The APLMF Guide

Guide to the application of ionizing radiation metrology in medicine under legal metrological system

Catalogue

1. Introduction

The Asia-Pacific Legal Metrology Forum (APLMF) is a regional and inter-government metrological technology organization, whose objective is harmonization of the regulations and rules applied by national metrological service, related organization and member economies and metrological supervision.。

The APLMF draft and guide are edited by the working group from member delegate. Some international and regional institutions could join editing if necessary.

The guide is edited in accordance with the general concept and regulations of ionizing radiation metrology in OIML and ISO publication. It refers to the general metrological requirements and regulations from other OIML publication as well as the fundamentals and application for measurements of ionizing radiation in ISO 11929-2010.

The objective of the guide is to provide the information for ionizing radiation metrology applicable to human's health and safety under the legal metrological system. The guide is edited by legal metrological working group of APLMF.

The APLMF publication is available to download from www.aplmf.org in PDF format.

2. Summary

2.1 The application of ionizing radiation in medicine field

Ionizing radiation has been widely applied in all walks of life, especially in medical treatment with longest history, widest spread and the greatest impact. Three branches have been formed including Medical X ray diagnosis, clinical nuclear medicine and radiation oncology. These medical radiation techniques have played a unique role in disease diagnosis and treatment and became indispensable component in modern medical science. Figure 1 shows the application of ionizing radiation in medical science.

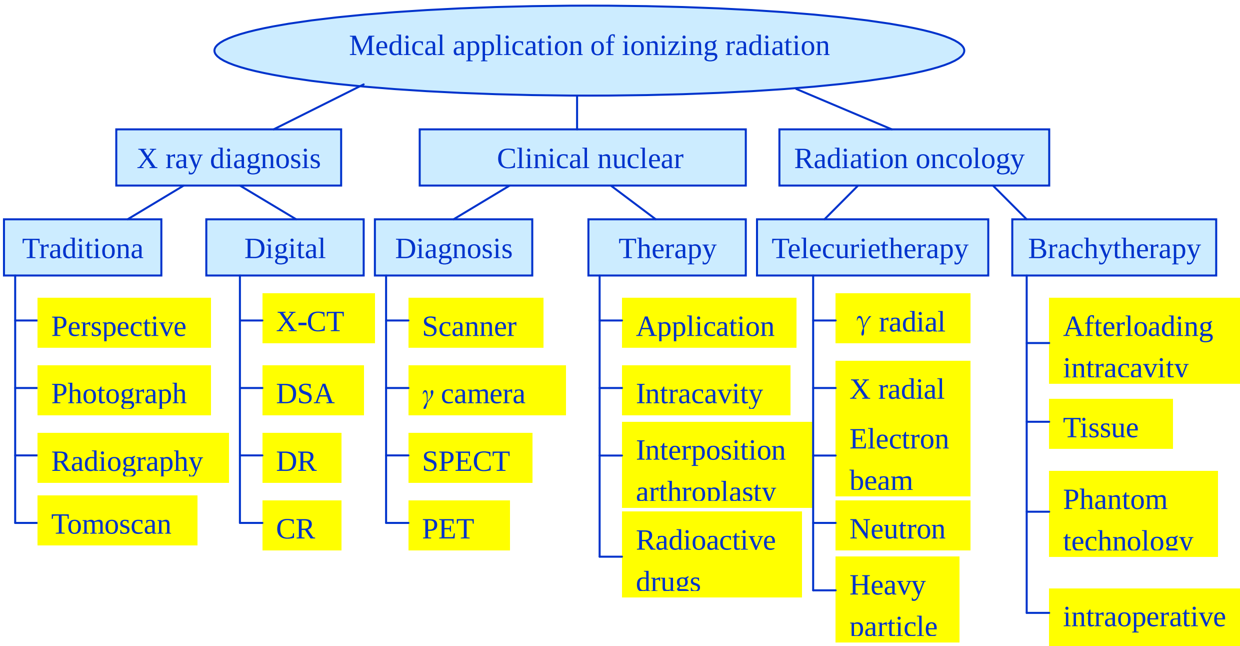


Figure 1: The application of ionizing radiation in medicine

Remark: X-CT: X-ray computed tomography; DSA: digital subtraction angiography; DR: digital radiography; CR: computed radiography; SPECT: Single-photon emission computed tomography; PET: positron emission tomography

