PUBLIC CONTRACTS APPEALS BOARD

Case No. 40

CT 2001/2004, Advertisement No. 94/2004, DH 2185/03
Pre-Qualification Questionnaire for the Supply, Installation and Commissioning of a CLINICAL WASTE DECONTAMINATION PLANT

In April 2004 the Health Division, through the Department of Contracts, issued a pre-qualification questionnaire document for the supply, installation and commissioning of a clinical waste decontamination plant together with ancillary equipment and services at *Mater Dei Hospital*.

The closing date for submissions was 15.06.2004

An Adjudication Board consisting of

Mr Joseph Stafrace	-	Assistant Director, Health Division (Chairman)
Dr Michael A Borg	-	Consultant Infection Control, St. Luke's Hospital
Mr Dennis Grech	-	Operations Manager, St Luke's Hospital
Eng. Chris Attard Montalto	-	Manager Medical Equipment, Mater Dei Hospital
Ms Henriette Debono	-	Hazardous Waste Officer, WasteServ Malta Ltd

was constituted to anlayse a total of twenty six (26) proposals.

Following clarifications requested by Messrs Environmental Services Ltd (representing WRE Ltd) and correspondence relating thereto, on 19.04.2005 the Adjudication Board formally reported to the General Contracts Committee that 'inter alia' "*This pathological waste efficacy requirement was the critical factor behind the original elimination of this bid. It is clear that the AB's original interpretation was correct and has been simply substantiated by further investigation. As a result the AB once again recommends, that the bid in question should not be short-listed for the second phase and to be eliminated for the very same reason for which it was not included in the original shortlist insofar as efficacy in the treatment of pathological waste is concerned*.", thus discarding in the process the offer submitted by Messrs Environmental Services Ltd.

As a result of this decision, Messrs Environmental Services Ltd filed a Notice of objection on 30.05.2005 against the decision taken by the General Contracts Committee not to short-list the Company's offer.

The Public Contracts Appeals Board (PCAB) made up of Mr. Alfred Triganza (Chairman) with Mr Anthony Pavia and Mr. Maurice Caruana, respectively acting as members, convened two public hearings on 18.07.2005 and 29.07.2005 to discuss this objection.

Present for the hearings were:

Environmental Services Ltd/WRE Ltd
Dr Anna Mallia – Legal Adviser
Dr Ramiro Cali-Corleo MD MSc – Managing Director, ESL
Dr Kenneth Stewart, Managing Director WRE Ltd, Scotland

Health
Mr J Degiorgio – Assistant Director, Finance
Ing Ray Piscopo – Mater Dei Hospital

Adjudication Board
Mr Joseph M Stafrace – Assistant Director, Health Division (Chairman)
Dr Michael A Borg – Consultant Infection Control, St Luke Hospital (SLH)
Mr Denis Grech – Operations Manager, Estates and Waste, St Luke Hospital (SLH)

After the Chairman's brief introduction, the representatives of ESL/WRE were invited to give a brief resume' relating to the motives leading to their objection.

Dr Anna Mallia, the appellant's legal representative, explained that her client was under the impression that on 8 February 2005 (the date of the PCAB's report relating to the first objection raised by her client in connection with the same tender) the PCAB had already decided in their favour after evaluating all the technical aspects of the tender and that they had already availed themselves of the procedure under Regulation 102 of Legal Notice 299/2003 and surpassed it. Therefore, she claimed that the next stage was to proceed with the tender process itself and not to return to the pre-qualification stage. She insisted that, in the prevailing circumstances, it was imperative that, first, one should clarify the legal considerations relating to this matter. Dr Mallia pointed out that Regulation 102 (9) of the Public Contracts Regulation 1999 specified that:

'The decision of the Board shall be final and binding on all parties and the award procedure shall proceed in accordance with its decision.'

At this stage, Mr A Pavia, PCAB, intervened to clarify that during the sitting of the 26th January 2005, this Board had found that the evaluation process had not been carried out in full due to a misunderstanding on two items and, as a consequence, it decided that the evaluation process should be carried out in full with the further necessary evaluation of the offer made by the same appellant.

Mr Stafrace contended that, technically speaking, they were still at the pre-qualification stage. He insisted that they had not yet concluded this phase and the PCAB had still to decide whether to include the appellant to the short listing for the closed tender phase.

Dr Cali-Corleo, contended that, following the PCAB's original decision, the Adjudication Board did not evaluate further but it actually re-evaluated what they had already examined before.

When asked by this Board about the exercise carried out in the pre-qualification process after the Board's decision, Dr Borg explained that in view of the fact that in the case of ESL the evaluation had stopped at the preliminary stage, they undertook the same detailed process of assessment as was done with other companies that had passed through the initial phase. He proceeded by saying that they reviewed documents which were not even available at the initial appeal stage including totally new scientific documentation. During this process they had to establish whether the technology they were proposing was capable to process all types of clinical waste. He contended that the appellant did not produce any scientific evidence to support its claim regarding efficacy. Mr Stafrace interjected and added that, apart from the point raised by Dr Borg, the facility proposed was not suitable for the need of the new hospital and therefore could not be accepted for further evaluation in the next tendering stage.

Mr Denis Grech, another member of the Adjudication Board, testified that following the PCAB's decision, they reviewed all the documentation, asked for further clarifications and documentation, raised a number of queries, and even allowed the appellant to make a presentation. He proceeded by explaining that this procedure was not adopted at the earlier stage with the appellant because they were eliminated at the preliminary stage. They came to the conclusion that the validation studies presented by ESL did not conform to the minimal standard set in the State and Territorial Association on Alternative Treatment Technology (STAATT) document. They also asked the bidder to submit copies of environmental/ state licences as they did with the others and as originally requested in the Pre-Qualification questionnaire. He said that from the documents submitted it was established that the Dublin Plant could not process blood products which was amongst the waste streams. They did not receive the copy of the Licence pertaining to the Antrim plant, which was brought up for the first time in the March presentation.

Dr Mallia claimed that the pre-qualification phase was not contemplated in the law and asked the PCAB to seek legal advice regarding the interpretation of the regulation before it proceeded with the technical reasons. However, the PCAB pointed out that, first, they had to establish whether they were re-discussing the same issues which were raised and decided upon in the first appeal.

