MEMO

TO:	Board of Directors	**FROM:**	Brian Donlon
CC:		**DATE:**	17 November, 2004

SUBJECT : Eco-Safe - Technical Committee Report on Objection to Proposed Decision - Reg. No. 54-1

Application details

Event	Issue Date(s)	Reminder(s)	Received
Article 14 (2) (b) (ii)	05/03/99		26/03/99, 04/05/99, 10/05/99
Article 14 (2) (a)	20/05/99		
Article 16	02/06/99 22/06/99		10/06/99 24/06/99, 02/07/99
Proposed decision	02/09/99		
Objections received	29/09/99 29/09/99		
Article 25(1) - Circulation of Objections	05/10/99		
Article 25(2) - Submissions on Objections	27/10/99		
Technical Committee discussions	26/11/99		

Objections received

Objection by Applicant	None
Objection by third parties	Two

Two third party objections were made to the proposed decision. Mr David Howell, 85 Thomond Road, Ballyfermot, Dublin 10 stated three grounds for objection and McHugh Consultants on behalf of Sterile Technologies Ireland Ltd., Unit 430 Western Industrial Estate, Naas Road, Dublin 12 objected on twenty-seven grounds in respect of the proposed decision on Eco-Safe Systems Ltd, Allied Industrial Estate, Kylemore Road, Co. Dublin. Eco-Safe Systems Ltd. made a reply to the latter in a letter to the Agency dated 27/10/99. A Technical Committee was established to consider the

objections made and any matters arising from Eco-Safe Systems Ltd's letter of 27/10/99. The Technical Committee's report is as follows.

This report is based on the findings of the Technical Committee which comprised of:

Brian Donlon, Inspector I (Chairperson)

Sara Kennelly, Inspector

Margaret Keegan, Inspector

The inspector dealing with the proposed decision was Donal Howley.

Objections

The objections were considered as detailed below:

Objection 1. Mr David Howell

Mr David Howell stated three grounds of objection.

Ground 1

The objector alleges that the disposal of radioactive waste is currently being carried out at the facility and that this was not mentioned in the application. The objection also states that there is no consent to discharge radioactive waste to foul sewer.

Technical Committee's Evaluation

Section 3(e) of the Waste Management Act, 1996 precludes radiological waste products from the requirements of the Act. As stated in the applicant's reply (27/10/99), the applicant has not commenced this activity - which is governed by legislation enforced by the Radiological Protection Institute of Ireland (RPII) - although the applicant has obtained a licence for the disposal of a restricted range of known radiological materials. Condition 5.4.2 of the PD requires proposals for dealing with radiological wastes where they have been indicated in the wastes considered acceptable under Condition 5.1. However, Condition 5.4.2 does not read correctly and the technical committee recommends that it be amended slightly as below.

Recommendation

*Amend Condition 5.4.2 to read "The licencee shall submit, prior to the commencement of waste activities on site, proposals for scanning the waste for radioactivity and procedures to be **undertaken** following the event that radioactivity is indicated",*

Ground 2

The objection asserts that under S.I. No. 311 of 1997 all drivers carrying radioactive waste should:

(i) have an appropriate Hazardous Chemical Training Cert. (which should be carried at all times); and

(ii) *completed additional specialised training for the transport of explosive substances and radioactive material.*

Technical Committee's Evaluation

This objection relates to legislation governing radioactive wastes which is under the remit of the RPII and is not a matter for the Agency.

Recommendation

No change

Ground 3

The objection contends that existing laboratory procedures undertaken in Ireland dictate that "such lab. waste", i.e. "highly infectious", must be treated first at the site it is generated before it is transported to any further treatment location.

Technical Committee's Evaluation

This objection is addressed below in the Technical Committee's Evaluation to Ground 5 of McHugh Consultants objection on behalf of Sterile Technologies Ireland Ltd.

Recommendation

See Ground 5 of McHugh Consultants objection on behalf of Sterile Technologies Ireland Ltd.

Objection by McHugh Consultants on behalf of Sterile Technologies Ireland Ltd.,

McHugh Consultants on behalf of Sterile Technologies Ireland Ltd objected on twenty-seven grounds.

