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PODIUM-WP 6: Dissemination of the project results

Task 6.3: Establishment of approval criteria for online dosimetry as legal dosimetry methodology

1 Objectives

An objective of Work Package 6 (WP6) is to stimulate the application of the PODIUM online dosimetry system as a tool for ALARA and training of exposed workers. Thanks to its graphic visualization capabilities, the dosimetry system developed by PODIUM can effectively enhance the awareness and the preparation of nuclear workers. However, the ultimate aim of PODIUM online dosimetry system is to be used for quantitative dosimetry, and not only for ALARA applications. Thanks to its real-time capabilities and to the accurate computational framework, we believe that in the near future PODIUM could substitute conventional dosimetry services based on dosemeters. Within this context an investigation has been performed for exploring the possibility of proposing criteria for a purely computational dosimetry system to be approved as dosimetry system for the estimation of the occupational exposure. These aspects have been addressed in Task 6.3 and presented in the present deliverable.

2 Methodology

The main aim of this document is to provide a possible approach to approve a computational dosimetry system to be used for the control of the occupational exposure. For this, the general criteria for legal dosimetry have been collected and discussed, and the approval criteria in different countries have been collected. Within the deliverable, we also report the discussions with the advisory board of PODIUM and their recommendations for obtaining legal approval.

For the collection of data related to the criteria used for the approval of dosimetry services the following data sources have been used:

- The European Directive for the establishment of the Basic Safety Standards, Euratom 59/2013 (1), as well as in the provisions that exist in the regulations of the European countries.
- The recommendations of Radiation Protection 160 of the European Committee (2)
- The IAEA safety standards (GSR part 3 (3) and GSG-7 (4)).
- The ISO 17025 standard (5)

The table in Annex 1 shows an overview of the regulations for a series of European countries, including the name of the competent authority, the national laws regulating dosimetry, a summary of the approval criteria and the authority in charge of inter-comparison programs.

3 International guidelines and directives

Within the European Directive (1) it is foreseen that any provider of dosimetry services shall be approved by the competent authority. The purpose of the approval procedure is to recognize and verify that a dosimetry service provider is technically competent and able to generate technically valid results.

Up to now, the majority of the dosimetry services are providers of passive detectors for the estimation of the occupational exposure from external sources. There are cases where active dosimeters are designated by the regulatory body to be used for record keeping purposes (the dosimeter of record).

In such cases, the procedure for approval is the same of passive dosimeters. For some categories of workers, it is sufficient to use computational tools to estimate the individual dose. For example, cosmic radiation fields in aircraft are fairly uniform and predictable. Computer codes have been developed for assessing the doses received by aircrew from cosmic radiation and have been validated against measurements. This methodology is also accepted for legal dose of record.

Based on the European (1) Directive "a dosimetry service means a body or an individual competent to calibrate, read or interpret individual monitoring devices, or to measure radioactivity in the human body or in biological samples, or to assess doses, whose capacity to act in this respect is recognised by the competent authority". In this sense a computational dosimetry system if performed by a dosimetry service can be considered as fulfilling this requirement.

It is underlined that specific approval criteria are not described in the Directive but freedom is given to Member States to specify their own criteria (Article 79 of the Directive). In Annex 1 some of the criteria are shown as they are specified in national regulations.

Regarding the IAEA GSR part 3 (3) "individual monitoring means the monitoring using measurements by equipment worn by individuals, or measurements of quantities of radioactive substances in or on, or taken into, the bodies of individuals, or measurements of quantities of radioactive substances excreted from the body by individuals". In this sense the computational dosimetry system is excluded from the individual monitoring part since "measurements" are clearly required. It is of course a discussion point what exactly is considered a "measurement". Also in the PODIUM approach, the doses are calculated based on measurements of the position of the worker, and based on measurements of the workplace field. This is done on an individual bases, so it is individual monitoring.

Requirement 25 of IAEA GSR part 3 (3) states that for assessment of occupational exposure and workers' health surveillance: "Employers, as well as self-employed persons, and registrants and licensees shall be responsible for making arrangements for the assessment of the occupational exposure of workers, on the basis of individual monitoring where appropriate, and shall ensure that arrangements are made with authorized or approved dosimetry service providers that operate under a quality management system." Again, it is said that individual monitoring is needed where appropriate. It can be interpreted that if computational dosimetry is better than "measurements" it could be used because it is more appropriate. But again, computation dosimetry as proposed in PODIUM can be considered individual measurements of the doses, as long as it is done by an authorized or approved dosimetry service provider.

