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Performance of Portable Radiation Survey Instruments

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Prepared for
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ABSTRACT

This report examines alleged and documented deficiencies in the performance and the calibration of existing portable radiation survey instruments. This report also examines a limited number of reported overexposures and excessive exposures attributed to instrumentation or calibration problems. The high failure rates in performance testing of a limited number of instruments indicate further testing is needed to demonstrate which instruments are acceptable and for what application. Further, the adequacy of calibration is not demonstrated at this time as many calibrations are performed by non-accredited calibration laboratories. A review of the regulatory requirements and practices of the NRC and Agreement States regarding the use of existing performance standards such as ANSI N42-17A-1988 and the use of accredited calibration laboratories demonstrates that (1) the regulatory programs do not require compliance with existing industry standards; and (2) instruments are generally not required to be calibrated by accredited laboratories. Options are recommended that might encourage the use of industry performance standards and calibration techniques.

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FOREWORD

Past studies, allegations, and reports have indicated that there may be deficiencies in the performance and calibration of portable radiation survey instruments to the extent that potential public health and safety concerns could result. Because of these concerns, the NRC is evaluating whether additional requirements or recommendations on instrument performance are necessary or desirable. This report provides information that could be used to assist the NRC in assessing its guidance and regulatory needs, if any, in this area.

NUREG/CR-6062 is not a substitute for NRC regulations, and compliance is not required. The results, approaches and/or methods described in this NUREG are provided for information only. Publication of this report does not necessarily constitute NRC approval or agreement with the information contained herein.

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1 INTRODUCTION

The purpose of this report is to assist the NRC staff in determining whether or not performance problems exist in the use of portable radiation survey instruments. NRC Headquarters staff, Regional staff and others such as the National Institute for Standards and Technology (NIST) have suggested that problems in calibration and performance may exist that would impact radiation protection. This report examines available documentation related to alleged deficiencies in existing portable radiation survey instruments. This report continues with a review of the use by NRC and Agreement State licensees of instruments that meet existing performance standards such as ANSI N42-17A-1988 and the use of certified calibration laboratories. This report further reviews reported overex[illegible]es and excessive exposures due to instrumentation or calibration problems.

1.1 Backgr[illegible]

The effectiveness of a radiation control program is critically dependent upon the quality of the measurements made to support that program. If measurement quality is low, radiation workers or members of the public may inadvertently be exposed to hazardous conditions that could be corrected or avoided. If the quality of measurements is high, there is adequate assurance that radiation exposure can be controlled to provide safe and beneficial applications of ionizing radiation. The assurance of adequate measurement quality at reasonable cost is a continuing challenge to regulators and users of ionizing radiation, as well as those who are actively involved in the various activities of the radiation measurement community.

Portable survey instruments are widely used to determine whether or not a hazardous level of ionizing radiation exists in a particular location. Accurate knowledge of radiation level is important so that appropriate actions may be taken to avoid, reduce, or eliminate the radiation, or to determine how long an individual may be exposed to the radiation without undue risk of harm. To obtain accurate knowledge, the survey instrument that is used to make the measurement must respond accurately to the set of conditions and circumstances encountered. The critical, enduring question is how well a particular survey instrument performed, or is capable of performing, over a reasonable range of circumstances.

The usual action taken in an attempt to achieve measurement accuracy has been calibration of the survey instrument. Such a calibration typically consists of subjecting the instrument to a known radiation level and observing its response, or comparing its response to a reference instrument when both are exposed to the same radiation field. Questions have been raised as to whether this action has been sufficient to assure the desired measurement accuracy.

1.2 Performance Testing of Survey Instruments

Adequate performance of survey instruments is a continuing concern in the radiation protection community. That concern led to the development and publication, in 1989, of American National Standard N42.17A, Performance Specifications for Health Physics Instrumentation--Portable Instrumentation for Use in Normal Environmental Conditions. Essential instrument performance characteristics are identified in this standard. The scope of the standard is stated as follows:

"This standard establishes minimum acceptable performance criteria for health physics instrumentation for use in ionizing radiation fields. Included are testing methods to establish the acceptability of each type of instrumentation. This standard does not specify which instruments or systems are required, nor does it consider the number of specific applications of such instruments."

The Standard's introduction expands on the scope somewhat by stating that in this standard, health physics instrumentation provides direct readout and includes "portable rate and integrating devices for beta, photon, and neutron radiations and monitors for surface contamination. Personnel dosimeters, instruments designed to be used as individual or personal monitors or warning devices, environmental monitoring instruments, and air monitors are outside the scope of this standard." The Standard does not include performance under extreme conditions of use. This Standard is further described in Appendix A, Performance Specifications for Portable Radiation Survey Instruments.

1.3 Calibration and Measurement Quality Assurance (MQA)

The common reference point for measurements made in the United States is the National Institute of Standards and Technology, which has as its primary function "the custody, maintenance, and development of the national standards of measurement, and the provision of means and methods for making measurements consistent with those standards"(Congress 1950). In a practical sense, accuracy is determined by the degree of agreement of a measurement result with the national standard. Close agreement means a high degree of accuracy, and a high degree of measurement quality. The "means and methods" that enable the achievement of accurate measurements are the supporting services provided by NIST. A basic limitation of this scheme is that there is only one NIST but there are tens of thousands of radiation measurers. It is physically impossible for NIST to provide support services directly to each member of the measurement community.

In recent years, several national programs have been developed that provide significantly greater assurance of measurement quality. Several of those programs will be described later in this report. An essential feature of each program is the use of performance (proficiency) tests to demonstrate a satisfactory level of agreement with NIST. Satisfactory measurement performance when tested is an indication that not only is the instrument or source properly calibrated, but that it is also being used properly. Following this reasoning, the performance testing mechanism should be preferred over the calibration mechanism because it extends to the measurement itself, instead of ending with an instrument or radioactive source.

Traditionally, the solution to calibration questions has been the establishment of a calibration hierarchy, whereby NIST calibrates an instrument or radiation source for a customer, who then calibrates an instrument or source for ensuing customers and so on down the chain. The errors introduced by the various calibrations that occurred along the chain, as well as the errors inherent in the instruments and measurement processes used, are likely to be unknown and undetected. As a result, the quality of the subsequent field-level measurement is also unknown, and its accuracy (i.e., its agreement with NIST) is merely implied. To complicate matters, once an instrument or source is calibrated there is no consistent policy as to when recalibration should occur (even when instrument components have been replaced).

