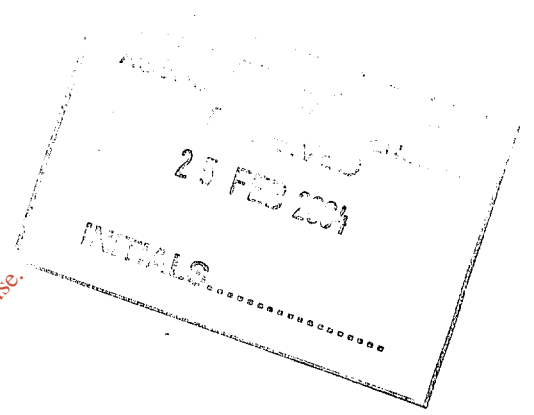


Appendix 2

Duty of Care Audit



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“DUTY OF CARE AUDIT”

Undertaken on

“Sterile Technologies” plant at

Dublin and Antrim.

Confidential report to

“The Board of Directors”

Sterile Technologies Ireland Limited

Commissioned by: Mr D Rodgers

Produced: June 2002.

**Produced by: P F Olko, C.Eng; MBA, B.Eng (H); BA, MIHEEM.
& R Winch, MIHM.**

Director(s) - Well Environmental Solutions Ltd.

Well Environmental Solutions Ltd.

63 Forest Road, Annesley Woodhouse, Nottinghamshire. NG17 9HA

Company Registration: 4353942 Telephone: 01623 759589 VAT: 789149077

Confidential

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INFORMATION CONTAINED WITHIN THIS REPORT.

The views expressed in this report are the opinions of the writer(s) from the facts derived and freely given by the audited company or its representatives from the site inspections over a four day period after an extensive review of their documentation prior and after this four day period, followed by a further visit of two days by Dr. M Holliday and two days within England verifying the systems for "Out of Ireland" incineration.

ACKNOWLEDGEMENTS.

The authors would like to express their thanks to Mr D Rodgers and all STI employees both at Dublin and Antrim plants, Cliniframe and White Rose Ltd. Bolton, for their help, assistance and openness in the release of information and opinions which greatly assisted in the formation of this report.

NOTE.

This report is purely concerned with the operations undertaken by STI Ltd, in the execution of its contracts within the "Island of Ireland", and does not cover the role of the client or its management of Clinical waste, which is subject to a separate report.

Bibliography of Directors and Company Profile - Well Environmental Ltd.

P F OLKO.

Born 1949, served a traditional Mechanical Engineering apprenticeship, with "Tully Engineering Ltd", twice gaining "Apprentice of the Year". Served with the company as "Liaison and Contracts Engineer" gaining an OND and HNC in Mechanical Engineering and HNC endorsements in Industrial Administration and Law.

Joined the National Health Service in 1974, as Assistant Engineer, progressing via promotion and differing hospitals to "Operational Estates Manager" at Kings Mill Hospital. This is a 600 bedded Acute hospital, with a budget of £80 Million. The Operational Estate manager was responsible for the control of all Engineering and Building services to the complex, which included the direct responsibility for 55 staff and a budget of £3.2 million per annum.

During this time the authority supported continuation study, resulting in the gaining of:

- BA (Open University);
- B.Eng. (Hons);
- MBA.

These qualifications and experience gained were used to gain Chartered Engineer status via the Institute of Health Engineering and Estate Management.

Implemented many environmental schemes at Kings Mill Hospital, including 40% reduction of Clinical waste, and drove all major KPI's below national averages. These measures helped to secure various awards including:

- 1999 - Best business partner - Environmental - with STWA
- 1999 - Highly Commended (runner up) in National Health Service Environmental award
- 2000 - National Winner "Green Apple Award".

Member of various NHS working parties including:

- NHS Energy and Environment Strategy Group,
- NHS Environmental Policy and Working group, co-producing the "New environmental strategy for the National Health Service" - published 2002.
- Chairman of the "Trent Region Energy Managers"

Retired from the NHS in 2001, following a serious motorcycle injury and formed with R Winch - Well Environmental Solutions Limited in 2002.

R WINCH.

Born 1955, served a traditional apprenticeship with East Midlands Gas Board. Left to join Randa Ltd within the Refrigeration/Beer Dispense Division in 1976 as Technical Supervisor, joining Whitbread Brewery in 1978 as "Installation and Service Technician Supervisor"

After four years at Whitbread promoted to Regional Auditor being responsible for auditing management procedures in an estate of 35 public houses/Restaurants. Secured Area Manager post three years later having direct responsibility for an estate with turnover in excess of £3.5 million per annum and staff of 325. Awarded "National Area Manager of the Year" for four years.

Advanced to "Area Training Manager" responsible for high benefit/profit turnover estate and also the training and assessment of 'new licensees' and 'area managers' for the company.

Left brewing industry in 1995, due to ill health, and later formed a consultancy company giving advice on training.