Moreover, based on article 41, paragraph 3 of the same Directive (1): "In cases where individual measurements are not possible or inadequate, the individual monitoring shall be based on an estimate arrived at from individual measurements made on other exposed workers, from the results of the surveillance of the workplace provided for in Article 39 or on the basis of calculation methods approved by the competent authority". In this regard the computational dosimetry system can be used on the basis of calculation methods, if the individual measurements are not possible or inadequate. Again, we can argue that if a computational system is better than a conventional one, it can be used.

4 Approval criteria mentioned in the literature review

RP 160 (2) sets as main requirement for the approval of a dosimetry service that it operates under a quality management system. Furthermore, the recommendations of RP 160 (2) underline the control of the system software used for the calculation of the operational quantity from the raw data. The system software should be tested with conformity demonstrated with national and international standards. If full testing is not possible, at least a validation exercise demonstrating the intended functionality should be performed and documented. Such validation exercises are of course crucial for

all computational dosimetry systems. In addition, as any product, functionality and technical specifications have to be provided by the vendor/seller. Still it is true that there are at present no international standards that can be applied for testing any computational dosimetry system.

In addition in GSG-7 (4) it is stated that from technical point of view, "For a service provider to be approved, the service provider should be able to provide an acceptable degree of accuracy in the assessment of dose, to achieve and maintain a high level of reliability, to communicate the results of routine dose assessments to the employer and/or the regulatory body within a reasonable period of time, and to rapidly communicate the results of dose assessments made in the event of an accident or other incident or occurrence". Again, this is clearly something that can be answered positively for the PODIUM computational approach. The whole system should be tested and set-up such that it can deliver sufficiently accurate dose assessment, at least comparable with the passive systems. When installing the calculation system, specific tests could/should be performed. Such tests may include measurement of radiation. And to communicate the results within a reasonable period of time is of course also possible (even more possible) for computational dosimetry.

Finally, for the approval criteria mentioned in national regulations, as per Annex 1, it is concluded that the crucial ones include:

- The participation in intercomparison exercises,
- The development and implementation of a management system, which is based on the ISO / IEC 17025,
- The metrological traceability to a National Metrology Institute and/or a Secondary Standard Dosimetry Laboratory and
- The submission of the dosimetry data to the National Dose Registry.

The above list is in agreement with the criteria found in the international and European safety standards.

The management system is a set of interrelated or interacting elements for establishing policies and objectives and enabling the objectives to be achieved in an efficient and effective manner. The management system integrates all elements of an organization into one coherent system to enable all the organization's objectives to be achieved. These elements include the organizational structure, resources and processes. Personnel, equipment and organizational culture as well as the documented policies and processes are parts of the management system. The only difference in the case of a computational dosimetry system with a conventional one is the process of the assessment of doses. If this is validated, then the criterion of management system is easily applicable in the on line dosimetry systems.

Intercomparison (or interlaboratoy) exercise is the organization, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions. It is clear that the conventional way of performing intercomparisons that is used now for passive dosemeters cannot be used. But it is possible to set-up other types of intercomparisons, specifically for computational systems, like it is done now for computational codes for aircrew dosimetry.

An intercomparison exercise among dosimetry services can be considered as an announced performance test. In the case of computational dosimetry services this can be considered as a verification test in the assessing the doses. The conditions of the test could be described to the computational service provider that will be asked to assess the respective doses. The computational dosimetry service provider should have as input different factors than the ones that the conventional service provider has. The computational provider would need to assess the doses using its own

methodology having the description of the scenario test conditions. Such tests could include measurements of radiation. However, this type of intercomparison exercise is missing at the moment and it is underlined that a specific way of handling the computation services providers should be developed to establish the guide on how to organize such intercomparison exercises.

