EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR ENERGY

DIRECTORATE D - Nuclear Energy
Radiation Protection

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

Luxembourg, 3 – 5 November 2009

SUMMARY REPORT

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

1. APPROVAL OF THE AGENDA

The agenda was approved without changes.

2. APPROVAL OF THE SUMMARY REPORT OF THE MEETING HELD IN LUXEMBOURG ON 9 – 11 JUNE 2009

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

3. PROCEDURAL ASPECTS: NOMINATION OF EXPERTS FOR THE NEW TERM OF THE GROUP OF EXPERTS REFERRED TO IN ARTICLE 31 OF THE EURATOM TREATY

The Secretariat informed the Group of Experts that the five years term of the current group will come to its end in spring 2010. The Euratom Scientific and Technical Committee (STC) has invited their members to nominate experts for the next five year term of the Article 31 Group of Experts. The nominations will be discussed and approved, if appropriate, at the STC meeting on 26 November 2009. The new Article 31 Group of Experts will be established in April 2010 and will meet for the first time in Luxembourg on 3 – 4 June 2010.

4. INFORMATION BY THE COMMISSION

4.1. Nuclear Safety

The Head of Unit H1 reported that on 25 June 2009 the Council adopted with unanimity Directive 2009/71/Euratom establishing a Community framework for the nuclear safety of nuclear installations[2].

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[1] The approved Summary Report of the June 2009 meeting can be found under http://ec.europa.eu/energy/nuclear/radiation_protection/article_31_en.htm

The European Nuclear Safety Regulators Group (ENSREG) has after two years of work presented their report to the European Parliament and to the European Council. The Council conclusions on the ENSREG report call for a renewed commitment to work on nuclear safety and nuclear waste. The Council wishes to be kept informed about the work of ENSREG.

Finally, the Head of Unit H1 informed the GoE about the Council initiative to prepare Council conclusions on the security of supply of radioisotopes for medical use[3].

The GoE took note of these initiatives and thanked the representative of Unit H1 for this information.

4.2 Radioactive Waste Management and Transport

The Director of Directorate H presented a draft proposal for a *Council Regulation on establishing a Community system for Registration of carriers of radioactive materials*. 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 the implementation of reporting and authorisation requirements, and to increase transparency allowing carriers and users to easily find the information on the applicable rules. The first draft which had been presented to the GoE earlier has greatly benefited from the work of the Working Group on Transport which had been established by the Article 31 GoE for this purpose. The new draft should be submitted to the Standing Working Group on the Safe Transport of Radioactive Materials.

The GoE discussed the presented draft proposal and the draft Opinion prepared by the Secretariat. The Group of Experts adopted a slightly modified Opinion which can be found in Annex 1 to this Summary Report[4].

Some Experts also raised a concern whether the international (IAEA) transport regulations would permit the exemption of a full conveyance of excepted packages. It was agreed that this was primarily a subject for IAEA's TRANSSC Committee

4.3. Status of legislative projects

Extension of post-Chernobyl regulation

The Secretariat informed the GoE that the extension, for another 10 years, of the Post-Chernobyl Regulation had been adopted by the Council on 23 October 2009[5].

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[2] Council Directive 2009/71/Euratom of 25 June 2009 on 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] The Council conclusions on the security of supply of radioisotopes for medical use have been adopted by the Council on 15 December 2009.

[4] The Opinion can also be found under http://ec.europa.eu/energy/nuclear/radiation_protection/article_31_en.htm

[5] Council Regulation (EC) No 1048/2009 of October 2009 amending Regulation (EC) 733/2008 on conditions governing imports of agricultural products originating in third countries following the

Development of the Drinking Water Directive

As already discussed at the last GoE meeting, the DG TREN proposal for a Euratom Directive on drinking water, on which the GoE had given a positive Opinion, did not pass the Inter Service Consultation. DG ENV has asked the Legal Service for a second opinion. DG ENV is currently proceeding with recasting the EC Directive on drinking water. The Secretariat will keep the GoE informed about progress with this matter.

