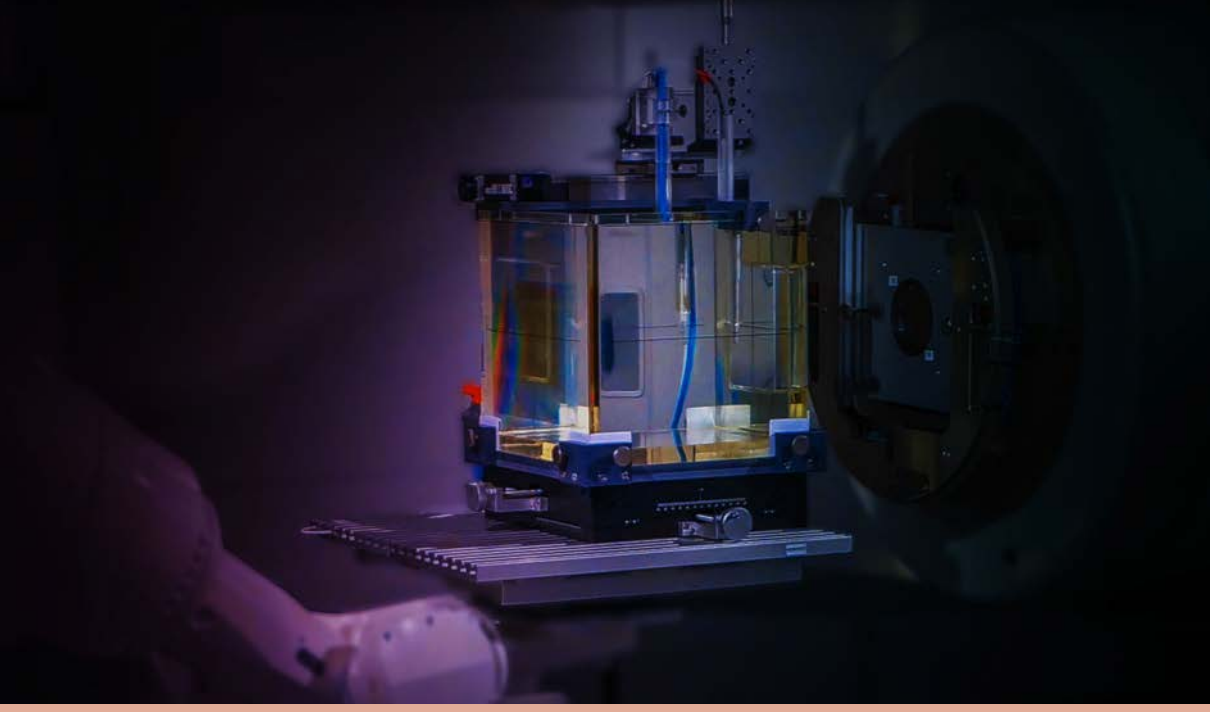

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No. 44

Establishing a Secondary Standards Dosimetry Laboratory

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ESTABLISHING A SECONDARY STANDARDS DOSIMETRY LABORATORY

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IAEA HUMAN HEALTH SERIES No. 44

ESTABLISHING A SECONDARY STANDARDS DOSIMETRY LABORATORY

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FOREWORD

Accurate measurement of the radiation dose received by patients being treated by radiotherapy or undergoing medical imaging is essential for ensuring effective and safe health care. Accurate measurement of radiation dose is equally essential to guide employers in the steps needed to protect their workforce from the harmful effects of ionizing radiation.

Many countries have established specialist centralized laboratories (secondary standards dosimetry laboratories (SSDLs)) to calibrate dosimeters and provide guidance for end users in hospitals and in industry. Some countries have national metrology institutes that hold primary standards for radiation dosimetry; calibrations at SSDLs are traceable to these primary standards, ensuring worldwide consistency of measurements.

Establishing an SSDL requires specific knowledge and skills. The aim of this publication is to provide detailed technical guidance on designing and operating an SSDL. This publication is also intended to help countries that are considering enhancing and augmenting the services offered by an existing SSDL.

A network of secondary standards dosimetry laboratories was established in 1976 by the IAEA and the World Health Organization (WHO). This network is known as the IAEA/WHO SSDL Network. The SSDL charter that explains the privileges, rights and duties of members in the network was originally published in 1999 and a second edition was published in 2018. The first edition contained some technical details for the establishment of an SSDL and the second edition covers the compulsory requirements for the SSDL to become a member of the network. Consequently, the scientific committee, which advises the network secretariat, has recommended that the IAEA develop and publish more specific, detailed guidance for establishing an SSDL.

Several laboratories in the SSDL network have been established or upgraded through the IAEA technical cooperation programme. The assistance provided by the IAEA includes coordinating the SSDL staff training, writing specifications and procuring equipment, reviewing sites for building an SSDL, and many other SSDL related activities. In addition, the IAEA has its own dosimetry laboratory, which is the central laboratory of the SSDL network.

This publication explains different aspects and steps of the process to establish an SSDL. Decision makers can follow the guidance in this publication in implementing a feasibility study in the initial planning process, and in estimating the cost and timelines of an SSDL establishment project. The technical descriptions and guidelines may also be helpful for SSDL radiation metrology staff when planning new calibration facilities or purchasing new equipment. In addition, this publication can be used as training and reference material for radiation metrologists.

The IAEA officer responsible for this publication was P. Toroi of the Division of Human Health.

CONTENTS

1. INTRODUCTION

1.1. BACKGROUND

Accurate radiation dose measurements are needed for the health and safety of the population in every country in which ionizing radiation is used [1]. Measurements are performed to determine the dose to patients, staff and the public. IAEA Safety Standards Series No. GSR Part 3, The Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [2] states that "the calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory".

The need for traceability for radiation dose measurements is highlighted in the medical use of radiation, particularly in radiation therapy, where successful treatment depends critically on the accuracy of dose delivery to the patient [3, 4]. When considering radiation protection of patients undergoing diagnostic radiology or nuclear medicine procedures other than radiation therapy, the uncertainty in the dosimetry may be greater, but the traceability of the measurements with a defined level of uncertainty is equally important [1, 5, 6].

GSR Part 3 [2] specifies dose limits for occupational and public exposure and requires the use of appropriate calibrated monitoring equipment for estimating or measuring this exposure. Traceability at a defined level of uncertainty is still essential for radiation protection purposes, although this uncertainty may be much greater than that in medical applications [2]. All of these applications relate directly or indirectly to human health, emphasizing the importance of the traceability of dosimetry measurements to avoid an unintended detriment to individuals [1].

A standards dosimetry laboratory has a key role in disseminating accurate and traceable dosimetry. Each country is to maintain either a national measurement standard for the relevant quantities or make arrangements for access to such standards that are established and maintained in another country [1]. Such standards are to be traceable to the International System of Units (SI[1]) and may be either a primary standard maintained at a primary standards dosimetry laboratory (PSDL) or a secondary standard maintained at a secondary standards dosimetry laboratory (SSDL) [1].

An SSDL can be traceable to the SI in diverse ways (Fig. 1). Many SSDLs are traceable to primary standards through the IAEA laboratory in Seibersdorf, Austria. Other SSDLs arrange for their standards to be calibrated at a PSDL. International consistency of measurements is assured by regular comparisons of the primary standards themselves to the high accuracy standards held at the

[1] A list of the abbreviations used in the text is given at the end of the publication.

Bureau International des Poids et Mesures (BIPM); some SSDLs use the BIPM's calibration services, which are based on these standards [7].

This international measurement system falls under the auspices of the International Committee for Weights and Measures (CIPM), which was established by the Metre Convention in 1875 [8]. In 1999, the CIPM agreed to a mutual recognition arrangement (the CIPM MRA), which allows the eligible PSDLs and SSDLs to obtain international recognition for their calibration and measurement capabilities (CMCs) [9, 10]. To achieve international recognition within the CIPM MRA, a country has to have ratified the Metre Convention and signed the CIPM MRA, and its laboratory has to have participated in relevant interlaboratory comparisons and demonstrated that its quality management system (QMS) is in line with the ISO/IEC 17025:2017 standard [11] or its updates. Regional metrology organizations (RMOs) are regional associations of national metrology institutes [1]. They organize interlaboratory comparisons within the framework of the CIPM MRA and carry out other actions designed to support mutual confidence in the validity of calibration and measurement certificates issued by participating institutes [9, 10].

In 1976, the IAEA, together with the World Health Organization (WHO), established a network of SSDLs, known as the IAEA/WHO SSDL Network [1]. The SSDL Network and the international measurement system offer a pathway for a Member State to establish an SSDL to help ensure that measurements of radiation doses are carried out with an accuracy that is fit for purpose and ultimately to obtain formal international recognition for this work.

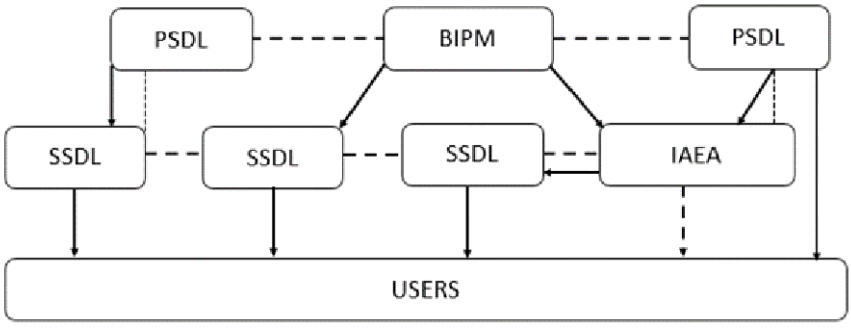

FIG. 1. A simplified representation of the international measurement system for radiation dosimetry. The arrows represent the calibrations that ensure the traceability chain to the international measurement standards and the dotted lines represent comparisons of primary and secondary standards. The dashed arrow represents exceptional calibrations of user instruments by the IAEA in the event that a country has no SSDL and has very limited resources. Adapted from Ref. [1].

1.2. OBJECTIVE

The role of an SSDL is to provide its users with a link to the international measurement system through its calibration services. In addition to traceable calibrations, SSDLs disseminate information, experience and expertise in metrology, dosimetry and calibration procedures. Some SSDLs also provide dosimetry audit services to check the implementation of dosimetry procedures in hospitals and/or personnel dosimetry programmes.

The difference between a PSDL and an SSDL lies in the way each determines the reference quantity used for calibration purposes. An SSDL uses a reference secondary standard instrument together with calibration coefficients that are provided by a PSDL. A PSDL, having a primary measurement standard for a given dosimetry quantity, establishes the quantity based on fundamental physical principles and can determine this without reference to any other instrument that measures the same quantity. Establishment of primary dosimetry standards is not covered in this publication. However, regardless of the difference in the determination of the reference values, the facility, equipment and calibration procedures of PSDLs and SSDLs are similar, and the guidelines given in this publication could also be applied in PSDLs. The definitions of primary and secondary standards are clear, but the naming of the laboratory is not always as straightforward. Some laboratories might hold both primary and secondary standards and some countries use different names for their SSDLs (e.g. accredited dosimetry calibration laboratories in the United States of America). However, the term SSDL has been used throughout this publication.

Guidance provided here, describing good practices, represents expert opinion but does not constitute recommendations made on the basis of a consensus of Member States.

1.3. SCOPE

An SSDL provides calibration services and issues calibration certificates that include, among other information, the calibration coefficients, the estimated measurement uncertainties and the traceability route. Accurate and precise measurements are fundamental for calibration work and uncertainty estimation in a laboratory supported by a quality management system. These also contribute to the laboratory achieving international recognition for calibration capabilities.

The SSDL Charter sets forth the minimum criteria to be met when a Member State wishes for its national SSDL to be accepted for membership in the IAEA/WHO SSDL Network [1]. However, only the general guidelines are presented in the charter (e.g. that the SSDL is to have appropriate human

resources, facilities, equipment, calibration services and a QMS). Technical guidelines on how to establish the SSDL are provided in this publication.

An SSDL can provide a variety of calibration services. The range of calibration services planned has a significant impact on any project to establish an SSDL, especially on the design of shielded rooms (bunkers), and therefore the possible future need to expand services is to be carefully considered when siting and designing the facilities. This publication concentrates on those calibration services that are widely used. A typical SSDL provides calibrations for measuring instruments used in radiation protection, diagnostic radiology and/or radiation therapy, or a combination of these services. These calibration services are performed in specialized irradiation rooms (bunkers) and beams, including irradiators and positioning systems.

Other calibration services, such as dosimeter calibrations in neutron fields, linear accelerators, beta radiation beams, and calibration of dose calibrators (activity meters) used in nuclear medicine, are not covered in this publication. For neutron and linear accelerator calibrations, specialized facilities are used. On the other hand, calibrations of contamination meters are provided by several SSDLs and for this service no specialized facilities are used. For radiation protection calibration services, some guidelines can be found in Safety Reports Series No. 16 [12].

SSDLs may also provide other services in addition to calibrations. Many SSDLs provide reference irradiations for personal dosimeters and dosimetry audit services for hospitals. These services do not require modifications to the SSDL infrastructure. Therefore, they are not a focus of this publication.

In addition to requirements related to recognition of its services, an SSDL has to comply with all safety and security requirements imposed by national regulations. All necessary licences for import, export, transport, storage and use of radioactive sources are to be obtained, according to the national radiation protection legislation and authorization processes. This publication provides guidelines on what to consider for safety and security and other requirements that are needed by the regulatory authorities.

1.4. STRUCTURE

The present publication is aimed at supplementing the guidelines given in the SSDL Charter by providing detailed technical information for the establishment of an SSDL. Establishing an SSDL is a lengthy process and involves different steps [1]. This publication provides information about establishing an SSDL, starting with the initial planning in Section 2 and staffing in Section 3. The publication defines facility guidelines and some key equipment in Sections 4

to 6. Once the SSDL has been established, additional steps are necessary to make the SSDL operational and ensure the quality of the services. These further steps are covered briefly in Section 7.

This publication provides guidelines for the establishment of an SSDL infrastructure and is not to be considered as guidance for calibration work. National or international codes of practice in dosimetry are to be followed as a reference when an actual calibration service is established. More specific guidelines on calibrations and international codes of practice can be found elsewhere, for example in several IAEA publications [4, 5, 12].

2. FEASIBILITY STUDY AND MASTER PLANNING

2.1. INTRODUCTION

The need for an SSDL within a country needs to be carefully evaluated by considering the national metrology system, relevant legal regulations and national priorities, as well as available resources. The quantity of dosimetry equipment that requires regular calibration justifies the establishment of an SSDL.

For a new facility, a feasibility study is to be conducted. The costs of calibration services provided by a foreign internationally recognized calibration laboratory for each user instrument and the risks associated with shipment of the equipment are to be considered. These costs are then to be compared with the costs of establishing and maintaining an SSDL. In addition to costs, the impact of not having an SSDL in the country and the mechanisms for filling the gap through cooperation and collaboration with well established and recognized SSDLs need to be assessed.

If the SSDL is already in existence and the plan is to extend its services, there are some matters that need to be considered. These include the demand for new services, international trends and developments in radiation dosimetry, and practical issues such as the availability of bunkers, their suitability for the new work, staff resources and any additional regulatory requirements.

The main output of these considerations is a comprehensive feasibility study that states the needs and sets out the framework for the establishment of an SSDL. It includes the results of all technical surveys and investigations pertaining to the siting as well as the time frames for services to be in place [13]. The study could describe several different options for siting, as well as the short, medium and long term plans for the SSDL. Risks and possible mitigation also ought to be included. An example of a risk register for a radiotherapy project

is given in IAEA Human Health Reports No. 10 [13]. Detailed information on the budget and options for financial resources are to be considered and reported. This section gives guidelines on all these issues. The use of this publication does not diminish the responsibility of the national team to develop a complete and accurately detailed concept design that meets the user's needs and complies with national regulations.

2.2. THE STATUS OF THE NATIONAL METROLOGY SYSTEM

Most countries have a national metrology institute (NMI), established under a metrology act or regulation, to ensure that measurements of physical quantities in the country are at an accuracy that is fit for purpose, underpin international trade and enhance the quality of life of the citizens. When establishing an SSDL, it is important to consider the existence of any such act or regulation in the country that establishes the quality infrastructure and gives rights to the NMI to maintain the national measurement standards and provide traceability. Ideally, the new SSDL is to be established as part of the NMI or be designated by the NMI as the responsible institute for ionizing radiation measurements in the country. Such a designation is a typical arrangement when the SSDL is supervised by an authority (national atomic energy authority, university, etc.) other than the NMI.

The NMI and the SSDL, being part of the NMI or designated by the NMI, can participate in the CIPM MRA as a member of the relevant RMO. However, to be eligible to publish its CMCs in the key comparison database (KCDB), maintained by the BIPM, the country has to be a party to the Metre Convention or be an associate of the General Conference on Weights and Measures. If the SSDL is not the designated institute or the country has not participated in the CIPM MRA, the calibration services of the SSDL cannot be published in the KCDB. Further details on the status and roles of NMIs and designated institutes under the CIPM MRA are given on the BIPM website [14].

2.3. LEGAL CONSIDERATIONS

The SSDL needs to comply with all safety and security requirements imposed by the national regulations. All necessary regulatory activities to ensure the safety and security of radioactive material, such as the import/export/transport, storage and use of radioactive sources, as well as the management of disused radioactive sources and decommissioning of irradiators, are to be conducted in accordance with the domestic regulatory framework for the control of radioactive material. These issues and all their associated cost implications need to be

considered and included in the planning. Due consideration is to be given to the national metrology regulations and their impact on the calibration services, especially if the SSDL is being established outside the metrology institute.

Due diligence is a prerequisite for conducting a feasibility study for establishing an SSDL; a formal investigation has to have been conducted to ensure that all legal aspects are met [13]. These include the regulatory infrastructure to support the safe and effective installation of an SSDL and the rights to the site [2, 13, 15].

2.3.1. Regulatory requirements

The regulatory authorities are of key importance in establishing SSDL services. When an SSDL is planned, various national regulatory authorities may need to be involved. These include regulators that will approve the proposal for building on the land identified, approve the building plans and license the use of the building as a laboratory. Their requirements may include an environmental impact assessment report.

The regulator that is responsible for ionizing radiation will be needed, particularly with respect to licensing the facility for use of specified radioactive sources, for example evaluating the management of radioactive sources and whether the walls will provide sufficient shielding for personnel, and assessing occupational and public exposure [13]. GSR Part 3 [2] states that the legal persons apply through the regulatory body for authorization to use radiation sources. A safety analysis report and a radiation protection programme are some of the measures that may be required of the SSDL.

The SSDL retains responsibility for ensuring that the national regulatory conditions are met, and in cases where these do not exist or are incomplete, the IAEA or other international standards can be followed. The IAEA has released several publications dealing with the safety standards, the radiation protection aspects, the specialized shielding calculations pertaining to radiation therapy and the guidelines for ensuring the security of radioactive material in use, storage and transport [13, 15–18]. These publications could be used as guidelines for designing irradiation bunkers.

2.3.2. Ownership of the land and planning permission

When planning to build an SSDL, establishing the ownership of the land is the first priority, followed by determining the suitability of the land for use as an SSDL and permission to use it for one, especially with high energy and high activity radiation sources. In some Member States, the land has to be zoned for laboratories, and in others, for business use as opposed to private or domestic

use. The process of zoning ensures that the land is, or can be, designated for SSDL purposes [13]. Confirmation is needed that the future plans of adjacent property owners have been investigated. Plans to build high rise buildings on adjacent land, for example, may affect the actual placement and orientation of the radiation bunkers, especially for radiation therapy level calibrations [13]. Before the beginning of the building phase, planning permission from the appropriate authorities, including an environmental impact study, may be required in some countries.

2.4. THE NEED FOR AN SSDL AND CALIBRATION SERVICES

The need for an SSDL is generally supported by surveys that evaluate the number of institutions using ionizing radiation in the country (medical, industrial and other sectors), and the estimated number and types of measuring instruments that need to be calibrated according to the regulatory requirements issued by the national regulatory body as part of the licensing process for users. Even if there are no legal requirements in a country for the traceability of dose measurements, GSR Part 3 states that a dosimetry system, used for measuring occupational or medical exposure, is to be calibrated and traceable to the International System of Units [2].

In most countries that have established an SSDL, the calibrations provided are mainly for radiation protection measuring instruments, such as survey meters, contamination meters and monitors, and personal dosimetry systems. These instruments are in widespread use in clinics, the oil and mining industry, and in nuclear power facilities. Therefore, the need for a radiation protection calibration service is generally easily justified.

