



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR ENERGY
DIRECTORATE D - Nuclear Energy
Radiation Protection

Luxembourg,
ENER/D4/D2011/

INVITATION TO TENDER No. ENER/D4/160-2011

(open procedure)

Dear Sir/Madam,

1. The European Commission invites tenders for a service contract regarding the following project:

Guidelines on a risk analysis of accidental and unintended exposures in radiotherapy

This invitation to tender follows the publication of:

- the contract notice in OJEU 2011/S 99-161218 of 24/05/11

2. If you are interested in this contract, you must submit a tender in **triplicate**, in one of the official languages of the European Union.

Tenders must be:

(a) either sent by registered mail or by private courier

The tender must be sent by registered mail or by private courier, dispatched not later than **07/07/2011** (the postmark or the receipt issued by the courier service serving as proof of the dispatch) to the following address:

European Commission
Directorate-General for Energy
For the attention of Mr R. Baranczyk– EUFO 4186A
Jean-Monnet Building
Plateau de Kirchberg
L-2920 Luxembourg

(b) or delivered by hand

Tenders must be delivered by hand at the **Central Mail of the European Commission** by **07/07/2011 not later than 4 p.m.** (Brussels time), at the following address:

European Commission
Directorate-General for Energy
For the attention of Mr R. Baranczyk– EUFO 4186A
Jean Monnet Building – main entrance
Rue Albert Wehrer,
Plateau de Kirchberg,
L-2920 Luxembourg

In this case, a receipt must be obtained as proof of submission, signed and dated by the official in the Commission's central mail department who took delivery. The department is open from 08.00 to 16.00 Monday to Friday. It is closed on Saturdays, Sundays and Commission holidays.

3. Tenders must be placed inside two sealed envelopes, one inside the other. **The inner envelope should be marked:**

Call for tenders No. ENER/D4/160-2011
not to be opened by the internal mail department
European Commission
Directorate-General Energy
Unit D4 Radiation Protection
EUROFORUM Building – Room 4186A
L-2920 Luxembourg

If self-adhesive envelopes are used, they must be sealed with adhesive tape and the sender must sign across this tape.

The non-compliance with these formal conditions will entail the rejection of the bids at the opening session.

4. Tenders will be opened at 10.30 a.m. on 14/07/2011 in the offices of the Directorate- General for Energy

EUROFORUM Building
Office 4198
1 rue Henry Schnadt
Zone d'activités Cloche d'Or
L-2530 Luxembourg

This opening session will be public. Each tenderer may be represented by not more than one person. At the end of the opening session, the Chairman of the opening committee will indicate the name of the tenderers and the decision concerning the admissibility of each offer received. The prices mentioned in the bids will not be communicated.

5. The specification, listing all the documents that must be produced in order to tender, including supporting evidence of economic, financial, technical and professional capacity and the draft contract are attached.

6. Tenders must be accompanied by a cover letter signed by the tenderer or his duly authorised representative. All tender documents shall be perfectly legible so that there can be no doubt as to words and figures.
7. Validity period of the tender: six months as from the final date for submission of tenders mentioned under point 2 above.
8. Submission of a tender implies acceptance of all the terms and conditions set out in this invitation to tender, in the specification, in the draft contract and, where applicable, waiver of the tenderer's own general or specific terms and conditions. The terms and conditions are binding on the tenderer to whom the contract is awarded during the performance of the contract.
9. Contacts between the awarding authority and tenderers are prohibited throughout the procedure except in exceptional circumstances and under the following conditions only:

Before the closing date for submission of tenders

- At the request of the tenderer, the awarding authority may provide additional information solely for the purpose of clarifying the nature of the contract.

Any requests for additional information must be sent in writing to the following address:

Mr Remigiusz Baranczyk
European Commission / ENER D4
EUFO 4186A
L-2920 Luxembourg
Luxembourg
Tel (+ 352) 4301-32998
Fax(+ 352) 4301-34646
e-mail: Remigiusz.Baranczyk@ec.europa.eu

Requests for additional information received less than five working days before the closing date for submission of tenders will not be processed.

- The Commission may, on its own initiative, inform interested parties of any error, inaccuracy, omission or any other material shortcoming in the text of the tender documents.

Further information will be sent simultaneously to all tenderers who have requested the specification in writing, where this is appropriate. Tenderers who have downloaded the documents from the Directorate-General for Energy (DG ENER) are invited to consult this site regularly until the deadline for submission.

After the opening of tenders

If a tender requires clarification, or if there is a need to correct material errors which have occurred in the drafting of the tender, the Commission may take the initiative and contact the tenderer(s). Such contact shall not lead to the conditions of the tender being altered in any way.

10. This invitation to tender is in no way binding on the Commission. A commitment will come about only when a contract with the successful tenderer has been signed.

Until a contract is signed, the awarding authority may decide not to award a contract or to cancel the tendering procedure, without the candidates or tenderers being entitled to claim any compensation. Where appropriate, the decision will be substantiated and brought to the attention of the tenderers.

11. Tenderers will be informed of whether their tenders have been accepted or rejected.
12. If processing your reply to the invitation to tender involves the recording and processing of personal data (such as your name, address and CV), such data will be processed pursuant to Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. Unless indicated otherwise, your replies to the questions and any personal data requested are required to evaluate your tender in accordance with the specifications of the invitation to tender and will be processed solely for that purpose by the Director of the Shared Resource Directorate MOVE/ENER, acting as data controller. Details concerning the processing of your personal data are available on the privacy statement at: http://ec.europa.eu/dataprotectionofficer/privacystatement_publicprocurement_en.pdf.
13. Your personal data (name, given name if natural person, address, legal form, registration number and name and given name of the persons with powers of representation, decision-making or control, if legal person) may be registered in the Early Warning System (EWS) only or both in the EWS and Central Exclusion Database (CED) by the Accounting Officer of the Commission, should you be in one of the situations mentioned in:

- the Commission Decision 2008/969 of 16.12.2008 on the Early Warning System (for more information see the Privacy Statement on http://ec.europa.eu/budget/info_contract/legal_entities_en.htm), or

- the Commission Regulation 2008/1302 of 17.12.2008 on the Central Exclusion Database (for more information see the Privacy Statement on http://ec.europa.eu/budget/library/sound_fin_mgt/privacy_statement_ced_en.pdf)

Yours faithfully,


Peter FAROSS
Director

TENDER SPECIFICATIONS
ATTACHED TO THE INVITATION TO TENDER

Invitation to tender No. ENER/D4/160-2011 concerning

Guidelines on a risk analysis of accidental and unintended exposures in radiotherapy

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I. SPECIFICATIONS

I.1. Introduction

The work of the European Commission in the field of radiation protection is governed by the EURATOM Treaty and the Council Directives made under it. The most prominent is the Council Directive 96/29/EURATOM¹ laying down the basic safety standards (BSS) for radiation protection of the workers and the members of the public. The BSS Directive is supplemented by the Council Directive 97/43/EURATOM (Medical Exposure Directive, MED)² defining the European legal requirements for radiation protection of individuals submitted to medical exposures.

Article 11 of MED requires that "Member States shall ensure that all reasonable steps to reduce the probability and the magnitude of accidental or unintended doses of patients from radiological practices are taken (...)" and stipulates that "the main emphasis in accident prevention should be on the equipment and procedures in radiotherapy (...)".

Radiotherapy is a highly complex, multi-step process, which requires the input of many different staff groups in the planning and delivery of the treatment. Complexity arises from the wide range of conditions treated, technologies used and professional expertise needed. This complexity is compounded by the multiple steps involved and the fact that processes are continually changing in the light of research and the introduction of new technologies. Though errors are rare, when they do occur the consequences can be significant for the patient, as proved by severe radiotherapy accidents occurred during the last years.

The objective of this project is to perform an EU-wide study on the implementation of the MED requirements aimed at the reduction of the probability and the magnitude of accidents in radiotherapy and to develop guidelines on a risk analysis of accidental and unintended exposures in external beam radiotherapy. Such guidelines describing proactive methods to identify vulnerable aspects of the radiotherapy treatment, using risk analyses can significantly contribute to the improvement of patient safety. Following on from that, the common and rarer risks could be mapped as a first step to reducing or eliminating them.

Publication of guidelines will support Member States in the implementation of the legislative requirement derived from the provision of Article 11 of MED.

Development of studies on the risk of accidental exposures was acknowledged as one of the main steps to improve patient safety at the International Conference on Modern Radiotherapy³ held in Versailles on 2-4 December 2009, organized by the French Nuclear Safety Authority in cooperation with the International Atomic Energy Agency, the World Health Organization and the European Commission.

