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**REVIEW OF AN UPGRADE TO A LOW ENERGY LUNG MONITOR; COMPARISON  
OF EMPIRICALLY DETERMINED DECISION LEVELS USING ACT-II VS. ACT-I  
DETECTORS, AND DEVELOPMENT AND USE OF DECISION LEVELS IN AN *IN*  
*VIVO* BIOASSAY PROGRAM USING ABACOS 2000**

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**Review of an Upgrade to a Low Energy Lung Monitor ;  
Comparison of Empirically Determined Decision Levels Using ACT-II vs. ACT-I Detectors,  
And Development and Use of Decision Levels in an *In Vivo* Bioassay Program Using  
ABACOS 2000**

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## **ABSTRACT**

In this paper the work previously reported in 1994 on the theory, development and use of empirically determined decision levels in an *in vivo* bioassay program is discussed. Recently performed hardware and software upgrades to the Low Energy Lung Monitor (LELM) are also discussed. New data that was collected after the upgrades is provided. The new data is compared to and contrasted with the data that was collected prior to the upgrades. Details on the use of ABACOS 2000 software to accomplish decision level reporting are provided.

## **BACKGROUND**

Lloyd Currie's work<sup>1</sup> on reporting radioassay results provides the statistical basis for HPS N13.30-1996 and ANSI N42.23-1996. Both of these standards provide important guidance to internal dosimetrists and radiochemists.

The decision level concept is key to Currie's work. The decision level, as defined in ANSI 42.23-1996, is that quantity of analyte at or above which an *a priori* decision is made that a positive quantity of the analyte is present. An *a priori* decision is one made prior to the measurement (as compared to a *posteriori* decision, or after the measurement decision).

In HPS N13.30-1996, the appropriate blanks for a sample, person, or phantom is discussed. An appropriate blank is ideally, identical physicochemically and radiologically to the sample or person of interest. However, in an *in vivo* program it is difficult to determine an appropriate blank or decision level because of the differences between the counting subjects. The diet, water supply, physiological differences, etc. vary between the counting subjects. The internal dosimetrist must factor all of these differences into an *in vivo* program.

We proposed, nearly a decade ago, the use of an empirically determined decision level. We have utilized this reporting methodology since 1992. In late 1999, significant upgrades to the LELM were implemented, including the replacement of Canberra ACT-I detectors with Canberra ACT-II detectors, the replacement of VAX-VMS based computers with NT based personal computers (PCs), and the replacement of the ABACOS PLUS software with the ABACOS 2000 software. Since decision levels are specific to the analytical system and process, we re-determined the decision levels for the LELM.

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<sup>1</sup> Analytical Chemistry, Volume 40, Number 3, March 1968

## RADIOLOGICAL WORKERS, NON-RADIOLOGICAL WORKERS, and EMPIRICAL DECISION LEVELS

The purpose of an *in vivo* bioassay program is to determine whether a radiological worker has been exposed to internal radioactivity as a result of his/her occupation (hereafter referred to as operational radioactivity) and to determine the dose, if exposure has occurred. The internal dosimetrist is only interested in operational radioactivity. The sensitivities of the current analytical systems allow the measurement of very low levels of non-operational radioactivity, including levels due to naturally occurring radioactivity, which are indistinguishable from operational radioactivity.

Since the potential for internal exposure is precluded by radiological engineering and work controls that are used to perform radiological work, we expect the overall results of routine lung scans and whole body counts for radiological and non-radiological workers to be the same. Stating this statistically, we do not expect the distribution of baseline results for people who have never handled the nuclide of interest to be any different from the distribution of routine samples for radiological workers who handled the nuclide of interest. Our expectation can be tested by the following equation:

$$T = \frac{(\bar{X}_1 - \bar{X}_2) - (\mu_1 - \mu_2)}{\sqrt{\frac{S_1^2}{n_1} + \frac{S_2^2}{n_2}}}$$

where:

T is the calculated test statistic,

$\bar{X}_1$  is the mean of data available for distribution 1,

$\bar{X}_2$  is the mean of data available for distribution 2,

$\mu_1$  is the true mean of distribution 1,

$\mu_2$  is the true mean of distribution 2,

$S_1^2$  is the variance of distribution 1,

$S_2^2$  is the variance of distribution 2,

$n_1$  is the number of results in distribution 1, and

$n_2$  is the number of results in distribution 2.

