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Analysis of Uranium Urinalysis and *In Vivo* Measurement Results from Eleven Participating Uranium Mills

Prepared by H. B. Spitz, J. C. Simpson, T. L. Aldridge

Pacific Northwest Laboratory
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ABSTRACT

Uranium urinalysis and *in vivo* examination results obtained from workers at eleven uranium mills between 1978 and 1980 were evaluated by Pacific Northwest Laboratory (PNL) at the request of the U.S. Nuclear Regulatory Commission (NRC). The main purpose of this evaluation was to determine the degree of the mills' compliance with bioassay monitoring recommendations given in the draft NRC Regulatory Guide 8.22 (USNRC 1978). The effect of anticipated changes in the draft regulatory guidance, as expressed to PNL in May 1982, was also studied.

Statistical analyses of the data showed that the bioassay results did not reliably meet the limited performance criteria given in the draft regulatory guide. Furthermore, quality control measurements of uranium in urine indicated that detection limits at $\alpha = \beta = 0.05$ ranged from 13 $\mu g/\ell$ to 29 $\mu g/\ell$, whereas the draft regulatory guidance suggests 5 $\mu g/\ell$ as the detection limit. Recommendations for monitoring frequencies given in the draft guide were not followed consistently from mill to mill.

The results of these statistical analyses indicate a need to include performance criteria for accuracy, precision, and confidence in revisions of the draft Regulatory Guide 8.22. Revised guidance should also emphasize the need for each mill to continually test the laboratory performing urinalyses by submitting quality control samples (i.e., blank and spiked urine samples as open and blind tests) to insure that the performance criteria are being met. Recommendations for a bioassay audit program are also given.

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ANALYSIS OF URANIUM URINALYSIS AND *IN VIVO* MEASUREMENT RESULTS FROM ELEVEN PARTICIPATING URANIUM MILLS

SUMMARY

Bioassay data collected between 1978 and 1980 by eleven uranium mills were evaluated by PNL at the request of the NRC. The primary objectives of the study were to evaluate the quality of the data and to determine whether bioassay monitoring practices at these eleven mills were consistent with recommendations given in the draft NRC Regulatory Guide 8.22 (USNRC 1978).

The only performance criteria for bioassay measurements cited in the draft NRC regulatory guidance are minimum detection limits for uranium urinalyses and *in vivo* examinations. The data in this study did not meet these criteria at the 95% confidence level; however, this level is not required in the draft regulatory guidance. Overall, these bioassay results were found to be highly variable and, thus, unreliable as a monitoring tool to determine whether millworkers have been exposed to airborne uranium. Measurement reliability would be improved significantly if guidance were proffered to establish minimum acceptable limits for measurement accuracy (bias), precision, and confidence. Furthermore, laboratories or vendors that perform uranium urinalyses or *in vivo* examinations must be tested on a routine basis by mill personnel to insure that the performance criteria are, in fact, being met.

The degree with which bioassay monitoring programs were found to comply with the draft NRC regulatory guidance varied from mill to mill and was apparently unrelated to the size of the work force or the type of yellowcake produced at the mill. Recordkeeping practices at the mills, as exemplified by the bioassay data received for study, were inadequate, at best. Records were essentially incomplete and could not easily be reviewed or analyzed for trends.

Both the regulatory agency and the uranium milling industry would benefit from an explicit statement of guidelines for performance criteria, recordkeeping, and testing their bioassay laboratories or vendors. With such guidelines, the reliability of bioassay measurement programs will be improved from that observed in this study.

INTRODUCTION

Yellowcake is the generic term applied to the end product of uranium milling. It has many different chemical forms and varies markedly from mill to mill, or even within the same batch produced at a single mill because of differences in uranium extraction and drying processes. Despite its name, yellowcake is not necessarily yellow but may be dark green or black when dried at high temperatures. The drying mechanism may produce yellowcake that is a fine powder or granular in appearance.

The drying temperature of uranium supposedly predicts the behavior of the yellowcake in the human respiratory system because it may affect the solubility of yellowcake in the lung and its ultimate translocation from the lung to other body organs and tissues (Eidson 1980; Kalkwarf 1979). For example, oxides created by high-temperature drying are, in general, the least soluble in lung fluid and hence produce the greatest radiological hazard to the lungs. Soluble yellowcake materials are less hazardous to the lungs but present a greater radiological and toxicological risk to other internal body organs and tissue (i.e., skeleton and kidney). Eidson and Mewhinney (1980), in their study of yellowcake dissolution conducted *in vitro* using simulated lung fluid, find that yellowcake solubility *in vivo* may be highly variable because the chemical composition of yellowcake varies greatly.

Routine urinalysis and *in vivo* examinations for uranium are proposed in the draft NRC Regulatory Guide 8.22 (USNRC 1978) as monitoring procedures for selected uranium mill workers. The terms "whole body count" and "in vivo examination" are used interchangeably in this report to represent a quantitative measurement of uranium present in the respiratory system of a worker by use of photon detectors placed on the anterior thorax. Results are used to verify that control procedures, which are designed to limit airborne uranium exposure to workers at the mill, are adequate. Furthermore, these monitoring procedures can also confirm the intake of uranium in an exposed worker and be used to evaluate dose resulting from internally deposited uranium. Whenever uranium bioassay measurements indicate that a uranium uptake may have occurred, actions can be taken by the mill health physicist to protect affected workers from any further uptake.

The objective of this work was to analyze uranium urinalysis and *in vivo* examination results from workers at eleven participating uranium mills from 1978 through 1980 and determine how well these bioassay monitoring programs complied with recommendations given in the draft NRC Regulatory Guide 8.22 USNRC 1978). We also were requested to study what impact, if any, might be expected from proposed changes in the draft regulatory guidance for bioassay at uranium mills. Management personnel from these eleven uranium mills volunteered the bioassay data to the NRC, which then requested that PNL perform the following tasks:

- determine the number and frequency of individual uranium urinalysis and whole body counter (WBC) examination results that exceed recommended and proposed (May 1982) action levels

- determine the number and frequency of individuals whose uranium urinalysis or WBC examination results exceed recommended and proposed (May 1982) action levels

- describe the distribution of uranium urinalysis and WBC examination results for each mill and for all the mills in the group

- evaluate the quality of the data obtained from the mills and investigate any observed trends

- investigate relationships or correlations among uranium urinalysis, WBC, and air sampler results

- recommend a uranium urinalysis sampling frequency based upon the observed excretion (or retention) of uranium in mill workers.

