# UPGRADING THE MEDICAL PHYSICS CALIBRATION LABORATORY TOWARDS ISO/IEC 17025: RADIATION STANDARDS AND CALIBRATION IN DIAGNOSTIC RADIOLOGY



**Asmaliza Hashim, Muhammad Jamal Md Isa, Abd Aziz Mhd Ramli, Wan Hazlinda Ismail, Norhayati Abdullah, Shahrul Azlan Azizan, Siti Sara Deraman, Nor Azlin Azraai, Md Khairusalih Md Zin**
Medical Physics Group, Radiation Safety & Health Division,
Malaysian Nuclear Agency (Nuclear Malaysia)
Bangi, 43000 Kajang, SELANGOR

**Abstract**

*Calibration of quality control (QC) test tools used in diagnostic radiology is legally required under the Ministry of Health (MOH) requirement. The Medical Physics Calibration Laboratory of the Malaysian Nuclear Agency is the national focal point for the calibration of quality control test tools used in diagnostic radiology. The Medical Physics Calibration Laboratory has measurement traceability to primary standard dosimetry laboratory (Physikalisch-Technische Bundesanstalt (PTB)), thus providing an interface between the primary standard dosimetry laboratory and Malaysian hospitals, clinics and license class H holder.*

*The Medical Physics Calibration Laboratory facility is comprised of a constant potential x-ray system with a capability of 160 kV tube and a series of reference and working standard ion chambers. The stability of reference and working standard ion chambers was measured using strontium-90. Dosimetric instruments used in diagnostic radiology is calibrated in terms of air kerma to comply with an International Code of Practices of dosimetry i.e. IAEA's Technical Report Series number 457. The new series of standard radiation qualities was established based on ISO/IEC 61267. The measurement of beam homogeneity was measured using film and ion chamber to define the field size at certain distance and kV output was measured using the spectrometer and non-invasive kVp meter. The uncertainties measurement was determined with expended uncertainties to a level of confidence of approximately 95% (coverage factor k=2).*

*This paper describes the available facility and the effort of Medical Physics Calibration Laboratory to upgrade the laboratory towards ISO/IEC 17025.*

**Abstrak**

*Tentukuran peralatan ujian kawalan mutu (QC) yang digunakan di dalam bidang radiologi diagnostik merupakan keperluan undang-undang di bawah bidang kuasa Kementerian Kesihatan Malaysia (KKM). Makmal Tentukuran Fizik Perubatan, Agensi Nuklear Malaysia merupakan pusat kebangsaan kepada tentukuran peralatan ujian kawalan mutu yang digunakan di dalam radiologi diagnostik. Makmal Tentukuran Fizik Perubatan mempunyai pengukuran kebolehkesanan kepada makmal dosimetri standard pertama (Physikalisch-Technische Bundesanstalt (PTB)), seterusnya meyediakan hubungan di antara makmal dosimetri standard pertama kepada hospital-hospital, klinik-klinik di Malaysia dan pemegang lesen kelas H.*

*Kemudahan Makmal Tentukuran Fizik Perubatan meliputi sistem sinar-x berpotensi malar dengan keupayaan tiub 160 kV dan siri kebuk pengionan rujukan dan bekerja piawai. Pengukuran kestabilan kebuk pengionan rujukan dan bekerja piawai adalah menggunakan strontium-90. Peralatan dosimetrik yang digunakan di dalam radiologi diagnostik ditentukur di dalam kerma udara untuk mematuhi Code of Practices dosimetri antarabangsa iaitu IAEA's Technical Report Series number 457. Siri baru standard kualiti sinaran telah dibangunkan berdasarkan kepada ISO / IEC 61267. Pengukuran keseragaman alur sinaran diukur menggunakan filem dan kebuk pengionan untuk menentukan saiz medan pada jarak tertentu dan output kV diukur menggunakan spectrometer dan non-invasive kVp meter. Pengukuran ketidakpastian telah ditentukan pada paras keyakinan 95% (faktor liputan k=2).*

