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EMPIRICALLY DETERMINED DECISION LEVELS DEVELOPMENT AND USE IN AN IN VIVO BIOASSAY PROGRAM

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Empirically Determined Decision Levels Development and Use in an *In Vivo* Bioassay Program

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ABSTRACT

This paper discusses a method to empirically determine and a use for reporting a decision level value for ^{137}Cs using a Canberra Accuscan II, direct radiobioassay (*in vivo*) system. The decision level value is used to determine the upper 5% of *in vivo* measurements for the purpose of recounting individuals. The paper overviews decision level concepts, the applicability of ANSI N13.30 and ANSI N42.2 and describes the specific process employed.

BACKGROUND

The concept of decision level reporting dates back nearly 30 years to the work of Lloyd Currie[1]. Currie's theory is based on two values: "Critical Level" (L_c), which is the value at which a signal *can not* be reliably detected and "Detection Limit" (L_D), the value at which a signal *can* be reliably quantified (see FIGURE 1). In direct radiobioassay (*in vivo*) counting, the term "Minimum Detectable Activity" (MDA) is used to describe L_D.

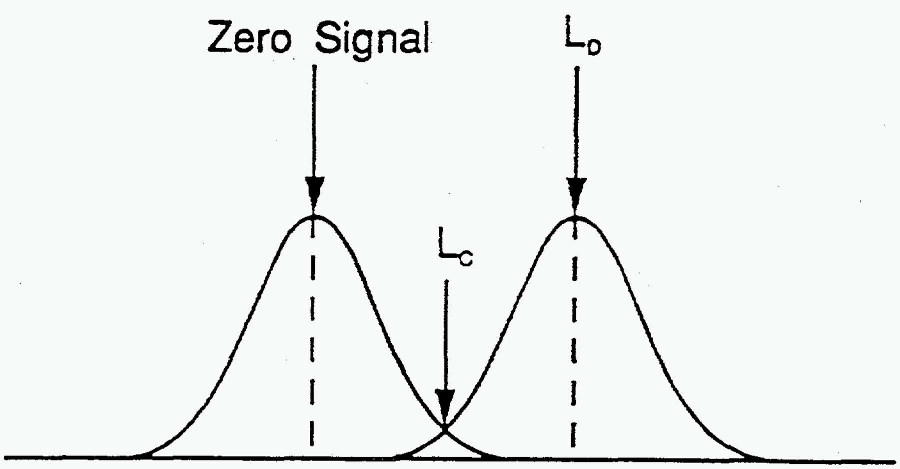

FIGURE 1

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[1] Analytical Chemistry, Volume 40, Number 3, March 1968

Note that if a sample were to contain activity that yields a count equal to L_c, there would be a Gaussian distribution having a mean of L_c and standard deviation σ_c representing all possible values that might be obtained from such a sample. For this distribution, 50% of the observations would be expected to be below the Critical Level. Thus, when a sample contains activity that yields a count equal to L_c, the probability of deciding that there is no signal (when in fact there is) corresponds to 50%. This is why an *a priori* determined L_c is not an adequate measurement of the detection capability of a counting system.

The challenge is in developing a logical methodology within the capabilities of the system in use, to determine the *Critical Level* or what we are calling an ***Empirically Determined Decision Level.***

The statistical portion of the ANSI N13.30 standard is based on Currie's work. Specifically, his work with Type I (α) and Type II (β) errors set to 0.05. The L_c value that he defines is related to the degree of confidence when generating results. That is to say there are two alternatives for consideration:

(i) decide that the observed counts are greater than background.

(ii) decide that the observed counts are not greater than background.

Over a period of time, erroneous decisions can be made. There are two types of errors:

(i) an error of the first kind (false positive), deciding that there is a signal, when in fact there is none.

(ii) an error of the second kind (false negative), deciding that there is not a signal, when in fact there is[2].

Currie's work is based on *zero* quantities of analyte being present in the *appropriate blank*. In reality, *zero* with respect to direct radiobioassay is slightly greater than true zero. This is due to the fact that the *appropriate blank* in direct radiobioassay is a person and all people contain some quantity of radionuclides, both natural and man-made as a result of dietary habits, water supply, physiological differences, etc. In an attempt to correct for this, empirically determined decision levels were developed. The empirically determined decision levels provide a logical cut off of ubiquitous radionuclide levels in personnel when evaluating potential occupational exposure.

[2]A Handbook of Radioactivity Measurements Procedures, NCRP Report No. 58, 1985.