The need for calibration is particularly important in radiation therapy. A missing, wrong, or intentionally manipulated calibration can cause serious harm to a patient. If a country has more than five radiation therapy centres and at least ten dosimetry standards to be calibrated biennially, there would be five calibrations per year. This may be enough to justify providing traceability at a national level. However, the justification is to be considered separately in each case. In countries with a small number of radiotherapy centres or insufficient resources, calibrations of hospital dosimeters on-site using clinical irradiators could be considered. For this purpose, the SSDL needs a special agreement with a centre to be used for on-site calibrations.

With the publication of the IAEA International Code of Practice for diagnostic radiology [5] and GSR Part 3 [2], awareness of the importance of patient dosimetry in diagnostic radiology has increased. It is common for countries to have several centres providing X ray examinations. Establishment of a calibration service

for diagnostic radiology can be justified by estimating the quantity of dosimetry equipment that needs to be calibrated regularly in order to perform traceable patient dosimetry, for example at least ten dose meters to be calibrated biennially. If the SSDL already has an X ray system for radiation protection or therapy calibrations, this system could be configured for diagnostic radiology calibrations. In this case, the additional cost for establishing a new service would be relatively low.

Sometimes a regional review of calibration demands and available services is valuable. A country may lack sufficient justification or resources to establish its own calibration capability, but if neighbouring countries have common needs for the same calibration service, some of these responsibilities could be shared. In addition, since the number of people working on calibrations nationally is typically small, potential cooperation at the regional or subregional level may be considered.

2.5. INFRASTRUCTURE CONSIDERATIONS

Infrastructure considerations for SSDL facilities are covered in this section; the technical needs related specifically to calibration work are discussed further in Section 4. The planning team prepares a development plan for the construction of an SSDL. The requirements may differ depending on whether a new facility is being planned or the scope of facilities is being extended. Facility planning includes not only the construction of specialized bunkers, but also the workflow in the facility when operational. In addition, it is important to consider how the facility could be expanded if needed in the future, without disrupting services.

2.5.1. Site location

When identifying an appropriate location for the laboratory, the following criteria are important [13]:

(a) Whether it offers clients easy access to the SSDL and its services, and facilitates the transportation of goods as well as the delivery of the radiation sources;
(b) Whether it is free from external environmental disturbances that are likely to influence the measurements, such as low frequency vibration, electromagnetic fields, magnetic induction and background radiation that is much higher than the average background radiation in the region;
(c) The impact on the surrounding environment;
(d) The possibility of extending the facilities in the future;
(e) Security considerations, such as population density in the vicinity and where local and off-site response forces are stationed [2].

If the laboratory is to be established in an existing complex, compromises on some of the criteria above may be unavoidable.

2.5.1.1. Geotechnical considerations

As detailed in Ref. [13]:

> "Geotechnical surveys confirm flood lines, earthquake zones and ground conditions, i.e. high water tables and soil characteristics. The purpose of the geotechnical investigation is to evaluate the subsoil stratigraphy and determine its character and physical properties in order to design the foundations of the building. The investigation should provide sufficient data for the geotechnical engineer to recommend the most appropriate and efficient design, and sufficient information for the contractor to bid appropriately and reduce change orders and claims. The type of structure to be built and the anticipated geological and field conditions have a significant bearing on the type of investigation to be conducted."

However, the level of investigation for SSDL purposes is not as comprehensive as, for example, in the case of radiation therapy facilities, nuclear power plants or radioactive waste management facilities. Therefore, knowledge of the intended project size and the anticipated building loads as well as the geological history of the area is needed for planning the geotechnical investigation [13].

2.5.1.2. Electromagnetic considerations

Electromagnetic fields may interfere with some electronic equipment. This could affect the uncertainty of measurement. For the dosimetry system used, for example, in radiation therapy, the electromagnetic field strength is to be <3 V/m in the frequency range of 80 MHz to 1 GHz according to IEC 60731 [19]. Thus, it is crucial that the electromagnetic field is assessed or measured for the identified site.

2.5.2. Premises

SSDL premises consist of at least one irradiation room (bunker), a control room, and suitable storage and office space [1]. The facility is to have appropriate supporting infrastructure to allow a smooth workflow when the SSDL is operational. The laboratory need not share space with incompatible activities, which could jeopardize the quality, safety or security of the service [1].

The premises are to be designed to meet local safety and security regulations. Access to the SSDL is restricted to prevent unauthorized actions. Computer based systems that support these physical access restrictions as part of a security system are to be protected against compromise (cyberattack, manipulation or falsification). Radiation safety and security requirements need to be considered and the bunker needs to be shielded appropriately [20]. The bunker also needs to be sufficiently shielded from extraneous radiation sources so that the background radiation is negligible. The construction of specialized bunkers is technically an engineering challenge and requires professional oversight to ensure long term structural integrity [13]. It is crucial that the design account for any future requirements and advances in technology. In addition, the plans for future expansions are to be taken into consideration. Section 4 includes more details on the facilities required for different applications.

2.5.2.1. Electrical considerations

For new premises, a power and signal plan showing the design for general use power points, communication and signal outlets, and the main circuit servicing the equipment is to be prepared, along with a lighting plan [13]. The power plan and the requirements of the planned equipment need to be in conformity. It is important to have a record of what was implemented in practice, as often the installations do not match the plans. Some of the equipment may require a three phase power supply. Load calculations are to be prepared by an electrical engineer based on the plans of the SSDL. The electrical capacity of the substation needs to be carefully evaluated to see whether its power supply can cater for the total needs of the SSDL facility as well as for the future expansion of services [13].

If power is not readily available, ensuring a consistent and permanent connection to the grid may incur additional costs. In such a case, considering a different site is justified. An alternative option, for example using diesel generators, transformers, power conditioners or uninterruptible power supplies (UPSs), will affect the level of technology that can be installed in the facility [13].

It is best practice to also provide an emergency backup power system to supply power to the essential illumination and high priority equipment, noting the stringent requirements for power conditioning of sophisticated equipment. In addition, strategically placed UPSs, as autonomous power sources, can be installed to support critical servers, workstations, light points, a fire alarm system, etc. [13]. The UPS will need a suitable rating with voltage regulation and spike protection to provide backup power for the time needed to ensure the return of any sources to their closed or ‘safe’ position. The time can be reduced if the UPS is powered by the emergency system and is provided only for the

switchover period or a programmed/ managed shutdown [13]. The options and costs for the backup power system are to be evaluated and included in the feasibility study report.

2.5.2.2. Information technology infrastructure and data protection

Calibration work involves much data processing, communication and storage. This information can also be transmitted across different communication channels, including removable devices such as USB sticks, which increases the possibility of data being compromised and manipulated. For the SSDL operation, it is important to have easy access to historical data. The information technology (IT) infrastructure requires computer security measures to protect and preserve the confidentiality, integrity and availability of information and security systems, and the calibration function of the SSDL. The procedures for protecting data are to include, but not be limited to, ensuring the integrity and confidentiality of data entry, collection, storage, transmission and processing. Access is to be restricted for confidential information, personnel and data files. Access to computers used for data acquisition, data processing and storage of calibration results, including calibration certificates, is to be restricted to authorized persons, which could be implemented by host (e.g. personalized passwords) and network (e.g. firewalls) access controls. All servers and computer files are to be secured by appropriate backup regimes. Therefore, the application of appropriate computer security measures to IT infrastructure, including personal computers and internet connections, is a prerequisite.

2.5.2.3. Water and sewage services

The availability of water supply and sewage systems at the site under consideration is to be assessed. The capacity of the system to handle the possible increase in demand from introducing the SSDL into the area needs to be evaluated. The use of water is to be estimated based on the number of personnel and the equipment that will use water for cooling. The water flow rate required for equipment needs to be ascertained to ensure that it is sufficient for cooling the machines as needed. If these systems are not sufficient or readily available, costs may be incurred to put them in place. The authorities need to ascertain the time it will take to install these services in order to plan appropriately.

2.5.2.4. Fire protection considerations

Since the SSDL has radioactive sources, the best practice is to include a fire protection engineer on the planning team to ensure effective planning for

the detection, containment, control and extinguishing of fire events at the earliest possible stage [13]. The building design has to comply with all requirements of the fire protection department and include escape doors, signage, fire alarm systems with smoke/heat detectors, indicator panels, call boxes, electronic sirens and wiring as well as escape facilities for disabled persons, provision of fire hydrants, fixed firefighting installations, portable firefighting equipment, etc. [13]. Special consideration needs to be given to the specification of smoke/heat detectors in radiation bunkers, as they are not to be sensitive to radiation (i.e. photoelectric) [13]. Lightning protection needs to be provided in some countries.

2.5.2.5. Regulatory considerations

Building regulatory requirements vary from country to country. The best practice is to have the regulators involved in the planning phase. Before equipment is installed, the various building requirements are to be approved by the relevant regulator(s) and licences obtained where relevant. When the irradiators are installed, the regulator responsible is to give approval for their operation. This might involve site visits for independent measurements by the regulator and verification that effective safety and security measures have been installed.

2.5.3. Technical infrastructure

Each calibration capability requires different equipment and facilities. Sections 4, 5 and 6 give technical examples of the facilities, calibration systems and measuring equipment for each dosimetry calibration service. The SSDL may establish different calibration capabilities in phases, depending on the country's needs, and later add other services. In an optimal situation, a clear vision of future calibration services ought to be developed in the planning phase.

This publication provides a technical description of different items needed for calibration work in SSDLs. In addition, examples of technical specifications are given on the SSDL Network website [21]. The specifications are to be adjusted based on the local needs and requirements of each SSDL. Generic guidelines on what topics are covered in the technical specifications are provided in the Appendix.

2.6. HUMAN RESOURCE CONSIDERATIONS

Human resource considerations are included in the feasibility study and planning. During the process of SSDL establishment, there is a need for different types of expertise. Therefore, the project is divided into steps and different teams

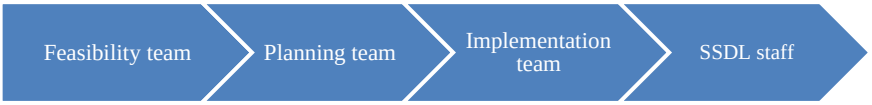

FIG. 2. Process flow and teams involved in the different phases of SSDL establishment.

are suggested for the entire process (Fig. 2). The best practice is to have at least one person with oversight of all of the steps. For the SSDL staff, it is important to anticipate the number of personnel and their competencies in order to plan their training in advance.

2.6.1. Feasibility study and planning team

The prerequisite for establishing a laboratory is a feasibility study that confirms its needs and whether the identified site is able to meet them and gives estimated costs and guidelines on the best way to establish the SSDL. The feasibility team is to be comprehensive and include all relevant technical team members to look after the designs, costs, risks, country programme plans and funding mechanisms. The feasibility study report is to be clear enough to enable the decision makers to make informed decisions on whether or not to establish the SSDL in the country and identify the funds needed for such a project as well as the funding mechanisms. The team is to be led by a project manager and include radiation metrologists, engineers, legal experts and accountants/economists.

If the project is approved based on the feasibility study, a planning team creates the first plan for the project. A draft plan can be made during the feasibility study to obtain a realistic estimate of the costs. The team includes representatives from at a minimum of the institutes responsible for managing the SSDL and representing the areas of regulation, finance, public infrastructure development and facility management. This will ensure coordinated oversight over the project duration.

2.6.2. Implementation team

The implementation team continues the work of the planning team. Once the decision to establish an SSDL has been made, careful coordination and monitoring of the planning and timelines will be key to the success of the project [13]. The implementation team required to design, construct and commission an SSDL needs to be multidisciplinary and include at least one person who is familiar with the special requirements related to the establishment of an SSDL.

At a minimum, the implementation team will consist of the following qualified experts or cover the relevant expertise (adapted from Ref. [13]):

(a) A radiation metrologist with competence in the planning of new SSDLs. It is important that the radiation metrologist participate fully in the specification and commissioning of appropriate equipment.
(b) A project manager.
(c) An architect, preferably one experienced in designing and constructing facilities housing equipment that produces ionizing radiation (such as radiotherapy facilities).
(d) A structural or civil engineer with experience in large concrete structures, for example dams or similar large structures, and expertise in casting large volumes of concrete.
(e) A mechanical engineer with experience in specialized laboratory design, including cooling, heating and ventilation systems.
(f) An electrical engineer experienced in the calculation and design of supply and standby electrical systems for specialized laboratories.
(g) An IT and computer security expert for designing the IT, communication lines, networking, and measures and procedures for information and computer security, including securing the computer based components of the security systems.
(h) A safety engineer to ensure adequate implementation of the fire and safety aspects.
(i) A financial expert for budget control.
(j) A regulatory authority member to ensure compliance with the safety and security regulations.
(k) A quality controller to ensure that the construction is in compliance with regulations and standards.
(l) A radiation protection officer to ensure that all safety requirements are met, including safety assessment, the radiation protection programme of the SSDL and the licensing procedure.

A single person may be responsible for more than one of the tasks listed above. If some expertise is not available locally, external experts with the relevant experience may be consulted [13]. In this case, a local professional may be assigned for shadowing purposes.

2.6.3. SSDL staff

The planning or implementation team, together with the management, are to define and find potential staff members for the SSDL. Training a qualified

radiation metrologist takes time and therefore, if one with previous experience of SSDL work is not available, the training of new staff members is to be initiated at the very beginning of the project. The guidelines for the qualifications of the radiation metrologist and other SSDL staff members are given in Section 3.

The best practice is to have technical and managerial personnel who have the authority, qualifications and competencies for radiation metrology [1]. At least one SSDL staff member is to be part of the planning team and available for input when the facility is under construction. The SSDL staff member is responsible for equipment selection, commissioning and the development of standard operating procedures.

Consideration also needs to be given to the sustainability of human resource capacity [13]. Full operation of the SSDL might involve more staff than were needed for its establishment. Additional staff may be needed when expanding services.

2.7. FINANCIAL CONSIDERATIONS

When considering the total cost of establishing an SSDL, the budget for each step in the process is to be evaluated. These steps include:

(a) Startup phase:
    (i) Feasibility study;
    (ii) Planning and design;
    (iii) Sustainability of the services.
(b) Human resources:
    (i) Personnel costs;
    (ii) Training and continuing education of staff;
    (iii) Consultants' costs.
(c) Technical infrastructure:
    (i) Construction of SSDL facilities;
    (ii) Irradiation units (selection, operation, maintenance);
    (iii) Measuring and other auxiliary equipment;
    (iv) Safety and security consideration and their related (initial and ongoing) costs.
(d) Operational costs:
    (i) Regular maintenance;
    (ii) Utilities, including safety and security;
    (iii) Replacement and final management of disused radioactive sources;
    (iv) Audits and accreditation;
    (v) Licences, including those of regulators;

(vi) Radiation monitoring programme and medical surveillance;
(vii) Recalibration of measuring equipment;
(viii) IT services.

2.7.1. Startup and human resources

Human resources with specific competencies that might not be readily available are needed for the startup and establishment of an SSDL. In some cases, external experts need to be consulted and this introduces additional costs that may be covered by the budget. In addition, the costs related to legal procedures, documents and permissions may be included in the overall costs.

When the SSDL is fully established, the staff not only perform calibration work, but also maintain the quality of the services. Preparation of the QMS is a significant effort in the beginning, but it also needs to be maintained continuously. In addition, the SSDL's regular participation in internal and external audits is important. All these activities need time and resources and need to be included in the financial considerations related to human resource allocation.

2.7.2. Technical infrastructure and operational costs

The cost of establishing an SSDL depends on the planned calibration activities and the infrastructure required (bunkers, offices, amenities, etc.). For example, an SSDL with a single spacious bunker containing a gamma beam irradiator and an X ray machine is cheaper than one with a separate bunker for each irradiator. However, it would not be possible to run both systems simultaneously, so there is a tradeoff between cost and throughput. The costs of the design process, including shielding calculations and the necessary equipment (power supply, air conditioning systems, IT infrastructure, etc.) need to be added to the total costs. Different irradiators and reference dosimeters are needed for different calibration services. Table 1 gives a rough cost estimate of irradiators, reference standards and accessories.

In addition to the initial set-up investment for an SSDL, provisions are to be included for the ongoing operating costs to maintain the calibration facilities and services. In most cases, the income generated from the laboratory will not necessarily be high enough to offset operational costs.

An adequately funded equipment replacement and maintenance programme is needed to ensure the sustainability and functioning of the SSDL; this will include, for example, procuring and replacing sources and returning decayed ones, replacing X ray tubes, renewing software licences, maintaining and servicing irradiators and associated equipment, recalibrating standards and maintaining the IT infrastructure. Air conditioning systems are maintained continuously, and

TABLE 1. CAPITAL COST ESTIMATES FOR THE MAIN EQUIPMENT AND ACCESSORIES OF AN SSDL *(as of 2020)*

Item	Capital cost (in thousands of euros)
Irradiator for radiation therapy (with Co-60)	200–500
Afterloader for high dose rate brachytherapy (with Ir-192)	100–200
Irradiator for radiation protection (with Cs-137)	100–300
X ray system (max. 250 kV)	120–300
Calibration benches	20–150 each
Reference standard ionization chambers	2–10 each
Reference electrometers	4–20 each
Radiation protection equipment (interlocks, radiation monitors, etc.)	80–100
Safety and security equipment	100–150

replacement parts are needed, and these costs are to be included in the running budget. Allowance is also made for electricity and water consumption. IT service contracts are essential, and they need to be funded.

Medium and high energy calibration services can increase the cost of the SSDL dramatically, since the level of shielding (thickness and material) in the bunker walls and doors is much greater than for radiation protection calibration services. In addition, the ^{60}Co irradiator needed for such services is more expensive. For therapy level calibrations, SSDLs are advised to consider the installation of a refurbished external beam ^{60}Co irradiator instead of purchasing a new one. This can be achieved by contacting radiotherapy departments in the country for irradiators that are no longer needed for clinical use. Significant overall cost savings can also be achieved if an agreement can be reached to cascade sources routinely from a hospital to the SSDL.

The largest periodic investment will be the need to replace and manage disused radioactive sources, for example high activity ^{60}Co calibration sources with a relatively short half-life (5.3 years). Depending on the initial activity of

the source, the useful working life of a radiation therapy level ^{60}Co source is approximately 10 years. The certified working life for the safe use of a source as stated by the manufacturer also needs to be considered with respect to the operational costs. In the case of ^{137}Cs sources, the half-life is longer (30.05 years), so the certified working life determines the source replacement frequency and not the activity.

An X ray system is much more complicated and less robust than irradiators with a radioactive source. The best practice is to maintain the X ray system regularly, and this requires more funds. Replacement of different parts of the system might be required and a specific budget for maintenance is to be included in the planning phase.

The costs related to regular calibration of all the reference standards and ancillary equipment are to be included in the budget, including the cost of shipping the instruments. The reference standards are to be calibrated at any PSDL, IAEA, BIPM (if the SSDL is eligible) or SSDL. A list of institutes offering a calibration service can be found in the KCDB maintained by the BIPM [14]. Ancillary instruments such as thermometers and barometers are to be calibrated by laboratories that offer an ISO/IEC 17025 accredited service.

2.8. PROJECT RISK ASSESSMENT

A risk (or value) assessment determines the affordability and sustainability of the project and concerns not only the buildings but also the maintenance, running costs, consumable supplies, staffing and access [13]. A commitment, for instance, to appoint staff immediately after long term training and to include budgeting for post-warranty equipment maintenance is needed. A project risk register provides the team immediately with alerts regarding potential challenges in the project and their origin (e.g. regulatory, financial, design, equipment, or staffing) [13].

2.9. TYPICAL TIME FRAME FOR THE ESTABLISHMENT OF AN SSDL

Figure 3 shows a sample process flow for a typical project plan. It can be used as a template for project planning and monitoring. The figure includes the timeline for the feasibility study and establishment of appropriate human resources, SSDL facilities (including equipment) and calibration services. These steps, shown in Fig. 3, contain several tasks, for example recruiting human resources, training human resources, recruiting external expert services, procuring

equipment, building facilities, installing and commissioning equipment, developing a QMS (including quality assurance (QA)/quality control (QC)), and approving and launching calibration services [13]. Some activities can be carried out in parallel (e.g. training human resources). There can also be a significant lead time; therefore, equipment specification and procurement procedures may be planned prior to the completion of construction [13].

2.10. IAEA SUPPORT

The IAEA has assisted in the establishment of many of the SSDLs that are now members of the IAEA/WHO SSDL Network [1]. IAEA Member States can obtain technical assistance, services from the dosimetry laboratory and support through the IAEA's technical cooperation programme. The technical support for SSDLs is coordinated by the SSDL officer at the IAEA.