The NRC further requested an evaluation of the bioassay data to determine the degree to which uranium mills were meeting the recommendations specified in the draft regulatory guidance. Measurement results were compared to the investigation level (15 μg/ℓ), action level (30 μg/ℓ), and the detection level (5 μg/ℓ) specified in the draft regulatory guide. In addition, the data were also evaluated against NRC's proposed action and investigation levels for uranium in urine as considered in May 1982 (viz., 20 and 32 μg/ℓ).

The NRC has proposed monitoring guidelines for bioassay measurements to aid in assessing the uranium exposure hazards of the work place. Uranium mill health physicists are expected to respond appropriately whenever bioassay measurement results approach or exceed levels considered potentially hazardous. Therefore, bioassay measurements should be highly reliable at those levels so that the frequency of false negative bioassay results is acceptably low for unknowingly exposed workers. This concept of measurement reliability is not part of the draft regulatory guidance, but we considered it important enough to include in the evaluation of the uranium mill bioassay data.

METHODS

This study involved 17,039 urinalysis and 1,677 *in vivo* uranium measurement results obtained from 1,369 and 909 workers, respectively. A PDP 11/70 minicomputer was used to process and store this data using a commercially available database management software package called "TOTAL". A computer file, containing uranium bioassay data as well as other related information, was created for each mill worker. Tables 1 and 2 illustrate the format used for uranium urinalysis and *in vivo* measurement results, respectively. A reproduction of a page from a worker's computer file is illustrated in Figure 1.

TABLE 1. Record Format Used for Analysis of Uranium in Urine (BIO)

Item	Specifications	Example
Name	First initials plus full last name, if available. This field is nonessential since ID # will be the fixed identifier.	AB Watanable
ID	Nine alphanumeric characters for Social Security number or other unique identifier created from a composite of mill and worker ID number. A unique worker number may be assigned if no other identification is provided by the mill.	999-99-9999
Job	The title or work location of the mill worker.	Acid Leach
Date	Date of collection (mo/d/yr) may be incomplete since some data exclude day.	072078
DL Flag	Detection level flag -- used whenever the result is equal to or less than the detection level for the particular procedure used by the mill or laboratory. The database will not contain the actual detection level value but will only flag those results that are appropriate.	
Result	The result is always assumed to be natural uranium and reported in µg/ℓ.	123.4
Error	Reported measurement error, if any.	±123.4
Mill ID	A unique identifier code will be assigned to each mill.	99
Refer	Whenever any other result (WBC, BIO, or AIR) is relatable to this result, a code is entered.	W, B, A
Comment	Thirty-character alphanumeric field.	

TABLE 2. Record Format Used for Whole Body Counter Examinations (WBC)

Item	Specifications	Example
Name	First initials plus full last name, if available. This field is nonessential since ID # will be the fixed identifier.	AB Watanable
ID	Nine alphanumeric characters for Social Security number or other unique identifier created from a composite of mill and worker ID number. A unique worker number may be assigned if no other identification is provided by the mill.	999-99-9999
Job	The title or work location of the mill worker.	Crusher
Date	Date of collectio (mo/d/yr) may be incomplete since some data exclude day.	071278
Time	Time of the examination (24-h clock).	1730
Result	Natural uranium.	123.4
Error	Reported measurement error, if any.	±123.4
Units	Natural uranium may be reported in nCi or mg. Only results in mg will be stored. Results reported in nCi will be converted to mg upon entry. A conversion equation will be created for this purpose.	mg
Result	235 U.	123
Error	Reported measurement error, if any.	±123
Units	Micrograms.	µg
Result	Some measurement results are available for 226 Ra.	12
Error	Reported measurement error, if any.	±99
Units	Nanocurie.	nCi
Mill ID	A unique identification code will be assigned to each mill.	99
Refer	Whenever any other result (WBC, BIO, or AIR) is relatable to this result, a code is entered.	W, B, A
Comment	Thirty-character alphanumeric field.	

ID	NAME	JOB OR LOCATION	MILL	SS NO
064215			06	- -

BIO MEASUREMENT	MO DAY YR	UG/L	ERROR	DET FL	ALI	COMMENT	REF
	11/26/78	24.0	0.0		1		
	10/31/77	1.0	0.0	Y		AT HOME	
	08/03/77	1.2	1.0			AT HOME	
	10/29/78	5.0	0.0	Y			
	10/29/78	4.0	0.0				
	10/09/78	5.0	0.0	Y			
	10/02/78	6.0	0.0				
	08/31/78	5.0	0.0	Y			
	03/20/78	1.0	0.0	Y			
	01/30/78	1.0	0.0	Y		AT HOME	
	12/05/77	1.0	0.0	Y		AT HOME	
	02/19/79	5.0	0.0	Y			
	07/25/60	5.0	0.0	Y			
	05/19/60	5.0	0.0	Y			
	04/01/60	5.0	0.0	Y			
	01/21/60	5.0	0.0	Y			
	11/19/79	5.0	0.0	Y			
	06/14/77	6.1	1.0			AT WORK	
	12/26/78	19.0	0.0				
	11/12/78	5.0	0.0	Y			
	11/05/78	7.0	0.0				
	04/14/79	5.0	0.0	Y			
	03/14/79	5.0	0.0	Y			
	09/20/79	5.0	0.0	Y			
	07/25/79	5.0	0.0	Y			
	06/19/79	5.0	0.0	Y			
	05/14/79	6.0	0.0				

W. B. EXAMINATION		NATURAL URANIUM					URANIUM-235		RADIUM-226			
MO DAY YR	TIME	MG	ERROR	NCI	ERROR	ALI	MICRO	ERROR	NCI	ERROR	REF	COMMENT
07-27-79	11:50	0.0	0.0	2.5	1.6		0.0	47.0	0.0	0.0		
09-25-78	08:00	0.0	0.0	1.4	1.2		0.0	44.0	0.0	0.0		
06-14-78	08:35	0.0	2.0	0.0	0.0		0.0	41.0	0.0	0.0		
07-20-77	08:18	0.0	2.0	0.0	0.0		0.0	0.0	0.0	0.0		

FIGURE 1. Sample of Data From Whole Body Counter Examination and Bioassay Measurement Results

Various mathematical expressions and terminology can be used to describe detection limits. Knowledge of detection limits and their reliability is critical if unknowingly exposed workers are identified solely from the results of routine bioassay monitoring. The statistical expressions adopted for this study (Currie 1978) involve establishing a decision limit, a detection limit, and a determination limit.

