



DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-4019

(Proposed Revision of Regulatory Guide 4.13, Rev. 1, dated July 1977)

ENVIRONMENTAL DOSIMETRY - PERFORMANCE SPECIFICATIONS, TESTING, AND DATA ANALYSIS

A. INTRODUCTION

Purpose

Environmental dosimetry methods such as Thermoluminescence dosimetry (TLD) and Optically Stimulated Luminance dosimetry (OSL) are widely used to measure levels of X and gamma radiation for environmental purposes at NRC-licensed nuclear facilities. This guide provides acceptable dosimeter design specifications, methods of testing, dosimeter deployment, and data analysis. The data analysis methods provide an acceptable method of determining the facility-related, direct radiation dose in the general environment outside the nuclear facility suitable for demonstrating compliance with the Environmental Protection Agency (EPA) 40 CFR 190, “Environmental Radiation Protection Standards for Nuclear Power Operations” (Ref. 1).

Applicable Rules and Regulations

- Title 10 of the *Code of Federal Regulations* (10 CFR), Part 20, (Ref. 2) Section 20.1301, “Dose limits for individual members of the public” provides limits on the total effective dose equivalent to individual members of the public from the licensed operation.
- 10 CFR 20.1302, “Compliance with dose limits for individual members of the public” requires demonstration by measurement or calculation that the dose to members of the public does not exceed the annual dose limits (including the dose limits of EPA’s generally applicable environmental radiation standards in 40 CFR 190). 10 CFR Part 20 Subpart F, “Surveys and Monitoring” further requires that a licensee conduct surveys as may be necessary to comply with the regulations of 10 CFR Part 20 including, when appropriate, the measurement of levels of radiation.

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received final staff review or approval and does not represent an official NRC final staff position. Public comments are being solicited on this draft guide and its associated regulatory analysis. Comments should be accompanied by appropriate supporting data. Written comments may be submitted through the federal government rulemaking Web site at <http://www.regulations.gov>. Alternatively, written comments may be submitted to the Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; or faxed to (301) 492-3446. Comments must be submitted by **[insert date – 60 days from issuance]**.

Electronic copies of this draft regulatory guide, previous versions of this guide, and other recently issued guides are available through the NRC’s public Web site under the Regulatory Guides document collection of the NRC Library at <http://www.nrc.gov/reading-rm/doc-collections/reg-guides/>. The draft regulatory guide is also available through the NRC’s Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>, under Accession No. **MLXXXXXXXXXX**. The regulatory analysis may be found in ADAMS under Accession No. **MLXXXXXXXXXX**.

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- 10 CFR 20.1501(a), requires each licensee to make or cause to be made, surveys of areas, including the subsurface, that may be necessary to comply with the regulations, and are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels, the concentrations or quantities of residual radioactivity, and the potential radiological hazards of the radiation levels and residual radioactivity detected.
 - 10 CFR 20.1501(c) requires that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated periodically for the radiation measured.
 - 10 CFR Part 50, (Ref. 3), Section 50.36 (a), “Technical Specifications on Effluents from Nuclear Power Reactors,” which requires that licensees estimate the maximum potential annual radiation doses to the public resulting from effluent releases.
 - 10 CFR 50, Appendix I, Paragraph IV.B(2), "Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion 'As Low As Is Reasonably Achievable' for Radioactive Material in Light-Water-Cooled Nuclear Power Reactor Effluents," requires that licensees establish appropriate surveillance and monitoring programs to provide data on measurable levels of radiation and radioactive materials in the environment.
 - 10 CFR Part 50, Appendix A, "General Design Criteria for Nuclear Power Plants," Criterion 64, "Monitoring Radioactivity Releases," requires that nuclear power plant designs provide means for monitoring the plant environs for radioactivity that may be released as the result of normal operations, including anticipated operational occurrences, and as the result of postulated accidents.