Dr Cali-Corleo said that in the first hearing the matter of skips was conceded and that of pathological waste treatment efficacy was also decided in their favour. In fact he claimed that in the PCAB's decision it was stated that:

'Appellant provided evidence to prove that the waste treatment system proposed was capable to process all types of clinical waste.'

He argued that the telefax message sent by the Department of Contracts on 11 May 2005 which stated that the bid should not be eliminated for the very same reasons for which it was not included in the original shortlist insofar as efficacy in the treatment of pathological waste was concerned meant that they had re-examined items that had already been decided upon.

However, Dr Borg said that originally their offer was eliminated not on the scientific and technical characteristics of the decontamination plant offered by the appellant since this aspect had not yet been evaluated. He contended that Messrs

Environmental Services Ltd were eliminated for other reasons in the remaining pre-qualification stage following evaluation of additional documentation.

At this stage, the PCAB suspended the sitting for a few minutes to deliberate on the matter.

When the hearing resumed, Mr Stafrace was called to take the witness stand since it was considered indispensable for the PCAB to determine on which of the critical criteria ESL's proposal failed in the initial stage, and on which others, if any, it failed following the PCAB's decision.

The witness testified that in the preliminary assessment the STI device did not satisfy two of the critical criteria, namely 1.6.21 '*… can function with waste containers > 500 litres*' and 1.6.18 1.6.18.1 *'Evidence validating compatibility and suitability for all infectious waste streams esp pathological'*- both marked N on the Grid. Mr Stafrace said that subsequent to the PCAB's decision , the appellant did not only fail again on the issue concerning pathological waste but also on other two critical criteria namely 1.3.2 *'Track record and reliability of the supplier and their local representative'* and 1.6.27 *'No potential problems with landfilling of end waste nor conflict with local waste or incineration legislation'*.

Dr Cali-Corleo interrupted Mr Stafrace and insisted that they were already judged on efficacy because they provided evidence.

Mr Stafrace replied by stating that the Board's technical people were not satisfied while Dr Borg insisted that during the first appeal's hearing he heard assertions and not evidence. It was emphasised that all documentation evaluated after the Board's decision was not assessed before.

A lengthy discussion ensued on the technical consideration of the STI devise with both Dr Borg and Dr Cali Corleo making reference to various documentation and correspondence to substantiate their arguments on whether the Adjudication Board's decision to eliminate ESL/WRE's bid was justified or not.

With regard to the *Antrim Waste Licence*, Dr Borg declared that they had never received such a licence while Dr Cali Corleo claimed that the said licence was sent by fax to the Adjudication Board.

ESL's representative rebutted the argument that the document issued by the State of Michigan pre-dated the STAATT technical manual, by pointing out that STAATT I was much more stringent than STAATT II and therefore demanded a higher standard of efficacy.

Mr Stewart, Managing Director WRE Ltd, clarified that the term "*identifiable body parts*" was a specific term used in health care waste treatment and only referred to amputated legs and arms. He said that the Maltese authorities did not intend to process these amputated body parts in a clinical waste decontamination plant because of ethical reasons. However, STI plant would be able to handle such body parts had there not been such ethical issues.

At this stage, the PCAB decided to request both parties to file written submissions on what was discussed during this hearing, insisting that these should base their arguments on the documentation received before the date of the Adjudication Board's report dated 19 April 2005. It was agreed that such written submissions had to be forwarded by 22 July 2005 at 14.00 hours, following which another public hearing would be held on 29 July 2005.

Following receipt of the said written submissions, the PCAB reconvened the hearing in order to enable both parties to rebut the points raised in their respective written submissions.

Before proceeding with the discussions that ensued during the hearing, it may be pertinent to reproduce (in their entirety) the written submissions presented to this Board by the respective parties:

Submission presented by Adjudicating Board

Quote:

CT 2001/2004, ADVERTISEMENT NO. 94/2004, DH 2185/03

PRE-QUALIFICATION PROCESS FOR THE SUPPLY, INSTALLATION AND COMMISSIONING OF A CLINICAL WASTE DECONTAMINATION PLANT AT MATER DEI HOSPITAL

Submissions following the Public Contracts Appeals Board hearing of 18th July 2005

Following the request of the Public Contracts Appeals Board (PCAB) at the meeting of 18 July 2005, the Adjudicating Board (AB) respectfully presents the following arguments in complete rebuttal of the arguments raised by Environmental Services Ltd (ESL) in their motivation letter dated 28 June 2004 (incorrect year?) and subsequently at the abovementioned hearing. In accordance with the PCAB chairman's instructions, the AB is basing its assertions on documentation received before the date of its report issued on the 19th April 2005.

Objection No 1: "False and misleading information"

The reference to "false and misleading" information (*Attachment 1*) is very specifically related to the assertion made by Dr. Cali Corleo at the first appeals hearing of the 26 January 2005 namely that " … *in Ireland, the documentation provided was sufficient for their devise to be granted the licence to handle all clinical waste*" [Pg 9 of PCAB report 8/2/05] [*Attachment 2A*] and subsequently in the ESL letter dated 1st April, 2005 where in para 3, he states "*Our Principals, WRE, have confirmed that the Dublin Plant does treat soft pathological waste and in particular placentae…..*" [*Attachment 2B*]. These statements have been proven to be incorrect by the unequivocal declaration forwarded on the 11 April 2005 by Mr. A. Stephens of the Office of Environmental Enforcement in Ireland stating that both soft anatomical waste (including placentae) and bulk body fluids are prohibited by the licence issued (*Attachment 3*). There can be no doubt in the minds of the AB members that these statements misled the PCAB in the first hearing to believe that the Dublin plant (which was used as a testimonial in the original tender submission) was authorized to treat these waste streams, when in fact this was factually not the case. Furthermore, if the AB had not undertaken the exhaustive initiative to seek independent confirmation of these false claims, it would also have been misled in the matter.

Objection No 2. Date and contents of Michigan document

The pre-qualification document clearly stated in PQ1.6.20 that "the level of treatment achieved by the plant as per classification defined by the United States State and Territorial Association on Alternate Treatment Technologies (STAATT) as validated by relevant testing."

