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TO WHOM IT MAY CONCERN

I am writing this letter to commend the efficacy and reliability of the Tempico Rotoclave system in its ability to deal with a wide range of biohazardous materials. I do so as an independent individual who was tasked with the role of Biosafety Officer of this University since the late 1980s (and also as a consultant to Ecosafe Systems, Dublin, in their genesis). This necessitated devising reliable methods for dealing with pathogenic micro-organisms and associated materials from our clinical and research laboratories and also with genetically manipulated organisms. The University output was too small to warrant installation of a private treatment plant and city-center space was at a premium. Available external waste services at the time consisted of incineration (due for closure because of age and location) or a selection of pre-shredding and steam or microwave treatments, none of which could guarantee sterile end-product. Traceability within these services was also deficient. It was decided that the University biohazardous waste stream could not, in conscience, be disposed of to these services even though the EC Waste Laws and Health and Safety laws were not yet in existence.

A new company, EcoSafe Systems, saw the gap in the market and solicited my help in putting together a biohazardous waste facility which could handle all levels of healthcare waste as well as laboratory wastes. This was to comply with EU legislation, have traceability systems in place, a Quality System, an Environmental Management System and Health and Safety Management System, an ADR licensed transport System and a licensed end-product disposal site.

In the search for core technologies, I visited incineration sites in France, Belgium, Austria and USA, microwave sites in Switzerland, Austria, and Ireland, Rotoclave sites in the USA, Chemclav sites in Ireland and hot-oil auger sites in England and Ireland.

It was clear that incineration was not going to be acceptable in Ireland and was losing support in many countries. Of the other technologies, only the Rotoclave system seemed to guarantee sterilization and functioned on the proximity principle and precautionary principle (reduce or remove the risk as close to origin as possible) thus protecting its operatives and the environment simultaneously.

The other factors that swayed the decision to choose Rotoclave technology were:

- As the waste was sealed until the cycle commenced, operatives were never exposed to the



possibility of infection. No shredding, sorting or recycling occurred until sterilization was completed.

- No extra chemicals were used in the process and all emissions were environmentally friendly which satisfied the Irish EPA
- The system was easily linked to a bin handling system for safety, traceability, and accounting purposes.
- The system was easily operated and tamperproof
- Performance was continuously monitored and recorded
- Contaminated contents would not be released from the vessel until duplicate set parameters were met
- The system operated as a batch system. One could guarantee that all of a batch was exposed to the same conditions.
- The system operated in excess of the 'Gold Standard' autoclave parameters, applying vacuum cycles, pressures and temperatures in excess of the norm for sterilization and agitated the load during all of this
- The system could process liquids, animals, pathology and laboratory wastes, blood and blood products, glass, metals and all routine healthcare wastes therefore avoiding extra waste streaming by the customer. None of the other systems assessed could handle this range and as a result, those services operating such equipment in Ireland have to export many classes of waste for treatment abroad at over €2000 per tonne.
- All servicing of Rotoclave equipment is external to the vessel. Were it to break down when full of waste there is no danger to operatives. Repairs done, the system can restart and complete the cycle without opening the vessel. This has not occurred in over four years operation of the two Rotoclaves at Ecosafe Systems.
- Prevention of damage to the shredding equipment is possible as metal or other large solid objects are visible or detectable post-sterilization and may be removed before damage is done. This is a major benefit over shred first, treat later systems both in time, money and personnel safety. (During trials of microwave and other systems in Ireland a regular feature was jamming or breakdown of the shredders full of infectious material and the necessity to manually enter and clear the system)
- The Rotoclave system in operation produces an almost dry product with little spillage or leakage facilitating keeping the plant clean and tidy. Auger-based systems tend to produce a wetter product and as they are not pressure sealed, leak leachate onto the factory floor.

The Rotoclave systems have been operating satisfactorily in Dublin for four years with little maintenance necessary. During that time, every batch processed has had *Bacillus stearothermophilus* spore testing carried out and occasional sterility sampling on product also. Not a single test has failed in that time. The factory holds a license from the Irish EPA and its performance records are on open access to the public.

Another clinical waste company (STI, Dublin) using pre-shred and auger technology has a similar license from the EPA and its performance records are also on public access. It is clearly having regular difficulties due to breakages and down-time with the pre-shredding process and also the technology regularly fails to sterilize, even when challenged with the less sturdy *Bacillus subtilis* spores.

This University, its teaching hospitals, many private hospitals and the majority of Irish biotechnology



companies now entrust their biohazardous waste to the Rotoclave technology at Ecosafe Systems. I have not yet encountered a more satisfactory technology although I keep a watching brief on anything new.

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