Metrological Traceability: Based on ISO 17025 standard the laboratory shall establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference. The establishment of the metrological traceability includes the following steps:

a) the specification of the quantity to be measured;
b) a documented unbroken chain of calibrations going back to stated and appropriate references;
c) that measurement uncertainty for each step in the traceability chain is evaluated according to agreed methods;
d) that each step of the chain is performed in accordance with appropriate methods, with the measurement results and with associated, recorded measurement uncertainties;
e) that the laboratories performing one or more steps in the chain supply evidence for their technical competence.
f) The respective steps for the computational traceability can be the following:
g) The quantity to be measured is the same with the conventional methods;
h) The documented unbroken chain of calibrations can be seen as the documented unbroken chain of the various components of the methodology on, which the computational method is based on, having the validation of the method as the main reference to “calibration” of the method. The whole methodology of the computational dosimetry is based on a series of measurements that validate the applied method. This validation can be considered as assessment of dose against the conventional true dose taken from the conventional dosemeters in the reference conditions or by reference dose, if possible;
i) The uncertainty should be assessed for each of the steps of the chain that contribute to the overall (and expanded) uncertainty;
j) Each step of the method is not performed based on methods that can be considered “appropriate”. However, each part has its own contribution to the quantity to be assessed and this contribution should be estimated as well as the relevant uncertainty. For example, when the whole body dosed is assessed the contribution of each part of the methodology (camera, Monte Carlo calculation, workplace to be used, etc.) should be linked to each other and have an estimated uncertainty;
k) The competence of the staff is important but from different point of view than the conventional dosimetry providers. The staff should be able to understand each part of the whole methodology in order to be able to interpret the final outcome accordingly.

Record keeping and submission of the relevant record to the national dose registry: Regarding recording keeping, the computational dosimetry system should be developed in a way to be possible to identify the various persons involved in practices with ionizing radiation with a specific identification number related to each workers. The rest of the requirements from the European directive (1) and more specifically those of Annex 1, can be easily applied as for the conventional dosimetry systems.

5 PODIUM Advisory Board

The use of computational dosimetry systems to be used as official dosimetry service provider was discussed in the 1st meeting with the advisory group. The following were the main conclusions of this discussion:

- The advisory group mentioned that because our system has to do with individual monitoring, which contains measurements, PODIUM dosimetry system cannot be similar to the calculation of the aircrew doses, where measurements cannot be performed.
- Moreover, such a system cannot be compared with the aircrew dosimetry system because the type of radiation and of dose calculation is totally different (there are no dose limits for the aircrew). The use of no physical measurements will create a sort of legal “problem”.
- Regarding the approval criteria, the advisory group paid attention to article 41, 1st paragraph of the European Directive. There is stated that the individual monitoring system should be based on measurements, if possible. And in fact the PODIUM doses are also based on measurements, so it could be accepted. The Advisory group also pointed out that if the system is used for dose optimization and protection of workers by having more accurate data, then it could be used as a dosimetry tool.

6 Conclusion:

It can be argued that also the computational method form the PODIUM approach can be considered as a measurement of the individual dose, as is now required in international standards. So a computational dosimetry system can be considered as an official dosimetry system for the estimation of the operational quantities. The computational dosimetry system should also be operated by an approved dosimetry service when certain criteria are met. These criteria include the verification of the methodology, the uncertainty estimation, the validation through intercomparison exersices, the record keeping and the management system of the provider, which can lead to a reasonable credible process of submitting the data to the respective national dose registry.

7 Annex 1: Competent authorities and regulations for the approval of dosimetry services

Country	Competent Authority	Legislative framework	Approval of dosimetry services	Intercomparison programs
Belgium	Federal Agency for Nuclear Control (FANC) with its subsidiary entity BelV	Royal Decree of 25 April 1997 FANC Decree of 1 July 2008	FANC approves the dosimetry services based on: - accreditation by ISO/IEC 17025 - the recommendations of RP73 - periodic national or international performance audits - for X and gamma rays, the criteria in ISO 14146 must be met.	Yes (at least every 3 years)
Bulgaria	Nuclear Regulatory Agency, National Center of Radiobiology and Radiation Protection-Ministry of Health	Regulation on basic norms of radiation protection	The requirement is the dosimetry service to be accredited.	Yes (every 3 years but not mandatory)
Finland	Radiation and Nuclear Safety Authority (STUK)	Radiation Act (592/1991) Radiation Safety Guide ST 1.9 / 23 November 2016	STUK approve dosimetry services based on: - accreditation by ISO/IEC 17025 - appropriate data systems for processing worker exposure data - accuracy requirements - annual blind tests	Based on the programme set for the accreditation
France	French Safety authority (ASN)	Labour code (articles R.4451-1 to R.4451-144)	ASN approves dosimetry services with the technical support of Institute for Radiological Protection and Nuclear safety (IRSN) based on: - accreditation by ISO/IEC 17025 –requirements to be met as set by standards on passive dosimetry like ISO 12794, EN 62387-1, ISO 21909	Yes (at least every 3 years).