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 cataract 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 cataract. The results of this task group will be evaluated by ICRP Committee 1. ICRP is also discussing the dose conversion convention for radon. Further guidance from ICRP is expected after the ICRP Main Commission meeting in Porto, in November 2009[6].

5.2 IAEA

The representative from the International Atomic Energy Agency (IAEA) summarised the activity highlights in Radiation, Waste and Transport Safety since the June meeting of the Article 31 Group of Experts. A Code of Conduct meeting in June 2009 discussed long term strategies for the management of radioactive sealed sources. The IAEA is planning a communication campaign early 2010 to help to overcome the denial of shipment issue. In May 2009, the Conference on remediation of land contaminated by radioactive material residues discussed the creation of a forum on the regulatory supervision of legacy sites to support the international initiative for the remediation of legacy sites in Central Asia. The IAEA representative reported also on an initiative to assess prospects and challenges for uranium production to support sharing of knowledge and best practices between uranium producing countries. Another initiative comprises discussions on licensing of geological repositories. The international workshop on "Justification of medical exposure in diagnostic imaging", jointly organised by EC and IAEA took place in Brussels, 2 - 4 September 2009. The International ISOE ALARA Symposium took place in Vienna, 13 – 15 October 2009. The Information System on Exposure in Medical-, Industrial- and Research (ISEMIR) has launched two working groups, one on interventional radiology and the other on industrial radiography. Finally, the IAEA is currently preparing a document on Radiation Protection in Modern Paediatric Radiology.

5.3 NEA

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accident at the Chernobyl nuclear power station was published in the Official Journal of the European Union, L 290/4, 6 November 2009.

[6] On 16 November 2009, ICRP published a ***Statement on Radon*** which can be found under http://www.icrp.org/icrp_radon.asp.

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

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

6. REVISION OF THE EUROPEAN BASIC SAFETY STANDARDS

6.1. 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. In June 2009, the WP RECAST had presented a full draft text of the Directive including all annexes (Version 5 May 2009) to the Article 31 GoE for discussion. WP RECAST held a three day meeting, 29 September – 1 October 2009, to address and incorporate comments received from the Group of Experts. The revised draft (Version 13 October 2009) has been sent to GoE for discussion at this meeting. The Secretariat prepared a draft GoE Opinion, which was also sent to the GoE before the meeting.

The Chairperson proposed to go through the text of the draft Directive (Version 13 October 2009) title by title and encouraged experts to suggest alternative text, and to address any conceptual issues and points of principle. In doing so, the experts should also take into account the text proposed for the Opinion of the Group of Experts.

The GoE welcomed the excellent work performed by the WP RECAST, and appreciated the possibility to discuss a well advanced draft Directive. The detailed discussion of the draft text is summarised under Agenda Item 6.3.

6.2 Revision of the international Basic Safety Standards

The IAEA representative informed the meeting about the status of revision of the International Basic Safety Standards. After discussion of draft 1.0 in November 2008, draft 2.0 was discussed in June 2009 and draft 2.5 posted on the RASSC website on 2 October 2009. Key changes since draft 2.0 were the introduction of overarching

requirements. Current planning foresees that RASSC and WASSC at their meetings in November 2009 would approve draft 2.5 for submission to Member States for consultation in early 2010. Comments from Members States shall be received by May 2010 followed by a presentation to all Safety Standards Committees in June 2010. Final approval by all Safety Standards Committees and subsequent submission to CSS is foreseen for end 2010.

6.3 Discussion of the draft European Basic Safety Standards

The Chairperson of the WP RECAST presented the draft Directive (Version 13 October 2009) title by title. On 29 October 2009, the Secretariat submitted an additional document proposing annotations to Title IV (Article IV.14), to Title VI (Articles VI.2, VI.3, VI.4, VI.7), to Title VIII (Article VIII.3) and to Title IX (Article IX.11) in order to resolve outstanding issues. The GoE decided to first discuss the text of the draft Directive (Version 13 October 2009) without the proposed amendments before discussing the proposed annotations.