The testimonial from Michigan is inadmissible because it pre-dates (not post-dates, as incorrectly stated in the motivation letter) the STAATT technical manual. The date of the STAATT report (which supersedes all previous STAATT documentation) is December 1998 (*Attachment 4A*). The Michigan documents submitted by ESL are dated April and November 1996 (*Attachment 4B*) - a full two years previously. In addition they refer to the Chem-Clav® model; the PCAB will recollect that one of the issues to which tenderers had objected to in the first appeal heard in January 2005 was the reference to the Chem-clav system in the AB pre-qualification report, which they said was not the model they were proposing for Malta.

Furthermore clause 1.6.2 of the pre-qualification questionnaire clearly states that proof of environmental authority authorisation should be from an EU country.

Objection No 3. Track record of similar plants in the EU which process the same waste streams as those required in Malta

This is a major issue since it directly affects two critical criteria which the AB adopted to eliminate other bidders in the pre-qualification process namely:

PQ 1.6.2	Track record of the technology
PQ 1.6.27	No potential problems in landfilling or complying with legislation

These clauses were included in the pre-qualification questionnaire at the specific instance of the Malta Environment Planning Authority (MEPA) that a documented track record showing that the technology is approved in EU countries to treat all infectious waste streams relevant for Malta would be a pre-requisite for ultimate issue of a permit for the plant finally chosen and also for approval for the end product to be landfilled. This pre-requisite was included in the AB pre-qualification report and made clear in the first appeals hearing where as already stated, Dr. Cali Corleo had said that this was not a problem because " … *in Ireland, the documentation provided was sufficient for their devise to be granted the licence to handle all clinical waste*" [Pg 9 of PCAB report] [Attachment 2A] and subsequently confirmed in the ESL letter dated 1st April, 2005 where in para 3, he states "*Our Principals, WRE, have confirmed that the Dublin Plant does treat soft pathological waste and in particular placentae…..*" [*Attachment 2B*].

However the AB was concerned when, as part of its independent research instituted as a result of inadequate official documentation provided by ESL, it came across in the internet a Technical Committee report from the Environmental Authority in Ireland which indicated that amongst the waste streams "*unsuited for treatment by the process*" were "*(iv) identifiable body parts and (v) blood products*" [*Attachment 5*]. The same document clearly states that "*all blood plasma (waste) was … exported to Scandinavia for treatment*". The AB was furthermore not convinced by the assertion from ESL that the term identifiable body parts referred to limbs. As a result the AB sought independent confirmation from the Office of Environmental Enforcement in Ireland which is the legal regulatory authority for the Dublin plant. Final and irrefutable clarification was obtained through the unequivocal declaration by Mr. A. Stephens of the EPA Ireland, stating that both soft anatomical waste including

placentae and bulk body fluids are currently prohibited by the licence issued [*Attachment 3*].

During a presentation made by ESL's principals, held at the Offices of the SLH CEO on the 15 March 2005, Mr Randall G. McKee, President STI Services made the first reference to another plant, this time in the United Kingdom (Antrim, North Ireland). Whilst the AB could have rejected any reference to this plant since it was not included in the pre-qualification submissions, for fairness sake, it was deemed admissible for evaluation as long as the necessary documentation was provided, namely:

- Full application including the working plan referred to above
- Commissioning report
- Environment Management Plan

It was also made clear that this documentation should have been submitted in the first instance and unless provided immediately, it would not be possible for the Board to include any reference to the Antrim plant in its considerations [*Attachment 6*].

Following this request, ESL faxed a letter from Mr. M. Johnston of the Environment & Heritage Service of North Ireland [*Attachment 7*]. Upon scrutiny however note that the following waste streams were *"not accepted at the* (Antrim) *site:*

f) Identifiable anatomical waste
g) *Animal carcasses or parts thereof.*

This was explained by ESL to be due to "ethical" issues (again repeated by Dr. Cali Corleo in the second appeal hearing) but as in the case of the Dublin plant, the AB was not convinced, particularly as it could not see ethical issues in the treatment of parts of animal carcasses.

The AB attempted to get additional further information of the Antrim facility from Mr. Johnston asking specifically whether the plant was authorized for the treatment amongst others of pathological waste and body fluids, similar to that provided by Mr. Stephens for the Dublin plant [*Attachment 8*]. However, the documents received did not in any way clarify whether the plant is actually approved and in use for the processing of soft tissue pathological waste, stating instead in a non-committal manner that their legislation "would allow" such waste to be processed by a non-burn technology [*Attachment 9*]. Several phone calls and a fax reminder was sent by the Chair of the AB to provide a clear definite reply to the queries raised [*Attachment 10*]. Mr Johnston replied on 18 April 2005, but simply stated that he was not in a position to provide any further information [*Attachment 11*]. In addition, the technical documentation requested from ESL was never provided by the tenderer other than a letter referring to Mr. Johnston's fax [*Attachment 12*]. The PCAB will agree that it was the onus of ESL to provide the necessary documentation to allow the AB to undertake the relevant technical evaluation and that they had more than ample time from June 2004 (when the pre-qualification document was published) to April 2005, to provide basic documentation pertaining to their own companies. In the light of the foregoing, the AB could not consider the Antrim plant as a testimonial since the bidders did not provide the specifically indicated documentation in support of their claims, despite clear and specific requests.

Hence the clear conclusion is that ESL were unable to show a sufficient track record that would satisfy the PQ requirements (PQ1.6.2) and would provide reasonable confidence that a permit would eventually be issued by MEPA without problems in obtaining approval of landfill disposal of the end waste (PQ1.6.27). Since these two were deemed as critical factors, the bid by ESL should not be considered.

Objection No 4. Efficacy documentation of technology

As already stated in Section 2, above, the pre-qualification document required compliance with STAATT protocols and methodology, particularly where microbiological tests to validate the efficacy of the system are concerned. These are set out in great detail including specific instructions on which organisms are to be used for the test [*Attachment 13*].

