

**Project Fiche – 2009 IPA Horizontal Programme
on Nuclear Safety and Radiation protection**

1. Basic information

- 1.1 CRIS Number:** 2009/021-640
1.2 Title: Reduction of Medical and Professional Exposure in Mammography
1.3 ELARG Statistical code: 03.64 - Nuclear Safety
1.4 Location: Bosnia and Herzegovina

Implementing arrangements:

1.5 Contracting Authority:

The European Union represented by the European Commission for and on behalf of Bosnia and Herzegovina.

1.6 Implementing Agency:

Not applicable.

1.7 Beneficiary (including details of project manager):

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Other beneficiaries:

State Regulatory Agency for Radiation and Nuclear Safety in Bosnia and Herzegovina
Ministry of Health of the Republic of Srpska, Ministry of Health of the Federation of Bosnia and Herzegovina.

Financing:

- 1.8 Overall cost (VAT excluded)¹:** EUR 495 000
1.9 EC contribution: EUR 386 000
1.10 Final date for contracting: No later than 31 March 2013
1.11 Final date for execution of contracts: No later than 31 March 2015
1.12 Final date for disbursements: No later than 31 March 2016

¹ The total cost of the project should be net of VAT and/or other taxes. Should this not be the case, the amount of VAT and the reasons why it should be considered eligible should be clearly indicated

2. Overall Objective and Project Purpose

2.1 Overall Objective:

To reduce medical and professional exposure in mammography screening while obtaining high-quality diagnostic information, in line with the *Council Directive 97/43 EURATOM* and the *European Guidelines for QA (Quality Assurance) in Breast Cancer Screening and Diagnosis*.

2.2 Project purpose:

To improve the fundamental aspects of mammography diagnostics and screening practice in Bosnia and Herzegovina through enhancement of the technical capacities in the diagnostic/screening centres in Bosnia and Herzegovina, primarily the two university clinical centres of Sarajevo and Banja Luka.

2.3 Link with AP/NPAA/EP/SAA

The Stabilisation and Association Agreement Between Bosnia and Herzegovina, and the European Communities and the Member States, stipulates under Article 107 that "Cooperation shall focus on priority areas related to the Community *acquis* in the field of energy, including, as appropriate, nuclear safety aspects..."

2.4 Link with MIPD

The IPA Multi-beneficiary Multi-annual indicative Planning Document (MIPD) 2009-2011², *section 2.3.3.11 - Nuclear Safety and Radiation Protection*, mentions that "all IPA eligible beneficiaries are facing radiological issues that are connected with the use of radionuclides for industrial and medical applications". It concludes that "radiological issues in the IPA beneficiaries should be addressed with the view to eventually transposing the *acquis* in the nuclear domain, including the international conventions to which the European Community is a party. This transposition would require a number of legislative and regulatory actions and would affect current management practices of radionuclides and radioactive materials".

2.5 Link with National Development Plan

Mid-term Development Strategy of Bosnia and Herzegovina (PRSP) 2004-2007 includes – among the others – Sector Priorities of *Health care, Environment and Information and Communication Technology*, precisely for the first two instances:

"V.3. SECTOR PRIORITIES – HEALTH CARE

1. Reform goals in the sector:

1.1. ensure a universally accessible, socially acceptable health care system based on the principles of solidarity and equity, ensuring access for various social groups (especially the poor) to a guaranteed basic package of health care rights and services,

1.2. ensure an efficient and transparent health care system focused on the promotion of health and the prevention of diseases,

² C(2009)4518 of 16 June 2009

1.3. *ensure a quality-oriented system with constant improvement of the quality of health care and clinical supervision,*

1.4. *ensure a system focused on health care needs, actively involving the interests and opinions of both patients and medical workers.”*

“V.7. *SECTORAL PRIORITIES – ENVIRONMENT*

1. *Goals:*

1.1. *Implement Environment Protection Action Plan BiH (NEAP)”*

2.6 Link with national/ sectoral investment plans

Ministries of Health in both the entities of Bosnia and Herzegovina have developed screening programmes awaiting wider implementation.

