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Recommended Procedures for Performance Testing of Radiobioassay Laboratories

Volume 2: In Vitro Samples

H. W. Fenrick
J. A. MacLellan

November 1988

Prepared for
the U.S. Department of Energy
Assistant Secretary for
Environmental, Safety and Health
and the U.S. Nuclear Regulatory Commission
under Contract DE-AC06-76RLO 1830
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Pacific Northwest Laboratory
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RECOMMENDED PROCEDURES FOR PERFORMANCE TESTING OF RADIOBIOASSAY LABORATORIES

VOLUME 2: IN VITRO SAMPLES

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November 1988

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Richland, Washington 99352

FOREWORD

In recent years, extensive research has been conducted to improve occupational radiation protection. Of particular concern to the U.S. Department of Energy (DOE) and U.S. Nuclear Regulatory Commission (NRC) have been the accuracy, quality control, and performance of personnel radiation dosimeters, radiation survey instruments, and bioassay laboratories.

The U.S. Department of Energy Order 5480.1, Chapter XI (DOE 1983) and Title 10, Part 20 of the U.S. Code of Federal Regulations (NRC 1982), require assessment of occupational radiation exposures. Accurate bioassay measurements are necessary to correctly assess internal exposure to radioactive materials. However, a concern of both DOE and NRC is that bioassay laboratories may not be providing accurate and consistent results. To address this concern a Health Physics Society working group was formed to prepare a draft American National Standards Institute (ANSI) standard on bioassay laboratory performance. The resultant document was designated draft ANSI N13.30, Performance Criteria for Radiobioassay.[a]

Draft ANSI N13.30 provides performance criteria in the form of the minimum numerical values necessary to meet an acceptable minimum detectable amount, relative bias, and relative precision. The acceptance values for these criteria have been reviewed and revised throughout the process of developing the draft standard.

The testing procedures described in this document were developed as a part of a project to evaluate the performance criteria of draft ANSI N13.30 by testing the current measurement capabilities of various bioassay laboratories. Included in the project was a nationwide, two-round bioassay intercomparison study to test the analytical performance of both in vitro (excreta analysis) and in vivo (external measurement) bioassay laboratories and to determine their capability to meet the minimum performance criteria specified in the draft standard.

(a) Copies of published draft ANSI N13.30 are available from the Executive Secretary, Health Physics Society, 8000 Westpark Drive, Suite 400, McLean, VA 22102.

The procedures used to prepare in vitro samples have been described in three previous reports of this research project, Performance Testing of Radiobioassay Laboratories: In Vitro Measurements, Pilot Study Report (Robinson, Fisher, and Hadley 1984), Performance Testing of Radiobioassay Laboratories: In Vivo Measurements, Pilot Study Report (Robinson et al. 1986), and Performance Testing of Radiobioassay Laboratories: In Vitro Measurements, Final Report (MacLellan, Traub, and Fisher 1987).

The purpose of this report is to provide recommended procedures for 1) preparing standard radionuclide solutions, 2) preparing and distributing test samples, and 3) evaluating the performance of bioassay service laboratories.

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SUMMARY

Draft American National Standards Institute (ANSI) Standard N13.30 (Performance Criteria for Radiobioassay) was developed for the U.S. Department of Energy and the U.S. Nuclear Regulatory Commission to help ensure that bioassay laboratories provide accurate and consistent results. The draft standard specifies the criteria for defining the procedures necessary to establish a bioassay performance-testing laboratory and program. The bioassay testing laboratory will conduct tests to evaluate the performance of service laboratories.

Pacific Northwest Laboratory[(a)] helped develop testing procedures as part of an effort to evaluate the draft ANSI N13.3D performance criteria by testing the existing measurement capabilities of various bioassay laboratories. This report recommends guidelines for the preparation, handling, storage, distribution, shipping, and documentation of in vitro test samples (artificial urine and fecal matter) for indirect bioassay. The data base and recommended records system for documenting radiobioassay performance at the service laboratories are also presented.

(a) Pacific Northwest Laboratory is operated for the U.S. Department of Energy under Contract DE-AC06-76RLO 1830 by Battelle Memorial Institute.

