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## Calibration Interval Technical Basis Document

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**CALIBRATION INTERVAL TECHNICAL BASIS DOCUMENT**

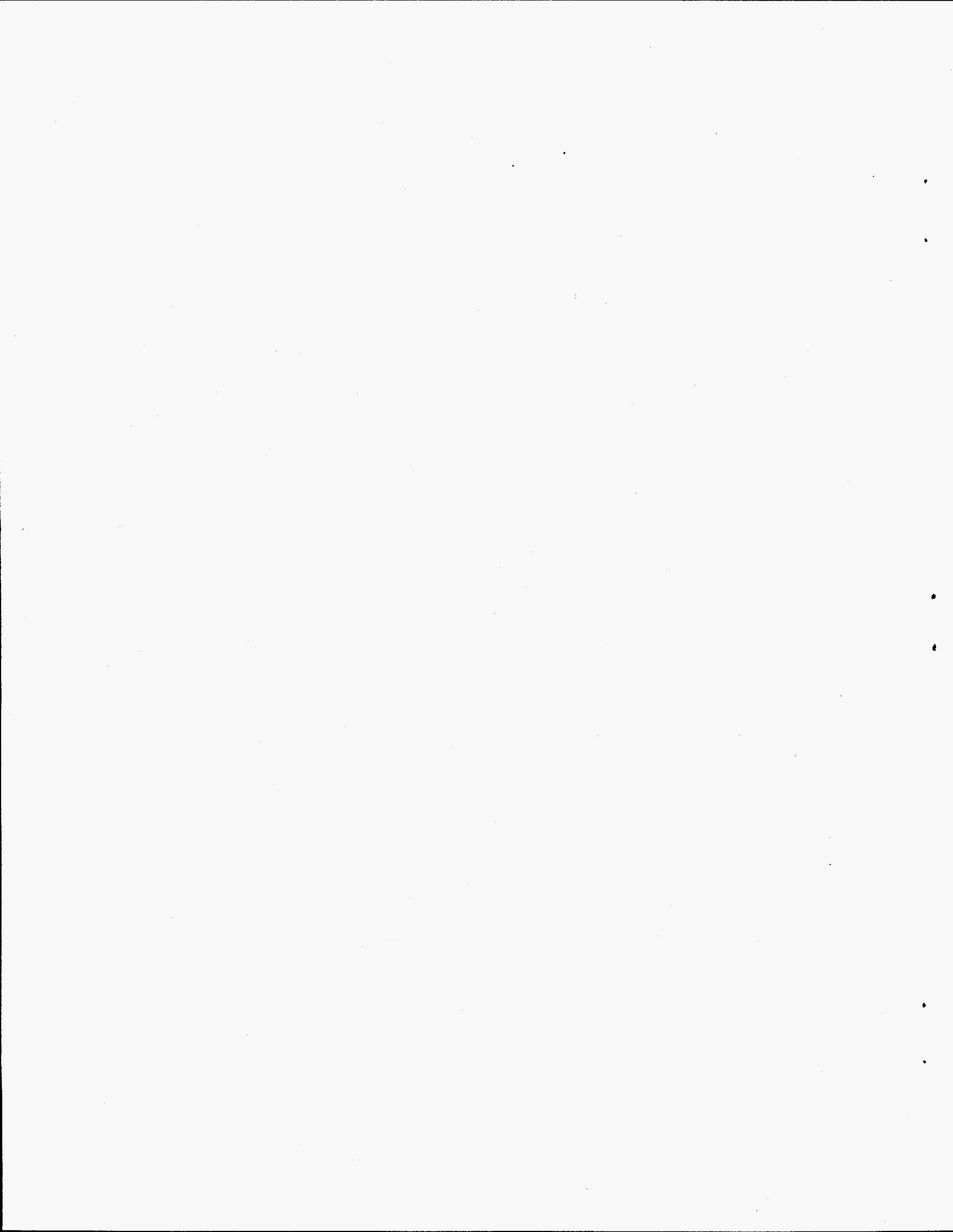
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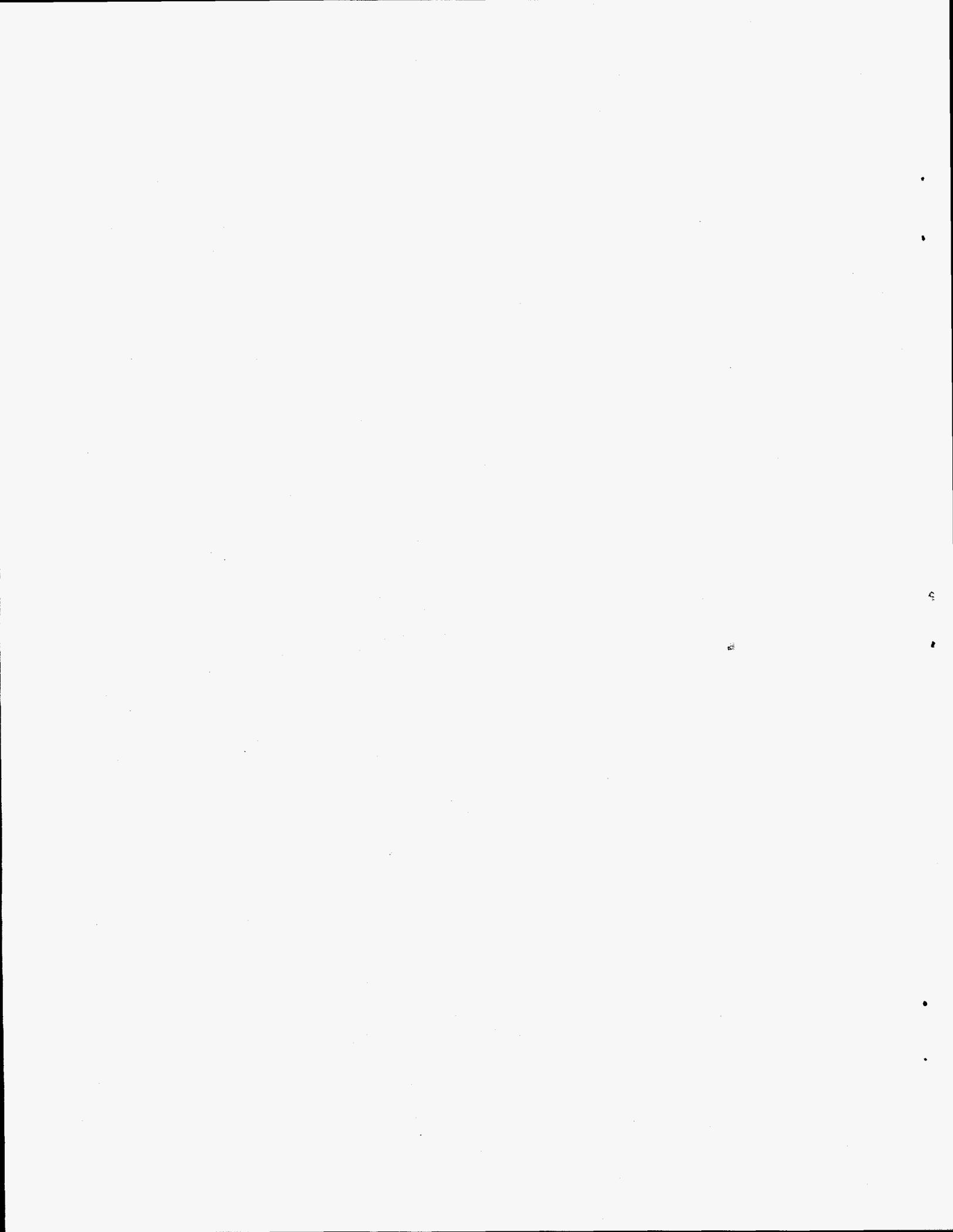
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## PREFACE

