Ministry of Industry Investment & Commerce

Jamaica's Business Ministry

HSRA

REGULATORY GUIDE – SERVICE PROVIDERS FOR IONIZING RADIATION SOURCES

HSRA/AUT/RG/03

HAZARDOUS SUBSTANCES REGULATORY AUTHORITY

AN AGENCY OF THE MINISTRY OF INDUSTRY INVESTMENT AND COMMERCE

8 REKADOM AVENUE, BUILDING 9, BUREAU OF STANDARDS, KINGSTON 10

TEL: 876-632-4289, 876-618-5761 EXT: 3461-68

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1.0 INTRODUCTION

The Nuclear Safety and Radiation Protection (NSRP)Act, 2015, makes provision for the regulation of activities involving the use of radiation sources. One of such activities includes the handling of sources of ionizing radiation for the purpose of maintenance, installation (assembly), measurement, construction and repair work and services such as alteration or dismantling, quality assurance and commissioning of facilities which includes applicable testing of equipment.

The term "use", in the context of radiation sources, is defined as any situation in which radiation occurs, regardless of whether or not that radiation is utilized.

“Application” means utilization of the equipment for its intended purpose, e.g. imaging, scanning, treatment, etc. Thus, while the terms 'use' and 'application' may be construed as synonymous in other contexts, in this context they do not denote the same. Use is broader than application, since use also includes installation, testing and quality assurance. Application is thus a specific type of use. In this Regulatory Guide (RG), the two terms will be used according to these specific definitions.

In accordance with the Second Schedule of the NSRP Act, 2015, appropriate authorization is required and obtained by the submission of the prescribed application and supporting documents.

This RG is aimed specifically at companies that install and perform service on radiation sources, and for all intent and purposes throughout this document, such undertakings or companies that perform service on radiation sources will be referred to as “service providers".

2.0 PURPOSE AND SCOPE

This RG provides the necessary guidance to ensure compliance of Ionizing Radiation Sources service providers with the NSRP Act, 2015 and attendant Regulations, 2019 as well as, a detailed layout of the requirements of service providers to obtain the mandatory authorization from the Hazardous Substances Regulatory Authority (HSRA) to perform such activities.

3.0 TERMS AND DEFINITIONS

Term/Abbreviation	Definition
Acceptance testing	Testing carried out for medical applications, prior to clinical commissioning and after any alterations and repairs, to ensure that the radiation source and equipment conform to the pre-defined specifications and applicable operational limits and conditions.
Alteration	Any type of work including cleaning, maintenance and repairs where the alteration might have implications from the point of view of radiation protection.

Term/Abbreviation	Definition
Authority	The Hazardous Substances Regulatory Authority as established by the NSRP Act, 2015
Authorization Holder	Any entity that has been granted legal permission to possess/use ionizing radiation sources under the NSRP Act and attendant Regulations. The holder of an authorization in the form of licence, registration or permit under the NSRP Act, 2015
Constancy Testing	Regular testing carried out for radiation sources for medical use to ensure that selected parameters for the radiation source and equipment remain within established tolerances.
HSRA	Hazardous Substances Regulatory Authority
Installation	Assembly, fitting, setting up and connecting of a radiation source and equipment to the application company's utilities (e.g. electricity and water) so that radiation can be generated
NSRP	Nuclear Safety and Radiation Protection
Performance Testing	Regular testing carried out for radiation sources for medical use to ensure that the radiation source and equipment continue to conform to the pre-defined specifications and applicable operational limits and conditions.
Quality Assurance	All planned and systematic actions, including quality control, necessary to provide adequate assurance that a radiation source, a facility, equipment, a system or component or a procedure will perform satisfactorily in compliance with agreed standards.
Quality Management System	A coherent and documented management system that ensures the quality of the organization's processes in a systematic and effective manner with a view to achieving the organization's safety and radiation protection objectives. The system typically comprises organizational structure, resources and processes, personnel and equipment, as well as policies, procedures and instructions.
Radiation Incident	A technical event or anomaly involving radiation which, although not directly or immediately affecting safety, may reasonably be expected to result in subsequent re-evaluation of safety provisions by the Authority.

