EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR ENERGY AND TRANSPORT

DIRECTORATE H - Nuclear Energy
Radiation Protection

Meeting of the Group of Experts (GoE) referred to in Article 31 of the Euratom Treaty

Luxembourg, 9 – 11 June 2009

SUMMARY REPORT

(Approved by the Group of Experts at the meeting 3 – 5 November 2009)

1. APPROVAL OF THE AGENDA

The agenda was approved without changes.

2. APPROVAL OF THE SUMMARY REPORT OF THE MEETING HELD IN LUXEMBOURG ON 26 – 27 NOVEMBER 2008

The Summary Report was approved with some minor amendments[1].

3. INFORMATION BY THE COMMISSION

3.1. Nuclear Safety

The Head of Unit H1 presented the current status of development of the Commission proposal to establish a legally binding Community framework for the nuclear safety of nuclear installations. The Council has concluded the technical discussions and has reached agreement on the text by all delegations. The European Parliament was consulted and gave its opinion. The adoption of the directive by the Council is still expected under the Czech presidency[2].

The GoE took note of the progress made and thanked the representative of Unit H1 for this information.

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[1] The approved Summary Report of the November 2008 meeting can be found under http://ec.europa.eu/energy/nuclear/radiation_protection/article_31_en.htm

[2] Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations was published in the Official Journal of the European Union, L 172/18, 2 July 2009

3.2 Radioactive Waste Management and Transport

A representative of Unit H2 presented an initiative to develop a Commission *Regulation on administrative procedures in the transport of radioactive materials (TRAM)*. The objectives for this new regulation are to maintain safety and health protection of workers and the general public during the transport of radioactive materials in the territory of the EU, to harmonise and simplify administrative procedures, and to increase transparency in TRAM legislation allowing carriers and users to easily find the information needed. An impact assessment has shown that a regulation would be the best option.

The GoE welcomed the attempt to harmonise administrative procedures within the EU, noted, however, that the text for this regulation is still in an early drafting phase and would profit from refinement. The experts were interested to hear the opinion of the Standing Working Group with regard to Transport which is composed of national experts in the field of transport. The Standing Working Group, however, scheduled its meeting shortly after the GoE and was therefore not yet consulted. Finally, the experts emphasised that Council Regulation 1493/93/Euratom deals with the transfer of radioactive material and should therefore not be concerned by this new initiative on transport.

The GoE concluded that the draft proposal is not yet mature enough to enable the group to give an opinion at this meeting. In order to help the Commission on its way forward, the GoE proposes to create an Article 31 Working Party composed of members from the GoE and from the Standing Working Group with regard to Transport. The Working Party shall meet over summer to further elaborate the draft. The Article 31 GoE shall be kept informed about progress and shall receive the minutes of the WP meetings.

3.3. Status of legislative projects

Extension of post-Chernobyl regulation

The Secretariat informed the GoE about the status of extension of the Post-Chernobyl Regulation [(EC) 733/2008, on conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station] on which the GoE had given an opinion in November 2008. The draft proposal for a Council regulation should be adopted by the Commission by Written Procedure on 18 June 2009 and then be forwarded to the Council for discussion and finale adoption.

Development of the Drinking Water Directive

The Secretariat informed the GoE about the status of adoption of the Euratom Directive on drinking water. The draft on which the GoE had given an opinion has gone into Inter Service Consultation, and has received a negative opinion from DG ENV. The Legal Service is currently investigating the option to issue the directive with two legal bases, the EURATOM Treaty and the EC Treaty. The Secretariat will keep the GoE informed about progress with this matter.

4. REVISION OF THE EUROPEAN BASIC SAFETY STANDARDS

4.1. Progress reports from the Working Party on the Recast of the European Basic Safety Standards (WP RECAST)

The Chairperson of the Working Party on the Recast (WP RECAST) presented a report on progress with the revision of the current BSS Directive (96/29/Euratom) and the consolidation of existing European Radiation Protection legislation. Since the Article 31 Group of Experts' meeting in November 2008, the WP held two meetings and discussed in detail:

- Dose limit for occupational exposure;
- Duties and recognition of radiation protection experts, medical physics experts, and radiation protection officers;
- Non-medical imaging exposures;
- Exposures of emergency workers;
- Protection of the environment, including use of screening levels.

During these meetings the WP RECAST raised the following issues for further consideration by the Article 31 GoE:

- Extend the scope to cover Outside Workers working in supervised areas?
- Replace the existing levels for HASS, based on IAEA Regulations for safe transport of radioactive materials, with the activity levels from IAEA Code of conduct?
- Revise structure of the Directive?

