



EXECUTIVE AGENCY FOR HEALTH AND CONSUMERS

Health Unit

Luxembourg,
EAHC LB/SS/IK/at D (2010)/100714

SPECIFICATIONS ATTACHED TO THE INVITATION TO TENDER

**Call for tender n° EAHC/2010/Health/03 concerning
Training transplant donor coordinators trainers**

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1. Title of contract

Training of transplant donor coordinators trainers

2. Purpose and context of contract

On 30 May 2007, the European Commission (hereafter referred to as the ‘Commission’) adopted a Communication on organ donation and transplantation¹. This Communication and the accompanying Impact Assessment made a number of suggestions for actions at Community and Member State levels designed to help increase the supply of organ donors across the EU and ensure the quality and safety of the procedures.

The Communication proposed a dual mechanism of action: an Action Plan² enhancing active coordination and cooperation between Member States complemented by a proposal for a legal instrument containing the basic quality and safety requirements.

The Commission adopted the Proposal for a Directive³ and Action Plan on 8th December 2008.

More precisely, the Commission identified 10 priority actions, which are grouped under three challenges in the Action Plan:

- Increasing organ availability
- Enhancing the efficiency and accessibility of transplantation systems
- Improving quality and safety.

The Action Plan aims at reinforcing the cooperation between Member States, through the identification and development of common objectives and guidelines, jointly-agreed indicators and benchmarks, regular reporting, and identification and sharing of best practices.

Currently, the demand for organs exceeds the number of available organs in all Member States and this demand for organs is increasing faster than organ donation rates. There are currently more than 56 000⁴ patients waiting for a suitable donor organ within the European Union. There are large differences in practices and results among Member States. Exchanging information and best practices will help countries with low organ availability to improve their

¹ COM (2007) 275 final; Communication from the Commission to the European Parliament and the Council —Organ donation and transplantation: Policy actions at EU level.

² COM (2008) 819 final, adopted 8.12.2008; Communication from the Commission – Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States.

³ COM (2008) 818 final, adopted 8.12.2008; Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation.

⁴ 2007-2008 figure, COMMISSION STAFF WORKING DOCUMENT *accompanying the* Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on standards of quality and safety of human organs intended for transplantation *and the* COMMUNICATION FROM THE COMMISSION Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States *Impact Assessment*. SEC(2008) 2956

availability rates. Implementation of elements of the Spanish Model in Italy, for example, has been very successful in increasing organ donation rates, which demonstrated that changes in the organisation of organ donation and procurement can substantially increase and sustain organ donation rates. Improvements in the complex process from donor identification to the transplantation of an organ have been shown to have a large impact on organ donation rates. The success of some Member States in increasing organ availability has been largely down to the organisation of the process, which shows that some ways of organising the organ donation process might be better suited to achieving high availability of organs than others. The combination of an efficient system for organ donor identification, detection and procurement has been identified as one of the keys to increasing deceased donation rates. In particular, the presence of a key donation person at hospital level (transplant donor coordinator), whose main responsibility is to develop a proactive donor detection programme, is the most important step towards optimising organ donation and improving donor detection rates.

Member States should therefore aim to incorporate in their Sets of National Priority Actions the objective of gradually appointing Transplant Donor Coordinators (Priority Action 15) in all hospitals where there is potential for organ donation. The Commission could have a coordinating and monitoring role in this respect; for that purpose Member States should be encouraged to report to the Commission the number of hospitals that have appointed a transplant donor coordinator. Building on this principal objective, the Action plan must help establish internationally recognised standards for transplant donor coordinator programmes in the forthcoming years (by 2015) and promote the implementation of effective training programmes for transplant donor coordinators.

Link to DG SANCO where you can find more information about the organ donation and transplantation initiative http://ec.europa.eu/health/blood_tissues_organ/organ/index_en.htm

The purpose of this contract is therefore to assist Member States to put in place these key health professionals by training a certain number of transplant donor coordinators in every Member State and providing them with the knowledge to further continue this training at national level.

3. Subject of contract

The aim of the contract is to, depending on each Member States' population, size and existing functioning structures, train from one to three persons from each Member State, who have been designated as organ transplant coordinator by their hospital/local/regional/national government. These persons will become "national trainers" and will be charged with the task of further training more transplant donor coordinators in specific regions of each Member State.

⁵ See the aforementioned Action Plan and its 10 Priority Actions.

The result should be an increased number of better trained transplant donor coordinators. It has been demonstrated that these key health professionals are instrumental in increasing organ donation rates⁶.

As a first step, the contractor will, in collaboration with the appropriate authorities at Member State level identify and propose 3-5 candidates per Member State according to each Member State's population, size and existing functioning structures. The DG SANCO in collaboration with EAHC will select one to three candidates per Member State.

Tasks

The work to be undertaken is divided into three work packages:

WP 1 – Selection of candidates and development and presentation of the training programme.