STAATT REQUIRES THAT: "*AS A MINIMUM, ALTERNATIVE TREATMENT TECHNOLOGIES SHALL TEST FOR THESE MICRO ORGANISMS:

- *MYCOBACTERIUM PHLEI* *
- *MYCOBACTERIUM BOVIS* (ATCC 35743) *
- *BACILLUS STEAROTHERMOPHILUS* (ATC 7953) *
- *BACILLUS SUBTILIS* (ATCC 19659) *

THE VALIDATION TESTS PROVIDED BY ESL [*ATTACHMENT 14*] ON THE 18TH MARCH 2005, ESL AND WHICH UNDERTAKEN IN DECEMBER 2004 BY ANALYTICAL SERVICES INC. AND INFORMATION FROM SCIENCE LLC, UTILISED "TREATED AND SHREDDED MEDICAL WASTE" SPIKED WITH DIFFERENT BACTERIA I.E.:

- *MYCOBACTERIUM TERRAE* (ATCC 15755)
- *BACILLUS ATROPHAEUS* (ATCC 9372).

AMONGST THE CONCLUSIONS, WAS THAT THE RESULTS WERE NON-CONCLUSIVE FOR MYCOBACTERIUM DECONTAMINATION AND "STI (HAD) DECIDED TO RE-TEST AT BOTH SITES FOR MYCOBACTERIUM REDUCTION".

The AB cannot therefore accept the validation studies presented by ESL since these did not conform with the minimal standards set in the STAATT document. Any claims of equivalence from individuals or consultants employed by ESL are not acceptable to the board which insists on compliance with the official document.

Objection No 5. Relevance of prior appeal decision

The AB strongly contends the arguments raised by ESL's legal counsel during the second appeal hearing of the 18 July 2005 that the PCAB's decision of the 8th February 2005 should result in the bid by ESL being automatically shortlisted for the closed tender phase, for the following reasons:

1. The AB report dated 8 November 2004 on the pre-qualification process clearly indicated that the actual pre-qualification process was preceded by "*an initial assessment of the offers and eliminated a number of proposals which prima facie clearly did not comply with one or more of the critical factors ….*" In this

process a number of companies including ESL were eliminated without the need to

- undertake in-depth analysis of the submissions,
- request further clarifications
- provide a presentation on the technology

In the case of ESL this followed the statement in their original submission that pathology specimens as well as small body parts, tissues, fluids and carcasses " *….. can be handled if an optional WR2 'Tissue Digester" is also installed"* and was interpreted to mean that the STI unit was not capable of processing them. Since this was a critical requirement, no further evaluation was deemed necessary [*Attachment 15*].

It therefore follows that the first objection by ESL was referent only to this preliminary process. The fact that the PCAB upheld this objection meant that the AB had to undertake the same detailed process of assessment as that done for the other companies that had passed through the initial preliminary phase. In fact the PCAB report dated 8 February 2005 states that *"the PCAB ruled that, should the appeal by Messrs Environmental Services Ltd be upheld, there would remain the opportunity to file another objection if their bid were to be eliminated for other reasons in the remaining pre-qualification stages"*. This is further deducible from the PCAB decision ruling that *"once it has upheld the appeal lodged by ESL, the evaluation process should now proceed with the necessary evaluation of the offer made by the same appellant"*. If the PCAB had decided otherwise, they would have simply instructed the AB to include ESL with the other short listed offers for the second closed tender phase.

2. It would appear that a major factor in deciding the first PCAB appeal in favour of ESL was as a result of the PCAB's conclusion that "*appellant provided evidence to prove that the waste treatment system proposed was capable to process all types of clinical waste"* [Pg 10, last para, PCAB report]. Since, during the first appeals hearing, ESL did not provide any documentation to the PCAB for review, it is the AB's opinion that the PCAB must have come to this conclusion based on the <u>verbal</u> submissions of ESL and its foreign advisors, especially the statement by Dr. Cali Corleo that " … *in Ireland, the documentation provided was sufficient for their devise to be granted the licence to handle all clinical waste*" [Pg 9 of PCAB report]. There can be no doubt that this statement referred to the Dublin plant (the Antrim plant was brought up for the first time in the March presentation) and that this assertion was later ascertained to be false and misleading, as proved above in Section 1.

3. The recommendation that the offer by ESL should not be shortlisted for the restricted tender phase is not only based on issues concerning pathological waste (which was the subject of the first appeal) but also on the lack of evidence to the AB's satisfaction of its microbiological ability, as well as a suitable track record and reliability to a level that the Board was satisfied of the likelihood of a complete and satisfactory completion of the project in compliance with the

Health Division's requirements as set out in the pre-qualification document and the AB's report of the 8 November 2004

4. Dr. Mallia's reference to article 102 of Legal Notice 299/03 during the hearing of the 18th July 2005 is not relevant, since these clearly refer to the three package system for tenders with an estimated value of over Lm250,000. This phase has not yet been reached since the pre-qualification process, which precedes the three-envelope tender phase, has not yet been concluded. Furthermore, these regulations have now been repealed by Legal Notice 177/05.

JOSEPH M STAFRACE
CHAIRMAN
ADJUDICATING BOARD

22nd July, 2005

Appendix 1:

Summary of critical factor compliance for the WR2 technology following complete pre-qualification assessment undertaken in compliance with the instructions of the PCAB dated 8 February 2005.

			1.01	1.01	1.6.01	1.6.2	1.6.05	1.6.1.1	1.6.18 1.6.18.1	1.6.21	1.6.24	1.6.27
			Pre-qualification questionairre completed satisfactorily + required documents supplied	Throughput of 250 kgs/hour at waste density of 100kg/m^3	Clear description of technology available containing all components	Track record and reliability of the supplier and their local representative	Foot print – ability to fit in waste treatment area at MDH & function on established utilities	Model name, type & model number identified	Evidence validating compatibility and suitability for all infectious waste streams esp pathological	Can function with waste containers > 500 litres	Does not requires special bags or waste containers	No potential problems with landfilling of end waste or conflict with local legislation
22	Environ-mental Services	WR2	Y	Y	Y	N	Y	Y	N	Y	Y	N

Unquote

Submission presented by Environmental Services Ltd

Quote:

ESL

ENVIRONMENTAL SERVICES LTD

Submission to the Public Contracts Appeal Board

RE: Advert Notice no 94/2004 – Pre-Qualification Process for the Supply, Installation and Commissioning of a Clinical Waste Decontamination Plant. Ref: CT2001/2004

Dear Sirs,

We and our Principals, WRE Ltd object to the decision of the General Contracts Committee to eliminate our bid a second time at the pre-qualification stage because:
1) the sole basis of this elimination was the waste treatment efficacy of the STI machine and this issue was already decided on in our favour by your good selves in the first appeal.
2) the General Contracts Committee decision is based on the erroneous interpretation by the Adjudication Board of the information made available to them and
3) we supplied all the information requested by the Adjudication Board that was in our power to supply, even when this was not specifically required in the Pre-Qualification Questionnaire and none of this information was misleading or false as was alleged by the Adjudication Board in their report to the General Contracts Committee.

