



Radiological Protection Institute of Ireland

An Institiúid Éireannach um Chosaint Raideolaíoch

**Guidelines for reporting radiological incidents
to the Radiological Protection Institute of Ireland
March 2009**

Introduction

Article 41 of the Radiological Protection Act, (Ionising Radiation) Order [S.I. No. 125 of 2000] requires the undertaking [licensee] to immediately notify the Radiological Protection Institute of Ireland of any loss, larceny or other misappropriation of any radioactive substance, nuclear device or irradiating apparatus. This Article also requires notification in the event of a release, or likely release, of a radioactive substance which could give rise to significant contamination.

In addition to this Article, and all other requirements of S.I. No. 25 of 2000, licensees must also adhere to the conditions the RPII attaches to each licence. As well as including the requirement for notification in the event of loss or theft of a licensed item the licence conditions also include a requirement for the licensee to report any *damage to, leakage from or other incidents/accidents involving a licensed item as soon as possible and at the latest within 24 hours.*

While in most situations it is clear what is meant by the loss, theft, damage or leakage in relation to a licensed item, additional guidance is required to explain what is meant by *other incidents/accidents*. This document provides guidance as to the types of incidents and accidents that are reportable to the RPII and how they should be reported and investigated. It should be noted that it is not possible to include every unplanned event in this document and the scenarios mentioned cannot be considered to be exhaustive.

Incidents that are reportable to the Radiological Protection Institute of Ireland

In accordance with Article 41 of S.I. No. 125 of 2000 the following incidents must be reported to the RPII:

- The loss, theft or other misappropriation of any radioactive substance, nuclear device or X-ray equipment held by the licensee. Where the licensee suspects, or has been informed, that such an occurrence has or may have taken place, it shall investigate the matter and submit a report of the investigation to the RPII.
- If a radioactive substance has been, or is likely to be, released to the atmosphere as a gas, aerosol or dust or has been spilled or otherwise released in such a manner as to give rise to significant contamination, and the quantity of the radioactive substance involved exceeds 10 times the quantity specified in Annex 1 of S.I. No. 125 of 2000 and 100 times the concentration figure given in Annex 1 of S.I. No. 125 of 2000.

The word *release* in this context should be taken to mean an incident where the radioactive substance has been unintentionally released from the controlled area relating to the source as designated by the licensee.

Furthermore, the licence conditions also set out additional incidents that must be reported:

- In the case of exposed workers the licensee shall:
 - (a) Investigate any practice, which, in any continuous sixteen-week period, has given rise to 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 RPII within two weeks of notification of the dose to the licensee.
- The RPII shall be notified of damage to, leakage from, or other incident/accident involving a licensed item as soon as possible and at the latest within 24 hours of occurrence of the incident/accident.
- The RPII shall be informed within seven days of any report querying the safety of using a licensed item.

In the context of the licence condition that requires reporting of *other incidents/accidents* the following incidents must also be reported:

- Any incident involving the unintended exposure of a person arising from a design flaw, malfunction or incorrect operation¹ of a licensed item.
- Any incident involving a dose, or suspected dose, in excess of any of the dose limits for members of the public and workers specified in S.I. No. 125 of 2000.
- Any incident involving contamination which might result in a person ingesting or inhaling more than one tenth of the annual limit of intake of the radionuclide involved (e.g. for ingestion, more than 80 kBq for iodine-131, 100 kBq of iodine-125 or 100 MBq of technetium-99m).
- Any incident occurring during the transport of radioactive materials. For example, if there is any damage or suspected damage to the packages being carried, or an incident which could give rise to public concern.
- A fault in a licensable item where that fault:
 - (i) could result in accidental exposure to workers or members of the public or in contamination of persons or the environment;
 - (ii) might be expected to occur in similar licensable items, i.e., be of a generic nature (for example, failure of the shutter on a gauge to close).
- An incident having off site consequences, e.g., a release of radioactive material to the environment in excess of the disposal limits prescribed in the licence or by a disposal method other than as prescribed in the licence.
- Failure of an interlock system, intended to prevent exposure to the operator or members of the public, which leads to the unintended exposure of a person.

Additionally, in the case of the medical and dental sectors the following incidents are also reportable:

- Any incident involving the unintended exposure of a person arising from a design flaw, incorrect calibration or malfunction of a licensed item.

¹ Incidents arising from the incorrect operation of a source of ionising radiation during a patient's diagnostic or therapeutic medical procedure are not reportable to the RPII.

