



Calibration services for X-ray multimeters in Europe: current situation and future needs

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ABSTRACT

Introduction: Optimization and quality control of the diagnostic and interventional radiology procedures is usually performed with an X-ray multimeter (XMM) based on the non-invasive measurements of different X-ray tube and output parameters obtained from the X-ray beam, such as air kerma, tube voltage and half-value layer. Standardization and metrological support need to be improved, and harmonized calibration procedures are not available for all quantities. There is also a lack of data on performance of XMMs in different measurement conditions relevant for clinical practice.

Methods: The needs for calibration of XMMs and current state of the art of calibration services were investigated by performing an overview of the standards, conducting surveys addressed to the clinical medical physicists and calibration laboratories and investigating the key comparison database.

Results: There are widely available calibration services for air kerma measurements for a large range of radiation qualities. However, there is a lack of calibration services for all other measured quantities, and very few laboratories besides the manufacturers are able to perform these calibrations. In addition, standardization gaps with non-harmonized calibration and measurement procedures for these quantities were found.

Conclusion: New calibration services with harmonized procedures are needed for XMMs, especially for quantities beyond air kerma. There is a need to better understand and reduce measurement uncertainty for some quantities. New procedures will be developed within the TraMeXI project and disseminated to the standardization bodies, metrology and medical physics community.

1. Introduction

Diagnostic and interventional procedures using X-rays are of critical importance for modern medicine, and they are the main contributor to

the dose from artificial sources of ionizing radiation. According to the UNSCEAR, 4.2 billion examinations based on X-ray imaging are performed annually [1]. General radiology examinations are the most common, but the dose to the population is the highest due to CT

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examinations. Due to the high collective effective dose and associated radiation risks that can arise from the medical application of X-rays, the relevant examinations should be optimized and well-controlled. The dose received by the patients should be minimized and effectively assessed, which requires accurate dosimetry measurements using calibrated dosimeters. Assessment of the radiation dose is mandated by EU legislation. Appropriate calibrations and proper use of dosimetry equipment are fundamental prerequisites to improve the quality of measurements. The European Council Directive, as well as the International Atomic Energy Agency (IAEA) Basic Safety Standards, require regular calibration of relevant measuring instruments [2,3]. Optimization of exposure is reliant on the knowledge of different quantities related to the X-ray beams used for medical examinations, such as air kerma, X-ray tube voltage or half-value layer (HVL).

Historically, the most common measuring instruments that were used in X-ray imaging were vented ionization chambers. They are still used to measure air kerma and HVL, especially by calibration laboratories. They have good metrological properties (e.g. linearity, energy dependence, long-term stability), and their calibration is relatively straightforward [4]. In recent years, solid-state semiconductor-based X-ray multimeters (XMMs) have become the most widely used dosimeters in clinical settings for most modalities, such as general radiology, fluoroscopy, and mammography. Many XMMs are based on solid-state detectors positioned behind internal filters. A wide range of derived X-ray tube and output related quantities can be calculated based on signals from these detectors. XMMs are often very simple to use and have the ability to measure multiple quantities in one exposure, including air kerma and X-ray tube high voltage, as well as additional quality control (QC) quantities such as the HVL, total filtration (TF), exposure time, maximum (peak) tube voltage (kVp), and practical peak voltage (PPV) [5]. However, many XMMs allow users to choose different software settings (e.g. tube voltage range, anode or filter material) which often affect the calibration functions and measurement results in non-transparent ways [6,7]. Because of this, such XMMs effectively function as black boxes, and end users and calibration laboratories have very limited insight in internal processes and control over the displayed values. In this study, a generic term XMM quantities is used for quantities measured by XMMs.

To achieve consistent, comparable, and traceable measurement results, XMMs must be calibrated with clinically relevant radiation qualities, measurement methods must be harmonized and measurement uncertainties must be estimated for these varying measurement conditions. Measurement uncertainty of 7 % with 95 % confidence level is considered appropriate for air kerma [4], but there are no commonly accepted requirements for the other XMM quantities. There are a number of papers investigating XMM capabilities when it comes to air kerma measurements in general radiology and fluoroscopy [8,9], interventional radiology [10], and mammography [6,7,11,12]. However, there are few studies on capabilities for measurements of other essential XMM quantities [11,13–15]. Air kerma measurements are well established and standardized [4], and there are many calibration laboratories with capabilities for this quantity [16], but other XMM quantities have a varying degree of metrological support, standardization and even theoretical basis. It is important to understand why and how these quantities are measured and assessed in clinical practice, what are the practical needs for measurement uncertainties with varying exposure scenarios and whether a sufficient level of metrological support can be achieved when using the existing X-ray systems and XMM technology.

Dosimetry methods must evolve alongside clinical practices, new imaging technology including novel X-ray spectra and new advances in radiation dosimetry technology. Calibration laboratories typically conduct calibrations within specific reference radiation setups, as defined in the International Electrotechnical Commission (IEC) standard IEC 61267 [17]. However, the range of clinically used radiation qualities exceeds the range currently specified in corresponding IEC standards and this trend is on-going. Consequently, the differences between the

laboratory calibrations and clinical measurement conditions can significantly influence the reliable implementation of XMMs, especially due to the differences in radiation quality (spectrum), dose rate and pulse length [10,18]. The reliability and acknowledged uncertainties of X-ray dosimetry are prerequisites for the reliable individualized patient dose determination in clinical radiology settings. Thus, the knowledge of the accuracy and limitations in the use of XMMs in clinical radiology practice have far-reaching consequences extending to the fundamental system of radiological protection which is becoming more individualized in the future (as indicated e.g. by the ICRP (International Commission on Radiological Protection) Task Group 128 [19] and AAPM (American Association of Physicists in Medicine) Task Group 430 [20]).

Joint research project 22NRM01 TraMeXI: Traceability in medical X-ray imaging dosimetry (in the following text: TraMeXI), a project within the European Partnership on Metrology, has started in June 2023, with the aim to update corresponding calibration and measurement procedures and to improve metrological support for the end users of dosimeters. A total of 14 partners are involved in the project, including 11 National Metrology Institutes (NMI) or Designated Institutes (DI) and three hospitals. In addition the project has an extensive stakeholder committee, including international organizations, standardization bodies, regulators, calibration laboratories, medical physicist societies and manufacturers [21].

In this paper, the current situation regarding the calibration services of X-ray imaging dosimeters in Europe was investigated. The analysis was performed for all essential XMM quantities that can be measured non-invasively by established dosimetric methods. An overview of standards and technical documents was performed, and the International Bureau of Weights and Measures (BIPM) Key Comparison Database (KCDB) was investigated, to gain an overview of the best calibration capabilities available [16]. In addition, two surveys were conducted, one aimed at medical physicists and another at calibration laboratories, to assess the XMM calibration needs and current state of calibration services in Europe. This data will be used by TraMeXI project for the development of new and more versatile X-ray dosimetry calibration and testing procedures.

