1. **Basic information**
2. Desire number: PL01.05.05
3. Title: Radiation Protection in Diagnostic Radiology
4. Sector: Environment
5. Location: Poland

2. **Objectives.**
2.1. **Wider objectives**
Implementation the effective and safe use of ionizing radiation in diagnostic radiology by optimizing the protection of patients undergoing medical X-ray diagnostics.
Harmonization and standardization of operational procedures applied by regional radiation protection laboratories (Voivodeship’s and Regional Sanitary Inspectorate Stations – Radiation Protection Department) with the requirements of the EC Directive 97/43/EURATOM.

2.2. **Immediate objectives**
Creation of the National system for: Quality Assurance, and Standardization of Radiation Protection in Diagnostic Radiology. Achieving, in a longer perspective, reduction of collective dose to Polish population by about 50%.

2.3. **Accession Partnership and NPAA priorities.**
AP: Short term: draft a legal approximation strategy for the environmental sector including directive specific approximation and implementation programmes. Medium term: continue transposition and start implementation.

3. **Description**
3.1. **Background and justification.**
Ionizing radiation is a well-known human carcinogen. During the past 50 years numerous epidemiological studies of adult human populations exposed to radiation from medical, occupational, or military sources have been conducted. The lowest dose at which a statistically significant radiation risk has been demonstrated is ab.100 mSv. Medical applications of ionizing radiation are accepted worldwide as essential tools for protection and improving human health. However, they also represent by far the largest man-made source of radiation exposure. The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) estimates that medical applications of radiation account for about 95% of the exposure from man-made sources. In Poland we have about 8 000 X-ray machines which are used to perform about 27 million X-ray examinations per year. Furthermore, there appears to be continuing increase in the prevalence of medical applications of radiation, including high dose procedures such as: the use of radiation in interventional procedures that replace major surgery and which can lead to very high doses, mostly to patients in some cases exceeding thresholds for deterministic effects, but to some extent also to the medical staff; helical and multiscan computed tomography has improved image quality and made CT faster and more flexible, but has also led to an increase in the number of procedures and the number of sections per procedure, and therefore to effective doses exceeding sometimes tens of milisilvert per examination. In diagnosis, the radiological protection objective is to keep doses as low as reasonably achievable while obtaining the necessary diagnostic information. However, it is a common finding that doses from similar radiological investigations can differ between individual X-ray labs by as much as two orders of magnitude. There is, therefore, a considerable scope for dose reduction in diagnostic and interventional radiology. Thus, within the field of optimization, strategies have been developed which include the hypothesis that the risks from any radiation source can be separated from the benefits. This is, perhaps, most clearly demonstrated in breast screening programs, which employ mammography. The level of image quality, cancer detection rates and doses delivered to a woman are not intimately related. Quality Criteria should therefore be extended to provide an operational framework for attempting to reduce patient dose whilst maintaining a reasonable level of acceptable image quality i.e. maintaining constant benefit. There is an
obvious need and scope for developing optimization strategies for radiation protection in diagnostic radiology which are able to extend and improve quality assurance programs and then provide the necessary advice and guidance to those responsible for their implementation. It is essential to develop national radiation safety policy fully compliant with the EU legislation, exemplified most closely in the Directive Euroatom 97/43. Such consistent and coherent radiation policy on a national level is necessary for the effective implementation of radiation safety. The education and training of the staff involved in this process provides the basis for quality assurance and radiation protection in practice. The staff groups concerned are primarily medical physicists, radiologist, radiographers but auxiliary staff should also be considered. The precise education and training requirements of the different staff groups are inter-related, changing and also varied. This will continue to have a significant impact on the scope, context and implementation of training programs in quality assurance and radiation protection. Very important aspect of the system is preparation of the principles for functioning of laboratories, for accreditation and introduction of the concepts of clinical audit, of external inspection, quality assurance and quality control as a basis for the effective radiation protection strategy. Currently radiation protection in diagnostic medicine is provided by the following main institutions: Nofer Institute of Occupational Medicine (NIOM), Radiation Protection Department in Lodz; National Institute of Hygiene, Department of Radiation Protection and Radiobiology; National Consultant of Radiology; Voivodeship’s and Regional Sanitary Inspectorate, Radiation Protection Departments. Technical Quality Assurance and proper radiation protection are necessary prerequisites for appropriate functioning of the clinical quality assessment and standardization (this latter area should be dealt with by radiological profession, a/o. by means of clinical audits). Realization of medical requirements included in the Directive 97/43 need, in order to their implementation, an effective organization as well as cooperation of all above-mentioned institutions. In Art. 13 of this Directive there is a requirement, that Member States shall ensure that a system of inspection enforces the provisions introduced in compliance with this Directive.