As a first step, the candidates will be selected for the training as stipulated above. Criteria for the selection shall be suggested in the offer and should include, as a minimum:

- A. Demonstrated medical expertise in the field of organ donation and transplantation. The eligible candidate could e.g. be a nurse or a medical doctor.
- B. Demonstrated experience as a trainer; or similarly demonstrated assurance that the candidate can give training.
- C. Practical experience or proven interest in the field of organ donation and transplantation.
- D. Language skills and in particular proficiency in English.
- E. Organisational capacity to transmit knowledge acquired and to perform further training.

As a second step, the training shall be developed in close cooperation with DG SANCO and EAHC. The training shall include both electronically based training and face to face training sessions. It shall be developed in English language and if the contractor sees fit translate it in any additional ones. .

The offer should include an outline of the training, including the learning objectives, the planned teaching session (face-to-face and online), the educational methods used, potential tutors, resources to be provided to the trainees etc.

The methodology for the whole planned training programme shall be developed and presented to DG SANCO/EAHC as the interim report. It shall be in electronic format (Word) and indicate possible challenges and particular advantages of the planned training.

The training programme should include as a minimum the following modules, which will take the form of workshop and/or simulation games imitating real life situations:

⁶ COMMISSION STAFF WORKING DOCUMENT *accompanying the Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on standards of quality and safety of human organs intended for transplantation and the COMMUNICATION FROM THE COMMISSION Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States Impact Assessment*. SEC(2008) 2956

A. Donor detection

The first step is the identification of potential deceased organ donors. This is with no doubt the more important step in the process, since different epidemiological studies show⁷ that mortality in the context of a severe brain damage is not virtually different between countries with a similar degree of development.

B. Brain death detection

The next step is the diagnosis of brain death and its legal certification, to be performed, according the international standards.

C. Donor maintenance

Once the potential donor has been identified, it is essential to proceed with an adequate maintenance, avoiding any incident which might lead to a deterioration of the organs or to an unexpected cardiac arrest before the process has been carried out. The more delicate the organ is, as the heart or the lung, the more possibilities exist of deterioration in the event a hemodynamic instability occurs.

D. Organ procurement/organisation

When the corresponding authorizations have been obtained it is necessary to prepare the intra-hospital logistics to proceed with organ recovery.

E. Family approach

Once the diagnosis of brain death has been completed and medical contraindications have been ruled out, it can be necessary to obtain the judicial authorization in some particular cases and in every single case an interview with the relatives of the potential deceased organ donor has to take place. This interview is essential in order to obtain a complete medical history and detect conditions or behaviours that might imply a risk for the recipient or simply for obtaining consent for donation.

As a third step, a draft exam needs to be developed by the Contractor. A description of it should be included in the offer. It should be developed in the English language and if the contractor sees fit translate it in any additional ones.

It should include testing modules for the internet learning as well as a final exam (to include e.g. multiple choice as well as text questions) after the training workshop.

Deliverables from WP1:

- a) training programme – internet based modules and a workshop
- b) the exam for participants in the training

The duration for WP 1 is 5 months.

⁷ COMMISSION STAFF WORKING DOCUMENT *accompanying the Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on standards of quality and safety of human organs intended for transplantation and the COMMUNICATION FROM THE COMMISSION Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States Impact Assessment*. SEC(2008) 2956

WP 2 – Execution of the training and exam.

The contractor can use web-training and/or electronic sessions, e-learning, distant learning, and a variety of other similar methods of the contractor's choice in order to enhance the impact of the training. However, the contractor must organise at least one face to face training workshop. At the end of the contract the "teaching tools and material" used by the contractor shall remain the property of DG SANCO.

This training workshop can take place in a Member State of the contractor's choice. The face to face session should last at least five days and no more than seven days. The number of sessions should be at least one and should not exceed three. This provides the contractor with flexibility on how to organise the face-to-face session(s) and potentially dividing Member States into subgroups in case the training cannot be performed in one setting. The amount provided will be in all cases the same; therefore the contractor must carefully select the location and the number of face-to-face training workshops.

During the training workshop, the aforementioned modules (A-E) will be elaborated, explained and clarified. This should be done in the form of lectures, seminars but more important through exercises simulating "real life" situations.

All costs for the training, travel, food and board subsistence, including the contracting of external tutors and trainers shall be covered by the contractor and included in the offer.

For those who succeed training by passing the aforementioned exam – a score of 75% is needed to succeed – a certificate will be issued by the contractor certifying that the participants completed all the modules of the training according to the specifications of this tender.

The training programme should be evaluated by the participants. The Contractor needs to develop the method and tools to facilitate this evaluation; all steps of the training, including the face-to-face workshop, need to be evaluated.

Deliverables of WP2:

- a) 1-3 workshops in Member States based on decision by contractor
- b) internet-based learning modules
- c) an evaluation of a) and b) by the participants

The timing for WP 2 is month 5 to 15.

