



Meeting of the Group of Experts (GoE) established under Article 31 of the Euratom Treaty

Luxembourg, 23 – 24 November 2010

SUMMARY REPORT

(Approved by the Group of Experts at the meeting 8 – 9 June 2011)

INTRODUCTION

The Chairperson welcomed the participants, in particular the representative of the Heads of European Radiological protection Competent Authorities (HERCA) who joined the group for the first time as an observer. The Secretariat informed the Group of Experts about apologies of members who could not participate.

1. APPROVAL OF THE AGENDA

The agenda was approved without amendments.

2. APPROVAL OF THE SUMMARY REPORT OF THE MEETING HELD IN LUXEMBOURG ON 3 – 4 JUNE 2010

The Summary Report was approved without amendments¹.

3. INFORMATION BY THE COMMISSION

3.1. Nuclear Safety

A representative of Unit D1 informed the Group of Experts about recent activities and initiatives related to nuclear safety and international relations of Euratom.

Negotiation mandates for a revised Euratom-Australia agreement and a Euratom-South Africa agreement have been adopted by the Council. A revised Euratom-Canada agreement and a Euratom-Russia agreement are currently being negotiated. A Commission proposal for a Euratom-China cooperation agreement is planned for the third quarter of 2011.

Regarding the implementation of the recently published nuclear safety Directive, the Commission is currently analysing incoming notifications of draft national legislation

¹ The approved Summary Report of the June 2010 meeting can be found under http://ec.europa.eu/energy/nuclear/radiation_protection/article_31_en.htm

under Article 33 of the Euratom Treaty. A seminar on the implementation of the nuclear safety Directive is planned for 2011.

The Commission is planning to prepare a Communication on Nuclear Energy, which shall be an update of the Nuclear Illustrative Programme (PINIC). The Communication will review the latest situation regarding MS policies, nuclear investment decisions and requirements. In view of the 20-20-20 climate change targets, it will discuss capacity issues and the contribution of nuclear for decarbonising electricity generation and the energy mix, as well as look into initiatives to promote the replacement of aging power plants by low-carbon electricity generation, especially nuclear. The Commission is obliged under the Euratom Treaty to report annually on investments in nuclear energy.

The Commission is planning to prepare a Communication or Directive on civil liability in the nuclear field, as legislation in Member States is based on different international conventions and liability levels vary. The aim of such an initiative is to facilitate the development of a more coherent and harmonized liability or insurance claims scheme.

3.2 Radioactive Waste Management and Transport

A representative of Unit D2 reported on a recent legislative initiative in the area of management of radioactive waste and spent fuel. On 3 November 2010, the Commission adopted a proposal for a Council Directive on the management of spent fuel and radioactive waste. This proposal updates and replaces the one tabled in 2004². To prepare it, the Commission engaged in a broad consultation through different initiatives at EU level, including an open public consultation. The constructive and detailed contribution made by the European Nuclear Safety Regulators Group (ENSREG) was of key importance, given the specific competence of the Group, which represents national nuclear regulatory or safety authorities, from Member States with and without nuclear power programmes.

The basic approach of the proposed legislation is that internationally accepted principles and requirements for spent fuel and radioactive waste management, laid down in the IAEA Safety Standards and the Joint Convention³, are regulated at EU level. Furthermore, specific requirements are established regarding the scope, contents and review of national programmes and transparency on spent fuel and radioactive waste management.

Member States will have to report to the Commission on the implementation of the proposed Directive. On the basis of the Member States' reports, the Commission will submit a progress report to the Council and the European Parliament.

Member States will invite international peer reviews of their national frameworks and national programmes with the aim of achieving the required high standards in the management of spent fuel and radioactive waste. The outcomes of any peer review will be reported to the Member States and the Commission.

The proposed Directive is currently under discussion in the Council's Working Party on Atomic Questions (AQG). Its adoption by the Council is expected during the Hungarian Presidency next year.

² COM (2004)526 final

³ Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management. Adopted in 1995 under the aegis of the International Atomic Energy Agency.

In the discussion following the presentation, members of the Group of Experts inquired on various issues, including the definition of radioactive waste, fuel from research reactors, legal issues regarding the ownership of the waste, financial guarantees at EU level, the possibility of shared repositories, and the management of uranium bearing waste.