2 MANUFACTURING AND PERFORMANCE

This section describes reported instrument malfunctions and related exposures; details the results of instrument performance testing; quantifies the present use of ANSI N42.17A by instrument manufacturers; and describes the use of ANSI N42.17A by NRC and Agreement-State licensees.

2.1 Instrument Malfunctions and Exposures

The impact of instrument performance limitations is difficult to assess. Essentially all of the available data are limited to experiences of NRC licensees, and there is indication that there are incidents which have not been reported or documented that resulted in unnecessary exposures or overexposures because of instrument performance problems. There is no documentation system for excessive exposures which are associated with instrument malfunction when the exposures are within NRC occupational limits. Further, poorly designed instruments entering the industry would not remain in the market as they would be unacceptable to licensees. When an instrument fails while in use, it is simply replaced. Only cases of exposures near or over a regulatory limit are documented. This lack of incident documentation was experienced while gathering data for this report, and a similar experience was reported in Merwin, Swinth, and Herrington (1986):

> "During both a national and an international meeting, one of the authors approached several senior people well known in the radiation protection area and asked them to relate instances of overexposures or unplanned exposures related to problems with portable radiation protection instruments. About one half of the people approached were willing to mention instances that were directly related to problems with instruments, but in all cases these incidents were not documented and the subjects were not willing to be quoted directly. For the instances recounted, the response time, overload, and radiofrequency (RF) susceptibility tests would have prevented the problems. The poor reliability of these instruments was a common complaint expressed by many of the people; however, most said that poor reliability was not usually a direct cause of unplanned exposures. There were instances where the people felt a lack of training led to unplanned exposures. That is, the instruments responded correctly but the operator did not interpret the readings correctly or felt the reading was incorrect and ignored it. The latter reflects a lack of confidence in the instrument because of operator experience with poor reliability."

Documentation of instrument performance limitation was presented during the Workshop on Radiation Survey Instruments and Calibrations held at the National Institute of Standards and Technology in July 1984, by two representatives of the NRC who stated the following (Federline and Alexander 1985):

> "In 1979, the NRC received information that significant problems may exist in the design and construction of portable health physics survey instruments. This information was provided through an extensive five-year instrument acceptance testing and evaluation program at Pacific Northwest Laboratory (PNL). Failure rates as high as 33% were reported for a commonly used beta-gamma dose rate survey instrument. The NRC staff has since observed other indications of poor performance of health physics instrumentation. A DOE national laboratory noted through personal communication a 100% failure rate on 100 beta-gamma dose rate survey instruments purchased on low bid. Less than half of the portable radiation survey instruments at TMI Unit 2 were operational at the time of the March 1979 accident. In at least two instances, individuals failed to leave high radiation areas in the TMI auxiliary building when their radiation survey instruments failed or deflected full scale. In one of these instances, the failures resulted in a whole-body exposure in excess of regulatory limits (Cordes 1979). NUREG-0855 (Cunningham, Wigginton, and Flack 1982), which describes the health physics

appraisal program conducted by the NRC, indicates that at many of the 48 commercial nuclear power plants visited, the supply of operable health physics instrumentation was marginal for routine operations and inadequate for an accident of the TMI magnitude. In general, it was noted that quality assurance programs for health physics instrumentation needed significant improvement.

The staff has continued to note other serious incidents which have resulted from or been related to poor performance of health physics instrumentation. Per IE Information Notice No. 82-31, in June 1982, a diver at a commercial nuclear power plant received 8.7 rems to the head due to erratic and intermittent performance of an underwater survey instrument. Information was provided by NRC regional staff personnel that a commonly used beta-gamma dose rate instrument employing a GM detector registers zero when exposed to a Sr-90 source at high dose rates. In 1983 two overexposures were reported from a radiography source containing 11 curies of Co-60, and, when the source was examined, the survey meter indicated zero in a high intensity field."

A more recent example of instrument malfunction was reported in NRC Information Notice No. 90-44, issued June 29, 1990. That notice was based on a DOE Safety Action Notice that described under response of two Bicron RSO-5 dose-rate instruments. The under response (by a factor of about 100) was observed while the second range (0-50 mR/h) of the instruments was being used. No personnel were overexposed to radiation when these instruments failed. Other instruments which hav[illegible] [illegible]me type of magnet arm switching design as the RSO-5 can have this same type of problem. Because of [illegible] [illegible]le mechanical problem, severe under response to the true radiation fields for these dose-rate survey instruments can occur as a result of switching between the lower two instrument ranges. This reduced sensitivity requires a true dose rate of 5,000 mR/h to produce a full-scale deflection on the second-range (0-50 mR/h) scale or a true dose rate of 500 mR/h to produce a full-scale deflection on the first-range (0-5 mR/h) scale. Although the magnet arm is aligned properly at the time of production, this alignment can shift with time and normal field usage.

A search of NRC records, primarily the NUDOCS system, in July and August of 1992, produced the following information. There are several examples of instrument malfunctions associated with exposures.

- In August 1990, an individual received a quarterly dose of 1.63 rem and the survey meter was reported to be shorting out periodically.

- NRC Information Notice No. 91-23, March 26, 1991, was issued in part to alert radiography licensees to survey after each exposure. However, in one of the case examples, a backup monitor called a chirper failed to alarm because it was malfunctioning.

The same record search yielded indications that some exposures occur due to operator error in proceeding with work without an operable survey meter or by not following procedures:

- An NRC report dated January 7, 1982, shows that two radiographers received whole body doses of 1.29 and 0.69 rem because no survey was made as the survey meter was malfunctioning.

- A radiographer received over 5 rems in 1989; the survey meter was described as inoperative.

- A radiographer received calculated doses of 6.1 rem whole body in 1988; the survey meter was described as inoperative.

2.2 Results of Instrument Performance Tests

Detailed information about the results of the instrument performance tests to evaluate the applicability and practicality of ANSI N42.17A is available elsewhere (Kenoyer et al 1986; Merwin, Swinth, and Herrington 1986). At the time of testing, the Standard was in draft form. Some changes in that document were made as a result of the evaluation, though few reflected substantive changes in the technical performance requirements. Perhaps the most significant change was the precision requirement of 2.5 percent being increased to 10 percent because the Standard was found to be too restrictive.

