

**Project Fiche - 2008 IPA Horizontal Programme
on Nuclear Safety and Radiation Protection**

1. Basic information

- 1.1 CRIS Number:** 2008/020-349
1.2 Title: Health Protection in Relation to Medical Exposure
1.3 ELARG Statistical code: 03.64 - Nuclear Safety
1.4 Location: Croatia

Implementing arrangements:

1.5 Implementing Agency:

Central Finance and Contracting Agency
Ms Marija Tufekčić Programme
Authorising Officer Ulica grada
Vukovara 284 10000 Zagreb, Croatia

1.6 Beneficiary:

Main beneficiary:
State Office for Radiological and Nuclear Safety
Frankopanska1 1 16, HR - 10020 ZAGREB
Responsible person:
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Beneficiaries: public hospitals and public medical care institutions, State Office for Radiological and Nuclear Safety

Financing:

- 1.7 Overall cost (VAT excluded):** EUR 878 000
1.8 EU contribution: EUR 700 000
1.9 Final date for contracting: 3 years following the date of conclusion of the Financing Agreement.
1.10 Final date for execution of contracts: 2 years following the end date for contracting.
1.11 Final date for disbursements: 3 years following the end date for contracting.

2. Overall Objective and Project Purpose

2.1 Overall Objective:

Compliance with general principles and basic measures of the health protection of individuals against the danger of ionising radiation in relation to occupational and medical exposure in the process of implementing relevant *acquis communautaire*.

2.2 Project purpose:

Governmental bodies relevant to ionising radiation protection, public health care institutions and expert technical services capacity building for efficient evaluation of medical exposure and correct application of the justification and optimisation principles in relation to medical exposure. SORNS' personnel capacity building for evaluation of occupational exposure and intercomparison of technical service performance.

2.3 Link with AP/NPAA / EP/ SAA

1. National Programme for the Accession of the Republic of Croatia into the EU - 2007:

In 2006 the Croatian Government passed the Act on Ionising Radiation Protection and Safety of Ionising Radiation Sources as a basic regulation by which legislation in the field of protection against ionising radiation was largely aligned with the *acquis communautaire*, especially as regards measures of radiological safety of ionising radiation sources, i.e. the increase of operative safety when performing activities involving ionising radiation sources, as well as in the field of physical safety measures of ionising radiation sources. The drafting of secondary legislation is in process. This project will enable further alignment with the *acquis communautaire* in the field of radiation protection.

2. Stabilisation and Association Agreement between the Republic of Croatia, of the one part, and the European Communities and their Member States, of the other part (May 2001), Article 102 (Nuclear safety)

"The Parties will co-operate in the field of nuclear safety and safeguards. Cooperation could cover the following topics:

- upgrading the Croatian laws and regulations on nuclear safety and strengthening the supervisory authorities and their resources;
- radiation protection, including environmental radiation monitoring;
- radioactive waste management and, as appropriate, decommissioning of nuclear facilities;"

3. European Commission Avis (April 2004)

Chapter 22: Environment

"Regarding nuclear safety and radiation protection, Croatia has established a legal framework for different aspects concerning the basic safety standards, medical exposure and emergency preparedness. However, the transposition of the directives laying down the basic safety standards and on health protection in relation to medical exposure remains to be completed and further developed."

2.4 Link with MIPD

Nuclear safety and radiation protection are stipulated as one area of intervention in the Multi-beneficiary Multi-annual Indicative Planning document 2007-2009. Objective of assistance under the respective priority is the following "To facilitate the strengthening of public administration capacities in the radiation protection and nuclear area, particularly with regard to nuclear safety, radiation protection, radioactive waste management and emergency preparedness".

This project will directly contribute to the strengthening of public administration capacities in the radiation protection (radiation protection authority and other publicly funded bodies).