M 5-9 Preparation of training; M 10-15 Training.

WP 3 – Final reporting

The tenderer shall present the final report describing the training programme and its results, including lessons learned from the training (online and the workshop) the participants' evaluation, if expected outcomes were reached or not, reasons for failing, if so, and recommendations for the future. The Contractor also needs to provide recommendations for the sustainability and transferability of the training programme in the future.

The final report should include the following detailed information:

1. Details on the selection procedure of the candidates to participate in the training.
2. Details of each module of the training and the complete set of training material. A Power Point presentation per module is required, including graphs and tables, where pertinent.
3. Details of the exam of the candidates; this shall include the exam procedure and results obtained.
4. Evaluation of the training programme – evaluation of the training by the participants.
5. Analysis of the above; strengths and weaknesses, attainment or not of objectives. Description of next steps; ways of continuing the training by the successful candidates; training future transplant donor coordinators.

The final report should include an executive summary of about 5 pages length.

In addition, the Contractor may be requested by DG SANCO/ EAHC to present the results to relevant stakeholders during a pertinent meeting in Brussels or Luxemburg. For this the Contractor should prepare a Power Point presentation. Cost for this should be included in the offer (Annex V).

Lastly, the Contractor is also requested to provide DG SANCO/EAHC with some text that can be used to formulate a press release on the results of this tender. It is up to DG SANCO/EAHC to decide if and how this text will be used and when it will be communicated to the press. The contractor shall not have any contact with the press without the express consent from DG SANCO/EAHC.

Deliverables from WP 3:

- a) final report (WORD and Power Point format)
- b) presentation at a workshop, as per the request of DG SANCO/EAHC
- c) text for a DG SANCO press release on the training performed.

The draft final report and deliverables c) must be sent to EAHC in month 17. The workshop where the Contractor should make the presentation on the training may also take place in this month, or later according to the DG SANCO schedule.

Timeframe for providing the services

The overall indicative timeframe is the following:

MONTH	ACTIVITY
M 1	Inception meeting with DG SANCO and EAHC.
M 5 WP 1	Selection of candidates to be trained Presentation of the training programme and the draft exam to DG SANCO and EAHC Approval of the training materials and the exam by DG SANCO and EAHC
M 5-14 WP 2	M 5-9 Preparation of training. M 10-15 Training. The training will take place – online and the face-to-face workshop(s)
M.15 WP 2	The exam
M 17 WP 3	Press release Draft final report and text for press release to be submitted
M17 -20 WP 3	Presentation of the results to stakeholders, as per the request by DG SANCO/EAHC
M 20 WP 3	Final report to be submitted

A detailed timetable should be provided in the offer.

4. Participation in the tendering procedure

Participation in tendering procedures is open on equal terms to all natural and legal persons coming within the scope of the Treaties and to all natural and legal persons in a third country which has a special agreement with the European Union in the field of public procurement on the conditions laid down in that agreement.

4.1. Consortia

Groups of economic operators (consortia) are authorised to submit tenders (joint offers). In this case, each member of the consortium shall fulfil the requirements and accept the terms and conditions set out in the tender specifications, the contract as well as in all the relevant Annexes.

The offer must identify the consortium members by filling in the relevant points of Annex Ia. The tenderer shall clearly specify the role and tasks of each member of the consortium. The members of the consortium shall designate one member as consortium leader with full authority to bind the consortium and each of its members. Each consortium partner shall fill in, date and co-sign with the consortium leader a mandate letter (Annex Ib). The consortium leader shall act as a single point of contact with the contracting authority in connection with the present public procurement procedure.

In case the awarded tender is submitted by a consortium, all members of the consortium will be jointly and severally liable towards the contracting authority for the performance of the contract.

The contracting authority may not demand that consortia must have a given legal form in order to be allowed to submit a tender. However, the consortium awarded to sign a contract may be required to adopt a given legal form after it has been awarded the contract and before the contract is signed, if this change is necessary to the proper performance of the contract.

The tenderer shall note that:

- The **exclusion criteria** as indicated in point 16.1 of the tender specifications will be applicable to each member of the consortium, therefore the ‘Declaration of honour’ (Annex IV) must be supplied in the offer by each member.

During the evaluation or before the signature of the contract, the contracting authority may request valid documentary evidence demonstrating that the exclusion criteria are met by the consortium partners in accordance with Annex IV.

The leader and the members of the awarded consortium will be obliged to submit the exclusion criteria evidence before the signature of the contract, except if they are public bodies.

- The consortium leader shall provide **evidence of access to contracts (proof of eligibility)** as stated in point 17.1 by filling in
 - Annex Ia (Tender submission form),
 - Annex Ib (Mandate letter filled in and dated by the consortium partner and co-signed by the consortium leader),
 - Annex IIa / IIb / IIc (Legal entity form) and
 - Annex III (Financial identification form).
- During the evaluation, the **selection criteria for economic and financial capacity** of the consortium members will be – partly individually and partly in a consolidated way – assessed therefore the offers must include evidence on this regarding each consortium member. Each consortium member shall fill in and sign Annex VII.
- During the evaluation, the **selection criteria for technical and professional capacity** will be assessed in relation to the combined capacities of all members of the consortium, as a whole; therefore the offers must include evidence on this.

