DEVELOPMENT OF A QUALITY ASSURANCE PROGRAM FOR IONIZING RADIATION SECONDARY CALIBRATION LABORATORIES

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Abstract - For calibration laboratories, routine calibrations of instruments meeting stated accuracy goals are important. One method of achieving the accuracy goals is to establish and follow a quality assurance program designed to monitor all aspects of the calibration program and to provide the appropriate feedback mechanism if adjustments are needed. In the United States there are a number of organizations with laboratory accreditation programs. All existing accreditation programs require that the laboratory implement a quality assurance program with essentially the same elements in all of these programs. Collectively, these elements have been designated as a Measurement Quality Assurance (MQA) program. This paper will briefly discuss the interrelationship of the elements of an MQA program. Using the Center for Devices and Radiological Health (CDRH) X-ray Calibration Laboratory (XCL) as an example, it will focus on setting up a quality control program for the equipment in a Secondary Calibration Laboratory.

INTRODUCTION

In today's world, most organizations are concerned with producing a quality product. One method of achieving this goal is to institute a quality assurance system to control factors which affect the quality of the product. The International Organization for Standardization (ISO) 9000 series[1,2,3,4,5] of standards describe the elements of a generic quality assurance system. They are widely used throughout the world. For specific industries, the general concepts are often incorporated into programs tailored for that industry. For example, for medical device manufacturers there are Good Manufacturing Practices,[6] for diagnostic radiologic facilities there are recommendations for quality assurance programs,[7] and for users of medical byproduct materials[8] and therapeutic radiation machines[9] there are requirements for implementing a Quality Management Program.

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For laboratories calibrating ionizing radiation instruments, the objective of the quality assurance system is to ensure that all factors which can affect the final quality of the product—a calibrated instrument in this case—have adequate controls. In 1980, the National Institute of Standards and Technology (NIST) was asked to examine the entire measurement system for ionizing radiation with the goal of determining how the system could be improved. This study[10] resulted in a quality assurance system which Eisenhower[11] later called MQA. The elements in the program were a forerunner of recent ISO standards and guides dealing with quality assurance systems that focus on measuring equipment[12,13] and testing (and calibration) laboratories.[14]

This paper is organized into three parts. The first part focuses on the interrelationship between MQA programs, quality assurance systems, and various different laboratory accreditation programs for ionizing radiation calibrations. The second part outlines the common elements of these accreditation programs, with emphasis on their application in an x-ray calibration laboratory. The final part discusses some specific quality control techniques, with specific examples taken from the CDRH XCL.

MQA AND QUALITY ASSURANCE SYSTEMS

Laboratories calibrating ionizing radiation instruments are fortunate in that various organizations which accredit these laboratories have built into their accreditation criteria the basic elements of a quality assurance system. If the laboratory follows all of the procedures agreed to in the accreditation process, then the basic elements the laboratory needs for ensuring quality will be in place.

Accreditation criteria for laboratories calibrating ionizing radiation measuring instruments have been developed by NIST's National Voluntary Laboratory Accreditation Program (NVLAP),(2) the Conference of Radiation Control Program Directors,(3) the American Association of Physicists in Medicine (AAPM),(4) and the Health Physics Society.(5) Laboratories which are accredited by one of these organizations will be designated as Secondary Calibration Laboratories (SCLs).

The accreditation criteria for each organization were developed so that the accuracy requirements appropriate for the intended use of the instruments would be met. For example, the general NVLAP criteria for SCL accreditation are contained in one of their Program Handbooks[15] and the operational criteria are in NIST Special Publication 812.[16] The corresponding accreditation information for the other organizations can be obtained directly from the organization.

ISO 9000 and its derivative standards are widely regarded as the definitive delineation of an infrastructure to assure the quality of products and services. The elements of this infrastructure have been assimilated into the most recent revision of ISO Guide 25, which is being adopted by NVLAP

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for all their calibration laboratory accreditation programs and by the Health Physics Society accreditation program. However, having an infrastructure does not guarantee high quality. Quality experts point to the need for a closed-loop process of continuous improvement in quality.

Any closed-loop process, or control system, has the following basic three elements: 1) a controlled parameter; 2) a means of measuring the controlled parameter; and 3) a feedback mechanism for modifying system operation to adjust the parameter value in the desired direction. For example, consider a system wherein a microprocessor controls x-ray generator voltage within desired limits. The controlled parameter is voltage; the means of measuring it are voltage sensors analyzed by the microprocessor; and the feedback mechanism is the signal the microprocessor sends to the control circuits of the generator to raise or lower the voltage.

The quality assurance system implemented by the calibration laboratory is an application of this quality control model. The controlled parameter is quality. Quality must be defined, characterized, and quantified in terms that permit routine measurement. In other words, the performance of the calibration system and its various components must be routinely measured and analyzed to assess conformance to the specified quality ideals. The feedback mechanism is the set of procedures that the management institutes to correct performance shortcomings, e.g., additional resources, and better training, administrative practices, and procedures.

