

MEASUREMENT QUALITY ASSURANCE FOR IONIZING RADIATION DOSIMETRY

Commission Sponsors:

P.M. DeLuca, Jr.
H.G. Paretzke

Committee:

J.C. McDonald – Chairman
P. Allisy-Roberts
P. Ambrosi
D.T. Bartlett
B.M. Coursey
L.A. DeWerd
E. Fantuzzi

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23

Contents

1. Introduction

2. Definitions

3. Development of the Quality System and Quality Manual

3.1 Principal Concepts

3.1.1 Elements of the Quality System for Accredited Secondary
Laboratories

3.1.2 Elements of the Quality System for Service Laboratories

3.1.3 Elements of the Quality System for Manufacturers

3.1.4 Elements of the Quality System for Users

4. Measurement Quality Assurance

4.1 Specification of Measurement Quality

4.2 Effects of Influence Quantities on Measurement Quality

4.3 Methods for the Evaluation of Uncertainty

4.3.1 Type A Methods

4.3.2 Type B Methods

4.3.3 Calculation of the Standard Uncertainty

4.3.4 Expanded Uncertainty and Coverage Factor

4.4 Equipment Control

4.4.1 Confirmation Calibration and Verification

4.4.2 Determination of Lower Limits of Detection

4.4.3 Corrections to Measurements

1

2 **5. Measurement Analysis Methods**

3 5.1 Control Charts

4 5.2 Treatment of Outliers

5 5.3 Error Correction Procedures

6 5.4 Review of Records

7

8 **6. Practical Applications and Examples**

9 6.1 Examples of Recorded and Reported Information

10 6.2 Example of Uncertainty Specification

11 6.3 Computer Data

12 6.4 Sampling Tests

13 6.5 Environmental Factors

14 6.6 Establishment of Calibration Procedures

15 6.7 Measurement Equipment

16 6.8 Interactions Between Manufacturers and Secondary Laboratories

17 6.9 Incorrect Use of Devices

18 6.10 Source Encapsulation Problems

19

20

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23

1. Introduction

This report describes methods for establishing, maintaining and evaluating the quality of ionizing radiation measurements and calibrations. The need for high quality measurements for ionizing radiation has been well documented. For example, the successful practice of radiation therapy requires the delivery of ionizing radiation to produce a specified absorbed dose. If the dose is either a few percent lower or higher than the required value, the result can be either a failure to control tumor growth or an unacceptably large amount of damage to surrounding healthy tissues. Measurements performed with personal dosimeters, or area survey meters, for radiation protection purposes also require specific levels of accuracy so that the dose equivalent received by an individual is neither underestimated nor overestimated. Environmental measurements of radioactivity and determinations of doses to members of the public are important to public health authorities and for epidemiological studies, therefore high quality dosimetry is also needed. Certain industrial applications, such as the sterilization of medical equipment and supplies, require accurate measurements of absorbed dose to ensure adequate sterilization while limiting radiation damage to the item being irradiated. The doses delivered in diagnostic radiology procedures, including mammography and interventional radiography, must also be accurately determined in order to maintain a reasonable balance between image quality and radiation risk to the patient. The methods used to ensure that appropriate levels of accuracy and long-term reproducibility are maintained in the above-mentioned areas are discussed in this report.

1

2 This report is directed primarily toward individuals and organizations responsible
3 for calibrations and measurements of ionizing radiation. The goal of the report is to
4 provide calibration and measurement laboratories with recommended procedures for
5 quality management that are consistent with the recommendations contained in applicable
6 national and international standards. The information and guidance provided should be
7 useful to personnel performing radiation measurements as well as to the users of
8 calibration services. The report is also expected to be of interest to agencies responsible
9 for regulating radiological activities.

10 Calibrations of dose-measuring devices and sources of radiation are frequently
11 performed in many institutions for various purposes. Some institutions obtain the
12 services of secondary dosimetry calibration laboratories to perform calibrations of dose-
13 measuring devices. In some instances national primary calibration laboratories are used
14 for this purpose. The accredited secondary calibration laboratories have generally
15 interacted directly with the user community so that the demand for the services of the
16 national primary calibration laboratories is lessened. Figure 1.1 shows schematically the
17 usual paths of interaction between the calibration laboratories and the user community.

18

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40

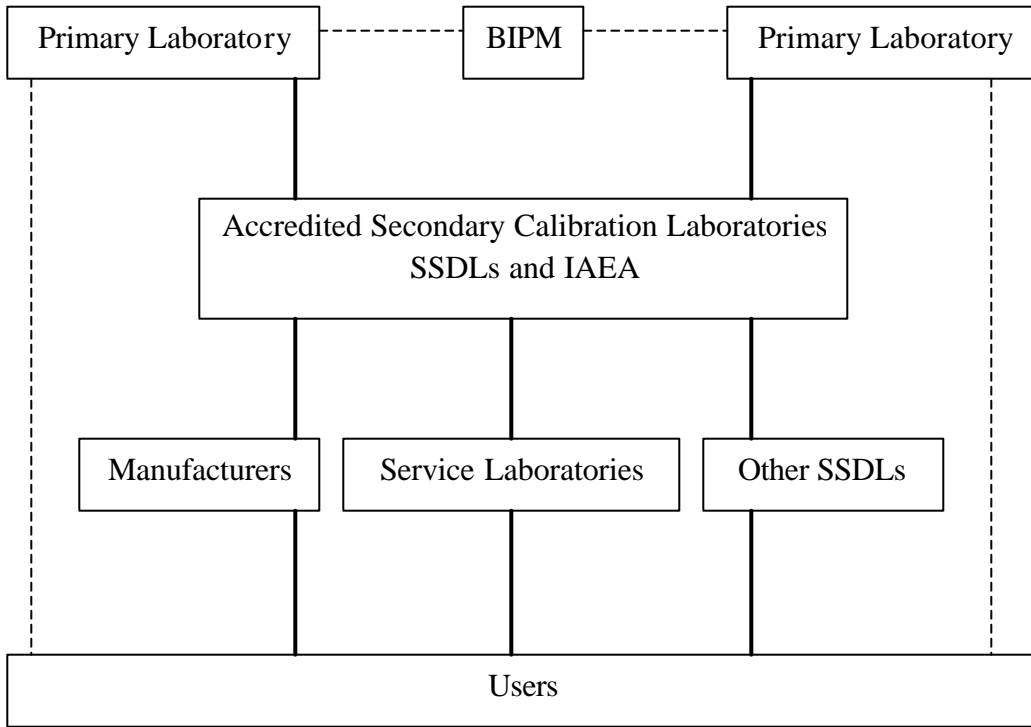


Figure 1.1. This block diagram illustrates the interactions among primary calibration laboratories, accredited calibration laboratories, manufacturers and users performing measurements of ionizing radiation. The solid lines indicate that direct traceability can be established. The dotted lines indicate that interactions take place or traceability can be established in some cases. The primary laboratories are accredited national metrological institutes disseminating primary standards. Accredited secondary calibration laboratories, secondary standard calibration laboratories (SSDLs) and the International Atomic Energy Agency calibration laboratory (IAEA) may also disseminate standards and establish traceability. Other SSDLs may be in a transitional phase of developing as secondary calibration laboratories. The manufacturers include those companies producing radioactive sources, radiation generating devices and radiation measuring devices. Users are the facilities performing measurements of radiation for specific purposes at hospitals, nuclear power plants, dosimetry services, radiation processing plants and radioanalytical laboratories.

1 The four types of groups that perform or require calibrations (the primary or national
2 laboratories, the accredited secondary laboratories, the manufacturers of instruments and
3 radioactive sources and the end users) have all made use of various methods for ensuring
4 the quality of their measurements. In the case of the latter three groups, efforts are made
5 to ensure the traceability of their measurements and calibrations to national standards,
6 and thus to the international system of measurement. The purpose of this report is to
7 describe measurement quality assurance methods that can be used by all of the groups
8 that perform measurements and calibrations of ionizing radiation.

9 Comparisons among calibration laboratories have demonstrated that in general
10 measurements of quantities of ionizing radiation have been consistent. However, detailed
11 descriptions of procedures used in the laboratories may not have been universally
12 documented in a form that would make it possible for others to reproduce the
13 measurements. In recent years, nearly all activities relating to the use of ionizing
14 radiation have come under increased scrutiny from regulating agencies and external
15 auditors. In response to the need for general guidance on the management of quality in
16 calibration laboratories, the International Organization for Standardization (ISO) has
17 published standard ISO 17025 (ISO, 1998) that is applicable for testing and calibration
18 laboratories. The ISO 17025 standard has been produced as the result of extensive
19 experience in the implementation of ISO/IEC Guide 25 and EN45001 (European
20 Standard, *General Criteria for the Operation of Testing Laboratories*. 1989), both of
21 which it now replaces. It also incorporates all those requirements of a quality system that
22 are relevant to the scope of testing and calibration laboratories from ISO 9001 and ISO
23 9002. Therefore, it contains all the requirements that testing and calibration laboratories

1 have to meet if they wish to demonstrate that they operate a quality system, are
2 technically competent, and are able to disseminate technically valid results. Adopting the
3 requirements of ISO 9001-9004 (ISO, 1987) does not itself demonstrate the competence
4 of the laboratory to produce and disseminate technically valid data and results. Some
5 examples of the organizations developing other standards that are relevant to the
6 organizations addressed in this report are listed in Appendix A.

7

1

2

2. Definitions

3

4 Definitions of dosimetric quantities can be found in ICRU Report 60 (ICRU, 1998),
5 but several useful definitions will be given here, for convenience. Additional terms are
6 defined because they are used in this report in specific contexts, and it is necessary to
7 have precise definitions to avoid misinterpretation.

8

9 **absorbed dose**, D , is the quotient of $d\bar{e}$ by dm , where $d\bar{e}$ is the mean energy imparted to
10 matter of mass dm , thus

11
$$D = \frac{d\bar{e}}{dm}$$

12 Unit: J kg^{-1}

13 The special name for the unit of absorbed dose is gray (Gy). The absorbed dose rate, \dot{D} ,
14 is the quotient of dD by dt .

15

16 **accredited calibration laboratory** is an organization disseminating

17

18 **arithmetic mean** or the **average**, \bar{q} , of individual observed values q_j ($j = 1, 2, \dots, n$) is
19 evaluated using,

20
$$\bar{q} = \frac{1}{n} \sum_{j=1}^n q_j$$

1 **calibration** is a set of operations that establish, under specified conditions, the
2 relationship between values indicated by a dosimetric device and the corresponding
3 known (*i.e.* conventional true) values of the quantity to be measured.

