Healthcare waste guidance - a summary of consultation responses

February 2020

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1. Introduction

The purpose of this consultation was to engage with relevant stakeholders to obtain their views on draft technical guidance. The guidance sets out the appropriate measures for permitted facilities that transfer or treat healthcare waste, including waste incineration plant.

Currently, relevant measures and standards for permitted facilities that take healthcare waste for treatment or transfer are set out in published technical guidance note EPR 5.07 Clinical Waste (January 2011). The proposed draft guidance will replace this guidance note and will be available as web guidance on the gov.uk website.

The guidance aims to achieve improvements in the design and operation of permitted facilities in the healthcare waste sector. It will also ensure that, where relevant, appropriate measures are applied consistently. The guidance also incorporates the relevant requirements of the waste treatment BAT Conclusions, made under the European Industrial Emission Directive (2010/75/EU), which apply to waste installation facilities permitted under the Directive.

An early pre-consultation version of the draft guidance was shared with key stakeholders in March 2019, to obtain initial comments and concerns, which fed into the preparation of the formal consultation.

Unless specifically stated in the guidance, the appropriate measures set out will apply to all permitted waste facilities that accept healthcare waste for transfer or treatment, including both waste installation and waste operation facilities.

Once published the guidance will apply to new permitted or substantially changed healthcare waste management facilities from the date of publication. We will implement this through the environmental permit application process. The guidance will also apply to existing healthcare waste management facilities through a process of permit review.

The existing Standard Rules that apply to operations involving the treatment or transfer of healthcare waste will be reviewed once the revised guidance has been published. This will ensure they provide an appropriate level of environmental protection and require appropriate measures and standards to be met.

2. How we ran the consultation

An early pre-consultation draft version of the guidance was shared with key stakeholders in March 2019. This was to obtain initial comments and concerns. These fed into the preparation of this guidance for the formal online consultation.

We ran the formal online consultation on the Environment Agency Citizen Space website for 6 weeks, from Monday 3rd June 2019 until Monday 15th July.

The consultation asked 11 questions relating to specific aspects of the draft guidance (Q5 - Q15 of the consultation) and also asked for any additional comments.

We received 15 responses to the questions asked by the online consultation. However, not all responses provided an answer to all of the questions asked.

We received 9 responses were from operators of healthcare waste management facilities. We also received:

- 2 responses from county councils
- 1 response from an NHS Trust
- 1 response from a trade association
- 1 response from a local authority national association
- 1 response from a consultancy

We received 2 additional responses by email from non-governmental organisations. These were manually uploaded to the Citizen Space website.

A list of the names of the organisations that responded to the consultation is provided in the Annex at the end of this document.

3. Summary of main findings and actions we will take

- The general management sections of the guidance were largely derived from the new Waste Treatment BAT Reference document and associated BAT Conclusions document. The majority of respondents agreed that the measures set out in this section were appropriate to facilities that store or treat healthcare wastes. The relevance of individual measures set out in this section will need to be determined on a site by site basis (for example, measures relating to the management of incompatible wastes would only need to be met if a facility is permitted to accept such wastes).
- We have considered the consultation responses, and taken into account the nature and composition of healthcare wastes and the way that it is stored and handled. As a result, we have revised the guidance to confirm that the accident and fire prevention measures provided in the guidance are appropriate for the management of healthcare waste. If other non-hazardous combustible wastes are stored at a facility then a fire prevention plan that meets the requirements of our fire prevention guidance may be required.
- Following consideration of the consultation responses received, we have revised the guidance to remove the specific requirement to check the labelling on all loose packaged items received. We have replaced this measure with a requirement to ensure that all waste can be tracked back to relevant waste acceptance records and documentation. This is in line with the current requirements of EPR5.07. The requirement for all healthcare waste bags and containers to be labelled remains a requirement of the current Department for Health guidance HTM 07 01.
- Following consideration of the consultation responses received, we remain of the view that the storage of clinical waste in a building represents Best Available Techniques (BAT) and is an appropriate measure. Storage of clinical waste in a building ensures that hazardous chemical and infectious wastes are stored safely and securely and potential emissions (for example, odour) are minimised and contained. We expect new facilities (permitted following the publication of the guidance) to be designed to satisfy this requirement from the commencement of operations. We expect existing facilities to work to achieve this requirement to an agreed timeframe. At facilities where the provision of storage buildings for infectious clinical waste is not economically or technically viable this must be justified. It must also be demonstrated that the measures in place at (or proposed for) the facility provide an equivalent level of environmental protection. Offensive waste and treated wastes (for example, autoclave floc material) should be stored in a building or in fully enclosed containers.
- Following consideration of the consultation responses received, we have revised the appropriate measures contained in the guidance for the storage of odorous wastes. The section of the guidance on fugitive emissions to air (for example, dust and odour) has been revised. It explains where the storage of odorous or dusty waste in an abated building is one of a range of measures that should be employed where it is necessary to control fugitive emissions to air. This means that the onus will be on the operator of the facility, based upon a site-specific risk assessment, to propose what measures are appropriate.
- The use of pallets for the storage and handling of rigid waste containers was widely supported by the consultation responses received. The use of pallets for these wastes

will be included in the guidance along with conditions for their use (including a revised maximum 2.2m stack height for palletised containers).