*Kertas kerja ini membincangkan kemudahan sedia ada dan usaha-usaha yang dilakukan oleh Makmal Tentukuran Fizik Perubatan untuk menaik taraf makmal ini ke arah ISO/IEC 17025.*

**Keywords/Kata kunci:** Calibration, dosimetric instrument, radiation qualities

## INTRODUCTION

Calibration of quality control test tools used in diagnostic radiology is legally required under the Ministry of Health (MOH). The Medical Physics Calibration Laboratory of the Malaysian Nuclear Agency is the national focal point for the calibration of quality control test tools used in diagnostic radiology. The Medical Physics Calibration Laboratory has covered all the calibration of quality control test tools used in diagnostic radiology which are dosimetric instruments (dosemeter, doserate meter, dose area product (DAP) meter), kVp meter, exposure timer, densitometer as well as sensitometer. Since 1998, the calibration of dosimetric instruments was used the clinical x-ray machine Bennett High Frequency Model HFQ6000SE with the limited short exposure time and limited kV tube which is only up to 125 kV. In 2009, Medical Physics Calibration Laboratory has take the one step furthers to perform the calibration of dosimetric instruments followed the radiation quality established by the IEC 61267: Medical Diagnostic X-Ray Equipment – Radiation Conditions for Use in the Determination of Characteristics, 2005 and IAEA Technical Reports Series No. 457: Dosimetry in Diagnostic Radiology: An International Code of Practice, 2007. For that purpose, the Bennett High Frequency Model HFQ6000SE x-ray machine has replaced by the Constant Potential Philips Industrial Model MG165 x-ray machine with the capability of longer exposure time (maximum to 999 seconds) and kV tube up to 160 kV. The Medical Physics Calibration Laboratory also has established the international dosimetry measurement linkage through calibration traceability to the primary standard dosimetry laboratory which is traceable to Physikalisch-Technische Bundesanstalt (PTB), thus providing an interface between the primary standard dosimetry laboratory and Malaysian hospitals, clinics and license class H holder.

## CALIBRATION FACILITIES

### (i) Irradiation facilities

The calibration of dosimetric instruments used in diagnostic radiology requires appropriate irradiation facilities. The Medical Physics Calibration Laboratory has one irradiation room namely Bunker Fizik Perubatan to accommodate x-ray source and to perform calibration of dosimetric instruments. The dimension of the bunker was approximately 5.8 m x 8.5 m. The floor, walls and ceiling are concrete. The design of the bunker is in accordance with the relevant national and international safety regulations. The shielding of the bunker are sufficient to ensure that the radiation doses to the staff and the public a kept as low as reasonably achievable and that the given dose limits are not exceeded. The bunker is equipped with x-ray source and calibration bench running on a pair of rails to accommodate measurements at various distances from the sources hence calibrate the dosimetric instruments. The ionization chambers or dosimetric instruments are positioned on the calibration benches where they can be positioned at the required distances from the x-ray source. The calibration distance is determined using a laser. Laser alignments are also installed in the bunker to ensure that the ionization chambers or dosimetric instruments are placed in the centre of the radiation beam during the measurements. The bunker is also provided with appropriate safety equipment and accessories such as warning lights, warning sign as well as closed-circuit television (CCTV).

The new building for Block 32T will be completely ready on September 2010, new bunker for standard mammography calibration of dosimetric instruments used in mammography will be also set-up base on standard radiation quality IEC 61267. The dimension of the bunker was approximately 8 m x 5 m and the floor walls and ceiling are concrete. This standard mammography bunker will be equip with the mammography x-ray source and calibration bench to perform the calibration of mammography dosimetric instruments.

### (ii) Radiation sources

The Medical Physics Calibration Laboratory facility is comprised of the Constant Potential Philips Industrial Model MG165 with the capability kV tube up to 160 kV and 1 mm Beryllium inherent filtration used to generate IEC radiation qualities. This constant potential x-ray system was used for calibration of dosimetric instruments since year 2009 replaced the existence clinical x-ray system Bennett High Frequency Model HFQ6000SE. With the capability of the constant potential x-ray system, the standard radiation quality based on IEC 61267 was established from 40 kV up to 150 kV. It covers all the range of the application in diagnostic radiology.

