



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

Luxembourg, 3 – 4 June 2010

SUMMARY REPORT

(Approved by the Group of Experts at the meeting 23 – 24 November 2010)

INTRODUCTION

This was the first meeting of the Group of Experts referred to in Article 31 of the Euratom Treaty in a new composition, as nominated by the Scientific and Technical Committee. The Secretariat welcomed the experts and asked the Vice-Chairperson to chair the meeting until after the election of a new Chairperson. The Secretariat welcomed also the representative of the World Health Organisation (WHO) who joined the group for the first time as an observer.

The experts presented themselves in a tour de table.

1. APPROVAL OF THE AGENDA

The agenda was approved with one additional agenda item 4.6 providing a presentation on the Heads of European Radiological protection Competent Authorities (HERCA).

2. PROCEDURAL ASPECTS

2.1. Rules of Procedure

The Secretariat briefly introduced the Rules of Procedure of the Group of Experts established under Article 31 of the Euratom treaty which were approved by the Group of Experts on 14 November 2007¹. The Group of Experts in the new composition took note of the Rules of Procedure.

2.2 Election of a new Chairperson for the period 2010 – 2012

The experts were contacted by the Secretariat before the meeting and asked to nominate candidates for the election of a new Chairperson for the period June 2010 – November

¹ The Rules of Procedure (Version 14 November 2007) can be found under http://ec.europa.eu/energy/nuclear/radiation_protection/article_31_en.htm

2012. The Secretariat presented a list of nominees received. The Secretariat and the observers left the meeting during the election of the new Chairperson.

The GoE elected a new Chairperson. From this agenda item on, the meeting was chaired by the new Chairperson.

2.3 Working Parties – creation and membership [This agenda item was discussed after agenda item 6]

The Group of Experts disbanded the Working Party on Medical Exposures (WP MED) and the Working Party on Research Implication on Health and Safety Standards (WP RIHSS) in their current composition.

After the discussion under Agenda item 6, the Group of Experts decided to reinstall both working parties and asked for experts willing to participate. The new WP MED will have 10 members plus two corresponding members. The new WP RIHSS will have seven members plus two corresponding members.

The GoE discussed the creation of additional Working Parties and decided to recommend to the Commission to create a Working Party on Radon and a Working Party on Dose Constraints. The Secretariat will prepare draft mandates and work programmes for both working parties which shall be discussed at a later meeting of the GoE.

3. INFORMATION BY THE COMMISSION

3.1. Nuclear Safety

No representative of Unit D1 could attend the meeting.

3.2 Radioactive Waste Management and Transport

No representative of Unit D2 could attend the meeting.

3.3 Status of legislative projects

a. 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. DG ENV prepares a proposal under joint EC treaty and Euratom treaty provisions. The Secretariat will keep the GoE informed about progress with this matter.

b. Revised Euratom Basic Safety Standards Directive

The Secretariat informed the GoE about the status of the revised Euratom Basic Safety Standards Directive. The Radiation Protection Unit is currently preparing the impact assessment which is hoped to be ready by the end of 2010. 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.

4. PRESENTATIONS FROM INTERNATIONAL ORGANISATIONS

4.1. ICRP

The Scientific Secretary of the International Commission on Radiological Protection (ICRP) reported on recent ICRP publications and on the status of work in progress. An ICRP Report on Activities is given in Annex 1. The GoE was particularly interested in recent developments with regard to radiation induced cataracts and with regard to radon. An ICRP Report on tissue reactions and other non-cancer effects of radiation is expected to be published by the end of 2010. This report shall include new information on effects of exposure to the lens of the eye. 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.

4.2 IAEA

The representative of the International Atomic Energy Agency (IAEA) summarised 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 justification of medical exposure, in the area of education and training, control of sources and the remediation of uranium mining legacies.

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. Two new ad-hoc groups will discuss the exclusion of reactors in decommissioning from the Paris Convention, and consumer products containing radioactive substances.