The WP RECAST prepared a full draft text of the directive including all annexes. Although further work is still needed, the WP RECAST considered this draft document mature enough to be presented to the Article 31 GoE for discussion.

The Chairperson of WP RECAST informed the GoE that the next meeting of the WP Recast will be held from 29 September to 1 October 2009 to address GoE comments. A revised draft will be sent to GoE for discussion and to seek agreement on a GoE Opinion at the next meeting in November 2009 meeting.

The GoE welcomed the excellent work performed by the WP RECAST, and appreciated the possibility to discuss a full draft directive. The detailed discussion of the draft text is summarised under Agenda Item 4.5.

4.2 Progress reports from related studies and projects

Education and Training (EUTERP)

Further to the status report presented at the June 2008 meeting and updated at the November 2008 meeting, the Secretariat informed the GoE that there has been no progress with the Commission financed project *European Radiation Protection Training and Education Platform (EUTERP Platform)* since June 2008. The project ended officially in March 2009. It is not expected that still missing deliverables will be provided by the contractor. This is particularly regrettable as EUTERP was expected to provide input for the education and training title of the revised Basic Safety Standards Directive.

An expert of the GoE who was also member of the EUTERP Steering Committee presented a written evaluation of the status of the EUTERP project to the Article 31 GoE which confirmed the assessment presented by the Secretariat. Notwithstanding the disappointing development of this project, the expert emphasised the importance of radiation protection education and training.

The GoE noted this disappointing development.

Comparative Study of EC and IAEA Guidance on Exemption and Clearance Levels

The Secretariat informed the GoE that the final report of the *Comparative Study of EC and IAEA Guidance on Exemption and Clearance Levels* is now available and was distributed to the GoE. A draft report of this study has already been discussed at the November 2008 meeting. The final report will be published in the Radiation Protection Series of the European Commission.

The GoE welcomed the finalisation of this study and the distribution of the final report containing important factual information which will support the discussion of the Basic Safety Standards.

4.3 Publication of agreed reports on the EUROPA website

The Secretariat gave a summary of the comments received at the web consultation on a document containing the European Commission Services' considerations with regard to natural radiation sources in the BSS Directive. It indicated that some comments made will be taken care of by guidance documents; some will lead to changes in the draft Directive whereas other comments will need further considerations by the WP Recast. The Secretariat suggested that a compilation of the comments would be sent to WP Recast along with possible ways to move forward.

The Article 31 Group of Experts discussed this and whether the WP Natural Sources should be asked to review the compilation or not. The WP Natural Sources had already provided their view in the reports presented to the Article 31 Group of Experts at previous meetings. The GoE concluded however that it would be appropriate to ask the WP Natural Sources to review the compilation of comments and to advise on possible ways forward to the next WP Recast meeting.

4.4 Revision of the international Basic Safety Standards

The IAEA representative informed the meeting about the status of revision of the International Basic Safety Standards. Since November 2008, several drafting meetings have been held to further develop the revised BSS. Based on these drafting meetings a cosponsors review meeting in April 2009 helped to finalise the latest draft 2.0 of the revised BSS. Draft 2.0 was sent to the IAEA Safety Standards Committees RASSC, WASSC, TRANSSC, NUSSC at the beginning of May 2009. It was also decided to change the format of the BSS to make it more compatible with the style of other IAEA Safety Requirements. The move to the new format requires the identification of important "umbrella" requirements which need to be endorsed by the cosponsoring organisations and the IAEA Safety Standards Committees. Current planning foresees a presentation of the proposed “umbrella requirements” to the RASSC/WASSC members in November 2009, the edition of the explanatory text and presentation of the complete draft to all Safety Standards Committees in June 2010, and the subsequent sending to all Member States for consultation. Final approval is tentatively planned for 2011.

4.5 Discussion of the draft European Basic Safety Standards

The Chairperson of the WP RECAST introduced the contents of the first complete draft directive (Version 8 May 2009).