Permit us to elaborate on the above points and provide documentary evidence confirming the truth of what we are stating in this document.

First of all and most importantly, please find attached a letter from our legal adviser, Dr Anna Mallia, to your good selves dated 21st July 2005 (Document 1) in which she contends that:
a) we have already gone through the procedure under regulation 102 of Legal Notice 299/2003 and your good selves decided in our favour and so since we have already availed ourselves of the procedure under regulation 102 of the said legal notice and surpassed it, according to the regulation the next stage is not to return to the pre-qualification stage but to proceed to the tender process itself.
b) Your good selves had already decided in our favour on the issue of waste efficacy - Appeal board decision on 8th February 2005 Pg 10, final paragraph – "Appellant provided evidence to prove that the waste treatment system proposed was capable to process all types of treatment waste" - and according to the Public Contracts Regulations, the decision of the Appeals Board is "final and binding on all parties" (LN 299/2003, Regulation 102, sub-paragraph 9)

Also permit us to bring to your attention that the Adjudication Board did not follow your instructions to them in your decision of 8th February 2005 which was: "The evaluation process should now proceed with the further necessary evaluation of the offer" (Appeal board decision on 8th February 2005 Pg 11, paragraph 2). What the Adjudication Board actually did was **re-evaluate** (document 2) what they had already

examined before and on which the Adjudicating Board had already declared that "all board members agreed to abide by their original decision" (Appeal board decision on 8th February 2005 Pg 9, paragraph 3).

Without prejudice to the above, we insist that the Adjudicating Board did misinterpret the documents we provided them with and this led them to erroneously believe that the STI device cannot treat pathological waste.

First of all, permit us to draw your attention that all that was requested in the Pre-Qualification Document was proof that "the plant being offered has been approved, accepted and authorized for use by an environmental authority or agency within a European Union (EU) member state" (PQ1.6.2) and " claims (of efficacy) must be backed up by relevant scientific documentation validated by independent third parties" (PQ1.6.18.1) and also "the level of treatment achieved by the plant as per classification defined by the United States State and Territorial Association on Alternate Treatment Technologies (STAATT) as validated by relevant testing" (PQ1.6.20) as well as "Any clinical waste decontamination technology shall be considered, including those not fully commercialized, as long as it has been approved, authorized or accepted for use by the relevant Environmental Authority (agency) of the state or country where it is manufactured" (PQ3.6.1)

All the required documents were provided with our original bid and these stated that STG Ireland (Sterile Technologies Group, which has no commercial relationship with our principals WRE or STI other than purchasing and employing STI treatment devices) was granted for the second time the all Ireland 4 year contract to treat and dispose of all the clinical waste of both the Republic of Ireland and Northern Ireland, therefore in 2 EU countries, through their two plants in Dublin and Antrim (document 3); supplied evidence of efficacy from independent laboratories (document 4) and showed approval by a State Regulator from the country of manufacture (document 5)

Contrary to what occurred with other bidders, we and our Principals WRE, were not approached for clarifications or asked to make a presentation to the Adjudication Board and subsequently on 26th November 2004 we were informed that our bid was not short listed. Following our formal request we were further informed that the reason for this rejection was:
a) the STI device was not effective for pathological waste treatment and
b) the STI device cannot function with the required size of skip. (document 6)

We appealed this decision on 20th December 2004 and during the first Public Contracts Appeal Board hearing the matter of the skips was conceded because it resulted that the Adjudicating Board had, through an oversight, misinterpreted the documents provided by us (Appeal board decision on 8th February 2005 Pg 8, paragraph 4). The matter of the pathological waste treatment efficacy was also decided on by your good selves in our favour and you upheld our appeal (Appeal board decision on 8th February 2005 Pg 10, final paragraph – "Appellant provided evidence to prove that the waste treatment system proposed was capable to process all types of treatment waste")

Following our successful appeal we received a number of requests for further documentation from the Public Contracts Adjudication Board which we did our very best to supply despite the narrow time frames and the fact that a number of the

requested documents are the property of third parties or of government authorities and were not in our possession. A presentation of the technology was also requested during which the Adjudication Board requested a number of documents all of which were supplied by us (documents 7 to 13) With regard to the time frames allowed us by the Adjudication Board to supply them with extra documents not specifically requested in the Pre-Qualification Document, these time frames were not as generous as the Adjudication Board would like your good selves to believe. Permit us to draw your attention to the ones requested during Easter week (document 8) and the fax sent on Friday 8th April in the afternoon requesting the immediate supply of third party owned documents (document 12)

We were extremely surprised that following this exercise we received a fax from the Department of Contracts which stated that our bid was again not short listed for the tendering process for the **very same reason** it has been rejected before, namely lack of proven pathological waste efficacy (document 2). At our request, the Director of Contracts kindly permitted us to examine the full report of the Adjudicating Board to the General Contracts Committee where we discovered that the Adjudicating Board had once again misinterpreted the evidence provided and reached incorrect conclusions.

The following are the reasons on which Adjudicating Board, in their report, recommended that our bid be rejected and our mitigation of these same reasons.

1. The Adjudicating Board claim that the document issued by the State of Michigan (document 5) whereby it grants approval to the STI device to treat blood products and pathological waste pre-dates the STAATT regulations (as stated in the original pre-qualification Document P.Q. 1.6.20) is totally incorrect. The STAATT document was issued in 1994, 2 years before the Michigan document (document 14). Although the Pre-qualification Document specified STAATT standards and not STAATT II as claimed in the Adjudicating Board report, please be aware that STAATT(1) was much more stringent than STAATT II and therefore demanded a higher standard of efficacy (document 15). Please also note that, contrary to what the Adjudicating Board stated in their report, the issuing body, The Department of Environmental Quality, is in fact the relevant state regulator for Michigan.