3.2. Linked activities

Project links with other activities:
- Pilot study of quality assurance system realized in Lodz Region (Project No SPR.04.10.41) financed by the State Committee for Scientific Research.
- Exposure of Polish population to X-radiation in diagnostic radiology (Project No PB 818/PO5/97) financed by the State Committee for Scientific Research.
- The role of Regional Sanitary Inspectorate in preparing a new system of radiation protection in medicine (Project No SPR 01.1.4) financed by the State Committee for Scientific Research.
- Image quality and patient's dose optimization in mammography in Poland (IAEA Research Contract No 10.947/RO), partly financed by the IAEA.

All above projects are realized by Radiation Protection Department, Nofer Institute of Occupational Medicine in Lodz and are included into the Scientific Program of the Institute. Those projects certify that some of necessary steps in this field have been made, i.e. allow for assessment of current exposure of Polish population to X-radiation in diagnostic radiology.

Currently running Project PI 9707-01-04-004 – Harmonization of Polish Consumer Protection and Health Safety Legislation to the Acquis Comminautaire – the EU and Polish experts are responsible for preparing a project referring to determinants and factors of the implementation costs.

3.3. Results

Foreseen results of the project: effective system of technical quality assurance and radiation protection in diagnostic radiology; full implementation of the EC Directive 97/43. This will cover scope and context for quality assurance and radiation protection. The relevant strategies including clinical audit, dosimetric inspection, optimization, education and training. It will also include mechanisms for establishing and implementing respective accreditation procedures (from the protection point of view); development of education and training programs for all professional groups which support the implementation of appropriate EU Directives; formulation of country-wide reference levels and typical values (guidelines) of effective doses in specific procedures of diagnostic radiology; instructions, recommendations, codes of practice for radiation protection in diagnostic medicine; intercomparison tests for participating dosimetric laboratories; forms of quality assurance and radiation protection documents and routs of their circulation; providing voivodeship’s and regional laboratories with instruments for quality assurance and quality control measurements; with instruments for determining the dose-area product and for dose and dose rate measurements, with "phantoms" (in most cases sources from EU countries); Creation of the network of certified Quality Assurance and Radiation Protection Laboratories in order to meet the requirements of
relevant EU Directives; Education and training of the staff of regional laboratories as well as medical staff in Quality Assurance and Radiation Protection.

3.4. Activities
Preparation of the premises and basic equipment for quality assurance and radiation protection in diagnostic radiology; Calibration the dosemeters for quality control for laboratories of the Sanitary Inspectorate Departments; Preparation of the programs for education and training of staff for the quality assurance; Organization and conducting training (4 one-week courses for staff from Sanitary Inspectorate and for medical staff – together about 100 trainees); Preparation of the instructions and document templates for technical quality assurance and radiation protection in diagnostic medicine; Preparation of the draft methodological requirements regarding quality assurance and radiation protection in medicine; Screening measurements of entrance dose (by TLD) for 3 typical X-ray examinations (chest radiography PA; thoracic spine AP and lumbo sacral spine AP) for all X-ray units in the country; Development of the prioritized list of X-ray units for inspection purpose relating to implementation of QA; Conducting adequate measurements for physical quality assurance and quality control in X-ray departments; Supervision of radiation protection officers to assure that they observe the daily, weekly and monthly control measurements in X-ray departments; Cooperation with factory services of X-ray units in a case X-ray machine should be repaired or its technical parameters should be corrected; Audit and certification of radiological facilities regarding technical quality assurance and radiation protection; Organization of periodical clinical audits and intercomparisons tests for quality assessment (and assurance) in diagnostic and interventional radiology on regional basis.