The project was recommended by the Working Party on Medical Exposures of the Article 31 Group of Experts (WP MED).

¹ http://ec.europa.eu/energy/nuclear/radioprotection/doc/legislation/9629_en.pdf

² http://ec.europa.eu/energy/nuclear/radioprotection/doc/legislation/9743_en.pdf

³ <http://www.conference-radiotherapy-asn.com>

I.2. Purpose of the contract

Objective

The objective of this contract is to verify implementation of the MED requirements aiming at reduction of the probability and the magnitude of accidents in radiotherapy in EU Member States (Article 11 of MED) and to develop guidelines on a risk analysis of accidental and unintended exposures in external beam radiotherapy.

In order to achieve this objective the contractor shall carry out three main tasks:

- conduct an EU-wide study on overall status and the legal and practical arrangements in EU Member States regarding the implementation of Article 11 of MED,
- organize a European Workshop on this matter, and,
- develop a European Guidance document on a risk analysis of accidental and unintended exposures in external beam radiotherapy.

Project organization

The project management will be carried out by a lead contractor with partners from a representative number of Member States. The contractor will set up a panel of European experts from national competent authorities, radiotherapy centres, institutes, bodies and organisations with relevant knowledge and experience in the field. The contractor will coordinate and supervise the work of the panel of experts and regularly report on progress to the Commission.

EU study on the implementation of MED requirements aiming at reduction of the probability and the magnitude of accidents in radiotherapy

The work will involve elaboration and distribution of a questionnaire to establish the overall status and the legal and practical arrangements in EU Member States regarding the implementation of the MED's requirement aimed at the reduction of the probability and the magnitude of accidents in radiotherapy.

The questionnaire shall be appropriately distributed to reach the relevant organizations/institutions in all EU Member States. The contractor shall identify the recipients of the questionnaire and present them as part of the technical proposal to the tender.

The answers to the questionnaire will serve to identify major issues, important discrepancies between the different countries and good practices and will be used to develop European guidance. The study shall include, but not be limited to, the following:

- comprehensive evaluation of national legal provisions imposed by the MED aimed at accident prevention in radiotherapy,
- evidence of pro-active approach to identification of potential exposures including their probability of occurrence, preventive control measures, cost effectiveness of preventive controls,
- existence and evidence of requirement to declare the occurrence of events involving or potentially involving accidents,
- existence and evidence of systems of registrations and analyses of events involving or potentially involving accidents,

- existence of systems to identify those facilities from whom no or few reports are submitted,
- examination of the tension between full reporting and regulation and identification of systems/solutions which address this issue (i.e. does the possibility of regulatory sanctions influence the level of reporting),
- harmonisation between radiotherapy event registration and other incident reporting systems,
- availability, process of development and update of study of risk of accidents in radiotherapy,
- availability of quality assurance programmes for radiotherapy procedures,
- existence of classification grid and coding system to describe the radiotherapy errors,
- existence and type of arrangements made to inform the referrer, the practitioner and the patient about an unintended or accidental exposures,
- means of communicating and sharing lessons from radiotherapy incidents within radiotherapy services and externally.

European Workshop on measures aiming at reduction of the probability and the magnitude of accidents in radiotherapy

The contractor will organize a European Workshop to discuss the results of the study. The contractor shall ensure the appropriate timing and participation at the workshop in order to guarantee that the final draft of the European Guidelines is appropriately discussed and widely accepted by the relevant organizations and professional groups in Member States. For this reason the workshop shall be held not later than **eighteen months** following the signature of the contract. The contractor will prepare proceedings of the European Workshop to be included in a final report submitted to the Commission.

European Guidelines on a risk analysis of accidental and unintended exposures in external beam radiotherapy

The most essential final result of the work is the development of a European Guidance document on a risk analysis of accidental and unintended exposures in external beam radiotherapy. The document should provide comprehensive description of best practices to conduct a study of risk of accidental or unintended exposures. Proactive methods to identify vulnerable aspects of the radiotherapy treatment, using risk matrix or probabilistic safety assessment, both methods being complementary, should be presented in detail. The document should also clarify the links between the risk analysis, the principle of defence in depth and user experience feedback, and examine the benefits of an effective exchange of risk analysis results between equipment manufacturers and users.

The relevant documents issued by the World Health Organization⁴, the International Commission on Radiological Protection⁵, the International Atomic Energy Agency⁶ and other

⁴ "Radiotherapy Risk Profile – Technical Manual", WHO, 2008
(http://www.who.int/patientsafety/activities/technical/radiotherapy_risk_profile.pdf)

⁵ "Preventing Accidental Exposures From New External Beam Radiation Therapy Technologies", ICRP Publication 112, 2009 (<http://www.sciencedirect.com/science/journal/01466453>)

institutions^{7, 8} shall be considered and observers from these organizations should be invited to contribute.

The contractor will present the draft intermediate and final reports of the project to the Working Party on Medical Exposures of the Group of Experts referred to in Article 31 of the EURATOM Treaty. In addition the contractor will submit the draft final report for comments to the appropriate European professional organisations.

The final report will be published in the Radiation Protection series and on DG ENER website.

I.3. Reports and documents to produce - Timetable to observe

Execution of the tasks begins after the date on which the Contract enters into force.

A **kick-off meeting** will take place in Luxembourg, at the latest one month following the signature of the contract, in order to settle all the details of the work to be undertaken. The contractor shall present to the Commission its methodology to achieve the project objectives.

In principle, the deadlines set out below cannot be extended. The Contractor is deemed solely responsible for delays occasioned by subcontractors or other third parties (except for rare cases of *force majeure*). Adequate resources and appropriate organisation of the work including management of potential delays should be put in place in order to observe the timetable below.

I.3.1. Interim report

An **interim report** showing progress of the work shall be submitted to the Commission at the latest **twelve months** after the date of signature of the contract.

The Commission shall have forty-five days from receipt to approve or reject the report. Within twenty days of receiving the Commission's observations, the Contractor will submit additional information or another report.

I.3.2. Final report

The contractor will submit a **final report** to the Commission at the latest **twenty months** after the signature of the contract. The final report shall include all relevant information about the execution of the contract including the results of the European survey on the implementation of MED requirements aimed at the reduction of the probability and the magnitude of accidents in radiotherapy, the proceedings of the European workshop on this subject and final draft of a European Guidance document including the comments provided by Working Party on Medical Exposures of the Group of Experts referred to in Article 31 of the EURATOM Treaty and by appropriate European professional organisations. Provided that during the contract implementation, the contractor identifies a need for further actions by the

⁶ Relevant Technical and Safety Reports Series Publications
(<http://rpop.iaea.org/RPOP/RPoP/Content/AdditionalResources/Publications/index.htm>)

⁷ "Towards Safer Radiotherapy", British Institute of Radiology, Institute of Physics and Engineering in Medicine, National Patient Safety Agency, Society and College of Radiographers, Royal College of Radiologists, 2008
(https://www.rcr.ac.uk/docs/oncology/pdf/Towards_saferRT_final.pdf)

⁸ "Articulation of essential requirements of Directive 97/43/ EURATOM and IAEA recommendations shared with the essential requirements of Directive 93/42/EEC concerning medical devices used in external radiotherapy", (PM-XX-ANI-RAP-2010-026008-Membres_du_GT-Etat_des_lieux_des_ERP-8_UK-3), ASN/AFSSAPS, 2010

Commission regarding reduction of the probability and the magnitude of accidents in radiotherapy, the respective proposals shall be included in the final report.

Within forty-five days after the submission of this draft final report the Commission will provide the contractor with its comments on the draft final report and the date of a meeting in Luxembourg will be agreed in order to discuss the Commission's observations.

After this meeting, the Contractor shall have twenty days in which to submit additional information or a new final report.

1.3.3. Report format and publication

The contractor will provide the results of his work in well-written, comprehensible documents at each stage of reporting.

The Commission intends to publish the final report in the "Radiation Protection" series. After the Radiation Protection Unit (DG ENER D4) has approved the work done, the final manuscript should be submitted in such a form that a printer's proof can be prepared from it directly. As regards tables and graphs, these must be designed so that they can be printed in black on white without any loss of information. For publication, the tenderer must ensure that the study is not subject to any restrictions deriving from intellectual property rights of third parties. Should he intend to use data in the study, which cannot be published, this must be explicitly mentioned in the offer.

The document may be written in any of the official languages of the European Union, but the printer's proof must be in English.

Five copies of the reports shall be supplied on paper form (A4 format) and two electronic versions (Word and PDF file format).

1.4. Duration of the tasks

The total duration of the tasks shall not exceed **twenty four months**. This period is calculated in calendar days.

