MEMO

TO:	Board of Directors	**FROM:**	Brian Donlon
CC:		**DATE:**	8/2/02

SUBJECT Gleneden Trading Ltd.Technical Committee Report

Application details

Application Details	
Applicant:	Gleneden Trading Ltd.
Location of Activity:	Raffeen Ind Estate, Monkstown, Cork
Reg. No.:	145-1
Licensed Activities under Waste Management Act 1996:	Third Schedule: Classes 7,12,13
Proposed Decision issued on:	2/10/01
Objections received:	1 – received on 30/10/01
Submission on Objection received	1 – received on 5/12/01
Inspector that drafted PD:	Sinead McMahon

Objections received

A Technical Committee was established to consider the objections.

The Technical Committee included;

Brian Donlon, Chairperson
Brendan Foley, Inspector
Maeve McHugh, Inspector

This is the Technical Committee's report on the objection.

The application is for the relocation of an existing licensed facility at Cork University Hospital (38-1) to a new location at Monkstown, Co Cork.

1. Objection from Mr Brian Gould

Objection 1.1 Operator Safety

The objector states that due to the nature of the waste being processed, and the fact that waste is shredded prior to being treated that there is the potential for infectious aerosols to be produced which would put the operators at risk.

They also state that 'There is evidence to suggest that a system, which incorporates a pre-shredder, has been the cause of TB infection in operators in the US. Further to this point we can provide press cuttings from Waste News, an American publication, which

documents concerns over the incidence of TB at a medical waste treatment facility. It is clear that these cases all occurred as a result of occupational exposure'.
The objector goes on to state that, in the event of mechanical failure of the shredder, operators may have to access the shredder in order to carry out essential repairs and that medical waste should not be shredded until after it has been safely treated.

Submission on Objection
The applicant states that the objector made reference to the evidence but did not provide the evidence. They further state that the facility has been operated by them for a number of years at another location and that there have been no instances of disease arising from occupational exposure. They state that they have concerns for their staff at all steps of the process not just the shredding and that all staff are equipped with personal protective equipment. They outline the in-built safety mechanisms and the maintenance regime of the shredder. They state that the reason that the waste is shredded prior to the heat treatment is to maximise the efficiency of heat transfer. They also state that the shredded area is ventilated using extract fans to their HEPA filters, which have operated, successfully at Cork University Hospital for 4 years.

Technical Committee's Evaluation
The Technical Committee notes that it is proposed to pull air from the shredder area through a HEPA (high efficiency particulate air) filter prior to discharging it to atmosphere. Condition 8.1 outlines the monitoring requirements and Condition 5.7 outlines the maintenance requirements for the air abatement equipment. Further, condition 7.4.3 requires spare filters to be held on site.
Some of the other matters raised in this objection relate to health and safety issues. The TC has access to some papers concerning worker safety from a previous objection to a Proposed Decision (55-1) for a waste healthcare facility. The TC notes the applicant's comments in relation to the lack of occupational exposure at the existing facility for the past four years. We consider that this objection and the applicant's response should be forwarded to the HSA for their information.

Recommendation

No Change.

Objection 1.2 Air Borne Emissions
The objector states that there is no evidence to show that the use of a HEPA filter to counter air-borne particulates produced in the treatment process will ensure that no emissions of hazardous material to atmosphere occur. He also states that HEPA filters may be unsuitable for the treatment process because high dust levels and damp air could casue clogging of the filters.
He also states that the 'safety of the local residents cannot be guaranteed by the use of a HEPA filter alone'.

Submission on Objection

The air is passed though a condenser which removes moisture prior to ventilation using extract fans to their HEPA filters which have operated successfully at Cork University Hospital for 4 years. They state that spare filter modules are maintained on site and clogging of filters is checked by use of pressure gauges. Used filter cores are double wrapped and exported for treatment.
They state that there were c. 145 houses plus the hospital (which also contained an acute respiratory unit) within 250m of the Cork University Hospital facility. They state that there has been no suggestion by the specialists operating the acute respiratory unit that the facility compromised their activities but that the facility is being relocated for reason of traffic congestion.

Technical Committee's Evaluation
The TC consider that the installation and maintenance of the abatement equipment (3-stage filter) required by the licence will prevent the emission of hazardous substances / emissions of air borne particulates. In addition to the other controls provided in the licence this will protect residents and the environment.
Recommendation

No Change

Objection 1.3 Ability of Process to Sterilise Clinical Waste
The objector refers to a submission, which was made to the EPA with regard to licence application no. 55-1 by Dr. Holliday, which stated that non-burn technologies would not be able to achieve sterilisation of waste. He referred to the highest level of treatment by the State and Territorial Association on Alternate Treatment Technologies (STAAT) is level IV which requires complete inactivation of *Bacillus stearothermophilus* spores at $6\log_{10}$ reduction or greater which this system would not be able to achieve.