Discussion of the draft Directive (Version 13 October 2009)

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. Further detailed suggestions for improvement to the text are welcomed and should be sent to the Secretariat by 23 November 2009.

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.

The GoE expressed its satisfaction with the text as it stands. It was mentioned that the legal basis for the inclusion of the protection of the environment still needs to be clarified.

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.

In some of the definitions, the GoE identified inconsistencies which were referred back to the WP RECAST for clarification and refinement. It was noted that the definition of high activity sealed source needs to be clarified.

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 1.

The discussion of this title focussed mainly on the dose limit for the lens of the eye, which in view of recent scientific findings is currently reviewed by ICRP. The GoE agreed that the current values of 150 mSv/y for occupational exposure, 50 mSv/y for apprentices and students and 15 mSv/y for public exposure need to be lowered. While awaiting guidance from ICRP, the GoE decided to replace the current values by placeholders X mSv/y and Y mSv/y plus a footnote stating that these placeholders will be replaced by the values recommended by ICRP.

In addition, the experts provided more detailed comments and proposals.

Title IV covers *Responsibilities for regulatory control*. The Title is structured in several sections: institutional infrastructure; control of sealed sources (with five Annexes); orphan sources; emergency exposure situations; existing exposure situations; system of enforcement.

For section 1 *Institutional infrastructure*, the experts offered a few detailed comments on the proposed concepts: occupational health services, dosimetry services, radiation protection experts, medical physics experts, and radiation protection officers.

With regard to the activity levels defining high-activity sealed sources (Annex 2), the GoE proposed to keep the activity levels currently included in Directive 2003/122/Euratom. In the Opinion, the Commission shall be invited to investigate the technical basis and the implications of a replacement of these values by the values given in the IAEA Code of Conduct for the sake of international harmonisation.

No comments were made on the sections on emergency exposure situations, existing exposure situations and the system on enforcement.

Title V covers *Requirements for Radiation Protection Education, Training and Information*. This title includes a general requirement on Member States to ensure the establishment of an adequate legislative and administrative framework for providing appropriate radiation protection education, training and information. In addition, the title contains specific requirements on training in the medical field, on information and training of workers in general, of workers potentially exposed to orphan sources, and to emergency workers.

The GoE welcomed this title and provided a few minor comments.

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 comprises also 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. The Title includes now also text on justification for non-medical human imaging, replacing “medico-legal” exposures.

The GoE was reasonably satisfied with the text, and proposed a few structural changes to enhance clarity for the reader.

Title VII deals with the Protection of Workers, Apprentices and Students. The Title retains practically all requirements already included in Council Directive 96/29/Euratom, in particular the categorisation of workers and classification of areas, and the requirements of the outside workers Directive (Council Directive 90/641/Euratom). Annex 10 contains requirements on centralised networks (national dose registry) and individual radiological monitoring documents. Emergency workers shall be subject to 50 mSv dose limit or a higher reference level for specific

cases identified in national emergency plans. Air crew is covered by this Title. Provisions for specially authorised exposures are retained (eg for space crew). Due to the restructuring of the document, the title now includes also text on radon in workplaces.

The GoE offered only a few minor comments on this well established text.

The requirements on recording and reporting of monitoring results include a provision to allow for the subtraction of exposures attributed to an existing exposure situation, which applies also for the recording and reporting of radon exposures in workplaces. Despite this general provision on background subtraction, one Expert preferred to reintroduce a fixed background value for radon.

Title VIII covers the Protection of Patients and Other Individuals Submitted to Medical Exposure.

There were only minor comments on this Title.

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. The text in relation to protection of public in planned exposure situations is largely copied from Title VIII of Directive 96/29/EURATOM. The draft Directive gives more precise indications for the establishment of discharge authorisations, with reference to Commission Recommendation 2004/2/EURATOM. Due to the restructuring of the Directive, the Title covers now emergency exposure situations and existing exposure situations, including contaminated areas, radon in dwellings and public buildings, and building materials.