The IAEA Dosimetry Laboratory plays a key role as a central laboratory of the SSDL Network. IAEA technical support could also include training courses

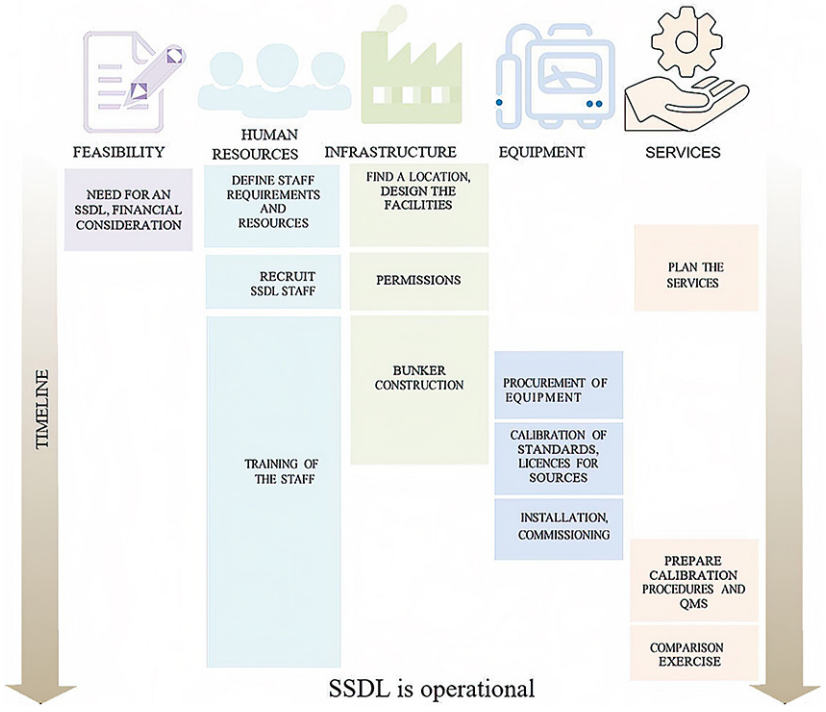

FIG. 3. Process flow for the establishment of an SSDL.

and seminars held at the IAEA Dosimetry Laboratory or at other operational SSDLs in Member States. In addition, the IAEA has prepared training manuals and publications in radiation dosimetry.

Member States may also request a Technical Cooperation Project to support their SSDL. For example, setting up an SSDL may require expert missions, staff training and the completion of necessary infrastructure, followed by the provision of basic equipment at the SSDL. Similarly, projects may be requested when upgrading and expanding the facilities and services of an SSDL.

The IAEA provides several opportunities for networking. The SSDL Network is just one framework. Additionally, IAEA coordinated research projects (CRPs), covering a wide range of topics related to radiation metrology and quality assurance procedures, have been organized, with many network members participating[2]. CRPs offer good opportunities to meet and exchange knowledge, experience and ideas. The IAEA also organizes training events, technical meetings and conferences, where professionals from all over the world can meet and share their experiences and expertise.

3. STAFF COMPETENCIES

SSDL services require technical knowledge and skills that are not generally taught in undergraduate academic physics or engineering courses. Therefore, some additional practical and theoretical training is to be provided. A shortage of adequately trained staff is a serious obstacle to the appropriate operation of an SSDL and its official recognition. This section summarizes the roles and responsibilities of SSDL staff and the proposed qualifications for radiation metrologists.

3.1. SSDL STAFF FUNCTIONS, RESPONSIBILITIES AND ROLES

The main service of an SSDL is the dissemination of radiation dosimetry standards to end users through instrument calibration [1]. Related to this function, radiation metrologists provide information on calibration procedures and practical advice to end users on instrument use in their application. Those SSDLs with the appropriate facilities and expertise may also provide other services, which may include but not be limited to conducting dosimetry audits, teaching

[2] http://cra.iaea.org/cra/index.html

and providing training to end users. This section focuses on the competencies needed to establish various calibration services.

The responsibilities depend to a certain extent on the scope of the SSDL and its services. However, some core responsibilities are needed in each SSDL. At a minimum, the following responsibilities are to be covered:

— Administrative management:
  (i) Availability of resources;
  (ii) Human resources management;
  (iii) Responsibilities of the staff;
  (iv) Staff competencies.
— Quality management:
  (i) QMS compliance with ISO/IEC 17025;
  (ii) QMS documentation preparation;
  (iii) QMS implementation.
— Technical tasks:
  (i) Development of calibration procedures;
  (ii) Performance of calibrations;
  (iii) Calibration data analysis;
  (iv) Approval of calibration certificates.
— SSDL operational considerations:
  (i) Instrumentation and electronics;
  (ii) Equipment maintenance;
  (iii) Radiation protection, safety and radioactive material security;
  (iv) IT services and equipment.
— Communication:
  (i) Communication and stakeholder interactions;
  (ii) International cooperation (IAEA, RMO, BIPM).
— Administrative support:
  (i) Equipment handling, reception and shipment;
  (ii) Billing.

Depending on the number of activities and resources of the SSDL, several members of staff may cover different responsibilities in the SSDL organization. On the other hand, there might only be one person covering many of them. The responsibilities are to be divided according to specific competencies of the staff. Typical roles in an SSDL are:

— SSDL head (or lead radiation metrologist);
— Radiation metrologist;
— Quality coordinator;

— Radiation protection officer (RPO);
— Security officer.

The roles of SSDL head, quality coordinator and RPO are to be defined and assigned when the SSDL is established to ensure the quality and safety of the services. Depending on the size of the SSDL and its parent organization and when it is practicable, the organization may decide to hire a quality coordinator and an RPO. These functions can be shared between several testing or measurement laboratories with the SSDL having someone co-ordinating for their own activities. The SSDL head has the overall responsibility for the work performed at the laboratory and holds a full time appointment. Optimally, the SSDL head will be a radiation metrologist with several years of experience [1].

Radiation metrologists are professionals with specific competencies for calibration work. The relevant competencies are described in the following section. Radiation metrologists are the core technical staff at an SSDL, and they are responsible for the calibration work. In some cases, an SSDL might have additional technical staff for routine measurements but a radiation metrologist is always responsible for the calibration procedure, uncertainty estimations, data review and approval.

The quality coordinator coordinates the establishment, implementation and maintenance of the QMS. This coordinator is to have the appropriate authority to make sure that the QMS is followed by all staff and will have direct access to the highest level of management, where decisions on laboratory policy and resources are made.

As ionizing radiation is used at an SSDL, most of the employees are occupationally exposed to radiation and thus are to be registered and participate in the national radiation monitoring programme and be subject to appropriate medical surveillance. Therefore, the SSDL is to nominate an RPO who has management authority to identify and prevent unsafe conditions and plays a key role in ensuring radiation safety. The RPO is to have relevant training and experience in radiation protection. The SSDL also needs to ensure that the radioactive sources and material used by the laboratory are secured. Therefore, the SSDL is to nominate a security officer who has training and experience in radioactive material security. Depending on the resources of the SSDL, the roles of RPO and security officer may be combined. This person will be responsible for liaison with the regulatory authorities and management regarding radiation protection, safety of personnel and radioactive material security.

These tasks, as well as the responsibilities and duties of all SSDL personnel (job descriptions), are to be documented in the quality manual or other internal document of the laboratory that is approved by the SSDL head. All personnel are

to be free from any undue external pressure and influence that may adversely affect the quality of the services offered by the SSDL.

3.2. QUALIFICATIONS

Based on the SSDL Charter, the SSDL personnel are to have the competence to perform the calibration work and be qualified on the basis of appropriate education, training, experience or demonstrated skills [1]. In addition, based on the ISO/IEC 17025:2017 standard, the SSDL has to ensure that the personnel have the competence to perform their activities and to evaluate the significance of potential deviations in the results [11]. It is best practice that the radiation metrologists responsible for calibration work have a comprehensive knowledge of radiation dosimetry, radiation safety and radiation protection. Their training is to include evaluation of measurement data and estimation of measurement uncertainty. Further, a good understanding of the different types of dosimeters specified in the relevant ISO or IEC standards is needed, in addition to familiarity with the general competencies of testing and calibration laboratories, in line with ISO/IEC 17025:2017 [11]. The competencies (education, qualification, training, technical knowledge, skills, experience) are to be documented for each function.

Ideally, the technical personnel of the SSDL are to have an educational background in physical sciences or engineering. Radiation metrologists are physicists, who preferably have studied ionizing radiation physics or similar topics. The SSDL head, as a lead radiation metrologist, is someone who has several years of experience in radiation measurements and calibrations.

Typically, there is only one SSDL per country, thus international cooperation is very important for SSDLs. It might be challenging to find personnel who have experience in working at a dosimetry laboratory if the SSDL is the first calibration laboratory in a country. Hands-on training can be obtained by sending personnel abroad to another SSDL or PSDL that has appropriately recognized competence in the calibration service being implemented. If this is not possible, staff have to be trained on-site with support from external experts. The SSDL may consider working in close cooperation with another recognized SSDL until personnel have the competencies and confidence for calibration work.

Training of personnel is continuous. Personnel will need to keep themselves abreast of developments in the field so that they are able to support their user community adequately and in a timely manner. Cooperation with other SSDLs in the SSDL Network is strongly encouraged. The IAEA/WHO SSDL Network supports SSDLs and organizes SSDL specific training. In addition, RMOs and the BIPM provide opportunities for training and SSDL cooperation.

4. SSDL FACILITY DESIGN

This section is intended to provide guidelines for designing SSDL facilities. The general considerations for the premises are covered in Section 2.5.2. This section overall, however, covers the workflow and technical details specific to calibration work. It describes the basic guidelines for room layouts; a specific design needs to be tailored to each calibration service.

4.1. SAFETY, SECURITY AND RADIATION PROTECTION MANAGEMENT

Photon radiation fields generated by X ray tubes or sealed radioactive sources are used in calibrating dosimeters. Therefore, several issues concerning radiation safety and the security of radioactive material are to be considered when an SSDL is established. The design of the SSDL is to facilitate safe operation of the laboratory and provide adequate and appropriate radiation protection to staff, visitors and the public. The design of the calibration facilities takes cognisance of the relevant national safety and security regulations and international standards and guidelines [2]. National dose limits and dose constraints are applied to the occupationally exposed staff and the public.

4.1.1. Room classifications

The bunker (irradiation room) where a device containing a radioactive source or radiation generator (irradiator) is installed is to be separate from the control room, from which irradiators and data acquisition systems are operated by authorized staff. Access to the bunker, classified as a *controlled area,* is restricted to assure safety and security. In controlled areas, specific radiation protection measures and safety provisions are needed to control normal exposures and to prevent unintended exposures. The control room is classified as a *supervised area*. Controlled and supervised areas are labelled with appropriate labels and safety signs at the entrances [2, 22].

4.1.2. Safety interlocks

The use of irradiators necessitates a strong radiation safety culture. Different kinds of safety interlocks for the bunker door are to be integrated into the master control system so that access or any violation or failure of the safety interlock system causes irradiation to be terminated automatically. Emergency

switches are to be located outside and inside the bunker to terminate irradiation in an emergency. In areas where two radiation sources are located, the interlock system is to be installed to ensure that only one source is operational at any one time and the interlocks need to work independently. During acceptance testing, all the safety features need to be tested.

When interlocks activate or if an electrical power failure occurs the radioactive source needs to be returned automatically to the shielded storage position or the shutter needs to be closed immediately. It is best practice that critical electronic components used in the irradiator control system are connected to a UPS for this purpose. The radiation room monitor, the safety interlocks and the measuring data storage driver are to be powered by the UPS to ensure safe and complete system shutdown. There has to be a capability to return radioactive sources to a safe position in the shield manually if the safety interlock/mechanism fails. The layout has to also allow staff to access the manual source return mechanism without being exposed to high radiation dose rates (i.e. point the beam away from the door).

4.1.3. Safety and security culture

The SSDL itself is to provide all the human and material resources necessary to ensure safe working conditions and compliance with all relevant safety and security regulatory requirements. Appropriate local rules are to be in place and approved by the SSDL head and the management of the organization. The SSDL is to ensure that all aspects of radiation protection, safety and security are provided systematically. To meet this objective, the SSDL needs to establish and maintain an integrated management system that includes a radiation protection and radioactive material security programme in which management have committed to develop and promote a safety and security culture that encourages a questioning and learning attitude towards the security of radioactive material and radiation protection and safety and discourages complacency. Also to be included in this commitment is the allocation of adequate time personnel and equipment.

4.1.4. Shielding considerations

The structural shielding of all the irradiation rooms needs to be appropriate to avoid radiation exposure of staff and the public and to keep background radiation in adjacent bunkers at levels consistent with the calibration capabilities, especially those for radiation protection instruments. Consideration needs to be given to the direction of the radiation beam, which is often fixed in the SSDL set-up.

The IAEA publication Safety Reports Series No. 47 [23] provides useful information, methodologies and examples of shielding calculations. In this publication, the shielding calculation methodologies are based on the annual or weekly workload (e.g. Gy/week or Sv/week) as well as on the instantaneous dose rates outside the shielding (i.e. the dose rates arising during irradiation, e.g. μSv/h).

Other reports that guide the calculation of shielding for radiation therapy and diagnostic radiology calibration rooms are NCRP 151 [24] and NCRP 147 [25]. However, the regulatory body needs to provide the go-ahead for the construction to proceed based on shielding calculations that have been performed adequately.

4.1.5. Radiation monitoring

All SSDL staff members who work with sources of radiation (including radionuclides and X ray machines) are considered occupationally exposed radiation workers, hence everything that is stipulated in respect of occupational exposure in the IAEA Safety Standards is to be fulfilled [2, 22]. Requirement 24 of GSR Part 3 [2] stipulates that:

> "**Employers, registrants and licensees shall establish and maintain organizational, procedural and technical arrangements for the designation of controlled areas and supervised areas, for local rules and for monitoring of the workplace, in a radiation protection programme for occupational exposure.**"

Personal dosimeters are to be issued to SSDL staff as stipulated by the national regulatory authority. The occupational exposure records are to be maintained and evaluated by the radiation protection officer and reported to the national regulatory authority. Any unusual or high doses are to be investigated and documented. In the absence of national regulations, international guidelines are to be followed.

In addition to personal monitoring, it is best practice to have area monitoring in and around the bunkers. Fixed installation area monitors are designed to detect elevated radiation levels and are to be equipped with remote displays. In addition, they trigger a visible and audible alarm when radiation levels reach a pre-set value. The alarm indicates when the beam is on and it could also be used to detect exceptional exposure situations (e.g. the source is stuck or the shutter is not operating correctly).

4.1.6. Security of radioactive sources

The SSDL is to include security measures to prevent unauthorized removal of the radioactive sources and sabotage with the intent to cause harmful radiological consequences [20]. Some of the previously described items (doors, walls, interlocks, etc.) that are intended to limit exposure to radiation will also contribute to the security of radioactive sources.

Table 2 shows some of the sources used at the SSDLs and the level required for security, in line with Categorization of Radioactive Sources, IAEA Safety Standard Series No. RS-G-1.9 [26] and IAEA Nuclear Security Series No. 11-G (Rev. 1) [20]. Security level A requires a high level of protection against unauthorized removal. Security level B requires an intermediate level of protection against unauthorized removal. Security level C requires a baseline level of protection against unauthorized removal [20, 26]. The security system developed is to include security measures to address deterrence, detection, delay and response, as well as security management measures [20].

The best practice is to have the technical security measures incorporated into the irradiation rooms accommodating radiation therapy and radiation protection level irradiators, including, for example, establishing balanced security layers around the radioactive material by employing delay barriers (doors, cages, tie-downs, etc., with access controls), detection before delay, locks and tamper detection at the irradiator head that detect the source being removed and

TABLE 2. CATEGORIES FOR SOME OF THE SOURCES USED AT SSDLS AND THE SECURITY LEVEL TO BE IMPLEMENTED

Source	Activity (TBq)	Field of use	Category	Security level
Co-60	3.7E+01 to 5.6E+02	Radiation therapy	1	A
Cs-137	~ 74E-02	Radiation protection	2	B
Ir-192	~ 4E-01	HDR[a], brachytherapy	2	B
Co-60	~ 8E-02	HDR, brachytherapy	2	B
Cs-137	3.7E-04 to 2.6E-02	LDR, brachytherapy	4	C
Sr-90	~ 7.4E-02	Various	4	C

[a] HDR — high dose rate; LDR — low dose rate.

prevent its removal. Portable sources (beta, check sources, etc.) are to be stored in a locked, fixed container that is situated in a room with controlled access. An inventory of sources is to be made regularly, and the associated information is to be protected against manipulation and falsification.

Computer based systems used as part of the security systems are to be protected against compromise. Technical, administrative and physical control computer security measures are to be considered to provide protective layers of defence against unauthorized access to the radioactive sources.

4.2. SITE CONSIDERATIONS

4.2.1. Supplies

The general considerations for the premises are covered in Section 2.5.2; this section covers the specific technical considerations related to calibration work. A water supply is a basic requirement for any working place. It may also be needed for calibration purposes — for example, for the water phantoms or as a cooling material for the X ray tubes — and appropriate water pressure and purity are required.

The power supply is to be appropriate (voltage, phases, type of fuse) for the operation of the irradiation systems, especially those consuming high power (e.g. X ray systems). It is advisable that separate electrical power lines (mains) be provided for the irradiators, air conditioner, security systems and data acquisition system. It is best practice to have a line conditioner and/or uninterruptible power supply to avoid voltage dips, short interruptions and voltage variation if the power supply is not reliable; this has to be specified for each piece of equipment. It is advisable that the SSDL building have a three phase main voltage. Several electrical sockets placed at 2–3 m distance from each other are to be available on the walls of the irradiation rooms and the control rooms. The walls also need to be equipped with elevated sockets for laser beams and cameras. At least two electrical connections are to be available above the entrance for the warning lamps and access interlocks.

4.2.2. Environmental conditions

Appropriate environmental conditions are to be maintained in the calibration bunkers; the use of air conditioning, cooling and heat exchange (outside the bunker) systems may assist in keeping the air temperature within the range of 18–24ºC inside the bunker. In addition, it is important to avoid temperature changes and gradients as much as possible. Usually, it is sufficient

if temperature changes are limited to a maximum of approximately ±1ºC/h. In some cases, it is necessary to use a dehumidifier/humidifier system to keep the relative humidity between 30 and 70%. The standard test conditions for the actual calibration procedure for the different types of dosimeters are specified in the relevant standards.

The temperature inside the bunker is to be as stable and uniform as possible. Best practice is to install a central air conditioning system, with its duct running along both side walls (along the major axis) of the bunker, to achieve and ensure homogeneous temperature distribution within the bunker. Therefore, the openings for the air flow are to be equally spaced (e.g. every 100 cm). However, any flow directly towards the calibration bench is to be avoided to prevent sudden changes in temperature. Temperature differences caused by switching between the heating and cooling function of the air conditioner are to be adjusted to achieve the slowest possible temperature change and fluctuation within the bunker.

4.3. BUNKER CONSTRUCTION

4.3.1. Bunker design

For each modality, namely radiation therapy, radiation protection and diagnostic radiology, specific radiation sources and set-ups are used. One example of the SSDL facility layout is presented in Fig. 4 and a typical example of a radiation protection level calibration bunker layout with a gamma beam irradiator is presented in Figs 5 and 6. In some cases, rooms and facilities could be shared between them. For example, the same X ray tube could be used to cover different radiation qualities needed for calibrations of dosimeters used in radiation protection, diagnostic radiology and radiation therapy. Sometimes more than one irradiator can be located in the same bunker. For example, a radiation protection level gamma beam irradiator and an X ray system may be installed in the same bunker with one common calibration bench. However, if a shared bunker is used, several considerations need to be made. The workload of the shared bunker needs to be considered as the irradiators cannot be used simultaneously. The installation of shared ancillary equipment, such as calibration bench, positioning systems, lasers and rulers, needs to be planned appropriately so that it supports both irradiators.

Care is to be taken not to house a measurement capability that needs low background radiation with a high activity source. For example, environmental level radiation protection calibrations need to be in a room with low background radiation and the irradiator used for this service cannot be placed in the same bunker with a ^{60}Co irradiator that is used for radiation therapy. All types of

external scattered radiation components (background radiation in the bunker, scattered radiation from the collimation system, leakage radiation from another source, backscattering from the walls and other objects) are to be assessed in order to keep the contribution of the scattered radiation to the measurements as low as possible.