4

5 **calibration laboratory** is an organization disseminating....

6

7 **conventional true value** is the best estimate of the value of the quantity to be measured,
8 determined by a primary or secondary standard or by a reference instrument that has been
9 calibrated against a primary or secondary standard.

10

11 **correction factor**...

12

13 **coverage factor**, k , is the quantity to be multiplied with the standard uncertainty, $u_c(y)$, to
14 yield the expanded uncertainty, U . The expanded uncertainty is an interval about the
15 measurement result, y , within which the value of the measurand, Y , is confidently
16 believed to lie.

17

18 $U = k u_c(y)$, and $y - U \leq Y \leq y + U$, which is commonly written as $Y = y \pm U$

19

20 **expanded uncertainty**...

21

22 **influence quantity** is a quantity that may have an effect on the result of a measurement
23 without being the object of the measurement.

1

2 **Kerma**, K , is the quotient of dE_{tr} by dm , where dE_{tr} is the sum of the initial kinetic
3 energies of all the charged particles liberated by uncharged particles in a mass dm of
4 material, thus

5
$$K = \frac{dE_{tr}}{dm}$$

6 Unit is $J\ kg^{-1}$.

7 The special name for the unit of kerma is gray (Gy).

8 Note: The quantity dE_{tr} includes the kinetic energy of Auger electrons.

9

10 **measurand** is a quantity subjected to measurement, evaluated in the state assumed by the
11 measured system during the measurement itself.

12

13 **measurement assurance program** is a process that quantifies the total uncertainty of
14 measurements by means of comparison to national standards and demonstrates that the
15 uncertainty is appropriate for the intended use of the measurements.

16

17 **measurement control system** consists of a set of operations to confirm the quality of
18 measuring equipment and measurement processes.

19 **model function (refer to Sect. 4.3)**

20 **output estimate**

21 **output and input quantities**

22

1 **point of test** is the point in the radiation field at which the **conventional true** value of a
2 quantity is known.

3

4 **reference conditions** are those

5

6

7 **reference direction** is the direction in the coordinate system of the dosimetric instrument
8 with respect to which the angle of the direction of radiation is measured in unidirectional
9 fields.

10

11 **reference orientation** of a dosimetric instrument is the orientation for which the
12 direction of incident radiation coincides with the reference direction of the dosimeter.

13

14 **reference point** is the point on a dosimetric instrument that is placed at the point of test
15 for calibration or test purposes.

16

17 **reference standard** is a measuring device of the highest metrological quality at the
18 facility.

19

20 **secondary standard dosimetry laboratory**, an organization disseminating....

21

22 **standard combined uncertainty**

23

1 **standard deviation**, $s(\bar{X}_i)$, or standard uncertainty, $u(x_i)$, is given as

2
$$s(\bar{X}_i) = u(x_i) = \left[\frac{1}{n(n-1)} \sum_{k=1}^n (X_{i,k} - \bar{X}_i)^2 \right]^{1/2}$$

3

4 where i is the number of independent observations of the quantity X .

5

6 **sensitivity coefficient** indicates the extent to which the output estimate is influenced by

7 variations in the input estimate.

8

9 **quality assurance** can be defined as those planned and systematic actions necessary to

10 provide adequate confidence that a structure, system, procedure, or component will

11 perform satisfactorily and comply with agreed upon standards.

12

13 **quality control** consists of the set of operations intended to maintain or improve quality.

14

15 **uncertainty**....

16

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23

3. Development of the Quality System and Quality Manual

3.1 Principal Concepts

In order to attain the required level of quality in the measurement of ionizing radiation, it is necessary to institute procedures for the management of quality in all aspects of laboratory operation. The establishment of a systematic approach to quality assurance is primarily the responsibility of the measurement laboratory's management, but all laboratory staff members should share the common goal of achieving the required degree of quality. Laboratory management should establish a structure of procedures for implementing the quality assurance system, and the resources for this implementation should be provided to laboratory personnel.

Although the establishment of a quality system appears, on the surface, as a set of arbitrary and artificially imposed rules, the principles of quality management are in fact a formalized, documented version of the good laboratory practices that are likely already in place. Documentation ensures that the practices are available for reference by the staff and by external reviewers. The scope of the quality system should be appropriate to the level of quality required, and the system should be designed to demonstrate that the required level of performance has been achieved. The basic elements of the quality system are described in a quality manual. This document should describe the level of quality to be expected and the methods the facility will employ to achieve their goal. The

1 relative importance of some of the following aspects of quality for the particular facility
2 should be described:

- 3 • Traceability
- 4 • Level of uncertainty
- 5 • Timeliness of reporting results
- 6 • Reliability
- 7 • Communication with customer
- 8 • Error handling and corrective actions
- 9 • Confidentiality

10

11 The degree of detail included in the quality manual should be appropriate to the size and
12 complexity of the facility.

13

14 This section describes measurement quality assurance techniques that should be used.

15 The extent and level of detail required in the quality programs may be different for the
16 primary and accredited secondary calibration laboratories from that needed for service
17 laboratories, manufacturers and users. However, there are certain common elements that
18 should appear in quality manual for each type of user.

19

20 The quality manual should address the following items:

- 21 • Objectives for Levels of Quality
- 22 • Quality Performance Goals
- 23 • Policies and Procedures of the Laboratory

- 1 • Competence and Training of Staff
- 2 • Responsibilities and Authorities of Staff
- 3 • Records Management Procedures
- 4 • Equipment Specifications
- 5 • Identification and Correction of Errors
- 6 • Reviews and Audits
- 7 • Reports and Certificates

8

9 Descriptions of the level of detail required for various organizations are provided in
10 Sections 3.1.1 through 3.1.4 . One of the basic elements of the quality system is the
11 documentation, including: the policy of operation, systems descriptions, procedures,
12 computer program descriptions. These elements all should be documented. Moreover,
13 the procedures for controlling all documents should be generated and maintained. The
14 quality manual as a whole should be periodically reviewed and revised as necessary.

15

16 All documents of the quality system should be uniquely identified and the
17 identification should include the date of issue and reference numbering. Records should
18 be maintained in order to trace all principal functions of the operation. In practice, this
19 means that all documents and files generated in processes carried out in the laboratory
20 have to be archived systematically so that the measurement process can be reconstructed
21 when needed. In addition to the quality manual, documents such as relevant regulations,
22 standards, specifications and instruction manuals of all equipment should be collected
23 and archived. The quantity and the extent of documentation may inhibit flexibility, but it

1 fosters stability and continuity. The establishment of this system also serves as training
2 and reference material for new staff.

3

4 The development of a quality manual and a quality system is an undertaking that is
5 complex and should not be undertaken in haste. For instance, it is not advisable to carry
6 out these activities as a hurried response to a negative audit. The bar chart (IAEA, 1994)
7 in Figure 3.1 is intended as a guide to the approximate order and duration of tasks
8 necessary to realize a quality program.

9

10

1
 2
 3
 4
 5
 6
 7
 8
 9
 10
 11
 12
 13
 14
 15
 16
 17
 18
 19
 20
 21
 22
 23
 24
 25

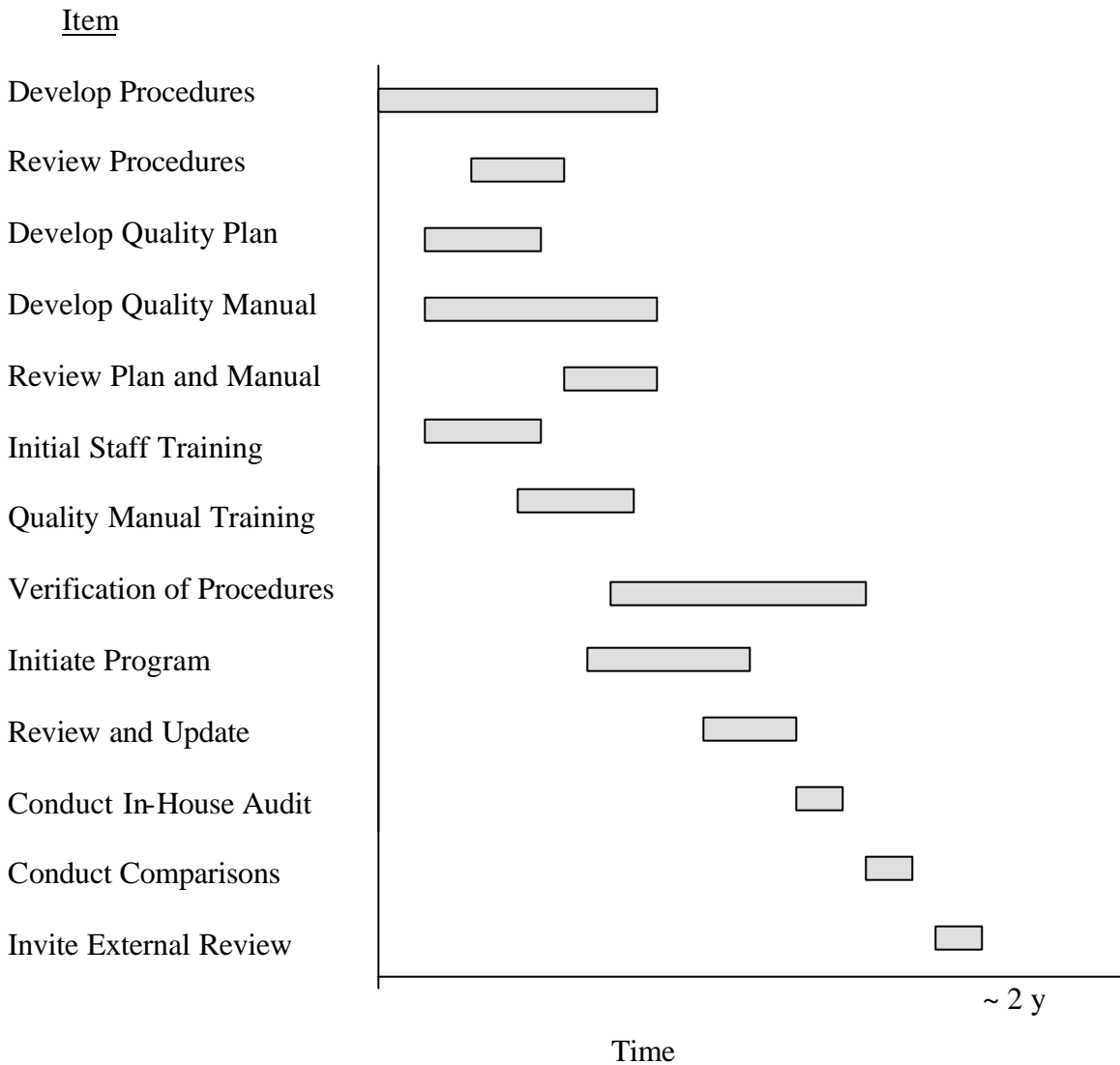


Figure 3.1. Bar chart showing order for developing elements of a quality program and the approximate time duration of each item. The development of the program is expected to require from one to two years to complete.

