

# Standard rules SR2008 No24 – clinical waste & healthcare waste transfer station

## Introductory note

This introductory note does not form part of these standard rules

When referred to in an environmental permit, these rules will allow the operator to operate a Clinical and Healthcare Waste Transfer Station at a specified location, provided that the permitted activities are not carried out within 200 metres of a European Site<sup>1</sup>, Ramsar site or a Site of Special Scientific Interest (SSSI). The activities shall not be carried out within Groundwater Source Protection Zone 1, or if a Source Protection Zone has not been defined then within 50m of any well spring or borehole used for the supply of water for human consumption. This must include private water supplies.

Permitted wastes are limited to non-hazardous and hazardous clinical and healthcare waste. The total quantity of waste that can be accepted at a site under these rules must be less than 75,000 tonnes a year. These rules will not permit the treatment of any waste or the mixing of hazardous waste. These rules will also not permit the burning of any wastes, either in the open, inside buildings or in any form of incinerator.

These rules do not allow any point source emission into surface waters or groundwater. However, under the emissions of substances not controlled by emission limits rule:

- Liquids may be discharged into a sewer subject to a consent issued by the local water company.
- Liquids may be taken off-site in a tanker for disposal or recovery.
- Clean surface water from roofs, or from areas of the site that are not being used in connection with storing waste, may be discharged directly to surface waters, or to groundwater by seepage through the soil via a soakaway.

**End of introductory note**

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<sup>1</sup> A candidate or Special Area of Conservation (cSAC or SAC) and proposed or Special Protection Area (pSPA or SPA) in England and Wales.

# Rules

## 1 – Management

### 1.1 General management

1.1.1 The operator shall manage and operate the activities:

- (a) in accordance with a written management system that identifies and minimises risks of pollution, including those arising from operations, maintenance, accidents, incidents, non-conformances, closure and those drawn to the attention of the operator as a result of complaints; and
- (b) using sufficient competent persons and resources.

1.1.2 Records demonstrating compliance with rule 1.1.1 shall be maintained.

1.1.3 Any person having duties that are or may be affected by the matters set out in these standard rules shall have convenient access to a copy of them kept at or near the place where those duties are carried out.

1.1.4 The operator shall comply with the requirements of an approved competence scheme.

### 1.2 Avoidance, recovery and disposal of wastes produced by the activities

1.2.1 The operator shall take appropriate measures to ensure that:

- (a) the waste hierarchy referred to in Article 4 of the Waste Framework Directive is applied to the generation of waste by the activities; and
- (b) any waste generated by the activities is treated in accordance with the waste hierarchy referred to in Article 4 of the Waste Framework Directive; and
- (c) where disposal is necessary, this is undertaken in a manner which minimises its impact on the environment.

1.2.2 The operator shall review and record at least every four years whether changes to those measures should be made and take any further appropriate measures identified by a review.

## 2 – Operations

### 2.1 Permitted activities

2.1.1 The operator is only authorised to carry out the activities specified in table 2.1 below ("the activities").

<b>Table 2.1 activities</b>	
<b>Description of activities</b>	<b>Limits of activities</b>
<b>D15:</b> Storage pending any of the operations numbered D1 to D14 (excluding temporary storage, pending collection, on the site where it is produced)	The maximum quantity of hazardous waste stored for disposal shall not exceed 10 tonnes and the maximum stored for recovery or disposal in aggregate shall not exceed 50 tonnes.
<b>R13:</b> Storage of wastes pending any of the operations numbered R1 to R12 (excluding temporary storage, pending collection, on the site where it is produced)	The maximum quantity of hazardous waste repackaged for disposal or recovery shall not exceed 10 tonnes per day.  There shall be no compaction of wastes.
<b>D14:</b> Repackaging prior to submission to any of the operations numbered D1 to D13	There shall be no mixing of hazardous waste.  The waste types permitted for storage (D15 and R13), and repackaging (D14) are set out in tables 2.2a and 2.2b.