3.3 Status of legislative projects

a. Revised Euratom Basic Safety Standards Directive

The Secretariat informed the GoE about the status of the revised Euratom Basic Safety Standards Directive. On 17 November 2010, the Radiation Protection Unit finalised the impact assessment report and sent it to the Impact Assessment Board. The Impact Assessment Board will meet on 15 December 2010 to discuss the report with the radiation protection unit. After approval of the Impact Assessment Report, it is planned to launch the Inter Service Consultation beginning of 2011 and to prepare a Commission proposal for March 2011. The Secretariat will keep the GoE informed about progress with this matter.

b. Drinking water directive

As already discussed during previous GoE meetings, the DG ENER proposal for a Euratom Directive on drinking water, on which the GoE had given a positive Opinion, did not pass the Inter Service Consultation due to a negative opinion of DG ENV. A meeting between the Director-General of DG ENV and the Director-General of DG ENER to resolve the issue is planned to take place in December 2010. The Secretariat will keep the GoE informed about progress with this matter.

c. Communication of the Commission to the European Parliament and the Council SEC(2010)974 on medical applications of ionizing radiation and security of supply of radioisotopes for nuclear medicine

The Secretariat informed the GoE about recent developments in relation to the above mentioned *Communication*⁴.

The Communication jointly proposed by Günther Oettinger, Commissioner responsible for Energy, and by John Dalli, Commissioner responsible for Health and Consumer Policy, was adopted on 6 August 2010. Following the adoption, the document was presented and discussed at the Council's Working Party on Atomic Questions (AQQ) and the Council's Working Party on Pharmaceuticals and Medical Devices. On that basis the Belgian Presidency of the Council prepared draft Council Conclusions *Towards the Secure Supply of Radioisotopes for Medical Use in the European Union*. Following several rounds of examination and taking into account input received from the Working Party on Pharmaceuticals and Medical Devices, the Working Party on Atomic Questions

⁴ Communication of the Commission to the European Parliament and the Council on medical applications of ionizing radiation and security of supply of radioisotopes for nuclear medicine; <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52010DC0423:EN:NOT>

Commission Staff Working Document Accompanying the Communication; http://ec.europa.eu/energy/nuclear/radiation_protection/doc/legislation/comm_sec_0974.pdf

(AQQ) reached agreement on the text to be adopted by the Council in December 2010. In the Conclusions, the Council urges the Commission to refine further, in close cooperation with Member States and stakeholders, the reference scenario for the secure supply of radioisotopes for medical use in Europe, taking into account the economic study published by the OECD/NEA and to define on that basis, a European solution for ensuring mid and long term security of supply.

The Secretariat informed that in response to this invitation the Directorate-General for Energy will host a meeting on 25 – 26 November 2010 with the EU Research Reactors Operators and Mo-99 Processors to share stakeholders' views on the proposed draft Council Conclusions and to identify the critical issues within the radioisotopes supply chain which are relevant to a European solution to be defined.

The Secretariat confirmed that the proposed Council Conclusions focus only on the security of supply of radioisotopes and do not deal with the issues of radiation protection of patients and medical staff, also broadly discussed in the Commission Communication. The Secretariat holds hope that upcoming Presidencies of the Council (Hungarian or Polish) will propose separate Council Conclusions also on this important matter.

The GoE took note of the information provided and asked to be kept informed about further developments in the area of supply of radioisotopes. The GoE expressed their concern about lack of reflections on radiation protection of patients and medical staff in the proposed Council Conclusions and shared the Secretariat's view that this important matter needs to be given careful consideration, preferably in form of separate Council Conclusions to be proposed by one of the next Presidencies of the Council.

4. PRESENTATIONS FROM INTERNATIONAL ORGANISATIONS

4.1. ICRP

The representative of the International Commission on Radiological Protection (ICRP) reported on recent ICRP publications and on the status of work in progress. ICRP will soon release the draft document "Lung Cancer Risk from Radon", a document to support the ICRP Statement on Radon made in November 2009.

The draft report "Tissue Reactions and Other Non-Cancer Effects of Radiation", which should be available for public consultation in late 2010 or very early in 2011, will be accompanied by an ICRP statement that will include, inter alia, recommendations on equivalent dose limits for the lens of the eye.