For the calibration of dosimetric instruments in mammography, the clinical x-ray mammography machine, the Bennett Mammographic Unit Model MF-150G is currently used. With the limited short exposure time and limited kV tube range, the new mammography x-ray source with dual target molybdenum and rhodium will be procure in the short coming period to fulfil the needs for calibration of mammographic dosimetric instruments. The establishment of radiation quality for mammography also cannot be perform use the existing x-ray machine due to total filtration permanently installed at the tube.

Expectantly in the coming 2011, the calibration of dosimetric instruments used in diagnostic radiology including mammography will be completely follow the IEC 61267 standard radiation qualities.

(iii) **Dosimetric equipments**

For the purpose of the calibration of dosimetric instruments, two classifications of standard chambers were established. The first classification is reference standard chambers and the second classification is working standard chambers. The reference standard chambers are PTW Unidos Model T10005 S/N: 50403 with 1 cc ion chamber Model TN77337 S/N: 0074 and 112 cc ion chamber Model TN77335 S/N: 2015. The reference standard chambers are traceable to the Primary Standard Dosimetry Laboratory (PSDL) which is Physikalisch-Technische Bundesanstalt (PTB). The 1 cc ion chamber was cover the calibration of dosimetric instruments for RQR and RQT radiation qualities while 112 cc ion chamber was cover the calibration of RQA radiation qualities. The working standard chambers is Radcal Radiation Monitor Model 9010 S/N: 90-2021 with 6 cc ion chamber Model 10X5-6 S/N: 16310, 180 cc ion chamber Model 10X5-180 S/N: 17892, 3CT ion chamber Model 10X5-3CT S/N: 8575. The 6 cc ion chamber was cover the calibration of dosimetric instruments for RQR series, 180 cc ion chamber was cover the calibration of dosimetric instruments for RQA series and 3CT ion chamber was cover the calibration of dosimetric instruments for RQT radiation qualities. The dosimetric instruments used in diagnostic radiology is calibrated in terms of air kerma to comply with an International Code of Practices of dosimetry i.e. IAEA's Technical Report Series number 457.

## CALIBRATION OF DOSIMETRIC INSTRUMENTS USED IN DIAGNOSTIC RADIOLGY

Half value layer (HVL) and standard radiation qualities series

Starting from 2009, the new series of standard radiation qualities for RQR, RQA and RQT was established based on IEC 61267. The new series of standard radiation qualities are based on HVL, total filtration and kV tube. It is due to replacement of x-ray tube from Bennett High Frequency Model HFQ6000SE to Constant Potential Philips Industrial Model MG165. Unfortunately, for standard radiation qualities for mammography (RQR-M and RQA-M), the series is not established yet due do used of clinical mammography x-ray machine Bennett Mammography Model MF-150G with target and filter combination of molybdenum/molybdenum. The procurement of new mammography tube with dual target combination (molybdenum and rhodium) is currently done for calibration of dose for mammography and hopefully in 2011, the series of standard radiation qualities for mammography will be establish.

The HVL of the radiation beam is the thickness of an absorber that attenuates the measured quantity to one half of its initial value. The first HVL ($HVL_1$) is defined as the thickness of the specified material which attenuates the air kerma or air kerma rate in the beam to one half of its original value measured without any absorber. The second HVL ($HVL_2$) is is defined as the thickness of the specified material which attenuates the air kerma or air kerma rate in the beam to one quarter of its original value measured without any absorber. The ratio between $HVL_1$ and $HVL_2$ is termed the homogeneity coefficient, $h$. ($h = HVL_1/HVL_2$). The value of $h$ gives a certain indication about the width of the x-ray spectrum. Its value lies between 0 and 1 and with higher values indicating a narrower spectrum. Typical values of $h$ for beams used in diagnostic radiology are between 0.7 and 0.9.

