Radiation Protection

Luxembourg, ENER/D3/D2013/

Dear Sir/Madam.

Subject:-

Invitation to tender no. ENER/D3/563-2013 for a service contract regarding "European reference methodology and guidance for a radiotherapy-dedicated risk assessment and for the reporting and analysis of adverse events" contract notice in OJEU 2013/S 163-283340 of 23/08/2013

- 1. The European Commission is planning to award the public contract referred to above. Please find enclosed the related tender specification listing all the documents that must be produced in order to submit a tender, and the draft contract.
- 2. If you are interested in this contract, you should submit a tender in one original [and two copies] in one of the official languages of the European Union. A copy of the offer on a CD/DVD/USB stick has also to be submitted.

Tenderers shall submit tenders by letter:

- a) either by post or by courier not later than 07/10/2013, in which case the evidence of the date of dispatch shall be constituted by the postmark or the date of the deposit slip, to the address indicated below.
- b) or delivered by hand not later than 16.00 on 07/10/2013 to the address indicated below. 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 08.30 to 17.30 Monday to Thursday, and from 08.30 to 16.30 on Fridays. It is closed on Saturdays, Sundays and Commission holidays.

| methodology and guidance for a radiotherapy-dedicated risk assessment and | 1  |
|---|--|
| for the reporting and analysis of adverse events                          | for the reporting and analysis of adverse events |
| European Commission   | European Commission                              |
| Directorate-General for Energy, Unit D3                                   | Directorate-General for Energy, Unit D3          |
| EUFO 4186A  | For the attention of M R. Baranczyk              |
| For the attention of M R. Baranczyk                                       | Jean Monnet Building – main entrance             |
| Jean Monnet Building  | Rue Albert Wehrer                                |
| Plateau du Kirchberg  | Plateau du Kirchberg                             |

| I 2020 Luyembourg I 2020 Luyembourg |                   |                   |   |
|-------------------------------------|-------------------|-------------------|---|
|                                     | – 2920 Luxembourg | L-2920 Luxembourg | 2 |

Tenders must be placed inside two sealed envelopes. The inner envelope, addressed as indicated above, should be marked as follows: "CALL FOR TENDERS – NOT TO BE OPENED BY THE INTERNAL MAIL DEPARTMENT". If self-adhesive envelopes are used, they must be sealed with adhesive tape and the sender must sign across this tape.

The inner envelope must also contain two sealed envelopes, one containing the technical tender and the other the financial tender. Each of these envelopes must clearly indicate the content ("Technical" and "Financial").

## For your bid to be found admissible the confidentiality thereof must have been ensured and the deadline for the submission of the bids met.

4. Tenders will be opened at 15.00 p.m. on 15/10/2013 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

Tenderers may attend the meeting but 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. Tenders must be:

- signed by a duly authorised representative of the tenderer. The original signature of the single tenderer's or lead partner's authorised representative) (preferably in blue ink) on the identification form (Annex 1 of the technical specifications) shall be considered as the signature of the tender, binding the single tenderer or the group of partners to the terms included in the tender;
- perfectly legible so that there can be no doubt as to words and figures;
- 6. The period of validity of the tender, during which tenderers may not modify the terms of their tenders in any respect, is six months from the final date for submission.
- 7. Submission of a tender implies acceptance of all the terms and conditions set out in this invitation to tender, in the tender specification and in the draft contract and, where appropriate, waiver of the tenderer's own general or specific terms and conditions. Submission of a tender is binding on the tenderer to whom the contract is awarded for the duration of the contract.
- 8. All costs incurred during the preparation and submission of tenders are to be borne by the tenderers and will not be reimbursed.

- 9. Contacts between the contracting authority and tenderers are prohibited throughout the procedure save in exceptional circumstances and under the following conditions only:
  - Before the final date for submission of tenders:
  - \* At the request of the tenderer, the contracting authority may provide additional information solely for the purpose of clarifying the nature of the contract.

Any requests for additional information must be made in writing only to Remigiusz.Baranczyk@ec.europa.eu

Requests for additional information received less than five working days before the final 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 clerical error in the text of the call for tenders.
- \* Any additional information including that referred to above will be posted on <a href="http://ec.europa.eu/dgs/energy/tenders/index\_en.htm">http://ec.europa.eu/dgs/energy/tenders/index\_en.htm</a> The website will be updated regularly and it is the tenderers' responsibility to check for updates and modifications during the tendering period.
- After the opening of tenders
- \* If clarification is required or if obvious clerical errors in the tender need to be corrected, the contracting authority may contact the tenderer provided the terms of the tender are not modified as a result.
- 10. This invitation to tender is in no way binding on the Commission. The Commission's contractual obligation commences only upon signature of the contract with the successful tenderer.
- 11. Up to the point of signature, the contracting authority may either abandon the procurement or cancel the award procedure, without the candidates or tenderers being entitled to claim any compensation. This decision must be substantiated and the candidates or tenderers notified.
- 12. Once the Commission has opened the tender, the document shall become the property of the Commission and it shall be treated confidentially.
- 13. You will be informed of the outcome of this procurement procedure.
- 14. 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: <a href="http://ec.europa.eu/dataprotectionofficer/privacystatement">http://ec.europa.eu/dataprotectionofficer/privacystatement</a> publicprocurement en.pdf.

- 15. Your personal data 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 <a href="http://ec.europa.eu/budget/contracts\_grants/info\_contracts/legal\_entities/legal\_entities\_en.cfm">http://ec.europa.eu/budget/contracts\_grants/info\_contracts/legal\_entities/legal\_entities\_en.cfm</a>), or
  - the Commission Regulation 2008/1302 of 17.12.2008 on the Central Exclusion Database (for more information see the Privacy Statement on <a href="http://ec.europa.eu/budget/explained/management/protecting/protect\_en.cfm#BDCE">http://ec.europa.eu/budget/explained/management/protect\_en.cfm#BDCE</a>)

Peter Faross Director

Date and signature

9.8.2013



#### **CALL FOR TENDERS**

no. ENER/D3/563-2013

European reference methodology and guidance for a radiotherapydedicated risk assessment and for the reporting and analysis of adverse events

## **TENDER SPECIFICATIONS**

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#### 1 INFORMATION ON TENDERING

#### 1.1 Participation

Participation in this tender procedure is open on equal terms to all natural and legal persons coming within the scope of the Treaties and to all natural and legal persons in a third country which has a special agreement with the Union in the field of public procurement on the conditions laid down in that agreement. Where the Multilateral Agreement on Government Procurement <sup>1</sup> concluded within the WTO applies, the participation to the call for tender is also open to nationals of the countries that have ratified this Agreement, on the conditions it lays down.

#### 1.2 Contractual conditions

The tenderer should bear in mind the provisions of the draft contract which specifies the rights and obligations of the contractor, particularly those on payments, performance of the contract, confidentiality, and checks and audits.

#### 1.3 Joint tenders

A joint tender is a situation where a tender is submitted by a group of economic operators (consortium). Joint tenders may include subcontractors in addition to the joint tenderers.

In case of joint tender, all economic operators in a joint tender assume joint and several liability towards the Contracting Authority for the performance of the contract as a whole.

These economic operators shall designate one of them to act as leader with full authority to bind the grouping or the consortium and each of its members. It shall be responsible for the receipt and processing of payments for members of the grouping, for managing the service administration and for coordination. The composition and constitution of the grouping or consortium, and the allocation of the scope of tasks amongst the members, shall not be altered without the prior written consent of the Commission.

The tenderers should indicate in their offer whether the partnership takes the form of:

a) a <u>new or existing</u> legal entity which will sign the contract with the Commission in case of award

or

b) a group of partners not constituting a new legal entity, who via a <u>power of attorney</u>, signed by an authorised representative of each partner (except the lead partner), designate one of the partners as lead partner, and mandate him as lead contractor to sign the contract with the Commission in case of award.

<sup>&</sup>lt;sup>1</sup> See http://www.wto.org/english/tratop E/gproc e/gp gpa e.htm

#### 1.4 Subcontracting

Subcontracting is permitted in the tender but the contractor will retain full liability towards the Contracting Authority for performance of the contract as a whole.

Tenderers must give an indication of the part of the services and proportion of the contract that they intend to subcontract.

Tenderers are required to identify subcontractors whose share of the contract is above 20%.

During contract execution, the change of any subcontractor identified in the tender will be subject to prior written approval of the Contracting Authority.

#### 1.5 Content of the tender

The tenders must be presented as follows:

Part A: Identification of the tenderer (see section 1.6)

Part B: Evidence for exclusion criteria (see section 2.2)

Part C: Evidence for selection criteria (see section 2.3)

Part D: Technical offer (see section 2.5)

Part E: Financial offer (see section 2.6)

Part F: Power of attorney (for consortia only)

#### 1.6 Identification of the tenderer: legal capacity and status

- The tenderer's identification form in **Annex 1** shall be filled in and signed by:
  - o The tenderer (including any member of a consortium or grouping)
  - o subcontractor(s) whose share of the work represent more than 20% of the contract
- In order to prove their legal capacity and their status, all tenderers (including any member of a consortium of grouping) must provide a signed **Legal Entity Form with its supporting evidence**. The form is available on:

http://ec.europa.eu/budget/contracts\_grants/info\_contracts/legal\_entities/legal\_entities en.cfm

Tenderers that are already registered in the Contracting Authority's accounting system (i.e. they have already been direct contractors) must provide the form but are not obliged to provide the supporting evidence.

- If it has not been included with the Legal Entity Form, tenderers must provide the following information
  - For legal persons, a legible copy of the notice of appointment of the **persons** authorised to represent the tenderer in dealings with third parties and in legal proceedings, or a copy of the publication of such appointment if the legislation which applies to the legal entity concerned requires such publication. Any delegation of this

authorisation to another representative not indicated in the official appointment must be evidenced.

- For natural persons, where applicable, a proof of registration on a professional or trade register or any other official document showing the registration number.
- The tenderer (only the leader in case of joint tender) must provide a **Financial Identification Form and supporting documents**. The form is available on: <a href="http://ec.europa.eu/budget/contracts">http://ec.europa.eu/budget/contracts</a> grants/info contracts/index en.cfm .

