

SECTION VI: APPENDICES

Appendix I – Key Terms and Definitions

For the purpose of this application:

“Radiation Source” means a radiation generator, a radioactive source or other radioactive material.

“Nuclear Material” means thorium, uranium or an element with an atomic number greater than 92; a derivative or compound of thorium, uranium or of an element with an atomic number greater than 92.

“High Risk” in relation to any activity or practice means that the possibility of suffering harm from or loss due to exposure to ionizing radiation is significant and/or likely. See Appendix II for categorization and classification of sources.

“Low Risk” in relation to any activity or practice means that the possibility of suffering harm from or loss due to exposure to ionizing radiation is low. See Appendix II for categorization and classification of sources.

“Variation” is an amendment to the scope of a previously issued authorization in which there is a material change with respect to the radiation sources and associated activities

“RSO” Radiation Safety Officer – designated person within a facility primarily responsible for maintaining the Radiation Safety Programme

“RPP” Radiation Protection Programme – the set of documented policies, procedures and associated controls established by a facility to ensure radiation safety.

“Qualified Expert” is an HSRA-authorized individual who provides specialized services in consultation and evaluation of radiation equipment/practices and possess specific academic knowledge and experience in radiation protection commensurate to the associated practice.

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Appendix II – Categorization of Generators and Radiation Sources

Category	Source / Practice	Activity Ratio (A/D) & Risk Level
1	<ul style="list-style-type: none"> High energy accelerators (Linacs, Cyclotron) Teletherapy (⁶⁰Co Unit) Gamma Knife Unsealed sources Nuclear Reactors Irradiators Storage of radioactive material or waste and disposal Radioisotope thermoelectric generators (RTGs) 	<p>A/D ≥ 1000 or Personally extremely dangerous (HIGH RISK)</p>
2	<ul style="list-style-type: none"> PET SPECT CT scanners (including CT simulators) Conventional Simulators Brachytherapy (High Dose Rate and Medium Dose Rate) Industrial radiography sources (including NDT devices) Gamma radiography camera Gamma radiography crawlers VACIS scanners 	<p>1000 > A/D ≥ 10 or Personally very dangerous (HIGH RISK)</p>
3	<ul style="list-style-type: none"> X-ray fluoroscopy machines Angiography machines C-Arm Plane X-ray machines (includes portable x-ray machines) Superficial X-rays Fixed industrial high-activity gauges Well logging gauges Density gauges Level gauges Backscatter gauges Moisture or density gauges In-stream analysis gauges Portable gauges 	<p>10 > A/D ≥ 1 or Personally dangerous (MEDIUM RISK)</p>
4	<ul style="list-style-type: none"> X-ray industrial gauges Low activity industrial gauges Panoramic and cephalometric dental X-rays Whole body bone densitometers Full scan vehicle imaging system 	<p>1 > A/D ≥ 0.1 or Unlikely to be dangerous (LOW RISK)</p>
5	<ul style="list-style-type: none"> Brachytherapy permanent implants X-ray Fluorescence (XRF) analysers X-ray Diffraction (XRD) machines Mammography units Intra oral and portable dental units Veterinary X-rays units Baggage scanners Portable bone densitometers Check sources 	<p>0.01 > A/D and A >= exempt or Not dangerous (LOW RISK)</p>



HAZARDOUS SUBSTANCES REGULATORY AUTHORITY
AN AGENCY OF THE MINISTRY OF INDUSTRY INVESTMENT AND COMMERCE
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Appendix III – Alternate RSO Details

(Append completed Alternate RSO Form to the NSRP Application Form A)

Name (1): _____

Job Title: _____

Telephone: _____ Ext.: _____ Fax: _____

Email Address: _____

Name (2): _____

Job Title: _____

Telephone: _____ Ext.: _____ Fax: _____

Email Address: _____

Name (3): _____

Job Title: _____

Telephone: _____ Ext.: _____ Fax: _____

Email Address: _____



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Appendix IV – Alternate Qualified Expert(s)

(Append completed Alternate Qualified Expert Form to the NSRP Application Form A)

Name (1): _____

Title: _____

Telephone: _____ Ext.: _____ Fax: _____

Email Address: _____

HSRA Registration No. (if applicable): _____

HSRA Registration Expiration Date: _____

Name (2): _____

Title: _____

Telephone: _____ Ext.: _____ Fax: _____

Email Address: _____

HSRA Registration No. (if applicable): _____

HSRA Registration Expiration Date: _____

Name (3): _____

Title: _____

Telephone: _____ Ext.: _____ Fax: _____

Email Address: _____

HSRA Registration No. (if applicable): _____

HSRA Registration Expiration Date: _____

Appendix V – Radiation Safety Programme Requirements

A. General Requirements

This section provides general guidance on meeting radiation protection programme (RPP) requirements for medium to high-risk activities. See Appendix II for classification criteria. Append RPP or other relevant documents that addresses the requirements stated in items 1. To 16. below. Refer also to additional requirements outlined in sections C. to J. based on specific activities.

