Standard Summary Project Fiche

Strengthening of administrative structures for radiation protection and safety use of ionizing radiation in diagnostics and therapy

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Strengthening of administrative structures for radiation protection and safety use of ionizing radiation in diagnostics and therapy

1. Basic Information

1.1 CRIS Number (Year 1): **2006/018-343.06.01**

1.2. Title: **Strengthening of administrative structures for radiation protection and safety use of ionizing radiation in diagnostics and therapy**

1.3. Sector: Environment

1.4. Location: Bulgaria

1.5. Duration: 18 months

2. Objectives

2.1.Overall Objective(s):

Strengthening of the administrative and institutional health care structures in Bulgaria in regard to the radiation protection, reduction of the radiation exposure of the population at medical use of ionizing radiation as required in the Medical Exposures Directive 96/29 EURATOM and the Medical Exposures Directive 97/43/EUROATOM, raising the level of the medical services and by this approaching a better quality of life.

2.2. Project purpose:

Increasing the safety use of ionizing radiation for medical purposes and effectiveness of early cancer diagnostics and treatment, applying comprehensive QA policy in diagnostic radiology, nuclear medicine and radiotherapy and innovation and enhancing the activity of the Secondary Standard Dosimetry Laboratory in accordance to the EC requirements.

2.3. Accession Partnership (AP) and NPAA priority (and implementing measures envisaged by the Action Plan for AP priorities related to strengthening administrative and judicial capacity)

Measures in favour of the improvement of the environment have been identified in the Accession Partnership 2003 as a short-term priority. The priorities for the Bulgarian authorities are:

– Update the overall assessment of the situation in the environment sector, including regarding the transposition of the EU *acquis*, in order to identify gaps to be filled in.

– Continue implementation of the *acquis* with particular emphasis on access to information, air quality, waste management, water quality, nature protection, industrial pollution and risk management as well as nuclear safety and radiation protection. Ensure that the environmental acquis, particularly the Environmental Impact Assessment Directive, is properly implemented in preparing large-scale infrastructure projects.

2.4. Contribution to National Development Plan (and/or Structural Funds Development Plan/SDP)

N/A

2.5. Cross Border Impact

N/A

3. Description

3.1. Background and justification:

Provisions for organisation of the state system for radiation protection in Bulgaria were set in the Order No 117 of 7th April 1964 of the Council of Ministers. The Ministry of Health was charged with the preparation of adequate regulations on the use of ionising radiation sources and the state supervision and control of such activities. In the seventies a number of legislative documents were issued regarding the different aspects of the radiation protection and safety use of radioactive materials. At this time the majority of sources of ionising radiation were x-ray generators and sealed γ-sources for application in medicine and in industry.

The licensed work sites for medical use of ionising radiation in Bulgaria are situated in big hospitals and ambulances with a lot of radiation sources. Due to the new economical changes the private medical practices using ionising sources increase continuously. Currently the equipment used in the hospitals includes:

- Diagnostic Radiology: more than 2000 machines and of them 120 Mammography units, 480 Dental, and 120 CT Scanners.
- Nuclear Medicine: 30 Linear Scanners, 10 planar Gamma Cameras and 8 SPECT Gamma Cameras
- Radiotherapy: Multi-mode accselerators – 2 LINACs; 11 Teletherapy (Cobalt 60) Units; 15 orthovoltage and 14 superficial X-ray therapy machines; Brachytherapy with 1 HDR remote afterloading unit (^{192}Ir) and 9 centers with manual afterloading (^{137}Cs for gynaecological applicators and ^{192}Ir wires for interstitial applications). The Ministry of Health has prepared a national strategy for modernization of radiotherapy by supply of linear accelerators, high dose rate brachytherapy equipment, computed tomography (CT) scanners and X-ray simulators.

At present, the matters of safety at work in nuclear and radiation facilities, and especially the problems concerning radiation and individual dose and health monitoring of occupationally exposed workers are regulated in accordance with the European Directives in the following acts, adopted by the Parliament:

- Act of the Safe Use of Nuclear Energy (*Promulgated in the State Gazette No. 63 of June 28, 2002*),
- Act on Health (*Promulgated in the State Gazette No. 70 of August 10, 2004*),
- Act on Safe Conditions of Labour.

The standards for the protection of individuals from the harmful effects of ionizing radiation are stated by the *Regulation for Basic Norms for Radiation Protection, promulgated in the State Gazette No.73 of August 20, 2004 stated by the* ***Governmental Decree No. 190*** from 30 July 2004, which is in accordance with the **Council Directive 96/29/EURATOM** (OJ L 159, 29. 6. 96).

The authorities having competence for development and implementation of legislation on radiation protection in Republic of Bulgaria are the Nuclear Regulatory Agency (NRA), the

National Centre of Radiobiology and Radiation Protection (NCRRP) under the Ministry of Health and the Ministry of Environment and Water (MEW).

The Council Directive 97/43/EURATOM for health protection of individuals against the dangers of ionizing radiation in relation to medical exposures is transposing into Bulgarian legislation by a new Ordinance of the Ministry of Health No30 from 31 October 2005 for Protection of Individuals at Medical Exposure, promulgated in State Gazette № 91 of November 15, 2005.