The decision limit (L_c) is the point at which the measurement procedure indicates the presence of the substance of interest (in this case uranium). The value of L_c was calculated so that an incorrect decision (i.e., uranium was present when actually it was absent) was made only $\alpha \times 100\%$ of the time, where the value of α was adopted a priori according to the degree of confidence needed to avoid false positive results. If the measured value was less than L_c, uranium was assumed to be absent; if the measurement result was greater than L_c, the sample was considered likely to contain uranium. The quantity of L_c was determined solely from measuring urine samples known to contain no uranium other than that amount derived naturally from a person's diet (i.e., blanks).

The detection limit (L_d) is based upon a specified degree of confidence in rejecting false negative results. It is the point at which $\beta \times 100\%$ of the results for samples containing L_d uranium are below the L_c and, thus, are judged to contain no uranium when, in fact, uranium is present. The value of β was adopted a priori according to the degree of confidence needed to avoid false negative results. Therefore, the L_d is the smallest quantity of uranium that could be detected in a sample with the probability $1 - \beta$ when L_c is the decision limit.

The determination limit (L_q) is defined as the point at which the analytical procedure is sufficiently precise to yield a satisfactory quantitative result. At the L_q the relative standard deviation is sufficiently small that the procedure yields a result close to the mean value. At the L_d, however, analytical procedure is only precise enough to yield a qualitative estimate (presence or absence) of uranium. When the L_q is reached (which may be several times larger than L_d), the results of the procedure will be more useful in a quantitative sense, such as for dose evaluation.

Appendix B indicates how, for Gaussian distributed results, the quantities L_c and L_d were calculated when a large number of blank and spiked samples were analyzed. Gaussian techniques were not used for this study because the laboratories performing the uranium urinalyses reported results for all measurements below their announced detection limit as "less than detection." This type of reporting, which statisticians call "data censoring", means that valid measurement results were discarded regardless of whether they were negative or highly unreliable. Therefore, to overcome data censoring, a pictorial, nonparametric technique was adopted to calculate L_c and L_d.

Figure 2 illustrates the "Box and Whisker" (BW) plot adopted as a nonparametric technique for this study. The rectangular box and its two "whiskers" were used in place of the Gaussian curve to illustrate how measurement results were distributed. The median of the distribution is shown by a vertical line

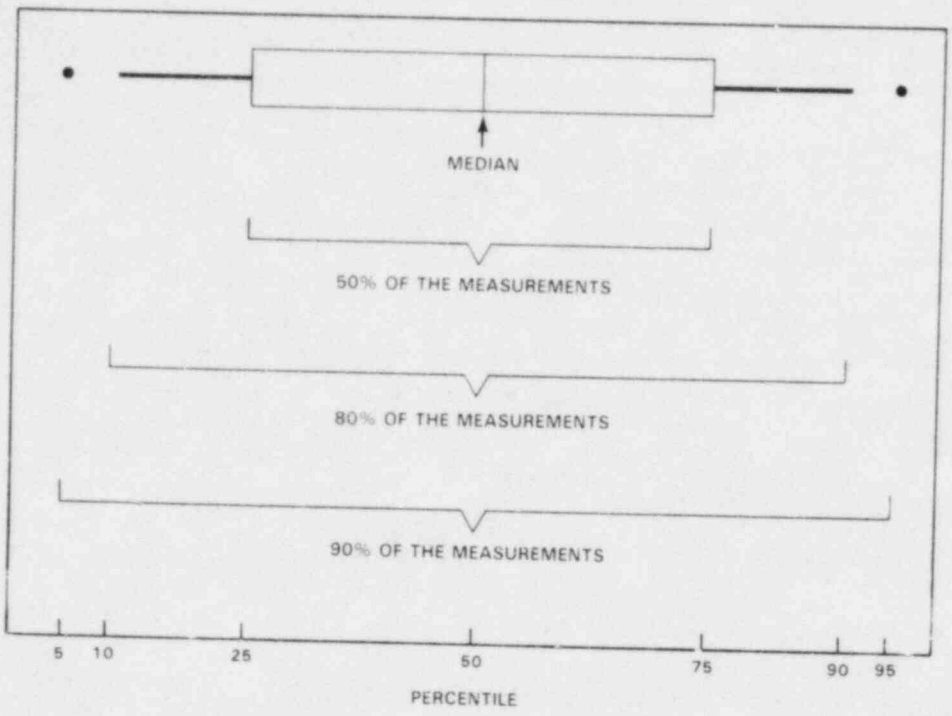

FIGURE 2. Box and Whisker Plot

drawn within the box at the appropriate place above the abscissa. The box is drawn such that its length includes 50% of the results along the abscissa. The length of the rectangular box plus its two whiskers represent 80% of the measured results. Ninety percent of the measurement results are distributed between the two dots drawn outside the whiskers of the rectangular box. If the data are censored, one end of the symmetric BW plot can be eliminated. Thus, the 5th, 10th, 25th, 50th (median), 75th, 90th, and 95th percentiles of the data set can be illustrated in a pictorial manner.

The values of L_c and L_d are determined by graphically comparing the BW plots showing the distribution of blank and spiked sample results as illustrated in Figure 3. If the values of L_c and L_d are defined such that $\alpha = \beta = 0.05$, then the BW plots should have the spatial relationship shown in the top half of Figure 3 where the 95th percentile (dot at the end of whisker) of the blank sample distribution should coincide (overlap) with the fifth percentile of the spiked samples. If L_c and L_d are defined such that $\alpha = \beta = 0.10$, then the BW plots will be spatially related as shown in the bottom half of Figure 3 where the 90th percentile (end of the whisker) of the blank samples distribution should coincide (overlap) with the 10th percentile of the spiked sample distribution. In these examples, the median of the blank sample distributions equals zero.