2.5 Link with National Development Plan:

Not applicable

2.6 Link with national/ sectoral investment plans:

Not applicable

3. Description of project

3.1 Background and justification:

According to the researches performed throughout the world medical exposure gives by far the largest contribution to the collective dose. Data published by the IAEA indicate that medical exposure contribute up to 97% of average doses received by population from the artificial sources of ionising radiation. In most EU Member States the greatest contribution to collective dose comes from computed tomography/CT (nearly 70%). The second largest contributor is the range of interventional procedures that are performed in place of surgery (Agency's publication *Nuclear Safety Review for the Year 2005*).

In the EU that issue is regulated by Council Directive 97/43/EURATOM of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom. At the present stage Croatia has transposed into national legislation cca 95% of the aforementioned Directive.

Regarding implementation, in Croatia ionising radiation protection infrastructure is in place. Regulatory authority is comprised of two governmental bodies: State Office for Radiological and Nuclear Safety (SORNS) and Ministry of Health and Social Welfare (MHSW). SORNS is responsible for licensing so it approves the carrying out of practices involving sources of ionising radiation, procurement, import, export, transport and transit of ionising radiation sources and authorises the use of ionising radiation sources. It also maintains and supervises records on ionising radiation sources and records concerning exposed workers, level of irradiation of exposed workers as well as the level of irradiation of persons subject to medical exposure and of other persons. MHSW is responsible for enforcement through its sanitary inspection.

Occupational exposure surveillance system in Croatia is in place. According to the Act on ionising radiation protection and safety of the ionising radiation sources the holder of the authorisation must ensure measuring of personal doses of exposed workers. Exposed workers are obliged to implement all the prescribed and standard self-protection measures against ionising radiation as well as measures for protection of other persons, to use protective devices and equipment for measuring personal doses. Therefore exposed workers are legally bounded to carry dosimeters. The measurement of personal doses is performed by approved technical services holding approval in the form of a decision issued by the State Office for Radiological and Nuclear Safety. SORNS maintains and supervises records of occupational exposure and provides dosimetric assessments of exposure of exposed workers.

In the EU countries this issue is regulated by Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers from ionizing radiation. This Directive is largely transposed into Croatian legislation.

SORNS is also in charge to keep and maintain records of doses of persons subject to medical exposure but this task is not carried out. In Croatia there is no evidence about the doses delivered to the patients from medical application of ionising radiation sources. Control of X - rays installations and nuclear medicine departments is performed annually by the approved expert technical services, but only radiotherapy departments conduct some sort of Quality Control. Quality Assurance is not regular feature of medical institutions.

Lack of the Quality Control equipment and know-how is preventing any effort to evaluate individual patient doses and contribution of medical exposures to the collective dose of the Croatian population. Majority of doctors have no idea as to the amount of radiation received by patients undergoing commonly requested investigations. This lack of awareness of the ionising radiation exposure level becomes particularly pertinent when the number of patients who receive inappropriate or repeated examinations is considered. Lacking the information on doses delivered to the patients in the course of diagnostic and therapeutic procedures, medical staff commits no effort to reduce the medical exposures. Doctors may often order more radiological investigations than they would if properly educated. Additionally, there is no patient awareness about the risks of unnecessary or repeated exposures to radiation. Patients do not understand and do not receive sufficient information about diagnostic and therapeutic procedures that they undergo. This lack of awareness of the nature of ionising radiation may result in refusal or, at the contrary, uncritical claim for some examination.

According to positive legislation in place, medical institutions have obligation to implement QA and QC protocols, but because of the lack of appropriate equipment and adequate knowledge this obligation is not performed.

In such circumstances the possibility to keeping patient doses as low as reasonably achievable is not feasible.

In the efforts to comply with general principles and basic measures of the health protection of individuals against the danger of ionising radiation in relation to medical exposure, international support to Croatian stakeholders dealing with radiation protection and medical exposure, particularly support in implementation of the Council Directive 97/43/EURATOM of 30 June 1997, is needed.

3.2 Assessment of project impact, catalytic effect, sustainability and cross border impact

Assessment of project impact and catalytic effect - The envisaged project impact is to improve the capacity of Croatian administrations dealing with radiation protection and medical institutions dealing with ionising radiation sources in order to build the system of health protection compliant to EU principles and measures. It will considerably contribute to that overall objective but further and continued efforts of Croatian administrations are needed to implement and eventually improve system of health protection in long term period.

