

Consultation on the Environmental Regulation of Healthcare Risk Waste Storage and Treatment

Circulation list:

- Department of the Environment, Community and Local Government
- Department of Health and Children
- Health Services Executive
- Health and Safety Authority
- County and City Managers Association
- Each Local Authority, Directors of Services, Environment
- National Waste Collection Permit Office
- National TFS Office
- Irish Waste Management Association
- Chartered Institution of Wastes Management
- Private companies

1. Background

Biological agents are widely found in the natural environment and as a result are also found in many work sectors. They include bacteria, viruses and fungi. Some of these agents are harmless while others have potential to cause ill health.

Due to its potentially infectious nature, waste that is contaminated with biological agents can be classified as a hazardous waste. It is common practice for healthcare risk waste (also called clinical waste) to be collected by a commercial operator and taken to one of two centralised facilities for treatment (i.e. sterilisation) prior to final disposal elsewhere. Certain fractions of this waste stream are exported directly for disposal by incineration. The treatment of this waste is a waste disposal activity and, depending on the scale of the activity, will require a waste licence or an Industrial Emissions licence from the Environmental Protection Agency.

A number of requests have been received by the Agency seeking a decision as to the type of waste authorisation that would be required to operate: 1) mobile units for healthcare risk waste treatment; 2) small stationary treatment units; and 3) healthcare risk waste collection hubs. This consultation paper is mainly concerned with small stationary treatment units. The question of collection hubs is also discussed. A short discussion on laboratory autoclaves is presented.

Specific points of discussion or questions are underlined in this document and interested parties are invited to address these points/questions directly, or to provide any other commentary on the matter in hand.

2. Classification of healthcare risk waste

The terms "waste" and "hazardous waste", as used in this document, are defined in the Waste Management Act 1996, as amended, most recently by the European Communities (Waste Directive) Regulations 2011 on foot of the revised Waste Framework Directive 2008/98/EC.

"Waste" means any substance or object which the holder discards or intends or is required to discard.

"Hazardous waste" means waste which displays one or more of the hazardous properties listed in the Second Schedule [of the Waste Management Acts].

Healthcare risk waste is also called clinical waste. It is hazardous waste and is so classified because it displays one or more of the properties of hazardous waste. The greatest proportion of healthcare risk waste is infectious or potentially infectious waste and must be treated to address this property. Other healthcare waste streams have chemical hazards that result in their classification as hazardous waste.

Infectious healthcare risk waste or potentially infectious healthcare risk waste is typically classified according to the following European Waste Catalogue (EWC) code:

- 18 01 03* wastes whose collection and disposal is subject to special requirements in order to prevent infection

This EWC code includes sharps and any other healthcare risk waste that exhibits or has the potential to exhibit the infectious property.

Other hazardous healthcare risk waste streams are:

- 18 01 06* chemicals consisting of or containing dangerous substances
- 18 01 08* cytotoxic and cytostatic medicines
- 18 01 10* amalgam waste from dental care.

The above codes are from sub-chapter 18 01 of the EWC and this chapter covers wastes from natal care, diagnosis, treatment or prevention of disease in humans. An equivalent set of codes is listed in sub-chapter 18 02 for waste from research, diagnosis, treatment or prevention of disease involving animals. This paper will primarily be concerned with chapter 18 01 codes involving waste from human healthcare facilities.

3. Generation of healthcare risk waste and its management in general terms

Healthcare risk waste is generated in healthcare facilities including hospitals, clinics, nursing homes and general practice and dental surgeries. It is also generated in people's homes and by district nurses and other healthcare practitioners that travel to people's homes to treat patients.

Less than 10,000 tonnes of healthcare risk waste were generated in Ireland in 2011, equating in round terms to around 27 tonnes per day.

Larger healthcare facilities typically have central areas on their premises where healthcare risk waste is deposited in large (1,100 litre) bins for collection by professional service providers. Healthcare risk waste from smaller facilities is sometimes transported to larger facilities for storage prior to collection. Such larger facilities, ones that also accept waste for storage from smaller facilities, will be termed "hubs" for the purpose of this paper.