4.2. Subcontracting

Subcontracting is allowed. However, the contracting authority may demand information from the tenderer on any part of the contract that the tenderer may intend to subcontract to third parties and on the identity of any subcontractor. The contracting authority reserves the right to validate the proposed subcontractor(s).

The offer must clearly identify the subcontractor(s) by filling in the relevant points of Annexes Ia of these tender specifications and prove their willingness to accept tasks proposed to them by the tenderer (e. g. by way of enclosing a written commitment of the

subcontractors(s)). Moreover, by filling in Annex Ia, the tenderer shall provide information as to what proportion of the contract the tenderer intends to subcontract in total and also by each subcontractor, in case there are more subcontractors identified. In addition to this, the offer shall describe which main task(s) will be subcontracted.

Once the contract has entered into force, the contractor shall retain full liability towards the contracting authority for the performance of the contract as a whole. The Executive Agency will not have any direct legal commitment with the subcontractor(s).

The tenderer shall note that:

- As a general rule, the **exclusion criteria** as stated in point 16.1 of the tender specifications will be applicable to the tenderer and each its subcontractor, therefore the ‘Declaration of honour’ (Annex IV) must be supplied in the offer by them.

During the evaluation or before the signature of the contract, the contracting authority may request valid documentary evidence demonstrating that the exclusion criteria are met by the subcontractor(s) in accordance with Annex IV.

Before the signature of the contract, the *awarded tenderer including the subcontractor(s)* will be asked to submit the exclusion criteria evidence. As an exception,

- that/those subcontractor(s) of the awarded tenderer who will be subcontracted for a value less than € 60 000 of the total amount of the contract,
- and the tenderer and/or the subcontractor(s) being a public body will not be obliged to submit such evidence.

- Only the tenderer shall provide **evidence of access to contracts (proof of eligibility)** as stated in point 17.1. by filling in
 - Annex Ia (Tender submission form),
 - Annex IIa / IIb / IIc (Legal entity form) and
 - Annex III (Financial identification form).
- When a subcontractor will be subcontracted for a value of more than € 60 000, the tenderer shall submit information and evidence on the **selection criteria for the economic and financial capacity** of the identified subcontractor by filling in Annex VII and enclosing the evidence as indicated in point 17.2.
- The **selection criteria for technical and professional capacity** will be applied to the combined capacities of the tenderer and the subcontractors identified whether in the tender or during the implementation of the contract –, to the latter in respect of the part of the work that they will perform, therefore the offers must include evidence on this.

Instructions on how to fill in the Annexes of these tender specifications in case of joint offers and/or subcontracting are available in Annex VIII (Checklist).

5. Documentation for tenderers

The following set of documents is provided to the tenderers:

- Invitation to tenderers
- Tender specifications
 - Annex Ia: Tender submission form
 - Annex Ib: Letter of mandate
 - Annex IIa: Legal entity form for public entities
 - Annex IIb: Legal entity form for private entities
 - Annex IIc: Legal entity form for individuals
 - Annex III: Financial identification form
 - Annex IV: Declaration of honour
 - Annex V: Financial offer form
 - Annex VI: Draft contract and annexes
 - Annex VII: Economic and financial capacity overview form
 - Annex VIII: Checklist

6. Visits to premises or briefing

Generally, the meetings with the contractor will take place in the offices of Unit C6 (Health Law and International), Directorate-General for Health and Consumers (Brussels, Rue Froissart 101) or at the Health Unit, Executive Agency for Health and Consumers (Luxembourg, Rue Guillaume Kroll 12.).

The following meetings are foreseen within the duration of the contract:

- M1 – inception meeting
- M5 – meeting with DG SANCO and EAHC to present the training programme. It shall be accompanied by a power point presentation with a clear illustration of the various training modules, what is included in the internet-base learning and what the training workshop will contain.

The presentation or any other documents should be sent to EAHC/DG SANCO at least 5 working days before the meeting. Minimum attendance includes the team leader and two team members.

The estimated travel and subsistence expenses must be indicated separately in the financial offer (Annex V). All eligible costs related to these meetings will be reimbursed according to the provisions of the contract (Annex VII).

7. Variants

Variants are not accepted.

8. Volume of contract

The total price is estimated at between EUR 250 000 and maximum 300 000 (two hundred fifty thousand to three hundred thousand) excluding VAT and other taxes.

The tasks covered by the contract shall be completed within **20 months** of the signature by the last contracting party. The duration of the contract is **22 months**.