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Joined Bernhard Metals (UK) Ltd (Europe's largest secondary aluminium re-cycler) to compile and present specific training courses within the company. Appointed as Operations Director in a new associate company -Well Services Ltd - to exploit opportunities in the Healthcare waste industry.

Undertook with the support of the company a "Risk Assessment" course (distinction) and "City and Guilds Teacher Training" certificate. In addition, through external courses run by the Institute of Waste Management, combined with home study and by mentoring with key professionals from within the industry, namely Dr Ed Krisinios Mt (ASCP) CIC MPH and Dr Ira Salkin Ph.D (State of New York Health Department) investigated and researched new alternative treatment technologies and systems of waste management.

Pioneered a waste management/segregation system at a local acute hospital - after agreement with the then Operational Estates Manager, P Olko - with success. The system was then introduced into Europe's largest purpose built teaching hospital, with huge savings and staff empowerment.

Sponsored by the DTI to travel to China lecturing on the systems introduced in the UK.

Currently studying "Waste and Environmental Management" at Northampton University.

Well Environmental Solutions Ltd.

Formed in 2002, after discussions with Bernhard Metals, who allowed the company to be transferred to a joint venture between Peter Olko & R Winch. Change of name to "Well Environmental Solutions Ltd" to reflect the broader spectrum of abilities within the company.

The company has associate members, whom we can call upon, from both the Private and Public sector, who have a blend of expertise, maturity and professionalism.

This ranges from:

The UK's leading Microbiologist in waste matters

Engineers who are proficient and authoritative within their fields and provide the following services:

- Water Services,
- Water Byelaws,
- Water distribution systems,
- Legionella prevention,
- Sterilization techniques and verification,
- Energy and utility management and auditing,
- Controls Assurance Standards within the NHS,
- Waste segregation systems,
- Environmental Management,
- Recycling Initiatives,
- Duty of Care audits (EPA 1990).

We offer a "one-stop solution" to waste management and environmental problems, offering engineering expertise blended with management change skills.

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FUNCTION AND SCOPE OF THE AUDIT.

Function.

To check that:

- The contracts entered into by STI Ltd. were being upheld;
- That all reasonable efforts were being undertaken to comply with working plans submitted by STI Ltd. in furtherance of their operation;
- That conditions laid down by the Environmental Bodies (the licensees) on STI to process the waste was being complied with;
- That all other legislation and "good guidance" practice etc., was being applied in the pursuit of a safe operation.

Scope of investigations.

In depth investigations were carried out into the following:

- The contract made between both parties, and terms of engagement;
- Waste movements between the hospital and STI, excluding the carriage of dangerous goods;
- Waste storage at STI;
- STI working plans and the relevant authorization;
- Safe working practices employed throughout the process chain;
- Validification of the treatment process;
- Sub- processes used off site - treatment of Pathological waste etc;
- Access to legislation and information;
- Record keeping in general.

Processes checked.

- The collection, storage of clinical waste groups A, B, C and E and the use of alternative low temperature process for its disposal and the plants efficacy.
- The collection and onward movement of Group D clinical waste to nominated known contractors.
- Bin washing and segregation.
- Record keeping and financial transactions.

MANAGEMENT OVERVIEW.

The Specification for disposal of Clinical/Healthcare Risk Waste called for "*a high quality service ... [and] ... the principles which underlie the service shall be ones which uphold the highest environmental and health and safety standards....the contractor...adapting to changing circumstances arising from new practices and evolving polices and legislation*"

In viewing the operations with STI Ltd, the company display excellent systems/protocols, managed by professional and technical staff, in the pursuit of a high level clinical waste process to Health Care providers enabling them to discharge their liabilities under the "Duty of Care" within the Environmental Protection Act 1990 with confidence.

For an embryonic company, the standards are indeed high, and would be viewed jealously by others in the field. It is suggested that these documents, where relevant, be extended out to sub-contractors within STI Ltd's control. Thus ensuring if needed that others are working to the same high standards that are employed by STI Ltd.

The documentation provides an ideal base for expansion outside the current locations, since it can be easily duplicated for similar plants of the Chem-Clav principle.

There were no visual or obnoxious emissions from the plant during the period of observation, or any indication of plant malfunction during this time, which underpins the reliability and overall effectiveness of the plant, especially in high population areas.

The only reservation would be that the "Duty of Care" audit should be applied to others within the supply chain, especially relating to sub-contractors used within the process of Clinical waste collection. That stated, this aspect was taken on board and is being instigated - see later comments regarding "Cliniframe" inspection, Page 2 & 13.

The efficacy testing is extremely detailed and frequent compared to others in the field, and it is advised that relaxation on both the frequency of testing and depth of testing be considered. [Testing frequencies in Dublin are approximately 50 times greater than in certain plants in mainland UK, and also the Antrim plant].

