Revision of HPS/ANSI N13.30 Performance Criteria for Radiobioassay

Jay MacLellan CHP
Radiation and Health Technology
Pacific Northwest National Laboratory

Pacific Northwest
NATIONAL LABORATORY
Proudly Operated by Battelle *Since 1965*

ANSI 13.30 History

- Work started around 1980
- Draft released 1989
- Rev. 0 issued in 1996 (withdrawn 2006)
- Adopted by the Department of Energy Laboratory Accreditation Program (DOELAP) 1998.
- Rev. 1 issued December 2011

Pacific Northwest
NATIONAL LABORATORY
Proudly Operated by Battelle Since 1965

Working Group Members

1989 Draft	1996 Version	2011 Version
Kenneth R. Heid, Chair Battelle	**Matt Lardy, Chair** Quanterra	**Jay MacLellan, Chair** PNNL
Matt Lardy U. S. Testing Company	**Jay A. MacLellan** Battelle	**Matt Lardy** TestAmerica Laboratories
Allen Brodsky U. S. NRC	**Allen Brodsky** Georgetown University	
Frazier Bronson Canberra/RMC	**Frazier Bronson** Canberra	**Frazier Bronson** Canberra
Dave McCurdy Yankee Atomic Electric Co.	**David E. McCurdy** Yankee Atomic Electric Co.	**David McCurdy** Technical Consultant
Roscoe Hall E. I. du Pont	**Kenneth G.W. Inn** NIST	**Kenneth Inn** NIST
Bill Moss LANL	**Myint Thein** ORNL	**Myint Thein** ORNL– Retired
Roger Falk **Rockwell International**	**Roger Falk** EG & G Inc.	**Thomas LaBone** MJW Corporation
Russ Mellor Yankee Atomic Electric Co.	**Stephen A. McGuire** U.S.NRC	**Dawn Lewis** LANL
Robert Wessman EAL Corporation	**Tom Buhl** LANL	**Steven Baker** PNNL
Mike Ortiz Eberline Laboratories	**Robert M. Loesch** U.S. DOE	**Anita Bhatt** RESL
	Tansy L. Taylor INEL	**J. Stan Morton** GEL Laboratories
	Gary Grothaus INEL *Consultant*	**Guy Marlette and Guy Backstrom.** RESL *Consultants*

- In 2001, a working group was reconvened to review the standard after 5 years of use.
  - Vowed wouldn’t take another 15 years to complete work.
  - The working group consensus was that the standard continued to serve as a useful framework for radiobioassay laboratory evaluation, but modifications were needed.
  - Deficiencies were identified in the recommended minimum detectable activity (MDA) equations, the relative bias and relative precision criteria were considered overly lenient, and new testing categories were needed for emerging analytical methods such as mass spectrometry.

N13.30 Revision

- Revised Draft Submitted to N13 May 2010
- N13 Comments Received July 2010
- N13 Comments Answered or Incorporated February 2011
- Received singe No Vote July 2011
- Minor changes proposed to draft couldn’t resolve No vote (wanted a exemption specified for their industry)
- Revised draft submitted for N13 vote July 2011
- N13.30 approved by ANSI December 2011

- All identified deficiencies have been addressed in the revision of the standard released in 2011.
  - The major section headings were retained,
  - Sections were reorganized, and
  - Content was revised to reflect lessons learned from 15 years of use.

1.0 Purpose and Scope

Substantially Unchanged

2.0 Normative References

"Application of this standard is contingent on adherence to the following references:"

Pacific Northwest
NATIONAL LABORATORY
Proudly Operated by Battelle Since 1965

3.0 Definitions

- Words defined in ISO Guide 99:2007 International Vocabulary of Metrology or NIST Tech Note 1297 not repeated.
- Added Combined Standard Uncertainty, which had replaced TPU in the lexicon.

Pacific Northwest
NATIONAL LABORATORY
Proudly Operated by Battelle Since 1965

4.0 Quality Assurance and Quality Control for Radiobioassay Laboratories (was 5.0)

- Consolidated *Records Retention* from 3.6 and 4.5
- Consolidated *Performance Criteria* from 3.4 and 4.3

Added Root Mean Square Error, the Combined Relative Bias and Relative Precision Criterion:

$$RMSE = \sqrt{B_r^2 + S_B^2} \leq 0.25$$

Pacific Northwest
NATIONAL LABORATORY
Proudly Operated by Battelle Since 1965

4.0 Continued

- Removed MDA equations (provided references)
- Added MDA self-test requirement (replicate measurements)

Table 1 – Maximum Acceptable Number of Incorrect Detection Decisions Out of N Measurements (5% significance level)

	Assumed Detection Error (α or β)		
N	**0.05**	**0.02**	**0.01**
5	1	1	1
10	2	1	1
15	2	1	1
20	3	2	1
25	3	2	1
30	4	2	1
35	4	2	1
40	4	2	2
45	5	3	2
50	5	3	2