The majority of the remaining limited objectives were completed using the computer to generate relative frequency distributions of various related data elements. These frequency distributions disclosed numbers and percentages of

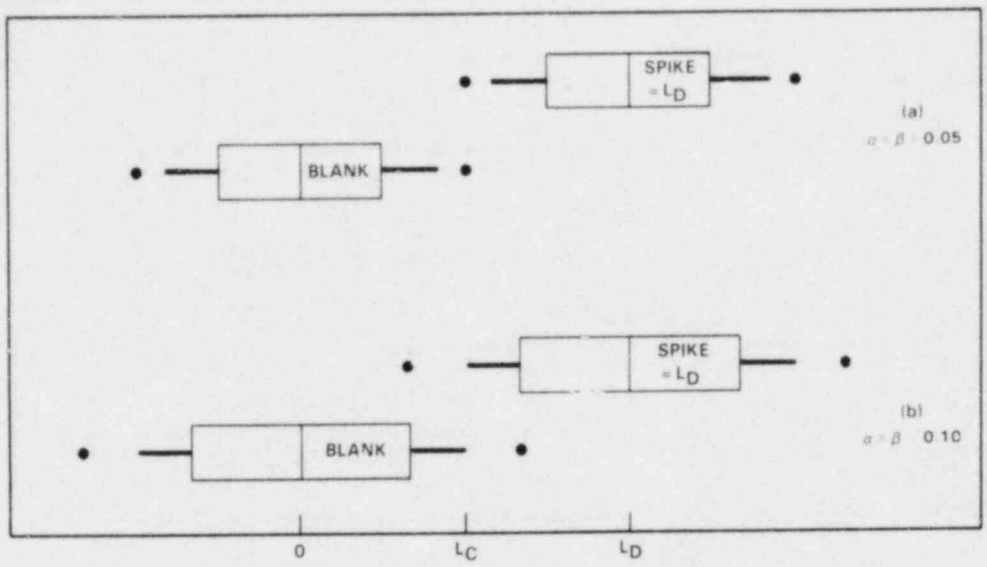

FIGURE 3. L_C and L_d for (a) $\alpha = \beta = 0.05$ and (b) $\alpha = \beta = 0.10$

uranium urinalyses and in vivo examinations performed for each worker at each mill and whether the results exceeded NRC recommended and proposed levels for action.

RESULTS

The draft NRC Regulatory Guide 8.22 (USNRC 1978) advises uranium mill health physicists to routinely check laboratories performing the mill's urinalyses by submitting samples containing known amounts of uranium along with blanks. Furthermore, the draft regulatory guidance specifies that test samples should be adjusted to contain 15 μg of U/ℓ or 30 μg of U/ℓ because these are the action or investigation levels specified by the NRC in the draft regulatory guidance. Blanks, of course, have no added uranium other than that excreted naturally from uranium in the diet.

LIMITS OF DETECTION

Only two mills (Mill 2 and Mill 6) submitted adequate test sample results from which L_c and L_d could be calculated. Mill 6 submitted test samples unknown (blind) to Laboratories A and B, whereas Mill 2 openly identified test samples submitted to Laboratory C. Unlike Mills 2 and 6, Mill 9 did not submit test samples to Laboratory C. Instead, Laboratory C was required to report results of their own spiked samples to Mill 9. Laboratory C did not report blank sample results for Mill 9, so L_c and L_d could not be calculated. The distribution of test sample results is illustrated with BW plots in Figures 4 through 7.

The distribution of results from test samples reported by Laboratory C for Mill 9 (Figure 7) was anomalous relative to the other distributions and was probably due to an inherent bias associated with Laboratory C processing its own test samples. Mill 2 also uses Laboratory C but the results were distributed as expected (Figure 6). Mill 2 test results appeared similar to those obtained by Mill 6 which uses Laboratory A (Figure 4) and Laboratory B (Figure 5). These results indicated that the mills should submit blind test samples to evaluate true laboratory performance.

According to the BW plots (Figures 4 through 6), the way in which the 95th percentile of the blank results approached the 5th percentile of the spiked sample distributions indicated that Laboratories A, B, and C would not achieve an L_d equal to 5 μg of U/ℓ. Five outliers having values greater than 29 μg of U/ℓ were observed among results reported by Laboratory C on blanks submitted by Mill 2. These were eliminated from the data set before estimating L_c. These results were so much higher than the remaining results (whose highest value was 16 μg of U/ℓ) that the deleted blanks were assumed to have been contaminated. The actual values of L_c and L_d were estimated by interpolation and are shown in Table 3 for $\alpha = \beta = 0.05$ and for $\alpha = \beta = 0.10$. Thus, even when α and β errors are relaxed and set at 10%, only Laboratory B could achieve a detection limit as good as 10 μg of U/ℓ. However, Laboratory B would still fail to comply with the draft NRC regulatory guidance which specifies $L_d = 5$ μg of U/ℓ.

The BW plots also illustrate that results for test samples containing 30 μ of U/ℓ were highly variable. The coefficients of variation (CV) for the 30 μg of U/ℓ test samples are shown in Table 4.

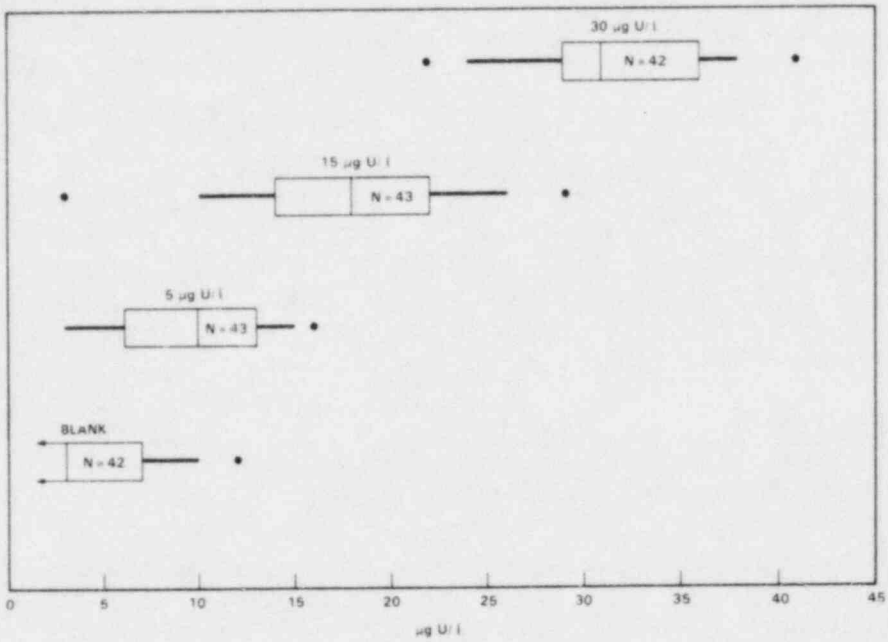

FIGURE 4. Results of Blank and Spiked Samples Submitted by Mill 6 to Laboratory A