Structure of the draft European Basic Safety Standards

WP Recast proposes to revise the structure of the Basic Safety Standards. Beside the option to retain the current form (***Option 1***), WP Recast identified two possible structures:

Option 2:

Planned exposure situations	**Emergency exposure situations**	**Existing exposure situations**
Occupational exposure	Occupational exposure	Occupational exposure
Public exposure	Public exposure	Public exposure
Medical exposure	Medical exposure	

Option 3:

Occupational exposure	**Public exposure**	**Medical exposure**
Planned exposure situations	Planned exposure situations	Planned exposure situations
Emergency exposure situations	Emergency exposure situations	Emergency exposure situations
Existing exposure situations	Existing exposure situations	

The GoE clearly expressed its preference for ***Option 3*** and asked the WP Recast to restructure the BSS accordingly.

Discussion of the draft text

The GoE decided to discuss the proposal article by article. Experts were asked to raise any conceptual issues and points of principle rather than discussing editorial comments. Detailed suggestions for improvement to the text are welcomed and should be sent to the Secretariat by the end of June 2009 for further consideration by the WP RECAST.

Title I defines the subject matter and general purpose of the Directive, and is a consolidation of five Directives. It uses ICRP 103 exposure situation terminology, and explicitly introduces consideration of exposure of biota in the environment as a whole. Title I has already been discussed at the Article 31 GoE meeting in November 2008.

The GoE discussed the exposure of space crew and agreed to keep it within the scope of the Directive, mentioned explicitly in Article 3 (c) (i).

Some experts expressed their concern about the potential inclusion of the protection of the environment in emergency situations. The GoE asked the WP Recast to analyse the inclusion of the environment in existing regulations for emergency situations and to report the outcome at the next GoE meeting.

Title II defines the terms used in the draft directive – based on the 5 directives included in the recast process, and updated for compatibility with ICRP 103.

The GoE identified the following terms which would merit a definition: emergency workers, outside workers, residual dose, reference level, and interventional radiology. In addition, the experts offered detailed comments which they were asked to send to the Secretariat by the end of June 2009.

Title III specifies the system of protection summarising the overarching principles of radiation protection: justification, optimisation, and dose limitation. Additional text is included on dose constraints and reference levels. Current requirements on dose limits for practices – now planned exposure situations – are included. Article III.4 refers to Annex III.1. Title III and Annex III.1 have already been discussed at the Article 31 GoE meeting in November 2008.

At the November 2008 meeting, the GoE recommended to introduce the optimisation principle and appropriate dose constraints also for organ doses. In order to accommodate this recommendation, it was decided to replace in Article III.2 the term *individual dose* by *individual effective or equivalent dose*.

Some experts offered comments on the requirement for optimisation, which could be softened. The role of this fundamental radiation protection principle has, however, been strengthened by ICRP in publication 103. It was also proposed to introduce a separate article on justification. The GoE decided to refer this discussion back to the WP Recast.

Finally, the GoE identified that the requirement on the protection of nursing women from bodily contamination is missing. As this requirement is included in Directive 96/29/Euratom, it was decided to reintroduce it.

Title IV and V (currently merged) cover *Responsibilities for regulatory control* and *Requirements for Education and Training*. The Title is structured in several sections: Institutional infrastructure; Radiation protection training and information; Control of sealed sources (with five Annexes); Orphan sources; Emergency management system; System of enforcement.

In order to emphasise the importance of education and training in radiation protection, the GoE recommends separating the previously merged titles and to reinstall Title V on Education and Training. The Secretariat and the WP MED were asked to consider in the next draft the following issues: changes in the definition of Medical Physics Expert (MPE) taking into account the EFOMP position; definition of the tasks of the MPE as already made for the RPE and the RPO, enhancement of the role and the need for radiation protection training of the medical radiological technicians, and the introduction of obligation to the Member States to ensure the incorporation of radiation protection training in the basic curriculum of medical schools.

It was suggested to consider the introduction of requirements for occupational health services and dosimetry services similar to those for radiation protection experts, medical physics experts, and radiation protection officers. It was mentioned that the recognition of these services should be limited in time.

Regarding section III on Control of sealed sources, it is proposed to change the activity levels currently included in Directive 2003/122/Euratom and to replace them by the values given in IAEA Code of Conduct. During discussion, the experts expressed differing opinions in favour and against the replacement. This fact may have to be reflected in the opinion of the GoE.

Title VI covers requirements for justification and regulatory control of planned exposure situations. Title VI includes requirements for release from regulatory control, and introduces general clearance levels; flexibility is retained for Member States to decide on specific clearance levels. It is proposed to include a graded approach to regulatory control with reporting and authorisation being replaced by notification, registration, licensing. The Title contains a new approach to regulation of NORM industries (those on a positive list): these are now regarded as planned exposure situations, which can be exempted or are regulated applying a graded approach. Title VI has already been discussed at the Article 31 GoE meeting in November 2008.

