THE QUALITY ASSURANCE PROGRAM AT K & S

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Abstract - K & S operates the largest and one of the most comprehensive Accredited Dosimetry Calibration Laboratories (ADCLs) in the American Association of Physicists in Medicine (AAPM) secondary laboratory system. It offers calibrations covering energies from Grenz-Ray (0.03-mm Al) to cesium-137 and cobalt-60, brachytherapy source and well chamber calibrations for low-activity sources, and, recently, high-dose-rate iridium-192. The present Quality Assurance (QA) program at K & S began with the AAPM Guidelines for Accreditation (Task Group #22 and #3, 1989) and grew over the past 10 years to include all aspects of providing a private, self-supporting calibration service from a free-standing independent facility. Some aspects of the QA program were prompted by the requirements of the nuclear power industry while other parts were from national consensus standards or the experiences of staff. Redundancy and teamwork are the most important characteristics of this QA program. K & S has participated in a National Institute of Standards and Technology (NIST) measurement quality assurance (MQA) program since 1982, and, in recent years, an ADCL intralaboratory intercomparison was conducted by Task Group 3 of the Radiation Therapy Committee of the AAPM. One measure of the credibility of a QA program is consistent performance on the MQA program and the ADCL intercomparisons over the past 10 years. An equally important measure of the ability of a program to assure quality results is the frequency of reported errors.

INTRODUCTION

The calibration laboratory at K & S provides a broad range of calibration services for both in-air type and re-entrant ionization chambers and the calibration of sealed sources. The primary focus of this description of the program will be limited to the calibration of in-air type chambers with only a few references to the QA program for brachytherapy. The brachytherapy part of the K & S QA program, however, is very similar in scope, control techniques, and program content.

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HISTORY

The laboratory at K & S was accredited by the AAPM in September 1982, after satisfying the requirements of the AAPM Guidelines and successfully completing a site visit and an initial proficiency test with the National Bureau of Standards (NBS). The Guidelines required the use of a written laboratory protocol which described all aspects of the operation of the laboratory. The protocol began as a collection of statements and procedures which described the facility, the equipment, the personnel, and the methods which would be used to calibrate dosimetry instruments within the required accuracy goals. After inquiries from several nuclear power facilities regarding compliance with the QA[1] requirements of the U.S. Nuclear Regulatory Commission (NRC) (NRC 1992), we began to investigate the feasibility of organizing a QA program around these regulations and other quality control standards. Although the regulatory criteria for QA programs required by these agencies was apparently directed at material suppliers, most of the basic components were usable as a supplier of services. The basic protocol was then reorganized to accommodate the specific needs of this industry. The suggestions, comments, and requirements of numerous audits by nuclear power QA managers, DoD contractors, and independent auditors over the years have been incorporated into the program.

REDUNDANCY

The QA program at K & S has as an underlying theme: the concept of redundancy. The AAPM Guidelines suggest the use of redundancy in measurements. The concept of redundancy, however, was proposed earlier (Rozenfeld and Jette 1984) for use as a tool in detecting changes in instrument sensitivity between periodic calibrations. This concept suggests that, with any given assumption of the individual failure rates of the components of a system of independent, redundant observations (or predictions as in decay), the probability of a failure in one component going undetected is significantly reduced with an increase in the number of components or a decrease in the interval between observations. It seems intuitively obvious that if we make more independent measurements of a physical property more often and compare the results, the possibility of missing a mistake is reduced. Yet, as Rozenfeld and Jette point out, many times independent measurements are made without taking advantage of the use of these data in a system of redundant intercomparisons. If the desired result is to maximize the benefit derived from each required measurement and to produce results having the highest level of confidence, the highest quality, then establishing a measurement process with as many redundant systems as possible is the answer. This concept has been extensively used in the K & S QA program with redundancy in local standards, procedures to achieve redundancy in measurements, redundancy in historical data control, redundancy in personnel, and redundancy in the QA review of the calibration report.

Redundancy in Standards

Dual local standards (each calibrated by NIST) provides the security and convenience of having more than one choice for direct traceability in the event of an accident or failure. Coupling these two components with a third, cobalt-60 or cesium-137 unit for isotope decay, creates a three-component

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(1) Terms such as quality, quality control, quality assurance, and quality management are defined in one or more of the references (ISO 1986).

redundant system which offers the reassurance of significantly reducing the probability of an error in one or the other of the standards going undetected. If an error is detected, the third component allows the capability of determining which component is defective. A weekly intercomparison interval of these three components provides a frequency which is slightly shorter than the normal calibration cycle of 7 working days. This results in a system of the highest confidence level. In the precision calibration business, high confidence in the local primary standards is the first step toward producing quality results.

Redundancy in Measurements

Redundancy in measurements is achieved through the duplication of each of the primary measurements in a separate system and in the careful recording of data which will allow an independent calculation to verify the initial results. The steps in each primary measurement have been formulated to provide at least one other redundant method of calculating independent results.

Redundancy in Historical Data

Access to historical calibration data is an extremely valuable tool in the review and assessment of the calibration data. The reports of calibrations for the current and previous 2 years are maintained in alphabetical order by customer name for ready access by the calibration review team. Log books extending back to the beginning are readily available in the calibration supervisor's office. A redundant file is available at the calibration bench which contains copies of calibration results filed by instrument manufacturer and model. Each file on a frequently calibrated chamber contains an energy response curve for reference by the review team as part of the QA protocol. This particular system is being automated through the use of an integrated report writing and multiple database system.

Redundancy in QA Review

Much of the literature on QA programs propose methods of quality control which involve sampling the results of a process and inferring the quality of a batch or lot. The K & S program, however, requires that every calibration receive a complete QA review by at least two members of the staff in addition to the person performing the calibration. The calibration technician, the laboratory director (or one of the associate directors) and the QA manager sign off on the logged data entries as well as the final report. The objective here is to get three differing points of view for the review of the raw data, the calculation of the factors, and the formal report. These three redundant checks not only result in a very high level of confidence in the final results, but they also allow each individual in the process to take pride in the product of their labors.

COMPONENTS OF THE QUALITY ASSURANCE PROGRAM

The major components of the QA program are: Quality Policy, Traceability Through MQA and ADCL Intercomparisons, Standards Control, Calibration Unit Control, Uncertainty Assessment, Calibration Procedures to Achieve Redundancy, Instrument Flow Control, Records/Document Control and Security, QA Review Process, Annual QA Audits, and QA System Performance Analysis.

Quality Policy

An overall quality policy is an essential component of the management of a QA program. The policy should identify the personnel, the resources, and the extent and direction of the program. The K & S quality policy is as follows:

1. All calibration laboratory personnel are considered part of the Quality Team. All operations will be conducted in accordance with the policies and procedures contained in the K & S QA program. Quality results depend on quality teamwork.

2. The QA program extends to all laboratory operations which are covered by the protocol.

3. The QA program will be revised and expanded to the extent necessary to assure the highest confidence in the quality of all laboratory operations.

Traceability Through NIST MQA and ADCL Intercomparisons

At the heart of the service provided by the ADCL secondary system approved by the AAPM is that the ADCL provide direct traceability. This requires the use of a calibration instrument which was calibrated by NIST. Although the AAPM Guidelines only require one of the two mandatory systems be calibrated by NIST, we have found that it is more practical from an operational point of view to have at least two instruments with the same NIST energies. We refer to this system as a redundant standard system. It not only allows the flexibility of choosing either standard for a precision calibration of a customer's instrument, but also prevents the possibility of a shutdown due to a failure of either standard. Each standard instrument received its initial traceability from NIST. This traceability is renewed on a biannual basis through participation in a NIST MQA program. Every other year an ADCL intercomparison provides interim confirmation that the instruments remain in good agreement with the national dosimetry standard. Figure 1 shows the 2-year ADCL Traceability Cycle using the redundant standard concept. The three-component system was established shortly after the initial NIST calibration using the cobalt unit. The local redundant intercomparisons are performed on a weekly basis.