## 2.2 Waste acceptance

2.2.1 Waste shall only be accepted if:

- (a) it is of a type and quantity listed in tables 2.2, 2.2a and 2.2b below;
- (b) it conforms to the description in the documentation supplied by the producer and holder;  
and
- (c) waste acceptance procedures are in place to determine (a) and (b).

<b>Table 2.2a Waste types permitted for storage (D15 and R13)</b>	
<b>Maximum Quantities</b> The total quantity of waste accepted at the site shall be less than 75,000 tonnes a year.	
<b>Exclusions</b> <b>Dangerous Goods :</b> Any waste, otherwise permitted by table 2.2a, that is either transported in a vehicle, or is packaged in a manner that does not meet the requirements for carriage of that waste, unless agreed in writing by Natural Resources Wales for that individual consignment or batch of waste.	
<b>Waste Code</b>	<b>Description</b>
<b>09</b>	<b>WASTES FROM THE PHOTOGRAPHIC INDUSTRY</b>
<b>09 01</b>	<b>wastes from the photographic industry</b>
09 01 01*	water-based developer and activator solutions (consisting of wastes arising from medical practices or associated research activities only)
09 01 02*	water-based offset plate developer solutions (consisting of wastes arising from medical practices or associated research activities only)
09 01 03*	solvent based developer solutions (consisting of wastes arising from medical practices or associated research activities only)
09 01 04*	fixer solutions (consisting of wastes arising from medical practices or associated research activities only)
09 01 05*	bleach solutions and bleach fixer solutions (consisting of wastes arising from medical practices or associated research activities only)
09 01 07	photographic film and paper containing silver or silver compounds (consisting of wastes arising from medical practices or associated research activities only)
09 01 08	photographic film and paper free of silver or silver compounds (consisting of wastes arising from medical practices or associated research activities only)

<b>18</b>	<b>WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)</b>
<b>18 01</b>	<b>wastes from natal care, diagnosis, treatment or prevention of disease in humans</b>
18 01 01	sharps (except 18 01 03)
18 01 02	body parts and organs including blood bags and blood preserves (except 18 01 03)
18 01 03*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
18 01 04	wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers) (consisting of non-clinical human offensive/hygiene waste and autoclaved waste from laboratories only)
18 01 06*	chemicals consisting of or containing hazardous substances (excluding X-ray photochemicals)
18 01 07	chemicals other than those mentioned in 18 01 06 (excluding X-ray photochemicals)
18 01 08*	cytotoxic and cytostatic medicines
18 01 09	medicines other than those mentioned in 18 01 08
18 01 10*	amalgam waste from dental care
<b>18 02</b>	<b>wastes from research, diagnosis, treatment or prevention of disease involving animals</b>
18 02 01	sharps (except 18 02 02)
18 02 02*	wastes whose collection and disposal is subject to special requirements in order to prevent infection
18 02 03	wastes whose collection and disposal is not subject to special requirements in order to prevent infection (consisting of non-clinical animal offensive/hygiene waste and autoclaved waste from laboratories only)
18 02 05*	chemicals consisting of or containing hazardous substances (excluding X-ray photochemicals)
18 02 06	chemicals other than those mentioned in 18 02 05 (excluding X-ray photochemicals)
18 02 07*	cytotoxic and cytostatic medicines
18 02 08	medicines other than those mentioned in 18 02 07
<b>20</b>	<b>MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS</b>
<b>20 01</b>	<b>separately collected fractions (except 15 01)</b>
20 01 31*	cytotoxic and cytostatic medicines
20 01 32	medicines other than those mentioned in 20 01 31
20 01 99	other fractions not otherwise specified (consisting of only the following: <ul style="list-style-type: none"> <li>• separately collected fractions of municipal clinical waste (not arising from healthcare and/or related research i.e. not including waste from natal care, diagnosis, treatment or prevention of disease) which is subject to special requirements in order to prevent infection); or</li> <li>• non-clinical human and animal offensive/hygiene waste (not arising from healthcare and/or related research i.e. not including waste from natal care, diagnosis, treatment or prevention of disease) which is not subject to special requirements in order to prevent infection))</li> </ul>