- The majority of consultation responses agreed it is important that wastes are stored in a way that ensures they can be easily and safely accessed for inspection and handling purposes. However, concerns were expressed that requiring all carts to be arranged in rows could significantly reduce the storage capacity of a site. Taking the consultation comments into account, we have revised the guidance. It states that all bulk waste containers must be stored in a way that allows safe and easy access for inspection at all times and minimises the need to remove others that may be blocking access. The guidance will also say that safe access (inspection aisles) must be maintained to at least one side of palletised wastes. This is consistent with existing technical guidance for other packaged hazardous waste (for example, EPR 5.06 Recovery and disposal of hazardous and non-hazardous waste).
- We have considered the consultation comments received and have increased the maximum storage duration from 7 to 14 days for infectious and offensive waste where it is stored within a building. The maximum duration will remain 7 days for waste stored outside. The guidance will also be revised to state that anatomical waste can be stored for up to 14 days in refrigerated storage, and no more than 24 hours (or 72 hours if over a weekend) if without refrigeration, provided there are no odour issues.
- Following the consultation comments, we have revised the section on chemical emissions to air. It only specifically includes dust and volatile organic compounds, which have monitoring requirements and limits; removing ammonia, which only had monitoring requirements. The section has also been revised to make it clear that the monitoring requirements and limits for these parameters only apply if they are identified as being relevant on a site-specific basis. This is based upon a facility's emissions inventory and environmental risk assessment (that is, if a substance is not emitted or is emitted in environmentally insignificant concentrations then the limits and monitoring requirements are unlikely to apply).
- Our current technical guidance on the management of clinical waste (EPR 5.07) applies the same requirements (appropriate measures) to waste installation and waste operation facilities, with the exception of the measures for waste pre-acceptance and acceptance. The majority of consultation responses agreed that the appropriate measures for waste pre-acceptance and acceptance should apply both to waste installation and waste operation facilities. The guidance makes it clear that the appropriate measures apply to both types of regulated facility.
- A wide range of additional comments were received in response to the consultation (Question 16 of the consultation). These have been summarised in this document along with the way they have been considered in the context of the healthcare waste guidance document.

4. Responses to consultation questions (5 to 16) and our response to these

Q5.

The General Management section of the draft guidance is generic to the waste treatment sector. Are there any additional measures relating to this section that you think we should include for the healthcare waste sector?

Summary of responses to question

- **Yes: 5**
- **No: 8**
- **Do not know: 1**

The majority of respondents (8) answered 'no' to this question; that there are no additional measures needed in the General Management section of the draft guidance. A number of respondents suggested additional measures could be included relating to sector-wide contingency measures. However, we have considered this and while we agree that it is an important issue we concluded that this would be outside the remit of the guidance. It is applicable to the operation of regulated facilities on a site-specific basis.

Q6.

Are there any measures included in the General Management section that you feel are not relevant to the healthcare waste sector?

Summary of responses to question

- **Yes: 5**
- **No: 10**
- **Do not know: 1**

The majority of respondents (10) answered 'no' to this question; that there are no measures included in the guidance that are not relevant to regulated facilities operating in the healthcare waste management sector.

A number of comments were made stating that some of the measures (for example, relating to incompatible wastes, or other hazardous chemicals) might not be relevant to individual sites. However, whether a measure is relevant to a site would need to be assessed on a site specific basis. Where it is not relevant (for example, because no hazardous or potentially incompatible chemicals are stored) at a specific site then the requirements would not be relevant. Therefore would not need to be complied with. Some comments were received questioning the requirement for sites to collect and contain firewater and other effluents. However, we consider this to be an appropriate requirement for all permitted facilities to protect the environment and prevent pollution. This is also referred to in Section 2.3.13 of the Waste Treatment BAT Reference document.

Q7.

Do you think that the Fire Prevention Plan (FPP) guidance should apply to the storage of non-hazardous healthcare wastes at permitted healthcare waste facilities (for example, treated and untreated offensive wastes, treated floc material)?

Summary of responses to question

- **Yes: 6**
- **No: 7**
- **Do not know: 0**

We received a mixed response to this question. 6 respondents answered 'yes'; that healthcare waste facilities should be required to have an approved Fire Prevention Plan, and 7 respondents answered 'no', that they should not be required to have one.

The majority of comments received in relation to this refer to the nature of healthcare waste (for example, its high moisture content). Also that the waste is packaged or containerised and not stored in loose form. Having considered the responses received, the nature of healthcare waste and the way that it is stored and handled on-site, we have revised the guidance to state that the fire prevention measures specified in this guidance are considered appropriate measures for this waste. However, if a permit authorises an operator to carry out an activity involving the storage of other non-hazardous combustible waste, they may need an approved fire prevention plan that meets the requirements of our guidance. This approach is consistent with that applied to the management of other hazardous wastes. We will review the guidance and this position regarding the applicability of the FPP guidance to healthcare waste in light of any future incidents in the healthcare waste management sector that involve fire.

Q8.

Chapter 5 of HTM 07 01 (Safe Management of Healthcare Waste) requires that containers and bags are tagged or labelled in order to identify the original producer and states that it is not sufficient to label bulk containers alone. Do you think the proposed requirement to check the labelling on every loose packaged item is appropriate?

Summary of responses to question

- **Yes: 4**
- **No: 10**
- **Do not know: 0**

The majority of respondents (10) answered 'no' to this question, that checking the labelling on every loose packaged item received is not an appropriate measure. In light of the consultation comments received and the implementation of the national waste tracking project, we have revised the guidance to temporarily remove this requirement. We have replaced this measure with a requirement to ensure that all waste can be tracked back to relevant waste acceptance records and documentation. This is in line with the current requirements of EPR5.07. We do support the requirement for all healthcare waste bags and containers to be labelled, as required by the Department for Health guidance HTM 07 01.

Q9.

Do you think that the storage and handling of healthcare waste in a building represents best practice and is an appropriate measure?

Summary of responses to question

– **Yes: 2**

– **No: 13**

– **Do not know: 0**

The majority of respondents (13) answered 'no', that storage of healthcare waste in a building is not an appropriate measure.

In summary, those respondents who did not agree with the use of storage buildings for all healthcare waste said that it represented 'gold plating' and was:

- not supported by the new BREF document
- would not be viable at some existing sites
- would require significant investment to implement, which would be passed on to the NHS or other customers

They stated that the requirements should be risk-based and site specific.