There are two commercial healthcare risk waste treatment facilities in the State, both located in Dublin. The logistics and economics of transporting the waste to these facilities would appear to favour the existence of a small number of larger hubs/facilities from which waste is collected in large vehicles, rather than a large number of smaller facilities which can only be serviced by smaller vehicles. There are service providers in smaller vehicles that collect waste from smaller facilities. These operators will either: (a) deposit the waste at a larger hub in the vicinity or (b) transport the waste directly to a waste treatment facility in Dublin (or alternatively arrange for its export to facilities in other countries).

The above description is highly generalised and does not reflect all the possible permutations of local practices, arrangements, partnerships and contracts. It is thought to be adequate for the purposes of the discussion in this paper.

4. Environmental regulation of healthcare risk waste

The environmental regulation of healthcare risk waste is concerned with two aspects of the management of healthcare risk waste:

- its collection and transport; and
- the facilities and installations (i.e. locations, premises) where it is stored and treated.

Its environmental regulation is directed primarily by the Waste Management Act 1996, as amended, and its subsidiary regulations. Certain installations (locations) will require regulation under the Environmental Protection Agency Act 1992, as amended, giving effect to the Industrial Emissions Directive.

5. Collection of healthcare risk waste

"Collection", according to the Waste Management Act 1996, as amended, means the gathering of waste, including preliminary sorting and storage of waste for the purposes of transport to a waste treatment facility.

The collection of waste is an activity that is regulated by the National Waste Collection Permit Office under the Waste Management (Collection Permit)

Regulations 2007, amended in 2008. The regulations are available for download at www.nwcpo.ie.

Any operator, regardless of scale, engaged in the collection and transport of healthcare risk waste must hold a valid waste collection permit. There are certain exemptions from the obligation to hold a waste collection permit, however none are available regarding the collection of healthcare risk waste.

The matter of the regulation by the NWCPO of the collection and transport of healthcare risk waste is neither within the remit of the Agency nor the scope of this consultation.

6. Regulation of healthcare risk waste at a facility or installation

Facilities or installations used for the storage or treatment of healthcare risk waste will generally require a licence from the Environmental Protection Agency. The Agency can grant two types of licence for such activities:

- an Industrial Emissions licence for installations involving the disposal or recovery of hazardous waste with a capacity exceeding 10 tonnes per day involving one or more of a list of 11 activities including:
 - physico-chemical treatment (e.g. the shredding and/or disinfection of healthcare risk waste);
 - blending or mixing; and
 - repackaging;

or

- a waste licence for facilities that are below the 10 tonne threshold for an Industrial Emissions licence. There is no lower threshold for a waste licence.

Note that the temporary storage of waste for less than 6 months, pending collection on the site where it is produced, is not an activity that requires waste authorisation. The following types of facilities will however, in accordance with the relevant legislation, require an Agency licence:

- healthcare risk waste treatment facilities; and
- healthcare risk waste storage facilities – that is, any facility, other than its place of generation, used for the storage of hazardous healthcare risk waste.

7. Storage of waste in hubs

The Agency is aware of a number of local arrangements whereby healthcare risk waste is collected commercially or carried by local staff and taken to a large healthcare facility for storage pending onward transport to a treatment facility (whether in Ireland or abroad).

There are several examples of models of depositing waste at central healthcare risk waste storage facilities or hubs, such as:

- Employees of the Health Service Executive or its healthcare contractors/agents (i.e. medical personnel), such as district nurses, generate healthcare risk waste as part of their normal activities in the community and carry it back to base or to a waste storage facility at a local hospital. Such

carriage is normally in their own vehicles or those provided by their employers.

- Commercial waste collectors are employed specifically and solely to carry healthcare risk waste from smaller facilities (clinics, nursing homes etc.) to a hub.
- Certain healthcare contractors deliver healthcare supplies to housebound patients and, at the same time, take away used materials as part of the service to the patient. The used material (waste) is taken to the location that is the base for such operations.

The Agency is seeking views as to whether the deposit of waste at a hub location means that the location/hub where the waste is deposited is a waste facility requiring authorisation?

8. New technologies for the on-site treatment of healthcare risk waste

The Agency is aware of the emergence of new technologies for the treatment of healthcare risk waste at its point of generation. Machines are becoming available that can be located:

- on the hospital ward where they are immediately available to medical personnel; or
- in a centralised location at a healthcare facility, with adequate capacity to treat the quantity of healthcare risk waste generated at that facility.