3. Description of project

3.1 Background and justification:

Article 9 of the Council Directive 97/43 requires the EU Member States to ensure that *“appropriate radiological equipment, practical techniques and ancillary equipment are used for the medical exposure:*

- *of children,*
- *as part of a health screening programme,*
- *involving high doses to the patient, such as interventional radiology, computed tomography or radiotherapy.*

Special attention shall be given to the quality assurance programmes, including quality control measures and patient dose or administered activity assessment, as mentioned in Article 8, for these practices.”

Article 7 explicitly mentions the importance of staff training:

“1. Member States shall ensure that practitioners and those individuals mentioned in Articles 5 (3) and 6 (3) have adequate theoretical and practical training for the purpose of radiological practices, as well as relevant competence in radiation protection.”

“3. Member States shall ensure that continuing education and training after qualification is provided and, in the special case of the clinical use of new techniques, the organization of training related to these techniques and the relevant radiation protection requirements.”

Article 8, dedicated to *Equipment*, states that *“Competent authorities shall take steps to ensure that necessary measures are taken by the holder of the radiological installation to improve inadequate or defective features of the equipment.”*

Article 11 of the same Council Directive requires the EU Member States to ensure that *“all reasonable steps to reduce the probability and the magnitude of accidental or unintended doses of patients from radiological practices are taken, economic and social factors being taken into account.*

In 2006 the European Commission issued the fourth edition of “European Guidelines for QA in Breast Cancer Screening and Diagnosis”. The Guidelines recognise that *“breast cancer is currently the most frequent cancer and the most frequent cause of cancer-induced deaths in women in Europe. ...Systematic early detection through screening,*

effective diagnostic pathways and optimal treatment have the ability to substantially lower current breast cancer mortality rates and reduce the burden of this disease in the population. In order that these benefits may be obtained, high quality services are essential.”

Ministries of Health of the Federation of Bosnia and Herzegovina (FBH) and the Republic of Srpska (RS) started mammography screening programmes. Unfortunately, little was done regarding reduction of patient doses, quality assurance and improvement of equipment.

According to estimates, more than 35 mammography units are currently in use in Bosnia and Herzegovina. Almost all of them use traditional film/screen imaging systems. It can be stated that, apart from clinical centres in Sarajevo and Banja Luka, no QA programme is established in medical institutions. The image quality, which is essential to mammography diagnostics and screening, is not monitored on a daily basis as it should be. Films are usually processed in automatic film processors for classical X-ray films. Apart from *a priori* inability to offer good enough viewing resolution, using plain X-ray films often brings to unnecessary repetition of examinations and/or increase of dose per patient. It is a serious issue in mammography screening since the vast majority of the patients screened are healthy women. With continuous increase in medical exposure of a broad population, chances of inducing secondary cancers as consequence of the examination itself increase too. Good image quality, necessary for early diagnosis of breast cancer, cannot be achieved through such systems.

Digitalization of equipment is a new approach in reduction of medical exposure in diagnostic radiology. Digital equipment reduces dose per image along with reducing the number of unnecessary exposures due to over- and underexposure. Apart from dose reduction, the enhanced contrast-and-resolution performance of the new equipment enables detecting micro-calcifications that may be signs of presence of a tumour and indicators of its benignity or malignance. The most up-to-date hardware and software solutions could help radiologists cope successfully with growing number of patients examined.

Sarajevo is the largest city in Bosnia and Herzegovina. The population in the region is more than 500 000. There is a need for increased capacity of mammography facilities. The purchase of new digital mammography unit will help patients, lower doses and increase image quality. Clinical Centre of Sarajevo University has capability for further additional education of medical staff through courses and other types of assistance.

In autumn of 2009 Faculty of Science of University of Sarajevo will organize post-graduate course on medical physics. It is essential that external lecturers help this process at the beginning. Newly recruited medical physicist will be responsible for QC (Quality Control) of radiological equipment, patient dose measurement and optimization (dose reduction) in radiology.

Another extremely important factor of reducing medical and occupational exposure in mammography is given by personnel training. Many radiologists need special education in mammography in order to be able to read off sensitive mammography images. University clinical centres could organize such education in near future. Also, education is needed for physicists that are supposed to conduct QC and patient dosimetry. They should be able to

implement a whole series of strategies aimed to dose reduction and creation of image quality improvement protocols in screening centres.

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

The project will contribute to systematically reduce medical and occupational exposure in mammography screening centres of Bosnia and Herzegovina. At the same time, it will lead to decisive improvement in health service because of improved quality of diagnostic imaging. The negative impact on the environment will be greatly reduced as chemical film processing will be eliminated and fewer films be used. Improved workflow and cost-effectiveness deserve to be mentioned as well.