Pacific Northwest NATIONAL LABORATORY
Proudly Operated by Battelle Since 1965

5.0 Direct Radiobioassay (In Vivo Counting) Measurements

(was 3.0 minus Performance Criteria and Records Retention)

6.0 Indirect Radiobioassay (In Vitro) Measurements

(was 4.0 minus Performance Criteria and Records Retention)

Pacific Northwest
NATIONAL LABORATORY
Proudly Operated by Battelle Since 1965

7.0 Performance Testing Program (was 6.0)

- Added stipulation to conduct program consistent with:

  ISO 17025 *General Requirements for the Competence of Testing and Calibration Laboratories*,

  ISO 43 *Proficiency Testing by Interlaboratory Comparisons*

  ANSI/NCSL Z540.2-R2002 *U.S. Guide to the Expression of Uncertainty in Measurement*

- Deleted the Option of Category Testing

  7.3 Test Selection

  The service laboratory shall designate from Table 2 (direct radiobioassay) and Table 3 (indirect radiobioassay) of this standard, the categories in which they want to be tested, and the specific radionuclide(s) to be used by the testing laboratory for testing.

Table 2 – Minimum Testing Level (MTL) for Direct Radiobioassay Performance Testing

Measurement Category	Type	Radionuclide	MTL [a,b]
I. Transuranium elements via L x-rays	Lung	^{238}Pu	9 kBq (0.24 µCi)
II. ^{241}Am	Lung	^{241}Am	0.1 kBq (2.7 nCi)
III. ^{234}Th	Lung	^{234}Th in equilibrium with its parent ^{238}U	0.5 kBq (14 nCi)
IV. ^{235}U	Lung	^{235}U	30 Bq (0.81 nCi)
V. Fission and activation products	Lung	Any two: ^{54}Mn ^{58}Co ^{60}Co ^{144}Ce or ^{57}Co Plus: ^{134}Cs[c] ^{137}Cs[c]	3 kBq (81 nCi) each 30 kBq (0.81 µCi) 3 kBq (81 nCi) See footnote c
VI. ^{237}Np	Lung	^{237}Np	30 Bq (0.81 nCi)
VII. Fission and activation products	Total body	All of: ^{134}Cs ^{137}Cs ^{60}Co[c] ^{54}Mn[c]	3 kBq (81 nCi) each See footnote c
VIII. Radionuclides in the thyroid	Thyroid	^{131}I and/or ^{125}I	3 kBq (81 nCi)

a. The upper bound of the testing range shall not exceed 20 times the stated MTL.
b. The activity of the highest and lowest testing radionuclides (also see footnote c) in any one test phantom shall be within a factor of three of each other except for ^{144}Ce in Category V, whose activity shall not exceed that of any other radionuclide by greater than a factor of 30.
c. These radionuclides shall be present in the phantom in appropriate amounts for interference, but shall not be tested.

Table 3 – Minimum Testing Level (MTL for Indirect Radiobioassay Performance Testing

Measurement Category	Radionuclide[a]	MTL [b] (per liter or per sample)
I. BETA activity: average energy <200 keV	^{3}H ^{14}C ^{35}S ^{228}Ra	2 kBq (54 nCi) 2 kBq (54 nCi) 20 Bq (0.54 nCi) 0.9 Bq (24 pCi)
II BETA activity: average energy = or >200 keV	^{32}P $^{89/90}Sr$ ^{90}Sr	5 Bq (135 pCi) 1 Bq (27 pCi)
III ALPHA activity: Isotopic analysis	$^{228/232}$ Th, ^{230}Th, ^{237}Np, ^{234}U, ^{238}U, ^{238}Pu or $^{239/240}Pu$, ^{241}Am	10 mBq (0.27 pCi)
IV Elemental mass ~~Elements (mass/volume)~~	Uranium	1 ~~20~~ µg
V Isotopic mass	^{99}Tc ^{129}I ^{235}U ^{236}U ^{238}U ^{237}Np ^{239}Pu ^{240}Pu	250 pg 250 pg 250 pg 250 pg 100 ng 250 pg 4 pg 4 pg
VI Photon activity: energy <100 keV	^{125}I ^{129}I	0.4 kBq (11 nCi)
VII Photon activity: energy = or >100 keV	^{60}Co ^{137}Cs	2 Bq (54 pCi)

Pacific Northwest NATIONAL LABORATORY

Proudly Operated by Battelle Since 1965

Annexes (formerly Appendices)

Deleted:

- Appendix A - Rationale for Methods of Determining MDA and Minimum Testing Level (MTL)
- Appendix B - Rationale and Practical Implications of the Bias and Precision Statistics, and the Criteria for Test Sample Accuracy

Retained:

- Annex A - Selection of Minimum Testing Levels (Appendix C)
- Annex B - Radiobioassay Procedures (Appendix D)
  - Table B-1 Synthetic Urine Matrix Recipe (added)
  - Table B-2 Synthetic Fecal Matrix Recipe (added)
- Annex C – Bibliography (now separate updated list)

Pacific Northwest NATIONAL LABORATORY
Proudly Operated by Battelle Since 1965