



IL9806321

THE EUROPEAN APPROACH TO QUALITY ASSURANCE IN DIAGNOSTIC RADIOLOGY

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The European and increasingly the international Organizations are emphasizing the importance of appropriate Quality Assurance (QA) programmes in diagnostic radiology.

The European Directive (particularly the directive 84/466/EURATOM), the various publications of the International Commission for Radiation Protection (ICRP), related to protection of the patients and workers and the Basic Safety Standards of the International Atomic Energy Agency (IAEA) might be considered the landmarks of the new approach to the problems of dose reduction and quality in diagnostic radiology.

In particular ICRP maintains a watching brief on all aspects related to radiation protection and makes recommendations concerning basic principles. Since ICRP 26 (1977), several ICRP publications have dealt with all the principal fields of diagnostic radiology. The IAEA has recently published the new Basic Safety Standards including guidance levels for the most common diagnostic investigations.

Within the European countries the European Union and the European legislation have strong influence on the implementation of radiation protection and QA at a national level. This has led to a substantial effort in the European countries to establish national standards and basic quality requirements.

1. THE CONCEPT AND THE ORGANIZATION OF QUALITY ASSURANCE

The concept of QA is very extensive and requires a different way of thinking and organizing the work. QA includes all the process involved in reaching a correct diagnosis and consequently the appropriate therapy for the patients. In diagnostic radiology the process starts with the correct choice of investigation, carried out using adequate equipment and good technique, reducing the cost and minimizing the risk to the patients and staff. In order to achieve this a comprehensive approach to the problem is necessary.

There are several different levels of actions, all of them essential and inter-related. At international level the role of the European Union and International Organizations is essential in establishing directive, international standards and recommendations. At national level the organization and assessment of national QA involves the competent Regulatory Authority and the Professional Organizations. At hospital level it is important to address all the professionals involved in the process. For the success of the programme it is essential to involve the medical and paramedical staff, for clinical evaluations, the scientific and technical staff for safety and quality control measurements, and also the management for cost-utility analysis. At department level the implementation of QA requires a clear definition of responsibility and appropriate protocols.

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It is generally accepted that for medical applications radiation protection should be part of the QA programme. However it is also recognized that the implementation of radiation protection regulation can be the way to introduce QA programmes. In the practice it would be almost impossible to distinguish the various aspects as all contribute to the process of optimization. It is not a problem of definition of the various components but of evaluation of the final result i.e. good diagnosis. This means good interpretation of good quality images. The quality of the image has usually to be "compromised" in the interest of the radiation protection of the patients. In order to achieve the optimization of the final result it is necessary to establish a comprehensive structure within which the various contributions must be defined.

It is very difficult to define a European approach to QA in diagnostic radiology, due to the very different conditions of the European countries as well as the different health care structures and different priorities given to the problem. Therefore the only common "umbrella" is the European directive, as the Member States have to convert it into national regulation. The following paragraphs of this presentation will focus on a very schematic presentation of the principles stated in the European directive and on trying to understand the problems related to the practical implementation. Despite these difficulties it appears from various surveys that the creation of awareness and the introduction of QA programmes (also only partially) has drastically reduced the dose to patients, with very encouraging results. There are common indications of those parameters to be included in QA programmes. The protocols and the procedures for quality control measurements are practically standardized, but the final definition of the programme is still left to the individual Member States.

2. CURRENT STATUS OF RADIATION PROTECTION

The current status of radiation protection in medicine is in a way less "advanced" than in other applications of radiation. Less attention has been given to the optimization of procedures in diagnostic medicine due to: the relatively low individual doses involved, the fact that medical diagnosis is generally accented as justified, and the direct benefit of the exposed individual. As a result of this attitude there is considerable scope for dose reduction in diagnostic radiology considering that this is the largest contribution to the collective dose from all man made sources of radiation.

All the European and international surveys have shown that the situation of radiation protection and quality assurance varies tremendously even in countries with comparable economical conditions, thus leading to very different doses to patients and number of investigations performed. This point is better explained in paragraph 5.

3. MAIN GUIDELINES ON THE ARTICLES OF THE EURATOM DIRECTIVE 84/466

Some articles of the EURATOM directives 84/466 are fundamental for the definition of the structure of the QA programme. The first four articles deal with the basic aspects and can be summarized as follows:

- Article 1: All medical exposures must be medically justified and kept as "low as reasonable achievable".
- Article 2: The need for doctors to have acquired competence in radiation protection and to be trained and experienced in the techniques used in diagnostic radiology, radiotherapy or nuclear medicine and for assistants to have received appropriate instruction in the techniques applied in suitable radiation protection procedures.

- Article 3: The drawing-up of an inventory of radiological equipment and nuclear medicine installations. The establishment of criteria for acceptability for radiological and nuclear medicine installations. The monitoring of all installations in use with regard to radiological protection and quality control .

