PUBLIC CONTRACTS APPEALS BOARD

Case No. 25

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

The pre-qualification Questionnaire for the supply, installation and commissioning of a 'Clinical Waste Decontamination Plant' was published in the Government Gazette (closing date – 15th June 2004) following a request received by the Director of Contracts from the Department of Health.

A total of twenty six questionnaire proposals were received by the Adjudication Board.

Following relevant recommendations made by the same Board, the Contracts Committee judged the submissions made by Messrs. Charles de Giorgio Limited and Messrs Environmental Services Limited respectively to be not compatible with the requirements put down in the questionnaire. The companies were duly notified to this effect by the Contracts Department and advised that they were not being short-listed to quote for the advert in question.

Both Companies filed an official complaint with the Contracts Department soon after.

The Public Contracts Appeals Board met on 26th January 2005 to discuss the objections raised by Messrs. Charles de Giorgio Limited and Environmental Services Limited respectively.

Mr A. Triganza chaired the proceedings accompanied by Mr A. Pavia and Mr M. Caruana who formed the other Boards members.

During the hearings

a. the *Adjudication Board* was represented by the

   Mr Joseph M Stafrace (Chairperson), Dr Michael A Borg, Mr Denis Grech, Eng Chris Attard Montalto and Ms Henriette Debono.

b. the *Health Division* was represented by the

   Mr E D'Agostino (Director, Finance and Administration) and
   Mr J Degiorgio (Asst. Director, Finance)

c. Mr. David Stellini spoke on behalf of Messrs. Charles de Giorgio Limited, exclusive local agents for *METEKA* represented during the hearing by Mr Ronald Katsching.

d. Mr. Ramiro Cali Corleo spoke on behalf of Messrs. Environmental Services Limited, local agents for *WRE*, who were in turn represented

during the hearing by the Company's Managing Director, Dr Kenneth Steward. Dr Anna Mallia acted as the Company's Legal Adviser.

e. Mr Michael Demarco, representing The Malta Transport Authority was also summoned as a witness.

At the start of proceedings it was agreed between all parties that the two objections would be held separately in view of certain confidential commercial information that might be needed to be divulged. The Board upheld this request and proceeded with the hearing of the appeal lodged by Messrs. Charles de Giorgio. The appeal lodged by Environmental Services Limited was heard separately at the sitting which followed immediately after.

At the beginning of the hearing the Chairman of this Board drew the attention of Messrs Charles de Giorgio Limited's representatives as regards the failure by the said Company to submit their objection according to normal practices, a concern also shown by Mr Stafrace.

Mr David Stellini explained that, following specific questions submitted by the Company in regard, an official from the Contracts Department informed them that, following statutory changes to previous procedure, an appellant was now no longer compelled to submit a motivated letter of objection. Mr Stellini stated that, this notwithstanding, his Company did prepare a motivated letter of objection to be considered by the Board during the hearing. Copies of this 'letter' were tabled for the Board's consideration.

At this stage Messrs Charles de Giorgio Limited's representative referred to the **first** point raised in his Company's letter mentioned earlier, addressing the issue of *Pathological Waste Efficacy*, this being the first reason given to his Company by the Adjudication Board, as to why METEKA's proposal was eliminated.

Quoting textually, Mr Stellini stated that the reason given by the Adjudication Board was:

"Inability to show evidence of pathological waste efficacy under the terms stated in para 7 of the critical factors. Despite request for clarification, the microbiological efficacy data forwarded was not deemed scientifically appropriate to validate this claim as it did not test correct surrogates of pathological waste. Nor was documentation provided that the unit was approved for pathological waste treatment anywhere in Europe or the USA."

Mr Stellini said that following a request made by Mr J Degiorgio on 27th July 2004, his Company submitted evidence showing that the MEDISTER 160 was in fact effective in disinfecting pathological waste. On 7th September 2004 they submitted the following three reports to prove their claim, namely:

a. Report dated 29th May 2000 issued by Prof. Manfred Rotter of the Hygiene Institute of the University of Vienna;

b. Report dated 22nd August issued by Prof. Walter Steuer and Dr Helmut Mucha of the TUV Berlin Germany;

c. Report dated 12th February 1999 issued by Dr H Gaya of the Department of Pathology of the London Clinic.

