, *Administrative Practices in Radiation Surveys and Monitoring*, Rev. 1, U.S. Nuclear Regulatory Commission, Office of Nuclear Regulatory Research, Washington, D.C., May 2011.

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Appendix A

NORTHWEST MEDICAL ISOTOPES, LLC
RADIOISOTOPE PRODUCTION FACILITY

EMERGENCY RESPONSE PLAN

Approved by the
U.S. Nuclear Regulatory Commission

License R-[TBD], Docket No. XX-XXXX

Last Revised: September 2017

Rev. 3 (DRAFT)

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CONTENTS

FIGURES

TABLES

TERMS

Acronyms and Abbreviations

^{99}Mo	molybdenum-99
AC	alternating current
CDE	committed dose equivalent
DAC	derived air concentration
DOE	U.S. Department of Energy
EAL	emergency action level
EPZ	Emergency Planning Zone
ESC	Emergency Support Center
FRMAP	Federal Radiological Monitoring Assessment Plan
LEU	low-enriched uranium
MU	University of Missouri
NOUE	notification of unusual event
NRC	U.S. Nuclear Regulatory Commission
NWMI	Northwest Medical Isotopes, LLC
PA	public address
PAG	protective action guide
PIO	Public Information Officer
RPF	radioisotope production facility
RSO	Radiation Safety Officer
SOP	standard operating procedure
TEDE	total effective dose equivalent
TLD	thermoluminescent dosimeter

Units

ft^2	square feet
hr	hour
km	kilometer
mi	mile
mR	milliroentgen
mrem	millirem
rem	roentgen equivalent in man

A1.0 INTRODUCTION

The Northwest Medical Isotopes (NWMI) Radioisotope Production Facility (RPF) is a 70,000-square foot (ft^2) facility located within on Lot 15 in Discovery Ridge, an emerging research park development north of Discovery Ridge Drive in Columbia, Missouri. The complex includes several buildings: the RPF, NWMI Administration Building, Waste Staging and Shipping Building, and Diesel Generator Building. The purpose of the RPF is to provide a domestic, secure, and reliable supply of molybdenum-99 (^{99}Mo) for medical diagnostics. The RPF is owned and operated by NWMI under U.S. Nuclear Regulatory Commission (NRC) License Number R-XXX (Docket Number XX-XXX).

The purpose of the RPF is to provide a national domestic supply of the isotope ^{99}Mo. The process by which this occurs involves:

- Receiving low-enriched uranium (LEU) from U.S. Department of Energy (DOE)
- Producing LEU target materials and fabrication of targets
- Packaging and shipping LEU targets to the university reactor network for irradiation
- Returning irradiated LEU targets for dissolution, recovery, and purification of ^{99}Mo
- Recovering and recycling LEU to minimize radioactive, mixed, and hazardous waste generation
- Treating/packaging wastes generated by RPF process steps to enable transport to a disposal site

The objective of this Emergency Response Plan is to provide a plan of action for responding to radiological and other emergencies and minimizing the consequences of such emergencies at the RPF. The plan specifies emergency action levels for applicable classes of emergencies, in response to which relevant parts of this plan will be activated.

A2.0 DEFINITIONS

Term	Definition
Action drill	A drill that tests the integrated capability of the emergency plan, or a component thereof, and may include instruction periods to develop and maintain skills in a particular operation.
Administrative Building	The western building in the RPF complex that houses business and administrative services.
Annual	Every 12 months, with an interval not exceeding 15 months.
Assessment actions	Those actions taken during or after an accident to obtain and process information that is necessary when deciding whether to implement specific emergency measures.
Biennial	Every 24 months, with an interval not exceeding 30 months.
Corrective actions	Those measures taken to ameliorate or terminate an emergency situation at or near the source of the problem.
Emergency	A condition that calls for immediate action, beyond the scope of normal operating procedures, to avoid an accident or to mitigate the consequences of one.
Emergency action level (EAL)	Radiological dose rates, specific concentrations of airborne, waterborne, or surface-deposited radioactive materials, specific observations, or specific instrument readings that may be used as thresholds for initiating specific emergency measures (e.g., designating a particular class of emergency, initiating a notification procedure, or initiating a particular protective action).
Emergency planning zone (EPZ)	The EPZ for the RPF is limited to the operations boundary and includes no off-site areas.
Emergency Support Center (ESC)	The room(s) from which effective emergency control directions will be given. This room is the RPF control room.
Emergency response implementing procedure (ERIP)	Procedures dedicated towards implementing the emergency plan. They are not considered to be part of the plan.
Federal Radiological Monitoring Assessment Plan (FRMAP)	A federally sponsored plan to provide expeditious and effective radiological assistance to those requesting it in the event of a radiological incident.
Monthly	Every 4 weeks, with an interval not to exceed 6 weeks.
Operations boundary	The area within the site boundary where the RPF Operations Manager has direct authority over all the activities, and for which there are prearranged evacuation procedures known to the personnel frequenting the area. For the RPF complex, the operations boundary is the area within the fence.

Term	Definition
Population at risk	Those persons for whom protective actions are being or would be taken in the event of an emergency.
Protective action (PA)	Those measures taken in anticipation of an uncontrolled release of radioactive material, or after an uncontrolled release of radioactive material has occurred, for the purpose of preventing or minimizing personnel radiation doses or dose commitments that would otherwise be likely to occur if the actions were not taken.
Protective action guide (PAG)	Projected radiation doses or dose commitments to individuals in the general population that warrant protective action following a release of radioactive material. Protective actions would be warranted provided the reduction in individual dose expected to be achieved by carrying out the protective action is not offset by excessive risks to individual safety in the process of taking the protective action. The projected dose does not include the dose that has unavoidably occurred prior to the assessment.
Quarterly	Every 3 months, with an interval not exceeding 4 months.
Radioisotope Production Facility (RPF)	The eastern building in the RPF complex.
Radioisotope Production Facility complex	The buildings situated at Lot 15 of Discovery Ridge Research Park in Columbia, Missouri, and include the RPF, NWMI Administration Building, Waste Staging and Shipping Building, and Diesel Generator Building.
Radiological assessment team	The team of individuals who will perform radiation dose rate, contamination, and environmental surveys to assess the radiological conditions existing within the site boundaries at the RPF complex.
Recovery actions	Those actions taken after an emergency to restore the facility to a safe status.
Semi-annual	Every 6 months, with an interval not exceeding 7.5 months.
Site boundary	The site boundary is that boundary, not necessarily having restrictive barriers, surrounding the operations boundary wherein the RPF Operations Manager may directly initiate emergency activities. The area within the site boundary may be frequented by people unacquainted with RPF operations. The site boundary consists of Lot 15 of Discovery Ridge Research Park.

A3.0 ORGANIZATION AND RESPONSIBILITIES

A3.1 AUTHORITIES AND RESPONSIBILITIES OF GOVERNMENTAL AGENCIES

This section describes the authorities, responsibilities, and support functions of federal, state, county, and local governmental agencies in an emergency situation. The information presented here pertains to any class of emergency.

Specific responsibilities and emergency response actions of these agencies are described in Section A7.0.

No formal arrangements have currently been made with any responding agency, including City of Columbia Police and Fire Departments, Boone Hospital, and University Hospital, to ensure a clear understanding of the emergency support responsibilities of these key support organizations. With respect to local agencies, introductory conversations have taken place with the City of Columbia Fire Department, the emergency preparedness department of the University of Missouri Hospital (also involved with the ambulance service), and the Boone County Office of Emergency Management. These discussions have been limited to a description of the NWMI RPF and draft emergency plan for the RFP. The Federal government agency, the NRC, by virtue of this application, is aware of the facility but no formal contacts or arrangements have been made. Continued interactions, discussions, and agreements are anticipated with these organizations before the Operating License Application is submitted.

A3.1.1 Federal Agencies

U.S. Nuclear Regulatory Commission

Title 10, *Code of Federal Regulations*, Part 20.2202, "Notification of Incidents," and the RPF Technical Specifications, as amended, outline requirements for the reporting of emergencies to the NRC. Notification procedures (e.g., telephone, electronic messaging, written reports, etc.) will be implemented as required in these documents. The NRC will assess the situation and determine if any further response is required of the agency.

A3.1.2 State Agencies

Missouri State Emergency Management

The Missouri State Emergency Management Agency has responsibility for the State's formal radiological emergency preparedness program. Notification procedures (e.g., telephone, electronic messaging, written reports, etc.) will be implemented as required by Missouri State Emergency Management Agency requirements.

A3.1.3 County Agencies

Boone County Office of Emergency Management

The Boone County Office of Emergency Management will assist by providing emergency support mainly in the form of transportation, communications, and equipment, when such assistance is sought by local emergency support agencies. Notification of incidents will be conducted by City of Columbia Fire or Police personnel or by the Boone County Sheriff's Department.

Boone County Sheriff's Department

The Boone County Sheriff's Department will assist in law enforcement activities as requested by the City of Columbia Police Department. Notification of incidents to the Sheriff's Department will be initiated by the Columbia Police Department, as deemed necessary.

A3.1.4 Local Agencies

Boone Hospital Ambulance Service

The Boone Hospital Ambulance Service operates a local ambulance service and will provide transportation for injured and/or contaminated personnel to the University Hospital in Columbia. The decision as to the need to transport injured and/or contaminated personnel to a hospital will be made by attending medical personnel with advice from the RPF Radiation Safety Officer (RSO).

City of Columbia Fire Department

The Columbia Fire Department will provide assistance during emergencies involving actual or potential fire, explosions, or injuries.

City of Columbia Office of Emergency Management

The Office of Emergency Management for the City of Columbia will assist by providing emergency support mainly in the form of transportation, communications, and equipment, when such assistance is sought by local emergency support agencies. Notification of incidents will be conducted by the City of Columbia Fire or Police personnel or by the Boone County Sheriff's Department.

City of Columbia Police Department

The responsibilities of the Columbia Police Department during an emergency are to:

- Respond in any emergency arising from a bomb threat or a threatened or actual breach in physical security. The standard operating procedure (SOP) detailed in the NWMI RPF Physical Security Plan will be followed in these situations. This SOP contains safeguards information, exempt from public disclosure, and is therefore not included in this plan.
- Monitor and maintain the security of the RPF complex after any emergency evacuation.
- Assist in crowd control around the RPF complex at all times.
- Make announcements to assembled personnel over the loudspeaker systems installed on police vehicles.
- Coordinate with other law enforcement agencies.

University of Missouri Health System Ambulance Service

The MU Health System Ambulance Service operates a local ambulance service and will provide transportation for injured and/or contaminated personnel to the University Hospital in Columbia. The decision as to the need to transport injured and/or contaminated personnel to the University Hospital will be made by attending medical personnel with advice from the RPF RSO.

A3.2 AUTHORITIES AND RESPONSIBILITIES OF NONGOVERNMENTAL AGENCIES

This section describes the authorities, responsibilities, and support functions of nongovernmental agencies.

American Nuclear Insurers

American Nuclear Insurers is the insurer of the RPF facility and will be notified of any emergency of Class I or greater. The insurer may, at its discretion, send a representative to advise and deal with any legal or liability matters.

University Hospital, Columbia

Arrangements have been made for injured personnel who may also be contaminated to be received and treated at the University Hospital in Columbia, Missouri.

Boone Hospital, Columbia

Arrangements have been made for injured personnel who may also be contaminated to be received and treated at the Boone Hospital in Columbia.

A3.3 FACILITY EMERGENCY ORGANIZATION

A3.3.1 Normal Facility Organization

The organizational chart for the ongoing administration and operation of the RPF is provided in Figure A-1. This chart will aid in understanding the emergency assignments of these personnel, which are described in Section A3.3.2.

The Safety, Security and Emergency Preparedness Manager will have organizational responsibility for maintenance and implementation of the Emergency Preparedness Program, including this plan, for facility equipment and personnel, including the scheduling and performance of equipment maintenance, personnel training, coordination with off-site support organizations, and drills associated with the emergency plan.

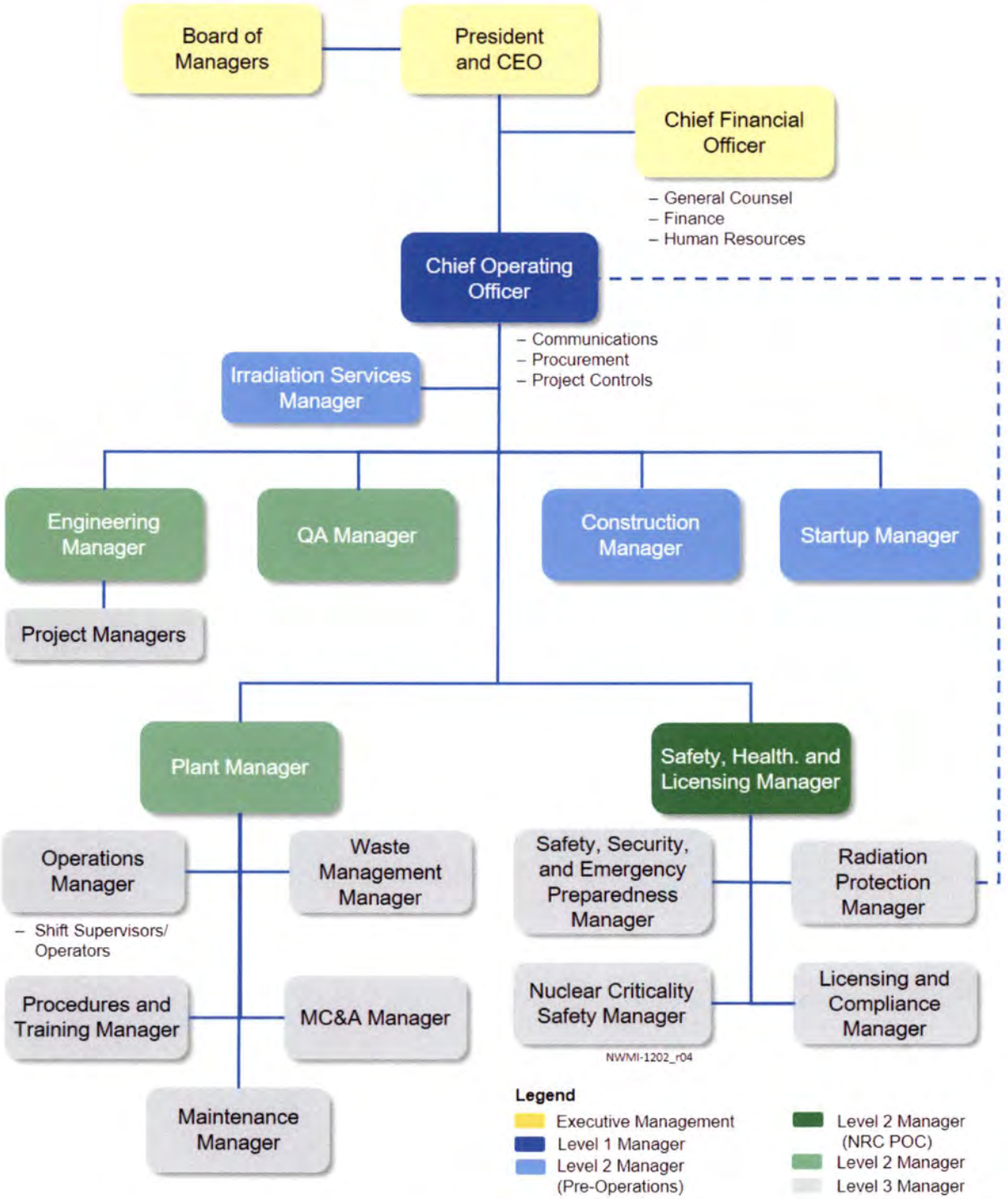


Figure A-1. Facility Organization Chart

A3.3.2 Authorities and Responsibilities of Facility Emergency Personnel

All RPF staff positions identified below are only by title, not by individual. The individuals who fill these staff positions will be identified in implementing procedures, which will be developed and submitted as part of the NWMI Operating License Application. The 24-hour on-shift positions include:

- Emergency Director – Plant Manager, Chief Operating Officer, and Operations Manager
- Emergency Coordinator – Operations Manager, Safety Health and Licensing Manager, and Radiation Protection Manager
- Radiation Safety Officer – Radiation Protection Manager, Safety Health and Licensing Manager, and Shift Supervisor
- Radiological Assessment Team – Radiation Protection Manager and Shift Supervisor

The Radiological Assessment Team will also comprise the hot cell operators, supervisors, health physicists, or process technicians on shift at the time of the emergency.

Emergency Director

In the event of an emergency, the RPF Plant Manager will be the Emergency Director. The line of succession and responsibilities of the Emergency Director are as follows.

Line of Succession

Responsibilities

- Direct emergency operation and ensure proper implementation of the emergency response plan
- Ensure that any necessary NRC notifications are made
- Authorize emergency workers to incur radiation exposures in excess of normal occupational limits, with the concurrence of the RSO, if available. This function cannot be delegated.
- Terminate an emergency and initiate recovery operations based on advice from the Emergency Coordinator
- Notify and coordinate with NWMI leadership
- Work and coordinate with the Public Information Officer with respect to the public and media
- Assess conditions in the RPF after termination of the emergency to determine the proper course of further recovery actions
- Establish and coordinate recovery/reentry efforts with the assistance of the Hot Cell Supervisor, the RSO, and the Vice President of NWMI
- Evaluate the causes of the emergency and recommend corrective actions before returning the facility to a normal operating status

Emergency Coordinator

In the event of an emergency, the RPF Operations Manager will be the Emergency Coordinator. The line of succession and responsibilities of the Emergency Coordinator are as follows:

Line of Succession

Responsibilities

- Declare and classify the emergency
- Fulfill any necessary requirements for notifying the NRC and keep the Emergency Director advised of all such notifications
- Take charge of the Emergency Support Center (ESC) and emergency control measures, and keep the Emergency Director informed regarding the emergency situation
- Ensure proper evacuation of the RPF (or portion thereof) that requires evacuation during the emergency
- Determine the course of further action with the assistance of the Emergency Director, Hot Cell Supervisor, RSO, and NWMI leadership
- Authorize reentry into the RPF (or portion thereof) that required evacuation during the emergency
- Coordinate emergency response actions with the off-site emergency support services
- Advise the Emergency Director on the possibility of terminating the emergency and initiating recovery operations

Radiation Safety Officer

In the event of an emergency, the RSO will be responsible for the radiological health physics aspects of the emergency. The line of succession and responsibilities of the RSO are as follows:

Line of Succession

Responsibilities

- Direct and oversee all actions of the Radiological Assessment Team
- Evaluate personnel doses received during the incident
- Assess subsequent potential doses and recommend protective actions, as appropriate
- Supervise the establishment of a release process for persons leaving the assembly point
- For fire emergencies, meet Fire Department personnel on their arrival onsite and coordinate their response in support of the emergency actions underway

- Assist the Emergency Director and help determine the course of further action

Radiological Assessment Team

Personnel

The Radiological Assessment Team will include RPF personnel who have been trained in radiological assessment techniques and do not have an assigned responsibility already specified in this section. This may include the following personnel as available during an emergency.

- Radiation Protection Manager (RSO)
- Health Physicist(s)
- Shift Supervisors
- Hot Cell Operator(s)
- Hot Cell Supervisor
- Process Technician(s)

Responsibilities

- Bring extra portable survey instruments to the assembly point during any evacuation
- Survey personnel at the assembly point after any evacuation, beginning with the emergency organization personnel
- Perform radiological assessment action as directed by the RSO

Public Information Officer

In the event of an emergency, NWMI leadership will be responsible for communicating with the media and public. The line of succession and responsibilities of the Public Information Officer (PIO) are as follows:

Line of Succession

Responsibilities

- Coordinate all public relations aspects of the emergency, interfacing with the public, press, television, and other media
- Coordinate with the Emergency Director to obtain current and accurate information regarding the emergency situation and recovery operations

Historian

The RPF Administration Building Receptionist will be the Historian for the emergency.

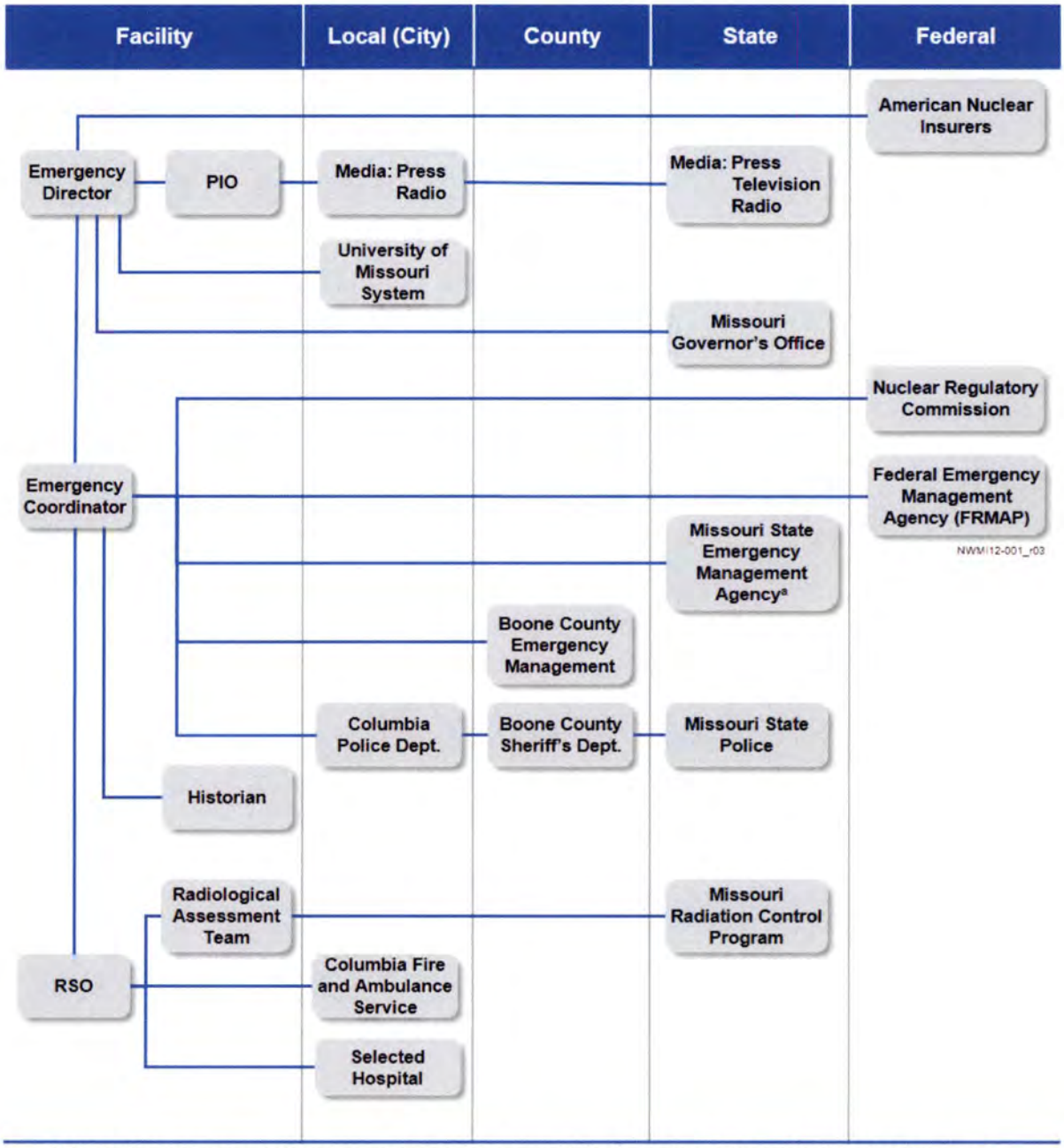
Line of Succession

Responsibilities

- Log the sequence of events, with the time, as the events take place in the ESC. Log as much pertinent information as possible. Use the available recorder as needed.