The Ministry of Health is charged with the organization, coordination and control over all activities directed towards protection of human health and assurance of healthy working conditions for the population. Concerning the problem of radiation protection and safety at the medical use of ionizing radiation, several institutions within the Ministry of Health such as the National Centre of Radiobiology and Radiation Protection (NCRRP) and the Inspectorates of Hygiene and Epidemiology, carry out preventive and routine control in the country.

The requirements of the Ordinance for Protection of Individuals at Medical Exposure based on the Council Directive 97/43 EURATOM has to meet a number of new activities and create new structures in order to be implemented until the end of 2007. This Ordinance stated new demands to radiological practices and set higher requirements to radiological equipment, which have not been previously included in the Bulgarian legislation. Introduction of these new requirements needs building up of new administrative structures, adequate training and qualification of professionals, which would be supported by some of the activities proposed in the present project.

The building of the administrative capacity to fulfil these objectives has started within the scope of the previous PHARE Project BG/2000/IB/EN 01-05 “Radiation Protection and Safety at the Medical Use of Ionizing Radiation”. As a result of this project Quality Assurance programmes in medical use of ionizing radiation were elaborated. These Programmes have to be realised into clinical practice in recent years. As stated in the Ordinance for Protection of Individuals at Medical Exposure within five years the radiological practice in the country should cover all EU requirements. The process of practical realisation of Quality control and Radiation Protection could be enforced by supply of necessary highly specialised equipment within the investment part of the present project.

One of the crucial points to fulfil the EU requirements remains the guaranteeing the accuracy of measuring devises for clinical dosimetry and for quality control in radiotherapy, nuclear medicine, diagnostic radiology and radiation protection as well as the traceability of the measurements to the National and International standards. These responsibilities are assigned to the National Secondary Standard Dosimetry Laboratory (SSDL) - unique for the country. It was established in late 70-thies to provide accuracy of the radiation treatment procedures by acceptance testing and calibration of radiotherapy units and to ensure metrologically the National system for individual dose monitoring in medicine as well in all other licensed radiation facilities incl. Nuclear Power Plant Kosloduy, This system includes approximately 14 000 persons. The radiation protection monitors are also under the SSDL periodical checks including approximately 800 dosemeters per year. Since 1980 the SSDL regularly takes part in IAEA/WHO TLD Postal Dose Quality Audit for high energy photons from cobalt-60 and Cs-protection level. The implementation of the requirements of EC Directive 97/43 EURATOM put new demands concerning Quality control of radiological equipment and patient dosimetry, new generation of control and measuring instruments and further introduction of dosimetric and calibration methods. All these imply further development of the SSDL.

Presently the SSDL works with more than 30 years old equipment and that is one of the reasons not to be accredited in the last years. This fact constrains the ensuring accuracy of

radiotherapy procedures and of the radiation protection measuring equipment. In this regard the SSDL urgently needs innovation by supply of modern calibration equipment and know-how transfer for updating the calibration methodology. This could be accomplished within the investment part of this project.

The following NGO's:

- Bulgarian Association of Radiology
- Bulgarian Society on Biomedical Physics and Engineering,
- Union of Scientists in Bulgaria
- Union of Physicists in Bulgaria
- Union of Scientific-medical Societies in Bulgaria
- Bulgarian Association of Radiobiology and Radiation Protection

have been consulted in the preparation phase of this proposal.

3.2. Sectoral rationale N/A

3.3. **Results**:

3.3.1– Building of modern and effectively operating National Secondary Standard Dosimetry Laboratory (SSDL) with the capacity to perform the following activities for:

- Calibration and metrological control of radiometers, dosemeters and quality control measuring devices for Radiotherapy, Nuclear Medicine, Diagnostic Radiology and Radiation Protection based on up to date methodology;
- Inter-comparison between radiotherapy treatment systems based on internationally approved advanced methods.
- Technological and methodological preparation for certification of the SSDL in accordance with national requirements.

3.3.2 – Developed system for quality audit in radiotherapy by:

- Creation of QA programme for all modalities used in radiotherapy;
- Pilot implementation of QA and QC procedures in a leading radiotherapy centre;
- Definition of scenarios for most probable accidental exposures in radiotherapy with corresponding emergency protocols.

3.3.3 – Optimised Radiation Protection of patients in Diagnostic Radiology and Nuclear Medicine by:

- Updating the previously established Diagnostic Reference Levels (DRL) in Diagnostic Radiography and Nuclear Medicine;
- Establishing new DRL for fluoroscopy guided procedures;
- Performing of a National Survey of Computed Tomography (CT) practice and establishing DRL in CT;
- Enlargement of national data base for patient dose monitoring including the number and frequency of X-ray examinations.
- Improving the methodology for estimation of the population radiation exposure due to medical procedures.

3.3.4 – Availability of the necessary equipment for calibration, radiation protection measurements and quality control by supply of:

- Measuring equipment for Quality Control and Radiation Protection in Diagnostic Radiology, Nuclear Medicine and Radiotherapy;
- Calibration and Measuring equipment for SSDL.

