



Standard rules consultation no 23: proposals for healthcare waste permits

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We are the Environment Agency. We protect and improve the environment.

We help people and wildlife adapt to climate change and reduce its impacts, including flooding, drought, sea level rise and coastal erosion.

We improve the quality of our water, land and air by tackling pollution. We work with businesses to help them comply with environmental regulations. A healthy and diverse environment enhances people's lives and contributes to economic growth.

We can't do this alone. We work as part of the Defra group (Department for Environment, Food & Rural Affairs), with the rest of government, local councils, businesses, civil society groups and local communities to create a better place for people and wildlife.

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1. Introduction

The Environmental Permitting (England and Wales) Regulations 2016 allow us to make standard rules to reduce the administrative burden on business while maintaining environmental standards. This consultation proposes:

- a revision to the standard rules permit for clinical and healthcare waste transfer stations
- to revoke standard rules for the treatment of healthcare waste

We would like your views on these proposals. We will take account of the consultation responses and publish the consultation response together with the revised standard rules sets (if any) on GOV.UK.

2. About this consultation

This document:

- describes what we are consulting on
- provides an overview of the relevant documents
- explains the standard rules permitting process

We have designed it to help you understand and comment on our proposals. We will consider your answers and comments. We'll use them to revise and finalise the rules. The consultation will be for a period of 12 weeks.

2.1. What we are consulting on

The Environmental Permitting (England and Wales) Regulations 2016 (EPR) allow us to develop standard rules for certain activities. We base the rules on our understanding of the risks. In this consultation we are asking your views on:

- revising [SR 2008 No 24: 75Kte clinical waste and healthcare waste transfer station](#) to make sure it provides an appropriate level of environmental protection to refer to the updated guidance set out in [Healthcare waste: appropriate measures for permitted facilities](#) - this guidance will replace existing guidance [EPR: 5.07 Clinical waste: additional guidance](#)
- revising the associated generic risk assessment document to SR 2008 No 24
- withdrawing [SR 2008 No 25: 75Kte clinical waste and healthcare waste treatment and transfer station](#), and its associated generic risk assessment - there are currently only 2 permits in place under this rules set
- withdrawing [SR 2013 No 1: treat 100 tonnes a year of clinical and healthcare waste](#), and the associated generic risk assessment - there are no issued permits under this rules set

2.2. What this consultation means to you

We think this consultation will be of particular interest to:

- **operators, trade associations and businesses:** this is your opportunity to make sure that the revised rules work for you and your industry but also provide the necessary protection to the environment and human health
- **other regulators, the public, community groups and non-governmental organisations with an interest in environmental issues:** this is your opportunity to make sure that the revised rules provide the necessary protection to the environment and human health, whilst still being useful to industry

3. How standard rules permits work

3.1. What a standard rules permit is

Standard permits contain one condition which refers to a fixed set (or sets) of standard rules that an operator must comply with. The standard rules define the activities that an operator can carry out. They also specify necessary restrictions on those activities, such as emission limits or the types of waste or raw materials that can be accepted at the sites. We publish standard rules on GOV.UK following public consultation.

Any operator who wishes to carry out a particular activity at a particular site or sites can look at the standard rules. If they can comply with them, they can decide to apply for a standard permit.

We are able to issue the standard permit more quickly and cheaply because we have no decisions to make on site specific permit conditions. An operator who cannot meet the requirements of the standard rules must apply for a bespoke permit and provide us with additional information. It takes us longer to issue a bespoke permit because we have to carry out a more detailed assessment of the application. This includes deciding whether to include site specific conditions and consult in line with our public participation statement.

There is no right of appeal against the rules in a standard permit because applying for a standard permit is voluntary. If an operator wants to change the way their site operates, they must apply to vary the standard permit to a bespoke permit when:

- their operation falls outside the scope of the standard rules
- they feel that the standard permit no longer works for their particular operation

Operators must apply for a bespoke permit for any regulated activities not covered by standard rules. These activities generally have a higher potential impact on the

environment or require more complex controls than operations for which standard rules can be used.

3.2. What standard rules are

When we develop sets of standard rules we carry out a single assessment of risk for a commonly undertaken activity. This enables us to define the risk boundary within which the rules can be used. This boundary comprises a number of restrictions such as size, location and operational controls. The restrictions will be those necessary to enable a consistent set of rules to reduce the risk to an acceptable level. The rules are the same for each operator carrying out that particular activity. Rules and risk assessments are published in advance so that operators and the public know precisely what controls we will apply to a proposed activity.

3.3. The generic risk assessment for the activities

We have updated the generic risk assessment for the activity. These list the potential risks and how to properly manage them. We did it by identifying possible pathways from the sources of the risks to the receptors (these are people, animals, property and anything else that could be affected by the hazard). Each risk is split into 3 sections.