#### 2 EVALUATION AND AWARD

#### 2.1 Evaluation steps

The evaluation is based on the information provided in the submitted tender. It takes place in three steps:

- (1) Verification of non-exclusion of tenderers on the basis of the exclusion criteria.
- (2) Selection of tenderers on the basis of selection criteria.
- (3) Evaluation of tenders on the basis of the award criteria (technical and financial evaluation).

Only tenders meeting the requirements of one step will pass on to the next step.

#### 2.2 Exclusion criteria

All tenderers shall provide a declaration on their honour (see Annex 2), duly signed and dated by an authorised representative, stating that they are not in one of the situations of exclusion listed in the Annex 2.

The declaration on honour is also required for identified subcontractors whose intended share of the contract is above 20%.

The successful tenderer shall provide the documents mentioned as supporting evidence in Annex 2 before signature of the contract and within a deadline given by the contracting authority. This requirement applies to all members of the consortium in case of joint tender. In case of doubt on this declaration on the honour, the contracting authority may also request the evidence for subcontractors whose intended share of the contract is above 20%.

#### 2.3 Selection criteria

Tenderers must prove their economic, financial, technical and professional capacity to carry out the work subject to this call for tender.

The tenderer may rely on the capacities of other entities, regardless of the legal nature of the links which it has with them. It must in that case prove to the Contracting Authority that it will have at its disposal the resources necessary for performance of the contract, for example

by producing an undertaking on the part of those entities to place those resources at its disposal.

#### 2.3.1 Economic and financial capacity criteria and evidence

In order to prove their economic and financial capacity, the tenderer (i.e. in case of joint tender, the combined capacity of all members of the consortium) must comply with the following criteria:

- Turnover of the last two financial years above € 300 000. The following evidence should be provided:
- Copy of the profit & loss account for the last two years for which accounts have been closed,
- Failing that, appropriate statements from banks,
- If applicable, evidence of professional risk indemnity insurance;

If, for some exceptional reason which the Contracting Authority considers justified, a tenderer is unable to provide one or other of the above documents, he or she may prove his or her economic and financial capacity by any other document which the Contracting Authority considers appropriate. In any case, the Contracting Authority must at least be notified of the exceptional reason and its justification in the tender. The Commission reserves the right to request any other document enabling it to verify the tenderer's economic and financial capacity.

#### 2.3.2 Technical and professional capacity criteria and evidence

#### a. Criteria relating to tenderers

Tenderers (in case of a joint tender the combined capacity of all tenderers) must comply with the following criteria:

- the tenderer must prove experience in the field of radiation protection of patients, in particular patient radiation safety in radiotherapy, with at least one project delivered in this field in the last three years with a minimum value of 50 000 EUR.
- the tenderer must prove experience with projects delivered in the last three years, which involved the analysis of national systems of risk management in radiotherapy and the national and international systems for classification, recording and reporting of adverse events or near misses concerning patient safety in radiotherapy.
- the tenderer must prove experience in drafting reports in English.
- the tenderer must demonstrate experience in organising international meetings.

#### b. Criteria relating to the team delivering the service:

The team delivering the service should include, as a minimum, the following profiles:

- A project leader, who will meet the following requirements:
  - professional qualifications in radiation oncology or medical physics;
  - minimum five years of clinical experience in external beam radiotherapy, after obtaining their professional qualification;

- recent (in the last five years) scientific publications in peer-reviewed journals on safety of radiotherapy.
- Task leaders, who will meet the following requirements:
  - professional qualifications in radiation oncology or medical physics;
  - minimum five years of clinical experience in external beam radiotherapy, after obtaining their professional qualification.

The tenderer or, in case of a consortium, the organization in charge of the workshops must demonstrate experience in organizing workshops and meetings.

#### c. Evidence:

The following evidence should be provided to fulfil the above criteria:

- List of relevant services provided in the past three years, with sums, dates and recipients, public or private. The most important services shall be accompanied by certificates of satisfactory execution, specifying that they have been carried out in a professional manner and have been fully completed;
- The educational and professional qualifications of the project and tasks leaders and the persons who will provide the most relevant tasks for this tender (CVs). Each CV provided should indicate the intended function in the delivery of the service;
- A reference to reports published in English in the past five years drafted entirely or mainly by the project team's member(s) assigned with the task of drafting the project report.
- List of international meetings (workshops, conferences, etc.) organized by the tenderer or the member of the consortium in charge of the project workshops in the past five years together with references to meeting web-pages and proceedings.
- A reference to the team and the task leaders' publications on safety in radiotherapy or radiotherapy risk assessment in peer-reviewed scientific journals.

#### 2.4 Award criteria

The tender will be awarded according to the best-value-for -money procedure. The quality of the tender will be evaluated based on the following criteria. The maximum total quality score is 100 points.

|     | Criteria and subcriteria   | Weighting |
|-----|--|-----------|
| 1   | Quality of the proposed methodology  | 40        |
| 1.1 | Planned contractor's activities to develop radiotherapy-<br>dedicated proactive risk assessment methodology.                                 | 10        |
| 1.2 | Planned contractor's activities to develop European Guidelines on reporting of adverse events and near misses in radiotherapy                | 10        |
| 1.3 | Planned contractor's activities to develop radiotherapy-<br>dedicated methodology for reactive analysis of adverse<br>events and near misses | 10        |
| 1.4 | Planning of the European Workshops   | 10        |
| 2   | Organisation of the work   | 40        |

| 3     | Quality system   | 20  |
|-------|------------------|-----|
| Total | number of points | 100 |

#### Quality of the proposed methodology (40 points - - minimum threshold 60%)

Sub-criterion 1.1 (10 points): This criterion serves to assess the proposed strategy and the planned contractor's activities to define radiotherapy-dedicated proactive risk assessment methodology. The proposed strategy shall allow assessing the actions to define, in the most efficient way, the integrated risk assessment methodology to be used as a reference method for the national developments. The proposed strategy shall allow assessing the actions to achieve wide acceptance of the developed methodology and shall include, in particular: a) reference to up-to-date studies and publications which will be used as a basis for the methodology and b) envisaged mechanisms to duly consult all concerned regulatory, professional and scientific bodies and other stakeholders representing the radiation protection and medical communities. The proposed methodology and the planned contractor's activities to ensure that the methodology document will be drafted in a clear, concise and user-friendly manner (easy to put in practice) will also be assessed.

Sub-criterion 1.2 (10 points): This criterion serves to assess the proposed strategy and the planned contractor's activities to develop European Guidelines on reporting of adverse events and near misses in radiotherapy. The proposed strategy shall allow assessing the actions to define the guidelines, including the classification scales, in the most efficient way. The proposed strategy shall allow assessing the actions to achieve wide acceptance of the guidelines and shall include, in particular: a) reference to up-to-date studies and publications which will be used as a basis and b) envisaged mechanisms to duly consult all concerned regulatory, professional and scientific bodies and other stakeholders representing the radiation protection and medical communities. The proposed methodology and the planned contractor's activities to ensure that the guidance document will be drafted in a clear, concise and user-friendly manner (easy to put in practice) will also be assessed.

Sub-criterion 1.3 (10 points): This criterion serves to assess the proposed strategy and the planned contractor's activities to define radiotherapy-dedicated methodology for reactive analysis of adverse events and near misses. The proposed strategy shall allow assessing the actions to define, in the most efficient way, the integrated radiotherapy-dedicated methodology to be used as a reference method for the national developments. The proposed strategy shall allow assessing the actions to achieve wide acceptance of the developed methodology and should in particular: a) identify recent studies and publications which should be taken into account and b) propose mechanisms to duly consult all concerned regulatory, professional and scientific bodies as well as other stakeholders representing both radiation protection and medical community.

Sub-criterion 1.4 (10 points): The proposed methodology shall also allow assessing the planning of the European Workshops.

#### • Organisation of the work (40 points – minimum threshold 60%)

This criterion will assess how the roles and responsibilities of the proposed team and of the economic operators (in case of joint tenders, including subcontractors if applicable) are distributed for each task. It also assesses the global allocation of time and resources to the project and to each task or deliverable, and whether this allocation is adequate for the work.

The tender should provide details on the allocation of time and resources and the rationale behind the choice of this allocation.

#### • Quality system (20 points – minimum threshold 60%)

This criterion will assess the quality system applied to the service foreseen in this tender specification concerning the quality of the deliverables, the language quality check, and continuity of the service in case of absence of a member of the team. The quality system should be detailed in the tender and specific to the tasks at hand; a generic quality system will result in a low score.

Tenders must score above 60% for each criterion, and above 70% in total. Tenders that do not reach the minimum quality thresholds will be rejected and will not be ranked.