The introduction of digital facilities (or CR digitalisation of the older analogue equipment) inevitably leads to dramatic improvement in the level of implemented IT technologies.

To ensure sustainability this project comprise a training component intended for the personnel who has to understand the new technologies/working processes.

There is no direct cross border impact. However, enhancement in mammography services as described in this project will provide excellent examples to follow for the other healthcare centres in the region.

3.3 Results and measurable indicators:

Results in relation with activity 1:

1. Personnel in relevant medical institutions trained in new method about radiation protection of staff and patients.
2. Educational material for the training of staff developed.
3. New procedures for QA/QC developed.
4. Written procedures on dose evaluation and reduction in mammography according to the article 4 of the Council Directive 97/43 EURATOM developed.
5. Technical specifications for supply drafted.

Measurable indicators in relation with activity 1:

- Number of educated personnel at local training courses, or fellowships at international mammography centres;
- Number of training courses;
- Number of tests;
- Number of presentations;
- Written materials for procedures on QA/QC in mammography available;
- Number of training courses for medical physicists;
- Number of trained medical physicists in QA/QC issues;
- Technical specifications available.

Results and measurable indicators in relation with activity 2:

1. The delivery of pieces of equipment in full compliance with the identification of the needs.
2. Number of staff trained to use the equipment.

3.4 Activities:

Activity 1: Service contract for assistance to the beneficiary institutions

- a) Run workshops for development of QA/QC procedures in mammography;
- b) Run workshops for development of dose reduction protocols in mammography;
- c) Conduct training courses for medical staff for the use of QA/QC equipment;
- d) Conduct training courses for medical staff for the use of digital mammography equipment;
- e) Conduct training courses for medical physicists for the use of QA/QC equipment;
- f) Supervision by external lecturers (at least 2 visits) for post-graduate course for medical physicists at the University of Sarajevo;
- g) Determination of the technical specifications of the equipment needed.

Activity 2: Supply contract for delivery of equipment needed for digitalization of existing mammography units, including training of staff to use equipment

- a) Supply of 2 CR software and hardware upgrades (CR equipment already exists made by two different manufacturers in Sarajevo and Banja Luka, respectively. Therefore, two different upgrades are needed.);
- b) Supply of 16 mammography CR plates (two different manufacturers for Sarajevo and Banja Luka);
- c) Supply of 2 computers with 2 mammography displays each with minimum 5 megapixel resolution;
- d) Repair of 1 digital stereotactic unit;
- e) Supply of mammography phantoms (at least 8);
- f) Supply of densitometers and sensitometers (at least 8);
- g) 1 new digital mammography unit in Sarajevo.

3.5 Conditionality and sequencing:

Delivery and installation of the equipment in full compliance with the identification of the needs prior to training of personnel.

The implementation of QA/QC procedures in mammography (under activity 1) requires the establishment and functioning of a regulatory body in charge of radiological issues in Bosnia and Herzegovina.

3.6 Linked activities:

Project is linked to the IAEA project BOH6011 “Strengthening Medical Physics Capacity in Diagnostic Radiology (Phase II)” and project BOH6012 “Establishing a Medical Radiation Physics Centre”. The project activities are related to quality control in diagnostic radiology with special attention to mammography, as well as education of medical physicists.

3.7 Lessons learned

Previous experience in implementation technical assistance projects in Bosnia and Herzegovina has shown that process of consultation with all relevant stakeholders is needed in initial stage of the project in order to provide support from all actors involved in the project.

4. Indicative Budget (amounts in EUR)

			SOURCES OF FUNDING									
			TOTAL EXPEND.	IPA COMMUNITY CONTRIBUTION		NATIONAL CONTRIBUTION					PRIVATE CONTRIBUTION	
ACTIVITIES	IB (1)	INV (1)	EUR (a)=(b)+(c)+(d)	EUR (b)	%(2)	Total EUR (c)=(x)+(y)+(z)	% (2)	Central EUR (x)	Regional/Local EUR (y)	IFIs EUR (z)	EUR (d)	% (2)
Activity 1	x		102 000	102 000	100							
Contract 1 - Service			102 000	102 000	100							
Activity 2		x	393 000	284 000	75	109 000	25					
Contract 2 - Supply			393 000	284 000	75	109 000	25					
TOTAL IB			102 000	102 000	100							
TOTAL INV			393 000	284 000	75	109 000	25					
TOTAL PROJECT			495 000	386 000	78	109 000	22					

