



Meeting of the Group of Experts established under Article 31 of the Euratom Treaty

Luxembourg, 19 – 20 November 2013

SUMMARY REPORT

(Approved by the Group of Experts at the meeting 4 – 5 June 2014)

INTRODUCTION

The Chairperson of the Group of Experts welcomed the participants. The Secretariat informed the Group of Experts about a new member of the Group of Experts replacing a retired colleague and about apologies of members who could not attend the meeting. The acting Director of the Directorate on Nuclear Safety and the Fuel Cycle briefly reported on the changes in staff of the Directorate-General for Energy: A new Director-General will take up duty on 1 January 2014. The Director of the Directorate on Nuclear Safety and the Fuel Cycle has retired on 30 September 2013, currently replaced by an acting Director, and a new Head of the Radiation Protection Unit has taken up duty on 1 September 2013.

1. APPROVAL OF THE AGENDA

The agenda was approved without amendments.

2. APPROVAL OF THE SUMMARY REPORT OF THE MEETING HELD IN LUXEMBOURG ON 26 MARCH 2013

The Summary Report was approved without amendments¹.

3. PROCEDURAL ASPECTS – ELECTION OF A NEW VICE-CHAIRPERSON FOR THE PERIOD 2013 – 2015

According to Article 3 of the Rules of Procedure a new Vice-Chairperson has to be elected every two and a half years, which was due at this Group of Experts meeting for the period 2013 to 2015. Before the meeting, the Secretariat invited experts to nominate candidates. The Secretariat received only the nomination of the current Vice-Chairperson who was ready to accept the nomination.

¹ The approved Summary Report of the March 2013 meeting can be found under http://ec.europa.eu/energy/nuclear/radiation_protection/article_31_en.htm

The Group of Experts re-elected the current Vice-Chairperson unanimously for the remaining period 2013 – 2015. The Vice-Chairperson accepted the election and thanked the experts for their confidence.

4. INFORMATION BY THE COMMISSION

4.1. Nuclear Safety

The acting Director of the Directorate on Nuclear Safety and the Fuel Cycle emphasised the importance of the Group of Experts established under Article 31 of the Euratom Treaty for the support of legislative initiatives and other activities under Chapter III of the Euratom Treaty. He briefly reported on three main activities which were initiated as follow-up reaction to the Fukushima accident in 2011.

The main objectives of the initiative to revise the Nuclear Safety Directive are the reinforcement of regulatory control and transparency and the establishment of mandatory high-level safety objectives. On 26 March 2013, the Group of Experts has given an Opinion on this proposal. After having obtained a positive Opinion of the European Economic and Social Committee in September 2013, the Commission Proposal has been adopted in October 2013 and is currently being discussed in the European Council Working Group for Atomic Questions (AQG). European Parliament will nominate the rapporteur for this file on 20 November 2013. It is hoped to achieve agreement in Council in March 2014 before the elections of the European Parliament.

Further to this the acting Director reported on the study on emergency preparedness and response which has been performed following the stress test outcome to gain a full overview of the cross-border arrangements in Europe. The final report of the study is expected soon. The European Commission will analyse the results of the study with a view to preparing a Commission Communication to be adopted in spring 2014. Currently, no legislative initiative is envisaged.

Finally, the acting Director informed the Group of Experts about the Commission activities in the area of civil nuclear liability, a long standing issue which had been discussed at a EC seminar in 2010 in Brussels followed by three topical working groups. The Commission is currently engaged in a public consultation which will be followed by a public event in January 2014. The plan is to prepare a Commission Communication on Nuclear Liability.

4.2 Radioactive Waste Management and Transport

A representative of Unit D2 updated the Group of Experts on Council Directive 2011/70/Euratom, of 19 July 2011, *establishing a Community Framework for the responsible and safe management of spent fuel and radioactive waste* which was to be transposed by the Member States by 23 August 2013. The representative of Unit D2 provided the experts with an overview on initiatives related to facilitating the correct transposition and implementation of the Directive by the Member States, taking due account of the Commission's partnership approach in this stage of the policy cycle. Furthermore, the expert's attention was drawn to future initiatives related to the reporting requirements of article 14.1, article 14.2 and article 15.3 of the Directive, which will be closely followed up by the Commission.