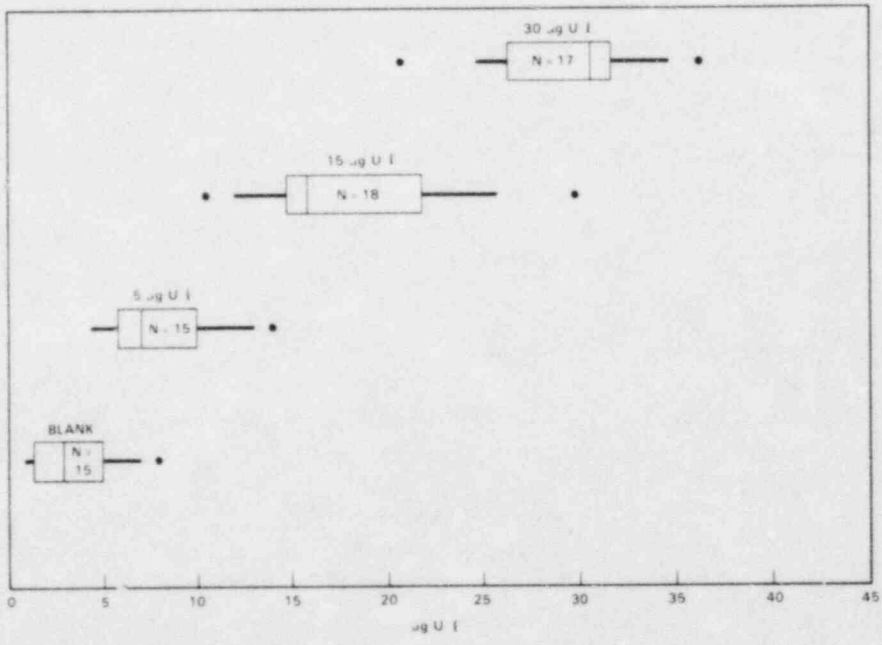

FIGURE 5. Results of Blank and Spiked Samples Submitted by Mill 6 to Laboratory B

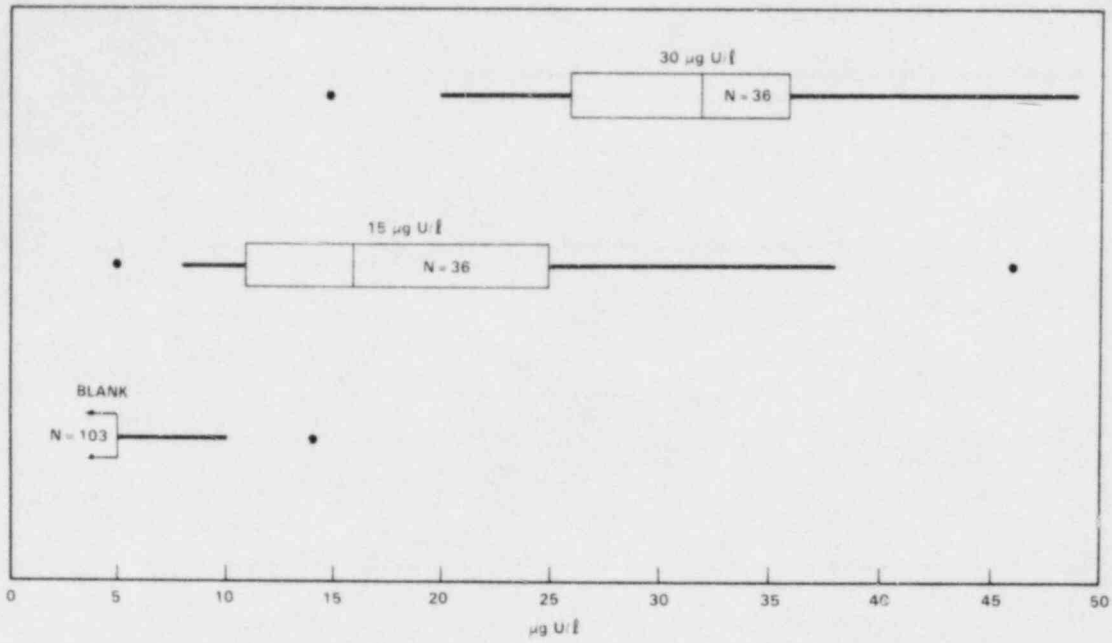

FIGURE 6. Results of Blank and Spiked Samples Submitted by Mill 2 to Laboratory C

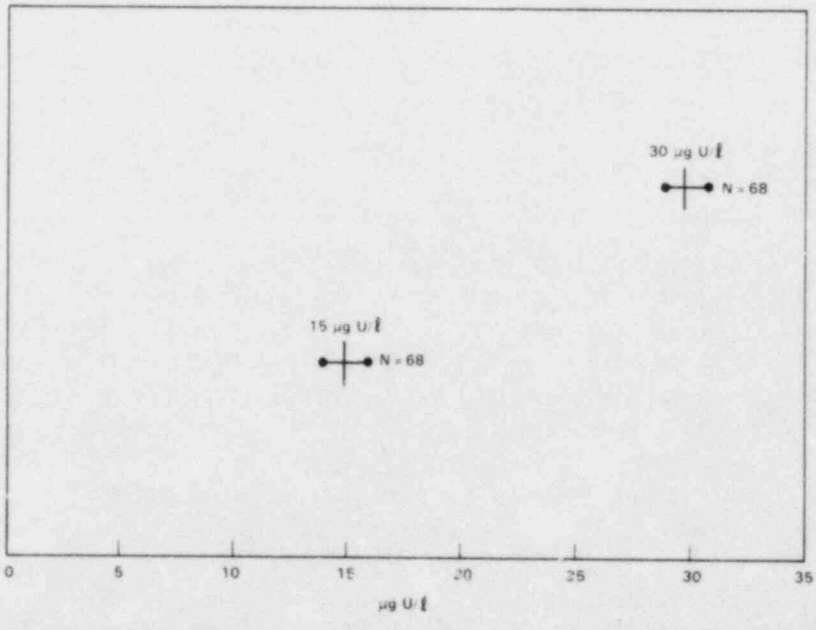

FIGURE 7. Results of Spiked Samples Prepared and Analyzed by Laboratory C for Mill 9

TABLE 3. Estimated L_c, L_d Values for Laboratories A, B, and C

Laboratory	$\alpha = \beta = 0.05$		$\alpha = \beta = 0.10$	
	L_c, µg of U/ℓ	L_d, µg of U/ℓ	L_c µg of U/ℓ	L_d µg of U/ℓ
A	12	22	10	15
B	8	13	7	10
C	14	29	10	18

TABLE 4. Coefficients of Variation for 30 µg of U/ℓ

Laboratory	$\bar{X}$(a)	S(b)	CV(c)
A	31.6	6.7	21.1
B	29.6	3.9	13.2
C	34.8	11.9	34.1

(a) $\bar{X}$ = mean.
(b) S = estimate of the sample standard deviation.
(c) $CV = \frac{S}{\bar{X}} \times 100\%$.