After evaluation of the quality of the tender, the tenders are ranked using the formula below to determine the tender offering best value for money. A weight of 60/40 is given to quality and price:

```
Score for tender x = \frac{price\ of\ lowest\ tender}{price\ of\ tender\ x} multiplied by 0.4

\frac{total\ quality\ score\ for\ award\ criteria\ for\ tender\ x}{100} multiplied by 0.6
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#### 2.5 Technical offer

The technical offer must cover all aspects and tasks required in the technical specification and provide all the information needed to apply the award criteria. Offers deviating from the requirements or not covering all requirements may be excluded on the basis of non-conformity with the tender specifications and will not be evaluated.

#### 2.6 Financial offer

The price for the tender must be quoted in euro. Tenderers from countries outside the euro zone have to quote their prices in euro. The price quoted may not be revised in line with exchange rate movements. It is for the tenderer to assume the risks or the benefits deriving from any variation.

Prices must be quoted free of all duties, taxes and other charges, including VAT, as the European Union is exempt from such charges under Articles 3 and 4 of the Protocol on the privileges and immunities of the European Union. The amount of VAT may be shown separately.

The quoted price must be a fixed amount which includes all charges (including travel and subsistence). Travel and subsistence expenses are not refundable separately.

Indicative price: The total value of the contract has been estimated at 300 000 EUR. 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 workshop participants; this does not preclude charging participants for workshop related miscellaneous costs like coffees, lunches or social events.

#### 3 TECHNICAL SPECIFICATIONS

#### 3.1 General background

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/Euratom laying down the basic safety standards (BSS) for radiation protection of the workers and the members of the public. The Euratom BSS Directive is supplemented by the Council Directive 97/43/Euratom (Medical Exposure Directive, MED) 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.

Though errors are rare, when they do occur the consequences can be significant for the patient, as proved by severe radiotherapy accidents which occurred during the last years.

With the aim to improve the patient safety in radiotherapy, the proposal for a revised Euratom BSS Directive (COM (2012)242) introduced several new requirements on accidental exposures in radiotherapy, namely:

- study of risks of accidental or unintended exposures, as part of the quality assurance programs;
- internal record keeping and analysis of events involving or potentially involving accidental or unintended exposures (adverse events and near misses).
- information to referrers, practitioners and patients on clinically significant unintended or accidental exposures;
- declaration of significant events to the competent authority;
- dissemination of information regarding lessons learned from significant events.

The revised Euratom BSS Directive is in its final stage of adoption by the Council and shall be transposed into national law within the next few years.

In line with the proposed new requirements the European Commission launched in 2012 a 2-year ACCIRAD project (ENER/11/NUCL/SI2.612180; <a href="http://www.accirad.eu">http://www.accirad.eu</a>) aimed at development of a Guidance document on risk analysis in radiotherapy. The draft document, discussed at the European Workshop held in Poznań, Poland in June 2013 (<a href="http://accirad-workshop.eu">http://accirad-workshop.eu</a>), provides a review of the available general risk assessment methods, both proactive and reactive, and discusses their benefits and shortcomings as for their application

in radiotherapy. The document provides also guidelines for development of event reporting and learning systems for radiotherapy. In its conclusions the ACCIRAD document indicates a need for further detailed work in these domains.

#### 3.2 General objectives

This project, being a follow-up to ACCIRAD, is intended to develop external beam radiotherapy-dedicated: a) proactive risk assessment methodology, b) guidance on reporting of adverse events and near misses and c) methodology for reactive analysis of adverse events and near misses.

#### 3.3 Tasks

The work will include four major tasks:

- Development of European reference methodology for external beam radiotherapydedicated proactive risk assessment.
- Development of European guidelines for reporting of adverse events and near misses in external beam radiotherapy including event classification scales to be used in the different levels of reporting.
- Development of European reference methodology for external beam radiotherapydedicated reactive analysis of adverse events and near misses.
- Organization of two European workshops to present and discuss the developed methodologies and guidance with the aim to reach wide consensus among the different stakeholders and to disseminate the outcomes of the project.

#### 3.3.1 European reference methodology for external beam radiotherapydedicated proactive risk assessment

Results of the ACCIRAD project as well as other work in this area shall be used to develop European reference methodology for external beam radiotherapy-dedicated proactive risk assessment using complete and integrated approach. A systematic approach is required including considerations of equipment failures, human errors and organizational factors. Such a methodology will be used as a reference method for the national developments. This will promote European harmonization and avoid a lot of duplicative work at national levels. Development of radiotherapy-dedicated risk assessment methodology requires a close cooperation between radiation protection and medical authorities and professional societies, both on national and European level.

# 3.3.2 European guidelines for reporting of adverse events and near misses in external beam radiotherapy

The revised Euratom BSS requires reporting of adverse events and/or near misses in radiotherapy on several levels: a) internal department/hospital reporting, recording and analysis of all adverse events and near misses, b) communicating to the involved clinicians and patients in the case of clinically significant events, c) declaration of 'significant events' and the associated investigations and corrective measures to the competent authorities, and d)

dissemination of information on the important lessons learnt to other departments in order to avoid recurrence elsewhere. The guidance developed under this task shall address the organisational and technical/technological arrangements on department, hospital and national level needed to deliver on the above responsibilities and shall establish classification scales to be used for the different levels of reporting. An important element of the work will be to define criteria for 'significant events' and to reach a broad consensus on them among the European national competent authorities and the relevant professional groups. General structures recommended by the international bodies like the WHO Conceptual Framework for the International Classification for Patient Safety should be followed as much as possible to get homogeneity. The development of the guidelines, and in particular the event classification scales, requires close cooperation between radiation protection and medical authorities and professional societies, both on national and European level.

#### 3.3.3 European reference methodology for external beam radiotherapydedicated reactive analysis of adverse events and near misses

Results of the ACCIRAD project and other relevant work shall be used to develop European reference methodology for radiotherapy-dedicated reactive analysis of events and near misses. A systematic approach is required including considerations of equipment failures, human errors and organizational factors. The methodology should take into account and be in line with the appropriate classification scheme and the reporting and recording guidelines developed under the previous task. Such a methodology will be used as a reference method for the national developments and will promote European harmonization and avoid a lot of duplicative work at national levels. Development of radiotherapy-dedicated risk assessment methodology requires a close cooperation between radiation protection and medical authorities and professional societies, both on national and European level.

The documents developed under tasks 3.3.1-3 should present the above subjects in clear, concise and user-friendly manner, allowing to the extent practicable for their direct implementation in hospital environments. For each element and wherever practicable the operational tasks and objectives should be specified to the actors involved in the process. The proposed European Reference Methodology and Guidelines documents will be presented to the Group of Experts established under Article 31 of the Euratom Treaty with the aim of receiving their approval for publication in the Radiation Protection Series of the European Commission. The contractor shall also seek the approval/endorsement of the developed methodology and guidelines by the European organisations and bodies representing the national competent authorities and the relevant medical professionals, i.e. the radiation oncologists, radiation therapists and medical physicists.

#### 3.3.4 European workshops

Two European workshops shall be organised to discuss the results of the above tasks with the aim of reaching wide consensus on them and to disseminate the outcomes of the project. Complete – i.e. addressing all foreseen elements – drafts of the three European reference methodology and guidance documents shall be presented and discussed at the first workshop, which should take place 20 to 22 months after the date of entry into force of the contract. The second workshop shall be aimed at disseminating the outcomes of the project and rectifying any remaining issues into the final version of the documents and shall take place not later than 33 months after the date of entry into force of the contract.

#### 3.4 Input by the Contracting Authority

The Commission will provide to the contractor access to all relevant information collected within projects funded by the Directorate-General for Energy, e.g. the data collected within the ACCIRAD project. Access to relevant information collected within other Commission programmes, e.g. the Seventh Framework Programme for Research and Innovation, shall be responsibility of the contractor.

#### 3.5 Intermediate outputs and deliverables

A progress report shall be submitted to the Commission at the latest 18 months after the date of entry into force of the contract. The progress report shall contain a) administrative report showing the main activities carried on to progress on the project work, b) first complete draft of the European reference methodology for external beam radiotherapy-dedicated proactive risk assessment, c) first complete draft of the European guidelines for reporting of adverse events and near misses in external beam radiotherapy, d) first complete draft of the European reference methodology for external beam radiotherapy-dedicated reactive analysis of adverse events and near misses, and e) the programme and other relevant information on the first European workshop.

The contractor will submit the progress report together with an invoice for interim payment in accordance with Article I.4 of the service contract in annex 5 to this Tender Specifications.

#### 3.6 Final output and deliverable

The contractor will submit a draft of the **final report** to the Commission at the latest **35** months after the entry into force of the contract.

The final report shall contain a) administrative report showing the main activities carried on to complete the project work, b) final draft of the European reference methodology for external beam radiotherapy-dedicated proactive risk assessment, c) final draft of the European guidelines for reporting of adverse events and near misses in external beam radiotherapy, d) final draft of the European reference methodology for external beam radiotherapy-dedicated reactive analysis of adverse events and near misses, and e) summary of the workshops including workshop conclusions.

The contractor will submit the final version of the final report together with an invoice for the payment of the balance in accordance with Article I.4 of the service contract in annex 5 to this Tender Specifications.

#### 3.7 Details on deliverables

The contractor will provide the results of his work in well-written, comprehensible documents at each stage of reporting. The intermediate and final reports must be in English and shall be supplied in paper (three copies, A4 format) and in electronic form (as Doc(x) and Pdf).

The contractor will present the progress 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 and specialty organisations.

The Commission will publish the European Guidelines on radiotherapy-dedicated risk assessment methodology and on harmonized classification scales for reporting of adverse events and near misses in radiotherapy in the "Radiation Protection" series. After the Radiation Protection Unit (DG ENER D3) has approved the work done, the final manuscripts 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 reports are not subject to any restrictions deriving from intellectual property rights of third parties. Should the tenderer intend to use data in the reports, which cannot be published, this must be explicitly mentioned in the offer.

#### 3.8 General guidance on methodology

The project management will be carried out by a lead contractor with partners having knowledge and experience in the area of radiation protection of patients, in particular patient radiation safety in radiotherapy and radiotherapy risk assessment. If necessary, the Contractor will establish a panel of advisers from scientific and clinical institutions and national, regional and international organizations. The contractor will co-ordinate and supervise the work of the partners and the advisers and regularly report on progress to the Commission.

