



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR ENERGY

DIRECTORATE D - Nuclear Safety and Fuel Cycle
Radiation Protection

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

Luxembourg, 19 – 21 November 2012

SUMMARY REPORT

(Approved by the Group of Experts via written procedure – version 25 April 2013)

INTRODUCTION

The Chairperson of the Group of Experts welcomed the participants. The Secretariat informed the Group of Experts about apologies of members who could not attend the meeting.

The Group held a minute's silence in commemoration of an expert who passed away this summer.

The Secretariat explained that the June 2012 meeting had to be cancelled for purely administrative reasons. To enable the Group to appropriately cover all issues in its work programme, it was decided to extend the current meeting to last for three days.

1. APPROVAL OF THE AGENDA

The agenda was approved with a slight rearrangement of the order of the items to adapt to the availability of meeting participants.

2. APPROVAL OF THE SUMMARY REPORT OF THE MEETING HELD IN LUXEMBOURG ON 22 – 23 NOVEMBER 2011

The Summary Report was approved with minor amendments¹.

3. PROCEDURAL ASPECTS – ELECTION OF A NEW CHAIRPERSON FOR THE PERIOD 2012 – 2014

According to Article 3 of the Rules of Procedure a new Chairperson has to be elected every two and a half years, which was due at this GoE meeting for the period 2012 to 2014. Before the meeting, the Secretariat invited experts to nominate candidates. The Secretariat received only the nomination of the current Chairperson who was ready to accept the nomination.

¹ The approved Summary Report of the November 2011 meeting can be found under http://ec.europa.eu/energy/nuclear/radiation_protection/article_31_en.htm

The GoE re-elected the current Chairperson unanimously for the remaining period 2012 – 2014. The Chairperson accepted the election and thanked the experts for their confidence.

4. INFORMATION BY THE COMMISSION

4.1. Nuclear Safety

This agenda item was merged with the presentation on a new legislative initiative in the area of nuclear safety (see agenda item 5).

4.2 Radioactive Waste Management and Transport

A representative of Unit D2 reported on initiatives facilitating the implementation of the *Council Directive 2011/70/Euratom establishing a Community Framework for the responsible and safe management of spent fuel and radioactive waste*, in particular on the transposition seminar held on 27 June 2012 in Luxembourg and the workshop on drafting and implementing national programmes held on 25 – 26 September 2012 in Brussels. Finally the representative of Unit D2 drew the attention of the Group to the *Eighth European Commission Conference on the Management of Radioactive Waste (EUROWASTE 2013)* which will be organised by DG RTD in cooperation with DG ENER and DG JRC and Lithuanian partners 14 – 18 October 2013 in Lithuania.

4.3 Status of legislative projects

a. Regulation on the registration of carriers

On 28 September 2012, the European Commission adopted the Proposal for a *Community system for registration of carriers of radioactive materials [COM(2012)561 final]* to which the Group of Experts had given an opinion in November 2009. The proposal is currently being discussed in the Council's Working Party on Atomic Questions (AQG).

b. 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. The proposal is currently being discussed in the Council's Working Party on Atomic Questions (AQG) under Cyprus Presidency and in the European Parliament Committee on Environment, Public Health and Food Safety (ENVI) and in the EP Committee on Employment and Social Affairs (EMPL). With the creation of a Technical Working Group of the Council's Working Party on Atomic Questions chaired by the incoming Irish Presidency, considerable progress could be made on the resolution of technical issues. The Secretariat will keep the Group of Experts informed about progress with this matter.

c. Drinking water Directive

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

On 28 March 2012, the European Commission adopted the *Proposal for a Council Directive laying down requirements for the protection of the health of the general public with regard to radioactive substances in water intended for human consumption [COM(2012)147 final]*. The proposal is currently being discussed in the Council's Working Party on Atomic Questions (AQG) and in the European Parliament. The Secretariat will keep the Group of Experts informed about progress with this matter.

d. Post-Fukushima actions with regard to emergency response

The proposed *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* will be discussed under agenda item 6.

In addition to this legal initiative, the Secretariat reported on the launching of the new WEBECURIE application on 3 December 2012. This new application will further facilitate ECUIRE information exchange and will no longer require specific software to be used.

Finally, it was mentioned that HERCA has launched a Working Group on Emergencies with the objective to discuss coordination and harmonisation of emergency response on an informal basis (see also Agenda Item 7.6).

e. Follow-up to the SCENIHR study on security scanners

The SCENIHR opinion on "Health effects of security scanners for passenger screening (based on X-ray technology)"³ was approved on 26 April 2012 (distributed by email to the GoE on 21 May 2012). The opinion did not reflect the concerns expressed by the Article 31 GoE members appointed to participate (by correspondence) in this task about possible proliferation of this equipment in other areas and dangerous simplifications made in parts of the SCENIHR assessment. The Secretariat informed the GoE about a letter from the Commission's Director General of DG for Mobility and Transport informing that notwithstanding the SCENIHR opinion the Commission "has no intention to propose legislation that would enlarge the use of security scanners to that of ionising radiation technology at EU airports".