Concrete is the cheapest of the materials that may be used in building a bunker. However, the quality of the concrete has to be checked, as concrete densities are not consistent. The IAEA's Safety Reports Series No. 47 recommends that an on-site concrete testing service be used during the pouring phase [23]. Reference [23] also states that:

> "In new construction, standard concrete of density 2350 kg·m^{-3} should be used, although there may be local variations in density. If there are space restrictions, then it may be necessary to use higher density materials such as steel or lead."

4.3.2. Floor and ceiling

Some calibrations are performed at different distances from the irradiator. A dosimeter positioned in the central beam axis at one distance is to remain in the correct position in the beam axis when it is moved to different distances using a calibration bench. The calibration bench needs the floor to be levelled to ensure that it is aligned with the central beam axis accurately.

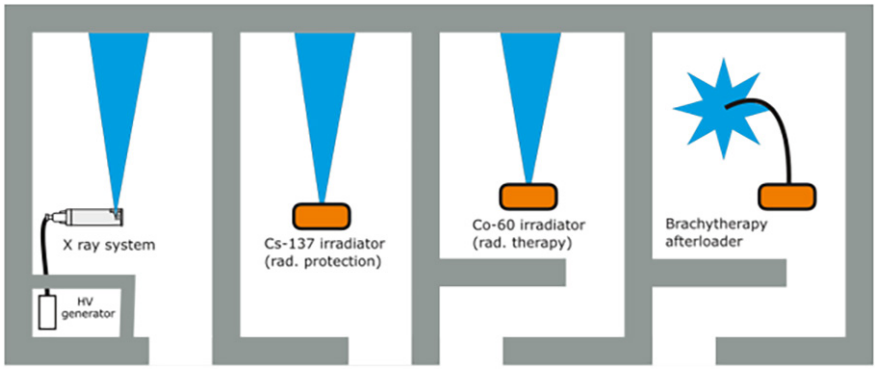

FIG. 4. Example of a design of a comprehensive calibration laboratory with four separate bunkers.

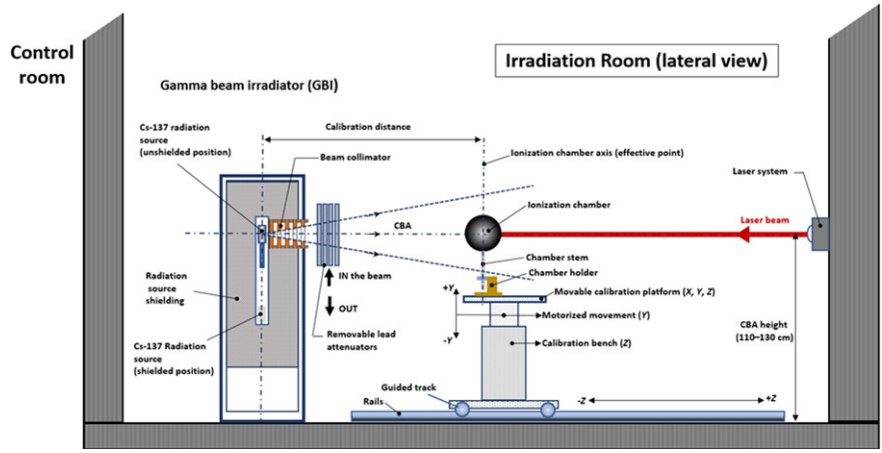

FIG. 5. Layout (lateral view) for a radiation protection level calibration bunker, including a gamma beam irradiator with a ^{137}Cs source.

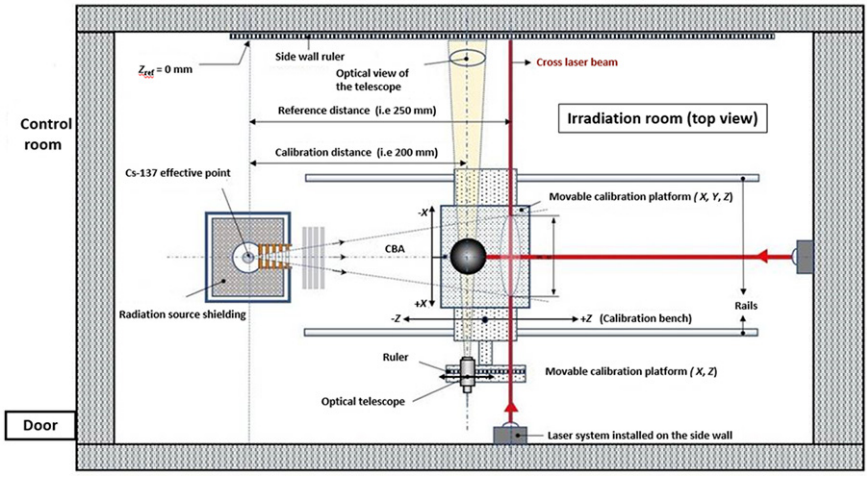

FIG. 6. Layout (top view) for a radiation protection level calibration bunker, including a gamma beam irradiator with a ^{137}Cs source.

4.3.3. Ducts between the bunker and control room

Special attention is to be paid to the feedthrough holes to ensure a connection between the bunker and control room. The connection is needed for the irradiator and the control panel and for the cables of various instruments and dosimeters and their electrometers or displays. Appropriate ducts between the

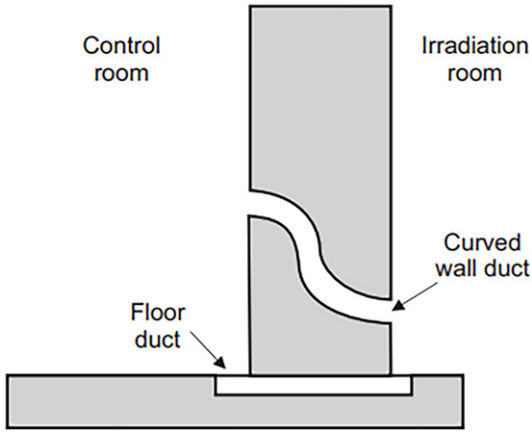

FIG. 7. Drawing visualizing floor and wall ducts between the control room and the bunker.

bunker and the control room are to be considered during the construction phase of the SSDL. Normally it is easier to include a tube for the ducts in the wall when the concrete is poured and moulded than it is to drill a hole later. When the ducts are used for the cables of measuring instruments it is best practice to line the duct with non-conductive material, which allows easy passage of the cables (e.g. a polyvinyl chloride (PVC) plastic tube could be used for this purpose). The diameter of the duct will depend on the number and the size of the cables.

There are different options for the duct positioning. 'Floor ducts' are located below protective barriers, as shown in Fig. 7. If the ducts are above floor level, their opening on the bunker side is to be located as close to the floor as possible, but as far from the radiation source as possible (e.g. at the corner of the bunker), and the cable path through the wall is to be tilted or curved.

One option for measurement cables is to tilt or curve the duct down towards the interior of the bunker, as shown in Fig. 7, with the lower end inside the bunker, ~10–30 cm above the finished floor, and the higher end on the side of the control room at a height of ~80 cm (i.e. at the level of the bench where the electrometer is normally located).

4.3.4. Bunker doors

The bunker door design and its fitting are to provide the same shielding as all other secondary shielding, without any gaps. An appropriately shielded door will overlap with the wall, floor and lintel, as indicated in Fig. 8. There has to be sufficient space to enable the movement of equipment and sources into and out of the bunker. The width of the door opening may be 100–200 cm. Heavy

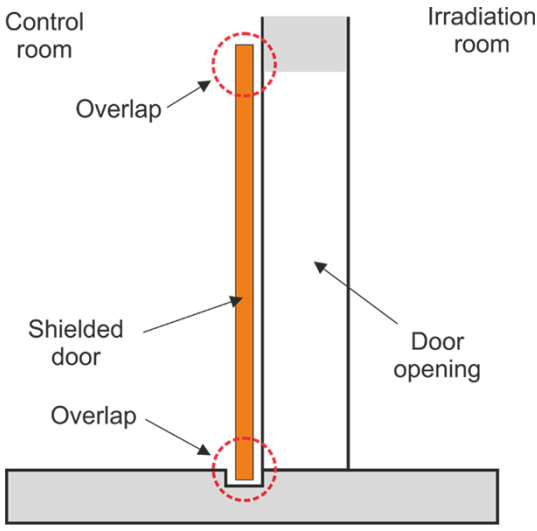

FIG. 8. Door design details.

bunker doors are often motorized with sliding movement. The doors are to meet radiation safety, fire safety and source security specifications.

4.3.5. Lights

The lighting level in the bunker and control rooms is to be in accordance with the national regulations for a laboratory. In the absence of national regulations, best practice is to have the working area illuminated at 500 lx with high illuminance uniformity and >80 colour rendering index produced with low glare and shadow free lighting systems [27]. It is best practice that two separate groups of lights be installed (splitting the room into two areas), which can be switched on and off independently using different switches. It is also advisable to have dimmer lights to facilitate the use of lasers for a more accurate set-up. Sufficient emergency lighting is to be provided in the event of a power failure.

4.3.6. Bunker for radiation protection calibrations

For radiation protection level calibrations, the inner dimensions of the bunker are to be large enough:

(a) To minimize the contribution of the scattered radiation (from walls, ceiling and floor) to the collimated primary beam;

(b) To apply more than 2 m source to detector distances to irradiate the phantom uniformly;
(c) To achieve a broad range of dose rates using the inverse square law.

The range of calibration distances varies from 1–4 m and a long bunker is needed to cover this range with appropriate margins (min. 1 m) from the wall to the point of measurements. In addition, some space is to be left around the irradiator (min. 1 m from rare and 1.5 m from adjacent walls) to allow sufficient access to it when required. Therefore, the bunker may be 7 m long and 4 m wide. In addition, the height is to be at least 3 m. Figures 5 and 6 show a typical example of a radiation protection level calibration bunker layout with a gamma beam irradiator.

4.3.7. Bunker for external beam radiation therapy calibrations

The dose rates for radiation therapy calibration systems are much higher than those used in radiation protection and therefore shielding requirements are much higher. If there is enough space, a labyrinth or maze might be a solution to avoid very heavy doors.

The radiation therapy calibrations are normally performed at a distance of 1 m from the source and the length of the bunker can be shorter than for radiation protection calibrations. However, increasing the length of the bunker in the primary beam direction decreases the thickness needed for the primary beam barrier. The bunker's design needs to also allow for access behind the irradiator so that, if the source does not return to the safe position, personnel will avoid the primary beam when accessing the irradiator head to drive the source back manually. Therefore, the bunker is to be at least 5 m long and 4 m wide. In addition, the height is to be at least 3 m.

4.3.8. Bunker for brachytherapy calibration

The design of a high dose rate (HDR) brachytherapy bunker, accommodating remote afterloading units, needs special attention. Since the calibration procedure is performed by loading high activity sources (approximately 400 GBq ^{192}Ir or 80 GBq ^{60}Co) into a well-type re-entrant ionization chamber, all of the walls, the floor and the ceiling are considered to be primary barriers and are to be of adequate thickness to protect the staff outside the calibration room during the calibration.

It is advisable to fix the positions of the afterloader and the calibration equipment. There is no need for a movable calibration bench, but well-type ionization chamber standards are to be positioned on a low scatter surface, at

least 1 m away from all walls and 1 m above the floor level to prevent undesired contributions from scatter to the readings.

HDR brachytherapy calibrations do not need a large bunker. However, due to the high activity of the gamma sources and 3D irradiation geometry, the shielding is to be properly designed. The size of the bunker and the distance of the source from the walls could be increased to decrease the thickness of the walls. In addition, it is possible to have a maze to the bunker to avoid heavy doors.

An HDR brachytherapy calibration system could also be accommodated in a radiation therapy calibration bunker if there is enough space. A special bunker is not necessary when low dose rate (LDR) brachytherapy sources are used for calibrations. However, protective equipment for manipulating the sources and protecting the personnel during source manipulation is needed.

4.3.9. Bunker for X ray calibrations

Kilovoltage X ray energy spectra are typically lower than the energies of the radionuclides used for calibrations. In addition, radiation is not possible without electrical power. Therefore, the shielding required differs from that in the previous examples. The selection of the maximum X ray tube voltage will have an impact on the available energies. Depending on the energies, the X ray system can be used for radiation protection, radiation therapy and diagnostic radiology calibrations. Sometimes one X ray system can be used to cover many different calibration services. In addition to X ray tube(s), space is needed for the X ray high voltage generator(s). The best practice is to place the generator in a separate room, adjacent to the X ray bunker, to avoid a possible temperature change caused by the heat produced.

A separate X ray tube may be needed for radiation qualities used for mammography calibrations. In some cases, two tubes can use the same generator and the X ray tubes are then installed side by side. X ray systems are typically used for several radiation qualities (combinations of tube voltages and filtrations). In some cases, it might be advisable to have separate X ray systems in different bunkers for different services and energy ranges. For example, an SSDL could have one X ray tube dedicated to diagnostic radiology with lower energies (maximum 160 kV), and another 320 kV X ray tube for radiation protection and radiotherapy calibrations. Consideration of the possible workload will indicate which set-up to adopt.

Calibrations for dosimeters used in diagnostic radiology and radiation therapy are normally performed at a distance of 1 m from the focal spot. For radiation protection dosimeters, larger distances (e.g. 2.5 m) are typically used to achieve the larger beam sizes that are needed to cover the size of the phantoms used for irradiations. At the same time, scattering from other objects (walls,

ceiling, floor, calibration bench) is to be avoided. Therefore, the bunker is to be at least 5 m long and 4 m wide with a height of at least 3 m.

4.4. OTHER SPACE AND ROOMS

In addition to irradiation bunkers, the SSDL is to have appropriate the following separate spaces:

(a) A control room or rooms, adjacent to the calibration bunkers, for control panels and data acquisition systems;
(b) A room for electronic measurements and other physical experiments (e.g. checking and preparing dosimeters for calibration);
(c) A storage room for SSDL equipment and items for calibration;
(d) An office or offices for the staff with appropriate IT infrastructure (i.e. a PC for each staff member, printer(s) and a network connection).

Additionally, it is highly advisable that the SSDL have access to and cooperation with a mechanical and electronic workshop, and IT services.

5. IRRADIATION UNITS AND POSITIONING SYSTEMS

The main part of a calibration system is the irradiation unit, which is used to produce radiation for calibration purposes. In general, irradiation units are remote controlled systems incorporating either radioactive source(s) or an X ray system. Irradiators provide radiation in which the reference dosimetry quantities are determined with a reference standard that is then used to calibrate other dosimeters. Irradiator units are mounted on a rigid support stand, allowing a fixed and typically horizontal radiation beam geometry. In addition, a calibration system includes a system that is used for accurate positioning of the dosimeters in the radiation beam.

5.1. IRRADIATION UNITS

5.1.1. Radiation beam set-up, quantities and radiation qualities

The irradiators used for calibrations are to be positioned in such a way that the scattered radiation from the floor and the adjacent and rear walls can be minimized for the measurements. The central beam axis (CBA) is to be at least 120 cm above the floor, such that a typical collimated radiation field would not strike the floor or the roof at the plane of measurement and the height is appropriate for easy and ergonomic positioning of dosimetry equipment. In addition, the CBA is to be ~1.5 m from the adjacent walls; similarly, calibration distances closer than 1 m from the rear wall are to be avoided.

In some cases, radiation can be produced by an individual source, which is positioned either manually or using a remote afterloader. In these cases (e.g. beta sources or gamma sources used for brachytherapy), the best practice is to fix the calibration set-up in such a way that the impact and potential variations related to scattering conditions can be minimized.

Each calibration scope has dedicated radiation quantities and qualities, as described in the dosimetry standards and codes of practice [4, 5, 12, 28, 29]. The most typical dosimetry quantities include the air kerma (K_a) and the absorbed dose to water (D_w). When a quantity is divided by time, the result is a rate (e.g. the air kerma rate). From air kerma, other quantities may be derived by using appropriate conversion factors (e.g. ambient dose equivalents or personal dose equivalents) or multiplying them with some dimensional quantities (kerma area products or kerma length products). Dosimetry in brachytherapy is based on the air kerma rate measured at a distance of 1 m from the radiation source free in air, corrected for air attenuation and scattering, denoted the 'reference air kerma rate, K_R'; see International Commission on Radiation Units and Measurements (ICRU) Rep. 58 [30].

5.1.2. Safety items related to irradiators

General safety issues related to SSDL premises, facilities and irradiation bunkers are discussed in Sections 2.5 and 4.1. Safety aspects directly related to irradiators are covered here. Safety items are to provide sufficient warning and safety for personnel with respect to unintended exposures. The safety systems are installed to protect and notify personnel about the presence of radiation and to minimize the likelihood of unintended exposures. The safety items could include the following:

(a) Electrically activated bunker door or access interlock switches connected to each irradiation unit. When the door is opened and/or the bunker is

accessed, the interlocks are activated and the source returns automatically to the safe position in its storage container, or in the case of X ray irradiators, the interlock activation moves the shutter to close the exit window of the X ray tube. The high voltage on the X ray tube is not to be switched off by the interlock system.

(b) Mechanical interlocks to prevent simultaneous irradiation if two or more irradiators are in the same bunker.

(c) Infrared beam light barriers (to detect movement in the bunker) may be installed in any irradiation bunker and serve the same (or backup) function as the door interlocks.

(d) Warning lights with discharge bulbs and a flash rate of one to two flashes per second are to be installed in both the bunker and the control room. They are connected to the source position or the shutter of the irradiation unit and activate when the beam is on.

(e) Emergency buttons in the bunker. When the button is pressed the source returns automatically to the safe position in its storage container and the X ray shutter (or system) is switched off.

(f) Emergency equipment in the event of a radioactive source not retracting into its shielded position.

5.2. GAMMA BEAM IRRADIATORS

The term gamma beam irradiator is used here for systems that consist of a container (head) housing the radioactive source, a source movement mechanism or a shutter and a field collimation system. The irradiator is operated remotely from the control room. Usually, a timer mechanism, incorporated with the system, is used to control the duration of the exposure (beam on). Gamma beam irradiators are used for the calibration of dosimeters used in radiation therapy and radiation protection.

5.2.1. Sources

For external beam radiation therapy dosimeters, the standard calibration is performed using a ^{60}Co source. For radiation protection dosimeters, ^{137}Cs is the reference radiation quality but ^{60}Co and/or ^{241}Am sources are also used. There are ISO standards that specify guidelines for source encapsulation and leak tests; see Refs [31, 32].

Radioactive sources decay and the air kerma rate changes with time. Therefore, a decay correction based on the half-life of that radioactive material is needed when measurements at different times are compared [33]. The half-life

ought normally to be taken from the Decay Data Evaluation Project [34]. The radioactive impurity content (isotopes other than the source isotope) is to be as low as possible. Contaminants with a different spectrum from the source isotope might have an impact on the radiation quality. Contaminants with a different half-life from the source isotope might affect calibrations when a decay correction is applied; it is always safer to use reference measurements and long term constancy checks to give an assurance of the effective half-life of the source.

5.2.2. Source container and shutter

Sources are stored in a source head, in a storage position, when not in use. The head is constructed such that the fluence is reduced to a level that limits workers' exposure to radiation to acceptable levels. The design is to ensure that the leakage radiation complies with the national regulations and GSR Part 3 [2]. The background radiation level within a bunker is to be kept such that it does not affect the measurement capabilities of the laboratory. If the background radiation does not conform to sufficiently low levels, additional measures are to be taken (e.g. extra shielding of the head).

Various methods are in use to move the source from its storage position to the irradiation position and back. Typically, the source can be moved on a pneumatic drawer or on a rotating cylinder. In some irradiators, the source is in a fixed position and a shutter made of heavy material, usually lead or steel, lowers in front of the source to block the radiation output when the source is stored. To produce a radiation beam, the shutter is elevated by an electromagnet. If the electricity is interrupted, the magnetic field disappears and the shutter closes.

5.2.3. Timers

The irradiation (beam on) time is measured with timers, which are triggered by either the movement of the source to the irradiation position or the opening and closing of the shutter. The use of timers is important for reference irradiations, in which a prescribed dose is delivered to the dosimeters. The resolution of the timer is to be less than a second. Two timers are usually present in radiation therapy irradiators: a primary timer which controls the irradiation time and a secondary timer which serves as a backup in case of primary timer failure.

5.2.4. Collimators for gamma beam irradiators

The collimator (diaphragm) defines the size of the beam at the point of measurement. If the beam size needs to be changed, the collimator is to be either adjustable or interchangeable. Adjustable collimators are permanently installed

in the head of a radiation therapy level irradiator and consist of two pairs of jaws. Removable collimators are to be supported by a rigid frame. The field shape can be circular or square. The collimator thickness is to be sufficient to transmit <0.1% of the primary radiation outside the useful beam. The collimator of the head is typically made from a heavy material, such as lead (Pb) or tungsten (W).