The traceability of the low-dose-rate brachytherapy program is also established initially with a NIST-calibrated source of each isotope offered by the laboratory. Cesium-137 is the only long-lived, low-activity source currently offered by the ADCLs, while iodine-125 seeds and iridium-192 seeds in ribbons are the short-lived isotopes. Redundancy is achieved in the long-lived standards through the use of four NIST-calibrated cesium sources. The redundancy in the short-lived sources, however, is achieved through the use of redundant measuring systems with the cesium sources used for system constancy and locally calibrated working standards of each isotope used for setup constancy. The uncertainty involved in transferring the calibration to a new working standard is included in the total uncertainty for well chamber calibrations. Periodically, K & S sends an iridium source to be calibrated by NIST to confirm the long-term stability of the redundant systems. One intercomparison has been conducted with NIST participation since the program was initiated in 1987-1988 with good agreement between the laboratories and the Radiological Physics Center (RPC) in Houston.

A NIST standard for high-dose-rate iridium-192 is pending. Currently, an interpolative interim standard approved by the AAPM is being used by the ADCL's offering this service.

Local Standards Quality Assurance

As pointed out above, one of the most important and unique aspects of the ADCL secondary system is its emphasis on redundancy and frequent local intercomparisons. Using cobalt decay and two of the local standard chambers produces a three-component redundant system as shown in Figure 2. In order to prevent the possibility of a change in the energy response of the chambers used for x-ray calibrations, the calibration factors for the transmission monitor on the most stable x-ray techniques are tracked on a monthly basis. This provides a fourth component in the redundant system. Examples of the routine system of the Shonka chambers and the PRM chambers are shown in Figures 3 and 4, and Figures 5 and 6, respectively. Any significant unexplained shift in the factor outside the normal range for one of the chambers would be cause for recalibration with one of the other standards. Two of these four-component systems are used in the QA program. One consists of a set of Exradin Shonka chambers models A2, A3, and A4, and the other consists of two PRM LE-0.8 beryllium window low-energy chambers.

Calibration Unit Control

The K & S facility was designed with the concept that the calibration procedures and chamber setup methods for each calibration unit would be as consistent as possible. The calibration facility has a Picker cobalt-60 unit, a Picker cesium-137 unit, a GE Maximar 250 III orthovoltage unit (60-300 kVp), a GE Maximar 100 unit (10-100 kVp), a Fisher 125 kVp (35-130 kVp) diagnostic unit, a Universal Grenz Ray unit (2-22 kVp), and the most recent addition is a Picker VTX-650, 600-mA, 150-kVp diagnostic unit. All calibration units (including the cobalt-60 unit and the cesium-137 unit) have been fitted with a custom-designed, dual-chamber, full-beam transmission monitor and a consolidated calibration stand, which permits the same calibration jig to be used on all units. Each unit has been fitted with at least two orthogonal lasers which locate the reference point on each unit. Thus a chamber set up on the cobalt unit for calibration and atmospheric communication tests will be in correct position on any of the other units. A dual-channel electronic thermometer with remote readout is used on each unit to measure the temperature at the transmission monitor and at the chamber position. A redundant thermometer is attached to the standard barometer in the calibration room with its reading being recorded with each calibration. Every physical aspect of the calibration laboratory layout and calibration unit location and capabilities have been formulated to reduce the possibility of errors in the setup and use of each unit. Any questionable results at one energy may be easily checked on a higher or lower technique on the same or a nearby unit.

Measurements of the physical characteristics of each calibration beam are made periodically and recorded in an ADCL Techniques Database on a desktop computer. A sample of the information stored in the database for each combination of energy, field size, and distance is shown in Figure 7. This database is used by the calibration technician to set up the beam on each unit using a computer at the calibration console. Records are also maintained on the previous monitor calibrations for technique tracking purposes. This information is also available on a printed current technique list or on computer for use by the QA review team to verify that the appropriate parameters were used in the calibration.

Uncertainty Assessment

Uncertainty assessment is a very important part of the K & S QA program. A statement of uncertainty represents to the consumer of the services of a secondary calibration laboratory a promise

of a high level of quality in the reported results. If quality were defined relative to calibration services, it would necessarily include the closeness of the results to the national dosimetry standard, and uncertainty is an estimate of that closeness. The method of uncertainty assessment used at K & S is the method adopted by a subcommittee of Task Group 3 (Ibbott et al, 1991) which follows the method published by NIST (NBS 250-16 [NBS 1988]). Figure 8 describes the basic format used in the assessment. Since uncertainty depends on the physical factors of the calibration, the standard used and the instrument being calibrated, it must be assessed for each group of calibrations offered by the ADCL. Although this method has not been formally adopted by Task Group 3, it has been in use at K & S for several years as a method of estimating the "Accuracy" of the calibration results as recommended in the AAPM Guidelines for accreditation.

Calibration Procedures to Achieve Redundancy

The calibration procedures of the K & S program have been formulated to achieve a balance between efficiency and redundancy. For example, a chamber submitted with an electrometer would be calibrated as follows:

A. The electrometer is bench calibrated using the standard capacitor and a precision voltage source.
B. The chamber is calibrated into one of the laboratory precision electrometers using a charge mode and a rate mode.
C. The chamber and electrometer are calibrated as a system, and the calibration factor thus derived is compared against the product of the individual factors. The system test also provides an intercomparison between the laboratory electrometer and the standard capacitors and voltage source.
D. Through the use of an independent, solid-state beam timer, the calibration factors are calculated on the basis of isotope decay and compared to results from above.
E. At least once a week (perhaps during the same calibration, the standard barometer is compared to the station pressure reported by the National Oceanic and Atmospheric Administration (NOAA).
F. Dual thermometers provide redundant temperature readout.
G. A redundant calibration of the full-beam transmission monitors for x-ray calibrations are routine procedure (before and after).

Every effort is made to obtain the greatest use of all physical measurements to enhance the overall quality of the results.

Instrument Flow Control

Instrument flow is described in the chart of Figure 9. After checking for shipping damage, the instruments are logged in and inventoried and assigned a test number. Precalibration tests are conducted to ensure proper operation prior to calibration. The QA program includes procedures for each phase of the process including receipt, inspection, handling, precalibration testing, calibration, data recording, verification, comparison to typical performance, previous history review, report preparation, formal report review, packaging, and shipping.

The Quality Team

The Quality Team is currently made up of seven individuals covering the basic functions of the calibration process which includes scheduling, materials management, instrument evaluation, data measurement and report processing. Figure 10 is a chart showing the relationship between the members of the team with an indication of the responsibilities of each member. The associate director performs the annual QA audit since he is not involved with the laboratory on a daily basis.

Records/Document Control and Security

Figure 11 indicates the document system which is being implemented at K & S. Data from the customer, such as shipping address, billing address, and person to contact, are combined with past test numbers and equipment lists to provide a resource for current as well as historical data. The ADCL Techniques Database contains a compilation of all the measured beam data for all the current and previous energies offered by the laboratory. This database is used to set up each technique at the point of calibration and to verify log entries during the QA review process. The Chambers Database, Electrometer Database, and the Other Database (digital meter calibration, etc.) are being established to provide quick access to historical data and to generate energy response curves to replace the existing hand-filing system. Each of these databases will be used to generate the formal report currently generated on a word processor.