1.5. Place of performance

The main tasks will be performed in the Contractor's premises. However, meetings between the contractor and the Commission may be held on Commission premises in Luxembourg. Provided that the contractor's premises can not accommodate the number of participants of the European Workshop, the event can be held in appropriate, easy accessible location within the European Union.

1.6. Estimate of the amount of work involved

The amount of work involved to carry out this contract is estimated to correspond to a total amount of **250 man-days**. This **includes** travel expenses and any operational costs incurred for implementing the project, including for the venue and implementation of the workshop. **No participation fee** may be charged to the workshop participants; this does not preclude charging participants for workshop related miscellaneous costs like coffees, lunches or social events.

II. TERMS OF CONTRACT

In drawing up his offer, the tenderer should bear in mind the provisions of the draft contract attached to this invitation to tender (Annex 5). Any limitation, amendment or denial of the terms of contract will lead to automatic exclusion from the procurement procedure.

The Commission may, before the contract is signed, either abandon the procurement procedure or cancel the award procedure without the tenderers being entitled to claim any compensation.

II.1. Terms of payment

Payments shall be made in accordance with the provisions specified in Annex 5, the draft service contract

II.2. Financial guarantees

Guarantee on pre-financing

For any pre-financing higher than 150,000 EUR, a financial guarantee equivalent to the amount of the pre-financing will be requested.

Depending on the financial situation of the tenderer, the Commission may ask for the financial guarantee for amounts lower than 150,000 EUR.

II.3. Subcontracting

If the tenderer intends to subcontract part of the service, he shall indicate in his offer which part will be subcontracted and to what extent (% of the total contract value).

Tenderers must ensure that Article II.17 of the contract (Annex 5) can be applied to subcontractors. Once the contract has been signed, Article II.13 of the above-mentioned contract shall govern the subcontracting.

II.4. Legal form to be taken by the grouping of service providers to whom the contract is awarded (if applicable)

Groupings, irrespective of their legal form, may submit bids. Tenderers may, after forming a grouping, submit a joint bid on condition that it complies with the rules of competition. Such groupings (or consortium) must specify the company or person heading the project and must also submit a copy of the document authorising this company or person to submit a bid. If awarded, the contract will be signed by the company or the person heading the project, who will be, vis à vis the Commission, the only contracting party responsible for the performance of this contract. Tenders from a consortium of firms or groups of service providers, contractors or suppliers must specify the role, qualifications and experience of each member of the consortium or group. Each member must provide all the necessary documents for assessing the bid as a whole with regard to the exclusion criteria, selection criteria (in their entirety) and award criteria.

III. FORM AND CONTENT OF THE TENDER

III.1. General

Tenders must be written in **one of the official languages** of the European Union.

Tenders must be clear and concise, with continuous page numbering, and assembled in a coherent fashion (e.g. bound or stapled, etc...). Since tenderers will be judged on the content of their written bids, they must make it clear that they are able to meet the requirements of the specifications.

III.2. Structure of the tender

All tenders must include three sections i.e. an administrative, a technical and a financial proposal.

III.2.1. Section One: administrative proposal

This section must provide the following information, set out in the standard identification forms attached to these tender specifications (Annexes 1, 2 and 3):

- Tenderers' identification (Annex 1)
 - All tenderers must provide proof of **registration**, as prescribed in their country of establishment, on one of the **professional or trade registers** or provide a declaration or certificate.
 - If the tenderer is a natural person, he/she must provide a copy of the identity card/passport or driving licence and proof that he/she is covered by a social security scheme as a self-employed person.

Each tenderer (including subcontractor(s) or any member of a consortium or grouping) must complete and sign the identification forms in Annex 1 and also provide above-mentioned documents. However, the subcontractor(s) shall not be required to fill in or provide those documents when the services represent less than 20% of the contract.

- Financial identification (Annex 2)

The **bank identification form** must be filled in and signed by an authorised representative of the tenderer and his/her banker. A standard form is attached in Annex 2 and a specific form for each Member State is available at the following Internet address:

http://ec.europa.eu/budget/contracts_grants/info_contracts/financial_id/financial_id_en.cfm

In the case of a grouping, this form must only be provided by the person heading the project.

- Legal entities (Annex 3)

The legal entity form in Annex 3 must be filled in and should be accompanied by a number of supporting documents, available on the Web site:

http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm

In the case of a grouping, this form must only be provided by the person heading the project.

The Commission reserves the right, however, to request additional evidence in relation to the bid submitted for evaluation or verification purposes within a time-limit stipulated in its request.

III.2.2. Section Two: Technical proposal

This section is of great importance in the assessment of the bids, the award of the contract and the future execution of any resulting contract.

Some guidelines are given below, but attention is also drawn to the award criteria, which define those parts of the technical proposal to which the tenderers should pay particular attention. The technical proposal should address all matters laid down in the specifications and should include models, examples and technical solutions to problems raised in the specifications. The level of detail of the tender will be extremely important for the evaluation of the tender. Tenderers must present in their bids a proposal on the methodology and the organisation of the work to carry out in the framework of the study.

The technical proposal must provide all the information needed for the purpose of awarding the contract.

III.2.3. Section Three: Financial proposal

All tenders must contain a financial proposal. A lump sum price must be provided including all expenses, such as travel expenses and daily allowances as well as the organization of the workshop. The tenderer's attention is drawn to the following points:

- Prices must be quoted in **euros**, including the countries which are not in the euro-area. As far as the tenderers of those countries are concerned, they cannot change the amount of the bid because of the evolution of the exchange rate. The tenderers choose the exchange rate and assume all risks or opportunities relating to the rate fluctuation;
- **Prices should be quoted free of all duties, taxes and other charges, i.e. also free of VAT**, as the European Union is exempt from such charges in the EU under Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union of 8 April 1965 (OJ L 152 of 13 July 1967). Exemption is granted to the Commission by the governments of the Member States, either through refunds upon presentation of documentary evidence or by direct exemption. For those countries where national legislation provides an exemption by means of a reimbursement, the amount of VAT is to be shown separately. In case of doubt about the applicable VAT system, it is the tenderer's responsibility to contact his or her national authorities to clarify the way in which the European Union is exempt from VAT;
- **Prices shall be fixed** and not subject to revision during the performance of the contract;

- For each category of staff involved in the project, the tenderer must specify:
 - the total labour costs;
 - **the daily rates and total number of days** (man/days) each member of staff will contribute to the project;
 - other categories of costs, indicating the nature of the cost, the total amount, the unit price and the quantity.

Bids involving more than one service provider (consortium) must specify the amounts indicated above for each provider.

IV. ASSESSMENT AND AWARD OF THE CONTRACT

The assessment will be based on each tenderer's bid.

All the information will be assessed in the light of the criteria set out in these specifications. The procedure for the award of the contract, which will concern only admissible bids, will be carried out in three successive stages.

The aim of each of these stages is:

- 1) to check on the basis of the exclusion criteria, whether tenderers can take part in the tendering procedure;
- 2) to check on the basis of the selection criteria, the technical and professional capacity and economic and financial capacity of each tenderer;
- 3) to assess on the basis of the award criteria each bid which has passed the exclusion and selection stages.

IV.1. Exclusion criteria (exclusion of tenderers)

IV.1.1. Exclusion criteria (Article 93 Financial Regulation⁹)

1. To be eligible for participating in this contract award procedure, tenderers must not be in any of the following situations:
 - (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 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 judgement 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 judgement which has the force of *res judicata* for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the Union's financial interests;
 - (f) they are currently subject to an administrative penalty referred to in Article 96(1) of the Financial Regulation¹⁰ for being guilty of misrepresentation in supplying the

⁹ Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities (OJ L 248 of 16.9.2002)

information required by the contracting authority as a condition of participation in a contract procurement procedure or by the authorising officer as a condition of participation in a grant award procedure, for failing to supply this information or for having been declared to be in serious breach of their obligations under contracts or grants covered by the Union budget.

2. The cases referred to in point IV.1.1. e) above 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 established by the Council Act of 26 July 1995 (OJ/C 316 of 27.11.1995, p. 48);
 - 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, established by the Council Act of 26 May 1997 (OJ/C 195 of 25.6.1997, p. 1);
 - c) cases of involvement in a criminal organisation, as defined in Article 2(1) of Joint Action 98/733/JHA of the Council (OJ/L 315 of 29.12.1998, p. 1);
 - d) cases of money laundering as defined in Article 1 of Council Directive 91/308/EEC (OJ/L 166 of 28.6.1991, p.77).

