Licence

L2601-04

The Environmental Protection Agency, in accordance with the terms of the Radiological Protection Act, 1991 (Ionising Radiation) Regulations 2019, hereby authorises the Undertaking

Rilta Environmental Ltd
Block 402 Grant's Drive,
Greenogue Business Park,
Rathcoole,
Dublin

to carry out the practice(s) listed in Table 1 using the Radiation Sources/Accelerators listed in Schedule 2 for the purposes therein at the authorised premises listed in Schedule 4 subject to the conditions listed in Schedule 1 of this Authorisation. These conditions may be amended at the discretion of the Environmental Protection Agency.

This authorisation does not exempt the Undertaking from compliance with other regulations or statutory requirements.

Signed Date 30 March 2019

On behalf of the Environmental Protection Agency

Table 1

Practice	Grade	Authorised From	Authorised To
Carriage of HASS radioactive sources	Licensed	01/04/2019	31/03/2029
Carriage of non-HASS radioactive sources	Registered	01/04/2019	Indefinite
Use of laboratory equipment incorporating sealed sources	Registered	01/04/2019	Indefinite

A. GENERAL

1. The Licensee or Registered Person shall note that compliance with this Authorisation and its Conditions does not exempt the Licensee or Registered Person from compliance with the following: Statutory Instrument No. 30 of 2019, the Radiological Protection (Amendment) Act, 2002, and where applicable, Council Regulation (Euratom) No. 1493/93 of 1993 and the European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) Regulations 2011 to 2018.

2. The Radiation Safety Procedures prepared by the Licensee or Registered Person shall have regard to the radiological risks and the nature of the practices carried out by the Licensee or Registered Person as well as the protective measures identified in the Licensee's or Registered Person's documented Prior Risk Assessment(s) pertaining to these practices. These should take account of guidance published by the International Atomic Energy Agency (IAEA) and relvant Codes published by the Agency (EPA).

3. The Licensee or Registered Person shall take all reasonable steps to ensure that the provisions of its Radiation Safety Procedures are observed.

4. The Licensee or Registered Person shall ensure that its Radiation Safety Procedures are brought to the attention of, and made available to, the relevant workers concerned.

5. The Licensee or Registered Person shall maintain a record of the date on which the Radiation Safety Procedures were made available to the relevant workers concerned and other persons who may be affected by the Procedures. This record must be made available for inspection by Inspectors of the Agency.

6. The Prior Risk Assessment(s) referred to above shall be reviewed by the Licensee or Registered Person (a) at least once during the period of validity of a licence, and (b) immediately, where circumstances arise in which the Licensee or Registered Person has reason to believe that the Prior Risk Assessment(s) are no longer appropriate,and shall be amended by the Licensee or Registered Person where required and the Radiation Safety Procedures revised where necessary.

7. Where there has been a change to the protective measures identified in the Prior Risk Assessment(s), a copy of the revised Risk Assessment(s) and the relevant section(s) of the Radiation Safety Procedures, where amended, shall in the case of licences, be submitted to the Agency. In the case of Registration, the revised documents shal be retained by the Registered Person for inspection by the Agency. The provisions in this Authorisation relating to Radiation Safety Procedures shall also apply to these amended Procedures.

8. The Radiation Safety Procedures shall be reviewed by the Licensee or Registered Person (a) at least once during the period of validity of an Authorisation, and (b) immediately, where circumstances arise in which the Licensee or Registerd Person has reason to believe that the Procedures are no longer appropriate,and shall be amended by the Licenseeor Registered Person where required.

9. The Licensee or Registered Person shall designate a Radiation Protection Officer (RPO) to perform the relevant radiation protection functions as set out in the provisions of IRR19. The designated RPO shall be listed in the Schedules attached to the Licence issued by EPA. In the event of a change in RPO being envisaged, the licensee shall notify the Agency, prior to any change taking effect, of the name, position within the company and evidence of attaining the minimum RPO training requirements of the proposed new RPO.

10. A copy of the Authorisation shall be publicly displayed in a suitable location in each of the premises listed in the Authorisation.