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ACRONYMS

AMDA	acceptable minimum detectable amount
ANSI	American National Standards Institute
CFR	U.S. Code of Federal Regulations
DOE	U.S. Department of Energy
DOT	U.S. Department of Transportation
HPSSC	Health Physics Society Standards Committee
MDA	minimum detectable amount
NBS	National Bureau of Standards
NCRP	National Council on Radiation Protection and Measurements
NRC	U.S. Nuclear Regulatory Commission
QA	quality assurance

1.0 INTRODUCTION

1.1 PURPOSE

This report provides recommended procedures for 1) handling standard radionuclide solutions, 2) preparing and distributing test samples for laboratories that participate in the bioassay performance-testing program, and 3) evaluating the performance of bioassay performance-service laboratories. The overall goal is to specify the content of the procedures that are necessary to establish a bioassay performance-testing laboratory. The intended purpose of the testing laboratory is to help the service laboratories establish acceptable radiobioassay practices.

1.2 SCOPE

The procedures recommended in this report are based on technical specifications given in the draft American National Standards Institute (ANSI) Standard N13.30, Performance Criteria for Radiobioassay.[a] This performance standard was prepared by Working Group 2.5 of the Health Physics Society Standards Committee (HPSSC). The U.S. Department of Energy (DOE) and the U.S. Nuclear Regulatory Commission (NRC) asked the HPSSC to provide guidance on acceptable criteria for bioassay laboratory measurements.

The procedures given in this report apply only to the performance testing of indirect (in vitro) bioassay measurements. The scope of the report does not include radiochemical methods for separating radionuclides from biological samples, or metabolic data and mathematical models for converting radiobioassay results into depositions or into absorbed dose and dose equivalent. Nor do the procedures apply to direct (in vivo) bioassay.

(a) Copies of draft ANSI N13.30 are available from the Executive Secretary, Health Physics Society, 8000 Westpark Drive, Suite 400, McLean, VA 22102.

1.3 PROCEDURE REVISION

The testing laboratory implementing the recommended procedures is expected to adapt them to the laboratory working environment. All revisions should be in conformance with Section 1.3 of Volume 1 of this report.

1.4 DEFINITION OF TERMS

The definitions of the terms used in this report are in accordance with Section 2 of draft ANSI N13.30. Specific terms are listed in Section 1.4 of Volume 1 of this report.

2.0 PREPARATION OF TEST SAMPLES FOR INDIRECT BIOASSAY

The following procedures are established for evaluating the performance of in vitro bioassay service laboratories.

2.1 PREPARATION OF TEST MATRICES

Artificial test matrices provide reproducible sample characteristics, and are therefore preferred over less stable natural matrices. The following sections describe the recommended procedures for preparing artificial test matrices.

2.1.1 Preparation of Artificial Urine

The artificial urine used for the preparation of test samples should be prepared using the recipe given in Appendix A. A batch-preparation form should be completed during the preparation of each batch of artificial urine. The form should contain the following information: batch number, preparation date, and name of the individual preparing the batch. The amount of each component should be recorded as it is added to the batch. For example, if a 50-kg batch is being prepared, the addition of components may be tabulated as follows:

Component	Mass Required, g	Component Added (Check)
Urea	800	X
NaCl	116	
etc.		

Prior to mixing any ingredients, the mass of water needed for the batch should be calculated. Approximately 60% of the required amount should be added to the container before adding any of the solute components. The remainder of the required water may be added as a rinse for the various components as they are added to the container.

The solution should be mixed well using a magnetic stirrer or suspended stirring motor and rod. No container that contains a magnetic stirrer should

be weighed, unless approximately 40 cm of cardboard or similar material is placed between the balance pan and the magnetic stirrer container.

If the color of the samples is judged by the testing laboratory to be important to the performance of the service laboratory, an appropriate natural coloring may be added to the samples.

2.1.2 Preparation of Artificial Fecal Matter

The artificial fecal matter used for the preparation of test samples should be prepared using the recipe given in Appendix B. A batch-preparation form should be completed during the preparation of each batch of artificial fecal matter, as for the artificial urine. The form should contain the following information: batch number, preparation date, and name of the individual who prepares the batch. The amount of each component should be recorded as it is added to the batch.