The goal of this particular program is to identify the upper 5% of all *in vivo* counts performed for the nuclide of interest for the purpose of recounting those individuals. The expectation is that counts of persons involved in radiological work will be indistinguishable from those who have never been occupationally exposed to the nuclide of interest, and any activity detected will be only from natural sources. This is the result of radiological engineering and work controls used in the performance of radiological work that precludes the potential of internal exposure. Therefore, the assumption is that the exposed population will have the same 5% follow-up as the unexposed population. When a count **is** identified as being greater than the decision level, the individual is recounted for a longer period of time, to reduce statistical error in the measurement to confirm the absence or presence of radioactivity.

American National Standards Institute (ANSI) N13.30, Performance Criteria for Radiobioassay, and N42.2, Measurement Quality Assurance for Radioassay Laboratories, are documents outlining the performance criteria for radiobioassay. They are focused around quality assurance, evaluation of performance and the accreditation of service laboratories. Specific criteria address bias, precision and the determination of the MDA. The intent is to provide a basis for creating a sound quality assurance program for a locally maintained program, or one that is serviced by a contractor.

Specific procedures and methodologies for performing measurements and analysis are not (yet) standardized and are beyond the scope of the standards.

Appendix A of ANSI N42.2 provides some of the most insightful guidance with regard to determining empirical decision levels. Section A.7.3, Interpretation of Individual Measurement Results, states:

> *"For the purpose of having a laboratory interpret whether an individual sample measurement is different from its representative appropriate blank, it is recommended that the laboratory compare the net count or count rate of the measurement with a decision level calculated using the sample specific "appropriate" blank. The "appropriate" blank should include measurement interferences from impurities (elevated compton continuum, channel crosstalk from higher energy particles measured by liquid scintillation of alpha spectrometers, etc.,) that are not typically known a priorily or included in the nominal a priori decision limit. This represents the appropriate blank at the time of measurement. For some measurement processes, the determination of the "true" appropriate blank for each sample may be impractical. However, every effort should be taken to properly assess the parameters of the appropriate blank..."*

Although specifically addressing *in vitro* type analysis, the same principles can be applied to *in vivo* type of measurements understanding that an "appropriate blank" is a person.

ANSI N13.30 provides the statistical development of the MDA and L_c and also defines Critical Level as Decision Level. The developments (again based on the work of Currie) yield the following widely accepted (simplified) equations:

EQUATION 1

$$MDA = \frac{4.65\ \sigma_b + 3}{K\ T}$$

EQUATION 2

$$L_c = \frac{2.33\ \sigma_b}{K\ T}$$

Where:

σ_b	=	The standard deviation of the (appropriate) blank
K	=	Calibration factor(s)
T	=	Standard subject counting time

As noted in the ANSI N42.2 Appendix, in order for σ_b to be a valid parameter for establishing L_c and MDA, σ_b must be well known or be determined under current measurement conditions from a series of replicate measurements assuring a normal distribution.

One approach to determining σ_b is to study a statistically sufficient series of measurements on persons that were never occupationally exposed to the nuclide of interest. In this approach, the replicate measurements are counts of a series of unexposed individuals as *blanks* rather than a series of counts of a single *blank*. These *baseline measurements* propagate all error associated with the measurement process (i.e., variation of actual radiation between *blanks*, detector positioning, etc.). An additional inherent assumption made in this methodology is that sufficient counts exist for both background and sample, such that normal probability densities are applicable.

The ANSI N13.30 standard defines decision level as:

> *"The amount of a count or final instrument measurement of a quantity of analyte at or above which a decision is made that the analyte is definitely present."*

The empirically determined decision level for a particular nuclide and analytical method is analogous to the L_c concept in the ANSI N13.30 standard.

METHODOLOGY

The nuclide of interest used for this particular study was cesium-137 (^{137}Cs). The following is a description of the Canberra Accuscan II used:

The Accuscan II is a state-of-the-art *in vivo* monitoring system designed primarily for the detection of higher energy activated corrosion products and mixed fission products. The system is comprised of a steel tub with four inch thick, low radioactivity steel walls, ceiling, and floor.

Two closed-end coaxial hyperpure germanium detectors are used to perform whole body and lung monitoring for higher-energy gamma and to a lesser extent, X-ray emitting radionuclides. The relative efficiency of these detectors is 25%. A typical resolution achieved by this system at 122 keV is 0.9 keV FWHM and 1.9 keV FWHM at 1332 keV.