We remain of the view that the storage of clinical waste in a building represents BAT and is an appropriate measure. Storage in a building helps to ensure that hazardous chemical and infectious wastes are stored safely and securely. It also improves the control of potential emissions (including odour), prevention of pests, containment of leaks and spillages, and surface disinfection.

However, taking the consultation comments into account, we have revised the appropriate measures for waste storage. We state that at existing facilities infectious waste must be stored in a building (along with pharmaceutical, anatomical and chemical wastes). This is unless it is not technically or economically feasible and alternative storage arrangements provide an equivalent level of environmental protection, supported by an appropriate site-specific environmental risk assessment. This is in recognition that at some existing healthcare waste management facilities, it may not be feasible to retrospectively construct buildings (due to technical restrictions, including planning permission).

We would expect all new facilities to be designed to ensure that all clinical waste can be stored and handled in a building. The guidance also states that facilities are able to store non-hazardous offensive waste and treated waste output materials (for example, autoclave floc) in a building or outside. This is as long as it is stored securely in rigid, enclosed, waterproof and leak-proof containers. At existing facilities, a timetable would need to be agreed for any necessary improvements needed to meet these requirements, taking into account the level of infrastructure and investment that may be necessary.

Q10.

Do you think that the storage, handling and treatment of odorous and dusty wastes in a building with fast acting doors and a suitable air circulation, extraction and abatement system represents best practice and is an appropriate measure?

Summary of responses to question

- **Yes: 3**
- **No: 11**
- **Do not know: 0**

The majority of respondents (11) answered 'no', that the storage of odorous and dusty healthcare wastes in an extracted and abated building is not an appropriate measure.

In response to the consultation comments received, we have revised the appropriate measures contained in the guidance for the storage of odorous wastes. The section of the guidance on fugitive emissions to air (for example, dust and odour) has been revised to include the storage of odorous or dusty waste in an abated building as one of a range of measures that should be employed, where it is necessary to control fugitive emissions to air.

This means that the operator of the facility will be required to decide and justify what measures are appropriate to take and when (that is, based upon a site-specific risk assessment), taking site history into account and the risk of odour posed by the facility.

The guidance confirms that the determination of whether a waste is odorous or not would need to be made by an operator, in accordance with their waste pre-acceptance and acceptance procedures, or during site inspection. At existing facilities, a timetable would need to be agreed for any necessary improvements needed to meet these requirements, taking into account the level of infrastructure and investment that may be necessary.

Q11.

Do you think that the use of pallets (secured with clear shrink-wrap) is an appropriate measure for the safe storage and handling of these wastes?

Summary of responses to question

- **Yes: 9**
- **No: 3**
- **Do not know: 1**

The majority of respondents (9) answered 'yes', that the storage and handling of healthcare wastes received in rigid containers on pallets is an appropriate measure.

The guidance sets out the relevant requirements that must be met when wastes are stored and handled on pallets. That is, the containers must be stable, not over-hanging the edge of the pallet and must be secured with clear shrink-wrap. The draft guidance stated that containers should be stack no more than 1.8 metres high. A number of consultation comments requested that this maximum height is increased to 2.2 metres, as long as the stacked containers remain stable and secure, and this has been reflected in the guidance.

Q12.

Do you think that the storage of pallets and carts of waste in rows, which ensure that they are accessible and can be identified and inspected, is an appropriate measure?

Summary of responses to question

- **Yes: 8**

– **No: 6**

– **Do not know: 0**

The majority of respondents (8) answered 'yes', that the storage of pallets and carts containing waste in rows, is an appropriate measure, and 6 respondents answered 'no' that it is not.

The majority of consultation responses agreed it is important that wastes are stored in a way that ensures they can be accessed for inspection and handling purposes. Concerns were expressed that requiring all carts to be arrange in rows could significantly reduce the storage capacity of a site. Taking the consultation comments into account, we have revised the guidance. It states that all bulk waste containers must be stored in a way that allows safe and easy access for inspection at all times. Also to minimise the need to remove others that may be blocking access. The guidance also requires that safe access (inspection aisles) must be maintained to at least one side of palletised wastes, which is consistent with existing technical guidance for other packaged hazardous waste (EPR 5.06).

Q13.

Do you think that the maximum storage times provided in the draft guidance are appropriate and achievable during normal operations?

Summary of responses to question

– **Yes: 7**

– **No: 8**

– **Do not know: 0**

We received a mixed response to this question, with 7 respondents answering 'yes' that the proposed maximum storage durations are appropriate, and 8 answering 'no' that they are not.

Managing the time that waste is stored at a facility is important, to prevent accumulation or abandonment of old waste and the associated issues this may cause, such as odour, pests, over-crowded sites. Waste should be managed in a way that ensures it is treated or transferred off-site as soon as a viable load is achieved and following the principle of first-in, first-out. According to the World Health Organisation (WHO) guidance on healthcare waste, in temperate climates, it is recommended that infectious waste is not stored for more than 72 hours in winter and 48 hours in summer prior to treatment, if it is not refrigerated.

We have considered the consultation comments received and have increased the maximum storage duration from 7 to 14 days for infectious and offensive waste where it is stored within a building. The maximum duration for waste stored outside remains 7 days. The extended storage time for wastes stored in a building reflects the lower potential risk posed by the waste, for example, as a result of improved security, control of potential emissions (including odour) and prevention of pests.

We have revised the guidance to state that anatomical waste can be stored for up to 14 days in refrigerated storage, and no more than 24 hours if without refrigeration (or 72 hours if over a weekend).

Following the consultation, we have also included storage times in the guidance for waste produced by alternative treatment plant (for example, autoclave floc), which are consistent with those provided for offensive wastes.

These timescales are consistent with recent permits and variations issued in the sector. They are also consistent with the timescales applied by other competent authorities (for example, SEPA).

At existing facilities a timetable would need to be agreed for any necessary improvements needed to meet these requirements. It would need to take into account the level of change and investment that may be necessary.