Cross border impact- Envisaged project will assure medical service to the public in compliance with EU standards.

Sustainability - Implementation of the Quality Assurance programs will be a long process involving more hospitals and medical institutions than those approached in the framework of this project. As mentioned before, developed QA programs could be subject to further improvements when their implementation will take place.

Equipment procured throughout the project will be owned and provided for by the State Office for Radiological and Nuclear Safety. The equipment will be distributed to the public hospitals and medical institutions it will be used by doctors, physicists and technicians. Training on the equipment usage will be delivered to the appointed SORNS staff and SORNS staff will deliver the knowledge further to the medical staff in relevant institutions. Train-the-trainer system will ensure continuous use of equipment in public hospitals and other public health care institutions which will ensure proper and regular maintenance of the equipment.

Knowledge gained on technical service intercomparison will contribute to the efficient evaluation of occupational exposure and to the maintenance of quality system in technical services.

3.3 Results and measurable indicators:

1. Quality Assurance programmes, including quality control measures and patient dose assessment developed, promoted and implemented

1.1. Action Plan on quality management implementation both through equipment quality control and patient dose management developed

1.2. Written protocols for every type of standard radiological practice for each equipment (CT, mammography, fluoroscopy, conventional radiography and intervention radiology) established.

1.3. All relevant stakeholders personnel in protocol application trained

1.4 Measures for protection and improvement of quality in medical practice developed

Measurable indicators for result 1:

- Report on Action Plan development
- Number of protocols delivered
- Number of staff trained in protocol application
- Development of appropriate documentation (guidelines, training programs, written procedures)

2. Equipment for public hospitals and other public health care institutions procured

2.1 Equipment procured and installed

2.2. Training to use this equipment for appointed SORNS staff (train-the-trainers system) performed

Measurable indicators for result 2:

- Number of appropriate equipment installed
- Number of SORNS staff trained to use installed equipment

3. Public awareness about ionising radiation exposures particularly due to medical exposure strengthened

3.1. The information material on CT, mammography, fluoroscopy, conventional radiography and intervention radiology for the purpose of public education prepared

3.2. Public campaign carried out

3.3. The website on radiological protection of patients as focal point for information of population on this topic established

3.4. Workshops for doctors performing radiodiagnostic procedures aiming to increase in awareness among about radiation risks and the need to protect patients conducted

Measurable indicators for result 3:

- Number of public campaigns performed
- Number of workshops delivered to targeted groups

4. Evaluation of the doses delivered to patients and evaluation of their contributions to the collective doses from various specific radiological techniques (CT, mammography, fluoroscopy, conventional radiography, interventional radiology) performed

Measurable indicators for result 4:

- Number of doses measured

5. SORNS's personnel enabled for intercomparison of technical services performance related to occupational exposure

Measurable indicators for result 5:

- Manual on intercomparison developed
- Number of SORNS's personnel trained
- Intercomparison results and report

3.4 Activities:

1. Development, promotion and implementation of Quality Assurance programmes, including quality control measures and patient dose assessment: contract 1 - TA

1.1. Development of Action Plan on quality management implementation both through equipment quality control and patient dose management

1.2. Establishment of written protocols for every type of standard radiological practice for each equipment (CT, mammography, fluoroscopy, conventional radiography and intervention radiology)

1.3. Training of all relevant stakeholders personnel in protocol application

1.4 Development of measures for protection and improvement of quality in medical practice input

2. Procurement of equipment for public hospitals and other public health care institutions: contract 2 - Supply

2.1 Equipment procurement and installation (X-rays multimeters for all type of x-ray systems, Set of test devices for quality control of film processing and of radiographic and fluoroscopic units, Test phantom for comprehensive image quality and AEC performance testing control of mammographic X-ray installations, CT and conventional radiography, DAP meters)

2.2. Training to use this equipment for appointed SORNS staff (train-the-trainers system)

3. Strengthening public awareness about ionising radiation exposures particularly due to medical exposure: contract 1 - TA