The instruments tested were of the following types and numbers: ion chamber (21); Geiger-Mueller (41); alpha-particle (26); neutron (11); low-dose-rate scintillation (2). They were obtained on loan from instrument vendors and users, or by direct purchase. The project was jointly funded by the NRC and the U.S. Department of Energy. Table 1 summarizes the results of the performance tests. It is reproduced from Merwin, Swinth, and Herrington (1986), which concludes the following:

> "The testing indicated that all of the tests are practical; instruments can be designed to meet the various performance criteria. Specific instrument designs had difficulty meeting selected criteria. Instruments using GM detectors showed poor energy response but Barclay (1986) has shown that GM detectors can be designed with adequate compensation to meet both the energy and angular response criteria. Poor precision with GM detector-based instruments is due to a low sensitivity (i.e.,cpm/mR/h) of the detector, and can be improved by the selection of the detectors. Alpha survey instruments using air-proportional counters as detectors are sensitive to high humidity and to changes in atmospheric pressure. This may not be correctable, but other probes (e.g., scintillation) are available that are not as easily influenced by environmental differences. Most of the problems identified are design-related and can be corrected. For applications as safety-related instrumentation such changes should be incorporated in the instruments."

Table 1. Performance of Instruments Tested Against Draft ANSI N42.17A

Test	Number of Failures/Number Tested By Instrument Category			
	Ion Chamber	GM	Alpha	Neutron
General Characteristics				
Power (AC)	NT	0/4	NT	NA
Battery Lifetime	1/5	7/19	1/5	NT
Electronic & Mechanical				
Alarms (reset,drift)	NT	1/3	NT	NA
Stability	1/9	3/35	6/15	3/4
Geotropism	3/9	4/20	9/14	NT
Response Time	8/13	13/22	0/7	3/3
Radiation Response				
Accuracy	1/4	6/12	NT	NT
Precision	0/15	13/23	7/8	0/3
Photon Energy Dependence	4/14	18/23	NA	NA
Radiation Overloads	LNT	1/4	NT	NT
Angular Dependence	8/9	19/20	NA	0/2
Interfering Response				
Extracameral Response	NA	0/12	NT	NA
Radiofrequency Fields	1/8	2/16	0/5	0/5
Microwave Fields	4/5	3/7	2/3	NT
Electrostatic Fields	0/7	0/13	NT	NT
Magnetic Fields	0/6	0/13	NT	NT
Environmental Factors				
Temperature	9/17	0/22	10/13	0/3
Temperature Shock	1/3	0/2	3/5	NT
Humidity	1/7	4/18	10/15	NT
Shock	0/3	0/8	0/7	NT
Vibration	1/4	1/7	0/7	NT
Ambient Pressure	0/7	0/5	12/13	1/6

GM - Geiger Mueller
NT - Not Tested
NA - Not Applicable
LNT - Limited Number Tested

A general summary of data contained in Table 1 is presented in Table 2 below.

Table 2, Failure Rate of Instruments Tested Against Draft ANSI N42.17A

Instrument Category	Percent Failure for All Tests
Ion Chamber	30
GM	31
Alpha	51
Neutron	27

Data from Tables 1 and 2 indicate that an instrument failing one test area could still be adequate for use in other applications. A core set of tests required for a particular survey application was not identified. This statement could be made for a class of instruments; for example, Table 1 of this report shows that half of the GM instruments failed the accuracy test, 57 percent failed the precision test, 78 percent failed the test for photon energy dependence, and 95 percent failed the angular dependence test. In other words, if an instrument passed all tests but the angular dependence, the instrument should be adequate except in uses where angular dependence is important.

Inherent limitations such as these may make a particular type of instrument unsuitable for its intended use. For example, a GM instrument would not be suitable for use in a situation where radiations with a range of energies need to be measured accurately. A typical calibration with Cesium-137 gamma rays would probably result in an over-response (on the order of a factor of six) when radiations with energies near 100 keV are measured. Although energy compensation may be added to the instrument, that modification will reduce instrument sensitivity at low radiation energies and may cause significant over-response at photon energies high enough to cause pair-production interactions.

Another example of inherent limitations that may make an instrument unsuitable for a particular use is the relatively low sensitivity and slow response of the ionization-chamber type of instrument. It would not, for example, be suitable for use in scanning to detect narrow beams of radiation leaking from a source container or an enclosed x-ray machine. Its inherent sensitivity to radiofrequency radiation could lead to further unsuitability and inaccuracy if the measured source of ionizing radiation is located near a source of RF radiation.

2.3 Current Use of ANSI N42.17A by Instrument Manufacturers

During July 1992, nine manufacturers of portable survey instruments were contacted by telephone to determine the extent to which American National Standard N42.17A-1989 is used by them. The results of that telephone survey are summarized as follows and listed in Table 3. The coding of instruments as either A, B, or C is explained in Appendix A, Table A-2.

- Six manufacturers responded that they do not use the Standard.
- One manufacturer said, "The standard is used inhouse, but not formally." (The Standard is used informally for Class B and C instruments.)

- Two manufacturers stated that they use the Standard to produce Class A instruments.
- One of the manufacturers of Class A instruments responded that the Standard is used only during the production of its newer models.
- One manufacturer stated that the Standard is used to produce Class B instruments for one model only.

Table 3. Use of ANSI N42.17A-1989 by Manufacturers of Portable Survey Instruments

Question	Manufacturers' Responses		
Do you use ANSI N42.17A?	Yes	No	
	3	6	
If your response to the above question is "yes", to what Class do you manufacture instruments?	A	B	C
	2	1	0
If you use ANSI N42.17A, do you provide with the survey instrument a certificate of conformance to that Standard?	Yes	No	
	1*	1	

* Only when requested

2.4 Use of ANSI N42.17A by US NRC and Agreement-State Licensees

During the period of this study (July 1992 though February 1993), approximately 40 licenses issued by the NRC were examined in detail, and similar information was obtained from an equivalently-sized sample of licenses issued by Agreement States. A deliberate attempt was made to examine licenses for different types of radiation applications (broad-scope academic/research, radiography, well logging, medical, manufacturers/distributors, reactors, and nuclear fuel cycle). This sampling of slightly less than 100 licensees was felt to be adequately representative of the national population of licensees.

This examination of licenses showed no use of ANSI N42.17A by licensees. Nowhere in any of the license applications was there an indication that an instrument that met the requirements of that Standard would be used. Further, inspection reports do not identify whether or not instruments in use meet the requirements of that standard. It is reasonable to infer that licensees are not using the standard because there are no requirements to do so.