At its meeting in October 2010, the Main Commission approved the creation of a Task Group on Protection of Aircraft Crew from Cosmic Radiation Exposure. This new Task Group includes membership from the airline industry. The Main Commission also approved revised terms of reference for the Task Group on Protection in Security Screening.

The first ICRP Symposium on the International System of Radiological Protection will be held in Bethesda, Maryland, USA, 24 – 26 October 2011 in conjunction with the upcoming joint meetings of the ICRP Main Commission and Committees. Details are found in the "First Announcement" available at the newly created website www.icrp.org.

4.2 IAEA

The representative of the International Atomic Energy Agency (IAEA) reported on the status of development of the International Basic Safety Standards since the last meeting of the Article 31 Group of Experts. The Joint Secretariat has prepared the current draft

4.0 which accommodates all comments received from Member States and international organisations during the consultation period. The IAEA is expecting that draft 4.0 will be adopted by all Safety Standards Committees, including the leading Radiation Safety Standards Committee (RASSC) in December 2010 and subsequently by the Commission on Safety Standards (CSS) in March 2011.

The IAEA representative summarised also the activity highlights in Radiation, Waste and Transport Safety since the last meeting of the Article 31 Group of Experts. The topics covered initiatives within the Action Plan for Occupational Radiation Protection, within the International Action Plan for the Radiation Protection of Patients, on radiation protection dosimetry, on waste safety, on the protection of the environment, and on transport safety. The IAEA presented also a new website ORPNET which shall become a medium for communication and exchange of information on occupational radiation protection: <http://www-ns.iaea.org/tech-areas/communication-networks/norp/default.asp>.

4.3 NEA

The representative of the Nuclear Energy Agency (NEA) presented recent developments in the NEA programme in radiological protection, in nuclear emergency matters, occupational exposure, best available techniques, public health perspective in radiological protection, radiological protection of the environment, stakeholder involvement issues, and qualified human resources in radiological protection. The new ad-hoc groups on the exclusion of reactors in decommissioning from the Paris Convention, and on consumer products containing radioactive substances held their first meetings in summer 2010. A new Expert Group on the implementation of international recommendations (ICRP and revised BSS) for emergency exposure situations shall start working in 2011. Preparations for the 3rd Science and Values workshop which is scheduled for October 2011 in Japan have just started. Further information can be found on the (new) NEA homepage: www.oecd-nea.org.

4.4. IRPA

No representative of the International Radiation Protection Association (IRPA) could attend the meeting.

4.5 WHO

The representative of the World Health Organisation (WHO) presented mandate and structure of the organisation with particular emphasis on units dealing with protection against ionising radiation. The activities of WHO cover various areas of radiation protection, such as existing exposures, e.g. from radon, emergency preparedness and response, chronic exposures from past accidents, and planned exposures, in particular in the medical area. Recent examples are the WHO initiative on radon as a "healthy housing" issue, the preparation of WHO guidelines for drinking water quality, the WHO Global Initiative on Radiation Safety in Health Care Settings, the WHO referral guidelines project related to medical imaging, and the WHO Workshop on Radiation Risk Communication in Paediatric Imaging held in September 2010.

4.6 HERCA

The chairperson of HERCA presented the terms of reference and the current work programme of the Heads of European Radiological protection Competent Authorities (HERCA). The objectives of HERCA are

- To build and maintain a network of Chief radiation safety regulators in Europe;

- To promote the exchange of experience and learning from each other's best practices;
- To develop a common approach to radiation safety and regulation in particular within the European Union;
- To discuss and, where appropriate, express its consensus opinion on significant regulatory issues.

The chairperson of HERCA stressed the importance of a good working relationship with the European Commission and the Article 31 Group of Experts and welcomed the decision of the GoE to accept HERCA as observer in Article 31 GoE meetings. The European Commission is already regularly participating in HERCA meetings. HERCA will further develop a policy with regard to interactions with other international and national organisations, associations, and platforms.

Work areas and first achievements of HERCA cover stakeholder involvement in medical activities, European radiation passbook, harmonised criteria on patient release after I-131 therapy, use of body scanners for security purposes and justification of the use of smoke detectors and other consumer goods containing radioactive substances. The HERCA proposal for a European radiation passbook was discussed by the Article 31 Group of Experts under agenda item 7.

HERCA is currently preparing a sustainable future of this new association.