Q14.

Do you think that the parameters, monitoring requirements and limits provided in the draft guidance are appropriate for the healthcare waste treatment sector?

Summary of responses to question

- **Yes: 4**
- **No: 5**
- **Do not know: 5**

We received a mixed response to this question, with 4 respondents answering 'yes' that the proposed monitoring requirements and limits for certain parameters are appropriate, 5 answering 'no' that they are not, and 5 answering that they 'do not know'. In general, those who answered with the latter did not operate treatment plant.

Some consultation comments agreed that providing monitoring requirements and emissions limits for certain non-microbial pollutants would be helpful. Others questioned the value of monitoring requirements when no limits are identified.

Following the consultation comments, we have revised the section on chemical emissions to air. It now only specifically includes dust and volatile organic compounds, which have associated monitoring requirements and limits; removing ammonia, which only had monitoring requirements.

The section has also been revised to make it clearer that the monitoring requirements and limits for these parameters only apply if they are identified as being relevant on a site-specific basis. This is based upon a facility's emissions inventory and environmental risk assessment. That is, if a substance is not emitted or is emitted in environmentally insignificant concentrations then the limits and monitoring requirements are unlikely to apply. Where the substances are emitted, the emission limits are provided as concentrations associated with the use of BAT for their abatement and to help ensure that a consistent approach is taken across the healthcare waste management sector. The limits proposed in the guidance are not mandatory and limits may be set in permits higher or lower than those in the guidance based upon an appropriate environmental risk assessment. The guidance also explains that where chemical or chemically contaminated wastes are not treated it is unlikely that any chemical monitoring or limits will be required.

Some comments were made that questioned the appropriateness of the monitoring methods and standards given for the parameters. The methods and standards have been checked and confirmed as being correct.

Q15. Do you think that the appropriate measures for waste pre-acceptance and acceptance should apply to all healthcare waste transfer facilities (waste installation and waste operation facilities)?

Summary of responses to question

- **Yes: 8**
- **No: 4**
- **Do not know: 1**

The majority of respondents (8) answered 'yes' to this question; that the appropriate measures for waste pre-acceptance and acceptance should apply to all regulated healthcare waste facilities.

The guidance makes it clear that the appropriate measures for waste pre-acceptance and acceptance apply to both types of regulated waste transfer facility (waste installation and waste operation).

Q16 Please tell us if you have any further comments

Further comments received that have not been considered in response to the specific consultation questions are summarised below, along with our response to them.

1. **Summary of comment(s) received**

It is not practical for pre-shredded material to be kept within an abated system at all times, the guidance should consider alternatives for example, lidded cover or risk assessment. Limits innovation.

Response

The guidance has been amended in response to the consultation comments. It removes the requirement for material to be kept within a contained and abated system at all times. However, containment of material and potential emissions from it will be required and the efficacy of this will need to be demonstrated through emissions monitoring.

2. **Summary of comment(s) received**

A permit provides storage and treatment capacity (tonnage) which could be verified at site and easily enforced instead of cart or container numbers.

Response

The appropriate measure in question, is regarding the management of waste in a way that helps to check and ensure that the site storage capacity of a facility, or storage area, is not exceeded. Storage capacity is a key control measure for ensuring that waste is managed in an effective and efficient manner, and for preventing the accumulation of waste. A tonnage figure alone of lone density wastes can be hard to visualise and check, whereas defining the available storage space of a site or an area of a site in terms of cart/container number is an effective method for checking existing waste inventory and available capacity whilst on-site, for example during a site inspection.

3. **Summary of comment(s) received**

Checking individual labelling of bags would be overly burdensome for little gain, when it is going to be in a cart with a bar code.

Response

The guidance has been amended in response to the consultation comments received. It no longer requires all bags to be checked for labelling, however it does require the operator to be able to track any waste back to the corresponding waste acceptance information.

4. **Summary of comment(s) received**

Many of the measures for the chemical sector are being shoehorned into healthcare when they are very different.

Response

No specific measures included in the guidance have been identified as being irrelevant to the healthcare waste sector. Most requirements (for example, in the accident management section) only apply if relevant, based upon the type or nature of waste accepted at a facility.

5. **Summary of comment(s) received**

The guidance should clarify the difference between high temperature incineration (HTI) and clinical waste incineration (CWI) – are they the same thing?

Response

In response to the consultation comments received, the guidance has been amended to refer to 'incineration' and to remove the separate terms HTI and CWI. The guidance explains that higher incineration temperatures are required for cytotoxic and cytostatic clinical wastes or wastes with high chlorine content.

6. **Summary of comment(s) received**

Who decides if improvements at existing facilities will require small or larger capital and associated improvement timescales?

Response

Timescales for improvements would need to be justified by the operator based on the scale of the investment or change required and agreed with the Environment Agency through the permitting process.

7. **Summary of comment(s) received**

Existing technology systems do not allow the dual coding of waste. Labelling and packaging requirements are sufficient with dual coding. Dual coding should be replaced by a hierarchy or risk approach – for example, in terms of waste coding, cytotoxic properties override infectious.

Response

The requirement to use dual coding for certain wastes is not specific to this guidance or the healthcare waste sector and is therefore outside of the remit of this guidance. This guidance reflects the approach set out in other existing guidance documents, Safe

Management of Healthcare Waste HTM 07 01 and Waste Classification Technical Guidance WM3.

8. **Summary of comment(s) received**

Sharps waste in orange colour-coded packaging has been removed from Table 2 and changed to yellow packaging. This is incorrect.

Response

Sharps in orange colour-coded packaging are included in Table 2, through the written description of waste type (that is, 'may contain sharps').

9. **Summary of comment(s) received**

Reporting every non-conformance is supported but should be done following a tiered system – minor/major/critical – with interpretation to be agreed with the regulator.