3 CALIBRATION

One of the purposes of this report was to determine to what extent accredited calibration laboratories are used by licensees. Accredited laboratories are those granted accreditation for the calibration of portable survey instruments under the three national programs described in this section. The common reference point for measurements made in the United States is the NIST, which has as its primary function "the custody, maintenance, and development of the national standards of measurement, and the provision of means and methods for making measurements consistent with those standards" (Congress 1950). In a practical sense, accuracy is determined by the degree of agreement between a measurement result and the national standard. Close agreement is interpreted as a high degree of accuracy and measurement quality. The "means and methods" that enable the achievement of accurate measurements are the supporting services provided by NIST. A basic limitation of this scheme is that there is only one NIST but there are tens of thousands of radiation measurers. It is physically impossible for NIST to provide support services directly to each member of the measurement community. This calibration system is described in more detail in Appendix B, National and Related Calibration Programs.

3.1 Calibration Performance Limitations

Information about calibration performance limitations is difficult to obtain. As a result, few users of survey-instrument calibration services have the ability to determine the quality of the service they obtained, and the accuracy of the measurement made with the survey instrument is, in most cases, undetermined. Following are summaries from two documents that report results of investigations of calibration accuracy.

The first is NUREG/CR-3775, Quality Assurance for Measurements of Ionizing Radiation (Eisenhower 1984). This document reported the results of studies of six models of commercial survey instruments used by NRC inspectors. One of these instruments was the Eberline Micro-R/h Meter Model PRM-7. Initial tests at the National Institute of Standards and Technology (then the National Bureau of Standards) with collimated cesium-137 gamma-ray beams resulted in significantly lower sensitivities (lower by 25 and 40%, respectively, for two instrument ranges) than those given by the manufacturer, who calibrated using a small 4-π cesium-137 gamma-ray source with a calibration traceable to NIST. After careful study, it was concluded that the discrepancy was caused by a considerable amount of low-energy scatter in the manufacturer's radiation field, to which this type of detector is particularly sensitive. As a result, the manufacturer adjusted the sensitivity control of the instrument (i.e., turned down the sensitivity) by more than would have been necessary, had the radiation field been that of a clean (low-scatter) cesium-137 gamma-ray source. Subsequent calibrations were done under low-scatter conditions and the sensitivity discrepancy was removed.

The second document that reports results of investigations of calibration accuracy is NUREG/CR-4511, Assessment of the Adequacy of the Calibrations Performed by Commercial Calibration Services for Ionizing Radiation Survey Instruments (Cooke et al 1986). Excerpts from that report follow:

- "The objective of this study -- to evaluate the adequacy of calibrations performed by a sample of commercial calibration services -- could only be partially accomplished because of limitations that were placed on the scope of the investigation. The data obtained were somewhat inconclusive regarding the necessity of an accreditation program. The investigation, as carried out, did not yield the data necessary to categorically support a recommendation to establish an accreditation program. The data supplied enough evidence to indicate that while no extreme deficiencies are apparent for the calibration services taken as a group, some improved service by the various commercial calibration services is in order."

- "Based upon the total data evaluation, the noted percent difference ranged from a few percent to hundreds of percent. The majority of the large variations were noted in the Phase I portion of this study. Much of this variation could be due to the use of multiple instrument types and models. Therefore, Phase II used a single ionization type survey instrument and the results ... indicate better instrument consistency, with resultant lower percent difference variability than observed in Phase I."

- "Though the majority of the services tested indicated acceptable performance within even the ±10% criteria, efforts should be directed toward the development of a survey instrument calibration measurement assurance program that could evaluate not only the radiation field intensity accuracies, but the overall instrument handling and calibration documentation procedures employed by the calibration services. The development of such a measurement assurance program would aid both the regulator and regulatee in the administration of ALARA radiation protection programs."

- "A review of the documentation provided by the calibrators indicated that not all calibrations were done in the same manner as discussed in the ANSI Standard [ANSI N323-1978, Radiation Protection Instrumentation Test and Calibration]. For example:

  Some of the calibrators used electronic pulsers for all but one point of a GM survey instrument calibration. The standard does not address pulser calibration, rather it refers to radiation field calibrations.

  Some calibrators did perform and document their calibration checks at the 20% and 80% settings of each range, while others used a midscale setting. Usually, it appeared that calibrators did not use the midscale region for calibration; rather they used the upper scale portion.

  Some calibrators used decade value points on logarithmic-scaled instruments for calibration but did not provide midpoint check values of each decade as recommended in the ANSI Standard.

  Some calibrators provided information on their field intensity errors, while others gave no indication as to their field intensity accuracy.

  Fifteen calibrators did not provide any information concerning their NBS source accuracy traceability.

  Most calibrators provided no information concerning atmospheric conditions that existed when open air ionization type instruments were calibrated.

  Some calibrators did not seem to correct (no document to verify any corrections) for source-to-detector geometry. One service calibrated a Panoramic 470A at 17 cm from the radiation source. This could easily lead to calibration errors with only a small error in measurement. Additionally, this calibrator did not supply any information as to which points were chosen for measuring the 17 cm from detector to the irradiation source."

3.2 NRC Operations

This section addresses current NRC policies and procedures as observed in current operations.

3.2.1 Guidance for Licensees

Although 10 CFR 20 establishes a requirement for the use of calibrated survey instruments, the NRC has not issued guidance as to what constitutes acceptable calibration or satisfactory instrument performance. Several other Parts of 10 CFR address instrument performance and calibration in limited, varying ways. In 1984, a draft Regulatory Guide and Value/Impact Statement titled "Test and Calibration of Radiation Protection Instrumentation" was issued for comment, but it was not published in final form.

The "Standard Review Plan for License Applications for the Use of Radioactive Materials in Calibrating Radiation Survey and Monitoring Instruments", which was issued in May 1985 by the NRC Office of Nuclear Material Safety and Safeguards, makes a limited attempt to address the quality of the calibration.

3.2.2 License Application Review and Licensee Inspection

As mentioned earlier in this report, approximately 40 licenses issued by the NRC were examined in detail during the course of this study. None of the licensees used the services of an accredited calibration laboratory. These laboratories may also perform instrument repairs and occasionally use non-standard components that can affect both the proper operation and the calibration. One repair and calibration facility reported that the worst maintenance problems are seen in instruments from end users that perform their own calibration.

Although the main purpose of those examinations was to determine the roles of accredited calibration laboratories and instruments that meet the performance requirements of ANSI N42.17A, other relevant observations were also made.

