INSPECTORS REPORT
WASTE LICENCE REGISTER NUMBER W054-2

(1) Summary:

Eco-Safe Systems Ltd is currently licensed to accept and sterilise Healthcare Risk Waste in a Rotoclave at their facility in Allied Industrial Estate, Ballyfermot, Dublin 10. The details of this were provided in the original Inspectors Report for the facility (54-1).

The principal amendments proposed by the applicant to the existing licence are as follows:

(i) to operate a transfer station at their facility (primarily for hazardous waste);
(ii) to sterilise additional waste types in their existing autoclave;
(iii) to sterilise obsolete mechanical equipment in a new static autoclave;
(iv) to provide a confidential data shredding service.

The review application also seeks amendment to a number of conditions of the existing licence. Section 2 of this report details the proposed amendments and my recommendations.

Summary of Key Application Details

Date of Grant of Original Licence	**21/12/99**
Date of Application	**5/6/02**
EIS Required	No.
Number of Submissions Received	One.

Activities recommended for licensing:

The applicant applied for the following waste activities: Classes 7,12,13 of the 3rd Schedule and 3,4,13 of the 4th Schedule of the Waste Management Act, 1996. It is recommended that the applicant be licensed for all the classes of activity applied for subject to the requirements of the Conditions of the recommended PD.

(2) Amendments to the Existing Licence Requested

(i) Increase in Waste Tonnage Accepted at the Facility

In the AER for 2002, the applicant stated that they treated 1,052 tonnes of waste for the year 2001 in the Rotoclave. The applicant now proposes to sterilise c. 3,260 tonnes per annum in either the Rotoclave or the Static Autoclave at the facility.

In this review application, the applicant also proposes to expand the types and quantities of waste stored at the facility and to operate as a Hazardous Waste transfer station (see Table 1 below). The applicant proposes to construct five bunded areas. They propose to store compatible hazardous wastes in these bunded areas.

Table 1: Total quantities of wastes proposed to be accepted at the facility.

YEAR	NON-HAZARDOUS WASTE (tpa)	HAZARDOUS WASTE NOTE 1 (tpa)	TOTAL ANNUAL QUANTITY OF WASTE (tpa)
Year 1	Approx 2,000	Approx. 5,000	Approx. 7,000
Year 2	Approx 3,000	Approx. 8,000	Approx. 11,000
Year 3	Approx 4,000	Approx. 12,000	Approx. 16,000
Year 4	Approx 5,000	Approx. 15,000	Approx. 20,000
Year 5	Approx 6,000	Approx. 18,000	Approx . 24,000

Note 1: This includes hazardous waste to be treated at the facility (3,260tpa) and other hazardous wastes to be accepted for storage prior to transfer off-site.

New Transfer Station

The applicant has estimated that the maximum quantity of hazardous waste that could be stored at any one time in the proposed five bunded areas combined is approximately 120 tonnes. Elsewhere in the application the applicant proposes to store such wastes for periods of up-to three months. I estimate that the maximum that could be stored in the bunded areas at the transfer station facility in one year is c480 tonnes.

An area has been set aside at the facility (inside the existing building) for the storage and destruction of non-hazardous wastes. The types of non-hazardous wastes proposed to be accepted for shredding include confidential medical, bank and insurance records. I am satisfied that the applicant has sufficient capacity for the storage and handling of this quantity of non-hazardous waste at the facility.

I recommend that the total annual quantity of waste to be accepted at the facility be set at 9,740 tonnes. This figure is based on the maximum quantity of non-hazardous waste requested (6,000 tpa), 3,260 tonnes of healthcare risk waste for treatment at the facility and 480 tonnes of other hazardous wastes to be stored at the Transfer Station facility.

I have included many of the standard requirements for the operation of a hazardous waste transfer station in the draft recommended PD. A number of these need to be agreed prior to commencement of operation of the transfer station (awareness and training, financial provision etc.).

(ii) Sterilise Additional Waste Types in Existing Autoclave

In addition to the waste types allowed under the existing licence, the applicant proposed to sterilise laboratory waste (non-autoclaved), anatomical parts, and endoscopes in their existing autoclave (Rotoclave).

The Dept. of Health and Children (DOH&C) have provided guidance on the heat treatment and handling of healthcare risk waste in two documents, which I will refer to in the following sections. The Joint Waste Management Board (DOH/DHSS/CSA) specification report on healthcare waste lists five waste types not suited for treatment by non-incineration technology. This list includes cytotoxic drugs, chemicals, pharmaceuticals, body parts and blood products.