9. Price

- Prices must be quoted in Euro using, if necessary, the conversion rates published in the C series of the Official Journal of the European Union on the day when the contract notice was published (if no notice was published, on the day when the invitation to tender was sent out).
- Prices must be fixed amounts in Euro.
- Estimated travel and subsistence expenses must be indicated separately.

This estimate should be based on Article I.3.3 of the contract annexed to these specifications and include any travel required to meet representatives of the Executive Agency. In any event, it should represent the maximum amount of travel and subsistence expenses payable for all the services provided.

- Prices should be quoted free of all duties, taxes and other charges, including VAT, as the Communities are exempt from such charges under Articles 3 and 4 of the Protocol on the privileges and immunities of the European Communities; the amount of VAT should be shown separately.
- Prices are firm and not subject to revision.

10. Terms of payment

- Pre-financing:

Following the signature of the contract by the last contracting party, within 30 days of the latest of the following dates:

- the receipt by the Executive Agency of a request for pre-financing with a relevant invoice;
- the inception report and the approval thereof;

A pre-financing payment equal to 30% of the total amount referred to in Article I.3.1 the contract (see Annex VI of the Technical Specifications) shall be made.

- Interim payment:

The request for interim payment of the contractor shall be admissible if accompanied by:

- an interim technical report on WP 1 – including the final training programme;
- the relevant invoice;
- a statement of reimbursable expenses (travel and subsistence allowances) for the reported period in accordance with Article II.7 of the contract.

The Executive Agency will have 45 days from receipt to approve or reject the interim technical report and the training programme, and the contractor shall have 20 days in which to submit additional information or a new report.

Within 30 days of the date of approval of the interim technical report, an interim payment corresponding to the relevant invoice, equal to 30% of the total amount referred to in Article I.3.1 of the contract shall be made, increased by the amount of approved reimbursable expenses.

- Payment of the balance:

The request for payment of the balance of the contractor shall be admissible if accompanied by:

- the final technical report in accordance with the instructions laid down in the Tender Specifications WP 3 – including the full training programme;
- the relevant invoice;
- a statement of reimbursable expenses (travel and subsistence allowances) for the reported period in accordance with Article II.7 of the contract.

The Executive Agency will have 45 days from receipt to approve or reject the final technical report, and the contractor shall have 20 days in which to submit additional information or a new report.

Within 30 days of the date of approval of the final technical report, payment of the balance corresponding to the relevant invoice, equal to 40% of the total amount referred to in Article I.3.1 of the contract shall be made, increased by the amount of approved reimbursable expenses.

- Payment for travel and subsistence expenses:

Reimbursement will be made on presentation of statements of reimbursable expenses according to Article II.7 of the contract, and after their approval.

11. Reports and documents to be submitted

The work carried out by the contractor under the contract will be the subject of the following reports, which must be sent to the Executive Agency by the contractor both in hard copy and electronic format.

All reports should have numbered paragraphs and pages.

- **The interim report – resulting from WP 1** : in 4 hard copies and in electronic format (Word and Power Point), in English

The interim report is defined as the deliverables from WP 1. These must be sent to the Executive Agency no later than 5 months after signature of the contract.

- **The final report – resulting from WP 3**: in 4 hard copies and in electronic format (Word and Power Point), in English and workshop presenting results to stakeholders.

The draft final report must be submitted to the Executive Agency no later than 17 months after signature of the contract. The Executive Agency will then either inform the contractor that it approves the draft or will send him its comments.

Within 30 days of receiving any such comments, the contractor will send the Executive Agency his final report, which will either take account of the comments or put forward alternative points of view.

In the absence of any comments from the Executive Agency within 30 days of its receiving the draft report, the contractor may request written acceptance of it.

The final report will be deemed to have been approved by the Executive Agency if it does not expressly inform the contractor of any comments within 30 days of its request.

12. Contractual terms and guarantees

In drawing up his bid, the tenderer should bear in mind the provisions of the standard contract attached to this invitation to tender (Annex VI).

Submission of a tender implies acceptance of all the terms specified in the present specifications and in particular in the attached standard contract including the general conditions applicable to contracts (Annex VI).

All documents presented by the tenderer become the property of the European Union and are deemed confidential.

The Executive Agency will not reimburse expenses incurred in preparing and submitting offers.

13. No obligation to award the contract

Completing the adjudication or the procedure of the call for tenders in no way imposes on the Executive Agency an obligation to award the contract.

The Executive Agency shall not be liable for any compensation with respect to tenderers whose tenders have not been accepted, nor shall it be liable when deciding not to award the contract.

14. Administrative and financial penalties

1. Without prejudice to the application of penalties laid down in the contract, candidates or tenderers and contractors who have been guilty of making false declarations or have been found to have seriously failed to meet their contractual obligations in an earlier procurement procedure shall be excluded from all contracts and grants financed by the Union budget for a maximum of two years from the time when the infringement is established, as confirmed after an adversarial procedure with the contractor.