3.4. Activities:

3.4.1.1. Preparatory activities for SSDL modernization with long term training of three Bulgarian specialists in a partner SSDL for know-how transfer.
3.4.1.2. Definition and preparation of Technical Specifications
3.4.1.3. Supply of the necessary measurement and control equipment
3.4.1.4. Updating the methodology for calibration and metrological control of radiometers, dosimeters and quality control measuring devices used in Radiotherapy, Nuclear Medicine, Diagnostic Radiology and Radiation Protection on the base of the European and International standards.
3.4.1.5. Improvement of the methods for traceability of measurements and inter laboratory comparisons between radiotherapy treatment systems
3.4.1.6. Preparation and application for certification of SSDL in accordance with national institutional requirements.

3.4.2.1 Creation of a national protocol for Quality Control in radiotherapy
3.4.2.2. Development of QA programmes in radiotherapy
3.4.2.3. Set up of a national auditing group for QA in radiotherapy as to EC-standards
3.4.2.4. Pilot implementation of the QA and QC procedures in a leading radiotherapy centre
3.4.2.5. Drafting scenarios for most probable accidental exposures in radiotherapy and emergency action protocols.

3.4.3.1 Enlargement of the national survey as to the utilized methodology for measurement and evaluation of patient doses in conventional radiography
3.4.3.2. Review of the national survey on the applied activities and standards in NM
3.4.3.3. Setting a national survey of CT practice – defining methodology, performing measurements, dose assessment for the standard CT examinations
3.4.3.4. Updating the established DRL in Diagnostic Radiography and NM and determination of DRL in fluoroscopy guided procedures and CT.
3.4.3.5. Enlargement of the existing national data base for patient dose monitoring by elaboration of special sheet for collection of number and frequency of X-ray examinations.
3.4.3.6.Improving the methodology for estimation of the radiation burden of the population due to medical exposure.

The means for the realisation of these activities shall be:

- Twinning contract – 0.7 mln. euro from Phare budget)
- Supply contract – 3 mln. euro (2.25 mln. euro from Phare budget and 0.75 from national co-financing)

3.5. Linked activities:

The Ministry of Health has been responsible for the implementation of the PHARE Project BG/2000/IB/EN 01-05 “Radiation Protection and Safety at the Medical Use of Ionizing Radiation”. Its wider objective was to assist in transposing and implementing the requirements of the Basic Safety Standards Council Directive 96/29/EURATOM and Council Directive 97/43/EURATOM for health protection of individuals against the dangers of ionizing radiation in relation to medical exposures by improving the institutional and administrative framework. During the project a draft of Ordinance for patient protection from medical exposure has been prepared; a large scale national patient dose survey in Diagnostic Radiology has been conducted and as a result national reference patient dose levels were elaborated. A national

data base has been prepared for monitoring the patient dose in the country. Quality control programmes were elaborated for all three areas of medical use of ionizing radiation and a pilot project for their practical implementation. New programmes for education and training in radiation protection have been designed for different groups of specialists involved into the medical exposure. A public awareness campaign has been conducted for the risk and benefit from the medical use of radiation. As a result of the project a big step has been done toward the enhancement of the quality of diagnosis and treatment and radiation protection at medical use of ionizing radiation in Bulgaria.

The present project submitted for PHARE 2006 AP Environment is proposed as a direct continuation of the above mentioned project BG/2000/IB/EN 01-05 and it envisages the full implementation of the Council Directive 97/43 EURATOM into radiological practice mainly focused on QA and Radiation Protection in Radiotherapy and enhancing the nation system for metrological assurance of radiological practices.

3.6. Lessons learned:

The new Ordinance for Protection of Individuals at Medical Exposure is fully transposing the requirement of Council Directive 97/43 EURATOM has to be fully implemented into practice in the recent years.

During the previous project new methods for patient dose measurements in Diagnostic Radiology have been introduced and on this basis for the first time National reference levels for certain radiographic practices in Bulgaria have been determined. A concept for a national data base for patient dose monitoring has been developed within the previous project that needs to be expanded further covering new modalities like CT and fluoroscopy.

This project is also aimed to set up a QA system for radiotherapy as well as a system for inter-comparison between treatment systems as a mean of increasing the effectiveness of cancer treatment. The QA system will be based on QA programme elaborated in the framework of the previous PHARE project and included as obligatory requirement in the Ordinance for Protection of Individuals at Medical Exposure.

A very serious problem remains guaranteeing the accuracy of measuring devises for clinical dosimetry and for quality control in radiotherapy, nuclear medicine, diagnostic radiology and radiation protection because the present situation at the unique for the country Second Standard Dosimetry Laboratory is critical concerning the available equipment and staff. In this regard certain activities are planned for the technological and methodological innovation of the National Secondary Standard Dosimetry Laboratory by supply of modern calibration equipment and know-how transfer of expertise.

4. Institutional Framework

The National Centre of Radiobiology and Radiation Protection is responsible for the organization and methodology, research, prevention, control, and diagnostics and treatment activities in the field of radiation protection of the population. The NCRRP has four departments: Radiation Protection, Radiation Control, Radiobiology, and Radiation Medicine. As a result of the former Project a new Laboratory at the NCRRP for Radiation Protection in Medicine has been established. Recently the Secondary Standard Dosimetry Laboratory has been included in the administrative structure of NCRRP. The five Radiation Protection Inspectorates are regionally structured and work under the methodological guidance of the NCRRP. Within the Ministry of Health they are responsible for the performing of radiation control in health care facilities.