Response

The guidance requires an operator to have a procedure for reporting non-conformances but does not specify the level of non-conformance that needs to be reported to the waste producer or regulator. This would be for the operator to clarify through their procedures

10.**Summary of comment(s) received**

We were not aware of this consultation until flagged by a contractor – the guidance will have an impact upon local authorities.

Response

We will ensure that we engage with the National Association of Waste Disposal Officers (NAWDO) where relevant in future correspondence and consultations.

11.**Summary of comment(s) received**

Not feasible for industry to operate without storage in trailers, it would not be an environmental improvement. Need to define 'imminent transportation'. Trailers meet the same objectives as storage in buildings, as they are leak proof and impermeable.

Response

The guidance confirms that waste should not be held in trailers unless it is being received or being prepared for imminent transfer. Imminent transfer has been defined in the guidance as transfer off-site within 24 hours, or 72 hours if over a weekend.

The storage of healthcare waste must be done in a way that ensures the requirements of the guidance can be met with regards to waste tracking and inspection. All waste must be available for inspection at all times it is stored on-site, by the operator, the regulator or producer audits. Whilst stored at a permitted waste facility, bagged waste should be stored in Eurocarts or similar containers that allow the inspection and tracking of waste and protect the integrity of packaging. Waste in rigid packaging can be stored in carts or on pallets, which again allow the waste to be inspected and tracked. We are unaware of ways to adequately identify and inspect waste once it has been loaded into a trailer. Therefore it

is only appropriate to keep waste in such an arrangement if it's for a short period of time upon arrival or in preparation for transfer.

Where the appropriate measures set out in the guidance cannot be met at an existing facility, a timetable for implementing improvements can be agreed. This will be between the operator and the Environment Agency, ensuring relevant requirements are met, taking into account the extent and cost of the changes required.

12.**Summary of comment(s) received**

How would you establish if a waste has a risk of radioactive contamination? The pre-acceptance audit may identify a producer using radioactive substances but if suitable systems are in place then this may not be a risk. If an appropriate system was not in place we would introduce one, rather than start checking for radioactive material.

Response

It would be up to the operator of a permitted facility to determine the level of risk of radioactive contamination associated with a waste or waste stream and the need for additional measures for the management of this waste. If an appropriate system is in place to confirm that waste does not contain radioactive material, then further checks may not be necessary. Where an operator identifies there is a risk of contamination, even with other control measures in place, then further checks would be required to confirm the presence of contamination during waste acceptance.

13.**Summary of comment(s) received**

Developing systems that track where a waste is on site entail significant costs. It is not clear what the benefits of such a system are given the size of facilities and the containerised nature of waste.

Response

The requirement to be able to track and identify where a waste is located on-site is an existing requirement of our clinical waste guidance (EPR 5.07). An operator should be able to identify where a waste is located on-site, whether it has been treated and transferred off-site, or is still in storage. If it is in storage, what storage area it is in, so that it can be located and retrieved if needed.

14.**Summary of comment(s) received**

Resolving discrepancies with consignments on receipt – what resolution or amendments would be acceptable under HWR (Hazardous Waste Regulations)?

Response

It would be for the operator to determine what discrepancies could be resolved with the waste producer based upon the specifics of the situation at hand. It may be possible to resolve relatively minor discrepancies in communication with the waste producer. However more significant discrepancies may not be resolvable, for example if they mean that the operator is unable to accept the waste (for example, if it is not a permitted waste).

15.**Summary of comment(s) received**

The guidance states that the repackaging or compaction of waste should be permitted as D14 or R12 waste operations. These were previously permitted as directly associated activities. It is requested that a pragmatic approach is taken to enforcement whilst permits are being updated.

Response

Permitted activities will be reviewed during the permit review process. We will take a pragmatic approach with regards to permit compliance until any inconsistencies have been resolved through this process.

16.**Summary of comment(s) received**

Will the requirement to assess stack height and dispersion apply to existing sites?

Response

The requirement will apply to new and existing sites. For new sites or activities, vent and stack heights should be assessed as part of the permit application process. For existing sites, it should be assessed as part of the permit review process and as part of relevant permit variation applications (for example, variations that involve changes to relevant emissions to air). An operator could also be required to review and assess the adequacy of emission dispersion as part of ongoing permit compliance activities at existing sites, for example, in response to an incident or complaints being received concerning emissions from the facility.

17.**Summary of comment(s) received**

Lockable carts are not appropriate if sites have high security – they increase handling and risk of injury. Is it necessary to securely close lid of cart if it contains bagged waste under cover?

Response

The use of closed and lockable carts or containers is an existing requirement of our clinical waste guidance note EPR 5.07. The updated guidance requires the lids of carts or containers to be closed and locked if stored externally.

18.**Summary of comment(s) received**

The guidance states that the different types of healthcare waste must not be mixed. Incinerators often need to mix/blend the types of waste prior to incineration to minimise emissions.

Response

The guidance has been amended to confirm that mixing of hazardous waste should not take place unless, and to the extent, authorised by the permit.

19.**Summary of comment(s) received**

Segregated storage is unworkable and not viable at certain facilities (waste incineration plant). Wastes listed for separate storage areas may be received in the same container or on same pallet – this would need to be manually handled increasing risk to operatives. Waste segregation should be by destination not waste type.

Response

Segregated storage is an existing requirement of our clinical waste guidance (EPR 5.07). Segregation of healthcare waste by the waste producer is also a requirement of HTM 07 01 and should be checked through waste pre-acceptance and acceptance procedures.

The segregation of waste set out in the guidance is by waste type, as well as the likely destination of the waste. The guidance requires that the different types of waste should be stored in separate containers or areas in order to provide segregation. Different waste types that go to the same destination may need to be segregated to prevent:

- damage to packaging (for example, bins and bags)
- the mixing of hazardous waste, cross-contamination between wastes and potential reactions between incompatible wastes (for example, chemicals, such as fixer and developer solutions)

20.**Summary of comment(s) received**

It would be difficult to check every single container for labelling, which would involve manual handling and increasing the risk to operatives; the statement needs clarity.

