



Office of Radiological Protection

# Licence

**L2601-02**

The Environmental Protection Agency, in accordance with the terms of the Radiological Protection Act, 1991 (Ionising Radiation) Order, S.I. No. 125 of 2000, hereby licenses

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

to carry on the practice(s) of

**Use, Custody, Transportation**

of the Radioactive Substances/Nuclear Devices/Irradiating Apparatus listed in Schedule 2 of this licence for the purposes specified therein and subject to the conditions given in Schedule 1 of the licence. These conditions may be varied or added to from time to time at the discretion of the Environmental Protection Agency.

This licence is valid from

**1 April 2017 to 31 March 2019**

This licence does not exempt the licensee from compliance with other regulations or statutory requirements relating to the licensed items.

Signed

Date

31 March 2017

*On behalf of the Environmental Protection Agency*

**A. GENERAL**

1. The licensee shall note that compliance with this licence and its Conditions does not exempt the licensee from compliance with the following: Statutory Instrument No. 125 of 2000, the Radiological Protection (Amendment) Act, 2002, and where applicable, Council Regulation (Euratom) No. 1493/93 of 1993, Statutory Instruments No. 349 of 2011 & No 238 of 2013 and Statutory Instrument No. 875 of 2005.
2. The Radiation Safety Procedures prepared by the licensee shall have regard to the radiological risks and the nature of the practices carried out by the licensee as well as the protective measures identified in the licensee's documented Risk Assessment(s) pertaining to these practices.
3. The licensee shall take all reasonable steps to ensure that the provisions of its Radiation Safety Procedures are observed.
4. The licensee shall ensure that its Radiation Safety Procedures are brought to the attention of, and made available to, the workers concerned.
5. The licensee shall maintain a record of the date on which the Radiation Safety Procedures were made available to the 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 Risk Assessment(s) referred to above shall be reviewed by the licensee
  - (a) at least once during the period of validity of this licence, and
  - (b) immediately, where circumstances arise in which the licensee has reason to believe that the Risk Assessment(s) are no longer appropriate,and shall be amended by the licensee where required and the Radiation Safety Procedures revised where necessary.
7. Where there has been a change to the protective measures identified in the Risk Assessment(s) a copy of the revised Risk Assessment(s) and the relevant section(s) of the Radiation Safety Procedures, where amended, shall be submitted to the Agency. The provisions in this licence relating to Radiation Safety Procedures shall also apply to these amended Procedures.
8. The Radiation Safety Procedures shall be reviewed by the licensee
  - (a) at least once during the period of validity of this licence, and
  - (b) immediately, where circumstances arise in which the licensee has reason to believe that the Procedures are no longer appropriate,and shall be amended by the licensee where required.
9. The Radiation Protection Officer (RPO) is named in Schedule 3. In the event of a change being envisaged, the licensee shall forward to the Agency the name, position within the company and evidence of competence of the proposed new appointee. The notification should be prior to any change taking effect so that the new RPO's appointment can be authorised by the Agency.
10. A copy of this licence shall be publicly displayed in a suitable location on each of the premises listed in Schedule 4.

11. The Schedules to this licence constitute part of the licence and may only be amended by the Agency. The Agency shall be informed in writing of any proposals to change Schedules 2 or 3 of this 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 amendment of this licence and/or the Schedules hereto.
12. Irradiating apparatus may only be acquired from a supplier who holds a valid licence from the Agency for the distribution of such irradiating apparatus, or alternatively from another source with the prior approval of the Agency.
13. The licensee shall carry out all practices licensed 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.
14. This licence may be revoked if any of the conditions herein are not observed.
15. The practices authorised by this licence 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 licence. The licensee shall note any licensing restrictions relating to sources that may be specified in Schedule 2.
16. Save where otherwise approved in writing in advance by the Agency this licence authorises the licensee to carry out the practices specified on the first page of this licence only insofar as such practices involve Radioactive Substances, Nuclear Devices or Irradiating Apparatus obtained by the licensee from a supplier holding a current licence from the Agency for the distribution and transportation of the said Radioactive Substances, Nuclear Devices or Irradiating Apparatus.