IV.1.2. Other cases of exclusion (Article 94 Financial Regulation)

Contracts will not be awarded to tenderers who, during the procurement procedure:

- a) **are subject to a conflict of interest;**

Tenderers must declare:

- that they do not have any conflict of interest in connection with the contract; a conflict of interest could arise in particular as a result of economic interests, political or national affinities, family or emotional ties, or any other relevant connection or shared interest;
- that they will inform the contracting authority, without delay, of any situation constituting a conflict of interest or which could give rise to a conflict of interest;
- that they have not made and will not make any offer of any type whatsoever from which an advantage can be derived under the contract;
- that they have not granted and will not grant, have not sought and will not seek, have not attempted and will not attempt to obtain, and have not accepted and will not accept, any advantage, financial or in kind, to or from any party whatsoever, constituting an illegal practice or involving corruption, either directly or indirectly, as an incentive or reward relating to the award of the contract.

The Commission reserves the right to check the above information.

- b) **are guilty of misrepresentation** in supplying the information required by the contracting authority as a condition of participation in the procurement procedure or fail to supply this information.

¹⁰ Council Regulation (EC, Euratom) n° 1605/2002 of 25 June 2002 on the Financial regulation applicable to the general budget of the European Communities, OJ L 248 of 16 September 2002, p. 1, amended by Council Regulation (EC, Euratom) n° 1995/2006 of 13 December 2006, OJ L 390 of 30 December 2006, p.1.

- c) find themselves in one of the **situations of exclusion**, referred to in paragraph IV.1.1. above for this procurement procedure.

IV.1.3. Evidence to be provided by the tenderers

1. When submitting their bids, each tenderer (including subcontractor(s) or any member of a consortium or grouping) shall provide a declaration on their honour, duly signed and dated, stating that they are not in one of the situations mentioned above (cf. IV.1.1 and VI.1.2). For that purpose, they must complete and sign the form attached in Annex 4. Where the tenderer is a legal entity, they shall, whenever requested by the Commission, provide information on the ownership or on the management, control and power of representation of the legal entity.
2. The tenderer to whom the contract is to be awarded shall provide, within 15 calendar days after notification of the results of the procurement procedure and in any case before the signature of the contract, the following evidence, confirming the declaration referred to above:

The Commission shall accept, as satisfactory evidence that the tenderer is not in one of the situations described in point IV.1.1 (a), (b) or (e) above, 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.

The Commission accepts, as satisfactory evidence that the tenderer is not in the situation described in point IV.1.1 (d) above, a recent certificate issued by the competent authority of the State concerned.

Where no such document or certificate is issued in the country concerned, 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.

3. Depending on the national legislation of the country in which the candidate or tenderer is established, the documents referred to in paragraph 1 and 2 above shall relate to legal and/or natural persons including, if applicable with regard to points b) and e), company directors or any person with powers of representation, decision-making or control in relation to the tenderer.
4. When the subcontracted part is above 20% of the contract value, the subcontractor(s) must also provide the above-mentioned declaration on honour. In case of doubt on this declaration on the honour, the contracting authority may also request the evidence referred to in paragraphs 2 and 3 above.
5. The Commission reserves the right to request any other document relating to the proposed tender for evaluation and verification purpose, within a delay determined in its request.

Remark:

The tenderers will be waived of the obligation to submit the documentary evidence above mentioned if such evidence has already been submitted for the purposes of another procurement procedure launched by Directorate General for Energy and Transport and provided that the documents are not more than one year old starting from their issuing date

and that they are still valid. In such a case, the tenderer shall declare on his honour that the documentary evidence has already been provided in a previous procurement procedure, specifying the reference of the call for tender for which the documents have been provided, and confirm that no changes in his situation have occurred.

IV.1.4. Administrative and financial penalties

Without prejudice to the application of penalties laid down in the contract, candidates or tenderers and contractors who have been found guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in the procurement procedure or have failed to supply this information or have been declared to be in serious breach of their obligations under contracts covered by the Union budget may be subject to administrative or financial penalties, in accordance with Article 96 of the Financial Regulation and Articles 134b and 133a of the Implementing Rules.¹¹

IV.2. SELECTION CRITERIA (SELECTION OF TENDERERS)

To be eligible, the tenderers must have the economic and financial capacity as well as the technical and professional capacity to perform the tasks required in this call for tender.

IV.2.1. Economic and financial capacity – References required

The tenderers must satisfy the following criteria regarding their economic and financial capacity:

- average annual turnover for the last three years must exceed 500.000 EUR

In the case of a consortium these criteria apply collectively to all members of the group and/or sub-contractors.

Evidence of this capacity shall be furnished on the basis of the following documents:

- a statement of overall turnover and turnover relating to the relevant services for the last three financial years, and
- the balance sheets or extracts from balance sheets for the last three financial years.

¹¹ Commission Regulation (EC, Euratom) n° 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities, OJ L 357 of 31 December 2002, p. 1, as amended.

IV.2.2. Technical and professional capacity – References required

The tenderers must satisfy the following criteria regarding the technical and professional capacity needed to perform the tasks required for this call for tender:

- the project leader and the experts leading the various project tasks shall have formal professional qualifications in medical physics, radiation oncology or in other speciality utilizing ionizing radiation for therapy purposes;
- the project leader and the experts leading the various project tasks shall have minimum five years of professional experience in the relevant area after obtaining their professional qualification;
- the project leader shall have minimum three years of specific professional experience (after obtaining his/her professional qualification) in the field of radiation safety in radiotherapy or risk analysis of radiotherapy accidents;
- the project leader must have participated (in the past five years) as a leader or a senior member in at least one project for development and practical implementation of system of registration and analyses of events involving or potentially involving accidents in radiotherapy;
- the project leader and the experts leading the various project tasks shall be active members of the relevant European or international professional bodies, networks or working groups;
- the tenderer or, in case of the consortium, the organization in charge of the workshop must have organized at least one international meeting for minimum one hundred participants in the past five years.

Evidence of this capacity shall be furnished on the basis of the following documents:

- detailed curriculum vitae of each staff member responsible for carrying out the work, including his or her educational background, degrees and diplomas, professional experience, research work, publications and linguistic skills;
- list of the main services and tasks delivered by the tenderer and the staff members during the last five years, including international projects and international meetings organized by the tenderer, with the dates and recipients, public or private;
- list of national and international organisations, professional bodies, networks, working groups, etc. of which the tenderer's individual staff members and participating organizations are active members or actively cooperate with.

If several service providers/subcontractors are involved in the bid, each of them must have and show that they have the professional and technical capacity to perform the tasks assigned to them.

The CV's shall be presented, preferably, in accordance to the Commission Recommendation on a common European format for curricula vitae, published in OJ L79 of 22 March 2002, p. 66.

IV.3. EVALUATION OF TENDERS – AWARD CRITERIA

The contract will be awarded according to the criteria given below, on the basis of the economically most advantageous tender.

Only bids that have reached a total score of a minimum of 70% and a minimum score of 60 % for each criterion will be taken into consideration for awarding the contract.

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

N°	Award Criteria	Weighting
1	<u>Understanding</u> : This criterion serves to assess whether the tenderers have fully understood all the aspects of what is required for the contract as well as of the content of the final products.	25
2	<u>Methodology</u> : This criterion serves to assess whether the proposed methodology and the planned contractor's activities will guarantee the successful achievement of contract objectives. A particular element to be assessed under this criterion will be the proposed actions to obtain the required data from all EU Member States. The methodology proposed in the tender should also provide details on the planned organisation of the workshop.	40
3	<u>Management and Resources</u> : This criterion relates to the quality of project planning and organisation of the team to cope with and fulfil the obligations of the contract in the time required for the completion of the project.	35
Total number of points		100

b) Total price

The contract will be awarded to the tender who offers the best ratio quality/price.

IV.4. INFORMATION FOR TENDERERS

The Commission will inform tenderers of decisions reached concerning the award of the contract, including the grounds for any decision not to award a contract or to recommence the procedure.

Upon written request, the Commission will inform the rejected tenderers of the reasons for their rejection and the tenderers having submitted an admissible tender of the characteristics and relative advantages of the selected tender and the name of the successful tenderer.

However, certain information may be withheld where its release would impede law enforcement or otherwise be contrary to the public interest, or would prejudice the legitimate commercial interests of economic operators, public or private, or might prejudice fair competition between them.