11. The Schedules to this Authorisation constitute part of the Authorisation and in the case of licences, may only be amended by the Agency. The Agency shall be informed of any proposals to change Schedules 2 or 3 of a licence prior to these changes taking effect. Licensed items may not be relocated or replaced, or new licensable items acquired without the Licensee securing from the Agency a prior approved Licence Change Request.

12. The Licensee or Registered Person shall carry out all practices authorised hereunder in such a manner that the radiation protection of staff and members of the public is optimised and, consequently, exposures are kept as low as reasonably achievable.

13. This Authorisation may be revoked if any of the conditions herein are not observed.

14. The practices authorised by this Authorisation may only be carried out with the items listed in Schedule 2, at the location or locations specified for such items in Schedule 2 and 4, except in the case of transportation, and in accordance with the Conditions set out in this Authorisation. The Authorisation shall include any restrictions relating to sources that may be specified in Schedule 2.

15. Save where otherwise approved in writing in advance by the Agency this Authorisation authorises the Licensee or Registered Person to carry out the practices specified on the first page of this Authorisation only insofar as such practices involve Radioactive Sources obtained by the Licensee or Registered Person from a supplier holding a current Authorisation from the Agency for the transportation and storage of the said Radioactive Sources.

16. Sealed radioactive sources shall be tested for leakage prior to their acquisition and the test certificate forwarded by the Manufacturer/Supplier to the Licensee or Registered Person. Sealed sources kept shall be tested for leakage at least once every two years or more frequently if recommended by the manufacturer. The Licensee or Registerd Person shall keep a copy of each leak test certificate. In the case of suspected damage to a sealed source or its housing, a leak test shall be immediately carried out. If the result of the leak test is positive then the Licensee or Registered Person shall consult with an RPA regarding disposal of said source. In the case of sealed radioactive sources containing krypton-85 or gaseous tritium, the test for leakage shall be carried out in accordance with the Manufacturer’s specifications.

B. ACQUISITION

1. Without prejudice to any other condition in this Authorisation, items which fall under the scope of IRR19 shall only be acquired following receipt of an authorisation from the Agency.

2. Prior to acquiring any item that falls within the scope of IRR19 or commencing a new application or procedure involving an authorisable item, the Licensee or Registered Person shall carry out an assessment of the risks of exposure to ionising radiation for any worker or member of the public for the purposes of identifying the appropriate protection measures for that item. The Licensee or Registered Person shall ensure that this Prior Risk Assessment has (a) in the case of Licensing been forwarded to the EPA prior to the equipment being used on patients and (b) in the case of Registration has been confirmed in the Self-Declaration and then retained by the Registered Person for inspection by Inspectors of the Agency.

3. Prior to the acquisition of sealed radioactive sources, the Licensee or Registered Person shall obtain written agreement from the Manufacturer/Supplier that each radioactive source will be accepted back when no longer required.

4. In cases where a sealed radioactive source is being acquired to replace an existing source, the Licensee or Registered Person shall arrange to return the sealed source being replaced to the manufacturer, or a successor, in accordance with the conditions of this Authorisation.

5. The Licensee or Registered Person shall ensure that an initial radiation survey is carried out by the Manufacturer/Supplier of each newly acquired radiation surce as part of the Installation Report.

C. DOSIMETRY AND REPORTING LEVELS

1. Notwithstanding the dose limits specified in IRR19, the Licensee or Registered Person shall carry out all practices authorised hereunder in such a manner that working conditions are optimised and, consequently, exposures are kept as low as reasonably achievable.

2. In the case of exposed workers, the Licensee or Registered Person shall investigate and document the findings of any practice, which, in any continuous sixteen-week period, has given rise to reported doses as follows: Category A Worker (including Apprentice & Student aged greater than 18 years) - Effective dose 6 mSv;Dose to lens of the eye 6 mSv;Dose to skin & extremities 150 mSv. Category B Worker (including Apprentice & Student aged greater than 18 years and Apprentice & Student aged between 16-18 years) -Effective dose 2 mSv;Dose to lens of the eye 5 mSv;Dose to skin & extremities 50 mSv. The report of the investigation, referred to above, shall be forwarded to the EPA within two weeks of notification of the dose to the Licensee or Registered Person.

