

ROADMAP

Title of the initiative: **Commission Communication on nuclear medicine and radioisotopes**
Type of initiative (CWP/Catalogue/Comitology): Communication from the Commission to the European Parliament and the Council (ad hoc inter-service group for drafting established)
Lead DG/contacts : DG ENER/A; DG ENER.DDG2.D.4
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Initial IA screening & planning of further work

The proposed Communication is dealing with two groups of issues having different relation to the Euratom radiation protection legislation:

a) The protection of the patients and the medical staff against the dangers of ionizing radiation is regulated by the existing Council Directives 97/43/Euratom and 96/29/Euratom being currently recast together with three other radiation protection Directives. The Communication will add to the recast process on two levels – firstly, by addressing the areas in which the legislation is not adequately implemented in the Member States and secondly, by proposing action beyond the scope of the Euratom legislation but aiming at more efficient and harmonized radiation protection of patients and medical staff.

b) The secure supply of radioisotopes for nuclear medicine is outside of the scope of the Euratom radiation protection legislation. However, the recurrent supply crises affect huge number of patients in the European Union and around the world and some actions to relieve the situation may be taken within the Euratom framework. There is no relation between this part of the Communication and the ongoing recast of the Euratom radiation protection Directives.

A. Context and problem definition

(i) What is the political context of the initiative? (ii) How does this initiative relate to past and possible future initiatives, and to other EU policies?

Ionizing radiation has been used in medicine for more than a century, allowing for the great progress made in both diagnosis and treatment of patients. The advance in this area has been especially rapid in the past decade or so, when a lot of new techniques have been developed and made available to more patients. These developments, however, have caused a number of new issues and concerns that have gained the attention of international organizations, national authorities, professional groups and the media and the general public. For example: a 2009 report showed that the United States population's total exposure to ionizing radiation has nearly doubled in the past two decades largely due to the medical use of radiation; in the economically developed countries there is a number of examples of inappropriate radiological examinations leading to unnecessary radiation exposure of patients; patient overexposure accidents have been reported, e.g. in radiotherapy in France and Belgium and in diagnostic radiology in the United States and Japan.

The European Union and Member States act in multiple ways in this area in accordance with their respective competences within the framework of the Treaties, and especially of the Treaty establishing the European Atomic Energy Community (Euratom). Within this legal framework, the Commission addresses today's challenges in the medical use of ionizing radiation. International organizations and European professional and scientific societies are also very active in this area.

What are the main problems identified?

There is a need to protect patients and medical staff against the dangers from medical use of ionizing radiation, as defined by the Euratom radiation protection Directives (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 ionising radiation and Council

Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure).

The following main elements should be addressed: overuse of diagnostic radiology and associated problems (inappropriate justification, high-dose examinations and increased collective dose), recent accidental and unintended exposures in radiotherapy, significant staff exposures and insufficient radiation protection training of medical professionals. There is a general lack of systematic information on the extent and the spread of these issues in individual Member States but indications exist that the problem is global and affects all and everyone.

Nuclear medicine currently is afflicted by a shortage of supply of radioisotopes. The European Association of Nuclear Medicine (EANM) investigated by means of a survey amongst its members that the supply shortage occurred in autumn 2008 seriously affected fourteen European countries. In line with the recently adopted Council Conclusions on the Security of Supply of Radioisotopes for Medical Use this calls for reflections on actions to be undertaken at EU level.

Who is affected?

The main groups affected are patients and staff in medical applications of ionizing radiation (radiodiagnostic and radiotherapeutic procedures) as well as national authorities and industry with regard to the supply of radioisotopes.

(i) Is EU action justified on grounds of subsidiarity? (ii) Why can the objectives of the proposed action not be achieved sufficiently by Member States (necessity test)? (iii) As a result of this, can objectives be better achieved by action by the Community (test of EU Value Added)?

Not applicable for the envisaged document (Communication).

B. Objectives of EU initiative

What are the main policy objectives?

It is necessary to identify a longer-term perspective on the medical application of ionizing radiation in the Union and stimulate the discussion on the necessary action, resources and distribution of responsibilities to address the challenges in this field. There is a need to provide an overview of the today's challenges on the medical application of ionizing radiation and provide visibility of the Community actions. The roles of the international organisations and the needs of continuous, and where appropriate enhanced, international co-operation should also be clarified.

Do the objectives imply developing EU policy in new areas or in areas of strategic importance?

No.

C. Options

(i) What are the policy options? (ii) What legislative or 'soft law' instruments could be considered? (iii) Would any legislative initiatives go beyond routine up-date of existing legislation?

Not applicable.

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

This initiative is coordinated with other Directorates-General, especially SANCO and RTD.

Explain how the options respect the proportionality principle

Not applicable.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the Impact Assessment Guidelines pages 32-37), even if these impacts would materialise only after subsequent Commission initiatives?

Not applicable – no impact assessment required.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

Not applicable.

Could the options have significant impacts on (i) simplification, (ii) administrative burden or on (iii) relations with third countries?

Not applicable.

E. Planning of further impact assessment work

When will the impact assessment work start?

Not applicable.

(i) What information and data are already available? (ii) Will this impact assessment build on already existing impact assessment work or evaluations carried out? (iii) What further information needs to be gathered? (iv) How will this be done (e.g. internally or by an external contractor) and by when?

(v) What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Not applicable.

Which stakeholders & experts have been/will be consulted, how and at what stage?

The draft outline of the Communication was consulted with the Group of Experts referred to in Article 31 of the Euratom Treaty (presentation and discussion at the meetings of the Group held on 9-11 June 2009 and 3-5 November 2009 and at the meetings of the WP on Medical Exposures held on 1-2 September 2009 and 2-3 February 2010).

The draft outline was presented and discussed with the international organizations (IAEA, UNSCEAR, WHO, NEA and ICRP) at the 14th meeting of the Inter-Agency Committee for Radiation Safety held in Paris on 14-15 January 2010.

Regarding the subject of the supply of radioisotopes for nuclear medicine the following stakeholders were/will be consulted:

- the representative from the European Isotopes Transport Association (48th meeting of Standing Working Group On Transport of Radioactive Materials held on 22 January 2010),
- the representatives from Covidien company, one of three EU major suppliers of isotopes for nuclear medicine (meeting organized in Luxembourg on 19 February 2010), the second major supplier – IRE company is invited to a meeting to be held in Luxembourg on 4-5 May 2010,
- the representatives from the nuclear regulatory authorities from all EU Member States and the experts from research reactors and an industry sector dealing with medical radioisotopes (The Directorate-General for Energy will host a Meeting on the Security of Supply of Medical Radioisotopes in EU Member States to be held in Luxembourg on 4-5 May 2010. The purpose of the meeting is to provide a forum to exchange information on possible short-term solutions and on details of the most promising reactor opportunities for securing Mo-99 production in the medium and long term. The planned Communication will reflect on the findings from the meeting).