Need for harmonization of extremity dose monitoring in nuclear medicine: results of a survey amongst national dose registries in Europe

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Abstract

Staff handling radiopharmaceuticals in nuclear medicine (NM) may receive significant extremity doses. Especially over the last decade there is an increase in NM procedures and new radiopharmaceuticals have been introduced. However, literature provides limited recent data on the exposure of the extremities. In addition, proper assessment of the equivalent dose to the skin can be difficult when applied to the fingertips. In order to gain insight in the actual exposure and to find out how the European countries are dealing with monitoring of the extremities, a survey was performed amongst European regulatory authorities. The questions covered general aspects of the National Dose Registries (NDRs), the measured extremity doses and the practice of the monitoring of workers. The survey shows that extremity dosimetry is performed for about 25-50% of the monitored workers in NM. Also, the recorded extremity doses in the NDRs are low (mean values 5-29 mSv per year) compared to the dose limit. Despite the recommendations that have been published in the last 10 years, few countries provide guidance on the wearing position of extremity dosemeters and the correction factor to estimate the maximum equivalent skin dose from the measured dose. This may lead to an underestimation of the maximum skin dose. Thermoluminescence ring dosemeters are widely used but wrist dosemeters are also very common, even though the correlation of the measurement with the maximum skin dose is worse than for ring dosemeters. Furthermore, not all countries had a central registration of the extremity dose at the time the survey was performed.

Keywords: extremity dose, equivalent dose to the skin, regulatory status, nuclear medicine

1. Introduction

Nuclear medicine (NM) involves the use of radioactive isotopes in the diagnosis and treatment of a disease. Staff working in NM are exposed to ionising radiation during the handling of radiopharmaceuticals and their administration to the patients. The whole-body doses of the staff in NM are mostly low and can easily be monitored using passive personal dosemeters worn on the chest [1]. However, during the process of labelling, dispensing and injecting of radiopharmaceuticals into the patients the workers need to closely manipulate the radionuclides and may receive significant radiation doses to their hands.

The dose limits for skin and extremities for planned exposure situations are given in the European Directive 2013/59 [2], and are based on the recommendations of the International Commission on Radiological Protection (ICRP) [3]: an equivalent dose limit of 500 mSv in a year. This equivalent dose limit for the skin applies to the average dose over 1 cm² of the most highly irradiated area of the skin. Thus, one needs to know which is the most exposed part of the body to ensure compliance. In general, in NM, the equivalent dose to the skin of the hand is a conservative estimate of equivalent dose to the extremities. However, performing an accurate measurement of the maximum skin dose in NM is a challenge, because of the close distance of the hand to the source and the wide variety of radiopharmaceuticals in use [4, 5].

The information available on annual extremity exposures in NM is limited. In 2008, Donadille et al. [6] published one of the few studies including official extremity dose record data of NM workers from seven European countries. Data were collected from France, Germany, Greece, Ireland, Poland, Spain and Switzerland. At that time, the use of positron emission tomography was starting to increase, as well as the use of unsealed radioactive sources for therapeutic applications in NM. The survey concluded that the mean annual doses reported in national dosimetric databases were systematically lower than measured doses in pilot research studies. The discrepancies were associated to the fact that either the most exposed workers were not monitored, or the dosemeters were not routinely worn or not worn at appropriate positions. The study also pointed out the of establishing harmonized importance monitoring procedures and of having international databases, such as UNSCEAR [7], ESOREX [1] or ISOE [8], with extremity dose data