- Any incident arising from a diagnostic or therapeutic procedure in which a wrong patient² receives a dose exceeding the dose limits of a member of the public.
- Any incident in which a foetus receives a dose in excess of 1 mSv as a consequence of the licensee either failing to establish or adhere to appropriate procedures in relation to the determination of possible pregnancy of a patient undergoing either a diagnostic or therapeutic procedure.

An incident which occurs due to a prescriber or practitioner (as defined in S.I. No. 478 of 2002) error is not reportable to the RPII. Examples of such incidents include a wrong procedure being carried out on a correct patient or a procedure being carried out incorrectly, possibly necessitating a repeat exposure. Guidelines are currently being developed by the Health Services Executive for the reporting of such incidents under S.I. No. 478 of 2002.

Reporting of the incident

As a general guide, incidents involving workers, members of the public or the environment that are likely to give rise to public concern should always be reported regardless of their radiological significance. In the case of doubt, the incident may be reported verbally to the RPII which will, following consideration of the circumstances, advise whether formal reporting is required. Furthermore, where the incident is of a sensitive nature, e.g. where litigation may ensue, the licensee may discuss the format of the report in advance with the RPII.

2 Article 10 (2) of S.I. No. 125 of 2000 states *inter alia* that the undertaking shall ensure that exposed workers, apprentices, students and members of the public are not exposed to ionising radiation in excess of the dose limits specified in Schedule 2 of the Order. However, dose limits are not applicable in the case of the exposure of individuals [patients] as part of their own medical diagnosis or treatment. For these patients it is assumed that the radiation dose that they receive is for their own direct benefit and that the diagnostic procedure or treatment has been optimised to afford the maximum protection to the patient. For the patient exemption to apply in respect of dose limits, the exposure would have to occur in the course of that person's "own medical diagnosis or treatment".

Where a patient undergoes an exposure which was clearly not intended for them they are classified as a "wrong patient". In these instances the exemption on dose limits will not apply and, under the scope of S.I. No. 125 of 2000, the person exposed must be classified as a member of the public. The corresponding dose limits for a member of the public, for example 1 mSv per annum in the case of effective dose, are therefore applicable.

Notwithstanding the above all incidents must be reported to the RPII within 24 hours from the time it is first realised that an incident has occurred. Incidents may initially be reported by phone. Should the incident require the urgent involvement of the RPII outside office hours, the RPII's answer phone gives a contact number for An Garda Síochána who will relay a message to the Duty Officer. Such incidents would include those requiring the evacuation of areas adjacent to the site of occurrence, and loss or theft of radioactive sources. In all cases a written report of the incident must be forwarded to the RPII.

Incident investigation

All reportable incidents involving a source of ionising radiation must be investigated by the licensee. There are four main objectives in investigating incidents:

- To establish the sequence of events leading to the incident;
- To identify the cause of the incident;
- To decide upon and implement remedial action to prevent a recurrence;
- To estimate the dose received by all persons involved in the incident.

It is important to identify from the outset, or as early as possible, the persons who will be involved in the investigation, including those conducting the investigation and those whose evidence is to be considered. People who should always be involved include:

- The person in charge of the facility/department/staff where the incident took place;
- The person who was exposed;
- The person(s) acting as operator during the exposure;
- The Radiation Protection Officer;
- The Radiation Protection Adviser (where appointed).

In the case of an incident which occurred as a result of defective equipment the following people should also be involved in the investigation:

- The service engineer who examined the equipment following the incident;
- The person who was responsible for quality assurance on the equipment.

In the case of incidents arising in the medical/dental sectors the following persons should also be involved:

- The person acting as prescriber for the exposure (as defined by S.I. No. 478 of 2002);
- The Medical Physics Expert (where appointed);

The above list should not be considered to be exhaustive and other persons may be involved in the investigation depending on the circumstances.

In all cases the licensee must ensure that the person who was exposed is fully briefed on the implications of the incident. This briefing should include information relating to both the potential risks of adverse health effects and to the dose limits for members of the public/workers as set out in S.I. No. 125 of 2000.

Investigation report

The findings of the investigation must be documented in an investigation report. It is recommended that the report should include at least the following information:

- The key facts concerning the incident;
- The consequences (if any) for the individual exposed;
- A record of the calculations and measurements that were made;
- Recommendations to avoid recurrence of the incident;
- Details of the follow up action with the exposed person.

The report should be signed and dated by the person who prepared it and forwarded to the RPII.

Records of all reportable incidents should be kept by the licensee and made available to an Inspector of the RPII, upon request.



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