4.3 Status of legislative projects

a. Revised Euratom Basic Safety Standards Directive (Euratom BSS)

On 30 May 2012, the European Commission adopted the Proposal for a *Council Directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation [COM(2012)242 final]*².

After intensive discussions under Cyprus Presidency (July - December 2012) and under Irish Presidency (January – June 2013), the European Council Working Group for Atomic Questions (AQG) reached an agreement on a compromise text on 29 May 2013, which was noted by the Council Committee of Permanent Representatives (Coreper) on 5 June 2013.

The European Parliament consulted the EP Committee on Environment, Public Health and Food Safety (ENVI), the EP Committee on Employment and Social Affairs (EMPL) and the EP Committee on Legal Affairs (JURI). Based on the reports and opinions of these committees, the European Parliament adopted on 24 October 2013 a non-binding Legislative Resolution, which recognises the importance of establishing basic safety standards for the protection against dangers arising from exposure to ionising radiation and which welcomes the Commission proposal. The European Parliament nevertheless proposes 132 amendments to the proposed Directive, many of which have also been identified during discussions in the European Council and are therefore already covered by the compromise text. The main amendment was the proposal to change the legal basis for the Basic Safety Standards Directive from the Euratom Treaty to Treaty on the functioning of the European Union. This change of legal basis, however, cannot be accepted by the Commission.

Taking note of the non-binding Legislative Resolution of the European Parliament, AQG sent the compromise text from 29 May 2013 unchanged to Coreper for adoption on 27 November 2013. The European Council adopted the *Council Directive laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation* on 5 December 2013. Publication of the Directive in the Official Journal of the European Union is foreseen for early 2014.

b. Drinking Water Directive

The *Council Directive 2013/51/Euratom of 22 October 2013 laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption* (Euratom Drinking Water Directive) was adopted by the Council on 22 October 2013 and published in the Official Journal of the European Union on 7 November 2013. The Directive will come into force on 28 November 2013 and will have to be transposed into national law before 28 November 2015.

Compared with the draft on which the Group of Experts has given an Opinion in 2008, the text has undergone some changes, for example, based on the opinion of the European Economic and Social Committee an additional parameter on radon with a parametric value of 100 Bq/l (up to a maximum of 1000 Bq/l in certain circumstances) was added. Moreover,

² The adopted proposal can be found on the Europa website under: http://ec.europa.eu/energy/nuclear/radiation_protection/radiation_protection_en.htm

the radionuclides Po-210 and Pb-210 need to be considered when determining the Indicative Dose. With regard to indicative monitoring of drinking water in bottles or containers reference is made to other relevant EU legislation.

Generally, the Directive gives enhanced flexibility in monitoring. For example for natural radionuclides, representative studies showing that there is no risk of elevated levels can be used to replace the setting up of a routine monitoring system. The recommended value for gross alpha screening of 0.1 Bq/l can be increased (up to the current WHO guidance value of 0.5 Bq/l) if the Member State can prove that the indicative dose will not exceed 0.1 mSv in a year.

The Commission is currently working on a strategy to accompany the transposition of the Directive into national law, e. g. by issuing a questionnaire. This could help to timely detect any problematic issues in transposition or implementation. In such a case guidance could be given either by another Member State that has resolved such an issue or by Commission services.

c. Maximum permitted levels of radioactive contamination of food and feed following a nuclear accident or any other radiological emergency

The Secretariat reported on progress with the *Revision of Council Regulation 3954/87/Euratom laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other radiological emergency*.

The draft proposal for a Council Regulation on which the Article 31 Group of Experts gave an opinion on 21 November 2012 has been adopted by the Commission on 8 August 2013 and transmitted to the European Economic and Social Committee (EESC). The latter adopted a favourable opinion without comments on 16 October 2013. The interservice-consultation on the final proposal for a Council Regulation was launched on 15 November 2013 and its adoption by the College is expected by the end of 2013. The Commission's final proposal will be on the agenda of the Hellenic Presidency of the European Council Working Group for Atomic Questions (AQG).