In 2010-2011, in the framework of the European project ORAMED [4], a large dosimetry campaign was organized to measure hand skin dose and hand skin dose distribution for NM workers in seven European countries. 124 workers were monitored and about 850 measurements were collected. The ORAMED study showed that finger skin doses in NM are high and can easily exceed the annual skin equivalent dose limit and it concluded that extremity monitoring is essential in these workplaces [9, 10]. The measurements' database was complemented with a wide set of Monte Carlo simulations to more accurately evaluate the efficiency of radiation protection means [11]. Based on their results the ORAMED group proposed guidelines for accurate monitoring and for reducing doses to the hands during NM procedures [12]. The authors emphasized the importance of using vial and syringe shields to reduce the hand dose. As regards to extremity monitoring, they showed that the tip of the index finger is, generally, the most exposed position on the hand. However, since this is not a very comfortable position for routine monitoring, they proposed to wear a ring dosemeter on the index finger of the non-dominant hand with the sensitive part of the dosemeter oriented towards the inside of the hand and to apply a correction factor of 6 to assess the maximum skin dose. The use of wrist dosemeters was discouraged because of the high underestimation and the lower correlation to the maximum skin dose.

Since 2011, there have been changes in procedures and pharmaceuticals [13, 14, 15] and a new international standard was published, ISO 15382 [16] providing guidance on procedures for monitoring the dose to the skin, the extremities and the lens of the eye. This standard describes the design of a monitoring program to ensure compliance with legal individual dose limits. It refers to the appropriate operational dose quantities, to the type and frequency of individual monitoring, to the type and positioning of the dosemeter and it proposes several approaches to assess and analyze skin and extremity doses.

In 2019, working group 12 of the European Radiation Dosimetry Group (EURADOS) prepared a EU-wide survey addressed to European regulatory authorities in order to investigate and update the information on how the European countries are dealing with the determination of extremity doses in NM and to gain insight in the exposure of these workers. This paper describes the survey that was distributed and summarizes the answers received.

2. Design of the survey

The survey was conducted using an electronic questionnaire. The questionnaire was divided into three main sections. The first section concerned information relating to the country and the regulator. The second section concerned general information regarding National Dose Registries (NDRs), the classification for types of work present in the NDR, the number of registered exposed workers in NM, the reporting level, the monitoring period and the mean annual extremity dose per monitored worker. The third and last section addressed the type of dosimetry, the type and position of extremity dose assessment and investigated if

there had been changes in the national guidelines due to the ORAMED recommendations [4], the new ISO [16] standard and/or the introduction of new radiopharmaceuticals.

The questionnaire was designed and distributed using Google Forms. The respondent was requested to answer 34 questions, consisting of multiple choice and open questions (mostly used for clarification). It took approximately 15 minutes to fill in the questionnaire.

The survey was distributed by email in 25 countries and it was, where possible, addressed to specific persons responsible for the NDR. There were two rounds of distribution, the first took place in October 2019 and the second in January 2020. In some situations, additional information was requested after the responses were received in order to clarify the initial response.

3. Results

3.1 Overview of responding countries

Responses were received from 16 countries (Figure 1). Of the responding countries, 13 countries are European Union members and have to comply with the EU BSS Directive [2], while the other 3 are currently not (Ukraine, Switzerland and Iceland).

All of the responding countries apart from Ukraine, store the dosimetric data of the monitored workers in national dose registries (NDRs). Ukraine keeps this information in local registries and databases. The databases of 13 out of the 15 NDRs contain a separate classification for workers active in the field of NM. Furthermore, some of the NDRs have subclassifications for production (4 respondents), diagnostics (3), therapy (3), PET (2) and cyclotrons (1).

3.2 Exposed workers

The number of monitored workers in NM, the percentage of workers wearing an extremity dosemeter and the availability of the extremity dose in the NDR is presented in Table 1. The table contains information from the questionnaire and was completed with additional data provided by a) the respondents when contacted for clarification, b) the ESOREX-platform and c) dosimetry services (Poland, Spain, the (Netherlands). This additional information is included in brackets. 25-50% of the monitored workers in NM make use of extremity dosimetry in almost half of the countries (7/16), in 5 countries it is less than 25%, and 4 countries it is more than 50%. In most countries the extremity dose data of monitored workers is available in the NDR, except for Croatia, France and the Netherlands. In Poland only category A workers are registered in the NDR.



Figure 1. Responding countries: Belgium, Croatia, Estonia, France, Germany, Greece, Iceland, Ireland, Lithuania, Luxembourg, Netherlands, Poland, Slovakia, Spain, Switzerland, Ukraine (in dark grey).