5. LEGISLATIVE INITIATIVE IN THE AREA OF NUCLEAR SAFETY

The Director of Directorate Nuclear Energy reminded the Group of Experts that, following the Fukushima accident, he was given a threefold mandate by the Heads of State – these were:

- With ENSREG to devise and arrange implementation of stress tests for all nuclear power plants in the European Union,
- To review existing Euratom nuclear safety legislation and propose strengthening if necessary
- To contact States neighbouring the European Union and involve them to the extent possible in the stress tests.

He welcomed the successful completion of the stress test and noted that there were no grounds for shutting down any of the nuclear power plants. Nevertheless there were a

³ Full text on: http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_036.pdf.

substantial number of recommendations for improvement that needed to be addressed. The Director informed the Group about a legislative initiative in relation to nuclear safety. The Director informed the Group that it is currently planned to prepare in a first step a document outlining the options for such an initiative followed by a first draft proposal for an amended nuclear safety Directive 2009/71/EURATOM. As this legal initiative will be based on Article 31 of the Euratom treaty, the Article 31 Group of Experts will be asked for an Opinion on the initiative. A Commission proposal is planned to be adopted before summer 2013. Given the time frame, the Article 31 Group of Experts may be asked to prepare an Opinion on this initiative by March/April 2013.

The Group of Expert thanked the Director of Directorate Nuclear Energy for the information and accepted to include the initiative in its work programme. With a view to the urgency of the file, it was agreed to create an ad-hoc Article 31 Working Party on the Nuclear Safety Directive to examine documents as soon as they become available with a view to preparing a draft opinion. An extraordinary Article 31 Group of Expert plenary meeting shall be planned to be held in March/April 2013 to discuss, finalise and eventually adopt the Opinion on the amended Nuclear Safety Directive.

6. 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 Secretariat presented the draft revised regulation and explained that the intention was not to change the maximum permitted levels, but to consolidate the existing legislation and to include new provisions compatible with the new "Comitology" system laid down in Regulation (EU) No. 182/2011, as required by the Lisbon Treaty. After a long and elaborate discussion, the Group of Experts gave its Opinion on the proposed revision, which is available on the Europa website⁴.

7. PRESENTATIONS FROM INTERNATIONAL ORGANISATIONS

7.1. International Commission on Radiological Protection (ICRP)

A representative of the ICRP reported on the results of the Main Commission meeting held in November 2012 in Fukushima City (Japan). The final report on "Initial Lessons Learned from the NPP Accident in Japan vis-à-vis the ICRP System of Radiological Protection" has been accepted. The recommendations in this report are taken into account in the programme of work of each Committee.

The representative from the ICRP reported also on the new procedure for nominations for membership in ICRP Committees.

Finally, it was announced that the second ICRP Symposium on the international system of radiological protection will be held 22 – 24 October 2013 in Abu Dhabi.

More information as well as recently published recommendations and publications in press can be found on the ICRP webpage www.icrp.org.

⁴ http://ec.europa.eu/energy/nuclear/radiation_protection/doc/art31/2012_11_opinion_foodstuff_regulation.pdf

7.2 International Atomic Energy Agency (IAEA)

The representative of the IAEA reported on the current work programme of the agency, in particular on the programme to assist in the implementation of the international Basic Safety Standards, the programme on occupational radiation protection, and the programme on patient protection.

The representative of the IAEA announced the *International Conference on Radiation Protection in Medicine – Setting the Scene for the Next Decade* which will be organised 3 – 7 December 2012, in Bonn, Germany, and will cover the protection of patients, workers, carers and comforters and the public.

The Secretariat informed the Group of Experts that on 14 August 2012, the Director General for Energy sent a letter to the IAEA to confirm that the European Commission, on behalf of European Atomic Energy Community, supports the publication of the revised *International Basic Safety Standards: Radiation Protection and Safety of Radiation Sources*, as a co-sponsored document and will promote the implementation of these International Basic Safety Standards within the framework of external relations of the European Atomic Energy Community.

7.3 World Health Organisation (WHO)

No representative of the WHO could attend the meeting.

7.4 Nuclear Energy Agency (NEA)

The representative of the NEA presented recent developments in the NEA programme in radiological protection, in nuclear emergency matters, occupational exposure, best available techniques, public health perspective in radiation protection, radiation protection of the environment, stakeholder involvement issues, and qualified human resources in radiological protection.