With regard to the **second** reason given by the Adjudication Board, Mr Stellini said that they were informed that they were also being eliminated due to the fact that they were '*unable to function on waste arriving at the facility in skips between 500 – 1100 litres since it needs waste to be collected at source in proprietary bins of 6, 18, 30 or 60 litre volume'*.

Mr Stellini said that the conditions did not state that the system must function by means of skips of 500 – 1100 litres. He added that MEDISTER 160 system was not just a disinfection device but also a complete concept of clinical waste management from the point of waste generation to disinfection. They had a unique system whereby the clinical waste was deposited directly by the users into the proprietary bins that were in turn placed in the waste decontamination systems known as the MEDISTER 160. It was a system whereby there was absolutely no handling of plastic bags from bins in hospitals into skips with all potential risks involved. He said that they were of the opinion that the use of 'proprietary bins' was an economical decision that should be addressed in the financial stage of the tender process.

Regarding the **third** and last reason given by the Adjudication Board, which specifically states that

"*Insufficient throughput capacity estimated from the information provided at 125 kg/hour" and that "despite specific requests for clarification, bidder failed to indicate alternatively",*

Mr Stellini stated that in their letter dated 7 September 2004 they submitted a declaration by Mrs Sabina Katschnig, Managing Director of Meteka GmbH, who had indicated that each unit of MEDISTER 160 had the following throughput capacity:

"the average length of a treatment cycle of a MEDISTER 160 Clinical Waste Disinfection devise is 45 minutes",

and

"the weight processed per cycle of a MEDISTER 160 is up to 15 Kg resulting in a treatment throughput capacity per hour of up to 20 kg."

He argued that, in view of the fact that MEDISTER 160 is a modular system such system did not consist of one unit but of a number of units. However, Mr Stellini argued that when considered holistically, these units were capable of achieving the required throughput of 250kg of clinical waste per hour.

Following Mr Stellini's intervention, this Board asked Mr Stafrace to present his counter-statements in regard to what had been mentioned by Messrs Charles de Giorgio Limited's representative.

The Adjudication Board's Chairman said that it was pertinent to point out that the purpose of the pre-qualification exercise was to identify those technologies that were

suitable for the *Mater Dei Hospital* and that fitted into the existing infrastructure. He said that this was not a question where the client had to adapt to what the contractors were offering but their technology had to be adapted to their present facilities. He clarified that the submissions were considered not in accordance with specifications and conditions. They were not eliminated because their system was bad but due to the fact that their technology was not compatible with the critical factors outlined at the beginning of the Board's report.

At this stage Ing Chris Attard Montalto stated that he wanted to stress the fact that the pre-qualification document was not a technical one but simply, a document whose prime intention was to find out what could be offered. The suppliers had to deliver decontamination technologies that were suitable for *Mater Dei Hospital*. Companies had to fit in within certain parameters and had to comply with policies adopted at the *Mater Dei Hospital*, EU directives and the Clinical Waste Management Plan, which were accessible to everyone.

Furthermore, Ing Attard Montalto also referred to the question of having a plant working on non-proprietary skips. According to the same witness, the fact that Messrs Charles de Giorgio Limited indicated that Meteka's proposal required that waste be collected at source in proprietary bins was against their policy. At this point Mr Stellini remarked that the pre-qualification questionnaire should thus have indicated that such containers were not acceptable. Ing Attard Montalto replied by quoting from PQ1.6.21 which stated that "*Bidders shall be required to indicate whether the plant can accept all types of non-proprietary skips and if special attachments would be required to accept skip manufactured by different companies."*

He said that the use of non-proprietary skips was approved by MEPA and was in accordance with *Mater Dei Hospital*'s policy. However, Mr Stellini insisted that it was not spelled out in the document that an offer would be disqualified if proprietary skips of 500 – 1100 litres were used. When asked specifically about the type of skips they used, Mr Stellini replied that they only used proprietary skips.

