



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

**Luxembourg, 12 – 13 June 2018**

### **SUMMARY REPORT**

(Approved by the Group of Experts at the meeting 14 – 15 November 2018)

#### **INTRODUCTION**

The Head of Unit *Radiation Protection and Nuclear Safety* opened the meeting and welcomed the Group of Experts.

The Secretariat informed the experts on a change in membership of the Group – two former experts have retired and two new experts have been nominated – and on presence and apologies for this meeting.

#### **1. APPROVAL OF THE AGENDA**

The agenda was adopted with a slight rearrangement of the items to account for the availability of individual presenters and with additional issues under Item 10 Emerging issues: Presentation of “National Monitoring Strategy in Radiological Emergencies in Finland - Progress report” and under Item 13 Other business: Discussion on radon dose coefficients.

#### **2. APPROVAL OF THE SUMMARY REPORT OF THE MEETING HELD ON 8 – 9 NOVEMBER 2017**

The Summary Report of the meeting held on 8 – 9 November 2017 has been approved without amendments and is published on the Europa website<sup>1</sup>.

#### **3. INFORMATION BY THE COMMISSION**

The Head of Unit *Radiation Protection and Nuclear Safety* informed the group about the key priorities for the Commission's work and about the proposed new EU budgetary framework for the coming years – the “Multiannual Financial Framework MFF” 2021-2027 which covers in particular in the area of decommissioning, ITER, and the Euratom Research Programme. Further to this, he highlighted the discussions in this meeting on the SAMIRA initiative, which will be presented under agenda item 4, the extension of the post-Chernobyl legislation to be

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<sup>1</sup> The approved Summary Report of the November 2017 meeting can be found under <http://ec.europa.eu/energy/node/1183>

discussed under agenda item 5, the work of the standing working parties, and the first draft work plan for the Group to be examined under agenda item 11.

#### **4. STRATEGIC AGENDA FOR MEDICAL, INDUSTRIAL AND RESEARCH APPLICATIONS OF NUCLEAR AND RADIATION TECHNOLOGY (SAMIRA)**

The Commission reported on the Strategic Agenda for Medical, Industrial and Research Applications of nuclear and radiation technology (SAMIRA). The SAMIRA initiative is intended to cover a broad range of safety and sustainability issues in the field of non-power applications with the aim to identify areas where EU action is needed.

As part of the preparatory work of SAMIRA, the Commission hosted a conference on “Addressing Societal Challenges through Advancing the Medical, Industrial and Research Applications of Nuclear and Radiation Technology” on 20-21 March 2018 in Brussels. The conference was opened by Climate Action and Energy Commissioner Miguel Arias Cañete and Health and Food Safety Commissioner Vytenis Andriukaitis, alongside other senior speakers including Mr Yukiya Amano, the International Atomic Energy Agency's (IAEA) Director General, and Dr Maria Neira from the World Health Organisation (WHO). It was attended by more than 120 participants from Member States and representative European networks, including regulators, industry, researchers, medical users, civil society and patients. More than 600 web-streaming visits were registered through the conference webpage.

The conference facilitated an in-depth discussion on a number of topics ranging from security of supply of medical radioisotopes to waste management, safety and innovation of non-power applications. The secretariat presented the main conclusions with regard to nuclear medicine and quality and safety of medical applications, which will inform the future Commission actions in these areas. Full video record of the meeting, collection of speeches and presentations and meeting summary report are available from the conference webpage: [https://ec.europa.eu/info/events/addressing-societal-challenges-through-advancing-medical-industrial-and-research-applications-nuclear-and-radiation-technology-2018-mar-20\\_en](https://ec.europa.eu/info/events/addressing-societal-challenges-through-advancing-medical-industrial-and-research-applications-nuclear-and-radiation-technology-2018-mar-20_en).

Following the conference and delivery of the EC funded SAMIRA study in July 2018, DG ENER is working with other services towards an action plan which will set out activities in the areas of security of supply, safety and innovation. This action plan is intended to provide the basis for coordinated action by the Commission, Member States, authorities and other relevant actors in the next five to ten years. The Article 31 Group of Experts' input will be sought on specific actions, wherever the need arises. It has therefore been decided to maintain SAMIRA as an agenda point in future meetings.

#### **5. FOOD AND FEED – EXTENSION OF THE POST-CHERNOBYL LEGISLATION**

##### *a. Information from the International Atomic Energy Agency*

The representative of the IAEA reported on a recent IAEA initiative with regard to radionuclides in food and drinking water, current situation and way forward.