2. STAATT II only requires testing of one species of Mycobacteria and of either B. stearothermophilus or B. subtilis as “the use of additional biological indicators to demonstrate the efficiency of treatment systems provides no additional safeguards to public health and safety” (STAATT II) (document 15). The efficacy tests presented at the time of the Pre-qualification Bid which are endorsed by the Department of Health of New York (document 4) as well as those carried out by Dr Ira Sulkin and Analytical Services Inc (document 16 and 17) confirm the efficacy of the STI device to achieve the standards required by STAATT. Therefore we totally disagree with the opinion of the Adjudicating Board that the tests we provided are not compliant with STAATT II. These tests, carried out by Dr Ira Salkin, a leading authority, are fully compliant with STAATT as testified by the documents from Analytical Services Inc and from Dr Salkin (documents 16 and 17)

3. With respect to the remark by the Adjudicating Board on the fact that certain efficacy tests were supplied to them after the Appeals Board of the 26th January 2005, permit us to point out that these extra specific tests were made or presented after the

Appeals Board hearing of 26th January 2005 because these were either specifically requested during that hearing by the Adjudicating Board or requested in communications received by us from them after the hearing. This was done as our wish was and still is to satisfy any request Adjudicating Board makes if it is within our power to do so even if these had not been specifically asked for in the Pre-Qualification Document

4. We fail to understand the objection of the Adjudicating Board regarding the apparent practice of the Dublin plant of bagging and not compacting the treated waste. This, if true, has no relevance at all to our bid as this is a purely personal choice of those operators and not an obligatory requirement of the STI device which in fact is usually presented, and has been offered by us, in use with a compactor (Document 18).

5. We also wish to bring to your attention that, contrary to the Public Contracts Adjudicating Board's statement, documentation has been provided from the relevant regulatory authority certifying that the required types of waste are allowed to be treated in the STI Ireland plant (document 19). We do not understand the distinction being made by the Adjudicating Board between "allowed" and "authorised" when it was the Chairman of the Adjudicating Board itself in his fax to the Ireland Regulator, who requested a specific clarification whether the STI plant in Antrim would be **allowed** to treat placentas and blood products (document 20). The fax from the Ireland regulator had specifically stated that the STI Plant in Antrim is allowed to treat placentas and blood products. It is reasonable that when the device is "allowed" to process such waste by the regulator in writing, the authority is satisfied that the device can treat the waste in question to the required standards.

6. With regard to question of the treatment of placentas at the Dublin Plant, please be aware that while this plant at the present time, but subject to review, does not treat this tissue, because of ethical issues and not because of efficacy problems, even though the Ireland Health Department is still recommending that blood and placentas are treated in a disinfection treatment plant and, as you are now aware, the disinfection treatment plants used in all of Ireland are STI units (document 21), the Dublin STI plant had been regularly treating placentas from March 2000 to April 2005 with full effectiveness (document 22). As for blood products, these have always been processed at the Antrim Plant and have not been processed at the Dublin plant for commercial reasons and not because of a limitation imposed by the regulator (document 23) This means that our statements were correct at the time we stated them on 26th January and 1st April and there was no intention to mislead or provide false information as was alleged by the Adjudicating Board in their report. Had the Adjudicating Board contacted us about this we would have been able to clarify the matter for them.

The Adjudicating Board had stated during the appeal hearing of the 18th of July that they were not supplied with the requested copy of the Antrim Waste License by the Environment and Heritage Service, the regulator for N. Ireland, even though the same regulator had sent us a copy of the documents sent. We have contacted the official responsible, Mr. Martin Johnston, who confirmed to us on the telephone that he did send by fax to the Adjudicating Board the copy of the Antrim waste license. Mr. Johnston also send a confirmation of this in writing by e-mail (document 25). Unfortunately it seems that this has been misplaced at the Health Department and did

not reach the Adjudicating Board. We are very unhappy that this happened but it is unfair that we are blamed for a document misplaced at the Adjudicating Board's end. However, Mr. Johnston has sent us copies of the documents he had faxed to the Adjudicating Board, including the license in question (document 24) and a full copy will be forwarded to the Adjudicating Board should they still wish it.

Although when questioned by the your good selves the Adjudicating Board claimed that the STI device did not satisfy two more of the Critical Criteria, even though these do not have any mention at all in their report to the General Contracts Committee, on questioning they admitted that even these two alleged failure points were directly related to and as a consequence of the Adjudicating Board's mistaken impression that the STI device is unable to treat pathological waste to the required STAATT standards. For example, the Adjudicating Board during the Appeals Board hearing of the 18th July 2005 claimed that landfilling may be a problem because of the Pathological Waste issue. However the suitability of the treated product to be land filled was testified by the copy of the landfill impact report and acceptability document supplied by us to the Adjudicating Board on 18th March and this document was never questioned even in their report to the General Contracts Committee.

Permit us also to clarify that the term "identifiable body parts", which was brought up during the Appeals Board hearing of the 18th July, is a specific term used in health care waste treatment and only refers to amputated limbs. We are aware that the Maltese authorities do not intend to process these amputated body parts in a clinical waste decontamination plant because of ethical reasons, (although the STI plant would be able to handle such body parts had there not been such ethical issues)

In conclusion, we respectfully request the Public Contracts Appeal Board to uphold our appeal firstly because it is clear that the Adjudicating Board have again rejected us for the "very same reason" (their words – Document 2) that they had rejected us before, that of pathological waste efficacy and this matter had already been successfully appealed by us before your good selves and secondly because, as we have demonstrated above and corroborated with the all relevant documents, the STI device which is a leader in non-burn technology is capable of handling the required waste streams

We thank you for your patience and feel confident in your looking favorably on our appeal which would permit us to finally qualify for short listing for the tender process itself.

Dr R. Cali-Corleo MD MSc
Managing Director
21th July 2005

Unquote

In the second public hearing, Dr Mallia and Dr Cali-Corleo dealt with the legal and technical points respectively.

During her intervention Dr Mallia mentioned all the points included in her letter dated 29 July 2005 to rebut the legal arguments brought up by the Adjudicating Board in Objection 5 of its written submissions.