V. ANNEXES

1. Identification of the Tenderer
2. Financial Identification
3. Legal Entity Form
4. Declaration by the Tenderer (relating to the exclusion criteria)
5. Draft Service Contract

ANNEX 1

IDENTIFICATION OF THE TENDERER

(Each service provider, including subcontractor(s) or any member of a consortium or grouping, must complete and sign this identification form)

Call for tender ENER/D4/160-2011

Identity	
Name of the tenderer	
Legal status of the tenderer	
Date of registration	
Country of registration	
Registration number	
VAT number	
Description of statutory social security cover (at the level of the Member State of origin) and non-statutory cover (supplementary professional indemnity insurance) ¹²	
Address	
Address of registered office of tenderer	
Where appropriate, administrative address of tenderer for the purposes of this invitation to tender	
Contact Person	
Surname: First name: Title (e.g. Dr, Mr, Ms) : Position (e.g. manager): Telephone number: Fax number: E-mail address:	

¹² For natural persons

Legal Representatives

Names and function of legal representatives
and of other representatives of the tenderer who
are authorised to sign contracts with third
parties

Declaration by an authorised representative of the organisation¹³

I, the undersigned, certify that the information given in this tender is correct and that the tender is valid.

Surname:
First name:

Signature:

¹³ This person must be included in the list of legal representatives; otherwise the signature on the tender will be invalidated.

ANNEX 2

(to be completed by the tenderer and his or her financial institution)

A specific form for each Member State is available at the following Internet address:

http://ec.europa.eu/budget/contracts_grants/info_contracts/financial_id/financial_id_en.cfm

ANNEX 3

Legal entity form

Complete the legal entity form, which should be accompanied by a number of supporting documents, available on the Web site:

http://ec.europa.eu/budget/contracts_grants/info_contracts/legal_entities/legal_entities_en.cfm

Please note that we can only accept either original documents or certified copies, which must be less than 6 months old.

In the case of a grouping, this form must only be provided by the person heading the project.

ANNEX 4

DECLARATION BY THE TENDERER

Each service provider, including subcontractor(s) or any member of a consortium or grouping, must sign this declaration

1. In accordance with Article 93 of the Financial Regulation¹⁴, I declare on my honour that I am not in any of the following situations which would exclude me from participating in this procurement procedure:
 - a) I am not bankrupt, being wound up or having my affairs administered by the courts, I have not entered into an arrangement with creditors, I have not suspended business activities, I am not the subject of proceedings concerning any such matters, and I am not in any similar situation arising from a similar procedure provided for in legislation or regulations;
 - b) I have not been convicted of an offence concerning my professional conduct by a judgment which has the force of res judicata;
 - c) I have not been found guilty of grave professional misconduct proven by any means which the contracting authority can justify;
 - d) I have not failed to fulfil 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 I am established or with those of the country or the contracting authority or those of the country where the contract is to be performed;
 - e) I have not 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 Union's financial interests;
 - f) I am currently not subject to an administrative penalty referred to in Article 96(1) of the Financial Regulation for being guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in a contract procurement procedure or by the authorising officer as a condition of participation in a grant award procedure, for failing to supply this information or for having been declared to be in serious breach of their obligations under contracts or grants covered by the Union budget.
2. In addition, the undersigned declares on his or her honour:
 - a) that on the date of submission of the tender, the company or organisation I do represent and the staff proposed for this tender are not subject to a conflict of interests in the context of this invitation to tender; I undertake to inform the Commission without delay of any change to this situation after the date of submission of the tender.
 - b) that the information provided to the Commission within the context of this invitation to tender is accurate, sincere and complete.

¹⁴ Council Regulation (EC, Euratom) n° 1605/2002 of 25 June 2002 on the Financial regulation applicable to the general budget of the European Communities, OJ L 248 of 16 September 2002, p. 1, amended by Council Regulation (EC, Euratom) n° 1995/2006 of 13 December 2006, OJ L 390 of 30 December 2006, p.1.

Done at on.....
Name
Title
Signature:

ANNEX 5



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR ENERGY

DIRECTORATE D - Nuclear Energy
Radiation Protection

DRAFT SERVICE CONTRACT

CONTRACT NUMBER – [complete]

The European Atomic Energy Community (hereinafter referred to as "the Community") represented by the European Commission (hereinafter referred to as "the Commission"), which is represented for the purposes of the signature of this contract by Mr Peter Faross, Director for Nuclear Energy in the Directorate-General for Energy,

of the one part,

and

[official name in full]

[official legal form] (Delete if contractor is a natural person or a body governed by public law.)

[statutory registration number] Delete if contractor is a body governed by public law. For natural persons, indicate the number of their identity card or, failing that, of their passport or equivalent

[official address in full]

[VAT registration number]

(hereinafter referred to as "the Contractor"), represented for the purposes of the signature of this contract by [name in full and function,]

of the other part,

HAVE AGREED

the **Special Conditions** and the **General Conditions** below and the following Annexes:

Annex I – Tender Specifications (Invitation to Tender No ENER/D4/160-2011 of [complete]) and Monitoring

Annex II – Contractor's Tender (No [complete] of [complete])

which form an integral part of this contract (hereinafter referred to as “the Contract”).

The terms set out in the Special Conditions shall take precedence over those in the other parts of the Contract. The terms set out in the General Conditions shall take precedence over those in the Annexes. The terms set out in the Tender Specifications (Annex I) shall take precedence over those in the Tender (Annex II).

Subject to the above, the several instruments forming part of the Contract are to be taken as mutually explanatory. Ambiguities or discrepancies within or between such parts shall be explained or rectified by a written instruction issued by the Commission, subject to the rights of the Contractor under Article I.7 should he dispute any such instruction.

I – SPECIAL CONDITIONS

ARTICLE I.1 - SUBJECT

- I.1.1.** The subject of the Contract is to verify implementation of the MED requirements aiming at reduction of the probability and the magnitude of accidents in radiotherapy in EU Member States (Article 11 of MED) and to develop guidelines on a risk analysis of accidental and unintended exposures in external beam radiotherapy.
- I.1.2.** The Contractor shall execute the tasks assigned to him in accordance with the Tender Specifications annexed to the Contract (Annex I).

ARTICLE I.2 - DURATION

- I.2.1.** The Contract shall enter into force on the date on which it is signed by the last contracting party.
- I.2.2.** Execution of the tasks may under no circumstances begin before the date on which the Contract enters into force.
- I.2.3.** The duration of the tasks shall not exceed **24 months**. This period and all other periods specified in the Contract are calculated in calendar days. Execution of the tasks shall start from the date of entry into force of the Contract. The period of execution of the tasks may be extended only with the express written agreement of the parties before such period elapses.

ARTICLE I.3 – CONTRACT PRICE

- I.3.1.** The maximum total amount to be paid by the Commission under the Contract shall be EUR [amount in figures and in words] covering all tasks executed.
- I.3.2** Not applicable

ARTICLE I.4 – PAYMENT PERIODS AND FORMALITIES

Payments under the Contract shall be made in accordance with Article II.4. Payments shall be executed only if the Contractor has fulfilled all his contractual obligations by the date on which the invoice is submitted. Payment requests may not be made if payments for previous periods have not been executed as a result of default or negligence on the part of the Contractor.

I.4.1. Pre-financing:

Following signature of the Contract by the last contracting party, within 30 days of:

- the receipt by the Commission of a request for pre-financing with a relevant invoice

a pre-financing payment of EUR [complete amount in figures and in words] equal to 30 % of the total amount referred to in Article I.3.1. shall be made.

I.4.2 Interim payment:

Request for interim payment by the Contractor shall be admissible if accompanied by:

- an interim technical report in accordance with the instructions laid down in Annex I.
- the relevant invoice(s)

provided the report has been approved by the Commission.

The Commission shall have forty-five days from receipt to approve or reject the report, and the Contractor shall have 20 days in which to submit additional information or a new report.]

Within 30 days of the date on which the report is approved by the Commission, an interim payment corresponding to [EUR complete amount in figures and in words] equal to 40 % of the total amount referred to in Article I.3.1 shall be made.

I.4.3. 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 Annex I
- the relevant invoice(s)

provided the report has been approved by the Commission.

The Commission shall have forty-five days from receipt to approve or reject the report, and the Contractor shall have 20 days in which to submit additional information or a new report.

Within 30 days of the date on which the report is approved by the Commission, payment of the balance corresponding to [EUR complete amount in figures and in words equal to 30 % of the total amount referred to in Article I.3.1 shall be made.

[For Contractors established in Belgium, the provisions of the Contract constitute a request for VAT exemption No 450, provided the Contractor includes the following statement in his invoice(s): "Exonération de la TVA, article 42, paragraphe 3.3 du code de la TVA" or an equivalent statement in the Dutch or German language.]