The representative of the NEA emphasised the work of Committee on Radiation Protection and Public Health (CRPPH) in relation to the Fukushima accident, in particular the NEA support for Fukushima-related conferences on decontamination and facilitating a dialogue with ICRP.

Further information can be found on the NEA homepage www.oecd-nea.org.

7.5. International Radiation Protection Association (IRPA)

No representative of IRPA could attend the meeting.

7.6. 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.

The Chair of the HERCA Working Group on Emergencies presented the action plan and the work programme of this working group and offered to discuss potential areas for collaboration with the Article 31 Group of Experts.

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

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

8.1. Dose Constraints (WP Dose Constraints)

The Chairperson of the Working Party on Dose Constraints presented progress with this working party. Since November 2011, the WP Dose Constraints held two meetings on 8 March 2012 and 18 September 2012.

The Working Party proposed to perform a survey on current practices and implementation of the concept of dose constraints in EU Member States. The Working Party could analyse twenty-two responses on a questionnaire, which had been prepared by the group and sent to the Article 31 Group of Experts. A more refined analysis shall be included in the report on dose constraints in the EU: Analysis and guidance for Member States which is currently being drafted by the group. The Working Party noted that the requirements on dose constraints currently foreseen in the proposed new Euratom Basic Safety Standards Directive may still change during on-going discussions of the proposal in the European Council Working Party on Atomic Questions (AQQ). These changes may have an impact on contents and structure of the guidance to be prepared by the Working Party.

The Working Party agreed to add a specific chapter to the report covering the new issue of constraints for organ doses. To gain more insight, it was proposed to organise a one day brainstorming meeting with a limited number of additional experts (five to ten) covering various topical areas. No date for this brainstorming had been fixed.

Finally, a literature search on dose constraints and a bibliography on existing publications discussing dose constraints have been finalised and will be annexed to the above mentioned report.

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

8.2. Medical Exposures (WP MED)

a. Progress report

The Chairperson of WP MED reported on the recent activities corresponding to the last two WP MED meetings on 10-11 April and 16-17 October 2012.

Most of the full members of WP MED attended the meetings and the corresponding members received all meeting information. The observers from the IAEA and WHO (for one of the meetings) were present while DG RTD sent apologies. External experts were present where results of recent Commission projects were discussed. The Commission, DG ENER Unit D3, provided Secretariat.

The following summarises the main topics in the WP MED agenda.

- The WPMED received updates by the secretariat on the revision of the BSS, supply of medical radioisotopes, the new EC website on medical applications, etc.
- Two new Commission RP publications on medical topics, RP 172 "Cone Beam CT for Dental and Maxillofacial Radiology" and RP 162 "Radiation Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy" (update of RP 91, 1997) were approved.
- IAEA activities were reported, including the advances in SAFRAD and SAFRON (educational systems to report incidents in interventional procedures and

radiotherapy). WHO activities on medical exposures were presented in the April 2012 meeting. ICRP Committee 3 and HERCA WP on Medical Applications updates were also made.

- The topic on the needs of European research in support of radiation protection in the medical field was considered closed after the discussion at the last Article 31 plenary meeting of November 2011.
- The programme of the EC session, on 5 December 2012, at the Bonn International Conference on RP in Medicine was discussed and agreed. The 90-minute session called "Revision of the Euratom Basic Safety Standards and Beyond" will have 3 short presentations: BSS changes in medical exposures; Accidents in RT; and Asymptomatic individuals, followed by a panel discussion on transposition and implementation.

The following summarizes the status of DG ENER projects on radiation protection in medicine.

- EMAN (European Medical ALARA Network, <http://eman-network.eu>) project has been finalized. The produced 'Synthesis Documents' (on Computed Tomography, Interventional Radiology and Fluoroscopy outside Radiology Departments) will be used in the future work of EMAN as self-sustainable network. The Synthesis Documents' recommendations for further action by the Commission will be discussed at the next WPMED meeting. The contractor presented a plan to ensure the network's sustainability and to involve most of the European radiological societies and other stakeholders.
- MPE (Medical Physics Expert, <http://portal.ucm.es/web/medical-physics-expert-project>) project was finalized. The final documents are: European Guidelines, Proceedings of the Symposium and Results of the European survey. Several corrections were suggested by the WPMED to the Guidelines draft, including considerably shortening the Guidelines. As part of the text is referring to the revised Euratom BSS, it was decided to wait for the final text of the new Directive before submitting the Guidelines for approval of the plenary of the Article 31 GoE.
- MEDRAPET (Implementation of the Medical Exposures Directive's Requirements on Radiation Protection Training, <http://www.medrapet.eu/>) interim report was received and the contractor was invited to present progress. The WPMED made several comments. The project should be finished by the end of 2012.
- Referral criteria (http://www.myesr.org/cms/website.php?id=/en/eu_affairs/) project's interim report and a summary of the workshop were received and the contractor (European Society of Radiology, ESR) was invited to present progress. Several comments and suggestions were made by the members of the WPMED. The project should be finished by March 2013.
- DDM2 (Population doses from medical exposure, <http://ddmed.eu/>) project's final report is due at the end of 2012 and will be discussed at the next WPMED meeting. It is expected that the results of this project will also be used by UNSCEAR. WPMED appointed two reviewers to look in-depth in the project report.
- ACCIRAD (Risk analysis of accidental and unintended exposures in radiotherapy, <http://www.accirad.eu/>) is a 2-year project led by the Greater