Furthermore ESL's legal reoresentative claimed that the law did not contemplate for two phases of pre- qualification. Her arguments were based on the fact that on their two notices of objection dated 20 December 2004 and 30 May 2005 respectively, the Department of Contracts noted that both objections were accompanied with the same mandatory deposit of Lm2, 050 and in terms of Clause 30 and Part XIII of the Public Contracts Regulations 2003.

When she made reference to the three-envelope procedure, her attention was drawn by Mr M. Caruana (PCAB) that according to the Pre-Qualification Questionnaire Document (pg 3) *'Only qualified applicants would then be invited to tender for the supply and installation of the infectious waste disposal technology and model approved at the pre-qualification stage.'*

Dr Cali-Corleo verbally responded on the technical aspect of the written submission received from the Adjudicating Board and presented the PCAB with a MEMO containing all his arguments expressed during this hearing.

Further to Objection 1 he said that the Dublin STI plant had been regularly treating placentas from March 2000 to April 2005 with full effectiveness. He said that this tissue at present was not being treated at this plant because of ethical issues and not because of efficacy problems.

Dr Cali-Corleo tabled a reference list to substantiate his claim, namely that the STI devise had a proven track record mentioned in Objection 3 of document forwarded to all interested parties during the hearing.

When he was rebutting Claim 5 under Objection No 3, Mr Denis Grech conceded that the fax could have been received and misplaced. Then, ESL's representative furnished the Adjudicating Board with the whole document of the Antrim's waste licence. Furthermore, while he was commenting on Claim 2 under Objection 4, Dr Cali-Corleo tabled three other documents to prove his point.

On his part, Mr Stafrace began by declaring that the Adjudicating Board did not include ESL/WRE in the shortlisting because of

(a) pathological waste treatment efficacy,
(b) track record and reliability of the supplier and local representative
(c) landfilling suitability – respectively, items (a) 1.6.18, 1.6.18.1, (b) 1.32 and (c) 1.6.27 on the "Grid" (Appendix 1 - "Critical Criteria" of the Adjudication Board's report dated 8 November, 2004.

He said that Doc Nos 15, 16 and 17 provided by ESL with their written submission should not be considered by the PCAB in its deliberations because these had never

been forwarded to the Adjudicating Board before and also because the latter two were post dated as the objection was filed on 30 June 2005 while these documents were dated 11 July 2005. Dr Mallia intervened to explain that such documents were additional clarifications to what had already been submitted regarding STAATT.

Continuing, Mr Stafrace mentioned that Article 102 of Legal Notice 299/03 was not relevant since this clearly referred to the three package system for tenders with an estimated value of over Lm 250,000. This phase had not yet been reached since the pre-qualification process preceded the three-envelope tender phase. He affirmed that the pre-qualification tender was the only offer issued. Then, he elaborated on this issue by quoting from the PCAB's sentence of 8 February 2005 wherein it was stated that:

".. there would remain the opportunity to file another objection if their bid were to be eliminated for other reasons in the remaining pre-qualification stages."

Moreover, the PCAB recommended that:

"… the evaluation process should now proceed with the further necessary evaluation of the offer made by the same appellant."

Mr Degiorgio contended that they were still at the pre-qualification stage.

With regard to their claim that in the PCAB's decision of 8th February 2005 it was stated that "*Appellant provided evidence to prove that the waste treatment system proposed was capable to process all types of treatment waste*", Mr Stafrace contended that the appellant did not produce any scientific evidence to support his claim regarding efficacy and that the facility proposed was not suitable for their needs.

Mr Stafrace said that from the documents made available to them it did not result that the technology offered by ESL/WRE processed pathological waste.

He remarked that MEPA would accept declarations regarding the efficacy of a system only from other regulators and not from private companies/ laboratories. He emphasised that Mr Martin Johnston said that STI plant at Antrem would be '*allowed*' and not '*capable*' to accept nondescript soft tissue such as placentas and pathological waste. Furthermore, ESL's statement that STG Ireland had been purchasing and employing STI treatment devices, implied that the claims made regarding efficacy were not submitted by independent third parties and that there was a close business relationship between them.

Mr Grech added that the document submitted by STG was not considered as a scientific proof. He said that PQ 1.6.18.1 specified that "*claims (of efficacy) must be backed up by relevant scientific documentation validated by independent third parties*".

Dr Cali-Corleo replied by stating that he failed to understand how they were interpreting that STG Ireland was part of their WRE group. He said that Sterile Technologies Group (STG) in Ireland was a totally separate organisation from Sterile Technology Industries (STI) in the USA. The only relationship between the two companies was that STG bought 4 decontamination plants from STI. He was of the

opinion that it was the operator who could certify the efficacy of waste treatment plants.

However, Mr Grech drew the attention of those present that it was the regulator who monitored the operator, and the latter had to abide by the licence and other conditions issued/imposed by the regulator. He explained that tests had to be made in laboratories according to the list of laboratories in STAATT.

With regard to State and Territorial Association on Alternate Treatment Technologies (STAATT), Mr Grech said that in the pre-qualification document they did not indicate STAATT I or STAATT II but mentioned only STAATT. It was explained that in actual fact STAATT II did not supersede STAATT I because some standards in STAATT I (which was issued in 1994) had been reviewed and included in STAATT II which was issued in 1998. He argued that, once they issued the pre-qualification in 2004, standards were to be compliant to STAATT II.

As regards the question of the treatment of placentas at the Dublin Plant, Mr Stafrace said that in their submission ESL admitted that it "*does not treat this tissue*" and that it did not process pathological waste. Also, he pointed out that the Antrim plant, which was first mentioned during the presentation, held in March 2005, did not accept 'Identifiable anatomical waste' and 'Animal carcasses or parts thereof'.

Dr Mallia explained that human and animal carcasses were not treated together because of ethical issues. She was of the opinion that, had there not been this issue, the STI plant would have treated such body parts.

Ms Henriette Debono testified that Mr Martin Johnston's letter dated 4th April 2005 clearly indicated the types of wastes that could be accepted in the plant or not. It was specifically stated that identifiable anatomical waste and animal carcasses or parts thereof should not be accepted. Thus it was understood that these were not accepted for operational and not for ethical reasons. This interpretation was corroborated by Mr Grech who added that these items were excluded from the specific licence. He claimed that the processing of placentas was legal in Ireland.