## **B. ACQUISITION**

1. Without prejudice to any other condition in this licence, licensable items shall only be acquired with the authorisation of the Agency and the full approval of the RPO.
2. Prior to acquiring a licensable item or commencing a new application or procedure involving a licensable item, the licensee 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 shall make and keep records of the assessment.
3. Prior to the acquisition of sealed radioactive sources, the licensee shall obtain written agreement from the supplier that each radioactive source will be accepted back by the supplier when no longer required.
4. The licensee shall obtain a traceable leakage test certificate in respect of each radioactive source acquired.
5. In cases where a sealed radioactive source is being acquired to replace an existing source, the licensee shall arrange to return the sealed source being replaced to the manufacturer, or a successor, in accordance with the conditions of this licence.
6. An initial radiation survey shall be carried out by the installer of each newly acquired irradiating apparatus and nuclear device and a copy of the results of the survey maintained by the licensee.

## **C. DOSIMETRY AND REPORTING LEVELS**

1. Notwithstanding the dose limits specified in S. I. No. 125 of 2000, the licensee shall carry out all practices licensed hereunder in such a manner that working conditions are optimised and, consequently, exposures are kept as low as reasonably achievable.

2. Where a personal dosimetry programme is in place, the licensee shall:
  - (a) Investigate the reason(s) for any unexpected reported dose on a dosimeter and document the findings.
  - (b) Where, in any continuous sixteen-week period, doses equal to or greater than the following values have been recorded for an individual, an investigation shall be carried out in conjunction with the appointed RPA: Effective dose 2 mSv; Dose to lens of the eye 15 mSv; Dose to skin, hands, forearms, feet or ankles 50 mSv.
  - (c) A copy of the investigation report referred to in (b) shall be forwarded to the Agency within two weeks of notification of the dose to the licensee.
3. In the case of exposed workers the licensee shall:
  - (a) Investigate and document the findings of any practice, which, in any continuous sixteen-week period, has given rise to reported doses equal to or greater than the following values:
    - Effective dose 2 mSv;
    - Dose to lens of the eye 15 mSv;
    - Dose to skin, hands, forearms, feet or ankles 50 mSv.
  - (b) Forward a report of the investigation, referred to above, to the EPA within two weeks of notification of the dose to the licensee;
  - (c) Forward to the EPA, on an annual basis, a summary of all doses received by any Category A workers throughout the preceding twelve months.

#### **D. DESIGN OF NEW RADIOLOGICAL FACILITIES**

1. Notwithstanding the dose limits specified in S. I. No. 125 of 2000, locations where nuclear devices, radioactive substances or irradiating apparatus are used or stored shall be designed so that the dose to all persons, other than exposed workers, is less than 0.3 mSv per year (Ref Design Code of Practice).

#### **E. MAINTENANCE QUALITY AND OPERATIONAL CONTROLS**

1. The licensed 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 a licensed item or of the area in which it is located shall only be carried out with the prior written authorisation of the Agency.
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. Sealed radioactive sources shall be tested for leakage at least once every two years, or more frequently if recommended by the manufacturer. In the case of suspected damage to any radioactive source or its housing, a leakage test shall immediately be undertaken.
5. If the removed activity from any sealed radioactive source is in excess of 200 Bq, use of that source shall be discontinued and the Agency notified.
6. A radiation survey meter shall be available whenever a portable gauge, such as a nuclear moisture/density gauge item, is removed from its storage location. This meter shall be used to check that:
  - (a) During use of the portable gauge, areas around the licensed item where the dose rate exceeds 2.5  $\mu$ Sv/h are suitably demarcated;
  - (b) Following use of the portable gauge, the sealed caesium-137 source is in the shielded position.