3.5. Inputs
Equipment for Secondary Standard Dosimetry Laboratory for calibration of instruments for quality assurance and quality control measurements (0.225M €), (mainly standard dosimetry and X-ray tube); Equipment for quality assurance and quality control measurements for 20 Sanitary Inspectorate Radiation Protection Departments (1.8M €).
Training costs (lecturers from abroad): 4 one-week courses × 0.05M € = 0.2M €; Study visits 0.135M €; Short term experts 0.14M €
Experts: Generally three short time experts, within the framework of Technical Assistance (TA), are required for implementation of the project.
First short term expert: at least 2 weeks is required. Task: review of organization system of practical implementation of Directive 97/43; providing training and consultation for radiation protection departments of Sanitary Inspectorates. Requirements: experience in implementation of directive 97/43 in Member State of EU, fluent knowledge of English and/or Polish.
Second short term expert: at least 2 weeks is required. Task: verification of specified equipment and purchase; assistance in creation of quality assurance system in diagnostic radiology; participation in the training for radiation protection officers (a course). Requirements: experience in dosimetry of radiation and quality control measurements, fluent knowledge of English and/or Polish.
Third short term expert: at least 2 weeks is required. Task: supervision of the quality assurance programme from the view point of estimation of image quality; participation of medical staff (radiologists). Requirements: radiologist with a practical knowledge of QA and quality control of radiological images, fluent knowledge of English and/or Polish.

4. Institutional Framework
Target institutions: The Ministry of Health, Chief Sanitary Inspectorate, National Consultant of Radiology, Professional surveillance on the radiological procedures (Professional surveillance on the proper using of radiological equipment as well as activity of medical and technical staff), Voivodeship’s and Regional Radiation Protection Departments of the Sanitary Inspectorate. [In Poland we have 49 Departments. Their main duties regarding radiation protection in medicine are: the measurements of dose rate (area monitoring) in diagnostic X-ray departments; authorization of usage of radiation sources in medicine; intervention in cases when the excessive doses are received by the staff (These doses are reported to the Inspectorate by NIOM); training of radiation protection officers for X-ray departments.], Nofer Institute of Occupational Medicine in Lodz [The main duties: Personal dosimetry of all persons working with X radiation in Poland (about 31 000 workers are under control); Secondary Standard Dosimetry for calibrating personnel dosimeters and dose rate meters; Estimation of doses received by Polish population from diagnostic X-ray examinations; Pilot studies of quality assurance and quality control measurements in diagnostic radiology; Education and training of radiation protection officers; Preparing the drafts of legislation acts regarding safety use of radiation in medical practice.], National Institute of
Hygiene [Studies of quality assurance and quality control measurements in diagnostic radiology; Education and training of radiation protection officers; Taking part in drafting of legislation acts regarding safe use of radiation; The measurements of dose rate in diagnostic X – ray departments; Authorization of using of radiation sources in medicine]. Voivodeships’ Sanitary Inspectorates will become the owners of the equipment.

5. Detailed Budget (in €)

<table>
<thead>
<tr>
<th></th>
<th>Investment</th>
<th>Institutional Building</th>
<th>Total Phare (IN + IB)</th>
<th>National co-financing</th>
<th>IFIs</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. SSDL</td>
<td>180 000</td>
<td>-</td>
<td>180 000</td>
<td>45 000</td>
<td></td>
<td>45 000</td>
</tr>
<tr>
<td>2. 20 Units</td>
<td>1 440 000</td>
<td>380 000</td>
<td>1 440 000</td>
<td>360 000</td>
<td></td>
<td>360 000</td>
</tr>
<tr>
<td>3. Training, study visits, experts</td>
<td>380 000</td>
<td>380 000</td>
<td>380 000</td>
<td>95 000</td>
<td></td>
<td>475 000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1 620 000</strong></td>
<td><strong>380 000</strong></td>
<td><strong>2 000 000</strong></td>
<td><strong>500 000</strong></td>
<td></td>
<td><strong>2 500 000</strong></td>
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</tbody>
</table>

The co-financing funds for the project implementation will be available. Poland will bear the following costs: reconditioning of laboratory premises, basic laboratory equipment, reagents and laboratory materials; preparation of the premises and basic equipment for quality assurance and radiation protection in diagnostic medicine; partial covering of the costs related to local training programs; partial covering of the costs related to preparation of the legislation acts, requirements, codes of practice, instrumentation, etc.; partial covering of the costs related to calibration of dosimeters for quality control.