2.2 STANDARDS OF THE NATIONAL BUREAU OF STANDARDS

All radionuclide solutions used in the preparation of test samples should be certified by the National Bureau of Standards (NBS) either directly or by traceability through the demonstrated-measurement-capability pathway. The certificates should be kept in the quality assurance (QA) notebook or in a file that is referenced in the QA notebook. Radioactive standard solutions should be stored in a Radiation Work Area. The supervisor of the testing laboratory should keep an inventory of radioactive materials.

2.3 PREPARATION OF TEST SAMPLES OF KNOWN RADIOACTIVITY

The test samples should be prepared as described in the following sections.

2.3.1 Selection of Test Radionuclides

Each service laboratory has the option of being tested and evaluated for an entire category of draft ANSI N13.30 or for a specific radionuclide in a category. If the service laboratory elects to be tested for an entire category the test radionuclide should be selected from the radionuclides listed for the category in Table 4 of draft ANSI N13.30. The selection process must give each radionuclide an equal probability of being selected.

If the service laboratory designates a specific radionuclide for which they wish to be tested, only that radionuclide may be used for testing and evaluation, and accreditation will be for that radionuclide only.

2.3.2 Preparation of Artificial Urine Samples

The NBS standard radionuclide solutions are generally diluted by a factor of several thousand but each step should not exceed 1000:1. Therefore, a multi-step procedure is usually required to prepare test samples that have the desired specific activity. The concentration of the radionuclide after the first dilution is

$$C_2 \text{ (first dilution)} = \frac{C1 \times 02}{D1 + D2} \qquad (1)$$

where C1 is the concentration of the radionuclide in the standard and D1 and D2 are as defined below:

D1 (Mass of Diluent) = M2-M1
M2 = Mass of container + diluent
M1 = Mass of empty container
D2 (Mass of NBS Standard added) = M3-M4
M3 = Mass of full NBS ampoule
M4 = Mass of empty NBS ampoule

Each measurement is recorded on a spike-dilution form as it is made.

The large surface tension of water makes it difficult to remove all of the NBS standard from the ampoule in which it is received. To accurately determine the amount of reference nuclide used, the standard should be transferred into a tared dilution container, and the mass differences of the full and the empty containers should be noted to obtain the mass of NBS standard added.

The concentration of the test radionuclide in the artificial urine after the second dilution is

$$C3 \text{ (artificial urine sample)} = \frac{C2 \times D4}{D3 + D4} \qquad (2)$$

where C2 is the concentration of the radionuclide after the first dilution and D3 and D4 are as defined below:

D3 (Mass of artificial urine) = M6-M5
- M6 = Mass of container + artificial urine
- M5 = Mass of empty container

D4 (Mass of first dilution NBS standard added) = M7-M8
- M7 = Mass of first dilution container with C2 (before spike is removed for artificial urine)
- M8 = Mass of first dilution container with C2 (after spike is removed for artificial urine)

If the NBS standard only has to be diluted by a factor of 1000:1, one dilution step may be used. The NBS standard on a known mass is added directly to a known mass of the artificial urine. If only one dilution step is used the concentration of the test radionuclide in the artificial urine is

$$C3 \text{ (first dilution)} = \frac{C1 \times D2}{D2 + D3} \qquad (3)$$

where C1, D2, and D3 are as defined above.

2.3.3 Preparation of Artificial Fecal Matter Samples

Prior to preparing the individual artificial fecal test samples, the first dilution of the NBS standard radionuclide solution should be carried out as described in Section 2.3.2.

Samples of artificial fecal material that contain a known amount of the test radionuclide should be prepared as follows:

1) Place solid matrix ingredients in quantities sufficient to prepare the desired number of samples in a tumbler and tumble them for 24 hours to assure uniform mixing.

2) Prepare a dissolved gelatin solution with a concentration of 5 g gelatin per 70 mL of water.

3) Heat seal the bottom of a small plastic bag to provide a double seal.

4) Add approximately 20 mL of gelatin solution to the bag.

5) Add approximately 30 g of artificial fecal matrix solids to the bag.