# 3.9 General delivery time and progress meetings foreseen with the Contracting Authority

#### The duration of the tasks shall not exceed 37 months.

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

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.

A kick-off meeting will take place in Luxembourg at the latest thirty days following the entry into force of the contract, in order to settle all the details of the study to be undertaken.

# 4 CONTENT, STRUCTURE AND GRAPHIC REQUIREMENTS OF THE FINAL DELIVERABLES

All studies produced for the European Commission and Executive Agencies shall conform to the corporate visual identity of the European Commission by applying the graphic rules set out in the European Commission's Visual Identity Manual, including its logo<sup>2</sup>.

The Commission is committed to making online information as accessible as possible to the largest possible number of users including those with visual, auditory, cognitive or physical disabilities, and those not having the latest technologies. The Commission supports the <u>Web Content Accessibility Guidelines 2.0</u> of the W3C.

For full details on Commission policy on accessibility for information providers, see: <a href="http://ec.europa.eu/ipg/standards/accessibility/index\_en.htm">http://ec.europa.eu/ipg/standards/accessibility/index\_en.htm</a>.

Pdf versions of studies destined for online publication should respect W3C guidelines for accessible pdf documents. See: <a href="http://www.w3.org/WAI/GL/WCAG20-TECHS/pdf.html">http://www.w3.org/WAI/GL/WCAG20-TECHS/pdf.html</a>.

#### 4.1 Content

#### 4.1.1 Final study report

The final study report shall include:

- an abstract of no more than 200 words and an executive summary of maximum 6 pages, both in English and French;
- the following standard disclaimer:
  - "The information and views set out in this publication are those of the author(s) and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission's behalf may be held responsible for the use which may be made of the information contained therein."
- specific identifiers which shall be incorporated on the cover page provided by the Contracting Authority.

#### 4.1.2 Publishable executive summary

The publishable executive summary shall be provided in both in English and French and shall include:

- the following standard disclaimer:

"The information and views set out in this publication are those of the author(s) and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission's behalf may be held responsible for the use which may be made of the information contained therein."

The Visual Identity Manual of the European Commission is available upon request. Requests should be made to the following e-mail address: <a href="mailto:comm-visual-identity@ec.europa.eu">comm-visual-identity@ec.europa.eu</a>

- specific identifiers which shall be incorporated on the cover page provided by the Contracting Authority.

#### 4.2 Graphic requirements

For graphic requirements please refer to the template available at Annex 4. The cover page shall be filled in by the contractor in accordance with the instructions provided in the template. For further details you may also contact <u>comm-visual-identity@ec.europa.eu</u>.

#### **5 ANNEXES**

- 1. Tenderer 's Identification Form
- 2. Declaration related to the exclusion criteria and absence of conflict of interest
- 3. Power of Attorney (mandate in case of joint tender)
- 4. Standard Word template for studies
- 5. Draft Contract

#### **ANNEX 1**

#### IDENTIFICATION OF THE TENDERER

(Each service provider, including any member of a consortium or grouping and subcontractor(s) whose share of the work is more than 20% of the contract must complete and sign this identification form)

#### Call for tender ENER/D3/563-2013

| 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) <sup>3</sup> |       |  |  |
| Addre   | ess i |  |  |
| 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:  |       |  |  |

<sup>&</sup>lt;sup>3</sup> 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 organisation <sup>4</sup> I, the undersigned, certify that the information given in this tender is correct and that the tender is valid. |            |  |
| Surname: First name:  | Signature: |  |

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

#### **ANNEX 2**

# Declaration of honour on exclusion criteria and absence of conflict of interest

(Complete or delete the parts in grey italics in parenthese)
[Choose options for parts in grey between square brackets]

The undersigned (insert name of the signatory of this form):

in [his][her] own name (for a natural person)

or

representing the following legal person: (only if the economic operator is a legal person)

full official name:

official legal form:

full official address:

VAT registration number:

- > declares that [the above-mentioned legal person][he][she] is not in one of the following situations:
- a) is bankrupt or being wound up, is having its 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) has been convicted of an offence concerning professional conduct by a judgment of a competent authority of a Member State which has the force of *res judicata*;
- c) has been guilty of grave professional misconduct proven by any means which the contracting authorities can justify including by decisions of the European Investment Bank and international organisations;
- d) is not in compliance with all its obligations relating to the payment of social security contributions and the payment of taxes in accordance with the legal provisions of the country in which it is established, with those of the country of the contracting authority and those of the country where the contract is to be performed;
- e) has been the subject of a judgement which has the force of *res judicata* for fraud, corruption, involvement in a criminal organisation, money laundering or any other illegal activity, where such activity is detrimental to the Union's financial interests;
- f) is a subject of an administrative penalty for being guilty of misrepresentation in supplying the information required by the contracting authority as a condition of participation in a procurement procedure or failing to supply this information, or having been declared to be in serious breach of its obligations under contracts covered by the Union's budget.
  - > (Only for legal persons other than Member States and local authorities, otherwise delete) declares that the natural persons with power of representation, decision-

making or control<sup>5</sup> over the above-mentioned legal entity are not in the situations referred to in b) and e) above;

- declares that [the above-mentioned legal person][he][she]:
- g) has no 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 affinity, family, emotional life or any other shared interest;
- h) will inform the contracting authority, without delay, of any situation considered a conflict of interest or which could give rise to a conflict of interest;
- i) 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 award of the contract;
- j) provided accurate, sincere and complete information to the contracting authority within the context of this procurement procedure;
  - > acknowledges that [the above-mentioned legal person][he][she] may be subject to administrative and financial penalties<sup>6</sup> if any of the declarations or information provided prove to be false.

In case of award of contract, the following evidence shall be provided upon request and within the time limit set by the contracting authority:

For situations described in (a), (b) and (e), production of a recent extract from the judicial record is required or, failing that, a recent equivalent document issued by a judicial or administrative authority in the country of origin or provenance showing that those requirements are satisfied. Where the tenderer is a legal person and the national legislation of the country in which the tenderer is established does not allow the provision of such documents for legal persons, the documents should be provided for natural persons, such as the company directors or any person with powers of representation, decision making or control in relation to the tenderer.

For the situation described in point (d) above, recent certificates or letters issued by the competent authorities of the State concerned are required. These documents must provide evidence covering all taxes and social security contributions for which the tenderer is liable, including for example, VAT, income tax (natural persons only), company tax (legal persons only) and social security contributions.

For any of the situations (a), (b), (d) or (e), where any document described in two paragraphs above is not 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.

If the tenderer is a legal person, information on the natural persons with power of representation, decision making or control over the legal person shall be provided only upon request by the contracting authority.

Full name Date Signature

This covers the company directors, members of the management or supervisory bodies, and cases where one natural person holds a majority of shares.

As provided for in Article 109 of the Financial Regulation (EU, Euratom) 966/2012 and Article 145 of the Rules of Application of the Financial Regulation

#### ANNEX 3

#### **POWER OF ATTORNEY**

#### mandating one of the partnes in a joint tender as lead partner and lead contractor 7

The undersigned:

- Signatory (Name, Function, Company, Registered address, VAT Number)

having the legal capacity required to act on behalf of his/her company,

#### HEREBY AGREES TO THE FOLLOWING:

- 1) To submit a tender as a partner in the group of partners constituted by Company 1, Company 2, Company N, and led by Company X, in accordance with the conditions specified in the tender specifications and the terms specified in the tender to which this power of attorney is attached.
- 2) If the European Commission awards the Contract to the group of partners constituted by Company 1, Company 2, Company N, and led by Company X on the basis of the joint tender to which this power of attorney is attached, all the partners shall be co-signatories of the Contract in accordance with the following conditions:
  - (a) All partners shall be jointly and severally liable towards the European Commission for the performance of the Contract.
  - (b) All partners shall comply with the terms and conditions of the Contract and ensure the proper delivery of their respective share of the services and/or supplies subject to the Contract.
- 1) Payments by the European Commission related to the services and/or supplies subject to the Contract shall be made through the lead partner's bank account: [Provide details on bank, address, account number].
- 2) The partners grant to the lead partner all the necessary powers to act on their behalf in the submission of the tender and conclusion of the Contract, including:
  - (a) The lead partner shall submit the tender on behalf of the group of partners.
  - (b) The lead partner shall sign any contractual documents including the Contract, and Amendments thereto and issue any invoices related to the Services on behalf of the group of partners.
  - (c) The lead partner shall act as a single contact point with the European Commission in the delivery of the services and/or supplies subject to the Contract. It shall co-ordinate the delivery of the services and/or supplies by the group of partners to the European Commission, and shall see to a proper administration of the Contract.

Any modification to the present power of attorney shall be subject to the European Commission's express approval. This power of attorney shall expire when all the contractual obligations of the group of partners towards the European Commission for the delivery of the services and/or supplies subject to the Contract have ceased to exist. The parties cannot terminate it before that date without the Commission's consent.

Signed in ..... on [dd/mm/yyyy]

Place and date:

Name (in capital letters), function, company and signature:

<sup>&</sup>lt;sup>7</sup> To be filled in and signed by each of the partners in a joint tender, except the lead partner;

# ANNEX 4 Standard Word template for studies



# Add document title 1

Add title 2

### **Table of Contents**

| How To Use This Document Template | 3 |
|-----------------------------------|---|
| Cover page                        |   |
| Page set up                       |   |
| Headings and subheadings          |   |
| Body text                         |   |
| Header                            |   |
| -ooter                            |   |
| Bulleted list                     |   |
| Hyperlinks                        |   |
| Fable of Contents                 |   |

#### **How To Use This Document Template**

#### Cover page

Add the title of the document which should be center aligned. Add any other relevant information if necessary which should be left aligned on the left vertical axe of the EC logo.

The font colour of the title should be White.

#### Page set up

Top margin: 3.5Bottom margin: 2.5

Left margin: 3Right margin: 2.5

#### Headings and subheadings

The following styles should be used for headings and subheadings.

Heading 1

Font type: Verdana Font Size: 14

Colour: R:38, G:54, B:115

Heading 2

Font type: Verdana Font Size: 11

Colour: R:38, G:54, B:115

Heading 3

Font type: Verdana

Font Size: 10

Colour: R:38, G:54, B:115

Do not use capital letters for the headings/subheadings, the format should always be "sentence case", except for abbreviations.

#### **Body text**

Font style: Verdana

Font size: 10

Font colour: Gray 80%

#### Header

The header should include the EU flag and the reference text:

- European Commission
- The title of the document
- Font type: Verdana Italic
- Font size: 8

#### **Footer**

Add the relevant name of the month and year in the footer which should appear to the left below the line.

- Font type: Verdana Italic
- Font size: 8.
- The page numbers will appear automatically.

