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An open appraisal of Tempico Rotoclave technology

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 and others since). 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-centre 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 tracability systems in place, a Quality System, an Environmental Management System an Health and Safety Management System, an ADR licenced transport System and a licenced 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, auger sites in Ireland and England and reviewed other technologies on paper.

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 sterilisation and functioned on the proximity principle and precautionary principle (reduce or remove the risk as close to origin as possible) thus protecting itsoperatives and the environment simultaneously.

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

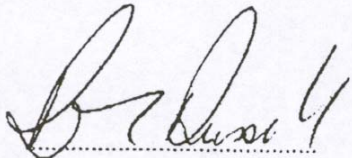
- **As the waste was sealed until inside the closed vessel and the treatment cycle commenced, operatives were never exposed to the possibility of infection. No shredding, sorting or recycling occurred until sterilisation was completed.**
- **No extra chemicals were used in the process and all emissions 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 and automatically monitored and recorded allowing traceability and parametric release for disposal.**
- **Contaminated contents could not be released from the vessel until duplicate set parameter limits (time, temperature, pressure) were met**
- **The system operated as a batch system. One could guarantee that all of a batch was exposed to the same conditions unlike continuous auger systems.**
- **The system operated in excess of the 'Gold Standard' autoclave parameters, applying vacuum cycles, pressures and temperatures in excess of the norm for sterilisation and in addition agitated the load during all of this**
- **The system could process liquids, dead 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, needed to export several classes of waste for treatment abroad at costs of up to €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.**
- **Prevention of damage to the shredding equipment is possible as metal or other large solid objects are visible or detectable post-sterilisation 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). In the US there are reported incidents of operatives contracting TB from use of shred-first, treat later systems.**
- **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 and leak leachate onto the factory floor.**
- **As a controlled batch process it is easy to document and build quality systems around.**
- **Tempico as a company understood and supported their technology to a very high degree and could point to many of their systems operating reliably for many years at different sites.**

To the best of my knowledge, 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 licence from the Irish EPA and its performance records are on open access to the public.

This University, its teaching hospital, many private hospitals and the majority of Irish biotechnology companies now preferentially entrust their biohazardous waste to the Rotoclave technology at Ecosafe Sytems. This I know is based on knowing that their waste is sterilised rather than disinfected and that the batch system provides a guarantee to that effect within a traceability system.

I have not yet encountered a more satisfactory technology although I keep a watching brief on anything new.

There are a number of features which could be improved upon such as the software and data presentation systems but these are secondary to the functionality and significant improvements have been made to these in the recent past.

SIGNED:  9th January 2004

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