1. **Scope of Activities:** *Tasks and operations to be performed by staff, frequency and duration of these activities as well as radiological risks associated with the work.*
2. **Management System:** *Description of the management and organizational structures that relate to radiation safety. Include details of roles and responsibilities of different management levels including Directors in charge, Radiation Safety Officers and workers. Include organizational chart showing radiation protection lines of responsibility as well as quality assurance program.*
3. **Monitoring Occupational Exposure**
 - a. Procedures for ascertaining, monitoring and recording radiation doses received by all workers. Include dose to the eye and extremities (hands and feet) and intakes of radioactive material.
 - b. For **new authorizations**, provide dose estimates for all categories of workers
 - c. For **renewals**, provide a summary of the annual radiation doses for each worker
 - d. Dose limits, dose constraints and optimization: I.e. for planned exposure situations, the established dose constraints that will be used as part of the organization's optimization of protection and safety.
 - e. List of all types of individual monitoring equipment that will be used, including the policy and procedure for acquisition, use, monitoring period, maintenance and storage, including the name of the individual monitoring service provider.
4. **Workplace Monitoring**
 - a. Policy and procedures for classifying areas, rooms or enclosures as controlled or supervised areas, including floor plans, arrangement of equipment, shielding and other measures for protection and safety. Include access control, posting of radiation warning signs, local (site) rules and/policies to be followed by workers and work supervision, as well as procedures for contamination control.
 - b. Policy and procedures for maintaining contamination control, including the procedure for monitoring contamination where unsealed radiative sources are used and stored; describe actions to be taken if contamination limits are exceeded.
 - c. Radiation detection instruments: List of all radiation detection and measuring instruments to be used, as well as the policy and procedures for the acquisition, use, maintenance, storage and calibration of said instruments and the calibration service provider. Provide the calibration certificates for all instruments listed.
5. **Health Surveillance of Workers:** Policies and procedures for monitoring the health of workers.
6. **Investigation Levels and Feedback of Operating Experience:** Details of investigation levels and the procedures to be taken if they are reached and/ or exceeded; as well as procedure to

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provide HSRA and suppliers with information regarding normal operating procedures, abnormal conditions and events.

7. Record and Reporting System – Policy and procedures:

- a. That outline the process for retention of records and the list of documents that will be retained at each location of licensed activity, including field locations.
- b. For the reporting of accidents, incidents, as well as any event in which the Authority should be notified; e.g. investigations conducted, release of radioactive materials into the environment, remedial actions etc.

8. Access control and security: Policy and procedures for restricting access to radiation sources and / or nuclear material, to only authorized and trained persons, as well as, the policy and procedure for alerting the applicant to the loss, theft or unauthorized use of/ access to radiation sources.

9. Controlling possession of radiation sources: Policy and procedures to account for radiation sources and / or nuclear materials, as well as, to ensure that inventory do not exceed the licence limit.

10. Worker Training and Authorization: Detailed description of the proposed (theoretical and practical) radiation safety training program for each job category, as well as, for contractors and subcontractors. (Also include all instructions and information provided for radiation safety and protection including safe work practices.)

11. Control of Public Exposure: Policy and procedures for controlling and monitoring discharge to the environment.

12. Management of Radioactive Waste and Disused Sources:

- a. Policy and procedures for handling and disposing of waste containing radioactive and/or nuclear materials namely waste generation; predisposal, pre-treatment, characterization, treatment, conditioning, storage, control of discharges, clearance, packaging strategies, transport, design and manufacturing of container, handling of waste packages, site evaluation, design, construction, closure and the post-closure stage of estate management facility.
- b. For disused sources, provide details of the safe management of the sources, as well as, means of disposal.
- c. Include financial provisions, where appropriate, and any contractual agreements regarding repatriation, disposal etc.

13. Emergency Procedures: Policy and procedures that will be used in incidents, accidents and other events that involve radiation source(s) and/nuclear materials. Include procedures for notification and response to events as well as policies and prevention and mitigation of accidents.