Response

The requirement to check individual packages has been amended in the guidance. We do not require checking of the labelling of every package/container to be checked. This is as long as an operator's waste tracking system can track the waste packages back to waste acceptance information.

21.**Summary of comment(s) received**

Specific consideration should be given to small volume collections from domestic properties and inherent differences between collecting this waste to that from commercial sources. Potential for disproportionate impacts.

Response

We have taken this into account through the amendments made to the guidance. For example, on the storage provisions at existing facilities and amendments to the maximum waste storage times. The introduction section of the guidance explains that an operator can propose alternative measures to those in the guidance if they achieve the same level of environmental protection. Or they can provide an explanation of why specific measures are not relevant.

22.**Summary of comment(s) received**

There is inconsistent use of the terms “healthcare waste” and “clinical waste” in the guidance – for example, in the section that defines frequency of audits.

Response

We have reviewed and amended the guidance to ensure that the terms are used appropriately and consistently.

23.**Summary of comment(s) received**

The guidance does not consider improvements to the industry or encourage new processes, instead it makes healthcare waste more difficult and expensive to manage – requiring new abatement, buildings, doors, storing less waste. It increases the risk of companies pulling out of the market.

Response

The guidance does allow for innovation and development in the healthcare waste sector. It also requires that permitted storage and treatment facilities have appropriate measures in place to protect human health and the environment. Many existing sites already meet these standards. We have taken comments made about increased costs into account as a result of this consultation. For example on the provision of storage buildings at existing facilities and odour abatement measures (as detailed in our response to consultation Questions 9 and 10), where operators can justify alternative measures.

The introduction section of the guidance explains that an operator can propose alternative measures to those in the guidance if they achieve the same level of environmental protection, or provide an explanation of why specific measures are not relevant.

Where the appropriate measures set out in the guidance cannot be met at an existing facility, the operator and the Environment Agency can agree a timetable for implementing improvements to meet the relevant requirements. We can take into account the extent and cost of the changes required.

24.**Summary of comment(s) received**

Standardising use of multiple European Waste Catalogue (EWC) codes and colour coding in the UK would be welcomed but would also take a long time to agree.

Response

The points raised are beyond the remit of the healthcare waste technical guidance. These would need considering and addressing in the context of other existing guidance. For example, Safe Management of Healthcare Waste HTM 07 01 and our technical waste classification guidance (WM3).

25.**Summary of comment(s) received**

The guidance should allow for innovative new technology for waste that currently requires high temperature incineration (HTI). The guidance should allow for the development of new technologies – for example, cold plasma oxidation. The guidance should not state that anatomical, medicinal/chemical waste must go for incineration.

Response

The forms of treatment identified in the guidance for the different types of healthcare waste are consistent with those listed in the Department of Health's guidance HTM 07 01 Safe Management of Healthcare Waste.

The guidance contains provisions for the alternative treatment of additional waste types, that is, other than orange bagged infectious wastes. These would be subject to the applicant or operator justifying and demonstrating that the proposed treatment process will provide effective and efficient treatment. This is explained in the introduction section of the guidance and in the section on waste treatment appropriate measures. We can review and

update the guidance, when necessary, to take into account future developments in the healthcare waste sector.

26.**Summary of comment(s) received**

Include reference in Table 2 (Types of Healthcare Waste) to potential reuse/recycling of single-use instruments.

Response

The table has been amended in the guidance to include single-use instruments.

27.**Summary of comment(s) received**

Appropriate measure 6 of the Waste acceptance section should refer to visually checking waste packages, not waste. Currently, it could be misinterpreted as meaning that the content of waste packages must be checked.

Response

We have amended the guidance to confirm that it is the waste packages that are to be visually checked, not the waste within the packages.

28.**Summary of comment(s) received**

Visual inspection of waste will not always be possible in waste reception.

Response

The guidance does not specify where or when the visual inspection of waste must take place prior to its treatment.

29.**Summary of comment(s) received**

Exclude offensive waste skips located in buildings from requirement to have a closed lid – otherwise contradicts requirement to minimise manual handling.

Response

We would expect all containers, including skips, to be closed or covered when waste is being stored in them, other than when waste is being loaded into or out of them. This is to contain and prevent any potential fugitive emissions to air, for example, odour. Also to help prevent items being inadvertently placed in them. This applies equally to waste stored in a building or outside.

30.**Summary of comment(s) received**

One frequently generated waste stream - “cytotoxic and cytostatic contaminated sharps”- is missing from the list of waste types provided in Table 2.

Response

We have amended the text of the table to include cytotoxic and cytostatic wastes that may contain sharps.

31.**Summary of comment(s) received**

Why is there a requirement for additional justification to be provided to send offensive waste to Alternative Treatment? Clinical infectious waste can be sent to Alternative treatment, why does offensive waste need a special permit to go? There is reference that is connected with emissions control. Is it possible to have a better explanation on that please?

Response

The requirements in the guidance regarding the alternative treatment of additional wastes, such as offensive wastes, anatomical and chemically or pharmaceutically contaminated wastes are in line with those set out in our existing clinical waste guidance (EPR 5.07). The purpose of treating clinical infectious waste through alternative treatment plant is usually to provide disinfection. Because offensive waste is not infectious, the purpose of treating this waste, through what is typically a thermal or chemical disinfection process, with the extra energy or raw material use, must be justified. The operator must also consider any impact the treatment of offensive waste could have upon emissions from the treatment process. For example, if the waste has a higher moisture content it could affect emissions to water or the potential for odorous emissions to air. Also, the treatment of other waste streams, for example, if treated together at the same time or in separate batches.