RELATIVE FREQUENCY DISTRIBUTIONS OF URANIUM URINALYSES

Eleven mills submitted 17,039 uranium urinalysis results for 1369 workers; however, the quantity of data from each mill varied greatly for 1978 through 1980. Table 5 shows the urinalysis frequency for each mill and the average number of samples collected from mill workers. The number of urinalyses ranged from 122 at Mill 10 to 4498 at Mill 9. The number of workers sampled at each mill ranged from 68 (Mill 8) to 333 (Mill 9). The mean number of urinalyses per worker ranged from 1.5 (Mill 10) to 31.2 (Mill 1). Samples were collected biweekly at three mills (Mills 1, 4, and 7) and monthly at four mills (Mills 2, 6, 8, and 9). The remaining mills apparently had no routine or fixed sampling schedule.

The relative frequency distribution of the uranium urinalysis results for each mill is given in Table 6. Results for all mills appeared to be log-normally distributed.

Table 7 shows the distribution of uranium urinalysis results at each mill relative to the action levels specified in the draft NRC regulatory guidance (viz., 15 µg of U/ℓ and 30 µg of U/ℓ). Overall, 12.4% of the results would equal or exceed 15 µg of U/ℓ, and 3.2% would equal or exceed 30 µg of U/ℓ.

TABLE 5. Number of Workers and Uranium Urinalyses per Mill (1978 to 1980)

Mill	Number of Workers	Number of Urinalyses	Urinalyses Per Worker	Sampling Frequency
1	83	2587	31.2	Biweekly
2	91	1129	12.1	Monthly
3	138	255	1.8	---(a)
4	147	2343	15.9	Biweekly
5	126	568	4.5	---(a)
6	72	2169	30.1	Monthly
7	129	2385	18.5	Biweekly
8	68	560	8.2	Monthly
9	333	4498	13.5	Monthly
10	81	122	1.5	---(a)
11	101	423	4.2	---(a)
Totals	1369	17039		

(a) A routine sampling frequency could not be determined from data. Either these mills did not adopt a routine sampling frequency for urinalyses or mill operations may have been curtailed.

However, considerable variability in the urinalysis result data existed among the mills. For example, at Mills 3 and 8 all results were well below the first action level, whereas Mills 4 and 9 each had approximately 19% of their results equal or exceeding 15 μg of U/ℓ.

The frequency with which a worker's uranium urinalyses exceeded action limits may indicate a need to limit the worker's exposure. If the frequency is high, the process responsible for the exposure condition would need to be redesigned or restructured. Possibly, the workers should use respiratory protection. The data presented in Table 8 show there were 540 workers (25.5%) with one or more uranium urinalysis result equal or exceeding 15 μg of U/ℓ and 265 workers (12.5%) with one or more result equal or exceeding 30 μg of U/ℓ. The results varied widely among individual mills.

The efficacy of uranium exposure controls and health physics monitoring practices at mills can be determined by evaluating the percentage of uranium urinalyses that exceed action levels. For example, mills with effective controls would rarely expect to find a high percentage of workers repeatedly excreting uranium above action limits. Table 9 shows the average percentage of urinalysis results equal to or exceeding 15 μg of U/ℓ for workers with one or more results equal to or exceeding this action level. Table 10 shows a similar analysis for uranium urinalyses equal to or exceeding 30 μg of U/ℓ. Only

TABLE 6. Relative Frequency Distribution of Uranium Urinalysis Results

Uranium Concentration, µg of U/ℓ	Mills (Frequency)											Total
	1	2	3	4	5	6	7	8	9	10	11	
0 ≤ 5	2012	512	219	998	403	1331	1427	369	2101	91	295	9758
5 < 10	479	264	35	502	101	374	337	156	892	12	86	3238
10 < 15	95	189	1	397	35	231	270	35	637	7	28	1925
15 < 20	1	62	0	174	17	81	144	0	328	4	5	816
20 < 25	0	38	0	100	4	55	75	0	207	3	4	486
25 < 30	0	16	0	54	4	27	44	0	125	1	2	273
30 < 35	0	14	0	41	2	17	32	0	54	0	1	161
35 < 40	0	7	0	22	0	7	13	0	39	2	2	92
40 < 50	0	11	0	21	1	11	18	0	46	2	0	110
50 < 75	0	10	0	14	1	12	18	0	33	0	0	88
75 < 100	0	2	0	8	0	4	2	0	13	0	0	29
100 < 250	0	4	0	10	0	8	5	0	14	0	0	41
250 < 500	0	0	0	1	0	4	0	0	4	0	0	9
500 < 1100	0	0	0	1	0	5	0	0	3	0	0	9
≥ 1100	0	0	0	0	0	2	0	0	2	0	0	4
Totals	2587	1129	255	2343	568	2169	2385	560	4498	122	423	17039

TABLE 7. Frequency of Uranium Urinalyses Results ≥15 and ≥30 μg of U/ℓ

Mill	Number of Urinalyses	Results ≥ 15 μg of U/ℓ		Results ≥ 30 μg of U/ℓ	
		Number	Percent	Number	Percent
1	2587	1	<0.1	0	0.0
2	1129	164	14.5	48	4.3
3	255	0	0.0	0	0.0
4	2343	446	19.0	118	5.0
5	568	29	5.1	4	0.7
6	2169	233	10.7	70	3.2
7	2385	351	14.7	88	3.7
8	560	0	0.0	0	0.0
9	4498	868	19.3	208	4.6
10	122	12	9.8	4	3.3
11	423	14	3.3	3	0.7
Totals	17039	2118	12.4	543	3.2

TABLE 8. Number of Workers with One or More Uranium Urinalysis Result ≥ 15 and 30 μg of U/ℓ

Mill	Number of Workers	Workers with One or More Results ≥ 15 μg of U/ℓ		Workers with One or More Results ≥ 30 μg of U/ℓ	
		Number	Percent	Number	Percent
1	83	1	1.2	0	0.0
2	91	62	68.1	30	33.0
3	138	0	0.0	0	0.0
4	147	116	78.9	59	40.1
5	126	27	21.4	4	3.2
6	72	57	79.2	40	55.6
7	129	80	62.0	39	30.2
8	68	0	0.0	0	0.0
9	333	178	53.5	86	25.8
10	81	8	9.9	4	4.9
11	101	11	10.9	3	3.0
Totals	1369	540	25.5	265	12.5