Term/Abbreviation	Definition
Safety Assessment	An assessment of all aspects of a company's specific use of radiation sources of relevance for safety and radiation protection.
Self-Shielded Radiation Source	A radiation source permanently integrated inside a shielding, which offers sufficient protection to permit the radiation source to be operated outside of facilities, with no restrictions on human proximity to the generator.
Service Provider	A company or individual whose primary use of radiation sources includes installation, quality assurance , alteration, or acceptance/performance testing. The use does not include application.

4.0 DEFINITION OF SERVICE ACTIVITIES

4.1 INSTALLATION OF RADIATION SOURCES

Installation means the assembly, fitting, setting up and or connecting of a radiation source and equipment to the authorization holder's utilities (e.g. electricity and water) so that radiation can be generated and or in preparation for use. Installation involves addressing factors from a radiation protection point of view and thus entails more than simply connecting the device to the power grid by plugging it into an electrical socket.

4.2 ALTERATIONS TO RADIATION SOURCES

Alteration means any work, including cleaning, maintenance and repairs, where that work might have implications from a radiation protection point of view in that it entails, for example, disassembling shielding, disconnecting an interlock system and other manipulation of a radiation source. Alteration in the context of radiation sources for medical application also includes switching between clinical mode and service mode.

Alteration covers any manipulation of the radiation source that might render it into a state of noncompliance with the technical requirements, even if the alteration is only temporary in nature. This would include the mounting and demounting of shielding, bypassing of security switches or making an alteration of an emergency stop. It is important to take note of the expression "might have", since alterations comprise not only those that would impact radiation protection with absolute certainty, but also any alterations that would only potentially affect radiation protection.

Radiation sources for medical application typically have a clinical mode of operation in which a number of built-in safety features ensure that irradiation is delivered exactly as prescribed for a given patient. If the equipment permits switch of mode of operation from clinical to a

service-only mode in which such safety features are disabled but in which the radiation source can still emit radiation, then the act of setting the radiation source to run in its service-only mode is regarded as an alteration requiring an authorization and must therefore be included in the authorized scope of activities. Conversely, the Authorization Holder ordinary alterations of examination protocols such as adjusting kV, mA and exposure time fall under optimization and are thus not regarded as being alterations subject to the authorization requirement.

4.3 QUALITY ASSURANCE OF RADIATION SOURCES

All radiation sources shall periodically undergo quality assurance to assess their status. The authorization holder is responsible for ensuring that quality assurance is duly carried out. Quality assurance means physical checking of the radiation sources general condition and general safety aspects with regard to radiation protection. This includes examining whether it is safe for users to work with the equipment. The service provider that installs a radiation source is often also involved in the subsequent task of conducting periodic quality assurance and, in some cases, also testing. Quality assurance should typically be planned in consultation with the authorization holder's designated qualified expert(s).

4.4 TESTING OF RADIATION SOURCES

Testing means acceptance testing and performance testing of the equipment to verify its conformity with pre-defined specifications and applicable operational limits and conditions, including whether the equipment operates within given tolerances. Acceptance testing and performance testing are required for medical or dental applications.

- Acceptance testing is carried out during commissioning, as well as, after alterations and repairs.
- Performance testing is performed at regular intervals to ensure continued conformity with specifications, i.e verify that the radiation source conforms to the pre-defined specifications and applicable operational limits and conditions, including whether the equipment operates within given tolerances. Performance testing typically requires special measuring equipment and special technical skills.
- For some radiation sources there is a need to carry out routine constancy testing to ensure that selected parameters for the radiation source and equipment constantly remain within the established tolerances. The measurements may be either of the same type as the performance tests or supplemental to the performance tests and conducted by means of other measuring equipment. For the majority of radiation sources for examinations, the nature of the constancy testing is such that it may be carried out by representatives of the authorization holder itself.