14. Decommissioning: Policy and procedures that are related to decommissioning or remediation of licensed locations.

15. Radiation Protection Program Policies:

- a. Policy and procedures of the As Low As Reasonably Achievable (ALARA) Program, including condition of service and special arrangement for female workers and persons under the age of 18 years.
- b. Policy and procedure for leak testing of sealed sources, including the name of the leak test service provider to be used, if applicable.
- c. Policy and procedure for the transfer of radiation sources and / or nuclear materials.
- d. Transfer of radiation sources and / nuclear materials – (for renewal, append a summary of the annual activity of each radiation source and/ nuclear materials transferred during the previous licensing period.)
- e. Policy and procedures for packaging and transporting radiation source and/nuclear materials, as well as the policy and procedure for receiving such shipments.)
- f. Internal review (arrangements for supervising and auditing the Radiation Protection Programme)

16. Safety Assessment: for facilities/activities involving Category 1 and 2 sources

B. Requirements for Low-Risk Sources

This section is exclusively applicable to non-specified low-risk use-types. See Appendix II for classification criteria. Append RPP or other relevant documents that addresses the requirements stated in items 1. To 7. below

1. Monitoring Occupational Exposure

- a. Procedures for ascertaining, monitoring and recording radiation doses received by all workers.
- b. Summary of the annual radiation doses for each worker, for renewals only.
- c. Dose limits for planned exposure situation, the established dose constraints that will be used as part of the organization's optimization of protection and safety.
- d. List of the type(s) of individual and workplace monitoring equipment that will be used, including the policy and procedure for acquisition, use, monitoring period, maintenance and storage, including the policy for calibration and the name of all service providers.

2. Record and Reporting System:

- a. Policies and procedures that outline the process for retention of records and the list of documents that will be retained at each location of licensed activity including field locations.
- b. Policies and procedures for the reporting of accidents, incidents, as well as any event in which the authority should be notified; e.g. investigations conducted, release of radioactive materials into the environment, remedial actions etc.

3. Access Control and Security: Policy and procedures for restricting access to radiation sources, to only authorized and trained persons, as well as, the policy and procedure for alerting the applicant to the loss, theft or unauthorized use of/ access to radiation sources.

4. Worker Training, Information and Instructions: details of the proposed radiation safety training program and all instructions and information provided for radiation safety including local rules.)

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5. **Leak Testing of Sealed Sources:** Policy and procedure for leak testing of sealed sources, including the name of the leak test service provider to be used, if applicable.
6. **Emergency Procedures:** Summary of the policy and procedures that will be used in incidents, accidents and other events that involve radiation source(s). Include procedures for notification and response to events as well as policies and prevention and mitigation of accidents.
7. **Management of Radioactive Waste and Disused Sources:**
 - a. Policy and procedures for handling and disposing of waste containing radioactive materials - namely waste generation; predisposal, pre-treatment, characterization, treatment, conditioning, storage, control of discharges, clearance, packaging strategies, transport, design and manufacturing of container, handling of waste packages, site evaluation, design, construction, closure and the post-closure stage of estate management facility.
 - b. For disused sources, provide details the safe management of the sources as well as means of disposal.
 - c. Include financial provisions where appropriate, and any contractual agreements regarding repatriation, disposal etc.

C. Additional Requirements for Medical Practices

1. **Administration of Radiation Doses for Therapeutic Treatment:** Policy and procedures for delivering radiation doses to patients for therapeutic purposes. Include protocols and procedures for administering radiation doses to pregnant patients.
2. **Quality Assurance Programme for Medical Exposure:**

NB: Quality assurance programme shall provide as appropriate: adequate assurance that the specified requirements relating to protection and safety are satisfied.

Append quality control mechanisms and procedures for reviewing and assessing the overall effectiveness of protection and safety measures. Include, where applicable: protocol and procedures for calibration, acceptance and commissioning testing and reports, maintenance and quality control testing of all equipment and software used for medical exposure.
3. **Instructions to Caregivers:** Instructions to be given to persons who will care for a patient who has undergone nuclear medicine therapy.
4. **Instructions to Patients and their Families:** Instructions to be given to patients who have recently received nuclear medicine therapy in order to control radioactive contamination effects and radiation exposures to others.
5. **Release of Patients:** Procedures for determining when patients that have received nuclear medicine therapy must be isolated and when they may be released from isolation.
6. **Decontamination and Release of Treatment Rooms:** Procedures for returning rooms that have been used for nuclear medicine therapy to a condition where they can be safely released for other purposes.