ARTICLE I.5 – BANK ACCOUNT

Payments shall be made to the Contractor's bank account denominated in euro, identified as follows:

Name of bank: [complete]
Address of branch in full: [complete]
Exact designation of account holder: [complete]
Full account number including codes: [complete]
[IBAN code: [complete]]

ARTICLE I.6 – GENERAL ADMINISTRATIVE PROVISIONS

Any communication relating to the Contract shall be made in writing and shall bear the Contract number. Ordinary mail shall be deemed to have been received by the Commission on the date on which it is registered by the department responsible indicated below. Communications shall be sent to the following addresses:

Commission:

European Commission
Directorate-General for Energy
Financial and Contractual Cell
Mr Alain Cluzeau – EUFO 4475
L-2920 Luxembourg

Contractor:

Mr/Mrs/Ms [complete]
[Function]
[Company name]
[Official address in full]

ARTICLE I.7– APPLICABLE LAW AND SETTLEMENT OF DISPUTES

- I.7.1.** The Contract shall be governed by the law of the Community and of the European Union, complemented, where necessary, by the national substantive law of Luxembourg.
- I.7.2.** Any dispute between the parties resulting from the interpretation or application of the Contract which cannot be settled amicably shall be brought before the courts of Luxembourg.

ARTICLE I.8 – DATA PROTECTION

Any personal data included in the Contract shall be processed pursuant to Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. Such data shall be processed solely for the purposes of the performance, management and monitoring of the Contract

by the Director of the Shared Resource Directorate MOVE/ENER acting as data controller without prejudice to possible transmission to the bodies charged with monitoring or inspection task in application of Community and European Union law.

II – GENERAL CONDITIONS

ARTICLE II.1 – PERFORMANCE OF THE CONTRACT

- II.1.1.** The Contractor shall perform the Contract to the highest professional standards. The Contractor shall have sole responsibility for complying with any legal obligations incumbent on him, notably those resulting from employment, tax and social legislation.
- II.1.2.** The Contractor shall have sole responsibility for taking the necessary steps to obtain any permit or licence required for performance of the Contract under the laws and regulations in force at the place where the tasks assigned to him are to be executed.
- II.1.3.** Without prejudice to Article II.3 any reference made to the Contractor's staff in the Contract shall relate exclusively to individuals involved in the performance of the Contract.
- II.1.4.** The Contractor must ensure that any staff performing the Contract have the professional qualifications and experience required for the execution of the tasks assigned to him.
- II.1.5.** The Contractor shall neither represent the Commission nor behave in any way that would give such an impression. The Contractor shall inform third parties that he does not belong to the European public service.
- II.1.6.** The Contractor shall have sole responsibility for the staff who execute the tasks assigned to him.

The Contractor shall make provision for the following employment or service relationships with his staff:

- staff executing the tasks assigned to the Contractor may not be given orders direct by the Commission;
 - the Commission may not under any circumstances be considered to be the staff's employer and the said staff shall undertake not to invoke in respect of the Commission any right arising from the contractual relationship between the Commission and the Contractor.
- II.1.7.** In the event of disruption resulting from the action of a member of the Contractor's staff working on Commission premises or in the event of the expertise of a member of the Contractor's staff failing to correspond to the profile required by the Contract, the Contractor shall replace him without delay. The Commission shall have the right to request the replacement of any such member of staff, stating its reasons for so doing. Replacement staff must have the necessary qualifications and be capable of performing the Contract under the same contractual conditions. The Contractor shall be responsible for any delay in the execution of the tasks assigned to him resulting from the replacement of staff in accordance with this Article.
- II.1.8.** Should any unforeseen event, action or omission directly or indirectly hamper execution of the tasks, either partially or totally, the Contractor shall immediately and on his own initiative record it and report it to the Commission. The report shall include a description of the problem and an indication of the date on which it started and of the remedial action taken

by the Contractor to ensure full compliance with his obligations under the Contract. In such event the Contractor shall give priority to solving the problem rather than determining liability.

II.1.9. Should the Contractor fail to perform his obligations under the Contract in accordance with the provisions laid down therein, the Commission may - without prejudice to its right to terminate the Contract - reduce or recover payments in proportion to the scale of the failure. In addition, the Commission may impose penalties or liquidated damages provided for in Article II.16.

ARTICLE II.2 – LIABILITY

II.2.1. The Commission shall not be liable for damage sustained by the Contractor in performance of the Contract except in the event of wilful misconduct or gross negligence on the part of the Commission.

II.2.2. The Contractor shall be liable for any loss or damage caused by himself in performance of the Contract, including in the event of subcontracting under Article II.13. The Commission shall not be liable for any act or default on the part of the Contractor in performance of the Contract.

II.2.3. The Contractor shall provide compensation in the event of any action, claim or proceeding brought against the Commission by a third party as a result of damage caused by the Contractor in performance of the Contract.

II.2.4. In the event of any action brought by a third party against the Commission in connection with performance of the Contract, the Contractor shall assist the Commission. Expenditure incurred by the Contractor to this end may be borne by the Commission.

II.2.5. The Contractor shall take out insurance against risks and damage relating to performance of the Contract if required by the relevant applicable legislation. He shall take out supplementary insurance as reasonably required by standard practice in the industry. A copy of all the relevant insurance contracts shall be sent to the Commission should it so request.

ARTICLE II.3 - CONFLICT OF INTERESTS

II.3.1. The Contractor shall take all necessary measures to prevent any situation that could compromise the impartial and objective performance of the Contract. Such conflict of interests could arise in particular as a result of economic interest, political or national affinity, family or emotional ties, or any other relevant connection or shared interest. Any conflict of interests which could arise during performance of the Contract must be notified to the Commission in writing without delay. In the event of such conflict, the Contractor shall immediately take all necessary steps to resolve it.

The Commission reserves the right to verify that such measures are adequate and may require additional measures to be taken, if necessary, within a time limit which it shall set. The Contractor shall ensure that his staff, board and directors are not placed in a situation which could give rise to conflict of interests. Without prejudice to Article II.1 the Contractor shall replace, immediately and without compensation from the Commission, any member of his staff exposed to such a situation.

II.3.2. The Contractor shall abstain from any contact likely to compromise his independence.

II.3.3. The Contractor declares:

- that he has not made and will not make any offer of any type whatsoever from which an advantage can be derived under the Contract,
- that he has not granted and will not grant, has not sought and will not seek, has not attempted and will not attempt to obtain, and has not accepted and will not accept, any advantage, financial or in kind, to or from any party whatsoever, where such advantage constitutes an illegal practice or involves corruption, either directly or indirectly, inasmuch as it is an incentive or reward relating to performance of the Contract.

II.3.4. The Contractor shall pass on all the relevant obligations in writing to his staff, board, and directors as well as to third parties involved in performance of the Contract. A copy of the instructions given and the undertakings made in this respect shall be sent to the Commission should it so request.

ARTICLE II.4 – PAYMENTS

II.4.1. Pre-financing :

Where required by Article I.4.1, the Contractor shall provide a financial guarantee in the form of a bank guarantee or equivalent supplied by a bank or an authorised financial institution (guarantor) equal to the amount indicated in the same Article to cover pre-financing under the Contract. Such guarantee may be replaced by a joint and several guarantee by a third party.

The guarantor shall pay to the Commission at its request an amount corresponding to payments made by it to the Contractor which have not yet been covered by equivalent work on his part.

The guarantor shall stand as first-call guarantor and shall not require the Commission to have recourse against the principal debtor (the Contractor).

The guarantee shall specify that it enters into force at the latest on the date on which the Contractor receives the pre-financing. The Commission shall release the guarantor from its obligations as soon as the Contractor has demonstrated that any pre-financing has been covered by equivalent work. The guarantee shall be retained until the pre-financing has been deducted from interim payments or payment of the balance to the Contractor. It shall be released the following month. The cost of providing such guarantee shall be borne by the Contractor.

II.4.2. Interim payment:

At the end of each of the periods indicated in Annex I the Contractor shall submit to the Commission a formal request for payment accompanied by those of the following documents which are provided for in the Special Conditions:

- an interim technical report in accordance with the instructions laid down in Annex I;
- the relevant invoices indicating the reference number of the Contract to which they refer;
- statements of reimbursable expenses in accordance with Article II.7.

If the report is a condition for payment, on receipt the Commission shall have the period of time indicated in the Special Conditions in which:

- to approve it, with or without comments or reservations, or suspend such period and request additional information; or
- to reject it and request a new report.

If the Commission does not react within this period, the report shall be deemed to have been approved. Approval of the report does not imply recognition either of its regularity or of the authenticity, completeness or correctness of the declarations or information enclosed.

Where the Commission requests a new report because the one previously submitted has been rejected, this shall be submitted within the period of time indicated in the Special Conditions. The new report shall likewise be subject to the above provisions.