The ISO standards, accreditation criteria manuals, and laboratory Quality Manuals tend to consider performance, procedures, and responsibilities in isolation, rather than in the context of a dynamic closed-loop process. Other important aspects of quality, such as consideration of the cost of quality, a focus on customer involvement and empowerment and recognition of employees, are not addressed at all. Thus, quality practices and procedures are necessary elements of an MQA program, but they alone do not inherently assure the quality of the product. Quality assurance requires the active and continuing participation of management to adjust the outcome of the calibration process in the desired direction to optimize and maintain the calibration accuracy goals stated in the Quality Manual.

MQA PROGRAMS AND LABORATORY ACCREDITATION

The MQA programs incorporated into the accreditation criteria of these four programs have the following elements designed to assure the traceability of routine calibrations to the national standards:

1) fully documented administrative and calibration procedures
2) properly calibrated laboratory instruments
3) periodic proficiency testing conducted by NIST
4) quality control procedures for critical elements of the calibration system
5) comprehensive uncertainty analysis for the entire calibration process
6) independent evaluation and audits of laboratory procedures.

Each of these six elements is discussed separately in the following paragraphs. For each element, application of the element to an x-ray calibration facility is described, with particular consideration given to opportunities for influencing quality through a closed-loop process.

Documented Procedures

The first element requires documented procedures for policy issues, calibration procedures, and quality assurance procedures. Quality assurance procedures include personnel training, complaint handling, document control, feedback procedures, and management policies. These documented procedures can also be used as training tools for new employees, to answer questions on specific details on various procedures for present employees, to provide a "paper trail" on the evolution of procedures within the lab, to provide on-site assessors with information they need in evaluating the capabilities of the lab, and to provide management with pertinent information on how proper quality assurance procedures will be implemented within the calibration laboratory. For an SCL, items which should be included in the documentation include:

- Management Policies
  - organizational structure
  - support
- Administrative Policies
  - Quality Manual update procedures
  - Quality Assurance/Quality Control (QA/QC) update procedures
  - software update procedures
  - process validation
  - feedback procedures to ensure quality
  - acceptance testing of equipment
  - personnel training
  - complaint handling
  - error notification
  - audit procedures
- Standard Operating Procedures (SOP)
  - precalibration SOP for each accreditation class or instrument type
  - radiation calibration SOP for each accreditation class or instrument type
  - in-house calibration equipment calibration
  - routine QC
- Facilities
  - specifications, model numbers, serial numbers for commercial equipment, etc.
  - as-built documentation for custom equipment
  - minimal equipment requirements
  - environmental conditions in the laboratory.

Calibration of Equipment

In the second element, calibration of equipment relates measured output under specified conditions to similar measurements made under reference conditions using a reference standard. For SCLs, the

reference standard used in the calibration should be to the appropriate national standard maintained by NIST. The calibration of equipment should occur when equipment is new or repaired, and thereafter on a periodic basis. Measurements of a test object under specified conditions in conjunction with routine calibrations serve as a reference point for a quality control program to indicate how a piece of equipment has drifted from its initial operating characteristics. This drift (as well as the uncertainty in the initial calibrations) can be incorporated into the uncertainty analysis for the laboratory's entire calibration process.

Proficiency Testing

The third element, proficiency testing, indicates how well the laboratory can perform a specific calibration on the particular transfer standard used in the test. If the transfer standard is calibrated against the appropriate national standard, it can be used to tell how calibrations done at the laboratory compare to the national standard. Proficiency testing exercises the entire calibration system (including the operator) of the laboratory. Compared to simply a calibration certificate from NIST, a proficiency test done by NIST is a much more meaningful method of verifying traceability to the national standards. The agreement in characterization of the transfer standard between NIST and the calibration laboratory provides demonstrated traceability to the national standards at a quantifiable level for that transfer standard.

Using documented procedures with equipment which has been shown to be operating within expected limits through periodic QA/QC procedures provides assurance that routine calibrations should achieve the same degree of "traceability" to the national standards as achieved in the proficiency test with the same equipment and personnel. The one obvious exception to this is an undetected "blunder" made by the calibrator and not detected in the calibration report review. Thus, it must be realized that the accrediting organization cannot guarantee the accuracy of all calibrations done at the laboratory. It can only state that the calibration laboratory has demonstrated that it is capable of calibrating instruments to within a certain consistency of the national standards.

Quality Control

The in-house QC procedures provide the link between routine calibrations done at the laboratory and the degree of agreement demonstrated during the proficiency test. The in-house QC programs should be easily performed. They should be designed to monitor one or more operating characteristics of laboratory equipment used for calibrating instruments. QC procedures are not calibrations but rather indicators of the constancy of the equipment. They are used to indicate where the equipment is operating within expected statistical limits or within predefined tolerance limits. The concept of redundancy is central to these QC measures. The idea is to use additional tests to permit cross-checking of results, and to use additional analysis of results to assure consistency of calibration to calibration over time.