The null hypothesis is that  $\mu_1 - \mu_2 = 0$ ; that is, there is no difference in the two means. To determine the test statistic(T) determine  $t_{v, 1-\alpha/2}$ , (using a Student t Distribution table) where  $\alpha = .05$  and  $v$  is determined by:

$$v = \frac{(a_1 + a_2)^2}{\frac{a_1^2}{n_1 - 1} + \frac{a_2^2}{n_2 - 1}}$$

where,  $a_1 = S_1^2/n_1$  and  $a_2 = S_2^2/n_2$ . If  $T < t_{v, 1-\alpha/2}$ , there is no statistically significant difference in the means of the two distributions, and our null hypothesis is upheld. Alternatively, if  $T > t_{v, 1-\alpha/2}$ , there is a statistically significant difference in the means of the two distributions.

This expectation of the equality of these two sample distributions is the basis for the development of what we call the empirical decision level.

Section A.7.3 of ANSI N42.23, **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 that are not typically known *a priori* or included in the *a priori* decision limit. This "true" decision level is different from the nominal *a priori* decision level in that it truly 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."

We consider that for **radiological worker *in vivo* bioassay**, the distribution of **non-radiological worker** results for the corresponding analytical process can be treated as the "appropriate blank". The decision level for radiological worker *in vivo* bioassay can be estimated by counting a population of non-radiological workers. The non-radiological worker results contain the interferences from impurities (and naturally occurring levels of radioactivity) that are typically present in lung scans and whole body counts for radiological workers.

If, as we stated earlier, Currie considers the decision level as that quantity of analyte at or above which an *a priori* decision is made that a positive quantity of the analyte is present, and we are willing to accept a 5% chance of a Type I (false positive) error, then the "true" decision level can be estimated by the 95th percentile of the distribution of results for non-radiological workers. By setting the empirical decision level at the 95th percentile of the distribution of results for non-radiological workers, we accept a false positive rate of approximately 5%. It is the 95th percentile of the distribution of results for non-radiological workers that is used to check individual results for radiological workers. Results below the decision level indicate that the subject is indistinguishable from a bioassay standpoint from the unexposed population, and followup is therefore not warranted.

As recommended in HPS N13.30-1996, Appendix A, equation A.9, the decision level can be calculated by:

$$L_c = 2.33S_b,$$

where  $S_b$  = standard deviation of the blank counts.

We have added an additional factor, the mean of the distribution, to this equation when distributions are not centered around zero, which is often the case.

$$L_c = \bar{X} + 2.33S_b,$$

where  $S_b$  = standard deviation of the blank counts and  $\bar{X}$  is the mean of the distribution of the results.

In addition, the decision level can be estimated from the 95th percentile result from the counts of the unexposed population. Comparing the calculated decision level and the 95th percentile result serves as a good crosscheck of the selected population and can be used to verify that the population is large enough, follows a normal distribution and does not have significant anomalies.

A critical point to make regarding empirical decision levels is that an empirical decision level is specific to a nuclide, an assay procedure, and the performing laboratory (i.e. counting equipment used). Any change to the analytical process could be reason to reestablish the decision level.

### **Pre-upgrade Testing and Assessment of Planned Upgrade**

In 1999, our inventory of ACT-I detectors, our VAX-VMS computer, counting chair, etc. was 10 years old. We were frequently changing detectors that caused a minimum downtime of about 4 hours each time, the computer, although operating well, was expensive to maintain, and the counting chair was definitely showing the wear and tear of 10 years of counting.

In the spring of 1999, Canberra brought an ACT-II detector pair to our facility for test and evaluation. A background count was obtained by using the installed banks of ACT-I detectors and recording the background for each detector. Then, one bank of detectors was disconnected, the ACT-II detectors, with a special shield ring installed, were connected, and a background count was repeated. Background was then determined for the ACT-II detectors.

When corrected for the differences in the detector surface areas, the ACT-II detector backgrounds were ~25% lower than the ACT-I detector backgrounds. Since decision level is essentially the study of background count results, it was our theory that if we switched from ACT-I detectors to ACT-II detectors, we could lower the decision level (and the corresponding "missed dose") by ~25%.