The Adjudication Board's Chairman intervened and declared that the containers that Messrs Charles de Giorgio Limited were offering did not suit their purpose. He pointed out that there were other bidders who were not short-listed for the same reason and that it was one of the critical factors on which they based their evaluation. He said those who needed to use proprietary skips were not acceptable for *Mater Dei Hospital*'s needs.

In her testimony, Ms Henriette Debono stated that, besides the waste generated by the *Mater Dei Hospital*, the Clinical Waste Decontamination Plant had to cater for all the clinical waste generated by all hospitals in Malta. The witness claimed that such waste could be collected and carried on the roads in accordance with ADR Regulations provided that it was transported in UN approved containers.

During his testimony, Mr Roland Katsching, Meteka's representative, stated that their containers were manufactured in Austria according to EU regulations and that it was much safer to transport clinical waste in their containers than in skips.

Ing. Attard Montalto gave information about the system proposed in the collection, handling and the transportation of clinical waste by quoting from the summary of the report '*The Management of Clinical Waste in Malta'* which *inter alia* stated that:

"Clinical waste bags will, when full, be sealed by means of plastic clips or adhesive tape identifying their origin for the purpose of accountability. This will ensure that in the event of an injury arising from an incorrectly filled bag, this can be traced at source. Tagging of bags will also allow auditing of segregation effectiveness. In addition, a workable documentation system will be devised to guarantee an audit trail throughout the system. These bags will then be placed in a lockable, wheeled bin (skip), which would have to be placed preferably in the refuse room just outside the ward. The use of the wheeled bins is central to any successful system and cannot be compromised if a workable system is to be adopted."

Mr Stellini intervened by stating that the size of the skips was not mentioned in the policy document and declared that even their containers were wheeled-bin skips.

Ing Attard Montalto did not agree with the appellant's claim that the issue of proprietary or non-proprietary skips should be considered as a later stage. The reason given was that the bidders who were short-listed had to tender with the same model and company as proposed in the pre-qualification offer.

This Board then asked those present to start discussing the issue of *pathological waste efficacy*.

Mr David Stellini started by furnishing the PCAB with copies of the reports referred to earlier in the hearing. He said that the reports submitted indicated that devises used in European countries were tested and approved for pathological waste treatment. Mr Roland Katshling stated that they were offering a technology that was approved and widely used all over Europe.

Dr Michael A Borg said that the MEDISTER 160 was a microwave technology. He said that clinical waste coming from hospitals was made up of different streams, one of which was pathological waste that consisted basically of organs coming from operating theatres, delivery rooms and mortuaries. When these types of organs were to be disposed of, they had to be sealed in UN approved containers.

The same witness also made reference to Meteka's documents regarding the Microbiological Examination of the MEDISTER 160 located at St Austell Hospital wherein it was stated that *'tightly wrapped and sealed clinical waste bags should not be included in the waste treated by this devise.*' Thus, he argued that, taking into consideration the fact that clinical bags had to be sealed, the system offered by Meteka was not compatible with the present local system of clinical waste collection. Consequently, they could not be treated in their devise because, due to the heat of the microwave, the plastic bags would stick to the sides. Mr Katsching strongly rejected such conclusion.

Dr Borg said that respondents had to provide copies of environmental authority/state licenses indicating that the specific model being proposed had been approved for pathological waste treatment by an appropriate authority in Europe and the USA and that validation studies carried out on suitable pathological waste surrogates packed

within UN approved containers showing the required post treatment reduction in appropriate microbiological inocula. He said that the only approval they had was for different waste streams and that they only submitted validation data. Despite request for clarification, the microbiological efficacy data forwarded was not deemed scientifically appropriate to validate this claim as it did not test correct surrogates of pathological waste. Dr Borg claimed that the documentation provided nowhere indicated that the unit was approved for pathological waste treatment anywhere in Europe or the USA.