A Digital Equipment Corporation (DEC) VAXstation 4000 is used to process *in vivo* monitoring files, calibration spectra and data, quality assurance data, and results. An Okidata OL830 Plus is used to print out ABACOS Plus reports and Spectra.

The analysis software utilized is Canberra Industry's ABACOS Plus, a state-of-the-art whole body counting software application. It provides all of the software functions needed to perform *in vivo* measurements of nuclide activity and calculate internal dose values (if required) for whole body counting subjects. It provides menu-format options to create and calibrate counting systems using various combinations of hardware. The program has been customized for decision level reporting.

Gamma-M is a peak search algorithm within ABACOS Plus that allows User Defined Parameters. The User Defined Parameters feature enables the determination of decision level values. The affected parameters are "Reject MDA sigma" and "Reject MDA constant". To determine decision level values, these parameters are adjusted when analyzing the spectra of the unexposed population until 5% of the population spectra are flagged as "positive."

These parameters are used in locating potential peaks during the library-driven peak search phase. They specify how large the net peak area must be, relative to the standard deviation of the underlying background continuum, to be retained and reported as statistically significant (and hence, be used in calculating an activity). Peaks will be identified if:

> Net Peak Area > [(Reject MDA sigma) X (Standard Deviation of Background)] + Reject MDA constant

As the two parameters are decreased, the net peak area becomes relatively larger and the system becomes more *sensitive* to identifying peaks.

Canberra's recommended values for the Reject MDA sigma and Reject MDA constant are 2.5 and 3.0 respectively[3].

Before an activity for a region of interest is calculated, a peak must first be identified. The ability to adjust sensitivity parameters relating to peak identification is the key in this methodology.

The description of the procedure that follows refers to data obtained to derive the ^{137}Cs decision level. The same basic procedure can be followed to derive decision levels for other nuclides.

The process begins with *in vivo* counting a statistically significant number of individuals that have never been occupationally exposed to the nuclide(s) of interest. It was determined for the purpose of this study that one hundred individuals was adequate.

The one hundred spectra were analyzed using ABACOS Plus. The total number of counts within the ^{137}Cs region of interest for the particular nuclide were extracted from each spectrum (see TABLE 1).

Note that fractional counts are the result of the software determining the number of counts in a region of interest based on the energy calibration of a nuclide and not the associated channel number (i.e. 661.7 keV resides in channel 1838.05, not exactly channel 1838).

The 95th percentile of the empirical data was 6 counts (see TABLE 1). This value was used to calculate the decision level activity of 2.7 nCi. Note that if the calculated σ_b (1.99) of the data is used in Currie's L_c equation (see EQUATION 2), the result is 5 counts. Using this value as opposed to the empirically determined value to calculate the activity results in a slightly higher follow up rate (~10% as opposed to the desired ~5%).

This calculated "activity", understanding that it is simply counts converted to activity and not real activity, becomes the empirically determined *Decision Level* for the nuclide of interest. In other words, this amount becomes the "activity" at which a decision is made, for the particular count time performed, that significant counts in the region of interest are present and are above the 95th percentile for a non-occupationally exposed population and for which a recount will be performed.

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[3]ABACOS Plus User's Manual, Canberra Industries, Inc., June 1994

#	COUNTS	#	COUNTS	#	COUNTS	#	COUNTS
1	0.000000	26	1.939940	51	3.155030	76	4.000000
2	0.000000	27	2.000000	52	3.155030	77	4.000000
3	0.000000	28	2.000000	53	3.155030	78	4.000000
4	0.000000	29	2.000000	54	3.155030	79	4.000000
5	0.000000	30	2.000000	55	3.155030	80	4.155030
6	0.155029	31	2.000000	56	3.155030	81	4.155030
7	0.155029	32	2.000000	57	3.155030	82	4.155030
8	0.155029	33	2.155030	58	3.629880	83	4.310060
9	0.155029	34	2.155030	59	3.629880	84	4.310060
10	0.629883	35	2.155030	60	3.629880	85	4.310060
11	0.784912	36	2.155030	61	3.629880	86	4.629880
12	1.000000	37	2.155030	62	3.629880	87	4.629880
13	1.000000	38	2.310060	63	3.629880	88	4.784910
14	1.000000	39	2.629880	64	3.784910	89	4.784910
15	1.000000	40	2.629880	65	4.000000	90	4.784910
16	1.000000	41	2.629880	66	4.000000	91	5.629880
17	1.000000	42	2.629880	67	4.000000	92	5.629880
18	1.000000	43	2.629880	68	4.000000	93	5.629880
19	1.155030	44	2.629880	69	4.155030	94	5.629880
20	1.310060	45	2.784910	70	4.155030	95	5.629880
21	1.310060	46	2.784910	71	4.155030	96	6.000000
22	1.629880	47	3.000000	72	4.310060	97	6.629880
23	1.629880	48	3.000000	73	4.310060	98	7.000000
24	1.784910	49	3.000000	74	4.310060	99	9.629880
25	1.784910	50	3.000000	75	4.629880	100	9.939940