Latest version of Title VI contains also a new approach to "medico-legal procedures", now defined as "non-medical imaging exposure". These are now dealt with as public exposures and requirements for their justification, optimization and national regulation have been introduced. Different opinions were expressed regarding the justification (in principle) of these procedures, the use of public dose constraints and the requirements for availability of alternative techniques. Further input on these issues is expected following the *International Symposium on Non Medical Imaging Exposures* in Dublin, 8 – 9 October 2009.

The discussion focussed on the proposal to introduce only one set of numerical values for exemption and for clearance and to use the values given in IAEA RS-G 1.7. The experts agreed that the values in IAEA RS-G 1.7 could be used as generic clearance levels. Some of the experts, however, emphasised that the use of RS-G 1.7 values as exemption values may create problems. No consensus could be found within the GoE on the adoption of clearance levels in particular the value of 1 Bq/g for natural occurring radionuclides. While some of the experts see no problem, others mentioned that for certain exposure pathways the dose limit of 1 mSv/year could be exceeded. As it seems very unlikely that this issue will be resolved within the GoE, it was decided to reflect upon these different positions in the opinion of the Article 31 GoE.

Title VII deals with Occupational Exposure (Workers, Apprentices and Students). Annex VII contains requirements on Centralised networks (national dose registry) and individual radiological monitoring documents. Emergency workers shall be subject to 50 mSv dose limit or for specific cases identified in national emergency plans and appropriate reference level. It is proposed to cover air crew and space crew in this Title. Article VII.4 says that if doses are liable to exceed 6mSv/y relevant requirements apply and exposures shall be kept under review if doses are between 1mSv/y and 6mSv/y.

It was mentioned that despite the definition of roles and responsibilities of radiation protection experts in Title IV, not many requirements in Title VII actually request the consultation or involvement of an RPE.

A discussion questioned the need and usefulness to categorise workers in A and B, without reaching a consensus. The GoE will reopen the discussion in November 2009.

Title VIII covers the Protection of Patients and other individuals submitted to medical exposure. This Title has been discussed and reviewed by the Working Party on Medical Exposure.

The experts offered comments on the following issues: appropriateness of the inclusion of carers and comforters in the definition of medical exposure, levels of justification of medical exposure and consideration of staff doses, level of involvement of MPE in different types of medical exposure procedures, feasibility of new requirement for dose-indicating devices in new equipment, and need of definition of accidental and unintended medical exposure. The experts were asked to send these comments to the Secretariat for further consideration at the next WP MED meeting.

There was a proposal to introduce requirement to the Member States to share information on accidents in medical exposure. The Secretariat proposed that this issue will be dealt with in a more general part of the Directive.

Title IX covers the Protection of Members of the Public. Member States are required to ensure the best possible protection of members of the public under the prevailing circumstances based on the principles set out in Title III System of protection.

Title IX in its current form offers little requirements about the setting of discharge authorisations. The Secretariat was asked to propose some text and discuss it with the WP Recast.

Title X introduces specific requirements for Protection of the Environment. This title is entirely new.

The experts agreed that the protection of the environment from ionising radiation is an important new issue and needs to be addressed in the new directive. The proposed text, however, would profit from refinement. It should refer to the ICRP approach and be more consistent with the scope of the directive. The GoE therefore referred the text back to the WP Recast.

Title XI deals with *Emergency exposure situations*. Elements to be included in an emergency management system are covered in Annex XI.1A. Elements to be included in an emergency response plan are covered in Annex XI.1B. These annexes are new. Prior information to the population likely to be affected by a radiological emergency is covered in Annex XI.2A. Information to be provided to the affected population in case of a radiological emergency is covered in Annex XI.2B. These annexes are taken from the Public Information Directive (89/618/Euratom).

After the agreed restructuring of the document, Title XI will disappear and the articles will be moved to other titles.

Annex III.1 offers bands of reference levels for existing and emergency exposure situations. It was proposed to define reference levels consistent with the proposal by ICRP in publication 103 which foresees optimisation above and below the reference levels. Similar to the discussion on dose constraints, reference levels shall also be introduced for organ doses. In setting reference levels, dose contributions from all exposure pathways need to be considered.

One expert mentioned the need for harmonisation between Member States with regard to preventive and protective actions. Annex III.1 sets ranges for reference levels and this could improve harmonisation. The Secretariat also informed the GoE about an ongoing EC study on the use of iodine prophylaxis in case of an emergency. The study will be finalised by the end of 2009.