In reply to a specific question by Mr A Pavia (PCAB), Mr Grech, under oath, testified that, in the pre-qualification stage, one of the bidders of a certain technology gave them a licence that was operational in Ireland which indicated that it accepted anatomical waste and animal carcasses or part thereof.

At this point, Dr Cali-Corleo said that he had information that the competitor did not treat such parts in Ireland but exported them to Belgium. He contended that they had the same licensing conditions.

On cross-examination by Dr Cali-Corleo, Mr Grech said that the system of the other competitor was called *autoclave technology*. He declared that they did not verify with the regulator whether it permitted the treatment of body parts and placentas because the appellant provided them with the licence which indicated what was precluded.

Mr Stafrace said that the STI model failed in the critical criteria of landfilling because they used chemicals in the treatment of waste.

Ms Debono took the witness stand again to testify on this issue. She said that Landfills were divided into three classes: - inert waste, hazardous waste and non-hazardous waste. She declared that no waste, even if treated, would be accepted in any type landfill if it was infectious. She said that they could not confirm that the residue of waste was not infectious because they had doubts about the efficacy in the process of pathological waste and on the use of chemicals.

Dr Cali-Corleo replied that they were again being eliminated because of pathological waste. He said that in their original submission they clearly indicated that chemicals were used for odour control purposes only. Furthermore, he declared that the use of chemicals, which was given as an option, was not obligatory. Dr Cali-Corleo claimed that they had submitted a document from an independent laboratory which confirmed that when the plant was tested without the use of chemicals the system proved to be effective.

However, Mr Grech alleged that when the Dublin Authority ordered them to remove the chemicals during the commissioning of the equipment, the temperatures rose and the plant did not function properly. In the commissioning report it was stated that they had to operate at lower temperature.

In reply to Mr Pavia's question, Mr Grech said that the other bidders that were accepted used different technology and processes. He confirmed that none of the plants chosen treated waste with chemicals.

Mr Stafrace reiterated that ESL/WRE's technology was eliminated because it did not satisfy all the critical criteria. He denied that they did not give them ample time to submit the required documentation.

In his concluding remarks Dr Cali-Corleo contended that once they provided documentary evidence about the efficacy in the system they were offering for the treatment of clinical wastes they deserved to be allowed to bid for the tender.

Mr De Giorgio said that only those bidders whose technology had been shortlisted in the pre-qualification would be allowed to tender.

Mr Stafrace declared that in the next phase, they would enter into greater detail and that any decision would be based on site visits to ensure that the actual process proposed by short-listed bidders was efficacious.

At this stage, the public hearing was concluded and the PCAB proceeded with its deliberations before reaching its decision.

This Board,

- having examined the reasons given by the General Contracts Committee for re-disqualifying Appellant's offer in terms of the telefaxed message dated 11th May, 2005, namely (quote):-

  > *"Further to the P.C.A.B.'s decision of the 8th February, 2005 a re-evaluation of the respective offer was carried out by the Adjudication Board. This Board's conclusions state:*

'This pathological waste efficiency requirement was the critical factor behind the original elimination of this bid. It is clear that the Adjudication Board's original interpretation was correct and has been simply substantiated by further investigation. As a result the Adjudication Board once again recommends, that the bid in question should not be short-listed for the second phase and to be eliminated for the very same reason for which it was not included in the original shortlist insofar as efficacy in the treatment of pathological waste is concerned

and

The above confirms that to date the efficacy of the STI Chem Clav have not been fully proven to STAATT II standards, as required by the Pre Qualification Document 1.6.20

The General Contracts Committee has accepted this recommendation"

- having considered the objections put forward in writing by Appellant, in terms of his motivated letter of objection dated 28th June, 2005;

- having heard the detailed reasons given by Appellant during the public hearings held on 18th July and 29th July, 2005 (supplemented by the written submissions dated 21st July, 2005) for objecting against the Contracting Authority's recommendation that Appellant's bid *"should not be short-listed for the second phase and to be eliminated for the very same reason for which it was not included in the original shortlist insofar as efficacy in the treatment of pathological waste is concerned"*

- having also heard the arguments put forward by Appellant's legal representative, who insisted all along that the decision taken by the Board on 8th February, 2005, was final and binding and therefore not subject to review; this, in terms of regulation 102 (9) of the Public Contracts Regulations, 2003 (Legal Notice No. 299 of 2003);

- having perused the Adjudication Board's report dated 19th April, 2005, supplemented by documentary evidence and substantiated by Adjudication Board's oral submissions during the public hearings held on 18th July and 29th July, 2005 as well as Adjudication Board's written submissions dated 22nd July, 2005, in support of Adjudication Board's contention that Appellant's bid should be re-disqualified;

- having heard the Chairman of the Adjudication Board explain that the next steps in the proceedings would involve the issue of a formal tender on the three packages system and that the examinations for the purposes of the verification of the technical details in the second package would also include site visits;

reached the following conclusions:-

1. The initiatives taken by the Adjudication Board leading to the issue of the same Board's second adjudication report dated 19th April, 2005 conformed satisfactorily with the Board's decisions taken on 8th February, 2005;

2. The documentary evidence produced by the Appellant and also by the Contracting Authority's representatives in support of their respective claims, rebuttals and counter-claims did not, according to the Board, result that either party's interpretations of such evidence produced was, without any reasonable doubt, clear and unequivocal and, therefore, not subject to different conclusions;

3. Given the findings at '2' above and the Contracting Authority's representatives declaration to the Board to the effect that the next stage of the adjudication process would include further technical investigations, including *site visits*, for the purpose of definitely accepting the other short-listed bidders' offered solutions and technologies, the Board decided that Appellant's offer should not be eliminated at this stage of pre-qualification but should be included in the short-list of applicants who will be invited to bid during the second phase.

4. The Board furthermore recommends that the deposit made by Appellant in connection with his appeal be refunded.

Alfred R. Triganza	**Anthony Pavia**	**Maurice Caruana**
Chairman	Member	Member

Date: ***8th August2005***