Body Parts/Anatomical Waste

The applicant has requested that they be allowed to treat human and animal anatomical waste (c.20 tonnes) in their Rotoclave as there is currently no appropriate facility in Ireland for this waste. The applicant has provided information that this waste type is processed in a Rotoclave in the US. However, the DOH&C guidelines indicate that anatomical waste should be excluded items for treatment in this type of technology – and should be disposed of by Incineration. I recommend that this waste type should not be acceptable for treatment at the facility.

Laboratory Waste

In the previous licence only pre-autoclaved **laboratory waste** was acceptable at the facility. The applicant now proposes to accept non-autoclaved infectious waste and to provide a service for the biotechnology industry and to treat laboratory waste. They state that certain facilities have contacted them to treat laboratory waste that has not been previously autoclaved. I consider that the acceptance and treatment of non-autoclaved lab waste could be allowed in the event that such waste <u>is not infectious</u> and where the applicant has the GMO licence/consent under SI 73 of 2001, if appropriate.

For infectious laboratory waste in which risk group organisms have been artificially cultivated to significantly elevated numbers these should ideally be autoclaved in accordance with the DOH&C segregation and storage guidelines prior to acceptance at this facility. However, these guidelines do allow a variation on this protocol where suitable autoclave facilities are not available. The guidelines allow packaging the waste under stringent conditions and the incineration of the outside container (yellow bin with black sealable lid). The applicant did not propose to incinerate the outside container. I have included the relevant extract in Appendix 2 of this report. I consider that the acceptance of non-autoclaved infectious laboratory waste could be allowed if the applicant were to submit a revised procedure based on the DOH&C guidelines and a revised awareness and training programme to the satisfaction of the

Agency. The acceptance of laboratory waste is covered in the Condition 5.2, 5.7 of the draft recommended PD.

I have discussed the acceptance and sterilisation of other infectious waste (also potentially odourous) types in Section 4 of this report.

In addition, the applicant has applied to increase the quantity of waste to be treated in an autoclave cycle from 0.4 tonne to 0.7 tonne. The applicant has indicated that they will need to replace the graphite bearings on the base of the rotating drum on a more frequent basis. I consider that the proposal is satisfactory and that the sterility of the end product will be adequate.

(iii) Use of Static Autoclave

The applicant has proposed to sterilise the following waste types in a static autoclave (obsolete medical equipment, HEPA filters and surgical equipment). The static autoclave is capable of treating up to c260 tonnes of such waste per annum. The temperature/pressure/ residence time set points and the monitoring programme will be agreed with the applicant as part of the commissioning process. I have some concerns regarding the anticipated air emissions from the sterilised equipment and more details would be required from the manufacturer of the equipment prior to agreement (see Condition 5.8).

This material will be sterilised and subsequently redirected to the metal recycling area of the facility for segregation and removal off-site for recovery.

(iv) Storage time of unprocessed waste

Condition 5.8 of the existing licence (54-1) limits storage of healthcare risk waste to a period of 36 hours. The applicant has breached the storage time limit in their existing licence on certain waste types (e.g. brucellosis waste material) for the reasons outlined in Section 4 below. The applicant proposes to extend this time period to 60 hours allowing for weekends, traffic congestion and mixing of waste types. The applicant proposes to install a negative air pressure in the controlled area of their facility.

Section 15 of Joint Waste Management Board (DOH/DHSS/CSA) specification proposed the following guidelines on storage of biological/infectious waste: (i) Upto 4 hours at room temperature, (ii) Up to 3 days at less than 8^{o}C, (iii) More than 3 days at –18^{o}C. Sharps and other waste could be stored for extended periods such that it does not give rise to offence or cause a nuisance.

I recommend allowing the extended storage period of 60hours subject to the satisfactory installation of refrigerated unit and/or the negative air pressure which would be agreed under Specified Engineering Works.

(v) Provision of a confidential data/tyres destruction service.

The applicant has proposed to shred confidential information from clients in a controlled manner. The applicant also proposes to shred tyres at their facility. The applicant will source suitable recycling outlets for these materials. Any such outlet would need to be agreed in advance with the Agency. Emissions from the shredder unit will pass through an appropriately sized filter.

(vi) Waste Acceptance Procedure

The original licence stated that waste should only be accepted in bins controlled and owned by the licensee. I agree with the applicant's request and recommend that other forms of appropriate packaging should be allowed subject to Agency agreement (Condition 5.2.3).

(vii) Other Proposed Amendments

The applicant also requested the amendment of a number of conditions relating to the management of the activity, location and installation of various site infrastructures and the development of working procedures. They indicated that a number of these are irrelevant as they related to the time period "prior to the acceptance of waste at the facility".