5. REVIEW AND PRIORITISATION OF THE ACTIVITIES OF THE WORKING PARTIES AND RELATED PROJECTS

5.1. Medical Exposures (WP MED)

Progress report

The Working Party on Medical Exposures (WP MED) had their first meeting in the new composition on 13 – 14 October 2010 where a new Chairperson and Vice-chairperson were elected. The GoE welcomed the choice of the WP MED and endorsed the election decision.

The Chairperson of the WP MED reported on progress with different tasks discussed at the last meeting of the working party. As this has been the first meeting of the renewed WP MED, the following priorities for its future work had been defined:

- a. To follow up on running projects and produced guidelines to help Member States in the application of the current European Directives in the area of medical exposures.
- b. To initiate a discussion on research priorities in the area of radiation protection in medicine.
- c. To analyse the European legislation on medical devices (including the European databank) and its relation to the radiation protection of patients.
- d. To improve the cooperation with other organizations working in RP for medical exposures. The Secretariat will invite HERCA Working Group on Medical Applications to appoint an observer to the WP MED.

The GoE agreed on the defined priorities.

In line with priority (b) the GoE was asked to give a mandate to the WP RIHSS and WP MED to jointly prepare a statement of the Group on the needs of European research in

support of practical radiation protection issues, with a focus on medical exposure. The requested mandate was given to the two working parties, who will prepare a draft statement for the June 2011 meeting of the GoE.

In line with priority (c) the WP MED will at their next meeting discuss the EU medical devices legislation and its radiation protection implications, including a report on this topic being prepared by the French competent authorities, a presentation from DG SANCO, etc. The French report, expected to be finalized by the end of 2010, will be also presented and discussed in the June 2011 meeting of the GoE.

5.2. Research Implications on Health and Safety Standards (WP RIHSS)

a. EU Scientific Seminar 2010 on Issues with internal emitters

The Chairperson of the WP RIHSS briefly summarised the results of the EU Scientific Seminar on *Issues with internal emitters*, which was held on 23 November 2010. Five internationally renowned scientists working in the field of internal emitters presented current knowledge. The speakers offered information on dosimetry, uncertainties, and risk estimates in the context of internal emitters, on progress in understanding radon risk, on the less known Thorium-232 decay chain, and on an update on lessons learnt from thyroid cancers after the Chernobyl accident. In addition, an expert of the GoE presented the MELODI project (www.melodi-online.eu). The presentations were followed by a round table discussion, in which the speakers and invited additional experts discussed potential policy implications and research needs.

At its next meeting, the WP RIHSS will further analyse the presentations and papers and prepare the draft proceedings together with a draft summary and draft conclusions and implications.

The GoE congratulated the WP RIHSS for the organisation of this Scientific Seminar, and for the high quality of the presentations and the round table discussions. The GoE is looking forward to receive the draft proceedings of the seminar for discussion at the June 2011 meeting.

b. Proposal of topics for the 2011 Scientific Seminar

At its meeting in October 2010, the WP RIHSS agreed to propose the following selection of topics for the EU Scientific Seminar 2011:

1. Individual radiosensitivity
2. Health effects of Chernobyl – where are we now
3. Radiation induced cancers after medical exposure
4. Dosimetry in accidents (which may be held 2012 or later)

In discussion, experts of the group proposed two additional potential topics for further scientific seminars:

5. Protection of the environment
6. Protection of children

The GoE thanked the WP RIHSS for this interesting selection of potential topics. After some discussions the GoE decided to hold the

- EU Scientific Seminar 2011 on ***Individual radiosensitivity*** and the
- EU Scientific Seminar 2012 on ***Protection of the environment***.

c. Additional work programme of the WP RIHSS

With a view to the 25th anniversary of the Chernobyl accident in 2011, the GoE asked the WP RIHSS to review recent scientific findings and publications on the health effects of Chernobyl and to prepare a summary report to be presented to the Article 31 Group of Experts at their next meeting in June 2011.

Another additional task of the WP RIHSS is mentioned under 5.1.

5.3 Dose constraints

At the Article 31 GoE meeting in June 2010, the GoE recommended to the Commission the creation of a Working Party on Dose Constraints.

Already in 2004, a working party of the GoE prepared a report on the use of dose constraints based on the at that time agreed definition and understanding of dose constraints in ICRP Publication 60 and in Council Directive 96/29/Euratom. This report shall be used as starting point for the discussions in the new working party.