3.1. Preparation of the information material on CT, mammography, fluoroscopy, conventional radiography and intervention radiology for the purpose of public education

3.2. Public campaign

3.3. Establishment of the website on radiological protection of patients as focal point for information of population on this topic

3.4. Workshops for doctors performing radiodiagnostic procedures aiming to increase in awareness among about radiation risks and the need to protect patients

4. Evaluation of the doses delivered to patients and evaluation of their contributions to the collective doses from various specific radiological techniques (CT, mammography, fluoroscopy, conventional radiography, interventional radiology): contract 1 - TA

4.1. Measurement of the doses delivered to the patients performed by medical staff in close cooperation with SORP staff

4.1. The doses delivered to patients via medical x - rays evaluated by SORNS's staff and SORNS appointed expert staff with the TA expert assistance

4.2. The contributions to the collective doses from various specific radiological techniques (CT, mammography, fluoroscopy, conventional radiography, interventional radiology) evaluated by TA expert

5. SORNS's personnel capacity building for intercomparison of technical services performance related to occupational exposure: contract 1 - TA

5.1. G&N analysis of the existing situation and development of the Action plan for improvement

5.2. Intercomparison manual on development

5.3. Training of the SORNS's personnel including study visit to the pre-selected CU country with well established intercomparison system

5.4. Intercomparison of the technical services performance in the field of occupational exposure done

3.5 Conditionality and sequencing:

Conditionality - The project results can be achieved if public hospitals and other public medical institutions are willing to participate in training sessions and to cooperate with SORNS. Therefore a written agreement between all relevant organisations is necessary before the project starts.

Sequencing - Project activity in relation to procurement of equipment (Activity 2.) will start at early stage because its realisation is necessary for performing evaluations of doses delivered to patients (Activity 4.). As it is not influencing start and progress of the activity in relation to Promotion and implementation of QA programmes (Activity 1.), both will be conducted in parallel. Activity 3, particular sub activities, will be conducted in the course of the whole project. Activity 5 will be conducted irrespective of other project activities during the last half-year of the project.

3.6 Linked activities

The International Atomic Energy Agency (IAEA) has approved technical assistance for a national project on Evaluation of Medical Exposure and Optimisation of Patient Protection in Medical Applications of Radiation (CRO 9/008), and regional project IAEA TC TSA 3 Radiological protection of patients and protection in medical exposure. These projects would be supplemental to the above mentioned project. The CRO 9/008 national project is closed and as a result it generated ground level information on patient exposure to X-ray examinations coming from conventional radiography and interventional radiography in representative medical centres in the country. The regional project TSA 3 is an ongoing project at present, and its relevant part is addressing estimation of patient exposure coming from mammography and CT examinations. It is foreseen that ground level data on patient exposure will be available by the end of this year.

If accepted, suggested EU project will have as a result increased quality in medical x-ray examinations compared to ground level information obtained from two IAEA projects, and QA programs implemented in medical institutions with proper equipment. The same staff from SORNS is involved in IAEA and suggested EU projects and will observe all three projects activities. Therefore, duplication of activities or equipment supplies shall thus be avoided.

According to the experience gained through above mentioned two IAEA projects, it has been decided within this project to focus on X-ray application in medical establishments and procurement of basic equipment needed for QA programme implementation in medical institutions. Nuclear medicine and radiotherapy issues will be addressed in future project if possible

3.7 Lessons learned

The lessons learned from the previous EU projects were mainly related with the need for preciseness preparation of the necessary documentation, dead-lines respecting and necessity of establishment of close cooperation with relevant institutions. Conclusions and recommendations from all on-going EU projects have been taken into account during the preparation phase and design of this project by identifying the managerial and other users' needs and from the methodological, organisational and technical aspect.