I have amended these conditions where relevant but consider that in certain cases that additional awareness and training procedures would be needed prior to the operation of the waste transfer station. The provision of certain site infrastructure will be agreed under Specified Engineering Works.

(3) Facility Development Status

The Original inspectors report detailed the relevant infrastructure proposed to meet the requirements of the original licensed operations. At present, the facility treats healthcare risk waste material and the existing infrastructure and a large number of operating procedures have been established and agreed with the Agency. Additional infrastructure will be required for the proposed activities: These include (i) modifications to the odour abatement equipment, (ii) static autoclave and associated abatement equipment, (iii) baling machine and (iv) segregated bunded areas for the waste transfer station activities.

I am satisfied that the applicant will be able to divert the incoming waste streams to appropriate areas of the facility pending treatment. There appears to be sufficient room to allow the construction of bunded areas at the rear of the facility for the storage of upto 120 tonnes of hazardous waste. Detailed waste acceptance procedures will need to be agreed with the Agency prior to the use of the bunded areas.

An updated awareness and training programme will be implemented to ensure that all staff members are aware of the new requirements.

Hours of Operation
The facility will operate on a 24 hour basis from Monday to Saturday. This is as a result of increased travel time in the greater Dublin area and is an increase in hours from the original licence (9am to 5pm on Mon-Friday). The shredding and baling operations are restricted to day-time hours.

(4) Licence History

Waste Handling
The original licence allowed the treatment of infectious waste and sharps waste at the facility. I consider that the existing treatment of certain infectious waste types (e.g. brucellosis waste, processed blood products) has the potential to give rise to odours. The DOH&C have identified the latter waste type as unsuitable for treatment in this type of facility. The potential for odour nuisance has been raised by the Agency previously. In the reply to our notification of non-compliance from an audit of the facility (notice dated 3/10/02) they state that brucellosis waste material can only be processed when the wind is from the west. This processing procedure resulted in breaches of the storage time period-allowed (36hours). I consider this to be an inappropriate method of dealing with the nuisance caused by processing of this waste.

They also state in their correspondence (3/10/02) *"there is no statement that restricts Eco-Safe Systems Limited from accepting blood products, which in their nature may be known or clinically assessed to be at risk of being contaminated with biological agents"*

I consider that exclusions should be placed in this recommended PD on the treatment of certain infectious waste until such time as a detailed programme of monitoring and odour abatement has been put in place to the agreement of the Agency (see Conditions 1.6 and 5.7).

However, the applicant has recognised the concerns of the Agency and nearby industry that odour has caused nuisance on occasion. The applicant carried out an in-depth odour audit of the facility and suggested some improvements in vent design and configuration that they intend to carry out in the future. During the odour audit actual measurements were taken and revealed that during the treatment of brucellosis waste an odour level of 110,000 ou/m^3 was detected at the autoclave vent. The emission is a complex mixture of organic and inorganic sulphur and nitrogen compounds. The consultant indicates that dispersion of odour is severely hampered by the nature and location of the emission points.

I consider that a detailed programme of works be carried out prior to the continued acceptance of the potentially odourous infectious wastes and that this waste type should not be accepted for treatment until an effective odour abatement procedure and

waste handling procedure is in place (Conditions 1.6, 5.7). In addition to the concerns that I have in relation to the sterilisation of infectious waste types, I consider that the existing odour abatement equipment may not be capable of treating emissions from liquid waste loads (e.g laboratory waste). The modifications to the odour abatement equipment are covered in the following section.

(5) Emissions to Air

Air emissions from the Rotoclaves are passed through a steam jet and then passed through an activated charcoal filter to eliminate any potential release of microorganisms to atmosphere. In recent months the applicant has modified the abatement equipment and its discharge route (now venting upwards) and air emissions are now being further abated (via boiler, additional condenser, UV filter and a biofiliter). On-going assessments are being made at present to assess the impact of these modifications.

Alterations will also be made to the odour abatement equipment to cater for the additional load from the static autoclave and these works are covered under Specified Engineering Works (Condition 3.2).

(6) Emissions to Sewer

There is one direct emission to a Dublin City Council foul sewer. The discharge is composed mainly of boiler blowdown containing condensed process water. There have been minor breaches of the volumetric effluent flow to sewer under the existing licence. However, a revised consent for the discharge has been obtained from Dublin City Council. Emission limit values and monitoring requirements are set out in *Schedules C and D,* respectively.