That period may be extended to three years in the event of a repeat offence within five years of the first infringement.

Tenderers or candidates who have been guilty of making false declarations shall also receive financial penalties representing 2 % to 10 % of the total value of the contract being awarded.

Contractors who have been found to have seriously failed to meet their contractual obligations shall receive financial penalties representing 2 % to 10 % of the total value of the contract in question.

That rate may be increased to 4 % to 20 % in the event of a repeat offence within five years of the first infringement.

2. In the cases referred to in paragraph 16.1 points (a), (c) and (d) of these specifications, the candidates or tenderers shall be excluded from all contracts and grants for a maximum of two years from the time when the infringement is established, as confirmed after an adversarial procedure with the contractor.

In the cases referred to in paragraph 16.1 points (b) and (e) of these specifications, the candidates or tenderers shall be excluded from all contracts and grants for a minimum of one year and a maximum of four years from the date of notification of the judgment.

Those periods may be extended to five years in the event of a repeat offence within five years of the first infringement or the first judgment.

3. The cases referred to in paragraph 16.1 point (e) of these specifications shall be the following:

(a) cases of fraud as referred to in Article 1 of the Convention on the protection of the European Communities' financial interests drawn up by the Council Act of 26 July 1995⁸;

(b) cases of corruption as referred to in Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union, drawn up by the Council Act of 26 May 1997⁹;

(c) cases of participation in a criminal organisation, as defined in Article 2(1) of Joint Action 98/733/JHA of the Council¹⁰;

(d) cases of money laundering as defined in Article 1 of Council Directive 91/308/EEC¹¹.

15. Requirement as to the tender

The tender must include:

- (a) an administrative part including all the information and documents required by the contracting authority for the appraisal of tenders on the basis of the exclusion and selection criteria set out under paragraphs 16 and 17 respectively of these tender specifications;
- (b) a technical part including all the information and documents required by the contracting authority for the appraisal of tenders on the basis of the award criteria set out under paragraph 18 of these tender specifications;
- (c) a financial part setting out prices in accordance with paragraph 19 of these tender specifications.

ADMINISTRATIVE PART

The evaluation will be made in three stages: exclusion, selection and award. Only the offers which fulfil the criteria detailed below will be selected for the award stage.

16. Exclusion criteria

16.1. Candidates or tenderers shall be excluded from participation in a procurement procedure if:

- (a) they are bankrupt or being wound up, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are

⁸ Official Journal of the European Communities, C 316, 27.11.1995, p. 48.

⁹ Official Journal of the European Communities, C 195, 25.06.1997, p. 1.

¹⁰ Official Journal of the European Communities, L 351, 29.12.1998, p. 1.

¹¹ Official Journal of the European Communities, L 166, 28.06.1991, p. 77.

the subject of proceedings concerning those matters, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;

- (b) they have been convicted of an offence concerning their professional conduct by a judgment which has the force of res judicata;
- (c) they have been guilty of grave professional misconduct proven by any means which the contracting authority can justify;
- (d) they have not fulfilled obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the contracting authority or those of the country where the contract is to be performed;
- (e) they have been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the Communities' financial interests;
- (f) they are currently subject to an administrative penalty referred to in Article 96 (1) of the Financial Regulation (The contracting authority may impose administrative or financial penalties on the following: (a) candidates or tenderers in the cases referred to in point (b) of Article 94, (b) contractors who have been declared to be in serious breach of their obligations under contracts covered by the budget. In all cases, however, the contracting authority must first give the person concerned an opportunity to present his observations.)

Points (a) to (d) of the first subparagraph shall not apply in the case of purchase of supplies on particularly advantageous terms from either a supplier which is definitively winding up its business activities, or from the receivers or liquidators of a bankruptcy, through an arrangement with creditors, or through a similar procedure under national law.

Candidates or tenderers must certify that they are not in one of the situations listed above by completing and signing the 'Declaration of honour' (Annex IV).

As a general rule, the successful tenderer will be requested, after the award and before the signature of the contract, to also provide evidence that it is not in any of the situations described in points (a), (b), (d) and (e) above within the time limit stipulated by the contracting authority. In case the successful tender was submitted by a consortium and/or subcontractors are identified, the exclusion criteria evidence shall be submitted in accordance with point 4 of the tender specifications.

This evidence must be in one of the forms described in paragraph 16.2 below.

16.2. Evidence

- (a) The contracting authority shall accept as satisfactory evidence that the candidate or tenderer to whom the contract is to be awarded is not in one of the situations described in point (a), (b) or (e) of paragraph 16.1, a recent extract from the judicial record or, failing that, an equivalent document recently issued by a judicial or administrative authority in the country of origin or provenance showing that those requirements are satisfied.