A3.3.3 Interfaces Between the Facility Emergency Organization, Off-Site Local Support Organizations, and State and Federal Agencies

A diagram showing the interfaces between the facility emergency organization, off-site local support organizations, and state and federal agencies is provided in Figure A-2.



[a] Missouri State Emergency Management Agency has responsibility for the State's formal Radiological Emergency Preparedness Program.

Figure A-2. Interfaces Between the Facility Emergency Organization, Offsite Local Support Organizations, and State and Federal Agencies

A4.0 EMERGENCY CLASSIFICATION SYSTEM

The purpose of this emergency classification system is to provide for improved communications between facility personnel, local off-site emergency support personnel, and state and federal organizations. The emergency classes addressed for the RPF are based on accidents associated with routine operations (many of which are very remotely possible), and on other lesser emergency situations but that otherwise divert resources and attention.

The emergency action levels (EAL) for each of the three classes of emergencies addressed for the NWMI RPF are intended to provide specific trigger points for the activation of the emergency organization, or applicable portions thereof, and the initiation of protective actions appropriate for the emergency event. The action levels listed below are not all inclusive. Situations or occurrences not listed under a specific emergency class, but having similar postulated consequences as those in one of the three classes of emergencies, will also be used to trigger emergency response actions applicable to that particular class of emergency. Identification of such occurrences is left to the judgment of the RPF staff on duty.

A4.1 PERSONNEL AND OPERATIONAL EMERGENCY

Personnel and Operational Emergencies are events less severe than higher category emergencies, which still require a response by at least part of the emergency organization. There usually will be no effect on the RPF, and action to alter RPF status is not normally required.

The following EALs will be used to initiate emergency measures associated with this emergency class:

- A major personnel injury such as a severe cut, wound, or burn
- A person experiencing a heart attack, stroke, or other severe physical ailment of rapid onset
- Any person receiving an estimated radiation dose equivalent greater than any occupational dose limit from sources external to the body, including doses caused by skin contamination
- Any person becoming internally contaminated with radioactive material sufficient to give a dose equivalent in excess of any applicable occupational dose limit
- Radiation levels in the RPF sufficient to trip the alarm on any single area radiation monitor, when such levels are from unknown sources, or sources known to represent a potential emergency situation
- Airborne radioactivity levels in the RPF sufficient to alarm a continuous air monitor or the stack monitor, when such levels are from unknown sources or sources known to represent a potential emergency situation
- An event that causes significant damage to the RPF complex

A4.2 NOTICE OF UNUSUAL EVENTS

The appropriate off-site agency described in Section A3.1 (depending on the nature of the emergency) will be notified within 15 minutes of the notice of an unusual event being declared. Notification shall be made to the NRC Operations Center as soon as is reasonably possible, but no later than one hour after the declared emergency. Notification of unusual events may be initiated by either man-made events or natural phenomena that can be recognized as creating a hazard potential that was previously nonexistent. There is usually time available to take precautionary and corrective steps to prevent the escalation of the accident or to mitigate the consequences if the accident occurs.

In a notification of unusual events (NOUE) emergency, one or more elements of the emergency organization are likely to be activated or notified to increase the state of readiness, as warranted by the circumstances. Although the situation may not have caused damage to the RPF, the event may warrant an immediate shutdown of the RPF or interruption of nonessential routine functions.

The following EALs will be used to initiate emergency measures associated with this emergency class:

- Receipt of information threatening, or confirming, a breach in physical security (e.g., bomb threat or signs of a hostile crowd assembling outside the building)
- Receipt of information that a severe natural phenomenon such as a flood, volcano, tornado, or earthquake, is likely to affect the Columbia area
- An explosion or a fire in the RPF complex lasting more than 15 minutes
- Actual or projected radiological effluents with concentrations resulting in an unrestricted area total effective dose equivalent (TEDE) of 15 millirem (mrem) accumulated in 24 hours (hr)

Note: The stack monitor will have alarmed, shut off the ventilation system, and closed the isolation dampers long before this concentration level is reached. However, the stack monitor will continue to function and will be used to project radiological effluent releases and detect radiation levels in the unrestricted area. Direct measurements with portable survey meters will also be used to evaluate radiation levels in the unrestricted area.

A4.3 ALERT

The appropriate off-site agency described in Section A3.1 (depending on the nature of the emergency) will be notified within 15 minutes of the alert being declared. Notification shall be made to the NRC Operations Center as soon as is reasonably possible, but no later than one hour after the declared emergency. Events leading to an alert would be sufficient to require response by the emergency organization. Modification of the RPF operating status is a probable corrective action. Protective evacuations or isolation of certain areas within the operations boundary could be necessary.

The following EALs will be used to initiate emergency measures associated with this emergency class:

- Actual or projected whole body radiation levels at the site boundary of 20 mrem/hr for 1 hr, or a 100 mrem thyroid dose (committed dose equivalent [CDE]).
- Actual or projected radiological effluents with concentrations resulting in an unrestricted area TEDE of 75 mrem accumulated in 24 hr.

Note: Determination of airborne effluent concentrations will follow the same process as described for an NOUE. Unrestricted area radiation levels will be determined by direct radiation measurements with portable survey meters.

A4.4 SITE AREA EMERGENCY

This class of emergency is not credible for the RFP because the doses predicted in Chapter 13.0 do not exceed the action levels specified for this emergency in ANSI/ANS-15.16, *Emergency Planning for Research Reactors*.

A4.5 GENERAL EMERGENCY

This class of emergency is not credible for the RFP because the doses predicted in Chapter 13.0 do not exceed the action levels specified for this emergency in ANSI/ANS-15.16.

A5.0 EMERGENCY ACTION LEVELS

The EALs for each RPF emergency class are included under the appropriate class in Table A-1 of this section. The action levels specified in Table A-1 are EALs for activating the emergency organization and initiating protective actions appropriate for the emergency event.

Table A-1. Emergency Classes and Action Levels (2 pages)

Emergency class	Emergency action levels
Personnel and Operational Events	• A major personnel injury, such as a severe cut, wound, or burn • A person experiencing a heart attack, stroke, or other severe physical ailment of rapid onset • Any person receiving an estimated radiation dose equivalent greater than any occupational dose limit from sources external to the body, including doses caused by skin contamination • Any person becoming internally contaminated with radioactive material sufficient to give a dose equivalent in excess of any applicable occupational dose limit • Radiation levels in the RPF sufficient to trip the alarm on any single area radiation monitor, when such levels are from unknown sources, or sources known to represent a potential emergency situation • Airborne radioactivity levels in the RPF sufficient to alarm the continuous air monitor or the stack monitor, when such levels are from unknown sources or sources known to represent a potential emergency situation • An event that causes significant damage to the RPF complex
Notice of Unusual Events	• Receipt of information threatening, or confirming a breach in physical security (e.g., bomb threat or signs of a hostile crowd assembling outside the building) • Receipt of information that a severe natural phenomenon such as a flood, volcano, tornado, or earthquake, is likely to affect the Columbia area • An explosion in the operations boundary or a fire in the RPF complex lasting more than 15 minutes • Actual or projected radiological effluents with concentrations resulting in an unrestricted area TEDE of 15 mrem accumulated in 24 hr **Note**: The stack monitor will have alarmed, shut off the ventilation system, and closed the isolation dampers long before this concentration level is reached. However, the stack monitor will continue to function and would be used to project radiological effluent releases and direct radiation levels in the unrestricted area. Direct measurements with portable survey meters would also be used to evaluate radiation levels in the unrestricted area.
Alert	• Actual or projected whole body radiation levels at the site boundary of 20 mrem/hr for 1 hr, or a 100 mrem thyroid dose • Actual or projected radiological effluents with concentrations resulting in an unrestricted area TEDE of 75 mrem accumulated in 24 hr **Note**: Determination of airborne effluent concentrations will follow the same process as described for an NOUE. Unrestricted area radiation levels will be determined by direct radiation measurements with portable survey meters.

NOUE = notification of unusual event.
RPF = radioisotope production facility.
TEDE = total effective dose equivalent.

Effluent monitors used to project dose rates and radiological effluent releases and any associated setpoints for such systems will be identified in the NWMI Operating License Application. The manufacturer, detection methodology, and (therefore) instrument setpoints will also be identified in the Operating License Application.

A6.0 EMERGENCY PLANNING ZONE

The emergency planning zone (EPZ) for the RPF used for all classes of emergencies covered in this Emergency Response Plan is the area within the operations boundary. The operations boundary is indicated in Figure A-3. A U.S. Geological Survey 7.5 series map is provided in Figure A-4.

The area within the operations boundary (the EPZ) is large enough to support emergency actions, if needed. The predetermined protective actions for the EPZ for each class of emergency are described in Section A7.0.

Figure A-5 provides the location of sensitive facilities near the RPF site, including hospitals/medical facilities, schools, nursing homes/retirement communities, nearest residence, fire stations, and other structures and facilities, that are important to emergency management with a of radius of 16.1 kilometer (km) (10 miles [mi]).

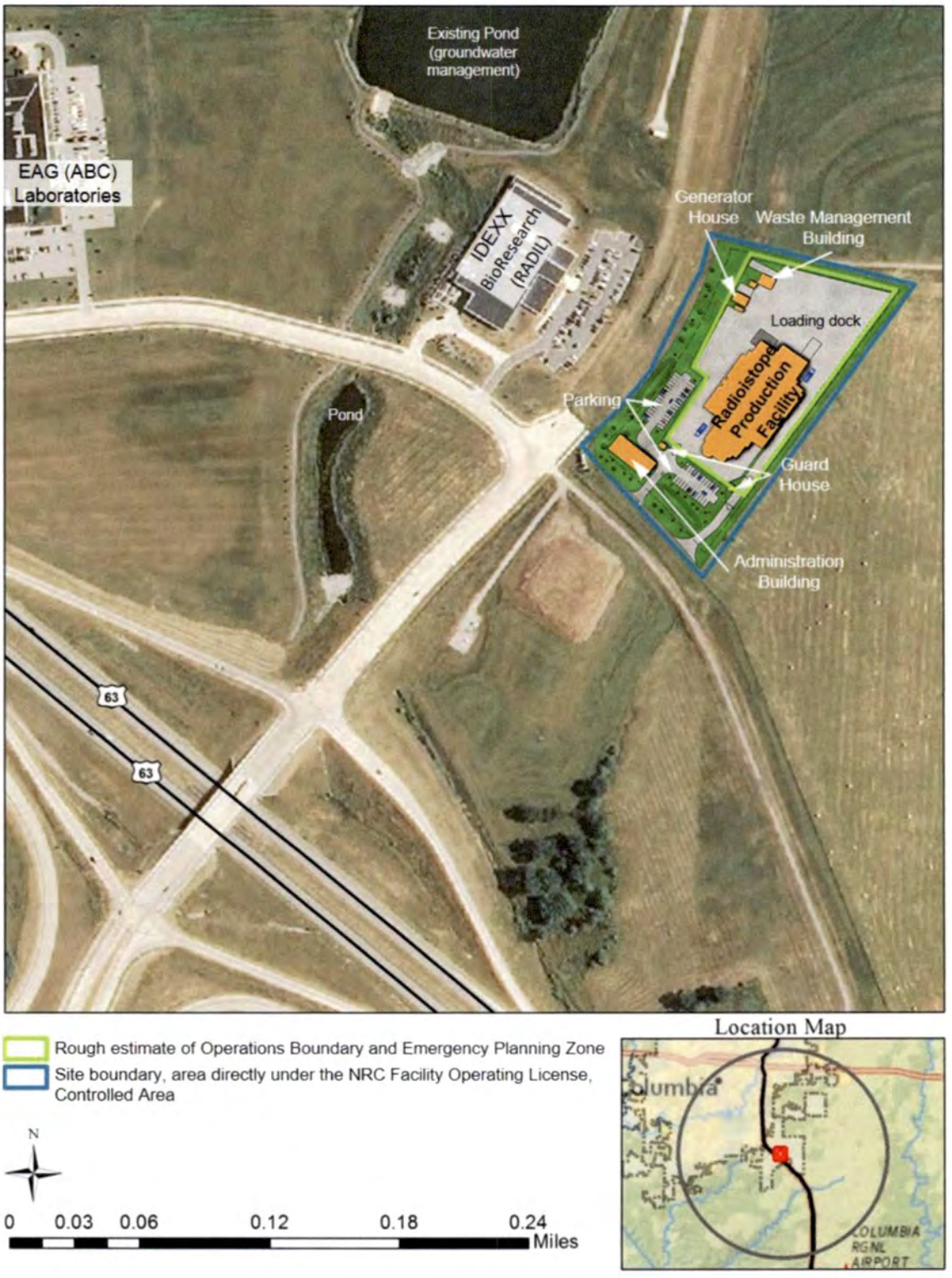


Figure A-3. Radioisotope Production Facility Complex in the Columbia Area

Figure A-4. U.S. Geological Survey 7.5-Minute Topographic Quadrangle with Property Boundary

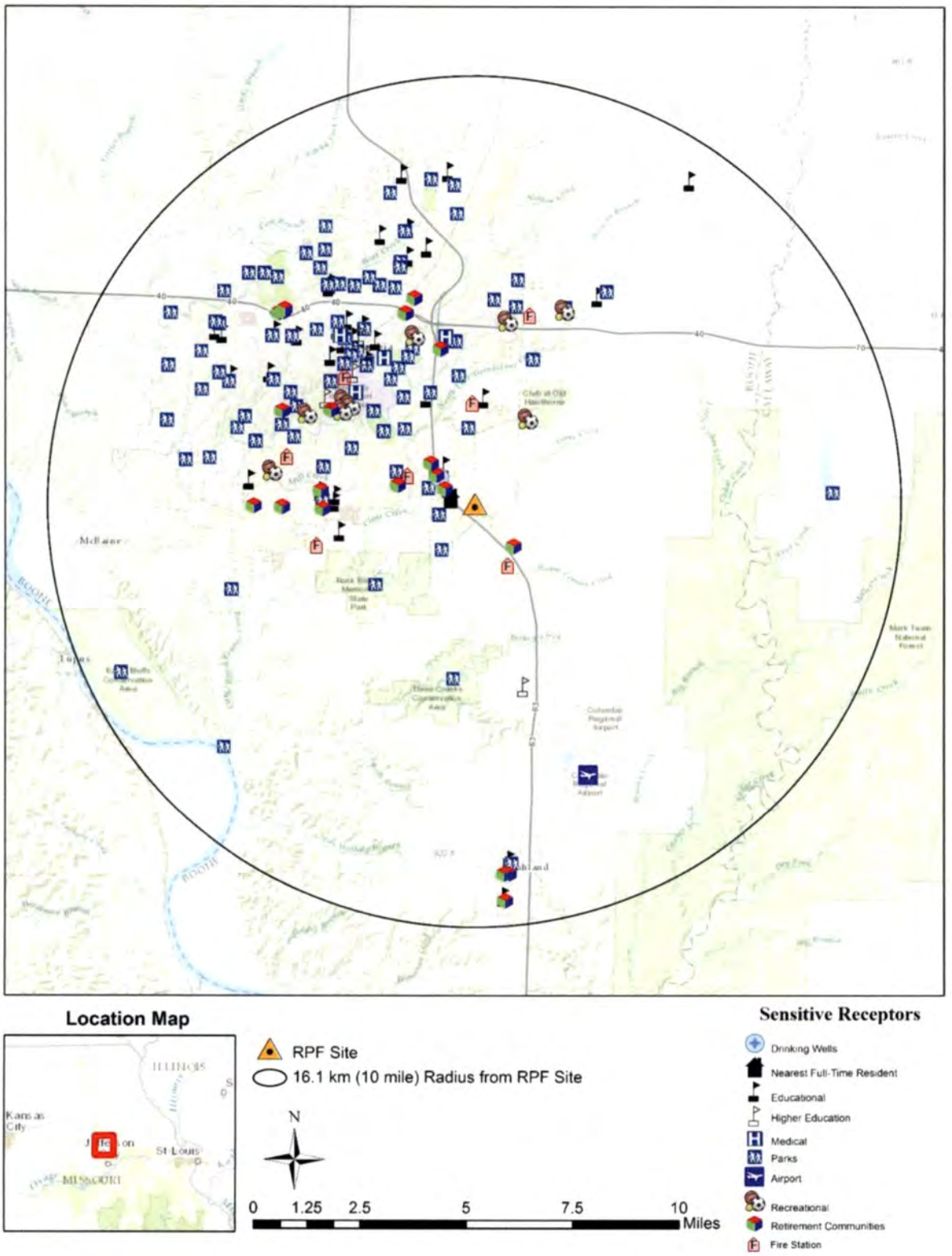


Figure A-5. Sensitive Receptors within 16.1 Kilometer (10-Mile) Radius of the Radioisotope Production Facility Site

A7.0 EMERGENCY RESPONSE

A7.1 PERSONNEL AND OPERATIONAL EVENTS

A7.1.1 Activation of Emergency Organization for Personnel and Operational Events

1. The individual who initially confirms an emergency situation will immediately contact the Emergency Coordinator and briefly describe the emergency.
2. The Emergency Coordinator will then mobilize that part of the facility organization appropriate for the emergency.
3. The 24-hr per day emergency call list for on-site staff emergency response personnel is posted throughout the RPF complex, including the ESC (RPF Control Room). The emergency call list includes the following RPF staff:
   - Emergency Director
   - Emergency Coordinator
   - Radiation Safety Officer
   - Radiological Assessment Team
4. Required off-site support agencies will then be mobilized (normally by telephone) by the Emergency Coordinator. Agencies that may be notified for this class of emergency include:
   - Columbia Fire Department
   - University Hospital
   - Boone Hospital
   - University of Missouri System
5. The NRC will be notified of this class of emergency by the Emergency Coordinator when required by applicable licenses and regulations.

A7.1.2 Assessment Actions for Personnel and Operational Events

1. Personnel injury or ailment – The nature and extent of any personnel injuries or physical ailment will be assessed by an RPF person trained in first aid and by other responding medical personnel.
2. Personnel radiation exposure (in excess of applicable limits)
   - Initial assessment of personnel radiation dose will be made by the RSO based on:
     - Any direct reading dosimeters worn
     - Measured dose rate and exposure time, or estimates of both
     - Calculation from available known data such as source strength, distance, etc.
   - As soon as possible, other dosimeters will be collected and returned to the supplier of the dosimetry service for emergency processing.
3. Personnel contamination with radioactive materials – Personnel contamination on external surfaces and/or ingestion of radioactive materials will be assessed by:
   - Direct radiation surveys with appropriate instruments
   - Smears and swabs of affected areas
   - Applicable bioassay techniques available at the RPF (e.g., urinalysis)

4. Area radiation monitor alarm
    - Radiation dose rates in the RPF initially will be assessed by the area radiation monitors. Several area radiation monitors are located in various positions throughout the RPF. These monitors have detection ranges for exposure rates between 0.1 milliroentgen (mR)/hr and 10,000 mR/hr. Alarm setpoints for these area radiation monitors are checked daily and are typically set between 20 mR/hr and 1,000 mR/hr. The area radiation monitors may be read locally or in the RPF Control Room.
    - Portable dose rate monitoring instruments will be used by the Radiological Assessment Team to further assess and characterize the radiation field. Instruments are available that cover a wide range of dose rates, radiation types, and energies.
5. Continuous air monitor or stack monitor alarm
    - Airborne radioactivity in the hot cell hall initially will be assessed by the installed air monitors. A continuous air monitor analyzes the air for particulate radioactivity. The lower limit of detection is approximately [TBD] for [TBD]. The alarm setpoint for the particulate channel is typically set at a small percentage of the applicable derived air concentration (DAC) for radionuclides normally expected.
    - In addition to the hot cell hall, the ventilation air in the hot cell is monitored as it exhausts through the main RPF stack. The lower limit of detection is approximately [TBD] for [TBD]. The stack monitor alarm setpoints are also typically set at a small percentage of the applicable DAC for radionuclides normally expected.
    - Both high- and low-volume portable air samplers are also available to take grab samples to further monitor any particulate or halogen airborne radioactivity, if necessary.
6. Uncontrolled surface contamination
    - If background radiation levels permit, direct surface contamination levels will be monitored using a portable thin window Geiger-Mueller detector. The lower limit of detection for this type of survey is consistently well below the EAL for contamination.
    - Gross smear surveys using smear pads and thin window pancake Geiger-Mueller detectors will also be used to determine the extent of the surface contamination, especially in the presence of higher background levels. The lower limit of detection for this survey technique is also consistently well below the EAL specified.
    - Analytical smear surveys will be taken using filter papers smeared over a known area and counted on appropriate instrumentation.
7. RPF complex – An assessment will be made by the Emergency Coordinator to determine if an event occurs that causes significant damage to the RPF complex.

A7.1.3 Corrective Actions for Personnel and Operational Events

1. Personnel injury or ailment
    - First aid by qualified individual
    - Transfer to appropriate medical treatment facility
2. Personnel exposure – Corrective actions for personnel exposure depend on the specific situation, but may include:
    - Shutting off equipment

- Moving or shielding sources
- Moving the individual out of the radiation field

3. Personnel contamination or uncontrolled surface contamination – Corrective actions will normally include initiating spill and contamination control procedures, along with decontamination procedures. Emergency procedures for laboratories and areas where radioactive materials are used are posted in numerous locations at the RPF. These procedures describe the correct actions for both minor and major spills, including:
   - Notifying other persons in the area that a spill or contamination has occurred
   - Preventing the spread of radioactive material
   - Shielding any large sources
   - Closing and locking the doors to the area
   - Calling for assistance
   - Decontaminating personnel and the affected area
4. Area radiation monitor alarms
   - The cause of the alarm will be determined, and if identified as indicating no potential problem, the device will be reset.
   - If the alarm is for an unknown reason or a cause known to present an emergency situation, the Operations Manager will be notified.
5. Continuous air monitor or stack monitor alarm
   - The cause of the alarm will be determined, and if identified as indicating no potential problem, the device will be reset.
   - If the alarm is for an unknown reason or a cause known to present an emergency situation, the Operations Manager will be notified.
   - As part of a stack monitor alarm, the RPF ventilation system will be shut down automatically, resulting in the fans being turned off and the hot cell isolation dampers being closed. If the ventilation system does not shut down automatically, the system will be shut down manually.
6. RPF complex – Corrective actions will be initiated by RPF staff with the objective of minimizing damage to the RPF complex.