We also determined that based on:

- the design of the ACT-II detectors that moved the pre-amplifier away from the fill and vent tubes,
- the larger dewar size which required filling only once every two days,
- the significantly reduced maintenance cost of the ACT-II, and
- the significantly reduced maintenance costs of the PCs

that there were paybacks in reduced operating and maintenance costs that could be realized by performing the upgrade.

The planned upgrade appeared technically sound and financially attractive, in spite of the large investment. Payback on a \$400,000 investment will be realized in less than 7 years.

### Analytical System Description

The LELM used in this study was built by Canberra in 1989, and upgraded significantly by Canberra Industries in 1999. The following is a description of the system pre- and post-upgrade.

#### **Low Energy Lung Monitor (LELM) – Pre-upgrade**

The LELM was an *in vivo* monitoring system designed primarily for the detection of  $^{235}\text{U}$  and selected transuranics. The system was comprised of an iron room with 6.4 inch thick, low radioactivity iron walls, ceiling, and floor and a 0.5 inch thick layer of low radioactivity lead on all inner surfaces.

Two, four-detector arrays (8 detectors in all) of hyperpure, low energy germanium detectors (LeGe) were used to perform lung monitoring, for a total detector surface area of  $16,000\text{ mm}^2$ . The detectors had an automatic liquid nitrogen ( $\text{LN}_2$ ) fill system and detector protection circuits to ensure that the LeGes operated at the required  $\text{LN}_2$  temperatures. The  $\text{LN}_2$  system was rendered inoperable during subject counting by a pressure sensitive interlock switch, installed in the subject chair for the subject's safety. Figure 1 is a picture of the inside of the pre-upgraded shield.

Each detector had an active diameter of 50.9 mm, which correspond to a total active area of slightly greater than  $2,000\text{ mm}^2$  for each detector, and  $16,000\text{ mm}^2$  for all eight detectors. The thickness of each detector was 15 mm. The distance from the inner surface of the 0.5 mm beryllium window to the detector was 4 mm. This distance allowed for slight flexing of the window without detector damage. The typical resolution achieved by these detectors at 5.9 keV was 350 eV full width at one-half maximum (FWHM) and 600 eV FWHM at 122 keV.

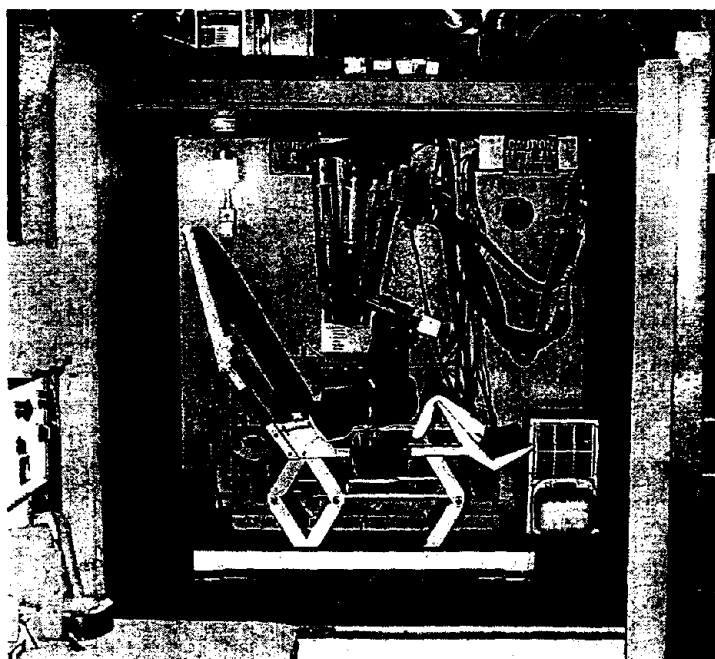


Figure 1: LELM Shield Room Pre-upgrade



## Computing Equipment

A Digital Equipment Corporation (DEC) microVAX 3400 computer and an X-terminal were used to process *in vivo* monitoring files, calibration spectra and data, quality assurance data, and results. An Okidata OL830 Plus was used to print out ABACOS PLUS reports and spectra. The microVAX 3400, LELM detectors, and X-terminal, as well as a VAXstation 4000, ACCUSCAN II detectors, and ACCUSAN II detector motion controller were nodes on a 50 ohm Thinwire Ethernet network.