The GoE expressed its satisfaction with the text in this title. After the recent publication of the WHO Handbook on Radon, the discussion focussed on the reference levels for indoor radon concentration in new buildings, existing dwellings and existing public buildings. The GoE agreed to await guidance from ICRP before concluding this discussion[7].

Title X covers the Protection of the Environment and introduces specific requirements for the protection of non-human species.

The Group of Experts notes the recent publication by ICRP on guidance on the definition of reference animals and plants (Publication 108), but observes that there is currently no agreed methodology available for the assessment of the impact of radiation on non-human species. It was therefore agreed that in the Opinion the Group of Experts will invite the Commission to leave enough time for transposition of these requirements in national law, pending the results of further research and international guidance of ICRP.

Finally, the GoE offered a few detailed comments on some of the **Annexes**.

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[7] On 16 November 2009, ICRP published a ***Statement on Radon*** which can be found under http://www.icrp.org/icrp_radon.asp. The ICRP statement proposes a maximum reference level for dwellings of 300 Bq/m^3.

Discussion of the annotations proposed by the Secretariat 29 October 2009

On 29 October 2009, the Secretariat submitted an additional document proposing annotations to Title IV (Article IV.14), to Title VI (Articles VI.2, VI.3, VI.4, VI.7), to Title VIII (Article VIII.3) and to Title IX (Article IX.11) in order to resolve outstanding issues. The annotations were submitted to the Group of Experts shortly before the meeting. Although the GoE welcomed the initiative in principle, the experts had too little time to study the proposal thoroughly. The annotations were therefore referred back to the WP RECAST. The Group of Experts was invited to send written comments on the annotations to the Secretariat by 23 November 2009.

6.4 Discussion of the draft Opinion of the Group of Experts referred to in Article 31 of the Euratom Treaty

The Secretariat prepared a draft Opinion of the Article 31 Group of Experts on the draft Basic Safety Standards Directive. The GoE congratulated the Secretariat for this well formulated first draft and discussed it paragraph by paragraph. The GoE identified additional topics, such as space crew and non-cancer effects, which need also to be addressed in the Opinion and offered comments and amendments to further improve the text. As the Opinion refers to a specific version (13 October 2009) of the draft Basic Safety Standards Directive and the decision on the above mentioned annotations was postponed, the GoE could not adopt the Opinion at this stage. The GoE agreed to make use of the additional meeting foreseen to take place on 23 – 24 February 2010, to discuss and eventually adopt the draft Opinion on the Basic Safety Standards Directive.

Way forward

The GoE agreed on the following way forward. Additional comments on the draft Basic Safety Standards, the proposal on non-medical imaging and the proposed draft Opinion shall be sent to the Secretariat by 23 November 2009. The WP RECAST will meet on 14 – 15 January 2010 to discuss and resolve the outstanding issues. The modified draft Basic Safety Standards Directive together with the modified draft Opinion shall be sent to Article 31 Group of Experts by 5 February 2010. The GoE will meet on 23 – 24 February 2010, to discuss and eventually adopt the draft Opinion on the Basic Safety Standards Directive.

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

7.1. 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. Since the last meeting of Article 31 GoE the WP MED had one meeting held in Brussels on 1 and 2 September 2009. Additional information about the different topics discussed by the WP MED is presented below.

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 main proposals agreed during the September 2009 meeting concerned the definition of interventional radiology, the definition of Medical Physics Expert (MPE) and her/his

competences and involvement in the different types of medical exposure procedures, the consideration of carers and comforters as medically exposed individuals and the requirements for devices or "equivalent tools" informing the practitioner about the quantity of radiation produced by the radiological equipment. Inputs from the European Federation of Organisations of Medical Physics (EFOMP) and the European Federation of Radiographer Societies (EFRS) were discussed.