A periodic check on the HVL of the beams is carried annually in order to verify that possible changes with respect to theoretical values do not exceed 3%. All the measurement of HVL of standard radiation qualities series was measured annually at 2009 and 2010.

Table 1: Radiation qualities for calibrations of diagnostic dosemeters

| **Radiation quality** | **Radiation origin** | **Material of an additional filter** | **Application** |
|---|---|---|---|
| RQR | Radiation beam emerging from x-ray assembly | No phantom | General radiography, fluoroscopy and dental applications (measurements free in air) |
| RQA | Radiation beam with an added filter | Aluminium | Measurements behind the patient (on the image intensifier) |
| RQT | Radiation beam with an added filter | Copper | CT applications (measurements free in air) |
| RQR-M | Radiation beam emerging from x-ray assembly | No phantom | Mammography applications (measurements free in air) |
| RQA-M | Radiation beam with an added filter | Aluminium | Mammography studies |

Table 2: Radiation qualities for RQR

| **Radiation quality** | **Tube potential (kV)** | **Additional filtration (mm Al)** | **HVL (mm Al)** |
|---|---|---|---|
| RQR2 | 40 | 2.6 | 1.41 |
| RQR3 | 50 | 2.7 | 1.78 |
| RQR4 | 60 | 2.9 | 2.18 |
| RQR5 | 70 | 3.1 | 2.58 |
| RQR6 | 80 | 3.2 | 3.00 |
| RQR7 | 90 | 3.5 | 3.47 |
| RQR8 | 100 | 3.7 | 3.96 |
| RQR9 | 120 | 4.1 | 5.00 |
| RQR10 | 150 | 4.8 | 6.58 |

Table 3: Radiation qualities for RQA

| **Radiation quality** | **Tube potential (kV)** | **Additional filtration (mm Al)** | **HVL (mm Al)** |
|---|---|---|---|
| RQA2 | 40 | 6.7 | 2.2 |
| RQA3 | 50 | 12.7 | 3.8 |
| RQA4 | 60 | 18.8 | 5.4 |
| RQA5 | 70 | 24.1 | 6.8 |
| RQA6 | 80 | 29.2 | 8.2 |
| RQA7 | 90 | 33.4 | 9.2 |
| RQA8 | 100 | 37.7 | 10.0 |
| RQA9 | 120 | 44.0 | 11.6 |
| RQA10 | 150 | 49.8 | 13.3 |

Table 4: Radiation qualities for RQT

| Radiation quality | Tube potential (kV) | Additional filtration (mm Cu) | HVL (mm Al) |
|---|---|---|---|
| RQT8 | 100 | 0.3 | 6.9 |
| RQT9 | 120 | 0.4 | 8.8 |
| RQT10 | 150 | 0.5 | 10.6 |

Table 5: Percentage different for $HVL_1$ compared to IEC 61267

| **Radiation Qualities** | **Tube potential (kV)** | **1st HVL (mm Al)** | | | | **Percentage different (%) compared to theory** | | |
|---|---|---|---|---|---|---|---|---|
| | | **Theory** | **2008** | **2009** | **2010** | **2008** | **2009** | **2010** |
| RQR2 | 40 | 1.42 | 1.45 | 1.44 | 1.41 | 2.11 | 1.41 | -0.70 |
| RQR3 | 50 | 1.78 | 1.79 | 1.78 | 1.78 | 0.56 | 0.00 | 0.00 |
| RQR4 | 60 | 2.19 | 2.18 | 2.15 | 2.18 | -0.46 | -1.83 | -0.46 |
| RQR5 | 70 | 2.58 | 2.54 | 2.60 | 2.58 | -1.55 | 0.78 | 0.00 |
| RQR6 | 80 | 3.01 | 2.96 | 3.00 | 3.00 | -1.66 | -0.33 | -0.33 |
| RQR7 | 90 | 3.48 | 3.40 | 3.45 | 3.47 | -2.30 | -0.86 | -0.29 |
| RQR8 | 100 | 3.97 | 3.96 | 3.95 | 3.96 | -0.25 | -0.50 | -0.25 |
| RQR9 | 120 | 5.00 | 5.00 | 4.90 | 5.00 | 0.00 | -2.00 | 0.00 |
| RQR10 | 150 | 6.57 | 6.60 | 6.60 | 6.58 | 0.46 | 0.46 | 0.15 |