## Computing Software

The analysis software utilized was Canberra Industries ABACOS PLUS. It provided the software functions needed to perform *in vivo* measurements of nuclide activity and calculate corresponding internal doses, if required. It provided menu-format options to create and calibrate counting systems using various combinations of hardware. The program, at our request, had been customized by Canberra to support decision level reporting.

Gamma M was the peak search algorithm within ABACOS PLUS that allowed the user to define certain parameter values. The ability to adjust the sensitivity parameters that relate to peak identification was the key to determine and utilize empirically determined  $L_c$  values using the Canberra ABACOS PLUS *in vivo* counting software. The user definable parameters were "Reject MDA sigma" and "Reject MDA constant". These parameters were used to locate potential peaks during the library-driven peak search routine. These parameters specified how large the 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 to calculate an activity). Peaks were identified if:

$$\text{Net Peak Area} > ((\text{Reject MDA sigma}) * (S_b)) + \text{Reject MDA constant.}$$

As the two parameters were decreased, the net peak area became larger relative to the screening criteria value, and the system became more "sensitive" to identify peaks. In effect, these two parameters were used to "trick" the software into thinking it saw these nuclides about 5% of the time. Special reporting templates that were added to our software were used to report data that was less than the determined decision level.

## Low Energy Lung Monitor (LELM) – Post-upgrade

The LELM is a state-of-the-art *in vivo* monitoring system still utilized primarily for the detection of  $^{235}\text{U}$  and selected transuranics. The system utilizes the same iron room with 6.4 inch thick, low radioactivity iron walls, ceiling, and floor and a 0.5 inch thick layer of low radioactivity lead on all inner surfaces. The old  $\text{LN}_2$  fill hardware and metal frame/canvas subject counting chair were replaced with a new  $\text{LN}_2$  fill box and a dental chair. There is substantially less hardware in the shield room now (see figure 2).

The two, four-detector arrays of hyperpure, low energy (ACT-I) detectors were replaced with

two ACT-II broad energy germanium (BeGe) detector pairs. Each ACT-II detector is 3800 mm<sup>2</sup> in area, for a total of 15,200 mm<sup>2</sup>, or 95% of the total detector surface area of the ACT-I detectors. These are installed in a trapezoid configuration rather than square to better match the location of lungs in humans. The ACT-II detectors utilize carbon vs. beryllium windows. An automatic liquid nitrogen (LN<sub>2</sub>) fill system and detector protection circuits are used to ensure that the BeGe detectors operate at the required LN<sub>2</sub> temperature. This LN<sub>2</sub> system is rendered inoperable during subject counting by an interlock switch in the LN<sub>2</sub> fill line.

Typical resolution achieved by these BeGe detectors at 5.9 keV is 403 eV full width at one-half maximum (FWHM) and 629 eV FWHM at 122 keV.



Figure 2 – LELM Shield Room post-upgrade

### Computing Equipment

The Digital Equipment Corporation (DEC) microVAX 3400 computer and X-terminal were replaced by a PC containing 160 MB RAM and a 4 GB hard drive (plus assorted CD readers and writers), and powered by a 200 MHz Pentium-Pro chip running Windows NT 4. The PC is used to process *in vivo* monitoring files, calibration spectra and data, quality assurance data, and results. A LaserJet 4000 printer is used to print out ABACOS 2000 reports and spectra. All *in vivo* monitoring systems are connected on a 50 ohm Thinwire Ethernet network, and personnel data is stored in a single DB2 file accessed by both the LELM and an ACCUSCAN-II whole body counter.

## Computing Software

The Canberra Industries ABACOS PLUS software was replaced with ABACOS 2000. ABACOS 2000 provides nearly the same software functions as ABACOS PLUS, but has some additional features that are very powerful and beneficial, and uses a true graphical user interface (GUI) design.