QA Review Process

As noted above, the QA program requires that each calibration will be audited by the secretary entering the report on the word processor, by the calibration technician, by the QA manager, and by the director. The review process begins with a completed preliminary data report submitted to the QA manager. Copies of the report are passed to the secretary for entry into the word processor to save time while the review is conducted. The report is verified against the data entered in the calibration log with check calculations of the factor and a check of the files for previous history. The QA manager also verifies that the calibrations performed match the order. Each calibration entry on the form and each page in the respective log book are initialed and dated. Next, the director spot-checks the various calculations, compares the results to previous data on the particular chamber type, prepares a graph if appropriate, and discusses any technical issues for clarification prior to initialing and dating the log entries. The formal report is then reviewed first by the secretary for typographical errors, then by the QA manager, by the calibration technician, and finally by the director for accuracy against the preliminary data.

Annual QA Audits

An annual audit of the QA program is conducted by the associate director. All aspects of the protocol and the procedures are evaluated from the point of view of someone who is not otherwise involved with the day-to-day activities of the laboratory. Calibration support activities, such as local standard intercomparisons, calibration procedures, history file maintenance, calibration QA audits, instrument handling procedures, packaging and shipping standards, procurement of calibration services from other facilities, and supplier qualification, are addressed in the QA audit. Interviews are conducted with each member of the program and a written report is filed with the QA manager.

QA System Performance Analysis

The performance of the QA system is evaluated on an annual basis after the annual QA audit by the associate director and is based in part on the following:

1. The results of the annual QA audit.
2. The results of the NIST MQA or the intercomparison between the ADCLs.
3. The evaluation of any reported errors.
4. The results of discussions with customers who have recently used the service.

Performance on the NIST MQA has been consistent over the years since 1982 as shown in Figure 12.

Two errors have been reported over the years since 1982. One error involved the use of a calibration factor for an energy other than on the one used in the calibration. This error occurred during the first year of operation. The second error occurred some years ago and involved the use of a large-volume chamber with its cobalt build-up cap on an x-ray energy. The cap was black and fit so tightly that the seam was invisible. Both errors were thoroughly investigated and resulted in many QA procedures which are still in place today.

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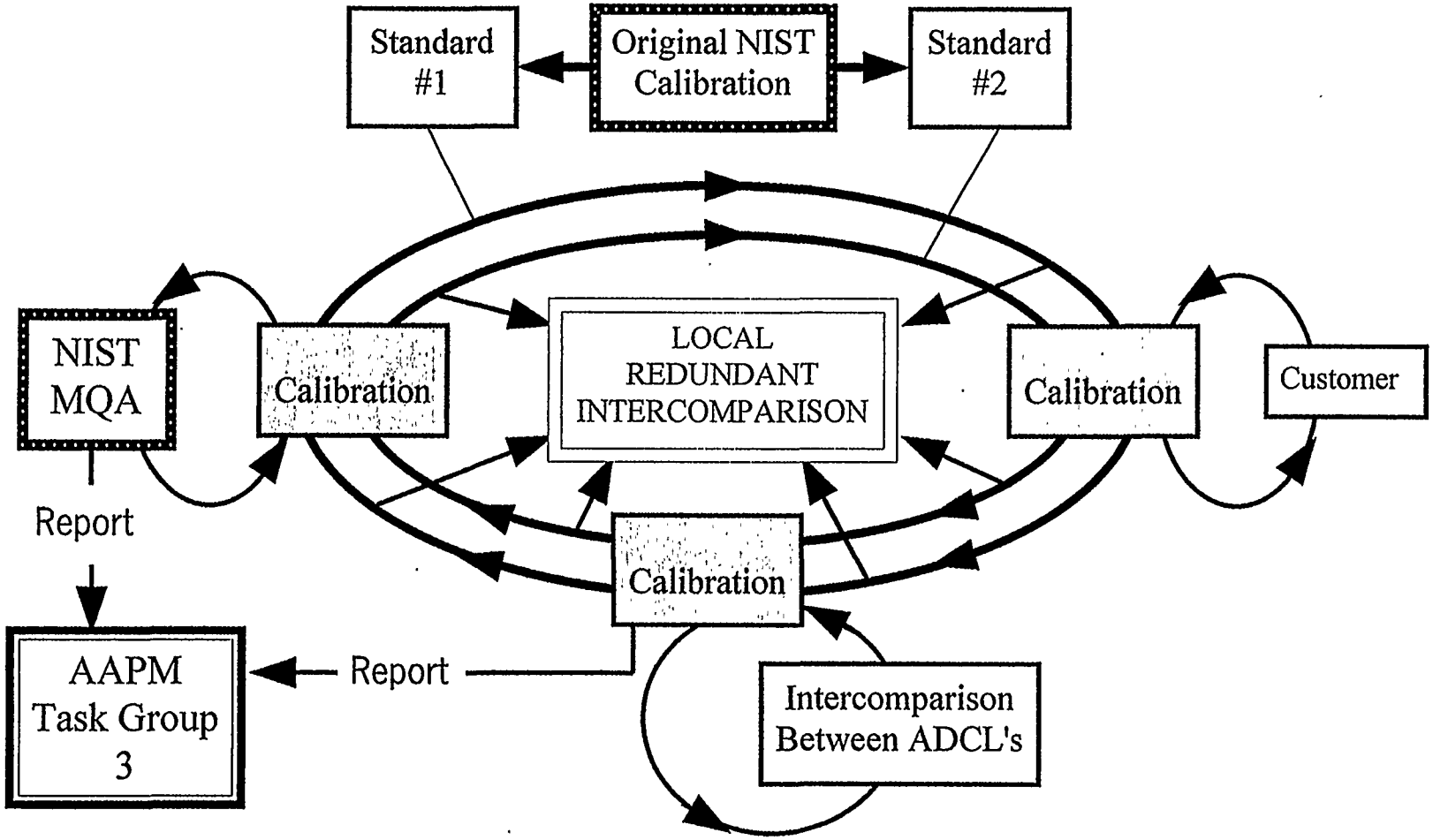