$\bar{x} = 3.11 \qquad \sigma = 1.99$

$x_{MIN} = 0 \quad x_{MAX} = 9.94$

TABLE 1

There is the possibility that the counts acquired in the region of interest are the result of Compton Scattering from varying levels of ^{40}K in the subjects or even spurious background counts. Regardless of the reason for the counts, the end result remains the same: an appropriate determination of σ_b.

The next step involved the use of a custom modification made to the ABACOS Plus software to allow decision level reporting. Similar capability is now commercially available in Canberra's Consolidated Distribution 4.0. The modification required utilizing a spare field in the detail portion of the ABACOS Plus *Nuclide Library Editor*. The field allows entry of a decision level value (as determined by the user) or may be left blank, in which case the software simply calculates (and reports if requested) the MDA for the nuclide. Basically, the value entered replaces the calculated MDA. The analysis algorithm compares this value to the count result in the analyzed spectrum. If the count result is greater than L_c, then the resultant activity will be reported (see Figure 2). Otherwise, the end result will be a report indicating a count result less than L_c.

The second change (not available on Consolidated Distribution 4.0) was an addition to the comment field of the final report to contain the words "Decision Level reported" when a zero activity is calculated (See FIGURE 3). This coincides with result reporting recommendations in ANSI N42.2.

The final step was adjusting the two Gamma-M peak search parameters so that when the total number of counts in the region of interest is equal to or greater than the desired value, a peak is located and the analysis reports a *positive* (i.e., greater than decision level) value. This is an empirical process and can not be appropriately demonstrated mathematically.

Although this may not be a *true* activity because of statistical error in identifying the peaks and the error associated with calculating an area of a *non-Gaussian* peak, it does provide a value that correlates to the number of counts in the region of interest.

There are several minor drawbacks to using this methodology. By setting the peak search parameters below the recommended values, the algorithm, in addition to identifying the peaks of interest, also identifies *any* other peaks that meet the peak search parameter setting criteria. The end result of this is the identification of a nuclide *not* of interest and for which a decision level has not been established (see FIGURE 4). This problem is especially evident when evaluating high energy spectrums. This is due primarily to the difference in background continuum and lower detection efficiencies in higher energy spectrums. The correction for this is identical to the one explained previously. Once the original analysis is complete and the nuclide of interest has been determined to be below the decision level, the settings of the peak search parameters are returned to the vendor recommended values. The spectrum is then reanalyzed with the reset parameters to confirm that the previously identified peaks are in fact below the MDA.

| ABACOS-Plus | | Printed:31-AUG-1995 11:03:49 | Page: 1 |

Subject name:	Identification #:
Employer:	Count Started: 2-FEB-1995 10:49:45.
Job Code:	Intake Date:
Reason:	Frequency:
Count type: Individual	Operator:
Height:	Weight:
Sex:	Date of Birth:
CVT:	
Comment:	

Counter: ACCUSCAN-II	Facility:
Arrangement/Geometry: STD/SSSUM	Elapsed Live Time: 0 00:10:00.00
Detector: WHOLE BODY	Elapsed Real Time: 0 00:10:00.11
Analysis limits: 150 to 4096	Count Rate: 6.445 6.040 0.00 0.00 0.00 0.00 0.00 0.00

Peak Search Results for STD/SSSUM

Nuclide	Energy (keV)	Activity (nCi)	%Error (2 SD)	%Gain	Fit	Area	Centroid (ch)	Comments
unknown?	238.44		68.2		0.62	18	662.44	
ANNIH	511.22	7.32	48.2	0.04	0.68	23	1419.62	
unknown?	609.12		71.4		0.31	11	1691.41	
CS-137	662.06	2.80	109.7	0.06	0.30	6	1838.39	
K-40	1460.49	249.	30.1	-0.02	0.21	49	4055.62	

Nuclide Results for STD/SSSUM

Nuclide	Activity (nCi)	%Error (2 SD)	Comments
K-40	249.	30.1	
CS-137	2.80	109.7	
ANNIH	7.32	48.2	
totals:	259.		