Special wastes - Cytotoxic, pharmaceutical and anatomical but excluding radioactive - from both Northern Ireland and Southern Ireland are transported to England and Belgium respectively for incineration. A detailed assessment was taken of the paper trail and process from STI Ltd, Antrim to its "Waste Broker" in England - Cliniframe -, including visiting and assessing the final incineration plant being used. Minor suggestions for improvements were put in place immediately. STI Ltd and Cliniframe work in a professional partnership. The client and STI ltd can be assured that waste is traceable throughout its life from cradle to grave. The company gave assurances that similar procedures were in place or being modified for the Belgium route.

Because of the ongoing nature of discussions between the JWMB and STI Ltd. radioactive waste was not investigated.

SCORING MECHANISM FOR TARGETED AREAS.

1 = Liable to prosecution, letter of improvement may be issued. This represents an organisation, where the bare minimum standards in regard to relevant legislation are not being met. No paperwork records of any kind, No risk assessment etc., poses possible major disruption to clients if the process is closed.

2 = The minimum standards laid down are only just being achieved. Major breaches may be present and poses a risk to any client. Paperwork records are not complete, not logically filed for reference etc., EA minimum licence standards are only just being achieved

3 = Minimum standards laid down are being achieved, with perhaps a few minor breaches. Paperwork is complete and resemblance of good management record keeping is kept. Risk assessment underpins policy document. Procedural documents in place but not always adhered to.

4 = Exceeds minimum standards laid down by the EA, paperwork filed and cross referenced, policy documents updated on a regular basis, sound and recorded training programs. Procedural documents are a live document.

5 = Far exceeds efficiency testing requirements, Risk assessments in place for all operations and activities, regular updating of policies and procedures, staff involvement at all levels - Model performer to industry.

Examples of compliance/non-compliance of all sections are given within the review section.

NOTE.

The ratings scored are the subjective views of Well Environmental Solutions Ltd., based on information received and seen at the time of the audit, furnished by the company being audited. Information not seen or which could not be verified at the time of the audit, cannot be deemed to be available or in existence, and was noted as such, although this may exist within the company concerned without the knowledge of the person(s) being interviewed.

Performance Score - STI Ltd.