Figure 1 - Two-Year ADCL Traceability Cycle

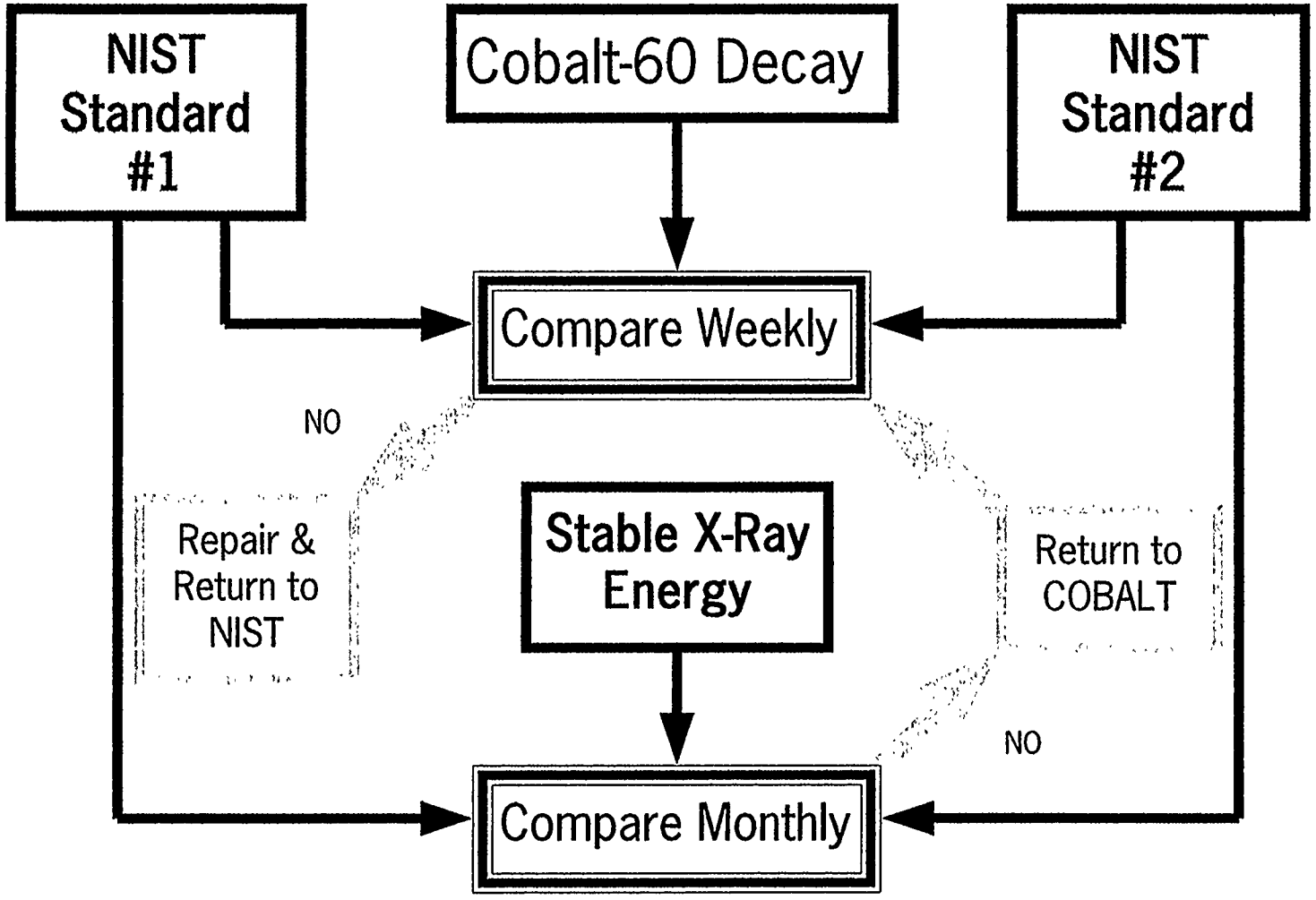

Figure 2 - Local Redundant Intercomparisons

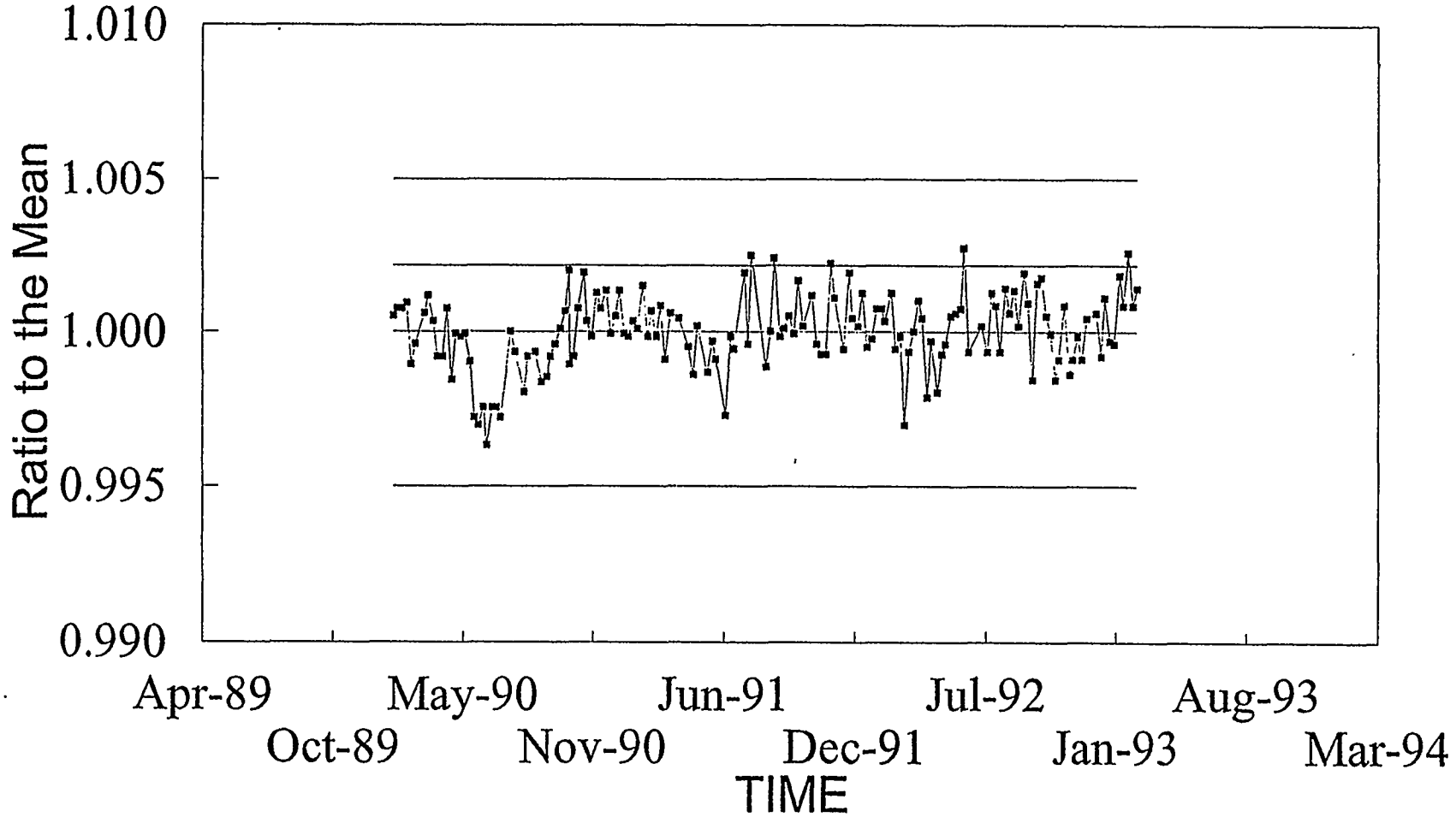

Figure 3 - Cobalt-60 Intercomparison Shonka Chambers

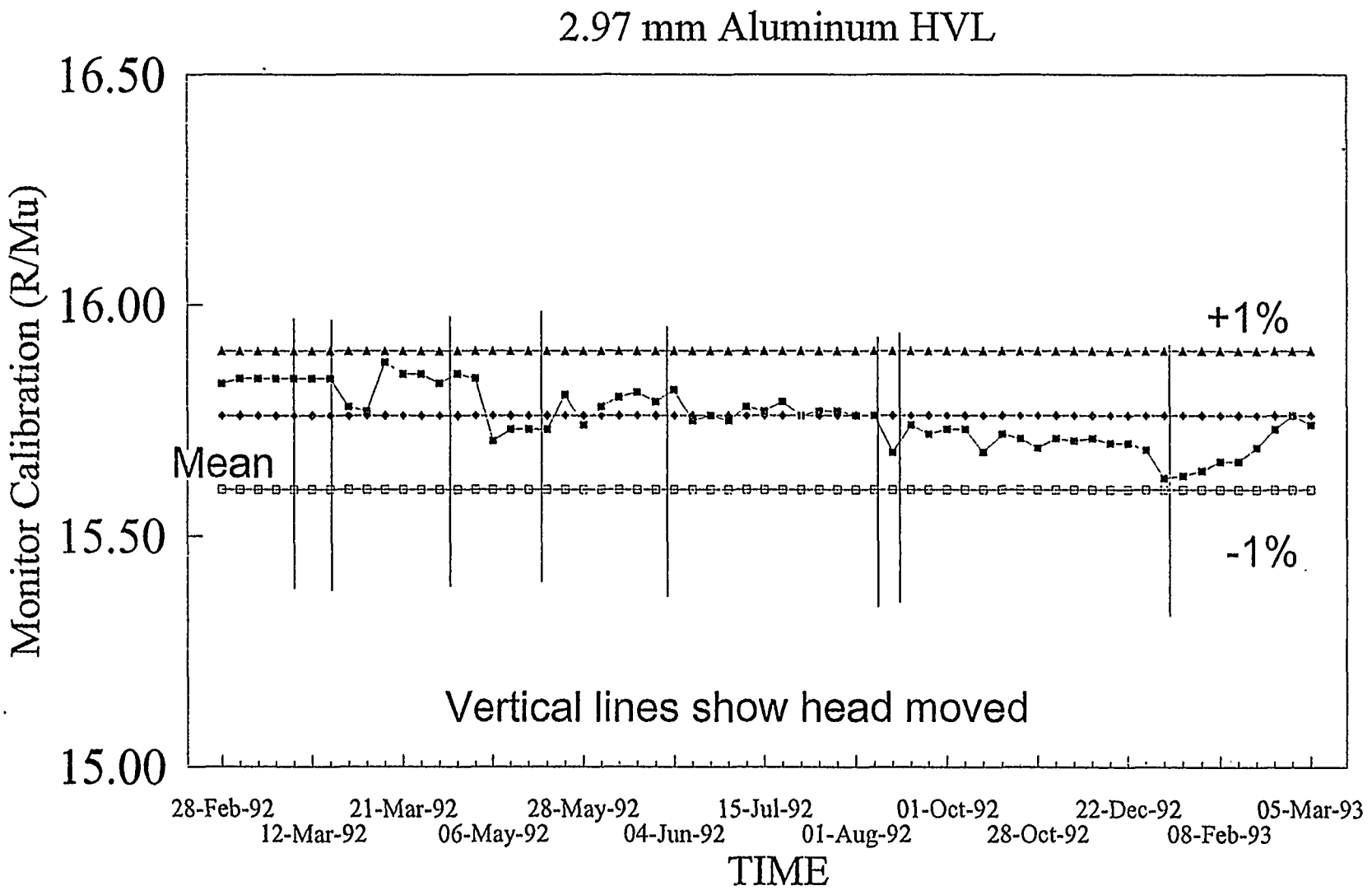

Figure 4 - Shonka X-Ray Intercomparison

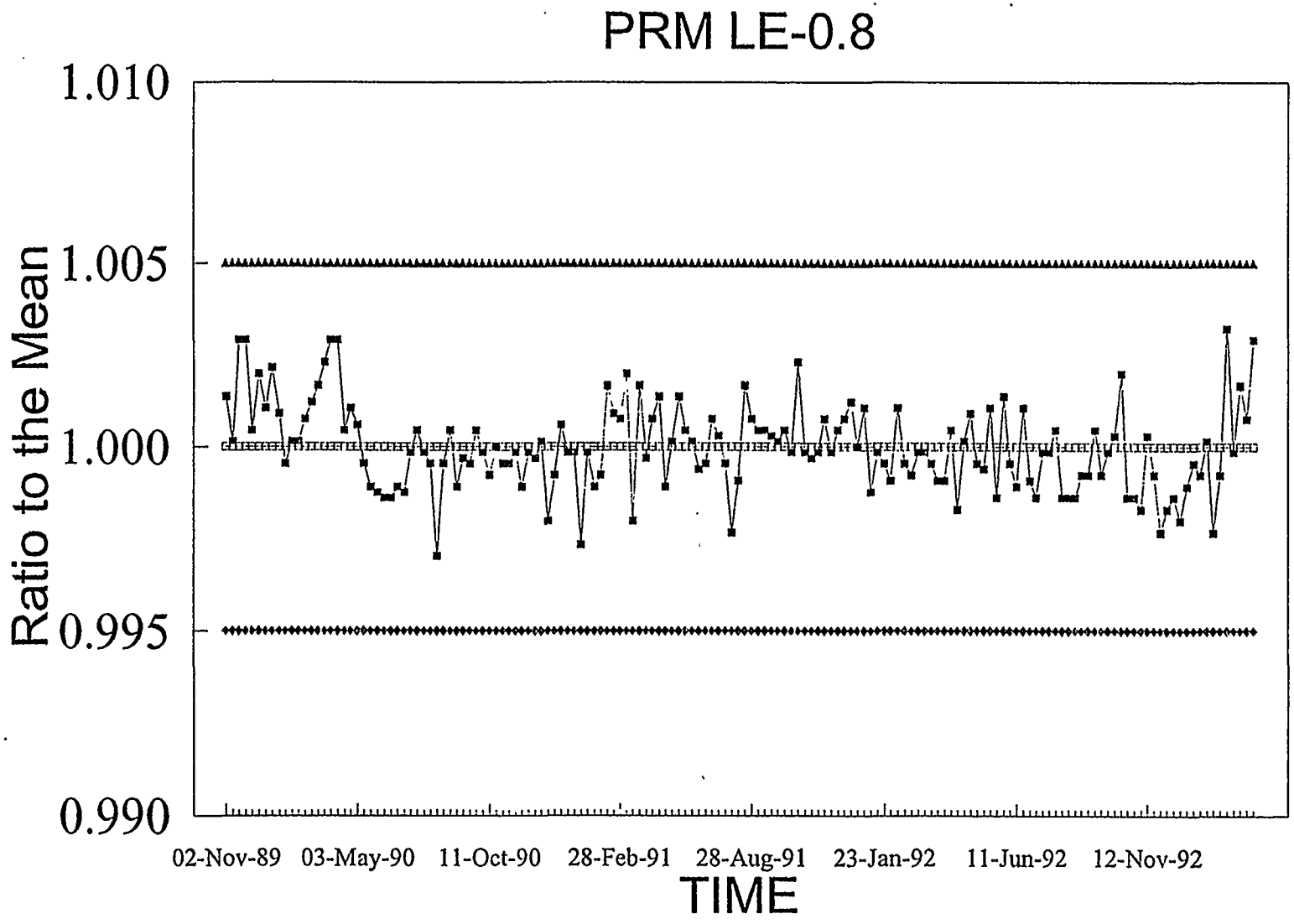

Figure 5 - Cobalt-60 Intercomparison PRM LE-0.8

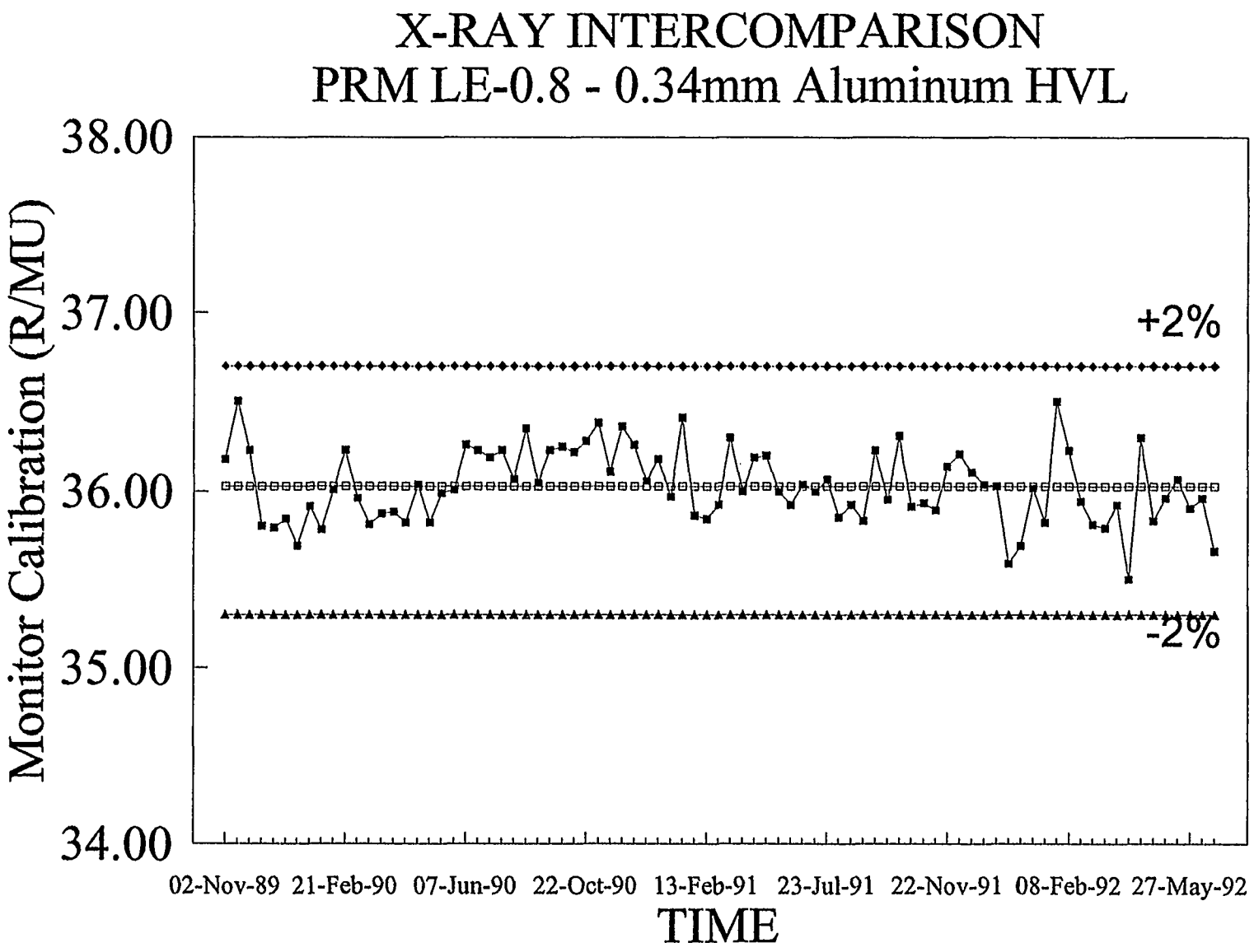

Figure 6 - Low-Energy Chamber Intercomparison

CODE: T24
UNIT: 250MAX
STATUS: AC
REPORT ==========
HVL: 1.05Cu
H.C.: 0.60