The Gamma M peak search algorithm used in ABACOS PLUS is retained in ABACOS 2000, allowing the user to define certain parameter values. However, integral to ABACOS 2000 reporting is built in the ability to have nuclide specific "reporting levels". These reporting levels are used to report data less than the reporting value as "<" and greater than the reporting level as the calculated activity. With ABACOS 2000, the ability to adjust peak sensitivity parameters, that directly drive peak identification, is no longer the key to determining and utilizing empirically determined  $L_c$  values. The software now utilizes the calculated activity as compared to the reporting level value, a much cleaner approach. The user definable parameters "Reject MDA sigma" and "Reject MDA constant" are still resident in the software and utilized for peak search sensitivity. For our application, we have used values of "0" for both parameters (i.e., maximum peak detection) for production counting.

## METHODOLOGIES FOR DETERMINING EMPIRICAL DECISION LEVEL( $EL_c$ )

### Prior Decision Level Work using ABACOS Plus

In 1992, decision levels for  $^{235}\text{U}$  and  $^{238}\text{U}$  ( $^{234}\text{Th}$  daughter) were determined for the LELM using the process outlined below.

- 1.) Personnel who had never been operationally exposed to the nuclide of interest were identified.
- 2.) A statistically meaningful number of counts (minimum of 40-50) were performed using the personnel identified above as subjects, and using the same analytical process that the operational subjects would be subject to.
- 3.) Results of the decision level samples were reported as counts in the region of interest.
- 4.) Once the data of the non-radiological worker population had been collected, the data was ranked in order of the results.
- 5.) The empirical decision level was determined by calculating the standard deviation of the results of the non-radiological worker population, multiplying the standard deviation by 2.33, and adding in the mean of the population, if the calculated value was non-zero.
- 6.) Decision level counts in the region of the interest were converted to activity to determine the decision level in nCi.
- 7.) Using an iterative process in ABACOS Plus, Reject MDA Constant and Reject MDA Sigma were adjusted until only counts with results above the decision level(s) were

reported as positive. These became the operational settings of ABACOS Plus.

Using the above process, decision levels of 0.068 nCi for  $^{235}\text{U}$  and 0.62 nCi for  $^{234}\text{Th}$  were determined. Over the years these decision levels were used for operational counts, approximately 5% of the counts performed yielded positive results as expected in theory. This is solid evidence that the decision levels were correct for the analytical process. All of the counts that were positive on the first count were always negative on recounting for a slightly longer period of time. Again, this is expected in theory and by the statistics, because assuming the operational population is no different than the population of non-radiation workers, these are truly, as the theory defines them, **FALSE POSITIVES**.

### **Current Decision Level Work Using ABACOS 2000**

ABACOS 2000 is a very powerful analytical tool. Its built in features provide simple yet very fast decision level determination capabilities as compared to ABACOS Plus.

Based on the pre-test performed, since decision levels are really the determination of a "zero" radioactivity distribution, a 25% reduction in background with the ACT-II detectors should translate into a 25% reduction in the determined decision level. We theorized that if we implemented ACT-II detectors, the decision levels should be ~ 0.05 nCi for  $^{235}\text{U}$  and 0.47 nCi for  $^{234}\text{Th}$ .

We established the Reject MDA Constant and Reject MDA Sigma at the same values used in our counting procedure for ABACOS Plus, and performed a series of 51 counts on people who have never handled un-irradiated uranium. No positive peaks were identified as was the expectation. Next, the Reject MDA Sigma and Reject MDA Constant were set to 0 (maximum peak detection sensitivity), and all 51 spectra were batch processed again. This took only a matter of minutes to accomplish. ABACOS 2000 calculated activity for any peak that was found. Using the 185 KeV peak for  $^{235}\text{U}$  and 93 KeV peak for  $^{234}\text{Th}$ , calculated activities were ranked.

Data reduction was performed two ways.

1.) The peak search parameters (Reject MDA Sigma and Reject MDA Constant) for ABACOS 2000 were set to "0", forcing all peaks to be found. Activities were calculated based solely on the key-line counts. All 51 spectra were reprocessed using these peak search parameters. The calculated (i.e., theoretical) decision levels for  $^{234}\text{Th}$  and  $^{235}\text{U}$  in nCi were determined from the standard deviation of the distribution for each nuclide, and then calculating the decision level ( $L_c$ ) by the formula:

$$L_c = (2.33 S_b)/K$$

where  $S_b$  = is the standard deviation in the background activity, and K is the calibration constant.

2.) Using the results from the 51 counts, the nCi data reported by ABACOS 2000 was reviewed to find the 95<sup>th</sup> percentile, i.e., 3<sup>rd</sup> highest result (0.051 nCi for  $^{235}\text{U}$  and 0.465 nCi for  $^{234}\text{Th}$ ).