4. Indicative Budget (amounts in €)

Activities	TOTAL PUBLIC COST	SOURCES OF FUNDING											
		EU CONTRIBUTION				NATIONAL PUBLIC CONTRIBUTION					PRIVATE		
		Total	%*	IB	INV	Total	tVP	%*	Central	Re	IFI	Total	
Activity 1, 3., 4. and 5.	278,000	250,00	90	250,000		28,000		10	28,000			0	0
Contract 1													
Activity 2	600,000	450,000	75		450,000	150,000	j	25	150,000			0	0
Contract 2													
TOTAL	878,000	700,000	80	250,000	450,000	178,000		20	178,000			0	0

Amounts net of VAT

* expressed in % of the Total Public Cost

** compulsory for INV (minimum of 25 % of total EU + national public contribution) : Joint cofinancing (J) as the rule, parallel

co financing (P) per exception

*** expressed in % of the Total Cost (public + private)

5. Indicative Implementation Schedule (periods broken down per quarter)

Contracts	Start of Tendering	Signature of contract	Project Completion
Contract 1 - TA	4 th Quarter 2011	2 nd quarter 2012	2 nd quarter 2014
Contract 2 - Supply	4 th Quarter 2011	3 rd quarter 2012	3 rd quarter 2013

6. Cross cutting issues (where applicable)

6.1 Equal Opportunity

Based on the fundamental principles of promoting equality and combating discrimination, participation in the project will be guaranteed on the basis of equal access regardless of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation.

All contractors shall be requested to provide monitoring data recording the participation of men and women in terms of expert inputs (in days) and of trainees benefiting under the project (in days) as an integral component of all project progress reports.

Participation will be open to both: female and male personnel. Records on staff participating in training and other project activities (e.g. project progress reports) will reflect this statement.

6.2 Environment

The project will not have any negative effects on the environment.

6.3 Minorities

Based on the fundamental principles of promoting equality and combating discrimination, participation in the project will be guaranteed on the basis of equal opportunity for minorities

ANNEXES

- 1- Log frame in Standard Format
- 2- Amounts contracted and Disbursed per Quarter over the full duration of Programme
- 3- Description of Institutional Framework
- 4 - Reference to laws, regulations and strategic documents:
 - Reference list of relevant laws and regulations
 - Reference to AP /NPAA / EP / SAA
 - Reference to MIPD
 - Reference to National Development Plan
 - Reference to national / sector investment plans
- 5- Details per EU funded contract

ANNEX 1: Logical framework matrix in standard format

LOGFRAME PLANNING MATRIX FOR Project Fiche		Programme name and number IPA: 2008 IPA Horizontal Programme on Nuclear Safety and Radiation Protection	2008/020-349
Health Protection in Relation to Medical Exposure		Contracting period expires: 3 years following the date of conclusion of the Financing Agreement	Disbursement period expires: 3 years following the end date for contracting
		Total budget: EUR 878 000	IPA budget: EUR 700 000
Overall objective Compliance with general principles and basic measures of the health protection of individuals against the danger of ionising radiation in relation to medical exposure in the process of implementing relevant <i>acquis communautaire</i>	Objectively verifiable indicators • Number of public hospitals and other public medical institutions where QA programs are implemented	Sources of Verification • QA audit reports • Inspection reports	
Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions
Governmental bodies relevant to ionising radiation protection, public health care institutions and expert technical services capacity building for efficient evaluation of medical exposure, and correct application of the justification and optimisation principles in relation to medical exposure	• Number of public hospitals and other public medical institutions where QA programs are developed • Reports on doses delivered to patients from different hospitals and cumulative report issued • Report on comparison of data on doses delivered to patients at the beginning and at the end of the project	• Project Final Report • SORNS Annual report • Hospitals' reports to SORNS	Public hospitals and other public medical institutions willing to participate and cooperate Further alignment with the <i>acquis communautaire</i> Further adequate provisions from state budget
Results 1. Quality Assurance programmes, including quality control measures and patient dose assessment developed, promoted and implemented 1.1. Action Plan on quality management implementation both through equipment quality control and patient dose management developed 1.2. Written protocols for every type of standard radiological practice for each equipment (CT, mammography, fluoroscopy, conventional radiography and intervention radiology) established 1.3. All relevant stakeholders personnel in protocol application trained 1.4. Measures for protection and improvement of quality in medical practice developed 2. Equipment for public hospitals and other public health care institutions procured 2.1. Equipment procured and installed 2.2. Training to use this equipment (train-the-trainers system) for SORNS staff performed	Objectively verifiable indicators • Report on Action Plan development • Number of protocols delivered • Number of staff trained in protocol application • Development of appropriate documentation (guidelines, training programs, written procedures) • Number of public campaigns performed • Number of workshops delivered to targeted groups • Number of appropriate equipment installed • Number of SORNS staff trained to use installed equipment	Sources of Verification • Project Progress Report • Annual Croatian report to IAEA • Training evaluation • Croatian Official Gazette • Public survey on radiation protection principles and measures results • Annual SORNS report • Supply contracts	Assumptions Enough skilled personnel in hospitals and other institutions available