The SSDL and the Laboratory for Radiation Protection in Medicine at the NCRRP as well as Oncological Centres in Sofia, Stara Zagora, Plovdiv, Shumen, Russe, Veliko Tarnovo, Vratza, Varna, Gabrovo, Pleven and the Medical University Hospitals in Sofia, Plovdiv, Varna, Pleven and are the target objects of the present project.

The project is to be implemented under the direct control and supervision of a Steering Committee. The Committee will comprise of members from the Ministry of Health, National Centre of Radiobiology and Radiation Protection, MoEW, CFCU, the EC Delegation in Sofia and from other institutions.

With the aim to prepare, co-ordinate the necessary activities and consequently implement the elaborated documents and decisions in practice a Working group will be established.

Different kinds of experts (practitioners, scientists, etc.) from the diverse institutions and NGO´s concerned will support the respective Working group, with relevant information and tools and coordination when implementing methods and procedures. The experts will closely collaborate with the twinning partner.

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5. Detailed Budget

	Phare/Pre-Accession Instrument support	**Co-financing**			**Total Cost**
€M		**National Public Funds (*)**	**Other Sources** *(**)*	**Total Co-financing of Project**	
Year 2006 - Investment support jointly co funded					
Contract 2 Supply of equipment	*2.250*	*0.750*		*0.750*	*3.0*
Investment support – sub-total	*2.250*	*0.750*		*0.750*	*3.0*
% of total public funds	***max 75 %***	***min 25 %***			
Year 2006 Institution Building support					
Contract 1	*0.700*	***		***	*0.700*

Twinning covenant					
IB support	*0.700*	***		***	*0.700*
Total	**2 950**			**0.750**	**3.700**

(*) contributions from National, Regional, Local, Municipal authorities, FIs loans to public entities, funds from public enterprises

(**) private funds, FIs loans to private entities

(***) Up to 10% of the Twinning project will be covered from the national budget through the National Fund Directorate at the Ministry of Finance. Phare and national co-financing will be tendered and contracted jointly.

6. Implementation Arrangements

6.1.Implementing Agency

The CFCU will be the Implementing Agency responsible for tendering, contracting and accounting with assisting in good project design and implementation and Phare procurement and payment rules. The CFCU (Ministry of Finance) is in charge of the contracting and financial management of the project.

Mrs. Gergana Beremska from the State Treasure, Ministry of finance will act as PAO of the project. Her contact details are:
Mrs. Gergana Beremska
State Treasure, Ministry of finance
102, "Rakowski" St.
1040 Sofia
Tel.: +359 2 9859 24 90
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6.2. Twinning

The Ministry of Health will be the body responsible for the day to day management of the project, for technical preparation and control.

MoH contact point:
Mihail Abrashev
Management of Projects and Programmes Directorate
Address: Ministry of Health
39, Alexander Stamboliyski Blvd
1000 Sofia, Bulgaria
Tel: + 359 2 9301203
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The twinning partner shall assure to the project long- and short-term senior experts, working continuously on site for the following periods of time:

The RTA for Phase 1 and Phase 2 should have experience in: implementing the legislation in radiation protection in practice and quality assurance and technologies are required.

The twinning partner is expected to provide a team of experts having acquired at least 15 years experience in a relevant central administrative structure of a Member-State, good familiarity with EU Environmental Acquis, knowledge and skills in quality assurance, dosimetry and radiation protection in Radiotherapy, Nuclear Medicine and Diagnostic Radiology, in calibration at a SSDL level as well as practical experience in implementation and management in the relevant fields.

Profile of the short and medium term experts

Short and medium term experts shall have experience in medical radiation physics applied to Radiotherapy, Nuclear Medicine and Diagnostic Radiology, particularly in:

- performing and supervising dosimetry and radiation calibrations at the level of secondary laboratories and in SSDL operation.
- performing and supervising quality assurance programmes in radiotheraphy and in organisation of quality audit;
- performing patient dose measurements for different modalities in Diagnostic Radiology and realisation of national patient dose survey with establishment of DRL

The experts will verify the technical specifications for the equipment needed prepared by the Bulgarian part and shall have experience in definition and preparation of technical specifications.

As English will be the working language, all experts are required to be fluent in English.

The responsible person for twinning arrangement at MoH is:

Mihail Abrashev, MD
Chief Expert
Management of Projects and Programmes Directorate
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6.3. Non-standard aspects

The PRAG Procedure will strictly be followed.

6.4. Contracts

Contract 1- Twinning contract	0.7 MEUR
Contract 2- Supply contract	3.0 MEUR

The contract for supply includes a respective training of the staff under the supervision of the appropriate RTA with regard to the operation and maintenance of the equipment, envisaged under the project.
Following the contract, the Partner has to organize a visit in a Secondary Standard Dosimetry Laboratory in Western Europe according to the best SSDL-practises within the project implementation as well as to ensure appropriate construction, installation and

operation of the new SSDL and calibration of the corresponding measurement and control devices according to the international standards.