2.2 The significance and development of ionizing radiation in medicine

With the development of economy and technology, the ionizing radiation plays a decisive role in diagnosis and treatment of modern medicine, especially the development of interventional radiology and seed source implanted treatment makes ionizing radiation application in medicine more widely. The X-ray was firstly used in medicine several months after discovered in November, 1895, which set a precedent to reveal the inner structure of human's living body. The discovery declared the arrival of modern medical physics era and the revolution of medicine.

After the new discipline-radiology emerged in the 20th century, it further developed into x-ray diagnosis and radiation oncology. The modern radiology not only shows its special advantage in disease diagnosis but also extends to interventional treatment with the development of biomedicine, materials science and other related technology.

The wide use of ionizing radiation in medicine is a remarkable and prominent achievement in the 20th century. It undoubtedly brings the huge profit to disease preventing and curing for human with the rise of interventional radiology and the flourishing development of three branches of medical radiology to the formation of imaging medicine. At the same time, the medical radiation exposure has become the biggest ionizing radiation source human suffering. How to use the ionizing radiation reasonably has drawn the high attention of each government and related international organization. The medical ionizing radiation prevention has been the increasingly distinct issue.

The ionizing radiation can result in cell death or damage when the radiation releases the energy in human organism. Under the long exposure of ionizing radiation with low doses, the human organism or partial organism could survive but finally it will cause high incident of cancer. High doses exposure will result in the cell death extensively. The impact of chronic radiation has: DNA transmutations, induced cancer, carcinoid, cataract, skin cancer, congenital disorder and etc., The radiation accident or special treatment will cause the acute radiation, which will result in acute radiation syndrome such as hemorrhage, bacterial infection, anemia, endocrine disease and etc., Besides these, it will result in cataract, cancer, DNA transmutations and etc., in the later period even death in the short time with extreme doses. Therefore, the radiation protection laws and regulations and metrology standard could not only make the biological effect of ionizing radiation use effectively and reasonably in the medical science but also protect the operators from radiation injury and ensure the patients with surrounding people healthy and safe as well as the coherence and credibility of quantity value in the radiation diagnosis and treatment.

The document's objective is to provide the guidance of ionizing radiation metrology in the medical application for the metrology service, hospital, radiation equipment manufacturers and other services under the legal metrological system. Even so, as the general guide, this document just provides the basic information. Users could refer to the details from other technical guide or standard edited by OIML、ISO、IAEA、IEC.

In order to promote the medical radiation techniques to make more benefit to human being, we should know and familiarize the performance of every types of medical radiation diagnosis and treatment equipment. We also should command the development trend of the radiation treatment physics and the related science so as to make more benefit and avoid harm. We take medical accelerator and CT as sample to introduce their development trend.

The medical accelerator is used widely in the medical treatment. Please see its development trend as follows,

1. The ray energy develops from low-energy machine to middle and high-energy machine.
2. Image guide radiation therapy-IGRT

The advantage of IGRT is accurate positioning, planning and exposure. The image guide and verification is the key point in the technique development of intensity modulated radiation therapy (IMRT).

3. Multi-dimensional conformal radiotherapy technique

The four-dimensional conformal radiotherapy technique is adding time concept based on the three-dimensional conformal radiotherapy technique. It mainly includes real-time radiotherapy and adaptive radiotherapy (ART), which will adjust the therapy in time according to the therapy effectiveness during the radiotherapy. The five-dimensional conformal radiotherapy technique includes the radiation biology of cancer and normal organism based on the four-dimensional conformal radiotherapy technique, which introduces the concept of biological target volume (BTV).

4. The research of BCRT

The BCRT will be accurate and highly efficient progressively through the BTV based on the biological image which gradually develops and target volume based on anatomy image.