<b>Table 2.2b Waste types permitted for repackaging (D14)</b>	
<b>Maximum Quantities</b>	
The total quantity of waste accepted at the site shall be less than 75,000 tonnes a year.	
<b>Exclusions</b>	
Dangerous Goods : Any waste, otherwise permitted by table 2.2a, that is either transported in a vehicle, or is packaged in a manner that does not meet the requirements for carriage of that waste, unless agreed in writing by Natural Resources Wales for that individual consignment or batch of waste.	
<b>Waste Code</b>	<b>Description</b>
<b>18</b>	<b>WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)</b>
<b>18 01</b>	<b>wastes from natal care, diagnosis, treatment or prevention of disease in humans</b>
18 01 04	wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers) (consisting of non-clinical human offensive/hygiene waste only)
<b>18 02</b>	<b>wastes from research, diagnosis, treatment or prevention of disease involving animals</b>
18 02 03	wastes whose collection and disposal is not subject to special requirements in order to prevent infection (consisting of non-clinical animal offensive/hygiene waste only)
<b>20</b>	<b>MUNICIPAL WASTES (HOUSEHOLD WASTE AND SIMILAR COMMERCIAL, INDUSTRIAL AND INSTITUTIONAL WASTES) INCLUDING SEPARATELY COLLECTED FRACTIONS</b>
<b>20 01</b>	<b>separately collected fractions (except 15 01)</b>
20 01 99	other fractions not otherwise specified (consisting of non-clinical human and animal offensive/hygiene waste (not arising from healthcare and/or related research i.e. not including waste from natal care, diagnosis, treatment or prevention of disease) which is not subject to special requirements in order to prevent infection only)

## 2.3 Operating techniques

2.3.1 The activities shall be operated using the techniques and in the manner described in Table 2.3 below.

<b>Table 2.3 Operating techniques</b>
<ol style="list-style-type: none"> <li>1. All permitted waste shall either be stored: <ul style="list-style-type: none"> <li>• within a building provided with an impermeable surface with sealed drainage system; or</li> <li>• within sealed containers located on an impermeable surface with sealed drainage system. Sealed containers shall be kept locked when not being loaded or unloaded.</li> </ul> </li> <li>2. Wastes which arrive in bags or other non-rigid containers shall be transferred into rigid containers immediately.</li> <li>3. Rigid containers for the storage of waste shall be of a design that: <ul style="list-style-type: none"> <li>• will prevent the escape of any liquid;</li> <li>• has a lockable lid or other means of securing the container.</li> </ul> </li> <li>4. Waste containing or contaminated with cytotoxic and cytostatic medicines shall be kept separate from other wastes.</li> <li>5. Waste medicines, dental amalgam, medicinally contaminated sharps (including fully discharged syringes) and non-medicinally contaminated sharps shall be kept separate from each other and other wastes and stored in a secure place.</li> <li>6. Body parts and organs shall be stored in designated refrigerated units within a building.</li> <li>7. The transfer of waste from vehicles or containers into other vehicles or containers shall only take place on areas with an impermeable surface with sealed drainage system.</li> <li>8. Waste dispatched from the site shall be packaged in accordance with, and loaded onto vehicles that meet, the appropriate requirements for the carriage of dangerous goods.</li> <li>9. Washing and disinfection of mobile containers shall take place on areas of impermeable surface with sealed drainage system.</li> </ol>

## **2.4 The site**

- 2.4.1 The activities shall not extend beyond the site, being the land shown edged in green on the site plan attached to the permit.
- 2.4.2 The activities shall not be carried out within 200 metres of a European Site or a SSSI.
- 2.4.3 The activities shall not be carried out within Groundwater Source Protection Zone 1, or if a Source Protection Zone has not been defined then within 50m of any well spring or borehole used for the supply of water for human consumption. This must include private water supplies.