kVp: 205 kVp
R/min: 12.7 R/mi
SCD (cm): 45cm
Gy/R: 8.7643E-03
TECHNIQUE ==========
Est. KeV: 81.0 **ma:** 5ma

FIELD: 10cm dia
Filter: 0.5Cu+1Al **SETTING:**
R/MU: 15.6 **AVG.R/MU:** 15.578 **AVG.R/min:** 12.463
STANDARDS ==========

	MFGR/MODEL	SERIAL	FACTOR 1	FACTOR 2	UNCERT
C1M:	PRM LE-.8	**C1S:** 8829	**CF1L:**	**CF1M:**	**C1U:**
C2M:	EXRADIN A2	**C2S:** 139	**CF2L:**	**CF2M:** 9.665E+08	**C2U:**
C3M:	EXRADIN A3	**C3S:** 137	**CF3L:**	**CF3M:** 9.281E+08	**C3U:**
C4M:	EXRADIN A4	**C4S:** 147	**CF4L:**	**CF4M:** 1.200E+08	**C4U:**
C5M:	PRM LE-.8	**C5S:** 8828	**CF5L:**	**CF5M:**	C5U:

HISTORY ==========
NOTES:

D01:	1/9/93	**SET01:**	32	**RMU01:**	15.59	**RM01:**	12.6	
D02:	2/8/93	**SET02:**	33	**RMU02:**	15.54	**RM02:**	12.35	
D03:		**SET03:**		**RMU03:**		**RM03:**		
D04:		**SET04:**		**RMU04:**		**RM04:**		
D05:		**SET05:**		**RMU05:**		**RM05:**		
D06:		**SET06:**		**RMU06:**		**RM06:**		
D07:		**SET07:**		**RMU07:**		**RM07:**		
D08:	10/23/92	**SET08:**	33	**RMU08:**	15.57	**RM08:**		
D09:	1/12/00	**SET09:**	32	**RMU09:**	15.6	**RM09:**	12.5	/
D10:	12/22/92	**SET10:**	32	**RMU10:**	15.59	**RM10:**	12.4	