61 **Related Rules and Regulations**

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- 10 CFR 20.2202, “Notification of Incidents,” requires each licensee to immediately report any event involving byproduct, source, or special nuclear material possessed by the licensee that may have caused or threatens to cause an individual to receive a dose meeting the limits of this Section of the NRC regulations.
 - 10 CFR 20.2203, “Reports of Exposure, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits,” requires a report to be sent to the NRC describing the reportable event.
 - 10 CFR 20.2205, “Reports to Individuals of Exceeding Dose Limits,” requires when a licensee is sending a report to the NRC of any exposure of an identified occupationally exposed individual, or an identified number of the public, to radiation or radioactive material, the licensee shall also provide the individual a report of the data included in the report to the NRC.

78 **Related Guidance**

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- ANSI N545-1975 “Performance, Testing, and Procedural Specifications for Thermoluminescence Dosimetry (Environmental Applications),” Provides minimum acceptable performance of TLDs used for environmental measurements. (Ref. 4)

- 84 • ANSI/HPS N13.37–2014, “Environmental Dosimetry,” provides improved methods of
85 performance testing and establishes performance criteria and improved methods of analyzing
86 environmental data to determine potential radiological impacts of facility operations (Ref. 5).
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88 • Regulatory Guide 4.1, “Radiological Environmental Monitoring for Nuclear Power Plants”
89 (Ref. 6)
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91 • Regulatory Guide 1.21, “Measuring, Evaluating, and Reporting Radioactive Material in Liquid
92 and Gaseous Effluents and Solid Waste” (Ref. 7).
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94 **Purpose of Regulatory Guides**
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96 The NRC issues regulatory guides to describe to the public methods that the staff considers
97 acceptable for use in implementing specific parts of the agency’s regulations, to explain techniques that the
98 staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants.
99 Regulatory guides are not substitutes for regulations and compliance with them is not required.
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101 **Paper Reduction Act**
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103 This regulatory guide contains information collection requirements covered by 10 CFR Part 20 that
104 the Office of Management and Budget (OMB) approved under OMB control number 3150-0014. The NRC
105 may neither conduct nor sponsor, and a person is not required to respond to, an information collection
106 request or requirement unless the requesting document displays a currently valid OMB control number.
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108 **B. DISCUSSION**
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110 **Reason for Revision**
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112 The 1977 (Revision 1) version of this Regulatory Guide (RG) endorsed (with exceptions) the
113 American National Standards (ANSI) N545 (1975) “Performance, Testing, and Procedural Specifications
114 for Thermoluminescence Dosimetry (Environmental Applications).” ANSI N545 has since been withdrawn
115 (removed from circulation) and superseded by the American National Standards Institute/Health Physics
116 Society (ANSI/HPS) N13.37 – 2014, “Environmental Dosimetry.”
117

118 Since the bases document for RG 4.13, Rev.1 has been replaced, the US NRC is revising RG
119 4.13. The RG 4.13, Rev. 2 (2014) is being issued to provide improved data analysis methods acceptable
120 for demonstrating compliance with regulatory requirements 10 CFR 20.1301(e); i.e., the Environmental
121 Protection Agency (EPA) 40 CFR 190, “Environmental Radiation Protection Standards For Nuclear
122 Power Operations.” This EPA standard establishes a dose limit of 25 mrem whole body, 75 mrem to the
123 thyroid, and 25 mrem to other organs for a real member of the public in the general environment (i.e., in
124 the unrestricted area).
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127 **Background**
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129 In 1975, the ANSI Committee N13 on Radiation Protection prepared the ANSI N545 standard
130 that specified minimum acceptable performance of TLDs used for environmental measurements; outlined
131 methods to test for compliance; and provided procedures for calibration, field application, and reporting.
132 ANSI N545 was subsequently approved and designated N545-1975 on August 20, 1975.
133

134 In ANSI N545, Appendix C, “Interpretation of Field Exposures to Isolate Contributions
135 Attributable to Man-Made Radiation Sources (Such as a Nuclear Power Plant)” guidance was provided on
136 acceptable methods of interpreting environmental monitoring results. In summary, the ANSI N545
137 guidance provided two methods of data analysis based on the premise that background dose rates were
138 either 1) invariant with location or 2) invariant with time, as follows:
139