4.4. IRPA

The representative of the International Radiation Protection Association (IRPA) presented current initiatives in the IRPA work programme and reported on the regional IRPA congresses organised in 2010 in Tokyo, Helsinki and Nairobi. The IRPA 13 Congress will take place 13 – 18 May 2012 in Glasgow, UK.

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 publication of the WHO Handbook on indoor Radon, as well as the WHO Consultation on Referral Guidelines for Appropriate Use of Radiation Imaging.

4.6 HERCA

A member of the Article 31 GoE 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.

Currently, 32 European Countries are active in HERCA. The discussed topics cover stakeholder involvement in medical activities, European dose passport, harmonised criteria on patient release after I-131 therapy, use of body scanners for security purposes and justification of the use of smoke detectors.

The work of HERCA shall be useful to help resolving outstanding harmonisation issues and to supplement the work of the European Commission.

The GoE agreed to invite HERCA on a regular basis to participate as observer in Article 31 GoE meetings.

5. REVISION OF THE INTERNATIONAL BASIC SAFETY STANDARDS

5.1 Status of the revision

The representative of the International Atomic Energy Agency (IAEA) summarised the status of revision of the International Basic Safety Standards. Draft 3.0 has been sent to Member States for consultation and to co-sponsoring organisations to receive input from their respective constituency. Comments had to be sent to the IAEA Secretariat by 31 May 2010. 33 Member States and 9 international organizations sent about 1400 comments covering the following issues:

- interface with security
- terminology e.g. “facilities and activities” versus “practice” and “source”
- exemption and clearance
- non-medical imaging
- air crew
- situations involving accidents that do not require activation of national emergency response plan, i.e. handled by the licensee
- education and training
- overarching requirements.

The IAEA secretariat will have to review the existing text and to finalise draft 4.0 after the BSS secretariat’s meeting, which will be held in August 2010. On 15 September 2010, draft 4.0 shall be send to the committees (RASSC will meet 6 – 10 December 2010) for their approval to submit the International BSS to CSS for endorsement at their meeting in March 2011.

5.2 Discussion of the international Basic Safety Standards (Draft 3.0)

The Secretariat reported on the active role the Commission has played in the drafting of the international Basic Safety Standards through its involvement in the international BSS Secretariat as a potential co-sponsor of the document.

The Secretariat presented a draft working document providing a comprehensive though not exhaustive overview of the differences in approaches and specific requirements in the international standards (draft 3.0) and the revised Euratom Basic Safety Standards Directive (version 24.02.2010, on which the experts had given an Opinion). It is

proposed to forward the recommendations contained in this document, if agreed by the GoE, to the IAEA and to discuss these at the next meeting of the BSS Secretariat.

The GoE discussed the document in detail and proposed various changes and clarifications.

In conclusion, the GoE found this comparison document to be very useful and recommended to forward it to the IAEA. The Experts were offered to send further comments to the Secretariat not later than 11 June 2010.

The Secretariat confirmed that the responsibility with the content of this comparative document will stay with the Commission.

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

6.1. Medical Exposures (WP MED)

a. Progress report

As this was the first meeting of the GoE in a new composition, the Vice-Chairperson of the Working Party on Medical Exposures (WP MED) provided general information about the WP MED and reported on activities corresponding to the last three year meetings.

The WP MED was created to discuss current issues in the radiation protection of patients and other individuals subject to medical exposures. Its mandate was revisited and refined in 2008. Some of the relevant tasks are: keep track of international recommendations relevant to radiation protection in medicine, discuss emerging issues in radiation protection in Member States, contribute to Article 31 discussions on radiation protection in medical exposures, review legislation relating to medical exposures, provide views on EC-funded projects and suggest new ones. The WP MED comprises 10 Experts and meets 2-3 times per year. Representatives from DG RTD, IAEA and WHO are invited to participate as observers in meetings of the WP MED.