The mean measured annual doses and the (approximate) number of monitored workers with doses greater than 5, 50, 150 and 500 mSv are presented in Table 2. Data from the Netherlands and Poland are dosimetry service data, expected to cover the largest part of the population of these countries. More than half of the responding countries were able to provide information on the mean annual extremity doses, ranging from 4.5 to 28.8 mSv. In France, Germany, Switzerland and Spain there were some workers exceeding the dose limit of 500 mSv in 2018. In Switzerland these exceedances were 552 mSv and 562 mSv for PET workers.

The extremity dose should be monitored in specific workplaces in nine of the responding countries. In seven countries such a requirement is present for NM, radiopharmacy, interventional radiology and cardiology. There are five countries where such a requirement is present for exposure in highly non-uniform radiation fields. Three of the respondents mention that the requirement is based on a dose level of more than 150 mSv (category A workers), one respondent mentions a dose level of more than 50 mSv (category A or B workers) in order to determine the need for extremity dose monitoring.

Country	Number of inhabitants in 2018 [million]	Number of monitored NM workers [Additional data] ^a	Percentage of monitored NM workers with an extremity dosemeter [Additional data] ^a	Extremity dose available in NDR
Belgium	11.4	1000-1500	> 50%	Yes
Croatia	4.1	0-500	0-25%	No
Estonia	1.3	0-500	25%-50%	Yes
France	67	> 1500 [6420]	25%-50% [36%]	No
Germany	82.8	> 1500 [12421]	25%-50% [39%]	Yes
Greece	10.7	500-1000 [836]	25%-50% [37%]	Yes
Iceland	0.4	0-500 [14]	> 50% [100%]	Yes
Ireland	4.8	0-500	25%-50%	Yes
Lithuania	2.8	0-500 [70]	25%-50% [42%]	Yes
Luxembourg	0.6	0-500	0-25%	Yes
Netherlands	17.2	> 1500 [1862]	0-25%	No
Poland	37.9	> 1500	0-25%	For A workers
Slovakia	5.4	0-500	25%-50%	Yes
Spain	46.7	> 1500 [2818]	>50% [60%]	Yes
Switzerland	8.5	500-1000 [730]	> 50%	Yes
Ukraine	44.6	0-500	0-25%	No

Table 1. Monitored nuclear medicine workers and registered data (most recent available data).

^a Additional data from the ESOREX-platform or provided by the survey respondents when contacted for clarification

Table 2. Mean measured annual	extremity dose an	d number of monitored	l workers exceeding	g various dose levels.

Country	Mean annual extremity dose	Number of monitored workers				
country	(mSv)	> 5 mSv	> 50 mSv	>150 mSv	> 500 mSv	
Belgium	8.5	109	20	1	0	
Estonia	8.3	15	0	0	0	
France	28.8	1292	344	28	1	
Germany	13.7	1840	386	39	2	
Greece	11.8	73	21	5	0	
Iceland	10.5	5	1	0	0	
Ireland	5	42	5	0	0	
Lithuania	10.4	16	3	0	0	
Luxembourg	4.5	2	0	0	0	
Netherlands	13	214	44	2	0	
Poland	7.0	93	15	0	0	
Slovakia	7.8	87	11	4	0	
Spain	21.3	795 ^a	223	29	1	
Switzerland	20	275	82	17	2	

^a Number of workers with a dose of more than 6 mSv instead of 5 mSv

3.3 Reporting levels and monitoring period

Seven of the responding countries specified a reporting level of 0.1 mSv for the measured extremity dose (this is the level below which it may not be necessary to issue a particular report but to wait until the next summary) [17]. According to the information we received, this reporting level is comparable to the most common reporting level for whole body dosimetry. For four countries the reporting level for extremity dose is higher (1 - 4.2 mSv). Two countries report all doses. The other countries provided various responses to the question on the reporting level. The situation in Belgium depends on the dosemeter and on the approval document of the dosimetry service that provides the dosemeter.