Rounded to two decimal places, the decision level values of 0.05 nCi for  $^{235}\text{U}$  and 0.47 nCi for  $^{234}\text{Th}$  were entered into the ABACOS 2000 report template to screen out any analyses with activity calculated below these values.

The 51 spectra were then re-processed using the above peak search parameter values (0,0) and the decision level screening levels (0.05 nCi, 0.47 nCi) to verify that 3/51 results (~5%) would be forced to be false positive. 3 results out of 51 (5.8%) had positive  $^{234}\text{Th}$  reported above the decision level, and 3 results out of 51 (5.8%) had  $^{235}\text{U}$  results reported above the decision level, as desired. A key difference between ABACOS PLUS and ABACOS 2000 is that in ABACOS PLUS the peak search parameters had to be adjusted to force the false positives, hence the present operating values of Reject MDA Sigma = 2.65 and Reject MDA Constant = 3. In ABACOS 2000, the peak search parameters can be left at their maximum sensitivity (Reject MDA Sigma = 0, and Reject MDA Constant = 0), and allow the software to use the entered decision level values to screen out positives below these values.

### DATA COLLECTED

The following table provides demographics and results for the 51 people counted for the LELM decision level study.

ID	Sex	Age	Wt	CWT	$^{235}\text{U}$ cts.	$^{235}\text{U}$ nCi	$^{234}\text{Th}$ cts.	$^{234}\text{Th}$ nCi
1	M	22	173	3.2	0	0	18	0.510
2	M	35	202	2.9	0	0	0	0
3	M	58	232	2.8	0	0	0	0
4	M	44	172	2.4	15	0.041	0	0
5	M	33	206	2.6	0	0	0	0
6	M	67	153	2.5	0	0	0	0
7	M	52	205	2.9	0	0	0	0
8	M	50	219	2.6	0	0	0	0
9	F	52	230	2.8	0	0	0	0
10	F	47	175	2.4	14	0.039	0	0
11	M	48	213	3.3	0	0	0	0
12	F	33	172	2.9	0	0	0	0
13	M	34	210	3.1	0	0	0	0
14	M	28	193	3.2	0	0	0	0
15	M	50	196	2.8	19	0.058	0	0
16	F	40	127	1.9	0	0	0	0
17	M	41	170	2.3	0	0	0	0
18	M	38	239	2.7	0	0	0	0
19	M	46	256	2.5	0	0	10	0.233
20	M	58	203	3.4	0	0	0	0
21	M	49	119	3.0	0	0	27	0.716
22	F	41	136	2.3	0	0	0	0
23	M	24	184	2.8	0	0	0	0
24	M	40	176	2.8	17	0.054	0	0

25	M	51	137	2.3	19	0.050	0	0
26	M	47	218	3.3	0	0	0	0
27	M	24	191	2.8	0	0	0	0
28	M	27	207	3.0	0	0	0	0
29	F	40	154	2.3	0	0	0	0
30	F	42	162	2.7	0	0	0	0
31	F	47	200	3.2	0	0	0	0
32	F	53	184	2.3	0	0	0	0
33	F	50	181	3.2	0	0	16	0.464
34	M	50	272	3.8	0	0	0	0
35	M	42	166	2.7	0	0	0	0
36	F	40	116	2.5	0	0	0	0
37	M	39	221	3.0	0	0	0	0
38	M	53	174	2.3	19	0.051 <sup>2</sup>	0	0
39	M	48	207	3.0	0	0	0	0
40	F	30	160	2.3	0	0	0	0
41	M	39	196	3.0	0	0	0	0
42	F	47	163	2.3	0	0	0	0
43	M	32	176	2.8	0	0	27	0.269
44	M	50	167	2.3	1	0.004	0	0
45	F	30	197	3.2	0	0	0	0
46	F	46	173	1.8	0	0	0	0
47	M	22	170	2.3	0	0	0	0
48	F	42	150	2.1	0	0	0	0
49	M	45	227	3.5	0	0	0	0
50	M	54	194	3.1	0	0	17	0.465 <sup>3</sup>
51	F	50	148	2.1	0	0	0	0

Based on a 25% reduction in background counts using ACT-II detectors versus ACT-I detectors, and the previous decision level values, the expected new decision level values are 0.068 nCi X .75, or 0.051 nCi for <sup>235</sup>U, and 0.62 X .75, or 0.465 nCi for <sup>234</sup>Th. These are exactly the numbers that were obtained empirically.