A7.1.4 Protective Actions for Personnel and Operational Events

1. Protective actions at this level of emergency are often not distinguishable from corrective actions. Evacuating the RPF for this class of emergency is not typically necessary; however, keeping nonessential personnel away from any problem area may be desirable.
2. Protective actions that may be applicable to this class of emergency include:
   - Performing first aid
   - Moving personnel away from high radiation fields
   - Dressing contaminated personnel in protective clothing prior to movement to contain the contamination
   - Moving personnel away from contaminated areas
   - Establishing restricted areas

A7.2 NOTIFICATION OF UNUSUAL EVENTS

A7.2.1 Activation of Emergency Organization for Notification of Unusual Events

1. The individual who initially confirms an emergency situation will immediately contact the Emergency Coordinator and briefly describe the emergency.
2. The Emergency Coordinator will then mobilize that part of the facility emergency organization appropriate for the emergency.
3. The 24-hr per day emergency call list for emergency response personnel is posted throughout the RPF complex, including the ESC (RPF Control Room).
4. Required off-site support agencies will then be mobilized (normally by telephone) by the Emergency Coordinator. Some of the off-site support agencies will receive automatic alarms for certain emergencies in this class.
5. The NRC and American Nuclear Insurers will be notified by the Emergency Coordinator. A system will be used to ensure that these off-site agencies have received the initial message and that they can verify its authenticity.
6. Contents of initial and follow-up emergency messages to the NRC will include the following, to the extent known and applicable:
    - Name, title, and telephone number of caller, location of emergency, and license or docket number
    - Description of emergency event and emergency class
    - Date and time of emergency initiation
    - Type and quantity of radionuclides released or expected to be released
    - Instructions to implement the callback verification procedure

A7.2.2 Assessment Actions for Notice of Unusual Events

Physical Security Threats or Breaches, Severe Natural Phenomena, and Explosions or Fires

The assessment actions for physical security threats or breaches in physical security, severe natural phenomena, explosions, and fires will consist of gathering data by direct visual observation or from personnel involved in the situation. This data will then be evaluated in an expedient and timely manner by the Emergency Director, Emergency Coordinator, and RSO.

Elevated Radiological Effluent Discharge to the Unrestricted Area

- Airborne radioactivity initially will be assessed by the installed air monitors. [system description TBD].
- In addition, ventilation air in the RPF is sampled as it exhausts through the stack. [system description TBD]
- Both high- and low-volume portable air samplers are available for sampling in the unrestricted area. The sampling would likely be performed by the Radiological Assessment Team.

A7.2.3 Corrective Actions for Notification of Unusual Events

1. Physical security threats or breaches
    - Hot cell operations will be secured.

- In all emergencies involving physical security, the next corrective action is to contact the Columbia Police Department, who will respond to the RPF complex. Further law enforcement support will be coordinated by Columbia Police Department. Procedures for these actions are included in the NWMI Physical Security Plan, which includes safeguards information, exempted from public disclosure, and thus not reproduced here.

2. Severe natural phenomena – On receipt of information that a severe natural phenomenon is likely to affect the Columbia area, the Emergency Director, Emergency Coordinator, RSO, and NWMI Vice President, if available, will immediately convene to determine an appropriate course of action. Actions that may be considered include:
   - Hot cell operations will be secured.
   - Evacuation of the RPF.
3. Explosions or fires
   - Hot cell operations will be secured.
   - Personnel initially discovering an explosion or fire will use individual judgment regarding the use of a fire extinguisher.
   - If the fire alarm has not been activated automatically, the alarm will be activated manually. Fire alarm boxes and fire extinguishers are located throughout the facility.
   - Doors not already closed should be shut to help prevent the spread of any fire or the spread of any radioactive contamination that may arise as a result of an explosion or fire.
4. Elevated radiological effluent discharge to the unrestricted area
   - Hot cell operations will be secured.
   - If the ventilation system has not shut down automatically, the system will be turned off manually so that the fans will be off and the isolating dampers closed in accordance with procedures.

A7.2.4 Protective Actions for Notification of Unusual Events

1. For most NOUE, the main protective action will be to evacuate the RPF.
2. Due to the nature of most NOUE emergencies, an evacuation may be initiated by any member of the staff.
3. There are three methods to evacuate the RPF:
   - Fire alarm system
   - Automated public address system evacuation announcement
   - Public address system for the entire RPF complex
4. Evacuation procedures are posted throughout the RPF complex. All personnel in areas where any evacuation alarm sounds will immediately evacuate the building by the shortest reasonable route. Personnel will reassemble outside the main entrance to the RPF Administrative Building (the west side of the building) unless ordered to another assembly point as part of the evacuation.
5. During any evacuation of the RPF, the intrusion alarm system will be activated by RPF staff.
6. In the assembly area, personnel who suspect that they are contaminated will assemble separately from other personnel.
7. Other appropriate protective actions may be communicated to individuals within the operations boundary by means of the public address system for the RPF complex.

8. A battery-operated public address device (bullhorn) is available in the emergency equipment locker to communicate protective actions and other information to personnel at the assembly area.
9. Personnel accountability within the operations boundary and/or the RPF complex is accomplished by two methods:
   - All personnel entering the RPF are required to check with the RPF Administrative Building receptionist on entry and exit so that the identity and number of people in the RPF are known at all times.
   - During an evacuation, RPF staff members have pre-assigned areas of the RPF complex to check on their way out of the building to ensure that everyone has evacuated.
10. Personnel evacuated from the RPF complex will remain in the assembly area until all the necessary information has been obtained, needed dosimeters have been collected for evaluation of doses, and personnel surveys have been completed. Nonessential personnel will then be released.

A7.3 ALERT, SITE AREA EMERGENCY, AND GENERAL EMERGENCY

A7.3.1 Activation of Emergency Organization for Alert, Site Area Emergency, and General Emergency

1. The individual who initially confirms an emergency situation will immediately contact the Emergency Coordinator and briefly describe the emergency.
2. The Emergency Coordinator will then mobilize that part of the facility emergency organization appropriate for the emergency.
3. The 24-hr per day emergency call list for emergency response personnel is posted throughout the RPF complex, including the Emergency Support Center (RPF Control Room).
4. Required off-site support agencies will then be mobilized (normally by telephone) by the Emergency Coordinator.
5. The NRC and American Nuclear Insurers will be notified by the Emergency Coordinator. A system will be used to ensure that these off-site agencies have received the initial message and that they can verify its authenticity.
6. Contents of initial and follow-up emergency messages to the NRC will include the following, to the extent known and applicable:
   - Name, title, and telephone number of caller, location of emergency, and license or docket number
   - Description of emergency event and emergency class
   - Date and time of emergency initiation
   - Type and quantity of radionuclides released or expected to be released
   - Instructions to implement the callback verification procedure

A7.3.2 Assessment Actions for Alert, Site Area Emergency, and General Emergency

1. High radiation levels at the site boundary
   - Radiation dose rates in the RPF initially will be assessed by the area radiation monitors. Several area radiation monitors are located in various positions throughout the RPF. These monitors have detection ranges for exposure rates between 0.1 mR/hr and 10,000 mR/hr. Alarm setpoints for these area radiation monitors are checked daily and are typically set between 20 mR/hr and 1,000 mR/hr. All of the area radiation monitors may be read locally or in the RPF control room.

- Portable dose rate instruments will be used by the Radiological Assessment Team to further assess and characterize the radiation field at the site boundary. Instruments are available that cover a wide range of dose rates, radiation types, and energies.

2. Elevated radiological effluent discharge to the unrestricted area
   - Airborne radioactivity in the hot cell hall initially will be assessed by the installed air monitors. A continuous air monitor analyzes the air for particulate radioactivity. The lower limit of detection is approximately [TBD] for [TBD]. The alarm setpoint for the particulate channel is typically set at a small percentage of the applicable DAC for radionuclides normally expected.
   - In addition to the hot cell hall, the ventilation air in the hot cell is monitored as it exhausts through the main RPF stack. The lower limit of detection is approximately [TBD] for [TBD]. The stack monitor alarm setpoints are also typically set at a small percentage of the applicable DAC for radionuclides normally expected.
   - Both high- and low-volume portable air samplers are available for sampling in the unrestricted area. The sampling would likely be performed by the Radiological Assessment Team.

A7.3.3 Corrective Actions for Alert, Site Area Emergency, and General Emergency

1. High radiation levels at the site boundary
   - Operations in the RPF will be shut down and secured.
   - The source of high radiation levels will be sought and shielded.
   - Personnel will be sent to the site boundary, out of the radiation field, to minimize access to the general area.
2. Elevated radiological effluent discharge to the unrestricted area
   - Operations in the RPF will be shut down and secured.
   - If the ventilation system has not shut down automatically, the system will be turned off manually so that the fans will be off and the isolating damper closed.

A7.3.4 Protective Actions for Alert, Site Area Emergency, and General Emergency

Protective actions for this class of emergency will be in accordance with Section A7.2.4.

A7.4 EMERGENCY EXPOSURE LEVELS

A7.4.1 Lifesaving Activities

For lifesaving situations, a TEDE of up to 25 rem is permissible without authorization, due to the implied urgency of the situation.

A7.4.2 Corrective Actions

For non-lifesaving corrective actions, the maximum TEDE that will be authorized is 10 rem. Authorization for this limit should be obtained from the Emergency Director with the concurrence of the RSO, if available.

A7.4.3 Other Emergency Actions

Emergency personnel who will be providing routine first aid, decontamination, or medical treatment services to injured persons will be subject to the normally applicable occupational dose limits.

A7.5 ACCESS CONTROL AND RESTRICTED AREAS

1. Following the assessment of radiation and contamination conditions in and around the RPF complex, to minimize exposures to radiation and the spread of radioactive contamination, the RSO will post appropriate warning signs and restrict access to areas where permissible contamination or radiation limits are exceeded.
2. No area will be returned to normal use until radiation and contamination levels have been reduced to the approximate background levels existing in the area prior to the incident. Such levels will be determined by conventional radiation surveys. In applicable situations, levels will be equal to or below the limits specified in current regulatory guidance for unrestricted use and access.

A7.6 PERSONNEL DOSIMETRY

1. Determination of the on-site radiation doses to personnel during an emergency will be made using Existing dosimeters regularly supplied to personnel.
2. Members of the RPF staff routinely wear, or have available, the following dosimeters:
   - Electronic dosimetry (0-2000 mR).
   - Xβγ film or thermoluminescent dosimeter (TLD) badge
   - Neutron-sensitive TLD component or equivalent (e.g., track etch).
   - TLD finger rings.
3. There are a large number of additional pocket ion chambers and electronic dosimeters available for issue in the event of an emergency. These devices would be used as necessary for assessing personnel doses.
4. The issuance, use, and recording of self-reading dosimeter doses during an emergency is under the direction of the RSO.

A7.7 PROTECTION ACTION GUIDES FOR WHOLE BODY AND THYROID DOSE EQUIVALENT FOR MEMBERS OF THE GENERAL PUBLIC WITHIN THE EMERGENCY PLANNING ZONE (THE OPERATIONS BOUNDARY)

Individual members of the general public requiring access within the operations boundary will be required to be escorted, issued dosimetry, and undergo a short orientation prior to entering. At this point, they will follow the policies and procedures in the radiation protection program for occupational workers.

A8.0 EMERGENCY EQUIPMENT AND FACILITIES

A8.1 EMERGENCY SUPPORT CENTER

The primary ESC will be the RPF Control Room. Adjacent offices may be used as necessary. This room also has the annunciators for the facility fire alarm and some physical security annunciators. The general evacuation alarms for the entire RPF complex may also be initiated and turned off in this room, and the exposure rates read that are measured by some of the area radiation monitors outside of the RPF.

The ESC will be the central point for receipt and evaluation of radiological data and the point from which emergency control directions will be given. The ESC also has microphones for the building public address (PA) system and an intercom to strategic laboratories and offices in the RPF complex.

A8.2 ASSESSMENT FACILITIES AND EQUIPMENT

A listing of the current locations for emergency equipment cabinets and other emergency equipment storage areas, plus representative equipment inventories for these storage locations, are given in Table A-2.

Table A-2. Emergency Equipment and Associated Storage Location

Equipment description	Quantity	Storage Location
[TBD]		

A8.2.1 Portable and Fixed Radiological Monitors

1. Many portable radiation monitoring instruments are available for use during an emergency. Some of these monitors are kept in the emergency equipment cabinets and others are routinely used for normal operations. A representative listing of these instruments includes:
   - High-range gamma ion chamber survey meters
   - Medium-range beta/gamma ion chamber survey meters
   - Beta/gamma Geiger-Mueller survey meters
   - Neutron survey meters
   - Alpha survey meters
2. A number of fixed radiological monitors are also available, and as described in Chapter A7.0, these monitors include:
   - Continuous air monitors located [TBD].
   - A stack monitor for the RPF ventilation discharge stack (particulate and gaseous) located in Room [TBD].
   - The multi-channel area radiation monitoring system in various locations around the RPF.
3. Criticality accident alarm system [TBD]

A8.2.2 Sampling Equipment

1. There are a number of portable air samplers available for use in an emergency. A representative listing of this equipment includes:
   - Continuous particulate air monitors (on carts)
   - High-volume particulate air samplers (alternating current [AC]-operated)
   - Medium-volume particulate and halogen air samplers (AC-operated)
   - Medium-volume, battery-operated particulate and halogen air samplers
   - Low-volume, battery-operated (lapel) particulate air samplers
2. Supplies are kept in the health physics laboratory for various other forms of sampling, including water and surface smear sampling. The emergency cabinets also contain a selection of necessary sampling materials.

A8.2.3 Instrumentation for Specific Radionuclide Identification and Analysis

A wide variety of laboratory analytical instrumentation is available in the RPF. The following systems are representative of available equipment and are also the most likely to be used in an emergency:

- Multichannel analyzer with a germanium detector for automated computer analysis of gamma spectra, located in Room [TBD] of the RPF
- Liquid scintillation counter located in Room [TBD]
- Gas flow proportional counter located in Room [TBD]

A8.2.4 Personnel Monitoring Equipment

Typical personnel monitoring equipment is described in Section A7.6.

A8.2.5 Nonradiological Monitoring Equipment

Fire detectors

- The RPF complex has fire detection devices in essentially all rooms and corridors. Most of these devices respond to temperature rate of rise; however, there are also a few smoke detectors.
- If one of the fire sensors detects a fire, an alarm will automatically activate in the building and at the City of Columbia Emergency Dispatch Center.
- An annunciator will also be lit in RPF Control Room (also the ESC) to indicate the origin of the fire alarm. A map in that office indicates the possible radiation hazards, if any, for each area of the
- The fire suppression system is composed of [TBD].

A8.3 FIRST AID, DECONTAMINATION, AND MEDICAL FACILITIES

A8.3.1 First Aid Training

One or more members of the emergency organization (e.g., first responders) will have a current Red Cross first aid qualification. Training, such as the American National Red Cross Standard Multimedia Course (refresher course every two years) or equivalent, will be provided to selected members of the facility emergency organization.

A8.3.2 Contamination Control and Personnel Decontamination

The RSO will coordinate any necessary personnel.

1. If there are a number of people involved in an emergency where there is a possibility for contamination, injured personnel will be monitored first.
2. All contaminated personnel will be kept in one area, as far away from other personnel as possible, to avoid the spread of contamination.
3. Injured personnel will normally be decontaminated and then dispatched to the either Boone Hospital or University Hospital.
4. Monitoring and decontamination may occur en route or after arrival, depending on the nature of the injury.
5. After all injured persons are cared for, uninjured personnel will be checked for contamination, and necessary action taken to remove whatever contamination is detected.

A8.3.3 First Aid, Decontamination Facilities and Equipment

1. Personnel first aid and decontamination kits are available throughout the RPF complex. The locations and typical contents of these kits are given in Table A-3.

Table A-3. First Aid and Decontamination Kit Contents

Equipment description	Quantity	Contents	Location
[TBD]			

2. Showers are available in room [TBD] that can be used for personnel decontamination. The water from this shower drains to the monitored liquid effluent system.
3. In the event that this shower is not accessible or available, there are personnel decontamination facilities at University Hospital.

A8.3.4 Medical Transportation

1. The attending medical staff will decide where injured persons are taken, based on the:
   - Nature and severity of their injuries
   - Level of radioactive contamination
2. During transportation, care will be taken to contain any contamination by dressing the person with protective clothing, covering the individual with blankets or plastic, or other appropriate means.

3. Personnel with obviously serious injuries, with contamination, will be transported by ambulance directly to the emergency room of University Hospital. Both the ambulance crews and hospital emergency room staff have been trained to handle radiological emergencies.

A8.3.5 Medical Treatment

1. The University Hospital in Columbia has an SOP for dealing with radiological emergencies, including contaminated patients.
2. NWMI will maintain a written agreement with the University Hospital that ensures that medical services are available, and that the staff are prepared to handle radiological emergencies.

A8.4 COMMUNICATIONS EQUIPMENT

1. Communications equipment or systems available for use during an emergency are:
   - Telephones – The RPF complex has a number of telephones, each with its own independent line. The ESC telephones can handle four simultaneous calls and includes displays that provide information about the calls. The telephones will continue to function in the event of a power loss to the RPF complex.
   - PA system – This system serves the RPF complex and is operable from the ESC. This system has backup emergency power.
   - Portable radios
   - A separate building intercom system throughout the RPF complex
   - Cell phones on individuals
2. The Columbia Police Department also has the capability of radio communications with other local law enforcement agencies and the ability to use the loudspeaker system on police vehicles as an external PA system, if necessary.

A9.0 RECOVERY

1. Recovery criteria for restoring the facility to a safe status will be dependent on the incident and will be determined by a task group consisting of:

   - Emergency Director
   - Emergency Coordinator
   - RSO
   - Hot Cell Supervisor
   - NWMI Vice President

2. As needed, recovery procedures will be written and approved by the procedure approval process for each operation prior to initiation. The recovery operations and any needed procedures will include consideration of the radiation and contamination levels.

3. After the emergency, a comprehensive written report of the events and subsequent actions will be prepared by designated RPF staff and filed.

A10.0 MAINTAINING EMERGENCY PREPAREDNESS

This section describes the elements necessary to maintain an acceptable state of emergency preparedness. Maintaining the effectiveness of the Emergency Response Plan includes training, review, and update of this plan and associated implementing procedures, and maintenance and inventory of equipment and supplies that would be used in emergencies.

A10.1 INITIAL TRAINING AND PERIODIC RETRAINING PROGRAM

1. Initial training and periodic retraining will be conducted for emergency response personnel to maintain the ability to perform their assigned functions during an emergency event.
2. The personnel involved in the training program will be:
   - Facility personnel responsible for decision-making and transmitting emergency information and instruction
   - Facility personnel responsible for accident assessment and assistance (e.g., first responders)
   - Facility radiological monitoring and assessment team members
   - Medical support personnel at Boone and University Hospitals[1]
   - Columbia Police Department personnel[1]
   - University and Boone Hospital ambulance and emergency department personnel[1]
3. Training will also include, as appropriate, information on the use of protective equipment, protective clothing, and monitoring devices used in emergency response relevant to the personnel listed above. Initial training on the emergency plan should nominally take two hours and annual retraining should take one hour to perform.

A10.2 EMERGENCY DRILLS

1. Annual on-site emergency drills will be conducted as action drills, with each required emergency measure being executed as realistically as is reasonably possible. Drills should be conducted such that:
   - Qualified individuals for each position in the emergency response organization demonstrate task-related knowledge through periodic participation.
   - Emergency drills demonstrate that resources are effective and used to control the site, mitigate further damage, control radiological releases, perform required on-site activities under simulated radiation or airborne and other emergency conditions, accurately assess the facility's status during an accident, and initiate recovery.
   - Emergency drills demonstrate personnel protection measures, including controlling and minimizing hazards to individuals during fires, medical emergencies, mitigation activities, search and rescue, and other similar events.
   - Emergency drills demonstrate that on-site communications effectively support emergency response activities.

[1] These personnel will receive regular training at fixed intervals, but initial training for all new employees is not considered feasible.

- Emergency drills demonstrate that the emergency public information organization disseminates accurate, reliable, timely, and understandable information.

2. Annual action drills will employ the use of written scenarios to more effectively fulfill their function.
3. Biennially, these drills will contain provisions for coordination with off-site emergency personnel and will test, as a minimum, the communication links and notification procedures with these off-site agencies and support organizations.
4. After each drill, there will be a debriefing, during which time observers will present their critiques of the exercise. These comments will then be evaluated by the facility emergency response personnel. Any deficiencies identified in the emergency plan, the implementing procedures, or their actual use during a drill will be corrected within 6 months of the exercise.

A10.3 EMERGENCY PLAN REVIEW AND UPDATE

1. The Emergency Response Plan will be reviewed and updated annually and will include modifications necessitated by changes in the facility and/or environs. The review committee will consist of the RPF Director, RPF Operations Manager, RSO, and Hot Cell Supervisor.
2. Revised or updated copies of the Emergency Response Plan, support agreements, and applicable implementing procedures will be distributed within 30 days of approval to all affected individuals and federal, state, county, and local organizations.
3. Changes to the Emergency Response Plan will be made in accordance with 10 CFR 50.54(q). Three copies of changes made without NRC approval that do not decrease the effectiveness of the plan, and proposed changes that may decrease the effectiveness of the plan, will be submitted to the NRC within 30 days after the changes are made or proposed. In accordance with 10 CFR 50.4(b)(5), a signed original will be sent to the NRC Document Control Desk in Washington, D.C., and two copies will be sent to the NRC Project Manager.

A10.4 EQUIPMENT MAINTENANCE AND INVENTORY

The operational readiness of all emergency communications and emergency health physics equipment is ensured by a routine maintenance program. Part of this maintenance is performed under the existing RPF surveillance and maintenance program, and the rest is performed as part of the routine health physics program.

A check of the emergency equipment security seals will be performed quarterly. If this seal is broken, an inspection and inventory will be immediately performed using the checklist for the given cabinet or room as appropriate. If the seal is not broken, the status of the seal will be recorded in the checklist. However, all emergency equipment will be inventoried and inspected annually regardless of the status of the security seals.

A10.4.1 Required Maintenance and Minimum Calibration Frequency

1. Communications equipment is repaired as necessary.
2. All portable survey instruments are repaired as necessary and calibrated annually.
3. The RPF fixed radiological monitors are repaired as necessary and calibrated annually.
4. Self-reading dosimeters are calibrated annually.
5. Air sampler flow rates are calibrated annually.
6. The automated evacuation announcement system will be tested annually.

A10.4.2 Functional Testing

1. Most communications equipment is in daily use, essentially undergoing continual functional testing. The emergency cabinet cassette recorder, cell phones, and two-way radios are functionally tested annually. In addition, NWMI will conduct quarterly checks of the ability to communicate with off-site responding agencies.
2. All portable survey instruments at the RPF complex are checked prior to operation, except those in the emergency cabinets, which are checked at least annually. A number of survey instruments are in routine use and are functionally checked on a daily basis.
3. The RPF fixed radiological monitors are in routine use and functionally tested daily during the normal work week.

A10.4.3 Equipment Inventory

The equipment in the emergency cabinets at the RPF complex is inventoried on an annual basis.

A11.0 REFERENCES

10 CFR 20, "Standards for Protection Against Radiation," *Code of Federal Regulations*, Office of the Federal Register, as amended.

10 CFR 50, "Domestic Licensing of Production and Utilization Facilities," *Code of Federal Regulations*, Office of the Federal Register, as amended.

ANSI/ANS-15.16, *Emergency Planning for Research Reactors*, American Nuclear Society, La Grange Park, Illinois, 2008 (W2015).