5.0 GENERAL REQUIREMENTS FOR SERVICE PROVIDERS

It is important to note that both authorization holder and service provider have a responsibility to be in compliance with the NSRP Legislations. If an authorization holder's radiation source is serviced by a service provider, leading to the possibility of exposure of service provider's workers the workers are to be considered outside workers of the authorization holder. Furthermore, in such cases, the

authorization holder and the service provider each bear their own responsibility and must jointly ensure overall compliance with all requirements.

The service provider, as an employer, is responsible for compliance with requirements regarding the training, radiological monitoring, knowledge, skills and competences of its workers, etc. (service providers, should provide individual monitoring for staff).

Service providers shall at all times have a radiation safety officer at their disposal. "At their disposal" means that the company and its employees can readily make contact with the radiation safety officer.

For service providers installing, altering, testing or performing quality assurance of radiation sources, the following tasks, in particular, requires assistance from the radiation safety officer:

- ensuring that use of radiation sources complies with the requirements in the service provider's instructions, including introducing workers to the instructions.
- ensuring that the service provider's instructions for workers comply with applicable regulatory requirements;
- setting up precautions in the event of accidents and incidents; and
- supervising implementation of the individual dose monitoring programme.

The service provider's radiation safety officer shall also assist in assessing the competences of the service provider's workers who use radiation sources. (Note this requirement is not applicable to individual service providers).

6.0 AUTHORIZATION REQUIREMENTS

6.1 GENERAL

A service provider intending to perform any of the tasks as listed in this document shall apply for authorization in the form of a licence. When a service provider applies for a licence to service radiation sources, by virtue of the definition of use for the purpose of this document, the applicant must provide information on:

1. The type of tasks or activities for which applicable services will apply;

2. The types of radiation sources for which service activities are performed;

3. Qualification and certification of staff, copies of relevant certification and CVs should be submitted. (The service provider's workforce shall possess the requisite technical and practical skills for all the types of radiation sources for which it is seeking authorization)

4. Disposal plans for sources - where this forms part of contractual agreement with authorization holder. *Some service providers dismantle and then repatriate radiation sources after useful life*.

5. Quality Management System:

Quality assurance denotes all planned and systematic actions, including quality control, necessary to provide adequate assurance that a radiation source, a facility, equipment, a system or component or procedure will perform satisfactorily in compliance with agreed standards.

To that end, service providers shall establish and maintain a quality management system commensurate with the nature and scale of their use (service activities) of radiation sources. This means that the greater the risk associated with their use, the stricter the requirement for the quality management system. The risk is assessed on the basis of, for example. shielding, mobility, complexity of use and risk of wear. The quality management system shall reflect the service provider's current use of radiation sources, i.e. the types of service tasks performed. The quality management system shall consequently substantiate that relevant document, such as procedures, safety assessments, security and emergency response plans and other relevant plans, inventories, registers, protocols and the like are up-to-date.

Basic Elements of the System
The quality management system shall, where relevant, ensure and/or, by means of inventories, protocols, registers and the like, document that:

- quality assurance is performed on measuring instruments used for servicing (if applicable);
- the safety assessment is up-to-date (where applicable);
- workers have received relevant information, training and instruction (Training Programme for staff);
- the listing of exposed workers is up-to-date;
- the knowledge, skills and competences of exposed workers are appropriate;
- exposed workers have the requisite qualifications;
- exposed workers have been correctly categorized and the date of the most recent annual health review of workers that handle high risk sources have been recorded;
- exposed workers' dose records are available and retained;
- instructions concerning use and precautions in the event of accidents are up-to-date;
- all radiation protection, security and emergency procedures (where applicable) are revised at suitable intervals;
- all reviews are performed in accordance with written instructions for that purpose, and that the results are retained and recorded systematically and initialed by the reviewer;
- all the service provider’s radiation sources and facilities have been inventoried in accordance with the specific requirements for such records.

6. Policies and procedures for each listed service task or activity and specific to each radiation source, including the intervals between testing of equipment.

7. Policies and procedures for interacting with clients or providing technical support. Include copies of templates of ALL servicing/ reporting forms post service activities.