Theoretical decision levels can also be calculated per appendix A of HPS N13.30, using the equation:

$$L_c = (2.33 * S_b)/K, \text{ where}$$

$S_b$  is the standard deviation of the background counts and K is the calibration factor for the nuclide of interest. For purposes of the  $L_c$  study, extrapolated efficiency factors for the average chest wall thickness (CWT) of 2.7 cm was used to determine  $L_c$ .

<sup>2</sup> 95<sup>th</sup> percentile for <sup>235</sup>U

<sup>3</sup> 95<sup>th</sup> percentile for <sup>234</sup>Th

For  $^{235}\text{U}$ : The standard deviation of the  $^{235}\text{U}$  counts was calculated to be 5.21. The calculated  $L_c$  is 0.035 nCi. Compared to the expected value, and the empirical value, the calculated decision level is about 30% lower. Using the calculated decision level value would force far more than 5% false positives.

For  $^{234}\text{Th}$ : The standard deviation of the  $^{234}\text{Th}$  counts was calculated to be 5.7. The calculated  $L_c$  is 0.32 nCi. Compared to the expected value, and the empirical value, again the calculated is about 30% lower. Using the calculated decision level value would force far more than 5% false positives.

We consider that the empirical and calculated data actually correlates fairly closely, considering that the calculated values are not expected to yield good approximation of  $L_c$  because the data is not normally distributed. Differences are reduced to about 20%, if distribution means are added in.

## IMPLEMENTATION OF DECISION LEVEL REPORTING

ANSI N.42.23 provides recommendations on the interpretation of radioassay results. Specifically, as mentioned in section A.7.3, the laboratory should compare the sample count or count rate to the decision level count or count rate using an appropriate blank. The empirical decision level, determined as above, becomes the screening level for reporting results as "positive" or negative. Again it is emphasized that a ~5% false positive rate is built into the process. Using the newly determined decision levels for the LELM, 102 LELM production counts have been performed for radiological workers, and 5 counts have had positive results reported on the initial count, exactly as decision level theory predicts.

Although ANSI N42.23 is moot regarding *in vivo* analysis specifically, we consider that these same principles can be applied to *in vivo* measurements with the understanding that an "appropriate blank" can be estimated from count results from an unexposed population of people.

Once the empirical decision level for a specific analytical process has been established, reporting requirements and processes need to be worked out. Section A.8 of ANSI N42.23 provides recommendations regarding results reporting. Our reporting is consistent with ANSI N42.23; however, we have specific recommendations regarding when and how this information should be reported. Our recommendation is to store the final ABACOS 2000 report in the radiation health record, including the following information recommended in ANSI N.42.23:

- sample identification code (i.e. name and social security number)
- reference date/time (specifically the count date/time)
- identification of the specific measurement procedure (counting system [LELM, high energy lung monitor (HELM), whole body count (WBC)] and we would add key instrumentation information like make, model serial numbers, etc.)
- identification of radionuclides specified for analysis and others found,
- the result reported as:
  - < Decision Level (Value & Units), if less than decision level, or
  - Result  $\pm 2 \sigma$  error, if greater than decision level.

We do not recommend that the actual analytical result be stored in the radiation health record unless the result exceeds the empirical decision level. Storing data less than the empirical decision level only serves to confuse the record system over time. As we stated earlier, results below the decision level indicate that the subject is indistinguishable from a bioassay standpoint from the unexposed population, and followup is therefore not warranted.

### **Summary**

Empirical decision levels provide a simple but powerful method of screening radiological worker *in vivo* sample results. ABACOS 2000 provides optimum functionality to easily establish decision levels and implement decision level reporting.

Conversion from ACT-I to ACT-II detectors has both significant technical and cost advantages. Reduced backgrounds with ACT-II detectors drives down decision levels by a corresponding fraction, and lowers the missed dose associated with performing an analysis at a given frequency. Elimination of VAX-VMS computers in favor of PCs has significant cost advantages.