Beam homogeneity

The measurement of beam homogeneity is intentionally to determine the field size at one metre chamber to focal spot distance for the various sizes of collimator. The measurement was performed using the ion chamber from the centre of focal spot point and moved left, right, up and down from the centre point of chamber position. The measurement of beam homogeneity was performed for the various sizes of collimator.

The radiographic film was also used to determine the field size for the various sizes of the collimator. The film was positioned at the centre of focal spot point with the different size of collimator and the image that appeared at the film was measured to determine the field size.

A periodic check of beam homogeneity is carried annually in order to verify the changes of field size.

Check source measurement

The regular measurements were done to check the stability of the reference and working standard chamber. The measurement was performed in term of check source measurement using the strontium-90 radioactive source with the half-life of 28.7 years. The check source measurement was performed in monthly basis for the all the reference and working standard chambers with the tolerance of 1 %.

Uncertainties measurement

The overall uncertainties of the calibration process are determined from combined effect of random ($U_A$) and systematic uncertainties ($U_B$). The type A standard uncertainty is based on any valid statistical method whereas type B standard uncertainty are based on scientific judgement using all relevant information.

The combined standard uncertainties here are the expanded uncertainties to a level of confidence of approximately 95% (coverage factor k = 2) taking into account the standard uncertainties of all influence quantities. The expanded uncertainty for the calibration of dosimetric instruments at the Medical Physics Calibration Laboratory was measured at 2.50 % with the confidence level of 95 %.

## ACCREDITATION OF LABORATORY

The Medical Physics Calibration Laboratory is established as the national focal point for the calibration of quality control (QC) test tools used in diagnostic radiology. To maintain the radiation dosimetry standard in accordance with an international standard, a comprehensive quality assurance programme based on ISO/IEC 17025 was adopted and implemented. The laboratory is being in process to seek the accreditation in the near future by the Department Standard of Malaysia (DSM) under the Laboratory Accreditation Scheme of Malaysia (SAMM) as a calibration laboratory for dosimetric instruments used in diagnostic radiology. The future accreditation will provide solid foundation for the Medical Physics Calibration Laboratory in strengthening and maintaining public and customers confidence in the measurements of ionizing radiation.

The accreditation of the Medical Physics Calibration Laboratory only cover the calibration of dosimetric instruments (dosemeter, doserate meter and DAP meter). The preparation for the accreditation involves two levels namely document preparation (quality manual, quality procedure and working instruction) and technical preparation that involves the preparation of the laboratory for calibration itself.

Series of discussion was conducted to prepare the documentation of Laboratory Quality Manual (LQM), Laboratory Quality Procedure (LQP) and Laboratory Working Instructions (LWI). The 15 management requirements and 10 technical requirements for LQM, 16 LQP and 20 LWI was prepared since January 2009 and completed at March 2010. The internal adequacy audit conducted by Quality Management Centre (QMC) was done at 23rd March 2010. Subsequence the internal audit was performed at 3rd May 2010 also conducted by QMC. The Management Review Meeting (MRM) was conducted at 26th May 2010 chaired by the Director of BKS to review the laboratory's quality management system and calibration activities and to ensure their continuing suitability and effectiveness, and also to introduce necessary changes or improvements. Finally the submission of the application form to DSM was done at 3rd July 2010.

## CONCLUSION

Calibration of quality control test tools used in diagnostic radiology is legally required under the Ministry of Health (MOH) requirement. As the national focal point for the calibration of quality control test tools, the Medical Physics Calibration Laboratory of the Malaysian Nuclear Agency is responsible to carried out calibration services in such a way to meet the requirements of SAMM accreditation and to satisfy the needs of the customer, the regulatory authorities and the requirements of ISO/IEC 17025.

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