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**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN
PARLIAMENT AND THE COUNCIL**

**on medical applications of ionizing radiation
and security of supply of radioisotopes for nuclear medicine**

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1. INTRODUCTION

Nuclear technology is important for electricity production and for a wide range of research, industrial and medical applications. Nuclear medicine, which is an important part of the medical applications of ionizing radiation, has developed tremendously over the past decades. It provides up-to-date medical diagnosis and treatment of many important diseases, including some of the most serious and frequent ones like cancer, cardiovascular diseases and brain diseases.

The branches of medicine using radiation sources include:

- nuclear medicine, where radioisotopes are used for diagnosis and treatment,
- radiological imaging, using X-rays for diagnostic, planning or guiding purposes, and
- radiotherapy, using radiation sources for cancer treatment.

As stated in the Commission's 2007 Nuclear Illustrative Programme¹, medical uses of ionizing radiation are becoming increasingly important, but these new technologies also administer ever-increasing radiation doses to the patient. This Communication identifies key challenges in this area, in particular:

- improving radiation protection of patients and staff,
- securing supply of radioisotopes for nuclear medicine.

The Commission addresses this Communication to the European Parliament and the Council and in order to propose a long-term perspective on the medical application of ionizing radiation in the Union and to stimulate the discussion on the necessary actions, resources and distribution of responsibilities to address challenges in this field. The Communication provides an overview of main challenges and aims at providing visibility of the Community actions.

The Communication looks into these actions from a broad perspective. Beyond the concern for radiation protection the main perspective is that of an efficient and sustainable public health policy. Within this framework the medical profession as well as the suppliers of medical equipment and of radioisotopes play a crucial role. For this purpose the Communication also covers the legislation and programmes outside the relevant provisions of the Euratom Treaty.

¹ Communication from the Commission to the Council and the European Parliament "Nuclear Illustrative Programme", COM(2007) 565, 4 October 2007

2. RECENT DEVELOPMENTS AND CHALLENGES IN THE MEDICAL APPLICATIONS OF IONIZING RADIATION

The medical use of ionizing radiation encompasses nuclear medicine, in which radioisotopes are used for specific diagnostic examinations or for therapy, and radiological X-ray imaging for similar diagnostic purposes, both including treatment planning or guidance (e.g. interventional radiology). Radiotherapy is another use which includes brachytherapy and external beam radiotherapy.

Ionizing radiation has been used in medicine for more than a century and has proven to be an essential component of modern medical diagnosis and treatment. The technology has made much progress in the past decades and it is fair to speak of a technological revolution, in X-ray imaging through (spiral) computerized technology, in nuclear medicine through the introduction of novel radioisotopes and techniques, and in radiotherapy through sophisticated computerized treatment planning and precision in the delivery of the radiation to the tumour, so as to limit exposure of healthy tissue.

At the same time ionizing radiation is a cause of concern because the exposure of the body may cause a health detriment. The overall population exposure due to medical procedures overwhelms any other man-made exposure. All over the world, the number of medical X-ray examinations is around 4 billion per year. The protection of the patient, and of medical staff, in medical practice, is therefore a priority task for the Commission under the Health and Safety Chapter of the Euratom Treaty.

The new medical techniques have considerably enhanced this concern. The benefit in medical diagnosis and treatment has come with an increase in the overall exposure. Accidental or unintended exposures have also become more frequent, especially in radiotherapy. The use of radioisotopes on the other hand faces a dramatic shortage of supply, essentially due to the ageing of research reactors used for their production, which has consequences on patients' health care.

2.1. Patient-related issues

Medical procedures are by far the largest man-made source of radiation exposure of the population. Exposure increased further in the past decades by the mass introduction of new radiation techniques for diagnosis and treatment of patients. At the same time, part of the diagnostic procedures is performed without clear medical need and/or with above-optimal radiation doses. In radiotherapy, but also in interventional medicine and in Computed Tomography (CT), accidents and mistakes can cause severe radiation injuries to patients. These issues are especially important when it comes to children or individuals exposed to radiation for disease screening purposes.

Some level of patient radiation exposure is inherent to various medical procedures. When the procedure is initiated and conducted appropriately all medical benefits it provides outweigh the risk associated with the radiation exposure. However, without appropriate precautions, patients may be exposed to radiation without real clinical need or benefit. This may result from performing a procedure that is not justified given the patient's individual characteristics, history and symptoms, from a radiation dose above the optimal for the examination or from accidents.