Appendix B

NORTHWEST MEDICAL ISOTOPES, LLC
RADIOISOTOPE PRODUCTION FACILITY

PHYSICAL SECURITY PLAN

Approved by the
U.S. Nuclear Regulatory Commission

XXXXX,XXXX

Last Revised: September 2017

Rev. 3 (DRAFT)

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Appendix C

QUALITY ASSURANCE PROGRAM PLAN FOR THE DESIGN, CONSTRUCTION, AND OPERATION OF THE RADIOISOTOPE PRODUCTION FACILITY

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QUALITY ASSURANCE POLICY STATEMENT

This Corporate Quality Assurance Program Plan (QAPP) describes the policies and requirements necessary to meet applicable Federal regulations such as ANSI/ANS 15.8, *Quality Assurance Program Requirements for Research Reactors*; Regulatory Guide 2.5, *Quality Assurance Program Requirements for Research and Test Reactors*; 10 CFR 70.64(a)(1), *Quality Standards and Records*; and ISO-9001, *Quality Assurance Requirements*. This QAPP applies to all nuclear, quality-related projects and activities that require conformance to a nuclear quality assurance program, and therefore shall be the standard for all Northwest Medical Isotopes, LLC (NWMI) personnel to follow for compliance to those requirements.

NWMI is committed to establishing, implementing, and maintaining a QAPP to ensure that all NWMI activities and processes are planned, reviewed, controlled, and verified for compliance with applicable Federal regulations, national standards, and contractual requirements. NWMI is committed to meeting all of our customer's quality objectives and exceeding their expectations for the quality of the services and products we deliver. In addition, NWMI is committed to fostering a culture that provides for a sustained and continuous quality improvement atmosphere such that our internal processes are continually examined, challenged, and improved for our benefit and that of our customers.

NWMI's primary goal is to provide a domestic, reliable, and securable supply of molybdenum-99 (^{99}Mo) at competitive prices based on known innovated technologies. To achieve this goal, NWMI will apply a well-planned, systematic management program for quality performance while continuing our tradition of personal involvement with our customers. Applying a well-planned, graded approach to NWMI's effective quality management system is the key to achieving our environmental, safety, quality, and compliance goals, and will result in productive, efficient, and cost-effective work performances.

NWMI encourages and empowers our employees and subcontractors to seek innovative and imaginative ways to solve our customers' needs and to provide quality products and services throughout the world. The QAPP promotes continuous improvements in our processes, item and service quality, and effective methods and procedures to achieve the desired quality. Each NWMI employee is trained to always be aware of nonconforming conditions, to report such conditions, and to continually seek ways to improve the quality of our processes, our products, and the services we provide. One of NWMI's basic tenets of quality management is that each employee is responsible and accountable for the quality of his or her work. Effective implementation of the QAPP by our employees and subcontractors is an essential element of our approach to meeting these expectations. Verification of quality is also an essential element of an effective quality management system. As Senior Managers of NWMI, we will ensure that all project quality verification personnel have sufficient authority, access to work areas, and organizational freedom to perform their duties as prescribed herein and in implementing procedures.

Nicholas Fowler, NWMI
Chief Executive Officer

Carolyn Haass, NWMI
Chief Operating Officer

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CONTENTS

FIGURES

TABLES

TERMS

Acronyms and Abbreviations

^{99}Mo	molybdenum-99
ALARA	as low as reasonably achievable
ANS	American Nuclear Society
ANSI	American National Standards Institute
ASL	approved suppliers listing
ASME	American Society of Mechanical Engineers
ASNT	American Society of Nondestructive Testing
ASTM	American Society for Testing and Materials
CEO	Chief Executive Officer
CFO	Chief Financial Officer
CFR	Code of Federal Regulations
COO	Chief Operating Officer
IROFS	items relied on for safety
M&TE	measuring and test equipment
NDE	nondestructive examination
NRC	U.S. Nuclear Regulatory Commission
NWMI	Northwest Medical Isotopes, LLC
QA	quality assurance
QAPP	Quality Assurance Program Plan
QC	quality control
QL	quality level
RPF	radioisotope production facility
SH&L	safety, health, and licensing
SSC	structures, systems, and components

C1.0 INTRODUCTION

C1.1 SCOPE

This Corporate Quality Assurance Program Plan (QAPP) describes the policies and requirements necessary to meet applicable Federal regulations and provides a description of the Northwest Medical Isotopes, LLC (NWMI) quality assurance (QA) program in a controlled document. The QAPP is based on Title 10, *Code of Federal Regulations*, Part 50.34 (10 CFR 50.34), "Contents of Applications; Technical Information," and associated ANSI/ANS 15.8, *Quality Assurance Program Requirements for Research Reactors*; Regulatory Guide 2.5, *Quality Assurance Program Requirements for Research and Test Reactors*; 10 CFR 70.64(a)(1), "Quality Standards and Records;" and ISO-9001, *Quality Assurance Requirements*. This QAPP applies to all nuclear, quality-related projects and activities that require conformance to a nuclear quality assurance program, and therefore shall be the standard for all NWMI personnel to follow for compliance to those requirements.

This QAPP and applicable implementing procedures will apply specifically to the NWMI Radioisotope Production Facility (RPF). This document meets the intent of the above documents and applicable NWMI policies and programs. The procedures that implement the requirements in this document are maintained in the NWMI document control system. The QAPP describes the administrative and engineered controls for ensuring compliance with applicable requirements. The QAPP applies to the design, construction, operation, and decommissioning of the RPF.

C1.2 APPLICATION

NWMI's QAPP has been developed to provide safety and reliability during design, construction, and operation activities of the RPF (e.g., at a minimum, activities related to general safety, material processing safety, criticality safety, engineered safety features, and applicable radiation monitoring systems [limiting conditions for operations provided in Chapter 14.0, "Technical Specifications"]).

NWMI will apply a graded approach to those items and activities that could affect the quality of safety-related structures, systems and components (SSC) and other components not specifically designated as safety-related. A quality level matrix is used to ensure that quality requirements are understood and specified for each SSC. An applicability procedure will be developed during preparation of the Operating License Application that will address the effective designation and traceability of quality levels. Applicable activities will be performed in accordance with a graded approach until a determination is made that the SSC has changed to another quality level. Activities that could affect quality include siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, repairing, maintaining, modifying, inspecting, testing, operating, and decommissioning.

NWMI will develop and implement the QAPP for design, construction, and operation of the RPF. The QAPP will focus on the development of appropriate controls to ensure that the RPF is properly designed and constructed and equipment fabricated to the design requirements identified in the NWMI-DRD-2013-030, *Design Requirements Document*. The majority of these controls will require documentation that attests to the facility quality to support an operating license. Following facility construction, the focus of this QAPP shifts to establishing those controls that ensure proper and reliable facility commissioning and operation. During the shift to operations, the QAPP requirements established during the design and construction phase will remain in-place, but will change in level of implementation appropriate to support facility operations. Each aspect of design, construction, and modifications will be implemented only as necessary. The operating phase will impose additional requirements related to the conduct of operations.

C1.3 COMPLIANCE

Table C-1, Table C-2, and Table C-3 present compliance of the QAPP with 10 CFR 50.34 and associated ANSI/ANS 15.8, 10 CFR 70.64(a)(1), and ISO-9001, respectively, and where in the QAPP the requirement resides.

Table C-1. Quality Assurance Program Plan Compliance with 10 CFR 50.34 and associated ANSI/ANS 15.8

	10 CFR 50.34 and associated ANSI/ANS 15.8 requirements[a,b]	QAPP reference	Focus
1	Organization	Section C2.1	• Quality assurance hierarchy • Organization responsibilities
2	Quality assurance program	Section C2.2	• Quality assurance hierarchy • Organization, personnel training and qualification
3	Design control (requirements, process, verification, document/records, commercial grade items change control)	Section C2.3 Section C2.5 Section C2.9	• Design control • Instructions, procedures, and drawings • Control of special processes
4	Procurement document control	Section C2.4	• Procurement document control
5	Procedures, instructions, and drawings	Section C2.5 Section C2.9	• Instructions, procedures, and drawings • Control of special processes
6	Document control	Section C2.6	• Document control
7	Control of purchased items and services (supplier selection, work control, verification, item or service acceptance)	Section C2.7	• Control of purchased items and services
8	Identification and control of items	Section C2.8	• Identification and control of items
9	Control of special processes	Section C2.9	• Control of special processes
10	Inspections	Section C2.10	• Inspections
11	Test control	Section C2.11	• Test control
12	Control of measuring and test equipment	Section C2.12	• Control of measuring and test equipment
13	Handling, storage, and shipping	Section C2.13	• Handling, storage, and shipping
14	Inspection, test, and operating status	Section C2.10 Section C2.11 Section C2.14	• Inspections • Test control • Inspection, test, and operating status
15	Control of nonconforming items and services	Section C2.15	• Identification and control of nonconforming items
16	Corrective actions	Section C2.16	• Corrective action
17	Quality records	Section C2.17	• Quality assurance records
18	Assessments	Section C2.18	• Audits, assessments, and surveillances
19	Experimental equipment		• Not applicable; no experimental equipment

[a] 10 CFR 50.34, "Contents of Applications; Technical Information," *Code of Federal Regulations*, Office of the Federal Register, as amended.

[b] ANSI/ANS 15.8, *Quality Assurance Program Requirements for Research Reactors*, American National Standards Institute/American Nuclear Society, LaGrange Park Illinois, 1995, R2005, R2013.

QAPP = Quality Assurance Program Plan.

Table C-2. Quality Assurance Program Plan Compliance with 10 CFR 70.64(a)(1)

	10 CFR 70.64(a)(1) requirement[a]	QAPP reference	Focus
1	Organization	Section C2.1	• Quality assurance hierarchy • Organization responsibilities
2	Quality assurance program	Section C2.2	• Quality assurance hierarchy • Organization, personnel training and qualification
3	Design control (requirements, process, verification, document/records, commercial grade items, change control)	Section C2.3 Section C2.5 Section C2.9	• Design control • Instructions, procedures, and drawings • Control of special processes
4	Procurement document control	Section C2.4	• Procurement document control
5	Procedures, instructions, and drawings	Section C2.5 Section C2.9	• Instructions, procedures, and drawings • Control of processes
6	Document control	Section C2.6	• Document control
7	Control of purchased items and services (supplier selection, work control, verification, item or service acceptance)	Section C2.7	• Control of purchased items and services
8	Identification and control of items	Section C2.8	• Identification and control of items
9	Control of special processes	Section C2.9	• Control of special processes
10	Inspections	Section C2.10	• Inspections
11	Test control	Section C2.11	• Test control
12	Control of measuring and test equipment	Section C2.12	• Control of measuring and test equipment
13	Handling, storage, and shipping	Section C2.13	• Handling, storage, and shipping
14	Inspection, test, and operating status	Section C2.10 Section C2.11 Section C2.14	• Inspections • Test control • Inspection, test, and operating status
15	Control of nonconforming items and services	Section C2.15	• Identification and control of nonconforming items
16	Corrective actions	Section C2.16	• Corrective action
17	Quality records	Section C2.17	• Quality assurance records
18	Audits	Section C2.18	• Audits, assessments, and surveillances
19	Provisions for changes	Section C2.19	• Initiation for changes

[a] 10 CFR 70.64(a)(1), "Quality Standards and Records;" *Code of Federal Regulations*, Office of the Federal Register, as amended.

QAPP = Quality Assurance Program Plan.

Table C-3. Quality Assurance Program Plan Compliance with ISO-9001

ISO-9001 requirement[a]		QAPP section	Focus
4.1	Responsibility and authority management representative	Section C2.1 Section C2.18	• Corporate organization • Audits, assessments, and surveillances
4.2	Quality systems	Section C2.2 Section C2.5	• Quality assurance program • Instructions, procedures, and drawings
4.3	Contract review	Not addressed	
4.4	Design control	Section C2.3 Section C2.5	• Design control • Instructions, procedures, and drawings
4.5	Document control	Section C2.6	• Document control
4.6	Purchasing	Section C2.4 Section C2.7	• Procurement document control • Control of purchased items and services
4.7	Purchaser supplied products	Section C2.7	• Control of purchased items and services
4.8	Product identification and traceability	Section C2.8	• Identification and control of items
4.9	Process control	Section C2.9	• Control of processes
4.10	Inspection and testing	Section C2.10 Section C2.11	• Inspections • Test control
4.11	Inspection, measuring, and test equipment	Section C2.12	• Control of measuring and test equipment
4.12	Inspection and test status	Section C2.14	• Inspection, test, and operating status
4.13	Control of nonconforming products	Section C2.15	• Identification and control of nonconforming items
4.14	Corrective action	Section C2.16	• Corrective action
4.15	Handling, storage, packaging and delivery	Section C2.13	• Handling, storage, and shipping
4.16	Quality records	Section C2.17	• QA records
4.17	Internal quality audits	Section C2.18	• Audits, assessments, and surveillances
4.18	Training	Section C2.2	• Quality assurance program
4.19	Servicing	Not addressed	
4.20	Statistical techniques	Not addressed	

[a] QAPP Section C2.19, "Provisions for Changes," is not required under ISO-9001, *Quality Assurance Requirements*, International Organization for Standardization, Geneva, Switzerland, 2008.

QAPP = Quality Assurance Program Plan.

C1.4 DEFINITIONS

The following definitions are listed to provide a uniform interpretation of terms and phrases used with the QAPP.

Term	Definition
Accept-as-is	A disposition requiring engineering justification and approval that when applied indicates the item does not meet all specified requirements, but will continue to meet its intended use and continue to meet code, functional, and safety requirements.
Assessment	The act of reviewing, inspection, testing, checking, surveying, auditing, or otherwise determining and documenting whether items, processes, or services meet specific requirements.
Audit	A documented activity performed in accordance with written procedures or checklists to verify by examination or evaluation of objective evidence that the applicable elements of the quality program have been developed, documented, and implemented in accordance with specified requirements.
Calibration	Comparison of a measuring or test device with a standard of sufficient accuracy to determine whether the device is within specified limits of accuracy over a required range of values and, if not, repairing and/or adjusting the device to conform to requirements.
Certification	The act of determining, verifying, and attesting in writing to the qualification of personnel, material, or documentation.
Certified operator	An individual authorized by the chartering or licensing organization to carry out the duties and responsibilities associated with the position requiring the certification.
Commissioning	The process during which constructed structures, systems, and components are made operational and verified to meet design requirements.
Contract	A form of agreement used to procure services or labor, and may include procurement of material and/or equipment.
Corrective action	A determination of the cause of adverse conditions and implementation of the action necessary to correct the condition and prevent recurrence.
Critical characteristics	Identifiable and measurable attributes/variables of an item that are critical to the item's function.
Design input	Criteria, parameters, bases, or other design requirements on which the detailed final design is based.
Design output	Drawings, specifications, and other documents used to define technical requirements of structures, systems, components, or computer programs.
Document	Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.
Finding	A deviation or departure from specified requirements.
Graded approach	The process in which the level of analysis, documentation, and actions necessary to comply with a requirement are commensurate with the relative importance to safety or the magnitude of any hazards involved.
Hold point	A specified point in a function or process at which an inspection shall be performed and beyond which work may not proceed without approval.

Term	Definition
Item	An all-inclusive term used in place of any of the following: appurtenance, facility, sample, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, or data.
Maintenance	Those activities necessary to maintain operability or restore systems to within specified design limits. Maintenance consists of repair, rework, replacement, adjustment, cleaning, or other actions necessary to maintain an item in or restore an item to an acceptable condition.
Management	Those persons within the RPF organization whose responsibility and authority includes the QAPP.
Modification	A change in the physical design or functional characteristic of a structure, system, or component.
Nonconformance	Any item, condition, or material that deviates from drawings, specifications, or specified requirements and cannot be corrected within the scope of such requirements or otherwise requires engineering disposition.
Observation	A condition or process noted that did not specifically deviate from specified requirements, but where the potential exists for a deviation to occur, or may be used as commendation for noteworthy practices.
Process	A series of planned actions that achieve an end or result
Procedure	A document that specifies or describes how an activity is to be performed.
Quality	The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.
Quality assurance (QA)	Prescribed and planned activities that provide confidence that quality is achieved, including those planned and systematic actions necessary to provide adequate confidence that the structure, system, or component will perform satisfactorily in service.
Quality assurance program	The overall program established by NWMI to implement quality assurance requirements.
Quality assurance program plan (QAPP)	A corporate quality assurance document that identifies the planning, implementation, and assessment procedures for a particular project, and any specific quality assurance and quality control activities.
Quality records	Written, electronic, or pictorial records that furnish documentary evidence of the quality of items or results achieved.
Record copy	The signed original of corporate and/or project-related documents (e.g., drawings, specifications, calculations, procedures, plans) that is maintained in project files.
Reject	The item, system, structure, material, or service found to be unsatisfactory or nonconforming to specified requirements.
Repair	The process of restoring a nonconforming characteristic to an approved acceptable condition even though the item still does not necessarily conform to the original requirement.

Term	Definition
Safety-related items	Those physical structures, systems, and components with an intended function to prevent accidents that could cause undue risk to the health and safety of workers and the public or to RPF programs, and to control or mitigate the consequences of such accidents.
Service	The actual performance of work, such as design, fabrication, inspection, nondestructive examination, repair, or installation.
Shall	Denotes a mandatory requirement that must be complied with to maintain the requirements, assumptions, or conditions of the facility safety basis.
Special process	An operation performed under controlled conditions in accordance with specified requirements using qualified procedures, equipment, and personnel. Examples of special processes include welding, brazing, heat treatment, and nondestructive examination.
Specification	An engineering document specifying technical and quality requirements for materials, items, or services.
Surveillance	The act of monitoring and verification of an item or activity, or analysis of records to ensure compliance with applicable requirements.

C2.0 DESIGN, CONSTRUCTION, AND MODIFICATIONS

C2.1 ORGANIZATION

NWMI has established an organizational structure designed to ensure that quality work performed is safely and cost-effective and meets or exceeds customer expectations and requirements. The responsibility for establishing the overall expectations for effective implementation of the QAPP and obtaining the desired end result rests with the President and NWMI senior management. However, all NWMI employees are individually responsible for achieving and maintaining the quality of products and services provided to customers within their respective areas of responsibility.

C2.1.1 Organizational Structure

Figure C-1 describes the NWMI corporate organizational structure and lines of communication for key management and functional positions. For each individual project, the organizational structure, functional responsibilities, levels of authority, and lines of communication for quality-affecting activities shall be documented in project-specific plans, when required by contract.

C2.1.2 Responsibilities

The organizational structure and assigned responsibilities for all quality-related projects at NWMI shall be such that:

- Senior management will establish overall expectations for effective implementation of the QAPP and will be responsible for obtaining the desired end results
- Quality will be achieved and maintained by those who have been assigned responsibility for performing work
- Quality achievement will be verified by persons or organizations not directly responsible for performing the work

Functional levels and assignments of responsibility have been developed by NWMI for the RPF. The functional levels and titles used in the QAPP are not intended to define a specific organization or to completely define the responsibilities of each level of organization. Responsibilities for various levels of the NWMI organization will be described in the administrative section of Chapter 14.0, "Technical Specifications," and will comply with ANSI/ANS-15.1, *The Development of Technical Specifications for Research Reactors*.

The NWMI RPF organization consists of personnel with responsibility for design, construction, operation, and maintenance of the RPF. The significant functional levels of the organization are presented in Figure C-1 and are described below. Additional detail of the NWMI organization will be provided in the Operating License Application.

C2.1.2.1 Chief Executive Officer

The President and Chief Executive Officer (CEO) will report directly to the NWMI Board of Managers and will be responsible for overall management and leadership, promoting continuous improvement of the company, and establishing company policies to ensure that customer and company expectations are fully met. The CEO will also provide direction to the COO and CFO to fulfill the organization's responsibilities.

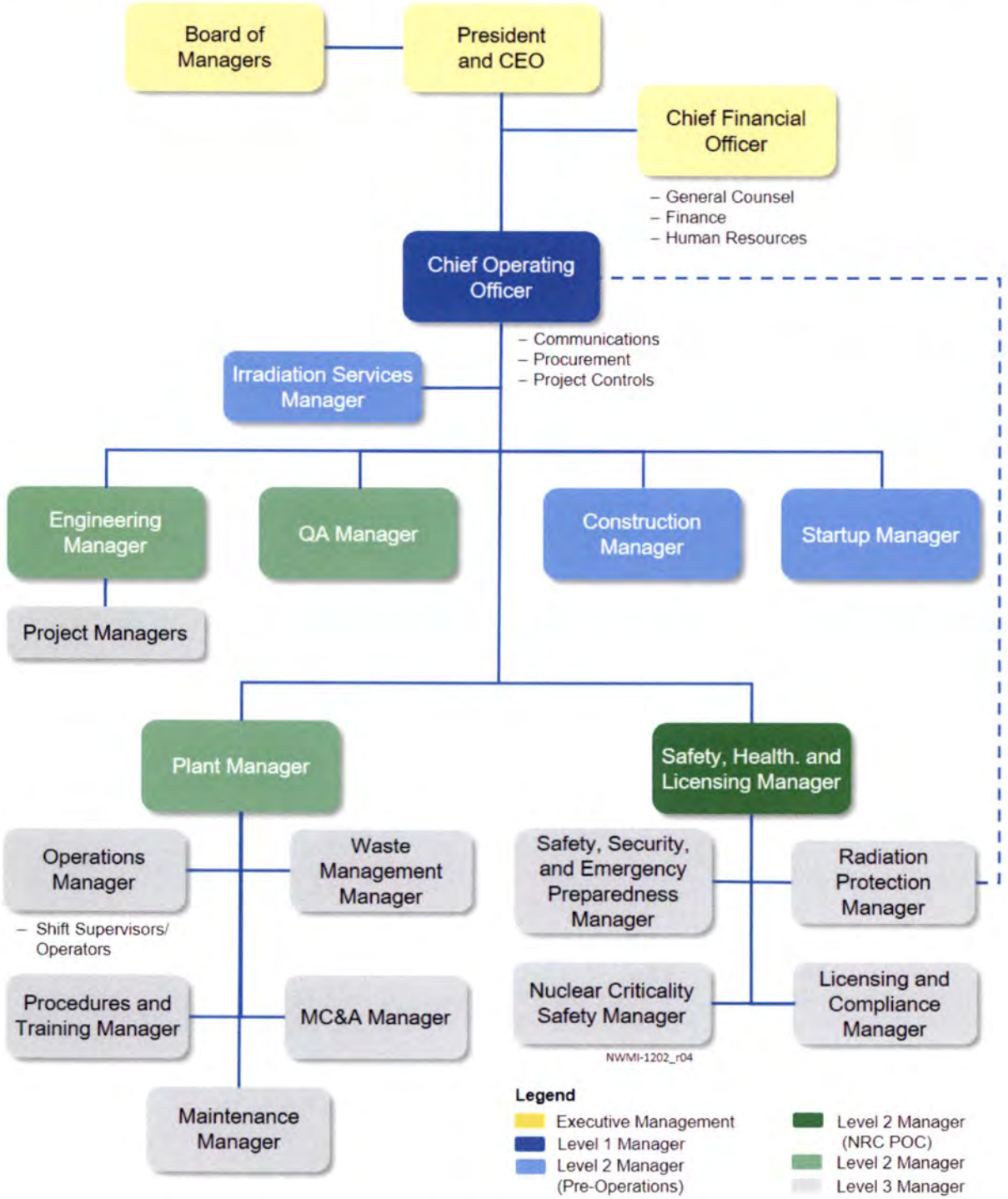

Figure C-1. Northwest Medical Isotopes, LLC Organization Chart

C2.1.2.2 Level 1

C2.1.2.2.1 Chief Operating Officer

The Chief Operating Officer (COO) will report directly to the President and CEO for operational aspects of the company, including safety, quality, security and safeguards, environmental stewardship, and, regulatory licensing and affairs. The COO will be responsible for ensuring the availability of appropriately trained and skilled personnel to successfully meet the needs of NWMI projects and that appropriate resources are allocated. The COO will assign priorities and responsibilities, and will maintain personal involvement in all aspects of NWMI's operations.