5.2.5. Gamma beam irradiators for external beam radiation therapy

5.2.5.1. Sources

The radiation therapy level dosimetry standards for megavoltage radiation are based on ^{60}Co beams and the use of beam quality correction factors. Typical ^{60}Co irradiation set-ups are shown in Figs 9 and 10. To maintain the appropriate dose rates — higher than 100 mGy/min — the activity of the source is to be at least 20 TBq at the end of its useful life [4]. The maximum allowable activity of the ^{60}Co is determined by the shielding available in the source head and the construction of the irradiation room. Typically, a source with an activity of up to 300 TBq is appropriate for radiation therapy level calibrations.

5.2.5.2. Beam properties

The irradiator is to have a secondary collimation system to define the radiation field at the given distance by means of the two pairs of jaws (horizontal and vertical). The standard field size for radiation therapy calibration is 10 cm × 10 cm at a distance of 1 m from the source. The guidelines for radiation field uniformity and symmetry given in an IEC standard [35] may also be used for the calibration set-ups.

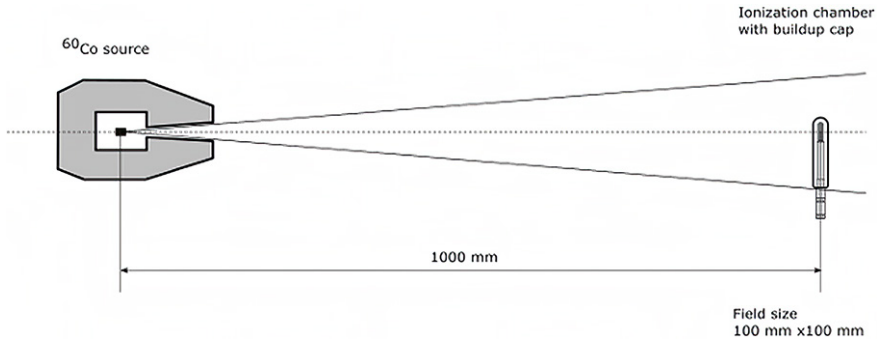

FIG. 9. Radiation therapy level ^{60}Co irradiation set-up for air kerma measurements.

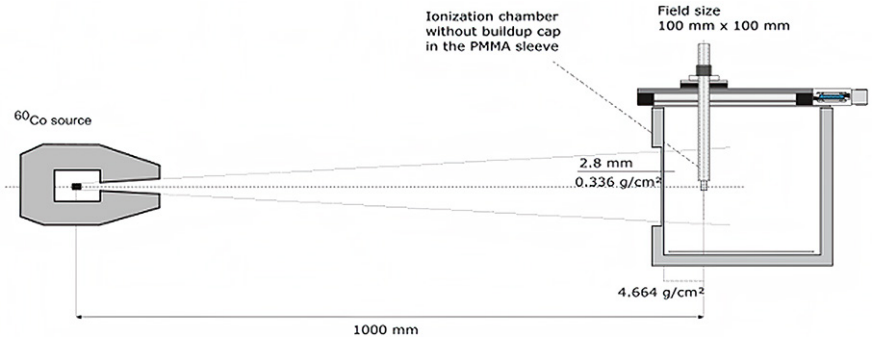

FIG. 10. Radiation therapy level ^{60}Co irradiation set-ups for absorbed dose to water measurements.

5.2.6. Gamma beam irradiators for radiation protection calibrations

5.2.6.1. Sources

Calibration of dosimeters used in radiation protection is to be carried out using the reference radiation qualities provided in ISO Standard 4037-1 [29]. Guidelines on the activities and chemical forms of the specified radionuclides are given in this standard. Caesium-137 is a standard radiation quality that is mostly used for radiation protection calibrations. In addition, a ^{60}Co or ^{241}Am source might be useful if X rays are not available and the energy dependence of dosimeters is to be tested. For each radiation quality (radionuclide), one source with attenuators or a set of sources with different activities is used. The combination of the source activity and the distance from the source allows a wide range of dose rates to be achieved. Specific guidelines for the calibration of different dosimeter types can be found in the ISO 4037 and IEC 60846 standards [29, 36–39].

5.2.6.2. Beam properties

The reference conditions for radiation protection level calibrations are described in the ISO 4037 standard [29, 39]. The collimator of the irradiator is to be designed according to ISO 4037 [29] to provide a circular radiation beam. A stepped collimator is used to minimize the amount of low energy scatter in the field. The collimator set-up consists of six apertures made from heavy metal alloy with a total thickness of up to 9 cm. The 15 mm thick apertures are to have 2 cm wide gaps between them. These gaps serve as traps for the scattered photons from the edges of the preceding aperture.

Radiation protection calibrations are typically performed at a large range of distances, and the dosimeter is placed inside the uniform beam area. Beam uniformity is to be within certain limits over the effective area (cross-section) of the detector being irradiated. Scattered radiation in the radiation field is limited to <5% [29].

The use of uncollimated geometries with radionuclide sources mounted free in the room (4π geometry) is not best practice because of the large contribution of scattered radiation. In the past, uncollimated beam geometries were used to irradiate a number of personal dosimeters simultaneously free in air. However, this is no longer possible, as the irradiations need to be performed on a slab phantom (e.g. for the quantity $H_p(10)$).

5.2.6.3. Attenuators

In some cases, when multiple sources of different activity are not available, lead attenuators could be used to attenuate the collimated beams of ^{137}Cs and ^{60}Co. The attenuators are placed on a rigid frame in close proximity to the collimator. A sequence of lead attenuators of different thicknesses can be used to reduce the air kerma rate by successive orders of magnitude and in this way a large range of air kerma rates can be obtained.

5.3. BRACHYTHERAPY AFTERLOADERS

An afterloader is a remotely controlled system that is used to drive a high activity source from a shielded safe through a transfer tube to a specific point and then retract the source back into a safe position automatically after a predetermined period of time. The set-up for brachytherapy calibrations is different from that in the other dosimeter calibrations that use collimated radiation beams. For routine measurements of reference air kerma rate, a well-type ionization chamber is used. The source is welded to the end of a drive cable and transferred to programmed locations (dwell positions) in an appropriate 'applicator', which is inserted into the well-type chamber for a programmed duration using a motor driven system. Manual handling of HDR sources is prohibited due to the high activity of the source.

5.3.1.1. Brachytherapy sources

Brachytherapy sources include many different designs and isotopes and consist of radioactive materials contained within an encapsulation to prevent contamination. LDR sources can be operated manually but an automatic remote

afterloader is needed for HDR sources. ^{192}Ir and ^{60}Co are widely used for HDR brachytherapy because of their high specific activity. Currently, most HDR remote afterloaders use a ^{60}Co and/or ^{192}Ir source with an initial activity of approximately 80 GBq or 400 GBq, respectively. The size of the encapsulated source is ~5 mm in length and <1.5 mm in diameter.

5.4. X RAY IRRADIATORS

An X ray irradiator consists of an X ray tube and a generator and their cooling and control systems, X ray housing and shutter, and a field collimation system. The term X ray calibration system is used here for systems that consist of an X ray irradiator, monitor chamber, and filters. X rays have a large range of energies and the spectra are broad. With an X ray system, the radiation qualities (and spectra) can be adjusted by changing the X ray tube voltage and/or adding filtration. This allows the testing of energy dependence in dosimeter response. Different standardized radiation qualities are used for calibrations of dosimeters in radiation therapy, radiation protection and diagnostic radiology [4, 5, 12, 28, 29]. A typical X ray calibration set-up is shown in Fig. 11.

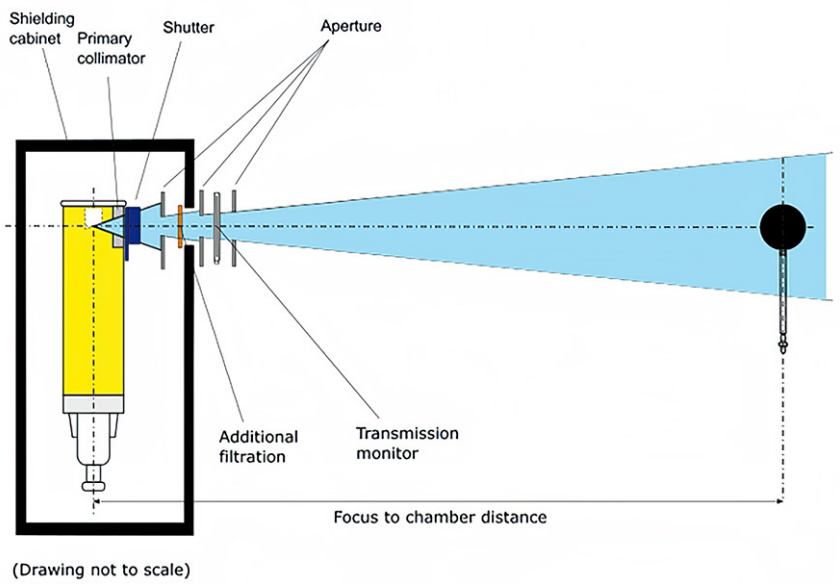

FIG. 11. An X ray tube and calibration set-up.

5.4.1. X ray tube and generator

The X ray unit is to be of the ‘constant potential’ type, with a high voltage ripple as low as possible. Modern, commercially available X ray generators exhibit ripple (measured under load) of <5 V/mA in unipolar systems with a 10 m cable. A mains stabilizer may be necessary to reduce the variation in the voltage (e.g. <0.3%) for unexpected changes in mains voltage or frequency.

The generating potential is the potential difference between the high voltage electrical connections of the protective tube housing. The tube voltage is the potential difference between the cathode and the anode of the X ray tube. The tube voltage can be lower than that of the generating potential if a protective resistor is built into the protective tube housing. In this case the voltage difference depends on the tube current and needs to be determined. The mean value of the tube potential is to be stable to within ±1%, and its deviation from the nominal value is not to be more than 1%. The best practice is to have a tube potential measured directly with high accuracy for measurements of the directional dose equivalent of low energy X ray beams (<40 kV). More detailed guidelines for radiation protection calibrations are given in the ISO 4037 standard [29].

The X ray system is to operate within the appropriate range of tube voltages. A full range of radiation qualities covers tube voltages from 10 to 400 kV. More than one X ray tube may be needed to cover this whole range. If tube voltages >225 kV are desired, a bipolar X ray system is needed. However, typically, a limited range from 40 to 200 kV is adequate for most radiation protection and radiation therapy calibrations. A lower range of tube voltages is used for diagnostic radiology calibrations (40–150 kV) and mammography (25–35 kV). One X ray tube may be procured to cover 50–200 kV and another tube to cover lower energies (20–40 kV) to allow the laboratory to cover all needed beam qualities.

The tube voltage and current are to be adjustable in steps of at least 0.1 kV and 0.1 mA, respectively. The X ray tubes used for calibration purposes are typically industrial types and it is to be noted that their air kerma rates are lower than for clinical X ray systems.

In addition to tube voltages, the anode material and angle affects the spectra. The anode is to be a reflecting type and is typically made of tungsten, but for mammography molybdenum and sometimes also rhodium anodes are used. The anode angle is to be >7° and typically 20° (15°–25°). In clinical imaging, a small focal spot provides good image quality. However, the heat load to the anode is high and extensive use of a small focus can affect the lifetime of the tube. In calibration laboratories, image quality is not an issue and longer exposures are performed. Therefore, larger focus sizes such as 4 mm × 4 mm are used.

The X ray exit window is typically 1 mm beryllium. The total inherent filtration of a tube (glass of the bulb, oil, exit window), including filtration of the monitor ionization chamber, used for the low energy range, is not to be more than 3 mm beryllium equivalent. Thicker filtration may result in an inability to realize low energy radiation qualities. It is to be noted that the ageing effect of X ray tubes can affect the spectra and beam uniformity.

5.4.2. X ray housing

The X ray tube is installed in the housing and mounted on a holder allowing geometrical alignment with the desired CBA. The shielding cabinet needs to totally enclose the X ray tube, the shutter and the cables, and provide mechanical support for a filter changing device (filter wheel). The cabinet needs to be shielded in all directions. The leakage radiation through the cabinet when the X ray system runs at full power with a closed shutter is to be measured and limited to an acceptable level. Best practice is for the enclosure to allow access to the tube and shutter for maintenance, preferably through a cabinet door with an interlock that disables power to the tube when opened.

5.4.3. Shutter

A remote controlled shutter is needed to activate the X ray beam from the control room. In addition, the shutter enables access to the bunker without switching off the high voltage from the tube and this helps to maintain X ray beam stability. The shutter is normally made of lead or tungsten to attenuate the beam to a safe level. The thickness is to be such that it reduces the transmitted air kerma rate to 0.1% for the radiation quality with the highest mean energy. Its function is part of the safety system of the bunker (i.e. closed position when the door is open).

A specific irradiation time is needed for reference irradiations of dosimeters and calibrations in terms of air kerma instead of air kerma rate. The transit time of the shutter is an important parameter for these measurements. The shutter has to be mounted close to the X ray tube exit window and has to be small in order to be as fast as possible. The shutter movement introduces uncertainty into the irradiation time and affects the beam profile. This is significant when the irradiation time is short or a simultaneous irradiation of several dosimeters is performed.

5.4.4. Collimators for X ray systems

Typically, three collimators are incorporated into the X ray calibration system. The primary collimator is often supplied as part of the tube housing. It

serves to limit the field size to the largest field expected to be used and is to be as close as possible to the tube [4].

The second collimator, positioned after the additional filtration, defines the size of the beam at the point of measurement. To use different field sizes for the different types of probes and types of calibration, the second collimator is to be either adjustable or interchangeable. Its thickness is to be sufficient to transmit <0.1% of the incident radiation [4].

A third shielding collimator is positioned after the monitor chamber, to reduce backscattering from a dosimeter or phantom to the monitor chamber, and to reduce the penumbra of the collimated beam. Its aperture is not to limit the beam size, as defined by the second collimator. Each collimator is to be made of lead or tungsten.

5.4.5. Radiation qualities and filters for X rays

In optimal situations, the radiation qualities used for the calibration service are to match those of the end user. The calibration capability has to cover the range of radiation qualities used in clinical practice to allow proper use of calibration coefficients in end user measurements. However, the clinically used combinations (anode material, tube voltage, filtration material, thicknesses) are extensive, and therefore sets of standardized radiation qualities are realized for different purposes. SSDLs need to have traceable calibrations for those radiation qualities that are used for their calibration services.

X ray spectra cannot be standardized because of the variation of tube voltages and filtration in the X ray tube. Therefore, radiation qualities are typically defined according to anode material and tube voltage plus total filtration and expressed in half value layer (HVL). To establish the standard X ray radiation qualities mentioned in Technical Reports Series No. 457 and the IEC 61267 and ISO 4037 standards [5, 28, 29], or as used at the BIPM, additional high purity filtration (at least 99.9%) and homogeneous filter foils are used.

Each filter foil has to be larger than the X ray beam so that it covers the beam completely. Filters are to be mounted as close as possible to the shutter, and the individual filters are to be arranged from the focus in decreasing order of atomic number to reduce characteristic radiation from elements with higher atomic numbers. Suitable sets of filter combinations can be mounted on a remote controlled wheel to facilitate changing radiation qualities and beam sizes [4].

5.4.6. Half value layer measurement assembly

The HVL is measured when different X ray radiation qualities are established and as part of quality control. Therefore, it might be useful to have a

special assembly for HVL measurements. The assembly is to include HVL filters, a filter wheel to position the filters at the CBA, and a special collimator to create a narrow beam geometry and remove scatter from the HVL filters.

High purity filter foils of aluminium (Al) and copper (Cu) are needed for HVL measurements. The actual thickness of the foils is to be known within an uncertainty of 10 μm. A micrometer of 1 μm resolution is used to measure the thickness of the HVL filter foils. This micrometer is to have sufficient arm length to measure the thickness at the centre of the filter foil.

In HVL measurements, the filter foils are placed successively in the beam, midway between the monitor chamber and the ionization chamber used for the measurements, to minimize the impact of radiation scatter. The radiation field size is to cover the chamber used and irradiate the sensitive volume of the chamber completely and uniformly.

5.4.7. Monitor chamber

The monitor chamber is used to monitor the long and short term stability of the X ray system. The monitor readings for standard radiation qualities are to be noted and plotted as a function of time to indicate potential changes of the output and indicate potential operational errors.

The monitor chamber is typically an unsealed parallel plate transmission air ionization chamber, which is installed adjacent to the added filtration. The total absorption of the monitor chamber as part of the inherent filtration needs to be considered for low energy X ray radiation qualities. For applications using an unsealed monitor chamber, each reading is to be normalized to the standard temperature and pressure. In order to do this, a temperature probe is to be positioned as close as possible to the monitor chamber, due to the high gradient temperature distribution in the X ray tube vicinity.

During calibrations, the monitor chamber is used to monitor the air kerma rate over a series of measurements with the reference instrument and dosimeter under calibration. The reading of the monitor chamber can be used to:

— Correct for any variations in the air kerma rate;
— Confirm that any variation in the air kerma rate is at an acceptable level (as included in the uncertainty budget).

The second application is only useful if the standard deviation of the corrected monitor chamber reading is less than the short term fluctuation of the X ray tube output. This is often not the case when using a high quality modern X ray system (<0.05% deviation of the output within a few hours).

5.4.8. Standard radiation qualities for radiation therapy calibrations

An X ray system, as described previously, can also be used for radiation therapy level calibrations (medium and low energies). Unfortunately, there are currently no international standardized guidelines for radiation qualities used for radiation therapy purposes. A wide variety of X ray radiation qualities are used in hospitals worldwide and may differ from the radiation qualities used for performing calibrations.

The national codes of practice of Germany (German Institute for Standardization (DIN) 6809-4), the Netherlands (Nederlandse Commissie voor Stralingdosimetrie (NCS)-10) and the United Kingdom (Institute of Physics and Engineering in Medicine), as well as the American Association of Physicists in Medicine (AAPM) TG-61 and Technical Reports Series No. 277, were published more than 15 years ago [40–44]. Best practice for the selection of the radiation qualities in SSDLs would be to follow AAPM TG-61 [42], which states that:

> "The chamber shall be calibrated at a beam quality sufficiently close to the user's beam quality in terms of *both* the tube potential *and* HVL to ensure the validity of the calibration factor in the clinical situation".

SSDLs have established Consultative Committee for Ionizing Radiation (CCRI) radiation qualities (CCRI low and CCRI medium), which were established at the BIPM for international comparisons of the primary standards and are provided by most PSDLs. Further details of the beam specifications (inherent and external filtrations, second HVL, etc.) are available on the websites of the PSDLs and details of the associated services can be found on the BIPM KCDB [14].

5.4.9. Standard radiation qualities for radiation protection calibrations

The reference X ray radiation qualities, phantoms and conversion coefficients to calculate operational quantities from measured air kerma are published in the ISO 4037 standards [29, 38, 39]. Four X ray radiation quality series (H, W, N, L) with different filtration and conversion coefficients are defined:

(1) The high air kerma rate series: H series;
(2) The wide spectrum series: W series;
(3) The narrow spectrum series: N series;
(4) The low air kerma rate series: L series.

The standard specifies the guidelines related to filter materials, thicknesses and impurities. The ISO 4037 has stricter guidelines for the personal and

directional dose equivalent measurements than for air kerma measurement if the conversion coefficients published in the ISO 4037-3 [39] are to be used.

For routine calibrations and other performance test measurements the narrow spectrum series (N series) is given as a guideline in the relevant IEC standard, including the technical guidelines for the dosimeters. The IEC 60846, 62387, 61526, 60325 and 61017 standards cover the most frequently used radiation protection level dosimeters [36, 37, 45–48].

If a photon energy <662 keV (^{137}Cs radiation) is needed for the calibration of radiation protection dosimeters, best practice is to establish one or more radiation qualities from the ISO N series. For the establishment of N series qualities <40 kV (N-40), best practice is for the SSDL to consider higher measurement uncertainties than the stated u_c = 2% of the conversion coefficients in ISO 4037-3 [39]. This 2% standard uncertainty can only be used if the beam specifications (tube high voltage, filtration, HVL values) are within the tolerance limits and the calibration set-up complies with the guidelines in ISO 4037-3 [39]. If the incident spectra of the X ray radiation quality are known, the individual conversion coefficient can also be calculated using the monoenergetic coefficients published in ISO 4037-3 [39].

5.4.10. Standard radiation qualities for diagnostic radiology calibrations

The challenge for diagnostic radiology calibration is the large variation of radiation qualities used clinically. Different combinations of anodes, filters and tube voltages between 25 and 150 kV are used, and not all can be established in the SSDL [5]. The guideline is for the SSDL to establish standardized radiation quality sets.