## **2.5 Hazardous waste storage and treatment**

- 2.5.1 Hazardous waste shall not be mixed, either with a different category of hazardous waste or with other waste, substances or materials, unless it is authorised by table 2.1 and appropriate measures are taken.

## **2.6 Waste labelling and tracking**

- 2.6.1 Containers shall be adequately and securely labelled at all times so that the producer, source of the wastes, contents and date of receipt can be identified.
- 2.6.2 The operator shall maintain a tracking system which can identify wastes prior to their onward dispatch.

## **2.7 Disinfection procedures**

- 2.7.1 The operator shall use appropriate measures to disinfect surfaces and static containers used for the storage of clinical and healthcare wastes.
- 2.7.2 All surfaces where waste is handled and stored shall allow effective disinfection.

# **3 – Emissions and monitoring**

## **3.1 Emissions of substances not controlled by emission limits**

- 3.1.1 Emissions of substances not controlled by emission limits (excluding odour) shall not cause pollution. The operator shall not be taken to have breached this rule if appropriate measures, including, but not limited to, those specified in any approved emissions management plan, have been taken to prevent or where that is not practicable, to minimise, those emissions.
- 3.1.2 The operator shall:
  - (a) if notified by Natural Resources Wales that the activities are giving rise to pollution, submit to Natural Resources Wales for approval within the period specified, an emissions management plan;
  - (b) implement the approved emissions management plan, from the date of approval, unless otherwise agreed in writing by Natural Resources Wales.
- 3.1.3 All liquids in containers, whose emission to water or land could cause pollution, shall be provided with secondary containment, unless the operator has used other appropriate measures to prevent or where that is not practicable, to minimise, leakage and spillage from the primary container.

## **3.2 Odour**

- 3.2.1 Emissions from the activities shall be free from odour at levels likely to cause pollution outside the site, as perceived by an authorised officer of Natural Resources Wales, unless the operator has used appropriate measures, including, but not limited to, those specified in any approved odour management plan, to prevent or where that is not practicable, to minimise, the odour.

- 3.2.2 The operator shall:
- (a) maintain and implement an odour management plan;
  - (b) if notified by Natural Resources Wales that the activities are giving rise to pollution outside the site due to odour, submit to Natural Resources Wales for approval within the specified period, a revised odour management plan;
  - (c) implement any approved revised odour management plan from the date of approval, unless otherwise agreed in writing by Natural Resources Wales.

### **3.3 Noise and vibration**

3.3.1 Emissions from the activities shall be free from noise and vibration at levels likely to cause pollution outside the site, as perceived by an authorised officer of Natural Resources Wales, unless the operator has used appropriate measures, including, but not limited to, those specified in any approved noise and vibration management plan, to prevent or where that is not practicable, to minimise, the noise and vibration.

- 3.3.2 The operator shall:
- (a) if notified by Natural Resources Wales that the activities are giving rise to pollution outside the site due to noise and vibration, submit to Natural Resources Wales for approval within the period specified, a noise and vibration management plan;
  - (b) implement the approved noise and vibration management plan, from the date of approval, unless otherwise agreed in writing by Natural Resources Wales.

## **4 – Information**

### **4.1 Records**

- 4.1.1 All records required to be made by these standard rules shall:
- (a) be legible;
  - (b) be made as soon as reasonably practicable;
  - (c) if amended, be amended in such a way that the original and any subsequent amendments remain legible or are capable of retrieval; and
  - (d) be retained, unless otherwise agreed by Natural Resources Wales, for at least 6 years from the date when the records were made, or in the case of the following records until permit surrender:
    - (i) off-site environmental effects; and
    - (ii) matters which affect the condition of land and groundwater.