5. TRANSPOSITION AND IMPLEMENTATION OF THE NEW BASIC SAFETY STANDARDS DIRECTIVE

After the publication of the new Basic Safety Standards Directive (BSS) in the Official Journal of the European Union early 2014, Member States of the European Union will have four years to transpose the Directive into national legislation and to implement the requirements therein. The Commission has been asked by Member States to provide support for the transposition and implementation of this technically challenging legislation.

Under this agenda item, the Group of Experts was invited to discuss openly potential measures to support the transposition and implementation of the new basic safety standards Directive.

The Group of Experts welcomed this initiative by the Commission and offered the following input. It was proposed to focus discussion and guidance on new requirements in the BSS and on major changes in the approach. The experts identified the following topical issues topics which merit further consideration:

- Radiation Protection Expert and Radiation Protection Officer – qualification;

- Radon – establishment of national action plans;
- Radiation protection of the environment;
- Graded approach to regulatory control;
- Dose constraints;
- Non-medical imaging exposures;
- Dosimetry of the lens of the eye;

In an early phase of the transposition period, conferences and topical workshops could be organised to invite Member States to present and discuss their transposition plans. This would allow already early in the process identifying issues with the transposition, exchanging first experiences, and identifying good practices. In parallel, guidance on some of the above mentioned technical topics could be developed either through projects or by Article 31 Working Parties, such as the WP on Dose Constraints the work of which should continue.

An expert reported in this context on a joint initiative of the French ASN and the Norwegian NRPA to organise a *Workshop on the Establishment of National Radon Action Plans* which will be held with interested countries in May 2014 in Paris.

The Group of Experts finally noted that there are international bodies which may be instrumental to assist with the transposition and implementation of the BSS, in particular the Heads of European Radiation protection Competent Authorities (HERCA), but also IRPA and its European Societies.

6. PRESENTATIONS FROM INTERNATIONAL ORGANISATIONS

6.1. International Commission on Radiological Protection (ICRP)

No representative of the ICRP could attend the meeting.

6.2 International Atomic Energy Agency (IAEA)

The representative of the IAEA reported on the current work programme of the agency, in particular on the programme on patient protection, on the programme on occupational radiation protection, on the programme to strengthen the capabilities for radiation protection of workers in emergency situation, on the development of a radon programme, and the upcoming International expert meeting on Radiation Protection After the Fukushima Daiichi Nuclear Power Plant Accident, which will be held in Vienna, 17 - 21 February 2014.

6.3 World Health Organisation (WHO)

No representative of the WHO could attend the meeting.

6.4 Nuclear Energy Agency (NEA)

No representative of the NEA could attend the meeting.

6.5. International Radiation Protection Association (IRPA)

The Executive Officer of IRPA presented IRPA's vision, the Strategic Priorities of IRPA for the years 2012-2016, the work of ongoing IRPA work groups and the list of upcoming IRPA

Regional Congresses, in particular the European Congress to be held in Geneva, Switzerland, 23 - 27 June 2014, and IRPA International Conference IRPA14, which will take place in Cape Town, South Africa, 9 -13 May 2016.

6.6. Heads of European Radiation protection Competent Authorities (HERCA)

The representative of HERCA reported on the functioning, internal and external policies, external relations and communication of HERCA. The topical working programme of HERCA covers the following issues organised in Working Groups: outside workers & the dose passport; non-medical sources and practices; medical activities; emergencies; and surveillance of collective doses from medical exposures.

More information on HERCA can be found on the HERCA homepage www.herca.org.

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

7.1. Dose Constraints (WP Dose Constraints)

The Secretariat informed the Group of Experts that due to the enhanced workload of the Secretariat during the adoption process of the Euratom Basic Safety Standards Directive no meeting of the Working Party on Dose Constraints could be held since the last meeting of the Group of Experts in November 2012. The Secretariat confirmed that it still intends to continue the work of this working party. It was mentioned that before this period the working party has made good progress and that there is a solid basis for the finalisation of the work programme.

The Group of Experts took note of the situation and emphasised the importance to continue the work performed by the WP Dose Constraints.

7.2. Medical Exposures (WP MED)

a. Progress report

The chairman of WP MED reported on the working party's activities corresponding to the last two meetings held on 3-4 April and 8-9 October 2013.