- (b) The contracting authority shall accept, as satisfactory evidence that the candidate or tenderer is not in the situation described in point (d) of paragraph 16.1, a recent certificate issued by the competent authority of the State concerned. Where the document or certificate referred to in paragraph 1 is not issued in the country concerned and for the other cases of exclusion referred to in paragraph 16.1, it may be replaced by a sworn or, failing that, a solemn statement made by the interested party before a judicial or administrative authority, a notary or a qualified professional body in his country of origin or provenance.
- (c) Depending on the national legislation of the country in which the candidate or tenderer is established, the documents referred to in paragraph 16.2 shall relate to legal persons and/or natural persons including, where considered necessary by the contracting authority, company directors or any person with powers of representation, decision-making or control in relation to the candidate or tenderer.

16.3. Contracts may not be awarded to candidates or tenderers who, during the procurement procedure:

- (a) are subject to a conflict of interest;
- (b) are guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in the contract procedure or fail to supply this information;
- (c) find themselves in one of the situations of exclusion, referred to in paragraph 16.1, for this procurement procedure.

Candidates or tenderers must certify that they are not in the situation in point (a) by completing and signing the form in Annex IV, 'Declaration of honour'.

17. Selection criteria

17.1. Proof of eligibility

The tenderer (in case of a consortium, the consortium leader) shall provide evidence of access to contracts (eligibility) according to the followings:

- a) the tenderer indicates in which State it has its headquarters or domicile (Annex Ia) and presents the supporting evidence normally acceptable under its own law.
- b) it indicates its VAT number (Annex IIa/IIb);
- c) it indicates the name and position of the person authorised to sign the contract (Annex Ia);
- d) it indicates its bank account number and bank address (R.I.B. or standard form in Annex III);

- e) if the tenderer is a natural person, it shall complete the standard form in Annex IIc.
- f) In case of a consortium, the consortium leader shall submit the Mandate letters (Annex Ib) signed and dated by the consortium members and co-signed by the consortium leader; in case of subcontracting the tenderer shall submit the written commitment proving the willingness of the subcontractor(s) to accept the task proposed to it / them by tenderer.

The tenderers' capacity will be assessed on the basis of the economic and financial capacity and the technical and professional capacity criteria:

17.2. Economic and financial capacity

For any tenderer participating in the call, verification of the organisation's economic and financial capacity is mandatory.

In order to be economically and financially viable, a tenderer must demonstrate:

- **Liquidity:** capable of covering its short-term commitments;
- **Solvency:** capable of covering its medium and long-term commitments;
- **Profitability:** generating profits, or at least with a self-financing capacity.

As a consequence, the liquidity, the solvency and the profitability of the tenderer shall be assessed by the Executive Agency.

Proof of its economic and financial capacity shall be furnished by the tenderer by the presentation of balance sheets or extracts from balance sheets and profit and loss accounts for at least the last two years for which accounts have been closed, where publication of the balance sheet is required under the company law of the country in which the economic operator is established.

Tenderers (and in case of a consortium, the consortium leader and the consortium members) are also requested to fill in the form 'Economic and Financial Capacity Overview' in Annex VII.

If, for some exceptional reason that the Executive Agency considers justified, the tenderer is unable to provide the references requested by the Executive Agency, he may prove his economic and financial capacity by any other means that the Executive Agency considers appropriate. In case of public bodies, other documents, in particular the body's budget for the current year could be considered as appropriate.

17.2.2.1 Used ratios and noteworthy value

The tenderer's economic and financial capacity check is based on three financial ratios defined as follows:

Purpose	Indicators	Ratios
Liquidity	Current Ratio ¹²	$\frac{\text{Current Assets (3)}^{13}}{\text{Trade and Other Debts (6)}}$
Profitability	Profitability Ratio ¹⁴	$\frac{\text{Gross Operating Profit (14)}}{\text{Turnover (7)}}$
Solvency	Financial Autonomy Ratio ¹⁵	$\frac{\text{Capital and Reserves (4)}}{\text{Total Liabilities (4 + 5 + 6)}}$

In addition, noteworthy values are used as complementary data (Flag).

Purpose	Indicators	Ratios
Financial Capacity	Turnover Flag	The average Turnover (7) of the last 2 accounting years minus $\frac{\text{Estimated Maximum Amount of the Services}}{\text{Duration of the provided service in years}}$
	Equity Flag	Capital and Reserves (4) minus Paid-up Capital (4.1)

¹² For the last year for which accounts have been closed

¹³ The figures mentioned between brackets refer to the respective accounts listed in Annex VII

¹⁴ For the best of the last two years for which accounts have been closed

¹⁵ For the last year for which accounts have been closed

17.2.2.2. Thresholds

According to the results obtained for each of the abovementioned ratios, the following quotes are given:

Purpose	Indicators	Weak	Acceptable	Good
		0	1	2
Liquidity	Current Ratio	$i < 1$	$1,00 \leq i \leq 1,25$	$i > 1,25$
Profitability	Profitability Ratio	$i < 0,05$	$0,05 \leq i \leq 0,15$	$i > 0,15$
Solvency	Financial Autonomy Ratio	$i < 0,20$	$0,20 \leq i \leq 0,33$	$i > 0,33$

Flags are assessed according the following criteria:

Purpose	Indicators	Weak	Good
Financial Viability and Capacity	Turnover Flag	$i < 0$	$i \geq 0$
	Equity Flag	$i < 0$	$i \geq 0$

17.2.3 Conclusion of the economic and financial capacity checks

The financial assessment on the basis of the above mentioned ratios results in scores of "Good", "Acceptable" or "Weak" for the liquidity, profitability and solvency aspects of the tenderer.