2. Materials and methods

2.1. Standards and technical documents

An analysis of standards and technical documents was performed to pinpoint the requirements for XMMs and other dosimeters used in diagnostic radiology as well as the requirements for measurements of different quantities related to X-ray machines used for medical imaging and the available calibration and testing procedures. Standards and technical documents were identified by search on IEC, ISO and IAEA platforms, by investigating the references, and general search on related databases like PubMed.

2.2. Medical physicist survey

A questionnaire was prepared and sent to clinical medical physicists with the support of the European Federation of Organisations for Medical Physics (EFOMP). This survey aimed to obtain information from medical physicists or other technical personnel on clinical use of X-ray imaging devices, corresponding exposure parameters and needs for measurement precision and reproducibility. The questions addressed in particular clinically relevant radiation qualities, dosimeter types in use and their calibration status, quantities and current methods of measurements, as well as for which purpose the measured quantities are used and what are the legal requirements for clinical measurements.

A total of 91 responses were received. In this paper, only the responses relevant to availability of calibration services and calibration needs in Europe are analyzed. Responses were received from a total of 19 out of 27 (70 %) European Union member countries and from 25 out

of 50 (50 %) European countries. The responses cover 84 institutions which operate in total several thousand X-ray units. Most respondents were medical physicists (54), from which 18 were chief medical physicists and 3 resident physicists in training. The rest of the participants were physicists, radiographers, engineers or other technical persons performing measurements.

2.3. State of the art calibration capabilities

Current state of the art calibration capabilities and related uncertainties were investigated by surveying the entries in KCDB [16]. This database holds verified calibration and measurement capabilities (CMC) of the signatories of the International Committee for Weights and Measures (CIPM) Mutual Recognition Arrangement (MRA). The signatories are NMIs or DIs, i.e. the metrology institutes operating at the highest level and in charge of dissemination of measurement units in their respective countries, they hold national standards, and in most cases have the best measurement capabilities. These capabilities are considered current state of the art. CMCs are supported by key or supplementary comparisons or other technical data and all have undergone rigorous peer review.

2.4. Dosimetry laboratory survey

The dosimetry laboratory survey was disseminated to all calibration laboratories within the TraMeXI research project. Further laboratories were contacted using relevant networks (European Metrology Network for Radiation Protection (EMN RP), European Association of National Metrology Institutes (EURAMET), Euro-Asian Cooperation of National Metrological Institutions (COOMET), European Radiation Dosimetry Group (EURADOS), IAEA/WHO (World Health Organization) SSDL (Secondary Standards Dosimetry Laboratory) Network. Professional contacts of the project participants were used to identify further laboratories. Dosimeter manufacturers were also contacted to provide answers to the survey. The total number of contacted laboratories from Europe was 54, out of which 22 laboratories didn't provide a response. Considering that 11 of these laboratories do not provide any calibration services for XMMs according to the SSDL database [22], the adjusted response rate is 32/43, i.e. 74.4 %.

The emphasis in this survey was on the existing calibration services, including the quantities and radiation qualities, and the requests for different calibrations by the users. There were 32 participants from 27 European countries in the laboratory survey, 25 of which are part of an NMI or DI, 3 are part of a regulatory organization (2 laboratories selected both previous answers), 3 dosimeter manufacturers and 3 other calibration laboratories. There were also 10 answers from outside of Europe, which are not analyzed in this paper.

A specially focused questionnaire was conducted to assess the current practices in measuring and calibrating the HVL in dosimetry laboratories. Responses were received from 9 laboratories, comprising 3 primary standard dosimetry laboratories (PSDL) and 6 secondary standard dosimetry laboratories, categorized based on their air kerma standards.

3. Results

3.1. Standards and technical documents

The IEC working group IEC TC62 SC62C WG 3 maintains several standards related to dosimetry in X-ray diagnostics. The IEC 61267 standard describes radiation conditions for use in the determination of characteristics of systems or components of medical diagnostic X-ray equipment [23]. The radiation conditions described in IEC 61267 are intended for testing and calibration of X-ray equipment under harmonized conditions defined to mimic typical clinical radiation beams. This includes conditions that are representative for diagnostic radiology

(RQR – used to simulate primary beams in general radiology; RQA – used to simulate beams emerging from the patients, i.e. attenuated radiation qualities, RQC – primary beams with added copper filtration), computed tomography (RQT) and mammography (RQR-M). In addition, the standard describes radiation conditions that are representative for specific conditions, e.g. RQN for narrow beam conditions and RQB for broad beam conditions, which can be used to investigate the performance of anti-scatter grids. The radiation conditions described in IEC 61267 have been adopted by several other standards and guidelines, e.g. IAEA technical report series (TRS) 457 [4].

The IEC 61674 standard [23] describes performance requirements for dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging for air kerma measurements. Several compliance tests described in this standard are based on IEC 61267 radiation conditions. This standard does not differentiate between XMMs and ionization chambers, and compliance tests are performed in the same way for both types of devices. In this standard, there is also no separation between reference- and field-class dosimeters as it is done for kerma area product (KAP) meters in IEC 60580 standard [24] and in IEC 60731 standard [25] for radiotherapy dosimeters. It should be noted that KAP is used in this paper to denote both kerma area product and dose area product, and similarly KLP is used to denote kerma length product and dose length product.

A very similar standard IEC 61676 [26] describes performance requirements for non-invasive measurement of X-ray tube voltage in diagnostic radiology in terms of practical peak voltage. The standard however is not based on the harmonized radiation conditions described in IEC 61267.

HVL measurements are described in different documents [4,27]. However, there is no guide available for calibration and uncertainty estimation and there is no IEC or similar standard specifying requirements for devices measuring HVL. There are no standards or requirements for other XMM quantities. The previously mentioned standards also do not give harmonized definitions for XMM quantities, such as exposure (or irradiation) time or HVL (simple definitions are not sufficiently detailed to establish harmonized calibration and measurement procedures).

There are several national standards, regulations and guidelines that define requirements for diagnostic dosimeters (including XMMs) based on IEC 61267 [17] and IEC 61674 [23]. The International Atomic Energy Agency (IAEA) has also drawn up its international code of practice for dosimetry in diagnostic radiology (TRS 457) on the basis of these standards [4]. TRS 457 states that the calibration laboratories should establish radiation qualities in accordance with IEC 61267. TRS 457 also introduces the concept of a reference class dosimeter but does not give very specific requirements for the classification. The rationale in TRS 457 is to introduce a class of dosimeters that should be used as secondary standards at SSDLs. In addition, the uncertainty scenarios for clinical measurements are given only for the case when a reference class dosimeter is used. Therefore, it seems that TRS 457 recommends the use of reference class dosimeters also for the clinical measurements when comparable uncertainties are needed.