1 It is not possible to specify precise values for the time scale because different
2 applications will necessarily require differing amounts of time for completion. The
3 simple bar chart is meant to indicate that several tasks should be started first. Ideally, the
4 development of procedures and the training of staff are ongoing tasks and should have
5 been begun before any thought was given to establishing a formal quality program.
6 These tasks are considered to represent good laboratory practice, along with periodic
7 reviews of procedures and training.

8 The objectives set out in the quality plan will represent input to the development of
9 the quality manual. The duration of this bar is highly variable depending on the
10 complexity of the operation. The quality manual for a primary or secondary calibration
11 laboratory may be a very large document.

12 The quality program can be initiated before completion of the quality manual. It is
13 prudent to carry out some of these tasks in parallel (thus, some bars overlap in time). In
14 this way, it can be determined whether certain planned actions are actually feasible or
15 whether modifications need to be made before routine implementation.

16 Preparations for formal implementation of the plan should include a number of cross
17 checks before the activities of the laboratory or service involve clients or customers.
18 These should include an informal audit or check performed by a staff member to verify
19 that the plan, the procedures and training are achieving the desired results as stated in the
20 quality manual. Comparison of results with similar laboratories or services is essential to
21 assure that measurements performed are consistent with those from similar facilities and
22 with national standards. After all elements are in place, review by external peers or by

1 accrediting bodies can be initiated. Successful completion of the external review can
2 signify approval to begin formal operations of the service.

3 The implementation of procedures described in the quality plan may make use of a
4 checklist. This format presents information and indicates sequences of operations in a
5 relatively efficient visual manner. In addition, a completed checklist may serve as a day-
6 to-day documentatio n of compliance with laboratory procedures. However, the
7 shortcoming of a checklist is the possibility for staff members to complete them
8 mechanically without sufficient attention to detail. Over-reliance on a checklist also does
9 not encourage sufficient development of the staff's capabilities. Training and education
10 of the staff supports the laboratory's goal of continuous improvement.

11

12 **3.1.1 Elements of the Quality System for Accredited Calibration Laboratories**

13

14 The level of complexity of the quality system required for a primary or secondary
15 calibration laboratory is relatively high due to the nature of the work performed by such
16 facilities. Calibration laboratories for the measurement of ionizing radiation have been
17 established in a number of fields. Examples of accredited secondary calibration
18 laboratories can be found in fields such as medical, radiation protection, radiation
19 sterilization and environmental radioactivity applications of ionizing radiation.

20

21 National primary laboratories need to ensure that standards are properly transferred to
22 the secondary laboratories. Primary laboratories also need to ensure that these standards
23 are properly maintained and compared at regular intervals. The end users also need to
24 verify that secondary laboratories have maintained traceability to national primary

1 standards. This traceability can be assured through the accreditation procedure. Many
2 accredited secondary laboratories are required to participate in periodic measurement
3 audits to verify the quality of their measurements. The most appropriate requirements for
4 secondary laboratories are provided in ISO Standard 17025 (ISO, 1999). This standard
5 specifies all the elements of an extensive quality system, however it is not meant to be a
6 checklist. As mentioned earlier, the extent of the quality management system should be
7 appropriate to the complexity of the operation and the level of quality required.

8
9 As mentioned in Section 3.1, a number of quality traits may be important to an
10 accredited secondary laboratory. All of these traits are important, but some may be
11 essential whereas others may be considered desirable. The degree of traceability to
12 primary standards and the level of uncertainty in measurements may be legislated or
13 required by the accrediting body. Therefore, these traits may be of primary importance.
14 Timeliness of reporting results and communications may be extremely important to some
15 customers, but in some instances may be of secondary importance. The confidentiality of
16 results is important to all customers, but for certain customers this trait may be more
17 important than all others.

18
19 Since there is usually more than one secondary laboratory serving a particular field, it
20 is possible for groups of laboratories to discuss common problems and compare results.
21 Round-robin comparisons are recommended to ensure consistency among the
22 laboratories. These comparisons may consist of exchanging measuring devices for
23 absorbed dose, air-kerma or dose equivalent and performing measurements in agreed

1 upon radiation fields (*e.g.* ^{60}Co or bremsstrahlung x-rays). Passive dosimeters can be
2 mailed to the participating laboratories in order to be irradiated in agreed upon radiation
3 fields. Peer reviews of laboratory procedures may also be useful to foster increased
4 communications and encourage suggestions for improving quality.

5
6 The goal of primary and secondary laboratories should be to disseminate standards
7 with the lowest possible uncertainty. These laboratories should provide detailed
8 estimates of measurement uncertainties for all of their reference radiations. The overall
9 measurement uncertainties must be maintained within agreed upon limits, depending on
10 the nature and use of the calibration information. Accredited secondary laboratories are
11 also expected to have appropriate procedures for the limitation of errors and an efficient
12 reporting system to inform users of identified errors and corrections. Also, since the data
13 processed by secondary laboratories may be confidential, procedures should be in place
14 to ensure the confidentiality of sensitive records.

15

16 **3.1.2 Facilities Performing Measurements**

17

18 Laboratories or facilities that serve individual institutions or corporations and have a
19 function to provide measurements and calibrations of ionizing radiations are referred to
20 as service laboratories. Examples might be found in hospital medical physics
21 departments, nuclear power reactor health physics departments or in the research
22 divisions of universities. Dosimetry services may include service laboratories for
23 personnel dosimeters, bioassay measurements, environmental measurements or radiation

1 processing measurements. These facilities use the measurements and calibrations
2 provided to them by primary or accredited secondary laboratories and must verify that
3 their own measurements are performed with a level of quality appropriate to their end use
4 or end users.

5

6 The basic requirements of a quality system for a service laboratory are the same as
7 those specified in Section 3.1. ISO Standard 17025 (ISO, 1998) should serve as a guide
8 to the required elements of the quality system, and this report provides additional
9 information and recommendations for the assurance of measurement quality.

10

11 Two-way interactions between service laboratories and the accredited secondary
12 laboratories are indicated in Figure 1.1. In order to optimize the effectiveness of such
13 interactions, it is recommended that both the accredited secondary laboratories and the
14 service laboratories follow the recommendations of ISO 17025 (ISO, 1998). The
15 requirements for documentation are of primary importance to both types of organizations
16 and should be followed as appropriate. All of the elements described in this Section
17 should be incorporated into the quality system of the service laboratory. Also, it is
18 expected that service laboratories may have higher uncertainty limits than the accredited
19 secondary laboratories.

20

21 **3.1.3 Elements of the Quality System for Manufacturers**

22

1 Manufacturers of radiation generating equipment or radioactive sources are required
2 to demonstrate compliance with many standards and legal documents. Therefore, the
3 development of an appropriate quality system is important, and the procedures for
4 documenting quality should be quite familiar to manufacturers. Accredited secondary
5 calibration laboratories, service laboratories and end users alike require various types of
6 manufacturer-supplied information. For example, the basic physical specifications of
7 radioactive sources must be documented so that the laboratories are permitted by
8 regulation to receive the sources for calibration. Information on the materials used, their
9 dimensions and geometrical configurations are required for proper measurements. Only
10 the manufacturer can supply such information, and procedures must be in place to ensure
11 the accuracy of the information.

12

13 When manufacturers supply radioactive sources or radiation generating equipment
14 with a calibration certificate indicating the traceability of the output quantities (reference
15 air kerma rate, activity, *etc.*) of those sources, the same procedures for developing a
16 quality system as recommended for accredited secondary laboratories should be followed
17 although again the uncertainty limits may well be higher for these facilities. Relevant
18 standards might include both the ISO 9000 Series (ISO, 1987 a,b,c,d) as well as ISO
19 17025 (ISO, 1998).

20

21 **3.1.4 Elements of the Quality System for Other End-Users**

22

1 Users of measurements and calibrations generally interact with manufacturers, service
2 laboratories and perhaps accredited secondary calibration laboratories. The user can be
3 supplied with a great deal of information, and it is the responsibility of the user to specify
4 that materials, measurements and calibrations supplied by manufacturers or service
5 laboratories have been processed using techniques consistent with the recommendations
6 in this report. This process can be verified by requesting evidence of certification
7 supplied by the accreditation process.

8

9 Users need to be familiar with, and follow, the basic recommendations of the above-
10 mentioned ISO standards and apply them as appropriate to their own operations.

11 If appropriate quality assurance procedures are not in place at an end user facility, there
12 will be no method available for determining whether a calibration, a source certificate or
13 other information supplied by primary laboratories, accredited secondary laboratories or
14 manufacturers is being disseminated correctly.

15

16 **4. Measurement Quality Assurance**

17

18 **4.1 Specification of Measurement Quality**

19

20 The assurance, or verification, of the level of quality of measurements is essentially a
21 three-step process. First, a level of uncertainty must be agreed upon or accepted from a
22 controlling standard or regulation. Second, a facility must have procedures in place that
23 will lead to performance at the specified level of uncertainty. Third, the facility must

1 demonstrate their ability to perform at the specified level uncertainty. An additional
2 related concept that follows from the third step is a plan for remedial action when a
3 facility is not able to perform at this specified level.

4 Measurement quality can be evaluated using a variety of techniques. Perhaps the
5 simplest method for evaluating the quality of a measurement is the direct comparison to a
6 reference standard. For instance, a working level ionization chamber may be periodically
7 compared to a reference or transfer standard that has in turn been compared to a national,
8 or primary, standard.

9 If the value of the quantity measured using the chamber agrees with the response of
10 the reference standard chamber to within a specified level of uncertainty, then the
11 measurement quality is assured at that level. If a larger than acceptable difference is
12 found, the cause of this difference should be investigated and appropriate remedial action
13 taken. Until the discrepancy is resolved, no measurements affected by the device should
14 be disseminated. The consistency or stability of measurements is dependent upon
15 maintaining the stability of ambient conditions in the laboratory. Changes in a number of
16 parameters can affect the quality of measurements, and the parameters that can produce
17 such effects are referred to as influence quantities.