- Limited guidance is available regarding calibration criteria for the license reviewer and the inspector.

- Many licenses do not contain detailed information on the types of instruments used, source and method of calibration, traceability, type of radiation measured by each instrument, its sensitivity, and its intended use. (One license application contained no description of the model or type of survey instrument to be used, and no information about the source or method of calibrations.)

A report, "Proposed Method for Regulating Major Materials Licensees", prepared by the Materials Regulatory Review Task Force, which was appointed by the Director, Office of Nuclear Material Safety and Safeguards, contains conclusions regarding the current licensing process for fuel cycle and large materials plants. These conclusions indicate in part that lack of uniformity and consistency in licensing and inspection is caused by (1) inadequate staff expertise and training, and (2) a lack of standard review guidance (NUREG-1324). This report and these findings in particular support a need for guidance in instrument performance and calibration.

Since it is perhaps unreasonable to expect all license reviewers and inspectors to be experts on radiation instrumentation, use, and calibration, adequate guidance is sorely needed. Although it was not within the scope of the present study to assess the availability and usefulness of existing guidance, cursory observations indicated deficiencies. The conclusions reached by the Materials Regulatory Review Task Force, as summarized above, are consistent with the observations made during the present study.

3.2.3 Calibration of Inspectors' Instruments

Effective and equitable enforcement of regulations requires measurements that are reliable, uniform, and sufficiently accurate. Uniformity of measurement results is of primary importance for conformity between the regulator and regulatee. A way to achieve adequate accuracy and uniformity is for both the regulator and regulatee to make measurements in terms of and consistent with the national physical measurement standards maintained by NIST. Appendix B describes examples of measurement quality assurance programs recommended to assure and demonstrate the necessary degree of consistency.

At the request of the NRC, a program was developed by NIST in 1984 to assure the accuracy of routine survey measurements made by NRC inspectors (Eisenhower 1984). The program was based on MQA interactions between NIST and those laboratories that calibrate the radiation survey instruments used by NRC inspectors. These MQA interactions are identical to those interactions employed now in the three laboratory accreditation programs described in Appendix B of this report. Of those current programs, those administered by the Health Physics Society and by NVLAP are available to accredit laboratories used by the NRC to calibrate inspectors' survey instruments.

4 FINDINGS AND RECOMMENDED OPTIONS FOR IMPROVEMENT

4.1 Findings

4.1.1 Manufacturing and Performance

- Records spanning the past ten years indicate a limited number of documented overexposures of individuals which were caused by poor instrument performance. Six cases are identified in this study; three could have probably been prevented had proper operating procedures been followed.

- Documented instances of poor instrument performance exist and were further supported by anecdotal accounts. Only a few instruments have been tested for performance against the Draft ANSI N42.17A. The performance of those tested was generally very poor (Tables 1 and 2), e.g., for the GM category, half failed the accuracy test, 57 percent failed the precision test, 78 percent failed the test for photon energy dependence, and 95 percent failed the angular dependence test.
  As discussed in Section 2.2, even with these results an instrument failing one test area could still be adequate for use in other applications. A core set of tests required for a particular survey application was not established.

- The licensing system does not prevent the purchase and use of a poorly designed or poorly functioning survey instrument. Licensees are not required to purchase and use instruments that conform to ANSI N42.17A, and therefore do not. There is almost no use of the Standard by NRC or Agreement State licensees at this time, and also there is very limited use by survey instrument manufacturers. Three manufacturers are reportedly making use of the Standard in the design of new instruments.

4.1.2 Calibration

- There is no conclusive evidence that survey-instrument calibration services are, or are not, providing calibrations with adequate accuracy. No documented incidents were found where excessive exposure or overexposure of an individual was caused by poor instrument performance due to improper or inadequate calibration. Since very few of the laboratories that provide these services are accredited, the quality of their calibrations remains undemonstrated. The study referenced in Section 3 of this report confirms the deficiency of documentation with respect to calibration services.

- The licensing system does not prevent poor calibration services from being introduced into the market and used by licensees. There are no definitive guidelines to license reviewers, inspectors, and licensees regarding requirements for instrumentation, calibration, and measurement quality. Licensees are not required to use accredited calibration laboratories, and therefore do not, as an examination of a sample of NRC licenses showed. Similarly, an examination of Agreement State licenses showed that only a small number use an accredited calibration laboratory.

4.2 Recommended Options for Improvement

When considering recommendations regarding portable survey instruments, it is useful to compare with the situation that existed in the mid-1970s regarding personal monitoring, and the actions subsequently taken. At that time, there was substantial uncertainty about the quality of data obtained from personal dosimeters. A wide range of test measurement results raised serious doubts about the reliability of the reported data. The radiation protection community in the absence of a performance standard was looking to the NRC for guidance. Through a concerted effort over a ten-year period, a suitable standard was prepared and a successful national program was developed. Because use of that program was made mandatory for NRC licensees, the uncertainty about quality of data was removed.

The quality of data regarding survey instruments parallels that of personal monitoring in the 1970s. Limited tests have shown problems with instrument performance, and some doubts exist about the reliability of instrument readings. Again, the radiation protection community is looking to the NRC for guidance. In this case the standards and mechanisms needed to implement a national program already exist although training will be required as documented by NUREG-1324.

As stated in Section 4.1 of this study, the limited testing of instruments has shown poor results, e.g., half failed the accuracy test for the GM category. There is also evidence of some overexposures which were not anecdotal. However, the findings of this study do not appear to support actions as strong as those taken in the case of personal dosimetry. However, these findings do appear to support less stringent actions that the NRC should take at this time to reduce the present uncertainty about the quality of measurements made with portable survey instruments. Although this uncertainty has existed for many years and actions to reduce it could possibly have been taken in the past, the lack of suitable standards and mechanisms would have made effective implementation of those actions difficult. The recent development of standards such as ANSI N42.17A and programs for the accreditation of calibration laboratories have, however, made possible the effective implementation of the following recommended actions.

Several optional actions that the NRC could consider taking in this area are identified and discussed below. Although the topics of instrument performance and instrument calibration are highly related and, in some respects, are difficult to separate, some distinction can be made.