6. Implementation arrangements.

6.1. Implementing Agency

PAO: Mr Paweł Samecki, Undersecretary of State at the Office for the Committee for European Integration, Aleje Ujazdowskie 9, 00-918 Warsaw, tel. (48 22)455-52-41, fax (48 22) 455 52 43
CFCU: Cooperation Fund, 6/12 Nowy Świat, 00-400 Warsaw, tel. +48 22 661 76 86, 661 76 33; fax +48 22 661 76 13. The CFCU is responsible for tendering, contracting and payments in contracts concluded on behalf of the MoH, which is responsible for preparing project and its implementation.

6.2. Twinning: n.a.

6.3. No non-standard activities are presumed in the project. DIS manual will be followed.

6.4. Contracts

Equipment for SSDL 0.225M€ (0.18M€ Phare and 0.045M€ National co-financing). Equipment for quality assurance and quality control measurements for 20 Sanitary Inspectorate Radiation Protection Departments 1.8M€ (1.44M€ Phare and 0.36M€ National co-financing). Training, study visit, experts 0.475M€ (0.38M€ Phare and 0.095M€ National co-financing).

7. Implementation schedule.

7.2. Start of project activity – I/II quarter 2002
7.3. Project completion – III/IV quarter 2003

8. Equal opportunity

Women and men will be appointed for the performance of separate stages of the project implementation on the basis of their qualification without discrimination.


11. Investment criteria: n.a.

12. Conditionality and sequencing.

Sequencing: Revising of the existing and preparation of the new legislation requirements, recommendations, code of practices, instructions etc. for quality assurance and radiation protection in diagnostic radiology, in compliance with the EU legislation. By the time of start the project the modified legislation should conform with requirements of the Directive 97/43 and should provide legal machinery for its implementation. Education of the staff to became capable of introducing and maintaining proper standards in quality assurance and radiation protection. Creation of the technical and organizational infrastructure necessary to perform relevant measurements. Implementation of a permanent system of quality control and quality assurance in diagnostic radiology.
### Annex 1: LOGFRAME PLANNING MATRIX FOR PROJECT.