As stated above, as hazardous waste disposal activities, these machines currently require regulation under a licence that can only be granted by the Agency. There is no scope for the Agency to exempt these from waste authorisation under current legislation. Nor is there scope for local authority regulation of the machines under a waste facility permit or certificate of registration.

An alternative model of regulation is proposed below.

The Agency is seeking views on the appropriate level of regulation for such machines/activities and whether the current level of regulation (i.e. an EPA licence) is proportionate to the environmental risk posed by these machines/activities.

The statutory cost of applying for a licence involving the disposal of hazardous waste is €30,000¹. The Agency is seeking views on whether such costs will have an impact on the development of new technologies.

9. Alternative regulatory models

As stated above, the Agency is the sole regulatory body in the State for activities involving the disposal of hazardous waste. Local authorities are currently responsible for the authorisation of certain waste activities. These activities are mostly recovery activities, although certain categories of small-scale waste disposal activities are regulated by local authorities.

¹ The Agency has the discretion to waive or refund up to 50% of the application fee for a waste licence or any portion of an Industrial Emissions licence application fee.

The Agency is seeking views as to whether there should be a change in regulation such that the following activities, for example, would be regulated by local authorities:

- The storage of healthcare risk waste in hubs where healthcare risk waste is accepted for storage from other healthcare facilities², subject to a maximum storage capacity of 20 tonnes, which the Agency understands is the maximum payload for a road trailer allowed on Irish roads. This would mean that the storage of hazardous healthcare risk waste at:
 - a storage facility with a capacity up to 20 tonnes would require a waste facility permit from a local authority;
 - a storage facility with a capacity greater than 20 tonnes but less than 50 tonnes will require a waste licence from the Agency; and
 - a storage installation with a capacity greater than 50 tonnes will require an Industrial Emissions licence from the Agency.
- The treatment of infectious or potentially infectious healthcare risk waste in machines at the hospital. The proposed maximum aggregate treatment capacity of (all) treatment machines at the facility is 1 tonne per day. It would appear that only a very small number of acute hospitals in the State are likely to generate more than 1 tonne of healthcare risk waste per day. This would mean that the treatment of hazardous healthcare risk waste at:
 - a hospital where up to 1 tonne per day can be treated (based on capacity, not throughput) would require a waste facility permit from a local authority; and
 - all other treatment activities would require a licence from the Agency.

The Agency is seeking views as to whether certain healthcare risk waste storage and treatment facilities/activities should be regulated by local authorities, reflecting the following factors which may be applicable:

- the level of environmental risk posed by the activities,
- their relatively small scale, and
- sensitivity to the high costs associated with applying for and maintaining an EPA licence.

10. Autoclaves

Autoclaves are commonly used in laboratories to sterilise materials that are (or could be) contaminated with biological agents.

In March 2010, the Environment Agency in the UK published a regulatory position statement in relation to the use of autoclaves in laboratories. The following is stated:

'The Environment Agency's position... [is that it]... will not pursue a permit application for the... treatment by laboratory autoclave of ... microbiological laboratory waste on the premises it is produced'

² Acknowledging that, as stated earlier in this paper, the temporary storage of waste at its own place of generation requires no waste authorisation.

It is acknowledged by the Environment Agency in their position statement that the requirement for authorisation in such circumstances would not be in the public interest because it would act as a disincentive to good waste management practices in such scenarios.

The application of containment/sterilisation measures is obligatory in certain facilities and instances which may indicate that the material is not discarded (and does not become waste) until such time as it has been sterilised.

The Agency is seeking views on what is the appropriate level of regulation for autoclaves used in laboratories for the treatment of laboratory waste.

11. Consultation

The objective of this paper is to make all parties aware of the current legislative framework governing the storage and treatment of healthcare risk waste and to invite submissions on an alternative approach. The Agency will take into account any submissions made by interested parties before deciding whether to make any recommendations to the Department of the Environment, Community and Local Government for regulatory change.

Submissions should be made by email to licensing@epa.ie by 19 September 2014. Please write "healthcare risk waste consultation" in the subject line of the email. Submissions can also be sent by post to:

Healthcare risk waste consultation
Environmental Licensing Programme
Environmental Protection Agency
PO Box 3000
Johnstown Castle Estate
Co. Wexford

All submissions will be published on the Agency's website.

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