4.1.2 The operator shall keep on site all records, plans and the management system required to be maintained by these standard rules, unless otherwise agreed in writing by Natural Resources Wales.

### **4.2 Reporting**

- 4.2.1 The operator shall send all reports and notifications required by these standard rules to Natural Resources Wales using the contact details supplied in writing by Natural Resources Wales.
- 4.2.2 Within one month of the end of each quarter, the operator shall submit to Natural Resources Wales using the form made available for the purpose, the information specified on the form relating to the site and the waste accepted and removed from it during the previous quarter.

## 4.3 Notifications

- 4.3.1 Natural Resources Wales shall be notified without delay following the detection of:
- (a) any malfunction, breakdown or failure of equipment or techniques, accident or emission of a substance not controlled by an emission limit which has caused, is causing or may cause significant pollution;
  - (b) the breach of a limit specified in these standard rules; or
  - (c) any significant adverse environmental effects.
- 4.3.2 Written confirmation of actual or potential pollution incidents and breaches of emission limits shall be submitted within 24 hours.
- 4.3.3 Where Natural Resources Wales has requested in writing that it shall be notified when the operator is to undertake monitoring and/or spot sampling, the operator shall inform Natural Resources Wales when the relevant monitoring and/or spot sampling is to take place. The operator shall provide this information to Natural Resources Wales at least 14 days before the date the monitoring is to be undertaken.
- 4.3.4 Natural Resources Wales shall be notified within 14 days of the occurrence of the following matters except where such disclosure is prohibited by Stock Exchange rules:
- a) Where the operator is a registered company:
    - any change in the operator's trading name, registered name or registered office address; and
    - any steps taken with a view to the operator going into administration, entering into a company voluntary arrangement or being wound up.
  - b) Where the operator is a corporate body other than a registered company:
    - any change in the operator's name or address; and
    - any steps taken with a view to the dissolution of the operator.
  - c) In any other case:
    - the death of any of the named operators (where the operator consists of more than one named individual);
    - any change in the operator's name(s) or address(es); and
    - any steps taken with a view to the operator, or any one of them, going into bankruptcy, entering into a composition or arrangement with creditors, or, in the case them being in a partnership, dissolving the partnership.

## 4.4 Interpretation

- 4.4.1 In these standard rules the expressions listed below shall have the meaning given.
- 4.4.2 In these standard rules references to reports and notifications mean written reports and notifications, except when reference is being made to notification being made "without delay", in which case it may be provided by telephone.

*"accident"* means an accident that may result in pollution.

*"Annex I"* means Annex I to Directive 2008/98/EC of the European Parliament and of the Council on waste.

*"Annex II"* means Annex II to Directive 2008/98/EC of the European Parliament and of the Council on waste.



*“authorised officer”* means any person authorised by Natural Resources Wales under section 108(1) of The Environment Act 1995 to exercise, in accordance with the terms of any such authorisation, any power specified in Section 108(4) of that Act.

*“building”* means a construction that has the objective of providing sheltering cover and minimising emissions of noise, particulate matter, odour and litter.

*“clinical waste”* has the meaning given in The Controlled Waste (England and Wales) Regulations 2012 as waste from a healthcare activity (including veterinary healthcare) that—

(a) contains viable micro-organisms or their toxins which are known or reliably believed to cause disease in humans or other living organisms,

(b) contains or is contaminated with a medicine that contains a biologically active pharmaceutical agent, or

(c) is a sharp, or a body fluid or other biological material (including human and animal tissue) containing or contaminated with a dangerous substance within the meaning of Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances,

and waste of a similar nature from a non-healthcare activity.

*“cytotoxic and cytostatic medicines”* means any medicinal product that possesses one or more of the hazardous properties H6 Toxic, H7 Carcinogenic, H10 Toxic for Reproduction and H11 Mutagenic.

*“D”* means a disposal operation provided for in Annex I to Directive 2008/98/EC of the European Parliament and of the Council on waste.