#### **F. SAFETY AND SECURITY**

1. The licensee shall have suitable security arrangements in place to prevent, in so far as is possible, the loss or theft of any licensed item and the unauthorised access to, or unauthorised removal from, its assigned location.
2. The licensee shall take all reasonable steps to implement and observe the security arrangements for the prevention of the loss or theft of any licensed item and the unauthorised access to, or unauthorised removal of a licensed 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 a licensed item.
4. The Agency shall be notified of damage to, leakage from, or other incident/accident involving a licensed 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 (Ref. Guidelines for Reporting Incidents).
5. The licensed 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. Licensed 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 shall immediately notify the Agency of the loss or theft of any licensed 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. For transfer between on-site and/or off-site locations, irradiating apparatus 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 notices, a warning sign shall be affixed to disused licensed items stating clearly that the items must not be moved from their storage location without the prior authorisation of the RPO and the Agency.
11. The licensee shall ensure that the Chief Fire Officer of the Local Authority is informed annually of the locations of all radioactive substances held by the licensee. A revised plan of the licensee's 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 all radioactive substances held by the licensee.
12. When not in use, licensed 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 licensed items 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.

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

1. Licensed items shall only be returned or removed following receipt of prior written authorisation from the Agency.
2. Disused sealed radioactive substances and nuclear devices shall be returned to the manufacturer, or to a successor company.
3. In the case of disused irradiating apparatus the licensee shall comply with the EPA Guidance Note on Management of X-ray Units at End-of-Life.

## **H. RECORDS**

1. The licensee shall make and fully maintain all relevant records for the licensed 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 licensed 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 licensable items are located.
2. The licensee shall ensure that all records pertaining to this licence 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. In the case of licences in which the practice of disposal is not specified on the first page, the licensee shall request written authorisation from the Agency to dispose of any radioactive sources.
3. If it is intended to transfer any licensed items to another company, the licensee shall ensure that the proposed recipient is aware of the requirement to take out a licence from the Agency before the transfer can take place.
4. In the event that licensed 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 shall maintain its licence in respect of such licensed items until same are accepted at the disposal facility and, in the event that the licensed items are not accepted at the disposal facility, or have to be returned to Ireland for any other reason, the licensee accept the return of the licensed items by the disposal facility or specialist disposal facilitator.

## **J. TRANSPORTATION**

1. The licensee 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 shall ensure that all persons, whether employees or contractors 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 licence shall be provided by the licensee to the drivers involved in the transportation of radioactive sources under this licence.
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.

## **K. EXPORT / IMPORT**

1. The exportation of radioactive substances to countries outside the European Union shall be limited to those items marked "For export" in Schedule 2 of this licence and to the supplier/destination specified.
2. The licensees shall obtain written confirmation verifying the receipt of the radioactive substance by the receiving destination and forward it to the Agency.
3. The importation of radioactive substances from countries outside the European Union shall be limited to those items marked "For import" in Schedule 2 of this licence 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) Order, 2000 (S. I. No. 125 of 2000).
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 2011-2017 (S.I. No 349 of 2011, S.I. No. 238 of 2013, S.I. No. 31 of 2015, S.I. No 288 of 2015 and S.I. No 5 of 2017).
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.

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

Location	Source Serial Number	Radioactive Source	Purpose
Laboratory	RS 985	Nickel-63	Analytical Use
	Device/Housing Id	Activity	Licensing Restriction
	RS 985	481.00 MBq	



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

<b>Location</b>	<b>Radioactive Source</b>	<b>Activity</b>
Block 402 Grant's Drive, Greenogue Business Park, Rathcoole, Co. Dublin.	N/A	
	<b>Source Details</b>	<b>Licensing Restriction</b>
	33 x ECD cells each containing 1 x Ni-63 sealed radioactive source with activity not greater than 555 MBq from Aquilant Analytical Services.	Export to the USA
<b>Location</b>	<b>Radioactive Source</b>	<b>Activity</b>
RILTA Environmental Ltd. Storage Cabinet	Carbon-14	MBq
	<b>Source Details</b>	<b>Licensing Restriction</b>
	Athlone Institute of Technology:100g of Carbon-14 Chloram Phenicol	FOR EXPORT TO IBI LABS, FLORIDA, U.S.A.
<b>Location</b>	<b>Radioactive Source</b>	<b>Activity</b>
RILTA Environmental Ltd. Storage Cabinet	Iodine-129	kBq
	<b>Source Details</b>	<b>Licensing Restriction</b>
	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)	FOR EXPORT TO NSSI, TEXAS, U.S.A.

Name	Title	Department / Location / Address
Mr. Sean Cotter	Radiation Protection Officer	

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