There is a significant deficiency in the practical implementation of the system of justification of radiological X-ray imaging, the medically unjustified procedures being at least one fifth of

all examinations and up to three fourths for some specific cases². At the same time there is growing use of medical imaging³, while new technology (e.g. Computed Tomography (CT), Positron Emission Tomography (PET) and hybrid modalities) often involves higher patient doses in comparison with traditional techniques.

Children are especially sensitive to ionizing radiation and deserve special attention. This should include robust justification of the procedure and optimization of the exposure and dosimetry protocols to their body size. Special attention shall also be given to the protection of the unborn child in the case of pregnant women and to the exposure of children when a breastfeeding mother is diagnosed or treated with radioisotopes.

Exposure to high doses of radiation can cause direct injuries (such as burns or hair loss) and even death. In Europe, cases of significant accidental exposure of patients occurred in radiotherapy, where very high doses are routinely delivered to targeted parts of the patient's body. Radiation-induced injuries are not uncommon in interventional procedures, where the patient is often exposed to radiation for long periods of time. Several cases of radiation burns have recently occurred (in the US and Japan) following CT examinations, during which patients were accidentally exposed to much higher doses of radiation than typical for such procedures.

In radiotherapy, about one in twenty patients will experience side effects and complications following treatment⁴, even if the procedure has been planned and conducted correctly. This is fed by differences in individual sensitivity to radiation exposure, which are still not fully understood.

New advanced radiotherapy techniques are sometimes broadly commercialised and marketed without sufficient evidence of improved survival and quality of life of cancer patients. Regulatory requirements to approve the use of a new technique in radiotherapy are not as developed as those for a new therapeutic drug. Very often the pace of innovation is so high that it could be in conflict with the development of quality assurance programmes.

Similarly, new imaging techniques and equipment are often introduced on the market without appropriate justification and regulatory supervision and their use is authorized before specific examination protocols, quality assurance procedures and training of the relevant staff are in place. This is especially challenging for equipment used outside radiology departments, which is the case in various interventional procedures and for the small and portable X-ray devices made available to medical doctors, dentists and other medical professionals.

² These numbers are confirmed by a number of studies from Europe and the United States, one of the most recent being a Finish study on "Unjustified CT examinations in young patients", European Radiology, May 2009, <http://www.springerlink.com/content/5m63p50k6377152v>

³ According to a March 2009 report by the National Council on Radiation Protection and Measurements (NCRP), the U.S. population's total exposure to ionizing radiation has nearly doubled over the past two decades; this is largely attributable to increased exposure from CT, nuclear medicine, and interventional X-ray fluoroscopy. A report of the French Institute for Radiation Protection and Nuclear Safety (IRSN, April 2010) shows that the radiation exposure of the French population from medical diagnostic procedures increased by 57% between 2002 and 2007, largely due to the increased number of CT scans and nuclear medicine procedures with, respectively 26 and 38 %

⁴ International Conference on Modern Radiotherapy (Versailles, 2-4 December 2009) - Synthesis and Main Findings, ASN/DIS, 27 May 2010, <http://www.conference-radiotherapy-asn.com>

The EU Health ministers, in their recommendation on patient safety of June 2009⁵, indicate that patients should be informed and empowered by involving them in the patient safety process. When ionizing radiation is used for medical diagnosis or treatment patients should receive adequate information on the benefits and the limitations of the procedure and the potential radiation exposure effects, to enable them to take informed decisions.

2.2. Staff-related issues

Medical staff bears a great deal of responsibility for ensuring radiation safety of patients but also their own. Lack of knowledge about the radiation doses involved in the procedures, general underestimation of health risks from ionizing radiation and, in some cases, shortage of staff not only feed the patient-related radiation protection issues but also lead to unnecessarily high radiation exposure of some professional groups.

Various medical procedures expose medical personnel (medical doctors, radiographers and radiation technologists, nurses, etc.) to ionizing radiation. There are wide variations in the practice and in the corresponding radiation doses among different medical establishments, in some cases the medical staff receiving doses around or even above the established dose limits. There are also problems with the effective monitoring of the medical staff doses, partly relating to the attitude and the radiation safety culture of the staff.

The availability of an appropriate number of adequately qualified staff is an important element of the system for health protection in any practice involving exposure to ionizing radiation. This is crucial for the deliberate exposure of patients, where the control of the doses depends largely on the personnel involved in the planning, conduct and follow-up of the procedure. There is a lack of qualified medical physicists (Medical Physics Expert, as defined in Article 2 of Directive 97/43/Euratom), which are in insufficient numbers in some countries and whose role is often not sufficiently appreciated.