Energy Calibration Performed: 14-AUG-1992 12:28:54 STD/SSSUM Efficiency Calibration Performed: 14-NOV-1992 19:28:59
Libraries Used: ND_WBC_LIB:INHALATION.WLB,ND_WBC_LIB:INHALATION.WLB,ND_WBC_LIB:INHALATION.WLB
Analyses By: GAMMAM V1.2,PEAKEFF V2.2,NID V3.1,WTMEAN V1.8,MINACT V2.5

Operator: ______________________ Date: __________

Reviewed by: ______________________ Date: __________

HPRS: __________ Date: __________

System desc: All equipment from Canberra. 2 54x50mm HPGe detectors. HV Model 3106D, Amp Model 2022 ADC Model 8701, AIM Model ND556. Interfaced to a DEC VAXstation 4000. Analysis by ABACOS-Plus software.

FIGURE 2

| ABACOS-Plus | | Printed:31-AUG-1995 10:54:41 | Page: 1 |

Subject name:
Employer:
Job Code:
Reason:
Count type: Individual
Height:
Sex:
CWT:
Comment:

Identification #:
Count Started: 1-AUG-1995 14:16:56.
Intake Date:
Frequency:
Operator:
Weight:
Date of Birth:

Counter: ACCUSCAN-II
Arrangement/Geometry: STD/SSSUM
Detector: WHOLE BODY
Analysis limits: 150 to 4096

Facility:
Elapsed Live Time: 0 00:10:00.00
Elapsed Real Time: 0 00:10:00.11
Count Rate: 6.761 6.348 0.00 0.00 0.00 0.00 0.00 0.00

Peak Search Results for STD/SSSUM

Nuclide	Energy (keV)	Activity (nCi)	%Error (2 SD)	%Gain	Fit	Area	Centroid (ch)	Comments
ANNIH	510.40	7.83	48.3	-0.12	0.31	23	1417.04	
K-40	1461.34	261.	30.8	0.04	0.33	48	4058.11	

Nuclide Results for STD/SSSUM

Nuclide	Activity (nCi)	%Error (2 SD)	Comments
K-40	261.	30.8	
CS-137	< 2.70		Decision level reported
ANNIH	7.83	48.3	
totals:	269.		

Energy Calibration Performed: 24-APR-1995 16:30:22 STD/SSSUM Efficiency Calibration Performed: 25-APR-1995 13:40:49
Libraries Used: ND_WBC_LIB:INHALATION.WLB,ND_WBC_LIB:INHALATION.WLB,ND_WBC_LIB:INHALATION.WLB
Analyses By: GAMMAM V1.2,PEAKEFF V2.2,NID V3.1,WTMEAN V1.8,MINACT V2.5

Operator: ______________________ Date: __________

Reviewed by: ______________________ Date: __________

HPRS: __________ Date: __________

System desc: All equipment from Canberra. 2 54x50mm HPGe detectors. HV Model 3106D, Amp Model 2022 ADC Model 8701, AIM Model ND556. Interfaced to a DEC VAXstation 4000. Analysis by ABACOS-Plus software.

FIGURE 3

One further problem occurs when the peak search algorithm identifies a nuclide as being greater than the decision level AND has also identified additional nuclides as being present (see FIGURE 5). Correction of this problem is achieved by following the same procedure outlined above. The problem is that by resetting the parameters and determining that the extraneous nuclides previously identified are in fact below MDA, the nuclide of interest may now be reported as being less than the decision level. The user must then decide which parameter settings to use in generating the final report. This unfortunately is not correctable and, therefore, must be administratively handled by the user.

CONCLUSIONS

After several years of experience and several hundred *in vivo* measurements utilizing this methodology, the decision level values and parameter settings established continue to approximately yield the desired 5% false positive results.

This relatively simple method of determining decision levels permits the user to comply with the recommended reporting format of the American National Standards Institute using a commercially available product.