- 140 1. Invariant with location: If background dose rates are assumed invariant from one
141 monitoring location to another, then dosimetry measurements could be made at control
142 stations (i.e., a field site remote from a nuclear facility) and compared to the measured
143 background (or changes in background) at indicator stations (i.e., field sites near the
144 facility).
145
- 146 2. Invariant with time: If background dose rate were invariant with time, then dosimetry
147 measurements could be made at each monitoring location and compared to prior
148 measurements at the same location.
149

150 Note: The ANSI N545 recognized that neither assumption was strictly valid; however, ANSI
151 N13.37 provides improved data analysis methods for background dose rates invariant with time. This
152 method compares current dosimetry measurements at each monitoring station with previous measurements
153 at the same location.
154

155 The ANSI/HPS N13.37 (2014) complements and extends the technical requirements and guidance
156 in International Standard IEC 62387, “Radiation protection instrumentation – Passive integrating dosimetry
157 systems for personal and environmental monitoring of photon and beta radiation” (Ref. 8). While the
158 performance criteria are generally comparable, by focusing specifically on passive environmental
159 monitoring dosimetry systems, the N13.37 testing approach may be seen as simplified from that in IEC
160 62387. Additionally, this standard extends beyond IEC 62387 by providing requirements and guidance for
161 deployment and data analysis of environmental monitoring dosimetry systems.
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164 **Harmonization with International Standards**

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166 The NRC has a goal of harmonizing its guidance with international standards, to the extent
167 practical. The International Commission on Radiological Protection (ICRP) and the International Atomic
168 Energy Agency (IAEA) have issued a significant number of technical guidance documents, and
169 recommendations addressing good practices in most aspects of radiation protection. Such documents
170 include:
171

- 172 • The International Standard IEC 62387, “Radiation protection instrumentation – Passive
173 integrating dosimetry systems for personal and environmental monitoring of photon and beta
174 radiation,” IEC/CEI 62387-1:2007, March, 2012.
175

176 The NRC encourages licensees to consult this international document and implement the good
177 practices that are consistent with NRC regulations. It should be noted, however, that some of the
178 recommendations issued by these international organizations do not correspond to the requirements
179 specified in the NRC’s regulations. In such cases, the NRC’s requirements take precedence.
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181 **Documents Discussed in Staff Regulatory Guidance**

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183 Although this regulatory guide utilizes information, in part, from one or more reports developed by
184 external organizations and other third party guidance documents, the regulatory guide does not endorse

185 these references other than as specified in this regulatory guide. These reports and third party guidance
186 documents may contain references to other reports or third party guidance documents (“secondary
187 references”). If a secondary reference has itself been incorporated by reference into NRC regulations as a
188 requirement, then licensees and applicants must comply with that requirement in the regulation. If the
189 secondary reference has been endorsed in a regulatory guide as an acceptable approach for meeting an NRC
190 requirement, then the reference constitutes a method acceptable to the NRC staff for meeting that regulatory
191 requirement as described in the specific regulatory guide. If the secondary reference has neither been
192 incorporated by reference into NRC regulations nor endorsed in a regulatory guide, then the secondary
193 reference is neither a legally-binding requirement nor a “generic” NRC approval as an acceptable approach
194 for meeting an NRC requirement. However, licensees and applicants may consider and use the information
195 in the secondary reference, if appropriately justified and consistent with current regulatory practice,
196 consistent with applicable NRC requirements such as 10 CFR Part 20.

197 198 **C. STAFF REGULATORY GUIDANCE**

199 200 **1. Quantitative Measurements**

201
202 Environmental dosimetry programs should provide accurate quantitative radiation measurements
203 and analyses that are capable of demonstrating compliance with regulations 10 CFR 20.1301 and EPA 40
204 CFR 190. In order to do this, dosimetry systems should:

- 205
206 • Meet environmental type testing criteria for system design
- 207
208 • Meet radiological type testing for accuracy, precision, and linearity criteria
- 209
210 • Be capable of measuring a quarterly dose of 20 mrem with a coefficient of variation not to
211 exceed ~7%
- 212
213 • Be capable of determining a facility-related dose of ~ 5 mrem per quarter or ~ 10 mrem per
214 year