Uncertainty Analysis

To estimate the overall uncertainty of routine calibrations based solely on the results of proficiency testing is a multi-year process. Proficiency tests are really a snapshot in time of the laboratory capabilities to calibrate a particular instrument under specific conditions. To convert this snapshot into a movie, it is necessary to use transfer standards which experimentally test all conditions in the laboratory over a long period of time. To make sure that the transfer standard itself is not a

perturbing factor, it is necessary to use transfer standards comparable to the instruments routinely calibrated at the laboratory. Finally, the sample size of proficiency tests must be large enough to derive a meaningful estimate of the accuracy of the laboratory's calibration process. Proficiency testing provides the accrediting organization with a tool for determining the ability of the SCL to perform proper calibrations under the test conditions.

However, proficiency testing is not a practical tool for the initial estimation of the overall uncertainty. An alternative method is to do an analytic uncertainty analysis. The ISO has recently issued a guide[17] for expressing uncertainty in measurements (or calibrations). The approach in the ISO Guide estimates uncertainty in each component, either using statistical methods (Type A uncertainties) or some other methods (Type B uncertainties). In the ISO approach, it is desirable to model the entire calibration process. The analytic uncertainty analysis provides an estimate of the uncertainty for routine calibration situations where there is no proficiency test (or an insufficient number of proficiency tests). There are two drawbacks to this approach: 1) using an incorrect model of the calibration process will lead to errors in the uncertainty estimate, and 2) one may not have sufficient data or measurements to estimate the expected variability in a particular component of the measurement model.

If one of the parameters in the uncertainty analysis has an associated QC program, the statistical spread in the QC data can be used to estimate the Type A variance for that parameter. If the parameter cannot be estimated by replicate measurements, then some other procedure must be used to estimate the Type B variance. This might simply be a "guesstimate" of the expected spread in the parameter. For example, a laser spot 2 mm in diameter is used to position the reference ion chamber at its geometric center. The user decides that there is equal probability that the true geometric center is uniformly distributed (variance equals 0.577 times the limit) over the diameter of the laser spot. The Type B standard deviation is then 1.2 mm. The combined uncertainty estimate should be equal to or larger than the proficiency test results if all the factors influencing the calibration were properly modeled and estimated.

Audits

The last element provides a formal mechanism for periodically reviewing all the elements in the laboratory's QA program. This audit should be done by personnel not directly connected with the operations or management of the calibration laboratory. All of the accreditation criteria specify an audit or on-site review by a team of technical experts supplied by the accrediting organization. In addition to these audits, the calibration laboratory should arrange for independent audits on at least an annual basis.

The management of the laboratory should use the results of this audit (and the results of all the other MQA processes described above) in a feedback procedure to correct any deficiencies which affect the quality of the calibration. As discussed earlier, to assure the quality of the product (i.e., calibrations), management must be actively involved in implementing all required actions to optimize and maintain the calibration accuracy goals. Understanding any deficiencies reported in the audit report and taking actions to correct these deficiencies is a key role for management to play in the QA program.

TYPES OF QUALITY CONTROL PROGRAMS FOR CALIBRATION LABORATORIES

As an example of how an SCL can develop an appropriate set of QC programs to monitor the performance of the calibration laboratory, the remainder of this paper will focus on the QC element of the MQA program. Typically, a QC program for the SCLs consists of a series of procedures and routine checks designed to monitor the constancy of equipment used in the calibration process. Four common types of procedures to monitor this constancy are:

1) automatic control tests to make sure measured values are within predetermined tolerance limits
2) periodic statistical quality control tests with optional predetermined larger tolerance or action limits
3) data trends
4) operational tests.

Automatic tests can be built into automated calibration procedures in order to monitor the equipment performance during actual calibrations. Periodic QC tests indicate whether test parameters used to indicate the equipment's performance are within normal statistical limits (i.e., control limits). When there are not enough data to determine meaningful statistical control limits, one can still plot the data and look for trends. For example, operational tests to monitor some function of the equipment can be used to verify that the result is within acceptable limits, but the results are not plotted on a control chart.

Each of these procedures can have tolerance limits. These are chosen to ensure that the routine calibrations are within the stated uncertainty. These tolerance limits are treated as "maximum" intervals in the uncertainty analysis and the corresponding variance for that parameter in the measurement model is estimated from this interval. The tolerance limit is typically larger than the statistical control limit.

Automatic Tests

For SCLs using computers to control the calibration equipment and gather and analyze the calibration data, the most monitored procedures are the automatic control tests. These will detect unacceptable changes which may occur in the time between scheduled QC procedures. The automatic control tests are implemented every time an instrument is calibrated in each reference radiation field. If measured parameters are outside the predetermined tolerance limits, the computer program will either repeat the measurement after making appropriate adjustments, or ask the operator to verify the data and to re-enter correct values. The calibration should not continue until the data are within the appropriate limits. In some defined situations, the operator may be allowed to override the computer control.

Periodic Quality Control Tests

Periodic QC procedures are designed to monitor two laboratory conditions that result in problems:

1) Short-term variations in individual measurements (or sets of measurements) of the test parameter which are outside statistical limits based on the previous history. This indicates that the deviant results are not conforming to the appropriate sample population, i.e., something in the calibration equipment has changed.