7. Implementation Schedule

Contract 1 - Twinning Starts of tendering – October 2006 Start of project activities- April 2007 Completion – March 2008
Contract 2 – supply investment support The technical specifications for the equipment will be prepared by Bulgarian experts. Under Project preparation facility (PPF), these TS will be subsequently reviewed by an external expert (PPF). The required assistance is also aimed to prepare a need assessment for the supply of all kind of equipment at all levels. The agenda for this activity is as follows: May 2006: creation of expert group to prepare first draft of the technical specifications June 2006: first draft ready July 2006: Terms of Reference for PPF submitted for approval October 2006: Contracting the PPF December 2006: finalized technical specifications Start of tendering/call for proposals: January 2007 Start of project activity (sign contract) November 2007 Project Completion: April 2008

8. Equal Opportunity

All participating Bulgarian institutions are equal opportunity employers. No discrimination of whatever nature will be applied.

9. Environment

The supplies will be delivered into existing premises. No environmental impact is expected and the supply of equipment does not require any sort of environmental assessment. The specifications will take into account the respective standards and norms applicable for IT systems.

10. Rates of return

The equipment will not generate incremental costs related to the current running of the laboratories. Staff and premises exist and are running. It will nevertheless generate additional income thanks to the increased quantity/type of samples per year. Non-tangible benefits will be related to increased human health protection.

11. Investment criteria

11.1 Catalytic effect:

The Phare contribution will accelerate the implementation of the radiation protection and safety policy and of the relevant legal framework..

11.2 Co-financing:

Twenty five percent of the project costs-for the equipment part will be financed through National public funds

11.3 Additionality:

The Phare contribution shall not displace other financiers.

11.4 Project readiness and size:

Technical specifications and tender documentation will be ready at the time of the signature of the Financing Memorandum.

11.5 Sustainability:

Sustainability of project results is assured through the need and commitment by Bulgaria to implement its radiation protection and safety policy in diagnostics and therapy. No new institutions or laboratories will be created. Staff increase (or decrease) is not expected as a result of the project. All supported investment actions (supplies) are sustainable in the long term beyond the date of Accession. They will comply with the EU norm and standards (accredited), and will be coherent with the sector policies of the EU. Future maintenance and operation costs will be covered by the Bulgarian national budget.

11.6 Compliance with state aids provisions

All investments will respect the state aid provisions of the Europe Agreement.

11.7 Contribution to NDP and/or Structural Funds Development Plan/SPD

Not applicable.

12. Conditionality and sequencing

Projects to be implemented through twinning require the full commitment and participation of the senior management of the beneficiary institutions. In addition to providing the twinning partner with adequate staff and other resources to operate effectively, the senior management will be whole-heartedly involved in the development and implementation of the policies and institutional change required delivering the project results. Commitment in this sense has already been taken.

The technical specifications for the measurement equipment will be prepared by Bulgarian experts in June 2006. These will subsequently be reviewed by an external contracted expert (PPF) in October-November 2006. The PPF expert will also prepare a need assessment for the equipment to be procured under the supply component.

The supply for the measurement equipment will be initiated after the PPF has been contracted and detail precise Technical Specifications prepared to specify and verify the precise equipment needs.

ANNEXES TO PROJECT FICHE

1. Logframe in standard format (compulsory) for each project

2. Detailed implementation chart (compulsory for year 1, optional for future years)
3. Contracting and disbursement schedule**,** by quarter, for full duration of project (including disbursement period) (compulsory for year 1)
4. For all projects: reference list of feasibility/pre-feasibility studies, indepth ex ante evaluations or other forms of preparatory work. For all investment projects, the executive summaries of economic and financial appraisals, environmental impact assessments, etc, should be attached (compulsory)
5. Reference list of relevant laws and regulations (compulsory)
6. Reference list of relevant strategic plans and studies (may include institution sector strategies, development plans, business development plans, etc) (compulsory)
7. Needs Analysis

ABBREVIATIONS

NCRRP - National Centre of Radiology and Radiation Protection
SSDL - Secondary Standard Dosimetry Laboratory
NRA - Nuclear Regulatory Agency
MoEW - Ministry of Environment and Water
MH - Ministry of Health
QA - Quality Assurance
QC - Quality Control
RP - Radiation Protection
DR - Diagnostic Radiology
NM - Nuclear Medicine
RT - Radiotherapy
CT - Computed Tomography
DRL - Diagnostic Reference Levels

Annex 1
Logframe

	Programme name and number:	
PROJECT: **Strengthening of administrative structures for radiation protection and safety use of ionizing radiation in diagnostics and therapy**	**Contracting period expires: November 2008**	**End of execution of contracts: November 2009**
	Total budget: : 3.7 MEuro	Phare budget 2,95MEuro