The majority of the countries allow the same maximum monitoring period for whole body dosemeters as for the extremities, which is 1 month (seven countries) or 3 months (seven countries).

3.4 Type of extremity dosemeters

All respondents indicated that ring dosemeters were used in NM. In half of the countries wrist dosemeters are being used as well.

Of the countries where both ring and wrist dosemeters are used, selection criteria for the type differ. In Belgium, the choice is made depending on the exposure conditions and in Spain, depending on the exposure conditions and the availability at the dosimetry service. In Greece, the wrist dosemeter is only worn whenever a ring is not convenient. In Slovakia, an individual selection is made by the wearer. Respondents from France, Germany, the Netherlands, and Poland indicate that there is no clear selection criterion for choosing between the two types.

In all countries thermoluminescence dosemeters (TLDs) are available for extremity dosimetry. In France and Germany other types are being used as well (such as radiophotoluminescence dosemeters in France, optically stimulated luminescence dosemeters in Germany).

In most countries only one extremity dosemeter is being used per worker. In Belgium, France Ireland, the Netherlands, Poland, Spain, and Ukraine a second dosemeter is sometimes worn as well. This is mostly decided by the radiation protection expert.

3.5 Position of extremity dosemeters

In 10 out of 16 countries there are certain recommendations for the wearing position of the extremity dosemeter. In Estonia, Ireland, the Netherlands, Slovakia, Spain, and Ukraine no recommendation is provided by the regulators (see the pie charts in Figure 2). The French response suggests the existence of a recommendation, but it doesn't seem to provide guidance on the finger, hand or dosemeter. orientation of the extremity Some recommendations cover only part of the wearing position (the choice of the hand is missing for Croatia, the finger for Poland).

The most common recommendation is to wear the extremity dosemeter on the index finger of the non-dominant hand, with the sensitive part inward towards the palm. In contrast, in Iceland and Poland the dominant hand is recommended and Croatia and Lithuania recommend wearing the dosemeter not on the index finger but on the middle finger. Most respondents do not provide information of the most frequent position of the dosemeter in practice. In Slovakia, Ukraine and Spain the most common hand in practice is the dominant hand.

Only five countries recommend a factor to correct for the difference between the measured and maximum skin dose (Table 3). The recommended correction factor varies between 2 and 6.

Table 3. Recommend	led	correction	factor 1	for	extremity dos	e.

	5
Country	Correction factor
Belgium	3 or 6 ^a
Greece	6
Iceland	4
Slovakia	2
Switzerland	5

^a Determined by the RPE based on the ISO [16] and ICRP [22] recommendations

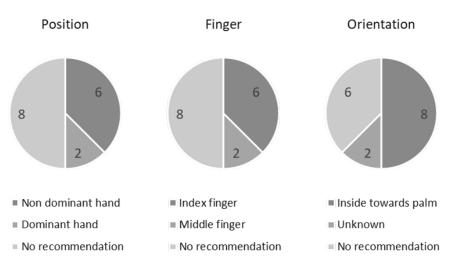


Figure 2. Number of countries with a recommendation on the wearing position of the extremity dosemeters (with respect to the hand, the finger and the orientation of the ring dosemeter).

4. Discussion

4.1 Comparison of registered extremity doses in the NDRs with 2005

The total number of monitored NM workers and their mean annual doses is compared in Table 4 for the years 2005 and 2018. The number of workers in 2018 could in most cases be estimated from the additional data we received. The mean dose values are expected to be a mixture of measured ring and wrist doses. The table shows that the number of extremity dosemeter wearers in NM has increased since 2005, but the number is still limited. The mean values of the measured annual dose are still in the same order of magnitude (5-29 mSv in 2018 compared to 2-29 mSv in 2005) and there are still hardly any occurrences of high measured dose values in the NDRs (Table 2). The increase of the registered doses (Table 4) may be explained by the more common use of ring dosemeters. In contrast to the situation in 2005, ring dosemeters are now available in all countries and – although the questionnaire did not inquire the use of ring dosemeters compared to wrist dosemeters – it is clear that the use of ring dosimetry is more widespread than in 2005. The additional data from Spain shows that that the mean dose for the wrist dosemeters (18 mSv in 2018) is lower than for the ring dosemeters (26 mSv in 2018) and that the use of wrist dosemeters is decreasing but can still be substantial (58% in 2018, 47% in 2019).