<p>3. Public awareness about ionising radiation exposures particularly due to medical exposure strengthened 3.1. The information material on CT, mammography, fluoroscopy, conventional radiography and intervention radiology for the purpose of public education prepared 3.2. Public campaign carried out via advertising material 3.3. The website on radiological protection of patients as focal point for information of population on this topic established 3.4. Workshops for doctors performing radiodiagnostic procedures aiming to increase in awareness among about radiation risks and the need to protect patients conducted 4.Evaluation of the doses delivered to patients and evaluation of their contributions to the collective doses from various specific radiological techniques (CT, mammography, fluoroscopy, conventional radiography, interventional radiology) performed 5. SORNS's personnel enabled for intercomparison of technical services performance related to occupational exposure</p>	<ul style="list-style-type: none"> • Number of doses measured • Manual on intercomparison developed • Number of SORNS's personnel trained • Intercomparison results and report 	<ul style="list-style-type: none"> • Intercomparison report 	
<p>Activities 1. Development, promotion and implementation of Quality Assurance programmes, including quality control measures and patient dose assessment 1.1. Development of Action Plan on quality management implementation both through equipment quality control and patient dose management 1.2. Establishment of written protocols for every type of standard radiological practice for each equipment (CT, mammography, fluoroscopy, conventional radiography and intervention radiology) 1.3. Training of all relevant stakeholders personnel in protocol application 1.4 Development of measures for protection and improvement of quality in medical practice 2. Procurement of equipment for public hospitals and other public health care institutions 2.1. Equipment procurement and installation 2.2. Training to use this equipment (train-the-trainers system) for SORNS staff 3. Strengthening public awareness about ionising radiation exposures particularly due to medical exposure 3.1. Preparation of the information material on CT, mammography, fluoroscopy, conventional radiography and intervention radiology for the purpose of public education 3.2. Public campaign 3.3. Establishment of the website on radiological protection of patients as focal point for information of population on this topic 3.4. Workshops for doctors performing radiodiagnostic procedures aiming to increase in awareness among about radiation risks and the need to protect patients 4.Evaluation of the doses delivered to patients and evaluation of their contributions to the collective doses from various specific radiological techniques (CT, mammography, fluoroscopy, conventional radiography, interventional radiology) 4.1. Measurement of the doses delivered to the patients performed by medical staff in close cooperation with SORNS staff 4.1. The doses delivered to patients via medical x - rays evaluated by SORNS's staff and SORNS appointed expert staff with TA expert assistance</p>	<p>Means Activity 1., 3, 4. and 5 . contract 1 - Technical Assistance Activity 2. contract 2 - Supply contract</p>	<p>Costs EUR 278 000 EUR 600 000</p>	<p>Assumptions Active participation of relevant stakeholders in training sessions Timely and dully delivered equipment</p>

4.2. The contributions to the collective doses from various specific radiological techniques (CT, mammography, fluoroscopy, conventional radiography, interventional radiology) evaluated by TA expert

5. SORNS's personnel capacity building for intercomparison of technical services performance related to occupational exposure: contract 4 - TA