The Vice-Chairperson of the WP MED summarised the status of Commission projects to assist Member States in the application and harmonisation of the medical Directive. The Criteria for Acceptability of Radiological Installations project is close to completion, the final draft being expected within a few weeks; in accordance with the decision of Art. 31 GoE from June 2009, the document will be published as a draft for consultation and a workshop to discuss the identified issues will be organized in 2010 before adopting the document as European guidelines. The European Medical ALARA Network (EMAN) contract was signed in the end of October; the kick-off meeting will be held in Luxembourg by the end of November 2009. The Medical Physics Expert call for tenders received two offers and the Commission is in a process of awarding the contract. The Referral Criteria for Imaging call for tender did not receive any offers; however an interest in a future project was expressed in writing by the European Society of Radiology, the Royal College of Radiology and the French Society of Radiology leading to a decision by the Commission to re-work the specifications and re-launch the project in 2010. It was confirmed that the other tenders to be launched in 2010 are a European patient dose survey and a study on the implementation of Medical Directive's training requirements.

The next meeting of the WP MED is scheduled for 2 and 3 February 2010.

European Commission Communication on the medical application of ionizing radiation

The Secretariat presented to the GoE a draft outline of the *Commission Communication on the Situation concerning Medical Applications of Ionizing Radiation in the European Union*. The current draft outlined was prepared by the Secretariat and reflects the discussion at the WP MED meeting from September 2009.

The draft outline 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: the awareness of medical doctors about the health risks from exposure to ionizing radiation, the role of the equipment manufacturers and health insurance companies, the safety of medical devices and software, the dosimetry protocols for new radiotherapy techniques, the development and use of information technology including web-based tools for justification of radiological procedures, etc.

International workshop on Justification of Medical Exposures in diagnostic imaging, Brussels, 2 – 4 September 2009

The Secretariat presented first conclusions from the *International Workshop on Justification of Medical Exposures in Diagnostic Imaging*, organized jointly by the IAEA and the Commission from 2 to 4 September 2009 in Brussels. The workshop was attended by about hundred participants from around the world, from international organizations and from European and international professional societies. The existence of a significant and systematic failure to apply the justification principle to medical exposure in diagnostic imaging was demonstrated in a series of cases from different parts

of the world. It was confirmed that efficient tools exist to deal with the justification problem but their implementation in practice is weak. Number of communication issues in relation to successful justification process were also identified and discussed. The IAEA and the Commission are working on the proceedings and their final conclusions from the workshop.

The GoE expressed their satisfaction with the results from the workshop and their hopes that the IAEA and the Commission will further support initiatives to address the different issues in relation to justification of medical exposures.

International symposium on Non Medical Imaging Exposures, Dublin, 8 – 9 October 2009

A member of the GoE presented the *International symposium on Non Medical Imaging Exposures (NMIE)*, held on 8 and 9 October 2009 in Dublin, under a contract with the Commission. The workshop was a follow-up to a similar meeting from 2002 (proceeding published as EC *Radiation Protection 130*) the objectives being to update the information about the implementation of these practices around the world and discuss the possible ways of bringing them under an effective radiation protection regulatory regime. The main conclusions from Dublin are that these exposures are implemented in the EU Member States and that they often escape adequate regulation, which is to a big extent caused by their current definition as "medico-legal procedures" within the "medical exposure" category. Specific issues with implementing the justification, optimization and dose limitation principles to the various cases of NMIE were discussed during the workshop. Workshop proceedings are expected in the beginning of 2010.

New Commission proposal on Non-medical Imaging Exposures taking into account the discussions during the Dublin workshop was presented to the GoE and received their general support. The members of the GoE will send their specific notes on the proposal to the Secretariat in the framework of the BSS recast process.

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

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

The Chairperson of the WP RIHSS briefly summarised the results of the EU Scientific Seminar on *Childhood leukaemia – mechanisms and causes*, which was held on 3 November 2009. Five internationally renowned scientists working in the field of childhood leukaemia presented current knowledge. The speakers offered a general overview on advances in childhood acute leukaemia, followed by a presentation on risk factors of childhood leukaemia – the French research program, a review of identified and possible aetiologies of childhood leukaemia, a summary of the ionising radiation epidemiology of childhood leukaemia, and a report on childhood leukaemia around nuclear installations. The presentations were followed by a round table discussion, in which the speakers and invited additional experts discussed potential policy implications and research needs.