Country	Number of monite	ored NM workers wearing an extremity dosemeter	Mean annual extremity dose (mSv)	
	2005	2018 (estimate)	2005	2018
France	1176	2345	12.2	28.8
Germany	3104	4788	7.1	13.7
Greece	45	308	1.5	11.8
Ireland	111	0 - 500	5.7	5
Poland	143	> 377	7.6	7.0
Spain	827	1684	19.1	21.3
Switzerland	404	730	9	20

Table 4. Number of monitored nuclear medicine workers and the mean extremity doses in 2018 and 2005 [6].

4.2 Requirements for dose monitoring in the EU

The questionnaire investigated in which situation extremity dose monitoring is required by the regulator. Three of the respondents refer to the expected extremity dose of more than 150 mSv, which corresponds to the requirement in EU BSS article 41 stating that an adequate system for monitoring should be set up when category A workers are liable to receive a significant exposure of the extremities [2]. One of the countries has chosen to require extremity monitoring of category B workers as well when their extremity dose is expected to be more than 50 mSv. This is probably done to comply with the requirement that the monitoring of category B workers should at least be sufficient to demonstrate their correct classification. Seven of the responding countries require extremity dose monitoring in specific workplaces: NM, radiopharmacy, interventional radiology and cardiology. However, the number of workers using extremity dosimetry in most of these countries does not seem to be higher than in countries without requirements for specific workplaces.

4.3 Reported extremity doses in NDRs

According to article 44 of the EU BSS [2], the results of individual monitoring should be part of the data system for individual radiological monitoring for category A workers. The responses in Table 1 and 2 show that although all EU respondents have implemented a NDR, 3 of the 13 EU member states have not (yet) implemented a centralized registration of the individual extremity dose.

The survey was distributed through the EURADOS network to persons in 25 countries. We received responses from 16 countries. Unfortunately we were not able to get a more complete overview of the situation in Europe. The data in ESOREX database suggests that NDRs are in place in other European countries as well (Bulgaria, Finland, Sweden, Slovenia). This database does not contain extremity dose data for these countries.

4.4 Representativeness of data in NDRs

The data we received from the NDRs can relatively easy be compared to the publication from Donadille et al. [6] (Table 4), it is however more difficult to compare the registered extremity doses with recent publications in literature. One of the more recent publications predicts that for a fraction (up to 10%) of the workers the dose limit can be exceeded [18], which is in line with the ORAMED data that suggests a fraction of 20% over the dose limit [4]. Other publications mention the potential dose savings that can be achieved by the use of automated devices (with a factor of 17-40)[13, 19] or report all doses below the dose limit [20]. The number of recent publications providing an overview of the extremity exposure is however too limited to draw the conclusion that the exposure of the extremities has been reduced since the ORAMED study.

We asked the respondents to report the number of monitored workers with a measured extremity dose greater than the specified dose level. It should be realized that the presented dose values in Table 2 underestimate the actual maximum skin dose, because a difference between the measured and maximum dose values can be expected. Correction factors between 2-6 are reported in the literature review by Martin et al. [21] from the base to the tip of the finger. The ORAMED study recommends applying a correction factor of 6 [4]. Even after applying such a factor, there is only a small group of workers in the dose registries who could exceed the 500 mSv skin dose limit (only a few % of the workers is reported with a measured dose of more than 50 mSv). It should be noted that this underestimation is worse for the wrist dosemeters. The ORAMED study [4] suggests that wrist dosemeters may underestimate the maximum finger dose with a factor of 20.