Ground 1 (ref. 1.1 & 1.2)

The objection contends that the requirements of Section C - Existing Environment, in the application, were not satisfied as adequate information on the ambient environmental conditions would have included information on a radioactive waste activity asserted to be carried out on site.

Technical Committee's Evaluation

The activity referred to is not currently being undertaken and falls under the remit of the RPII (see Technical Committee's Evaluation to Ground 1 of Mr Howell's objection).

Recommendation

No change

Ground 2 (ref. 1.3)

The objection contends that no indication of the source of waste arisings has been provided.

Technical Committee's Evaluation

The licence specifies in Condition 5 how healthcare risk waste is to be accepted and treated at the facility. The applicant has stated that they made a commercial judgement that the Irish clinical waste sector could sustain a number of service providers.

Recommendation

No change

Ground 3 (ref. 1.4)

The objection contends that there are no formal procedures for the identification and proper preventative segregation of unsuitable waste streams. The lack of a regulatory obligation on the privately produced waste stream is highlighted.

Technical Committee's Evaluation

Condition 5.1 limits those wastes that can be accepted at the facility. The applicant is

therefore required to ensure that only those wastes approved for acceptance under for Condition 5.1 are accepted. The Technical Committee considers that a written declaration by all healthcare waste generators using the facility that they are aware of this requirement of this licence is needed.

Recommendation

Add to Condition 3.11 the following: ***(f) written declaration by each waste producer using the facility that they have been made aware of the conditions of this licence, in particular with regards to waste segregation.***

Ground 4 (ref. 1.5)

The objection contends that, in conjunction with Ground 3, there is the potential for incompatible waste stream elements to be mixed (e.g. cytotoxic and pharmaceutical wastes). It is also contended that there is no legal routing for unsuitable wastes arriving at the facility to alternative disposal locations in mainland Europe.

Technical Committee's Evaluation

The Technical Committee's Evaluation to Ground 3 is also relevant here. Condition 5.7 requires that all unacceptable wastes identified at the facility be immediately separated, stored in the designated quarantine store and at the earliest possible time removed to an appropriate facility. The Environmental Management Programme, required within six months of the date of grant of the licence (Condition 2.3), requires procedures for dealing with unacceptable wastes.

Recommendation

No change

Ground 5 (ref. 1.6 & 1.7)

The objection states that the wastes identified as being acceptable in Schedule H includes such wastes as "Non autoclaved laboratory wastes". It is requested that such wastes are deemed unacceptable at the facility, and as a minimum that Condition 3.1 be amended to include an additional item that is contained in the PD for licence application 40-1, i.e. ***"the acceptance of any waste which is unsuitable for treatment by the autoclave"****.*

Technical Committee's Evaluation

The list of acceptable wastes should be altered to specify that, in the case of laboratory wastes only those that have been autoclaved are acceptable. This should be included as a note to Schedule H1 under infectious waste to ensure that only lab waste that has been autoclaved be accepted.

With regard to uniformity of PDs, the Technical Committee consider that Condition 3.1 be amended to include the additional item mentioned above.

Recommendation

Include as a sub-condition under 3.1 the following:

(k) the acceptance of any waste which is unsuitable for treatment by the Autoclave

Amend Schedule H.1 to read:

2. Infectious(Note 1), where infectious waste is any healthcare waste known or clinically assessed to be at risk or being contaminated with	
(a)	**Any of the biological agents mentioned in Article 2(d) groups 3 and 4 or identified through the procedure set out in Article 3 of Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work; or**
(b)	**With other biological agents artificially cultivated to significantly elevated numbers**
Note 1: Laboratory waste e.g. cultures and clinical samples may only be accepted at the facility following prior autoclaving	

Ground 6 (ref. 1.8)

The objection states that there is no detail in the application identifying the proposed final disposal location of the treated waste, and that consequently this constitutes a failure to provide sufficient information in accordance with Article 12(n) of the Waste Management (Licensing) Regulations 1997.

Technical Committee's Evaluation

The applicant indicated in the application the intention to dispose of the waste at landfill. Condition 5.22 requires that the "*ultimate recovery or disposal facility for processed healthcare risk waste shall be agreed in advance with the Agency"*.