Overall objectives(s)	**Objectively verifiable indicators**	**Sources of verification**	
Strengthening of the administrative and institutional health care structures in Bulgaria in regard to the radiation protection, reduction of the radiation exposure of the population at medical use of ionizing radiation as required in the EC Basic Safety Standards 96/29 EUROTOM and the Medical Exposures Directive 97/43/EUROATOM, raising the level of the medical services and by this approaching a better quality of life.	• Achieved EC standards for radiation protection at medical use of ionizing radiation; • Applied Quality assurance structure in Radiotherapy, Nuclear Medicine and Diagnostic Radiology	• Annual reports from MH and MoEW according to the harmonized legislation • Reports from the Steering Committee • NCRRP	
Project purposes	**Objectively Verifiable Indicators**	**Sources of Verification**	Assumptions
Increasing the safety use of ionizing radiation for medical purposes and effectiveness of early cancer diagnostics and treatment, applying comprehensive QA policy in diagnostic radiology, nuclear medicine and radiotherapy and innovation and enhancing the activity of the Secondary Standard Dosimetry Laboratory in accordance to the EC requirements.	• Legislation documents implemented • QA and QC programmes implemented in special fields of Diagnostic Radiology and radiotherapy • National Diagnostic Reference Levels elaborated • SSDL activity enhanced	• MoEW • MH, NCRRP • EU-Delegation	•
Results	**Objectively Verifiable Indicators**	**Sources of Verification**	**Assumptions**
R1 – Modernized and effectively operating National Secondary Standard Dosimetry Laboratory (SSDL) R2 – Developed system for quality audit in radiotherapy R3 – Optimised Patient Radiation Protection in Diagnostic Radiology and Nuclear Medicine by means of the Diagnostic Reference Levels (DRL) R4 - Availability of the necessary measurement, calibration and control equipment	• One methodology for calibration and metrological control of dosemeters used in Radiotherapy- April-June 2008 • One methodology for calibration and metrological control of dosemeters used in Radiation Protection – Febr-Oct 2007 • One methodology for calibration and metrological control of dosemeters and quality control measuring devices used in	MoEW MH, NCRRP Regular progress reports Reports from working groups Reports from Steering Committee	- Adequate expertise is provided -Support from other institutions concerned

	Diagnostic Radiology – Febr-Oct 2007 • One methodology for inter-comparison between radiotherapy treatment systems – June-Oct 2007. • QA programme for radiotherapy, implemented in one reference radiotherapy centre – May-Oct 2007 • List of instructions for action at accidental exposures in radiotherapy – July-Oct 2007 • Updated DRL's for eight radiography procedures and for most frequently performed NM-examinations - May-Oct 2007 • Established new DRL for three fluoroscopy guided procedures – July-Oct 2007; • National Survey of Computed Tomography (CT) practice (at least 30 scanners) and established DRL for ta least three CT-examinations – Febr-Oct 2007; • Enlarged national data base for patient dose monitoring including the number and frequency of X-ray examinations – March-Oct 2007. • Methodology for estimation of the population radiation exposure due to medical procedures (based on improved conversion coefficients) – March-Oct 2007. • Availability of the necessary measurement, calibration and control equipment – Jan-July 2007		
Activities	**Means**	**Costs**	**Assumptions**
A1.1.Preparatory activities for SSDL modernization with long term training of three Bulgarian specialists in a partner SSDL for know-how transfer. A1.2. Definition and preparation of Technical Specifications	• Twinning contract - 0.7 mln. euro from Phare budget)	Regular progress reports to Delegation Twinning reports Independent Monitoring	Inter ministerial and institutional co-operation

A1.3. Supply of the necessary measurement and control equipment A1.4. Updating the methodology for calibration and metrological control of radiometers, dosimeters and quality control measuring devices used in Radiotherapy, Nuclear Medicine, Diagnostic Radiology and Radiation Protection on the base of the European and International standards. A1.5. Improvement of the methods for traceability of measurements and inter laboratory comparisons between radiotherapy treatment systems A1.6. Preparation and application for certification of SSDL in accordance with national institutional requirements. A2.1 Creation of a national protocol for Quality Control in radiotherapy A2.2. Development of QA programmes in radiotherapy A2.3. Set up of a national auditing group for QA in radiotherapy as to EC-standards A2.4. Pilot implementation of the QA and QC procedures in a leading radiotherapy centre A2.5. Drafting scenarios for most probable accidental exposures in radiotherapy and emergency action protocols. A3.1 Enlargement of the national survey as to the utilized methodology for measurement and evaluation of patient doses in conventional radiography A3.2. Review of the national survey on the applied activities and standards in NM A3.3. Setting a national survey of CT practice – defining methodology, performing measurements, dose assessment for the standard CT examinations A3.4. Updating the established DRL in Diagnostic Radiography and NM and determination of DRL in fluoroscopy guided procedures and CT. A3.5. Enlargement of the existing national data base for patient dose monitoring by elaboration of special sheet for collection of number and frequency of X-ray examinations. A3.6.Improving the methodology for estimation of the radiation burden of the population due to medical exposure.	• Supply contract - 3 mln. euro (2.25 mln. euro from Phare budget and 0.75 from national co-financing)	Reports Minutes of meetings with Working Groups	

			Preconditions - PPF contact signed - Technical specification of the equipment ready and confirmed