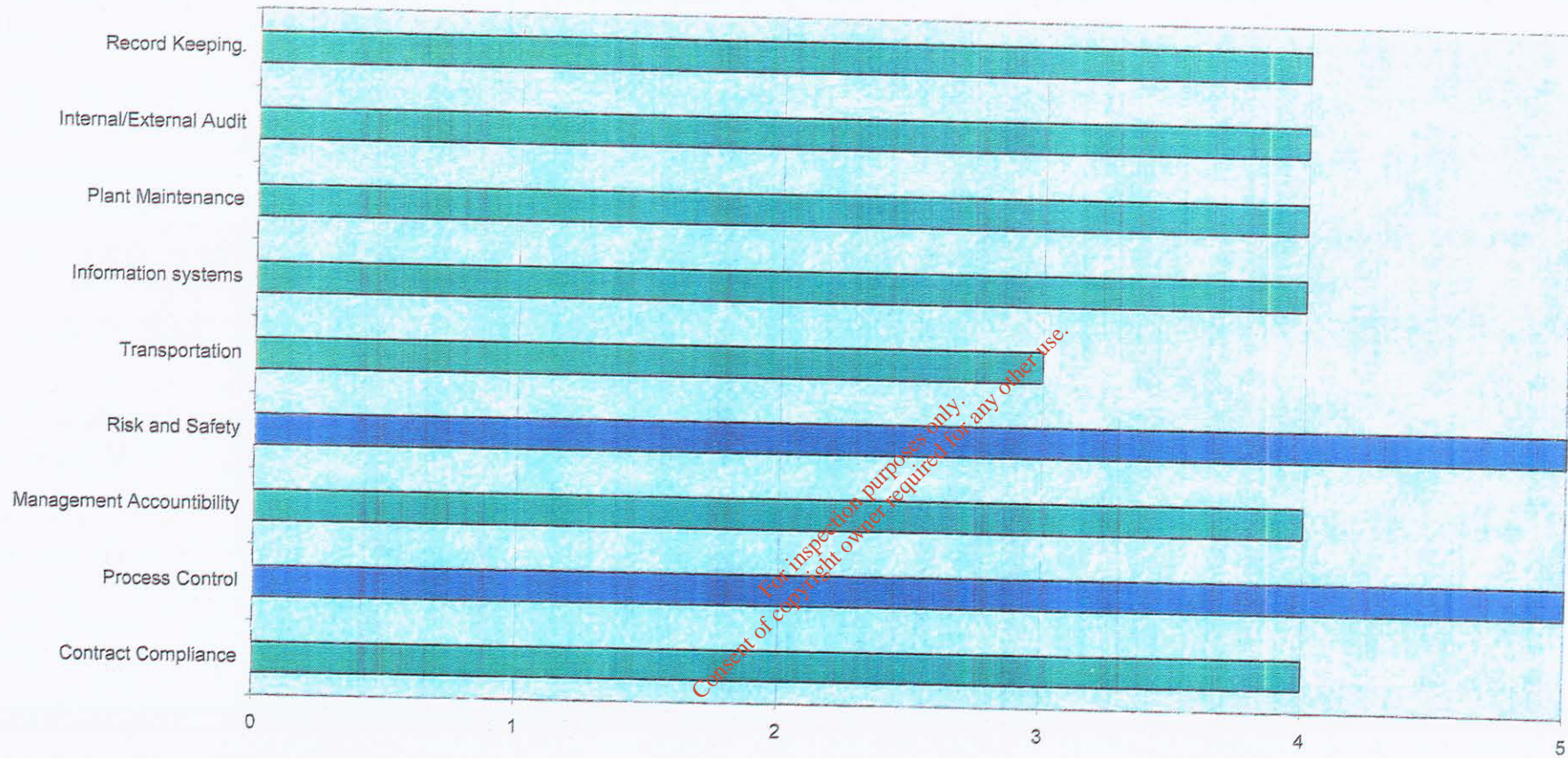


CHART 1 - Scores achieved by STI Ltd.

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SCORE CHART STRUCTURE PROFILE.

The following elements were considered in assessing the various categories. Consideration was given to the elements contained within the following publications – Environmental Protection Act (1990); Safe Disposal of Clinical Waste (HSC); HTM 2075; Controls Assurance (NHS) ; Greencode (NHS) etc.,

1. Contract compliance

Key elements of the Specification, response by STI and compliance.

2. Process Authorisation and validation.

Correctness of the working plan submitted by STI, to accurately portray the working practices employed by the company, in the gaining of its authorisation.

Updates to the EA or relevant authorising bodies to reflect any changes in practices since the original submission.

Compliance to the standards dictated by the EA or other relevant bodies in their authorisation.

3. Management Accountability.

Clear routes of management accountability throughout the organisation, with nominated officers throughout the process, ensuring that all due diligence has been exercised.

4. Risk Management, and Health and Safety issues.

Evidence of risk assessments throughout the process, documented procedures, staff induction processes; inoculations etc.

Evidence of procedures for reporting of incidents and accidents; logging of the same; investigations; staff appraisals to determine current levels of knowledge; concerns that staff may have about processes, and staff representation on committees

5. Transportation, Storage and movement of materials.

Correct handling procedures, transport procedures, training of transport staff, prevention of cross infection, undue storage time, movement of "special materials" to authorised sites.

6. Information systems and expert guidance.

Availability of information concerning the process, updates on legislation, expert guidance sources.

7. Plant maintenance procedures

Evidence of proactive and safe maintenance taking into account risk associated with material being processed, confirmation of a robust reporting procedure and feedback on any work done, adequate spares to minimise downtime.

8. Internal/external audit.

Evidence of key performance indicators, indicative of management monitoring of key elements of the process and overall efficiency/efficacy of the plant. Compliance and action plans set as a result of either internal or external audits.

9. Record keeping.

The general ability of the organisation to keep relevant paperwork, in a concise and organised manner, leading to easy retrieval and confirmation of adherence to management or other agreed procedures.

CONTRACT COMPLIANCE

The response by STI indicated that a service over and above that required would be given in the execution of its contracts. This is generally the case, in all aspects from collection, to final disposal of residue with a few minor exceptions.

The waste is collected and processed via the alternative process treatment within 24 hours and within the time frame set by the licences granted. Adequate capacity is available. The time span between collection and destruction could be fed back to the client as a key performance indicator. There had been a few breakdowns of the plant but these were mostly associated to occurrences where segregation had not been undertaken correctly by the client. The relationship with licensing bodies is extremely good, with good communications taking place both verbally and followed up in writing. An example of this is a request to extend the hours of operation of the Dublin plant. A procedure is in place for all breaches of contract/licence compliance to be recorded and notified to the authorities without delay.

Storage of waste at STI is logical and systematic. All containers are counted onto the lorries, counted into the yard in strictly defined zones/batches, weighed and treated together. This gives the ability to easily track waste, define which batches may be responsible for foreign objects - metal objects - and also invoice creation. The invoices give a detailed breakdown on the consignments/weights of the bins enabling the customer to verify, if required, his average bin weight and number of bins sent.

Marking of the containers to differentiate between "special waste" and normal Clinical Waste, is adhered to by both sides.

Whilst there are endeavours to assist the hospitals in segregation, the responses of the hospitals vary. Whether this is the blinkered view from the hospitals, that a contractor whose primary role and financial gain, is in the treatment and disposal of the waste rather than its reduction, is a moot point, or just the inability of the hospital within their current climate to introduce the changes remains to be seen.

