



GUIDANCE NOTE

Management of X-ray Units at End-of-Life

January 2011 (Revision)

This document is for guidance only. It does not purport to be and should not be considered a legal interpretation of the legislation referred to herein. Readers are advised to refer to the relevant legislation for comprehensive information on requirements

1. **Introduction**

X-ray units are included in the scope of legislation¹ relating to electrical and electronic equipment (EEE). This legislation falls under the general principle of producer responsibility, where the producer of a product must take responsibility for that product when it reaches end-of-life². When such equipment reaches end-of-life, it becomes waste electrical and electronic equipment (WEEE) and must be managed in an environmentally sound manner. In addition, the custody and use of X-ray units are subject to licensing³ by the Radiological Protection Institute of Ireland (RPII).

2. **Purpose of this guidance**

The objective of this guidance note is to provide information on how to dispose of disused X-ray units, which are considered waste electrical and electronic equipment (WEEE), when they reach the end of their useful life, and to ensure full compliance with RPII licence conditions⁴ and the WEEE Regulations.

This guidance has been developed jointly by the Environmental Protection Agency (EPA) and the Radiological Protection Institute of Ireland (RPII). It aims to provide clarity and promote best practice in an area of common interest without prejudice to the respective statutory responsibilities and obligations of each organisation.

The guidance is aimed at the following groups:

- X-ray equipment licensees (including dental and veterinary surgeons, hospitals, industry, embassies, ports and airports, etc.);
- WEEE collective compliance schemes and their approved waste management contractors;
- Waste collection permit holders and waste licence/facility permit holders handling WEEE;
- Operators and managers of waste management facilities; and,
- EPA, RPII and local authority enforcement inspectors.

¹ Waste Management (Waste Electrical and Electronic Equipment) Regulations 2005 (S.I. No. 340 of 2005, as amended by S. I. No 375 of 2008); European Parliament and Council Directive 2002/96/EC on waste electrical and electronic equipment (as amended by Directive 2003/108/EC).

² The essence of producer responsibility lies in the Polluter Pays Principle, making sure that the producer is responsible for the environmentally sound management of the electrical product at end-of-life.

³ Details of the RPII's licensing system can be found on the RPII's website www.rpii.ie.

⁴ It is a condition of each licence issued by the RPII that prior written authorisation must be obtained from the RPII before disposing of a licensed item.

3. Respective roles of the EPA and the RPII

3.1 Role of the EPA

The Environmental Protection Agency (EPA) is an independent public body established in 1993 under the Environmental Protection Agency Act, 1992. The EPA has responsibilities for a wide range of licensing, enforcement, monitoring, assessment, guidance, reporting and research activities associated with environmental quality and protection. In the context of these responsibilities it should be noted that the Waste Management Act, as amended, does not apply to a radioactive substance within the meaning of the Radiological Protection Act, 1991. However, the WEEE Regulations referred to above explicitly require the removal of components containing radioactive substances from separately collected WEEE⁵.

3.2 Role of the RPII

The Radiological Protection Institute of Ireland (RPII) is the national organisation with regulatory, monitoring and advisory responsibilities in matters pertaining to ionising radiation. In particular the RPII is the competent authority for the protection of workers and members of the public from the harmful effects of exposure to ionising radiation. It was established in 1992 under the Radiological Protection Act, 1991. The RPII operates a licensing system for all holders and users of sources of ionising radiation such as sealed radioactive source and X-ray equipment.

4. WEEE and Batteries Regulations

The Waste Management (Waste Electrical and Electronic Equipment) Regulations (S.I. No. 340 of 2005, as amended by S.I. No. 375 of 2008) came into force on 13 August 2005. The Waste Management (Batteries and Accumulators) Regulations (S.I. No 268 of 2008), hereafter referred to as the Batteries Regulations came into effect on 26 September 2008. The EPA is the lead enforcement authority for the WEEE and Batteries Regulations and enforcement responsibility is shared with the local authorities. Many items of electrical and electronic equipment contain batteries, for the operation of a unit for example, mobile X-ray units or as a backup power supply for the memory of the unit,

The WEEE and Batteries Regulations set up a framework whereby WEEE and waste batteries and accumulators can be managed in an environmentally sound manner. The regulations place significant

⁵ Refer to the Seventh Schedule of the Waste Management (Waste Electrical and Electronic Equipment) Regulations, 2005 (S.I. No 340 of 2005, as amended by S.I. No. 375 of 2008).

obligations on Producers⁶ placing electrical and electronic equipment (EEE) or batteries (including portable, automotive and industrial batteries and batteries incorporated into appliances) on the market in the Republic of Ireland or Distributors⁷ of those products once they are in the country.