18

19 **4.2 Effects of Influence Quantities on Measurement Quality**

20

21 An influence quantity may have an effect on the result of a measurement without
22 being the object of the measurement itself. Examples of influence quantities that may

1 affect the uncertainty in ionizing radiation measurement are shown in Table 4.1, along
2 with the reference conditions.

3 The effects of influence quantities on the measurement should be assessed, and if
4 standard test conditions are specified, care should be taken to ensure that standard test
5 conditions are met while measurements are performed (or appropriate corrections are
6 made). Reference conditions are normally within the range of standard test conditions,
7 however it is not necessary to control ambient conditions to match the reference
8 conditions. Corrections can be made to normalize measurement results to the reference
9 conditions. For instance, a simple formula can be used to
10 compute a correction factor, k_{TP} , for the response of an ambient-air-filled ionization
11 chamber, as given below.

$$12 \quad k_{TP} = \frac{t_a}{t_r} \cdot \frac{p_r}{p_a}$$

13 where t_a is the ambient temperature, $273.15 + t$ (°C), t_r is the reference temperature,
14 293.15, (20 °C), p_r is the reference atmospheric pressure of 101.325 kPa (760 Torr), and
15 p_a is the ambient pressure.

16

17 **Table 4.1** *Some examples of influence quantities, reference conditions and standard test*
18 *conditions* (IEC, 1999)

19

Influence Quantities	Reference Conditions	Standard Test Conditions
Ambient temperature	20° C	18°C to 22°C ^a
Relative humidity	65%	50% to 75% ^a

Atmospheric pressure	101.3 kPa	86 kPa to 106 kPa ^a
Stabilization time	15 min.	> 15 min.
Electromagnetic fields	Negligible	< Value causing interference
Radioactive contamination	Negligible	Negligible
Radiation background	$\leq 0.1 \mu\text{Gy/h}$	$\leq 0.25 \mu\text{Gy/h}$

a. The actual values of these quantities at the time of test shall be stated. The values in this table are intended for tests performed in temperate climates. In other climates, it may be permitted to exceed the ranges of the standard test conditions beyond those stated in this table, where instruments are to be used in these climates.

1

2

3

4.3 Methods for the Evaluation of Uncertainty

4

5 The '*Guide to the Expression of Uncertainty in Measurement*' (ISO, 1995)

6 recommends the use of standard uncertainties, which are evaluated in two ways that are

7 classified as 'Type A' and 'Type B'. Once numerical values have been determined for

8 these two types of uncertainties, no further distinction is made and the values can be

9 combined. The Type A evaluation of standard uncertainty consists of determining the

10 uncertainty by the statistical analysis of a series of observations. In this case the standard

11 uncertainty is the experimental standard deviation of the mean that follows from an

12 averaging procedure or an appropriate regression analysis. The Type B evaluation of

13 standard uncertainty determines the uncertainty by means other than the statistical

14 analysis of a series of observations. In this case the evaluation of the standard uncertainty

15 is based in part on additional scientific knowledge or experience gained from previous

16 measurements.

17

1 The prerequisite of any measurement and of the evaluation of the standard uncertainty
2 is a model of the procedure of the measurement and the method of evaluation. This model
3 can be represented by a model function, f , which may be determined experimentally or
4 exist only as a computer algorithm, or it may be a combination of these. The model
5 function f describes the functional relationship of the measurand, or output quantity, Y , on
6 the input quantities, X_i ($i = 1, 2, \dots, N$)

7
$$Y = f(X_1, X_2, \dots, X_N).$$
 (1)

8 Actual measurements will only yield best estimates of the measurand, Y , the
9 output estimate denoted by y , and the input quantities X_i , the input estimates denoted by
10 x_i . The relation between these two quantities is given by

11
$$y = f(x_1, x_2, \dots, x_N).$$
 (2)

12

13 It is of great importance that the list of input quantities X_i is complete, that means
14 that all input quantities must be listed, even those whose value is not known and usually
15 is assigned unity. These (unity) values may have a large uncertainty and thereby may
16 contribute considerably to the overall uncertainty.

17

18 There is software available (GUM, 2000) to assist in performing the uncertainty
19 analysis. Of course, the software also needs the input of the model function, f , and the
20 uncertainties of the input quantities.

21

1 **4.3.1 Type A Methods to Evaluate the Uncertainty**

2

3 The Type A evaluation of standard uncertainty can be applied when several
4 independent observations have been made for one of the input quantities under the same
5 conditions of measurement. If there is sufficient resolution in the measurement process
6 there will be an observable scatter or spread in the values obtained. Assume that the
7 repeatedly measured input quantity X_i is the quantity Q . With n statistically independent
8 observations ($n > 1$), the estimate of the quantity Q is \bar{q} , the arithmetic mean or the
9 average of the individual observed values q_j ($j = 1, 2, \dots, n$)

10
$$\bar{q} = \frac{1}{n} \sum_{j=1}^n q_j \quad (3)$$

11 The uncertainty of measurement associated with the estimate \bar{q} is evaluated according to
12 one of the following methods:

13 (a) An estimate of the variance of the underlying probability distribution is the
14 experimental variance $s^2(q)$ of values q_j that is given by

15
$$s^2(q) = \frac{1}{n-1} \sum_{j=1}^n (q_j - \bar{q})^2 \quad (4)$$

16 Its (positive) square root is termed experimental standard deviation. The best
17 estimate of the variance of the arithmetic mean q is the experimental variance of
18 the mean given by

19
$$s^2(\bar{q}) = \frac{s^2(q)}{n} \quad (5)$$

1 Its (positive) square root is termed experimental standard deviation of the mean.
2 The standard uncertainty $u(\bar{q})$ associated with the input estimate \bar{q} is the
3 experimental standard deviation of the mean

$$4 \quad u(\bar{q}) = s(\bar{q}) \quad (6)$$

5 It must be noted that, when the number n of repeated measurements is low
6 ($n < 10$), the reliability of a Type A evaluation of standard uncertainty, as
7 expressed by equation (6), has to be considered. If the number of observations
8 cannot be increased, other means of evaluating the standard uncertainty given in
9 the text have to be considered.

10 (b) For a measurement that is well-characterized and under statistical control a
11 combined or pooled estimate of variance s_p^2 may be calculated that characterizes
12 the dispersion better than the estimated standard deviation obtained from a limited
13 number of observations. If in such a case the value of the input quantity Q is
14 determined as the arithmetic mean \bar{q} of a small number n of independent
15 observations, the variance of the mean may be estimated by

$$16 \quad s^2(\bar{q}) = \frac{s_p^2}{n} \quad (7)$$

17 The standard uncertainty is deduced from this value using equation (6).

18

19 **4.3.2 Type B Methods to Evaluate the Uncertainty**

20

21 The Type B evaluation of standard uncertainty is the evaluation of the uncertainty
22 associated with an estimate x_i of an input quantity X_i by means other than the statistical

1 analysis of a series of observations. The standard uncertainty $u(x_i)$ can be evaluated by
2 scientific judgment based on all available information on the possible variability of X_i .

3 Values belonging to this category may be derived from

- 4 • previous measurement data;
- 5 • experience with or general knowledge of the behaviour and properties of relevant
6 materials and instruments;
- 7 • manufacturer's specifications;
- 8 • data provided in calibration and other certificates;
- 9 • uncertainties assigned to reference data taken from handbooks.

10 The proper use of the available information for a Type B evaluation of standard
11 uncertainty of measurement calls for insight based on experience and general knowledge.
12 It is a skill that can be learned with practice. A well-based Type B evaluation of standard
13 uncertainty can be as reliable as a Type A evaluation of standard uncertainty, especially
14 in a measurement situation where a Type A evaluation is based only on a comparatively
15 small number of statistically independent observations. The following cases are given as
16 illustrative examples.

17 (a) When only a single value is known for the quantity X_i , e.g. a single measured
18 value, a resultant value of a previous measurement, a reference value from the
19 literature, or a correction value, this value will be used for x_i . The standard
20 uncertainty $u(x_i)$ associated with x_i is to be adopted where it is given. Otherwise it
21 has to be calculated from unequivocal uncertainty data. If data of this kind are not
22 available, the uncertainty has to be evaluated on the basis of experience.

- 1 (b) When a probability distribution can be assumed for the quantity X_i , based on
2 theory or experience, then the appropriate expectation or expected value and the
3 square root of the variance of this distribution have to be taken as the estimate x_i
4 and the associated standard uncertainty $u(x_i)$, respectively.
- 5 (c) If only upper and lower limits a_+ and a_- can be estimated for the value of the
6 quantity X_i (e.g. manufacturer's specifications of a measuring instrument, a
7 temperature range, a rounding or truncation error resulting from automated data
8 reduction), a probability distribution with constant probability density between
9 these limits (rectangular probability distribution) has to be assumed for the
10 possible variability of the input quantity X_i . According to case (b) above this leads
11 to

$$x_i = \frac{1}{2}(a_+ + a_-) \quad (8)$$

13 for the estimated value and

$$u^2(x_i) = \frac{1}{12}(a_+ - a_-)^2 \quad (9)$$

15 for the square of the standard uncertainty. If the difference between the limiting
16 values is denoted by $2a$, then equation (9) becomes

$$u^2(x_i) = \frac{1}{3}a^2 \quad (10)$$

18 The rectangular distribution is a reasonable description in probability terms of one's
19 inadequate knowledge about the input quantity X_i in the absence of any other information
20 than its limits of variability. But if it is known that values of the quantity in question near
21 the center of the variability interval are more likely than values close to the limits, a
22 triangular or normal distribution may be a better model. On the other hand, if values close

1 to the limits are more likely than values near the center, a U-shaped distribution may be
2 more appropriate.

3

4 **4.3.3 Calculation of the Standard Uncertainty of the Output Estimate**

5

6 For uncorrelated input quantities, the square of the standard uncertainty associated
7 with the output estimate y is given by

8

$$9 \quad u^2(y) = \sum_{i=1}^N u_i^2(y) \quad (11)$$

10 Note: There are cases, seldom occurring in calibration, where the model function is
11 strongly non-linear or some of the sensitivity coefficients [see equation (4.2) and (4.3)]
12 vanish and higher order terms have to be included into equation (4.1). For a treatment of
13 such special cases see ISO (1995).