The guidelines for the performance of diagnostic radiology dosimeters are given in IEC 61674 [49]. The calibration of diagnostic radiology dosimeters is performed according to the radiation qualities that are described in the IEC 61267 standard [28] and in Technical Reports Series No. 457 [5]; this is achieved using appropriate filtration at the specified tube voltage. The calibration of these dosimeters is to be performed according to their application; there are several radiation qualities. The adequate radiation qualities for the calibration of dosimeters used in general diagnostic, fluoroscopy and interventional radiology are the RQR (incident beams) and RQA (attenuated beams) series, while the RQT series specified in IEC 61267 [28] and Technical Reports Series No. 457 [5] is for computed tomography (CT) dose measurements both in terms of air kerma and air kerma length product.

Regarding mammography, a wide variety of radiation qualities (depending on the combination of high voltage, anode and filter materials) are used in clinical practice, depending on the type of mammography machine. The two radiation

quality series RQR-M and RQA-M specified in IEC 61267 [28] and Technical Reports Series No. 457 [5] can only be used when the SSDL has an X ray tube with a molybdenum (Mo) anode. If an X ray tube with only a tungsten (W) anode is available at the SSDL, other radiation qualities cannot be established according to the types of mammography machine used in the clinical practice. Detailed specifications for the radiation qualities available for the calibration of reference chambers of the SSDLs are available at some PSDLs and at the IAEA dosimetry laboratory. International traceability is available for the RQR-M and W+Mo qualities, as they have been established at the BIPM.

5.4.11. Special collimators for diagnostic radiology

Special collimators are needed for the calibration of detectors that are partially irradiated, namely air kerma area product (KAP) chambers and pencil type CT chambers [5]. An additional collimator is placed close to the KAP or CT chamber to define the irradiation field. The collimator is to be made of heavy material (Pb) with appropriate thickness (e.g. 5 mm) to absorb the X ray beam completely. The set-up has to allow for accurate determination of the field size or width at the plane of measurement.

For KAP chamber calibrations, the aperture (opening) of the collimator is to be either square or circular and have a size of approximately 50 mm × 50 mm (or Ø 50 mm) for the calibration of a typical KAP chamber with an effective area of 150 mm × 150 mm. However, several collimators with various apertures or an adjustable aperture are to be available, in order to test the area dependence of KAP chamber response, for example in the range of 30 mm × 30 mm to 100 mm × 100 mm.

For CT chamber calibrations, an additional collimator that has a rectangular (slit) aperture with a width of ~50 mm (along the CT chamber axis) to cover half of the CT chamber length is used. The other dimensions of the aperture (vertical to the CT chamber axis) are not important, assuming that it is much wider than the chamber diameter. Apart from this standard size, several aperture widths or an adjustable aperture width may be available to test the width dependence of the response and the residual signal of the CT chamber (in the range of 10 to 90 mm).

5.5. CALIBRATION BENCH

A positioning and alignment bench (calibration bench) is used for accurate positioning of the reference dosimeters and the instruments being calibrated in the radiation beam. The calibration bench can be moved along rails in front of the irradiator in parallel with the CBA, so that the distance of the plane of

measurement from the source or the X ray focal spot can be adjusted. A typical distance range is 1–5 m for radiation protection level calibrations. For radiation therapy and diagnostic radiology, calibrations are performed at a distance of 1 m.

The calibration bench has to have a movable cross table to enable accurate positioning of dosimeters in all directions. In the horizontal direction (left–right), the table size is to enable positioning of two probes side by side and the table movement is to allow for irradiation without repositioning of the probes on the table (substitutional calibration method). An example of a calibration bench with three instrument holders is presented in Fig. 12.

The movements of the bench and cross table can be controlled manually or remotely. Each of the three dimensional movement ranges are to have ≤1 mm reproducibility and the positions are to be scaled or displayed with 1 mm resolution. In the vertical direction (up–down) the cross table is to enable the positioning of differently sized and shaped probes, so that their reference point is at the CBA. The table is to allow the mounting of rigid but adjustable holders that can be used for accurate positioning of different types of probes.

The bench, the table and the holder construction are to assure minimum radiation scatter of the primary beam (e.g. the metal parts of the bench and the cross table are not to be positioned in the primary radiation beam and the probe holders are to be made of lightweight material).

The cross table is to hold at least 50 kg without deflection. For example, for radiation therapy calibrations, the measuring bench has to have the possibility to hold and align a water phantom of approximately 40 cm × 40 cm × 40 cm. For radiation protection calibration, the measuring bench has to allow for an ISO water slab phantom (30 cm × 30 cm × 15 cm) to be set up. For directional radiation protection quantities, being able to rotate the cross table or another platform could be a useful property.

5.6. ANCILLARY EQUIPMENT FOR POSITIONING AND READING DOSIMETERS

The ancillary equipment for positioning could include lasers, an optical telescope, a rod micrometer set and a digital calliper. Sharp contours and stable laser lines or spots are essential. The resolution of the telescope and the size of the laser beams are to allow for reproducible positioning with a measurement uncertainty of <1 mm.

The CBA of the collimated beam, the directions of the movable calibration bench and cross table, and the laser/telescope directions are to be precisely aligned to each other. A positioning laser is usually fixed on the wall opposite the irradiator and aligned with the CBA to facilitate setting up instruments in the beam.

FIG. 12. A calibration bench with three instrument holders.

Different methods can be used for adjusting the distance from the radiation source/focus. A fixed laser can be used at specific distances to mark commonly used calibration distances. An optical telescope or a laser could be fixed on the calibration bench oriented perpendicular to the CBA to mark the position on a ruler fixed on the wall. A rod micrometer and a removable metal plate to hold the micrometer in the CBA could be used for absolute distance measurement from the radiation source/focus.

A fine focus camera, with an autofocus lens mounted on the calibration bench is used to read the instrument display during calibration. The camera is connected to monitors that are located in the bunker and the control room. The scattered radiation from this camera set-up to the point of measurement is to be negligible.

6. MEASUREMENT EQUIPMENT

6.1. INTRODUCTION

A range of different types of equipment is used for radiation measurements. However, this section only covers the equipment that is needed for establishing a calibration service in an SSDL. The SSDL needs to have at least one secondary standard for a dosimetry quantity. Ionization chambers are used as a secondary standard for the determination of air kerma, reference air kerma rate and absorbed dose to water. The term 'dosimetry system', where used, is defined to be an ionization chamber (detector), an instrument for measuring electric charge or current (electrometer) and a connecting cable. In addition, some other measuring equipment for different quantities (e.g. air temperature, pressure) and phantoms providing scattering and/or attenuation conditions are needed for standardized measurements and calibrations.

The dosimetric accuracy achieved depends on the properties of the equipment used for the calibrations. Therefore, the dosimetry systems are to be of the highest quality and it is best practice that only reference class dosimeters be used as standards, as defined in the relevant documentary standard (see Section 6.2.1). This equipment is to have long term stability and low energy dependence. In addition to the reference standard, the SSDL is to have at least one backup or working standard for each type of calibration. The standards are to be maintained with the utmost care and stored under stable environmental conditions.

The traceability of the standards, including the associated current measurement equipment, is to be maintained in accordance with the QMS of the SSDL. Calibration at an internationally recognized laboratory — a PSDL, the IAEA or directly at the BIPM — is required for each radiation quality and quantity of the calibration service.

Different types of dosimeters are used in practice by end users. Therefore, the radiation metrologists working in an SSDL are to be familiar with the dosimetry equipment. Field instruments are not considered under the scope of this publication; only the reference class equipment is described.

6.2. IONIZATION CHAMBERS

Ionization chambers comprise a cavity filled with gas surrounded by a wall of conductive material, and have a collecting electrode [33, 50]. The ionization

chamber type, design and size are chosen based on the radiation beam quality and the measured kerma/dose rate.

A reference class ionization chamber is typically cylindrical, spherical, plane parallel or well-type. For low energy photon, electron, alpha and beta measurements, the chamber is typically a plane parallel with a thin window. Cylindrical or spherical chambers are used for higher energies and well-type chambers for brachytherapy.

Plane parallel ionization chambers (also known as parallel plate chambers) use two parallel positioned walls, one serving as an entrance window and as the polarizing electrode, and the other as the collecting electrode and as a guard ring system. They are used with their plates oriented perpendicular to the CBA; the entrance window faces the source. The reference plane is chamber specific.

Cylindrical, thimble and spherical chambers (also known as shell chambers [19]) contain a central electrode, and the reference point is typically in the centre of the cavity volume. For cylindrical or thimble ionization chambers, the reference point is located on the chamber axis at a specified distance from the tip. The construction of well-type chambers is described in Section 6.2.1.3.

The main advantages of ionization chambers are simplicity and the small variation of response with varying radiation energies because of the carefully selected volume, wall and electrode materials. Furthermore, they have good long term stability because vented construction allows operation at ambient temperature and pressure. The current in a vented chamber depends on the density of air, so it has to be corrected to 20ºC (or 22ºC in some regions) and 101.325 kPa, which are considered the reference temperature and pressure. The reference conditions ought to be stated clearly in technical procedures and in calibration certificates. The humidity dependence of air density in the relative humidity range of 30 to 70% can be neglected [51].

6.2.1. Reference standards for radiation therapy calibrations

The quantities used for dosimetry in external beam radiotherapy are air kerma and absorbed dose to water, while for brachytherapy reference air kerma rate is used. If the chamber is to be used in a water phantom, the ionization chamber is to be waterproof, or a waterproof sleeve is to be used. The detailed characteristics and the use of these chambers in external beam radiation therapy dosimetry are explained in IEC 60731 [19], Technical Reports Series No. 398 [3], Technical Reports Series No. 469 [4], and Technical Reports Series No. 277 [40], and for brachytherapy they are explained in IEC 62467 [52] and IAEA-TECDOC-1274 [53].

The IEC 60731 standard [19] sets out the general requirements for dosimeters used in radiation therapy and specifically defines the concept of

reference class dosimeters. Reference class ionization chambers used for radiation therapy calibration at SSDLs are to have long term stability of better than ±0.5% over one year. If the chamber is used for X ray calibrations (low and medium energy X rays) a flat energy response is essential to reduce the uncertainty associated with the difference in radiation qualities at the PSDL and the SSDL. A generic limit in the energy dependence of a particular detector within the radiation qualities used for calibration purposes is 2% [19].

6.2.1.1. Cylindrical chambers

At SSDLs, cylindrical ionization chambers are used as reference standards for radiation therapy calibrations in ^{60}Co gamma beams and medium energy X rays (>50 kV). In clinical practice, they are the most common chambers used in radiation therapy beams and, in addition to medium energy X rays and ^{60}Co gamma radiation beams, they are used for high energy photons, protons and heavy ion beams. Typically, plane parallel chambers are used for clinical dosimetry of MeV electron beams. However, at SSDLs these dosimeters can also be calibrated in the ^{60}Co gamma beam against a cylindrical reference standard chamber.

The end of a cylindrical chamber is typically hemispherical or conical to minimize the variation in electric field strength at the effective point of measurement. Technical Reports Series No. 398 [3] gives specific guidelines for selecting an appropriate chamber for clinical measurements. Some of these data can also be used for selecting a reference chamber for an SSDL. The guideline in Technical Reports Series No. 398 [3] is that the active volume of a chamber cavity is to be between approximately 0.1 cm^3 and 1 cm^3. This size range is a compromise between the need for sufficient sensitivity and the ability to measure dose at a point. These guidelines are met with an air cavity with an internal diameter not greater than 7 mm and an internal length not greater than 25 mm. Cylindrical ionization chambers with walls made of graphite are known to be stable and are thus suitable as reference ionization chambers. If the chamber is used free in air in a ^{60}Co beam it is to be equipped with a buildup cap to establish electron equilibrium.

Most modern cylindrical ionization chambers are waterproof and can be immersed into a water phantom for measurements. A schematic representation of cylindrical ionization chambers used as reference standards for radiation therapy calibrations is shown in Fig. 13, which also illustrates the basic design of a 0.6 cm^3 Farmer type cylindrical chamber.

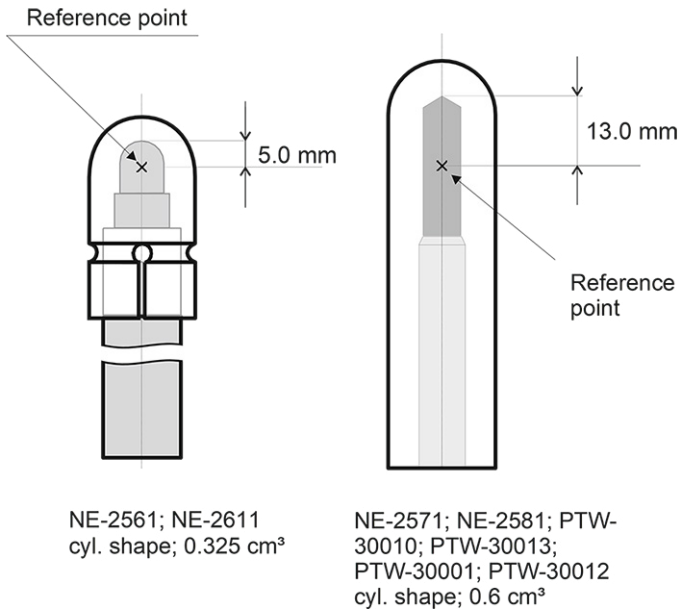

FIG. 13. A schematic representation of cylindrical ionization chambers used in radiation therapy dosimetry. A typical Farmer type chamber is on the right.

6.2.1.2. Plane parallel chambers

Thin window plane parallel ionization chambers are only used as secondary standards at SSDLs for very low energy X ray beams (<50 kV). The construction of parallel plate chambers used for electron dosimetry is very different from that of those used for low energy X rays; they are not to be used interchangeably.

For low energy X rays, ionization chambers are to have an energy response within 4%. The chamber window thickness is to be sufficient to allow full buildup of the secondary electron spectrum. This will also prevent secondary electrons generated in the collimator from entering the chamber. A schematic representation of plane parallel ionization chambers used as a secondary standard for low energy X rays is shown in Fig. 14.

6.2.1.3. Brachytherapy well-type ionization chambers

Well-type re-entrant ionization chambers are used for brachytherapy calibrations, and they are also used in clinical measurements for most brachytherapy photon sources, as well as for intravascular beta sources [52]. A well-type chamber for brachytherapy calibrations can measure the reference air kerma rate of both LDR

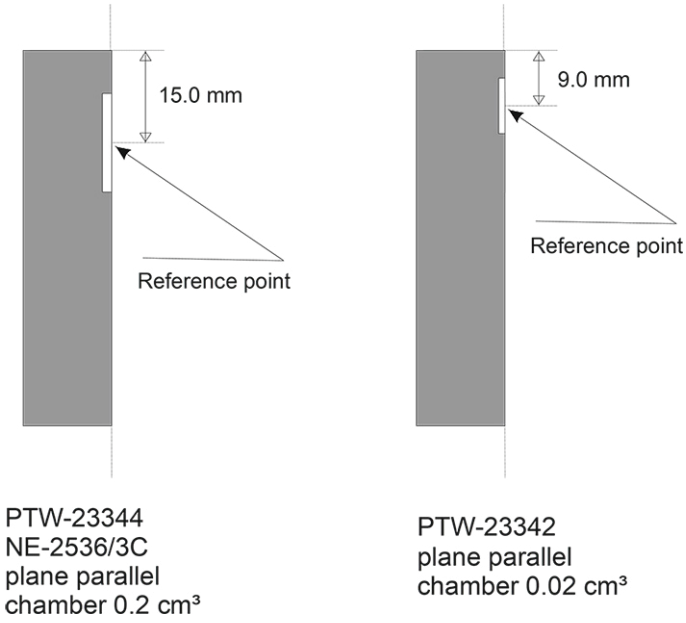

FIG. 14. A schematic representation of thin window plane parallel ionization chambers used as a secondary standard for low energy X rays.

and HDR sources (Fig. 15). The well-type chamber is to be open to the atmosphere, as the sealed chambers may develop slow leakage of gas when the pressure of the gas is higher than that of the ambient atmosphere [53].

The well-type chamber has a cylindrical outer wall, and an opening for inserting and positioning the source. A source holder is used to establish a reproducible source position within the chamber cavity. The chamber is to be large enough to accommodate the source to be measured while approximating complete sphere (4π) geometry. All practical chambers generally have what is referred to as a 'sweet spot' where the chamber signal is maximized. For HDR measurements, the afterloader is used to detect the position of the sweet spot, but for LDR measurements the height is defined by the source holder (also referred to as spacer).

6.2.2. Reference standards for radiation protection calibrations

A radiation protection level reference instrument for γ and X ray radiation is generally a spherical ionization chamber (Fig. 16). Reference instruments do not indicate the operational dose equivalent quantities for calibrating radiation protection monitoring instruments. Rather, the air kerma (rate) is deduced from charge or current measurements, and the ambient, personal or directional dose

(rate) equivalents can then be determined by using appropriate beam specific conversion coefficients [12, 39].

The air kerma rates measured in radiation protection calibrations are lower than for radiation therapy calibrations and therefore the chambers used are larger. The most commonly used reference standard chamber has a spherical or cylindrical volume of 800–1000 cm^3. In radiation protection calibrations, a large range of calibration distances are used, and it is important to know the reference plane accurately.

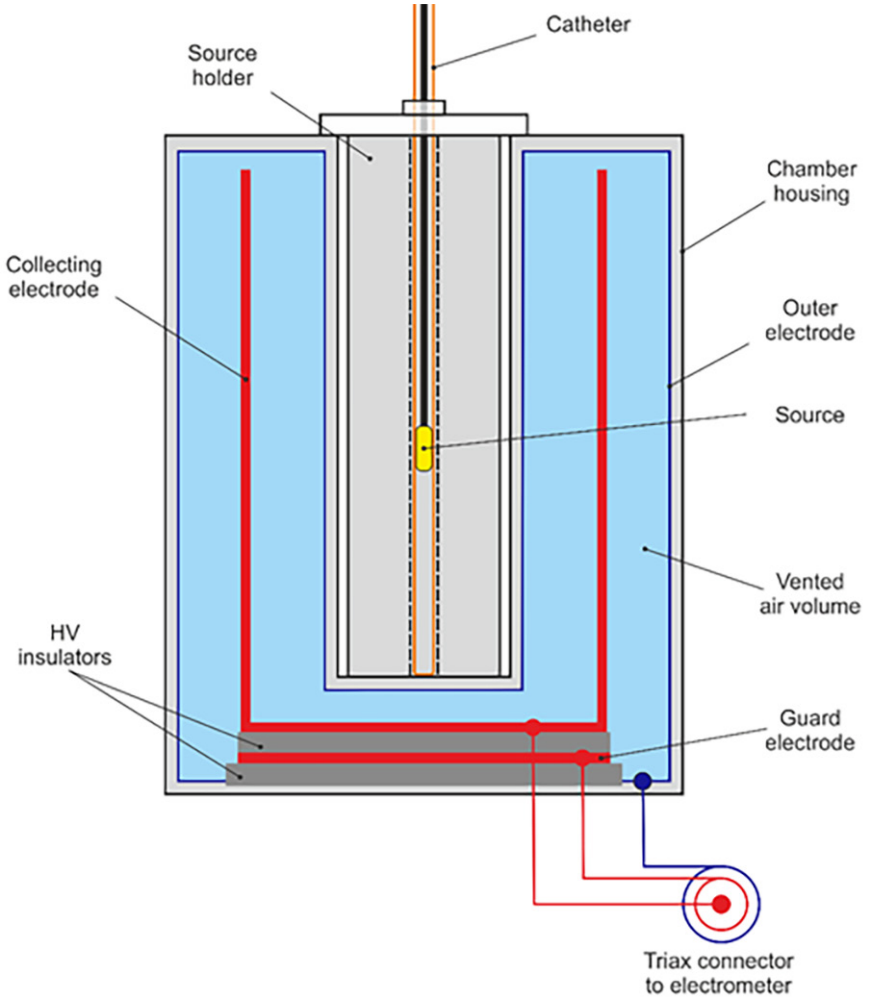

FIG. 15. Cross-section of a typical well-type chamber, including the source holder for positioning the source inside the well.