II.4.3. Payment of the balance:

Within sixty days of completion of the tasks referred to in Annex I the Contractor shall submit to the Commission a formal request for payment accompanied by those of the following documents which are provided for in the Special Conditions:

- a final technical report in accordance with the instructions laid down in Annex I;
- the relevant invoices indicating the reference number of the Contract to which they refer;
- statements of reimbursable expenses in accordance with Article II.7.

If the report is a condition for payment, on receipt the Commission shall have the period of time indicated in the Special Conditions in which:

- to approve it, with or without comments or reservations, or suspend such period and request additional information; or
- to reject it and request a new report.

If the Commission does not react within this period, the report shall be deemed to have been approved. Approval of the report does not imply recognition either of its regularity or of the authenticity, completeness or correctness of the declarations and information enclosed.

Where the Commission requests a new report because the one previously submitted has been rejected, this shall be submitted within the period of time indicated in the Special Conditions. The new report shall likewise be subject to the above provisions.

ARTICLE II.5 – GENERAL PROVISIONS CONCERNING PAYMENTS

II.5.1. Payments shall be deemed to have been made on the date on which the Commission's account is debited.

II.5.2. The payment periods referred to in Article I.4 may be suspended by the Commission at any time if it informs the Contractor that his payment request is not admissible, either because the amount is not due or because the necessary supporting documents have not been properly produced. In case of doubt on the eligibility of the expenditure indicated in the payment request, the Commission may suspend the time limit for payment for the purpose of further verification, including an on-the-spot check, in order to ascertain, prior to payment, that the expenditure is eligible.

The Commission shall notify the Contractor accordingly by registered letter with acknowledgment of receipt or equivalent. Suspension shall take effect from the date of

dispatch of the letter. The remainder of the period referred to in Article I.4 shall begin to run again once the suspension has been lifted.

II.5.3. In the event of late payment the Contractor shall be entitled to interest, provided the calculated interest exceeds EUR 200. In case interest does not exceed EUR 200, the Contractor may claim interest within two months of receiving the payment. Interest shall be calculated at the rate applied by the European Central Bank to its most recent main refinancing operations (*"the reference rate"*) plus seven percentage points (*"the margin"*). The reference rate in force on the first day of the month in which the payment is due shall apply. Such interest rate is published in the C series of the Official Journal of the European Union. Interest shall be payable for the period elapsing from the calendar day following expiry of the time limit for payment up to the day of payment. Suspension of payment by the Commission may not be deemed to constitute late payment.

ARTICLE II.6 – RECOVERY

II.6.1. If total payments made exceed the amount actually due under the Contract or if recovery is justified in accordance with the terms of the Contract, the Contractor shall reimburse the appropriate amount in euro on receipt of the debit note, in the manner and within the time limits set by the Commission.

II.6.2. In the event of failure to pay by the deadline specified in the request for reimbursement, the sum due shall bear interest at the rate indicated in Article II.5.3. Interest shall be payable from the calendar day following the due date up to the calendar day on which the debt is repaid in full.

II.6.3. The Commission may, after informing the Contractor, recover amounts established as certain, of a fixed amount and due by offsetting, in cases where the Contractor also has a claim on the Community or the European Union that is certain, of a fixed amount and due. The Commission may also claim against the guarantee, where provided for.

ARTICLE II.7 - REIMBURSEMENTS

II.7.1. Where provided by the Special Conditions or by Annex I, the Commission shall reimburse the expenses which are directly connected with execution of the tasks on production of original supporting documents, including receipts and used tickets.

II.7.2. Travel and subsistence expenses shall be reimbursed, where appropriate, on the basis of the shortest itinerary.

II.7.3. Travel expenses shall be reimbursed as follows:

- a) travel by air shall be reimbursed up to the maximum cost of an economy class ticket at the time of the reservation;
- b) travel by boat or rail shall be reimbursed up to the maximum cost of a first class ticket;
- c) travel by car shall be reimbursed at the rate of one first class rail ticket for the same journey and on the same day;
- d) travel outside Union territory shall be reimbursed under the general conditions stated above provided the Commission has given its prior written agreement.

II.7.4. Subsistence expenses shall be reimbursed on the basis of a daily allowance as follows:

- a) for journeys of less than 200 km (return trip) no subsistence allowance shall be payable;
- b) daily subsistence allowance shall be payable only on receipt of a supporting document proving that the person concerned was present at the place of destination;
- c) daily subsistence allowance shall take the form of a flat-rate payment to cover all subsistence expenses, including accommodation, meals, local transport, insurance and sundries;
- d) daily subsistence allowance, where applicable, shall be reimbursed at the rate specified in Article I.3.3.

II.7.5. The cost of shipment of equipment or unaccompanied luggage shall be reimbursed provided the Commission has given prior written authorisation.

ARTICLE II.8 – OWNERSHIP OF THE RESULTS - INTELLECTUAL AND INDUSTRIAL PROPERTY

Any results or rights thereon, including copyright and other intellectual or industrial property rights, obtained in performance of the Contract, shall be owned solely by the Union, which may use, publish, assign or transfer them as it sees fit, without geographical or other limitation, except where industrial or intellectual property rights exist prior to the Contract being entered into force.

ARTICLE II.9 – CONFIDENTIALITY

II.9.1. The Contractor undertakes to treat in the strictest confidence and not make use of or divulge to third parties any information or documents which are linked to performance of the Contract. The Contractor shall continue to be bound by this undertaking after completion of the tasks.

II.9.2. The Contractor shall obtain from each member of his staff, board and directors an undertaking that they will respect the confidentiality of any information which is linked, directly or indirectly, to execution of the tasks and that they will not divulge to third parties or use for their own benefit or that of any third party any document or information not available publicly, even after completion of the tasks.

ARTICLE II.10 - USE, DISTRIBUTION AND PUBLICATION OF INFORMATION

II.10.1. The Contractor shall authorise the Commission to process, use, distribute and publish, for whatever purpose, by whatever means and on whatever medium, any data contained in or relating to the Contract, in particular the identity of the Contractor, the subject matter, the duration, the amount paid and the reports. Where personal data is concerned, Article I.8 shall apply.

II.10.2. Unless otherwise provided by the Special Conditions, the Commission shall not be required to distribute or publish documents or information supplied in performance of the

Contract. If it decides not to publish the documents or information supplied, the Contractor may not have them distributed or published elsewhere without prior written authorisation from the Commission.

- II.10.3.** Any distribution or publication of information relating to the Contract by the Contractor shall require prior written authorisation from the Commission and shall mention the amount paid by the Union. It shall state that the opinions expressed are those of the Contractor only and do not represent the Commission's official position.
- II.10.4.** The use of information obtained by the Contractor in the course of the Contract for purposes other than its performance shall be forbidden, unless the Commission has specifically given prior written authorisation to the contrary.

ARTICLE II. 11 – TAXATION

- II.11.1.** The Contractor shall have sole responsibility for compliance with the tax laws which apply to him. Failure to comply shall make the relevant invoices invalid.
- II.11.2.** The Contractor recognises that the Commission is, as a rule, exempt from all taxes and duties, including value added tax (VAT), pursuant to the provisions of Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union.
- II.11.3.** The Contractor shall accordingly complete the necessary formalities with the relevant authorities to ensure that the goods and services required for performance of the Contract are exempt from taxes and duties, including VAT.
- II.11.4.** Invoices presented by the Contractor shall indicate his place of taxation for VAT purposes and shall specify separately the amounts not including VAT and the amounts including VAT.

ARTICLE II.12 – FORCE MAJEURE

- II.12.1.** Force majeure shall mean any unforeseeable and exceptional situation or event beyond the control of the contracting parties which prevents either of them from performing any of their obligations under the Contract, was not due to error or negligence on their part or on the part of a subcontractor, and could not have been avoided by the exercise of due diligence. Defects in equipment or material or delays in making it available, labour disputes, strikes or financial problems cannot be invoked as force majeure unless they stem directly from a relevant case of force majeure.
- II.12.2.** Without prejudice to the provisions of Article II.1.8, if either contracting party is faced with force majeure, it shall notify the other party without delay by registered letter with acknowledgment of receipt or equivalent, stating the nature, likely duration and foreseeable effects.
- II.12.3.** Neither contracting party shall be held in breach of its contractual obligations if it has been prevented from performing them by force majeure. Where the Contractor is unable to perform his contractual obligations owing to force majeure, he shall have the right to remuneration only for tasks actually executed.

II.12.4. The contracting parties shall take the necessary measures to reduce damage to a minimum.

ARTICLE II.13 – SUBCONTRACTING

II.13.1. The Contractor shall not subcontract without prior written authorisation from the Commission nor cause the Contract to be performed in fact by third parties.