- Article 4: Appropriate steps to be taken by Member States to discourage the unnecessary proliferation of equipment for radiodiagnostic, radiotherapy and nuclear medicine.

From the analysis of these articles, it appears clearly that the European directive include the basic concepts of radiation protection and QA, such as:

- Justification and Optimization. This includes the introduction of the practice of acceptance tests and performance tests and follow up action using written protocols.

- Responsibilities. Concept of overall clinical responsibility for the medical doctor, but also the concept of delegation of responsibilities for practical aspects to other staff members.

- Surveillance. The surveillance should be organized at national level (competent Authority) and at department level (QA programmes).

- Inventory. This will be the base for national planning and avoiding unnecessary proliferation. The inventory is also essential for the organization of national surveys and inspection programmes.

- Training at different levels. The Member States must lay down appropriate curricula for all medical and paramedical staff and recognize corresponding diplomas and qualifications. Refresher courses should be organized. Information about criteria must be provided to the prescriber of the exposures.

- Auditing. Quality audits should be organized by the Member States in order to verify the results of the directive in the field of radiation protection.

Another important point is the definition of the medical physicist as an expert in radiation physics, recognized by the competent Authority in terms of training and capacity to act. The medical physicist gives advice on patient dosimetry, on the development and use of complex techniques and equipment, on optimization and good practice techniques, on QA including quality control measurements, and on matters relating to radiation protection. For radiodiagnostic practices a medical physics shall be available for consultation on the above mentioned subjects.

The main fields of application and scopes of the European legislation are:

- Medical diagnosis or treatment.

- Medico-legal or insurance purposes.

- Mass screening

- Comfort to patients.

- Medical and biomedical research.

4. ROLE OF THE EUROPEAN FEDERATION OF ORGANIZATION FOR MEDICAL PHYSICS

The Federation is working in collaboration with the European Union in particular in the fields related to the role of medical physics in the QA programme and in organizing training physicists. The principal aims and purpose of the Federation, as set in the Constitution, are:

- Fostering and co-ordinating the activities of Member Organizations in the field of Medical physics and collaborating with other Organizations.
- Encouraging exchanges between the Member Organizations and disseminating professional and scientific information.
- Encouraging scholarship and exchange of Medical physicists between countries.
- Proposing guidelines for training, education and accreditation programmes
- Making recommendations on the appropriate general responsibilities, organizational relationships and roles of workers in the field of medical physics.
- Encouraging the formation of organizations for medical physics where such organizations do not exist.

5. SITUATION OF DIAGNOSTIC RADIOLOGY IN THE EUROPEAN COMMUNITY

The European situation regarding diagnostic radiology can be summarized as follows:

- + 320 million habitants.
- + 200 million radiological examinations per year.
- + 500 million radiographic films per year.
- + 300 to 1500 uSv contribution to the exposure of each person of the general public per year in the various Member States.
- + 500 uSv average value for the European Community.

As already mentioned the situation of diagnostic radiology, in terms of number of investigations performed, number of films used and dose to patients, in the European countries, is very different. Some examples of national values are given in the following table.

| Member States | N. of X-ray (*) invest. per 1000 people per year | Mean number of films per investigation | Genetically Significant Dose uSv | Effective Dose Equivalent per caput uSv (**) |
|---------------------|--|--|----------------------------------|--|
| Fed. Rep. Germany | 1200 | 2.2 | 400 | 1000 |
| France | 825 | 3.6 | 295 | 1580 |
| Great Britain | 444 | 2.3 | 120 | 282 |
| Ireland | 460 | 2.2 | 164 | - |
| North-East Italy | 665 | 3.1 | 248 | 763 |
| Spain (Madrid area) | 680 | 2.2 | 252 | 1210 |
| Portugal | 696 | 2.3 | 200 | 530 |

(*) without dental investigations

(**) remainder organs included

The distribution of the frequency and of the kind of investigation performed, is also different in the European countries. As an example the following is the percentage contribution of the various investigations to the collective dose, in the UK.

| Examinations | Frequency (%) | Collective Dose (%) |
|-----------------------|---------------|---------------------|
| Computed Tomography | 2.0 | 17 |
| Lumbar Spine | 3.3 | 15 |
| Barium Enema | 0.9 | 14 |
| Barium Meal | 1.6 | 12 |
| Intravenous Urography | 1.3 | 11 |
| Abdomen | 2.9 | 8 |
| Pelvis | 2.9 | 6 |
| Chest | 24 | 2 |
| Limbs and Joints | 25 | 1.5 |
| Skull | 5.6 | 1.5 |
| Thoracic Spine | 0.9 | 1 |
| Dental | 25 | 1 |

It should also be taken into account that the kind and frequency of examinations is changing continuously due to the introduction of new techniques, more sophisticated equipment and different diagnostic approaches.