##### *b. Extension of the Post-Chernobyl legislation*

The Commission informed the Article 31 Group of Experts about the expiry date of the Post-Chernobyl legislation (Council Regulation 733/2008 amended by Council Regulation 1048/2009) in March 2020.

The Post-Chernobyl regulations – Council Regulation 733/2008<sup>2</sup> amended by Council Regulation 1048/2009<sup>3</sup> – provide the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station. The regulations lay down maximum permitted levels of radioactivity in agricultural products intended for human consumption. The accumulated maximum radioactive level in terms of <sup>134</sup>Cs and <sup>137</sup>Cs are 370 Bq/kg for milk, milk products and infant foodstuffs and 600 Bq/kg for all other products. Member States need to check compliance of any food product originating in third countries affected by the Chernobyl accident with the maximum permitted levels before the product is released for free circulation. The checking may also include the presentation of export certificates.

Certain products originating in third countries affected by the Chernobyl accident still show radioactive caesium contaminations exceeding the above-mentioned maximum permitted levels. A study by the German GRS, dated January 2008 and launched in the context of the latest extension until March 2020, analysed the situation in 2008 and concluded that a further extension of the measures for another period of ten years or more at least for wild products (mushrooms, berries, game, etc.) could be justified.

The Post-Chernobyl regulations currently in force will expire on 31 March 2020.

The Group of Experts was asked to discuss specific questions on the need to further control agricultural products originating in third countries affected by the Chernobyl accident, the need for a legally binding instrument beyond 31 March 2020, the need to review the list of food products, and the validity of the current maximum permitted levels. The main objective of the discussion was to arrive at an Article 31 Group of Expert's Opinion on this matter, which would allow the Commission to develop the issue further.

The Group unanimously advised the Commission to extend the Post-Chernobyl legislation.

It was agreed to create an ad-hoc working party which will prepare a draft Opinion of the Group for discussion and eventual adoption at the November 2018 meeting.

## **6. ACTIVITIES RELATED TO THE TRANSPOSITION AND IMPLEMENTATION OF RECENT DIRECTIVES (BASIC SAFETY STANDARDS, NUCLEAR SAFETY, DRINKING WATER)**

The Commission presented a brief overview of the European Commission activities related to the transposition and implementation of recent Directives, notably the Basic Safety Standards Directive, the Nuclear Safety Directive and the Drinking Water Directive. As these Directives are at different stages of transposition and implementation, activities and priorities with regard to transposition and implementation differ. Two projects are currently

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<sup>2</sup> Council Regulation (EC) No 733/2008 of 15 July 2008 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station (codified version), Official of the European Union, L 201, 30.07.2008, p. 1 – 7.

<sup>3</sup> Council Regulation (EC) No 1048/2009 of 23 October 2009 amending Regulation (EC) No 733/2008 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station, Official of the European Union, L 290, 6.11.2009, p. 4–4

in place to support the Commission with the completeness and compliance checks for the Drinking Water Directive and the amended Nuclear Safety Directive. After the transposition deadline of the Basic Safety Standards Directive has passed in February 2018, the Commission is currently preparing another project to check compliance of Member States transposition measures with the Basic Safety Standards Directive. Some legal proceedings on non-transposition have been launched.

The Commission will keep the Article 31 Group of Experts informed about further developments.

## **7. EMERGENCY PREPAREDNESS AND RESPONSE**

The Commission presented an overview of recent activities and initiatives at the EU-level in the policy area of emergency preparedness and response (EP&R). These included: the post-Fukushima stress tests covering on-site emergency response; the ENCO review of off-site emergency preparedness in European countries; the adoption of Directive 2013/59/Euratom (BSS Directive) and Directive 2014/87/Euratom (amendment to the Nuclear Safety Directive); Council Conclusions on off-site EP&R; various workshops, studies and meetings organised by the Commission with MS's authorities to promote coherent transposition and implementation of the new Directives; research projects under the Euratom Horizon 2020 programme; seminars and workshops involving civil society and NGO groups; and the start of the legal conformity checks of national transposition measures of the BSS and NSD Directives. The initiatives by nuclear safety regulatory authorities and expert groups (HERCA-WENRA Approach) was mentioned, as well as the interest of various institutions and stakeholders (European Parliament, NGO's and civil society groups) in further activities in this area.

The presentation highlighted the Commission's principal objective which is to seek effective and coherent implementation of the legislative requirements, in particular those strengthened provisions in the BSS and NS Directives. The Commission is seeking the views of the Article 31 Group of Experts on future activities to support this policy area.