4.2.1 Instrument Performance

Use of the ANSI N42.17A Standard was discussed at the Workshop on Measurement Quality Assurance for Ionizing Radiation in March 1993. During that discussion, it became evident that manufacturers are unlikely to implement the Standard until required to do so by their customers, and that their customers (i.e., NRC licensees) will not require implementation until the NRC takes action that would encourage use of the Standard. Ideally, industry standards such as ANSI N42.17A are developed and implemented voluntarily. This would occur if purchasers of instruments cited conformance with its requirements as a condition of purchase, or if a manufacturer felt it advantageous to offer instruments that conform to those requirements. Without encouragement by the NRC, neither of these voluntary actions seem likely to occur because of the cost.

The cost for type-testing and certification for all of the performance characteristics identified in ANSI N42.17A are detailed and explained in Appendix C, Impact and Instrument Testing Costs. The instrument testing costs associated with implementation of a national instrument performance program is considered a major deterrent to implementation. Further, the high cost of testing for all performance characteristics may not be warranted for all applications. Many licensees would be required to pay for performance characteristics that are not pertinent for their particular application. Small volume manufacturers would be at an economic disadvantage because the type-testing cost would have to be recovered as an add-on for a relatively small number of instruments.

The NRC could encourage use of the standard by providing appropriate guidance in a Regulatory Guide which would describe how to select instruments for performing surveying and monitoring required by the regulations, and at least in part, endorse the standard. The following two options are presented as a means to promote the use of reliable instruments by licensees.

- The NRC could provide guidance for selection of an instrument that has been individually tested and certified for a limited, basic (core) set of characteristics selected from the many identified in ANSI N42.17A. In addition, that model instrument could be type-tested and certified for those characteristics felt by the NRC to be pertinent for a particular application, e.g., use in radiography. The core characteristics would be pertinent for <u>all</u> applications, and might include accuracy, precision, overload, and response time, for example. (The exact content of this basic set could be determined as a cooperative effort by the NRC with manufacturers and users.) Implementing this guidance would be much less costly than for full testing, and would not require licensees to pay for performance characteristics not required by their application.

- The NRC could provide guidance for selection of an instrument that has been individually tested and certified for a limited, basic (core) set of characteristics selected from the many identified in ANSI N42.17A. No additional test and certification would be recommended regardless of instrument application. This option would have almost no associated cost, because most instrument manufacturers already perform tests comparable to those that would be required for the core characteristics. The major disadvantage would be that for economics or other reasons, a licensee might use an instrument that would perform inadequately for the additional characteristics needed for a particular application.

4.2.2 Calibration

Under the current practice, only very general requirements for instrument calibration are stated in 10 CFR 20, with little regulatory guidance on how those requirements are to be implemented. This leads to a range of interpretations and non-uniform implementation. Some specific requirements are provided in Parts of 10 CFR (e.g., Part 35), but these are limited in scope. A fragmented approach of this type may lead to inconsistencies among the various Parts and increased confusion. It is acknowledged, however, that one of the findings of this study is that there is no documented incident where overexposure of an individual was caused by inadequate instrument calibration.

More definitive comprehensive guidance may help avoid confusion and questionable survey results. Such definitive guidance could include, for example, a clear statement of the calibration technique important for the use of that instrument in a particular type of licensed activity. That same guidance could be used by the license application reviewer, the NRC inspector, and the licensee who purchases the instrument.

The NRC could present appropriate guidance in a Regulatory Guide which would describe how to perform and document calibration and how to select calibration services to demonstrate compliance with the regulatory requirements. This option may encourage use of the existing national mechanism for laboratory accreditation. A listing of accredited calibration laboratories could be provided to licensees. Implementation of this option may reduce the uncertainty that presently exists regarding the quality of calibration services, and it would correct the deficiency in the documentation provided by some calibration services.

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Appendix A

PERFORMANCE SPECIFICATIONS FOR PORTABLE RADIATION SURVEY INSTRUMENTS

Adequate performance of survey instruments is a continuing concern in the radiation protection community. That concern led to the development and publication, in 1989, of American National Standard N42.17A, Performance Specifications for Health Physics Instrumentation--Portable Instrumentation for Use in Normal Environmental Conditions. Essential instrument performance characteristics are identified in this standard. The scope is stated as follows:

"This standard establishes minimum acceptable performance criteria for health physics instrumentation for use in ionizing radiation fields. Included are testing methods to establish the acceptability of each type of instrumentation. This standard does not specify which instruments or systems are required, nor does it consider the number of specific applications of such instruments."

The introduction expands on the scope somewhat by stating that in this standard, health physics instrumentation provides direct readout and includes "portable rate and integrating devices for beta, photon, and neutron radiations and monitors for surface contamination. Personnel dosimeters, instruments designed to be used as individual or personal monitors or warning devices, environmental monitoring instruments, and air monitors are outside the scope of this standard." The standard does not include performance under extreme conditions of use.

The instrument performance characteristics for which requirements are established in the N42.17A standard are listed in Table A.1. They are grouped into the following categories:

- General Characteristics
- Electronic and Mechanical
- Radiation Response
- Interfering Responses
- Environmental Factors

Many of the general characteristics are design features that are not subject to quantification. Their presence (or absence) is confirmed by inspection, and no test or measurement is required. For all the other categories of characteristics, tests based on measurements are required. A specific test is prescribed for each instrument characteristic of interest. When that particular test is conducted, all other conditions that affect instrument performance must remain constant and must be within an acceptable range.

The N42.17A standard also establishes classes of instruments, whose requirements are as summarized in Table A.2.

Table A.1 Instrument Performance Characteristics Considered in the N42.17A Standard

General Characteristics Units of Readout Scaling Factors Ease of Decontamination Moisture Protection Alarm Threshold Markings Battery Status Indication Protection of Switches Zero Set AC Power Battery Power Battery Power Indicator AC-Powered Instruments with Battery Backup	**Radiation Response** Accuracy Probe Surface Sensitivity Photon Energy Dependence Beta Energy Dependence Neutron Energy Dependence Photon Radiation Overload Angular Dependence **Interfering Responses** Extracameral Response Radiofrequency Fields Microwave Fields Electric Fields Magnetic Fields Interfering Ionizing Radiations
Electronic and Mechanical Check Circuits Alarms Stability Geotropism Response Time Coefficient of Variation Line Noise Susceptibility	**Environmental Factors** Temperature Temperature Shock Humidity Mechanical Shock Vibration Ambient Pressure Splashproof

Table A.2. Requirements for the Classes of Instruments Specified in ANSI N42.17A

Class	Requirement
A	Instruments shall meet all of the applicable requirements listed in the standard.
B	Instruments shall meet all the applicable requirements specified below, and such others as the manufacturer shall so designate and the purchaser specify: General Characteristics (all) Electronic and Mechanical (all) Radiation Response (all) Extracameral Response Temperature Temperature Shock Humidity
C	Instruments shall meet requirements as specified by the purchaser or the user group and shall be tested in accordance with the guidance in the standard.