*“emissions of substances not controlled by emission limits”* means emissions of substances to air, water or land from the activities, either from emission points specified in these standard rules or from other localised or diffuse sources, which are not controlled by an emission limit.

*“European Site”* means Special Area of Conservation or candidate Special Area of Conservation or Special Protection Area or proposed Special Protection Area in England and Wales, within the meaning of Council Directives 79/409/EEC on the conservation of wild birds and 92/43/EEC on the conservation of natural habitats and of wild flora and fauna and the Conservation (Natural Habitats &c) Regulations 1994. Internationally designated Ramsar sites are dealt with in the same way as European sites as a matter of government policy and for the purpose of these rules will be considered as a European Site.

*“groundwater”* means all water, which is below the surface of the ground in the saturation zone and in direct contact with the ground or subsoil.

*“hazardous property”* has the meaning in Annex III of the Waste Framework Directive.

*“hazardous substance”* means a substance classified as hazardous as a consequence of fulfilling the criteria laid down in parts 2 to 5 of Annex I to Regulation (EC) No 1272/2008.

*“hazardous waste”* has the meaning given in the Hazardous Waste (Wales) Regulations 2005 (as amended).

*“healthcare waste”* means a waste classified under Chapter 18 of the List of Wastes, which is waste from Human and Animal Health Care and/or Related Research.

*“impermeable surface”* means a surface or pavement constructed and maintained to a standard sufficient to prevent the transmission of liquids beyond the pavement surface, and should be read in conjunction with the term “sealed drainage system” (below).

*“mixing of hazardous waste”* means mixing hazardous waste as defined by Regulation 18 of the Hazardous Waste (England and Wales) Regulations 2005.

*“Natural Resources Wales”* means the Natural Resources Body for Wales established by article 3 of the Natural Resources Body for Wales (Establishment) Order 2012. The Natural Resources Body for Wales (Functions) Order 2013 transferred the relevant functions of the Countryside Council for Wales, and

functions of the Environment Agency and the Forestry Commission in Wales to the Natural Resources Body for Wales.

"*pollution*" means emissions as a result of human activity which may—

- (a) be harmful to human health or the quality of the environment,
- (b) cause offence to a human sense,
- (c) result in damage to material property, or
- (d) impair or interfere with amenities and other legitimate uses of the environment.

"*quarter*" means a calendar year quarter commencing on 1 January, 1 April, 1 July or 1 October.

"*R*" means a recovery operation provided for in Annex II to Directive 2008/98/EC of the European Parliament and of the Council on waste.

"*requirements for carriage*" means the requirements of the current Carriage Regulations, which implement the ADR.

"*sealed container*" means a container which is fully enclosed, weather proof, does not allow any solid or liquid content to escape and is lockable.

"*sealed drainage system*" in relation to an impermeable surface, means a drainage system with impermeable components which does not leak and which will ensure that:

- (a) no liquid will run off the surface otherwise than via the system;
- (b) except where they may lawfully be discharged to foul sewer, all liquids entering the system are collected in a sealed sump.

"*sharps*" means items that could cause cuts or puncture wounds. They include needles, hypodermic needles, scalpels and other blades, knives, infusion sets, saws, broken glass, and nails.

"*SSSI*" means Site of Special Scientific Interest within the meaning of the Wildlife and Countryside Act 1981 (as amended by the Countryside and Rights of Way Act 2000).

"*waste acceptance*": appropriate measures to determine if waste is of a type and quantity listed in table 2.2 and conforms to the description in the documentation supplied by the producer and holder are set out in Environment Agency guidance EPR 5.07 Version 1.0.

"*Waste code*" means the six digit code referable to a type of waste in accordance with the list of wastes established by Commission Decision 2000/532/EC as amended from time to time (the 'List of Wastes Decision') and in relation to hazardous waste, includes the asterisk.

"*year*" means calendar year commencing on 1<sup>st</sup> January.

**End of standard rules**