The COO will have overall responsibility for the QA Program. The COO will delegate the necessary responsibility and authority to direct reports to:

- Ensure that quality is achieved and maintained by those who have been assigned the responsibility for performing the work
- Ensure that appropriate controls have been established
- Verify that activities have been correctly performed
- Ensure that quality achievement is verified by persons not directly performing the work.

The COO will also be responsible for all external operations of NWMI, including supplier organizations, and integrating all quality requirements as defined in the QAPP across the internal and external organizations. The COO will provide the authority to access necessary work areas and will encourage managers and employees to identify problems; initiate, recommend, or provide corrective action; and ensure corrective action implementation.

C2.1.2.2.2 Chief Financial Officer

The Chief Financial Officer (CFO) will report to the CEO and have responsibility for all financial matters for NWMI. The CFO will partner with senior leadership and the Board of Directors to develop and implement financial strategies across the organization. Additional responsibilities will include legal, finance, and human resources in support of NWMI projects.

C2.1.2.3 Level 2

C2.1.2.3.1 Safety, Health, and Licensing Manager

The Safety, Health, and Licensing (SH&L) Manager will report to the COO, with overall responsibility for the development and implementation of programs addressing worker safety and health, U.S. Nuclear Regulatory Commission (NRC) licensing, and State and local permitting (including monitoring compliance with those licenses and permits). Other responsibilities will include nuclear criticality safety, radiation protection/chemistry, environmental protection, integrated safety analysis, industrial hygiene and safety, chemical safety, fire protection, security, and emergency preparedness. With respect to operations, the SH&L Manager will be responsible to confirm the safety of these operations, and will have the authority to order facility shutdown for RPF operations that are judged to be unsafe for continued operations or noncompliant with applicable regulatory requirements and to approve restart of operations.

C2.1.2.3.2 Engineering Manager

The Engineering Manager will report directly to the COO, with responsibility for site characterization, facility design and the design control process, configuration management, engineering, and acceptance test coordination, including test control of facility modifications. Other responsibilities will include:

- Ensuring that common design processes (e.g., standardization of work processes, design methodologies, technologies, and systems and equipment) meet company and project needs
- Ensuring that each project managers is trained to the appropriate requirements prior to assuming the role of project manager and performing such duties
- Developing and revising engineering procedures and project procedures
- Overseeing records management and document control activities
- Approving the disposition of nonconforming items when dispositioned as "repair" or "use-as-is" during operations

C2.1.2.3.3 Quality Assurance Manager

The QA Manager will report directly to the COO and will have independent oversight responsibility for implementation of the QAPP. The QA Manager will be responsible for:

- Auditing for compliance with regulatory requirements and procedures through assessments and technical reviews
- Monitoring organizational processes to ensure conformance to commitments and licensing document requirements
- Maintaining sufficient independence from other priorities to identify issues affecting safety and quality
- Serving as a focal point for matters involving quality, with the authority to identify, initiate, recommend, or provide solutions to those problems, verify implementation of the solutions, and resolve any related concerns reported to employees, management, and/or NWMI customers
- Implementing training of all assigned project personnel

C2.1.2.3.4 Plant Manager

The Plant Manager will report to the COO and have direct responsibility for the safe operation of the RPF, including the protection of workers and the public against radiation exposure resulting from facility operations and materials. Other responsibilities will include:

- Ensuring compliance with applicable NRC, State, and local regulations and license/permits
- Implementing the RPF conduct of operations program
- Establishing and managing the required training programs to support the operations organization

C2.1.2.3.5 Construction Manager

The Construction Manager will report to the COO and have responsibility for managing construction and future modifications to the RPF. This responsibility will include managing the activities of qualified contractors who are tasked with the preparation of construction documents and construction of the facility, including modifications and expansion.

C2.1.2.3.6 Startup Manager

The Startup Manager will report to the COO and have responsibility for the overall preoperational and startup test program for the RPF. Other responsibilities will include:

- Developing preoperational, startup, and operational test procedures
- Providing technical advice to personnel conducting the tests
- Briefing personnel responsible for RPF operations during the tests
- Ensuring that tests are performed in accordance with applicable procedures
- Preparing test reports

C2.1.2.4 Level 3

C2.1.2.4.1 Operations Manager

The Operations Manager will report to the Plant Manager and have responsibility for day-to-day RPF operations activities. Inherent in this responsibility is the assurance that operations are conducted safely and in compliance with license conditions.

C2.1.2.4.2 Procedure and Training Manager

The Procedure and Training Manager will report to the Plant Manager, with responsibility for the development, implementation, and administration of the RPF training programs, including maintenance of the RPF training database. The training programs provided and/or coordinated by the Training Manager will address qualifications of workers to perform work and identify safety training requirements. In addition, the Procedure and Training Manager will be responsible for maintaining and updating facility procedures.

C2.1.2.4.3 Material Control and Accountability Manager

The Material Control and Accountability Manager will report to the Plant Manager, with responsibility for ensuring the proper implementation of the Nuclear Material Control and Accountability Plan. This position will be separate from and independent of other departments to ensure a definite division between the safeguards group and the other departments. In matters involving safeguards, the Safeguards Manager will have direct access to the COO.

C2.1.2.4.4 Maintenance Manager

The Maintenance Manager will be responsible for safe and reliable performance of preventive and corrective maintenance and support services on SSCs (including items relied on for safety [IROFS]). Other responsibilities include integrated planning and scheduling.

C2.1.2.4.5 Nuclear Criticality Safety Manager

The Nuclear Criticality Safety Manager will report to the SH&L Licensing Manager and have responsibility for the development and implementation of the nuclear criticality safety program. Other responsibilities will include:

- Performing nuclear criticality safety analyses and evaluations of applicable operations involving special nuclear material and changes to those operations
- Establishing limits and controls based on those analyses and evaluations
- Ensuring the proper incorporation of limits and controls into applicable procedures and instructions

- Monitoring plant compliance with nuclear criticality safety requirements

C2.1.2.4.6 Radiation Protection Manager

The Radiation Protection Manager will report to the SH&L Manager and have responsibility for the development and implementation of programs to limit personnel radiological exposures and environmental impacts associated with facility operations, including the as low as reasonably achievable (ALARA) program. Other responsibilities include implementation of the chemistry analysis programs and procedures for the RPF. In matters involving radiological protection, the Radiation Protection Manager will have direct access to the COO.

C2.1.2.4.7 Safety, Security, and Emergency Preparedness Manager

The Safety, Security, and Emergency Preparedness Manager will report to the SH&L Manager, with responsibility for implementation of the integrated safety analysis, industrial hygiene and safety, chemical safety, fire protection, security, and emergency preparedness programs.

C2.1.2.4.8 Licensing and Compliance Manager

The Licensing and Compliance Manager reports to the SH&L Manager and will have responsibility for regulatory oversight functions, regulatory and licensing/permitting compliance, facility change process, and commitment management.

C2.1.2.4.9 Project Managers

Project managers will report directly to the Engineering Manager and have overall responsibility for providing planning, management, and execution of NWMI projects in accordance with this QAPP and established requirements. Project managers will be responsible for:

- Ensuring that all project personnel are properly trained and indoctrinated to perform their intended duties
- Ensuring that all project personnel are provided with the proper information and tools, support, and motivation to carry out their assigned duties
- Ensuring that quality is integrated into daily work activities at the earliest time consistent with established schedules, and periodically assessing their respective organizations to ensure adequate and effective implementation of the QAPP
- Planning and accomplishing work affecting quality under suitably controlled conditions, including the use of appropriate equipment and environmental conditions, and ensuring that the prerequisites for the given activity have been satisfied
- Identifying opportunities for improvement and initiating actions to fully realize these opportunities
- Periodically conducting management assessments of their respective organizations and projects to ensure that company objectives and customer expectations are fully satisfied
- Verifying the achievement of quality by performing audits, assessments, or surveillances of ongoing or completed activities

C2.1.2.5 Other

C2.1.2.5.1 Shift Supervisors

The shift supervisors will report to the Operations Manager. The shift supervisors will be responsible for the safe operation of the RPF and will authorize day-to-day site activities, including:

- Control of access to the facility
- Work activities (e.g., work permits and execution of specific operations procedures)
- Deliveries and shipments
- Decisions to start or shutdown equipment
- Directing abnormal or emergency actions, including notifications

C2.1.2.5.2 Operators

Senior operators and operators will be responsible for conforming to applicable rules, regulations, and procedures for RPF operations. All operators will accept responsibility for safe and efficient operation of a designated area of the facility when assigned by the shift supervisor.

C2.1.2.5.3 Employees

NWMI employees will be responsible for conducting work in accordance with the QAPP, company policies, and implementing procedures. Employees will be encouraged to measure their own performance and recommend quality improvements. Each NWMI employee working on a project will also be responsible for the achievement and maintenance of quality within their assigned area of responsibility by following the requirements of this QAPP and its implementing procedures.

C2.1.3 Staffing

NWMI will provide sufficient resources in personnel and materials to safely conduct operations. Facility staffing considerations, including minimum staffing levels, allocation of control functions, overtime restrictions, facility status updates during turnover between shifts, procedures, training, and availability of senior operators during routine operations, will be defined in the Operating License Application.

C2.1.4 Verification

Those responsible for ensuring that an appropriate QA program has been established and those verifying activities affecting quality have sufficient authority, direct access to responsible levels of management, organizational freedom, and access to work areas to perform their function, including sufficient independence from cost and schedule when opposed to safety function considerations. These verification functions include the following:

- Identifying quality problems
- Initiating, recommending, or providing solutions to quality problems through designated channels
- Verifying implementation of solutions
- Ensuring that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred

C2.1.5 Interfaces

Requirements shall be established for controlling interfaces. Where more than one organization is involved in the execution of activities, the responsibilities, interfaces, and authority of each organization shall be clearly defined and documented. The external interfaces between organizations and the internal interfaces between organizational units, and any changes thereto, shall be documented.

C2.1.6 Quality Assurance Organization Responsibilities

The QA organization is responsible for independent oversight of the RPF activities covered by this QAPP. This includes the responsibility and authority for:

- Maintaining the QAPP
- Reviewing and approving implementing procedures
- Reviewing and approving supplier QA programs
- Providing oversight of supplier QA program implementation
- Performing QA technical reviews of procurement documents
- Maintaining the approved suppliers list (ASL)
- Administering corrective action and the nonconformance process
- Administering the auditor and lead auditor certification process
- Monitoring implementation of the QAPP and assessing its effectiveness through audit and surveillance
- Investigating any aspect of the QAPP to identify problems with execution, and verifying that corrective action is taken in a timely manner
- Stopping unsatisfactory work or controlling further processing when warranted for safety considerations
- Attending status meetings, and staying informed regarding day-to-day activities to ensure adequate oversight
- Providing quality control (QC) activities for purchased and in-house manufactured items

C2.1.7 Quality Assurance Organizational Independence

Independence shall be maintained between the organization or organizations performing the checking (QA and QC) functions and the organizations performing the functions. This provision is not applicable to design review or verification.

C2.1.8 Applicable Implementing Procedures

The following procedures define the requirements and processes for implementing the organizational structure:

- NWMI-PROJ-PRO-014, *Project Initiation*
- NWMI-PROJ-PRO-015, *Project Closeout*
- NWMI-PROJ-PRO-016, *Project Baseline Management*
- NWMI-PROJ-PRO-040, *Project Manager Qualifications*

C2.2 QUALITY ASSURANCE PROGRAM

The NWMI QA program describes the policies and requirements necessary to meet applicable Federal regulations such as 10 CFR 50.34 and associated ANSI/ANS 15.8, Regulatory Guide 2.5, 10 CFR 70.64(a)(1), and ISO-9001. This QAPP applies to all nuclear, quality-related projects and activities that require conformance to a nuclear QA program, and therefore shall be the standard for all NWMI personnel to follow for compliance to those requirements.

The QAPP provides the basis for a planned and systematic approach to cost-effective achievement of safety, quality, and reliability. The primary method to achieve this is through implementation of NWMI procedures. The NWMI QA procedures are delineated, managed, and maintained by the Quality Manager with support from all NWMI employees. Delegated responsibilities may be performed under a supplier's QA program, provided that the supplier has been approved in accordance with the QAPP. Periodic assessments of supplier QA programs are performed to ensure compliance with this QAPP and implementing procedures. In addition, routine interfaces with supplier personnel provide added assurance that quality expectations will be met.

Assessments may be planned and performed by qualified assessors, independent contractors, or consultants as determined by the Quality Manager. Personnel assigned to implement elements of the QAPP shall be capable of performing their assigned tasks.

NWMI establishes and maintains formal and informal training programs for personnel performing, verifying, or managing activities within the scope of the QAPP to ensure that suitable proficiency is achieved and maintained. Sufficient managerial depth is provided to cover absences of incumbents. When required by code, regulation, or standard, specific qualification and selection of personnel is conducted in accordance with those requirements as established in applicable NWMI procedures. Records of personnel training and qualification will be maintained.

This QAPP is further intended to ensure that reliability and performance of NWMI products and services are maximized through the application of effective and prudent business management practices commensurate with the risk to workers, the public, and environment. NWMI has adopted a graded approach to quality such that the level of analysis, verification and validation, documentation, and actions are determined based on safety, quality, and/or project risk. This graded approach determines the appropriate level of effort necessary to attain and document the technical and quality requirements.

A project's quality level (e.g., important to safety or quality, commercial safety or quality) is determined at the onset of a project as part of the authorization to proceed (NWMI-PROJ-PRO-014). This graded approach helps NWMI maintain appropriate flexibility on projects and/or items that do not need to meet ANSI/ANS 15.8. This QAPP shall be implemented to the following activities, as applicable to the scope of work defined by each particular project:

- Design activities
- Quality-affecting procurement activities
- Fabrication activities
- Repairs, modifications, decommissioning, and site remediation
- Waste treatment
- Facility and site operation activities
- Audit, inspection, and surveillance activities
- Testing activities
- Equipment manufacturing
- Technical support/consulting
- Handling, storage, shipping, and receiving activities

C2.2.1 Program Hierarchy

The QAPP will be implemented for all NWMI work activities. In addition, the QAPP may be supplemented by project-specific QA plans, where appropriate and when necessitated by unique customer requirements. Implementation of this QAPP will be as required by regulators, customer contract, or imposed by NWMI senior management. The NWMI QA program is inclusive of this QAPP and applicable implementing procedures, as necessary, to effectively address the requirements of the company and its customers.

NWMI senior management encourages and promotes continuous quality improvement throughout the company and sponsors periodic management assessments to ensure that company objectives and customer expectations are fully met. Responsibilities for implementing the QA program are discussed in Section C2.1.2.

C2.2.2 Requirements

The QAPP, along with applicable project-specific QA plans, shall be established at the earliest time consistent with the schedule for accomplishing the designated activities. These plans shall include monitoring activities against acceptance criteria in a manner sufficient to ensure that the activities affecting quality are satisfactorily performed.

Graded Approach

The QAPP will employ a graded approach to achieve NWMI's environmental, safety, quality, and compliance goals that will result in productive, efficient, and cost-effective work performances. The QAPP shall:

- Provide for planning and accomplishing activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment and suitable environmental conditions for accomplishing the activity to ensure that prerequisites for the given activity have been satisfied.
- Identify special controls, processes, test equipment, tools, and skills to attain the required quality of activities and items and for verification of that quality. The responsible organizations shall establish and implement the necessary controls and processes to detect and correct quality problems.
- Provide controls over activities affecting quality to an extent consistent with their importance.

The graded approach to quality is a process by which the level of analysis, documentation, and actions necessary to comply with a requirement is commensurate with the safety significance. The graded approach permits the implementing organization to focus resources on those activities that are deemed, by qualitative analysis, to reduce the associated risks and hazards. The activities and tasks are performed in accordance with approved implementing procedures.

The assignment of safety-related classification and use of codes and standards conforms to the requirements NWMI's QAPP for the development of a Quality Group classification and the use of codes and standards. The classification system provides a recognizable means of identifying the extent to which SSCs are related to safety-related and seismic requirements, including American Nuclear Society (ANS) nuclear safety classifications, NRC quality groups, American Society of Mechanical Engineers (ASME) Code Section III classifications, seismic categories, and other applicable industry standards. The definitions of QA Levels 1, 2, and 3 are provided below.

The basis for the difference in Quality Level (QL)-1 and QL-2 is a graded approach to quality, by which the level of analysis, documentation, and actions necessary to comply with a requirement is commensurate with the safety significance. The graded approach permits the implementing organization to focus resources on those activities that are deemed, by qualitative analysis, to reduce the associated risks and hazards. The activities and tasks are performed in accordance with approved implementing procedures.

The graded approach to quality is a process by which the level of analysis, documentation, and actions necessary to comply with a requirement is commensurate with the safety significance. A graded approach permits the implementing organization to focus resources on those activities that are deemed, by qualitative analysis, to reduce the associated risks and hazards.

QL-1 will implement the full measure of the QAPP and will be applied to IROFS. IROFS are QL-1 items in which failure or malfunction could directly result in a condition that adversely affects workers, the public, and/or environment, as described in 10 CFR 70.61, "Performance Requirements." The failure of a single QL-1 item could result in a high or intermediate consequence. The failure of a QL-2 item, in conjunction with the failure of an additional item, could result in a high or intermediate consequence. All building and structural IROFS associated with credible external events are QL-1. QL-1 items also include those attributes of items that could interact with IROFS due to a seismic event and result in high or intermediate consequences, as described in 10 CFR 70.61. Examples include:

- Items to prevent nuclear criticality accidents (e.g., preventive controls and measures to ensure that under normal and credible abnormal conditions, all nuclear processes are subcritical)
- Items credited to withstand credible design-bases external events (e.g., seismic, wind)
- Items to prevent degradation of structural integrity (e.g., failure or malfunction of facility)

QL-2 will be applied to non-QL-1 safety SSCs. The QA program is important to the acceptability and suitability of the item or service to perform as specified. Acceptance methods shall be specified (including acceptance and other applicable performance criteria), documented, and verified before use of the item or service. Some of the required characteristics may be examined less rigorously than for QL-1. Examples of QL-2 items include:

- SSCs to meet 10 CFR 20, "Standards for Protection Against Radiation," normal release or exposure limits
- Fire protection systems
- Safeguards and security systems
- Material control and accountability systems

QL-3 will include non-safety-related quality activities performed by NWMI that are deemed necessary to ensure the manufacture and delivery of highly reliable products and services to meet or exceed customer expectations and requirements. QA Level 3 items include those items that are not classified as QL-1 or QL-2. QL-3 items are controlled in accordance with standard commercial practices.

These quality activities are embodied in this QAPP and will be further specified in the Operating License Application, and when necessary.

C2.2.3 -Special Processes

NWMI personnel performing project management, inspection, test, nondestructive examination (NDE), surveillances, assessments, and audit activities shall be qualified or certified in accordance with applicable requirements for the specific activity. An evaluation of a candidate's education, experience, training, and either test results or capability demonstration can be used to meet initial certification.

In addition, NWMI personnel performing NDE activities, such as radiographic (RT), magnetic particle (MP), ultrasonic (UT), liquid penetrant (PT), electromagnetic (ET), neutron radiographic (NR), leak testing (LT), acoustic emission (AE), and visual testing (VT) to verify conformance to the specified requirements shall be qualified in accordance with the applicable American Society of Nondestructive Testing (ASNT) recommended practices and/or standards, including edition and appropriate supplements, as applicable.

NWMI may reserve the right to delegate qualification examination activities to an independent certifying agency, but when doing so, shall retain the responsibility for conformance of the examination and its administration. Integrity of the examination shall be maintained by NWMI or the certifying agency through appropriate confidentiality of files, and where applicable, proctoring of examinations.

NWMI encourages and promotes continuous process improvement. This process will include proactive employees identifying areas for improvement and communicating with management on opportunities for improvement. Tools used to evaluate, promote, and document areas of improvement will include nonconformance reports, corrective action reports, surveillance reports, audit reports, assessment reports, and process improvement forms.

C2.2.4 Stop Work Authority

All NWMI employees will be empowered with the authority to stop work when observing unsatisfactory work or unsafe conditions that may threaten the quality, health and safety of workers, the public, or environment. Such conditions shall be immediately reported to NWMI management for corrective action evaluation. Any work that has been stopped will be processed for restart relative to and commensurate with the complexity and significance of the conditions preceding the stopped work. All stopped work will be documented as to the condition and the corrective action taken prior to resumption of work.

C2.2.5 Applicable Implementing Procedures

The following procedures define the requirements and processes for implementing NWMI's QA program:

- NWMI-QA-PRO-008, *Quality-Affecting Procedures and Instructions*
- NWMI-QA-PRO-017, *Quality Records*
- NWMI-QA-PRO-022, *Training and Qualification of Project Personnel*
- NWMI-QA-PRO-034, *Assessments and Surveillances*
- NWMI-QA-PRO-038, *Lead Auditor Qualifications*
- NWMI-QA-PRO-039, *Training and Qualification of Inspection and Test Personnel*
- NWMI-PROJ-PRO-040, *Project Manager Qualifications*

C2.3 DESIGN CONTROL

This section describes the processes to be implemented by NWMI to ensure that the SSCs designed by or for NWMI are defined, controlled, and verified. The design of SSCs is affected by the design input, analysis, verification, and interfaces. Design changes shall be consistently controlled throughout the design life-cycle.

C2.3.1 Responsibilities

C2.3.1.1 Engineering Manager

The Engineering Manager will be responsible for preparing engineering procedures to ensure that all NWMI-sponsored designs of items, SSCs, and services are conducted in a controlled manner, in accordance with the QAPP and customer requirements.

C2.3.1.2 Quality Assurance Manager

The QA Manager will be responsible for reviewing and performing audits or surveillances of NWMI-sponsored designs of items and SSCs to ensure compliance with the QAPP and customer requirements.

C2.3.1.3 Contracts Administrator

The Contracts Administrator, with assistance from the COO and project managers, will be responsible for procurement of all NWMI goods and services. The Contract Administrator will ensure that goods and services are procured from an evaluated supplier, as appropriate, and prepare specific procurement procedures, as necessary, to comply with the QAPP and customer expectations.

C2.3.1.4 Project Managers

The project managers will be responsible for preparing and approving procurements of items or services of a technical nature.

C2.3.2 Requirements

Design control measures shall ensure that design activities are accomplished on a timely basis and translated into design documents. The design inputs shall be specified to the level of detail necessary to enable the design process to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes. Applicable design inputs shall be identified and documented, and their selection reviewed and approved. Design changes, including field changes, shall be controlled in a manner consistent with that applied to the original design.

The responsible design organization shall prescribe and document the design activities to the level of detail necessary to enable the design process to be carried out in a correct manner and for verification that the design meets requirements. Design documents shall support facility design, construction, and operations.

The following design activities, interfaces, and documents shall be controlled to ensure that applicable inputs (e.g., design basis, regulatory requirements, codes, and standards) are correctly translated into the final design.