TABLE 9. Mean Percentage of Total Uranium Urinalysis Results ≥ 15 μg of U/ℓ for Workers with One or More Results ≥ 15 μg of U/ℓ

Mill	Workers with One or More Results ≥ 15 μg of U/ℓ	Number of Results ≥ 15 μg of U/ℓ	Average Percent of Total Results ≥ 15 μg of U/ℓ
2	62	164	24.3
4	116	446	32.1
6	57	233	12.1
7	80	351	20.0
9	178	868	28.1

TABLE 10. Mean Percentage of Total Uranium Urinalysis Results ≥ 30 μg of U/ℓ for Workers with One or More Results ≥ 30 μg of U/ℓ

Mill	Workers with One or More Results ≥ 30 μg of U/ℓ	Number of Results ≥ 30 μg of U/ℓ	Average Percent of Total Results ≥ 30 μg of U/ℓ
2	30	48	14.4
4	59	118	19.0
6	40	70	5.3
7	39	88	11.0
9	86	208	17.9

Mills 2, 4, 6, 7, and 9 were included in these tables because the remaining mills did not have enough data to make the analysis meaningful.

RELATIVE FREQUENCY DISTRIBUTIONS OF IN VIVO EXAMINATIONS

Nine mills submitted 1677 *in vivo* examination results for 909 workers. Unlike the urinalyses results, differences observed in *in vivo* results cannot be attributed to vendors because the same whole body counter examination service was used by all mills. Table 11 shows the number and frequency of *in vivo* examinations for each mill.

The frequency with which *in vivo* examination results exceeded action limits specified in the draft NRC regulatory guidance (viz., 8 mg and 14 mg of uranium) is shown on Table 12. There were 412 *in vivo* uranium examination results (24.6%) that equaled or exceeded 8 mg and 75 results (4.5%) that equaled or exceeded 14 mg. The data for Mill 5 were divided into two categories because results for 1978 were significantly different from later years. For example, in 1978 Mill 5 had 57 results (93.4%) that equaled or exceeded 8 mg of uranium and 47 results (77.1%) that equaled or exceeded 14 mg of

TABLE 11. Number of Workers and In Vivo Examinations Per Mill

Mill	Number of Workers	Number of Examinations	Examinations Per Worker
1	95	119	1.3
2	84	95	1.1
3	49	55	1.1
4	42	73	1.7
5(a)	61	61	1.0
5(b)	111	189	1.7
6	158	369	2.3
7	177	355	2.0
8	20	20	1.0
9	172	341	2.0
Totals	909	1677	

(a) For 1978 only.
(b) For 1979 and 1980.

uranium. Mill 5's results for 1978 were so different from those in 1979 and 1980 (and different from results at all other mills) that the cause of the unusual distribution should be identified or the validity of the results questioned. No information was submitted by mill 5 or the vendor to explain the unusual results for 1978.

The relative frequency distribution of all in vivo uranium examination results is shown in Table 13. Unlike uranium urinalysis results, in vivo uranium measurement results are apparently not log-normally distributed.

Test data was not available to determine L_c and L_d for in vivo examinations because neither the vendor nor the mills submitted calibration or background data for the whole body counter. However, we can make use of the fact that 27 individuals received two or more in vivo examinations within one week, calculate the CV for these sequential exams and infer the quality of the measurements from the magnitude of the observed variations. Repeat measurements of this sort are usually performed to verify an initially high result. Large variations in sequential in vivo examination results may be due to surface contamination on the skin which the worker removes by showering or changing cloths between the exams. An in vivo exam should effectively discriminate against surface contamination because the objective is to measure internally deposited activity, in this case uranium in the lungs rather than uranium on the skin.

TABLE 12. Number of Whole Body Counter Examinations ≥ 8 and 14 mg of Uranium

Mill	No.	Examinations ≥ 8 mg		Examinations ≥ 14 mg	
		Number	Percent	Number	Percent
1	119	12	10.1	1	0.8
2	95	10	10.5	0	0.0
3	55	1	1.8	0	0.0
4	73	11	15.1	1	1.4
5(a)	61	57	93.4	47	77.1
5(b)	189	40	21.2	3	1.6
6	369	144	39.0	11	3.0
7	355	66	18.6	6	1.7
8	20	14	70.0	1	5.0
9	341	57	16.7	5	1.5
Totals	1677	412	24.6	75	4.5
Totals minus Mill 5's 1978 results	1616	355	22.0	28	1.7

(a) For 1978 only.
(b) For 1979 and 1980.

A BW plot of the CV for 27 individuals is shown in Figure 8. Fifty percent of these 27 individuals had CVs greater than 23%. Other sources which might contribute to this high variability include procedural changes, detector background fluctuations or new acute or chronic uranium exposures since the last in vivo examination. Because the same vendor was used by all mills, the differences between mills could not be attributed to differences between vendors.

RELATIONSHIPS BETWEEN URANIUM URINALYSES AND IN VIVO EXAMINATION RESULTS

Routine monitoring programs should reliably identify workers who become unknowingly exposed to uranium on the job. Although uranium urinalysis and in vivo examination results may not jointly confirm any particular exposure because of metabolic differences in yellowcake materials, mills with consistently high exposures should rank high in both urinalyses and in vivo results. Therefore, to investigate the relationship between uranium urinalyses and in vivo examination results, the percentage of urinalyses equal to or exceeding 15 µg of U/ℓ and in vivo examinations equal to or exceeding 8 µg of U/ℓ were ranked in descending order. The results of this ranking are shown in Table 14. Mill 8, which had no urinalyses results above the action level (i.e., 15 µg of U/ℓ), was ranked highest for the percentage of in vivo examinations equal to or