The rapid development, growing complexity and easy availability of medical radiation technology poses new challenges on the training of the professionals involved in radiological procedures. Today, many medical specialties have access to, and use, radiological imaging without having enough knowledge of the radiation exposure involved in the procedures and of the possible detriment of the exposure on their patients and on themselves. The professionals delivering the exposure in general receive at least basic training on radiation protection and on the specificity of the procedure but huge differences exist among the different Member States on how, and to what extent, this requirement in Directive 97/43/Euratom is effectively implemented.

2.3. Cross-cutting issues

2.3.1. Regulatory control of medical exposures

Practices involving medical exposure are subject to regulatory supervision by the Member States' competent authorities in radiation protection. The regulatory control should be based on a system of authorization, inspection and enforcement complemented by national regulations, regulatory guidance and, where appropriate, involvement with other regulators and stakeholders.

⁵ Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections, O.J. C151 of 3 July 2009

Member States have transposed the Euratom radiation protection provisions and secondary legislation (Euratom Basic Safety Directive⁶ and Medical Exposures Directive⁷) in their national law and have national regulatory authorities in charge of radiation protection of the public and the workers. However, the practical implementation of the requirements for radiation protection of patients, and in some cases of medical staff, is often weak. This is caused, to some extent, by an unclear distribution of responsibilities between national authorities and by the lack of adequately trained regulatory staff.

2.3.2. Emerging evidences for radiation induced cardiovascular diseases and radiation induced cataracts

Recent scientific findings indicate that there is an increased risk of cardiovascular diseases in the range of radiation doses typical for certain radiotherapy and interventional procedures, which could also be reached for patients undergoing repeated radiodiagnostic examinations. There is ongoing research to explain the underlying biological mechanisms and to define the most radiosensitive part of the heart.

Another issue of concern is the scientific evidence from the last few years that the eye lens is more sensitive to radiation exposure than previously thought. Currently, the internationally recommended limits for radiation doses to the lens are under review, to be most likely followed by changes in the legally prescribed limits. Meanwhile, Member States may consider reviewing the arrangements for radiation protection, dosimetry and medical surveillance of staff exposed to high eye doses.

2.4. Supply and use of radioisotopes in nuclear medicine

Radioisotopes are used in medicine for the diagnosis and treatment of various diseases, including some of the most important ones, like cancers, cardiovascular and brain diseases. Over 10000 hospitals worldwide use radioisotopes for the *in vivo* diagnosis or treatment of about 35 million patients every year, of which 9 million in Europe. The majority of the nuclear medicine procedures today are for diagnosis, with about 100 different nuclear medicine imaging procedures available. Imaging using radioisotopes is often indispensable, for instance due to its ability to identify various disease processes early, long before other diagnostic tests. Technetium-99m (Tc-99m) is the most widely used (diagnostic) isotope.

Europe is the second largest consumer of Tc-99m, accounting for more than 20% of the global market. Tc-99m demand is rising worldwide, mostly due to the ageing population of Europe and North America, and its growing use in emerging countries⁸.

The production of Tc-99m is a complex process which includes irradiation of uranium targets in nuclear research reactors to produce Molybdenum-99 (Mo-99), extraction of Mo-99 from targets in specialised processing facilities, production of Tc-99m generators and shipment to hospitals. Due to their short decay times, Mo-99 and Tc-99m cannot be stockpiled and must

⁶ Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation, OJ L 159, 29 June 1996

⁷ Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom, OJ L 180, 9 July 1997

⁸ Preliminary Report on Supply of Radioisotopes For Medical Use And Current Developments In Nuclear Medicine, SANCO/C/3/HW D(2009) Rev. 8, 30 October 2009

be produced continuously and delivered to hospitals weekly. Any supply disruption can lead to a situation where crucial diagnostic imaging tests must be cancelled or postponed with negative and sometimes life-threatening consequences for patients.

Unfortunately, the current Tc-99m supply relies on an unsustainably low number of production reactors. Worldwide, only seven government-owned research reactors provide about 95% of the world's Mo-99 production: the NRU reactor in Canada, the HFR reactor in The Netherlands, the BR2 reactor in Belgium, the OSIRIS reactor in France, the SAFARI reactor in South Africa, since March 2010 the MARIA reactor in Poland and since May 2010 the REZ reactor in Czech Republic. The five reactors in Europe provide around 60% of the production.