Appendix B

NATIONAL AND RELATED CALIBRATION PROGRAMS

● The National System

The national system for accreditation of secondary laboratories that calibrate survey instruments was completed in 1991. Ten years earlier, in 1981, the National Institute of Standards and Technology (then called the National Bureau of Standards), after broad concurrence from the radiation measurement community, published the results of a study which showed that secondary laboratories were needed in three distinct sectors -- state, private, and federal (NBS 1981). Expressed reasons for maintaining this sector distinction included: (1) the system had already developed along those lines; (2) regulatory relationships; and (3) the desire to avoid possible conflicts of interest. It was felt, for example, to be inappropriate for a regulatory agency to have its instruments calibrated by a licensee who would then be inspected with those same instruments. Some members of the measurement community felt that only a program developed by a particular sector would be sufficiently responsive and effective in satisfying the specific needs of that sector. In response to such concerns, three programs were developed that now constitute the national system. The state-sector program is operated by the Conference of Radiation Control Program Directors (CRCPD), the program aimed at the private sector is operated by the Health Physics Society (HPS), and the National Voluntary Laboratory Accreditation Program (NVLAP) operates the program developed by and for the federal sector.

Although the programs were developed and are operated in three distinct sectors, they have in common the four basic elements considered to be essential for measurement quality assurance (MQA) in a secondary laboratory: (1) documented performance criteria that must be met; (2) periodic proficiency testing of the secondary laboratory by NIST; (3) documented quality assurance procedures that are routinely followed; and (4) documented procedures used to provide services to customers. Further commonality exists because each program was developed in close cooperation with, and with guidance from, the NIST Office of Radiation Measurement.

The three programs also use the same procedures for evaluation of candidate laboratories. Sequential steps in that process include: submittal of an application with supporting information; review of the laboratory procedures manual (also called the quality manual); proficiency test by NIST; on-site assessment by peer assessors; resolution of deficiencies (if any); and final review and decision. Thus, the three programs are similar because each is based on the four essential MQA elements and uses the same evaluation procedures. There are, however, differences in the scope covered by each program.

The state-sector program is administered by the Radiation Measurements Committee of the CRCPD, and only state-owned calibration laboratories are considered for accreditation. At this time, the scope includes x and gamma radiation used to calibrate survey instruments and those instruments suitable for measurement of medical diagnostic beams. Four laboratories have been accredited since the program began in 1984 (Illinois, Washington, South Carolina, and California). Operational costs are low because volunteer committee labor is used, and minimal financial support was provided by NIST through a Cooperative Agreement.

The program developed by the Health Physics Society (HPS) became operational in 1987. It is aimed at the private sector but is available to any laboratory that calibrates portable instruments used for radiation protection. Two HPS committees administer the program, assisted by a part-time technical director and a headquarters staff person. The scope is presently limited to the use of x and gamma radiation for survey instrument calibration, but expansion to include neutrons and beta particles is in process. This is the only program that has criteria for accreditation of tertiary, as well as the usual secondary, calibration laboratories. In the case of a tertiary laboratory, its proficiency is tested by an accredited secondary laboratory. The approximate accreditation fee for a secondary laboratory is $5,000, and the corresponding fee at the tertiary level is about $3,000. These fees provide a three-year accreditation, and cover HPS operational costs for the program. The cost of the annual proficiency test of the secondary or tertiary laboratory is not included in these fees. Two private-sector secondary laboratories have been accredited, and more are currently under evaluation.

The NVLAP-administered program uses performance criteria developed by representatives of 19 federally-owned laboratories that are potential applicants for accreditation. This program is available to any laboratory that can demonstrate conformance with the criteria. Included in the relatively broad scope are:

- Calibration of survey instruments using gamma, x, beta, neutron, and alpha-particle radiation;
- Irradiation of personnel dosimeters using gamma, x, neutron, and beta-particle radiation;
- Calibration of gamma-ray sources in terms of exposure (air kerma) rate at one meter;
- Calibration of instruments for medical diagnostics using x rays; and
- Calibration of reference-class instruments using gamma and x radiation.

NVLAP must recover all program operational costs through fees charged to applicant laboratories. The estimated fee for initial accreditation of a laboratory is $16,000, and the annual renewal fee is expected to be a few thousand dollars less. These fees do not include the cost of the annual proficiency test by NIST. Since the program was announced in March 1991, one laboratory has been accredited. Additional laboratories have submitted applications and are currently being evaluated.

A calibration laboratory that has been accredited under any of these three programs has demonstrated a high level of competence, which has formally been acknowledged. Customers who use the accredited services of such laboratories are making the most meaningful link to the national physical measurement standards maintained by NIST. The periodic (usually annual) proficiency testing of accredited secondary laboratories by NIST and, as in the HPS program, testing of tertiary laboratories by secondary laboratories, provides the strongest possible form of what is commonly called "traceability". That, along with the required routine quality control procedures, provides reasonable assurance that high-quality performance is consistently available from an accredited laboratory.

An essential feature of each program is the use of performance (proficiency) tests to demonstrate a satisfactory level of agreement with NIST. This performance testing mechanism is preferred over the calibration mechanism because it extends to the measurement itself, instead of ending with an instrument or radioactive source. Satisfactory measurement performance when tested is an indication that not only is the instrument or source properly calibrated, but that it is also being used properly.

A long-range goal for the radiation measurement community is the development of a sufficient number of national programs that extend the proficiency-testing mechanism to the field-level measurements made routinely for radiation protection. The first step is development of a system of secondary laboratories that will have their proficiency tested periodically by NIST. Steady progress has been made, and the secondary-laboratory system is actively being developed. When this first step has been completed, more effort can be directed toward the second step, which is demonstrated agreement between the secondary laboratories and field-level measurers.

Secondary laboratories can provide essential services to laboratories or radiation measurers at lower levels in the measurement hierarchy. Those services include calibrations, the testing of measurement proficiency, and survey instrument performance testing.

● Related Programs

When considering the possible actions that might be taken regarding implementation of programs on instrument performance testing and calibration, it is useful to examine past actions taken by the Nuclear Regulatory Commission (NRC) to implement other programs that have similar objectives.