14 The quantity $u_i(y)$ ($i = 1, 2, \dots, N$) is the contribution to the standard uncertainty
15 associated with the output estimate y resulting from the standard uncertainty associated
16 with the input estimate x_i

$$17 \quad u_i(y) = c_i u(x_i) \quad (12)$$

18 where c_i is the sensitivity coefficient associated with the input estimate x_i , i.e. the partial
19 derivative of the model function f with respect to X_i , evaluated at the input estimates x_i ,

$$20 \quad c_i = \frac{\partial f}{\partial x_i} = \left. \frac{\partial f}{\partial X_i} \right|_{X_1=x_1 \dots X_N=x_N} \quad (13)$$

21 The sensitivity coefficient c_i describes the extent to which the output estimate y is
22 influenced by variations of the input estimate x_i . It can be evaluated from the model

1 function f by equation (4.3) or by using numerical methods, i.e. by calculating the change
2 in the output estimate y due to a change in the input estimate x_i of $+u(x_i)$ and $-u(x_i)$ and
3 taking as the value of c_i the resulting difference in y divided by $2u(x_i)$. Sometimes it may
4 be more appropriate to find the change in the output estimate y from an experiment by
5 repeating the measurement at e.g. $x_i \pm u(x_i)$.

6

7 Whereas $u(x_i)$ is always positive, the contribution $u_i(y)$ according to equation (4.2) is
8 either positive or negative, depending on the sign of the sensitivity coefficient c_i . The
9 sign of $u_i(y)$ has to be taken into account in the case of correlated input quantities.

10 If the model function f is a sum or difference of the input quantities X_i

$$11 \quad f(X_1, X_2, \dots, X_N) = \sum_{i=1}^N p_i X_i, \quad (14)$$

12

13 then the output estimate according to equation (2) is given by the corresponding sum or
14 difference of the input estimates

$$15 \quad y = \sum_{i=1}^N p_i x_i \quad (15)$$

16 whereas the sensitivity coefficients equal p_i and equation (11) converts to

$$17 \quad u^2(y) = \sum_{i=1}^N p_i^2 u^2(x_i) \quad (16)$$

18 If the model function f is a product or quotient of the input quantities X_i

$$19 \quad f(X_1, X_2, \dots, X_N) = c \prod_{i=1}^N X_i^{p_i} \quad (17)$$

20 the output estimate again is the corresponding product or quotient of the input estimates

1
$$y = c \prod_{i=1}^N x_i^{p_i} \tag{18}$$

2 The sensitivity coefficients equal $p_i y/x_i$ in this case and an expression analogous to
3 equation (16) is obtained from equation (11), if relative standard uncertainties
4 $w(y) = u(y)/|y|$ and $w(x_i) = u(x_i)/|x_i|$ are used,

5
$$w^2(y) = \sum_{i=1}^N p_i^2 w^2(x_i) \tag{19}$$

6 If two input quantities X_i and X_k are correlated to some degree, i.e. if they are
7 mutually dependent in one way or another, their covariance also has to be considered as a
8 contribution to the uncertainty. See **(Appendix D)** for how this has to be done. The
9 ability to take into account the effect of correlations depends on the knowledge of the
10 measurement process and on the judgment of mutual dependency of the input quantities.
11 In general, it should be kept in mind that neglecting correlations between input quantities
12 could lead to an incorrect evaluation of the standard uncertainty of the measurand.
13 The covariance associated with the estimates of two input quantities X_i and X_k may be
14 taken to be zero or treated as insignificant if

- 15 (a) the input quantities X_i and X_k are independent, for example, because they have
16 been repeatedly but not simultaneously observed in different independent
17 experiments or because they represent resultant quantities of different evaluations
18 that have been made independently, or if
- 19 (b) either of the input quantities X_i and X_k can be treated as constant, or if
- 20 (c) investigation gives no information indicating the presence of correlation between
21 the input quantities X_i and X_k .

22

1 Sometimes correlations can be eliminated by a proper choice of the model function.
2 The uncertainty analysis for a measurement (sometimes called the uncertainty budget of
3 the measurement) should include a list of all sources of uncertainty together with the
4 associated standard uncertainties of measurement and the methods of evaluating them.
5 For repeated measurements the number n of observations also has to be stated. For the
6 sake of clarity, it is recommended to present the data relevant to this analysis in the form
7 of a table. In this table all quantities should be referenced by a physical symbol X_i or a
8 short identifier. For each of them at least the estimate x_i , the associated standard
9 uncertainty of measurement $u(x_i)$, the sensitivity coefficient c_i and the different
10 uncertainty contributions $u_i(y)$ should be specified. The dimension of each of the
11 quantities should also be stated with the numerical values given in the table.

12

13 A formal example of such an arrangement is given as Table 4.1 applicable for the case
14 of uncorrelated input quantities. The standard uncertainty associated with the
15 measurement result $u(y)$ given in the bottom right corner of the table is the root sum
16 square of all the uncertainty contributions in the outer right column.

17

1

2 The gray part of the table is not filled in. Check with Peter about this.

3 **Table 4.1.** Schematic of an ordered arrangement of the quantities, estimates, standard
 4 uncertainties, sensitivity coefficients and uncertainty contributions used in the
 5 uncertainty analysis of a measurement.

6

7

Quantity	Estimate	Standard uncertainty	Combined Standard Uncertainty	Sensitivity coefficient	Contribution to the standard uncertainty
X_i	x_i	$u(x_i)$		c_i	$u_i(y)$
X_1	x_1	$u(x_1)$		c_1	$u_1(y)$
X_2	x_2	$u(x_2)$		c_2	$u_2(y)$
:	:	:		:	:
X_N	x_N	$u(x_N)$		c_N	$u_N(y)$
Y	y				$u(y)$

8

9 **SPLIT STANDARD UNCERTAINTY TABLE INTO TYPE A AND TYPE B**

1

2 **4.3.4 Expanded Uncertainty, Coverage factor k**

3

4 Most applications for the measurement of ionizing radiation require the use of a
5 measure of uncertainty that defines an interval about the measurement result, y , within
6 which the value of the measurand, Y , will be found with high probability. This interval is
7 referred to as the expanded uncertainty of measurement, U , obtained by multiplying the
8 standard uncertainty $u(y)$ of the output estimate y by a coverage factor k ,

9
$$U = k u(y) \tag{20}$$

10 In cases where a normal (Gaussian) distribution can be attributed to the measurand and
11 the standard uncertainty associated with the output estimate has sufficient reliability, the
12 standard coverage factor $k = 2$ shall be used. The assigned expanded uncertainty
13 corresponds to a coverage probability of approximately 95%. These conditions are
14 fulfilled in the majority of cases encountered in calibration work.

15

16 The assumption of a normal distribution cannot always be easily confirmed
17 experimentally. However, in the cases where several (i.e. $N \geq 3$) uncertainty components,
18 derived from well-behaved probability distributions of independent quantities, e.g.
19 normal distributions or rectangular distributions, contribute to the standard uncertainty
20 associated with the output estimate by comparable amounts, the conditions of the Central
21 Limit Theorem are met and it can be assumed to a high degree of approximation that the
22 distribution of the output quantity is normal.

23

1 The reliability of the standard uncertainty assigned to the output estimate is
2 determined by its effective degrees of freedom (see Appendix E). However, the reliability
3 criterion is always met if none of the uncertainty contributions is obtained from a Type A
4 evaluation based on less than ten repeated observations.

5 If one of these conditions (normality or sufficient reliability) is not fulfilled, the standard
6 coverage factor $k = 2$ can yield an expanded uncertainty corresponding to a coverage
7 probability of less than 95%. In these cases, in order to ensure that a value of the
8 expanded uncertainty is quoted corresponding to the same coverage probability as in the
9 normal case, other procedures have to be followed. The use of approximately the same
10 coverage probability is essential whenever two results of measurement of the same
11 quantity have to be compared, e.g. when evaluating the results of an inter-laboratory
12 comparison or assessing compliance with a specification.

13

14 Even if a normal distribution can be assumed, it may still occur that the standard
15 uncertainty associated with the output estimate is of insufficient reliability. If, in this
16 case, it is not expedient to increase the number n of repeated measurements or to use a
17 Type B evaluation instead of the Type A evaluation of poor reliability, the method given
18 in Appendix E should be used.

19

20 For the remaining cases, *i.e.* all cases where the assumption of a normal distribution
21 cannot be justified, information on the actual probability distribution of the output
22 estimate must be used to

23

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23

obtain a value of the coverage factor k that corresponds to a coverage probability of approximately 95%.

For reports or calibration certificates, the complete result of the measurement consisting of the estimate y of the measurand and the associated expanded uncertainty U shall be given in the form $(y \pm U)$. To this, an explanatory note must be added which in the general case should have the following content.

The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor $k = 2$, which for a normal distribution corresponds to a coverage probability of approximately 95%. The standard uncertainty of measurement has been determined in accordance with EAL Publication EAL-R2 (or the Guide to the Expression of Uncertainty in Measurement).

However, in cases where the procedure of **Appendix E** has been followed, the additional note should read as follows:

The reported expanded uncertainty of measurement is stated as the standard uncertainty of measurement multiplied by the coverage factor $k = XX$, which for a t -distribution with $n_{eff} = YY$ effective degrees of freedom corresponds to a coverage probability of approximately 95%. The standard uncertainty of measurement has been determined in accordance with EAL Publication EAL-R2 (or the Guide to the Expression of Uncertainty in Measurement).

1

2 The numerical value of the uncertainty of measurement should be given to at most
3 two significant figures. The numerical value of the measurement result should in the final
4 statement normally be rounded to the least significant figure in the value of the expanded
5 uncertainty assigned to the measurement result. For the process of rounding, the usual
6 rules for rounding of numbers have to be used (for further details on rounding see ISO
7 31-0:1992, Appendix B). However, if the rounding brings the numerical value of the
8 uncertainty of measurement down by more than 5%, the rounded up value should be
9 used.

10

11

4.4 Equipment Control System

12

13 The purpose of equipment control or measurement quality assurance is to confirm
14 the quality of measuring equipment and measurement processes. A control system
15 provides the methods for demonstrating that the required level of performance in the
16 calibration and measurement of ionizing radiation has been achieved. Documented
17 evidence of the traceability to, or consistency with, national standards is part of the
18 metrological confirmation process. In order to ensure the proper operation of
19 measurement and test equipment, one or several of the approaches in the following
20 sections may be employed.