#### **Bulleted list**

The bullet should be square and the colour should be Black. For reference please see list under "Headings and subheadings". To apply the style of the list, select "List Bullet 2" from the "Style" drop down menu.

#### **Hyperlinks**

By default the hyperlinks will appear in blue (colour coder: R:26, G:63, B:124), no underline.

#### **Table of Contents**

This template is complete with Styles for a Table of Contents. From the **Insert menu**, choose **Reference**, then **Index and Tables**. Click on the tab **"Table of Contents"**. In the "Format" box, select "From template".

#### ANNEX 5



## EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR ENERGY

Directorate D - Nuclear Safety and Fuel Cycle D.3 - Radiation Protection

#### 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 contracting authority"), which is represented for the purposes of the signature of this contract by Mr Faross Director in the Directorate-General for Energy, Directorate for Nuclear Energy & Fuel Cycle,

on the one part, and

[full official name]

[official legal form]

[statutory registration number]<sup>2</sup>

[full official address]

[VAT registration number]

[(hereinafter referred to as 'the contractor'),][represented for the purposes of the signature of this contract by [forename, surname and function,]]

[The parties identified above and hereinafter collectively referred to as 'the contractor' shall be jointly and severally liable vis-à-vis the contracting authority for the performance of this contract.]

on the other part,

Delete if contractor is a natural person or a body governed by public law.

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

#### **HAVE AGREED**

to the **special conditions**, the **general conditions for service contracts** and the following annexes:

**Annex I** – Tender specifications (reference No ENER/D3/563-2013 of [insert date])

**Annex II** – Contractor's tender (reference No [complete] of [insert date])

[Other annexes]

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).

#### I - SPECIAL CONDITIONS

#### ARTICLE I.1 – SUBJECT MATTER

- **I.1.1** The subject matter of the contract is the European reference methodology and guidance for a radiotherapy-dedicated risk assessment and for the reporting and analysis of adverse events.
- **I.1.2** The contractor shall execute the tasks assigned to it in accordance with the tender specifications annexed to the contract (Annex I).

#### ARTICLE I.2 – ENTRY INTO FORCE AND DURATION

- **I.2.1** The contract shall enter into force on the date on which it is signed by the last party.
- **I.2.2** Under no circumstances may performance commence before the date on which the contract enters into force.
- I.2.3 The duration of the execution of the tasks shall not exceed 37 (thirty-seven) months. Unless otherwise specified, all 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 task may be extended only in exceptional and duly justified cases and with express written agreement of the parties. If the request for extension is made by the contractor, he must send it to the contracting authority in good time before it is due to take effect and at all events one month before the period of the execution of the tasks elapses, except in cases duly substantiated by the contractor and accepted by the contracting authority.

#### ARTICLE I.3 -PRICE

- **I.3.1** The maximum total amount to be paid by the contracting authority under the contract shall be EUR [amount in figures and in words] covering all tasks executed.
- **I.3.2** Price revision not applicable

#### ARTICLE I.4 – PAYMENT ARRANGEMENTS

#### I.4.1 Interim payment

The contractor shall submit an invoice for an interim payment of EUR [amount in figures and in words] equal to 30 % of the total amount referred to in Article I.3.1.

Invoices for interim payment shall be accompanied by a progress report or any other document in accordance with the tender specifications. The contracting authority shall make the payment within 60 days from receipt of the invoice. The contractor shall have 20 days in which to submit additional information or corrections or a new progress report or documents if required by the contracting authority.

#### I.4.2 Payment of the balance

The contractor shall submit an invoice for payment of the balance.

The invoice shall be accompanied by the final progress report or any other document in accordance with the tender specifications. The contracting authority shall make the payment within 60 days from receipt of the invoice. The contractor shall have 20 days in hich to submit additional information or corrections, a new final progress report or other documents if it is required by the contracting authority.

\*\*\*

[Where VAT is due in Belgium, the provisions of the contract constitute a request for VAT exemption No 450, Article 42, paragraph 3.3 of the VAT code (circular 2/1978), provided the contractor includes the following statement in the invoice(s): "Exonération de la TVA, Article 42, paragraphe 3.3 du code de la TVA (circulaire 2/1978)" or an equivalent statement in the Dutch or German language.]

[Where VAT is due in Luxembourg, the contractor shall include the following statement in the invoices: "Commande destinée à l'usage officiel de l'Union européenne. Exonération de la TVA Article 43 § 1 k 2ième tiret de la loi modifiée du 12.02.79." In case of intra-Community purchases, the statement to be included in the invoices is: "For the official use of the European Union. VAT Exemption / European Union/ Article 151 of Council Directive 2006/112/EC."]

#### ARTICLE I.5 – BANK ACCOUNT

Payments shall be made to the contractor's bank account denominated in [euro][insert local currency where the receiving country does not allow transactions in EUR], identified as follows:

Name of bank:

Full address of branch:

Exact designation of account holder:

Full account number including [bank] codes:

[IBAN<sup>3</sup> code:]

#### ARTICLE I.6 - COMMUNICATION DETAILS AND DATA CONTROLLER

For the purpose of Article II.6, the data controller shall be the Director of the Shared Resources Directorate.

Communications shall be sent to the following addresses:

Contracting authority:

**European Commission** 

Directorate-General for Energy

[Directorate [complete]]

[Unit [complete]]

<sup>&</sup>lt;sup>3</sup> BIC or SWIFT code for countries with no IBAN code.

Contract number: [complete]

[Postcode and city]

Email: [insert functional mailbox]

Contractor:

[Ms/Mr/Mrs]

[Function]

[Company name]

[Full official address]

Email: [complete]

#### ARTICLE I.7- APPLICABLE LAW AND SETTLEMENT OF DISPUTES

- **I.7.1.** The contract shall be governed by Community and Union law, complemented, where necessary, by the law of Luxembourg.
- **I.7.2.** Any dispute between the parties in relation to the interpretation, application or validity of the contract which cannot be settled amicably shall be brought before the courts of Luxembourg.

#### ARTICLE I.8 - EXPLOITATION OF THE RESULTS OF THE CONTRACT<sup>4</sup>

#### I.8.1 Modes of exploitation

In accordance with Article II.10.2 whereby the Community acquires ownership of the results as defined in the tender specifications (Annex I), these results may be used for any of the following purposes:

- [(a) use for its own purposes:
  - (i) making available to the staff of the contracting authority
  - (ii) making available to the persons and entities working for the contracting authority or cooperating with it, including contractors, subcontractors whether legal or natural persons, Union institutions, agencies and bodies, Member States' institutions
  - (iii) installing, uploading, processing
  - (iv) arranging, compiling, combining, retrieving
  - (v) copying, reproducing in whole or in part and in unlimited number of copies
- (b) distribution to the public:
  - (i) publishing in hard copies
  - (ii) publishing in electronic or digital format
  - (iii) publishing on the internet as a downloadable/non-downloadable file
  - (iv) broadcasting by any kind of technique of transmission

This clause must be filled in and adapted with care. All information is in the Explanatory note on Intellectual Property Rights on:

http://intracomm.ec.testa.eu/budg/imp/procurement/\_doc/\_pdf/ipr-note-en.pdf

As an absolute minimum, delete all irrelevant elements including especially those in italics and add missing parts if need be.

- (v) public presentation or display
- (vi) communication through press information services
- (vii) inclusion in widely accessible databases or indexes
- (viii) otherwise in any form and by any method
- (c) modifications by the contracting authority or by a third party in the name of the contracting authority:
  - (i) shortening
  - (ii) summarizing
  - (iii) modifying of the content
  - (iv) making technical changes to the content:
    - necessary correction of technical errors
    - adding new parts or functionalities
    - changing functionalities
    - providing third parties with additional information concerning the result (e.g. source code) with a view of making modifications
  - (v) addition of new elements, paragraphs titles, leads, bolds, legend, table of content, summary, graphics, subtitles, sound, etc.
  - (vi) preparation in audio form, preparation as a presentation, animation, pictograms story, slide-show, public presentation etc.
  - (vii) extracting a part or dividing into parts
  - (viii) use of a concept or preparation of a derivate work
  - (ix) digitisation or converting the format for storage or usage purposes
  - (x) modifying dimensions
  - (xi) translating, inserting subtitles, dubbing in different language versions:
    - English, French, German
    - all official languages of EU
    - languages used within EU
    - languages of candidate countries
    - [list of name other languages]
- (d) the modes of exploitation listed in article II.10.4
- [(e) rights to authorise, license, or sub-license in case of licensed pre-existing rights, the modes of exploitation set out in any of the points (a) to (c) to third parties.

Where the contracting authority becomes aware that the scope of modifications exceeds that envisaged in the FWC, specific contract or order form the contracting authority shall consult the contractor. Where necessary, the contractor shall in turn seek the agreement of any creator or other right holder. The contractor shall reply to the contracting authority within one month and shall provide its agreement, including any suggestions of modifications, free of charge. The creator may refuse the intended modification only when it may harm his honour, reputation or distort integrity of the work.

#### I.8.2 Pre-existing rights and transmission of rights

All pre-existing rights shall be licensed to the Community in accordance with Article II.10.3. fully and irrevocably acquired by the Community as provided for in Article II.10.2 and by derogation to Article II.10.3.

All pre-existing rights incorporated in the results and directly related to the uses foreseen in Article I.8.1 shall be fully and irrevocably acquired by the Community as provided for in Article II.10.2 and by derogation to Article II.10.3.

The contractor shall provide to the contracting authority a list of pre-existing rights and third parties' rights including its personnel, creators or other right holders as provided for in Article II.10.5.

The contractor shall present relevant and exhaustive evidence about the acquisition of all the necessary pre-existing rights and third parties' rights [together with delivery of the final report at the latest] [together with presentation of relevant result] [specify other stage]. This obligation should be fulfilled by presentation of the contractor's statement prepared in accordance with Annex A and third parties' statements prepared in accordance with Annex B and the relevant evidence listed in article II.10.5 as appropriate.<sup>5</sup>

# **ARTICLE I.9 – TERMINATION BY EITHER PARTY**

Either party may, unilaterally and without being required to pay compensation, terminate the contract by formally notifying the other party by giving [one month's] notice. Should the contracting authority terminate the contract, the contractor shall only be entitled to payment corresponding to part-performance of the contract before the termination date. The first paragraph of Article II.14.3 shall apply.

#### **SIGNATURES**

| For the contractor,                      | For the contracting authority, |
|--|--------------------------------|
| [Company name/forename/surname/function] | Peter Faross, Director         |
|  |                                |
|  |                                |
| signature[s]:                            | signature[s]:                  |
|  |                                |
| Done at [Brussels], [date]               | Done at Luxembourg, [date]     |
| In duplicate in English.                 |                                |
|  |                                |

<sup>&</sup>lt;sup>5</sup> Annexes A and B are enclosed; they are optional

# II – GENERAL CONDITIONS FOR SERVICE CONTRACTS

## ARTICLE II.1 – PERFORMANCE OF THE CONTRACT

- **II.1.1** The contractor shall perform the contract to the highest professional standards.
- **II.1.2** The contractor shall be solely responsible 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 it are to be executed.
- **II.1.3** Without prejudice to Article II.4 any reference made to the contractor's personnel in the contract shall relate exclusively to individuals involved in the performance of the contract.
- **II.1.4** The contractor must ensure that the personnel performing the contract possesses the professional qualifications and experience required for the execution of the tasks assigned to it.
- **II.1.5** The contractor shall neither represent the contracting authority nor behave in any way that would give such an impression. The contractor shall inform third parties that it does not belong to the European public service.
- **II.1.6** The contractor shall be solely responsible for the personnel who executes the tasks assigned to the contractor.

The contractor shall stipulate the following employment or service relationships with its personnel:

- (a) personnel executing the tasks assigned to the contractor may not be given orders directly by the contracting authority;