32.**Summary of comment(s) received**

It would be a good opportunity to encourage plants to plan shutdowns when other sites are still available. We recently had several off line at the same time for maintenance that resulted in serious pressure on waste producers.

Response

Whilst we recognise the benefits of the proposed measure, it is considered beyond the remit of this guidance to require a wider sector planned approach to planned plant shutdowns. We understand that operators do this routinely for planned shutdowns but cannot for unplanned events. The guidance is for the site specific management of waste and operation of facilities.

33.**Summary of comment(s) received**

Figure 1 actually shows red-lidded anatomical waste bins, not orange-lidded bins.

Response

We have amended the labelling of the photograph to refer to red-lidded bins.

34.**Summary of comment(s) received**

With regard to the statement that the bins are not stacked upright – the bins are each UN approved containers for solids. These containers do not require orientation arrows and therefore do not need to be stacked in a particular orientation. The stacking of the rigid bins within the bulk bin (acting as an overpack for transport) may not be necessary if the certificate of conformity does not require it.

Response

The requirement to store containers or bins upright has been taken forward from our existing clinical waste guidance (EPR5.07). It is general good practice to prevent the

release of contents (leakage) or damage to containers. However we appreciate that it may not be possible to ensure that containers are always kept upright. We have amended the guidance to require that they are kept upright as far as possible during storage and handling.

35.**Summary of comment(s) received**

Table 2 provides a packaging requirement for “non-infectious sharps, not contaminated with chemicals / medicines” – stating that they should go into the yellow waste stream. There is currently no yellow packaging available on the market that would be suitable as all are labelled with a biohazard diamond.

Response

We have updated the table in the guidance document so that it no longer requires this waste to be placed in yellow packaging.

36.**Summary of comment(s) received**

The guidance states that supporting evidence for the pre-acceptance audit requires the provision of safety data sheets for pharmaceuticals. Pharmaceuticals are exempt from the requirement of a Material Safety Data Sheet (MSDS) under EU legislation.

Response

We have amended the guidance to state that safety data sheets should be provided for pharmaceuticals if they are available.

37.**Summary of comment(s) received**

Not all rigid boxes have a ‘lid’. It would be better if the guidance referred to a “secure closure mechanism”.

Response

We have amended the guidance to include reference to containers that have lids or other secure closing mechanisms.

38.**Summary of comment(s) received**

The convention within scientific papers is to utilise italics for the Genus and species names, for example, *Bacillus atrophaeus* and *Geobacillus stearothermophilus*.

Response

We have amended the guidance document to include the correct use of italics, however italic text cannot be used on gov.uk website pages.

39.**Summary of comment(s) received**

The spore count numbers in the waste treatment validation section of the guidance should read 1 x 10^6 not 1 x 106.

Response

We have amended the guidance to include superscript formatting where relevant.

40.**Summary of comment(s) received**

The final section containing suggestions relating to the auditing of a hospital ward makes no mention of staff training.

Response

The section of the guidance on appropriate measures for waste pre-acceptance sets out the information that must be included in waste pre-acceptance audit reports. This includes information on the staff training provided at waste producer premises.

41.**Summary of comment(s) received**

Members often operate across borders – this can cause issues resulting from inconsistent waste classification and colour coding practices in other countries. Request consideration of national system of colour coding.

Response

The Environment Agency regulates facilities and producers in England, which we would expect to follow HTM 07 01 guidance for the coding and classification of healthcare waste. Whilst we recognise the potential benefits of a national system of colour coding, we consider this to be beyond scope of the technical guidance to deliver this. We have shared, and consulted on, our draft technical guidance with the other environmental regulators in the United Kingdom of Great Britain and Northern Ireland (that is, Scottish Environmental Protection Agency (SEPA), Natural Resources Wales (NRW) and Northern Ireland Environment Agency (NIEA)) in the hope that we work towards a consistent system.

42.**Summary of comment(s) received**

Some operators have 18 01 06 on their permits, for X-ray fluids (fixer and developer) – because this is a ‘healthcare waste chemical’ – not a waste from the photographic industry. If the Environment Agency has since taken a stance on using 09 codes for this, will it update permits?

Response

Chapter 09 codes are referred to in the HTM 07 01 guidance document (Safe Management of Healthcare Waste) for these wastes. We consider they provide the most appropriate descriptions for these waste types. Permits would require a variation to ensure that appropriate codes are included (for example, for storage and transfer activities involving these wastes). Where necessary, these changes can be requested and made as part of the permit review programme planned for the healthcare waste sector.

43.**Summary of comment(s) received**

An option is required in Table 2 of the guidance for 18 01 01 and 18 02 01 wastes to be placed in orange packaging - to facilitate the recycling of sharps that are not infectious and not contaminated with chemicals or medicines. Suggest that ‘or suitably approved alternative treatment’ is included in the table for 18 01 01 and 18 02 01 wastes.

Response

We have changed the colour code provided in the guidance so that it is consistent with HTM 07 01 - that is, no specific colour given. We have also provided additional text to state that this waste can go for disposal or recovery at a suitably authorised facility. It is unclear why this waste would require alternative treatment if it is uncontaminated and non-infectious and this would require further justification before it could be permitted.

44.**Summary of comment(s) received**

Municipal incinerators rarely have offensive waste codes on them so cannot accept this. The current sector issue has led to this type of waste being diverted to such sites with no apparent ill effect. It is questioned whether these codes could be added to incinerator plant permits on a routine basis.

Response

We have checked and believe that currently approximately 50% of the environmental permits for municipal waste incineration facilities include the waste codes for offensive wastes. They are therefore able to accept and burn it. Incinerator plant operators can, if they choose, apply to the Environment Agency to vary their permits to add the relevant waste codes for offensive wastes to their environmental permits if they do not currently have them. We also are aware of municipal waste incinerators that do not wish to accept offensive waste that have the code on the permit, due to poor segregation practices by the producer.