The documents produced by the WP MED or by external contractors are discussed by the Group and submitted to the Article 31 GoE to receive approval for publication. Most of the documents are guidelines to help Member States in the application of the Directive on Medical Exposures 97/43/Euratom (MED).

WP MED has also promoted or been involved in several international conferences dealing with medical exposures: International Workshop on Justification of Medical Exposure in Diagnostic Imaging (Brussels, September 2009), International Symposium on Non-Medical Imaging Exposures (Dublin, October 2009) and International Conference on Modern Radiotherapy (Versailles, December 2009).

During the last two years, the WP MED has been involved in the revision of Euratom Basic Safety Standards Directive (mainly Title VIII).

Further to the report from the Vice-Chairperson, the Secretariat presented latest developments with ongoing EC-projects to assist Member States in the application and harmonization of the MED:

- European Medical ALARA Network (EMAN) - stakeholders network on optimization of radiation protection in medical exposure, a three year project launched in October 2009 – more information can be found under <http://eman-network.eu>;
- Guidelines on Medical Physics Expert (MPE) - aimed to improve implementation of MED provisions related to MPE and to facilitate the harmonization of MPE education and training among the Member States, a two year project launched in January 2010 - more information can be found under <http://portal.ucm.es/web/medical-physics-expert-project>.

The following projects shall be launched in 2010:

- DOSE DATAMED 2 (collection of EU wide data on doses from medical exposures; testing RP 154 guidelines; European Workshop in 2011)
- Implementation of MED's requirement on RP training of medical professionals in the EU (Project to perform a study on the implementation of the MED's requirements on RP training of medical professionals and to update RP 116 (2000): Guidance on Education and training on radiation protection for medical exposures)
- Radiation criteria for acceptability of medical radiological equipment used in diagnostic radiology, nuclear medicine and radiotherapy – finalization of the document and organisation of European Workshop.

b. European Commission Communication on nuclear medicine and the supply of radioisotopes

The Secretariat presented a draft *Commission Communication on nuclear medicine and the supply of radioisotopes*. The current draft was prepared by the Commission's Ad-hoc Inter-Service Group set-up for this purpose at the beginning of the year, with the participation of representatives from DG ENER, SANCO, RTD, JRC and the European Medicines Agency. The draft reflects also the discussion at the WP MED meeting held in February 2010.

The draft received general positive response by the GoE. Members of the Group expressed their views on some important issues that need to be addressed in the final document, including: side effects and complications following radiotherapy, differences in patient individual sensitivity to radiation exposures, the safety of medical devices and software and high doses to the medical staff in nuclear medicine (especially in PET procedures).

The Secretariat informed the GoE that an Inter-Service Consultation on the draft Communication will be held in June and an adoption by the Commission through a written procedure is scheduled for July/August.

c. Summary of the International Symposium on Modern Radiotherapy: Advances and Challenges in Radiation Protection of Patients, Versailles, France, 2 – 4 December 2009

A member of the GoE summarised the results of the *International Symposium on Modern Radiotherapy: Advances and Challenges in Radiation Protection of Patients*, which took place 2 – 4 December 2009 in Versailles, France. 360 delegates from 50 countries across the world participated in this three days conference with 41 presentations made and 67 posters displayed. Final report, presentations, posters, videos, and photos can be found on

the webpage of ASN (see www.asn.fr). Nine main findings addressed the following issues:

- Generic justification of radiotherapy.
- Risk-benefit analysis
- Responsibilities of manufacturers and suppliers
- Side effects and complications
- Events/precursors likely to have possible effects on patients
- Accidents
- Research programs
- Responsibilities of authorities
- Patient involvement.

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

As this was the first meeting of the GoE in a new composition, the Chairperson of the Working Party on Research Implications on Health and Safety Standards (WP RIHSS) provided general information about the work of the WP RIHSS and reported on the success of the Scientific Seminars which are the major deliverables of this group.

a. Summary of the EU Scientific Seminar 2009 Childhood leukaemia – mechanisms and causes

The Chairperson of the WP RIHSS presented the draft proceedings of the EU Scientific Seminar on *Childhood leukaemia – mechanisms and causes*, which was held on 3 November 2009.