Figure 7 - ADCL Technique Database

```
DATE: 10/18/90
CODE: Cs02     BEAM: NEL Cesium      RATE:  7.800E-03R/min   DIST: 150cm
FIELD: 35cm     Gy/R:  8.7780E-03 EXP: 6.84684E-05Gy/min MONITOR (Y/N): y
================================================================================
STD.CHAMBER STDCMFGR: Exradin       STDCMOD: A4           STDCSN:          147
            STDCVOL: 30ml
STD.ELECT   STDEMFGR: PRM           STDEMOD: SH-1         STDESN:         8603
================================================================================
CHAMBER  TYPE: spherical    CATAGORY: >5cm
CUST.CHAM   CUSCMFGR: Exradin       CUSCMOD: A6           CUSCSN:
            CUSCVOL: 800ml

CUST.ELECT  CUSEMFGR:               CUSEMOD:              CUSESN:
================================================================================
                            TABLE I                          TABLE II
                        TYTPE A      TYPE B          TYPE A       TYPE B
1. CHARGE           C1A:  0.109 C1B:  0.033      C2A:  0.046  C2B:  0.033
2. TIMING           T1A:     0% T1B: N/A         T2A:     0%  T2B: N/A
3. AIR DENSITY      A1A:  0.077 A1B: N/A         A2A:  0.077  A2B: N/A
4. RECOMBINATION    R1A:     0% R1B:  0.067      R2A: N/A     R2B:  0.067
5. DISTANCE         D1A:     0% D1B:      0      D2A:     0%  D2B:  0.223
6. BEAM UNIFORM.    B1A:     0% B1B:  0.038      B2A:     0%  B2B:  0.067
================================================================================
                    QUADSUM1: 0.157582           QUADSUM2: 0.134581
CALIBRATION         NIST:          0.5           EXPCAL:  0.524244218
                              OVERALL:  1.082486028
NOTES
N1: C1A=WORST OF 5 R/MU, SIG/3=.327/3 N2: C2A=WORST OF 3 CALS,0.1/3
N3: A1A=.2DEG,2mm: .23/3              N4: C2B= ELECT=0.1/3