All those reactors were constructed for a variety of research related purposes (nuclear research and material science). When Mo-99 production from those reactors was developed, it was considered as a “sideline” activity, so that reactor operators only required reimbursement of direct short-run marginal costs. The historical neglect of the broader costs led to prices for target irradiation that were and still are too low to be of interest to industrial and commercial investors, at least at the level of production of raw Mo-99. Therefore the present economic structure does not provide sufficient incentive for current reactors to produce Mo-99 and for new ones to be constructed.

As those reactors were constructed in the 1950s and 1960s, they are approaching the end of their lifespan, which causes an increasing need for planned maintenance shutdowns and a growing frequency of unplanned production interruptions. As a result, the global supply of radioisotopes has become more fragile, particularly in recent years. Ten interruptions have occurred around the world since 1997, of which five in the last 3 years.

The European Union already undertook several initiatives to respond to the critical situation regarding the supply of radioisotopes for medicine in 2008-2010. The issue has been discussed by the EU Health Security Committee and by the Council, who came with conclusions⁹ calling for further actions by the Commission and Member States. The European Medicines Agency and the Commission took several initiatives to identify possible short-, medium- and long-term solutions to the current situation, including the organization of a Workshop on Current Use and Future Needs of Radiopharmaceuticals Labelled with Radionuclides Produced in Reactors and Possible Alternatives (February 2010) and a Meeting on the Security of Supply of Medical Radioisotopes in EU Member States (May 2010).

The Commission co-operates with international organizations and stakeholders under the High-Level Group on Medical Radioisotopes (HLG-MR) created by the OECD/NEA, aimed at overseeing and assisting, where necessary, efforts of the international community to address the challenges of medical radioisotopes supply reliability.

3. WAY FORWARD

In response to the above challenges and taking into account the existing instruments under Euratom and EC provisions, the Commission proposes the following actions:

⁹ Council Conclusions on the Security of Supply of Radioisotopes for Medical Use, 2986th Agriculture and Fisheries Council Meeting, Brussels, 15 December 2009

3.1. Strengthen the existing regulatory framework

The Basic Safety Standards Directive is currently being recast with four other radiation protection Directives, including the Medical Exposure Directive. The recast of Euratom radiation protection legislation will allow to better integrate the protection of patients with the protection of medical staff and the management of effluents and radioactive waste from nuclear medicine; it is also an opportunity for better distinguishing medical exposures from the deliberate exposure of individuals for other purposes, e.g. security screening. While the spirit of recast calls for few amendments to the Directives, it will strengthen some requirements so as to meet the concerns highlighted in this Communication, for instance to enhance the safety culture in the medical area and prevent accidental or unintended exposures.

There is a need to enhance the regulatory supervision of medical applications of ionizing radiation to ensure that the legal requirements are respected. A clear delineation of responsibilities is needed and independence of the regulatory authority for radiation protection from other responsibilities in the public health sector, as well as its competence and resources, must be ensured. Increased networking between national regulators will be promoted for the consensual development of common practical tools, complementary to the legal initiatives of the Commission.

Strengthening the implementation of the requirements of the Directive is not only a matter of legal enforcement but even more so of motivating the stakeholders and of providing tools facilitating practical implementation. The Commission will further undertake studies to assess the effectiveness of the requirements, launch projects and seek advice from the Art. 31 Group of Experts to provide guidance endorsed by the medical profession.

Good radiation protection in medical applications as well as enhanced safety culture depend on the availability of technical expertise, for instance to ensure proper dosimetry in radiotherapy. The role of the Medical Physics Expert will therefore be strengthened in the recast Euratom legislation and greater mobility of such experts will be fostered through harmonisation of the requirements for the recognition of their expertise.

The Commission will continue to monitor the trends in medical exposures and develop better instruments for the collection of data. Such information will allow focusing efforts on specific aspects and developments. The Commission will associate national regulatory authorities in these efforts.

3.2. Raise awareness and safety culture

Promoting radiation protection in medical applications is a challenge in an environment where the perspective on life and health is very different from other practices. The medical profession must receive adequate training as part of its curriculum and receive regular updates on good practice, but above all has to be made sensitive to its responsibility in ensuring both good medical care and adequate radiation protection.

National health policies should recognise the possible risks of a proliferation of new technology and make arrangements to ensure the justification of all medical exposures. This policy will be pursued jointly by the Commission services in charge of health policy and those in charge of radiation protection.

Awareness also needs to be raised among patients and among the general population, so that an adequate dialogue between patients and the referring practitioner leads to justified

radiological examinations. Radiological examination of a patient without an appropriate referral from a medical professional is in principle excluded. The awareness of parents with regard to high exposures of children (e.g. through CT) is crucial. The Commission will prepare information and publicity campaigns to this effect in cooperation with national health authorities.