D. DESIGN OF NEW RADIOLOGICAL FACILITIES

1. Notwithstanding the dose limits specified in IRR19, locations where radiation sources are used or stored shall be designed so that the dose to persons, other than exposed workers, is less than 0.3 mSv per year (see Design Code of Practice).

E. MAINTENANCE QUALITY AND OPERATIONAL CONTROLS

1. The authorised items shall be checked for correct operation and shall be serviced and maintained at least every 12 months or more frequently, depending on use, by suitably qualified and competent persons in accordance with the manufacturer's instructions.

2. Modification of an authorised item or of the area in which it is located shall only be carried out following consultation with an RPA and the RPO. In the case of licences, prior approval of the Agency will be required for said modifications.

3. All radiation measuring instruments, used in the radiological surveillance of working environments, shall be individually calibrated before first use and annually thereafter, using sources or equipment traceable to appropriate national standards. Calibration records must be maintained for a period of at least five years from the date on which the record is made.

4. A radiation survey meter shall be available whenever any portable gauge, such as a nuclear moisture/density gauge item, is removed from its storage location. This meter shall be used to check that during use of the gauge, areas around the gauge where the dose rate exceeds 2.5 μSv/h are suitably demarcated, and that the source has returned to the shielded position following use of gauge.

F. SAFETY AND SECURITY

1. The Licensee or Registered Person shall have suitable security arrangements in place to prevent, in so far as is possible, the loss or theft of any authorised item and the unauthorised access to, or unauthorised removal from, its assigned location.

2. The Licensee or Registered Person shall take all reasonable steps to implement and observe the security arrangements for the prevention of the loss or theft of any authorised item and the unauthorised access to, or unauthorised removal of any authorised item from its assigned location.

3. The Agency shall be notified within seven days of any report from a manufacturer or supplier querying the safety of using an authorised item.

4. The Agency shall be notified of damage to, leakage from, or other incident/accident involving an authorised item, which could or has given rise to an unintended dose, as soon as possible and at the latest within 24 hours of occurrence of the incident/accident (see Guidelines for Reporting Incidents).

5. The authorised items shall be clearly labelled at all times and appropriate warning notices shall be used to indicate the ionising radiation hazards associated with these items.

6. Authorised items taken out of use and put into storage shall be stored in a secure location. Radioactive sources put into storage shall be adequately shielded. A visual check of these items, or where a prior agreement has been made with the Agency a check on the on-going security arrangements, shall be carried out at monthly intervals. A record shall be kept of these checks.

7. The Licensee or Registered Person shall immediately notify the Agency of the loss or theft of any authorised item.

8. When not in regular use, irradiating apparatus shall be safely and securely stored and clearly identified as being capable of producing ionising radiation. Appropriate measures shall be put in place to ensure that irradiating apparatus cannot be switched on.

9. Irradiating apparatus, when being transferred between on-site and/or off-site locations, shall be carried in a manner that prevents the possibility of it being energized by unauthorized personnel if, for example, the vehicle that is carrying the irradiating apparatus should be stolen.

10. In addition to the standard radiation warning notices, a warning sign shall be affixed to each disused authorised item stating clearly that the item must not be moved from its storage location without the prior authorisation of the RPO or RPA. In the case of licences, prior authorisation shall be required from the Agency.

11. The Licensee or Registered Person shall ensure that the Chief Fire Officer of the Local Authority is informed annually of the locations of all radioactive sources held by the Licensee or Registered Person. A revised plan of the Licensee or Registered Persons premises shall be submitted to the Chief Fire Officer following a change in the location of any fixed radioactive source. The Chief Fire Officer shall also be advised in writing upon the removal of any or all radioactive substances held by the Licensee or Registered Person.

12. When not in use, authorised items shall be safely and securely stored in such a manner that radioactive sources are segregated from non-radioactive materials and appropriate measures are in place to ensure that irradiating apparatus cannot be switched on.