- Design interfaces shall ensure that interfacing systems will fit and function, whether from singular or multiple design organizations. Design information transmitted across interfaces shall identify the status of the design (or design document) provided and identify incomplete items that require further evaluation, review, or approval. Organizational interfaces will include NWMI, its subcontractors, and customers.
- Design inputs shall be established through a design requirements document. Deviations from the established and documented design inputs, including the reason for changes, shall be documented and controlled.
- Design analyses shall be sufficiently detailed such that a person technically qualified in the subject can review and understand the analyses and verify the adequacy of the results without recourse to the originator.
- Design outputs such as specifications and drawings shall specify quality characteristics such as materials, parts, equipment, or processes that are essential to the function of the SSC. These design outputs shall include, as appropriate, acceptance criteria for inspection and test purposes. In addition, design outputs shall be legible and in a form suitable for reproduction, filing, and retrieval.
- Qualification testing shall be performed to demonstrate the adequacy of performance of SSCs under conditions that simulate the most adverse design conditions. Formal testing or analysis will be required to verify conformance of designated SSCs to specified requirements and demonstrate satisfactory performance for service or to collect data in support of design or fabrication.

Test results will be documented and evaluated by a responsible authority to ensure that test requirements have been satisfied.

- Computer programs used to establish the design basis or used to perform design analysis shall be verified and validated to an extent commensurate with the design. In addition, computer programs shall be controlled to ensure that changes are documented and approved by authorized personnel. The computer program shall be verified to show that correct solutions for the encoded mathematical model will be produced within defined limits for each parameter employed. The encoded mathematical model shall also be shown to produce a valid solution to the physical problem associated with the particular application. When changes to previously valid computer programs are made, documented revalidation shall be required for the change. Verification of custom designed computer programs shall include appropriate benchmark testing. Grading of applicable software shall be performed to ensure that the software is compliant with all applicable requirements.
- Computer programs used for operational control will be tested in accordance with an approved verification and validation plan and will demonstrate required performance over the range of operation of the controlled function or process.
- Design adequacy and accuracy shall be verified by individuals or organizations other than those who designed the item or computer program (independent design review), and who are technically competent in the subject activity. The extent of the design verification will be commensurate with the risk, complexity, and consequence of failure. Design verification methods can include one or a combination of the following: (1) design reviews, (2) alternate calculations, or (3) qualification tests. Design verification shall be performed prior to release of the design for procurement, manufacture, fabrication, or construction. In all cases, final design verification will be completed before the design is relied on to perform its function.
- Design documents and records that provide evidence that the design and design verification processes were performed shall be collected, stored, and maintained for the life of the safety-related system or unit.
- When the design incorporates commercial-grade items, the characteristics of the item(s) to be verified shall be documented for acceptance purposes. Characteristics to be verified are those that will provide reasonable assurance that the item(s) will perform its intended function. Changes to design inputs, final designs, field changes, and temporary and permanent modifications to SSCs or computer codes shall be documented, justified, and subject to design control measures commensurate with those applied to the original design. These measures shall include evaluation of effects of those changes on the overall design and on any analysis on which the design is based.

C2.3.3 Design Changes

Engineering change control procedures (e.g., NWMI-ENG-PRO-002, *Engineering Change Control*) have been developed for the RPF design and construction to ensure that modifications to safety-related SSCs, or computer codes, will be based on a defined "as-exists" design. Changes to verified designs will be documented, justified, and subject to design control measures commensurate with those applied to the original design. The control measures will include assurance that the design analyses for the SSC, or computer code, are still valid. Where a significant design change is necessary because of an insufficient design, the design process and verification procedure will be reviewed and modified as necessary.

C2.3.4 Applicable Implementing Procedures

The following procedures define the requirements and processes for implementing design control activities:

- NWMI-ENG-PRO-002, *Engineering Change Control*
- NWMI-ENG-PRO-003, *Design Verification*
- NWMI-ENG-PRO-004, *Design Inputs*
- NWMI-ENG-PRO-005, *Checking*
- NWMI-ENG-PRO-006, *Calculations*
- NWMI-ENG-PRO-007, *Engineering Specifications*
- NWMI-ENG-PRO-009, *Engineering Drawings*
- NWMI-ENG-PRO-010, *Interface Control*
- NWMI-ENG-PRO-011, *Software Design Control*
- NWMI-ENG-PRO-012, *Engineering Reports*
- NWMI-ENG-PRO-013, *OTS Software Maintenance*
- NWMI-ENG-PRO-018, *Engineering Design Control*
- NWMI-ENG-PRO-020, *Commercial Grade Items (CGI)*
- NWMI-ENG-PRO-041, *Safety Software Requirements*

C2.4 PROCUREMENT DOCUMENT CONTROL

This section establishes controls necessary to ensure that correct quality requirements will be formally and effectively communicated to NWMI suppliers of items and services. Procurement document control shall include sufficient technical and quality requirements to ensure that the items or services will satisfy the needs of the purchase and all documents at all procurement levels shall identify the documentation to be reviewed by purchaser. Procurement documents for safety-related items should prohibit the supply of substandard or counterfeit parts and materials.

C2.4.1 Responsibilities

C2.4.1.1 Quality Assurance Manager

The QA Manager will be responsible for reviewing and approving purchase requisitions initiated for the procurement of quality-affecting items or services. In addition, the QA Manager will ensure that receipt inspection is completed and will notify the responsible procurement representatives of any nonconforming conditions that exist.

C2.4.1.2 Contracts Administrator

The Contracts Administrator, with assistance from the COO and project managers, will be responsible for procurement of all NWMI goods and services. The Contract Administrator will ensure that goods and services are procured from an evaluated supplier, as appropriate, and prepare specific procurement procedures, as necessary, to comply with the QAPP and customer expectations.

C2.4.1.3 Project Managers

The project managers will be responsible for preparing and approving procurements of items or services of a technical nature.

C2.4.2 Requirements

Procurement documents shall specify the requirements necessary to ensure that purchased items and services relied on for safety and applicable SSCs are of the desired quality. Applicable design bases and other requirements necessary to provide reasonable assurance of quality will be included or referenced in documents for procurement of IROFS, services relied on for safety, and applicable SSCs.

To the extent necessary, procurement documents will require suppliers to have a QA program consistent with the requirements specified in this QAPP.

Procurement documents will convey the requirements for a specific item or service to the supplier(s). To ensure the quality of the item or service, procurement documents issued at all tiers of procurement shall include the following provisions, as deemed necessary by NWMI.

- Statement of work
- Technical requirements (including safety and environmental requirements)
- QA requirements
- Right of access to the supplier's facility
- Documentation requirements
- Nonconformance reporting requirements
- Spare and/or replacement parts

A review of procurement documents, including changes thereto, shall be made and documented prior to award of the contract to ensure that documents transmitted to prospective supplier(s) and/or subcontractor(s) include appropriate provisions for the items and/or services to meet the specified requirements. Technical or QA program changes made as a result of bid evaluations or negotiations shall be incorporated into the procurement documents prior to issuance to the supplier. Procurement documents shall be reviewed by technically qualified personnel with access to relevant information and who have an adequate understanding of the requirements and intent of the procurement documents.

Changes to procurement documents affecting the technical and/or QA program requirements shall be subjected to the same degree of control and review as used in the preparation of the original documents.

C2.4.3 Applicable Implementing Procedures

The following procedure defines the requirements and processes for implementing procurement document control activities:

- NWMI-QA-PRO-023, *Procurement Documentation*

C2.5 PROCEDURES, INSTRUCTIONS, AND DRAWINGS

This section describes the requirements for the preparation and use of instructions, procedures, and drawings when conducting or performing quality-affecting activities at the RPF. Activities affecting quality shall be performed in accordance with documented instructions, procedures, or drawings appropriate to the activity and shall reference appropriate quantitative or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished.

C2.5.1 Responsibilities

C2.5.1.1 Engineering Manager

The Chief Engineer will be responsible for preparing engineering instructions and procedures for work performed by NWMI.

C2.5.1.2 Quality Assurance Manager

The QA Manager will be responsible for preparing QA instructions and procedures for work performed by NWMI personnel. The QA Manager will also review and approve the engineering instructions and procedures that are developed for controlling quality-affecting activities.

C2.5.1.3 Contracts Administrator

The Contracts Administrator will be responsible for preparing procurement procedures that are necessary to effectively meet the requirements of the QAPP.

C2.5.1.4 Project Managers

Project managers will be responsible for the production of engineering deliverables, including drawings, specifications, project-specific procedures, and other engineering document deliverables.

C2.5.2 Requirements

Activities that affect the quality of work performed by NWMI or its suppliers/subcontractors will be prescribed and performed in accordance with documented instructions, procedures, and/or drawings, as appropriate for the particular scope of work.

Activities affecting the availability and/or reliability of IROFS or applicable SSCs will be prescribed by and accomplished in accordance with documented procedures, instructions, and drawings of a type appropriate to the circumstances. These documents will include or reference appropriate acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. Standard guidelines for the format, content, and review and approval processes will be established.

Instructions, procedures, and/or drawings shall identify and reference, as appropriate, any necessary process controls and/or applicable codes or standards, and the qualitative and quantitative acceptance criteria for determining that prescribed results have been adequately attained.

Activities shall be described in instructions and procedures to a level of detail commensurate with the complexity of the activity and the need to ensure consistent and acceptable results. The level of detail in each instruction or procedure will be based on the complexity of the task, significance of the item or activity, work environment, and worker proficiency and capability (e.g., education, training, and experience).

Instructions and procedures will be prepared by the cognizant organization. NWMI managers having responsibility for the activities prescribed in the instructions or procedures will be designated as the document owners. Document owners will be responsible for initial approval, revision approval, control, and implementation of assigned procedures.

Major revisions to instructions, procedures, and drawings shall be subject to the same level of review as extended to the original document. The reviewing organization shall have access to pertinent background data or information on which to base their approval. Minor changes, such as those that do not alter work or affect how work is performed, may be expedited for release without a formal review and approval process. To avoid an omission of a possible major change, the types of minor changes that will not require a formal review and approval process or additional training are identified in Section C2.6.2.2. In addition, the persons who can authorize such a decision shall be clearly delineated.

Procedures, instructions, and drawings shall be controlled in accordance with Section C2.5.

C2.5.3 Applicable Implementing Procedures

The following procedures define the requirements and processes for implementing activities associated with the development of procedures, instructions, and drawings:

- NWMI-QA-PRO-008, *Quality-Affecting Procedures and Instructions*
- NWMI-ENG-PRO-009, *Engineering Drawings*

C2.6 DOCUMENT CONTROL

This section establishes the requirements for the preparation, review, issuance, change control, and distribution of project and other quality-related documents that are developed by NWMI or its subcontractors. The preparation, issue, and change of documents that specify requirements that affect quality shall be controlled to ensure that the correct documents are used. The document control system shall be documented, and will:

- Identify of documents to be controlled and their specified distribution
- Identify the assignment of responsibility for preparing, reviewing, approving, and issuing documents
- Specify the review of documents for adequacy, completeness, and correctness prior to approval and issuance

Major changes to controlled documents shall be reviewed and approved by the same organizations that performed the original review and approval, unless other organizations are designated.

C2.6.1 Responsibilities

C2.6.1.1 Quality Assurance Manager

The QA Manager will be responsible for the preparation, control, and distribution of QA documents such as the QAPP, QA procedures, and QA reports. The QA Manager will also be responsible for performing audits and/or surveillances of document control activities to ensure compliance with the QAPP and customer requirements.

C2.6.1.2 Contracts Administrator

The Contracts Administrator will be responsible for the distribution of procurement-related documents, and the preparation, control, and distribution of procurement-related procedures.

C2.6.1.3 Project Managers

Project managers will be responsible for preparing, controlling, and distributing engineering and procurement documents such as drawings, specifications, calculations, procedures, engineering studies, purchase requisitions, and purchase orders.

C2.6.1.4 Document Control Administrator

The Document Control Administrator will be responsible for controlling and distributing project-related documents such as drawings, specifications, calculations, reports, procedures, manuals, and procurement documents.

C2.6.1.5 Records Management Administrator

The Records Management Administrator will be responsible for the safe storage of project records in the records management system. The Records Management Administrator will also be responsible for reviewing completed documents and records to verify completeness and correctness before storing the approved documents in the records management system.

C2.6.2 Requirements

Documents and changes to documents that prescribe or specify quality requirements or activities affecting the availability and/or reliability of IROFS shall be controlled in a manner that ensures the use of correct documents. Such documents, including changes thereto, will be reviewed for adequacy and approved for release by authorized personnel.

Procedures and instructions ensure that documents are:

- Prepared and reviewed for adequacy, correctness, and completeness by a qualified individual
- Approved for release by authorized personnel
- Distributed to the location where the activity is performed prior to commencing work
- Used in performing the specified activity

Obsolete or superseded documents will be removed or appropriately identified. Procedures shall:

- Identify the documents to be controlled
- Specify responsibility for preparing, reviewing, approving, and issuing documents to be used
- Require the establishment of current and updated distribution lists
- Require the creation and maintenance of a controlled document index to track and control approved revisions of those documents

C2.6.2.1 Implementing Procedures

Implementing procedures shall be developed for the preparation of documents and shall include provisions for review and approval to ensure adequacy for use. These procedures shall specify the following:

- How documents will be identified
- How documents will be controlled
- How documents will be prepared, reviewed, and approved
- How documents will be reviewed for adequacy, completeness, and approval for distribution
- Methods to ensure that correct documents are being used
- How documents will be distributed
- How documents will be retired or recalled

C2.6.2.2 Minor Changes

Minor changes to documents will not require the same level of review, approval, and retraining as the original documents. To avoid a possible omission of the required review process, the following types of minor changes have been identified as not requiring an additional review, approval, or retraining process:

- Typographical corrections
- Grammatical corrections
- Format adjustments
- Punctuation corrections
- Capitalization adjustments
- Additions or deletions of references

C2.6.2.3 Major Changes

Major changes to documents shall be reviewed and approved by the same individuals or organizations that provided the original review and approval, unless others are specifically designated. The reviewing individual or organization shall have access to pertinent background data or information on which to base their approval.

C2.6.3 Applicable Implementing Procedures

The following procedures define the requirements and processes for implementing document control activities:

- NWMI-QA-PRO-001, *Document Control*
- NWMI-QA-PRO-021, *Procedures and Forms Index*

C2.7 CONTROL OF PURCHASED ITEMS AND SERVICES

This section describes the controls applied to the procurement of items and services. These controls are established to ensure that purchased materials or services conform to the procurement documents. Controls will include, as appropriate, source evaluation and selection, evaluation of objective evidence of quality furnished by the supplier, periodic source inspection or audit, and examination of the item or service on delivery or completion.

C2.7.1 Responsibilities

C2.7.1.1 Engineering Manager and Project Managers

The Engineering Manager and/or project managers will be responsible for performing technical evaluations of potential subcontractors, suppliers, and vendors, and documenting the results on appropriate reports or forms.

C2.7.1.2 Quality Assurance Manager

The QA Manager will be responsible for performing vendor evaluations, source evaluations or inspections, periodic surveillances of supplier activities, and receipt inspection, as appropriate, and for maintaining the NWMI ASL.

C2.7.1.3 Project Managers

Project managers will be responsible for evaluating potential vendors to ascertain their ability to meet the technical requirements of the procurement activity.

C2.7.2 Requirements

C2.7.2.1 General

The procurement of QA Level 1 and QA Level 2 items and services shall be controlled through procedures to ensure conformance with specified requirements. These controls will provide for the following, as appropriate:

- Source evaluation and selection
- Evaluation of objective evidence of quality furnished by the supplier
- Source inspection
- Audit
- Examination of items or services on delivery or completion

Procurement planning will consider the function and complexity of the item or service to be procured and require sufficient advance notice for the evaluation and selection of suppliers.

C2.7.2.2 Supplier Selection

Potential suppliers of items or services shall be evaluated and the results documented as to their capability and experience in providing the required items or services in accordance with the requirements of the procurement documents. Evaluations will include one or more of the following:

- Supplier's history for providing identical or similar products or items that perform satisfactorily in actual use (**Note**: The supplier's history shall reflect current capabilities.)
- Assessment of the supplier's current quality records supported by qualitative and quantitative information that can be objectively evaluated
- Assessment of the supplier's technical and quality capabilities by direct evaluation of the supplier's facility, personnel, and QA program implementation

C2.7.2.3 Proposals

Bid proposals shall be evaluated by individuals or organizations having the necessary expertise to measure the supplier's capabilities. Evaluations shall consider the following, as appropriate, for the intended scope of work:

- Technical considerations
- QA requirements
- Personnel requirements
- Production capability
- Past performance
- Supplier's QA program
- Any exceptions to the contract agreement

C2.7.2.4 Supplier's Performance

The supplier's performance shall be evaluated throughout the life of the contract or purchase order. Evaluation methods will include review of the supplier's plans and procedures, source surveillance or inspection, QA assessments, receipt inspections, deviations, waivers, and corrective actions. The extent of verification, including planning, shall be a function of the relative importance, complexity, duration, and quantity of the item or services procured, and the supplier's ability to meet the technical and quality requirements. Verification shall be accomplished by qualified personnel, as appropriate for the method.

C2.7.2.5 Supplier-Generated Documents

Supplier-generated documents shall be controlled, handled, and approved in accordance with established requirements. Submittal requirements will be identified in the procurement documents. Measures shall be established for the acquisition, processing, and recorded evaluation of QA, technical, inspection, and test documentation or data against acceptance criteria.

C2.7.2.6 Item or Service Acceptance

Prior to offering the item or service for acceptance, the supplier shall verify that the item or service being furnished complies with the procurement requirements. Methods of acceptance of items or services provided by a supplier shall be established. These methods include one or more of the following:

- **Certificates of conformance** – When used, the following minimum criteria must be met:
  - Certificate identifies the purchased material, and/or the equipment or purchase order number
  - Certificate identifies the specific procurement requirements met
  - Certificate identifies any procurement requirements that were not met and includes an approved waiver
  - Certificate is authenticated by a person responsible for this QA function
  - Procedures used for the preparation, review, and approval of the certificate are described in the supplier's QA program or the purchase order
  - Validity of the supplier's certificates and effectiveness of certification system are verified, with the interval of verification based on the supplier's past quality performance
- **Source verification** – When used, this method will be performed at intervals consistent with the quality level and complexity of the item or service and include plans to perform inspections, examinations, or tests at predetermined points. Source inspection may be performed at lower-tier supplier locations, when necessary. The results may be used to support receipt inspection.
- **Receipt inspection** – When used, purchased items will be inspected to verify conformance to procurement documents. This method will verify by objective evidence such features as proper configuration; identification; dimensional, physical, or other characteristics; no damage from shipping; cleanliness; and review of supplier documentation when procurement requirements specify the documentation to be furnished.
- **Post-installation testing** – When used, post-installation test requirements and acceptance criteria will be established in conjunction with the supplier, if necessary.
- **QA Level 1 items** – A certificate of conformance, plus one or more of the other methods established above, will be used to establish acceptance of items.
- **QA Level 2 items** – Any one or more of the methods, established above, will be used to establish acceptance of items.
- Acceptance of services only

Documented evidence of acceptability must be complete prior to placing an item in service. Controls will be established for conditional release, such as for post-installation testing.

The acceptance of services will be based on one or more of the following methods:

- Technical verification of data produced
- Surveillance and/or audit of the activity

- Review of objective evidence for conformance to procurement document requirements

Acceptance of services will include review of contractor deliverables (including documentation and records), determination of acceptability for NWMI use, completion of acceptance testing, completion of startup testing, and turnover.

Supplier nonconformances will be processed in accordance with Section C2.15.2. Supplier nonconformances will consist of one or more of the following:

- Violation of a technical or material requirement in NWMI-supplied documents
- Violation of a requirement in purchaser-approved supplier documents

Supplier nonconformances may be identified either by NWMI or by the supplier. For a supplier-identified nonconformance, the supplier shall include a recommended disposition and technical justification for the identified condition. Nonconforming items will not be released for use until the nonconforming condition is reviewed and accepted by Engineering, and the implementation of the disposition is verified, except under conditional release provisions. Records of supplier nonconformance will be maintained.

C2.7.2.7 Procurement of QA Level 1 and QA Level 2 Items and Services by Commercial-Grade Dedication

The methods to procure commercially available items and services will be performed in accordance with approved procedures. The criteria and methods for identifying the critical characteristics used for acceptance will be established and subject to design control measures in accordance with Section C2.3. The critical characteristics, once selected to be verified, shall provide reasonable assurance that the item or service provided meets specified requirements. In selecting the critical characteristics, the impact of the activities associated with the item or service on the safety function of plant equipment will be considered.

Commercial-grade items will be identified in procurement documents by the manufacturer's published product descriptions, in accordance with Section C2.4. Commercial-grade services will be identified in the purchase order by the service provider's published service description (e.g., supplier's bulletin describing standard calibration services that are provided by the supplier) or other appropriate documents.

A commercial-grade item or service will satisfy the following:

- Not subject to design or specification requirements that are unique to nuclear facilities
- Used in applications other than nuclear facilities
- Ordered from the manufacturer or supplier on the basis of a specification set forth in the manufacturer's published product description (e.g., catalog)

As a minimum for acceptance of commercial-grade items, receipt inspection, as described below, will be performed to provide reasonable assurance that the item received is the item ordered and to ensure that the item will fulfill its intended safety function. Acceptance reviews will be performed for commercial-grade services to provide reasonable assurance that the service performed is the service ordered and that required documentation is received and is deemed acceptable.

Based on the complexity of the item or services or its importance to safety, one or more of the following will be used to provide reasonable assurance that the item or service meets the acceptance criteria for the characteristics identified to be verified for acceptance:

- Special test(s) or inspection(s) or both
- Commercial-grade survey of the supplier
- Source verification

- Acceptable supplier history of performance (can be used when a supplier's history has been established and at that point, the supplier's history shall be used with at least one other method)

The selection of the method or combination of methods, as described above, will be based on the following:

- Selected critical characteristics
- Available supplier information
- Quality history
- Degree of standardization of the service
- Importance to safety and complexity of the service

Receipt inspections of commercial-grade items will be performed to determine that damage was not sustained during shipment, the item received is the item ordered, and inspection and testing were performed by the supplier, as required by Engineering, to ensure conformance with acceptance criteria and to ensure that required documentation is received and is acceptable.

Dedication of a commercial-grade item or service will occur when that item is accepted in accordance with the above requirements. NWMI will assume 10 CFR 21, "Reporting of Defects and Noncompliance," reporting responsibility for all items identified as QA Level 1 or QA Level 2 items.

C2.7.2.8 Item Disposition

NWMI and its suppliers shall establish and document a system for disposition of items or services that do not meet the procurement specifications. This system shall include the following provisions:

- Evaluation of nonconforming items or services
- Submittal of nonconformance notices to NWMI
- NWMI disposition of supplier recommendations
- Verification of disposition completion
- Record maintenance of nonconformances

C2.7.2.9 Approved Suppliers List

The QA Manager will be responsible for the development and maintenance of the ASL. The ASL will identify those suppliers with acceptable QA programs that have been evaluated and accepted by NWMI in accordance with approved procedures. The NWMI QA organization will perform and document an evaluation of each supplier every 12 months. Satisfactory results will allow the supplier to remain on the ASL. Suppliers will also be evaluated by means of an audit at least triennially, if initial approval was by audit or survey. Suppliers that have unacceptable evaluations or that have not had a procurement placed with them in three years will be removed from the ASL.