In 1972 the American Association of Physicists in Medicine (AAPM) began accrediting laboratories that calibrate instruments used to characterize radiation beams used for therapy. Five laboratories are now accredited to operate in accordance with criteria developed by the AAPM in cooperation with NIST. For this program, the incentive provided by regulations was added. Beginning in 1979, the NRC required through 10 CFR Part 35 that AAPM-accredited laboratories or NIST be used to calibrate dosimetry systems that are, in turn, used to calibrate teletherapy units. That requirement was retained when 10 CFR Part 35 was revised effective April 1987, and remains in effect at this time.

A second example of action taken by the NRC to implement a national measurement quality assurance program exists in the area of personnel dosimetry. The reasons for development of this MQA program, and the history of actions taken during its development, are documented elsewhere (Gladhill, Horlick, and Eisenhower 1986; and 10 CFR Part 20). Program development began in response to a recommendation made by the Conference of Radiation Control Program Directors in 1973 which resulted from a concern that "...users of personnel dosimetry devices have little assurance that the reported dose assessments are reliable" (DHEW 1973). Earlier attempts to establish a suitable program were unsuccessful because consensus standards available at the time addressed only the performance of the dosimeter and not the equally important issue of the performance of dosimetry processors. By 1983, a document was prepared that established performance criteria suitable for use in a national testing program (ANSI 1983). General guidance and policy were provided by an interagency committee chaired by NIST, and the NRC and U.S. Food and Drug Administration provided critical financial support. In 1982 the NRC formally requested that the National Voluntary Laboratory Accreditation Program (NVLAP) develop an accreditation program for dosimetry processors. That program became operational in January 1984. On February 12, 1988, an amendment to 10 CFR Part 20 became effective that requires NRC licensees to use only personnel dosimeters that are processed by a NVLAP-accredited dosimetry processor.

Appendix C

INSTRUMENT TESTING COSTS

● Impact in Terms of Cost

Merwin, Swinth, and Herrington (1986) examines the impact of instrument performance limitations in terms of cost. That cost is then combined with the cost to instrument manufacturers to determine total costs against which the benefits of implementation of ANSI N42.17A are balanced.

Although it is beyond the scope of this study to consider cost/benefit ratios, the various factors that must be considered to determine costs are of interest. They are identified and described by Merwin, Swinth, and Herrington as:

- Serious overexposures
- Other exposures
- Other incidents
- Miscellaneous costs
- Litigation

"Serious overexposures" include those that exceed applicable annual or quarterly limits specified in 10 CFR 20. It is estimated that 1.2 incidents of this type occurred to NRC licensees annually from 1977 to 1983 due to poor instrument performance or lack of confidence in instrument performance. This number is estimated to be 80% higher if Agreement State licensees are included.

"Other exposures" are those that do not exceed limits specified in 10 CFR 20, and therefore need not be reported to regulatory agencies. As a result, they are not well documented and their impact is difficult to estimate.

"Other incidents" are events that are caused by poor performance of radiation survey instruments but do not involve radiation dose to workers.

"Miscellaneous costs" result from modifications of procedures or instruments due to the inadequacies of present survey instruments. The literature contains numerous descriptions of such problems (Selby et al 1985), which include the added maintenance and inventory of instruments required to ensure an adequate supply of survey instruments to satisfy the many needs of the user.

"Litigation" refers to the costs incurred by claims based on poor instrument performance. Present costs of such litigation are low because attorneys have limited knowledge of issues relating to instrument performance, but their awareness of those issues is likely to increase in the future.

Instrument Testing Costs

Merwin, Swinth, and Herrington (1986), in order to determine benefit/cost ratios for various possible methods of program implementation, calculated the benefits by determining the fraction of those identified costs that would be saved by the implementation of a performance testing program. In effect, the benefits were assumed to be the elimination of approximately 80% of the costs incurred by the lack of a program.

The instrument testing costs that would be associated with implementation of a national instrument performance testing program have been the major deterrent to implementation. Those estimated costs, in 1986 dollars, are summarized in Table C.1 (Merwin, Swinth, and Herrington 1986). They are based on experience gained from the extensive testing program conducted by the Battelle Pacific Northwest Laboratory (PNL) over a period of ten years.

The costs shown in Table C.1 are those for conducting a type test of a particular model of instrument. ANSI N42.17A requires a type test on five instruments from the initial production run. (It is estimated that testing only one instrument would reduce the cost from $21,750 to $12,500.)

Testing costs for the characteristics grouped under Interfering Responses and Environmental Factors are shown individually because these are most likely to be considered as being optional. Total costs for a type test of a Class B instrument, for example, would be approximately $17,445, as compared with $21,750 for a Class A instrument.

Table C.1. Estimated Costs of Instrument Type Testing in Accordance with ANSI N42.17A (Merwin, Swinth, and Herrington 1986)

Performance Characteristic	Testing Cost ($)
General Characteristics (all)	950
Electronic and Mechanical (all)	2800
Radiation Response (all)	3800
Interfering Responses	
Extracameral Response	625
Radiofrequency Fields	300
Microwave Fields	350
Electrostatic Fields	300
Magnetic Fields	300
Interfering Radiations	625
Subtotal	2500
Environmental Factors	
Temperature	1730
Temperature Shock	870
Humidity	1170
Mechanical Shock	620
Vibration	1000
Ambient Pressure	500
Splashproof	310
Subtotal	6200
Total for Performance Characteristic Tests	16,250
Administrative and Report Costs	3000
Test Equipment Charges	2500
GRAND TOTAL	21,750

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11. ABSTRACT *(200 words or less)*

This report examines alleged and documented deficiencies in the performance and the calibration of existing portable radiation survey instruments. This report also examines a limited number of reported overexposures and excessive exposures attributed to instrumentation or calibration problems. The high failure rates in performance testing of a limited number of instruments indicate further testing is needed to demonstrate which instruments are acceptable and for what application. Further, the adequacy of calibration is not demonstrated at this time as many calibrations are performed by non-accredited calibration laboratories. A review of the regulatory requirements and practices of the NRC and Agreement States regarding the use of existing performance standards such as ANSI N42-17A-1988 and the use of accredited calibration laboratories demonstrates that (1) the regulatory programs do not require compliance with existing industry standards; and (2) instruments are generally not required to be calibrated by accredited laboratories. Options are recommended that might encourage the use of industry performance standards and calibration techniques.

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