Poland Cancer Centre, which is progressing as expected. The project will develop guidelines on risk analysis of accidental and unintended exposures in radiotherapy, to be completed by the end of 2013.

WPMED advised on the following future Commission's work:

- New project on DRLs (Diagnostic Reference Levels) in paediatrics. The technical specifications were discussed and several potential countries interested to contribute were identified. It is expected to publish the call for tenders for this project during the first months of 2013.
- Follow up of the running projects and suggest new ones if appropriate in the future, especially for the transposition and implementation of the new BSS. It is also expected to discuss the conclusions of the IAEA-WHO Conference on Radiation Protection in Medicine to be held in Bonn in December 2012.

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

b. Result of the written procedure on RP162 "Criteria for Acceptability of Medical Radiological Equipment"

The Secretariat reported on the written procedure on RP 162, which took place in June-August 2012. In total twenty-four responses have been received from Article 31 Group members – all experts who responded were in favour of the publication, and some gave comments to the text. The draft publication "Radiation Protection 162: Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy" has therefore been approved with some comments. The document will be finalised and published on the Radiation Protection webpage as soon as possible.

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

a. Result of the written procedure on EU Scientific Seminars from 27 June 2012

The Secretariat informed the Group of Experts about the results of the written procedure on EU Scientific Seminars which had been launched in June. The results can be summarised as follows:

- The Group of Experts approved the draft proceedings of the *EU Scientific Seminar 2011 on Individual radiosensitivity*, as prepared and approved by the WP RIHSS, for publication, as RP 171⁵, in the Radiation Protection Series of the European Commission.
- The Group of Experts approved the draft programme for the *EU Scientific Seminar 2012 on Protection of the Environment*, as prepared by WP RIHSS.
- The Group of Experts agreed to hold the next EU Scientific Seminar 2013 on *Radiation induced long-term health effects after medical exposure*.

b. Proceedings of the EU Scientific Seminars 2010 on Issues with internal emitters

⁵ The publication can be found under http://ec.europa.eu/energy/nuclear/radiation_protection/doc/publication/171.pdf.

The Group of Experts approved the draft proceedings of the *EU Scientific Seminar 2010 on Issues with internal emitters*, as prepared and approved by the WP RIHSS, for publication, as RP 168⁶, in the Radiation Protection Series of the European Commission.

c. EU Scientific Seminar 2012 on Protection of the Environment

At the EU Scientific Seminar 2012 on *Protection of the Environment*, held on 20 November 2012, internationally renowned scientists presented current knowledge on why and how protecting the environment, the ecological impact of ionising radiation, the protection of the environment in planned exposure situations, effects of non-human species in areas affected by a radiation accident, stakes and limits of bioremediation, and ethical and legal aspects of the issue. 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 2012.

All presentations given at the EU Scientific Seminar 2012 on *Protection of the Environment* together with a short introductory text and the programme have been posted on the Europa Website⁷.

The Group of Experts congratulated the WP RIHSS for the organisation of this interesting and though provoking EU Scientific Seminar 2012.

d. Preparations for the EU Scientific Seminar 2013 on Radiation induced long-term health effects after medical exposure

The Chairperson of the WP RIHSS presented a first draft programme for the EU Scientific Seminar 2013 on *Radiation induced long-term health effects after medical exposure*. WP RIHSS will meet in February 2013 to further work on the programme and to identify suitable speakers.

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

9. PUBLIC EXPOSURE OF THE LENS OF THE EYE

At the June 2011 meeting, the Group of Experts recognised that additional information on potential scenarios for public exposure of the lens of the eye and on radiation effects for different age groups is needed. In particular, potential situations where planned exposure situations can lead to exposures exceeding 1 mSv/year for the lens of the eye should be explored.

An expert informed the Group that the findings of a literature review on potential scenarios for public exposure of the lens of the eye and the respective dose estimations based on these scenarios are now published in the report *IRSN bibliographic study: Risk of radiation exposure of the lens of the eye for members of the public*.

⁶ The publication can be found under http://ec.europa.eu/energy/nuclear/radiation_protection/doc/publication/168.pdf.