Recommendation

No change

Ground 7 (ref. 1.9)

The objection contends that the proposed technology has not received any technical vetting from the Department of Health and Children.

Technical Committee's Evaluation

The PD requires commissioning procedures to be undertaken, such that the highest level of treatment (i.e. level IV inactivation) of the waste is shown to be achieved, prior to the commencement of the waste activity at the facility. The commissioning tests and the ultimate process efficacy are covered in Conditions 5.13 and 5.14.2.

Recommendation

No change

Ground 8 (ref. 1.10)

The objection contends that the operation of the proposed treatment system will require manual handling of untreated waste product from the collection bins to special autoclave carts.

Technical Committee's Evaluation

The intention of the PD is that there should be no manual handling of the waste prior to treatment. The technical committee recommend that Condition 5.25 be added to Condition 5 to read as below

Recommendations

Add Condition 5.25 as follows: ***5.25 Emptying of the receptacles into autoclaves and the removal of treated waste from autoclaves shall be from date of grant of licence be automated.***

Ground 9 (ref. 1.11 & 1.12)

The objection contends that the regulatory requirement of packaging certain healthcare wastes in UN approved rigid leak proof containers means that, as the waste is not shredded until after the treatment process, the effectiveness of the treatment process is inhibited. Reference is made to sharps containers.

Technical Committee's Evaluation

See response to Ground 10.

Ground 10 (ref. 1.13)

The objection states that most countries that authorise non-burn technologies for hazardous waste treatment advocate shredding of the waste material and packaging prior to the treatment process as this ensures that the entire waste product is exposed to the treatment process.

Technical Committee's Evaluation

The Rotoclave is widely used in the US and a recent review paper (Malloy, 1997) stated that there are 17 such units operating in the US and 6 operating abroad and that 50 States in the US permit its use.

The *Rotoclave* consists of an autoclave chamber along with an internal rotating drum to which vanes/blades are attached. The premise of the *Rotoclave* is that the waste in the chamber is sterilised through the use of steam heat under pressure for a set period of time. The vanes/blades on the internal drum slice open boxes and bags and along with agitation from the rotation of the drum enable the surfaces to be exposed to the sterilising steam. Shredding of autoclave treated waste is optionally performed after the heat treatment process for all the autoclave models listed (Malloy, 1997).

Recommendation

No change

Ground 11 (ref. 1.14)

The objection contends, in the case of post shredding devices which are applied to wet autoclave systems, that:

(i) there tends to be release of odours to atmosphere with associated substantial risks and nuisance to the environment;

(ii) pathogens and particles may be released into the atmosphere from items in sealed containers, jars or other low pressure containment;

(iii) this compares unfavourably to systems which incorporate pre-shredding including a hopper device operating under negative pressure to prevent airborne escapes;

(iv) should the treatment process fail to successfully treat the waste, this will not be known at the time the waste is shredded;

(v) the proposed shredder is open to the environment without enclosure, negative pressure or HEPA filters.

Technical Committee's Evaluation

Conditions 6.3 and 6.4 relate to requirements regarding odours. However, the Technical Committee considers that control of the abatement treatment system should be covered in the licence by the inclusion of Tables F.4.3 and F.4.4 below.

As referred to in the Technical Committee's Evaluation to Ground 10, the premise of the technology is to sterilise waste through the use of steam heat under pressure for a set period of time in conjunction with the use of an internal rotating drum containing vanes/blades to enable contact of the steam with the waste surfaces. The shredders are fully enclosed (attachment D.2 of the waste licence application). The PD requires the applicant to submit a proposal to the Agency for its agreement, at least two months prior to the commencement of waste activities on site, to provide for the enclosure of the treated waste along the conveyor belt system which transfers the waste to the shredders and the compactor.

Recommendation

The following tables be inserted into Schedule F.4.