C2.7.3 Applicable Implementing Procedures

The following procedures define the requirements and processes for implementing the control of purchased items and services:

- NWMI-ENG-PRO-020, *Commercial Grade Items (CGI)*
- NWMI-QA-PRO-023, *Procurement Documentation*
- NWMI-QA-PRO-024, *Supplier Evaluations*
- NWMI-QA-PRO-025, *Control of Purchased Items and Services*
- NWMI-QA-PRO-028, *Inspections*

C2.8 IDENTIFICATION AND CONTROL OF ITEMS

This section describes the requirements and controls necessary to ensure that only correct and accepted items are used or installed. As appropriate, these requirements and controls will provide the necessary identification on the item, in documents traceable to the item, or in a manner that ensures identification is established and maintained.

C2.8.1 Responsibilities

C2.8.1.1 Quality Assurance Manager

The QA Manager will be responsible for preparing procedures, as necessary, that describe the requirements and controls to ensure that only correct and acceptable items are used and installed. The QA Manager will ensure compliance to this section through surveillances, inspections, or audits, as appropriate.

C2.8.2 Requirements

Controls shall be established to ensure that only correct and accepted items are used or installed. Identification will be maintained on the items or in documents traceable to the items, or in a manner that ensures identification is established and maintained as described in this section. Items will be identified and controlled, as necessary, from initial receipt and fabrication of the items up to and including installation and use, so that only correct and accepted items are used or installed. Physical identification will be used to the maximum extent possible. When physical identification is either impractical or insufficient to control the item, physical separation, procedural controls, or other means will be employed. When markings are used, measures will be established to ensure that the markings are clear, legible, and do not have a detrimental effect on the function or service life of the item. Markings will be transferred to each part of an identified item when subdividing and will not be obliterated by surface treatments or coatings unless another means of identification is provided.

For QA Level 1 items, traceability of these items to specific records will be provided when specified by codes, standards, or specifications.

When codes, standards, or specifications include specific identification or traceability requirements (e.g., identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records), procedures shall be developed to address such identification and traceability.

Where specified, items having a limited operating life or shelf life will be identified and controlled to preclude use of items whose operating life or shelf life has expired.

Provisions shall be made for control of item identification consistent with the planned duration and conditions of storage, and can include:

- Maintaining or replacing markings and identification records due to damage during handling or aging
- Protecting the identification on items subject to excessive deterioration due to environmental exposure
- Updating existing plant or facility records

C2.8.3 Applicable Implementing Procedures

The following procedure defines the requirements and processes for implementing the identification and control of items:

- NWMI-QA-PRO-026, *Identification and Control of Items*

C2.9 CONTROL OF SPECIAL PROCESSES

This section describes the measures required to control special processes and to ensure that qualified personnel perform the work using applicable procedures in accordance with industry standards, codes, and specifications.

C2.9.1 Responsibilities

C2.9.1.1 Engineering Manager

The Chief Engineer will be responsible for developing, reviewing, approving, and qualifying special process procedures, including NDE procedures.

C2.9.1.2 Quality Assurance Manager

The QA Manager will be responsible for:

- Ensuring compliance to this section through surveillances, inspections, or audits, as appropriate
- Reviewing and approving all special process procedures
- Ensuring personnel employing these special process techniques are properly trained and qualified

C2.9.2 Requirements

Special processes affecting the quality of items and services shall be controlled. Procedures, instructions, drawings, checklists, travelers, work orders, or other appropriate means will ensure that special process parameters are controlled and that specified environmental conditions are maintained.

Special processes that control or verify quality (e.g., those used in welding, heat treating, and NDE) shall be performed by qualified personnel using applicable procedures in accordance with specified requirements, codes, or standards. When the outcome of the process is highly dependent on personal skills, such individuals will be certified in accordance with specified requirements. When the outcome is highly dependent on control of process parameters, the process and equipment will be prequalified in accordance with specified requirements. Special process procedures shall prescribe the necessary equipment, process parameters, calibration, and acceptance criteria.

Each special process shall be performed in accordance with approved instructions or procedures that include or reference qualification requirements and the information and conditions necessary to accomplish the process. This information or condition may include the following:

- Proper equipment
- Controlled parameters
- Proper environmental conditions
- Calibration requirements
- Personnel qualifications
- Acceptance criteria

Records of currently qualified personnel, processes, and equipment for special processes will be maintained in accordance with Section C2.17.

All special process records pertaining to the qualification of personnel and equipment shall be retained by NWMI as quality records.

C2.9.3 Applicable Implementing Procedures

The following procedure defines the requirements and processes for implementing the control of special processes:

- NWMI-QA-PRO-027, *Special Processes*

C2.10 INSPECTIONS

This section describes the requirements for the planning and execution of inspections to verify conformance of an item or activity to specified requirements.

C2.10.1 Responsibilities

C2.10.1.1 Quality Assurance Manager

The QA Manager will be responsible for ensuring that inspections are performed by qualified and/or certified personnel, as specified in design documents, and for ensuring that surveillances are performed on specific activities, as appropriate, to monitor compliance with specified inspection requirements.

C2.10.1.2 Project Managers

Project managers will be responsible for ensuring that the design prescribes the requirements for inspections and tests, as appropriate, for the specific structure, system, item, or component.

C2.10.2 Requirements

C2.10.2.1 General

Inspections are defined as an activity such as examining, measuring, testing, or gauging one or more characteristics of an entity and comparing the results with specified requirements. Inspections for acceptance shall be performed by persons other than those who performed or directly supervised the work being inspected.

Inspections required to verify conformance of an item or activity to specified requirements or continued acceptability of items in service shall be planned, executed, and documented. Characteristics to be inspected and the inspection methods to be employed shall be specified and the results documented. Inspection requirements and acceptance criteria shall include the specified requirements in applicable design documents or other pertinent technical documents approved by the responsible design organization.

Inspection activities shall be documented and controlled by instructions, procedures, drawings, checklists, travelers, or other appropriate means.

C2.10.2.2 Hold Points

Mandatory inspection hold points are defined inspection points where work may not proceed without the specific consent of the designated representative. Hold points may only be waived with the consent of the designated assigning representative who imposed the hold points. Waiver approval shall be documented prior to continuation of work beyond the specific hold point. Specific hold points shall be indicated in applicable documents.

C2.10.2.3 Planning

Inspection planning is part of the inspection process and must be documented. Documentation shall identify characteristics, methods, and acceptance criteria, and will provide for recording objective evidence of inspection results.

C2.10.2.4 Acceptability

When sampling is used to verify acceptability of a group of items, the sampling procedure shall be based on standard statistical methods with engineering approval.

C2.10.2.5 Inspection of Items Under Construction

Inspections shall be performed for items under construction (or otherwise in-process), when necessary, to verify quality. If inspection is impossible or disadvantageous, indirect control by monitoring of process methods, equipment, and personnel will be employed. Both inspection and process monitoring will be provided when control is inadequate without both. When a combination of process control and inspection are used to verify quality, these functions will be performed in a manner to ensure control of the process and quality of the item for the duration of the process. Controls shall be established and documented for coordination and sequencing of the activities at established inspection points, where required, during successive stages of the process.

C2.10.2.6 Final Inspections

Final inspections shall include a records review of results and the resolution of any nonconformances identified by prior inspections. Final inspections will verify conclusions made regarding conformance of the item(s) to specified requirements. Completed items shall be inspected for completeness, markings, calibration, adjustments, protection from damage, or other characteristics, as required, to verify the quality and conformance of the item. Quality records will also be reviewed for adequacy and completeness, as appropriate.

C2.10.2.7 Modifications, Repairs, or Replacement of Items

Modifications, repairs, or replacements of items accomplished after final inspection will require reinspection or retest, as appropriate, to confirm acceptability. Inspection records shall identify, as a minimum, the following:

- Item to be inspected
- Date of inspection
- Inspector's name
- Type of observation
- Results or acceptability
- Reference to any nonconformance

C2.10.3 Applicable Implementing Procedures

The following procedures define the requirements and processes for implementing inspection activities performed:

- NWMI-QA-PRO-028, *Inspections*
- NWMI-QA-PRO-039, *Training and Qualification of Inspection and Test Personnel*

C2.11 TEST CONTROL

This section describes the requirements for planning, conducting, and documenting tests to specific requirements that provide evidence of product or computer program acceptability and demonstrate satisfactory performance for service. Testing activities (e.g., prototype qualification tests, proof and functional tests) will be completed under the QA program of the organization that is completing the work.

C2.11.1 Responsibilities

C2.11.1.1 Quality Assurance Manager

The QA Manager will be responsible for reviewing and approving test procedures and for ensuring that test personnel are qualified to perform specific tasks as directed by the test procedures or plans.

C2.11.1.2 Startup Manager

The Startup Manager will be responsible for planning, conducting, and documenting that equipment and computer programs are acceptable and demonstrate performance for service.

C2.11.1.3 Project Manager

Project managers will be responsible for preparing, controlling, and approving test procedures; preparing test plans; and maintaining and controlling test records.

C2.11.2 Requirements

C2.11.2.1 General

Tests required to collect data (e.g., for siting or design input), verify conformance of an item or computer program to specified requirements, or demonstrate satisfactory performance for service shall be planned and executed.

Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented, and their conformance with test requirements and acceptance criteria shall be evaluated by a responsible authority to ensure that test requirements have been satisfied.

C2.11.2.2 Test Requirements and Acceptance Criteria

Test requirements and acceptance criteria shall be provided or approved by the responsible design organization. Test procedures and test plans shall be prepared to demonstrate that a product will perform satisfactorily in service, and will:

- Include or reference the requirements and acceptance criteria for testing as established by the design documents
- Specify calibrated equipment and instrumentation required to perform the test
- Identify the prerequisites that must be met prior to the start of testing
- Specify required environmental conditions, if applicable
- Provide instructions for test performance
- Identify records required for test data and results
- Identify, when applicable, mandatory hold points required by NWMI, the customer, or other inspection agency

As an alternative to Section C2.11.2.2, appropriate sections of related documents, such as American Society for Testing and Materials (ASTM) methods, supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria, may be used. Such documents shall include or be supplemented with appropriate criteria from Section C2.11.2.2 to ensure adequate procedures for the test.

C2.11.2.3 Test Records

Test records shall be established and maintained to indicate the ability of the item or computer program to satisfactorily perform its intended function or to meet its documented requirements. These test records shall, as a minimum, identify the following:

- Item tested
- Date of test
- Person or persons performing test or data recorder
- Observations noted
- Results and acceptability
- Corrective actions taken to correct any deviations
- Person evaluating test results

Test records may vary depending on the test type, purpose, and application.

C2.11.2.4 Computer Software

When used in design development, computer programs and software shall be tested and computer program test procedures shall ensure that the computer program produces correct results. Testing shall include verification tests, hardware integration tests, in-use tests, or other tests as specified by the customer, as appropriate.

Computer software testing will be required by all suppliers to verify and provide evidence of the quality of their software products. In addition, methods to control and approve supplier-generated documents will be established. Based on the complexity of the product and importance to safety, NWMI will independently verify the quality of the supplier's product using source surveillances, inspections, audits, and review of supplier's nonconformances, dispositions, waivers, and corrective actions. NWMI-QA-PRO-029, *Testing*, identifies the process by which computer software testing will be completed.

The software requirements review will be performed at the completion of the software requirements documentation and will ensure that the requirements are complete, verifiable, consistent, and technically feasible. The review will also ensure that the requirements will result in feasible and usable code.

During software testing, the design as implemented in code will be exercised by executing the test cases. Failure to successfully execute the test cases will be reviewed to determine if modifications of the requirements, design, implementation, and/or test plans and cases are required. The code will be validated and verified to ensure adherence to the requirements and that the software produces correct results for the test cases. To evaluate technical adequacy, the software test case results can be compared to results from alternative methods, including analysis without computer assistance, experiments and tests, standard problems with known solutions, or confirmed published data and correlations.

C2.11.2.5 Qualifications

Testing shall be accomplished by qualified personnel in accordance with documented test procedures.

C2.11.2.6 Test Results

Test results shall be documented and evaluated by a responsible authority to ensure that test requirements have been satisfied. Test results for design qualification tests and software design verification shall be evaluated by the responsible design organization.

C2.11.3 Applicable Implementing Procedures

The following procedures define the requirements and processes for implementing testing activities:

- NWMI-QA-PRO-029, *Testing*
- NWMI-QA-PRO-039, *Training and Qualification of Inspection and Test Personnel*

C2.12 CONTROL OF MEASURING AND TEST EQUIPMENT

This section describes the requirements for the control of measuring and test equipment (M&TE). M&TE are those tools, gauges, instruments, and other measuring and test equipment used for acceptance testing, verification, and data collection.

C2.12.1 Responsibilities

C2.12.1.1 Quality Assurance Manager

The QA Manager will be responsible for developing and maintaining the M&TE program requirements, including the development of implementing procedures and ensuring through inspection or surveillance that only controlled and calibrated equipment is used for testing, verification, and data collection.

C2.12.1.2 Maintenance Manager

The Maintenance Manager is responsible for ensuring control and calibration of M&TE used for acceptance testing, verification, and data collection.

C2.12.2 Requirements

M&TE used in activities affecting the availability and/or reliability of IROFS will be controlled, calibrated, and adjusted at specified intervals to maintain equipment performance within required limits. Procedures will ensure that devices and standards used for measurement, test, and calibration activities are of the proper type, range, and accuracy. Calibration control will not be necessary for rulers, tape measures, levels, and other similar devices.

C2.12.2.1 Calibration and Maintenance

M&TE will be calibrated, adjusted, and maintained at prescribed times or intervals and whenever the accuracy of the M&TE is suspect. Calibration will be against and traceable to certified equipment having a known valid relationship to nationally recognized standards, or to international standards known to be equivalent to and verified against corresponding nationally recognized standards. Where no such standards exist, the basis for calibration shall be defined.

The method and frequency of calibration of M&TE shall be defined and based on the type of equipment, stability characteristics, required accuracy, intended use, and other conditions that may affect measurement control.

When M&TE is overdue for calibration or is found to be out of calibration, an evaluation of the validity of previous inspection or test results and the acceptability of items previously inspected or tested shall be performed and documented. M&TE found to be out of calibration will be tagged or segregated and not used until the equipment has been recalibrated. Equipment consistently found to be out of calibration will be repaired or replaced. Calibration shall be performed on any piece of M&TE when the accuracy of that equipment is suspect.

M&TE shall be handled and stored to provide protection and maintain accuracy. M&TE will be suitably marked, tagged, labeled, or otherwise identified to indicate calibration status and establish traceability to calibration records.

Calibration and control is not required for devices such as rulers, tape measures, levels, or other devices where normal commercial equipment provides adequate confidence of accuracy. In addition, calibration will not be required for a device used to measure or test, if the results of the measurement or test are not used to accept or reject the item or test.

C2.12.2.2 Records

Records of calibration and repair, including as-found conditions, shall be maintained to indicate calibration status and the capability of the M&TE to satisfactorily perform its intended function.

C2.12.3 Applicable Implementing Procedures

The following procedure defines the requirements and processes for implementing control of M&TE:

- NWMI-QA-PRO-030, *Control of Measuring and Test Equipment*

C2.13 HANDLING, STORAGE, AND SHIPPING

This section describes the requirements for handling, storage, cleaning, packaging, shipping, and preservation of items to prevent damage or loss and to minimize deterioration.

C2.13.1 Responsibilities

C2.13.1.1 Quality Assurance

The QA Manager will be responsible for ensuring compliance to requirements for handling, storage, cleaning, packaging, shipping, and preservation of items through inspection and/or surveillance activities.

C2.13.1.2 Project Managers

Project managers will be responsible for:

- Defining requirements for handling, storage, cleaning, packaging, shipping, and preservation of items, systems, and components for NWMI-sponsored designs
- Preparing procedures for handling, storage, cleaning, packaging, shipping, and preservation of items, systems, and components, as appropriate

C2.13.2 Requirements

C2.13.2.1 General

Handling, storage, cleaning, packaging, shipping, and preservation of items will be conducted using established work and inspection instructions, specifications, drawings, procedures, or other pertinent documents specified for use in conducting the activity.

When required for a particular item, special equipment and special protective environments shall be specified, provided, and their existence verified. When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation will be used.

C2.13.2.2 Special Handling Tools and Equipment

Special handling tools and equipment shall be used and controlled, as necessary, to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested in accordance with procedures at specified intervals (or prior to use) to verify that the tools and equipment are adequately maintained. Operators of special handling and lifting equipment shall be experienced or trained in the use of the equipment.

C2.13.2.3 Marking and Labeling

Instructions for marking and labeling for packaging, shipping, handling, and storage will be established, as necessary, to adequately identify, maintain, and preserve the item, including indication of the presence of special environments or the need for special controls.

C2.13.3 Applicable Implementing Procedures

The following procedure defines the requirements and processes for implementing handling, storage, and shipping activities:

- NWMI-QA-PRO-031, *Handling, Storage, and Shipping*

C2.14 INSPECTION, TEST, AND OPERATING STATUS

This section establishes the requirements for identifying the status of inspection and testing of items during fabrication, in process, or in storage.

C2.14.1 Responsibilities

C2.14.1.1 Quality Assurance Manager

The QA Manager will be responsible for monitoring, inspecting, and testing items to ensure compliance with requirements and for review or removal of status indicators.

C2.14.1.2 Project Managers

Project managers will be responsible for designing, fabricating, and testing items, and for specifying the requirements for inspection and testing.

C2.14.2 Requirements

The status of inspection and test activities shall be identified either on items or in documents traceable to the item where it is necessary to ensure that required inspections and tests are performed. The status of inspection and tests will assist in ensuring that items, which have not passed required inspections or tests, are not inadvertently installed, used, or operated. This status shall be maintained through indicators such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means.

C2.14.2.1 Authority

The authority for applying and removing status indicators will be inherent in the respective implementing procedure that initiated assignment of the status.

C2.14.2.2 Indicators

Status indicators shall also provide for indicating the operating status of RPF systems and components, such as by tagging valves and switches, to prevent inadvertent operation.

C2.14.3 Applicable Implementing Procedures

The following procedure defines the requirements and processes for implementing inspection, testing, and operating status:

- NWMI-QA-PRO-032, *Inspection, Testing, and Operating Status*

C2.15 CONTROL OF NONCONFORMING ITEMS

This section establishes requirements for reporting and controlling items, services, or activities that do not conform to specified requirements, to prevent their inadvertent installation or use.

C2.15.1 Responsibilities

C2.15.1.1 Quality Assurance Manager

The QA Manager will be responsible for:

- Documenting deviations from drawings, specifications, or specified requirements on a nonconformance report
- Issuing, controlling, approving the disposition
- Closing the nonconformance report
- Ensuring that further processing, delivery, installation, or use is controlled until proper disposition of the nonconformance report, deficiency, or unsafe condition has occurred

C2.15.1.2 Engineering Manager

The Engineering Manager will be responsible for the overall development and implementation of a program to ensure that nonconforming items are identified, controlled, dispositioned, and corrected. The Engineering Manager will also be responsible for verifying that a nonconforming item is suitable for use prior to its release.

C2.15.1.3 Project Managers

Project managers will be responsible for reviewing the nonconformance report, providing disposition, and ensuring closure of the reported condition.

C2.15.1.4 Employees

Each NWMI employee will be responsible for reporting suspect conditions that potentially deviate from drawings, specifications, or specified requirements.

C2.15.2 Requirements

Items, services, or activities that do not conform to specified requirements, or whose conformance is indeterminate, shall be controlled to prevent inadvertent installation or use. These controls shall provide for identification, documentation, segregation when practical, dispositioning, and for notification to affected organizations.

Nonconformance reports shall be tracked to closure to ensure approved dispositions are properly implemented.

Nonconforming items shall be identified by marking, tagging, or other acceptable methods that are not detrimental to the item. Identification shall be either on the item, the container, or the package containing the item, and shall be legible and recognizable.

When practical, nonconforming items shall be segregated by placing the item(s) in an identifiable and designated storage holding area until properly dispositioned. When segregation is impractical or impossible due to size, weight, or access limitation, other precautions will be employed to preclude inadvertent use of the nonconforming item.

Nonconforming characteristics shall be reviewed and evaluated, and their recommended dispositions shall be proposed and approved in accordance with documented procedures. Further processing, delivery, installation, or use of a nonconforming item shall be controlled pending the evaluation and an approved disposition of the reported condition by authorized personnel.

C2.15.2.1 Authority

The responsibility and authority for the evaluation and disposition of nonconforming items and activities shall be defined in the implementing procedure. The responsibility for the control of further processing, delivery, installation, or use of nonconforming items and/or activities will also be described in the implementing procedures. Personnel performing the evaluations to determine a disposition shall have demonstrated competence in the specific area they are evaluating, an adequate understanding of the requirements, and access to relevant background information to perform their evaluation.

C2.15.2.2 Disposition

Dispositions (e.g., use-as-is, reject, repair, rework, or other) of the condition shall be identified and documented. Technical justification for the acceptability of a nonconforming item dispositioned as repair or use-as-is will be documented. Nonconformances to design requirements dispositioned as repair or use-as-is shall be subject to the same design control measures commensurate with those applied to the original design or subsequent design changes. Required as-built records, if such records are required, shall also reflect the use-as-is or repair conditions. Recommended dispositions may allow for "conditional release" of nonconforming items. The conditional release designation will only be used for unusual circumstances and will not create any situation that will obstruct or hinder the final resolution of the nonconforming condition.

C2.15.2.3 Rework or Repair

Items reworked or repaired will be reexamined in accordance with the original acceptance criteria unless the disposition has established alternate acceptance criteria.

C2.15.2.4 Nonconforming Condition

NWMI, as the license holder of the RFP, has responsibility for reporting defects and nonconforming conditions under 10 CFR 21. NWMI-QA-PRO-035, *Identification and Control of Nonconforming Items,* identifies the process by which nonconforming conditions will be identified and controlled. When required by contract or specification, the nonconforming condition shall be transmitted to the customer for evaluation as a potentially reportable condition under 10 CFR 21.

C2.15.3 Applicable Implementing Procedures

The following procedures define the requirements and processes for implementing the identification and control of nonconforming items:

- NWMI-QA-PRO-019, *10 CFR Part 21 Reporting*
- NWMI-QA-PRO-035, *Identification and Control of Nonconforming Items*

C2.16 CORRECTIVE ACTION

This section describes the requirements for identifying conditions adverse to quality, safety, or the environment. NWMI's policy is that these conditions will be immediately and promptly identified, documented, and corrected as soon as practical.

C2.16.1 Responsibilities

C2.16.1.1 Quality Assurance Manager

The QA Manager will be responsible for evaluating reported conditions, determining significance, documenting, approving resolution and disposition, tracking to closure, and promptly reporting significant conditions to NWMI senior management and the customer, as required.

C2.16.1.2 Employees

All NWMI employees will be responsible for immediately reporting conditions adverse to quality, safety, or the environment to NWMI senior management.

C2.16.2 Requirements

Conditions adverse to quality, safety, and the environment shall be identified promptly and corrected as soon as practical. Nonconformance reports, audit/assessment findings, or other forms of observation that identify adverse conditions will be reviewed to determine significance. If the condition is determined to be a significant condition adverse to quality or safety, a corrective action report shall be initiated.