TRS 457 also states requirements for uncertainties for clinical measurements of air kerma. Accuracy of 20 % is considered sufficient for measurements to estimate the absolute risk from radiology examinations of adults. However, lower uncertainty is required for some special cases: when deterministic effects are expected, for measurements intended to compare different procedures, technologies, or techniques and for estimating the risk due to pediatric examinations, or risk due to dose delivered to a fetus. Measurement uncertainties of calibration coefficients provided by the calibration laboratories should be sufficiently low to achieve targets in clinical measurements. Example uncertainty budgets are given in the document [4].

In addition, there are several IEC standards prepared under working groups of IEC SC 62B, giving general requirements for X-ray systems and their performance (e.g. under IEC 60601 standard series). They give

specific requirements for technical parameters such as total filtration, HVL and tube voltage, which then consequently impact on the measurement requirements of these quantities. For example, there are requirements that the error of the indicated value of the X-ray tube voltage shall not be greater than 8 % for general radiology [28] and the tube voltage shall be accurate within ± 5 % of the indicated values within the selectable range in mammography [29]. HVL is generally used to check that the requirements for permanent filtration of the X-ray beam comply with the requirements given in the IEC standards. The requirements for exposure time are 10 % + 1 ms.

A fundamental challenge in these requirements is that the actual clinical testing conditions for various modern clinical X-ray systems are not identical to the harmonized conditions defined in the IEC 61267. Therefore, the change in measurement conditions introduces additional uncertainty to the clinical measurement and this component is not always easy to evaluate. The only exception found is the series of standards IEC 62220-1 [30], which describes the determination of the detective quantum efficiency (DQE) for imaging detectors based on IEC 61267 radiation conditions. However, as the DQE reflects the image signal propagation descriptive of image formation capabilities of the image detector, it is beyond the scope of X-ray beam quantity measurements of dosimeters.

3.2. Medical physicists survey

The analysis was based on the 84 replies received from institutions around Europe. The survey showed that the uptake of XMMs by medical physicists is almost universal – about 90 % of the respondents use XMMs. However, ICs are also still widely used (e.g. for computed tomography), with around three quarters of medical physicists using them. Most of the respondents stated that they perform air kerma and HVL measurements, and measure these quantities either with ICs or XMMs.

The survey showed that 90 % of institutions use XMMs for measurements related to regular QC where conformance of measurements with existing limiting values is assessed, and 76 % use XMMs to check conformance of dose values displayed by X-ray units like KAP-values, while about 35 % use XMMs specifically for research purposes. About 25 % of institutions stated that they use XMMs as reference devices. Data were slightly different but mostly similar for mammography.

Most respondents stated that they calibrate their dosimeters at least once (only 1 respondent stated that the dosimeters are not calibrated). Most dosimeters have factory calibration when they are purchased. Regular calibrations are performed almost twice more often at

manufacturers' than in other calibration laboratories in case of XMMs. However, in case of ICs calibrations are more often performed in other calibration laboratories. Most of the respondents that use ICs in general radiology calibrate their equipment every 2–3 years (32 respondents), a smaller number does annual calibrations (7) and an even smaller number every 4–5 years (4). Similarly, ICs used in mammography are calibrated every 2–3 years by most of the respondents, and fewer calibrate annually or every 4–5 years. Calibrations of ICs used in CT are performed every 2–3 years (39 respondents), annually (7) or every 4–5 years (5). Calibrations of XMMs in terms of air kerma show very similar distribution.

Six respondents use XMMs for air kerma measurements only, while 68 measure additional quantities, such as tube voltage (60 respondents measure it for at least one modality), PPV (15), exposure time (62), total filtration (TF) (50), tube current or tube current time product (16) and others. In Fig. 1, the percentage of respondents that measure different quantities is shown, broken down by modalities.

More than half of the respondents receive dosimeters already calibrated for at least some of the additional quantities, and 85 % calibrate them regularly. Most participants calibrate XMMs at the manufacturers', but a significant minority (up to 1/3 for mammography) calibrates XMMs in other calibration laboratories. Only 4 respondents state that they either don't calibrate their XMMs or that they don't know the calibration status for other quantities. Calibration status by quantity is shown in Fig. 2. It can be seen that most dosimeters are calibrated for tube voltage, HVL and exposure time, while calibrations for all other quantities are less common. The medical physicist survey also shows that there are cases where calibrations are performed for some quantities, but the quantities are not used in clinical measurements.

The respondents were also asked how they use calibration coefficients for air kerma measurements, and the breakdown is shown in Fig. 3. A very low percentage of institutions use calibration coefficients to correct measurement results. The majority of users does not use air kerma calibration coefficients and rely on the manufacturer's calibration and adjustment of the dosimeter.

Medical physicists were also asked about legal requirements for dosimeter calibrations and measurement of different quantities, to gain a better understanding of their needs. There were several cases of conflicting responses received from the same country. These conflicts are not taken into account here, and the results are reported as received.

According to the responses, most countries have national legal regulations regarding the dosimeters used in QC measurements in diagnostic and interventional radiology and corresponding to calibration,

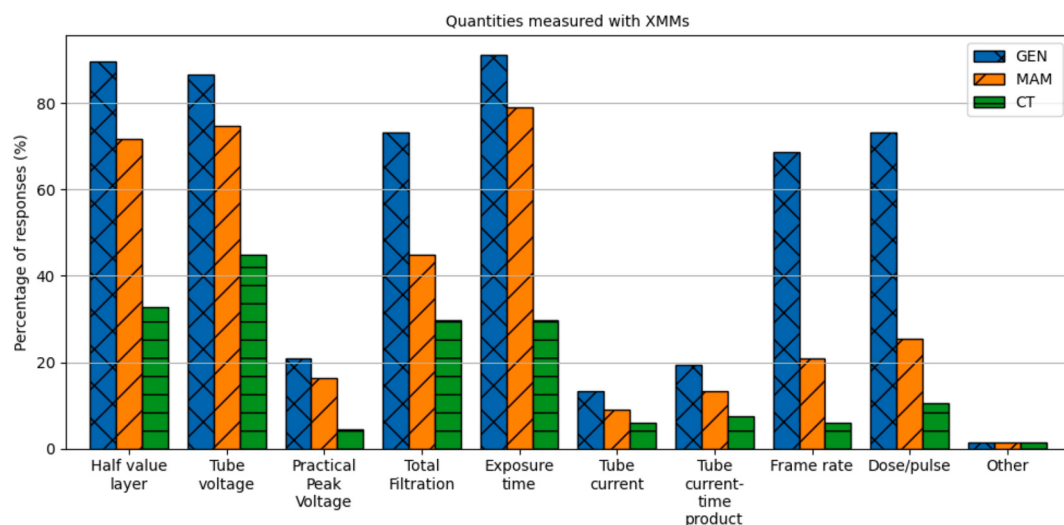


Fig. 1. Number of respondents that use XMMs to measure different quantities, broken down by modality (GEN: general radiology, interventional and dental imaging, MAM: mammography, CT: computed tomography).