5. RPII licensing

5.1 *Licensing of X-ray units*

In accordance with S.I. 125 of 2000⁸ all users of sources of ionising radiation are required to hold a valid licence from the RPII for the custody and use of sources of ionising radiation such as X-ray units and radioactive sources. Although this licensing requirement applies only to those X-ray units that have a kV greater than 30kV, the advice outlined in this guidance document should be followed for all X-ray units, even if not licensable by the RPII. If an X-ray unit is rendered permanently incapable of producing X-rays it is no longer deemed to be source of ionising radiation and not subject to licensing requirements. Refer to section 6.3 below for more information.

5.2 *Licence amendment details*

It is a condition of each licence issued by the RPII that:

“The Institute 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 Institute a prior amendment of this licence and/or the Schedules hereto”.

Where a licensee proposes to discard an X-ray unit, it is considered WEEE and therefore regard should be had to the WEEE Regulations in arranging for its environmentally sound management at end-of-life. This is further outlined in section 6 below and the particular options available to the final end-user will

⁶ A **WEEE producer** means any person who irrespective of the selling technique used, including by means of distance communication – (i) manufactures and sells electrical and electronic equipment under his or her own brand, (ii) resells electrical and electronic equipment produced by other suppliers under his or her own brand, (iii) imports electrical and electronic equipment on a professional basis into the State, (iv) exports electrical and electronic equipment on a professional basis from the State to another Member State of the European Union, or (v) distributes electrical and electronic equipment from a producer who is deemed not to be registered under the provisions of article 12(2); a **battery producer** means any person in a Member State that, irrespective of the selling technique used, including by means of distance communication as defined in Directive 97/7/EC of the European Parliament and of the Council of 20 May 1997 on the protection of consumers in respect of distance contracts, places batteries or accumulators, including those incorporated into appliances or vehicles, on the market for the first time within the territory of that Member State on a professional basis.

⁷ A **WEEE distributor** means any person who provides electrical and electronic equipment on a commercial basis to the party who is going to use it; a **battery distributor** means any person that provides batteries or, as appropriate, accumulators on a professional basis to an end-user.

⁸ Radiological Protection Act, 1991 (Ionising Radiation) Order, 2000

depend on the date on which the X-ray unit was first placed on the market by the producer. In addition, the following administrative step should be taken, in compliance with the conditions of the RPII licence (where applicable):

A licensee shall request prior written authorisation from the RPII before discarding a licensed item, such as an X-ray unit.

The end-of-life X-ray unit should be managed in accordance with the requirements of the WEEE Regulations. After the end-of-life X-ray unit has been correctly managed as WEEE, a Schedule 2 amendment form should be completed providing the necessary details of its management so that it can be removed from the inventory of X-ray equipment of the licence. This amendment form can be downloaded from the RPII website www.rpii.ie and completed forms should be submitted to the RPII.

6. Environmentally sound management of X-ray units at end-of-life

The age profile of X-ray units in current use throughout Ireland will vary and may exist in situations including dentists, veterinary surgeries, hospitals, embassies, as well as airports and ports. The options available for the management of end-of-life X-ray units will depend on the date on which it was placed on the market, as the WEEE Regulations and the associated take-back obligations came into effect on 13 August 2005. It will also depend on whether or not the unit is being replaced. In addition to the environmentally sound management of end-of-life X-ray units as WEEE, regard should be given to the RPII licensing conditions outlined in section 5.2, above and the unit rendered permanently incapable of producing ionising radiation, as outlined in section 6.3 below.

6.1 Where an end-of life X-ray unit is being replaced by a new one

Where an end-user of an X-ray unit is replacing an old unit with a new unit, the producer of the new unit (as defined under the WEEE Regulations, refer to section 4 above) must provide free take back for the end-of-life X-ray unit, and finance its environmentally sound management as WEEE. This requirement stands irrespective of the brand of the old unit or the brand of the new unit being supplied. In the case of such replacements, it also does not matter when the old unit was originally placed on the market.