The following document provides a technical basis for the determination and control of calibration intervals for radiation protection instruments used at U.S. Department of Energy facilities. The Appendix contains an implementation guide statement for instruments and equipment used for radiation protection purposes.



## 1. PURPOSE AND APPLICABILITY

This document provides a method for the establishment and evaluation of calibration intervals for radiation protection instrumentation. This document is applicable to instrumentation used by personnel at U.S. Department of Energy (DOE) facilities for the measurement of radioactive contamination and the measurement and monitoring of radiation fields for protection of personnel and the environment. Special calibrations are not addressed by this document and should be handled separately.

## 2. BACKGROUND

Many standards exist today that address radiation instrumentation. These standards have been and continue to be used by organizations and programs across the DOE complex to establish a required calibration interval (time between calibrations) for radiation protection instrumentation. The most commonly referenced standard is American National Standards Institute (ANSI) N323-1978. This standard is used as the basis for *Title 10, Code of Federal Regulations, Part 835.401(c)(1)* [10 CFR 835.401(c)(1)], which states that "Instruments used for monitoring and contamination control shall be: Periodically maintained and calibrated on an established frequency of at least once per year."

Unfortunately, most standards are based on outdated technology. This is especially true regarding nondetector circuitry. Most instruments are now manufactured with more stable components and microprocessors, and some include self-diagnostic routines that can alert the user of fault conditions. These improvements have contributed to better overall instrument reliability.

Before these changes, instruments often required adjustment during scheduled calibrations because of out-of-tolerance responses obtained during the calibration or routine field check. Because of the incorporation of more stable circuitry, adjustments during routine calibrations are much less frequent, with most instruments being adjusted because the calibrator wants to make adjustments or as a result of certain types of repairs.

In addition to circuitry improvements, tests are now often performed that help identify weaknesses in an instrument's design. This action has encouraged instrument manufacturers to make design changes that have improved the overall reliability of some instruments.

Finally, and most important, routine performance checks are required before an instrument is used. These checks alone, when done properly, ensure that an instrument is operating correctly.

### 3. "REQUIRED CALIBRATION INTERVAL"

The purpose of this document is to recommend a process to permit extension of required calibration intervals while ensuring that instrument operational quality remains acceptable.

To accomplish this, the following items should be in place.

- An instrument policy
- Routine operational checks
- Operational history
- Documentation

#### 3.1 POLICY

As stated in Sect. 2, instrument stability has improved with the incorporation of modern components. Adjustments have become the exception, not the rule. Field failures, typically found during the performance of routine preoperational checks or through an instrument's automated self-check protocol, are typically caused by malfunctioning detectors or detector circuitry, rather than meter or control circuitry. These field failures usually have nothing to do with the calibration stability of an instrument. For an instrument program to be of necessary and sufficient quality, a policy should be established regarding how radiation protection instruments are controlled. This policy should address the following as a minimum.

- **Instrument Approval**—Instruments should be approved for use by a site-specific governing body. The body's decision should be based on information obtained from prepurchase or trial use testing, other users, and the manufacturer.
- **Ownership**—The organization that owns the instrument should not set the policy regarding calibrations. Policy should be established by the site radiation protection program.
- **Responsibilities**—The instrument policy should establish who is responsible for performing routine preoperational checks, calibration, and maintenance and for handling and storing all paper or electronic records. Most of these responsibilities typically belong to the users for portable instruments or to the facility for installed instruments.

## 3.2 ROUTINE OPERATIONAL CHECKS

To ensure that an instrument operates properly, periodic checks shall be performed. These checks ensure that the calibration has not drifted substantially and that the unit is functioning properly. They can be done manually by exposing an instrument in a reproducible geometry to a source of radiation or by the instrument's self-check protocol.

Routine operational checks can be divided into two types: preoperational and response verifications. Preoperational checks are typically used to ensure that an instrument operates correctly and are required either daily or before each use. Response verifications are performed periodically and are typically executed to tighter tolerances than preoperational checks. Response verifications should use sources that are traceable to the National Institute of Standards and Technology (NIST), whereas this level of source control is not required for preoperational checks.

Self-checking instruments typically use background radiation as the source. This type of instrument commonly uses an average background value to establish an acceptance range. At each check interval, the instrument verifies that the current response is within an acceptance range.

To use either preoperational checks or response verifications as a means to justify an extended calibration interval, the following guidance should be used.

### 3.2.1 Manually Performed Checks

#### Reference Readings

Acceptance ranges must be based on sets of readings obtained from a group of the same model instrument, or instrument by instrument. Readings must be obtained when an instrument is delivered to the field and should be based on what is necessary and sufficient for the facility. This means that if an instrument is not operated using a certain range or scale, it should not be necessary to response check that range or scale.

Individual readings are obtained by exposing the instrument to a radiation field in a reproducible geometry. An average reading is then derived. The acceptance range is then established using the following guidance.

1. **Response verification**— $\pm 10\%$  of the full decade value (neutron dose-equivalent instruments shall be  $\pm 30\%$  for ranges  $\leq 10$  mrem/h and  $\pm 20\%$  for ranges  $> 10$  mrem/h).
2. **Preoperational check**— $\pm 20\%$  of the average reading.

If preoperational checks are performed to the values stated in step 1, routine response verifications should not be necessary.

### **3.2.2 Automatically Performed Checks**

As stated previously, instruments that have self-check capabilities will commonly use ambient background as the reference source. The self-check routine typically compares the current reading with a previously determined average reading to ensure that no substantial changes have occurred. As a minimum, an acceptable protocol should include automatic indication of low or high count failure.