With the sustainable development of CT technique, its clinical impact constantly rises. The types of CT could be divided into the following phases according to the X-ray technique development procedure: no slip ring CT, slip ring CT, spiral CT and MDCT. There will be X-ray Flat Panel Sensor in the near future. The development trend of CT has the following character:

1. Lower dose
2. Faster collecting and rebuilding
3. Better image quality

The guide just mentions the development trend of ionizing radiation instead of the guidance of technique and medical equipment in the medical science. The development of ionizing radiation in medical science is sure to push the development of ionizing radiation. However due to the particularity of the combination of ionizing radiation and medical science, it is especially important to hold the related activities according to this guide under the metrology system. In order to ensure the ionizing radiation measurement technique more reliable in human health and safety application in medical science, the staff must make research constantly.

3. Concept and Terms

The terms mentioned in the article are the same as the ones in the following documents:

International vocabulary of metrology - basic and general concepts and associated terms (VIM)

International vocabulary of terms in legal metrology (VIML)

Related ISO and OIML publications

3.1 The concept of ionizing radiation metrology

Ionizing radiation is electromagnetic radiation or particle radiation which directly or indirectly make article produce radiation(cause radiation by making article produce ionizing),e.g. X-rays, Alpha particles, Gamma rays, cosmic rays and neutron rays.

3.2 Metrological traceability

Metrological traceability is defined as "the property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons, all having stated uncertainties." The level of traceability establishes the level of comparability of the measurement: whether the result of a measurement can be compared to the previous one, a measurement result a year ago, or to the result of a measurement performed anywhere else in the world. Every measurement result has contribution to the uncertainties.

3.3 Legal metrological control

To ensure all the legal metrology activities accurate and effective

The legal metrological control includes:

3.3.1 Legal control of measuring instruments

3.3.2 Metrological supervision

3.3.3 Metrological expertise

Remark: D9 in OIML publication involves the details of the above mentioned concepts.

3.4 The legal metrological management of medical ionizing radiation equipments

3.4.1 Medical radiation source

Medical X-ray machine, CT machine, Co-60 teletherapy unit, medical accelerator and etc., are the medical equipment to diagnose the patients through the physical quantity value provided by the radiation source.

3.4.2 The legal metrological control of the medical ionizing radiation measuring instrument

The medical ionizing radiation measuring instruments are the medical equipments with medical radiation source. Its principle is using the ionizing radiation to measure the human's physical and pathology to make sure the energy output. The ionizing radiation measuring instrument aims to diagnose and treat the patients through the quantity value from control equipment. If the output quantity value's MPE could not meet with the requirement, we could not make sure the position of lesion and the accuracy of lesion physical dimension. Even it will cause the serious injury to the patient's body. If the patients are irradiated by overdose ionizing radiation, the DNA transmutations, cancer and so on will arise and if the dose of ionizing radiation can not achieve therapy level, the disease will be delayed.

Therefore the physical quantity value from the medical ionizing radiation measuring instrument is correct or not is the foundation for the hospital quality guarantee system. Meanwhile it is the main technique guarantee of the legal rights and interests for the patients and doctors.

In order to provide the measuring guarantee to the medical ionizing radiation measuring instrument, we should unify the dose quantity value to make sure the traceability of medical ionizing radiation dose quantity value. We must make the legal metrological control of the medical ionizing radiation measuring instrument. Each economies member should have the related laws to control the medical ionizing radiation measuring instruments.

4. Standards, measurement methods and quantity value traceability

The CT and electron accelerators are taken as typical examples which develop relatively maturely in the diagnosis and treatment to offer the information of the application of the ionizing radiation metrology in the medical science under the legal metrology system.

4.1 Standards

4.1.1 International measurement standards of CT

IAEA Technical Reports Series No. 457 Dosimetry in Diagnostic Radiology: An International Code of Practice.

ASTM E1441-2011 Standard Guide for Computed Tomography (CT) Imaging.

ASTM E1570-2011 Standard Practice for Computed Tomographic (CT) Examination.

ASTM E1672-2006 Standard Guide for Computed Tomography (CT) System Selection.