Mr Stellini stated that according to the pre-qualification document they had to comply with clause PQ 1.6.18.1 which stated that claims of decontamination efficacy for specified clinical waste streams "*must be backed up by relevant scientific documentation validated by independent third parties"*. He said that it was in the clarifications that they added the 'UN approved containers'.

The Adjudication Board member intervened to draw the attention of Mr Stellini that due to the fact that it was confirmed that this addendum was brought to the attention of all bidders, it had to be considered as an integral part of the pre-qualification document.

Mr Denis Grech was the main witness to respond to Messrs Charles de Giorgio's comments on the throughput capacity of clinical waste that could be treated by the proposed plant. He said that throughput as given by Meteka technology could not satisfy their requirements as indicated in the pre-qualification document and other documents. Here he quoted from the 2nd paragraph of PQ 1.1 Use of Pre-Qualification Questionnaire which textually stated that "*The Health Division … had undertaken a thorough investigation into the various procurement strategies available for purchasing this plant and has decided to select a Contractor who would be in a position to offer a holistic integrated global solution and any related service that might be required to furnish, operate and maintain an Infectious Waste Decontamination Plant capable of processing a minimum of 250 kilograms of infectious waste per hour."*

He said that this holistic integrated system was in conformity with *The National Waste Management Strategy* because in the future all clinical waste arising throughout the island would have to be disposed of at the National facility at *Mater Dei Hospital*.

He said that Meteka submitted two different types of possible equipment that could satisfy their needs and that they did not indicate the number of units that would be required to treat the expected volume. Here, Mr Stellini reiterated that although the Meteka systems were modular and not one single system, the MEDISTER 160, which consisted of a number of units, was capable of achieving the required throughput of 250 kgs of clinical waste per hour with 13 units. The appellant's representative stated also that the total was reached by taking into account the fact that each unit had a throughput capacity of 20 kgs per hour. Furthermore, he claimed that their system was flexible because they could either put all the units in one room at *Mater Dei Hospital* or else they could be placed strategically at different hospitals thereby eliminating the risk of having untreated clinical waste transported on the roads.

Mr Denis Grech rebutted these arguments by stating that this was not concurrent with the established policy of having a holistic plant installed at the *Mater Dei Hospital* as a national clinical waste treatment facility. Mr Stellini insisted that they could still meet this requisite as all thirteen units could be placed at *Mater Dei Hospital*. The appellant also stated that another advantage of having a modular system was that if one of the units were to break down the Client could still have the other twelve working. This would not be the case if the facility were to be equipped with one plant, contended Mr Stellini.

Dr Borg said that they needed and wanted a 'hands-free' automatic loading and unloading system and not a 'manual' handling system. The witness continued by stating that the Client wanted the waste to reach the plant, be loaded, treated and disposed of in a completely automatic manner.

Mr Stellini replied by declaring that the procedure used by their system was completely different as they did not need to handle the yellow clinical bags because the containers themselves were put into the machine.

There not being further witnesses, this Board adjourned the first hearing and requested that representatives from Messrs Charles de Giorgio would leave the room and those representing Messrs Environmental Services Ltd would be called in for the second hearing to commence. Furthermore, the Chairman of the PCAB drew the attention of all witnesses that they were still under oath from the first hearing.

The Board then proceeded to hear the appeal lodged by Environmental Services Limited.

Dr Anna Mallia requested that the Chairman of the Adjudication Board would confirm that her clients were eliminated at the initial stages of the adjudication process due to the fact that they were already not compatible to two of the critical factors as stipulated in their report. Dr Borg, acting on behalf of the Adjudication Board, declared that the *scientific* and *technical* characteristics of the decontamination plant being offered by the appellant had not yet been evaluated. Therefore, as far as this system was concerned, the pre-qualification process would have to continue. In view of these statements, 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.