A tenderer subject to a verification of its economic and financial capacity who obtains an overall score of less than 3 points as a result of the above ratios will be considered to have a "Weak" economic and financial capacity.

Moreover, despite an overall score of 3 points or more under the abovementioned ratio analysis, the economic and financial capacity of a tenderer will be considered as "Weak", if both the noteworthy values, knowing the Turnover Flag and the Equity Flag, are considered "Weak".

17.3. Technical and professional capacity

Technical and professional capacity of the tenderer shall be evaluated and verified in accordance with point 17.3.1 and 17.3.2 as follows:

17.3.1. Requirements

The tenderer must meet the following criteria:

- i. at least 5 years of relevant professional experience in the field of organising advanced training in the medical field;
- ii. the capacity to put together a team with members of at least 3 years experience of relevant professional activities in the medical field. The team shall have a leader with at least 2 years of relevant professional experience in organ donation and transplantation.
- iii. the team shall at least have one medical doctor and/or preferably a transplant coordinator;
- iv. the team members shall have a proven adequate working knowledge of English. This shall be proven either by internationally accredited language diplomas or by proof of working in English or multi-cultural environments.

Technical and professional capacity of tenderers shall be evaluated and verified in accordance with paragraph 2.

17.3.2. Evidence

Evidence of the technical and professional capacity of tenderers shall be furnished on the basis of the following documents:

- (a) the educational and professional qualifications of the service provider or contractor and/or those of the firm's managerial staff and, in particular, those of the person or persons responsible for providing the services or carrying out the works.

The tenderer shall enclose the curricula vitae as well as a summary table of main expertise of the persons responsible for providing the services. A list of the publications in scientific journals of the team members shall also be enclosed.

- (b) a reference list of the principal services provided in the past three years, with the sums, dates and recipients, public or private;

TECHNICAL PART

The technical proposal shall describe in detail how the services listed in point 3 will be provided by the tenderer.

18. Award criteria

The contract will be awarded to the tenderer who submits the most economically advantageous bid, as assessed on the basis of the following factors:

(a) Technical evaluation criteria in their order of importance as weighted by percentage:

N°	Qualitative Award criteria	Weighting (max. points)
1.	Understanding of the nature and objectives of the work to be done and of the means needed to be deployed for its development and conduct	20
2.	Organisational structure with in the team and breakdown of the work plan so as to perform the work within the time scale provided	20
3.	The qualitative methodology of the work; the manner in which the work will be carried out, including the description of the activities to be undertaken.	40
4.	Scientific quality of the draft training programme and the draft exam, clarity and content of both	20
<i>Total points</i>		100

The criteria are detailed as follows:

1. The tender shall contain a separate chapter or section describing the overall and the specific understanding of the work to be done. It shall show a clear understanding of the actual situation of organ transplantation in the EU and its challenges. It shall also demonstrate coherence and plausibility of the proposal for tackling the different tasks described.
2. The tender shall reflect the assurance of a qualitative organisational capacity to perform the contract within the indicated timeline and as requested in the tender specifications.
3. The methodology presented in the tender shall describe the assurance of the capacity to execute the tasks in a logical and structured manner. Importance will be given to the contractor's degree of pedagogic/teaching capacities, innovation and efficiency of the training programme.

4. The draft training plan and the draft exam shall include the relevant topics and the draft questions. The assessment is being done on the accuracy, i.e. the scientific level, clarity and content of the topics and draft questions. The drafts shall reflect, in an organised way, an in depth knowledge and competence in the field of organ transplantation.

For each criterion above, a 70 % threshold is required. Tenderness falling below these thresholds will be eliminated.

Moreover, tenders that have not obtained a total at least 60 out of the 100 points will be excluded.

(b) Price.

Technical quality will be weighed against price on a 70/30 basis.

The points of the price are calculated by the following formula:

$(\text{price of the lowest passing bid} / \text{price of the bid in question}) \times 100.$

Then, the price and quality scores will be calculated by multiplying:

- The points awarded for the technical quality by 0.70
- the points awarded for the financial bid by 0.30.

The price and quality scores are then added together and the contract will be awarded to the tender achieving the highest score.

FINANCIAL PART

19. Financial part

Prices must be presented in the standard format of Annex V.