Title XII defines the requirements for *Existing exposure situations*. Annex XII.1 gives an indicative list of items to be covered in the national action plans for radon in dwellings and workplaces. Annex XII.2 provides definition and use of the activity concentration index for the gamma radiation emitted by building materials. Annex XII.3 offers an indicative list of types of building materials considered for control measures with regard to their emitted gamma radiation.

After the agreed restructuring of the document, this title will disappear and the articles in this title will be moved to other titles.

It was agreed to delete Article XII.7.3.

The given reference values for indoor radon concentration triggered some discussions between the experts. The GoE decided to await recommendations from ICRP before concluding this discussion. Some experts expressed concern about the subtraction of a background of 400 Bq/m^3 from recorded occupational exposure to radon and the reference levels proposed in the draft BSS.

Annex VI.3 Some experts expressed concern about not including in the dose increment due to naturally occurring radionuclides the radon exposure pathway for workers, except where this is known to be a dominant pathway, and ingestion of drinking water for members of the public.

Further detailed suggestions and comments should be sent to the Secretariat by the end of June 2009.

5. PRESENTATIONS FROM INTERNATIONAL ORGANISATIONS

5.1. ICRP

The representative of the International Commission on Radiological Protection (ICRP) reported on the current status of ICRP publications in development. The GoE was particularly interested in recent developments with regard to radiation induced cataracts and with regard to radon. ICRP Recommendation 103 still confirmed the dose limit for the lens of the eye, but introduced a comment stating that this dose limit is currently being reviewed. The ICRP Task Group on tissue injury after high doses of radiation is

currently reviewing recent scientific findings on radiation induced cataracts. The results of this task group will be evaluated by ICRP Committee 1. ICRP is also discussing the dose conversion convention for radon which differs from the UNSCEAR approach. A decision on the dose conversion convention is expected from the ICRP Main Commission at its next meeting in Porto, in November 2009.

5.2 IAEA

The representative from the International Atomic Energy Agency (IAEA) summarised the activity highlights in Radiation, Waste and Transport Safety. Radiation protection in medicine is one of the main focuses covering the development of safety guidance in different areas, in particular with regard to new medical imaging techniques, the development of global knowledge and experience exchange via dedicated web sites, and the development of incidents reporting databases. The SmartCard project has been launched to develop a methodology for the long-term record of radiation doses to patients. The international workshop on "Justification of medical exposure in diagnostic imaging", jointly organised by EC and IAEA will be held in Brussels, 2 - 4 September 2009. The International Conference on Modern radiotherapy: challenges and advances in radiation protection which will be held in Paris 2 - 4 December 2009. With regard to radiation protection of workers, a new project to collect information on occupational exposure in medical, industrial and research applications, called Information System on Exposure in Medical-, Industrial- and Research (ISEMIR), has been launched. The objective of this project is to help to improve occupational radiation protection programmes in medical, research and industrial areas and to contribute to minimizing the likelihood of accidents, e.g. by identifying precursors, user feedback and experience. The International Conference on Control and Management of Inadvertent Radioactive Material in Scrap Metal was held in Tarragona, Spain, 23 – 27 February 2009. The conference recommended promoting information exchange between those concerned with the problems of inadvertent radioactive material in scrap metal; the development of an international agreement between countries on the subject coordinated by the IAEA (recommendations for trade); and the development of a Safety Guide on orphan sources and contaminated material in the metal recycling industry.

5.3 NEA

The representative from the Nuclear Energy Agency (NEA) presented recent developments in the NEA Programme in Radiological Protection. The NEA Committee on Radiation Protection and Public Health (CRPPH) engages in several topical issues, including 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. Its programme on Nuclear Emergency Planning and Management increasingly focuses on approaches to agriculture and recovery issues, on strategies for emergency management decision making, and, together with the NEA Nuclear Law Committee on compensation and decision making. The planning for a new international nuclear emergency exercise series, INEX 4, has started. The Expert Group on Occupational Exposure investigates policy and strategic areas of operational radiation protection with a focus on the nuclear power sector. The Expert Group on Public Health discusses topics such as radon, justification of medical exposure, public health judgement in decision making based on new scientific evidence, and management of individual differences. The 2nd CRPPH Workshop on Science and Values will be held 30 November – 2 December 2009, in Vaux de Cernay, France.