13. A suitable warning notice shall be affixed to all authorised items when taken out of use and put into storage stating clearly that the items must not be used or moved from their storage location without the prior authorisation of the RPO or RPA.

G. RETURN OR REMOVAL OF SEALED SOURCES AND/OR IRRADIATING APPARATUS

1. Licensable items shall only be returned or removed following receipt of prior written authorisation from the Agency.

2. Disused sealed radioactive sources shall be returned to the Manufacturer, or to a successor Company as soon as possible following the decision that no further use is required of said sources.

3. In the case of disused irradiating apparatus the Licensee or Registered Person shall comply with the EPA Guidance Note on Management of X-ray Units at End-of-Life.

H. RECORDS

1. The Licensee or Registered Person shall make and fully maintain all relevant records for the authorised items. These shall include, but not be limited to, details of acquisitions, leakage tests on radioactive sources, the serial numbers and/or other unique identifiers for authorised items, installation and servicing reports, dates on which Radiation Safety Procedures were made available to the workers concerned and other persons who may be affected by the procedures, instrument calibrations and any associated deficiencies, incidents/accidents, monthly visual checks, radiation surveys, HASS record sheets, returns/removals or other disposal arrangements, individual dose monitoring of personnel and monitoring of areas in which authorised items are located.

2. The Licensee or Registered Person shall ensure that all records pertaining to an Authorisation are fully maintained and readily available for inspection, at all reasonable times, by Inspectors of the Agency.

I. DISPOSAL

1. Licensed items shall only be disposed of following receipt of written authorisation from the Agency.

2. If it is intended to transfer any authorisable items to another company, the Licensee or Registered Person shall ensure that the proposed recipient is aware of the requirement to take out an Authorisation from the Agency prior to the transfer taking place.

3. In the event that items are authorised for disposal to a disposal facility, whether directly to such facility or through the services of a specialist disposal facilitator, the Licensee or Registered Person shall maintain its Authorisation in respect of such items until same are accepted at the disposal facility and, in the event that the items are not accepted at the disposal facility, or have to be returned to Ireland for any other reason, the Licensee or Registered Person accept the return of the items by the disposal facility or specialist disposal facilitator.

J. TRANSPORTATION

1. The licensee or Registered Person shall ensure that all activities associated with the transport of radioactive material, including shielding, packaging and labelling, shall be in accordance with the current International Atomic Energy Agency's Regulation for the Safe Transport of Radioactive Material, the Modal Instruments and national transport Regulations.

2. The licensee or Registered Person shall ensure that all persons involved in the transport of radioactive material shall have received appropriate training in compliance with that specified in the Modal Instruments.

3. A copy of this Authorisation shall be provided by the licensee or Registered Person to the drivers involved in the transportation of radioactive sources under this Authorisation.

4. Transit sites such as warehouses and other temporary storage areas for radioactive sources shall be safe and secure and accessible only to authorised personnel.

5. Radioactive sources must be transferred directly from one location to another and transportation by road within the State may only be undertaken with the authorisation of the Agency.

6. Secure and safe parking shall be provided for any vehicle left unattended while that vehicle contains a radioactive source. The vehicle shall also be fitted with a suitable alarm system that shall be set whenever the vehicle is left unattended.

7. Carriers and consignors engaged in the carriage of high consequence radioactive material (typically HASS sources) shall adopt, implement and comply with a security plan that addresses as a minimum, the elements specified in Chapter 1.10 of the current ADR. A tracking system shall also be used to determine the location of the vehicle used to transport High Activity Sealed Sources.

K. EXPORT / IMPORT

1. The exportation of radioactive substances to countries outside the European Union shall be limited only to those items marked “For export” in Schedule 2 of this Authorisation and to the supplier/destination specified.

2. The Licensees or Registered Person shall obtain written confirmation verifying the receipt of the radioactive substance at the receiving destination and forward it to the Agency.

3. The importation of radioactive substances from countries outside the European Union shall be limited only to those items marked “For import” in Schedule 2 of this Authorisation and from the supplier/destination specified.