Annex 2

DETAILED IMPLEMENATION CHART

	2006							2007										
Activities	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N
A1.1.Preparatory activities for SSDL modernization with long term training of three Bulgarian specialists in a partner SSDL for know-how transfer.																		
A1.2. Definition and preparation of Technical Specifications																		
A1.3. Supply of the necessary measurement and control equipment																		
A1.4. Updating the methodology for calibration and metrological control of radiometers, dosimeters and quality control measuring devices used in Radiotherapy, Nuclear Medicine, Diagnostic Radiology and Radiation Protection on the base of the European and International standards.																		
A1.5. Improvement of the methods for traceability of measurements and inter laboratory comparisons between radiotherapy treatment systems																		
A1.6. Preparation and application for certification of SSDL in accordance with national institutional requirements.																		
A2.1 Creation of a national protocol for Quality Control in radiotherapy																		
A2.2. Development of QA programmes in radiotherapy																		
A2.3. Set up of a national auditing group for QA in radiotherapy as to EC-standards																		
A2.4. Pilot implementation of the QA and QC procedures in a leading radiotherapy centre																		
A2.5. Drafting scenarios for most probable accidental exposures in radiotherapy and emergency action protocols																		
A3.1 Enlargement of the national survey as to the utilized methodology for measurement and evaluation of patient doses in conventional radiography																		

A3.2. Review of the national survey on the applied activities and standards in NM																		
A3.3. Setting a national survey of CT practice – defining methodology, performing measurements, dose assessment for the standard CT examinations																		
A3.4. Updating the established DRL in Diagnostic Radiography and NM and determination of DRL in fluoroscopy guided procedures and CT.																		
A3.5. Enlargement of the existing national data base for patient dose monitoring by elaboration of special sheet for collection of number and frequency of X-ray examinations																		
A3.6.Improving the methodology for estimation of the radiation burden of the population due to medical exposure.																		
Reports										R1			R2			R3		R4

Annex 3

CONTRACTING AND DISBURSEMENT SCHEDULE

Contracts	2006												2007												2008											
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D
Contract 1 Twinning										T	T	T	T	T	T	C	I	I	I	I	I	I	I	I	I	I	I	E								
Contract 2 Supply													T	T	T	T	T	T	T	T	T	T	C	I	I	I	I	I	E							

T-Tendering, C- Contracting, I- Implementing, E- End

Cumulative contracting schedule by quarter in M Euro								
	2007				2008			
	1q	2q	3q	4q	1q	2q	3q	4q
Twinning contract	0.000	0.700	**0.700**	**0.700**	**0.700**	**0.700**	**0.700**	**0.700**
Supply contract	0.000	0.000	0.000	**3.000**	**3.000**	**3.000**	**3.000**	**3.000**
Total contracted:	**0.000**	**0.700**	**0.700**	**3.700**	**3.700**	**3.700**	**3.700**	**3.700**
Cumulative disbursement schedule by quarter in M Euro								
Twinning contract	0.000	**0.560**	**0.560**	**0.560**	**0.560**	**0.700**	**0.700**	**0.700**
Supply contract	0.000	0.000	0.000	**1.800**	**2.700**	**3.000**	**3.000**	**3.000**
Total disbursed:	**0.000**	**0.560**	**0.560**	**2.360**	**3.260**	**3.700**	**3.700**	**3.700**

Annex 4. Financial appraisals for the investment project

List of equipment for the National Center of Radiobiology and Radiation Protection, for the Oncological centers and for the Medical University Hospitals in Bulgaria

Investment support					
No	Item	Unit price (Eur)	Quantity	Total (Eur)	
A. QC and RP equipment					
1	Mammography imaging phantom for accrediatation and CT	1000	1	1000	
2	CT imaging phantom for accreditation and QC	10000	1	10000	
3	X-ray analyser options for CT	5000	5	25000	
5	Additional accessories for X-ray measurement kits	4000	5	20000	
4	Storage dewar and withdrawal device for liquid nitrogen	2000	1	2000	
6	Isotope calibrators	8000	5	40000	
7	Phantoms for NM	8000	5	40000	
8	Calibration sources	2000	5	10000	
9	National monitoring data base	60000	1	60000	
10	Electronic personal dosemeters	500	20	10000	
11	Direct individual dose control device for DR and NM	2000	20	40000	
12	TL dosimetry system for personal dose monitoring and options	80000	1	80000	
13	Whole body contamiination system	40000	1	40000	
14	Beta/gamma contamination monitor	2000	10	20000	
15	Portable area spectroscopic surveymeter	5000	7	35000	
16	RP-control for neutrons	4000	3	12000	
19	Area surveymeter for gama- and beta- radiation for RT	4000	11	44000	489000
B. QA in radiotherapy					
16	Dosimetry systems incl.special ionizing chambers	20000	5	100000	
17	Set of Ionisation chambers for radiotheraphy	15000	5	75000	
18	Electric test device for dosimeters	2000	3	6000	
19	Tissue characterization phantoms for CT	10000	4	40000	
20	Multifunctional fantom for calibration and verification of TPS	5000	11	55000	
21	Treatment planning systems	35000	9	315000	
22	Positioning & immobilization systems	50000	11	550000	1141000
C. SSDL-equipment					
23	Calibration benches incl. filters & control	200000	2	400000	
24	X-ray generator	210000	1	210000	
25	Radiation source calibration irradiator	60000	1	60000	
26	Checking sources, incl. 242-Am,137-Cs,60-Co	5000	6	30000	
27	Dosimetry system incl.spec.ionizing chambers	35000	2	70000	
28	Mobile measur.&calibr.lab,incl.van	310000	1	310000	
29	X-ray generator with Mo-target and energy range up to 50 kV	90000	1	90000	
30	Interlock, radiation detection and warning systems	50000	2	100000	
31	Calibration sources for beta-dosimetry	2500	10	25000	
32	Radiometer for beta-dosimeter	15000	2	30000	1325000
	Total			**2955000**	**2955000**