6) Use a calibrated repipette to add the desired volume of the spike solution.[(a)]

7) Add approximately 50 mL more gelatin solution to the bag.

8) Double heat seal the top of the plastic bag.

9) Mix the contents of the bag by kneading the bag with gloved hands.

10) Repeat steps 2 through 7 for the remaining samples.

The service laboratory is requested to analyze the bag and contents together and report results in terms of activity per sample.

The activity per sample is

$$A = C2 \times D4 \qquad (4)$$

where C2, and D4 are as defined in Section 2.3.2.

2.3.4 Sample Distribution

For performance-testing purposes, each service laboratory should be provided with a minimum of five samples spiked with a known amount of the test radionuclide and five blank samples. The test samples should consist of artificial urine or fecal matter spiked within the activity ranges specified in Table 4 of draft ANSI Standard N13.30 with known quantities of one or more of the test radionuclides.

(a) The NBS Report of Test generally gives radioactivity concentration in becquerels per gram. If samples are to be prepared by adding a known volume of the test radionuclide rather than a known mass, the NBS Report of Test must include the density of the standard solution and the becquerels per milliliter calculated.

At least five test samples with quantities below 10 times the acceptable minimum detectable amount (AMDA) should also be submitted to service laboratories for the purpose of evaluating performance near the AMDA of a given analytical procedure. However, performance on test samples below 10 times the AMDA should not be expected to meet the performance criteria for the relative bias or relative precision.

2.3.5 Certification of Activity

The amount(s) of activity of the test radionuclide(s) in the test sample should be estimated with an overall propagated standard deviation of 5% or less using methods given in Appendix C. An aliquant of each test sample batch should be analyzed by a laboratory with demonstrated measurement traceability to the NBS as described in NCRP 58 (NCRP 1985). The amount estimated by the testing laboratory shall not differ from the analyzed amount by more than 5%. If the estimated uncertainty or difference between the estimated and measured activity exceeds 5% the test-sample batch will not be used in the accreditation program.

2.4 LABELING AND PACKAGING

Samples should be labeled and packaged in a manner that allows proper documentation of chain of custody and sample identification.

2.4.1 Labeling and Packaging Artificial Urine Samples

All samples (except those for tritium analysis) should consist of approximately 1400 mL of artificial urine that contain a known concentration of the test radionuclide. Tritium samples should contain about 100 mL of artificial urine. The samples should be contained in polyethylene bottles. Sample bottles should be labeled as in the following example:

RADIOACTIVE SR-090 DATE
AAUSr0898702123 <100 pCi/L
Expiration Date 11/5/87

The first two letters are an identification code for the service laboratory being tested and the third letter identifies the sample type (U for urine). The next two letters identify the test radionuclide. The first two numbers represent the last two digits of the current year. The third through fifth numbers are the artificial urine batch number. The last three numbers are the sample number.

Sample bottles should be packaged in boxes that have double-wall construction and are approved by the U.S. Department of Transportation (DOT) for shipment of radioactive material. The bottles should be packaged in a nest of absorbent materials such as vermiculite. Samples should be analyzed prior to the expiration date, which is 2 months from the sample preparation date.

2.4.2 Labeling and Packaging Artificial Fecal Matter Samples

The plastic bag that contains the artificial fecal matter sample should be labeled as in the following example:

RADIOACTIVE	Sr-090	DATE
AAFPu2398701125	<100 pCi/L	
Expiration Date		11/5/87

The first two letters are an identification code for the service laboratory being tested and the third letter identifies the sample type (F for fecal). The next two letters identify the test radionuclide. The first two numbers represent the last two digits of the current year. The third through fifth numbers are the artificial fecal material batch number. The last three numbers are the sample number.

Sample bags should be packaged in DOT-approved boxes that contain an absorbent material. The service laboratory is instructed to ash the plastic bag along with the sample material. Analysis again should be completed within 2 months of the sample preparation date.

2.5 STORAGE

If samples are not shipped immediately to the bioassay service laboratory, they should be stored in a designated storage area. This storage area

should be separate from any other radioactive materials use to avoid external contamination of the shipping container.