Procedures will establish the corrective action program and include the following process elements:

- Promptly identifying and correcting conditions adverse to quality
- Evaluating significant conditions adverse to quality for reportability to the NRC (when required) under 10 CFR 21 or other applicable reporting requirements, and reporting such conditions when warranted
- Stopping work, if applicable
- Determining root cause and corrective actions to preclude recurrence for significant conditions adverse to quality
- Performing follow-up actions to verify implementation of corrective actions for significant conditions adverse to quality

"Conditions adverse to quality" is an all-inclusive term used in reference to failures, malfunctions, deficiencies, deviations, defective items, and/or nonconformances associated with activities and services. Conditions adverse to quality shall be documented and reported to the appropriate levels of management.

A significant condition adverse to quality or safety is one wherein the condition imperils the uninterrupted progress of a project, poses an imminent health or safety concern for personnel or the public, or could potentially result in a serious or repeated breach of requirements. When determined that the condition represents a significant condition adverse to quality, safety, and/or the environment, a corrective action report shall be initiated documenting the condition. The cause of the condition shall be identified after analysis, and corrective action will be taken to preclude recurrence. The identification, cause, and proposed corrective action(s) will be reported to the CEO, COO, and other senior management, as appropriate.

Conditions adverse to quality are classified in one of two categories with regard to their significance and corrective actions to be taken. The two categories of significance include:

- **Conditions adverse to quality** – These conditions are promptly identified and corrected. The cause of the condition is determined, and corrective action taken to preclude recurrence. These conditions, their causes, and corrective actions are documented, reported to appropriate levels of management, and follow-up action taken to verify implementation of corrective actions, as appropriate.
- **Significant conditions adverse to quality** – These conditions require follow-up action to be taken to ensure that satisfactory implementation of the approved corrective actions were performed within prescribed time limits. All significant conditions adverse to quality, safety, and/or the environment shall be documented in corrective action reports and tracked to closure to ensure that approved corrective actions were properly implemented. When required by contract or specification, significant conditions adverse to quality, safety, and/or the environment shall be transmitted to the customer for evaluation as a potential reportable condition under the 10 CFR 21.

Significant conditions adverse to quality include the following:

- Deficiency that would seriously impact an item, activity, or service from meeting or performing its intended function or output of ensuring public health and safety
- Deficiency in design that has been approved for fabrication or construction, where the design deviates extensively from design criteria and basis
- Deficiency in fabrication/construction or significant damage to SSCs that require extensive evaluation, redesign, or repair to establish the adequacy of the SSC to perform its intended function of ensuring public health and safety
- Deviation from performance specifications that require extensive evaluation, redesign, or repair to establish the adequacy of the SSC to perform its intended function
- Significant error in a computer program used to support activities affecting quality after the program has been released for use
- Deficiency, repetitive in nature, related to an activity or item subject to this QAPP
- Condition that, if left uncorrected, has the potential to have a serious negative impact on activities or items subject to the NWMI QAPP controls

Procedures establishing the corrective action program will include a requirement for management to take follow-up action to verify implementation of the corrective action taken to address significant conditions adverse to quality. The QA organization will be responsible for conducting periodic assessments of these follow-up actions.

Procedures establishing the corrective action program will assign organizational responsibility for trending significant conditions adverse to quality and the criteria for determining trends. Reports of significant conditions adverse to quality will be evaluated to identify adverse quality trends and help identify root causes. Trend evaluation will be performed in a manner and at a frequency that provides for prompt identification of trends that are adverse to quality. Identified adverse trends will be handled in accordance with the established corrective action program and reported to the appropriate management personnel.

C2.16.3 Applicable Implementing Procedures

The following procedures define the requirements and processes for implementing corrective actions:

- NWMI-QA-PRO-019, *10 CFR Part 21 Reporting*
- NWMI-QA-PRO-033, *Corrective Action*
- NWMI-QA-PRO-036, *Causal Analysis and Preventative Action*

C2.17 QUALITY RECORDS

This section describes the requirements for the control of records that furnish documentary evidence of quality.

C2.17.1 Responsibilities

C2.17.1.1 Plant Manager

The Plant Manager will be responsible for establishing and maintaining a records control system for the identification, collection, indexing, filing, and maintenance of quality records.

C2.17.1.2 Quality Assurance Manager

The QA Manager will be responsible for measuring compliance to this section through surveillances and/or audits, as appropriate.

C2.17.1.3 Project Managers

Project managers will be responsible for ensuring that all project records are complete, accurate, legible, and are transmitted to the Records Management Administrator for inclusion into the project records storage files.

C2.17.1.4 Records Management Administrator

The Records Management Administrator will be responsible for filing, indexing, and protecting project-generated documents from loss or deterioration.

C2.17.2 Requirements

Records shall be distributed, handled, and controlled in accordance with written procedures. These records shall furnish documentary evidence that items or activities meet specified quality requirements. NWMI senior management shall establish a records system, consistent with schedules for accomplishing the work activities. QA records shall furnish documentary evidence that items or activities meet specified quality requirements. The records system, as defined and implemented, shall be enforced through written procedures or instructions.

NWMI-QA-PRO-017, *Quality Records*, identifies the process by which quality records are identified and maintained. Items identified in Section 6.1 of the procedure as quality documents are relevant to the final design and construction phase. These include:

- Contracts and specifications (including any modifications)
- Drawings
- Procurement records
- Test procedures
- Test reports
- Engineering reports (including calculations, and software verification and validation reports)
- Inspection reports
- Assessment reports
- Supplier evaluation reports
- Training records
- Project-specific QA Plan
- Corporate Environmental, Safety, and Health Program Plan
- Corporate QAPP
- Implementing procedures
- Material test reports
- Certifications of conformance
- Personnel qualification/certification records
- Design review reports
- Project-specific procedures
- Calibration records
- Nonconformance reports
- Corrective Action reports
- Stop work requests

Applicable design specifications, procurement documents, test procedures, or other pertinent quality documents shall specify the records to be generated, authenticated, supplied, and/or maintained, and their final disposition. The requirements and responsibilities for these activities will be specified in applicable implementing procedures.

All quality records will be retained for the life of the RPF. Documents that are designated to become records shall be legible, accurate, complete, traceable to associated items or activities, and accurately reflect the work accomplished or information required. Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. Records may be originals or reproduced copies.

C2.17.2.1 Indexing

Records shall be indexed. The indexing system shall include, as a minimum, record retention times and the location of the record system. The records and/or indexing system(s) will provide sufficient information to permit identification between the record and the item(s) or activity to which it applies.

C2.17.2.2 Classification

Records shall be classified as "lifetime" or "nonpermanent" by NWMI customers, as applicable. Lifetime and nonpermanent records will be delineated within implementing procedures. Lifetime records will be classified consistent with the recommendations found in ANSI/ANS 15.8.

C2.17.2.3 Corrections

The methods for correcting records will be delineated within implementing procedures, which will provide for appropriate review or approval by the originating organization. Corrections shall include the date and identification of authorized person making the correction.

C2.17.2.4 Receipt

A receipt control system shall be established to provide protection of records from loss or damage. The control system shall allow for a current and accurate status of records during receipt.

C2.17.2.5 Storage

Records shall be stored in predetermined locations that meet customer requirements, codes, standards, and regulatory requirements, as appropriate. Records shall be stored in a manner to preclude deterioration and loss. Provisions shall be made considering environmental controls and unique storage requirements. Entry to designated storage locations shall be controlled to prevent unauthorized entry. All essential network shared drives containing records and documents shall be backed-up at predetermined schedules.

C2.17.3 Applicable Implementing Procedures

The following procedure defines the requirements and processes for implementing the quality records management system:

- NWMI-QA-PRO-017, *Quality Records*

C2.18 ASSESSMENTS

This section describes the processes and expectations to implement a system of audits, assessments, and surveillance of activities affecting quality. These processes are intended to ensure that audits, assessments, and surveillances are planned, scheduled, and conducted to identify strengths and weaknesses that affect organizational and company objectives.

C2.18.1 Responsibilities

C2.18.1.1 Quality Assurance Manager

The QA Manager will be responsible for ensuring that all audits, assessments, and surveillances are scheduled, planned, and conducted. Other responsibilities will include:

- Conducting independent quality assessments and/or surveillances of subcontractors and suppliers
- Conducting internal independent assessments and/or surveillances
- Assisting other organizations with their obligations, as requested.

C2.18.1.2 Project Managers

Project managers will be responsible for planning, scheduling, and performing management assessments of their organization to ensure that company objectives and customer expectations are being met.

C2.18.1.3 Employees

Each NWMI employee will be responsible for seeking improved methods for conducting business. NWMI employees will be encouraged to communicate suggestions that would serve to meet or exceed company and customer expectations.

C2.18.2 Requirements

C2.18.2.1 General

Audits shall be performed to verify that performance criteria are met and to determine the effectiveness of the NWMI QA program. Audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited.

Audits shall be scheduled in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity. Scheduled audits will be supplemented by additional audits of specific subjects, when necessary, to provide adequate coverage.

The auditing organization shall develop an audit plan for each audit. This plan shall identify the audit scope, requirements, auditing personnel, activities to be audited, organizations to be notified, applicable documents, the audit schedule, and any written procedures or checklists. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective.

C2.18.2.2 Documenting and Reporting

Audit results shall be documented and reported to and reviewed by the manager of the audited organization. The audit report shall be signed, or otherwise endorsed by the lead auditor, and issued to the organization being audited. The report shall contain the following information:

- A description of the audit scope
- Identification of the auditors and any personnel contacted during the audit process
- A summary of the audit results, including a statement on the effectiveness of the elements audited
- A description of any adverse audit finding

C2.18.2.3 Adverse Audit Findings

Management of the audited organization or activity shall investigate all adverse audit findings, schedule corrective actions, including measures to prevent recurrence of significant conditions adverse to quality, and notify the appropriate organization (in writing) of actions taken or planned.

C2.18.2.4 Follow-Up

Follow-up action shall be taken to verify that corrective action was accomplished as scheduled.

C2.18.3 Assessments

C2.18.3.1 Types of Assessments

For the NWMI RPF, three types of assessments will be performed:

- **Independent assessments** – Conducted by an independent organization (e.g., QA or SH&L) to provide an independent evaluation of a process, organization, or company.
- **Management assessments** – A self-assessment by management of their own organizational effectiveness to meet company and customer expectations. These assessments can be applied at any working level.
- **Self-assessments** – Routine assessments conducted by employees daily as a function of their job responsibilities. Self-assessments are not required to be documented, but are acknowledged as being conducted through reviews, inspections, and other relevant activities.

C2.18.3.2 Requirements for Independent Assessments

Independent assessments (e.g., surveillances, audits) shall be:

- Scheduled, planned, and conducted by an organization (typically the QA organization) independent from the organization being assessed
- Performed by individuals technically qualified and knowledgeable in the areas being assessed who have sufficient authority and freedom from the assessed organization to carry out their responsibilities
- Conducted to evaluate the performance of work within a given process, organization, or company, including management processes that affect product quality or performance
- Conducted using established criteria
- Conducted to enhance the quality of the process, organization, or company
- Documented and reported to a level of management capable of responding to any needed actions

The scope, rigor, frequency, and level of formality of the independent assessment will be commensurate with the size, scope, complexity, and risk associated with the process, organization, or company's tasks. Responses to independent assessments will address, as applicable, remedial actions to correct deficiencies, analysis of the root cause, and actions taken to preclude recurrence. Actions will be tracked to closure, and the effectiveness of corrective actions will be verified.

C2.18.3.3 Requirements for Management Assessments

Management assessments may be conducted from an organizational top-down approach, from a bottoms-up approach, or a combination of both. Regardless, the objective of a management assessment will be to focus on systemic and resource issues or problems that would hinder the organization from meeting objectives. Processes that may be part of management assessments include organizational interfaces, cost or variance reports, performance indicators, and deficiency reports. Effective assessments should cover training, communications, adequacy of human resources, and consideration of employee knowledge, motivation, and morale. Direct observation of employees at work is also an effective method of assessment and will be encouraged.

Management assessment tools may vary and include one or a combination of interviews, drills/exercises, documentation reviews, direct observation, customer surveys, employee feedback, independent assessments, performance indicators, or other means to effectively measure the overall performance of the organization or project. The rigor, level of formality, and frequency of management assessments should be responsive to the organization's level of responsibility in meeting established company objectives and customer requirements.

Management assessments will be:

- Used by all levels of management to assess management processes and adequacy, and effective implementation of the QAPP, including any problems that may hinder NWMI from achieving company and customer expectations
- Planned and conducted periodically to assess an organization's performance and to identify the management systems that would impede and those that would enable management to meet company and customer expectations
- Documented and used as input to improve organizational operations. Resultant actions will be tracked by the respective organization to ensure that problems that could hinder the achievement of objectives are identified and corrected.

C2.18.3.4 Requirements for Self-Assessments

Self-assessments will be conducted on a routine basis by every employee as part of their individual job tasks. These assessments may take a variety of forms and are considered informal. Self-assessments will often be conducted as a means of improving processes in which the employee is involved.

Employees will be encouraged to bring suggestions or concerns to all levels of NWMI management for consideration of appropriate action. NWMI management will be responsible for being responsive to employee suggestions or concerns to improve company or organizational processes.

C2.18.4 Requirements for Surveillances

A surveillance is described as the act of monitoring or verifying the status of an item or activity or the analysis of records to verify that specific requirements are being fulfilled (i.e., a snapshot of a particular activity). Surveillances shall be:

- Performed by individuals who are independent from the specific activity yet knowledgeable in the topic area being surveyed
- Performed by individuals who are trained and qualified
- Planned, performed, documented, tracked, and reported to management of the affected organization

C2.18.4.1 Reporting

Surveillance reports shall include, as a minimum:

- Report number
- Date of surveillance
- Description of the surveillance activity
- Personnel conducting the surveillance
- Personnel contacted or interviewed during the surveillance
- Results of the surveillance
- Any findings or observations noted
- Summation of actions taken to correct deficiencies

C2.18.4.2 Applicable Implementing Procedures

The following procedures define the requirements and processes for implementing audits, assessments, and surveillances:

- NWMI-QA-PRO-022, *Training and Qualification of Project Personnel*
- NWMI-QA-PRO-034, *Assessments and Surveillances*
- NWMI-QA-PRO-037, *Audits*
- NWMI-QA-PRO-038, *Lead Auditor Qualifications*

C2.19 EXPERIMENTAL EQUIPMENT

NWMI does not intend to have any experimental equipment; therefore, there will be no potential impacts to safety-related items from such equipment.

C2.20 PROVISIONS FOR CHANGES

This section describes the measures required to change the QAPP. These changes may be initiated by events such as reorganizations or revised activities, lessons learned, changes to applicable regulations, process changes, or other reasons. QAPP changes will be governed by approved procedures.

C2.20.1 Responsibilities

C2.20.1.1 Engineering Manager

The Chief Engineer will be responsible for ensuring compliance to this section through reorganizations, revisited activities, and changes to regulations or processes, as appropriate.

C2.20.1.2 Quality Assurance Manager

The QA Manager will be responsible for developing, reviewing, approving, and qualifying changes to the QAPP, including implementing procedures.

C2.20.2 Requirements

Prior to NRC issuance of the materials license, changes to the NWMI QA program will be incorporated into the QAPP and submitted to the NRC with the next revision of the license application, or no later than annually, whichever occurs first.

After the materials license is issued, changes to the QAPP that do not reduce the commitments as accepted by the NRC will be submitted annually. The revision must reflect all changes up to a maximum of 6 months prior to the date of filing. Any changes that reduce commitments in the QAPP will be submitted to the NRC for review and approval prior to implementation.

C2.20.3 Applicable Implementing Procedures

The following procedure defines the requirements and processes for implementing the provisions for change:

- None

C3.0 FACILITY OPERATIONS

This section identifies the elements of the NWMI QA program for conduct of operations at the RPF. The requirements will be applied to any equipment or operation, as appropriate, and be consistent with its potential safety impact or program goals. Many program requirements will be satisfied by existing documentation or by procedures and activities required by other requirements, design standards, and guidelines of Federal or State agencies. In addition, several requirements of the QA program for operations may be found in other documents (e.g., training program, emergency preparedness plan, security plan, technical specifications) and will not be duplicated in the QAPP. Additional detail will be developed in the Operating License Application.

C3.1 ORGANIZATION

NWMI shall provide sufficient resources in personnel and materials to safely conduct operations. Planning will anticipate needs as appropriate for the task. The organization structure shall be defined as required by Chapter 14.0, "Technical Specifications."

C3.2 QUALITY ASSURANCE PROGRAM

NWMI shall establish a QA program by implementing a policy for the conduct of operations. The policy will assign personnel to implement the policy and identify the goals for operating the RPF. Personnel assignments and progress toward achieving goals will be documented.

C3.3 PERFORMANCE MONITORING

NWMI will monitor RPF performance relative to the goals that will be used as performance indicators. NWMI will also document periodic observations of operations and identify and assess any deficiencies to ensure the execution of corrective actions that will prevent recurrence. If appropriate, trend analysis should be performed to indicate where improvements or lessons learned could be implemented. Violations of operating practices should be addressed and documented as appropriate.

C3.4 OPERATING EXPERIENCE

NWMI will document the methods for maintaining operator experience. Operators will be responsible for maintaining experience in operating the RPF. This experience may be achieved by routine operation of the RPF and documentation of associated activities. Vital and priority facility operations information will be provided to operators as it relates to facility operations, and individual job assignments will be provided in a timely manner. Operator training will be implemented as required in ANSI/ANS-15.4, *Standard for the Selection and Training of Personnel for Research Reactors*.

C3.5 OPERATING CONDITIONS

Pre-operations checklists will be used to determine or verify required pre-operational conditions and readiness to operate. Operating equipment will be periodically monitored to detect abnormal conditions or adverse trends. Operating conditions will be documented in an operations logbook or other record. Operators will notify the appropriate level of management of any abnormal situations.

C3.6 OPERATIONAL AUTHORITY

NWMI will establish methods for conducting operations and the responsibility for each operations shift. Shift supervisors and operators will conduct a comprehensive review of appropriate records and equipment before assuming responsibility for the facility. Operational authority may be transferred through a documented turnover briefing and facility walk-through procedures, including checklists to record items important to facility status.

C3.7 CONTROL AREA

Operators shall be alert and attentive to the control console's indications, alarms, and other activities within the control area. Only persons specifically authorized or certified to operate the RPF will operate control area equipment. Trainees may operate equipment only when directly supervised by certified operators. Control area activities and access should be limited to ensure that the operators are attentive to control responsibilities. A procedure shall be in place for quick placement of the NWMI RPF in a safe configuration if evacuation of the control area or site is necessary.

C3.8 ANCILLARY DUTIES

Operators shall not be assigned ancillary duties to be performed during operations to the extent that these duties could interfere with the ability to monitor facility parameters and maintain control of the RPF.

C3.9 EMERGENCY COMMUNICATIONS

Operators shall be able to rapidly contact the appropriate level of management and shall have the means to notify all affected personnel promptly of on-site operations upsets or emergencies.

C3.10 CONFIGURATION CONTROL

Equipment shall be identified that requires configuration control. NWMI will be responsible for establishing and maintaining proper configuration control and will authorize any changes to safety-related items. All configuration changes to safety-related items will be documented. Before placing equipment into operation, the system will be properly calibrated or checked, as appropriate, and any deficiencies in the equipment or the current configuration of the system documented. Configuration control activities will also address methods for documenting temporary modifications and maintenance that requires a change in the RPF.

C3.11 LOCKOUT AND TAGOUT

Locks and tags will be placed on equipment, for safety or other special administrative reasons, when controls must be established. If there is potential for equipment damage or personnel injury during equipment operation, maintenance, inspection, or modification activities, or from inadvertent activation of equipment, a facility lockout/tagout procedure shall be implemented.

C3.12 TEST AND INSPECTION

Tests will be performed following system maintenance, design changes, or inspection that involves dismantlement of components or systems. A documented test plan will be used to demonstrate that the component or system is capable of performing its intended function. All test results will be documented and retained in facility records, as appropriate.

C3.13 OPERATING PROCEDURES

Operating procedures will provide appropriate direction to ensure that the facility is operated normally within its design basis and in compliance with technical specifications. In addition, operating procedures will be written, reviewed, approved by appropriate management, controlled, and monitored to ensure that the content is technically correct and the wording and format are clear and concise.

NWMI's policy on the use of procedures will be documented and clearly understood by all operators. The extent of detail in a procedure should depend on the complexity of the task; the experience, education, and training of the users; and the potential significance of the consequences from an error. The process for making changes and revisions to procedures will be controlled, documented, and maintained in the control room or equivalent area.

C3.14 OPERATOR AID POSTINGS

Any posted information that aids operators in performing their duties will be current and accurate. NWMI Level 2 management will review operator aids to confirm that the information is necessary and correct before approving the postings. Postings will be checked periodically for continued applicability.

C3.15 EQUIPMENT LABELING

Equipment will be labeled to enable RPF personnel to positively identify the equipment they operate and maintain. Information on labels should be consistent with information found in facility procedures, valve lineup sheets, piping and instrument diagrams, or other documents. Labels will be permanent, securely attached, readable, and have appropriate information.

C4.0 APPLICABILITY OF EXISTING FACILITIES

The RPF will be a newly constructed facility; therefore, this requirement does not apply to the RPF.

C5.0 DECOMMISSIONING

This section of the QAPP will be addressed in the Operating License Application.

C6.0 REFERENCES

10 CFR 20, "Standards for Protection Against Radiation," *Code of Federal Regulations*, Office of the Federal Register, as amended.

10 CFR 21, "Reporting of Defects and Noncompliance," *Code of Federal Regulations*, Office of the Federal Register, as amended.

10 CFR 50.34, "Contents of Applications; Technical Information," *Code of Federal Regulations*, Office of the Federal Register, as amended.

10 CFR 70.61, "Performance Requirements," *Code of Federal Regulations*, Office of the Federal Register, as amended.

10 CFR 70.64, "Requirements for New Facilities or New Processes at Existing Facilities," *Code of Federal Regulations*, Office of the Federal Register, as amended.

ANSI/ANS-15.1, *The Development of Technical Specifications for Research Reactors*, American National Standards Institute/American Nuclear Society, La Grange Park, Illinois, 2004 (R2013).

ANSI/ANS-15.4, *Standard for the Selection and Training of Personnel for Research Reactors*, American National Standards Institute/American Nuclear Society, La Grange Park, Illinois, 2007.

ANSI/ANS 15.8, *Quality Assurance Program Requirements for Research Reactors*, American National Standards Institute/American Nuclear Society, La Grange Park, Illinois, 1995, R2005, R2013.

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NWMI-ENG-PRO-020, *Commercial Grade Items (CGI)*, Northwest Medical Isotopes, LLC, Rev. 1, Corvallis, Oregon, 2014.

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NWMI-PROJ-PRO-040, *Project Manager Qualifications*, Northwest Medical Isotopes, LLC, Rev. 0, Corvallis, Oregon, 2013.

NWMI-QA-PRO-001, *Document Control*, Northwest Medical Isotopes, LLC, Rev. 2, Corvallis, Oregon, 2015.

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NWMI-QA-PRO-028, *Inspections*, Northwest Medical Isotopes, LLC, Rev. 1, Corvallis, Oregon, 2014.

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