- (b) the contracting authority may not under any circumstances be considered to be the employer of the personnel referred to in point (a) and the personnel shall undertake not to invoke against the contracting authority any right arising from the contractual relationship between the contracting authority and the contractor.
- **II.1.7** In the event of disruption resulting from the action of one of the contractor's personnel working on the contracting authority's premises or in the event that the expertise of a member of the contractor's personnel fails to correspond to the profile required by the contract, the contractor shall replace him without delay. The contracting authority shall have the right to make a reasoned request for the replacement of any such personnel. The replacement personnel 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 it resulting from the replacement of personnel.
- **II.1.8** Should the execution of the tasks be directly or indirectly hampered, either partially or totally, by any unforeseen event, action or omission, the contractor shall immediately and on its own initiative record it and report it to the contracting authority. 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 its obligations under this contract. In such an event the contractor shall give priority to solving the problem rather than determining liability.

**II.1.9** Should the contractor fail to perform its obligations under the contract, the contracting authority may - without prejudice to its right to terminate the contract - reduce or recover payments in proportion to the scale of the unperformed obligations. In addition, the contracting authority may claim compensation or impose liquidated damages in accordance with Article II.12.

### ARTICLE II.2 - MEANS OF COMMUNICATION

- **II.2.1** Any communication relating to the contract or to its performance shall be made in writing and shall bear the contract number. Any communication is deemed to have been made when it is received by the receiving party unless otherwise provided for in this contract.
- II.2.2 Electronic communication shall be deemed to have been received by the parties on the day of dispatch of that communication provided it is sent to the addressees listed in Article I.6. Without prejudice to the preceding, if the sending party receives a message of non-delivery to or of absence of the addressee, it shall make every effort to ensure the actual receipt of such communication by the other party.

Electronic communication shall be confirmed by an original signed paper version of that communication if requested by any of the parties provided that this request is submitted without unjustified delay. The sender shall send the original signed paper version without unjustified delay.

**II.2.3** Mail sent using the postal services is deemed to have been received by the contracting authority on the date on which it is registered by the department responsible referred to in Article I.6.

Any formal notification shall be made by registered mail with return receipt or equivalent, or by equivalent electronic means.

# ARTICLE II.3 - LIABILITY

- **II.3.1** The contractor shall be solely responsible for complying with any legal obligations incumbent on it.
- II.3.2 The contracting authority shall not be held liable for any damage caused or sustained by the contractor, including any damage caused by the contractor to third parties during or as a consequence of performance of the contract, except in the event of wilful misconduct or gross negligence on the part of the contracting authority.
- II.3.3 The contractor shall be held liable for any loss or damage sustained by the contracting authority in performance of the contract, including in the event of subcontracting, and for any claim by a third party, but only to an amount not exceeding three times the total amount of the contract. Nevertheless, if the damage or loss is caused by the gross negligence or wilful misconduct of the contractor or of its personnel or subcontractors, the contractor shall have unlimited liability for the amount of the damage or loss.

- II.3.4 The contractor shall indemnify and hold the Community harmless for all damages and costs incurred due to any claim. The contractor shall provide compensation in the event of any action, claim or proceeding brought against the contracting authority by a third party as a result of damage caused by the contractor during the performance of the contract. In the event of any action brought by a third party against the contracting authority in connection with the performance of the contract, including any alleged breach of intellectual property rights, the contractor shall assist the contracting authority. Such expenditure incurred by the contractor may be borne by the contracting authority.
- II.3.5 The contractor shall take out an insurance policy against risks and damage relating to the performance of the contract, if required by the relevant applicable legislation. It 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 contracting authority should it so request.

# **ARTICLE II.4 - CONFLICT OF INTEREST**

- **II.4.1** The contractor shall take all the necessary measures to prevent any situation of conflict of interest. Such situation arises where the impartial and objective performance of the contract is compromised for reasons involving economic interest, political or national affinity, family or emotional ties, or any other shared interest.
- **II.4.2** Any situation constituting or likely to lead to a conflict of interest during the performance of the contract shall be notified to the contracting authority in writing without delay. The contractor shall immediately take all the necessary steps to rectify the situation. The contracting authority reserves the right to verify that the steps taken are appropriate and may require that additional steps be taken within a specified deadline.
- II.4.3 The contractor declares that it 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, when such advantage constitutes an illegal practice or involves corruption, either directly or indirectly, in so far as it serves as an incentive or reward relating to the performance of the contract.
- **II.4.4** The contractor shall pass on all the relevant obligations in writing to its personnel and to any natural person with the power to represent it or take decisions on its behalf and ensure that it is not placed in a situation which could give rise to conflicts of interest. The contractor shall also pass on all the relevant obligations in writing to third parties involved in the performance of the contract including subcontractors.

# ARTICLE II.5 – CONFIDENTIALITY

**II.5.1** The contracting authority and the contractor shall treat with confidentiality any information and documents, in any form, disclosed in writing or orally in relation to the performance of the contract and identified in writing as confidential.

The contractor shall:

- (a) not use confidential information and documents for any purpose other than fulfilling its obligations under the contract without prior written agreement of the contracting authority;
- (b) ensure the protection of such confidential information and documents with the same level of protection it uses to protect its own confidential information, but in no case any less than reasonable care;
- (c) not disclose directly or indirectly confidential information and documents to third parties without prior written agreement of the contracting authority.
- **II.5.2** The confidentiality obligation set out in Article II.5.1 shall be binding on the contracting authority and the contractor during the performance of the contract and for five years starting from the date of the payment of the balance unless:
- (a) the disclosing party agrees to release the other party from the confidentiality obligation earlier;
- (b) the confidential information becomes public through other means than in breach of the confidentiality obligation, through disclosure by the party bound by that obligation;
- (c) the disclosure of the confidential information is required by law.
- **II.5.3** The contractor shall obtain from any natural person with the power to represent it or take decisions on its behalf, as well as from third parties involved in the performance of the contract, an undertaking that they will comply with the confidentiality obligation set out in Article II.5.1.

# ARTICLE II.6 - PROCESSING OF PERSONAL DATA

- **II.6.1** Any personal data included in the contract shall be processed pursuant to Regulation (EC) 45/2001 of the European Parliament and of the Council of 18 December 2000 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 by the data controller solely for the purposes of the performance, management and monitoring of the contract without prejudice to its possible transmission to the bodies charged with monitoring or inspection tasks in application of Community and Union law.
- **II.6.2** The contractor shall have the right to access its personal data and the right to rectify any such data. The contractor should address any queries concerning the processing of its personal data to the data controller.
- **II.6.3** The contractor shall have right of recourse at any time to the European Data Protection Supervisor.
- **II.6.4** 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 rights.
- **II.6.5** The contractor shall grant its personnel access to the data to the extent strictly necessary for the performance, management and monitoring of the contract.

- **II.6.6** 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 gaining access to computer systems processing personal data, and especially:
    - (i) unauthorised reading, copying, alteration or removal of storage media;
    - (ii) unauthorised data input, as well as any unauthorised disclosure, alteration or erasure of stored personal data;
    - (iii) unauthorised use 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 authority;
  - (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.

# ARTICLE II.7 - SUBCONTRACTING

- **II.7.1** The contractor shall not subcontract without prior written authorisation from the contracting authority nor cause the contract to be de facto performed by third parties.
- **II.7.2** Even where the contracting authority authorises the contractor to subcontract to third parties, it shall nevertheless remain bound by its contractual obligations and shall be solely responsible for the proper performance of this contract.
- **II.7.3** The contractor shall make sure that the subcontract does not affect rights and guarantees granted to the contracting authority by virtue of this contract, notably by Article II.18.

# ARTICLE II.8 – AMENDMENTS

- **II.8.1** Any amendment to the contract shall be made in writing before fulfilment of any new contractual obligations and in any case before the date of payment of the balance.
- **II.8.2** The amendment may not have the purpose or the effect of making changes to the contract which might call into question the decision awarding the contract or result in unequal treatment of tenderers.

# ARTICLE II.9 – ASSIGNMENT

- **II.9.1** The contractor shall not assign the rights, including claims for payments, and obligations arising from the contract, in whole or in part, without prior written authorisation from the contracting authority.
- **II.9.2** In the absence of such authorisation, or in the event of failure to observe the terms thereof, the assignment of rights or obligations by the contractor shall not be enforceable against the contracting authority and shall have no effect on it.

# ARTICLE II.10 – OWNERSHIP OF THE RESULTS - INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS

#### **II.10.1 Definitions**

In this contract the following definitions apply:

- (1) 'results' means any intended outcome of the performance of the contract which is delivered and finally accepted by the contracting authority.
- (2) 'creator' means any natural person who contributed to the production of the result and includes personnel of the contracting authority or a third party.
- (3) 'pre-existing rights' means any industrial and intellectual property rights, including background technology, which exist prior to the contracting authority or the contractor ordering them for the purpose of the contract execution and include rights of ownership and use by the contractor, the creator, the contracting authority and any third parties.

#### II.10.2 Ownership of the results

The ownership of the results shall be fully and irrevocably acquired by the Community under this contract including any rights in any of the results listed in this contract, including copyright and other intellectual or industrial property rights, and all technological solutions and information contained therein, produced in performance of the contract. The contracting authority may exploit them as stipulated in this contract. All the rights shall be acquired by the Community from the moment the results are delivered by the contractor and accepted by the contracting authority. Such delivery and acceptance are deemed to constitute an effective assignment of rights from the contractor to the Community.

The payment of the price as set out in the order forms or specific contracts is deemed to include any fees payable to the contractor in relation to the acquisition of ownership of rights by the Community including all forms of use of the results.

The acquisition of ownership of rights by the Community under this contract covers all territories worldwide.

Any intermediary sub-result, raw data, intermediary analysis made available by the contractor cannot be used by the contracting authority without the written consent of the contractor, unless the contract explicitly provides for it to be treated as a self-contained result.

#### II.10.3 Licensing of pre-existing rights

The Community shall not acquire ownership of the pre-existing rights.

The contractor shall license the pre-existing rights on a royalty-free, non-exclusive and irrevocable basis to the Community which may use the pre-existing right as foreseen in Article I.8.1 or in order forms or specific contracts. All the pre-existing rights shall be licensed to the Community from the moment the results were delivered and accepted by the contracting authority.