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7. **Medical Emergencies:** Policy and procedures for responding to medical emergencies that involve patients treated with radiation sources during the activities to be licensed, as well as investigations of unintended and accidental medical exposures.
8. **Assignment of Nuclear Medicine Therapy Rooms (For Therapeutic Nuclear Medicine):** Procedures used to assure that patients undergoing nuclear therapy will be assigned to a specifically designated private room with a private washroom.
9. **Diagnostic Studies Protocols and Procedures**
10. **Biomedical Research:**
 - a. Include a statement of the proposed research studies and their proposed radiation dose constraints.
 - b. Policy and criteria for selecting human research volunteers.
 - c. Policy and procedures for obtaining and assuring informed consent of volunteers.
11. **Research Review Committee:** Information regarding proposed human research review committee or its equivalent.

D. Additional Requirements for Industrial Radiography

NB: this section is supplementary to the applicable clauses under Section A. General Requirements

1. **Emergency and Operating Procedures**
2. **Application for Registration of Use of Packages** (one per certificate)
3. **Maintenance and Use of Exposure Devices (for renewals only):** Append sample copies of records of the quarterly and annual maintenance of exposure devices and associated equipment and of camera use records.
4. **Safety and Emergency Equipment:** All safety and emergency equipment used as part of the daily radiography operations. List any additional shielding materials.
5. **Transport Plan:** Policy and procedure for transporting gauges. Include all special requirements for personnel, vehicle, monitoring, security and emergencies.

E. Additional Requirements for Veterinary Nuclear Medicine

NB: this section is supplementary to the applicable clauses under Section A. General Requirements

1. **Administering Treatment to Animals:** Policies and procedures used to administer radiation sources to animals. Owners of animals should provide a (written) consent before radionuclides is used on animals. Append a copy of the treatment consent form.
2. **Animal Housing:** Policy and procedures regarding the housing controls imposed on animals undergoing veterinary nuclear medicine.)

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3. **Disposal of Animal Waste:** Policy and procedures for management of animal waste arising from veterinary nuclear medicine.
4. **Monitoring and Release of Animal Housing**
5. **Release of Animals:** Criteria to decide when animals treated with radiation sources can be released to their owners.

F. Additional Requirements for Other Industries that use Nuclear Material

NB: this section is supplementary to the applicable clauses under Section A. General Requirements. This section is only applicable for industries where nuclear material is used; however, the industry or use is not otherwise specified in this application form.)

1. **Procedures outlining controls of the use of nuclear material.**
2. **Disposals:** Policy and procedures for management of waste arising from the use of nuclear material.
3. **Monitoring:** Policy and procedures for monitoring the use of nuclear material.

G. Additional Requirements for Operators of Gauges (Fixed and Portable)

1. **Handling Procedures**
2. **Rules for Entry into the Vessels or Hoppers**
3. **Operating Conditions and Maintenance Programme:**
4. **Operation of Insertion-Type Fixed Gauges:**
5. **Installation and Dismounting of Fixed Gauges:**
6. **Transport Plan:** Policy and procedure for transporting gauges; include all special requirements for personnel, vehicle, monitoring, security and emergencies.)
7. **Emergency Procedures:** In addition to the information provided in Section A 13., append procedures specific to dealing with fire. For portable gauges this must include procedures for responding to and managing situations involving crushed or damaged portable gauges.
8. **If No Radiation Survey Meter is Available on Site:** Append information to demonstrate that the survey meter will be available during an emergency in less than four (4) hours.

H. Additional Requirements for Petroleum Exploration (Well Logging)

1. **Release:** Policy for monitoring release of radiation source(s) and/ nuclear materials to the environment.
2. **Fishing for Stuck Tools/Sources:** Policy and procedure that will be used during an emergency that involves fishing for stuck tools and sources.

3. **Policy and procedure for the proposed abandonment of sealed source.**
4. **Abandonment of Unsealed Sources:** Policy and procedures for the abandonment of unsealed radiation sources and/ nuclear materials following sub-surface zone location or sub-surface tracer studies.

I. Additional Requirements for Servicing

1. Servicing Procedures: Append a copy of servicing procedures, specific to each radiation device identified in the application for this activity.

J. Manufacturing

1. Manufacturing or Development Procedures: Append a copy of all manufacturing or development procedures, specific to each sealed source or radiation device identified in the application for this activity.

DOCUMENT END

(Template reference: HSRA/ADM/TMP/05 Form Template – Portrait)