⁷ The presentations can be found under http://ec.europa.eu/energy/nuclear/radiation_protection/seminars/scientific_seminar_en.htm

The Chair of WP RIHSS presented a review of publications on radiation induced cataracts and age at exposure, which is given in Annex 1.

10. EUROPEAN NETWORK FOR EDUCATION AND TRAINING IN RADIATION PROTECTION – ENETRAP II

An expert who was nominated by the Article 31 Group of Experts to participate in the ENETRAP II Advisory Board presented feed-back from the advisory board meeting held in February 2012. The main goals of ENETRAP II are:

- define requirements for national and mutual recognition of RPEs within EU Member States; develop a mechanism for the mutual recognition of RPEs between Member States;
- develop an appropriate European Radiation Protection Training Scheme (ERPTS) for both initial and refresher training of RPEs, taking into account the nature and requirements of the RPE role;
- define requirements for the competencies of RPOs according to their area of work and specific radiation protection tasks, and establish European reference standards for RPO training;

The Advisory Board emphasised the importance of involvement of the regulator in this work which could possibly be achieved through HERCA. For a potential involvement in the future project ENETRAP III, input from the Article 31 Group of Experts would be welcomed.

The Group of Experts thanked the expert for this input and asked to be kept informed about progress with ENETRAP II.

11. RADIOLOGICAL PROTECTION AGAINST RADON EXPOSURE

The representative of ICRP presented the status of preparation of the draft *ICRP Report on Radiological protection against radon exposure* which had been published on the web for public consultation. The report aims at describing and clarifying the application of ICRP 103 and ICRP 101 (Optimisation) while remaining in line with ICRP 65. It shall also take into account the *Statement on radon and future ICRP 115* which suggests that the nominal risk is approximately twice the value previously assumed.

An expert of the Article 31 Group of Experts presented an analysis of the ICRP draft report and its potential impact on the proposed draft Euratom Basic Safety Standards Directive.

The Group of Experts thanked both experts for their interesting and thought provoking presentations.

12. OTHER BUSINESS

No other business was raised.

13. DATES OF THE NEXT MEETINGS

The next meeting of the Group of Experts will be held on **19 – 20 November 2013**, in meeting room M6, **European Commission – Jean Monnet Building, rue Alcide de Gasperi – L-2920 Luxembourg – Kirchberg.**

ANNEX 1:

Radiation induced cataracts and age at exposure: Review of publications

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

During the EU Scientific Seminar 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. Kleiman concluded that the evidence to date pointed to a dose threshold no greater than 700 mGy, which challenged the ICRP guidelines, based at this time 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), with corresponding figures for single acute exposures of 0.5-2 and 5 Sv. The dose limit for the lens of the eye for members of the public was based on “an arbitrary reduction factor of 10” (ICRP 60, p 46, 194). Moreover, Kleiman reported new observations that are 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 should be considered to be the salient injury, rather than cell killing. For this reason, the classification of cataracts as a deterministic effect was called into question.

Since the 2006 EU Seminar, a lot of new evidence confirming Kleiman’s conclusions has been published and reviewed (among others by the WP RIHSS). Based on the work of its Task Group on early and late non-cancer effects of radiation in normal tissues and organs, ICRP finally issued a Statement on tissue reactions on 21 April 2011. According to this Statement, “the threshold in absorbed dose for the lens of the eye is now considered to be 0.5 Gy” and, “for occupational exposure in planned exposure situations, the Commission now recommends an equivalent dose limit for the lens of the eye of 20 mSv in a year, averaged over defined periods of 5 years, with no single year exceeding 50 mSv”.

In the current EC proposal for new BSS, based on the above-mentioned ICRP statement, the dose limit for the lens of the eye is lowered for exposed workers (20 mSv/y).

Regarding dose limits for the lens of the eye for members of the public (including infants and children), ICRP did not propose anything explicitly in its statement but, from oral explanations of the ICRP secretary and of ICRP members, it appears that no change was considered necessary.

This issue was discussed during a meeting of the Article 31 Group of Experts and the WP RIHSS was asked to review the literature data concerning specifically the possible role of the age at exposure on the risk of radiation-induced cataracts. With this in view, Serena Risica gathered together all the possibly relevant publications. Based on this and on the data found in other recent reviews, the WP RIHSS tried to summarize in this document the published information specifically in relation with the risks of radiation-induced lens defects after exposure at young age. While not highlighting particularly the age at exposure effect, the ICRP draft report on “Early and late effects of radiation in normal tissues and organs: threshold doses for tissue reactions and other non-cancer effects of radiation in a radiation protection context”, contains a comprehensive compilation and a

discussion of most of the relevant publications and will then be used as one of the basic sources in this document. Work currently in progress in UNSCEAR on “Effects of radiation exposure on children” has also be taken into account.