2) Long-term drifts in measured test parameter values which are within calculated statistical limits. Even though the statistical test may not show results outside of control limits, if corrections are not made, a significant error in the calibration could be introduced.

As an example of these two conditions, consider the measurements of output of a gamma-ray source. Short-term replicate measurements of the source output will be governed by the sampling statistics of the measuring equipment. A long-term "drift" is the radioactive decay of the source. If the short-term replicate measurements are in statistical control, then long-term effects due to source decay can be corrected back to some reference time.

Statistical QC tests are one way to determine the constancy of the laboratory equipment over time. They are a way to anticipate the need for recalibration of individual laboratory instruments if significant drifts appear in the data. There are many procedures for determining statistical control limits and plotting the corresponding control charts, depending on sample size, comparison against a standard or previous data, sampling from a known sample distribution, etc.

For the equipment used in the calibration laboratory, normally there is very little performance variation. Hence the control limits are very tight, e.g., typically a few tenths of a percent. If the QC test measurement on a particular day is only slightly outside the statistical control limit, there is no practical effect on determining the test instrument's correction factor. Thus a second set of limits is established, which, if exceeded, will cause an unacceptable error in the correction factor. These are termed "action limits" or "tolerance limits." If they are exceeded, the cause must be determined before any more calibrations are done.

Data Trends

In some cases, it is not possible for the sample to have enough data points to determine statistically valid control limits. Typically, about 25 observations need to be made before "constant" control limits are achieved. In these cases, the data are merely plotted on a chart and one tries to determine if there are obvious trends in the charts as a function of time. Some anomalies in the trend charts may be explained by physical reasons, e.g., the reference ion chamber was damaged and repaired, resulting in a change of the calibration factor.

Operational Tests

These are very similar to the automatic tests except that these tests are done manually and often there are no numerical tolerance limits. Three examples of operational tests include: 1) observing by visual inspection that operating the shutter moves it to the appropriate microswitch, 2) observing that the warning lights are on when appropriate fault conditions are simulated, and 3) verifying that a computer code gives the expected results for a set of test cases.

SETTING UP APPROPRIATE QUALITY CONTROL PROGRAMS

The first consideration in determining what QC procedures the SCL should develop is to look at the entire calibration process and decide which pieces of equipment or operations significantly affect the accuracy of the calibration. If one has already modeled the entire calibration process in preparation for the uncertainty analysis, it is a simple matter to determine the overall uncertainty for various limits on the performance of the calibration equipment. Once the critical equipment and operations

used in the calibration process have been identified, appropriate QC programs should be developed to periodically monitor some easily measured parameter representative of its performance.

As an example of setting up a complete QC program for an SCL, the procedures developed for the CDRH XCL will be used. Figure 1 shows the main components for x-ray instrument calibrations at the CDRH XCL. This calibration system has been described elsewhere[18] and [6][7] and will only be summarized here. The x-ray generator is operated at a specified x-ray tube current and voltage; a shutter is opened for a preset time, and the actual elapsed time is measured; a filter wheel containing filters for various beam qualities is positioned; the beam is collimated by one of two collimators; the reference ion chamber is positioned in the beam and its output is measured on a precision electrometer; the measured ion chamber current is corrected for the actual air density inside the ion chamber; the test instrument is positioned, and its reading is compared to the reference value; the computer controls the operations of the calibration and performs the required calculations; the calibration report is generated by the computer and the data is stored for future reference; and there are interlocks with alarms to shut down the x-ray generator if unsafe conditions exist in the radiation room.

For the CDRH XCL, the following is a list of critical components of the calibration system or operations performed during the calibration. Each component is listed under the type of QC procedure used to monitor its constancy:

- Computer automatically monitors/calculates/sets/monitors for each beam:
  - x-ray tube kV
  - x-ray tube current
  - x-ray tube yield
  - value of electrometer zero
  - ion chamber leakage current
  - coefficient of variation of radiation measurements
- Statistical QC measurements, results plotted on control charts:
  - picoampere source
  - electrometer
  - barometer
  - thermometer
  - hygrometer
  - correction factors of in-house test instrument
  - x-ray generator high voltage
  - beam quality (HVL)
  - ratio of two large-volume, spherical ion chambers

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[6] See the article "Services of the CDRH X-ray Calibration Laboratory and Their Traceability to the National Standards" by H. T. Heaton and F. Cerra, published in these proceedings.

[7] See the article "Characterization of X-ray Fields at the Center for Devices and Radiological Health" by F. Cerra, published in these proceedings.

- QC measurements, results within predetermined tolerance limits:

  - filter wheel positioning
  - positioning reference ion chamber
  - positioning test instrument
  - chronometer
  - elapsed time

- Trends:

  - NIST calibration factor of reference ion chamber intercomparsion of calibration factor of reference ion chamber measured at two CDRH x-ray sets

- Operational checks:

  - shutter operation
    computer hardware
    computer interface hardware
    computer program
    interlocks
    warning lights
    area radiation detectors.