Messrs Environmental Services Ltd's legal representative started by asking the Adjudication Board from where they got the information regarding the *'Declaration by the manufacturer that the Chem-Clav system on offer is not effective for pathological waste treatment'* and that her client's system '*cannot function on waste arriving at the facility in skips between 500 – 1100 litres, needing bins of 90 gallons volume'*. She said that such information was required because (i) "Chem Clav" was not the system that her clients were offering and (ii) her clients did not make such statement in their tender document, respectively.

Dr A Borg replied by quoting from Messrs Environmental Services Ltd's tender document, which stated that '*WRE offers the STI Chem-Clav – an alternative to Incineration that treats and destroys potentially infectious waste.'*

Mr Kenneth Steward explained that 'Chem-Clav''s name was no longer used as this was not a chemical process and so the name could have easily created possible misunderstanding. Dr Mallia categorically denied that her clients proposed such a system because Chem-Clav was limited whereas the system they offered, namely the WRE Clinical Waste System, related to the physical process of all stages of the clinical waste categories as indicated in other parts of the tender document.

With regard to volume of the skips , Mr Denis Grech made reference to a printout from one of the diskettes submitted which related to Design Features (4th bullet), namely, *'Sized for up to 90 gallon cart.'*

Mr Ramiro Cali Corleo said that this was not the model they were offering because it was a small one. He declared that they were offering the STI Series 2000 as indicated in their tender document, namely PQ 1.6.5, PQ 1.6.6 (wherein it was also indicated that it had a throughput of 272 kg/hr) and PQ 1.6.12. Furthermore, he said that at PQ 1.6.21 it was indicated that the skips (*waste carts*) handled *'All standard types of waste cart dumper.'*

In view of this clarification, it was mooted that this point might be dropped for the purpose of the objection once it had been acknowledged that this happened through an oversight of the Adjudication Board.

With regard to the Board's statement that '*the bidder offered to provide an optional Tissue Digester/s which is totally different and separate technology'*, Mr Kenneth Steward declared that they only suggested this system as a value-added option as there could be regulatory or social reasons why certain categories of waste, such as recognisable human anatomical part, should be disposed of by interment or reductive processing. However, he confirmed that the WRE Clinical Waste System corroborated with the client's needs as it could process all categories of waste detailed in the questionnaire. Mr Cali' Carleo emphasised that WRE had offered a single process solution and that as an additional option, they offered a second independent process which could be more appropriate for categories of the above mentioned clinical waste.

Dr Borg explained that they arrived at the conclusion that WRE Ltd were offering a 'hybrid system' using two different technologies for different waste streams because against the '*Pathology or autopsy specimen*', '*Small body parts, tissues, fluids, carcasses*' and *'Recognizable human anatomical parts'* featuring in the list of different types of waste there was a 'Yes*' and the asterisk (*) stated that '*these items can be handled if an optional WR2 "Tissue Digester" unit is also installed.'* He claimed that the words '*can be handled if*' meant that the types of waste indicated could only be handled by the "Tissue Digester" unit.

Mr Steward clarified that the asterisks were only highlighting the 'alternative'.

At this point, Dr Borg indicated that, under the prevailing circumstances, he would be inclined to continue with the adjudication process. However, it was imperative that WRE Ltd produced all the required documentation to demonstrate that the STI 2000 had all the necessary approvals, namely, validation for pathological waste efficacy, an

environmental license from any EU country and validation studies carried out on suitable pathological waste surrogates within UN approved containers.

Mr Stafrace intervened by stating that, in his capacity of Chairman of the Adjudication Board, he was of the opinion that the Board should rely on the information originally made available as was done with all the other bidders, arguing that there were other companies which were eliminated for the same reasons.

After consulting the other Board members, Mr Stafrace declared that all members agreed to abide by their original decision and as already expressed in their report. However, he continued by stating that it was up to the PCAB to decide whether their recommendation to eliminate the appellant should be overruled or not.