The GoE congratulated the WP RIHSS for the organisation of this Scientific Seminar, and for the high quality of the draft proceedings, which were adopted for publication as RP 163 in the Radiation Protection Series of the European Commission².

b. EU Scientific Seminar 2010 on Issues with internal emitters

The Chair of WP RIHSS presented the draft programme for the EU Scientific Seminar 2010 on *Issues with internal emitters*. The GoE briefly discussed and approved the draft programme.

7. MEDICAL EFFECTIVENESS OF IODINE PROPHYLAXIS IN A NUCLEAR REACTOR EMERGENCY SITUATION AND OVERVIEW OF EUROPEAN NATIONAL PRACTICES

The Secretariat summarised the results of the study on the *Medical effectiveness of iodine prophylaxis in a nuclear reactor emergency situation and overview of European national practices*.

The GoE welcomed this very good document which should be published by the European Commission in its Radiation Protection Series³. The report presents a

² The proceedings of the EU Scientific Seminar 2009 on *Childhood leukaemia – mechanisms and causes*, RP 163, as well as all the presentations given at the seminar can be found under http://ec.europa.eu/energy/nuclear/radiation_protection/scientific_seminar_en.htm.

³ The Study "Medical Effectiveness of Iodine Prophylaxis in a Nuclear Reactor Emergency Situation and Overview of European Practices" has been published in the Radiation Protection Series of the

consensual European approach, which may form a basis for further harmonisation efforts within the EU and beyond. It was mentioned that WHO is currently revising its guidance on iodine prophylaxis.

The GoE was asked to send written comments on the draft document before 11 June 2010.

8. MEDIWASTE - MANAGEMENT OF LIQUID RADIOACTIVE EFFLUENTS ARISING FROM MEDICAL ESTABLISHMENTS IN EU MEMBER STATES AND CANDIDATE COUNTRIES

The Secretariat briefly presented the results of the study *Management of liquid radioactive effluents arising from medical establishments in EU member states and candidate countries (MEDIWASTE)*.

The study shows that in EU member states liquid radioactive effluents from medical establishments are handled in different ways. While some countries require the collection of liquid radioactive effluents in storage tanks to allow for the decay of short-lived radionuclides, other countries do not require any treatment of the effluents. The discussion during the GoE meeting confirmed this inhomogeneous picture.

The GoE recommended waiting with the decision on a publication of the report until after the final report has been made available.

9. INFORMATION ON SPECIFIC ISSUES FOR POSSIBLE DISCUSSION

IAEA Position Statement on Release of Patients after Radionuclide Therapy

The representative of the International Atomic Energy Agency (IAEA) presented the IAEA Position Statement on the Release of Patients after Radionuclide Therapy, an IAEA policy statement on the use of delay tanks for excreta and the criteria for the release of patients after radiotherapy.

The GoE was concerned about the use of the words "dilute and disperse" in connection with the management of radioactive waste ("The IAEA recommends that in most cases it is better to dilute and disperse the waste activity in a continuous sewage system rather than to concentrate and store activity for decay."). In densely populated areas the IAEA approach may not be protective enough. In addition, the message given by the IAEA may be misinterpreted and may lead to a degradation of radiation protection. In any case, the radiological basis which would allow drawing such conclusions needs to be established.

Radioactivity in consumer goods – lamps

The Secretariat informed the GoE that the European Commission has recently been contacted by the European Lamp Companies Federation (ELC) to discuss the issue of lamps containing small amounts of radioactivity. While a single lamp can be exempted from regulatory control, the ELC is concerned about varying requirements on the authorisation of transport and storage of large amounts of lamps containing radioactivity.

The IAEA informed the group that no amendment to the International BSS or the transport regulations is envisaged for this purpose, but a Safety Guide is being prepared.