215 216 **2. Regulatory Guide 4.13, Rev. 1 (1977)**

217
218 RG 4.13, Rev. 1 (1977) continues to provide methods acceptable to NRC to demonstrate
219 compliance with the public dose limits of 10 CFR 20.1301. This 1977 version established the NRC position
220 that the ANSI N545-1975 standard is generally acceptable as a basis for using environmental dosimetry for
221 measurement of direct radiation in the environs, subject to the stated additional provisions and
222 qualifications listed in the Regulatory Guide 4.13, Revision 1.

223
224 Environmental dosimetry systems in current use that have been demonstrated to meet the
225 Regulatory Guide 4.13, Revision 1 criteria do not need to be retested to the radiation and environmental
226 type tests of ANSI/HPS N13.37-2014. However, licensees should have documentation that the
227 environmental dosimetry system has been tested and meets the criteria of RG 4.13, Revision 1 (or
228 equivalent), and provide adequate methods of data analysis to identify facility-related dose.

229 230 **3. ANSI/HPS N13.37 (2014)**

231
232 ANSI/HPS 13.37 (2014) provides improved acceptance criteria and data analysis methods for
233 analysis of direct radiation in the environs of NRC-licensed facilities. This Regulatory Guide endorses the

234 ANSI/HPS N13.37 standard as providing acceptable methods of performance testing environmental
235 dosimetry and analyzing environmental monitoring data.

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237

238 4. Data Analysis Techniques provided in ANSI N13.37

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240 An analysis of environmental dosimetry measurements must be analyzed using acceptable scientific
241 techniques. Data should be analyzed for each monitoring period (in lieu of annual review) so that
242 corrective actions can be taken promptly.

243

244 The first step in this method is to identify obvious data outliers and investigate apparent
245 discrepancies. This data should be analyzed before data corrections/adjustments (e.g., subtraction of
246 extraneous dose) (see definitions in Appendix A) or data normalizations occur (e.g., adjusting data to a
247 normalized, 91 day monitoring period).

248

249 Acceptable analysis methods include analyzing results for each monitored location independently
250 from the other locations:

251

252

a. Evaluate Element Readings

253

254 i. Obtain element readings (from the field dosimeters, dosimeters at a control station,
255 and control dosimeters stored in lead shield). Note the distinction in terminology
256 between “dosimeters at a control station” (remote from the facility) and “control
257 dosimeters stored in a lead shield.”

258

259 ii. Identify characteristics of each element’s filtration and /or phosphor (so that
260 element reading outliers can be properly determined).

261

262 iii. Perform a qualitative review of the element readings, and identify and investigate
263 any obvious outliers and make notations as to the circumstances

264

265 iv. Calculate¹ the standard deviation (SD) and the coefficient of variation (CV) of the
266 remaining (credible and valid) element readings (i.e., after outliers have been
267 removed from the data set)

268

269 v. Review SD and CV data (i.e., for those elements expected to measure the same
270 dose quantity based on the same filtration or same phosphor). Identify and
271 document the reason for CVs greater than 10%.

272

273 vi. Calculate the valid (after removal of outliers) “gross” field dosimeter readings (i.e.,
274 the field dose plus the extraneous dose) for each monitored location. Note: Data
275 from dosimeters located at control stations is not particularly relevant in an analysis
276 method that is “invariant with time,” but the dosimeter readings at control stations
277 should be evaluated anyway and reported for consistency.

278

279 vii. Calculate the valid control dosimeter doses (i.e., after removal of outliers based on
280 control dosimeters stored in a lead shield)

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282

b. Determine The Extraneous² Dose

283

1 The SD and the CV of a small data set are not accurate measures of performance, but do provide an initial indication of performance.

² Extraneous dose (e.g., storage dose, transit dose) has been the least understood process over the history of these measurements. ANSI/HPS N13.37 provides details on proper methods of determining extraneous dose. Onsite processors can minimize extraneous dose by performing the processing very soon before deployment and after collection.