Possible areas of future initiatives include further activities to facilitate the coherent implementation of the BSS requirements, taking account of expert group approaches, input to the development of international guidance and standards taking account of European specificities, and development of EU level guidance to promote more harmonised approaches.

In the discussion that followed, it was highlighted that lack of a fully harmonised approach amongst neighbouring countries remains a very important issue, and that an Article 31 Working Party on harmonised approaches has previously existed to tackle this issue. The use of different criteria in neighbouring countries e.g. for administering ITB could have very negative consequences, given the need to maintain credibility amongst the public. There is a need for harmonised action levels following an emergency, but full harmonisation may not be realistic.

The benefits of an all-hazards approach and the importance of involving civil protection authorities in the definition of protective measures was mentioned, as ultimately these authorities will be responsible for their practical implementation. It is also a challenge to train and inform officials who would be responsible for decision-making them on the specificities of nuclear and radiological emergencies.

The HERCA-WENRA Approach aims to achieve greater coherence without necessarily harmonising reference levels for exposure in emergency situations or generic criteria for protective actions. Currently, the achievement of coherent response is based on bilateral or multilateral cooperation agreements between countries. It should also be emphasised that the goal should be promoting harmonisation not specifically at EU level but at the regional level. It was mentioned that reference levels should be adaptable according to the developing situation.

Another issue concerns the increased needs for resource sharing. This was a recommendation of the ENCO report. Indeed some countries favour exclusively the existing but little used IAEA RANET system, whereas there is a possibility of taking advantage of the wider experience in overall disaster response in the EU through the CPM mechanism managed by DG ECHO, where the Emergency Response and Coordination Centre (ERCC) acts as the single point of contact. Identifying capabilities/modules (especially those which are expensive and rarely used) could be included within ERCC's 'European Pool of Assets' with a view to making more effective use of limited resources.

A real accident could involve large releases and last a long time. Further attention and research is needed on the impacts of long-term contamination and possible effects following radiological releases. Both in the accident and transition phases the real priority for protection are fetuses/pregnant women. In cross-border situations, the harmonisation of reference levels alone does not address the challenges of responding to contaminated areas and contaminated produce. The matter is more complicated as it involves both objective and ethical criteria. There is a need to better engage the experts and the public. There will be EU Scientific seminar in November 2018 on the management of long-term exposure after a nuclear or radiological accident which will examine topics in relation to these issues.

Public perception of EPR arrangements and the needs of civil society in response to an emergency are important too. The value of stakeholder involvement in emergency planning is recognised, although there has been only a small engagement with the public so far. As part of their preparation efforts, the French authorities are preparing answers to 200 anticipated questions from the public. The medical community is also being involved in formulating answers.

In conclusion, the Commission thanked the working group for their very encouraging comments and indicated that this first discussion of ideas could be continued in a more dedicated session. One possibility is to consider the initiation of a specific Working Party on EP&R, as has been considered in the paper on strategic and work programme aspects of the Article 31 Group of Experts (meeting of October 2015). This point will be further discussed under point 11 on "Discussion and preparation of a road-map for issues to be discussed by the GoE in coming years".

## **8. SECURITY OF SOURCES**

EU requirements for safety and security of high-activity sealed sources were laid out in the High-Activity Sealed Sources Directive 2002/122/Euratom in 2003. The provisions of this Directive were transferred with only minor modifications to the new Basic Safety Standards Directive Articles 85-95 in 2013. The Secretariat presented the Commission past activity to review the implementation of the High-Activity Sealed Sources Directive. They outlined the results of the 2013 implementation review and informed that the Commission plans to

initiate a new study in 2020 to review implementation of the past recommendations and the status of implementation of Articles 85-95 of the Basic Safety Standards. The project should provide guidelines for safe and secure management of radioactive sources in the EU. The results will be presented in a workshop at the end of the project.

## **9. REVIEW AND PRIORITISATION OF THE ACTIVITIES OF THE WORKING PARTIES AND RELATED PROJECTS**

### *9.1 Natural Radiation Sources (WP NAT)*

The Chair of the Working Party on exposure to natural sources of ionising radiations (WP NAT) reported on progress made since the last Group of Experts' meeting. The WP NAT held its third meeting 6 – 7 March 2018 to further elaborate the material on Radon in workplaces.

The next meetings of the WP NAT are scheduled for 14 June 2018 and for 3 – 4 October 2018.