2.6 SHIPPING

The test radionuclide activity levels qualify under the "limited quantity" designation of Section 173421 of Title 49 of the U.S. Code of Federal Regulations, Transportation (CFR 1986). The sample containers should be packaged and labeled in compliance with federal regulations for packaging and shipping nonradioactive materials. The shipping of "limited quantity" activity levels does not require any external radiation labeling of the box. Samples are generally shipped by surface carrier.

2.7 DOCUMENTATION AND RECORD KEEPING

The QA notebook should contain or reference the storage location of the NBS certificates for the standard radionuclide solutions used in the preparation of the test samples. Worksheets that are not included in the QA notebook should be referenced and their storage location recorded. It is important that individual weights be recorded so that checks can be made on the calculations of radionuclide concentrations. All information from the individual sample labels, as well as the known radionuclide concentration for the samples, should be maintained within the process control data base.

3.0 ANALYSIS REPORT EVALUATION

Following the receipt of analysis data for all samples sent to a service laboratory, the test statistics for the performance report should be calculated. The test statistics include the relative bias (B_r), relative precision (S_A and S_B), and the minimum detectable amount (MDA) for each test nuclide analyzed by the service laboratory. Test statistics are calculated in accordance with draft ANSI N13.30.

3.1 RELATIVE BIAS AND RELATIVE PRECISION

The B_r, S_A, and S_B are easily calculated from the analysis data reported by the service laboratory using the following equations:

$$B_{rij} = \frac{A_{ij} - A_{ai}}{A_{ai}} \tag{5}$$

$$B_r = \sum B_{rij} = \sum_{i=1}^{M} \sum_{j=1}^{N} B_{rij}/N \cdot M \tag{6}$$

$$S_A = \left[\sum_{i=1}^{M} \sum_{j=1}^{N} (A_{ij}/A_i - 1)^2 /(N \cdot M - 1) \right]^{1/2} \tag{7}$$

$$S_B = \left[\sum_{i=1}^{M} \sum_{j=1}^{N} (B_{rij} - B_r)^2 /(N \cdot M - 1) \right]^{1/2} \tag{8}$$

where A_{ij} = the reported result for the jth sample in the ith activity category

A_{ai} = the true activity for the ith activity category

N = the number of samples per activity category

M = the number of activity categories

$A_i = \sum A_{ij}/N$ = the mean reported result for the ith activity category

3.2 MINIMUM DETECTABLE AMOUNT

Estimation of the MDA requires evaluation of the variability observed in the measurement of the appropriate blanks. The specific form of the MDA equation will depend on the assumptions that may be made about the count distribution. If the performance test identifies a relative bias for the reported analysis data, the calculated MDA must be multiplied by $1/(1+B_r)$ to obtain the bias-corrected MDA.

3.2.1 Sample Distribution

The goodness of fit of the data to the Poisson distribution should be tested using the Chi-squared test (Remington and Schork 1970):

$$\chi^2 = \sum_{i=1}^{n} (x_i - \bar{x})^2/\bar{x} \qquad (9)$$

where n is N·M and χ has n-1 degrees of freedom.

The sample variance equals $\sum(x_i-\bar{x})^2/(n-1)$ and the variance of a Poisson distribution equals the mean. Therefore, the above equation may be rewritten as follows:

$$s^2/\sigma^2 = \chi^2/(n-1) \qquad (10)$$

Because we are usually only concerned when there is variability in excess of the Poisson estimate, a one-sided test for significance is appropriate. The hypothesis that the distribution is Poisson will then be rejected when the ratio of the sample variance and the mean exceeds the value in the third column of Table 1.

The power of this test (probability of detecting a true variance that is greater than the mean) may be estimated using the data in Table 2.