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

The GoE congratulated the WP RIHSS for the organisation of this Scientific Seminar, and for the high quality of the presentations and the round table discussions. The GoE is looking forward to receive the draft proceedings of the seminar for discussion at the June 2010 meeting.

Proposal of topics for the EU Scientific Seminar 2010

At its meeting in October 2009, the WP RIHSS agreed to propose the following selection of topics for the EU Scientific Seminar 2010:

- Biomolecular and nanotechnology perspectives in assessing radiation induced health effects
- Issues with internal emitters
- General overview of radiation sources
- Dosimetry in accidents
- Regulatory requirements on sound dosimetry during medical exposures and further patient follow-up.

The GoE thanked the WP RIHSS for this interesting selection of potential topics and decided to hold the EU Scientific Seminar 2010 on ***Issues with internal emitters***.

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. In June 2009, 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*[8]. 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. At this meeting, the WP RIHSS presented a written report which is attached as Annex 2 to this summary report.

The GoE thanked the WP RIHSS for this excellent analysis, and endorsed the written report.

8. OTHER BUSINESS

No other business was raised under this agenda item.

[8] 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.

9. DATE OF THE NEXT MEETINGS

The next meeting of the Group of Experts will be held **23 – 24 February 2010** in meeting room **EUFO 0001, European Commission – Euroforum Building, 10, rue Robert Stumper – L-2557 Luxembourg – Gasperich** starting at 13:30 on 23 February 2010.

The June meeting of the Group of Experts is scheduled for **3 – 4 June 2010** in meeting room **EUFO 0001, European Commission – Euroforum Building, 10, rue Robert Stumper – L-2557 Luxembourg – Gasperich.**

ANNEX 1: OPINION OF THE GROUP OF EXPERTS REFERRED TO IN ARTICLE 31 OF THE EURATOM TREATY ON THE DRAFT PROPOSAL FOR A COUNCIL REGULATION (EURATOM) ESTABLISHING A COMMUNITY SYSTEM FOR REGISTRATION OF CARRIERS OF RADIOACTIVE MATERIAL

Opinion of the Group of Experts referred to in Article 31 of the EURATOM Treaty

On the

Draft proposal for a Council Regulation (Euratom) establishing a Community system for Registration of carriers of radioactive material

The Group of Experts examined the proposal for a Council Regulation on this subject at their meeting on 3-5 November 2009.

The Group of Experts noted:

- The IAEA Regulations for the Safe Transport of Radioactive Material (TS-R-1) and the modal regulations based on them as transposed directly or via EU Directives into Member States Law have for many years established the standards of safety which provide an appropriate level of control of the radiation, criticality and thermal hazards to persons, property and the environment that are associated with the transport of radioactive material. The IAEA regulations apply a graded approach in specifying the performance standards.
- Council Directive 96/29/Euratom laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionising radiation requires reporting or authorisation for the transport of radioactive materials as a practise. Member States has implemented this requirement in different ways resulting in very different approaches in the 27 Member States without any significant impact on the level of transport safety or incidents experience.
- The European Commission proposes a common approach to the administrative procedures relating to carriers of radioactive materials by the establishment of a Community system for Registration of carriers allowing for a reduction of the administrative burden on carriers and competent authorities and a strengthening of the functioning of the common market.
- In the proposal the Commission applies a graded approach in line with the IAEA regulations by excluding excepted packages from the regulation and by allowing for additional national requirements for the transport of fissile material and high activity materials.
- The proposal also ensures that the competent authorities have access to all data regarding carriers operating in their country.

The Group of Experts endorses the principles of a graded approach to transport regulation and transparency between competent authorities in the solution proposed by the Commission. The Group of Experts is aware of the very detailed administrative provisions in the proposal and therefore recommends that the competent authorities in the Member States and other affected parties are consulted before a final proposal is submitted, including through the Standing Working Group on the Safe Transport of

Radioactive Materials. The Group of Experts stresses the need for coordinating at the European level the regulatory control of transport of radioactive material.