The WP MED meetings were attended fully or partially by the appointed Article 31 experts and observers, except by DG RTD. Some external experts attended specific points of the agenda in order to present recent EC-funded projects. There were changes in the secretariat of WP MED as one of the ENER D3 staff dealing with it left the Unit in September 2013.

WP MED followed the work of international organisations (HERCA, IAEA, ICRP and WHO) and provided advice on Commission's activities on radiation protection in medical exposure. Besides the activities on European projects (see below), WP MED helped in finalising the report from the EC breakout session at the International Conference on Radiation Protection in Medicine, 3–7 December 2012, Bonn.

In the specified period WP MED provided critical review and advice on documents and guidelines developed under several projects funded by DG ENER. Summary of the projects status is provided below.

- EMAN (European Medical ALARA Network - <http://eman-network.eu/>). Follow up of the network activities. A periodic newsletter is being published.

- MPE (Medical Physics Expert - <http://portal.ucm.es/web/medical-physics-expert-project>). Last comments were provided to the contractor. The new amended version has been received and judged appropriate for submission to Article 31 Group of Experts' approval for publication as European Guidelines RP 174.
- MEDRAPET (Implementation of the Medical Exposures Directive's Requirements on Radiation Protection Training - <http://www.medrapet.eu>). Upon suggestion by WP MED the Guidelines were endorsed by the relevant European professional organisations. The final version has been received and judged appropriate for submission to Article 31 Group of Experts' approval for publication as European Guidelines RP 175.
- Referral Criteria for medical imaging in the European Union (study on the implementation of Council Directive 97/43/Euratom - http://www.myesr.org/cms/website.php?id=/en/eu_affairs/newfilename.htm). The Final report was considered appropriate to be published at the EC website as RP 178.
- DDM2 (Population doses from medical exposure, called Dose DataMed 2 - <http://ddmed.eu/>). The final report is being revised taking into account the comments of WP MED.
- ACCIRAD (Risk analysis of accidental and unintended exposures in radiotherapy - <http://www.accirad.eu/>). The final report, received in September, contains a guideline document and the results of a European survey. WP MED suggested to the contractor to present a shorter guideline and the complementary material as an annex. WP MED expects to review and approve the revised guideline at the next meeting in April 2014.

Future Commission projects in the medical area include:

- a) DRLs (Diagnostic Reference Levels) in paediatrics call for tenders where one proposal (headed by the European Society of Radiology) has been received, and
- b) new call to complete the work of ACCIRAD published in August 2013.

WP MED will provide follow up of the running projects and could suggest new ones if appropriate in the future, especially for the transposition and implementation of the new BSS.

The Group of Experts thanked the WP MED for their intensive and valuable work. This was followed by discussion on the draft documents RP 174, RP 175 and RP 178. Some editorial comments were made and the experts were given two weeks following the meeting to submit additional comments in writing to the Secretariat. The Group of Experts approved the publication of the documents.

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

a. Proceedings of the EU Scientific Seminars 2012 on Protection of the Environment

The Group of Experts approved the draft proceedings of the *EU Scientific Seminar 2012 on Protection*, as prepared and approved by the WP RIHSS, for publication, as RP 177, in the Radiation Protection Series of the European Commission.

b. EU Scientific Seminar 2013 on Radiation induced long-term health effects after medical exposure

At the EU Scientific Seminar 2013 on *Radiation induced long-term health effects after medical exposure*, held on 19 November 2013, internationally renowned scientists presented current knowledge on

- Dosimetry in radio-diagnostic procedures – risk issues and research needs;
- Second primary cancers in adults after radiotherapy – an epidemiological review;
- Cardiovascular diseases after radiotherapy;
- Late effects in children after radiotherapy;
- CT scan studies – present results and the future; and on
- Risk communication.

The presentations were followed by a round table discussion, in which the speakers and invited additional experts discussed potential policy implications and research needs.

The Chairperson of the WP RIHSS presented first and preliminary conclusions of the EU Scientific Seminar 2013.

All presentations given at the EU Scientific Seminar 2013 on *Radiation induced long-term health effects after medical exposure* together with a short introductory text and the programme have been posted on the Europa Website³.