Financial paperwork relating to the execution of the contract is extremely good, with paperwork, leaving the factory to the administration offices, several times per day, to be entered and any queries chased within 24 hours, resulting in an accurate and responsive system.

Unfortunately, the only negative comment in this section, relates to the non-functioning of the automatic weighing system, when collecting site material. This was to be a fully integrated system, linking all facets of the process operation between collection and process destruction. However, the company, have actively been investigating alternatives which will soon be installed and trailed. The client had not suffered as a result of this small problem, which demonstrates STI's proactive stance to be customer driven. (It is now understood that this has now been fully trailed and integrated into the IT network 28/6/00)

PROCESS AUTHORISATION AND VALIDIFICATION.

STI Ltd, operate very good relations with the licensing bodies, and no exceptions to the working plan were evident. Any proposed changes were already in consultation stage with the appropriate bodies. Indeed without exception, STI Ltd, were the proactive party, in ensuring that over-compliance and process efficacy was the order of the day.

In addition, not only do STI Ltd carry out independent verification of the process efficacy, but also they also employ resources in terms of equipment and staff to duplicate the tests themselves

The process verification was in excess of that requested for the plant. STI verification of once per shift (2 times per day) in comparison to some of the plants operating in the UK, at once per month, proves the commitment to ensuring high and continuous standards and is to be applauded. However, this is not achieved without financial cost, and consideration, should be given to process testing at a reduced frequency, with the possibility of all tests being carried out in house, with external verification once per week. Obviously this will need approval from the licensing authorities. There was no evidence of any failure of tests evident in the records examined. Whilst, the writer is satisfied that the process efficacy testing results are sound, further confirmation is being sought. This will be undertaken by Dr Malcolm Holiday, a leading microbiological expert, an Associate within Well Environmental Solutions Ltd. Dr M Holiday's personal opinion, based on a short previous visit, to be introduced to the new technology, is that the testing is over and above any standards set in the UK, and that the process efficacy is not in doubt. It is also suggested that Dr M Holiday, use the time when inspecting in depth to determine an optimal testing regime. He will, if required, support this application to the licensing bodies. (Please see Dr. M Holliday's comments pg 24/25)

The Licence in Dublin calls for a yearly in-depth microbiological test. Whilst this was carried out last year, STI are having great difficulty in finding a laboratory who are willing to carry out the tests. It is Dr M Holiday's opinion, to be verified in writing, that these tests are too exhaustive and potentially dangerous to verify the process efficacy and that simpler tests exist. Again he is prepared within the Well Environmental Solutions Ltd framework, to prepare a paper on this respect and assist STI, in the relaxation of the testing regimes.

STI - Dublin - have produced an Environmental report in accordance with the licence. This report shows the performance of the plant against key indicators It also shows areas of non-compliance (very minor items) and action plans for the forthcoming year. It is an excellent document. Whilst not a requirement for the Antrim Plant, similar should be considered.

Compliance to non-storage of waste on site prior to treatment for more than 24 hours is well complied with.

Record tracking for special wastes was of similar lines to that of Clinical Waste. This waste being passed to 3rd parties for destruction, in the UK or Belgium. Further verification of the time that waste is stored prior to treatment and actual proof of treatment - copies of the chart recorders of incinerator temperature - rather than in some cases, delivery notes should be sought, to bring this area to the same high - class leader - standards as the others undertaken by the company. (Please see further updated report within Transportation section)

Staffing is of a high standard, with shift leaders and shift operators being present at all times, with no lone working, this being generally in line with the process authorisation, to keep and retain minimum staffing levels during operations.

"Technically Competent Persons" are in the final stages of training at both plants, and a high calibre of management expertise is in evidence throughout all levels of the company. In addition, Mr D Rodgers possesses expert knowledge of the process working closely with the parent company.

The company adopt a policy of noting all non-conformity. A small improvement would be a history file of ad-hoc or specialist non-preventative maintenance carried out on the plant.

It was noted that all equipment, which controlled the plant process parameters, to ensure process efficacy, was padlocked off, to prevent interference or alteration. This is an extremely good practice, which on any other plant assessed by Well Environmental Solutions Ltd, will be suggested to be introduced as a minimum standard.

All key parameters as requested by the licence were monitored. However, it was noted that the temperature pen recorder at Antrim was running out of ink and only just legible. This was an exception on the day rather than normal day to day practice.

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MANAGEMENT ACCOUNTABILITY.

There was a very clearly defined management structure committed to paper.

A chain of responsibility and authority was apparent from everyone spoken to.

The Health and Safety Advisor was proficient in his task, which enabled others to carry out their duties more competently and efficiently.

Management reports are apparent in the company. These only need strengthening in the area of inserting timescales and named officers. This has already been taken on board.