Further to this, the Working Party presented a first draft of the report on **“Radon in workplaces”**. The Article 31 Group of Experts congratulated the working party for the progress made and discussed the draft report. The Article 31 Group of Experts provided some preliminary comments and agreed to send written comments by **31 August 2018**.

### *9.2. Medical Exposures (WP MED)*

Report on the Working Party on Medical Exposures (WP MED) was given by its vice-chair. The WP MED chair sent apologies.

WP MED last met on 11 June in Luxembourg. The meeting was attended by only three of the current ten members and one observer (IAEA). Due to the low attendance, the election of a new chair was postponed.

WP MED assisted with the preparation of the Euratom session in the international conference on radiation protection in medicine, organized by the IAEA on 11-15 December 2017 in Vienna. The session was chaired by a member of WP MED and consisted of talks by the Commission and HERCA and a panel with industrial, professional and scientific stakeholders. The talks and the panel interventions emphasized the high standards of protection of patients achieved in Europe due to the existence of up-to-date Euratom legal framework in this area. The importance of the Commission action to support the implementation of requirements in practice, which should continue to involve all key stakeholders, was highlighted. The panel concluded that further progress should be achieved in integrating radiation protection into a broader quality and safety context in medicine as well as into the basic medical education curriculum and everyday clinical practice.

WP MED discussed the development of the Commission project on European Study on Clinical DRLs (EUCLID). The 1st interim report, including an overview of DRLs in Member States, dose survey methodology and list of clinical indications to be covered, was approved in April. This was based, among others, on review and comments received by members of WP MED. The main outstanding issues relate to the roles and interactions of the two panels advising the contractor, the representativeness of the survey with respect to the average clinical practice (only “Eurosafely Imaging stars” hospitals with high standards of patient protection included) and the exclusion of cardiac procedures from the study. The Commission will follow up with the contractor on these issues and invite them to report to

the next meeting of the WP MED. It is also planned to invite the European Society of Cardiology to the next WP MED meeting.

WP MED considered the need to organize a focus session on Nuclear Medicine in order to discuss issues raised by the European Association of Nuclear Medicine (EANM) with respect to dosimetry in radionuclide therapy. It was agreed to organize such session in the next meeting of WP MED and invite EANM, HERCA and IAEA to it.

The European Federation of Organisations of Medical Physics (EFOMP) has recently issued a policy statement on the roles and competences of medical physicists and medical physics experts (MPEs) under the BSS Directive 2013/59/EURATOM. The statement summarises the relevant provisions of the BSS Directive and the implementation guidance issued with the Commission support in 2014 (publication Radiation Protection 174) and calls to the member societies of EFOMP to take action nationally. WP MED recognizes that, in some Member States, availability and qualification issues with regard to MPEs persist. This is likely to cause problems with the implementation of the BSS Directive's strengthened requirements for involvement of MPEs in computed tomography and interventional radiology.

A member of the WP MED presented the results of an ESR survey on implementation of article 63 of the BSS Directive concerning "accidental and unintended exposures". 17 EU member states provided feedback; 10 reported an implementation of article 63 into their national regulations; 8 reported a definition of "exposure significant different than intended"; 14 had to report significant events to the national authorities; 7 use physical dose parameters (DAP, CDTivol, DLP, AGD, ESAK) for diagnostic procedures; 9 use physical dose parameters (DAP, ESAK) for interventional procedures; the rest use effective dose or text-based parameters. The ESR considers issuing a 'white paper' reporting on these results and possibly recommending the use of physical dose parameters as a way to address heterogeneous implementation of the BSS Directive at national level.

Presentations were given on the relevant activities of the IAEA and ICRP.

WP MED reviewed and confirmed the rolling list of proposed studies in the medical area, to be considered by the Commission under the 2019 budget.

The vice-chair of WP MED issued a call to the Group of Experts to consider inscribing as members of WP MED and also provide the names of experts in nuclear medicine and radiotherapy that may be invited for specific points of the agenda. The secretariat will follow this up after the meeting.

The next meeting of WP MED will be held on 13 November (the day before the next Article 31 plenary) in Luxembourg. The main point of the agenda will cover the election of a new chair and sessions on nuclear medicine and DRLs (including cardiology). Initiations will be issued to experts in nuclear medicine and cardiology, as required.

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

#### *a. EU Scientific Seminar May 2017 on Emerging Issues with regard to Organ Doses*

The Working Party presented the draft proceedings of the *EU Scientific Seminar on Emerging Issues with regard to Organ Doses* which took place on 17 May 2017.

The Group of Experts discussed the presented draft proceedings and approved it for publication in the Radiation Protection series of the European Commission.