The Group of Experts congratulated the WP RIHSS for the organisation of this interesting EU Scientific Seminar 2013.

c. Topics for the EU Scientific Seminar 2014

The Chairperson of the WP RIHSS proposed topics for the EU Scientific Seminar 2014.

After some discussion, the Group of Experts agreed to hold the EU Scientific Seminar 2014 on *Fukushima - lessons-learned and issues*.

The Group of Experts thanked the WP RIHSS for their valuable work.

8. EDUCATION AND TRAINING IN RADIATION PROTECTION

An Article 31 expert updated the Group of Experts on EUTERP and HERCA's recent activities on education and training (E&T) in radiation protection.

EUTERP (www.euterp.eu) was created as a 'platform' with EC funding and played an important role in the decision to introduce the Radiation Protection Officer (RPO) and the Radiation Protection Expert (RPE) in the revised Euratom BSS. Since June 2010 the EUTERP Foundation is a registered self-sustainable entity whose main role is to:

- a) promote the mobility of experts between EUTERP countries,
- b) facilitate access to radiation protection education and vocational training, and

³ The presentations can be found under http://ec.europa.eu/energy/nuclear/radiation_protection/seminars/scientific_seminar_en.htm

- c) undertake any and all initiatives in connection with or conducive towards the attainment of the goals.

E&T was identified as a top priority for HERCA from its establishment in 2007 but until recently there was no action in order to avoid duplicating work already covered under EC-sponsored projects (ENETRAP and EUTERP). A decision to set up a HERCA Task Force on E&T was taken in 2012 and its mandate was defined as:

- a) to present to the HERCA Board a general picture of the situation on E&T in RP, and
- b) to identify the current needs for harmonisation among HERCA members and eventually, if needed, the mandate of a future working group on E&T.

The Group of Experts discussed the progress in this area and in particular the need of European Guidance to support the implementation of the changes in the area of E&T introduced by the revised Euratom BSS Directive. There was a general agreement that such guidance would help Member States but there were different ideas of what form that should take and who should undertake this work. The Group of Experts will further monitor progress in this area and discuss the need of further action within the framework of the future implementation of the revised BSS (see item 5 of the agenda).

9. EUROPEAN PLATFORM FOR OCCUPATIONAL RADIATION EXPOSURE – ESOREX

An expert reported on a project, initiated and financed by DG ENER, to establish a European Platform for Occupational Radiation Exposure (ESOREX) which will allow representatives from national dose registers and from dosimetry services to discuss emerging issues, assess dose trends, and exchange experience.

The main objectives of the ESOREX Platform are

- To allow easy information and experience exchange between experts in occupational radiation exposure (e.g. from national dose registries)
- create a database on occupational radiation exposure
- establish and maintain an overview on national arrangements for occupational radiation exposure in Europe
- promote the harmonization of data and information reporting formats within Europe and beyond
- To assist in the implementation of requirements on occupational radiation protection in the Euratom Basic Safety Standards Directive
- To establish working relationships with other relevant international organisations and bodies (in particular with UNSCEAR, HERCA, IAEA, EAN, EURADOS)
- To develop appropriate mechanisms and establish the appropriate infrastructure to enable the sustainable continuation of operation of the ESOREX platform beyond the 3-years project, without further European Commission financial support.

The project has started in December 2012 and will be finalised by December 2015.

The Group of Experts thanked the expert for this information and expressed its wish to be regularly updated on progress with the ESOREX Platform.

10. PROJECT TO DEVELOP TECHNICAL RECOMMENDATIONS FOR MONITORING INDIVIDUALS FOR OCCUPATIONAL INTAKES OF RADIONUCLIDES

The Secretariat informed the Group of Experts about a project to establish *Technical Recommendations for Monitoring Individuals for Occupational Intake of Radionuclides*.

The Commission wishes to establish European technical recommendations on internal exposure as guidance for the practical implementation of recent developments in internal dosimetry and to achieve harmonisation of the methodology for the assessment of intakes of radionuclides applied by dosimetry services. The target audience of this document shall be internal dosimetry services as well as competent authorities. These technical recommendations for monitoring individuals for occupational intakes of radionuclides shall consider state-of-the-art information in the area of dose assessment due to internal exposure, and shall take account of recent international guidance, such as the upcoming ICRP reports on occupational intakes of radionuclides and ISO standards on internal dosimetry. These technical recommendations shall be an authoritative document on internal dosimetry which shall also be used for training purposes.