There appears to have been no checks under the "Duty of Care " on either any external transportation companies employed or where the final residue is being deposited, at the time of our visit, particularly in Dublin. Management took this comment on board and steps are being taken either, to rectify this or verify in writing and by personal inspection, the verbal comments given to them previously by these companies.

Management accountability is also underpinned by the rigid adherence to Safety Protocols, including a section for complaints, which must be recorded. Examination of the Dublin records showed only one complaint from a local electrical contractor, which was verified and responded to within a few days. Such is the unobtrusive nature of the plant that no other complaints had been received regarding any operational aspect.

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RISK MANAGEMENT, AND HEALTH AND SAFETY ISSUES.

There is an extensive and exhaustive set of risk assessments associated with each plant. These were necessary for the granting of the initial licences. These are an excellent set of documents, which along with the process validation will give the company the ability to give a pedigree of experience for either new contracts or possible new sites/new licences. It is therefore imperative that these are kept up to date. There were one or two minor instances of this not being achieved. This was recognised and is being rectified.

All staff operatives had been assessed for risks in the waste that they were handling and appropriate inoculations given. Strict procedures were enforced for visitors especially in the laboratory areas. There are several companies – subcontractors - who are engaged in the transfer of the waste; whilst these companies are stated to have similar procedures there was no evidence to prove the same. The companies should provide this information. STI Ltd should consider the possibility of sub-contracting their Health and Safety Manager to undertake risk assessment and safety training to these companies as an incentive to partnership working.

Regular meetings were being held to discuss management and worker issues including those relating to Health and Safety issues. Issues and rectifications were recorded, along with officers who are responsible for the tasks. The tasks were not prioritised and did not have time scales. This was immediately rectified upon being mentioned.

Staff training was taking place with priorities being set by the Health and Safety Manager. These were being supplemented by specialist video sessions. Whilst the company is small enough for all personnel to know each other and their method of work, formal assessments on the training given has not been undertaken. It is suggested that an appraisal on the effectiveness of the training – by way of a simple questionnaire or test – be undertaken. This will prove invaluable in the case of limited English speaking workers. Simple staff training information books, which the staff could refer to, would be advantageous. Due to the recent management changes it was noted that regular staff appraisals had ceased. This should recommence if at all possible.

Protective equipment was provided for all tasks requiring such and staff were observed to be using it.

Inspection audits in line with the procedure manuals are in place. It should be considered that a record of these audits be placed on all main notice boards, along with the dates of future inspections, inviting any comments to be forwarded to Management beforehand.

There was a recording system for accident reporting. There appeared to have been no serious accidents or incidents since the plant commenced working in both locations as would be expected from such tight and sound management systems.

TRANSPORTATION, SEGREGATION, STORAGE AND MOVEMENT OF MATERIALS.

Comments regarding training of sub-contractors were covered within risk assessment.

All drivers with STI Ltd had received training and the requisite inoculations. Spillage kits were confirmed as being available on all vehicles.

From our experience of visiting two sites that had contracts with STI Ltd, the segregation of waste seemed to vary. Every possible means being undertaken to ensure that all staff were aware of the need to ensure that non-acceptable material - tissue, amputations etc., along with special waste - was not transported to STI. However there have been occasions when non-acceptable waste has been received. STI Ltd have a good policy of quarantining the offending bin and returning it to the hospital at cost for correct segregation. This attitude is applauded. It is recommended that this clause and also the clause regarding downtime of the machine caused by offending articles be standard clauses within any contract. It is our experience that unless hospital management adopt a waste strategy of segregation underpinned by top management support that poor segregation will only result.

Special waste is collected on specific days and passed immediately to a "Special Consignee" at Dublin. STI Ltd are looking to establish their own waste transfer station themselves at this location, already operating such a facility at Holywell hospital, Antrim. Bringing in in-house outside arrangements will only improve the synergy of the company. It is recommended that STI Ltd ask for more exhaustive proof than delivery tickets to the transporters of their waste for incineration and the processor, asking for substantive proof of the consignment into the incineration process and also carry out a Duty of Care audit on these third party operators.

Bin weights are fed back to the user to ensure that packing densities can be maximised. This obviously saves on transport and environmental pollution, which is to be recommended.

Once delivered to STI Ltd, the waste is segregated by lorry collection and hospital. Each batch is then destroyed after bin weighing. Each shift a sample of the residue is taken to verify the process. Only after this has proved satisfactory - always on the records, which we observed - is the residue allowed to be sent for landfill. Any failure would be subject to re-processing and re-verification.

Special Wastes.

Of most concern to hospitals are those wastes which are considered more hazardous than the normal Clinical wastes derived from normal nursing care, these are Cytotoxic, Pharmaceutical and Anatomical. STI plants in Ireland are not licensed to destroy this waste. To ensure compliance to the contract it is sub-contracted and incinerated either in Belgium or England.