The reference ion chambers are periodically intercompared to reduce the chance of introducing biases which may take several proficiency test cycles to verify. Their calibration factors are monitored on a trend chart. Since there are only a few cycles of calibration factors for any individual reference ion chamber, one can only look for trends in the reported calibration factors.

CONTROL CHARTS

There are many methods of calculating control limits and plotting the results on control charts, depending on exactly what feature is to be monitored and the sampling method used for the monitoring, e.g., see the American Society for Testing and Materials (ASTM) report, STP 15D,[19] or MIL-HDBK-683.[20] On control charts, the abscissa is the sequence number of the sample (or day of sample) and the ordinate is the value of the statistical parameter being monitored, e.g., the observed value, the average value of the sample, its standard deviation. The ASTM procedures calculate statistical control limits such that 99% of the results should lie between the upper and lower limits under the assumption that the data are normally distributed.

Methods for determining control limits are based on how the data are sampled and tested: 1) controls with no standard given, 2) controls with respect to a given standard, and 3) individual measurements. In the first two methods, one determines the average value and standard deviation, or ranges of a finite random sample from the population being monitored. These statistical parameters are used to determine if the results for the given sample are within statistical limits for a number of situations such as large and small sample size, samples of the same (or different) size, results compared against a standard or compared to previous results. In the last method, the individual results (rather than averages) are used to determine the control limits.

For many components of the calibration system, there are multiple factors which affect the value of the parameter being sampled. In these cases the day-to-day variation of the average value is often greater than expected based on the standard deviations of the corresponding measurements taken over a short time interval; i.e., the statistical variations in data sets can result from short-term or long-term processes as discussed in the last section. The type of variation depends explicitly on the nature of the process controlling the random variation. For measurements used to monitor the control limits of the calibration equipment, the short-term standard deviation of a set of replicate measurements is usually much less than the corresponding long-term standard deviation. For this reason, the Method of Moving Ranges (as discussed in ASTM report, STP 15D) was used for generating control charts for the calibration equipment in the CDRH XCL.

The mean moving range procedure is based on the measurement value of the current point, x_i, and on the measurement value of the preceding point, x_{i-1}. For n points, the mean value is

$$\overline{x} = \frac{1}{n}\sum_{i=1}^{n} x_i$$

and the mean range is

$$\overline{R} = \frac{1}{n-1}\sum_{i=2}^{n} |x_i - x_{i-1}|$$

This control limit procedure is called "mean moving range" because the mean value of R (and x) changes as the number of observations "moves" (i.e., n increases).

The control limits on the mean value of the raw data points are

$$upper: \overline{x} + 2.66\ \overline{R}$$

$$lower: \overline{x} - 2.66\ \overline{R}$$

and the control limits on the range are

$$upper: 3.27\ \overline{R}$$

$$lower: 0$$

Control charts show trends in the observed test points as a function of time. They also show individual results outside of expected statistical limits. For many applications, there are processes occurring which are not due to random sampling on a short-term basis but rather depend on physical conditions, e.g., the change in the output resistance of a picoampere source with ambient room temperature.

EXAMPLES OF QUALITY CONTROL PROCEDURES

The remainder of this paper will deal with three specific examples of QC procedures taken from the CDRH XCL. The actual QC procedure for each of the critical pieces of calibration equipment may have several different test procedures designed to monitor different aspects of its performance. At present there are 138 different control charts used to monitor the calibration equipment at the XCL. These are given in more detail in the CDRH Quality Manual for Quality Control and Uncertainty Analysis.[21]

Example 1) Large Volume Ion Chamber Ratio

To verify compliance with the TV and cabinet x-ray performance standards, it is necessary to calibrate survey instruments at exposure rates as low as 0.5 mR/h. This low exposure rate is achieved by using both a low tube current and a large source-detector distance (750 cm). The reference field for these low exposure rates is determined as follows. First, for large x-ray tube currents, the exposure rate is measured at both the normal 100 cm distance and at 750 cm. The ratio of these exposure rates is independent of the tube current needed to produce a particular exposure rate. Thus, by measuring the exposure rate at 100 cm and using this ratio, the reference field can be accurately determined at the 750-cm position for any tube current.

The exposure rate at any distance depends on the inverse square of the source-detector distance and attenuation in the air path. The actual attenuation in the 650-cm air path depends on the actual air density and the spectrum-averaged value of the mass-attenuation coefficient for air, which can be considered constant, with small changes in the spectrum due to air density variations. Hence, the product of air attenuation and the measured ratio should be stated for air density at reference temperature and pressure conditions, i.e., 22°C and 760-mm Hg.

When survey instruments are calibrated, the air attenuation factor is adjusted for the actual temperature and pressure at the time of the calibration. Thus, for a given tube current, the exposure rate at 750 cm is based on the adjusted ratio and the exposure rate measured at the 100-cm position. When an x-ray tube is replaced, the new physical dimensions may be different, causing a change in the nominal 750-cm, source-detector distance. This changes the value of the ratio, but will have virtually no change on the spectrum-averaged value of the mass attenuation coefficient for air.