ABACOS-Plus	Printed:31-AUG-1995 11:14:42	Page: 1

Subject name:
Employer:
Job Code:
Reason:
Count type: Individual
Height:
Sex:
CWT:
Comment:

Identification #:
Count Started: 28-AUG-1995 09:16:58
Intake Date:
Frequency:
Operator:
Weight:
Date of Birth:

Counter: ACCUSCAN-II
Arrangement/Geometry: STD/SSSUM
Detector: WHOLE BODY
Analysis limits: 150 to 4096

Facility:
Elapsed Live Time: 0 00:10:00.00
Elapsed Real Time: 0 00:10:00.11
Count Rate: 6.616 6.275 0.00 0.00 0.00 0.00 0.00 0.00

Peak Search Results for STD/SSSUM

Nuclide	Energy (keV)	Activity (nCi)	%Error (2 SD)	%Gain	Fit	Area	Centroid (ch)	Comments
CE-141	145.32	4.35	165.6	-0.09	0.47	10	403.68	
unknown?	238.41		100.9		0.50	12	662.03	
ANNIH	510.99	8.53	45.0	0.00	0.66	25	1418.67	
unknown?	1333.11		173.4		0.08	4	3701.83	
K-40	1460.88	228.	32.9	0.00	0.29	42	4056.82	

Nuclide Results for STD/SSSUM

Nuclide	Activity (nCi)	%Error (2 SD)	Comments
K-40	228.	32.9	
CS-137	< 2.70		Decision level reported
CE-141	4.35	165.6	
ANNIH	8.53	45.0	
totals:	241.		

Energy Calibration Performed: 24-APR-1995 16:30:22 STD/SSSUM Efficiency Calibration Performed: 25-APR-1995 13:40:49
Libraries Used: ND_WBC_LIB:INHALATION.WLB,ND_WBC_LIB:INHALATION.WLB,ND_WBC_LIB:INHALATION.WLB
Analyses By: GAMMAM V1.2,PEAKEFF V2.2,NID V3.1,WTMEAN V1.8,MINACT V2.5

Operator: ______________________ Date: __________

Reviewed by: ______________________ Date: __________

HPRS: __________ Date: __________

System desc: All equipment from Canberra. 2 54x50mm HPGe detectors. HV Model 31060, Amp Model 2022 ADC Model 8701, AIM Model N0556. Interfaced to a DEC VAXstation 4000. Analysis by ABACOS-Plus software.

FIGURE 4

ABACOS-Plus	Printed:31-AUG-1995 11:09:31	Page: 1

Subject name:
Employer:
Job Code:
Reason:
Count type: Individual
Height:
Sex:
CWT:
Comment:

Identification #:
Count Started: 17-FEB-1995 13:41:52
Intake Date:
Frequency:
Operator:
Weight:
Date of Birth:

Counter: ACCUSCAN-II
Arrangement/Geometry: STD/SSSUM
Detector: WHOLE BODY
Analysis limits: 150 to 4096

Facility:
Elapsed Live Time: 0 00:10:00.00
Elapsed Real Time: 0 00:10:00.11
Count Rate: 6.455 5.833 0.00 0.00 0.00 0.00 0.00 0.00

Peak Search Results for STD/SSSUM

Nuclide	Energy (keV)	Activity (nCi)	%Error (2 SD)	%Gain	Fit	Area	Centroid (ch)	Comments
CE-144	133.50	30.8	113.1	-0.03	0.58	15	371.21	
unknown?	238.26		66.6		0.59	18	661.96	
ANNIH	510.95	6.14	55.6	-0.01	0.33	19	1418.88	
CS-137	662.09	2.97	97.7	0.07	0.13	7	1838.45	
K-40	1461.14	127.	45.2	0.02	0.36	25	4057.43	

Nuclide Results for STD/SSSUM

Nuclide	Activity (nCi)	%Error (2 SD)	Comments
K-40	127.	45.2	
CS-137	2.97	97.7	
CE-144	30.8	113.1	
ANNIH	6.14	55.6	
totals:	167.		

Energy Calibration Performed: 14-AUG-1992 12:28:54 STD/SSSUM Efficiency Calibration Performed: 14-NOV-1992 19:28:59
Libraries Used: ND_WBC_LIB:INHALATION.WLB,ND_WBC_LIB:INHALATION.WLB,ND_WBC_LIB:INHALATION.WLB
Analyses By: GAMMAM V1.2,PEAKEFF V2.2,NID V3.1,UTMEAN V1.8,MINACT V2.5

Operator: ______________________ Date: __________

Reviewed by: ______________________ Date: __________

HPRS: __________ Date: __________

System desc: All equipment from Canberra. 2 54x50mm HPGe detectors. HV Model 3106D, Amp Model 2022 ADC Model 8701, AIM Model N0556. Interfaced to a DEC VAXstation 4000. Analysis by ABACOS-Plus software.

FIGURE 5