6.2 Where an end-of-life X-ray unit is NOT being replaced

There may be situations where a final end-user of an X-ray unit may wish to discard it and not replace it with a new unit, for example, when a dental practice ceases operation. In such situations, the final end-user is responsible for ensuring the end-of-life X-ray unit is managed properly as WEEE, where the unit was originally placed on the market before 13 August 2005.

If, in the above situation, the X-ray unit to be discarded was originally placed on the market after 31 August 2005, then the producer which placed that unit on the market is responsible for ensuring its environmentally sound management at end-of-life. The final end-user should contact the supplier of the unit to make appropriate arrangements.

6.3 Disposal and recovery

Prior to disposal and in order to comply with RPII's licence conditions (refer to section 5.2 above), the end-of-life X-ray unit must be rendered permanently incapable of producing ionising radiation⁹. This can be done for example by arranging for a suitably qualified and competent person¹⁰ to disable the unit by disconnecting the timer unit and removing cables. The X-ray unit should be otherwise left fully intact. This approach should also be followed in the case of X-ray units that are not licensable by the RPII, i.e. those that are under 30kV.

X-ray units, manufactured prior to 1986

Old-X-ray units could contain oils which could potentially contain PCBs¹¹. As a general rule of thumb, equipment that was manufactured prior to 1986¹² may contain PCB oils in transformers or capacitors. More information is available in the PCB Management Plan, available to download from the EPA website (www.pops.ie)¹³. Where such end-of-life X-ray units are being discarded as WEEE, they should be assumed to contain PCBs, unless certified PCB-free, and transferred to an authorised waste management operator, where all relevant hazardous and non-hazardous components will be managed in

⁹ X-ray units can ONLY produce ionising radiation when connected to an electrical power source. X-ray units are not inherently radioactive and once the timer unit has been disconnected and the power cables/batteries permanently removed it can no longer generate X-rays. In this case it can be considered solely as WEEE.

¹⁰ Suitably qualified electrician or engineer or similarly approved. Details may be available to the end user from the distributor of the equipment.

¹¹ PCBs (polychlorinated biphenyls) are chemical substances that may occur in older electrical equipment such as transformers, capacitors and fluorescent lighting ballasts. PCBs are persistent organic pollutants and are extremely harmful to the environment and, at higher levels, to human health. More information is available at www.pops.ie.

¹² In the EU, the sale of certain items of PCB-containing equipment was banned from 1986. In the absence of contrary information, any transformer which was manufactured in 1986 or earlier (or if from the USSR or former USSR countries, 1993 or earlier) should be considered to potentially contain PCB oils until such time as analytical testing or other evidence may prove otherwise. PCBs are known to have been used in capacitors up until 1989 and in the absence of contrary information, any capacitor manufactured during or prior to 1989 should be assumed to contain PCBs.

¹³ <http://www.epa.ie/whatwedo/resource/hazardous/pcb/>

an environmentally sound manner in accordance with the WEEE regulations. The final end-user should inform the waste management facility in writing that the end-of-life X-ray unit may contain PCB oils. A certificate of destruction should be issued from the recovery operator.

7. WEEE waste management facilities

Any waste facility must be appropriately authorised either by holding a waste licence issued by the EPA or a waste facility permit or certificate of registration issued by the relevant local authority. EPA-licensed waste management facilities are listed on the EPA website (www.epa.ie). A final end-user of EEE such as an end-of-life X-ray unit must make their own decision as regards which authorised waste management operator to engage, unless the unit is being replaced with a new one and its environmentally sound management arranged by the producer.

8. Useful contact information

Regulators

Environmental Protection Agency

Office of Climate, Licensing and Resource Use
PO Box 3000, Johnstown Castle Estate,
Wexford

Tel: 053 9160600

Fax: 053 9160699

Email: weee@epa.ie; batteries@epa.ie

Web: www.epa.ie

www.weee-enforcement.ie

www.batteries-enforcement.ie

Radiological Protection Institute of Ireland

Regulatory Services Division
3 Clonskeagh Square

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Dublin 14

Tel: 01 2697766

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