5.4. IRPA

The representative of the International Radiation Protection Association (IRPA) summarised recent and current IRPA activities. The 56th Executive Council meeting was held at the occasion of the 12th IRPA International Congress in Buenos Aires. It was decided to hold the 13th IRPA International Congress on *Living with Radiation – Engaging with Society* in Glasgow, 13 – 18 May 2012. Before this date regional IRPA congresses will be held in Tokyo, Japan, 24 – 28 May 2010, in Helsinki, Finland, 14 – 18 June 2010, in Nairobi, Kenya, 19 – 24 September 2010 and in Medellin, Columbia, October 2010. IRPA has worked on the professional recognition of the radiation protection expert within the *ILO International Standard Classification of Occupations*, published a document offering *Guiding Principles for Stakeholder Engagement*; and started work on *Guidance for improving the radiation protection culture*. Further information is available under http://www.irpa.net.

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

6.1. Medical Exposures (WP MED)

Progress report

The Vice-Chairperson of the Working Party on Medical Exposures (WP MED) reported on recent activities of the WP MED. The WP MED continued the discussion of the Title VIII *Protection of Patients and other individuals Submitted to Medical Exposure* of the recast Basic Safety Standards. The Vice-Chairperson of the WP MED is represented at WP RECAST meetings to act as a link between the expert groups. The WP MED will help the WP RECAST to incorporate the comments received at this Article 31 GoE meeting.

The Vice-Chairperson of the WP MED summarised the status of on-going projects to assist Member States in the application and harmonisation of the medical Directive. The results of two finalised projects are discussed later (see next header). The European Medical ALARA Network (EMAN) project is just being set up; calls for tenders regarding the projects on Harmonisation of the Medical Physics Expert and the Update of the Referral Criteria of Imaging were published. Further to these, the following proposals for future projects are being discussed: European patient dose survey (application of Dose Datamed guidance and collection of data for the 27 EU Member States); Study on the implementation of the Medical Directive's requirements on RP training of medical professionals in Europe.

The international workshop on *Justification of Medical Exposures in diagnostic imaging* will be held in cooperation with IAEA in Brussels, 2 – 4 September 2009. The international symposium on *Non Medical Imaging Exposures* will take place in Dublin, 8 – 9 October 2009.

A proposal was made from one of the experts that the WP MED and the Secretariat should consider the elaboration of guidance on the implementation of the proposed new Euratom BSS requirements for risk assessment in radiotherapy and for reporting of accidental and unintended medical exposures. It was felt that detailed discussion of this

issue is premature at this stage; it will be discussed again during and after the *International Radiotherapy Conference* in Paris, 2-4 December 2009.

The GoE thanked the members of the WP MED for their valuable work and expressed its hopes that the Vice-Chairperson would continue his engagement in the WP RECAST.

European Guidelines on Clinical Audit for Medical Radiological Practices

A representative of the contractor presented the draft *European Guidelines on Clinical Audit for Medical Radiological Practices* which were prepared under Contract TREN/07/NUCL/S07.71512.

The GoE thanked the expert for this interesting presentation and for the preparation of the draft guidelines. The GoE approved formally the draft *European Guidelines on Clinical Audit for Medical Radiological Practices* and the presented foreword for publication in the Radiation Protection Series of the Commission.

Radiation Criteria for Acceptability of Radiological, Nuclear Medicine and Radiotherapy Installations

A representative of the contractor presented the draft document on *Radiation Criteria for Acceptability of Radiological, Nuclear Medicine and Radiotherapy Installations*, prepared under Contract TREN/07/NUCL/S07.70464 to replace Radiation Protection Publication 91 from 1997. The subject has proven to be very complex, and the contractor reported on difficulties to define conclusive acceptability criteria in some cases, and in particular in diagnostic imaging.

The Vice-chairperson of the WP MED presented the group's proposal to publish the document as a technical report for public consultation and to collect feedback during a period of about one year. Based on the technical report and the comments collected during the consultation period, a European Guidelines document could be prepared and published later.

The GoE thanked the expert for this interesting presentation and for the preparation of the draft document. The GoE accepted the WP MED's proposal on the way forward with this publication.

European Commission Communication on the medical application of ionizing radiation

The Secretariat informed the GoE about plans to develop a *Commission Communication on medical uses of ionizing radiation, for the benefit of the patient and public health.* The draft communication shall be prepared by the Secretariat under the auspices of the WP MED and presented to the Article 31 GoE in June 2010. Adoption is planned for end 2010.