4. For sealed radioactive sources shipped within the European Union, the Standard Document pursuant to Council Regulation 1493/93 must be completed by the consignee and stamped by the relevant regulator in advance of the proposed shipment. A copy of the 1493/93 form stamped by the relevant regulator must be forwarded to the Agency in advance of shipments from Ireland.

L. REFERENCES

1. Radiological Protection Act, 1991 (Ionising Radiation) Regulations 2019 (S.I. No. 30 of 2019)

2. Radiological Protection (Amendment) Act, 2002 (No. 3 of 2002).

3. Council Regulation (Euratom) No. 1493/93 of 8 June 1993 on Shipments of Radioactive Substances between Member States.

4. European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) (Amendment) Regulations 2011-2018.

5. ADR. European Agreement Concerning the International Carriage of Dangerous Goods by Road. UNECE (January 2017).

6. International Civil Aviation Organisation 'Technical Instructions for the Safe Transport of Dangerous Goods by Air', 2015-2016 Edition.

7. International Maritime Organisation 'International Maritime Dangerous Goods Code', 2014 Edition.

8. Guidelines for Reporting of Incidents, Radiological Protection Institute of Ireland, August 2013.

Environmental Protection Agency

Schedule 2

Office of Radiation Protection and Environmental Monitoring

Inventory of Sealed Sources

Authorisation No: L2601-04 **Expiry Date:** 31/03/2029 **Authorised:** Rilta Environmental Limited

Premises: Block 402 Grant's Drive, Greenogue Business Park, Rathcoole, Dublin

Location	Source Serial Number	Radioactive Source	Purpose
Rilta Environmental Ltd	LG-900	Nickel-63	Disused Source
Licensing Restriction		**Activity Level**	**Device/Housing Id**
Custody pending Disposal		555.00 MBq	17580
Practice			
Use of sealed sources in industry			
Activities			
Custody, Disposal, Exportation, Transportation			

Premises: Block 402 Grant's Drive, Greenogue Business Park, Rathcoole, Dublin

Location	Radioactive Source	Activity Level	Source Details
Block 402 Grant's Drive, Greenogue Business Park, Rathcoole, Co. Dublin.	N/A		33 x ECD cells each containing 1 x Ni-63 sealed radioactive source with activity not greater than 555 MBq from Aquilant Analytical Services.
Practice		**Licensing Restriction**	
Use of laboratory equipment incorporating sealed sources		Custody pending Export to the USA	
Activities			
Custody, Exportation, Storage, Transportation			

Location	Radioactive Source	Activity Level	Source Details
RILTA Environmental Ltd. Storage Cabinet	Iodine-129	kBq	Cork University Hospital Wilton Cork:1 in number: Iodine-129/ Radionuclide Mix in Gel with an activity of 4.42 kilobecquerels (Serial Number: XR78/BZ630)
Practice		**Licensing Restriction**	
Use of sealed sources in industry		Custody pending EXPORT TO NSSI, TEXAS, U.S.A.	
Activities			
Custody, Exportation, Storage, Transportation			

Location	Radioactive Source	Activity Level	Source Details
RILTA Environmental Ltd. Storage Cabinet	Carbon-14	MBq	Athlone Institute of Technology:100g of Carbon-14 Chloram Phenicol
Practice		**Licensing Restriction**	
Use of unsealed sources in industry/laboratories		Custody pending EXPORT TO IBI LABS, FLORIDA, U.S.A.	
Activities			
Custody, Exportation, Storage, Transportation			

Environmental Protection Agency

Schedule 3

Office of Radiation Protection and Environmental Monitoring

Radiation Protection Officers / Radiation Protection Advisers

Authorisation No: L2601-04 **Expiry Date:** 31/03/2029 **Authorised:** Rilta Environmental Limited

Name	Title	Department / Location / Address
Mr. Eamonn Corbett	Radiation Protection Officer	Rilta Environmental Ltd 402 Greenogue Business Park, Rathcoole, Co DUblin

Authorisation No: L2601-04 **Expiry Date:** 31/03/2029 **Authorised:** Rilta Environmental Limited

Name	Address
RILTA Environmental Limited	Block 402 Grant's Drive, Greenogue Business Park, Rathcoole, Dublin