*b. EU Scientific Seminar November 2017 on Epigenetic effects – potential impact on radiation protection*

The Working Party reported on progress with the preparation of the proceedings of the EU Scientific Seminar November 2017 on *Epigenetic effects – potential impact on radiation protection* took place in the afternoon of 8 November 2017. Currently, there are two contributions missing. It is planned that the draft proceedings shall be ready for discussion and approval at the November 2018 meeting of the Article 31 Group of Experts.

*c. EU Scientific Seminar 2018 on Management of long-term exposure after a nuclear or radiological accident*

The Working Party presented the draft programme of the EU Scientific Seminar 2018 on *Management of long-term exposure after a nuclear or radiological accident* to be held 14 November 2018.

The Group of Experts discussed, provided input, and approved the draft programme.

*d. Topics for upcoming EU Scientific Seminar*

The Working Party will prepare a list of topics for discussion at the next meeting of the Group of Experts.

## **10. EMERGING ISSUES IN MEMBER STATES WITH POTENTIAL IMPLICATIONS ON A EUROPEAN**

Individual members of the Article 31 Group of Experts offered the following presentations:

- An expert from Denmark presented the “Release of Cl-36 gas from reactor graphite due to plasma cutting”
- An expert from Finland presented “National Monitoring Strategy in Radiological Emergencies in Finland - Progress report”.

Each of the presentations triggered discussions and stimulated an exchange of experience. The Group of Experts thanked the experts for their interesting presentations.

The Group of Experts welcomed the contributions to this section on the agenda of the Group and encouraged other members to embark on this initiative.

## **11. DISCUSSION AND PREPARATION OF A “ROAD MAP” FOR ISSUES TO BE DISCUSSED BY THE GROUP OF EXPERTS IN THE COMING YEARS**

The Commission presented a first draft “road map” to outline the anticipated work programme of the Article 31 Group of Experts for the coming years. The Group of Experts welcomed this initiative and agreed to send written comments by **31 August 2018**. It was further agreed to regularly discuss and update the “road map”.

## **12. ISSUES OF INTEREST FROM INTERNATIONAL ORGANISATIONS**

### *12.1. International Commission on Radiological Protection (ICRP)*

No representative of the ICRP could attend the meeting. More information on ICRP can be found on the ICRP homepage <http://www.icrp.org/>.

### *12.2 International Atomic Energy Agency (IAEA)*



The representative of the IAEA reported on the role of the IAEA in the area of radiation safety, and the current areas of work in radiation protection, in particular on radiation protection in medicine, radiation protection of the public, occupational radiation protection, and radiation safety technical services. More information on IAEA can be found on the IAEA homepage <https://www.iaea.org/front>.

#### *12.3 World Health Organisation (WHO)*

No representative of the WHO could attend the meeting. More information on WHO can be found on the WHO homepage <http://www.who.int/en/>.

#### *12.4 Nuclear Energy Agency (NEA)*

No representative of the NEA could attend the meeting. More information on NEA can be found on the NEA homepage <http://www.oecd-nea.org/>.

#### *12.5. International Radiation Protection Association (IRPA)*

No representative of the NEA could attend the meeting. More information on IRPA can be found on the IRPA homepage <http://www.irpa.net/>.

#### *12.6. Heads of European Radiation protection Competent Authorities (HERCA)*

The representative of HERCA reported on background, participation, and structure and functioning of HERCA. HERCA's current activities are in the areas transposition of the Euratom BSS, medical applications, emergency preparedness and response, natural radiation sources, education and training, veterinary applications, and research and industrial sources and practices. More information on HERCA can be found on the HERCA homepage <http://www.herca.org/>.

### **13. OTHER BUSINESS**

#### *Radon dose coefficients*

The Article 31 Group of Experts discussed different options with regard to the application of the new radon dose coefficients recently published by ICRP, issues with the practical implementation, and the need for guidance to facilitate a harmonised approach within Europe.

### **14. DATES OF THE NEXT MEETINGS**

#### **November 2018**

The **November 2018 meeting** of the Group of Experts will be held on **14 – 15 November 2018** in Luxembourg, in Room E, **European Convention Center Luxembourg, 1, rue du Fort Thüngen, L-1499 Luxembourg (Kirchberg)**

#### **June 2019**

The **June 2019 meeting** of the Group of Experts is scheduled for **12 – 13 June 2019**, in meeting room EUFO 0001, **European Commission – Euroforum Building, 10, rue Robert Stumper – L-2557 Luxembourg – Gasperich.**