The GoE welcomed this important initiative and is looking forward to receive and discuss the draft Communication

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

Draft Proceedings of the 2008 Scientific Seminar ***Emerging Evidence for radiation induced circulatory diseases***

The Chairperson of the WP RIHSS presented the draft proceedings of the Scientific Seminar 2008 on ***Emerging evidence for radiation induced circulatory diseases***, which was held on 25 November 2008.

The GoE congratulated the WP RIHSS for the organisation of this Scientific Seminar, and approved the draft proceedings for publication in the Radiation Protection Series of the Commission[3].

Proposal of a draft programme for the EU Scientific Seminar 2009 Childhood leukaemia – mechanisms and causes

The Chairperson of the WP RIHSS presented the draft programme for the EU Scientific Seminar on *Childhood leukaemia – mechanisms and causes*. The draft programme is attached to this summary report.

The GoE approved the well prepared programme and asked the WP RIHSS to continue its preparations for the seminar.

Review of recent scientific findings with regard to radiation induced cataracts

At the meeting in November 2008, the GoE asked the WP RIHSS to review recent scientific findings with regard to radiation induced cataracts and to prepare a report on new evidence.

The Chairperson of the WP RIHSS reported that there have been only a few publications since the review presentation of Norman J. Kleiman on *Radiation Cataracts* at the EU Scientific Seminar 2006 on *New insights in radiation risk and basic safety standards*[4]. These recent publications confirm the conclusions already presented by Norman Kleiman. The Chairperson of the WP RIHSS informed the GoE that an ICRP Task Group is currently preparing a report on tissue injury after high doses of radiation which shall also cover radiation induced cataracts.

The GoE thanked the WP RIHSS for this analysis and asked the WP RIHSS to prepare a written summary of the publications collected for discussion at the next Article 31 GoE meeting in November 2009. The WP RECAST was asked to keep this analysis in mind when further reviewing the Basic Safety Standards Directive.

7. ESTABLISHMENT OF EUROPEAN TECHNICAL RECOMMENDATIONS FOR MONITORING INDIVIDUALS EXPOSED TO EXTERNAL RADIATION

A member of the GoE presented the result of the project to review and revise the *European technical recommendations for monitoring individuals exposed to external*

[3] The proceedings of the EU Scientific Seminar 2008 on *Emerging evidence for radiation induced circulatory diseases* were published in the Radiation Protection Series, N° RP158 and can be found under http://ec.europa.eu/energy/nuclear/radiation_protection/scientific_seminar_en.htm.

[4] The proceedings of the EU Scientific Seminar 2006 on *New insights in radiation risk and basic safety standards* were published in the Radiation Protection Series, N° RP145 and can be found under http://ec.europa.eu/energy/nuclear/radiation_protection/scientific_seminar_en.htm.

radiation. The draft document which shall replace the previous publication RP 73 from 1994 has undergone a broad consultation of relevant stakeholders.

The GoE thanked the expert for this very interesting presentation and congratulated the contractor for the preparation of the draft document. The GoE approved formally the draft *European technical recommendations for monitoring individuals exposed to external radiation* and the presented foreword for publication in the Radiation Protection Series of the Commission.

8. EFFECT OF DEPLETED URANIUM

At the meeting in November 2008, the GoE discussed a document on recent scientific studies on the effect of depleted uranium prepared by the *International coalition to ban uranium weapons (ICBUW)*. The document includes a list of recent scientific publications in this field. Pending further detailed review of these publications, the GoE concluded that there is not any new scientific evidence that would invalidate their earlier opinion on the health effects of depleted Uranium[5].

Since the meeting in November 2008, an Expert of the GoE performed a detailed examination of the references given in the ICBUW document. In his analysis, the expert concluded that the assessment by ICBUW is partial, some recent publications are not taken into account, not all given references are relevant. The given publications relate exclusively to the chemical toxicity of Uranium, not to its radiological impact.

Another expert of the GoE reported on the outcome of a seminar on *Depleted Uranium Research: An Update* which was held in Rome, 17 December 2008. Programme, abstracts and presentations of this seminar can be found on the ISS webpage under http://www.iss.it/tesa/even/cont.php?id=197&lang=1&tipo=8.

The GoE concluded that there is not any new scientific evidence that would invalidate their earlier opinion on the health effects of depleted Uranium.