ASTM E1695-1995(2006)e1 Standard Test Method for Measurement of Computed Tomography (CT) System Performance.

ASTM E1935-1997(2008) Standard Test Method for Calibrating and Meausring CT Density.

4.1.2 International measurement standard of accelerator

IAEA Technical Reports Series No. 398 Absorbed Dose Determination in External Beam Radiotherapy: An International Code of Practice for Dosimetry based on Standards of Absorbed Dose to Water.

IAEA Technical Reports Series No. 277 Absorbed Dose Determination in Photon and Electron Beams.

IEC 60601-2-1-2009 Medical electrical equipment-Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV.

IEC 60976-2007 Medical electrical equipment-Medical electron accelerators Functional performance characteristics.

IEC TR 60977-2008 Medical electrical equipment-Medical electron accelerators -Guidelines for functional performance characteristics.

4.1.3 Safety and protection standards

Basic Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources （IAEA Safety Series No. 115，year 1996 version）

This standard guarantees the health safety and medical quality of the staff and public, involving people, equipment, site, environment and etc., to make sure the ionizing radiation safe and effective application in the medicine for maximum under the system.

4.1.3.1 Ionizing radiation metrology management about patients received

The method for measuring and calibrating radiation dose caused by the radiation diagnosis or treatment equipments in use process is needed concerning ionizing radiation metrology management of patients, including definition of related radiation dose index or parameters.

Venders should provide typical radiation dose, conversion factor as well as the maximum deviation caused by different systems to users corresponding to different application situations in accordance with the existing industry standards and regulations, therefore the users can determine the ionizing radiation dose accurately in the error range to control the ionizing radiation level the patients suffer by making reasonable scan parameters on the basis of assuring diagnostic and therapeutic demand.

Representative parameter to describes the dose for CT is CTDI (Computed Tomography Dose Index) which is widely used in quality control, dose survey and so on, its definitions, test conditions and test methods should conform to the relevant international or local laws and regulations such as:

IEC 60601-1-3: Medical electrical equipment- Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment

IEC 60601-2-44 Medical electrical equipment-Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography

CFR 1020.33 Performance Standards for Ionizing Radiation Emitting Products

For medical accelerators can refer to ASTM F526-2011 Standard Test Method for Measuring Dose for Use in Linear Accelerator Pulsed Radiation Effects Tests

4.1.3.2 Ionizing radiation metrology management about employees

Individual radiation dose of related occupation personnel should be monitored and managed from protection point of view, including the measurement and calibration of individual dose, setting and monitoring of exposure limit and etc. For users, scanning (exposure) parameters should be set in accordance with ALARA (as low as reasonably achievable) principle. Related detection methods and exposure limits should comply with international and regional legislation, usually mandatory regulations and monitoring mechanism which can be implemented should be established, according to the nature of the work different annual radiation dose exposure level and measuring instruments of personal radiation dose should be set, all personal dosimeters and measuring equipments should be incorporated into the legal metrology system.

4.2 Measurement items and methods

4.2.1 Measurement items and methods of CT

The main metrological performance of CT requires: the accuracy of the tube voltage, the accuracy of the tube current, output radiant matter, dose index , well-distribution, the level of the noise, CT index, the depth, the low contrast resolution, the spatial resolution and etc.,. The main testing instrument has: integrator with penciled ionization chamber, clamp multi-meter, standard aluminum sheet or half-value layer measuring instrument, dose phantom of head, dose phantom of abdomen and other measuring instrument. The detail of testing method refers to the related international measurement standard in 4.1.1.