N5: R1B=WORST CASE=0.2/3              N6: A2A=A1A
N7: D1B=0:difference in table II      N8: D2B=5mm in 150cm,.668/3
N9: B1B= .038 (A4)                    N10: B2B=N-3,p232 worst=0.2;0.2/3
N11:                                  N12:
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Figure 8 - Uncertainty

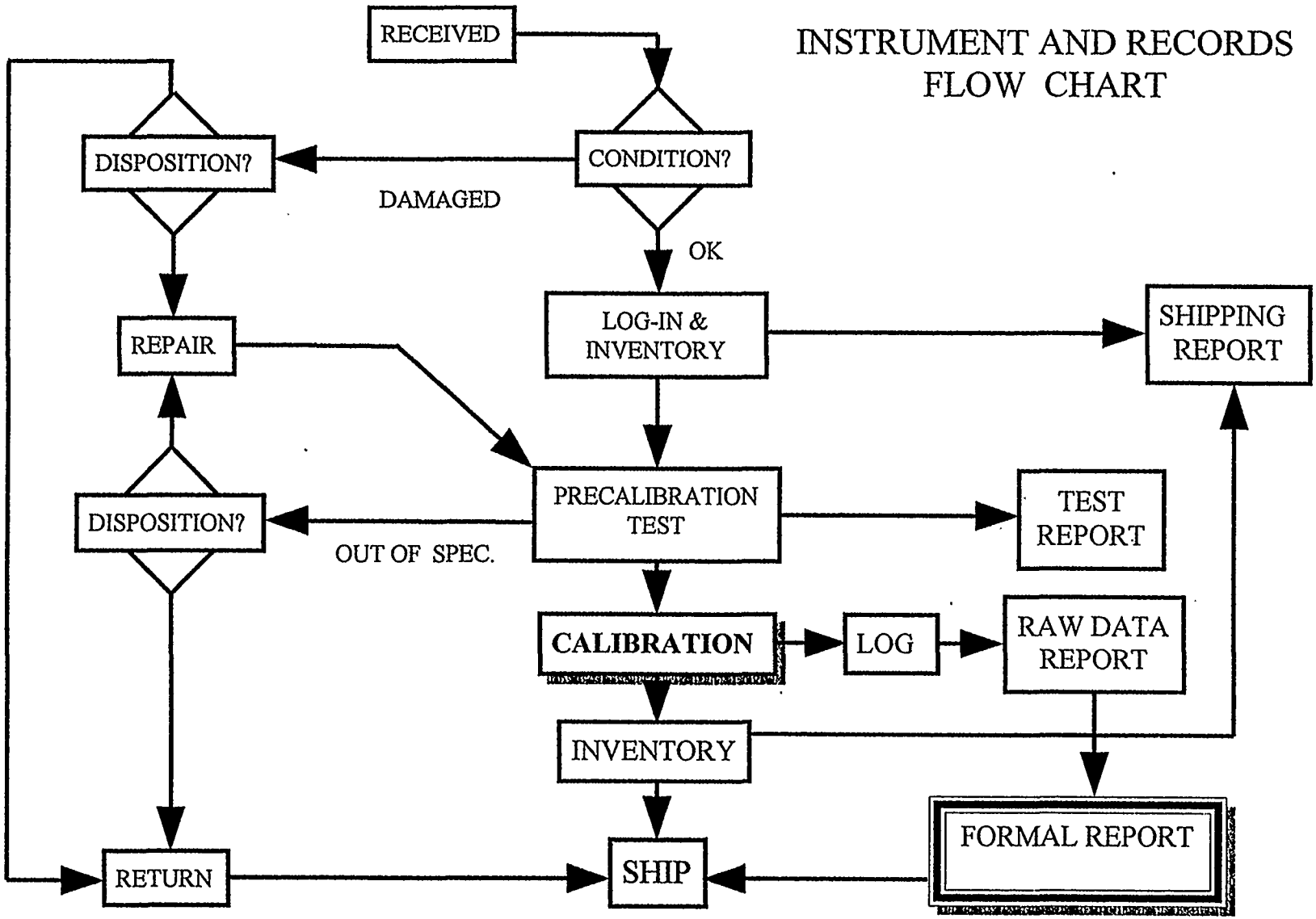

Figure 9 - Instrument and Records Flowchart

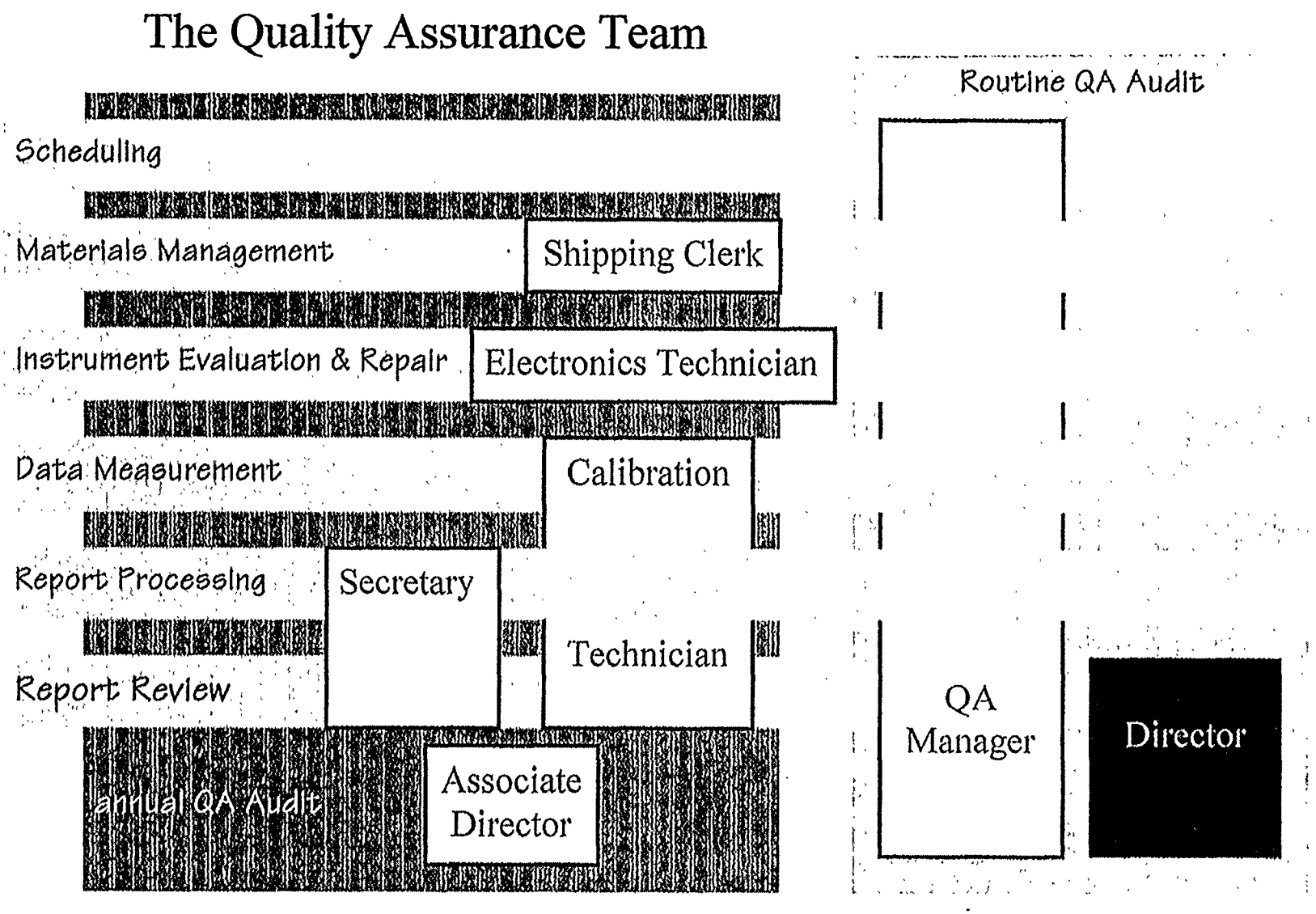

Figure 10 - The Quality Assurance Team

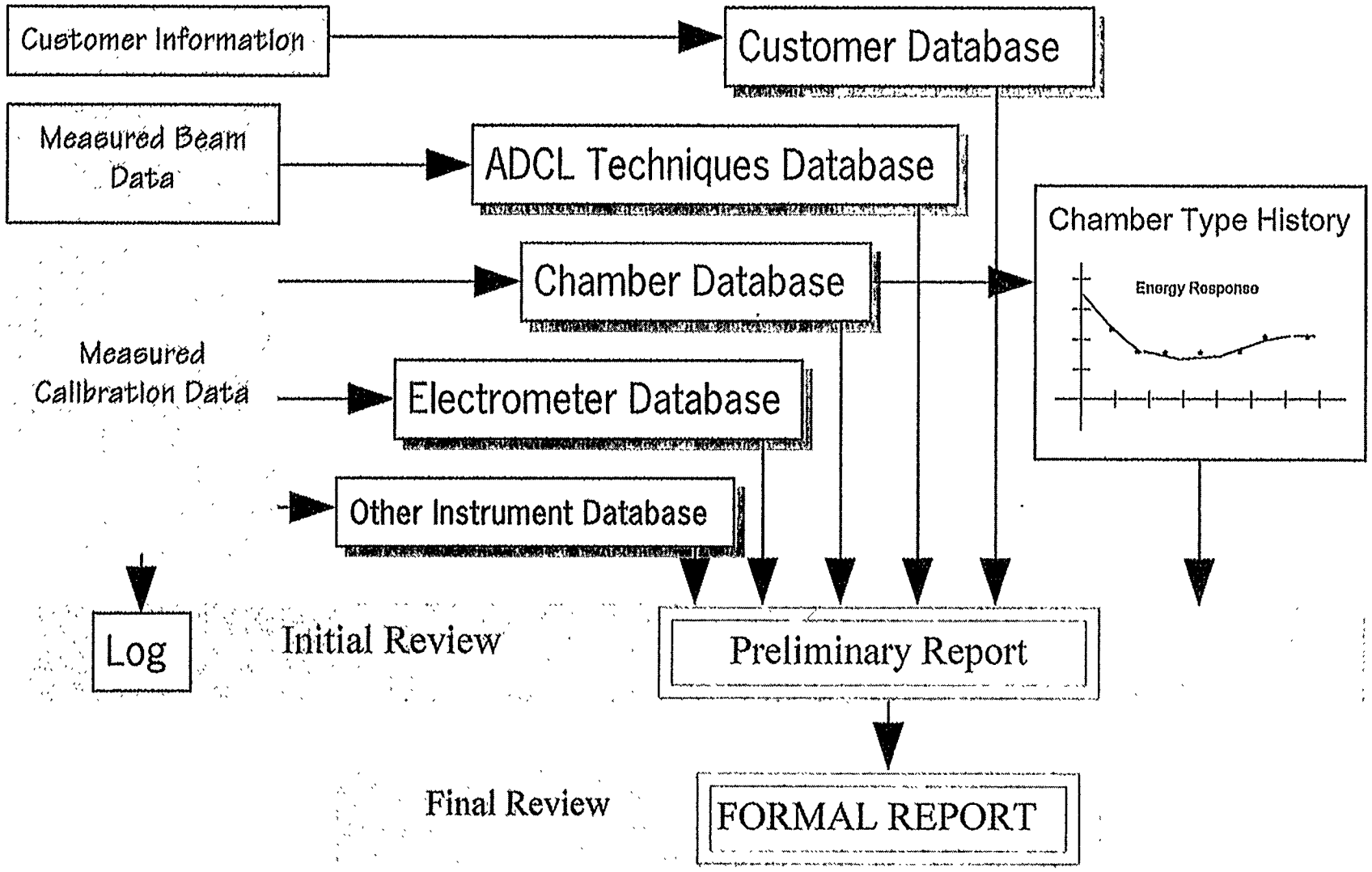

Figure 11- Data Management System

PERCENT DEVIATION

NIST BEAM CODE	HVL	1982	1983 Cham #1	1983 Cham #2	1985 Cham #1	1985 Cham #3	1986-1987 Cham #1	1986-1987 Cham #2	1989-1990 Cham #1	1989-1990 Cham #2	1990 Supplement	AVERAGE	#PTS
L10 (L-B)	0.029mmAL								1.1			1.10	1
L15 (L-C)	0.050mmAL								1.4			1.40	1
L20 (L-D)	0.071mmAL								0.6			0.60	1
L30 (L-G)	0.22mmAL								0.9			0.90	1
L40	0.49mmAL								1.2			1.20	1
L50 (L-I)	0.75mmAL								1.3			1.30	1
L80	1.83mmAL								-0.1			-0.10	1
L100(L-M)	2.8mmAL											ERR	0
M20	0.152mmAL								1.2			1.20	1
M30 (L-G)	0.36mmAL								0.4		-0.24	0.08	2
M40	0.73mmAL								0.9		0.13	0.52	2
M50 (L-I)	1.02mmAL	1.14	0.9	0.3	0.5	0	-0.5	0	0.6	0.4	0.4	0.37	10
M60 (MFB)	1.68mmAL	-1.04	0.1	0.4	-0.4	-0.7	0.1	0.4		0.5	0.33	-0.03	9
60(MFC)	2.79mmAL	-0.54										-0.54	1
75(MFE)	3.39mmAL	-0.75										-0.75	1
M100(MFG)	5.00mmAL	-0.63	0.1	0.2	0	-0.9	0	0.5		0.2		-0.07	8
M150(MFI)	10.2mmAL	-0.22	0.2	0.3	0.1	-0.7	0.5	0.3		0.4		0.11	8
200(MFK)	13.2mmAL	0.34											
M200	14.9mmAL		0.1	0.4	0.4	-0.4	0.4	0.6		0.6		0.30	7
250(MFM)	15.8mmAL	0.23										0.23	1
M250(MFO)	18.5mmAL	0.63	-0.1	0.4	0.2	0	0.3	0.5		0.6		0.32	8
M300	22mmAL							0.3				0.30	1
Cesium 137	32mmAL						-0.1	-0.2		-0.2		-0.17	3
Cobalt 60	46mmAL	-0.2	0.6	0	-0.2	-0.3	-0.4	-0.2		-0.2		-0.11	8

Figure 12 - NIST MQA