When comparing these low percentages of workers with high doses with the literature, the question can be raised how many of the NM workers receiving high exposures are being monitored with ring dosemeters and if they are wearing them throughout the year. An ongoing task of EURADOS working group 12 is to investigate the extremity exposure in NM using a survey amongst the members of the European Association of Nuclear Medicine (EANM). This may provide a more complete picture of the extremity exposure in the daily practice of NM.

4.5 Guidance for extremity monitoring in Europe

Based on the responses in Figure 2, it seems that there is still little harmonization between countries in the monitoring location of the extremity dosemeters in NM. An overview of the several recommendations on extremity dose monitoring is given in Table 5. Out of the 16 respondents, only 5 countries (Belgium, Luxemburg, Germany, Greece and Switzerland) seem to follow the recommendation published in 2015 by the ISO (15382) [16] to wear a ring dosemeter on the base of the index finger of the non-dominant hand, in line with the recommendations of the ORAMED study for NM [4].

Aspect	ISO 15382 [16]	ORAMED [4]	ICRP 106, Annex E [22]	IPEM topical report (90Y therapy or other* imaging) [5]	IPEM topical report (imaging procedures) [5]
Hand	non-dominant hand	non-dominant hand	dominant hand	no recommendation	no recommendation
Position	fingertip or base	base	preferably fingertip, especially for ⁹⁰ Y	fingertip	base
Finger	index finger	index finger	middle finger	index finger	index finger
Orientation	towards the source	to the palm	no recommendation	to the palm	to the palm
Correction factor	no recommendation	6	3 (palm) or 6 (back)	none	2 (second phalanx) or 6 (base)

Table 5. Overview of recommendations on extremity dose monitoring.

In most countries there is no guidance at all. Of the other countries where certain guidance is available, none is consistently following the (older) recommendation of ICRP 106, Annex E in 2008 [22]. The same conclusion can be drawn with respect to the factor to correct from measurement to the maximum skin dose. Although five of the respondents mention the use of such correction factors, there is no consistency in the use of these factors. It should be noted that the ISO publication itself does not contain an explicit recommendation for the correction factor and different choices can be made based on the options in Table 5. The ORAMED group [4] and IPEM report [5] recommend, when possible, to perform trial measurements to establish individual specific correction factors when using ring dosimetry. Another observation that can be made is that although these publications recommend to use either ring or fingerstall dosemeters, the use of wrist dosemeters is still quite common. Finally, the answers to the survey show that the reporting level and the monitoring period are not harmonized either. Although there may be valid reasons for the selected reporting level and monitoring period, it would be helpful for a better comparison among countries to reach some consensus.

5. Conclusion

This investigation shows that the use of extremity dosimetry has increased since 2005, but is still limited to about 25-50% of the workers in NM (Table 1). With mean values between 5-29 mSv per year, the registered extremity dose values are relatively low compared to the dose limits. These values are in most cases based on the measurements with TLD ring dosemeters. Monitoring

with a ring dosemeter may be the most practical solution, but may underestimate the maximum extremity dose by a factor of 6, based on the ORAMED recommendations for NM. In the cases where wrist dosemeters are being used, this underestimation is even worse. It is hard to judge how well these dose values represent the actual extremity exposure in NM because there are only few recent publications providing insight in this exposure. Although the EU BSS [2] requires the member states since February 2018 to register the results of individual monitoring for category A workers in a NDR, some of the countries had not implemented this for the extremities dose at the time the survey was performed (at the end of 2019). Despite the recommendations that have been provided in the last 10 years, in many countries there is no or limited guidance for the monitoring location and correction factor to be used in the monitoring of the extremities in NM. The authors would like to emphasise the need of harmonization in this field to ensure an appropriate radiological protection of the workers. In particular, considering the latest publications [4, 5] wrist dosemeters should be replaced by ring or fingerstall dosemeters. In case of using a ring dosemeter, the base of the index finger of the non-dominant hand towards to the palm, would be the recommended position and a correction factor of 6 would need to be used to assess the maximum skin dose.

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