Figure 2 shows the control chart for data points for the large volume ion chamber ratio. In Figure 2, it is clear that the ratio changed when the x-ray tube was replaced. This was due to an increase of 12 cm in the larger distance. Normally, one would begin a new control chart at this point, since one is now sampling from a different sample population. To show this change, all of the data points are being retained.

Figure 3 shows the associated control chart for the range and is included to show that there are control charts both for the mean value (Figure 2) and for the standard deviation estimator, the range in this case.

Figure 4 shows the results for the measured mass-attenuation coefficient. Here it can be seen that statistical control is maintained even for the new distance. The change in the ratio is solely due to the larger source-to-survey instrument distance.

Example 2) Electrometer

The QC program for the electrometer consists of several components: 1) stability of its internal voltage source, 2) stability of measured 6.00 x 10^{-11} setting on the picoampere source times a normalization constant, 3) stability of measured 0.60 x 10^{-11} setting on the picoampere source times a normalization constant, 4) "correction" factor for the electrometer coulomb range assuming the output of the picoampere source is calibrated, and 5) "correction" factor for the electrometer's coulomb range assuming that the electrometer's voltage source and value of standard air capacitor are correct. Since the picoampere source, reference voltage source, and air capacitor are not independently calibrated before this procedure is performed, this is not a calibration of the electrometer, but rather a check on its constancy for a specific set of test conditions.

Figure 5 shows the control chart for the "capacitor correction factor" method of the electrometer's coulomb range. There is some indication that the first three data points on this control chart may be drawn from a different sample than the remaining data points, or if they are all from the same sample, that there may be a slow downward drift. However, the control limits are only a few tenths of a percent. Even if there is a drift or change, it will have no practical effect on x-ray instrument calibrations as long as QC measurements continue within the current control limits. The data point above the upper control limit is real. Examining the data after the fact showed that there was unaccounted leakage on the air capacitor.

Example 3) In-house Test Instrument

As part of the monthly QC program, the 6 cm^3 probe of a dedicated x-ray monitor is calibrated in the M20, M30, L80, L100, and M100 beams. Contrary to the normal calibration procedure, no adjustments are made to this instrument. The ratio of the measured reference field and the observed instrument reading, e.g., the correction factor, shows the constancy of the entire reference field measuring system and the in-house test instrument. Control charts for the correction factors for each beam and the corresponding beam yield are plotted on control charts. Other tests done during the monthly QC program include: the temperature sensor probe is compared against a reference thermometer, the pressure probe is compared against a reference aneroid barometer, the position of the instrument table is verified, and readings of two separate metering circuits are compared for both the tube mA and kV settings.

Figure 6 shows the data control chart for measured L100 beam correction factors and Figure 7 shows the corresponding control chart for the yield for this beam. As in the case of the large volume ion chamber ratio, it is clear in Figure 7 that the tube yield changed when the x-ray tube was changed, but from Figure 6 it can be seen that this had no effect on the L100 correction factor.

CONCLUSIONS

This paper reviewed the main elements in an MQA program, their interrelationship to each other, and the overall role of MQA programs in various calibration laboratory accreditation programs. The paper then focused on the elements of QC programs a typical Secondary Calibration Laboratory would include to monitor the consistency of its routine calibrations as compared to the results obtained in a performance test with the NIST. Finally, some specific examples were given of QC programs and the use of control charts taken from the CDRH XCL.

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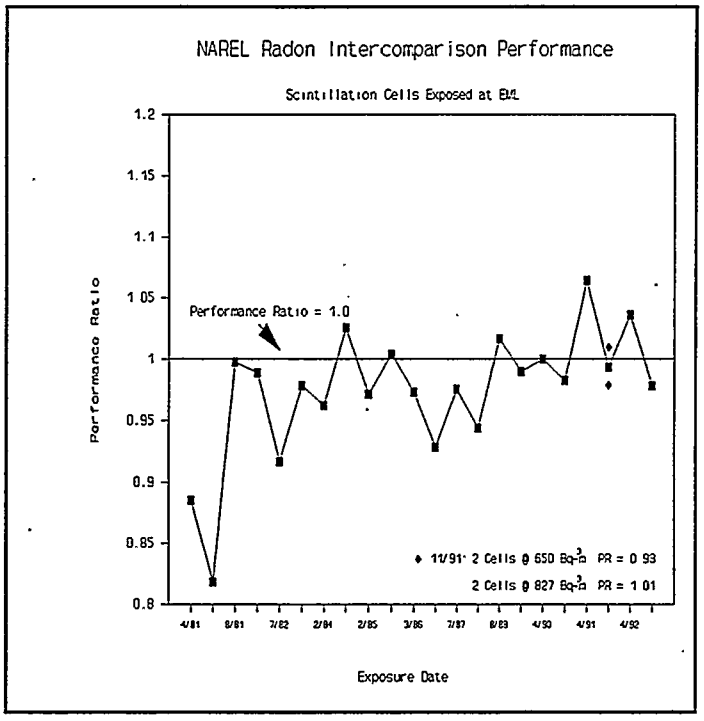