II.13.2. Even where the Commission authorises the Contractor to subcontract to third parties, he shall none the less remain bound by his obligations to the Commission under the Contract and shall bear exclusive liability for proper performance of the Contract.

II.13.3. The Contractor shall make sure that the subcontract does not affect rights and guarantees to which the Commission is entitled by virtue of the Contract, notably Article II.17.

ARTICLE II.14 – ASSIGNMENT

II.14.1. The Contractor shall not assign the rights and obligations arising from the Contract, in whole or in part, without prior written authorisation from the Commission.

II.14.2. In the absence of the authorisation referred to in 1 above, or in the event of failure to observe the terms thereof, assignment by the Contractor shall not be enforceable against and shall have no effect on the Commission.

ARTICLE II.15 – TERMINATION BY THE COMMISSION

II.15.1. The Commission may terminate the Contract in the following circumstances:

- (a) where the Contractor is being wound up, is having his affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, is the subject of proceedings concerning those matters, or is in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
- (b) where the Contractor has been convicted of an offence concerning his professional conduct by a judgment which has the force of *res judicata*;
- (c) where the Contractor has been guilty of grave professional misconduct proven by any means which the contracting authority can justify;
- (d) where the Contractor has 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 he is established or with those of the country applicable to the Contract or those of the country where the Contract is to be performed;
- (e) where the Commission seriously suspects the Contractor of fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the Community's or European Union's ' financial interests;
- (f) where the Contractor is in breach of his obligations under Article II.3;

- (g) where the Contractor was guilty of misrepresentation in supplying the information required by the Commission as a condition of participation in the Contract procedure or failed to supply this information;
- (h) where a change in the Contractor's legal, financial, technical or organisational situation could, in the Commission's opinion, have a significant effect on the performance of the Contract;
- (i) where execution of the tasks has not actually commenced within three months of the date foreseen, and the new date proposed, if any, is considered unacceptable by the Commission;
- (j) where the Contractor is unable, through his own fault, to obtain any permit or licence required for performance of the Contract;
- (k) where the Contractor, after receiving formal notice in writing to comply, specifying the nature of the alleged failure, and after being given the opportunity to remedy the failure within a reasonable period following receipt of the formal notice, remains in serious breach of his contractual obligations.

II.15.2. In case of force majeure, notified in accordance with Article II.12, either contracting party may terminate the Contract, where performance thereof cannot be ensured for a period corresponding to at least to one fifth of the period laid down in Article I.2.3.

II.15.3. Prior to termination under point e), h) or k), the Contractor shall be given the opportunity to submit his observations.

Termination shall take effect on the date on which a registered letter with acknowledgment of receipt terminating the Contract is received by the Contractor, or on any other date indicated in the letter of termination.

II.15.4. Consequences of termination:

In the event of the Commission terminating the Contract in accordance with this Article and without prejudice to any other measures provided for in the Contract, the Contractor shall waive any claim for consequential damages, including any loss of anticipated profits for uncompleted work. On receipt of the letter terminating the Contract, the Contractor shall take all appropriate measures to minimise costs, prevent damage, and cancel or reduce his commitments. He shall draw up the documents required by the Special Conditions for the tasks executed up to the date on which termination takes effect, within a period not exceeding sixty days from that date.

The Commission may claim compensation for any damage suffered and recover any sums paid to the Contractor under the Contract.

On termination the Commission may engage any other contractor to complete the services. The Commission shall be entitled to claim from the Contractor all extra costs incurred in making good and completing the services, without prejudice to any other rights or guarantees it has under the Contract.

ARTICLE II.16 – LIQUIDATED DAMAGES

Should the Contractor fail to perform his obligations under the Contract within the time limits set by the Contract, then, without prejudice to the Contractor's actual or potential liability incurred in

relation to the Contract or to the Commission's right to terminate the Contract, the Commission may decide to impose liquidated damages of 0.2% of the amount specified in Article I.3.1 per calendar day of delay. The Contractor may submit arguments against this decision within thirty days of notification by registered letter with acknowledgement of receipt or equivalent. In the absence of reaction on his part or of written withdrawal by the Commission within thirty days of the receipt of such arguments, the decision imposing the liquidated damages shall become enforceable. These liquidated damages shall not be imposed where there is provision for interest for late completion. The Commission and the Contractor expressly acknowledge and agree that any sums payable under this Article are in the nature of liquidated damages and not penalties, and represent a reasonable estimate of fair compensation for the losses that may be reasonably anticipated from such failure to perform obligations.

ARTICLE II.17 – CHECKS AND AUDITS

II.17.1. Pursuant to Article 142 of the Financial Regulation applicable to the general budget of the European Communities, the Court of Auditors shall be empowered to audit the documents held by the natural or legal persons receiving payments from the budget of the European Union from signature of the Contract up to five years after payment of the balance.

II.17.2. The Commission or an outside body of its choice shall have the same rights as the Court of Auditors for the purpose of checks and audits limited to compliance with contractual obligations from signature of the Contract up to five years after payment of the balance.

II.17.3. In addition, the European Anti Fraud Office may carry out on-the-spot checks and inspections in accordance with Council Regulation (Euratom, EC) No 2185/96 and Parliament and Council Regulation (Euratom) No 1074/1999 from signature of the Contract up to five years after payment of the balance.

ARTICLE II.18 – AMENDMENTS

Any amendment to the Contract shall be the subject of a written agreement concluded by the contracting parties. An oral agreement shall not be binding on the contracting parties.

ARTICLE II.19 – SUSPENSION OF THE CONTRACT

Without prejudice to the Commission's right to terminate the Contract, the Commission may at any time and for any reason suspend execution of the tasks under the Contract or any part thereof. Suspension shall take effect on the day the Contractor receives notification by registered letter with acknowledgement of receipt or equivalent, or at a later date where the notification so provides. The Commission may at any time following suspension give notice to the Contractor to resume the work suspended. The Contractor shall not be entitled to claim compensation on account of suspension of the Contract or of part thereof.

ARTICLE II.20 – DATA PROTECTION

- II.20.1** The Contractor shall have the right of access to his/her personal data and the right to rectify any such data. Should the Contractor have any queries concerning the processing of his/her personal data, s/he shall address them to the entity acting as data controller provided for in Article I.8.
- II.20.2** The Contractor shall have right of recourse at any time to the European Data Protection Supervisor.
- II.20.3** Where the Contract requires the processing of personal data by the Contractor, the Contractor may act only under the supervision of the data controller, in particular with regard to the purposes of the processing, the categories of data which may be processed, the recipients of the data, and the means by which the data subject may exercise his/her rights.
- II.20.4** The Contractor shall limit access to the data to the staff strictly necessary for the performance, management and monitoring of the Contract.
- II.20.5** The Contractor undertakes to adopt appropriate technical and organisational security measures having regard to the risks inherent in the processing and to the nature of the personal data concerned in order to:
- a) prevent any unauthorised person from having access to computer systems processing personal data, and especially:
 - aa) unauthorised reading, copying, alteration or removal of storage media;
 - ab) unauthorised data input as well as any unauthorised disclosure, alteration or erasure of stored personal data;
 - ac) unauthorised using of data-processing systems by means of data transmission facilities;
 - b) ensure that authorised users of a data-processing system can access only the personal data to which their access right refers;
 - c) record which personal data have been communicated, when and to whom;
 - d) ensure that personal data being processed on behalf of third parties can be processed only in the manner prescribed by the contracting institution or body;
 - e) ensure that, during communication of personal data and transport of storage media, the data cannot be read, copied or erased without authorisation;
 - f) design its organisational structure in such a way that it meets data protection requirements.

SIGNATURES

For the Contractor,
[Company name/forename/surname/function]

For the Commission,
Peter Faross, Director

signature[s]: _____

signature: _____

Done at [Brussels], [date]

Done at Luxembourg, [date]

In duplicate in English.

ANNEX I

Tender Specifications and Monitoring

The purpose of this Annex is to enable the Commission to conduct, throughout the duration of the Contract, an accurate appraisal of whether the Contractor is executing the tasks assigned to him in accordance with the provisions of the Contract.

So that the Commission can regularly identify the progress made in execution of the tasks in accordance with the Tender Specifications, appropriate monitoring, assessment, and supervisory procedures shall be set up. For these purposes, this Annex shall include all necessary details, in particular, where relevant, the following:

- (i) schedule of interim and final reports – terms for approval, structure and content (where provision is made for such reports and a specific annex is not necessary);*
- (ii) schedule of audits to be carried out in accordance with Article II.17 of the Contract.*

All details on Monitoring and Reporting are to be indicated and included in the Tender Specifications.

ANNEX II

Contractor's Tender