Regarding chronic irradiation, minor posterior subcapsular opacities were reported after only a few years follow up in children in the Chernobyl area with an excess among those in the exposed areas compared with the unexposed area (Day et al., 1995). There was a small but statistically significant increase in the incidence of sub-clinical posterior subcapsular lens changes (3.6%), greatest among males 12-17 years old at the time of examination, in ~1,000 exposed children, compared to a matched population of ~800 unexposed subjects. *Estimates of cumulative dose ranged from 29-86 mSv.*” The ICRP draft report noted, however, that dose estimates contain large inherent uncertainties; for example, individual dose estimates were not determined but instead based on recorded environmental exposure levels. The authors also noted that the ophthalmologists were not blinded as to the identity of the exposed and unexposed subjects as exposed children were mainly defined by the environmentally contaminated villages where they currently lived. To minimise potential observer bias, the study included examination by two independent ophthalmologists. The authors also noted that population migration after the disaster may have affected the results in unknown ways as the exposed population was selected from those who resided in formerly contaminated areas at the time of the ophthalmic examinations and thus did not represent a random sampling of all children exposed at the time of the accident. On the other hand, the ICRP draft underlined that *the presence of posterior subcapsular defects of a type consistent and characteristic of ionising radiation exposure and not normally found in a paediatric population is suggestive of cause and effect.* If additional support for continued ophthalmological examinations and better dose reconstruction in this cohort is forthcoming, a well-designed epidemiological study has the potential to provide additional statistical support for these findings.

There were some (often not translated and not referenced in Pubmed) publications from Russian, Ukrainian or Byelorussian authors related to cataracts in children (for ex. Arinchin, 1998, or Shubik VM and Kvasova MD, 1996), with sometimes unusual information, as the detection of antibodies against antigens of the lens in persons living in areas contaminated after the Chernobyl accident.

A study of a paediatric population accidentally exposed while living in ⁶⁰Co-contaminated apartment was conducted in Taiwan. It allowed evaluating quantitatively the lenticular changes in a young population exposed to chronic low-dose-rate gamma radiation (Chen et al., 2001). A total of 114 exposed individuals participated in a thorough ophthalmological examination in 1998. The lenticular opacities were evaluated by slit-lamp biomicroscopy after full pupil dilatation and were scored by the Lens Opacities Classification System III (LOCS

III) and a modified subclinical minor lenticular focal defects system. These individuals were further divided into those less than 20 years old, those between 20 and 40 years old, and those more than 40 years old to evaluate the effects of age. *Mean cumulative exposure of 170 mGy* was noted in this population although doses ranged from 1-1,200 mGy. *A significant dose-dependent increase in the numbers of focal lens defects in those less than 20 years old was demonstrated,* while less significant changes were observed in the other two age groups or by the LOCS III scoring. Results suggested that chronic low-dose-rate irradiation might induce minor lenticular changes, *especially in lenses of young subjects.*

A recent follow-up of some of these children after a second ophthalmology examination, all still less than 23 years old, indicated that radiation induced lens changes, measured as sub-clinical focal lens defects (FLD), continued to increase in size and number years after relocation from the contaminated site (Hsieh et al., 2010). The progressive nature of such changes five years later, in a paediatric population now removed from the contaminated environment, demonstrates that such radiation induced lens changes may persist and progress with time.

The radiation-induction of lens opacities was evident in adults who were treated as infants (<18 months old) with external X-ray or radium therapy to treat haemangiomas of the head, face or neck (Hall et al., 1999), when compared with a control population of 89 unexposed, age-matched individuals who presented with skin haemangiomas as infants but were not treated with ionising radiation. The LOCS II lens opacification classification criteria was used and lens dose was estimated based on patient treatment records and photographs, type of radiotherapy (flat applicators, type and number of externally placed tubes or needles or X-ray treatments) and experimental lens absorbed dose calculations using a phantom. These individuals were treated between 35 and 54 years earlier and exposed subjects received an average of two treatments with a cumulative mean dose of 0.4 Gy (median 0.2 Gy, maximum 8.4 Gy). Lens opacities of any type were found in 37% of exposed subjects compared to 20% of controls. A dose response relationship was noted, regardless of age at exposure.

Another study of 20 persons 30-45 years after being treated for skin haemangioma in infancy noted pre-cataractous subcapsular lens changes in the eyes on the untreated side of the face, *where lens doses were estimated to average 0.1 Gy* (Wilde and Sjostrand, 1997). Although the number of cases is limited, this study suggests a very low dose threshold for radiation-induction of cataracts in young children (median age 6 months).