End Contracting: 15/12/2003 - End Disbursement: 15/12/2004

<table>
<thead>
<tr>
<th>Project number: PL01.05.05</th>
<th>Total budget 2.5M€</th>
<th>Total 2.5M€ - Phare: 2M€</th>
</tr>
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<tr>
<td><strong>Wider objectives</strong></td>
<td><strong>Indicators of Achievement</strong></td>
<td><strong>Sources of information</strong></td>
</tr>
<tr>
<td>Implementation the effective and safe use of ionizing radiation in diagnostic radiology by optimizing the protection of patients undergoing medical X-ray diagnostics. Harmonization and standardization of operational procedures applied by regional radiation protection laboratories (Voivodship's and Regional Sanitary Inspectorate Stations – Radiation Protection Department) with the requirements of the EC Directive 97/43/EURATOM.</td>
<td>Level of effective dose for Polish population from diagnostic X-ray examinations. Existence of national network of laboratories’ evidence by properly accredited laboratories.</td>
<td>Documents provided by Ministry of Health and its Agencies (NIOM), Analysis and evaluations by NIOM.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Immediate objective</strong></th>
<th><strong>Indicators of Achievement</strong></th>
<th><strong>Sources of information</strong></th>
<th><strong>Assumption and Risks</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Creation of the system for Quality Assurance and Radiation Protection in Diagnostic Radiology. Achieving in a longer perspective, reduction of collective dose to Polish population of about 50 %</td>
<td>Official Quality assurance and Radiation Protection Laboratories meeting EU requirements. Appropriate legal acts regarding quality assurance and radiation protection in medicine. Percentage of X-ray units tested yearly for quality assurance and radiation protection in medicine.</td>
<td>Documents provided by Ministry of Health. Analyses and evaluation by NIOM.</td>
<td>Adequately prepared technical specification for the equipment purchased.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Outputs of Project</strong></th>
<th><strong>Indicators of Achievement</strong></th>
<th><strong>Sources of information</strong></th>
<th><strong>Assumption and Risks</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>effective system of technical quality assurance and radiation protection in diagnostic radiology, full implementation of the EC Directive 97/43; development of education and training programs for all professional groups which support the implementation of appropriate EU Directives; formulation of country-wide reference levels and typical values (guidelines) of effective doses in specific procedures of diagnostic radiology; Instructions, recommendation, codes of practice for radiation protection in diagnostic medicine; intercomparison tests for participating dosimetric laboratories; forms of quality assurance and radiation protection documents and routes of their circulation; providing voivodship’s and regional laboratories with instruments for quality assurance and quality control measurements; with instruments for dose-area product and for dose and dose rate measurements, with “phantoms” (in most cases sources from EU countries); creation of the network of certified Quality Assurance and Radiation Protection Laboratories in order to meet the requirements of relevant EU Directives; education and training of the staff of regional laboratories as well as medical staff in Quality Assurance and Radiation Protection.</td>
<td>Existence of the relevant documents (instructions, code of practice, test forms, training programs, reporting templates); Participation in schedule of quality assurance and radiation protection coordinated by EU or other international organizations (IAEA, WHO); Number of persons trained; Number of labs ready accredited; Amount of equipment purchased; The EU directed reporting system; Equipment; Expert visits; Training infrastructure; Laboratories infrastructure; Scientific visit.</td>
<td>Documents provided by Ministry of Health; Analyses and evaluations by NIOM.</td>
<td>Project results depend on the involvement of respective authorities and laboratories personnel.</td>
</tr>
</tbody>
</table>
Main activities: preparation of the premises and basic equipment for QA and radiation protection in diagnostic radiology; calibration the dose meters for quality control for laboratories of the sanitary Inspectorate Departments; preparation of the programmes for education and training for staff of QA; organization and conducting training (4 one-week courses for staff from Sanitary Inspectorate and for medical staff – together about 100 trainees); preparation of the instructions and document templates for technical QA and radiation protection in diagnostic medicine; screening measurements of entrance dose; development of prioritized list of X-ray units for inspection purpose relating to implementation of QA; conducting adequate measurements for physical quality assurance and quality control in X-ray departments; supervision of radiation protection officers to assure that they observe the daily, weekly and monthly control measurements in X-ray departments; cooperation with factory services of X-ray units in a case X-ray machine should be repaired or its technical parameters should be corrected; audit and certification of radiological facilities regarding technical quality assurance and radiation protection; organization of periodical clinical audits and intercomparisons tests for quality assessment (and assurance) in diagnostic and interventional radiology on regional basis.

Annex 2-4: Implementation, contracting and disbursement schedules.

<table>
<thead>
<tr>
<th>Radiation protection in diagnostic radiology</th>
<th>Date of Drafting</th>
<th>01.2001</th>
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<tr>
<td>Planning Period</td>
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<th>Budget Allocation (in MEURO)</th>
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<tr>
<td>IV’01</td>
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<td>I</td>
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<td>0,38</td>
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Legend: D = design of sub-projects / C = tendering and contracting / I = contract implementation and payment

Annex 5: Equipment specification (the main purchases within the framework of this project)
1. Equipment for Secondary Standard Dosimetry Laboratory SSDL. Standard dosimeters, type UNIDOS, with ionization chambers set for: energy range from 10 keV to a few MeV, dose range from 0,1 mGy to 1 Gy and dose rate from 0,4 mGy/min to 2 KGy/min.
2. Automatic TLD reader
3. 20 sets of instruments for quality assurance of X-ray units’ parameters, including instruments measuring: dose rate; time of exposure; kV; mA; mAs; filtration; colimation of primary beam; dimension of source; and screen film contact tools, test tool for anticatter grid, sensitometers, densitometers, etc.
4. 20 sets of “phantoms” for image quality assessment