Annex 5
List of relevant laws and regulations

1. Act on Health, promulgated in State Gazette № 70 of August 10, 2004
2. Act of the Safe Use of Nuclear Energy, promulgated in the State Gazette No. 63 of June 28, 2002
3. Act on Measurements, promulgated in State Gazette № 46 of May 7, 2002
4. Ordinance No30 of the Ministry of Health from 31 October 2005 for conditions and order for providing protection of the individuals at Medical Exposure, promulgated in State Gazette № 91 of November 15, 2005 - according Directives 97/43 and 96/29 of EC
5. Regulation for Basic Norms for Radiation Protection, promulgated in the State Gazette No.73 of August 20, 2004 stated by the Governmental Decree No. 190 from 30 July 2004.
6. Ordinance No32 of the Ministry of Health from 7 November 2005 for performing of individual dose monitoring of individuals working with sources of ionizing radiation, promulgated in State Gazette № 91 of November 15, 2005 - according to Directive 96/29 of EC
7. Ordinance No29 of the Ministry of Health from 16 September 2005 for health norms and requirements at work with ionizing radiation – according Directive 96/29 of EC.
8. Ordinance for conditions and order for providing medical norms for protection of the individuals in case of nuclear accidents – according Directive 96/29 of EC.
9. Bulgaria Standard EN/ISO/IEC 17025. General requirements for the competence of testing and calibration laboratories. May 2001.

Annex 6

Reference list of relevant strategic plans and studies

1. National Strategy for the Development of Radiotherapy 2005-2010
2. National Strategy for Early Detection of Breast Cancer 2005-2010
3. National Strategy for Osteoporosis Treatment

ANNEX 7

NEEDS ANALYSIS

The new Ordinance for Protection of Individuals at Medical Exposure based on the Council Directive 97/43 EURATOM states new demands to the radiological practices and set higher requirements to radiological equipment, which have not been previously included in the Bulgarian legislation. The process of practical realisation of the new demands needs highly specialised equipment for Radiation Protection and Quality Control. A first part of this equipment has been supplied within the investment contract in the previous PHARE Project BG/2000/IB/EN 01-05 "Radiation Protection and Safety at the Medical Use of Ionizing Radiation". It matched the needs of the most important hospitals and health care facilities in Bulgaria to a certain degree particularly with regard to Quality Assurance in Diagnostic Radiology and Nuclear Medicine. The reason to add a supplement (part A in the provisional Technical Specification) is to complete the set of measurement and control devices fully to cover the mandatory QA procedures up to the EU standards.

As long as the previous Project was mainly focussed on Diagnostic Radiology, Nuclear Medicine, the Radiation Protection as such and the Quality Assurance in Radiotherapy were only modestly concerned. Hence, in the present Project attention is drawn on the supply (part B of the TS) of the corresponding lacking equipment. In this manner the present Project will actively contribute to a successful realization of the National Strategy for Development of the Radiotherapy 2005-2010 and by this, to an improvement of the quality of life in accordance with the EU-policy.

One of the crucial points to fulfil the EU requirements remains the guaranteeing the accuracy of measuring devises for clinical dosimetry and for quality control in radiotherapy, nuclear medicine, diagnostic radiology and radiation protection as well as the traceability of the measurements to the National and International standards. These responsibilities are assigned to the National Secondary Standard Dosimetry Laboratory (SSDL) - unique for the country. It has been established in late 70-thies to ensure accuracy of the radiation treatment procedures by acceptance testing and calibration of radiotherapy units. It also ensures metrologically the National system for individual dose monitoring in medicine as well for all other licensed radiation facilities incl. Nuclear Power Plant Kosloduy, The implementation of the requirements of EC Directive 97/43 EURATOM put new demands concerning Quality control of radiological equipment and patient dosimetry, new generation of control and measuring instruments and further introduction of dosimetric and calibration methods. All these imply further development of the SSDL. Presently the SSDL works with more than 30 years old equipment and was one of the reasons not to be accredited in the last years. This fact constrains the ensuring accuracy of radiotherapy procedures and of the radiation protection measuring equipment. In this regard the SSDL urgently needs innovation by supply of modern calibration equipment and know-how transfer for updating the calibration methodology (part C of the TS).

The present Project represents a continuation of the previous one and ensures by this a continuity in the undertaken efforts for: harmonization of the Bulgarian legislature with the European one in the field of radiation protection and quality assurance at medical exposure and their effective realization in practice, reduction of the population radiation exposure and finally of achieving a higher quality of life.