Submission on Objection
The applicant stated that Dr. Hollidays preference for incineration ignores the fact that throughout Ireland (including Cork University Hospital (CUH)) that hospital waste incinerators have been closed down because of the associated health risks. They state that they are committed to operating the facility in accordance with Condition 5 of the PD. They are aware that the EPA carried out their own independent tests on the performance of the plant while it was in use at CUH and are confident that the plant is capable of achieving the desired level of sterilisation.

Technical Committee's Evaluation
In the objection outlined above the objector makes reference to a STAAT report that requires complete inactivation of Bacillus stearothermophilus spores at 6 $\log_{10}$ reduction or greater (Level IV). This report was published in 1994 but it should be noted that this report does allow the use of <u>Bacillus</u> <u>subtilis</u> as the organism to be tested.
However, a revised STAATT II report (December 1998) lessened the stringency required and recommended a 4 $\log_{10}$ (99.99%) reduction in the level of <u>Bacillus</u> spores to

demonstrate microbial efficacy. Bacillus stearothermophilus or Bacillus.subtilis spores are recommended as the biological indicators for chemical and thermal treatment processes.
This facility will be operated to the higher standards of 6 log_{10} reduction (i.e. 99.9999% reduction) of the spores as surrogate pathogens. This provides an additional level of control. The applicant has indicated that it will be able to meet these standards, which also apply at other healthcare waste treatment facilities (Reg. Nos. 54-1, 55-1).

Recommendation

No Change.

Objection 1.4 Validation of Sterilisation monitoring
The objector states that it is 'extremely difficult to validate the disinfection of waste in such a process' and he cites a paper by Holliday *et al*, which he states examines the difficulty in validating such a system. He states that (i) the paper also refers to the fact that not all spore test strips are recovered from the system on each occasion; (ii)that spore strip failures occur and (iii) that spore strips in carriers can be insulated by dryer waste compacted on top of them and that these inadequacies can result in untreated waste being disposed of to landfill. He says that the paper referred to also states that the operating parameters to be used in such a system should be computer controlled to eliminate the possibility of manual interference.

Submission on Objection
The applicant states that the objector did not state whether he was the "K.F. Gould" identified as co-author to M.G. Holliday on the paper. The applicant also states that they have access to the paper by Holliday but not a copy of the paper by Mr Gould *et al*. Consequently, they have no access to protocols employed by the unidentified process that is the basis of the Gould/Holliday paper. They indicate that they have developed two methods for insertion and retrieving spore strips from the process (tennis ball or short length of pipe). They state that as the spore strips were not retrieved in the Gould/Holliday study this does not automatically imply that the process they were validating was not effective.
They state that "there is no opportunity for spore strips in the carriers being insulated by drier waste compacted on top of them" as outlined in the objection.
They also state that the process is controlled by PLC and that access to the PLC is password protected which are exclusive to owner and their consultants (FT and Co.)

Technical Committee's Evaluation
The Technical Committee notes that the validation of any system treating healthcare waste is critical. The use of suitable carriers for the surrogate pathogens (i.e."spiked" spores) and effective laboratory procedures are necessary to assess the microbiological efficacy for process validation.
The TC note the findings/recommendations of the updated STAATT II report (1998) which *suggested that more focus should be placed on the introduction of the "spiked spore-formers" in appropriate containers/carriers such as coloured shredded paper /*

cotton balls. The TC also are aware of a study commissioned by the Agency under the RTDI programme entitled "Small Scale Study on Microbiological Efficacy Testing for Healthcare-Risk Waste Facilities" which made a number of recommendations regarding the microbiological testing for process validation. These included recommendations for suitable carriers for biological indicators, suitable temperature testing and microbiological procedures. These recommendations have been incorporated in the proposed decision.
Tamper proof settings will be set on the processing unit to prevent unauthorised tampering with the residence time and temperature set points (Condition 5.3.6).

Recommendation

No Change.

Objection 1.5 Disposal of Treated Waste
The objector again states that the system 'will not sterilise the clinical waste but disinfect it. This does not guarantee the total kill of organisms present'. He also states that the leachate generating potential of this treated waste should be determined. Wastes with a 40% moisture content have been shown by the US EPA to generate 40 to 115 litres of leachate per dry tonne per day. This will be operationally detrimental to a landfill site.

Submission on Objection
The applicant disagrees with the objector's opinion and contends that that the treated waste will be suitable for landfill disposal. The applicant contends that upon heat treatment that the moisture content will be significantly reduced and that its absorptive capacity will be greater that MSW.

Technical Committee's Evaluation
The TC notes that Condition 5.5.4 requires that all processed healthcare risk waste shall be accompanied by a consignment note and shall be certified as treated in accordance with their licence by a technically competent person from the testing laboratory. This information will be supplied to the facility accepting the waste and will ensure that a facility operator considering the acceptance of the waste can make an informed decision. The TC considers that upon heat treatment that the moisture content of the treated waste will be significantly reduced and that its absorptive capacity will be greater that MSW.

Recommendation

No Change.

Signed

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Dr. Brian Donlon
Chairperson TC