9. URANIUM IN MINERAL WATER

The Secretariat reported on an activity by the European Food Safety Authority (EFSA) at the request of the German Federal Institute for Risk Assessment (BfR) in view of differing regulations on uranium in mineral water in different countries and uncertainties over its long term health effects. The expert panel of EFSA endorsed the guidance by WHO on a tolerable daily intake (TDI) for soluble uranium of 0.6 µg per kg of body weight. As EFSA's expert panel only considered the chemical toxicity of uranium, EFSA called on DG TREN to address the radiological risks with the GoE. With the note from 7 May 2009, the Secretariat offered its analysis of the radiological risk of uranium in mineral water to the GoE and asked for endorsement.

The GoE examined and fully endorsed the analysis presented by the Secretariat.

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[5] The Opinion of the Group of Experts established according to Article 31 of the Euratom Treaty on Depleted Uranium can be found under: http://ec.europa.eu/energy/nuclear/radiation_protection/doc/art31/2001_03_opinion_en.pdf

10. OTHER BUSINESS

European High Level Group on Nuclear Safety and Waste Management (ENSREG)

The Chairperson of the Article 31 Group of Experts reported on the 8th meeting of the European High Level Group on Nuclear Safety and Waste Management (ENSREG). At this meeting, he was given the opportunity to present the Group of Experts referred to in Article 31 of the Euratom Treaty, its legal basis, mandate, rules of procedure, membership, meeting frequency, working parties, and work programme. During the presentation, the GoE Chair highlighted the fact that the group is consulted by the Commission on legislative initiatives with regard to basic standards for the health and safety of workers and members of the public and he informed ENSREG about the ongoing revision of the Basic Safety Standards Directive. Finally, the relation between the Article 31 GoE and the Commission and the relation between the Commission and Member States' Expert Groups such as ENSREG, HERCA, WENRA was visualised. The presentation was well received by ENSREG members.

Announcement of the second workshop of the European NORM ALARA network

The Secretariat reported that the European ALARA Network for NORM is currently preparing its second workshop which will be held 24 – 26 November 2009 in Dresden (Germany).

11. DATE OF THE NEXT MEETINGS

The next meeting of the Group of Experts will be held on **3 – 5 November 2009 in meeting room M6 at the Jean Monnet Building, rue Alcide de Gasperi – L-2920 Luxembourg-Kirchberg**. In conjunction with the Article 31 GoE meeting, the EU Scientific Seminar 2009 on ***Childhood leukaemia – mechanisms and causes*** will be held on 3 November 2009, starting at 13:30 and ending at about 18:00.

Depending on progress with the revision of the European Basic Safety Standards, an additional meeting of the Article 31 Group of Experts may be scheduled for **23 – 25 February 2010 in meeting room EUFO 0001, European Commission – Euroforum Building, 10, rue Robert Stumper – L-2557 Luxembourg – Gasperich.**

Annex 1: **EU Scientific Seminar 2009**

Childhood Leukaemia – mechanisms and causes

Luxembourg, 3 November 2009

starting at 13:30 - ending at 18:00

in meeting room M6

European Commission – Jean Monnet Building
rue Alcide de Gasperi – L-2920 LUXEMBOURG (Kirchberg)

Draft Programme

(Version 9 September 2009)

Chairman: John Stather, United Kingdom

Rapporteur: Jean Piechowski, France

13:30	**Objectives of the seminar** *Patrick Smeesters, on behalf of the Article 31 WP RIHSS*
13:45 – 14:15	**Childhood leukaemia – General overview and ongoing studies in France** *Danièle Sommelet and Jacqueline Clavel, France*
14:15 – 14:45	**Review of identified and possible aetiologies of childhood leukaemia** *Heribert Jürgens, Germany*
14:45 – 15:30	**Ionising radiation epidemiology of childhood leukaemia** *Richard Wakeford, United Kingdom*
15:30 – 16:00	***Coffee Break***
16:00 – 16:45	**Childhood leukaemia around nuclear installations** *Wolfgang-Ulrich Müller, Germany*
16:45 – 17:30	**Round table discussion: Policy implications and research needs** ***Which scientific approaches should be designed to clarify the causes and mechanisms of childhood leukaemia?*** *Moderator: John Stather, United Kingdom* *Round table: Ruth Jarrett, Britt Gustafsson, Danièle Sommelet, Heribert Jürgens, Leo Kinlen, Richard Wakeford, Wolfgang-Ulrich Müller*
17:30 – 18:00	**Conclusions** *Patrick Smeesters, Chairman of the RIHSS WP*
18:15	***Cocktail***