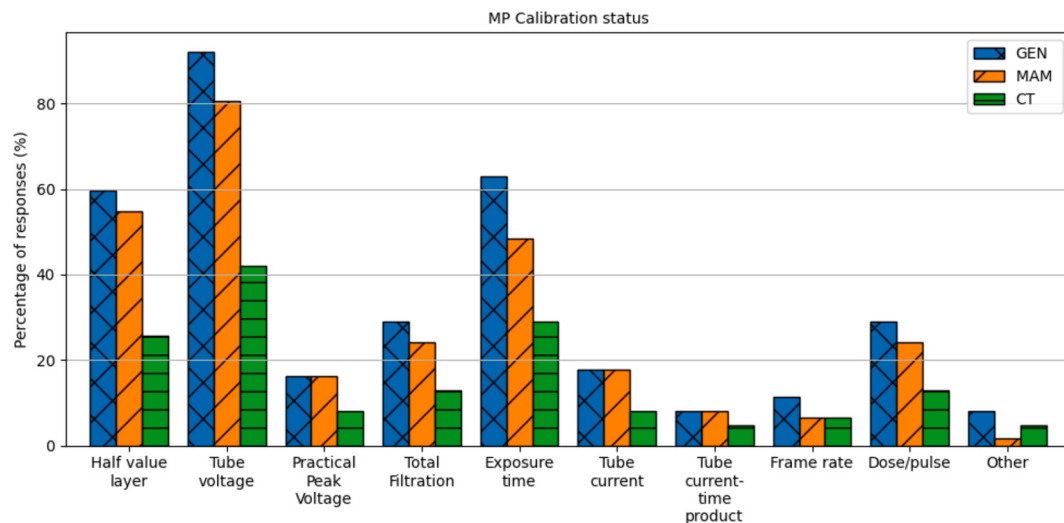


Fig. 2. Percentage of XMMs calibrated for different quantities, broken down by modality (GEN: general radiology, interventional and dental imaging, MAM: mammography, CT: computed tomography).

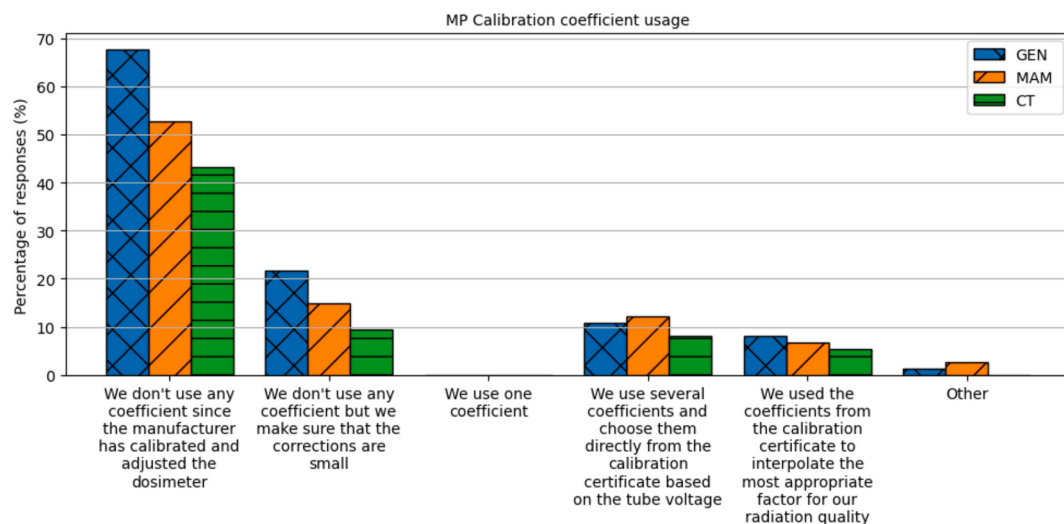


Fig. 3. Percentage of usage of the air kerma calibration coefficient for XMMs, broken down by modality (GEN: general radiology, interventional and dental imaging, MAM: mammography, CT: computed tomography).

verification or testing of the dosimeters. Overall, 53 respondents stated that there are some legal requirements for dosimeters used in QC (33 for calibration, 13 verification, 3 type testing and 16 other – multiple choices were allowed). Out of 33 respondents that selected that calibration is required, the most common interval of calibration is 2 years, but in some countries, interval is one, three or five years. There is a similar situation with verification, where the most common interval is also 2 years but verification is done in some countries annually or every 3 years. However, legal requirements depend on the type of usage. Out of 53 respondents, more than half stated that dosimeters used for any type of dosimetry measurements are covered by regulation. In addition, 11 responses stated that dosimeters used for patient dosimetry are covered by the regulations, 14 responses report this for dosimeters for QC, and a smaller number for other applications.

Based on the survey, the quantities that are generally required by national regulations to be measured include dose related quantities like air kerma, KAP, KLP or computed tomography dose index (CTDI), radiation quality related quantities like HVL or total filtration, and tube voltage related quantities like kVp or PPV. Additionally, exposure time measurements are also commonly mandated for use in radiology. The

measurement of tube current, tube current-time product, frame rate, and dose/pulse are typically required for radiology and dental modalities. The measurements of these quantities are mandated by over 60 % of national regulations for the aforementioned modalities. In contrast, in mammography, these quantities are only required by approximately 20 % of national regulations, with the exception of tube current, which is more frequently mandated. For computed tomography, the measurement of these quantities is required by only about 10 % of the regulations.

3.3. State of the art calibration capabilities

CMCs for Ionizing Radiation can be stated only for the quantities selected by the Consultative Committee for Ionizing Radiation (CCRI). Considering diagnostic radiology and TraMeXI project, the following quantities are of interest: air kerma/rate and X-ray tube voltage. All the other quantities relevant for diagnostic radiology can't be entered in KCDB. The services are also grouped by "sources". In case of diagnostic radiology, the sources of interest, as defined in KCDB, are "X-ray, 10 kV to 50 kV" (low energy X-rays) and "X-ray, 50 kV to 300 kV" (medium to

high energy X-rays). The old categorization had source “X-ray, 50 kV to 420 kV” instead of “X-ray, 50 kV to 300 kV” and many institutes still haven’t changed CMCs. These two sources are considered together in this analysis.