- 277 i. Determine the mean (average) dose on control dosimeters stored in a lead shield.
- 278 ii. Calculate the extraneous dose (the dose that the field dosimeters accrued while not
- 279 deployed in the field). Note: The mean control dosimeter dose is not an adequate
- 280 measure of the extraneous dose. See ANSI N13.37 methods of determining
- 281 extraneous dose.
- 282
- 283 c. Determine Field Doses
- 284
- 285 i. Determine the accrued field dose at each monitored location by subtracting the
- 286 extraneous dose. Note: A simple subtraction of the control dosimeter readings
- 287 from the field dosimeter readings is not an accurate method of assessing field dose.
- 288 ii. Normalize the data to a standard 91-day quarter (or other normalized period).
- 289 iii. Perform a qualitative comparison of the normalized, quarterly field doses to the
- 290 base-line background dose rate for each monitored location.
- 291 iv. Identify apparent outliers and investigate anomalies.
- 292 v. Remove substantiated outliers from the data set and document justifications.
- 293
- 294 d. Determine the dosimetry system's quarterly and annual minimum detectable dose (MDD).
- 295 Note: The MDD accounts for 3 standard deviations in measurements.
- 296
- 297 e. Determine the base-line background dose rate (at each monitored location).
- 298
- 299 f. Determine Quarterly Facility-Related Doses (at each monitored location)
- 300
- 301 i. Sum the quarterly MDD and the quarterly baseline background dose rate.
- 302 ii. Subtract the sum from the normalized field dose (to determine the facility-related
- 303 dose).
- 304 iii. Identify any detectable facility-related dose (e.g., exceeding 5 mrem during the
- 305 quarterly period).
- 306 iv. Investigate any detectable facility-related dose, and document substantiated
- 307 facility-related dose, and remove (with justification) any unsubstantiated doses
- 308 from the data set.
- 309
- 310 g. Determine the annual Facility-related Dose at each monitored location.
- 311 i. Sum the annual MDD³ and the annual baseline background dose rate.
- 312 ii. Subtract the sum from the normalized annual field dose to determine the annual
- 313 facility-related dose.
- 314 iii. Identify any detectable facility-related dose (e.g., exceeding ~10 mrem during the
- 315 annual period).
- 316

317 5. Quality Assurance

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319 The quality assurance methods described in ANSI/HPS N13.37 are suitable methods of performing
320 quality assurance. In summary, there should be:

- 321
- 322 • End-user quality assurance checks/measures

³ The annual MDD is less than the sum of the quarterly MDD's since the statistics are better.

- 323 • Annual audits of the end-user by independent assessors
- 324 • Annual blind spike testing
- 325 • Triennial audits of the processor

326
327 Note: a processor laboratory accreditation program may be needed if the results of the quality
328 assurance program routinely identify unsatisfactory results.

329
330 **6. Data Reporting**

331 Report environmental data and analyses in accordance with Technical Specifications (e.g., in
332 accordance with the Offsite Dose Calculation Manual).

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334
335 **D. IMPLEMENTATION**

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337 The purpose of this section is to provide information to applicants and licensees regarding the
338 NRC’s plans for using this regulatory guide.

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340 Methods or solutions that differ from those described in this regulatory guide may be deemed
341 acceptable if they provide sufficient basis and information for the NRC staff to verify that the proposed
342 alternative demonstrates compliance with the appropriate NRC regulations. Current licensees may continue
343 to use guidance the NRC found acceptable for complying with the identified regulations as long as their
344 current licensing basis remains unchanged. Backfit and issue finality considerations do not apply to
345 licensees and applicants under 10 CFR Part 20.