21

4.4.1 Confirmation, Calibration and Verification

22
23

1 Metrological confirmation is a general term that encompasses all the operations
2 necessary to assure that measuring equipment fulfills the requirements for intended use.
3 (ISO 10012, 1999) This may include calibration with respect to a national standard and
4 periodic verification or checks to ensure stability of response. A dosimetric device may
5 only be compared to a national standard once a year, or perhaps even less frequently.
6 However, periodic verifications can be performed by placing the same device in a
7 specially constructed jig that ensures a reproducible geometry and exposing it to a
8 radiation source with a long half-life, such as ^{137}Cs , on a more frequent schedule. This
9 routine check on the stability of the air kerma response of the device may be performed
10 every day, or just before use.

11

12 Consideration should be given to the frequency of routine checks or calibrations.
13 Initially, requirements for this frequency may be set by regulations, but the first interval
14 may also be set based on experience or recommendations from knowledgeable staff
15 members. Some measurement equipment may require more frequent calibration or
16 verification. Several factors need to be considered in the determination of methods used
17 and the frequency of confirmation (See Section 6...).

18 Practical considerations will rule out the performance of full calibrations before each
19 use of a dosimetric device. First of all, such devices are generally quite stable and do not
20 require frequent calibration. In addition, the effort and expenditure associated with
21 frequent calibrations must be weighed against the possible benefit accrued. Not to be
22 minimized is the risk associated with frequent use of a valuable reference instrument.
23 Each time it is used it is possible that the device will receive some damage. Graphite

1 walled ionization chambers may be mechanically shocked, and the affect of this accident
2 may not be readily apparent until the device is used in a critical measurement.

3

4 An approach that is often applied requires the verification frequency to depend on the
5 results of the previous measurement. If the response of the device is found to be within
6 required limits, the frequency of verification is decreased. If the response is found to be
7 outside of required limits, the frequency is increased.

8

9 As mentioned in Section 5.4.1, control charts can aid in the assessment of calibration
10 frequency. Drifts in the response of instruments can be calculated, and recalibration
11 frequency can be set based on these calculations. Although, with the high stability of
12 dosimetric devices, it may be difficult to determine when changes are to be made, since
13 drifts may be almost imperceptible.

14

15 The time between verifications can be arbitrarily set at one week, one month, or
16 longer. The interval can also be based on in-use time. A device that is used more often
17 may be susceptible to greater drift, and therefore a shorter interval between calibrations
18 may be justified.

19

20 Another approach is to focus on one critical characteristic of the measuring device.
21 For instance, it may be appropriate to frequently confirm that the air kerma response to
22 medium energy photons such as those produced by ^{137}Cs or ^{60}Co is within specified
23 limits. Other characteristics of the device such as the variation of response with photon

1 energy may be assumed to be constant barring any change in the components of the
2 device. This method may represent an effective as well as a safe and efficient approach
3 for specific instruments.

4

5 **4.4.2 Determination of Lower Limit of Detection or Minimal Detectable Amount**

6 [We need to look at the following ISO documents]

7 ISO 11929-1:2000 Determination of the detection limit and decision threshold for
8 ionizing radiation measurements -- Part 1: Fundamentals and application to counting
9 measurements without the influence of sample treatment
10 ISO 11929-2:2000 Determination of the detection limit and decision threshold for
11 ionizing radiation measurements -- Part 2: Fundamentals and application to counting
12 measurements with the influence of sample treatment
13 ISO 11929-3:2000 Determination of the detection limit and decision threshold for
14 ionizing radiation measurements -- Part 3: Fundamentals and application to counting
15 measurements by high resolution gamma spectrometry, without the influence of sample
16 treatment.

17

18 **4.4.3 Corrections to Measurements**

19 [Needs More Input]

- 20 • May be related to influence quantities
- 21 • May be systematic, and related to the instrument
- 22 • Under what conditions do we make a correction?
- 23 • How do we verify the correction factors are accurate?

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23

5. Measurement Analysis Methods

5.1 Control Charts

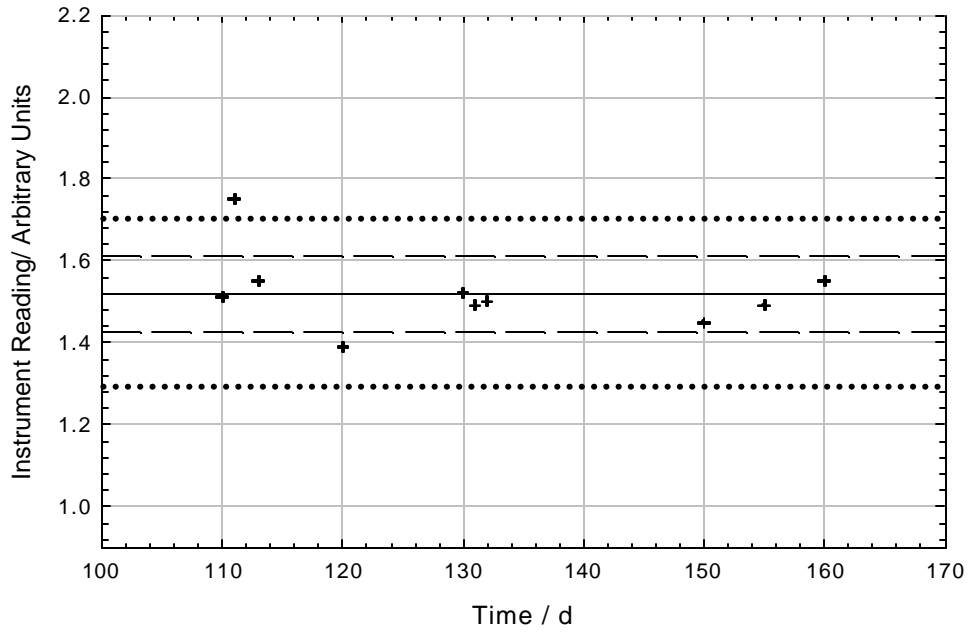
Graphical presentation of data can provide valuable information about variations and trends. This type of presentation is also very well suited for demonstrating the stability of calibration measurements as a function of time to laboratory personnel and others that may need to examine the data. In addition, a large amount of data can be presented in a control chart format. Comparisons between measurements performed many years ago can easily be compared to recent data. Although many of these same operations can be performed using data presented in tabular form, it is often easier to detect small trends or drifts in the data when presented in a graphical form.

Data may be plotted either as ratios relative to a reference value or simply as the numerical values of the measured quantity. Normally, these values are plotted as a function of time. Graphical indicators of deviation levels that should trigger investigation or action can be plotted above and below an expected value for the measurand. As an example, two indicators may be placed at positions that represent $\pm 1\%$ variations from the reference value. A data point that exceeds this indicator is easily visible and may trigger an investigation of a possible drift in stability. A second set of indicators may be placed at $\pm 1\%$, or $\pm 3\%$. If it is found that a measurement exceeds one of these indicators, a work stoppage may be required along with an investigation of the cause of

1 the deviation. It is appropriate to record notes as to the cause of the deviation and the
2 rectification of the problem that caused that deviation. A schematic representation of a
3 typical control chart is shown Figure 5.1.

4

1



2

3 **Figure 5.1** Data plotted as a function of time with mean value indicated as well as
4 control limits (Control Chart).

5

6

1

2

5.2 Treatment of Outliers

3

4

During the performance of a series of measurements, something unexpected or unknown may happen that causes incorrect measurements. Individual data points that are clearly different from the expected distribution for the measurand are called outliers. If the unexpected event causing the incorrect measurement has been observed, *e. g.* a transient in the line voltage, then the measurement affected by this event should be deleted. If no causative event has been observed and no deviation is evident from standard test conditions of temperature, pressure, *etc.*, then statistical methods can be used to verify that the measurement can be considered an outlier and may be ignored. Such a method can only be used if the number of measurements is large (greater 10). In this case, single measurements with measured values, q_j , differing by more than $3s(q)$ of the value of \bar{q} may be classified as outliers and should be omitted from the database. This procedure should only be performed once and not repeated on the reduced set.

16

17

5.3 Error Correction Procedures

18

19

One of the most important activities of a facility for the calibration and measurement of ionizing radiation is the awareness of and elimination of errors. It cannot be assumed that mistakes will never happen. In fact, it is probably a more realistic viewpoint to assume that errors will occur, but that every effort will be taken to minimize their occurrence. A result of this latter assumption is the necessity to develop techniques for

22

23

1 dealing with mistakes, correcting erroneous results, and revising procedures that may
2 have caused the problem.

3 An advisable way to be followed in case of mistakes is that the record of each mistake
4 should be crossed out, not erased or made illegible. For example, in a report the correct
5 value should be entered alongside the wrong value. All such alterations to records should
6 be signed and dated by the person making the correction. Records of errors or, in
7 general, of malfunctions in any part of the process of measurement should retained and
8 periodically checked, in order to avoid recurrences of the same error.

9

10 The laboratory must have procedures in place for dealing with mistakes. These
11 procedures should ensure that responsibilities of staff members are defined and that
12 action is taken when a problem is uncovered. Staff members should have the authority to
13 stop work when a significant problem comes to their attention. Once a mistake has been
14 uncovered either within the facility, or by a client or customer of the measurement
15 facility, corrective actions must be taken. When appropriate, the client or customer is to
16 be notified. Appropriate verifications of measurement quality should be performed
17 before work is authorized to continue.

18

19 Several methods have been found to be useful in reducing the occurrence of errors.
20 Informal audits of measurement quality, performed by a member of the laboratory, are
21 effective in identifying potential problems. One staff member may be designated with
22 the responsibility for reviewing procedures and requesting measurements (as if that
23 person were a client or customer). Periodic round-robin comparisons with similar

- 1 calibration facilities are useful checks on measurement quality, and these interactions also
- 2 encourage communication of common problems and successful solutions.

3

4 **5.4 Review and Approval of Records**

5 Need Input

6

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23

6. Practical Applications and Recommendations

6.1 Examples of Recorded and Reported Information

It is necessary to record any information that is relevant to the quality of the measurements or calibrations performed. Values for influence quantities (see Sect. 4.1) are to be included in a record, but additional information is required for a number of reasons. Measurements and calibrations are nearly always repeated on a regular basis. In order to ensure that subsequent measurements of the same quantity are duplicated as nearly as possible, as much information as is practical should be recorded. When the results of measurements are provided to a user, it is necessary to prepare a report that will include some, or all, of the information recorded by the measurement laboratory. As an example of the types of items that should be recorded on a calibration certificate, the following list is provided.