It should be noted that there are many institutes which have some calibration capabilities, but do not have published CMCs. This can be due to many reasons, such as lack of key/supplementary comparisons to support the CMCs, the institute policy, or the CMCs may be pending review and publication. Therefore the list presented below is not comprehensive and it should be understood that it is only used to evaluate current state of the art. It should also be noted that all the published CMCs are supported by key or supplementary comparisons or other technical data, and that all CMCs have undergone rigorous peer review. According to the CCRI rules, all measurement uncertainties are stated with a coverage factor of 2, which approximately corresponds to 95 % level of confidence.

It should also be noted that the minimum possible uncertainty for air kerma calibrations in X-rays has become 0.7 %, since the publication of ICRU Report 90 describing the key physical data including photon cross sections for ionizing radiation dosimetry [31]. The physical constant W/e (the energy of ionizing radiation needed to release charge of the same sign equal to 1C in dry air), which every primary lab uses, now has an uncertainty of 0.35 % ($k = 1$). This document was implemented on January 1, 2019, and any CMCs approved before this date still need to take changes into account.

There are a total of 70 CMC lines for air kerma/rate for low energy X-rays, published by a total of 23 countries. After eliminating the CMC lines that are explicitly stated to be related to radiation protection calibrations, therapy level calibrations, other types of samples, and also the lines with beam specifications from ISO 4037 standard (used for radiation protection calibrations) [27], 43 lines remain from a total of 19 countries. BIPM (CCRI) radiation qualities were also considered, unless it was explicitly stated that they are used only for radiotherapy level calibrations. Minimum measurement uncertainty stated by any institute is 0.7 %, while several institutes have 0.8 % uncertainty, although these are CMC’s approved before the ICRU-90 implementation date. Minimum measurement uncertainty stated by any institute after the ICRU-90 implementation date, is 1.0 %. Only primary laboratories achieved such a small uncertainty, and all of them use free air chambers. The range of radiation qualities established for the mentioned services is very wide, from 10 kV to 50 kV, including RQR, RQA and CCRI radiation qualities, as well as different mammography radiation qualities (including attenuated), with different filters. However, the only anode material stated in the published CMCs with such low uncertainty is tungsten (W). Considering secondary methods, the smallest uncertainty achieved for mammography is 1 % and for general radiology 1.1 %. Maximum uncertainty among the metrology institutes is 3 %. Out of all the CMC lines related to secondary methods, 8 have the uncertainty larger than 2 %, 8 have smaller uncertainty, and one has the uncertainty of exactly 2 %.

There are a total of 88 CMC lines from a total of 29 countries for medium and high energy X-rays. After selecting the CMCs in the same way as for the low energy X-rays, 43 CMC lines from 20 countries remain. Minimum measurement uncertainty is 0.7 %–0.8 %, although these are again CMC’s approved before the implementation date of ICRU-90. Minimum measurement uncertainty stated by any institute, approved close before or after the ICRU-90 implementation date, is 0.9 %–1.0 %. These uncertainties are only achieved by primary laboratories, using free air chambers, the same as for low energy X-rays. The uncertainty range for secondary laboratories is also the same, between 1 % and 3 %, with similar distribution. The range of covered radiation qualities includes RQR, RQT, RQA and CCRI series, as well as other radiation qualities, including user defined. The only anode that is used is tungsten (W).

There are only two institutes with published CMCs for X-ray tube voltage. The ranges of voltages that are covered are either from 20 kV to

150 kV or from 40 kV to 150 kV, respectively. One institute stated an uncertainty of 1.2 %, the other institute of 2 %. Two different methods are used: high voltage divider and HPGe spectrometer. There is no official key comparison or finished supplementary comparison for X-ray tube voltage and there are not many other comparisons. A supplementary comparison is currently being organized within the TraMeXI project, registered in KCDB as EURAMET.RI(I)-S20.

3.4. Dosimetry laboratory survey

The laboratory survey gives an overview of the calibration capabilities and availability of calibration services in Europe covering 32 replies. Most of the respondents that participated in this survey perform dosimeter calibrations (94 %), and many respondents also perform verifications (34 %), testing (47 %) and type testing (31 %). Around half of the respondents perform research, and less than a quarter provide other technical services (e.g. inspection of X-ray facilities). According to the survey the users of services offered by these organizations come mostly from industry, medical services, national authorities, research institutions and accredited dosimetry laboratories. Only 13 participants have SSDLs as users. Some respondents have customers that manufacture X-ray systems (28 %) or ionizing radiation dosimeters (44 %).

Laboratories were asked about the range of established radiation qualities and the radiation qualities requested by their users and the overview is shown in Fig. 4. The survey has shown that the majority of laboratories maintain reference calibration fields defined in the IEC 61267 standard [17], which are also recommended in IAEA TRS 457 [4]. Almost all respondents (29 out of 32) established RQR radiation qualities. Almost half of the respondents use additional radiation qualities – in most cases, mammography radiation qualities with non-standard but clinically used target-filter combinations (e.g. Mo/Rh, W/Al, W/Mo, Rh/Rh, Mo/Al, etc.). In around a third of the laboratories (10) the established radiation qualities match the requests made by the users, a third (11) established more radiation qualities than requested, and a third (10) didn’t establish all the requested radiation qualities. For 7 out of 10 laboratories, the missing radiation qualities include mammography radiation qualities (usually RQR–M).

The survey also contained questions about dosimetric and other QC quantities. The overview of available calibration services and requested calibration services is presented in Fig. 5. Almost all of the respondents provide calibration services in terms of air kerma. Ability to perform calibration for HVL and different quantities for tube voltage measurements, is also widespread (it is not certain how many laboratories actually provide calibrations to end users). Calibrations in terms of other quantities are provided by very few laboratories – usually the laboratories set-up by the XMM manufacturers. The requests for calibrations in terms of air kerma match the laboratory capabilities very well. The requests for further quantities are not sufficiently met by the calibration laboratories. The largest difference is for exposure time and tube current time product. In both cases almost half of the laboratories receive requests for calibrations. If XMM manufacturers are excluded, only 4 (exposure time) and 2 (tube current time product) laboratories provide these services. Considering tube current and tube current time product measurements, the follow-on questions to the participating laboratories and manufacturers revealed that the currently available XMMs are not capable of measuring this quantity dosimetrically, but instead the measurements are performed either invasively or using special probes available that use the Hall Effect.

Further questions regarding HVL measurements were sent to 9 laboratories (no manufacturers), which are TraMeXI partners and collaborators. The answers showed that none of these laboratories currently offer HVL calibration services, despite evidence of client demand and the available technical capabilities to provide this service. Only one laboratory reported having an uncertainty budget for mammography HVL measurements.