4.2.2Measurement items and methods of medical accelerator

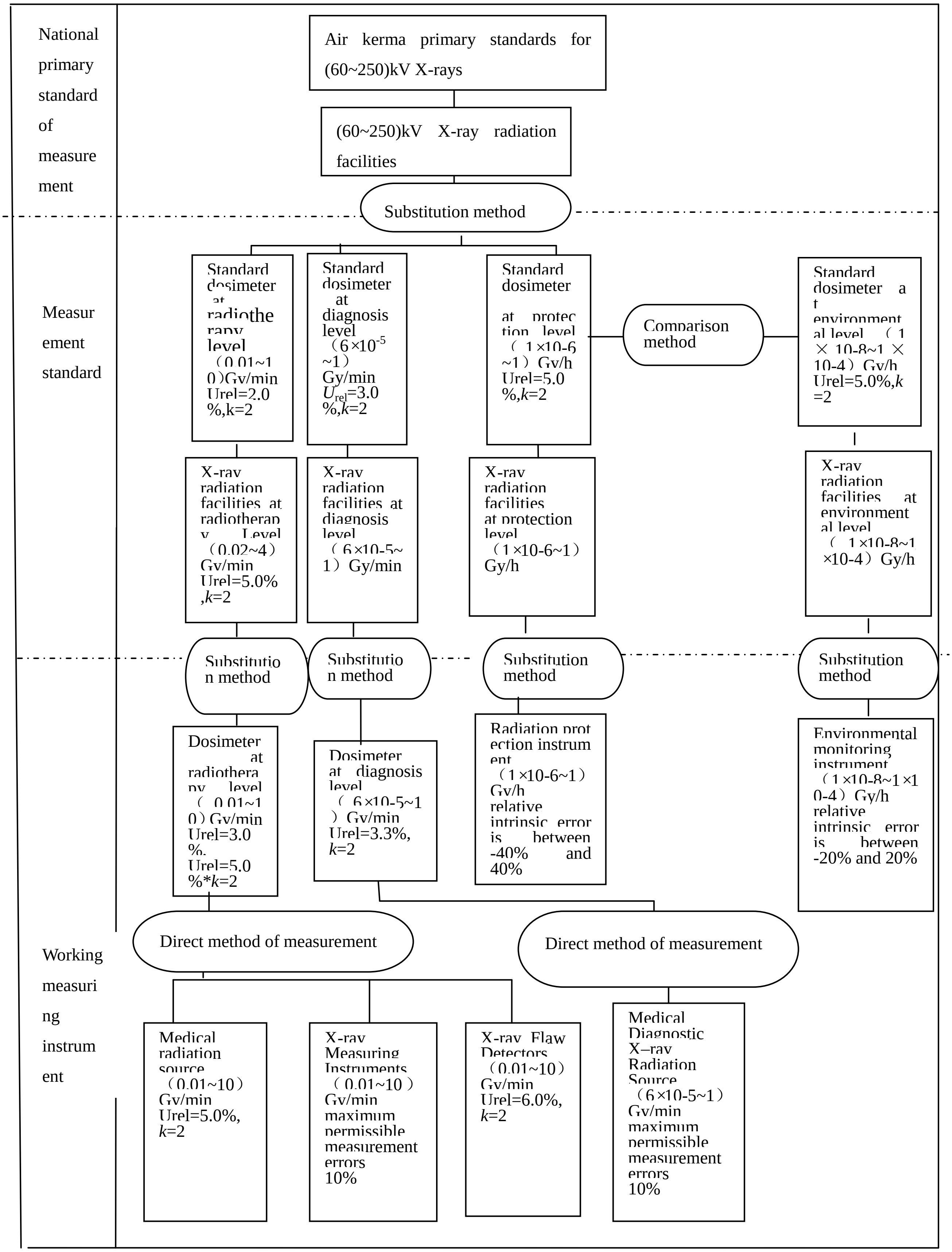
4.2.2.1 The main metrological performance of medical accelerator X radiation source includes: X-ray radiant matter, the flatness of X-ray radiation field, the coincidence of X-ray radiation field and light field, the symmetry of X-ray radiation field, the repetitiveness of X-ray dose indication, the linearity and the error of X-ray dose indication and etc.

4.2.2.2 The main metrological performance of the medical accelerator electron beam radiation source includes: the electron beam radiation matter, the flatness of the electron beam radiation field, the symmetry of electron beam radiation field, the repetitiveness of electron beam dose indication, the error of X-ray dose indication and etc.