The processes and paper trail from Antrim plant was audited with the following observations being made:

- Once received at Antrim it is stored within a secure area, anatomical waste being stored in refrigerated containers. These facilities are checked at least once per day.
- The waste is then palletised and transported via an approved disposal contractor in England via the control of "Cliniframe" Ltd.

- "Cliniframe" are managed/operated by a management team who have over 20 years experience in the clinical waste management industry. The company operate a registered Waste Brokers license approved by the EA. (The original document was seen) "Cliniframe" has a range of preferred licensed "incinerator" contractors it can place the waste with. These are normally with such companies as White Rose, BFH etc.,
- The received waste is either shipped direct or stored at a licensed transfer station. This transfer station has a licence to store waste for up to 4 weeks, including freezers for the anatomical waste

Transfer notes were examined for recent loads and also the last shipment tracked to White Rose of Bolton.

The systems employed throughout the chain allow the following to be noted:

- Date of collection from hospital, weight and STI consignment number,
- Date of palletisation, total palletisation weight and shipping transfer note - Plant to docks, Port to Waste transfer station,
- Waste movement from transfer station to approved incinerator operator.
- Date of receipt by incinerator operator, time of incineration of waste, weight of waste incinerated.

The incinerator at Bolton was visually checked, it was noted that 109 days had elapsed since the last reportable incident, and previous to that 1079 days, indicating a good health and safety record. All records requested were quickly retrieved indicating a good system of management. The Environment Agency visit sheets were checked and no adverse comments were noted. It was noted that waste once received at the plant was generally incinerated with 4 -12 hours

Within the previous month - Well Environmental Solutions - had carried out a "Duty of Care" audit on a sister plant to that of the Bolton Plant, and we concluded that the company operated a good system of management and record keeping as well as incineration of waste at/above the legal limits.

Both "Cliniframe" and "STI" work in close partnership to ensure the adequate tracking of information to ensure not only that the waste is incinerated correctly but also that a pedigree of information is available should it be required to prove to the hospital that "special" waste has been disposed of correctly.

Obviously different incinerator companies employ different documentation procedures, and whilst not a problem, it is suggested that "Cliniframe" attempt to standardise the information given to STI. (It is acknowledged that this has been taken on board and is being investigated.)

The mechanism/paperwork for waste shipped to Europe (Belgium) whilst not checked is - and I have no reason to doubt it - being subjected to the same rigorous management checks as that described above.

Note.

Radioactive waste was not tracked, since this area is currently undergoing discussions with STI/JWMB.

INFORMATION SYSTEMS AND EXPERT GUIDANCE.

Copies of the key documents, safety information, non-conformance reports are held in the main reception, to be viewed by members of the public on request. This stance typifies the openness and confidence that STI Ltd have in their plant and management.

A vast library of information on this technology, standards to be employed and standards within alternative process technologies was available at the Dublin HQ. In addition, a research engineer is employed who can assist the General Managers and other staff should it be required. However, the standard of prepared information, is such that this should be the only information that needs to be referred to, except of course for further improvements or recourse to new legislation.

It is suggested that as part of the audit process, that each General Manager at least twice per year, carry out a structure audit on each other's plants in addition to the normal audits. Often a fresh pair of eyes can see items that others cannot.

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PLANT MAINTENANCE PROCEDURES

The continuous availability of the plant confirms that a high standard of maintenance is being carried out.

Standard sheets incorporating visual inspections and regular maintenance tasks were inspected and found to be complete. One task had been discontinued, but was not removed from the sheet, although a line was scored through this. It is recommended that the sheet be revised to eliminate this entry, in case it is thought that it was not done.

There is evidence of safety procedures including disinfection of the plant and "Permits to Work" for both in-house labour and outside contractors. Whilst it is accepted that the plant is safe after disinfection, it is recommended that a risk assessment be undertaken for outside contractors who are working on the internal components of the machine or in other areas within the factory. Culminating from this risk assessment, the company should recommend the appropriate training or/and inoculations for the staff involved.

The Dublin plant is a single item of plant. Problems had been experienced in the past with damage to the shredder blades (incorrect segregation at the hospital), to remedy this an extra shredder has been incorporated. At Antrim this situation does not exist, since there is a duplex plant arrangement. This arrangement reduces the need for spares and ensures continuation of the process without disruption to the client.

The process is underpinned by the adherence to time and temperature relationship, with all key parameters monitored and recorded. It was extremely gratifying to note that all control panels were locked off so that no modifications could be made. This regime will be suggested for all future plants examined by Well Environmental Solutions Ltd. All instruments, including the weigh-bridge had been subjected to a calibration check by an independent outside company.

Maintenance is carried out on the containers, and no adverse comments on this respect were made by any of the clients we visited. Although the company, informed us, that it is aware of criticism in this respect. STI Ltd are instigating both an increase in the number of bins and also are in the process of implementing a maintenance system that will replace/overall the bin locks and ensure that this aspect of the service reaches customer requirements.