5.1. G&N analysis of the existing situation and development of the Action plan for improvement

5.2. Intercomparison manual on development

5.3. Training of the SORNS's personnel including study visit to the pre-selected CU country with well established intercomparison system

5.4. Intercomparison of the technical services performance in the field of occupational exposure done

Pre conditions:
- necessary resources
provided

ANNEX 2: amounts (in €) Contracted and disbursed by quarter for the project

Contracted	2012 Q1	2012 Q2	2012 Q3	2012 Q4	2013 Q1	2013 Q2	2013 Q3	2013 Q4	2014 Q1	2014 Q2	2014 Q3
Contract 1		100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	
Contract 2			600,000	600,000	600,000	600,000	600,000				
Contract 3		100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	100,000	
Contract 4		78,000	78,000	78,000	78,000	78,000	78,000	78,000	78,000	78,000	
Cumulated		278,000	878,000	878,000	878,000	878,000	878,000	878,000	878,000	878,000	
Disbursed											
Contract 1		15,000	15,000	15,000	15,000	50,000	50,000	50,000	75,000	100,000	
Contract 2			90,000	400,000	400,000	500,000	600,000				
Contract 3		15,000	15,000	15,000	15,000	50,000	50,000	50,000	75,000	100,000	
Contract 4		10,700	10,700	10,700	10,700	39,000	39,000	39,000	52,000	78,000	
Cumulated		40,700	130,700	440,700	440,700	639,000	739,000	739,000	802,000	878,000	

ANNEX 3: Description of Institutional Framework

The Beneficiary organisation will be State Office for Radiological and Nuclear Safety in cooperation public hospitals and other public medical care institutions.

The legal framework of the SORNS is defined on the Act on Radiological and Nuclear Safety ("Official Gazette" No. 28/10). The regulatory, inspection and technical tasks of the SORNS are to: approve the carrying out of nuclear activities,

- approve the carrying out of practices involving sources of ionising radiation,
- approve procurement, import, export, transport and transit of ionising radiation sources,
- authorise the use of ionising radiation sources,
- conduct independent safety analyses and issue decisions or certificates regarding the location, design, construction, operation and decommissioning of a facility in which a nuclear activity is to be performed,
- take part in the procedure for issuing location permits, building permits, permits for removal and in the procedure for issuing use permits for structures that accommodate sources of ionising radiation or in which practices involving sources of ionising radiation are carried out in accordance with *lex specialis*,
- approve and supervise the professional operations of authorised technical services and authorised experts for nuclear safety,
- organise and supervise, and where necessary also carry out tests on the presence of the type and intensity of ionising radiation in the environment, food and feed, medicinal products and general use products under regular conditions as well as in cases of suspected emergency,
- keep records on the licences, approvals, decisions and certificates which it has issued within the scope of its authority, and maintain and supervise records on ionising radiation sources, licensees and licence holders, beneficiaries, exposed workers, level of irradiation of exposed workers as well as the level of irradiation of persons subject to medical exposure and of other persons,
- carry out inspections to ensure the implementation of the provisions of this Act and regulations adopted on the basis thereof,
- elaborate technical platforms for teaching curricula and programmes for regular and additional education as well as for renewal of knowledge in the field of protection against ionising radiation,
- ensure expert assistance in implementing the national plan and programme for procedures in the event of a nuclear accident and emergencies connected with sources of ionising radiation,
- inform the mass media, competent bodies, organisations, associations and international institutions on emergencies connected with sources of ionising radiation,
- provide expert assistance and cooperation in activities for preventing illicit trafficking in nuclear and other radioactive material to state administration bodies competent for such activities,
- monitor safety conditions at nuclear power plants in the region and carries out assessments of the threat of nuclear accidents there, especially in the Krško Nuclear Power Plant in Slovenia and the Paks Nuclear Power Plant in Hungary,
- provide dosimetric assessments of exposure to ionising radiation of exposed workers, of the population from medical exposure and from exposure to ionising radiation originating from environmental radionuclides,
- fulfil the obligations which the Republic of Croatia has assumed through international conventions and bilateral agreements concerning protection against ionising radiation, nuclear safety and the application of protective