4.2.2.3 The main testing instrument of medical accelerator has: ionizing radiation dosimeter used in treatment, measuring phantom, radiation profiler. The detail of testing method refers to the related international measurement standard in 4.1.2.

4.3 Metrological traceability of relative instruments' quantity value

Figure 2 and figure 3 demonstrate traceability figures for metric instruments of (60～250)kV X ray air kerma and γ ray air kerma (the traceability of CT and medical accelerator correspond to the traceability of diagnosis radiation source in figure 2 and therapy radiation source in figure 3 respectively, the following traceability figure just take china as example, all economies should take the circumstances into consideration).



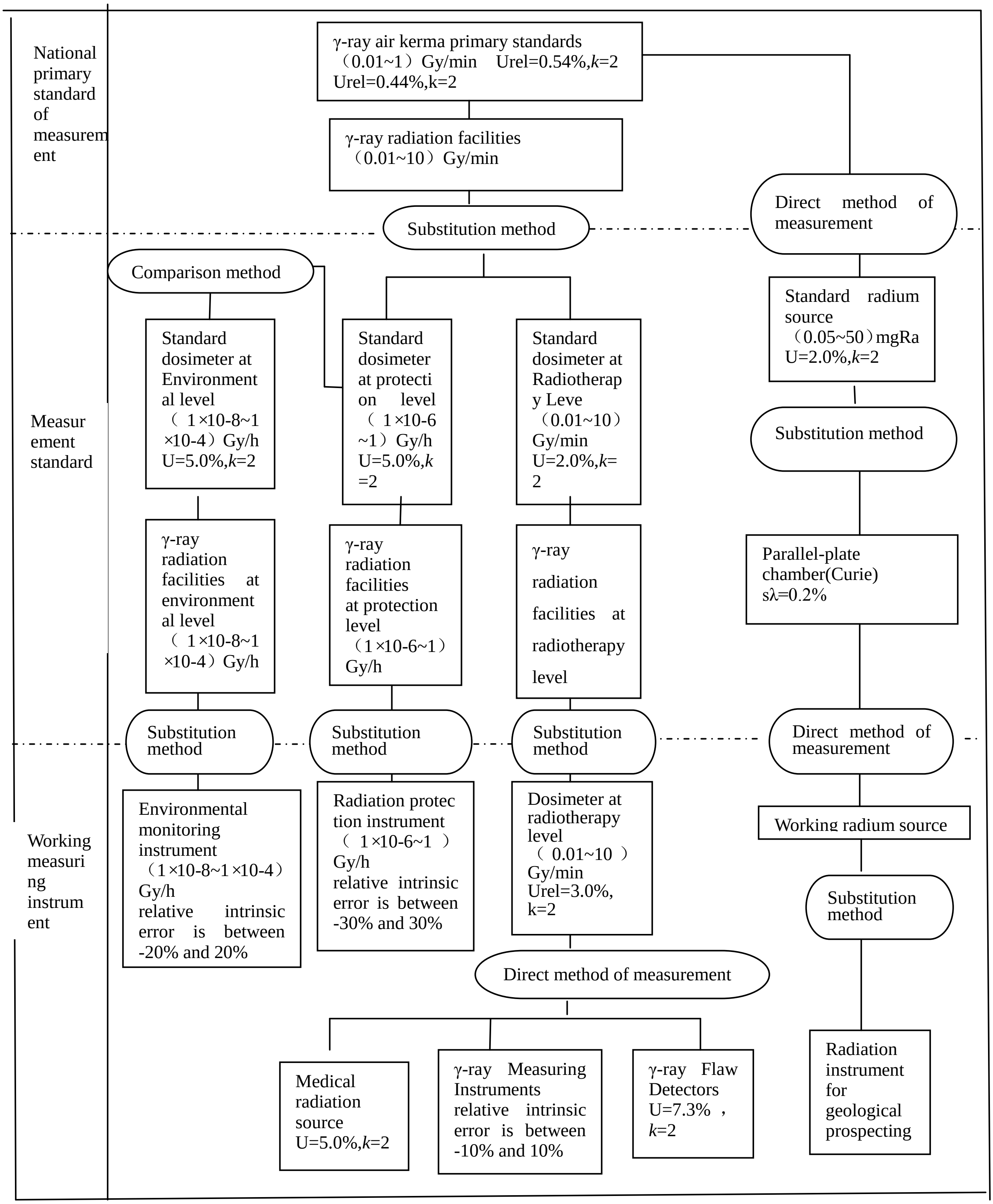
Note: *The expanded uncertainty of dosimeter at radiotherapy used in verification of X-ray radiotherapy facilities is U, U≤3.0%. The expanded uncertainty of dosimeter at radiotherapy used in verification of X-ray Flaw Detectors and other instruments is U, U≤5.0%.