Figure 1 - Overview of Equipment Used for X-ray Calibration at the CDRH XCL

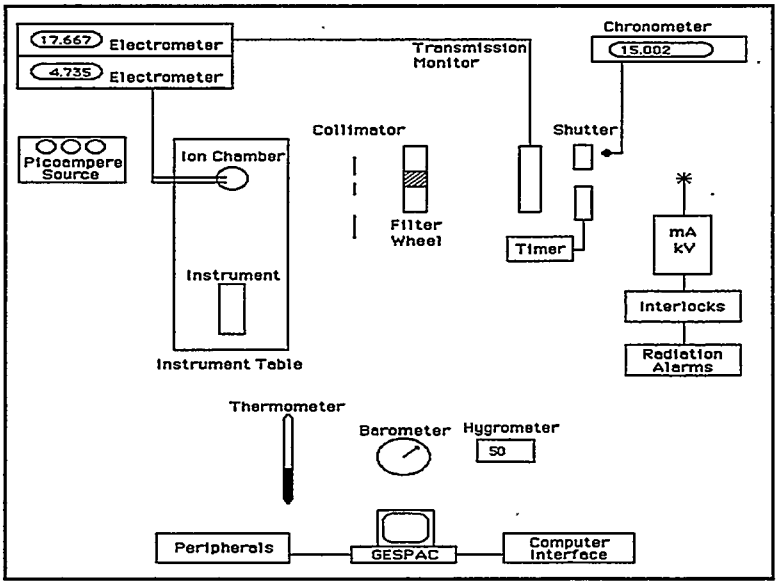

Figure 2 - Data Control Chart for Large Volume Ion Chamber Ration Measurements

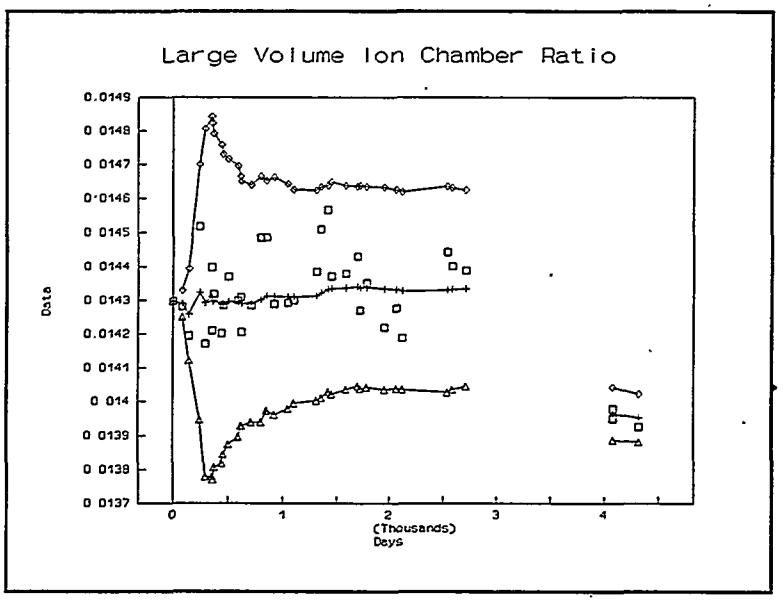

Figure 3 - Data Control Chart for Spectrum Averaged Mass-Attenuation Coefficient for Air

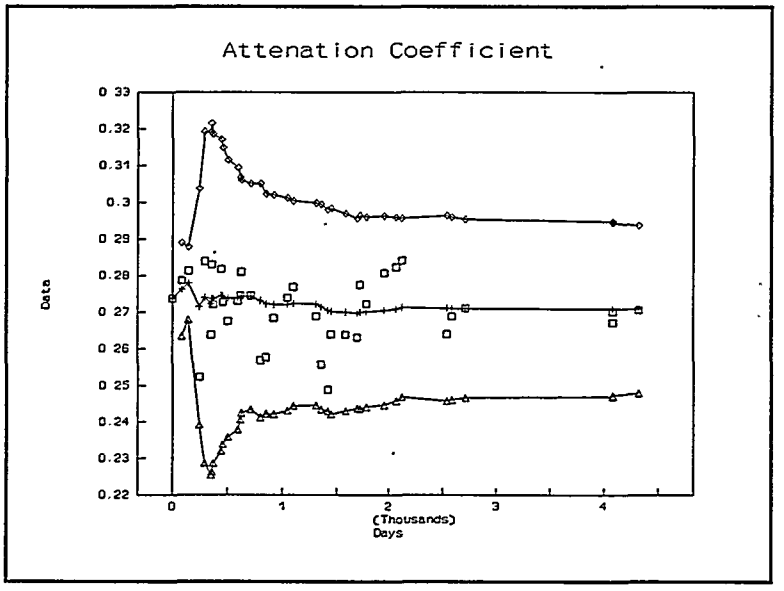

Figure 4 - Data Control Chart for "Capacitor Correction Factor" Method of Electrometer's Coulomb Range.