- measures aimed at the non-proliferation of nuclear weapons,
- cooperate with international and domestic organisations and associations in the area of protection against ionising radiation and nuclear safety, and appoint its own expert representatives to take part in the work of such organisations and associations or to monitor their work,
- coordinate technical cooperation with the International Atomic Energy Agency for all participants from the Republic of Croatia,
- stimulate and support scientific and research and development activities, encourage professional, statistic and other research in accordance with the demands and requirements of the development of nuclear safety and protection against ionising radiation in the Republic of Croatia,
- issue instructions for implementing international recommendations and standards in the area of protection against ionising radiation and nuclear safety and design the standards and methods in monitoring the state of protection against ionising radiation,
- carry out other activities under its competence pursuant to this Act, regulations adopted on the basis thereof, and other regulations.

There are three expert Sectors and three independent supporting organization units within the SORNS. The three Sectors are: Sector for Nuclear Safety, Sector for Activities with Ionizing Radiation Sources and Dosimetry and Sector for Inspection and Emergency Events. There are 25 employees currently working in SORNS and for the future it is planned to boost human resources up to 49 employees.

To ensure successful implementation of the project and all of its foreseen activities Project Implementation Unit is established and its members received Project Cycle Management and other relevant training.

ANNEX 4: Reference to laws, regulations and strategic documents

1. Council Directive 97/43/EURATOM of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure repealing Directive 84/466/Euratom
2. Act on Radiological and Nuclear Safety ("Official Gazette" No. 28/10)
3. Regulation on the methods and time intervals of the surveillance of the sources of ionising radiation, personnel monitoring, monitoring of exposure of the patients, on maintaining records and registers and on reporting (*Official Gazette No. 127/07*)
4. Ordinance on the conditions for application of ionising radiation sources in medicine and dentistry (*Official Gazette No. 125/06*)

ANNEX 5: Details per EU funded contract:

For *TA contracts*: account of tasks expected from the contractor

For activities 1. and 4. the contractor is expected to be able to fulfil the following requirements:

- The expert must have university degree in natural sciences or in medical field and at least 5 years of experience.
- The expert must have participated in at least 1 technical assistance project within the past five years. He/she must indicate that it contributed with minimum 70% to the project providing expertise in the field of:
 - Development and deployment of Quality Assurance programmes, including quality control measures and patient dose assessment.
- The expert must be familiar with QA programmes with particular regard to QA implementation in healthcare institutions.

For activities 3. the contractor is expected to be able to fulfil the following requirements:

- The expert must have university degree in social sciences and at least 5 years of experience
- The expert must have participated in at least 1 technical assistance project within the past five years. He/she must indicate that it contributed with minimum 70% to the project providing expertise in the field of:
 - Development and deployment of public awareness increase.
- He/she must have PR and advertising experience as well as event/workshops organisational experience, excellent social and communication skills
Web page design knowledge would be an asset or sub-contracting for web page design (activity 3.3.) is an acceptable option

For activities 5. the contractor is expected to be able to fulfil the following requirements:

- The expert must have university degree in natural sciences, background and knowledge in health physics and at least 10 years of working experience
- The expert must have at least 5 years of experience in intercomparison
- The expert must have participated in at least 1 technical assistance project within the past five years. He/she must indicate that it contributed with minimum 70% to the project providing expertise in the field of:
 - Development and deployment of intercomparison system.
- He/she must have experience in manual development, knowledge transfer and facilitating stakeholders participation

For *investment contracts*: reference list of feasibility study as well as technical specifications and cost price schedule + section to be filled in on investment criteria

- X-ray multimeters for CT, mammography, conventional radiography and interventional installations
- QC equipment for film processing
- Test phantoms for image quality and AEC performance testing of CT
- Test phantoms for image quality and AEC performance testing of mammography
- Test phantoms for image quality and AEC performance testing of conventional radiography and interventional installations
- DAP meters for patient dose calculations

Market study results are in the attached separate document (please refer to Market Analysis attachment).