Luxembourg, 4 November 2009

Kaare Ulbak

Chairperson of the Group of Experts

ANNEX 2:

Radiation induced cataracts and Basic Safety Standards:

Evolutions since the EU Scientific Seminar 2006

Patrick Smeesters, on behalf of the

Working Party "Research Implications on Health and Safety Standards" of the Article 31 Group of Experts

In the current BSS, dose limits for the lens of the eye (150 mSv/y for the exposed workers and 15 mSv/y for members of the public) are based on ICRP recommendations in Publication 60 (1991). These recommendations were based on postulated threshold doses of **5 Sv** (equivalent dose) for detectable opacities and **8 Sv** for visual impairment (cataract) in conditions of highly fractionated or **protracted exposure** (adult population) (ICRP 60, annexe B, p 103, table B-1). Corresponding figures for single acute exposures were 0.5-2 and 5 Sv. Note that these ICRP 60 figures are the same as those from ICRP Publication 41 (1984) (ICRP 41, p 28, table 6), based themselves on radiotherapy studies. The dose limit for the lens of the eye for members of the public are based on "an arbitrary reduction factor of 10" (ICRP 60, p 46, 194).

During the EU Scientific Seminar *(1)* held in Luxembourg on 17 October 2006 about "New Insights in Radiation Risk and Basic Safety Standards", Norman J. Kleiman, Director of the Eye Radiation and Environmental Research Laboratory in the Columbia University reviewed the new available evidence regarding radiation-induced cataracts. In various exposed populations, including those undergoing CT scans (Klein, 1993), radiotherapy (Wilde, 1997; Hall, 1999), the astronaut pool (Cucinotta, 2001; Rastegar, 2002), atomic bomb survivors (Minamoto, 2004; Nakashima, 2006), residents of contaminated buildings (Chen, 2001) and the Chernobyl accident "liquidators" (Worgul, 2003, 2007), dose-related lens opacification at exposures significantly lower than 2 Gy was reported. Kleiman noted that the evidence to date points to a dose threshold **no greater than 700 mGy**, which challenges the current ICRP guidelines.

Moreover, Kleiman reported new observations that are even consistent with the absence of a dose threshold**.** Although the mechanism of radiation induced cataracts is not known precisely, genomic damage resulting in altered cell division, transcription and/or abnormal lens fibre cell differentiation is now considered to be the salient injury, rather than cell killing. For this reason, the classification of cataracts as a deterministic effect must be called into question. Several lines of evidence from experimental and epidemiologic studies suggest a **stochastic** basis for radiation cataracts. Animal studies have shown that individuals that are haplo-insufficient for genes involved in DNA damage repair and/or cell cycle checkpoint control may be more susceptible to the cataractogenic effects of ionizing radiation than wild-types. Atm, Brca1 and Rad9 heterozygotes demonstrate enhanced sensitivity to radiation-induced cataract formation. Heterozygosity of the *Atm* gene is estimated to occur in 0.5-1% of the Western population. The roles of Atm, Rad9 and Brca1 in the cell cycle and during DNA repair are consistent with a genotoxic basis for radiation cataractogenesis. These findings may have important implications for radiosensitive subsets of the human population and for the astronaut core.

Kleiman concluded that, given that all national and international risk standards for ocular exposure are predicated on a relatively high threshold, current risk guidelines for ocular radiation safety require reassessment.

Since the 2006 EU Seminar, a lot of new evidence was published that confirmed these conclusions.

In 2007, Chumak *et al.(2)* investigated the lens dosimetry in the above-mentioned (Worgul, 2007) study of a cohort of exposed clean-up workers (liquidators) at the Chernobyl Nuclear Power Plant and concluded that the current dosimetric methodology provides reasonable estimates of individual γ-ray and ß-particle doses to the lens of the eye that are *sufficiently accurate* to have utility in this kind of epidemiological/clinical study.