First evidence on an age at exposure effect in Japanese survivors came from the studies of Choshi (Choshi et al, 1983) and Otake (Otake et al, 1992). Later, the study of Minamoto [Minamoto et al, 2004] on 913 individuals, including mostly persons who were younger than 13 years at the time of the bombings, showed a significant increase in cortical and posterior subcapsular cataracts. Nakashima (Nakashima et al, 2006) tested the fitness of the threshold model and the age at exposure effect in a reanalysis of practically the same data as in Minamoto's study. The results suggested that, in 730 atomic-bomb survivors, we cannot conclude there is a threshold for cortical cataract and posterior sub-capsular opacity (lower 90% CI <0.0). Threshold dose point estimates were 0.6 Sv (90% CI, <0.0-1.2 Sv) and 0.7 Sv (90% CI, <0.0-2.8 Sv) for cortical cataract and posterior sub-capsular opacity, respectively. In addition, there was a clear increase in the dose-effect odds ratio for posterior subcapsular opacity with decreasing age at exposure ($p < 0.001$). The OR/Sv was 1.44 at age of exposure of 10 y (95% CI, 1.19-1.73), and *this dose effect decreased significantly with increasing age at exposure and could no longer be demonstrated at an exposure age of 30 years*.

Further data on the incidence of *cataract extractions* in the A-bomb AHS cohort have also indicated an age-at-exposure effect ($p = 0.006$) [Neriishi et al, 2012]. A total of 1,028 persons out of the cohort of 6,066 had a first cataract extraction during 1986–2005. An analysis adjusted for city, gender, diabetes and time since exposure showed that fifty years after exposure, the relative risks at 1 Sv were 1.61, 1.32 and 1.15 for those exposed at ages 10, 20 and 30 years, respectively.

A recent publication of IRSN (Michel et al, 2011) aims to estimate the eye lens doses of a pediatric population exposed to repeated head CTs. Children treated for a cholesteatoma, who had had at least one CT-scan of the middle ear before their tenth birthday, were included. At the time of the study (mean age: 16 years), the mean number of CT per child was 3. Cumulative mean effective and eye lens doses were 1.7mSv and 168mGy, respectively. This study is worth mentioning as it illustrates that medical exposures of children can easily exceed threshold doses observed in the above mentioned studies.

Paragraph 697 of the ICRP report on “Early and late effects of radiation in normal tissues and organs: threshold doses for tissue reactions in a radiation protection context” (ICRP publication 118, 2012), concludes that “Overall, the general consistency of the collective results for both early lens opacities and advanced cataracts makes a compelling “weight of evidence” judgment that the recommended acute dose threshold for the purposes of radiation protection should be lowered from its current value to a nominal value of 0.5 Sv” but that “this is subject to the caveats that the progressive nature of assessed opacities into cataracts, and the *likely greater sensitivity of the lens in children compared to post-adolescents*, require further characterization”.

Paragraph 698 states that “For fractionated and protracted exposures, the current epidemiological evidence indicates that the threshold is not larger than for acute exposures, although animal data suggest that a higher value might be plausible. For chronic exposure over several to many years, much of the evidence refers to opacities rather than frank cataracts. The uncertainties about progression of opacities into cataracts, and *the age at exposure problem mentioned above, make difficult any judgment about dose thresholds for chronic exposures*”.

Interesting in this respect is this judgment coming from the recent ICRP publication 118: “Most tissues show a sparing effect of dose fractionation, so that total doses for a given endpoint are higher if the dose is fractionated rather than when given as a single dose. However, for reactions manifesting very late after low total doses, particularly for cataracts and circulatory disease, it appears that the rate of dose delivery does not modify the low incidence. *This implies that the injury in these cases and at these low dose levels is caused by single-hit irreparable-type events*”.

In a recent publication, Thorne MC concluded that the accumulating radiobiological and epidemiological evidence makes it more appropriate to treat cataract induction as a stochastic rather than a deterministic effect (Thorne, 2012).

In 2009, the German Commission on Radiological Protection (SSK) also reviewed the available data and adopted new recommendations regarding radiation-induced cataracts. 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. *According to SSK, the effects of early childhood exposure to radiation merit particular attention.*

According to Shore (Shore et al, 2010), a question of importance for radiation protection purposes is the degree to which the risk of radiation associated opacities is modified by age at exposure.

“Several different studies reported that exposure at an early age confers more risk per unit dose than exposure at a later age, although some human data have not provided support for this.”

For Ainsbury too (Ainsbury 2009), the importance of age at exposure is evident in a number of the studies, and in particular for posterior subcapsular opacities.