(7) Waste Management, Air Quality and Water Quality Management Plans

The four local authorities in the Dublin Region have adopted a regional Waste Plan. This plan refers to the adoption of the National Hazardous Waste Management Plan. There is no relevant Air or Water Quality Management Plan for the facility.

(8) Other Significant Environmental Impacts of the Development

Financial Requirements

I consider that the operation of the transfer activities will increase the quantity of hazardous waste that is stored at the facility. I recommend that no hazardous waste (other than healthcare risk waste) be accepted on site until adequate financial provisions, acceptable to the Agency, are in place (Condition 12.2).

Amendments to Microbiological Monitoring Requirements

Based on the applicants proposals, the original licence had a requirement for the microbiological testing (i) the taking of spiked spore samples with each batch of waste

treated and (ii) the daily testing of random grab samples of treated waste. I consider that the requirement for spore testing which is a much more stringent test should be maintained and that the daily testing should be dropped. However, I recommend that there should be a bi-annual examination of ambient air for airborne micro-organisms levels (Schedule D). This is in accordance with recently published EA guidance for this type of waste facility.

Testing of Treated Waste
I recommend that the treated waste should be analysed on a biannual basis due to the potential for banned wastes such as cytotoxic waste being inadvertently accepted at the facility. (Schedule D.7) Upon discovery of this waste it is separated and stored in quarantine pending removal off-site.

Asbestos Fibre Monitoring
Asbestos waste may be accepted at the facility. In accordance with other hazardous waste transfer stations there is a requirement for asbestos fibre monitoring.

(9) Submissions

One Submission was received from Mr Ray Woodroofe, Director Tennant and Ruttle, Allied Industrial Estate, Kylemore Road, D10 (rec'd 1/7/02)

1. He formally objected on the grounds of noxious odours emanating from EcoSafe Systems premises. Complaints have been made verbally and by solicitors letters.
2. They note that despite several assurances from Ecosafe Systems the problems of noxious odour still continues (resulting in a person vomiting in one instance)
3. They have made several requests for the appointment of an environmental consultant to carry out and inspection and audit of the facility – this has not yet been addressed by the applicant
4. Until they commence operating in a responsible manner and cease to cause nuisance and risk to their operations they will vigorously object to any extension of the licence and would also request that the current licence be suspended.

Inspectors Response
The applicant undertook an odour audit of the facility which was carried out by an agreed odour consultant. Modifications have been proposed to the odour abatement configuration and are being tested on an on-going basis. I consider that the treatment of certain waste types (brucellosis waste, blood products) have the potential for significant odour nuisance and that these should not be treated until a full programme of works have been agreed with the Agency.

Signed _____ Dated:
Name Brian Donlon, Inspector

APPENDIX 1

Location Plan
+
Facility Layout

APPENDIX 2

Extracts from DOH &C Guidelines (2nd Edition, July 2002)

SEGREGATION, PACKAGING AND STORAGE GUIDELINES FOR HEALTHCARE RISK WASTE

6.6 Laboratory Waste

It is essential that good laboratory procedures apply to the management, packaging and handling of all wastes generated in laboratories. Comprehensive waste management procedures should form an important part of any laboratory operating procedures. These should be spelt out in detail in the Laboratory Safety Management Plan.

Where considered necessary for the prevention of disease laboratory waste should be autoclaved prior to disposal. In any event, laboratory waste in which Risk Group 3 or Risk Group 2 organisms have been artificially cultivated to significantly elevated numbers e.g. culture plates in bacteriology, or specimens from patients known to have, or highly suspected of having infections with Risk Group 3 organisms, should be autoclaved prior to disposal.[#4]. Suitably qualified personnel, who understand the nature of the infectious materials and the handling, transportation and disposal process to be used, must be employed to make such an assessment.

Laboratory waste where there has been no multiplication of organisms e.g. blood specimens in clinical chemistry or haematology laboratories which have not come from patients known or highly suspected of having an infection with Risk Group 3 organisms, do not need to be autoclaved and may be packaged untreated in a yellow box or sharps box.

Under no circumstances should glassware such as bottles, slides, pipettes etc. be placed in plastic bags even if autoclaved beforehand.

[#4] Where suitable autoclave facilities are not available laboratory waste containing elevated numbers of Risk Group 2 or Risk Group 3 organisms must be contained within an inner receptacle, outer liner and outer rigid UN approved container. It must be labelled accordingly. The outer container should consist of yellow rigid box with a black sealable lid and it must be disposed of by incineration. If the waste involves liquid an absorbent material, such as cotton wool, saw dust or peat, should be added, sufficient to absorb any accidental spillages.