When asked how the traceability for non-standard radiation qualities

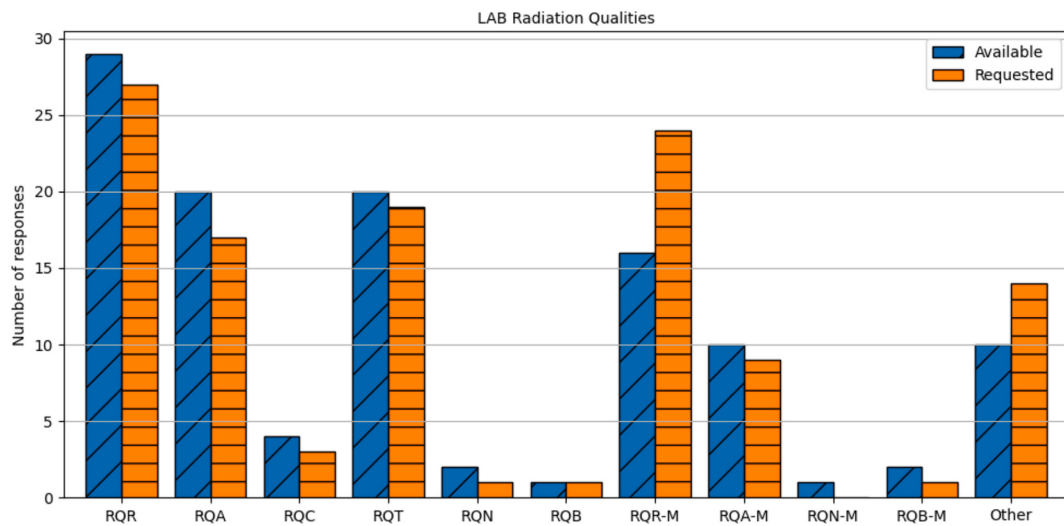


Fig. 4. Overview of established and requested radiation qualities.

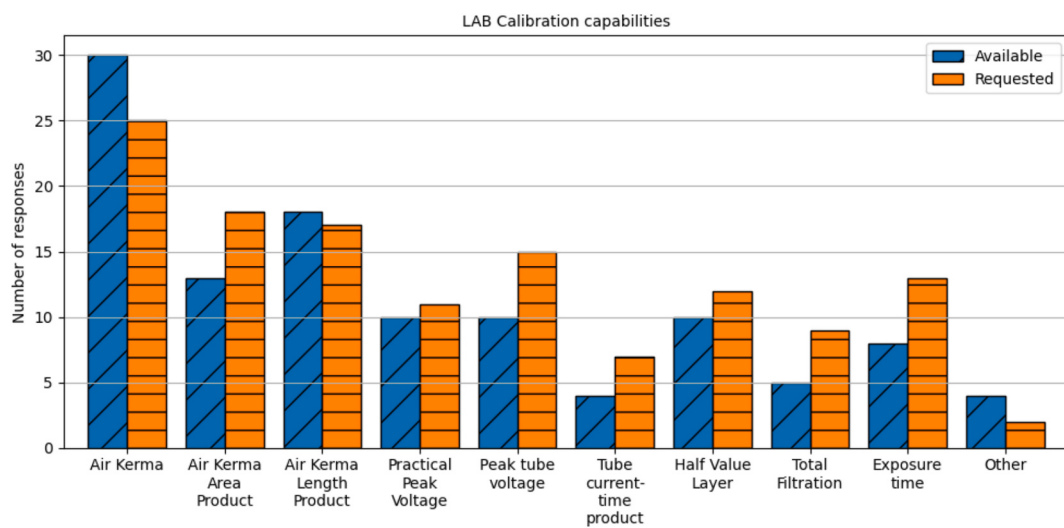


Fig. 5. Calibration capabilities and user requests broken down by the quantity.

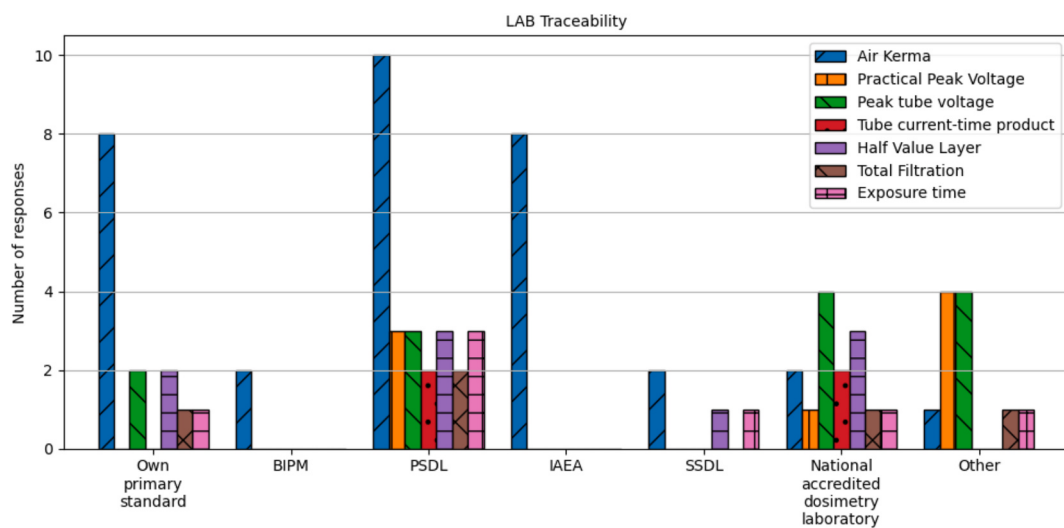


Fig. 6. Source of traceability for different quantities.

is achieved, 10 respondents said that they request specific calibration from a PSDL or another laboratory, 5 responded that they have their own primary standards and 7 respondents stated that they interpolate the values of calibration coefficients for reference instruments based on the available calibration coefficients for standard radiation qualities. Traceability is also established in different ways, depending on the quantity. The survey results are shown in the Fig. 6. All the respondents use ICs as reference instruments for air kerma. Only 3 respondents use XMMs as reference instruments for some quantities. Other measuring instruments are also used as reference instruments for some quantities, such as HV-dividers or non-invasive tube voltage measuring devices.

The respondents were also asked if there are any legal requirements for dosimeter calibration, verification or type testing in their respective countries. 17 respondents answered that there are legal requirements for calibration, 12 for verification, 7 for type testing and 4 that there are no requirements at all (multiple choices were allowed). Half of the respondents stated that the legal requirements vary based on the intended use of the dosimeter, and breakdown of the answers is given in Fig. 7. Calibration interval for reference dosimeters is either 2 years (8 respondents) or 5 years (3), while verification interval for reference dosimeters is 2 years (6 respondents) or 5 years (1). Field class dosimeters have different calibration intervals: 1 year (2), 2 years (5 respondents) or 5 years (1). Verification interval is 1 year (2 respondents), 2 years (for 8), 5 years (2) or 3 years (1).