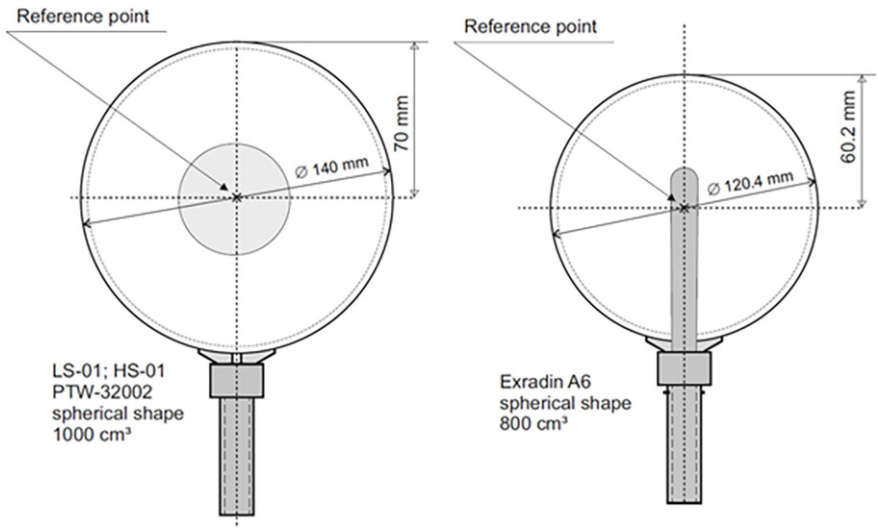

FIG. 16. Schematic drawings of typical spherical ionization chambers used as radiation protection level reference standards.

Additional ionization chambers with different volumes might be needed to cover measurements at different distances. A large chamber of 10 000 cm^3 is used for very low air kerma rates to cover measurement ranges close to background radiation. A smaller chamber of ~300 cm^3 is used to make measurements at higher air kerma rates and, for example, to perform profile or HVL measurements.

6.2.3. Reference standards for diagnostic radiology calibrations

The ionization chambers used to measure air kerma in diagnostic radiology are plane parallel, spherical, or cylindrical (Fig. 17). The reference standard is calibrated in air kerma for a range of reference radiation qualities. The other quantities used for calibrations, kerma area product (P_{KA}) or kerma length product (P_{KL}), can be derived from the air kerma measurements by using the collimator dimensions.

The ionization chamber is to be in compliance with IEC 61674 [49]. It is not best practice to use semiconductor detectors as reference or working standards at SSDLs, and SSDLs are discouraged from using these commercial dosimeter assemblies as reference diagnostic radiology dosimeters due to their energy dependence. Reference class equipment is not strictly defined in IEC 61674 [49], but Technical Reports Series No. 457 [5] provides more information on the specifications of detectors that may be used as reference standards in diagnostic radiology.

The RQR, RQT and RQM radiation qualities are used to simulate the clinical beams incident to the patient and the air kerma rates are higher than those for attenuated RQA and RQA-M beams, which simulate the beam behind the patient. Different chamber volumes might be needed to cover the full range of different air kerma rates. Typical measuring volumes vary from 1–6 cm^3 and chambers with different shapes and constructions are used.

The tube voltage range used in general radiology is 40–150 kV; preferably, one standard is to be used to cover the whole set of radiation qualities (e.g. RQR). The tube voltages and radiation energies used in mammography are lower (25–35 kV) and typically thin window plane parallel chambers are used. The radiation qualities used for mammography calibrations are typically specified based on the tube voltage, anode, and filter material and HVL. The spectra used in PSDL and SSDL calibrations might be different, hence it is important to use a standard that has a low energy response.

6.3. ELECTROMETERS

Ionization chambers normally only produce a very small current or charge. A sensitive electrometer is needed for this kind of measurement. Table 3 gives the electrometer specifications needed for establishing different capabilities at the SSDL.

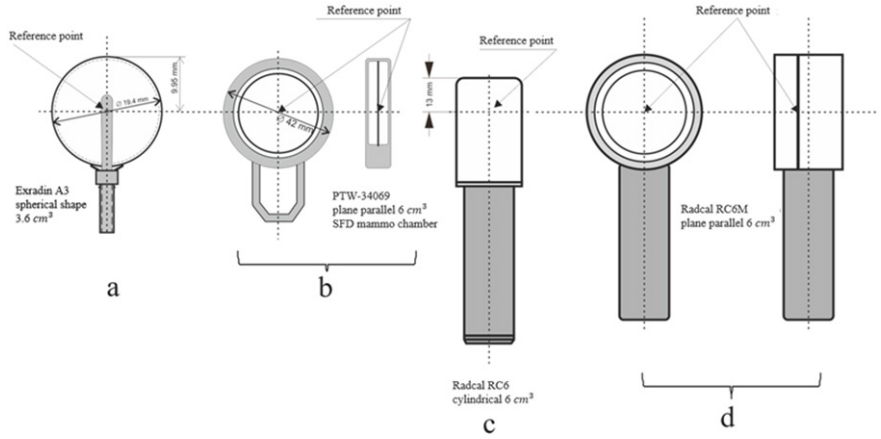

FIG. 17. Schematic diagrams of chamber designs with (a) a spherical chamber (Exradin A3, Standard Imaging), (b) a parallel plate (PTW-34069, PTW), (c) a cylindrical chamber (RC6, Radcal) and (d) a plane parallel plate (RC6M, Radcal).

TABLE 3. REFERENCE ELECTROMETER SPECIFICATIONS

Specification	Value
Measured quantity	Charge/current
Measuring range	10 pC/10 pA to 1 C/1 μA
Resolution	10 fC/1 fA
Long term stability	≤0.2%/year
Zero drift	≤5 fA
Leakage	≤10 fA
Non-linearity	≤5 fA
Built-in high voltage source	at least ±400 V

6.3.1. Charge or current measurements

The signal collected from ionization chambers is an electrical current that is typically in the range of picoamperes or nanoamperes. An electrometer with the capability of measuring in the picoampere or nanoampere range is desirable. Electrometers have a special input characteristic that allows the measurement of low values of current or charge. The most important parameter, which distinguishes the electrometer from a conventional digital multimeter, is its very high input impedance, which is typically in the range of teraohms.

The modern electrometers used in dosimetry consist of an operational amplifier with a capacitor or resistor feedback element. The theory of operation is beyond the scope of this publication. However, it is important to be aware of the different operational modes, the connector types and the polarity settings of the high voltage for different ionization chambers. Further details are provided in Ref. [54].

6.3.2. Data acquisition software

Modern electrometers are often supplied together with a communication protocol allowing computer controlled data acquisition. Such instruments can be connected to a PC via RS-232, GPIB or USB interfaces. Some protocols only

allow the transfer of data, whereas others allow full control of the instrument. Using data acquisition software, especially when combined with measuring temperature, pressure and humidity, enables the automation of the calibration process. Thorough knowledge of how to operate a given electrometer and of the principles of low current and/or charge measurements is needed for the development of such software. It is important that the software be thoroughly tested and validated before it is used for calibration measurements.

6.4. CABLES, CONNECTORS AND ADAPTERS

6.4.1. Cables

In most cases, the ionization chamber and the electrometer are physically separated by several metres. Therefore, the ionization chamber is to be equipped with a cable of adequate length or an extension cable has to be used. Accuracy is of major importance when making measurements; therefore, the cables, connectors and adapters are not to degrade the measured ionization current significantly.

For measurements of low electric charge or current in the range of picoamperes or picocoulombs, coaxial or triaxial cables are used. Coaxial cables consist of a single conductor surrounded by an insulator and shield, while a triaxial cable has a second shield around the first one.

The inner shield of the triaxial cable can be set to the guard potential to reduce cable leakage and minimize the circuit rise times. The outer shield is usually connected to the chassis ground or, in some cases, to the common terminal. The proper shielding of the conductor protects against electrostatic interference. Both coaxial and triaxial cables are available in low noise versions that are to be used for low charge or current level measurements. Low noise cables have internal graphite coatings to minimize current generated by triboelectric effects.

Parameters such as cable resistance, capacitance and leakage currents increase with cable length. It is therefore important to keep all connecting cables as short as possible. The friction between the conductor and the insulator can generate so-called triboelectric currents. It is therefore advisable to avoid any movement of the cable during measurement. Similarly, piezoelectric currents can be generated when mechanical stress is applied to certain materials. Therefore, any mechanical stress (stepping on the cable, compression by moving parts of the calibration bench, etc.) is to be avoided to minimize any unwanted degradation of the measured signal.

6.4.2. Connectors

Ionization chambers, electrometers and cables have different types of connectors and it is important to have connectivity between different parts. There are three types of connectors in general use with commercially available ionization chambers:

(1) Coaxial;
(2) Triaxial;
(3) Special.

A coaxial connector includes a central conductor and shield connection (Fig. 18(a)), while a triaxial connector includes a central conductor and an inner and outer shield (Fig. 18(b)). Special connectors (e.g. PTW M type) are usually a combination of coaxial and single conductor in a common housing (Fig. 18(c)). Both coaxial and triaxial connectors are available with two different types of housing (i.e. the outer body of the connector itself). The difference between the two types is the locking mechanism. Thread housing is commonly referred to as TNC and is available for both coaxial and triaxial connectors (Fig. 18(d)). The bayonet type is referred to as BNC or sometimes BNT (Fig. 18(e))). In addition to these types of housing, coaxial connectors with so called miniQuick housing (earlier models of NE Technology, Ltd chambers) are also available. The names of the housing types are generally used to describe the connectors, although some manufacturers may use other names (Fig. 18(f)).

Each component of the path between the ionization chamber and electrometer contributes to the total leakage current. It is therefore important that the connectors are always protected with the corresponding cap (when not in use), preventing dust contamination. Touching the conductor or insulators of the connector with bare hands can also increase the leakage of the connector. If necessary, the connectors may be cleaned using either clean compressed air or cotton buds soaked in ethanol.

6.4.3. Adapters

Some calibration laboratories are faced with the task of calibrating ionization chambers assembled with a different connector from the electrometer to be used (e.g. a chamber with the triaxial BNC connector to be connected with an electrometer with a TNC connector). In such cases an appropriate adapter is used. Adapters can be referred to as an interface between two different connectors. Various adapters are available commercially from different manufacturers.

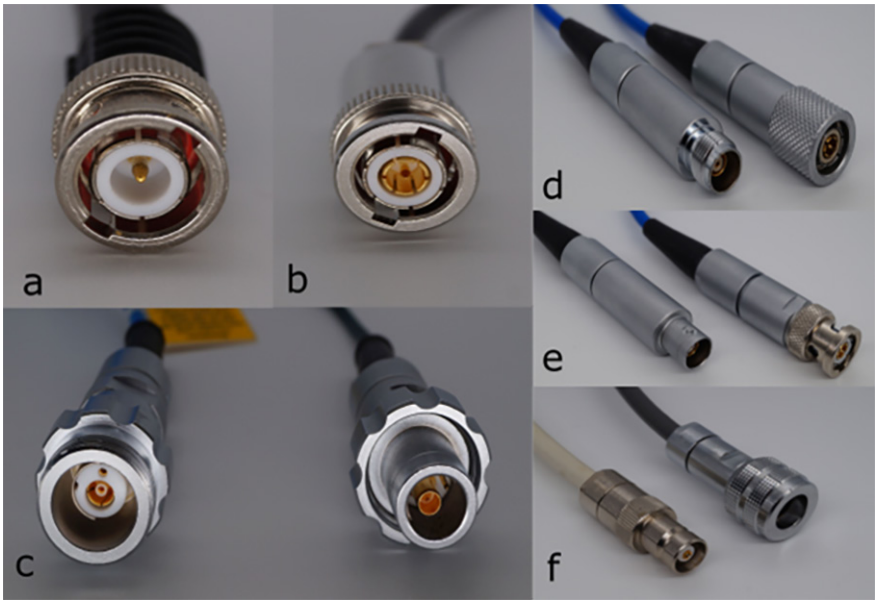

FIG. 18. Connector types: (a) coaxial, (b) triaxial, (c) PTW M type, (d) TNC, (e) BNC and (f) miniQuick.

Some adapters are straightforward (e.g. triaxial TNC to triaxial BNC, miniQuick to coaxial BNC, etc.) and can be used without any special considerations. However, certain combinations combining coaxial and triaxial connectors may result in the presence of polarizing voltage (bias) on the outer housing of the connector. It is not best practice to use such adapters without a thorough knowledge and understanding of the electrometer connection scheme. Incorrect use may not only lead to damage of the instrumentation, but may constitute a safety hazard.

6.5. PHANTOMS

Phantoms are generally used to simulate the human body or to generate appropriate scattering conditions or attenuation in different radiation set-ups. For calibrations, phantoms are used in a standardized way. Different media are used for different calibration capabilities. The guidelines for the phantoms used are described in detail below.

In general, phantoms are not used for brachytherapy or diagnostic radiology calibrations because the dosimetry quantities refer to reference air kerma and

air kerma free in air. In radiation therapy, X ray (low and medium energy) calibrations are typically performed free in air. Therefore, those calibrations are not included in this section.

6.5.1. Phantoms for radiation therapy calibrations

Water is a medium for absorbed dose measurements in high energy photon and electron beams. The codes of practice for dosimetry measurements and calibrations in terms of absorbed dose to water give guidelines for measurements to be performed in a water phantom [3].

For external beam radiation therapy, the water phantom is to extend to at least 5 cm beyond all four sides of the largest field size employed at the depth of measurement. There also needs to be a margin of at least 5 g cm^{-2} beyond the maximum depth of measurement [3]. In horizontal beams, the window of the phantom is to be made of polymethyl methacrylate (PMMA) with a thickness range of 0.2 to 0.5 cm [3].

6.5.1.1. Waterproof sleeve for calibrations in water

Unless the ionization chamber is waterproof, the chamber is to be placed inside a waterproof sleeve. The sleeve to be made of PMMA, with a wall that is sufficiently thin (preferably not greater than 1.0 mm in thickness) to allow the chamber to achieve thermal equilibrium with the water in less than 10 min [3, 55]. The sleeve is to be designed to allow the air pressure in the chamber to reach ambient air pressure quickly [3]. It is preferable that the end user provide a chamber together with the sleeve they use for clinical dosimetry to reduce the calibration uncertainty.

The use of a thin rubber sheath is not best practice, especially for a reference chamber [3]. There is a greater risk of water leakage and such a sheath restricts the pressure equilibration of the air in the chamber. Moreover, manufacturers usually coat the inner surface of the rubber sheaths with a fine powder. This powder can find its way into the chamber cavity or obstruct the air venting hole, affecting the chamber response [3].

6.5.2. Phantoms for radiation protection calibrations and reference irradiations

Survey meters are used to measure ambient dose levels and are calibrated free in air. Personal dosimeters are typically worn by radiation workers; therefore, calibrations and reference irradiations are performed on standardized phantoms that are suitable for the type of dosimeter and measured quantity. The selection

of phantoms to be used in the SSDL depends on the range of dosimeters used in the country.

Four phantoms are used for calibrations and reference irradiations [12, 39, 56]:

(1) The ISO water slab phantom is used for the calibration of whole body dosimeters and represents the human torso. The slab phantom's outer dimensions are: width — 30 cm; height — 30 cm; depth — 15 cm. The front face of the water phantom consists of a 2.5 mm thick PMMA plate; the other PMMA walls are 10 mm thick. A solid PMMA phantom can be used instead of a water phantom if calibrations are only performed with ^{137}Cs or higher mean energies.
(2) The ISO cylinder phantom is used for eye lens dosimeters and represents the human head. This phantom is not yet included in the ICRU set of phantoms, but a cylindrical phantom with an outer diameter of 200 mm and a length of 200 mm was recommended in ISO 4037-3:2019 [39]. The cylinder walls and the end faces are to be made of PMMA and have a thickness of 5 mm.
(3) The ISO water pillar phantom is used to test wrist or ankle dosimeters and represents a lower arm or leg. The phantom is a right circular cylinder with an outer diameter of 73 mm and a length of 300 mm. The walls of the phantom consist of PMMA; the circular walls are 2.5 mm thick and the end walls have a thickness of 10 mm.
(4) The ISO rod phantom is used for finger dosimeters and represents a finger. The rod phantom is a circular PMMA cylinder with a diameter of 19 mm and a length of 300 mm.

6.6. EQUIPMENT FOR MONITORING AMBIENT CONDITIONS

Air conditioning the laboratory space may be necessary in many countries to control the room temperature and humidity and maintain them within a specified range. In addition, equipment for the measurement of ambient conditions is very important, especially to measure the two quantities — temperature and pressure — that directly influence the density of air in the cavity of an ionization chamber and thus the ionization signal. The influence of humidity is comparatively small if the relative humidity is within the limits stated for proper operation of the standards. It is therefore sufficient to have monitoring equipment that verifies that the humidity is within acceptable limits.

6.6.1. Thermometers

A dosimetry laboratory is to possess at least one high quality reference thermometer, with a calibration certificate that is traceable to a primary standard for temperature. The thermometers can initially be calibrated more often until their stability is known. The recalibration period can then be reviewed based on the stability results and experience of using the instrument.

The range of thermometers are to span from at least 10 to 30°C, with a resolution of 0.2°C or higher. Available thermometer types include analogue (such as mercury or spirit in glass) and electronic digital thermometer (e.g. thermistors, platinum resistance thermometers, electronic temperature recorders). Mercury in glass thermometers, while intrinsically stable and reliable, are fragile and are to be well protected from shock to avoid breaking the mercury column, noting that the production and use of mercury in consumer products (e.g. thermometers) is restricted in some countries for environmental pollution reasons (e.g. EC Directive 2007/51) [57]. Electronic digital display thermometers, on the other hand, are usually more robust but need more frequent calibration.

For each room where calibration measurements are performed, the temperature is to be measured using a thermometer. The thermometer probe is to be placed close to the ionization chamber position to give a representative result. There might be large gradients near electrical equipment (e.g. X ray generators) or at different heights. To simulate the temperature changes inside the ionization chamber very accurately the thermometer may be placed inside a dummy chamber.

6.6.2. Barometers

A barometer capable of measuring the atmospheric pressure with a resolution of 0.5 hPa or better is needed. The measurement range is heavily dependent on the altitude at which it will be used. The barometer is to have a calibration certificate that is traceable to a primary standard of pressure and the calibration uncertainty is not to exceed 0.1%.

A mercury precision barometer usually does not need recalibration if the mercury surface remains clean and the meniscus remains sharp and easy to read. If aneroid or electronic barometers (based on a piezo crystal) are used, they are to be calibrated regularly. This can be done by a calibration laboratory that is traceable to a primary standard of pressure and accredited to ISO/IEC 17025 [11].

6.6.3. Hygrometers

A hygrometer is needed to monitor the relative humidity of the ambient air in the laboratory and verify that it is within the given limits. The accuracy needed is relatively low (5–10%) but the instrument is to have a traceable calibration. If the relative humidity is between 30 and 70% at the usual operating temperatures no humidity correction is needed [51]. When the relative humidity is high, the functioning of the electronic equipment and the ionization chamber may be affected, and the results may not be reliable. The relative humidity of both the operational and storage conditions of standards is to be within the accepted range. Humidity can be measured with a whirling arm hygrometer or a hair hygrometer, or with electronic hygrometers based on a variety of methods (e.g. electric impedance or capacity sensors), with the first being the most precise method.

7. BRINGING AN SSDL INTO OPERATION

This publication covers the process of establishing SSDL facilities. There are some additional steps that need to be taken before an SSDL is ready to provide calibrations. In this section these additional tasks are described briefly and references for further information are provided.

7.1. COMMISSIONING

When an irradiator is received, the vendor is responsible for installation and the acceptance testing is performed together with the end user. After that, the end user commissions the equipment. The results of the commissioning are used as a baseline for future quality control measurements. The details of the warranty period (including the start date of the warranty) are to be recorded by the SSDL.

7.1.1. Installation and acceptance

The vendors are fully responsible for the installation of the equipment (irradiator, calibration bench, security system, etc.). Installation is to be carried out by qualified personnel and the instructions supplied by the manufacturer are to be followed. After installation, a check is to be performed to confirm that all accessible parts of the X ray generator and the calibration bench are properly

grounded. It is advisable for the SSDL staff to be present for the duration of the process in order for them to be familiar with all of the components at the facility.

Acceptance tests are performed by both the SSDL staff and the representative from the manufacturer. Acceptance tests are to verify the delivery of all equipment components and their integrity and good condition, as well as their proper installation, functioning and operation, according to the manufacturer's performance specifications, together with any other conditions agreed upon by the SSDL and the supplier. The protocol of the manufacturer/supplier is applied for the acceptance tests. However, the SSDL personnel are to conduct independent tests, according to their laboratory procedures and technical specification. The SSDL is not to use the acceptance test results as reference values or baselines for calibration purposes. The supplier is to deliver a report of the acceptance test that has been signed by both parties.