3.2.2 Poisson-Based Minimum Detectable Amount

If the hypothesis that the distribution is Poisson is not rejected, the MDA should be calculated using the following equation, which is equivalent to

TABLE 1. Five Percent Rejection Levels for Poisson Goodness of Fit

Sample Size	Chi-Squared	Chi-Squared/ (n-1)
3	5.991	3.00
4	7.815	2.61
5	9.488	2.37
6	11.070	2.21
7	12.592	2.21
8	14.067	2.01
9	15.507	1.94
10	16.919	1.88

TABLE 2. Power of Chi-Squared Test to Identify Non-Poisson Variability

Sample Size	σ^2/mean		
	1.1	1.4	1.54
5	0.69	0.90	0.95
10	0.72	0.96	0.99

the equation of Section 4.3.1.2 of draft ANSI N13.30.

$$MDA = (3.29s_0 + 3)/KT \tag{11}$$

where K is the calibration factor for the measurement process in counts per minute per nanocurie, T is the counting time, and $s_0 = s_B(\eta)$ is the standard deviation of the net blank count.

The value of the net blank standard deviation equals the sample standard deviation times a factor (η), which depends on the ratio (b) of the background and sample count times (T):

$$\eta = (1 + 1/b)^{1/2} \tag{12}$$

The MDA equation therefore reduces to

$$MDA = (3.29(n)s_B + 3)/KT \quad (13)$$

For paired observations (each sample compared to a single blank) the equation reduces further to

$$MDA = (4.65s_B + 3)/KT \quad (14)$$

The calibration factor, K, is equal to the product of the fractional chemical yield, detector counting efficiency, sample volume, and the physical conversion factor for nuclear transformations per unit activity (i.e. decays per minute per nanocurie). Use the lower 5% bound of the estimate of K based on the t distribution (i.e., K(1-t)).

If a separate calibration factor is calculated for each sample using a tracer isotope, the standard deviation of the population of values for the quotient of B and K is used for the MDA equation, which becomes

$$MDA = 3.29s_B\ (n) + (3/KT) \quad (15)$$

3.2.3 Non-Poisson-Based Minimum Detectable Amount

If the hypothesis that the distribution is Poisson is rejected it should not be assumed that the standard deviation of the sample distribution is known. Therefore, a t distribution should be assumed. With a one-tailed test, the MDA equation then becomes

$$MDA = [2(t)(n)s_B + 3]/KT \quad (16)$$

The first term of the above equation may be determined using the data in Table 3.

The sample size for the t term refers to the number of replicate blank counts in the performance test, while the sample size for the n term refers to

TABLE 3. Student's t (5%) and η Terms for the Direct Bioassay MDA Equation

Sample Size	t	η
1	-	1.414
2	6.3138	1.225
3	2.9200	1.155
4	2.3534	1.118
5	2.1318	1.095
6	2.0150	1.080
7	1.9432	1.069
8	1.8946	1.061
9	1.8595	1.054
10	1.8331	1.049
large	1.645	1.000

the number of replicate counts used to determine the background for the service laboratory.

For the normal case using five replicate counts of the appropriate blank and a single background count for comparison the MDA equation reduces to

$$MDA = (6.03s_B + 3)/KT \qquad (17)$$

3.2.4 Minimum Detectable Amount Based on the Laboratory-Estimated Standard Deviation

The MDA should be calculated using the Equation (11) (Section 3.2.2) and the standard deviation estimate supplied by the service laboratory.

3.3 PERFORMANCE REPORTS

The performance report returned to the service laboratory by the testing laboratory should include for each replicate count the sample code, the reported activity, the true activity, and the individual relative bias (B_{rij}). For each group of counts with the same spike activity the relative precision

(S_A and S_B), and the mean relative bias (B_r) should be listed. The report should also specify the calculated standard deviation for the appropriate blank, whether Poisson statistics were rejected, and the calculated MDA. The MDA calculated from the standard deviation of the blank supplied by the service laboratory should also be included.

If the service laboratory passes all criteria except the MDA based on the performance test, passes the MDA criterion when the MDA is calculated based on the blank standard deviation they supplied, and has reported no false negatives for samples spiked at a level near the AMDA, a site visit may be scheduled to determine the validity of their estimate. If the laboratory-supplied estimates of the blank standard deviation are determined to be valid following the site visit, the laboratory will be considered to have passed the MDA criterion. If the calculated value for any test statistic exceeds the acceptance criteria of draft ANSI N13.30, the service laboratory shall not be accredited for that category.