Abatement /Treatment Control

Table F.4.3 Monitoring at Emission Point 1 – Air Vent

Monitoring to be carried out	Monitoring	Monitoring Equipment
Set point pressure levels	Continuous	Pressure gauge with audible alarm
Filter Integrity	Daily "sniff test"	Not applicable
Filter Integrity	Visual Weekly Check	Not applicable

Table F.4.4 Equipment

Equipment	Equipment Maintenance	Equipment backup
Air Abatement Equipment	See Note 1	Spares as recommended by the manufacturer held on

		site

Note 1: Preventative maintenance as per manufacturers instruction

Ground 12 (ref. 1.15)

The objection contends that

(i) autoclaved waste which goes through a post treatment shredding process becomes more like sludge and is not suitable for placing in a compactor as a means of onward transport to landfill;

(ii) *there is no detailed indication as to how the residual liquid draw that emanates from the shredder will be controlled and treated; and*

(iii) *following on from this the lack of a condition requiring formal groundwater monitoring at the premises is a serious omission from the PD.*

Technical Committee's Evaluation

The Inspector's Report states that "the vacuum/condensing system employed is intended to dry the waste although the waste coming from the autoclave chamber is expected to still be moist .... Condition 7.5 requires that there be no emission from the compactor". The activity is to be undertaken within an existing building and it was not considered necessary to require any groundwater monitoring. With regard to any liquid draw from the shredder or along the conveyor belt system Condition 4.9 should be altered to require proposals for the collection of such and subsequent treatment.

Recommendation

Include a sentence at the end of Condition 4.9

This proposal shall include provisions for the drainage and collection of any liquid drawing from this system and its subsequent treatment.

Ground 13 (ref. 1.16)

The objection contends that post shredding of waste from an autoclave leaves a liquid type substance and the proposed polythene wrapping activity will not be effective in preventing potential nuisances such as seepage and odours.

Technical Committee's Evaluation

Condition 5.16 requires that all processed healthcare risk waste be wrapped in polythene and stored in fully enclosed containers in the red line zone of the facility until such time as test results confirm successful treatment. Conditions 6.3 and 6.4 relate to requirements regarding odours.

Recommendation

No change

Ground 14 (ref. 1.17)

The objection questions how sharps and other processed wastes can be shredded to two different size standards, or any standard, as this is not fully described in the application.

Technical Committee's Evaluation

The inclusion of two size standards in the PD was in the interest of uniformity with PD 55-1. This is a requirement of the Joint Waste Management Board tender document. However, as is stated in the applicant's reply to the objection, they do not intend having two separate waste streams and that all waste is to be shredded to the smaller size, i.e. 15mm diameter.

Recommendation

No change

Ground 15 (ref. 1.18)

The objection contends that no specific procedures are described for contingency arrangements should the shredding device become blocked during operation or for rendering the machinery safe for human intervention.

Technical Committee's Evaluation

Operator safety in terms of machine maintenance is a health and safety consideration. Condition 5.5 requires that shredders be operated and maintained in accordance with operator's instructions.

Recommendation

No change

Ground 16 (ref. 1.19)

The objection contends that a vital abatement measure against the potential emissions of micro-organisms and viruses is lacking i.e a. HEPA filter. It refers to VOC emissions and contends that the post-shredding operation; being neither enclosed, under negative pressure, nor filtered prior to release from atmosphere; may accelerate such potential emissions. Reference is made to BATNEEC in this context.

Technical Committee's Evaluation

Condition 4.9 requires proposals for the enclosure of the treated waste along the conveyor belt system. The shredding process, which is to occur following treatment, will be carried out in fully enclosed shredders. Additional control of the proposed abatement system has been outlined under ground 11 (ref 1.14) of this report. However, Condition 7.4.1.5 should be amended to cover an investigation into the requirements of abatement equipment to cater for biological emissions such as HEPA filtration. The results from the testing of indicator organisms performed during commissioning (Condition 7.4.1.6) will provide information on the requirement for microbiological/viral filtration abatement equipment.

Recommendation

Alter Condition 7.4.1.5 to read *"The licensee shall, within six months from the date of grant of this licence and as part of the EMP, submit a report investigating alternative abatement technologies* ***(for VOCs and biological indicators)*** *to be used at Emission Point 1 - Air Vent."*

Ground 17 (ref. Schedule A)

The objection refers to the authorised activities referred to in Schedule A and expresses concern that the specific manufacturers plant is not explicitly defined. The objection makes reference to PDs 40-1 and 55-1 in this regard.