- Date of report
- Result of measurement with associated uncertainty
- Statement of uncertainty determination procedure and limitations
- Description of equipment used, including unique identifiers such as serial numbers
- Description of procedures used
- Names of persons performing measurements (with date)

- 1 ▪ Names of persons checking the report (with date)
- 2 ▪ Values for relevant influence quantities with their acceptable limits (when
- 3 relevant)
- 4 ▪ Description of traceability path for measurements
- 5 ▪ Description of any functional problems with equipment being calibrated
- 6 ▪ Values for device response found on receipt and values after adjustment
- 7 (w when relevant)

8
9

10 **6.2 Examples of Uncertainty Specification**

11

12 The following text is only an outline which can be expanded if we think it is useful. The

13 idea is, that even with the same model the overall uncertainty is largely depending on the

14 knowledge about the measurement conditions. This description would show what each

15 participant in the process should do.

16 **6.2.1 Manufacturer**

17 Consider an idealized situation where a manufacturer of sources or dose measuring

18 equipment delivers all components for one type of device. The technical data sheet for

19 the device includes a statement of the uncertainties for specified data, *e.g.* correction

20 factors for energy and angle of radiation incidence, for ambient conditions or influence

21 quantities, for linearity of dose equivalent response. The manufacturer should have a

22 model function, as described in Section 4, that will be used to evaluate uncertainty.

1 The manufacturer should specify the production tolerances that might include
2 uncertainties for the homogeneity of the device components, the distribution of the
3 correction factors for energy and angle of radiation incidence for the same radiation
4 quality. This gives information as to how representative one measurement is for the
5 whole batch of device.

6

7 **6.2.2 Secondary Laboratory**

8

9 One major task of a secondary laboratory is the dissemination of calibrations for
10 dose-measuring devices at the reference energy and specification of the uncertainty of
11 this calibration. In addition, the secondary laboratory can determine correction factors for
12 energy and angle of radiation incidence, for specified conditions. The secondary
13 laboratory may also be requested to determine the activity of a radioactive source used
14 for radiation therapy. Similar considerations apply to such measurements.

15

16 **6.2.3 Dosimetry service**

17 The dosimetry service has to state much larger uncertainties of the measured dose
18 equivalent value – even with the same model – due to unknown values of some influence
19 quantities, e. g. energy and angle of radiation incidence, climate etc. that would not be
20 known for the actual conditions when the dosimeter is worn by a worker.

21

1 **6.2.4 User**

2 In special cases, the uncertainties given by the dosimetry service can be reduced, if the
3 rated ranges are smaller than anticipated by the dosimetry service, *e. g.* it is known that
4 one person only works in the environment of a ^{137}Cs source.

5 [Expand this section]

6

7

8 **6.3 Computer Handling of Data and Measurement Control**

9

10 Computer handling of measured data should not cause any additional uncertainty, the
11 uncertainty (error) in computer arithmetic is much lower than the measurement
12 uncertainty in radiation protection. The quality control in the field of computer handling
13 of measured data and in measurement control has to focus on how to avoid bugs in the
14 software, how to verify the software and how to avoid (unintentional) manipulation of the
15 software. There are different ways to achieve this, one is to specify guidelines how to
16 write the software and how to check the written software, *e. g.* as subparts. The other way
17 is to test the whole software while using it with well known experiments and to gain
18 experience and thus trust on the software after a long time of use.

19 [Expand this Section]

20

21

22 **6.4 Sampling Tests**

23

24 [I'm not sure what needs to go here]

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23

6.5 Environmental Factors

The physical location and design of a calibration or measurement laboratory can have an affect on the work performed in the laboratory. Variations in influence quantities such as ambient temperature, humidity, atmospheric pressure, electrical supply voltage or frequency, stray magnetic fields, electromagnetic radiation or mechanical vibrations can affect ionizing radiation measurements. Their effects should be controlled, minimized or, if control is not possible as in the case of atmospheric pressure, values for these quantities should be measured and recorded. Procedures need to be developed to ensure that the environmental conditions to which the laboratory is subjected do not adversely affect results.

For those environmental parameters that can be controlled or monitored, tests should be performed to establish the acceptable limits for changes in these parameters that will not affect measurements. Procedures should be developed for dealing with situations when the environmental parameters are shown to be outside of the limits established for accurate work. These procedures may include stopping work, or performing work in another location that has been shown to be within established limits.

Activities that are incompatible with the required measurements, such as the presence of intense radioactive sources nearby a low-level counting facility, need to be physically or administratively controlled. When physical separation or shielding are impractical, administrative procedures shall be established to prevent adverse interference.

Simple physical access to a calibration or measurement area should be restricted to only those employees authorized or qualified to be present and to perform the work

1 designated for a particular laboratory. Good general laboratory techniques should be
2 practiced.

3

4 **6.6 Establishment of Calibration Procedures**

5 Dosimetric methods have been described in a number of ICRU reports (14, 21, 26,
6 34, 35, etc.), but these reports are not meant to be laboratory manuals. The details as to
7 how dosimetric methods are to be applied to the calibration of dosimetric instruments
8 need to be developed by the laboratory personnel. There are at least two basic types of
9 calibration procedures. One relies on the use of a characterized source of radiation to
10 which the dosimetric device is exposed. Another type of procedure is used to determine
11 the dosimetric quantity for the source of radiation itself using a primary standard or
12 transfer standard instrument.

13

14 **6.6.1 Characterization of the Field**

15 This type of measurement involves determination of the dosimetric quantity at the point
16 in the radiation field at which the conventional true value of a quantity is required. As
17 mentioned in Section 2, this is the point of test. A number of methods may be used to
18 determine the conventional true value of a quantity at the point of test. Direct
19 measurements may be performed using a reference instrument provided by a primary or
20 secondary laboratory. The measurements may be supported by complementary
21 calculations using Monte Carlo computer codes or basic equations describing the
22 radiation field.

23

1 If the device being calibrated is similar in size and shape to the reference instrument,
2 then the method of substitution may be employed where the two devices are alternately
3 placed with their reference points (see Section 2) at the point of test. If measurements
4 and calculations have been carried out previously, and the radiation source has a well-
5 known half life or if a monitoring device is used, then the device being calibrated may be
6 placed at the point of test at any time.

7

8 **6.6.2 Calibration of Device in the Field**

9

10 If the objective of the measurement is to determine the activity or the air kerma rate at
11 a specified distance away from a radioactive source, then the problem can be
12 characterized as a source calibration. Methods similar to those employed for the field
13 calibration can be used. A reference device can be used to measure the quantity desired,
14 and complementary Monte Carlo calculations may support the measurement.

15 The procedures used to perform the above-mentioned calibrations should be
16 documented in detail sufficient to use for training laboratory personnel and for review by
17 peers or external auditing agencies. The procedures should be periodically reviewed and
18 authorized by appropriate laboratory staff or laboratory management. An example of a
19 procedure is given below:

20

1

Laboratory Name	Department or Group	Procedure Number
Measurement and Test Equipment Calibration and Handling		
Page 1 of __		
Use Category: Reference	Revision No.:	Effective Date:
Concurrence/Approvals		
Author: _____ <div style="text-align: center; margin-left: 100px;">Concurrence</div>		Date: ____ / ____ / ____
Quality Manager: _____ <div style="text-align: center; margin-left: 100px;">Concurrence</div>		Date: ____ / ____ / ____
Cognizant Project Manager/Reviewer: _____ <div style="text-align: center; margin-left: 100px;">Concurrence</div>		Date: ____ / ____ / ____
Procedure Administrator: _____ <div style="text-align: center; margin-left: 100px;">Concurrence</div>		Date: ____ / ____ / ____

3
4

When the Project Manager completes a review of this document, and no revision is required, a signature and date entered below will provide a two-year extension.		
Date:	Date:	Date:
Signature:	Signature:	Signature:

5
6
7

1

2

6.7 Materials and Equipment Control

3

4

Documented procedures should be developed for the purchase, repair and replacement of equipment and materials. Any materials that have a critical affect on the

5

outcome of measurements performed in the laboratory need to be controlled. For

6

instance, the following points are given as being representative of the process: (1)

7

documentation should be generated that specifies the purity of metal foils that may be

8

used to perform x-ray half-value layer measurements, (2) Specifications for the size

9

shape and chemical composition of alanine dosimeters should be documented, (3)

10

Required characteristics of materials used for radiobioassay measurements should also be

11

specified in the quality system for the laboratory.

12

Documentation for major equipment items such as x-ray generators or

13

spectrophotometers is usually available from the manufacturers and should be filed with

14

other laboratory records. However, the original specifications generated to purchase the

15

equipment should also be archived. It is inevitable that equipment will fail ultimately or

16

will have to be replaced due to age. Therefore, complete records pertaining to the

17

original purchase of the equipment may be useful at the time of replacement. This

18

documentation will also serve to justify the purchase of the new item to an auditor or

19

external reviewer who might ask whether the new item is sufficiently similar to the

20

previously used item as is required for the purpose.

21

When equipments fails, procedures must be in place to document the steps taken to

22

ensure that measurement quality will not be degraded during the time when the

23

1 equipment is being repaired or replaced. If an equipment item is replaced temporarily by
2 a similar piece of equipment, steps must be taken to verify that the replacement item will
3 provide results identical to the item it is replacing.

4 Some items to be kept in mind regarding materials and equipment control include
5 (Inhorn, S.L., 1978):

- 6 • Inventory – List all equipment, the location of the items, description, date of
7 purchase, person responsible for the item
- 8 • Service and Repair Log – A record must be kept showing describing any
9 servicing or repair performed on the equipment, who performed the repair and
10 what checks were performed to ensure the satisfactory performance after the
11 repair.
- 12 • Operating Personnel – Each major equipment item should have associated with it
13 a primary operator or person responsible for the item. No one else should be
14 operating the equipment except with the permission or under the guidance of the
15 responsible operator
- 16 • Special Instructions – Each major equipment item will have documented
17 procedures for operation in the laboratory's quality manual, but any special
18 instructions are available near the equipment. Hand written notes taped on to the
19 item are not considered good practice since they may not have been properly
20 reviewed or documented, and worse yet, they may fall off.
- 21 • Start Up and Operating Procedures – Detailed operating procedures are
22 documented in the quality manual. Qualified operators have been trained
23 according to documented training procedures, however a short check list type

1 procedure may be used if it has been reviewed and approved for use by the
2 laboratory supervisor.

- 3 • Surveillance – The operator of the equipment item should undertake certain
4 rudimentary tests that are performed each day or each time the equipment is used
5 to ensure proper operation of the item. For instance, a monitor ionization
6 chamber’s current may be observed for a particular x-ray technique. If it is
7 substantially different from the expected value for the technique, no
8 measurements should be attempted until the reason for the discrepancy is found
9 and rectified.