4. Discussion

4.1. Standardization gaps

There are several standards and guides available for air kerma and tube voltage measurements and calibrations (section 3.1). There is a need to give further guidance on the use of different tube voltage quantities, and to create detailed calibration procedures, because only one calibration procedure was identified for practical peak voltage (in TRS 457), while other quantities are not covered [4].

Calibration procedures and standard requirements for other quantities that are measured by XMMs are not available yet, and in some cases, there is a lack of harmonized definitions to ensure consistency of calibration procedures. Even though the dosimetry laboratory survey showed that manufacturers offer calibration services for most of the quantities (Fig. 5), there is still a need for harmonized calibration procedures that can be used by other laboratories to perform calibrations independently or at least to perform verifications.

Some quantities that are relevant for calibration and testing of

diagnostic radiology dosimeters are also relevant for radiation protection dosimeters, e.g. tube voltage and HVL, and are also covered by the standards for radiation protection dosimeters [27]. The harmonization and standardization efforts for these quantities can benefit both areas of ionizing radiation metrology. To bring things forward in that area, there is an ongoing collaboration with another metrology project, 22NRM07 GuideRadPROS: Harmonisation, update and implementation of standards related to radiation protection dosimeters for photon radiation, as well as the European Metrology Network for Radiation Protection [32].

4.2. Needs for accuracy

Based on the medical physics survey (Figs. 1 and 2) and needs specified in the analyzed standards and technical documents, needs for accuracy and reproducibility for different measurement quantities provided by XMMs can be assessed. The uncertainty requirements are different for the measurements and tests that are done in calibration laboratories, which are related to dosimeter testing, development and calibration, and the clinical measurements, which are related to X-ray equipment testing in practical hospital settings. In case of clinical measurements, uncertainty of the calibration coefficient is only one component of the combined uncertainty. Other components may include XMM energy dependence, linearity, electromagnetic compatibility or the measurement setup. These components often dominate the uncertainty budget [4,10,17].

For technical measurements in calibration laboratories, e.g. to prove compliance with limiting values stated in standards, it is necessary that precision and reproducibility are clearly smaller than the tolerances. The required ratio of the measurement uncertainty and the tolerance is not clear cut. For example, in some metrology fields, a so called “golden rule of metrology” is used, stating that the uncertainty should be less than 10 % of the tolerance [33]. However, this ratio is often not achievable in dosimetry. Standard IEC 61674 that is used for dosimeter testing requires the uncertainty of air kerma to be less than 20 % of the relevant limit, and if the uncertainty is between 20 % and 50 % of the limit, it should be taken into account in the evaluation of the equipment performance [23]. The required uncertainty of tube voltage reference values is not defined in the IEC 61676 [26], but it is implied by stating that the overall uncertainty of 5 % is required for clinical measurements. There are also no official requirements or recommendations for other quantities. In general, it can be suggested that the resulting measurement uncertainty has to be smaller than the tolerance at least by a factor of two to five. The feasibility of achieving such uncertainties depends on the quantity. It is also necessary to select an appropriate decision rule,

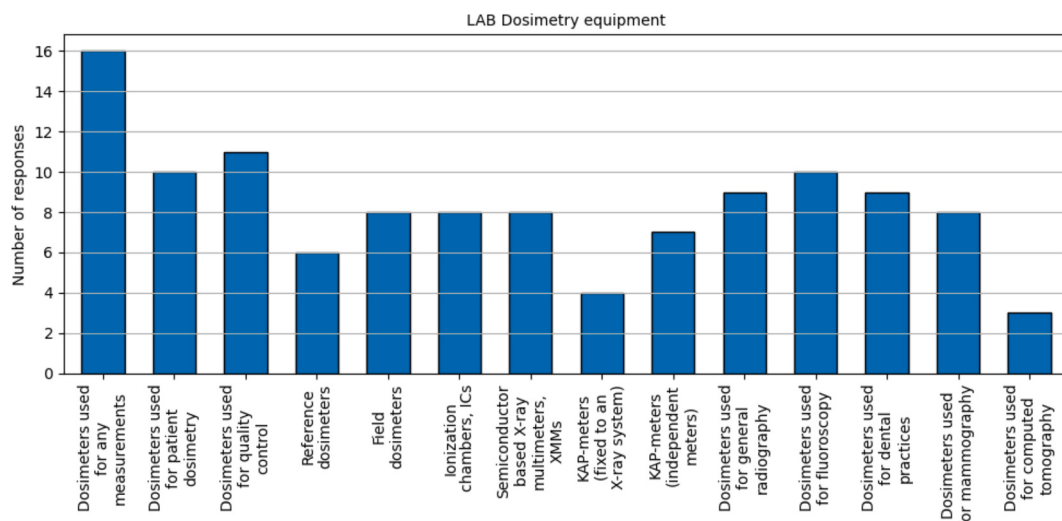


Fig. 7. Existence of legal requirements by dosimeter type and the intended use.

which will take into account the ratio of the measurement uncertainty and the tolerance. Some standards already define the decision rule, and general guidance is also available, e.g. in International Laboratory Accreditation Cooperation guide 8 [34].

In case of clinical measurements, the need for accuracy and precision of measurements depends on the clinical use of the measurement device. Based on the type of usage, applications with needs for high precision (acceptance tests, research, use as reference device) and applications with moderate needs (consistency tests, patient dose estimates) can be separated. In research, it is often necessary to measure small effects, and the uncertainties have to be small enough for the result to be statistically significant. For measurements of air kerma, a target uncertainty of 5 % ($k = 2$) and reproducibility of 1.5 % can be concluded for QC purposes [4,35]. For specific optimization and research purposes, better accuracy might be required. For tube voltage quantities the IEC 60601 series standards require accuracy of 8 % in general radiology and 5 % in mammography [28]. Therefore, the measurement uncertainty should be clearly lower. Based on the existing measurement capabilities, the target uncertainty of 2 % for accuracy and 1 % for reproducibility can be proposed, which is supported by some references [36–38]. For time related quantities (e.g. pulse length), 2 % uncertainty for accuracy and 1 % reproducibility are targeted for pulse lengths above 10 ms [35,39]. For HVL the target uncertainty depends on the use. If it is only used to check the permanent filtration, the accuracy requirement is relevant only for that specific measurement point. However, if the HVL is measured for example to calculate the mean glandular dose (MGD) in mammography [40], then the accuracy requirement might be stricter.

Currently, these needs are only partially addressed in corresponding standards and recommendations addressing requirements for measurement devices. Also, calibration services are not able to provide the calibrations for all quantities or at all the considered levels of uncertainty, as evidenced by the state of the art calibration capabilities (Section 3.3) and dosimetry laboratory survey (Fig. 5). Here, a compromise between technical feasibility, costs and clinical as well as research interests has to be found in the medical physics and metrology community. In addition to these device related uncertainties, the measurement setup related uncertainties are relevant and have to be addressed in corresponding guidelines, too, in order to achieve a sufficiently small total measurement uncertainty.

