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Pravna podrška pregovorima - Policy & Legal Advice Centre

## Terms of Reference (ToR) for a Short-Term assignment

<b>Technical assistance requested:</b>	1 (one) Senior Non-Key Expert in the area of Ch 15 – Energy; Nuclear safety and Radiation Protection - Authorisation of practices in medical application of radiation sources
<b>Project Title:</b>	Policy and Legal Advice Centre (PLAC III)
<b>Ref:</b>	EuropeAid/139295/DH/SER/RS
<b>Service Contract No.:</b>	(CRIS) 2018/404-529
<b>Main beneficiary:</b>	The Ministry of European Integration of the Republic of Serbia and the Negotiating Team
<b>Target Beneficiaries:</b>	Negotiating Group Ch. 15; Serbian Radiation and Nuclear Safety and Security Directorate (SRBATOM)
<b>Budget Line / Expert Category:</b>	One Senior Non-Key Expert
<b>Duration of the assignment:</b>	50 working days (WD), from October 2019 until December 2020 (50 WD SNKE)

### 1. Relevant background information

#### Background information in relation to PLAC III project:

The scope of PLAC III project is to provide support to relevant national institutions in charge of alignment of national legal acts with the Union *acquis* and to contribute to further building of capacities of relevant national structures for successful carrying out of accession negotiations.

The PLAC III project should achieve two results:

**RESULT 1** - Enhanced compatibility of national legislation with EU legislation and its effective implementation

**RESULT 2** - Enhanced capacities of the relevant national structures for successful carrying out of accession negotiations

In general, the project aims at fostering the process of accession negotiations of the Republic of Serbia by supporting the effective alignment of national legislation with the Union *acquis* and its implementation and by further building the capacities of involved carriers of the EU integration process in the Republic of Serbia. After completion of screening process in 2015, Serbian public administration has entered into much more demanding and obliging exercise of accession negotiations, whereby each step and every decision should result in approaching actual membership in the EU. For this scenario to happen in accordance with planned dynamics, preparedness, adequate institutional capacity of public administration with highly competent staff is of crucial importance. In the core period of the negotiations, PLAC III Project shall support domestic line institutions and the negotiating structures both in performance of quality operational work in relation to harmonisation process and in the effective coordination during various stages and phases in the process for different negotiation chapters.

## **2. Background information in relation to Chapter 15 – Energy; Radiation protection and nuclear safety area**

The general responsibilities of the Member States and competent authorities and other requirements for regulatory control, as required by the Directive are partially transposed into Serbian legal framework. According to the Screening Report, Chapter 15 - Energy (III.i.), Serbia will need to further adapt its national legislation to reach full alignment with Council Directive 2013/59/Euratom laying down Basic Safety Standards for Protection against the Dangers arising from Exposure to Ionising Radiation and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom, and 2003/122/Euratom.

In the third revision of National Programme for Adoption of the Acquis - NPAA, for the period 2018-2021, section 3.15.3, further improvements of the national legislation are planned to comply with requirements of EU *acquis* in the field of radiation protection and nuclear safety, i.e. with Council Directive 2013/59/Euratom. In this connection, new legislation is planned to be adopted by 2021 (Law – Q1 of 2019 and bylaws by Q4 of 2021).

In December 2018, the Law on Radiation and Nuclear Safety and Security (*Official Gazette of the Republic of Serbia, No. 95/18 and 10/19*) came into force. The law is partially harmonised with the Council Directive 2013/59/Euratom and a full harmonisation is expected in the next 2 years according to the NPAA. One of the most demanding parts for harmonisation in particularly the implementation and enforcement of the requirements of Directive 2013/59/Euratom is the establishment of the system for recognition of Medical Physics Experts (MPE). Another long-lasting and demanding, in terms of human capacity, activities is the estimation of population doses following Article 64 of Directive 2013/59/Euratom which prescribes that the distribution of individual dose estimates from medical exposure for radiodiagnostic and interventional radiology purposes is determined taking into consideration (where appropriate) the distribution by age and gender of the exposed and taking into account the European Commission issued publications on radiation protection in particularly the Radiation Protection (RP) series publication numbers. EC 2008, EC Radiation Protection 154: European Guidance on Estimating Population Doses from Medical X-Ray Procedure and European Commission, 2014. EC Radiation Protection 180: Medical Radiation Exposure of the European Population.