Germany	Federal Ministry for Environment, Nature Conservation and Nuclear Safety (BMU) – responsible for the implementation of the Atomic Energy Act and the Radiation Protection Act Federal Office for Radiation Protection (BfS)	Radiation Protection Act (Section 170 StrlSchG) Guideline on standards for personal dosimetry services according to Radiation Protection Act (StrlSchG) and X-Ray Ordinance (RöV) of 10.12.2001	In Germany, the principles of occupational radiation protection are stipulated by the Radiation Protection Act (Section 170 StrlSchG) The responsibility in the field of monitoring occupational radiation exposure lies with the sixteen Federal States and their Federal State administrations, which act on behalf of the Federal Government.	Yes (annually)
Greece	EEAE (Greek Atomic Energy Commission)	Law 4310/2014 (A '258) Presidential decree 101/2018 (A' 194) Ministerial Order 45872 /2019 (B' 1103)	- quality management system ISO 9001:2015 or accredited with the requirements of ISO/IEC 17025, - technical requirements of the following standards: IEC 62387 IEC 61526 ISO 1414 - traceability at a National Metrology Institute or a secondary standard dosimetry laboratory (SSDL).	Yes (at least every 2 years)
Ireland	Environmental Protection Agency (EPA)	The EPA maintains a register of the dosimetry services approved in accordance with Part 10 of the Ionising Radiation Regulations (2019) Approval of Dosimetry Services in Ireland – Guidelines for Applicants, May 2017	EPA approves the dosimetry services based on: - accreditation by ISO/IEC 17025 - participation in national, European or international intercomparisons - type testing as set out by ISO 15382:2015 IEC 62387:2012 ISO 21901-1:2015 IEC 61526:2010 - supply of data to NDR	Yes (every 2 years)

Luxembourg	Division de la Radioprotection	Règlement grand-ducal du 14 décembre 2000 Chapter 5 to 9 especially 6.5 of the national regulation	Minister of Health approves dosimetry services.	
Spain	Nuclear Safety Council (CSN)	Guideline Nº 7.1 'Technical-Administrative Requirements for the Personnel Dosimetry Services'	Individual dosimetry shall be carried out by the Personal Dosimetry Services expressly authorized to do so by the Nuclear Safety Council. Criteria based on IEC 62387:2012	The CSN organizes approximately every five years an intercomparison exercise
Sweden	Swedish Radiation Safety Authority (SSM)	Swedish Radiation Protection Act (2018:396) SSMFS 2018:1 General rules for licensing activities with ionizing radiation.	SSM approve dosimetry services based on: - accreditation (ISO/IEC 17025) or equivalent quality management system - annual blind tests	No
Switzerland	Federal Office of Public Health (BAG) for medical field, research and education Swiss Federal Nuclear Safety Inspectorate (ENSI) for nuclear field Swiss National Accident Insurance Fund (Suva) for industry	Radiological Protection Ordinance of January of 2019 (RPO) Personal dosimetry ordinance of 1 January 2013	ENSI approves dosimetry services for nuclear field. BAG approves dosimetry services for all other fields.	Yes (yearly)

The Netherlands	Ministry of Social Affairs and Employment and its Inspectorate (SZW) Authority for Nuclear Safety and Radiation Protection (ANVS)	The legislative and regulatory framework concerning occupational radiation protection is laid down in a royal decree. The protection of workers against the hazards arising from ionising radiation is laid down in a ministerial decree.	The service provider shall comply with: - the recommendations of the European Commission included in Radiation Protection 73 - Technical Recommendations Report EUR 14852 EN (1994). - accredited according to the criteria stated in NEN-EN-ISO / IEC standard 17025.	The service shall participate in periodic national or international performance tests as specified in ISO 14146
United Kingdom	Health and Safety Executive (HSE)	Ionising Radiations Regulations 2017: IRR2017	HSE approve personal dosimetry services under the IRR2017 - unique UK testing process	HSE Performance Tests at least every 18 months –

8 References:

[1] Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom

[2] EUROPEAN COMMISSION Radiation Protection 160, Technical Recommendations for Monitoring Individuals Occupationally Exposed to External Radiation

[3] IAEA Safety Standards Series No. GSR Part 3 Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards

[4] IAEA Safety Standards Series No. GSG-7 Occupational Radiation Protection

[5] ISO/IEC 17025:2017(en) General requirements for the competence of testing and calibration laboratories