3.3. Fostering radiation protection and sustainable supply and use of radioisotopes in medicine through research

Further research can lead to improved protection of patients and medical staff as well as to the development of a more sustainable supply and use of radioisotopes in medicine. In line with current practice, and the strategic approach being developed within MELODI¹⁰, future actions within the Euratom Framework Programme will concentrate on better understanding the health risks from exposure to low doses of ionizing radiation, including the individual sensitivity to radiation exposure, thereby leading to optimised health protection and, possibly, changes in regulation. The more general health theme under the EU Framework Programme should integrate appropriate protection of patients and staff with consideration of the further development of medical radiation technology and the more efficient use of the available isotopes. The development of harmonised uranium targets (including the transition to low-enriched targets) and transport containers will require the close collaboration of the medical radioisotope production sector.

The Sustainable Nuclear Energy Technology Platform (SNETP)¹¹ promotes research, development and demonstration in the area of nuclear systems and safety in line with an agreed vision and strategic research agenda (SRA), consistent with Strategic Energy Technology Plan (SET-Plan) goals. SNETP's SRA also identifies future needs regarding research infrastructures and competences, including new large flexible irradiation facilities, three of which (JHR in France, PALLAS in the Netherlands and MYRRHA in Belgium) have clear potential for radioisotope production in the future.

3.4. Integration of policies

Medical applications of ionizing radiation call for good integration of different policies, on public health, research, trade and industry as well as radiation protection. With regard to nuclear medicine further integration with nuclear safety, waste management, transport and research is required.

The success of efforts towards improving the situation rests to a large extent on the manufacturers of medical devices and of radiopharmaceuticals. Since the marketing of medical devices is subject to EC legislation, a standing platform for looking into the radiation protection features of such devices needs to be set up. Research on novel medical technology shall bear in mind not only medical justification but also its impact on the population exposure.

It will be important to ensure that the planning of X-ray health screening programmes at national or European level take into account the risks from mass exposure of healthy individuals to ionizing radiation. The screening should therefore focus on target groups of the population for which the benefit is demonstrated to outweigh the radiation-related risk.

¹⁰ Multidisciplinary European Low-Dose Initiative, <http://www.melodi-online.eu>

¹¹ Strategic Research Agenda, SNETP, May 2009, <http://www.snetp.eu>

Patient and staff protection should be managed in an integrated way, in particular in interventional imaging, nuclear medicine and CT.

3.5. International cooperation

The issues in Europe are very much the same as in other parts of the world. While the "Western" world shares the feature of over-consumption and resulting increase of exposures, the problems of developing countries are not so much the proliferation of equipment but the unbalance between old-fashioned equipment and novel technology for which the infrastructure and training are lacking. The WHO and regional organisations (PAHO¹²) are very active in developing policies in this area, and IAEA has built up important programmes and information tools. All these efforts must be coordinated and the Commission will support all initiatives in this direction.

The shortage of isotopes is a world-wide problem. Therefore the Commission continues to participate actively in the work of the OECD/NEA for a global approach of the issue. Within the EU, the Commission will further built up a network of information and serve as an observatory.

3.6. Financing mechanisms to ensure sustainable supply of radioisotopes

The possibility of financing mechanisms to ensure a sustainable supply of radioisotopes in the interest of public health and an equitable share of public expenditure by all Member States will be explored together with the Council and European Parliament, and the Commission will ensure appropriate follow-up to the Council Conclusions on this matter. The needs will be established on the basis of the conducted technical and economic studies and of a reference scenario for the replacement of ageing reactors.

For this purpose the Commission could envisage two mechanisms. Euratom loans (Article 172 of the Euratom Treaty) to support isotope production projects may provide an incentive for appropriate investment in research reactors and/or in production facilities. European Investment Bank loans and guarantees may also serve this purpose.

In addition, it could be examined whether a Joint Undertaking (Article 45 Euratom Treaty) may be useful in achieving not only a regular and sustainable supply, but also in gaining control of the entire cycle, from irradiations of uranium "targets" to distribution of Tc-99m generators to end users, so as to ensure a better balance between public financing and private benefit. This instrument will require a thorough preliminary analysis of all organisational and financial aspects.

3.7. Facilitating transport of radioisotopes

The Commission will soon make a proposal for the simplification of administrative procedures for the trans-border transport of radioactive materials, which might facilitate transport of radioisotopes for medical use.

¹² Pan American Health Organization, <http://new.paho.org>