Amounts net of VAT

- (1) In the Activity row use "X" to identify whether IB or INV
- (2) Expressed in % of the **Total** Expenditure (column (a))

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

Contracts	Start of Tendering	Signature of contract	Project Completion
Contract 1 – Service	Q3 2011	Q4 2011	Q4 2013
Contract 2 – Supply	Q1 2012	Q2 2012	Q3 2013

6. Cross cutting issues

6.1 Equal Opportunity

The issue of access is mainstreamed into the project and the design at the territorial level allows for a more targeted equal opportunity framework for addressing different institutions and patients all over the country thus giving equal opportunity to everybody to get better medical care.

6.2 Environment

Digitalization (by introducing either CR plates or Digital Mammography) renders mammography decisively more environment-friendly at least for these two reasons:

- Thanks to the image post-processing software techniques (allowing for extracting diagnostically valid information even out of over- and underexposed images), the number of repeated examinations strongly decreases, which leads to decreased number of films used.
- No more need for chemical film processing, which reduces/eliminates chemical pollution from radiology departments.

6.3 Minorities

Considering that the project will contribute to the overall development of society through better medical care it is expected that access of disabled and minorities groups (including Roma) to medical services would be improved.

ANNEXES

- I- Logical framework matrix in standard format
- II- Amounts (in EUR) contracted and disbursed per quarter over the full duration of the project
- III- Description of Institutional Framework
- IV - Reference to laws, regulations and strategic documents:
- V- Details per EC funded contract (where applicable)

ANNEX I: Logical framework matrix in standard format

LOGFRAME PLANNING MATRIX FOR Project Fiche	Programme name and number: 2009 IPA Horizontal Programme on Nuclear Safety and Radiation Protection	
Reduction of Medical and Professional Exposure in Mammography	Contracting period expires: No later than 31 March 2013	Disbursement period expires: No later than 31 March 2016
	Total budget : EUR 495 000	IPA budget: EUR 386 000

Overall objective	Objectively verifiable indicators	Sources of Verification	
To reduce medical and professional exposure in mammography screening while obtaining high-quality diagnostic information, in line with the Council Directive 97/43 EURATOM and the European Guidelines for QA in Breast Cancer Screening and Diagnosis.	Bosnia and Herzegovina State Agency for Radiation Protection and Nuclear Safety Agency reports on lower exposure of professionals dealing with mammography screening	Bosnia and Herzegovina State Agency for Radiation Protection and Nuclear Safety Agency annual reports	
Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions
To improve the fundamental aspects of mammography diagnostics and screening practice in Bosnia and Herzegovina through enhancement of the technical capacities in the diagnostic/screening centres in Bosnia and Herzegovina, primarily the two university clinical centres of Sarajevo and Banja Luka	Bosnia and Herzegovina State Agency for Radiation Protection and Nuclear Safety Agency reports on implementation of Directive 97/43 EURATOM article 4 of the Council	Bosnia and Herzegovina State Agency for Radiation Protection and Nuclear Safety Agency documentation Documentation of Clinical Centre Sarajevo and Banja Luka	
Results	Objectively verifiable indicators	Sources of Verification	Assumptions
<p>Activity 1 Personal in relevant medical institutions trained in new method about radiation protection of staff and patients.</p> <p>Educational material for the training of staff developed.</p> <p>New procedures for QA/QC developed. Written procedures on dose evaluation and reduction in mammography (article 4 of the Council Directive 97/43 EURATOM) developed.</p> <p>Technical specification for supply drafted</p>	<p>Number of educated personnel at local training courses, or fellowships at international mammography centres;</p> <p>Number of training courses</p> <p>Number of tests</p> <p>Number of presentations</p> <p>Written materials for procedures on QA/QC in mammography available;</p> <p>Number of trained medical physicists in QA/QC issues</p> <p>Technical specification available</p>	<p>Training reports</p> <p>Printed educational materials</p> <p>Bosnia and Herzegovina State Agency for Radiation Protection and Nuclear Safety Agency documentation Documentation of Clinical Centre Sarajevo and Banja Luka Hospital</p>	
<p>Activity 2 The delivery of pieces of equipment in full compliance with the identification of the needs.</p>	<p>Equipment installed</p> <p>Number of staff trained to use the equipment</p>	Provisional acceptance certificates	
Activities	Means	Costs	Assumptions
<p>Activity 1: Service contract for assistance to the beneficiary institutions</p> <p>a) Run workshops for development of QA/QC procedures in mammography,</p> <p>b) Run workshops for development of dose reduction protocols in mammography</p> <p>c) Conduct training courses for medical staff for the use of QA/QC equipment</p> <p>d) Conduct training courses for medical staff for the use of digital mammography equipment</p> <p>e) Conduct training courses for medical physicists for the use of QA/QC equipment</p> <p>f) Supervision by external lecturers (at</p>	TA contract	EUR 102 000	f) Post-graduate course organized as planned