The instruments invented recently or having a different name might be not included in this verification scheme.

The dissemination of the value of these measuring instruments should be performed properly according to the measurement range and working principle of them, referring to working principle and measurement range of measuring instruments included in this verification scheme .

Medical diagnostic radiation source refers to X ray diagnostic equipments, the X ray dosimetry produced by them can be traced to national benchmark for (60～250)kV X ray air kerma through diagnostic dosimetry meter

Figure 2. Traceability figure for metric instruments of (60～250)kV X ray air kerma



Note: The instruments invented recently or having a different name might be not included in this verification scheme. The dissemination of the value of these measuring instruments should be performed properly according to measurement range and working principle of them, referring to working principle and measurement range of measuring instruments included in this verification scheme.

Medical therapeutic radiation source refers to medical accelerators, the X ray and electron beam dosimetry produced by them can be traced to national benchmark for γ ray air kerma through therapeutic dosimetry meter.

Figure 3. Traceability figure for metric instruments of ***γ*** ray air kerma

5. Requirements for testing laboratory

The testing laboratory should meet the General requirements for the competence of testing and calibration laboratories (ISO/IEC17025:2005). All the calibration and testing laboratories could adopt and implement the ISO17025 standard. According to the international practice, the data provided by the laboratories passing the ISO17025 standard should have the legal effect and get the international ratification.

ISO17025 standard mainly includes the management requirement and technical requirement. The management requirements include organization, management system, document control, review of contracts, subcontracting and etc. The technical requirements mainly include personnel, equipment, accommodation, test methods and validation, measurement traceability and etc. The core of this standard is equipment and standard material, quantity value traceability and calibration, the method of calibration and testing, sampling. The point of above mentioned is to evaluate whether the laboratories' calibration and testing ability could reach the expected requirement.

How to utilize the ISO/IEC17025 to evaluate the testing laboratories refers to OIML International Document D 30 Guide for the application of ISO/IEC 17025 to the assessment of Testing Laboratories involved in legal metrology. The special requirement for the ionizing radiation testing laboratories refers to OIML International Document D 21 Secondary standard dosimetry laboratories for the calibration of dosimeters used in radiotherapy.

Annex A

Bibliography

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A.2 OIML International vocabulary of terms in legal metrology (VIML), 2000

A.3 OIML International Document D 1, Elements for a Law on Metrology, 2004

A.4 OIML International Document D 9, Principles of metrological supervision，2004

A.5 OIML International Document D 16，Principles of assurance of metrological control，2011

A.6 OIML International Document D 30 Guide for the application of ISO/IEC 17025 to the assessment of Testing Laboratories involved in legal metrology

A.7 OIML International Document D 21 Secondary standard dosimetry laboratories for the calibration of dosimeters used in radiotherapy

A.8 OIML International Recommendation R 131 Polymethylmethacrylate (PMMA) dosimetry systems for ionizing radiation processing of materials and products

A.9 OIML International Recommendation R 132 Alanine EPR dosimetry systems for ionizing radiation processing of materials and products

A.10 ISO 11929-2011 Determination of the characteristic limits (decision threshold, detection limit and limits of the confidence interval) for measurements of ionizing radiation - Fundamentals and application

A.11 ISO 361-1975 Basic Ionizing Radiation Symbol-First Edition

A.12 ISO/ASTM51261-02 Standard Guide for Selection and Calibration of Dosimetry Systems for Radiation Processing