Body scanners for security screening

The Secretariat informed the GoE about recent developments in relation to the use of whole-body security scanners utilising ionising radiation e.g. for screening of passengers at EU airports. Following the last meeting of the GoE, the Secretariat sent a set of questions to the members of the GoE asking for additional information on national legal requirements and regulatory guidance on this practice. The answers provided indicate that in the majority of Member States neither legislative provisions nor regulatory guidance on the issue are available or in preparation. In the few cases where the national competent authorities for radiation protection gave specific consideration to the use of X-ray body scanners for aviation security, it was concluded, with one notable exception, that the practice was not justified. The Commission Directorate-General for Mobility and Transport is preparing a Communication on the use of security scanners at EU airports, covering the different technological options, expected to be adopted later in June 2010. An information paper on the use of ionizing radiation screening devices in airports was prepared by the Inter-Agency Committee on Radiation Safety and a statement on this issue is being elaborated by HERCA.

The GoE asked the Secretariat to monitor the developments in this area and to update the Group whenever necessary.

DG SANCO Consultation on Depleted Uranium

In spring 2010, DG SANCO (Health and Consumer Protection) and the Scientific Committee on Health and Environmental Risks (SCHER) launch a consultation on a scientific opinion on the environmental and health risks posed by depleted uranium.

The Group of Experts was highly unsatisfied with the draft DG SANCO scientific opinion on the environmental and health risks posed by depleted uranium, the content of which did not reflect the Opinion⁴ on the radiological risk of depleted uranium given by the Group of Experts at an earlier occasion. Individual members of the Group of Experts have sent comments to DG SANCO.

The Secretariat will distribute these comments to the new Group of Experts and forward the above paragraph in the minutes of this meeting to DG SANCO.

Supply of radioisotopes (current situation)

The Secretariat briefly informed about the current situation with the supply of Mo-99/Tc-99m for medical use.

Despite the effort of the Canadian engineers and staff, the NRU reactor in Canada will not be operational before August 2010. This situation, added to the current HFR reactor stop for repairs (The Netherlands), will create two major shortage periods: the first one between 15 and 20 May, with nearly zero output of Mo-99 from current reactors, and the

⁴ The Opinion of the Group of Experts on Depleted Uranium can be found under http://ec.europa.eu/energy/nuclear/radiation_protection/doc/art31/2001_03_opinion_en.pdf

second one, with a very limited output from 1 July until 20 July. This level of shortage has never been occurred before.

In addition to this information, the Secretariat reported on a Meeting on the Security of Supply of Medical Radioisotopes in EU Member States held in Luxembourg on 4–5 May 2010, aimed at providing a forum to exchange information on possible medium-term solutions and on details of the most promising reactor opportunities for securing Mo-99 production in the long term. About 50 participants from 20 Member States attended the meeting, including the main stakeholders (reactor operators, Mo-99 processors and Mo-99/Tc-99m generator producers), the representatives from international organizations and professional associations (OECD/NEA HLG-MR, AIPES and EANM).

The GoE took note of the information provided and asked to be kept informed about further developments in this area.

Draft Commission Regulation on scrap metal in relation to the Waste Directive (2008/98/EC)

The Secretariat informed the Experts on a draft EC Regulation establishing criteria determining when certain types of scrap metal cease to be waste under the Waste Directive. While this EC Directive is without prejudice to Euratom legislation, there is a logic in that this proposed legislation, exempting certain materials from the application of the Waste Directive, should ensure compliance with certain criteria, including those on the content of radioactive substances. Hence, the Regulation includes requirements for monitoring levels of radioactivity in scrap metal and for documentation of controls at the point of origin.

10. OTHER BUSINESS

No other business was raised.