8. Occupational monitoring programme for exposed workers. Details of dosimetry service provider; dose records should be maintained up to age 75 for workers or 30 years after cessation.

9. Security measures and storage, where service activities are done at service providers location.

10. Record and Reporting System

    For each acceptance or performance test, the service provider that performs the test shall issue a test report presenting the results of the test to the authorization holder that owns the radiation source. The results of acceptance tests shall be retained by the authorization holder, as well as, the service provider for a minimum of seven (7) years. For performance tests, a record shall be retained so that the results of the performance tests may be compared over time in order to assess any trends in the measurements. Technical Safety reports should also be retained.

    For quality assurance, the service provider that performed the inspection is required to submit an inspection report to the authorization holder, stating the results of the quality assurance. The quality assurance report shall, as a minimum, also state the following:
    - Date of the quality assurance activity;
    - Location of radiation source;
    - The items assessed during the quality assurance activity;
    - The result of assessment against criteria (e.g. OK/not OK);
    - Where quantitative measurements are included, a record of measurement data expressed in a sufficient number of significant digits or tolerances (any specific equipment used during testing and specs of equipment);
    - Any remarks/corrective actions;
    - Name or initials of the individual who performed the quality assurance.

    The above data shall be specifically stated in the report and must not be conveyed by the file name alone. Any built-in self-tests (the device's integral program for testing the condition of the device) shall be assessed against minimum requirements in applicable international technical standards of relevance to the specific use from a radiation protection point of view.

11. Specifications of special equipment used during testing, as well as, calibration certificates or standard certificates, where applicable.

12. Conditions of Service: There should be a policy for conditions of service of workers which should emphasis that the prime responsibility for protection and safety while operating in the capacity of a service provider rests with the owner of the service provider company or individual. Also, special compensatory arrangements or preferential considerations with respect to salary, insurance coverage, working hours, extended vacations, additional holidays or retirement benefits will not be offered or used as substitutes for proper protection and safety measures.

13. Emergency procedures:
    The service provider shall ensure that readily comprehensible instructions are available for its workers on precautions to be taken in the event of an emergency, accident or incident. The instructions shall be readily available during the work and should comprise all relevant measures as well as a description of how they are to be implemented

14. Notification protocols of the Hazardous Substances Regulatory Authority
    The Authority shall be notified promptly in the event of:
    - Emergencies, accidents or incidents that have resulted in unintended exposure any discovery, theft, loss, fire, flooding or the like of significance from a radiation protection point of view incidents that could have resulted in the above – the service provider and the authorization holder shall both determine the likelihood that an incident might have resulted in unintended exposure, and whether the service provider and the authorization holder are thereby subject to the notification requirement. In case of doubt, contact the HSRA.
    - Cases in which the design or functioning of a radiation source, including any serious defect or deficiency or repeated incorrect use or a work procedure, might result in unintended exposure.
    - Overexposure of workers

15. Safety Assessment Report (High-Risk Sources – Categories 1 and 2)

    Both the authorization holder and service provider that perform tasks outside of the authorized facility's location shall perform a safety assessment in relation to their respective use. The safety assessment is a systematic review of all factors of relevance for safety and radiation protection required by the planned use. It typically comprises a cradle-to-grave description of the radiation risks, safety functions, siting, radiation protection arrangements, the design and robustness of the radiation source or facility, as well as, human factors. The safety assessment involves factors concerning facilities and radiation sources in addition to work procedures, and the authorization holder's safety assessment may therefore include inputs from the manufacturer or the service provider.

    The purpose of the service provider's safety assessment is to ensure the optimization of radiation protection and the service provider's compliance with all relevant requirements for safety and radiation protection during normal service tasks, anticipated operational incidents and in the event of accidents. In the process of carrying out the safety assessment, the service provide typically identifies, elaborates on and improves a number of relevant circumstances, features and arrangements, e.g. procedural descriptions and safety equipment for specific service tasks. The service provider then identifies and selects the most appropriate radiation protection solutions to be implemented for the purpose of service tasks. The process is not complete until the necessary radiation protection measures have been adequately identified so as to ensure compliance with all relevant safety and radiation protection requirements during the performance of service tasks.