INTERNAL/EXTERNAL AUDIT.

Internal benchmarks.

Throughput per month, process downtime caused by incorrect materials, customer bin weights are all recorded. Whilst this is discussed in management meetings, no formal presentation or graphics were upon company notice boards highlighting these. It is suggested that these be formally charted and displayed, including the % conformity of samples.

Copies or extracts of the environmental report should also be posted on main notice boards both as an illustration both to the workforce and any visitors just how well the company is performing.

There were no adverse comments from the Council in Antrim, who license the plant. Indeed they were very happy about the complex. The Environmental report forms the basis of inspection requirements with Dublin. Examination of the correspondence with the relevant licensing authority found no adverse comments.

STI Ltd should consider producing a similar "Environmental report" for Antrim as is produced by Dublin. This will strengthen the external audit requirements for Antrim and portray STI Ltd as an open organisation.

Copies of the environmental report should be placed in main reception, along with such items as efficacy testing results etc., to show an open organisation and indicate that high performance standards are being achieved.

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RECORD KEEPING.

Examination of the records gave a clear indication of a very good system of management control, in that:

Delivery tickets/ weigh tickets were collected from the factory floor at regular intervals and inputted into the computer systems. Invoices were cross-related to these tickets. No backlog was evident. All documentation was punched and filed

All Efficacy testing results were complete, up to date, punched and filed and no missing dates/paperwork was evident.

Evaluations are taking place for a new computerised bar-coded tracking system for the containers. This can only improve the already tight and good systems in place.

Medical records relating to staff were checked and found to be complete.

Training records were present to show which subjects operatives had been trained on. It is recommended that each member of staff has his own folder for training publications, appraisals etc., and that certificates of competence be issued following an assessment of the training given. This will achieve a three-fold purpose:

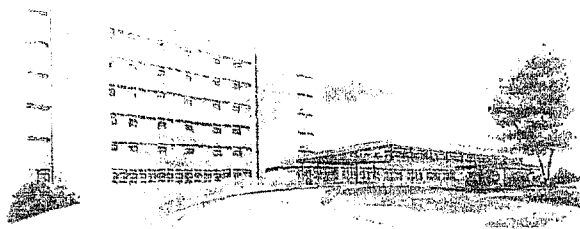
- Allow management to assess the effectiveness of the training material issued/ the mode of training
- Evaluate the ability of the operatives to digest the information and put into practice that which he/ she has learnt.
- Recognise their achievement.

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SUPPLEMENTARY INFORMATION – Dr. M Holliday.

Dr. M Holliday, Consultant microbiologist, visited Antrim and Dublin plants over a two-day period. His assessment, which is attached, supplemented and verified, the investigations of Well Environmental Solutions Consultants. No adverse comments were noted either verbally, at the time of inspection, or within the letter.

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— CPA ACCREDITED LABORATORIES —

Mr Peter Olko
Well Environmental Solutions Ltd
63 Forest Road
Annesley Woodhouse
Nottinghamshire
NG17 9HA

18/04/2002

Dear Peter,

Re: Sterile Technologies Ireland Ltd

Having inspected both the Dublin and Antrim clinical waste treatment plants operated by STI Ltd and having viewed operations and records on-site, I concur with the findings in the Duty of Care Audit carried out by Well Environmental Solutions Ltd.

In respect of the Microbiological testing procedures employed, it is my opinion that STI have undertaken an extremely proactive and sound approach to ensuring that the testing is valid.

In particular I find:

- 1) The original Microbiological commissioning and validation protocol was drawn up by experienced and competent Microbiologists and was agreed by all parties prior to commencement. The protocols employed are sound and valid and exceed the requirements for Microbiological validation in England, Scotland and Wales.
- 2) In addition to regular external validation by spore test (recognised as the most resistant form of microbial life and therefore the most difficult challenge to set), STI have instituted a voluntary programme of daily in-house spore testing. The methods used are sound and valid and are overseen by an operative with Microbiological experience. The tests are also checked by an experienced Microbiologist from the external testing laboratory on a regular basis. This is far in excess of the Microbiological testing performed in any other clinical waste treatment facility that I am aware of.
- 3) As long as the original Microbiological commissioning and validation tests were satisfactory, and routine spore testing shows satisfactory results, in my opinion, there

is no need for an annual repeat of the commissioning tests. This would not prove anything that had not already been proven.

- 4) It is my opinion that the parametric monitoring performed by STI coupled with the comprehensive in-house spore testing would support a reduction in the frequency of external testing (providing that there are no causes for concern shown by the results) to perhaps once a fortnight or once a month. The use of colour change thermometric strips daily would provide further parametric evidence of satisfactory heat disinfection.

I found the STI plants to be well run, with a commitment to quality and safety.

Yours sincerely



Dr M G Holliday
Head Scientist and Laboratory Manager

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