4.3. Calibration service gaps

The KCDB CMC database shows that metrology institutes provide traceability for air kerma for all standard and many non-standard radiation qualities, which allows establishing traceability chains. Uncertainties for air kerma/rate of 0.7 % to 0.8 % are reported by primary laboratories, while secondary laboratories can achieve uncertainties starting from 1 % [16]. However, all the CMCs with the uncertainties under 0.9 % were entered before ICRU-90 was adopted [31]. Around a half of the secondary laboratories have the uncertainty between 2 % and 3 %. The uncertainties in clinical air kerma measurements can never be below the value of the uncertainty of the calibration coefficients, provided by the calibration laboratories.

The laboratory survey has shown that most laboratories meet the requests of their users regarding the availability of radiation qualities (Fig. 4). There are certain gaps, but they are mostly related to mammography applications. It should also be noted that many users are not aware of all standard radiation qualities and their different uses, and that calibration conditions are often suggested by the calibration laboratories. Therefore, the real gaps in radiation qualities could be larger, especially for applications in research and development, where a larger range of radiation qualities and measurement conditions needs to be covered. Many laboratories do not establish standard mammography radiation qualities. Main reason is that standard radiation qualities use Mo/Mo combination of target material and filter, and require a separate X-ray tube, compared to the radiation qualities used for general

radiology and CT applications. This gap is not so easy to bridge, because of the significant investment needed in the equipment, and also related needs of laboratory space and radiation quality maintenance. On the other hand, there are many (and increasing) different combinations of target and filter material used in hospitals [18] and therefore some users request other specific radiation qualities from calibration laboratories.

Regarding the quantities, air kerma calibrations are widely available to the users, but there is a gap for all other quantities (Fig. 5). Most laboratories establish direct traceability for air kerma either to their own or to another primary standard, but for other quantities this is not the case. Ionization chambers are used as reference instruments for air kerma, but for other quantities, different types of reference instruments (including XMMs) are used by different laboratories (Fig. 6). Both surveys and the literature have shown that medical physicists measure many different XMM quantities and that they request calibrations for these quantities, but many laboratories can't provide the corresponding calibrations (Figs. 1, 2, 5). However, the measurements of different quantities are also required by national regulations in many countries (Section 3.2). For some quantities, more than half of the laboratories that provide calibrations are the manufacturers. It should be noted that most XMMs can't measure all quantities and not all medical physicists use them to measure all quantities, so a low percentage of calibrated XMMs for some quantity doesn't necessarily mean that users couldn't find a suitable calibration service.

There is also a problem of multiple quantities used for tube voltage measurements, which introduces the problem of traceability, but also introduces the confusion among some end users. The values of all the quantities that are commonly used are equal if a theoretical constant potential X-ray generator is used, but their values have finite differences with real generators. In extreme cases, the differences can be very large [4], but this is mostly related to older X-ray generators. Many quantities are often erroneously used interchangeably. The only quantity for tube voltage with standard requirements for non-invasive measurement devices is PPV [26] (i.e. not kVp), but relatively few end users use this quantity, as shown by both surveys (Figs. 1, 2, 5).

Even though the clinical survey shows that tube current and tube current time product are measured by some respondents (Fig. 1), responses by the manufacturers and calibration laboratories show that modern XMMs do not provide the possibility to measure them non-invasively by dosimetric methods, and that the corresponding calibration services do not fall into the scope of dosimetry calibration laboratories.

4.4. Calibration or verification and use of calibration coefficients

The results showed that there are many different requirements for dosimeter calibration, testing and verification in different European countries, and that there is no clear consensus about the best approach so far (Section 3.2, Fig. 7). The answers were contradictory in many cases when multiple responses were available for the same country (e.g. different medical physicists, or a medical physicist and a metrologist), showing that even the experts in the field do not always have clear understanding of the legal requirements. There is a clear need for better communication between regulatory bodies, calibration laboratories and the end users.

There is also a problem of inconsistent use of calibration coefficients in clinical conditions (Fig. 3). Calibrations are performed in standard radiation qualities, which in some cases differ from clinical radiation qualities [10,18]. Even if the exact conditions of calibration and use are known, it is often difficult to choose or interpolate calibration coefficients. XMMs often function as black boxes, using one or more calibration functions that are not known to the user [6,7]. Therefore, interpolations are not suitable in many cases. Other influence quantities can impact and complicate the use of calibration coefficients and the uncertainty calculations, such as dose rate, pulse length, field size, but also electromagnetic interferences, etc. [23,26].

XMMs in many cases use special software for data evaluation and the user does not have access to the “raw” data. Different settings may be available that influence the result of the measurement, either in the software or directly on the device. For example, the user can be requested to enter nominal tube voltage range, anode/filter material, total filtration, or to select calibration coefficient or detector. The settings may also be applied automatically by the device in some cases. Use of wrong settings introduces a smaller or larger systematic error (mostly unknown to the user), depending on the conditions and the detector, in some cases even larger than 15 % [6,7].

Calibration coefficients for XMMs should always be taken with great care, taking into account all the settings and the conditions during the calibration and the clinical use. Another influencing factor in mammography beams is introduced by the compression paddle, which is typically present in clinical beams, but often not during the calibration [11,12]. Considering the low photon energies in mammography spectra, this may have a clear effect on the measurement [11].

5. Conclusion

The results of the surveys have shown that a majority of clinical medical physicists measure additional quantities related to X-ray tubes and X-ray beams besides air kerma. The measurements are required by the national regulations in many European countries. On the other hand, calibration laboratories in many cases are not able to provide the whole range of requested calibrations. Some types of calibrations are performed almost exclusively by manufacturers. The situation is further exacerbated by the often complicated or non-transparent software used by XMMs, and some settings that can be accessed only by the manufacturers. There are standardization gaps for many quantities and for some quantities, not even harmonized calibration or testing procedures are available. There is also a lack of data on XMM performance for measurement of different quantities in clinical and laboratory conditions, and on the transferability of calibrations performed in laboratory conditions to clinical conditions. The requirements for calibration or testing measurement uncertainties are not clear for many quantities. In some cases, the uncertainties that are achievable are comparable with the tolerances or limits, making it hard to make decisions, especially in clinical measurements.

The results of this research will be used within the TraMeXI project to develop harmonized calibration procedures, which will be provided to IAEA, IEC and ISO, as well as the metrologist and medical physicist communities with the goal to improve the coverage of calibration services, shorten and improve traceability chains, improve the quality of measurements and improve the evaluation of measurement uncertainty.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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