Globally, while it is clear that the number of data related to the risk of radiation-induction of cataracts after exposure of children is currently limited, there is growing evidence of an increased risk compared with this related to adult exposures and of low threshold values. The current evidence seems sufficient to be cautious with exposures of children’s eyes, as well in the medical field (the cumulative eye lens dose of 3 CT for a child can approach 200 mGy) as in accidental and post-accidental situations. In normal situations, while a recent study of IRSN has shown that sources of eye exposure are currently practically inexistent for children and members of the public, it would be wise to limit eye exposures to a significantly lower level than the level tolerated for exposed workers, for reasons of consistency and taking into account possible future sources within consumer products.

References

1. EC, *New Insights in Radiation Risk and Basic Safety Standards*, Proceedings of the EU Scientific Seminar 2006, Radiation Protection 145, Luxembourg, 2007.
2. EC, *Recent scientific findings and publications on the health effects of Chernobyl*, Radiation Protection 170, Luxembourg, 2011.
3. Day, R., Gorin, M.B., Eller, A.W., 1995. Prevalence of lens changes in Ukrainian children residing around Chernobyl. *Health Phys.* 68, 632-642.
4. Arinchin, A.N. and Ospennikova, L.A. Lens opacities in children of Belarus affected by the Chernobyl accident (KURRI-KR--21). Imanaka, T. (Ed.). Japan (<http://www.rri.kyoto-u.ac.jp/NSRG/reports/kr21/kr21pdf/Arinchin.pdf>)
5. Shubik VM, Kvasova MD. Immunological studies on cataracts under conditions of exposure to low-dose radiation. *Vestn Oftalmol.* 1996 Sep-Oct;112(4):21-3 (1996) [Article in Russian]
6. Chen, W.L., Hwang, J.S., Hu, T.H. et al., 2001. Lenticular opacities in populations exposed to chronic low-dose-rate gamma radiation from radiocontaminated buildings in Taiwan. *Radiat. Res.* 156, 71-77.
7. Hsieh, W.A., Lin, I.F., Chang, W.P., et al., 2010. Lens opacities in young individuals long after exposure to protracted low-dose-rate gamma radiation in 60Co- contaminated buildings in Taiwan. *Radiat. Res.* 173, 197-204.
8. Hall, P., Granath, F., Lundell, M., et al., 1999. Lenticular opacities in individuals exposed 7237 to ionizing radiation in infancy. *Radiat. Res.* 152, 190-195
9. SSK, *Radiation-induced cataracts, Recommendations of the Commission on Radiological Protection with scientific reasoning*, SSK, Bonn, 2009
10. Wilde, G. and Sjostrand, J., 1997. A clinical study of radiation cataract formation in adult life following gamma irradiation of the lens in early childhood. *Br. J. Ophthalmol.* 81, 261-266.
11. Choshi, K., Takaku H., Mishima et al. 1983. Ophthalmologic changes related to radiation exposure and age in the adult health study sample, Hiroshima and Nagasaki. *Radiat. Res.*, 96(3), 560-579
12. Otake M, Finch SC, Choshi K. et al, 1992. Radiation-related ophthalmological changes and aging among Hiroshima and Nagasaki A-bomb survivors: a reanalysis. *Radiat Res.* 131 (3): 315-24.
13. Nakashima, E., Neriishi, K., Minamoto, A., 2006. A reanalysis of atomic-bomb cataract data, 2000-2002: a threshold analysis. *Health Phys.* 90, 154-160.
14. Neriishi K, Nakashima E, Akahoshi M, Hida A, Grant EJ, Masunari N, Funamoto S, Minamoto A, Fujiwara S, Shore RE., 2012. Radiation dose and cataract surgery incidence in atomic bomb survivors, 1986-2005. *Radiology* 265(1):167-74. Epub 2012 Aug 8.
15. Ainsbury EA, Bouffler SD, Dörr W, Graw J, Muirhead CR, Edwards AA, Cooper J, 2009. Radiation cataractogenesis: a review of recent studies. *Radiat. Res.* 172, 1-9.

16. Shore, R. E., Neriishi, J. and Nakashima, E. 2010. Epidemiological Studies of Cataract Risk at Low to Moderate Radiation Doses:(Not) Seeing is Believing. *Radiat. Res.* 174, 889–894.
17. Michel M, Jacob S, Roger G, Pelosse B, Laurier D, Le Pointe HD, Bernier MO. 2012. Eye lens radiation exposure and repeated head CT scans: A problem to keep in mind. *Eur J Radiol.* 81 (8): 1896-1900
18. Thorne MC, 2012. Regulating exposure of the lens of the eye to ionising radiations. *J. Radiol. Prot.* 32, 147–154
19. ICRP, 2012 ICRP Statement on Tissue Reactions / Early and Late Effects of Radiation in Normal Tissues and Organs – Threshold Doses for Tissue Reactions in a Radiation Protection Context. ICRP Publication 118. *Ann. ICRP* 41(1/2)