11. DATE OF THE NEXT MEETINGS

The next meeting of the Group of Experts will be held on **23 – 24 November 2010** in meeting room M1 and M4, **European Commission – Jean Monnet Building, rue Alcide de Gasperi – L-2920 Luxembourg – Kirchberg.**

The June 2011 meeting of the Group of Experts is scheduled for **8 - 9 June 2011** in meeting room EUFO 0001, **European Commission – Euroforum Building, 10, rue Robert Stumper – L-2557 Luxembourg – Gasperich.**

ICRP Summary Report on Activities
to the
Article 31 Group of Experts
June 3 – 4, 2010

The International Commission on Radiological Protection (ICRP) is an independent, international group of experts in radiological protection, established to advance for the public benefit the science of radiological protection, in particular by providing recommendations and guidance on all aspects of protection against ionising radiation.

Recent Publications

The following editions of the Annals of the ICRP were published in the last year:

- ICRP *Publication 108*: Environmental Protection: the Concept and Use of Reference Animals and Plants
- ICRP *Publication 109*: Application of the Commission's Recommendations for the Protection of People in Emergency Exposure Situations
- ICRP *Publication 110*: Adult Reference Computational Phantoms (jointly with ICRU)
- ICRP *Publication 111*: Application of the Commission's Recommendations to the Protection of People Living in Long-term Contaminated Areas after a Nuclear Accident or a Radiation Emergency
- ICRP *Publication 112*: Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies

These reports are available through Elsevier. Information the Annals of the ICRP is available at <http://www.icrp.org/prod01.asp>. The Annals of ICRP are also available on line for free or at very low cost to local, not-for-profit institutions in developing countries through the World Health Organization HINARI Access to Research Initiative (www.who.int/hinari/).

As well, the joint ICRU/ICRP report "Reference Data for the Validation of Doses from Cosmic-Radiation Exposure of Aircraft Crew" will be published as a report of ICRU by Oxford University Press later this year.

Work in Progress

ICRP is currently seeking comments on the draft document "Radiological Protection Education and Training for Healthcare Staff and Students". Comments must be submitted through the ICRP web site no later than August 6, 2010.

www.icrp.org/draft_education.asp

ICRP will soon release the draft document "Lung Cancer Risk from Radon", a document to support the *ICRP Statement on Radon* made available in November 2009. Once the report is available we will seek feedback on both it and the statement together.

http://www.icrp.org/icrp_radon.asp

An ICRP report on tissue reactions and other non-cancer effects of radiation is expected out for consultation later this year. This report assesses, inter alia, new information on effects of exposure to the lens of the eye. A reduction to the dose limit for the lens of the eye is not unlikely, but the amount of the reduction, should one be recommended, is not yet settled.

Work continues on many other topics, each of which either supports or further elaborates on the system of radiological protection presented in ICRP *Publication 103*, The 2007 Recommendations of the International Commission on Radiological Protection, including:

- Internal SAF Values in the Reference Adult Male and Female
- Occupational Intakes of Radionuclides (in 3 parts)
- Paediatric Reference Computational Phantoms
- Radiation Protection for Cardiologists performing Fluoroscopically Guided Procedures
- Radiation Protection in Paediatric Diagnostic Radiology
- Avoiding adverse radiation effects to doctors and patients in fluoroscopically guided procedures - practical guidelines
- Application of the Commission's Recommendations to NORM
- Radiation Protection in Space
- Geological Waste Disposal
- Integrating the ICRP systems of protection for humans and for non-human species
- Environmental Protection: Transfer parameters for Reference Animals and Plants

Other Initiatives

ICRP is working on an overhaul of our website. This will allow users to more easily stay aware of public consultations and other news by registering for e-mail notifications, and to find information on ICRP work in progress through a listing of active Task Groups including their mandates and membership.

As part of an effort to modernize and strengthen operations, ICRP is seeking expressions of interest from organizations that may wish to provide a cost-free staff loan to the ICRP Scientific Secretariat www.icrp.org/docs/Inviting_Expressions_of_Interest_for_Cost-Free_Staff_Loan.pdf



Christopher Clement CHP
Scientific Secretary