<p>least 2 visits) for post-graduate course for medical physicists at the University of Sarajevo</p> <p>g) Determination of the technical specifications of the equipment needed.</p> <p>Activity 2: Supply contract for delivery of equipment needed for digitalization of existing mammography units</p> <p>a) Supply of 2 CR software and hardware upgrades (CR equipment already exists made by two different manufacturers in Sarajevo and Banja Luka, respectively. Therefore, two different upgrades are needed.)</p> <p>b) Supply of 16 mammography CR plates (two different manufacturers for Sarajevo and Banja Luka)</p> <p>c) Supply of 2 computers with 2 mammography displays each with minimum 5 megapixel resolution</p> <p>d) Repair of 1 digital stereotactic unit</p> <p>e) Supply of mammography phantoms (at least 8) ,</p> <p>f) Supply of densitometers and sensitometers (at least 8) ,</p> <p>1 new digital mammography unit in Sarajevo</p>	Supply contract	EUR 284 000
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ANNEX II: Amounts (EUR) contracted and disbursed per quarter over the full duration of the project (EC funded)

Contract ed	Q4 2011	Q1 2012	Q2 2012	Q3 2012	Q4 2012	Q1 2013	Q2 2013	Q3 2013	Q4 2013
Contract 1 - Service	102 000								
Contract 2 - Supply			284 000						
Cumulated	102 000	102 000	386 000	386 000	386 000	386 000	386 000	386 000	386 000
Disbursed									
Contract 1 - Service	80 000								22 000
Contract 2 - Supply				142 000				142 000	
Cumulated	80 000	80 000	80 000	222 000	222 000	222 000	222 000	364 000	386 000

Annex III Description of Institutional Framework

The new Law on Radiation Protection and Nuclear Safety in Bosnia and Herzegovina plans the establishment of a "state regulatory agency for radiation protection and nuclear safety with appropriate set of functions and responsibilities, and resources required for the establishment of regulatory control". According to article 26 of this Law, "within six months after this Act enters into force, the regulatory agency shall issue the regulations on radiation safety and nuclear safety, radioactive waste management, and on safe transportation of radioactive substances". This scope of the Law should cover both political entities, i.e. the Federation of Bosnia and Herzegovina and the Srpska Republic of Bosnia and Herzegovina. This agency should therefore be fully operational when the project starts, i.e. during the 3rd Q of 2009. In the Article 2, it is stated that the purpose of the Law is to: "Establish and maintain a regulatory programme for ionising radiation sources, and thereby ensure compatibility with international standards on safety of radiation sources and for protection against ionising radiation. "

Annex IV Reference to laws, regulations and strategic documents:

Law on Radiation Protection and Nuclear Safety in Bosnia and Herzegovina

Annex V Details per EC funded contract

Contract 1: A service contract for an amount of EUR 102 000 will be concluded following a tender that will be launched in Q3 2011. The Contractor is expected to fulfil all the activities listed in section 3.4 for activity 1 with the support of local partners established in Bosnia and Herzegovina. Technical specification for the equipment to be purchased under the supply contract will be drafted through technical assistance component.

Contract 2: A supply contract for an amount of EUR 284 000 will be concluded following a tender that will be launched in Q1 2012. Co-financing from the national budget of Bosnia and Herzegovina should be 25% of the total cost of the contract for the supply component (parallel co-financing).

The project will be tendered, awarded and implemented in accordance with the PRAG.