The licensing of pre-existing rights to the Community under this contract covers all territories worldwide and is valid for the whole duration of intellectual property rights protection.

#### II.10.4 Modes of exploitation

The Community shall acquire ownership of each of the results produced as an outcome of this contract which may be used for any of the following purposes:

- (a) giving access upon individual requests without the right to reproduce or exploit, as provided for by Regulation 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents;
- (b) storage of the original and copies made in accordance with this contract;
- (c) archiving in line with the document management rules applicable to the contracting authority.

# II.10.5 Identification and evidence of granting of pre-existing rights and rights of third parties

When delivering the results, the contractor shall warrant that they are free of rights or claims from creators and third parties including in relation to pre-existing rights, for any use envisaged by the contracting authority. This does not concern the moral rights of natural persons.

The contractor shall establish to that effect a list of all pre-existing rights and rights of creators and third parties on the results of this contract or parts thereof. This list shall be provided no later than the date of delivery of the final results.

In the result the contractor shall clearly point out all quotations of existing textual works. The complete reference should include as appropriate: name of the author, title of the work, date and place of publication, date of creation, address of publication on internet, number, volume and other information which allows the origin to be easily identified.

Upon request by the contracting authority, the contractor shall provide evidence of ownership or rights to use all the listed pre-existing rights and rights of third parties except for the rights owned by the Community.

This evidence may refer, inter alia, to rights to: parts of other documents, images, graphs, tables, data, software, technical inventions, know-how etc. (delivered in paper, electronic or other form), IT development tools, routines, subroutines and/or other programs ("background technology"), concepts, designs, installations or pieces of art, data, source or background materials or any other parts of external origin.

The evidence shall include, as appropriate:

- (a) the name and version number of a software product;
- (b) the full identification of the work and its author, developer, creator, translator, data entry person, graphic designer, publisher, editor, photographer, producer;

- (c) a copy of the licence to use the product or of the agreement granting the relevant rights to the contractor or a reference to this licence;
- (d) a copy of the agreement or extract from the employment contract granting the relevant rights to the contractor where parts of the results were created by its personnel;
- (e) the text of the disclaimer notice if any.

Provision of evidence does not release the contractor from its responsibilities in case it is found that it does not hold the necessary rights, regardless of when and by whom this fact was revealed.

The contractor also warrants that it possesses the relevant rights or powers to execute the transfer and that it has paid or has verified payment of all due fees including fees due to collecting societies, related to the final results.

#### II.10.6 Creators

By delivering the results the contractor warrants that the creators undertake not to oppose that their names be recalled when the results are presented to the public and confirms that the results can be divulged. Names of authors shall be recalled on request in the manner communicated by the contractor to the contracting authority.

The contractor shall obtain the consent of creators regarding the granting of the relevant rights and be ready to provide documentary evidence upon request.

#### II.10.7 Persons appearing in photographs or films

If natural, recognisable persons appear in a result or their voice is recorded the contractor shall submit a statement of these persons (or of the persons exercising parental authority in case of minors) where they give their permission for the described use of their image or voice on request by the contracting authority. This does not apply to persons whose permission is not required in line with the law of the country where photographs were taken, films shot or audio records made.

#### II.10.8 Copyright for pre-existing rights

When the contractor retains pre-existing rights on parts of the results, reference shall be inserted to that effect when the result is used as set out in Article I.8.1 with the following disclaimer: © - year — European Union. All rights reserved. Certain parts are licensed under conditions to the EU.

#### II.10.9 Visibility of Union funding and disclaimer

When making use of the results, the contractor shall declare that they have been produced within a contract with the Community and that the opinions expressed are those of the contractor only and do not represent the contracting authority's official position. The contracting authority may waive this obligation in writing.

#### ARTICLE II.11 – FORCE MAJEURE

II.11.1 'Force majeure' means any unforeseeable and exceptional situation or event beyond the parties' control which prevents either of them from fulfilling any of their obligations under the contract, which was not attributable to error or negligence on their part or on the part of subcontractors and which proves to be inevitable in spite of exercising due diligence. Any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a

relevant case of force majeure, as well as labour disputes, strikes or financial difficulties, cannot be invoked as force majeure.

- II.11.2 A party faced with force majeure shall formally notify the other party without delay, stating the nature, likely duration and foreseeable effects.
- **II.11.3** The party faced with force majeure shall not be held in breach of its contractual obligations if it has been prevented from fulfilling them by force majeure. Where the contractor is unable to fulfil its contractual obligations owing to force majeure, it shall have the right to remuneration only for the tasks actually executed.
- **II.11.4** The parties shall take all the necessary measures to limit any damage due to force majeure.

# ARTICLE II.12 – LIQUIDATED DAMAGES

The contracting authority may impose liquidated damages should the contractor fail to complete its contractual obligations, also with regard to the required quality level, according to the tender specifications.

Should the contractor fail to perform its contractual obligations within the time-limits set by the contract, then, without prejudice to the contractor's actual or potential liability or to the contracting authority's right to terminate the contract, the contracting authority may impose liquidated damages for each and every calendar day of delay according to the following formula:

 $0.3 \times (V/d)$ 

*V* is the amount specified in Article I.3.1;

d is the duration specified in Article I.2.3 expressed in calendar days.

The contractor may submit arguments against this decision within 30 days of receipt of the formal notification. In the absence of a reaction on its part or of written withdrawal by the contracting authority within 30 days of the receipt of such arguments, the decision imposing the liquidated damages shall become enforceable.

The parties 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 incurred due to failure to fulfil obligations which may be reasonably anticipated.

# ARTICLE II.13 – SUSPENSION OF THE PERFORMANCE OF THE CONTRACT

#### **II.13.1** Suspension by the contractor

The contractor may suspend the performance of the contract or any part thereof if a case of force majeure makes such performance impossible or excessively difficult. The contractor shall inform the contracting authority about the suspension without delay, giving all the necessary reasons and details and the envisaged date for resuming the performance of the contract.

Once the circumstances allow resuming performance, the contractor shall inform the contracting authority immediately, unless the contracting authority has already terminated the contract.

#### II.13.2 Suspension by the contracting authority

The contracting authority may suspend the performance of the contract or any part thereof:

- (a) if the contract award procedure or the performance of the contract prove to have been subject to substantial errors, irregularities or fraud;
- (b) in order to verify whether presumed substantial errors, irregularities or fraud have actually occurred.

Suspension shall take effect on the day the contractor receives formal notification, or at a later date provided in the notification. The contracting authority shall give notice as soon as possible to the contractor to resume the service suspended or inform the contractor that it is proceeding with the termination of the contract. The contractor shall not be entitled to claim compensation on account of suspension of the contract or of part thereof.

# ARTICLE II.14 – TERMINATION OF THE CONTRACT

#### II.14.1 Grounds for termination

The contracting authority may terminate the contract in the following circumstances:

- (a) if a change to the contractor's legal, financial, technical or organisational or ownership situation is likely to affect the performance of the contract substantially or calls into question the decision to award the contract;
- (b) if 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 contracting authority, taking into account Article II.8.2;
- (c) if the contractor does not perform the contract as established in the tender specifications or fails to fulfil another substantial contractual obligation;
- (d) in the event of force majeure notified in accordance with Article II.11 or if the performance of the contract has been suspended by the contractor as a result of force majeure, notified in accordance with Article II.13, where either resuming performance is impossible or the modifications to the contract might call into question the decision awarding the contract or result in unequal treatment of tenderers;
- (e) if the contractor is declared bankrupt, is being wound up, is having its 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;
- (f) if the contractor or any natural person with the power to represent it or take decisions on its behalf has been found guilty of professional misconduct proven by any means;
- (g) if the contractor is not in compliance with its 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 it is established or with those of the country of

the applicable law of this contract or those of the country where the contract is to be performed;

- (h) if the contracting authority has evidence that the contractor or natural persons with the power to represent it or take decisions on its behalf have committed fraud, corruption, or are involved in a criminal organisation, money laundering or any other illegal activity detrimental to the Union's or Community's financial interests;
- (i) if the contracting authority has evidence that the contractor or natural persons with the power to represent it or take decisions on its behalf have committed substantial errors, irregularities or fraud in the award procedure or the performance of the contract, including in the event of submission of false information;
- (j) if the contractor is unable, through its own fault, to obtain any permit or licence required for performance of the contract.

#### II.14.2 Procedure for termination

When the contracting authority intends to terminate the contract it shall formally notify the contractor of its intention specifying the grounds thereof. The contracting authority shall invite the contractor to make any observations and, in the case of point (c) of Article II.14.1, to inform the contracting authority about the measures taken to continue the fulfilment of its contractual obligations, within 30 days from receipt of the notification.

If the contracting authority does not confirm acceptance of these observations by giving written approval within 30 days of receipt, the termination procedure shall proceed. In any case of termination the contracting authority shall formally notify the contractor about its decision to terminate the contract. In the cases referred to in points (a), (b), (c), (e), (g) and (j) of Article II.14.1 the formal notification shall specify the date on which the termination takes effect. In the cases referred to in points (d), (f), (h), and (i) of Article II.14.1 the termination shall take effect on the day following the date on which notification of termination is received by the contractor.

#### II.14.3 Effects of termination

In the event of termination, the contractor shall waive any claim for consequential damages, including any loss of anticipated profits for uncompleted work. On receipt of the notification of termination, the contractor shall take all the appropriate measures to minimise costs, prevent damages, and cancel or reduce its commitments. The contractor shall have 60 days from the date of termination to draw up the documents required by the special conditions for the tasks already executed on the date of termination and produce an invoice if necessary. The contracting authority may recover any amounts paid under the contract.

The contracting authority may claim compensation for any damage suffered in the event of termination.

On termination the contracting authority may engage any other contractor to execute or complete the services. The contracting authority shall be entitled to claim from the contractor all extra costs incurred in this regard, without prejudice to any other rights or guarantees it may have under the contract.

# ARTICLE II.15 - REPORTING AND PAYMENTS

#### II.15.1 Date of payment

Payments shall be deemed to be effected on the date when they are debited to the contracting authority's account.

#### II.15.2 Currency

The contract shall be in euros.

Payments shall be executed in euros or in the local currency as provided for in Article I.5.