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APPENDIX A

RECIPE FOR ARTIFICIAL URINE

APPENDIX A

RECIPE FOR ARTIFICIAL URINE

Component	g/kg
Urea (CH_4N_2O)	16.0
Sodium Chloride (NaCl)	2.32
Potassium Chloride (KCl)	3.43
Creatinine ($C_4H_9N_3O_2$)	1.10
Sodium Sulfate (Anhydrous) $Na_2SO_4 \cdot H_2O$	4.31
Hippuric Acid ($C_9H_9NO_3$)	0.63
Ammonium Chloride(NH_4Cl)	1.06
Citric Acid ($C_6H_8O_7$)	0.54
Magnesium Sulfate (anhyd.)$MgSO_4$	0.46
Sodium Phosphate, Dibasic ($NaH_2PO_4 \cdot H_2O$)	2.73
Calcium Chloride (Anhydrous) ($CaCl_2 \cdot 2H_2O$)	0.63
Oxalic Acid ($C_2H_2O_4$)	D.02
Lactic Acid ($C_3H_6O_3$)	0.094
Glucose ($C_6H_{12}O_6$)	0.48
Sodium Silicate (Anhydrous) ($Na_2SiO_3 \cdot 9H_2O$)	0.071
Pepsin	0.029
Concentrated (70%) Nitric Acid (HNO_3)	5.0

Note: Each kilogram of artificial urine also contains 961 g of distilled water.

APPENDIX B

RECIPE FOR ARTIFICIAL FECAL MATTER

APPENDIX B

RECIPE FOR ARTIFICIAL FECAL MATTER

Component	g/Sample
Calcium Hydroxide ($Ca(OH)_2$)	0.97
Ferric Ammonium Sulfate (NH_4FeSO_4)	0.04
Magnesium Carbonate ($MgCO_3$)	0.61
Potassium Carbonate (K_2CO_3)	0.83
Ammonium Dihydrogen Phosphate (H_6NO_4P)	2.1
Sodium Sulfate (Na_2SO_4)	0.37
Ammonium Chloride (NH_4Cl)	0.04
Zinc Sulfide (ZnS)	0.01
Stannous Sulfide (SnS)	0.03
Leucine ($C_6H_{13}NO_2$)	7.1
Lysine ($C_6H_{14}N_2O_2$)	5.1
Methionine ($C_5H_{11}NO_2S$)	0.8
Threonine ($C_4H_9NO_3$)	2.0
Palmitic Acid ($C_{16}H_{32}O_2$)	3.0
Stearic Acid ($C_{18}H_{36}O_2$)	2.0
Oleic Acid ($C_{18}H_{34}O_2$)	1.0
Cellulose $(C_6H_{10}O_5)_n$	4.0

Note: Each sample of artificial fecal matter also contains approximately 70 mL of distilled water with 5 g of dissolved gelatin.

APPENDIX C

PROPAGATION OF ERROR IN SPIKED IN VITRD SAMPLES

APPENDIX C

PROPAGATION OF ERROR IN SPIKED IN VITRO SAMPLES

The methods used to estimate the total error in the analysis of in vitro test samples and in vivo phantoms shall be the same as those discussed by Kanipe (1977). Assume that the individual components of the total error are independent normally distributed variables and that propagation for the manipulation of various functions is expressed as below.

Function	Error Formula
$Q = X \pm Y$	$\sigma_Q = (\sigma_x^2 + \sigma_y^2)^{\frac{1}{2}}$
$Q = aX \pm bY$	$\sigma_Q = (a^2 \sigma_x^2 + b^2 \sigma_y^2)^{\frac{1}{2}}$
$Q = XY$	$\sigma_Q = XY\ (\sigma_x^2/X^2 + \sigma_y^2/Y^2)^{\frac{1}{2}}$
$Q = X/Y$	$\sigma_Q = X/Y\ (\sigma_x^2/X^2 + \sigma_y^2/Y^2)^{\frac{1}{2}}$

Using the error formulas above, the equations detailed in the procedure, and the error estimates quoted in the solution certificates supplied for each nuclide, the total error in the prepared samples may be estimated.

REFERENCE

Kanipe, L. G. 1977. Handbook for Analytical Quality Control in Radioanalytical Laboratories. PB-277-254, U.S. Department of Commerce National Technical Information Service, Springfield, Virginia.

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