In addition it is important to consider that the difference in terms of doses to patients varies enormously for the same kind of investigation performed in different countries. The variation also in the same country is extremely high, showing the influence of technique and training of personnel. Only as an example next table shows the values measured for the entrance surface dose (ESD) in some common investigations, in 1991 during one trial of the Commission of the European Community (CEC).

| Investigation | ESD min. uGy | ESD max. uGy | ESD mean uGy | Total number |
|---------------|--------------|--------------|--------------|--------------|
| Abdomen | 77 | 3210 | 650.5 | 45 |
| Skull ap | 152 | 4514 | 1252.7 | 57 |
| Chest ap/pa | 21 | 979 | 131.3 | 69 |
| Spine | 107 | 4351 | 1128.0 | 31 |
| Chest newborn | 11 | 386 | 67.8 | 64 |
| Chest infant | 34 | 718 | 128.5 | 37 |
| Pelvis | 18 | 1369 | 401.1 | 50 |

It should also be considered that in case of investigations involving fluoroscopy the difference between countries and centres is much higher due to the variation of the fluoroscopy time and parameters used. This shows the strong need of establishing guidelines and methods for standardization of techniques and creation of awareness on the problem of patients protection.

6. RESEARCH PRIORITIES IN THE CEC

Within the Radiation Protection programme, the topic of reduction of patient exposure is extensively developed including:

- Quality Criteria for special examination and techniques
- Impact of quality criteria on patient exposure
- Dose assessment for special irradiation conditions
- Evaluation of dose reduction measures
- Evaluation of data for the quantification of individual risk.

Under "optimization and management of radiation protection" one section is dedicated to reduction of patient exposure in diagnostic radiology. The tasks of the European Community research programme are:

- to put emphasis on research which produces prerequisite for optimum diagnostic efficacy, at reasonable doses to the patient and staff, at a reasonable cost.
- to contribute to the implementation of the EC Directive laying down basic measures for the radiation protection of persons undergoing diagnostic investigations or treatment.
- to evaluate data and support a global use of the research results in daily routine.

In order to achieve the above tasks practical actions have been established in the light of given priorities. The main actions of the above research programme are:

- + Dose assessment and evaluation of risks
- + Quality Assurance and referral criteria
- + Quality Assurance parameters in digital radiology
- + Dose related factors during the whole diagnostic process
- + Nuclear Medicine- patient dosimetry.

7. ORGANIZATION AND OPTIMIZATION OF PROTECTION AND QUALITY ASSURANCE

As already mentioned, the system for the organization and optimization of protection and QA is very complex and for the time being it has been implemented at different levels in the European countries. The degree of application of the system is even more different, leading to a not homogeneous situation.

There is general agreement on the parameters to be included in the QA programme, which are the following:

* Design, safety and organizational parameters:

- appropriate shielding
- appropriate setting of the department
- classification of personnel and areas
- prompt detectability of system failure
- prevention of human errors
- compliance with national and international standards
- safety features of equipment (clear indication of the parameters on the equipment control panel, radiation beam control, "dead man switch", etc.)
- safety interlocks, etc.

* Operation of equipment and good technique:

- selection of appropriate equipment
- selection of appropriate techniques to minimize dose to patients and staff
- implementation of regular quality control measurements on the equipment
- acceptance tests of equipment

- performance tests of equipment
- accurate follow up and record keeping
- training

*Personal and clinical dosimetry

- implementation of appropriate personal dosimetry for the staff using the equipment
- monitoring of representative values of entrance surface dose, dose area product, dose rate, organ dose
- accurate record keeping and follow up
- training

* Assessment of image quality

- evaluation of image quality versus dose to patients and diagnostic requirements
- evaluation of image quality versus conditions of equipment and diagnostic requirements.
- training

* Cost-utility analysis to radiological protection

- analysis of cost for the implementation of the programme versus results

8. DEVELOPMENT OF NEW TRAINING SCHEMES

Within the European Community particular attention is given to the development of training modules for the various professionals involved in diagnostic radiology. Among these, in the field of medical physics the Leonardo da Vinci project " EMERALD" will develop training modules in the fields of X-ray diagnostic radiology, radiotherapy and nuclear medicine. The modules are dedicated to the post graduate training of physicists. The project includes the preparation of guidelines, manuals and also multimedia. The Medical Physics and Bioengineering Department of the King's College, London U.K., is coordinating the project. A different approach is given in the " Tempus" projects which are also aimed to the organization of various training, establishing collaborations between Universities. Usually the aim is to train staff in the Central and Eastern Europe countries, establishing collaboration with Universities in Western Europe. The collaboration includes exchange of scientists and the organization of formal training.