Conversion between the euro and another currency shall be made according to the daily euro exchange rate published in the *Official Journal of the European Union* or, failing that, at the monthly accounting exchange rate established by the European Commission and published on its website, applicable on the day on which the payment order is issued by the contracting authority.

#### II.15.3 Costs of transfer

The costs of the transfer shall be borne in the following way:

- (a) costs of dispatch charged by the bank of the contracting authority shall be borne by the contracting authority,
- (b) cost of receipt charged by the bank of the contractor shall be borne by the contractor,
- (c) costs for repeated transfer caused by one of the parties shall be borne by the party causing repetition of the transfer.

#### II.15.4 Invoices and Value Added Tax

Invoices shall contain the contractor's identification, the amount, the currency and the date, as well as the contract reference.

Invoices shall indicate the place of taxation of the contractor for value added tax (VAT) purposes and shall specify separately the amounts not including VAT and the amounts including VAT.

The contracting authority is, as a rule, exempt from all taxes and duties, including VAT, pursuant to the provisions of Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union.

The contractor shall accordingly complete the necessary formalities with the relevant authorities to ensure that the supplies and services required for performance of the contract are exempt from taxes and duties, including VAT exemption.

#### II.15.5 Pre-financing and performance guarantees

Pre-financing guarantees shall remain in force until the pre-financing is cleared against interim payments or payment of the balance and, in case the latter takes the form of a debit note, three months after the debit note is notified to the contractor. The contracting authority shall release the guarantee within the following month.

Performance guarantees shall cover performance of the service in accordance with the terms set out in the tender specifications until its final acceptance by the contracting authority. The amount of a performance guarantee shall not exceed the total price of the

Contract number: [complete]

contract. The guarantee shall provide that it remains in force until final acceptance. The contracting authority shall release the guarantee within a month following the date of final acceptance.

Where, in accordance with Article I.4, a financial guarantee is required for the payment of pre-financing, or as performance guarantee, it shall fulfill the following conditions:

- (a) the financial guarantee is provided by a bank or an approved financial institution or, at the request of the contractor and agreement by the contracting authority, by a third party;
- (b) the guarantor stands as first-call guarantor and does not require the contracting authority to have recourse against the principal debtor (the contractor).

The cost of providing such guarantee shall be borne by the contractor.

#### II.15.6 Interim payments and payment of the balance

The contractor shall submit an invoice for interim payment upon delivery of intermediary results, accompanied by a progress report or any other documents, as provided for in Article I.4 or in the tender specifications.

The contractor shall submit an invoice for payment of the balance within 60 days following the end of the period referred to in Article I.2.3, accompanied by a final progress report or any other documents provided for in for in Article I.4 or in the tender specifications.

Upon receipt, the contracting authority shall pay the amount due as interim or final payment within the periods specified in Article I.4, provided the invoice and documents have been approved and without prejudice to Article II.15.7. Approval of the invoice and documents shall not imply recognition of the regularity or of the authenticity, completeness and correctness of the declarations and information they contain.

Payment of the balance may take the form of recovery.

#### II.15.7 Suspension of the time allowed for payment

The contracting authority may suspend the payment periods specified in Article I.4 at any time by notifying the contractor that its invoice cannot be processed, either because it does not comply with the provisions of the contract, or because the appropriate documents have not been produced.

The contracting authority shall inform the contractor in writing as soon as possible of any such suspension, giving the reasons for it.

Suspension shall take effect on the date the notification is sent by the contracting authority. The remaining payment period shall start to run again from the date on which the requested information or revised documents are received or the necessary further verification, including on-the-spot checks, is carried out. Where the suspension period exceeds two months, the contractor may request the contracting authority to justify the continued suspension.

Where the payment periods have been suspended following rejection of a document referred to in the first paragraph and the new document produced is also rejected, the contracting authority reserves the right to terminate the contract in accordance with Article II.14.1(c).

#### II.15.8. Interest on late payment

On expiry of the payment periods specified in Article I.4, and without prejudice to Article II.15.7, the contractor is entitled to interest on late payment at the rate applied by the European Central Bank for its main refinancing operations in Euros (the reference rate), plus eight points. The reference rate shall be the rate in force on the first day of the month in which the payment period ends, as published in the C series of the *Official Journal of the European Union*.

The suspension of the payment periods in accordance with Article II.15.7 may not be considered as a late payment.

Interest on late payment shall cover the period running from the day following the due date for payment up to and including the date of actual payment as defined in Article II.15.1.

However, when the calculated interest is lower than or equal to EUR 200, it shall be paid to the contractor only upon request submitted within two months of receiving late payment.

# **ARTICLE II.16 - REIMBURSEMENTS**

- II.16.1 Where provided by the special conditions or by the tender specifications, the contracting authority shall reimburse the expenses which are directly connected with execution of the tasks on production of original supporting documents, including receipts and used tickets, or failing that, on production of copies or scanned originals, or on the basis of flat rates.
- **II.16.2** Travel and subsistence expenses shall be reimbursed, where appropriate, on the basis of the shortest itinerary and the minimum number of nights necessary for overnight stay at the destination.

#### **II.16.3** 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;

In addition, travel outside Community territory shall be reimbursed provided the contracting authority has given its prior written consent.

- **II.16.4** Subsistence expenses shall be reimbursed on the basis of a daily subsistence allowance as follows:
- (a) for journeys of less than 200 km for a return trip, no subsistence allowance shall be payable;
- (b) daily subsistence allowance shall be payable only on receipt of supporting documents proving that the person concerned was present at the destination;

- (c) daily subsistence allowance shall take the form of a flat-rate payment to cover all subsistence expenses, including meals, local transport which includes transport to and from the airport or station, insurance and sundries;
- (d) daily subsistence allowance shall be reimbursed at the flat rates specified in Article I.3;
- e) accommodation shall be reimbursed on receipt of supporting documents proving the necessary overnight stay at the destination, up to the flat-rate ceilings specified in Article I.3.
- **II.16.5** The cost of shipment of equipment or unaccompanied luggage shall be reimbursed provided the contracting authority has given prior written authorisation.
- **II.16.6** Conversion between the euro and another currency shall be made as specified in Article II.5.2.

# ARTICLE II.17 – RECOVERY

- **II.17.1** If an amount is to be recovered under the terms of the contract, the contractor shall repay the contracting authority the amount in question according to the terms and by the date specified in the debit note.
- II.17.2 If the obligation to pay the amount due is not honoured by the date set by the contracting authority in the debit note, the amount due shall bear interest at the rate indicated in Article II.15.8. Interest on late payments shall cover the period from the day following the due date for payment, up to and including the date when the contracting authority receives full payment of the amount owed.
  - Any partial payment shall first be entered against charges and interest on late payment and then against the principal amount.
- II.17.3 If payment has not been made by the due date, the contracting authority may, after informing the contractor in writing, recover the amounts due by offsetting them against any amounts owed to the contractor by the Union or by the European Atomic Energy Community or by calling in the financial guarantee, where provided for in Article I.4.

# ARTICLE II.18 - CHECKS AND AUDITS

**II.18.1** The contracting authority and the European Anti-Fraud Office may check or have an audit on the performance of the contract. It may be carried out either directly by its own staff or by any other outside body authorised to do so on its behalf.

Such checks and audits may be initiated during the performance of the contract and during a period of five years which starts running from the date of the payment of the balance.

The audit procedure shall be deemed to be initiated on the date of receipt of the relevant letter sent by the contracting authority. Audits shall be carried out on a confidential basis.

**II.18.2** The contractor shall keep all original documents stored on any appropriate medium, including digitised originals when they are authorised by national law and

under the conditions laid down therein, for a period of five years which starts running from the date of payment of the balance.

- **II.18.3** The contractor shall allow the contracting authority's staff and outside personnel authorised by the contracting authority the appropriate right of access to sites and premises where the contract is performed and to all the information, including information in electronic format, needed in order to conduct such checks and audits. The contractor shall ensure that the information is readily available at the moment of the check or audit and, if so requested, that information be handed over in an appropriate form.
- **II.18.4** On the basis of the findings made during the audit, a provisional report shall be drawn up. It shall be sent to the contractor, which shall have 30 days following the date of receipt to submit observations. The final report shall be sent to the contractor within 60 days following the expiry of that deadline.

On the basis of the final audit findings, the contracting authority may recover all or part of the payments made and may take any other measure which it considers necessary.

- **II.18.5** By virtue of Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspection carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities and Regulation (EC) No 1073/1999 of the European Parliament and the Council of 25 May 1999 concerning investigation conducted by the European Anti-Fraud Office (OLAF), the OLAF may also carry out on-the-spot checks and inspections in accordance with the procedures laid down by Community and Union law for the protection of the financial interests of the Community and Union against fraud and other irregularities. Where appropriate, the findings may lead to recovery by the contracting authority.
- **II.18.6** The Court of Auditors shall have the same rights as the contracting authority, notably right of access, for the purpose of checks and audits.

#### [Optional]

### Annex A - Statement of the contractor concerning rights to delivered results

I, [insert name of the authorised representative of the contractor] representing [insert name of the contractor], party to the contract [insert title and/or number of the contract] warrants that the contractor holds all transferred rights to the delivered [insert title and/or description of result] which is/are free of any claims of third parties.

The above mentioned results were prepared by [insert names of creators]. The creators transferred all their relevant rights to the results to [insert name of the entity that received rights from the creators] [through a contract of [insert date] [a relevant extract of which is] herewith attached.

The creators [received all their remuneration on [insert date]] [will receive all their remuneration as agreed within [complete] weeks from [delivery of this statement] [receipt of confirmation of acceptance of the work]. [The statement of the creators confirming payment is attached].

Date, place, signature

#### Annex B - Statement of creator / intermediary in delivery

of the [title of the result] within the Contract No [complete] concluded between the contracting authority and [name of the contractor(s)]

I, [insert name of the authorised representative of the intermediary] representing [insert name of the intermediary] state that I am the right holder of: [identify the relevant parts of the result] [which I created] [for which I received rights from [insert name]].

I am aware of the above contract, especially Articles I.8 and II.10 and I confirm that I transferred all the relevant rights to [insert name].

I declare that [I received full remuneration.] [I agreed to receive remuneration by [insert date]].

[I also confirm that I do not oppose my name being recalled when the results are presented to the public and confirm that the results can be divulged.]<sup>6</sup>

Date, place, signature

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<sup>&</sup>lt;sup>6</sup> Necessary for creators