Also, the protocol should be evaluated by appropriate site personnel to ensure that it is equivalent to the manually performed preoperational checks. If it is determined that the protocol is necessary and sufficient to ensure that the instrument is reliable, no additional manual checks are required. If the protocol is not acceptable, checks should be performed using the guidance stated for manual checking.

### **3.3 OPERATIONAL HISTORY**

How an instrument model operates during field use and its reliability and stability are important factors in determining whether routine calibrations are required. Justification for any interval should be part of the technical basis of the instrument. This technical basis does not necessarily have to be developed in-house. Many other DOE facilities use similar instruments, and through the Internet and focused user groups, information sharing has become common. All information should be evaluated for quality and appropriateness before incorporation into the technical basis. A recommended method for establishing reliability and ensuring stability follows.

#### **Establishing Reliability**

Reliability and stability evaluations should be performed periodically for each instrument model unless the instrument uses an acceptable automated self-checking routine. Manual evaluations can be done by reviewing routine preoperational check results, or by using an appropriate database program that tracks the number of actual out-of-tolerance results.

Anytime an instrument fails a preoperational check, it is critical to determine the cause of the failure, such as electronic drift or a bad detector. A bad or broken detector would not typically be an indicator of an unstable instrument model that would require routine calibrations. The following steps describe a method that can be used to perform a field reliability and stability evaluation.

1. Determine and record the total number of instruments checked during the previous calendar quarter for each instrument model ( $Q_c$ ).
2. Determine and record the number of instruments that were not operational when checked because of a broken or bad component ( $Q_b$ ).

3. Determine and record the total number that failed the preoperational check ( $Q_f$ ).
4. Calculate and record the failure rate of checked instruments (F) for each model by

$$F = \frac{Q_f}{Q_c - Q_b} \times 100.$$

#### NOTE

Limits stated in the following steps are recommended values. Other values may be used as deemed necessary by a specific facility

5. If F is  $\geq 15\%$ , the instrument model should be evaluated further. The evaluation should look into source geometry reproducibility, weak electronic components, an unstable detector, etc. If the evaluation indicates the need for routine service, the initial interval should be based on the evaluation interval used at the facility.
6. If F is  $< 15\%$ , the instrument should be considered acceptable.

If an instrument model uses an acceptable automated self-check protocol, performing a manual routine response check of the instrument should not be necessary.

### 3.4 DOCUMENTATION

Quality documentation (electronic or paper) must be available to justify the instrument program. Because many reference standards are available that can provide guidance regarding the handling of quality records, the specifics are not addressed here. The following information contains recommendations specific to radiation protection instrumentation.

#### 3.4.1 Document Control

Records obtained as part of a quality instrumentation program should be handled and controlled by a single organization. These records should be stored by model and instrument and should contain all records concerning the overall operation of that instrument model.

#### 3.4.2 Document Review

Periodic independent reviews of the operational history of each model should be conducted. This review could be performed by a member of the governing organization responsible for approval of radiation instrumentation at the site. The review should include field failure rates, indicated operational trends, and user concerns.

#### 4. GUIDANCE DOCUMENTS

ANSI N323-1978, "Radiation Protection Instrumentation Test and Calibration," American National Standards Institute.

10 CFR Pt. 835, "Occupational Radiation Protection."

NCSL RP-1, "Establishment and Adjustment of Calibration Intervals," National Conference of Standards Laboratories.

ANSI N323A-1997, "Radiation Protection Instrumentation Test and Calibration, Portable Survey Instruments."

## APPENDIX

### Calibration Frequency Implementation Guide Statement

- c) Instruments and equipment used for monitoring and surveys shall be:
1. Periodically maintained and calibrated on an established frequency based on the instrument's demonstrated reliability

Reference document ANSI N323A-1997 states that "calibration shall be required at least annually (Section 4.9)." This statement has been used for many years to set the calibration interval for radiation instrumentation. Experience has shown that it is more appropriate to use an instrument's demonstrated reliability to set the calibration interval. If routine checks indicate that an instrument is stable, the interval between periodic calibrations may be increased without upper limits. Conversely, if an instrument, because of either field use or design characteristics, is less stable, requiring frequent repair or adjustment, its interval may be reduced to ensure proper operation. To determine an instrument's reliability, data from routine performance check or as-found test results should be collected and analyzed based on guidance from RP-1, "Establishment and Adjustment of Calibration Intervals," National Conference of Standards Laboratories Recommended Practice. This analysis will validate the interval between calibrations and indicate whether changes are necessary or practical.

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