- information about the source, pathway and receptor – and the potential harm to that receptor
- a judgement of the level of risk and justification of that judgement
- actions for managing the risk (through permitting) and a residual risk rating after managing it

A set of standard rules may contain a rule which requires an operator not to carry out an activity within a certain distance of specified nature conservation sites. The broad sensitivity of habitats and species groups to the potential hazards from facilities we regulate through EPR is well understood. Harm can occur through hazards such as toxic contamination, nutrient enrichment, habitat loss, siltation, smothering, disturbance and predation.

We use specified distances to identify which activities could affect the interest features of these sites and species. Activities that do not can be eligible for a standard rules permit. In line with our public participation statement we do not consult the nature conservation bodies on an individual applications for standard rules permits.

4. Proposed changes to the rules sets

4.1. Why we need to revise SR 2008 No 24

In July 2020, following a formal consultation process, the Environment Agency published updated guidance for the management of healthcare waste - [Healthcare waste:](#)

appropriate measures for permitted facilities. This guidance will replace existing guidance EPR: 5.07 Clinical waste: additional guidance.

The new guidance aims to deliver improvements in the design and operation of permitted facilities in the healthcare waste sector. It will make sure that, where relevant, appropriate measures are applied consistently.

The existing standard rules permit for healthcare waste SR 2008 No 24: 75Kte clinical waste and healthcare waste transfer station, needs to be updated to make sure:

- it provides an appropriate level of environmental protection
- it refers to the updated appropriate measures and standards set out in the revised guidance

At the same time, we have taken the opportunity to review the quantities of waste permitted under the existing rules set. We looked at the actual quantities of waste that operators receive as detailed in their operator returns information. No site reported receiving more than 5,000 tonnes of waste. We are proposing to reduce the annual limit from 75,000 tonnes to 5,000 tonnes.

4.2. Withdrawing rules sets

The proposal under this consultation includes the withdrawal of 2 existing standard rules sets:

- SR 2008 No 25: 75Kte clinical waste and healthcare waste treatment and transfer station - there are currently only 2 permits in place and we will move these operators to a bespoke waste operation (or installation) permit as applicable
- SR 2013 No 1: treat 100 tonnes a year of clinical and healthcare waste - there are no issued permits under this rule set

5.Responding to this consultation

5.1. Important dates

This consultation will start on 29 March 2021 and run until 10 May 2021.

5.2. How to respond

You can view the consultation documents and questions online at:

<https://consult.environment-agency.gov.uk/waste/standard-rules-consultation-no-23>.

Here you can submit your response using our online tool which will enable you to manage your comments more effectively. It will also help us to gather and summarise responses quickly and accurately as well as reducing the costs of the consultation.

If you prefer to submit your response by email or letter, or if you would like to ask for a printed version of the document to be posted to you, please contact our National Customer Contact Centre on 03708 506 506 (Minicom, for the hard of hearing; 03702 422 549), Monday to Friday, 8am to 6pm, or email standard-rules@environment-agency.gov.uk.

If you would like to send your response by post, please send your completed response form by 10 May 2021 to: Future Regulation - Permitting [Standard Rules Consultation No 23] Environment Agency, Horizon House, Deanery Road, Bristol BS1 5AH.

5.3. How we will use your information

We will use your information to help shape these standard rules.

During the consultation we will look to make all responses publicly available after the consultation, unless you have specifically requested that we keep your response confidential. We will not publish names of individuals who respond.

We will also publish a summary of responses on our website in which we will publish the name of the organisation for those responses made on behalf of organisations.

We will not respond individually to responses. After the consultation has closed we will publish a summary of the responses on our website and contact you to let you know when this is available.

In line with the Freedom of Information Act 2000, we may be required to publish your response to this consultation, but will not include any personal information. If you have requested your response to be kept confidential, we may still be required to provide a summary of it.

For more information see our [Personal information charter](#).

5.4. Privacy notice

The Environment Agency would like to keep you informed about the outcomes of the consultation.

If you would like to receive an email acknowledging your response and be notified that the summary of responses has been published, please give us your email address in your response to this consultation.

By providing us with your email address you consent for us to email you about the consultation. We will keep your details until we have notified you of the response document publication. We will not share your details with any other third party without your explicit consent unless required to by law.

You can withdraw your consent to receive these emails at any time by contacting us at: standard-rules@environment-agency.gov.uk

5.5. Consultation principles

We are running this consultation in line with the guidance set out in the [government's Consultation principles](#). If you have any queries or complaints about the way this consultation has been carried out, please email:

consultation.enquiries@environment-agency.gov.uk

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