The NEA Expert Group on Occupational Exposure (EGOE) is currently working on a case study on dose constraints. Due to its mandate and its specific membership, the EGOE focuses exclusively on the use of dose constraints for occupational exposure in the nuclear industry. Being represented at EGOE, the Secretariat will ensure that the work programmes of the EGOE and of the proposed Article 31 Working Party on Dose Constraints are coordinated and have no overlap.

The Secretariat proposed to create a small brainstorming group which should meet once in the first quarter of 2011 to prepare a draft mandate, including objectives and deliverables, of such a working group and a draft work programme, which shall be presented to the GoE in June 2011.

The GoE agreed with this proposal and formed a brainstorming group consisting of three members of the GoE.

6. INTERNATIONAL SYMPOSIUM ON MEDICO-LEGAL EXPOSURES, DUBLIN, 8 – 9 OCTOBER 2009

Prior to the meeting, the GoE had received the final report and the draft proceedings of the Commission-supported International Symposium on Non-medical Imaging Exposure, held on 8 – 9 October 2009 in Dublin. The Secretariat asked the Group to share their views on the needs of future work in this area and on the working arrangements within the GoE to address the outstanding issues. While there was a general agreement that Non-medical Imaging Exposures will need further guidance and networking as proposed in the final report) there were no concrete proposals for Commission projects in this area.

The detailed consideration of the needs and necessary action was referred to the WP MED and would be included in their next meeting agenda. The members of the GoE would have one week following the meeting to submit comments on the final report and the proceedings of the Dublin symposium.

The GoE asked the WP MED to keep the group updated on progress with this issue and to propose future actions, if appropriate.

7. EUROPEAN RADIATION PASSBOOK FOR OUTSIDE WORKERS – A PROPOSAL FROM HERCA

A HERCA working group prepared a report on the progress to draft a European Radiation Passbook for Outside Workers to meet the requirements of Council Directive

90/642/Euratom. This report has been approved by HERCA for a wider stakeholder consultation. The report includes, *inter alia*, a proposal for the content of a radiation passbook, split in mandatory data and optional entries.

The Secretariat presented this initiative to the Group of Experts with a view to obtain a first reaction of the Group on a potential incorporation of the content of a radiation passbook in the revised Euratom Basic Safety Standards Directive.

The GoE welcomed this initiative to harmonise the data which need to be provided on an outside worker before working in the controlled area of an undertaking, and supported the proposed data content. The GoE recommended, however, investigating further the final form in which these data need to be presented and asked for the possibility to use modern technology such as network connections, electronic files or chip cards. It was further discussed whether these data need to be presented in one file or could be provided in more than one file, if in a Member State these data are collected by more than one organisation (for instance the medical certificate for fitness for radiation work is often not incorporated in the passbook).

The GoE decided to wait for the outcome of HERCA's wider stakeholder consultation on this issue before advising on a potential incorporation in the revised Euratom Basic Safety Standards Directive.

8. FOLLOW-UP ON ISSUES DISCUSSED AT THE PREVIOUS MEETING

Body scanners for security screening

The Secretariat updated the Group on the aviation security screening initiative of the Commission's Directorate-General for Mobility and Transport (DG MOVE). In June 2010, the Commission published COM(2010) 311 *on the use of security scanners at EU airports*. In July 2010, DG MOVE began preparing an Impact Assessment on possible action to address the current legal obstacles to the installation of security scanners at EU airports. The draft impact assessment is being discussed in a Steering Committee where the Radiation Protection Unit of the Directorate-General for Energy is taking active part. The impact assessment is expected to be published after January 2011.

9. OTHER BUSINESS

An expert informed the Group that the French nuclear safety authority (ASN) will be organising an international seminar on post-accidental issues, which will take place 5 – 6 May 2011 in Paris, France.

10. DATE OF THE NEXT MEETINGS

The next meeting of the Group of Experts will be held on **8 - 9 June 2011** in meeting room EUFO 0001, **European Commission – Euroforum Building, 10, rue Robert Stumper – L-2557 Luxembourg – Gasperich.**

The November 2011 meeting of the Group of Experts is scheduled for **22 - 23 November 2011** in meeting room M1, **European Commission – Jean Monnet Building, rue Alcide de Gasperi – L-2920 Luxembourg – Kirchberg.**