The SSDL staff are to be trained appropriately on the operation of the installed equipment by a representative from the supplier and, where possible, on fault finding mechanisms to facilitate easy communication, especially when equipment is imported and there is no local support from the manufacturer. For irradiators incorporating radioactive sources, the vendor is to demonstrate the safety features of the system and all necessary actions to be taken in case the source fails to return to the safe position or the shutter fails to close. This procedure is to be clearly documented.

7.1.2. Commissioning process

In the case of a calibration laboratory, commissioning refers to all tests and checks to prepare the system for calibrations. Here, the system refers to the irradiator, the ancillary equipment (e.g. lasers, telescopes) and the calibration bench, as well as the calibration procedures and the determination of all necessary dosimetry reference values and data.

Some of the tests might also be part of the acceptance testing. However, during the commissioning they need to be repeated using the local equipment and protocols. This will provide a baseline for future measurements.

The first step consists of ensuring that the security and safety system operates properly. This includes verifying the operation of all interlocks as well as radiation protection surveys (e.g. dose rates at the premises, wipe tests, radiation leakage measurements). The second step concerns verifying the geometric and mechanical alignments of the positioning systems, the calibration bench, the central beam axis and the irradiation field. The third step comprises verifying the beam specific parameters, such as radiation qualities and their HVL values, beam profiles, field sizes, source positioning and timer errors.

The SSDL staff are to document all the performed tests so that they can be repeated afterwards. Some tests, such as beam parameters and alignment, are to be repeated at shorter intervals in the beginning to build confidence in the system performance. The periodicity of the tests can be decreased gradually once stability has been confirmed.

7.2. ESTABLISHMENT OF THE SERVICES

This publication gives guidelines for establishing an SSDL; it is not a code of practice for calibration work. International dosimetry codes of practice, for example Refs [3–5, 12, 53], are to be followed as a reference when the actual calibration service is established. The guidelines on calibration procedures provided by the IAEA are in Technical Reports Series No. 469 [4] (for radiation therapy), IAEA-TECDOC-1274 [53] (for brachytherapy), Safety Reports Series No. 16 [12] (for radiation protection) and Technical Reports Series No. 457 [5] (for diagnostic radiology), or updates of these publications.

The essential steps for the establishment of a calibration service procedure and their time sequence are outlined below:

(a) The SSDL is to select a reference class ionization chamber and a reference class electrometer that are suitable for each calibration service to be provided. This set (ionization chamber and electrometer) comprises the ‘reference dosimeter’, which will provide the traceability of dosimetry standards to the SSDL.
(b) The reference dosimeter is to have a traceable calibration for those radiation quantities and qualities that have been established at the SSDL.
(c) Each reference dosimeter is to have a backup device to use in case of failure.
(d) The dosimeter that is routinely used for measurements is called a working standard and can be a reference or a backup standard or another dosimeter that is calibrated against the reference standard.
(e) The SSDL is to use the working standard to determine the reference dosimetry quantities and their uncertainties [58, 59] at all radiation qualities available in the laboratory.
(f) The calibration procedures (including handling and shipment of the equipment, responsibilities, technical instructions, etc.) are to be defined and the uncertainty budgets for the calibrations prepared.
(g) The calibration methods and reference irradiations are to be tested and verified for several field instruments; these may be end user instruments for trial calibrations.

(h) It is best practice to participate in comparison exercises with other laboratories (e.g. the IAEA) to validate the set-up and calibration procedures.
(i) The calibration certificate templates are to be developed to include all information relevant to the end user.
(j) The SSDL is to establish and implement a comprehensive quality management system, including quality assurance and quality control systems, in accordance with the ISO/IEC 17025 standard [11], as outlined in Section 7.3.
(k) The SSDL is to assure a sustainable recording system for the results and calibration data, and consider establishing a database or a customer registry.
(l) The SSDL is to establish and implement computer security measures to ensure the confidentiality, integrity and availability of all sensitive information, data and computer functions needed to perform its services [11].

7.3. QUALITY SYSTEMS

Systematic operation using harmonized procedures is a key factor in accurate dosimetry and effective operation. As part of the quality system the calibration procedures and personnel responsibilities are to be clearly defined. The quality system also provides opportunities for continual development.

The following are the main terms used in describing the quality system:

— Quality management system (QMS): a systematic and consistent process to ensure and maintain the quality of services and enhance customer satisfaction [60, 61];
— Quality assurance (QA): all planned, systematic administrative and procedural activities that are to be implemented to achieve and maintain high quality services and fulfil the guidelines for a quality system that is defined by the SSDL according to international standards and guidelines [60, 61];
— Quality control (QC): an aspect of QA that is technically oriented, as described in Section 7.3.3 [61].

Although both QA and QC refer to ways of ensuring the quality of a service within the scope of the QMS, QA is wider in scope, objectives and implementation (Fig. 19) than QC. The terms QA and QC are not to be used interchangeably to avoid confusion [60, 61]. Further details are given in the sections below.

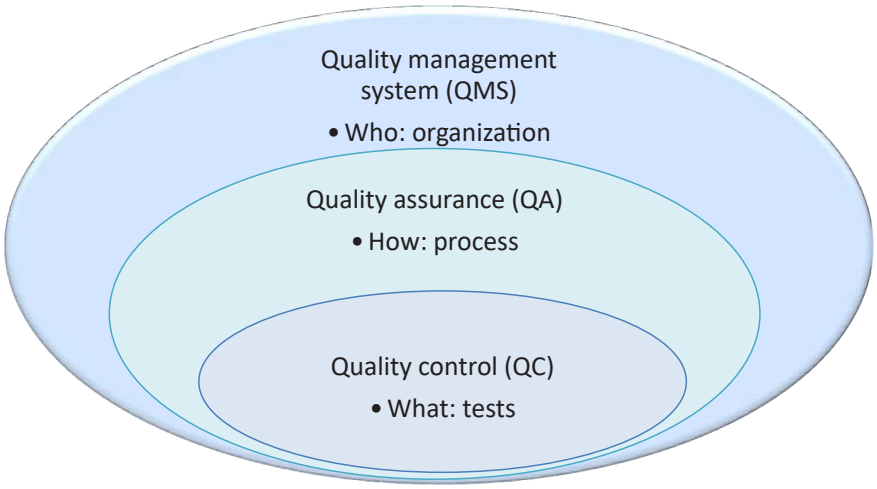

FIG. 19. The relationship between QMS, QA and QC. Adapted from Ref. [61].

7.3.1. Quality management system

The term quality management system is a generic concept used by manufacturing and service organizations. Many of them follow the standards under the ISO 9000 series (e.g. ISO 9001:2015). However, for an SSDL, ISO/IEC 17025:2017 [11] is the most appropriate standard. The implementation of ISO/IEC 17025 is often a mandatory prerequisite for an SSDL to participate in dosimetry forums, including the IAEA/WHO SSDL Network. This standard specifies the general requirements for the competence to carry out tests and calibrations.

The QMS is an integrated and structured system of policies, processes and procedures and it is performance oriented. In addition to QA, QMS includes managerial issues, for example management and staff commitments and policies, job descriptions, measures for customer satisfaction and customer feedback, evaluation of suppliers, procedure for procurement, documentation, and records. It may be applied to any laboratory regardless of the number of personnel. The following is the full list of requirements included in ISO/IEC 17025:2017 [11]:

(a) General requirements:
    (i) Impartiality;
    (ii) Confidentiality.
(b) Structural requirements.
(c) Resource requirements:
    (i) General;

(ii) Personnel;
(iii) Facilities and environmental conditions;
(iv) Equipment;
(v) Metrological traceability;
(vi) Externally provided products and services.

(d) Process requirements:
(i) Review of requests, tenders and contracts.
(ii) Selection, verification and validation of methods:
— Selection and verification of methods;
— Validation of methods.
(iii) Sampling.
(iv) Handling of test or calibration items.
(v) Technical records.
(vi) Evaluation of measurement uncertainty.
(vii) Ensuring the validity of results.
(viii) Reporting of results:
— General;
— Common requirements for reports (test, calibration or sampling);
— Specific requirements for test reports;
— Specific requirements for calibration certificates;
— Reporting sampling — specific requirements;
— Reporting statements of conformity;
— Reporting opinions and interpretations;
— Amendments to reports.
(ix) Complaints.
(x) Nonconforming work.
(xi) Control of data and information management.

(e) Management system requirements:
(i) Management system documentation;
(ii) Control of management system documents;
(iii) Control of records;
(iv) Actions to address risks and opportunities;
(v) Improvement;
(vi) Corrective actions;
(vii) Internal audits;
(viii) Management reviews.

It is best practice that all calibration services be covered by the ISO/IEC 17025 standard and be included in the scope of the calibration of the SSDL. Should there be any activities that do not follow the requirements set

out under the ISO/IEC 17025 [11] standard, these activities ought to be clearly indicated and distinguished from those that are in accordance with the standard.

In addition to internal purposes, the QMS is also used to indicate the quality of the services for any external bodies. A proper implementation of the QMS and recognition of the services would allow any customer to have confidence in their calibration certificate. Establishment of the QMS documentation is not sufficient for compliance with the standard: the SSDL needs to verify and show appropriate and sufficient implementation of the QMS through an audit process. In some countries, a formal approval of the QMS through an accreditation or recognition under an MRA is required (see Sections 1.1 and 7.5).

7.3.2. Quality assurance

Quality assurance (QA) is process oriented. It may focus on such activities as developing and monitoring processes, programming activities, assessing services and work, evaluating deviations and errors, implementing corrective and preventive actions, scheduling new activities and training staff. Some indicative elements of the QA for SSDLs include the following:

— Implementation of the quality control programme;
— Maintenance of the traceability of dosimetry standards through recalibration of reference and working standard dosimeters;
— Organization of and/or participation in dosimetry comparisons;
— Organization and implementation of internal and external audits and peer reviews of the SSDL services and QMS;
— Continuous assessment and evaluation of services, comparison results, audit and review results and workload;
— Identification and management of errors and deviations;
— Establishment of preventive and corrective actions, including service and eventual replacement of equipment;
— Improvement of services, infrastructure upgrades, follow-up of methodologies;
— Continuous training of staff.

In addition, an SSDL ought to develop and implement processes for the radiation protection and safety of staff and the public from SSDL activities and radiation sources.

7.3.3. Quality control

The QC programme is one of the most important elements for ensuring the maintenance of the dosimetry standard(s) and the quality of calibration services. It includes all measurements, tests and checks that are to be performed in a consistent manner according to recognized methodologies and defined periods.

As part of the QC programme, the SSDL is to define the following:

(a) The equipment and parameters to be tested;
(b) The methods and tests to be applied;
(c) The instrumentation used for these tests;
(d) The tolerance and acceptance criteria;
(e) The frequency with which these tests are to be performed;
(f) The personnel responsible for each test;
(g) The relevant reference standards and the codes of practice that are followed.

As an indication, QC is to include the verification of all the important functional and performance parameters covering at least the following:

(a) SSDL facilities:
    (i) The operation of safety items:
        — Door interlocks;
        — Infrared barriers;
        — Radiation monitoring and alarm systems;
        — Surveillance cameras and monitors.
(b) Irradiation units and positioning systems:
    (i) Field size.
    (ii) Field uniformity and symmetry.
    (iii) Central beam axis alignment.
    (iv) Shutter operation.
    (v) Output reproducibility.
    (vi) X ray tube voltage and current accuracy and repeatability.
    (vii) X ray radiation qualities (e.g. HVL measurement).
    (viii) Ancillary equipment:
        — Laser and telescope alignment and operation;
        — Calibration bench movements;
        — Distance indicator accuracy.
(c) Measuring equipment:
    (i) Reference, backup and working standard ionization chambers and electrometers:
        — Condition and integrity;

— Consistency of the calibration coefficients;
— Long and short term stability;
— Leakage current.

(ii) Electrometer scales/operation modes.
(iii) Thermometers, barometers and hygrometers.

(d) Calibration process:
(i) The reference dosimetry quantities: air kerma, reference air kerma and absorbed dose to water, monitor chamber readings, etc.;
(ii) Datasheets, templates and databases.

All measurements, including raw data and results, as well as evaluations and assessments, are to be recorded in either electronic or manual logbooks. The SSDL is to determine the annual QC activities in advance and allow sufficient time for their implementation. It is estimated that as much as half of the laboratory workload may be devoted to the performance of QC, especially in new SSDLs.

7.4. INTERLABORATORY COMPARISONS AND AUDITS

SSDLs are expected to participate in international interlaboratory comparisons and audits and to provide continuing assurance of the accuracy of calibration services; staff time ought to be allocated for these activities. Interlaboratory comparisons, more commonly referred to as comparisons, are important to validate the calibration and measurement capabilities and the applied calibration methodologies of the SSDL. Usually, a comparison involves the calibration of an instrument by two or more laboratories under agreed predefined conditions (a protocol), and the calibration results and the associated uncertainties are then compared. Comparison results are used as supporting evidence for the calibration services and successful participation is a requirement for full approval of the service in the IAEA/WHO SSDL Network database (DOLNET) and for accreditation.

One of the duties of the IAEA regarding the SSDL Network is the organization of laboratory comparisons, which are normally carried out as bilateral comparisons between the IAEA and one of the members of the SSDL Network. It is the responsibility of the SSDL to take part in these or other comparisons, as defined in the SSDL Network Charter [1]. Further details of the IAEA comparisons and the associated audit programme are given below. SSDLs may also organize and participate in bilateral or multilateral comparisons with other SSDLs.

7.4.1. IAEA comparison and audit services

The IAEA Dosimetry Laboratory offers bilateral comparisons between the IAEA and IAEA/WHO SSDL Network members; usually a transfer ionization chamber is calibrated by the SSDL and the IAEA, and the calibration coefficients are compared. The IAEA plays the role of the pilot laboratory. The comparisons are conducted according to their technical protocols, which are available on the SSDL Network website. The transfer instruments (ionization chamber(s)) are provided by the IAEA. The SSDL performs the measurements, reports the calibration results to the IAEA within the agreed time schedule, and provides all necessary information for the comparison evaluation. The comparison results are shared with the SSDL in written form.

The IAEA also provides remote dosimetry audits to validate the calibration of SSDL dosimeters used in radiation therapy and radiation protection. Small passive dosimeters (optically stimulated luminescent or glass dosimeters) are distributed by mail to participating SSDLs for irradiation under specified conditions and upon their return they are read at the IAEA Dosimetry Laboratory. The dose measured is compared to the dose stated by the participant. The interpretation of individual results involves a detailed analysis of the dosimetry procedures reported by the participants. When discrepancies occur, a follow-up action is organized to resolve the problems and correct the dosimetry at the participating institutions.

Some SSDLs are also designated institutes under the CIPM MRA (CIPM MRA P-13) [62] and can publish services as CMCs on the KCDB, once the claim for the services has passed a peer review process. Successful participation in an interlaboratory comparison is an important part of the package of evidence to support such a claim.

7.4.2. Key comparisons

Key comparisons in dosimetry involve the comparison of primary standards and are organized between the BIPM and the PSDLs. From the key comparison results the degrees of equivalence are calculated. The comparisons are used to support the relevant CMCs of the participants. There might be some differences between PSDLs, but the BIPM maintains the reference values. The degree of equivalence is relevant information for SSDLs, especially if the results of two SSDLs are compared, and traceability is obtained from different PSDLs. The SSDLs can link to the key comparisons by participating in an RMO key comparison.

7.4.3. Supplementary comparisons

Supplementary comparisons are primarily organized by the RMO to which the PSDLs and SSDLs belong, although other regional laboratories may be invited to participate:

> "A **supplementary comparison** is intended to cover areas or techniques not addressed by key comparisons. These are complementary to key comparisons and are not intended as second-level comparisons" [63].

These comparisons are needed to demonstrate the measurement capabilities of the SSDLs.

7.4.4. Other comparisons

Since SSDLs typically do not hold primary standards, they cannot participate in CIPM key comparisons, so they need to participate in RMO comparisons. However, if these comparisons are to be accepted to support CMC claims in the CIPM KCDB, the comparison report is to be made a public document.

7.5. RECOGNITION OF THE SSDL

Establishing an SSDL leads to international recognition of the expertise in the field within the country, starting with membership in the IAEA/WHO Network [1]. The objective of the Network is to support the SSDLs to achieve formal recognition in their countries and internationally. There are three levels of membership [1]:

(1) Full member. This is an SSDL that complies with all the requirements of the Charter. Full members will have access to all benefits described in the Charter. A full member may act as a regional designated centre supporting the SSDL Network by coordinating the activities in a particular region.
(2) Provisional member. This is a temporary position of an SSDL that does not fully comply with the Charter, and consequently might not receive all the benefits.
(3) Affiliated member. This is typically a PSDL that cooperates with the IAEA in the operation of the SSDL Network. An affiliated member can also be an international organization with a mandate in the field of dosimetry or metrology.

The Network, through SSDLs designated by the IAEA Member States, provides a traceability route for national dosimetry standards to the SI units. The SSDL Charter sets forth the minimum criteria to be met when a Member State wants a national SSDL to be accepted for membership in the IAEA/WHO Network [1]. The benefits of membership are detailed in the Charter [1].

The Network also supports SSDLs in obtaining formal accreditation of their quality system. In many countries, accreditation is a specified requirement for acceptance of calibration certificates. Accreditation is a process in which an independent body with authority recognizes the technical competence of staff in a particular institute to perform specific laboratory measurements following their procedures and that the institute has an established QMS. The SSDLs that have established QMSs can seek accreditation through their national accreditation body or other nationally accepted accreditation bodies.

If a country is a signatory of the CIPM MRA [63], some SSDLs may also be recognized as designated institutes or be part of the national metrology institute. SSDLs with this status can publish their services in the BIPM's internationally recognized KCDB [14]. The process to become a designated institute and eligibility are described in a BIPM publication [63]. For the services to be published, the SSDL has to take part in international comparisons. The results from the comparison exercises are also published on the KCDB. Peer review is needed to demonstrate the quality of their measurements through their QMS, in line with ISO/IEC 17025 [11]. Further details can be found on the BIPM website [14]. The SSDL Network also supports its members in meeting these requirements.

Not being signatory to the CIPM MRA means that a SSDL will not be able to submit their results to the KCDB, nor have their CMCs published in that database. For these SSDLs, the traceability of their standards through the IAEA and participating in comparisons with the IAEA are both crucial to support the credibility of their SSDL measurement capability.

Appendix

TEMPLATE OF TECHNICAL SPECIFICATIONS

Technical specifications are used to define the technical details of the equipment to be purchased. Suggested content of technical specifications:

(a) Scope/introduction:
    (i) Brief description of the items to be purchased and the intended purpose for which they will be used.
(b) Applicable and legal documents:
    (i) References and standards used in the specifications;
    (ii) In a conflict situation the content of the specifications ought to take precedence.
(c) Definitions, acronyms and abbreviations.
(d) Technical requirements:
    (i) Describes the functional, performance and technical requirements of the items.
(e) Markings.
(f) Transportation and packing.
(g) Replacement and disposal of sources.
(h) Testing and acceptance:
    (i) Type and location (factory, SSDL);
    (ii) Approval;
(i) Installation;
(j) Training:
    (i) Where;
    (ii) How long;
    (iii) How many participants.
(k) Deliverable documents:
    (i) Source certificates and manuals;
    (ii) Preferred language.
(l) Supporting documents:
    (i) Layout picture;
    (ii) Photographs.

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ABBREVIATIONS

BIPM	Bureau International des Poids et Mesures
CBA	central beam axis
CIPM	International Committee for Weights and Measures
CMC	calibration and measurement capability
CT	computed tomography
HDR	high dose rate
HVL	half value layer
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
KAP	air kerma area product
KCDB	key comparison database
LDR	low dose rate
MRA	mutual recognition arrangement
NMI	national metrology institute
PMMA	polymethyl methacrylate
PSDL	primary standards dosimetry laboratory
QA	quality assurance
QC	quality control
QMS	quality management system
RMO	regional metrology organization
RPO	radiation protection officer
SSDL	secondary standards dosimetry laboratory
UPS	uninterruptible power supply
WHO	World Health Organization

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The accurate measurement of radiation doses received by patients undergoing radiotherapy or medical imaging is essential for ensuring effective and safe health care. Equally, the accurate measurement of radiation doses is required to guide employers in protecting their workforce from the harmful effects of ionizing radiation. Secondary Standards Dosimetry Laboratories (SSDLs) are specialist laboratories used to provide calibration and guidance for end users in hospitals and industry. This publication provides detailed technical information for countries on how to establish an SSDL, including planning processes, cost estimates and timelines. The technical descriptions and guidelines may also be helpful to existing SSDL radiation metrology staff when upgrading calibration facilities or purchasing new equipment. The same principles may be used by other dosimetry calibration laboratories.

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