PLAC III assistance is needed to assist the Serbian Radiation and Nuclear Safety and Security Directorate (SRBATOM) to further harmonise with the EU requirements in the field of medical application of radiation sources, namely a support in drafting a Guidance on criteria for recognition of Medical Physics Experts (MPE) population, a support in drafting a methodology for estimation of population doses regarding article 64. Directive 2013/59, a support in drafting a Guidance for establishing Quality Assurance Programmes, and a support in drafting a Guidance for accidental and unintended exposures regarding article 63. Directive 2013/59. In this context 3-days workshop on a theme: Justification of practices and justification of non-medical imaging exposure will be very important to build the knowledge and the capacity of the Directorate.

## **3. Description of the assignment:**

### **3.1 Specific objectives**

The specific objective of this assignment is to assist the Serbian Radiation and Nuclear Safety and Security Directorate in further harmonisation of the Union requirements related to Radiation protection and nuclear safety area by drafting four documents (Guides and methodologies) as listed below:

- a) Drafting a proposal of the scheme for the formal recognition of MPE defining requirements for MPEs in sense of knowledge, training, and competence and developing criteria for recognition of Medical Physics Experts (MPE) as required by Articles 4, 14, 22.4.c (i) 57, 58, 59, 79 and 83 of the Council Directive 2013/59/Euratom taking into account national regulatory infrastructure in the field of medical application of radiation sources. (related bylaws and guides)
- b) drafting a Methodology for estimation of population doses from medical exposure for radiodiagnostic and

interventional radiology purposes conducted in the country following Article 64 of Directive 2013/59/Euratom, European Commission, 2008. EC Radiation Protection 154: European Guidance on Estimating Population Doses from Medical X-Ray Procedure and, European Commission, 2014. EC Radiation Protection 180: Medical Radiation Exposure of the European Population

- c) developing a Guidance for establishing Quality Assurance Programmes as required by Articles 4, 56, 60, 61, 63, 82, 83 of the Council Directive 2013/59/Euratom taking into account national regulatory infrastructure in the field of medical application of radiation sources.
- d) developing a Guidance for accidental and unintended exposures regarding Articles 63 and 96 of the Council Directive 2013/59/Euratom taking into account national regulatory infrastructure in the field of medical application of radiation sources in order to minimize the probability and magnitude of accidental and unintended exposures of individuals subject to medical exposures.

In addition, transfer of knowledge will be also given through 3 days interactive WS (the final duration and set up to be agreed in details during the expert's mission) on a theme: "Justification of practices and justification of non-medical imaging exposure" in order to further implement Articles 29, 69, 70, 81 and 83 of the Law referring to justification of the exposure for non-medical imaging purposes, the justification of a new class of radiation practice, justification of medical exposure, and further transpose and implement Articles 19, 20 (with Annex IV), 21, 22, 55 and 77 of the Council Directive 2013/59/Euratom in bylaws and through established procedures in practice expert support to SRBATOM is needed in conducting workshop that will cover especially (indicative themes):

- examples and practical experience of ways for formal justification of radiation practices
- examples and practical experience of ways for formal justification of practices involving consumer products
- examples and practical experience of ways for formal justification of practices involving medical exposures (as new types of practices before being generally adopted, as individual medical exposures)
- levels of justification in medical exposures on patient (three levels)
- role and responsibilities of referrer and practitioner in justification of individual medical exposures
- specific justification for medical radiological procedures as a part of a health screening programme

### **3.2 Requested services**

**The Senior NKE in the area of authorisation of radiation practices of medical application of radiation sources is expected to provide the following services:**

- a) To assist the beneficiary in drafting a Guidance on criteria for recognition of Medical Physics Experts (MPE) as required by Articles 4, 14, 22.4.c (i) 57, 58, 59, 79 and 83 of the Council Directive 2013/59/Euratom
- b) To assist the beneficiary in drafting and preparation of a Methodology for estimation of population doses as required by Article 64 of the Council Directive 2013/59/Euratom
- c) To assist the beneficiary in drafting a Guidance for establishing Quality Assurance Programmes as required by Articles 4, 56, 60, 61, 63, 82, 83 of the Council Directive 2013/59/Euratom
- d) To assist the beneficiary in drafting a Guidance for accidental and unintended exposures regarding Article 63 of Directive 2013/59/Euratom
- e) To prepare and hold a 3-days workshop on a theme: Justification of practices and justification of non-

medical imaging exposure

### 3.3 Output

The **Senior NKE** is expected to deliver the following outputs:

- a) A draft Guidance on criteria for recognition of Medical Physics Experts (MPE) as required by Articles 4, 14, 22.4.c (i) 57, 58, 59, 79 and 83 of the Council Directive 2013/59/Euratom
- b) A draft Methodology for estimation of population doses as required by Article 64 of the Council Directive 2013/59/Euratom
- c) A draft Guidance for establishing Quality Assurance Programmes as required by Articles 4, 56, 60, 61, 63, 82, 83 of the Council Directive 2013/59/Euratom
- d) A draft Guidance for accidental and unintended exposures regarding Article 63 of Directive 2013/59/Euratom
- e) 3-days workshop on a theme: Justification of practices and justification of non-medical imaging exposure held

### 3.4 Reporting

The **SNKE** shall provide the following reports by using the templates of the Project:

- **Final Mission Report**, no later than 1 week after completion of tasks under this assignment. This report will include description of all activities and outputs provided by the SNKE in the context of this assignment.
- A brief interim report - only upon a request of the PLAC III team: TL and/or KE 2

Submission of reports:

- Draft mission report shall be submitted to the Team Leader of the Project for review and comments at the end of the mission.
- Final version of the mission report reports prepared in the agreed quality shall be submitted to the Team Leader of the Project for a review, comments and the final approval.
- The reports shall be signed by the SNKE and the Team Leader, responsible for endorsing the reports.
- The reports and all prepared documents shall be submitted in a hard copy and electronic version to the Team Leader of the project.

### 3.5 Specifics

The selected SNKE shall work under the guidance and follow the instructions of the Team Leader. The SNKE shall collaborate with the project team, other experts involved and representatives of the relevant beneficiary institutions.

Each of the short-term missions, the timing and duration shall be agreed with the Beneficiary and the PLAC team prior to each planned mission.

### 3.6 Expert input

#### 3.6.1 Total working days

50 working days (WDs) in total have been planned for Senior Non-Key Expert for this assignment.

#### 3.6.2 Period of the assignment and Starting day

It is expected that the work will be performed in the period from October 2019 until December 2020 at latest and

starting, at the earliest, from 14 October 2019 onwards. However, the exact starting date will be agreed at a later stage.

### **3.6.3 Location/Place of assignment**

The SNKE has to deliver 100% of the input in Belgrade, Serbia.

### **3.6.4 Working language**

English

## **4. Expert's Profile - Senior NKE (50 WD):**

### **4.1 Qualifications and skills (25 points)**

- A level of education, which corresponds to completed university studies of at least 3 years attested by a diploma such as engineering, science or similar, relevant to the assignment
- Proficiency in English language
- Computer literacy
- Be proficient in report drafting
- Excellent communication and analytical skills
- Be independent and free from conflicts of interest in the responsibilities they take on

### **4.2 General professional experience (25 points)**

- At least 8 (eight) years of general postgraduate professional experience gained in a competent authority for authorisation of radiation practices in medical application of radiation sources, gained in an EU Member State, candidate or potential candidate country

### **4.3 Specific professional experience (50 points)**

- Postgraduate professional experience in transposition and/or implementation of the medical part of Council Directive 2013/59/Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation
- Proven postgraduate professional experience in the authorisation of radiation practices in medical application of radiation sources and/or management of the radiation protection system
- Knowledge of Serbian legal system would be an advantage

## **5. Applications**

Applications (EU format CV and application letter, both in English) need to be submitted by e-mail to [mbayard@dmiassociates.com](mailto:mbayard@dmiassociates.com) and [ehoward@dmiassociates.com](mailto:ehoward@dmiassociates.com) no later than September 13, 2019, 17:00 hrs, titled: "**Application for the position – Senior NKE in the area of Ch 15 – Nuclear Safety and Radiation Protection; Authorisation of radiation practices of medical application of radiation sources**".

References must be available on request. Only short-listed candidates will be contacted.

The Project is an equal opportunity employer. All applications will be considered strictly confidential.

Advertised posts are not available to civil servants or other officials of the public administration in the beneficiary country, Serbia.

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*Please note that all the pre-selected experts are requested to sign a Statement of Availability (SoA) in which they acknowledge and confirm their availability to accomplish this assignment within the indicated period, at the indicated starting date (if any) and within the number of working days requested.*

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For more information, please contact Project Manager at DMI Associates Marion Bayard: mail to [mbayard@dmiasociates.com](mailto:mbayard@dmiasociates.com) or Elizabeth Howard [ehoward@dmiasociates.com](mailto:ehoward@dmiasociates.com)