11 **6.8 Interactions Between Manufacturers and Calibration Laboratories**

12

13 Manufacturers need to meet the requirements of many national and international
14 standards in order to market their products. Manufacturers must also have complete
15 information regarding the characteristics of their products. Calibration laboratories
16 should be aware of the fact that their measurements may have widespread impact not
17 only with the manufacturer and their ability to market their products, but also with the
18 end users that rely on both the accuracy of the manufacturer’s information and the
19 calibration supplied by the secondary laboratory.

20 A manufacturer may have to provide sensitive design information to the secondary
21 laboratory which may have to assure the manufacturer that any results it provides are kept
22 confidential. This may require the generation of procedures to provide for secure
23 communications between the secondary laboratory and the manufacturer.

1 It should be anticipated that differences may arise between the measurements
2 performed by a manufacturer and those performed by a calibration laboratory.
3 Procedures should be in place to document what steps will be taken to review the
4 measurements and possibly consult with a third party at a primary laboratory. If such
5 procedures are in place, it can alleviate serious arguments about problems that may arise.

6

7

6.9 Incorrect Use of Devices

8 Procedures for the use of all measurement and test equipment are required to be
9 included in the quality manual and should be followed. However, there are situations
10 when an instrument, or some other device, is not used properly resulting in an incorrect
11 measurement. The fact that a proper procedure exists does not preclude the possibility
12 for errors in the use of a device. Steps can be taken to minimize the possibilities for such
13 errors. For example, any maintenance, battery changes, re-calibrations, etc. should be
14 noted in a log that can be checked by the operator. Procedures for the use of the devices
15 should be reviewed by one other knowledgeable person. Specific instructions for
16 changes in the operation of equipment must be approved, recorded and conveyed to the
17 operators in a regulated fashion.

18

19 Spot checks of data and daily checks of instrument responses to known inputs
20 should be performed in order to verify that measuring devices are operating correctly.
21 Obviously, the sooner a problem is detected the less impact it has on facility operation. It
22 would be most desirable to detect and correct a problem as soon as it occurs. The
23 situation that is to be avoided is for a customer or user to discover an error, or for an

1 external reviewer to uncover an unresolved problem. Therefore, intermediate spot checks
2 and reviews should be performed before the final results are released.

3 No system of quality assurance can prevent errors; therefore procedures must also
4 be in place to deal with the occurrence of errors. There are several basic steps to be taken
5 when an error is suspected.

- 6 • Identify that there is an error
- 7 • Inform affected parties
- 8 • Resolve the cause of the error and alter procedures as needed
- 9 • Avoid recurrences of the same error
- 10 • Repeat the measurement or calibration and ensure that the error has been
11 corrected
- 12 • Inform affected parties of correct values for measurement or calibration

13

14 **6.10 Source Encapsulation Problems**

15 [Again, I'm not sure what needs to go here Check ANSI Std on encapsulation,
16 maybe ISO]

17 DIN 25426-3 (1991) Sealed radioactive sources; leakage test methods as part of
18 production and prototype testing

19 ISO 2919:1999 ISO Radiation protection -- Sealed radioactive sources – General
20 requirements and classification

1 ISO 9978:1992 ISO Radiation protection -- Sealed radioactive sources -- Leakage test
2 methods

3 Source encapsulation problems may arise in two general areas. First, source leakage
4 may be both a radiation protection hazard as well as a difficulty associated with
5 calibration. A source may have leaked or may have been otherwise altered during its
6 transport to a calibration laboratory. This situation represents a shared problem with the
7 manufacturer or owner of the source, the transportation company and the recipient, that
8 may be the calibration laboratory or the end user. It is prudent to assume that such
9 problems are inevitable, so that having procedures in place before such a problem occurs
10 will be very helpful.

11 Another aspect of source encapsulation that may cause difficulties is the improper
12 specification or the improper interpretation of the physical properties of the source
13 encapsulation by the source manufacturer, the calibration laboratory or the end user. As
14 mentioned in Section 6.7, the materials used in construction of a radioactive source
15 should be documented in sufficient detail so that their composition, dimensions and
16 physical placement are unambiguously described for anyone using the source.

17 Source documentation may include (ISO, 1999):

- 18 • Source contents
- 19 • Container description
- 20 • Model or Identification Number
- 21 • Internal and External Dimensions
- 22 • Special Handling Instructions

23

References

[I'm not sure if we can use urls in references, I'll check]

ANSI/IEEE Standard 1016-1987 An American National Standard IEEE Recommended Practice for Software Design Descriptions. The Institute of Electrical and Electronics Engineers, New York, New York (1987)

ANSI N42.23 American National Standard, Traceability of Radioactive Sources to NIST and Associated Instrumentation Quality Control, American National Standards Institute, New York (1995).

BÖHM, J AND AMBROSI, P. (1990) Mandatory Type Tests of Solid State Dosimetry Systems as an Appropriate Aid to Quality Assurance in Individual Monitoring. Radiat. Prot. Dosim. 34(1-4) 123-126.

EISENHOWER, E.H. (1988) Measurement Quality Assurance. Health Phys. 55(2) 207-213.

European co-operation for Accreditation (EA): Expression of the uncertainty of Measurement in Calibration, EA-4/02, December 1999, (<http://www.european-accreditation.org/>)

FRAASS, B., DOPPKE, K., HUNT, M., KUTCHER, G., STARKSCHALL, G., STERN, R. AND

VAN DYKE, J. (1998) American Association of Physicists in Medicine Radiation Therapy

- 1 Committee Task Group 53: Quality Assurance for Clinical Radiotherapy Treatment
2 Planning. Med. Phys. 25(10) 1773-1829.
3
4 GUM, 2000 GUM Workbench, The Tool for Expression of Uncertainty in Measurement,
5 (see <http://www.gum.dk> for further information and download of software)
6
7 IAEA Safety Series No. 113 Quality Assurance for the Safe Transport of Radioactive
8 Material. International Atomic Energy Agency, Vienna, (1994).
9
10 IEC, 1999. Beta, X and Gamma Radiation Dose Equivalent and Dose Equivalent Rate
11 Meters and/or Monitors for Use in Radiation Protection. International Electrotechnical
12 Commission, (Geneva, Switzerland) (1999).
13
14 IEEE Standard 1074-1991 IEEE Standard for Developing Software Life Cycle
15 Processes. The Institute of Electrical and Electronics Engineers, New York, New York
16 (1992)
17
18 IEEE 830 IEEE Recommended Practice for Software Requirements Specifications
19 The Institute of Electrical and Electronics Engineers, New York, New York (1993)
20
21 INHORN, S.L. (1978) Quality Assurance Practices for Health Laboratories (American
22 Public Health Association, Washington D.C.)
23

- 1 ISO/ASTM 51261 (formerly E 1261) MQA Standard for Radiation Processing
2
- 3 ISO 1995 *Guide to the Expression of Uncertainty in Measurement*, first edition, 1993,
4 corrected and reprinted 1995, International Organization for Standardization (Geneva,
5 Switzerland).
6
- 7 ISO 11929-1:2000 Determination of the detection limit and decision threshold for
8 ionizing radiation measurements -- Part 1: Fundamentals and application to counting
9 measurements without the influence of sample treatment
10
- 11 ISO 11929-2:2000 Determination of the detection limit and decision threshold for
12 ionizing radiation measurements -- Part 2: Fundamentals and application to counting
13 measurements with the influence of sample treatment
14
- 15 ISO 11929-3:2000 Determination of the detection limit and decision threshold for
16 ionizing radiation measurements -- Part 3: Fundamentals and application to counting
17 measurements by high resolution gamma spectrometry, without the influence of sample
18 treatment.
19
- 20 ISO 9000-9004 Quality Management and Quality Assurance Standards, International
21 Organization for Standardization (Geneva, Switzerland).
22

- 1 ISO 17025 General Requirements for the Competence of Testing and Calibration
2 Laboratories, International Organization for Standardization (Geneva, Switzerland).
3
- 4 ISO/DIS 10112 Measurement Control Systems, International Organization for
5 Standardization (Geneva, Switzerland).
6
- 7 NCRP, (1988), Quality Assurance for Diagnostic Imaging, National Council on
8 Radiation Protection and Measurements, Bethesda, MD.
9
- 10 NIST SP-676-I and II “Measurement Assurance Programs – Part I and II”, National
11 Institute of Standards and Technology, Washington, D.C.
12 Reference Doses and Quality in Medical Imaging: What the Referring Practitioner and
13 Directing Medical Staff Should Know. Proceedings of a Workshop, Luxembourg, Oct.
14 23-25, 1997, Radiat. Prot. Dosim. 80(1-3) (1998).
15
- 16 VAN DIJK, J.W.E AND JULIUS, H.W. (1996) Dose Thresholds and Quality Assessment by
17 Statistical Analysis of Routine Individual Monitoring Data. Radiat. Prot. Dosim, 66(1-4),
18 17-22.
19

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33

OUTLINE OF APPENDICES

Appendix A – This Appendix will contain information about the organizations that develop standards and documents related to MQA in their areas: AAPM, IEC, ISO, SNM, etc.

Table 1.1. *Listing of relevant standards providers for several activities requiring the measurement and calibration of ionizing radiation. The providers are listed by the initials of the organization: American Association of Physicists in Medicine (AAPM), American Society for Testing and Materials (ASTM), the International Electrotechnical Commission (IEC), the International Organization for Standardization (ISO), and the Society of Nuclear Medicine (SNM).*

Activity	Relevant Standards Provider
Therapeutic Radiology	AAPM
Diagnostic Radiology	IEC
Nuclear Medicine	SNM
Radiation Protection	ISO, IEC, ANSI, HPS
External	
Internal/Radiobioassay	
Environmental	
Radiation Processing	ASTM
Plastics Curing	
Sterilization of Medical Supplies	
Blood Products	
Food	
Radiochemical Analyses	ANSI
High Level	
Radiobioassay	
Environmental	

1 Specific standards are cited as references in the text, but other applicable
2 standards are available from these organizations, and information on how to contact the
3 organizations can be found in Appendix A.

4

5 **Appendix B ?**

6 **Appendix C ?**

7 **Appendix D – Covariance Analysis of Uncertainty Refer ISO Guide**

8 **Appendix E – Determination of the effective degrees of freedom of the**
9 **uncertainty assigned to the output estimate. Refer ISO Guide**

10