346
347 **REFERENCES**

- 348
349 1. Environmental Protection Agency (EPA) 40 CFR 190, “Environmental Radiation Protection
350 Standards for Nuclear Power Operations.”⁴
- 351
352 2. *Title 10 of the Code of Federal Regulations* (10 CFR), Part 20, “Standards for Protection against
353 Radiation,” U.S. Nuclear Regulatory Commission, Washington, DC 20555.⁵
- 354
355 3. 10 CFR Part 50, General Design Criterion 64, "Monitoring Radioactivity Releases," of Appendix A,
356 "General Design Criteria for Nuclear Power Plants."
- 357
358 4. American National Standards Institute (ANSI) N545 (1975) “Performance, Testing, and Procedural
359 Specifications for Thermoluminescence Dosimetry (Environmental Applications).”⁶

4 Copies of EPA Library Services may be obtained through their Web site:
http://www.epa.gov/libraries/library_services.html.

5 Publicly available NRC-published documents are available electronically through the NRC Library on the NRC’s public Web site at <http://www.nrc.gov/reading-rm/doc-collections/>. The documents can also be viewed online or printed for a fee in the NRC’s Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD; the mailing address is USNRC PDR, Washington, DC 20555; telephone 301-415-4737 or (800) 397-4209; fax (301) 415-3548; and e-mail pdr.resource@nrc.gov.

6 Copies of American National Standards Institute (ANSI) documents may be purchased through their Web site at: <http://webstore.ansi.org/>.

- 360
361 5. American National Standards Institute/Health Physics Society (ANSI/HPS) N13.37 - 2014,
362 “Environmental Dosimetry – Criteria for System Design and Implementation.”⁷
363
364 6. Regulatory Guide 4.1, “Radiological Environmental Monitoring for Nuclear Power Plants.”
365
366 7. Regulatory Guide 1.21, “Measuring, Evaluating, and Reporting Radioactive Material in Liquid and
367 Gaseous Effluents and Solid Waste.”
368
369 8. International Standard IEC 62387, “Radiation Protection Instrumentation – Passive integrating
370 dosimetry systems for personal and environmental monitoring of photon and beta radiation.”
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Appendix A

Plain Language Definitions (see also ANSI/HPS 13.37)

374
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377
378 Accuracy: A measure of the difference between the measured value and the conventionally true value
379 (expressed either as the standard deviation or as the coefficient of variation (also referred to as the bias)).

380
381 Coefficient of Variation (CV): The standard deviation (of a series of measurements) divided by the mean
382 value of the measurements.

383
384 Baseline background dose (B_Q or B_A): The average background radiation dose based on historical
385 averages.

386
387 Bias: The mean deviation from the conventionally true value (expressed as a fraction of the
388 conventionally true value).

389
390 Conventionally true value (D): The best estimate of the delivered radiation dose.

391
392 Extraneous dose: The extra dose accumulated on a dosimeter prior to and after field deployment.

393
394 Facility-related dose (F_Q or F_A): The dose from radiation originating from the monitored facility.

395
396 Mean: The arithmetic average.

397
398 Minimum differential dose (MDD_x): The smallest amount of facility-related dose that can be reliably
399 detected.

400
401 Performance Quotient (P): A measure of the accuracy in spiked dosimeter testing. The P value is
402 calculated as the spiked dosimeter reading, minus its spiked dose, divided by its spiked dose. The average
403 P value should not exceed 0.15 for the set of spiked dosimeters.
404

⁷ Copies of American National Standards Institute /Health Physics Society (ANSI/HPS) documents may be purchased through their Web site at: <http://webstore.ansi.org/> or through HPS Web site at <http://www.hps.org>.

405 Precision: The variation of measured values around its mean measured value (expressed quantitatively as
406 either the standard deviation or as the coefficient of variation).

407

408 Standard deviation S_x : The average variation in a series of measurements, calculated as:

409

410

$$S_x = \sqrt{\frac{1}{(N-1)} \sum_{i=1}^N (x_i - \bar{x})^2}$$

411

$$\text{where } \bar{x} = \frac{1}{N} \cdot \sum_{i=1}^N x_i$$

412

413 and

414 **N = the number of test results**

415 **x_i = the values of the test results**

416

417

418 Transit dose: The dose received by a field dosimeter when not deployed in the field. This occurs from the
419 time of annealing to the time the dosimeter is deployed in the field, and from the time the dosimeter is
420 removed from the field to the time the dosimeter is processed. Transit dose does not include storage dose
421 during field deployment.