Technical Committee's Evaluation

Schedule A refers back to Condition 5 of the PD, Condition 5.7 specifies the manufacturers plant in pages 8-9 of the Article 14 reply received on 26th of March 1999.

Recommendation

No change

Ground 18 (ref. Condition 2.8.2 & Schedule C)

The objection contends that there is no requirement to monitor or report the estimated annual and cumulative quantity of indirect emissions to groundwater. Reference is made to Condition 9.7 of PD 55-1 in this regard.

Technical Committee's Evaluation

During consideration of the application it was determined that groundwater monitoring was unnecessary as the proposed operations at the facility are all indoors.

Recommendation

No change

Ground 19 (ref. Condition 5)

The objection contends that the annual quantity of waste to be treated on site is not set out in the PD and request that this is done. Reference is made to PDs 40-1 and 55-1 in this regard.

Technical Committee's Evaluation

The quantity of waste to be treated at the facility is limited by the following factors; (i) the capacity of the two autoclave chambers which is controlled by *Condition 5.2*, (ii) the duration of an individual cycle which will be set during commissioning, and (iii) the hours of operation (as per *Condition 5.3*).

Recommendation

No change

Ground 20 (ref. Condition 5 & Table D2)

The objection contends that the PD does not provide for procedures for the handling of waste from leaking or otherwise ruptured containers. Reference is made to PDs 40-1 and 55-1 in this regard.

Technical Committee's Evaluation

Condition 5.4 of the PD requires that waste acceptance be as detailed in Attachment E.2 and Section E of Article 16 further information received on 10th June 1999. In the Article 16 reply, details are given regarding procedures for spillages or accidents. The Technical Committee considers that this does not fully address the objection and propose the inclusion of a new condition (from PDs 40-1 and 55-1) to cover procedures for handling of waste from leaking or otherwise ruptured containers.

Recommendation

Include as Condition 5.26 **All containers accepted at the facility shall be whole and sound. Any leaking or otherwise ruptured containers shall immediately be overdrummed or the contents transferred to a sound container in a manner which will not adversely affect the environment. Any spillages should be cleaned up so as not**

to adversely affect the environment or the performance of the oil interceptor. Within three months of the date of grant of this licence, a procedure for undertaking this activity shall be submitted to the Agency for its agreement.

Ground 21(ref. Condition 5.13.3)

The objection requests that this condition be amended to require that any waste used during the commissioning phase be exported for disposal, as is referred to in PD 55-1.

Technical Committee's Evaluation

The technical committee considers Condition 5.13.3 requires that the waste processed during commissioning be disposed of at an appropriate facility which allows for export of the waste if there is no suitable outlet in Ireland. This is consistent with PD 40-1.

Recommendation

No change

Ground 22(ref. Condition 7)

The objection requests that Condition 7.7.4 in PD 55-1 should be included.

Technical Committee's Evaluation

For the PD 55-1 South Dublin Co. Co. are the sanitary authority. For this proposed decision Dublin Corporation are the Sanitary Authority and they stipulated that this requirement was not necessary. The Technical Committee also considered it unnecessary to include this requirement.

Recommendation

No change

Ground 23(Condition 7)

The objection requests that Condition 7.7.11 should be amended such that it reflects Condition 7.7.12 in PD 55-1.

Technical Committee's Evaluation

Annual reporting of the microbiological screening programme was stipulated by the Sanitary Authority, Dublin Corporation. The Technical Committee considered it unnecessary to increase this reporting requirement.

Recommendation

No change

Ground 24(ref. Condition 9.7.2 & Table F.1.1)

The objection contends that the sewer monitoring parameters and frequencies are at variance with those in PD 55-1

Technical Committee's Evaluation to Grounds 21-24

Conditions 7.7 & 9.7.2 and Table F.1.1 reflect the Section 52 Consent Conditions agreed by the Sanitary Authority, Dublin Corporation. The Agency had tightened these conditions to request monthly monitoring of temperature and pH and included the biological monitoring over and above that requested by the Sanitary Authority.

Recommendation

No change

Signed:_____
Technical Committee Chairperson