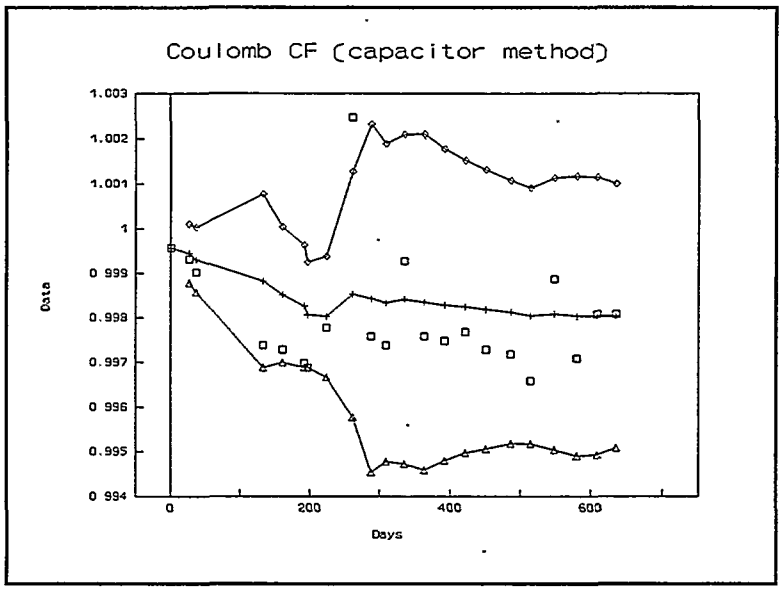

Figure 5 - Range Control Chart for Large Volume Ion Chamber Ratio Measurements

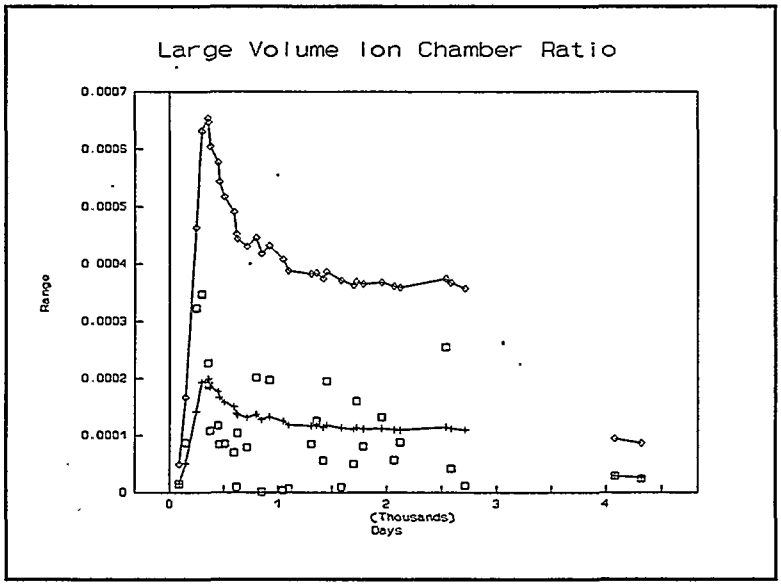

Figure 6 - Data Control Chart for L100 Yield Measurements

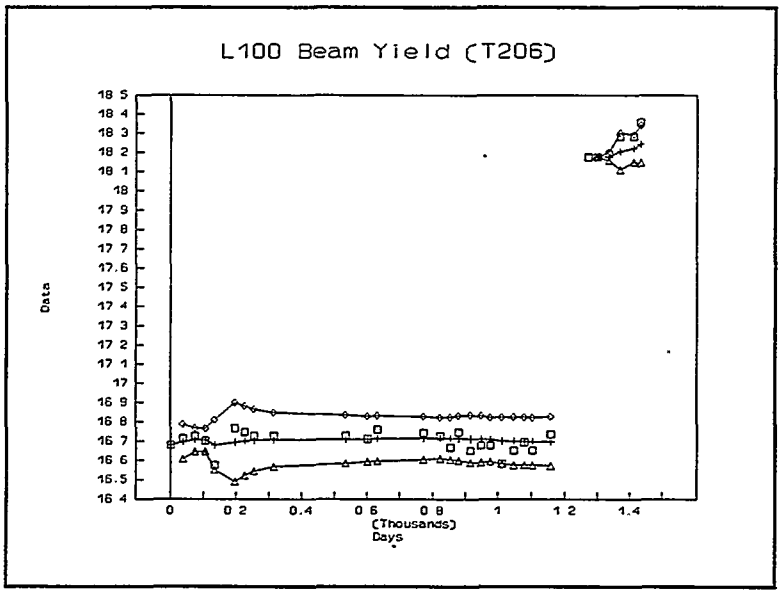

Figure 7 - Date Control Chart for L100 Correction Factor