Also in 2007, Kleiman *et al.(3)* investigated the impact of *dual heterozygosity* for *Mrad9* and *Atm* (genes regulating multiple cellular responses to DNA damage) on radiation-induced cataractogenesis in mice. Posterior subcapsular cataracts, characteristic of radiation exposure, developed earlier (and were more severe) in X-irradiated (50 cGy) double heterozygotes than in single heterozygotes, which were more prone to cataractogenesis than wild-type controls.

There was also a new study regarding Atomic Bomb Survivors published in 2007. Neriishi *et al.* (Radiation Effects Research Foundation) *(4)* investigated the radiation dose response in postoperative cataract cases among atomic bomb survivors. Because many in the radiation protection community have believed that, while relatively low doses of radiation may cause small, clinically insignificant opacities, a large dose threshold (in the order of 5 Gy) exists for large, vision-impairing cataracts, this study was designed to evaluate evidence regarding *clinically significant* cataracts, namely, those that were removed surgically. The prevalence of postoperative cataracts in A-bomb survivors increased significantly with A-bomb radiation dose. The estimate (0.1 Gy) and upper bound (0.8 Gy) of the dose threshold for operative cataract prevalence was much lower than the threshold usually assumed by the radiation protection community and was statistically compatible with no threshold at all.

In 2008, Chodick *et al*. *(5)* presented the results of a 20-Year prospective cohort study among more than 35,000 US radiologic technologists, aiming to determine the risk of cataract with respect to occupational and non occupational exposures to ionizing radiation and to personal characteristics. For workers in the highest category (mean, 60 mGy) versus lowest category (mean, 5 mGy) of occupational dose to the lens of the eye, the adjusted hazard ratio of cataract was 1.18 (95% confidence interval: 0.99, 1.40). Although based on questionnaires and self-reports, this study supports the hypothesis that the lowest cataractogenic dose in humans is substantially less than previously thought.

The results of a NASA study of cataracts in astronauts (Chylack *et al.,* 2009) *(6)* also suggest increased cataract risks at smaller radiation doses than have been reported previously.

Vano *et al. (7)* investigated in 2008 radiation doses to the eye lens of the interventionalist from medical procedures performed with and without use of radiation protection measures. With typical reported workloads, radiation doses to eye lenses may exceed the ICRP threshold for deterministic effects (ie, lens opacities or cataracts) after several years of work if radiation protection tools are not used.

An international study called RELID (Retrospective Evaluation of Lens Injuries and Dose) was initiated by the IAEA in 2008. A number of eye testing exercises have been held and show that large proportions (sometimes going to 40 %) of interventional cardiologists and even technicians or nurses had posterior subcapsular opacities. The majority did not use leaded protective lenses nor suspended leaded screens.

In a recent review performed by a team including HPA experts, E.A. Ainsbury *et al (8)* concluded that recent studies indicate that "the threshold for cataract development is certainly less than was previously estimated, **of the order of 0.5 Gy**, or that radiation cataractogenesis may in fact be more accurately described by a linear, no-threshold model".

On 14 May 2009, the German Commission on Radiological Protection (SSK) also reviewed the available data and adopted new recommendations regarding radiation-induced cataracts. *(9)*

The SSK considered that recent epidemiological studies have not demonstrated any threshold value below which damage to the lens of the eye from ionising radiation can be ruled out with certainty and that there is a **strong probability that the threshold dose is < 0.8 Gy**.

In various studies, an increase in the cataract rate was indeed observed after radiation exposure of around 0.5 Gy. As comparable effects were observed after short-term exposure and after exposure over longer periods, the SSK stressed the importance of looking to the lifetime dose, instead of only to the annual dose. The current dose limit for the lens i.e. 0.15 Gy, would amount to a cumulative dose of 3 Gy over a 20-year exposure period. This dose is higher, by a factor of almost 6, than the dose at which additional cataracts have been observed, and according to current knowledge, would more than double the risk of spontaneous cataract. The SSK recommends that the German regulatory provisions "be brought into line with the latest scientific findings" and that, for activities which are known to be associated with possible significant lens exposure, appropriate protection measures must be foreseen, as well measurement of the lens dose and occupational medical examination of the lens.

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