The service provider shall describe the safety assessment conducted in a report. The report constitutes the documentation that relevant requirements for safety and radiation protection have been addressed and that the arrangements implemented by the service provider are deemed sufficient to ensure the optimization of radiation protection. The report shall be submitted to the HSRA as part of the licence application.

The safety assessment shall be of a suitable scope commensurate with the risk associated with the particular use of radiation sources. For service companies, this typically depends on the types of radiation sources the service provision involves, by what means and how often the service is provided, the reliability and complexity of systems and components as well as their accessibility for maintenance, quality assurance , testing and repair.

NOTE: Where radioactive materials such as radioisotopes are utilized for any service activities, the service provider is required to obtain authorization to possess and use and meet the requirements of the HSRA accordingly.

6.2 SUPPORTING DOCUMENTATION

Additionally, the following supportive documents should be submitted with the completed NSRP Application Form:

- Copy of company TRN
- Copy of certificate of Incorporation
- Completed Fit and Proper Declaration Questionnaire
- Copy of Valid ID of Legal Operator

NOTE: For individuals operating independently as service providers, details of place of employment (name and address) must be provided (if not self-employed) along with all job title, years of employment with company and applicable details as listed in Authorization Requirements. Letters of reference may be requested, and is at the discretion of the Authority. Applicants must be actively engaged within the last 12 month at the time of application.

6.3 SUPPLEMENTAL GUIDANCE

Alterations to radiation sources

Service providers have a responsibility to communicate any alterations to all relevant individuals with a 'need to know' in the application where alterations are made to the configuration or examination protocols during quality assurance , testing or any other service. Following any alteration of a radiation source, the service provider responsible for that alteration shall ensure that the radiation source is in a satisfactory technical state from the point of view of safety, before any application of the radiation source.

Acceptance and performance testing (medical application only)

Acceptance testing must be performed after installation of a new radiation source and after the repair of or alterations to an existing radiation source if the alterations might have had implications for radiation protection.
The interval between the periodic performance tests must not exceed 13 months. However, for radiation sources used in intraoral radiography, the interval is extended so that performance testing for these shall be carried out at intervals not exceeding 2 years.

Constancy testing must be carried out more frequently than performance testing, for example monthly, weekly, or maybe even daily in order to rapidly detect and rectify any anomalies. There are no specific regulatory requirements for the interval between constancy tests, but recommendations may be provided in equipment guides for certain types of use, or intervals may be agreed upon in consultation with the medical physics expert.

The interval between quality assurance s must not exceed 13 months. It is advisable that the radiation source be labelled with information of the date of the latest quality assurance as well as the latest date for the next quality assurance , or the information shall be made easily accessible by other means to anyone using or handling the radiation source.

7.0 CONCLUSION

Service providers play a fundamental role in ensuring radiation protection for radiation workers, the medically exposed and the general public. Regulators rely heavily on their experience, expertise, qualifications and recommendations to instill confidence that authorized and regulated activities are conducted in the safest possible manner, using appropriate equipment of recognizable and acceptable standards that are routinely serviced and maintained. As such it is necessary that service providers are also regulated for their activities and, are too compliant with the fore-guiding legislation and requirements of the regulatory authority.

8.0 REFERENCES

Author/Source	Title (Year)
Government of Jamaica	Nuclear Safety and Radiation Protection Act (2015)
Government of Jamaica	Nuclear Safety and Radiation Protection Regulations (2019)
Danish Health Authority	Radiation Protection. Radiation sources for Service Companies Guide (2020)
IAEA	General Safety Requirements Part 3 (No. GSR 3): Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards

9.0 APPENDIX

9.1 HSRA RECOMMENDED TRAINING AND MINIMUM EXPERIENCE FOR SERVICE PROVIDERS

FORMAL EDUCATION AND CERTIFICATION	MINIMUM EXPERIENCE**
RADIATION SOURCES	
School Leaving certificate/High school diploma and CSEC/ CAPE/ A levels in physical sciences. AND Technician/ Instrumentation certification in specialized services from a (FDA, ISO, IEC, EU or other approved standard), manufacturer/supplier.	6 years technical work experience involving activities similar to those to be performed.
School Leaving certificate/High school diploma and CSEC/ CAPE/A levels in physical sciences. AND 6 years supervised working experience with certified technician.	8 years technical work experience involving activities similar to those to be performed.
Associates of Science Degree in Engineering/Engineering Technology, Physics, Biomedical Engineering/Biomedical Engineering Technology or any other applicable natural sciences or closely related field from accredited institution. AND Technician/ Instrumentation certification in specialized services from a (FDA, ISO, IEC, EU or other approved standard), manufacturer/supplier.	4 years technical work experience involving activities similar to those to be performed.
Associates of Science Degree in Engineering/Engineering Technology, Physics, Biomedical Engineering/Biomedical engineering Technology or any other applicable natural sciences or closely related field from accredited institution. AND 3 years supervised working experience with certified technician.	5 years technical work experience involving activities similar to those to be performed.

FORMAL EDUCATION AND CERTIFICATION	MINIMUM EXPERIENCE**
RADIATION SOURCES	
Bachelors of Science or higher degree in Engineering, Physics, Biomedical Engineering or any other applicable natural sciences or closely related field from accredited institution. AND Technician/Instrumentation certification in specialized services from a (FDA, ISO, IEC, EU or other approved standard) organization, manufacturer/supplier.	2 years technical work experience involving activities similar to those to be performed.
Bachelors of Science or higher degree in Engineering, Physics, Biomedical Engineering or any other applicable natural sciences or closely related field from accredited institution. AND 2 years supervised working experience with certified technician.	3 years technical work experience involving activities similar to those to be performed

FORMAL EDUCATION AND CERTIFICATION	MINIMUM EXPERIENCE**
EQUIPMENT WITH ENCLOSED SEALED RADIOACTIVE SOURCE (High Risk- Cat 1-3)	
Bachelors of Science or higher degree in Engineering, Physics, Nuclear Physics, Biomedical Engineering or any other applicable natural sciences or closely related field from accredited institution. AND Technician/Instrumentation certification in specialized services from a (FDA, ISO, IEC, EU or other approved standard) organization, manufacturer/supplier.	3 years technical work experience involving activities similar to those to be performed.
Bachelors of Science or higher degree in Engineering, Physics, Nuclear Physics, Biomedical Engineering or any other applicable natural sciences or closely related field from accredited institution. AND 3 years supervised working with certified technician.	4 years technical work experience involving activities similar to those to be performed.

FORMAL EDUCATION AND CERTIFICATION	MINIMUM EXPERIENCE**
EQUIPMENT WITH ENCLOSED SEALED RADIOACTIVE SOURCE (Low Risk- Cat 4 & 5)	
Associates Degree in Engineering, Physics, Nuclear Physics, Biomedical Engineering or any other applicable natural sciences or closely related field from accredited institution. AND Technician/Instrumentation certification in specialized services from a (FDA, ISO, IEC, EU or other approved standard) organization, manufacturer/supplier.	4 years technical work experience involving activities similar to those to be performed.
Associates degree in Engineering, Physics, Nuclear Physics, Biomedical Engineering or any other applicable natural sciences or closely related field from recognized institution AND 3 years supervised working with certified technician.	5 years technical work experience involving activities similar to those to be performed
Bachelors of Science or higher degree in Engineering, Physics, Nuclear Physics, Biomedical Engineer or any other applicable natural sciences or closely related field from accredited institution. AND Certification in specialized services from a (FDA, ISO, IEC, EU or other standard) organization, manufacturer/supplier	2 years technical work experience involving activities similar to those to be performed.
Bachelors of Science or higher degree in Engineering, Physics, Nuclear Physics, Biomedical Engineer or any other applicable natural sciences or closely related field from accredited institution. AND 2 years supervised working with certified technician.	3 years technical work experience involving activities similar to those to be performed

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