The ongoing tendering procedure will probably be finalised by the end of 2013, and the project is planned to start in the beginning of 2014.

The Group of Experts thanked the Secretariat for this information.

11. RESULTS OF THE COMMISSION REVIEW OF THE IMPLEMENTATION OF THE HASS DIRECTIVE IN MEMBER STATES

The HASS Directive entered into force on 31 December 2003 and its legal enactment period ended two years later. Article 14 of the Directive requires the Member States to report on its implementation before the end of 2010. The Commission is then required to provide an implementation report of the Directive to the European Parliament and the European Economic and Social Committee. The implementation review was carried out by analysing the individual reports submitted by the EU Member States. The review results indicate variable practices in the practical implementation of the Directive requirements. This is not surprising, since the number of HASS sources in the EU Member States range from only a few to several thousands.

The supporting study project, "Study on the current status of radioactive sources in the EU, on the origin and the consequences of the loss of control over radioactive sources and on successful strategies concerning the detection and recovery of orphan sources", was initiated by the European Commission in order to provide an overview of the situation in the EU on (1) the control of high activity sources in use, (2) the management of disused sources and (3) strategies for handling orphan sources. The project was part of the EU CBRN (chemical, biological, radiological, nuclear) Action Plan. It is based on questionnaires, interviews and fact-finding missions among the European stakeholders. The study identifies best practices and possible weaknesses in the detection and recovery of orphan sources and provides an overview of incidents of loss of control in Europe.

HASS Directive principles have been well implemented in the EU, although there are significant differences in implementation practices among the EU Member States. The only major weak area in implementation is the organisation of orphan source recovery

campaigns, which have been implemented in only about 50% of the Member States. In addition there are areas where implementation is about 80-90% complete (undue delay in storage, training of personnel potentially confronted with an orphan source, source identification and marking).

Based on the lessons learnt, the authorities of the EU MS recommend the following in order to keep radioactive sources under control and to safely manage incidents:

- systems for ensuring traceability of radioactive sources throughout their life cycle,
- regular inspections,
- requirements of physical protection in high-risk facilities,
- compulsory training of the personnel,
- border controls to detect radioactive materials,
- exchange of information among the national and international competent authorities,
- public information, and
- testing of pre-established plans for prevention of and for response to incidents involving HASS.

The proposed new EU Basic Safety Standards Directive represents a major revision of the whole EU radiation protection legal framework. Chapters concerning HASS were not difficult to include in this framework, since the HASS Directive has been well accepted by the EU Member States and there was no need for major modifications in the HASS control, although the new BSS Directive corrects several deficiencies of the HASS Directive. In particular, the achieved harmonisation with the IAEA regulations places the EU Member States in a good position to fulfil both EU and IAEA requirements on the control of high activity sealed sources and orphan sources.

The Group of Experts thanked the Secretariat for this informative and comprehensive presentation.

12. OTHER BUSINESS

An expert presented the findings of *The WHO Fukushima reports on Preliminary dose estimation from the nuclear accident after the 2011 Great Japan Earthquake and Tsunami* and on the related *Health Risk Assessment*.

An expert presented the project *Ionising radiation metrology for the metallurgical industry (MetroMetal)*, a Joint Research Project funded by European Metrology Research Programme (EMRP) under EURAMET. The expert presented also the project *Metrology for processing materials with high natural radioactivity (MetroNORM)*, another Joint Research Project funded by European Metrology Research Programme (EMRP) under EURAMET.

The Group of Experts thanked the experts for their interesting presentations.

13. DATES OF THE NEXT MEETINGS

The next meeting of the Group of Experts will be held on **4 – 5 June 2014** in meeting room EUFO 0001, **European Commission – Euroforum Building, 10, rue Robert Stumper – L-2557 Luxembourg – Gasperich.**

The November 2014 meeting of the Group of Experts is scheduled for **18 – 19 November 2014**, in meeting room M6, **European Commission – Jean Monnet Building, rue Alcide de Gasperi – L-2920 Luxembourg – Kirchberg.**