At this stage, Dr Mallia asked whether there was anything in the tender document which precluded the *hybrid system*. Dr Borg replied that, on its own, the system was good but it did not meet their requirements. The same Adjudication Board member argued that even though they were to accept a *hybrid system,* the Adjudication Board was still not given enough information on the Tissue Digester/s system. They wanted one system that was effective in the treatment of all type of wastes.

Mr Cali' Carleo stated that the Data on Disk 1, submitted with the questionnaire, included the '*Waste licence and report on independent tests of effectiveness'*. Dr Borg replied that such data referred to general *validation tests* and not to specific *pathological wastes*. He insisted that these tests were indispensable. He quoted from page 15 of the tender document which stated that '*these claims must be backed up by relevant scientific documentation validated by independent third parties, which are to accompany the submission.'* Mr Cali' Carleo replied by stating that, for example, in Ireland, the documentation provided was sufficient for their devise to be granted the license to handle all clinical waste. However, Dr Borg claimed that, as far as he was aware, the system used in Ireland was for general waste because pathological waste was exported to the UK.

At this stage the public hearing was concluded and the PCAB adjourned before proceeding with its deliberations.

The Public Contracts Appeals Board,

- having examined the reasons for disqualification communicated in writing to the two objecting respondents,

- having considered the full text of the objections put forward by the appellants,

- having heard the detailed explanations and clarifications given by
  (a) the two appellants and
  (b) the Client's representatives, during the public hearing held on 26th January, 2005,

- having established that the Client's particular requirements under consideration, as documented in the published call, including the 'clarification' letters communicated to all prospective bidders, which were

allegedly not satisfied by respondents, were clear enough to have been properly understood and also interpreted by all interested respondents,

reached the following conclusions:-

in respect of the submissions put forward by Messrs Charles de Giorgio Ltd – METEKA (T.6):-

The Board decided to reject this appeal on the following grounds:-

- The appellant failed to prove that the technology and the system proposed in connection with the requirements listed under PQ1.6.18 of the *Pre-Qualification Questionnaire*, were fully supported by the related scientific documentation, particularly that required in terms of PQ1.6.18.1, to validate the claim relating to the microbiological efficacy data, since it did not test correct surrogates of pathological waste;

- The skips proposed were essentially of the "proprietary" type, as confirmed by the appellant during his oral submissions and also in his motivated letter of objection (quote: "*The use of 'proprietary bins' is an economical decision and should be addressed in the financial stage of the tender process*"), implying that the plant offered would not "*accept all types and sizes of non-proprietary skips*" – a requirement stated in PQ1.6.21 of the Pre-Qualification Questionnaire.

- In general terms the technology offered by the company did not fit within the policy drawn up by the Health authorities, as requested in the opening paragraphs of the Pre Qualification Questionnaire.

in respect of the submissions put forward by Messrs Environmental Services Ltd – WRE (T.22):-

The Board decided to uphold this appeal for the following reasons:-

- Appellants have proved, through their submissions, that the technology they offered was capable of processing waste coming to the facility in skips and containers of sizes ranging from 500 to 1100 litres, thereby complying with the waste management strategy adopted at the *Mater Dei Hospital*;

- The reference made to the "Chem-Clav" system by the Adjudication Board proved to be a misunderstanding of statements, a matter which was clarified during the public hearing;

- Appellant provided evidence to prove that the waste treatment system proposed was capable to process all types of clinical waste. Besides the single-process solution proposed, the bidder offered a second independent process rather as an option, in the event that the Client would prefer, or else be

required to dispose of certain categories of waste through the process of interment or reductive processing.

This Board finally recommends that, once it has upheld the appeal lodged by Messrs Environmental Services Limited, the evaluation process should now proceed with the further necessary evaluation of the offer made by the same appellant.

This Board, furthermore, recommends that the deposit made by Messrs Environmental Services Limited in connection with their appeal be refunded. The deposit made by Messrs. Charles de Giorgio should be retained.

A. Triganza	**A. Pavia**	**M. Caruana**
Chairman	Member	Member

8th February 2005