45.**Summary of comment(s) received**

Many operators use an electronic tracking system and the information is retained in that, not on the waste containers. It is suggested that this labelling is not required if a company has a functioning electronic tracking system.

Response

The guidance refers to the use of 'unique identifiers' as well as labels. A unique identifier would include bar codes, as employed by electronic tracking systems.

46.**Summary of comment(s) received**

It is requested that labelling of fast-flowing wheelie bins or carts is exempt as labels could need to be changed daily which is impractical.

Response

All carts or similar bulk containers must be either labelled or marked with a unique identifier for the waste to be tracked on-site. This is a requirement of the existing clinical waste guidance (EPR 5.07).

47.**Summary of comment(s) received**

Many of the smaller waste carriers could not accept the financial burden of implementing a barcode and scanning system and the impact of drivers having to scan bags one by one would not work logistically. It is suggested that operators can have a paper based system, electronic, or a mix of the two and this will work.

Response

The new Waste Treatment BREF and BAT Conclusions require facilities to have computerised waste tracking systems. We consider use of a computerised tracking system to be an appropriate measure. This is because it helps ensure accurate and up-to-date (live) records are kept at facilities of wastes accepted, stored, treated and transferred. It also enables copies of the records to be accessed and backed-up off-site. Tracking is usually done by cart (or similar bulk container) not by individual bags or containers. Existing sites that currently do not have computerised tracking systems would be able to agree an appropriate timescale with the Environment Agency for the development and implementation of such a system.

48.**Summary of comment(s) received**

It is suggested that double stacking well wrapped pallets is a stable way to store rigid containers of waste (for example, sharps bins).

Response

The maximum stack height for containers on pallets has been increased in line with consultation comments (to up to 2.2m high). Pallets should not be stacked unless held in a dedicated racking system, to ensure that the integrity of the packages at the base of the load is not compromised and the load remains stable.

49.**Summary of comment(s) received**

Some sites use jet washers that discharge to sewer for cleaning small quantities of carts, instead of purpose-built bin washers. This should be reflected in the guidance.

Response

The guidance does not specify how bins or carts are cleaned. Due to the potential nature of the residues that may be present in carts the guidance requires appropriate measures to be in place. This is to prevent fugitive emissions to air and for effluent to be discharged to sewer or sealed drainage. The guidance also states that sharps or medicines (for example, resulting from the washing of reusable sharps bins) must not be discharged to surface water, storm drainage or foul sewer.

50.**Summary of comment(s) received**

The guidance should be risk based and should not include "must do's".

Response

The introduction section of the guidance (When appropriate measures apply) explains that the guidance is risk based. It allows operators to propose alternative measures to those set out in the guidance. However, they need to justify and demonstrate that they are providing an equivalent level of environmental protection, based upon a site-specific risk assessment. Operators can also explain and justify why certain measures are not relevant, on a site-specific basis. To help provide consistent interpretation and application of the guidance, we have worded it so that the appropriate measures stated in the guidance 'must' be met if they are relevant and no alternative measures are proposed and agreed.

51.**Summary of comment(s) received**

The guidance should not require a list or diagram of wards and departments to be provided for waste pre-acceptance, specific processes producing waste should be covered by the other pre-acceptance procedures.

Response

The requirement to provide a list or diagram of the different wards and departments that are at a premises, and covered by a waste pre-acceptance audit, is a requirement of our current guidance (EPR 5.07). It is important that this information is provided, as the type of wards and departments at a premises is likely to be an indicator of the types of healthcare wastes that will be produced. It also means that at larger premises the scope of audits can be reduced to cover one-third of the units and departments per year, over a 3 year cycle. Without information detailing which wards and departments have been covered by a specific audit it would not be possible to confirm which wards and departments have or have not been audited.

52.**Summary of comment(s) received**

Public sector contracts are often let for 5 year durations. The guidance could require a full audit prior to year 1 then audits of 25% of the practice prior to years 2, 3, 4 and 5 and provide an equal level of environmental protection.

Response

The current guidance (EPR 5.07) allows for a third of a large medical practice to be audited per year following a satisfactory audit of the entire premises in the first year. We consider this to be reasonable and proportionate. Therefore we have included it as an appropriate measure in the updated healthcare waste guidance.

53.**Summary of comment(s) received**

Bulk container labelling requirements (when adding/removing waste from a container) do not provide additional environmental protection, therefore represent best practice, not an appropriate measure. If waste tracking can be provided by barcode this is an unnecessary additional cost, increasing use of resources (such as pens, paper) for additional labelling.

Response

The waste labelling requirements set out in the guidance are necessary to ensure that waste can be tracked. The labelling requirements in question only apply if waste packages are moved from one container or pallet to another. Without the ability to track such movements, where they occur, a waste tracking system would not be reliable. The guidance does not specify how the tracking system must be designed to record such movements or the way that the relevant containers and pallets are labelled or marked.

5. Next steps

Following consideration of the consultation responses received we will finalise the text of the guidance document for publication.

We will publish the finalised guidance on the gov.uk website.

So that the guidance is fully accessible and can be published on the website, we will convert the PDF document that was used for the consultation to HTML format.

Individuals who wish to follow up their responses, or points made within this document, in more detail are welcome to contact us (wastetreatment@environment-agency.gov.uk).

6. Annex

List of consultation respondents (by organisation name):

- Epsom and St Helier NHS Hospitals Trust
- Grundon Waste Management Ltd
- Hampshire County Council
- Initial Medical Services Ltd
- Leicester County Council
- Medisort Ltd
- Nation Association of Waste Disposal Officers (NAWDO)
- National Performance Advisory Group (NPAG)
- Sanitary Medical Disposal Services Association (SMDSA)
- Sharpsmart Ltd
- Stericycle (UK) Ltd
- Tradebe Healthcare National Ltd
- Wardell Armstrong LLP
- Wastecare Ltd

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