TABLE 13. Relative Frequency of In Vivo Examination Results

Examination Results for U, mg	Mills (Frequency)											Totals Less Mill 5's 1978 Results
	1	2	3	4	5(a)	5(b)	6	7	8	9	Totals	
< 1	31	2	40	6	0	8	16	78	0	57	238	238
1 < 2	2	7	1	0	0	5	1	1	0	6	23	23
2 < 3	11	19	7	6	1	27	11	23	0	54	159	159
3 < 4	17	20	2	17	0	38	25	33	1	42	195	195
4 < 5	15	14	2	9	0	33	31	45	1	32	182	182
5 < 6	17	10	2	9	0	32	45	38	0	48	200	200
6 < 8	14	13	1	15	3	31	96	71	4	45	293	290
8 < 10	10	7	1	9	1	4	74	40	6	32	184	183
10 < 12	0	3	0	1	6	5	41	13	3	15	87	81
12 < 14	1	0	0	0	3	2	18	7	4	5	40	37
14 < 16	0	0	0	1	4	2	5	3	1	3	19	15
16 < 20	1	0	0	0	9	1	4	1	0	1	18	9
20 < 25	0	0	0	0	10	1	0	1	0	1	13	3
25 < 30	0	0	0	0	8	0	1	0	0	0	9	1
30 < 35	0	0	0	0	11	0	0	0	0	0	11	0
35 < 40	0	0	0	0	1	0	0	0	0	0	1	0
40 < 50	0	0	0	0	2	0	0	0	0	0	2	0
50 < 75	0	0	0	0	1	0	0	0	0	0	0	0
75 < 100	0	0	0	0	1	0	0	0	0	0	1	0
≥ 100	0	0	0	0	1	0	0	1	0	0	2	1
Totals	119	95	55	73	61	189	369	355	20	341	1677	1616

(a) For 1978 only.
(b) For 1979 and 1980.

exceeding 8 mg of U. In contrast, Mill 3, which also had no urinalyses results above the action level, was ranked lowest for the percentage of in vivo examinations equal or exceeding 8 mg of U. These differences in ranks are inconsistent with the expectations of a uranium mill's routine personnel monitoring program especially because both mills were producing yellowcake of the same generic solubility (i.e., dried at high temperatures).

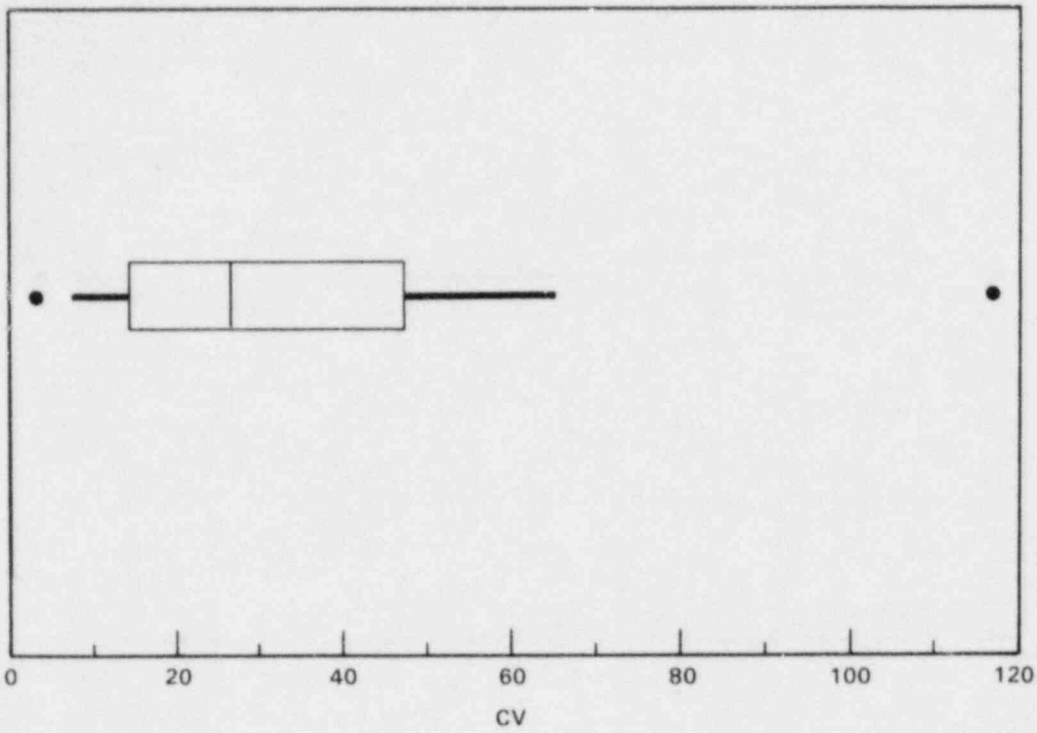

FIGURE 8. Coefficients of Variation for 27 Individuals with Two or More Examinations Within One Week

TABLE 14. Uranium Analysis and In Vivo Examination Results

Mill	Descending Rank According to Percentage of Urinalyses ≥ 15 μg of U/ℓ	Descending Rank According to Percentage of in vivo examinations ≥ 8 mg of U
1	7	8
2	4	7
3	8.5	9
4	2	6
5(a)	6	3
6	5	2
7	3	4
8	8.5	1
9	1	5

(a) For 1979 and 1980.

Natural uranium provides a unique inherent opportunity to evaluate the accuracy of the in vivo examinations results because approximately 0.7% of the mass of natural uranium is ^{235}U. Although natural uranium is mostly ^{238}U, the ^{235}U can easily be measured when in vivo examination results exceed a few milligrams of natural uranium. (Cohen 1977; Spitz et al. 1980) Table 15 compares the amount of ^{238}U and ^{235}U measured in vivo simultaneously. Even when natural uranium results exceeded 12 mg, only 19.1% of the ^{235}U results were greater than zero when, in fact, the expected amount of ^{235}U that should have been detected was greater than 86 μg. This amount of ^{235}U is significantly above L_d and should be detected almost 100% of the time.

Figure 9 is a scattergram of the amount of natural uranium reported versus the amount of ^{235}U. The straight line in Figure 9 represents the expected relationship between natural uranium and ^{235}U which, apparently, was not achieved.

CORRELATION OF URANIUM URINALYSES, IN VIVO, AND AIR SAMPLER RESULTS

Guidance from the NRC indicates that air sampling is the primary health physics monitoring tool to detect and measure airborne uranium exposure (USNRC 1978). Uranium urinalyses and in vivo examinations are, therefore, of secondary and tertiary importance, respectively. Furthermore, NRC guidance explains that routine uranium urinalyses are primarily useful in certifying the efficacy of the air sampling program. The adequacy of the NRC position relative to uranium air sampling, urinalyses, and in vivo examinations can be tested by determining whether results from the aforementioned monitoring programs are correlated.

TABLE 15. Relationship Between Natural Uranium and ^{235}U Measured In Vivo

Natural U mg	Number of In Vivo Examinations	Number of In Vivo Examinations where $^{235}U > 0$ mg	Percent of In Vivo Examinations where $^{235}U > 0$ mg
0	205	9	4.4
>0 to <3	161	6	3.7
3 to <4	173	12	6.9
4 to <5	165	13	7.9
5 to <6	170	20	11.8
6 to <8	248	37	14.9
8 to <12	191	34	17.8
≥12	47	9	19.1

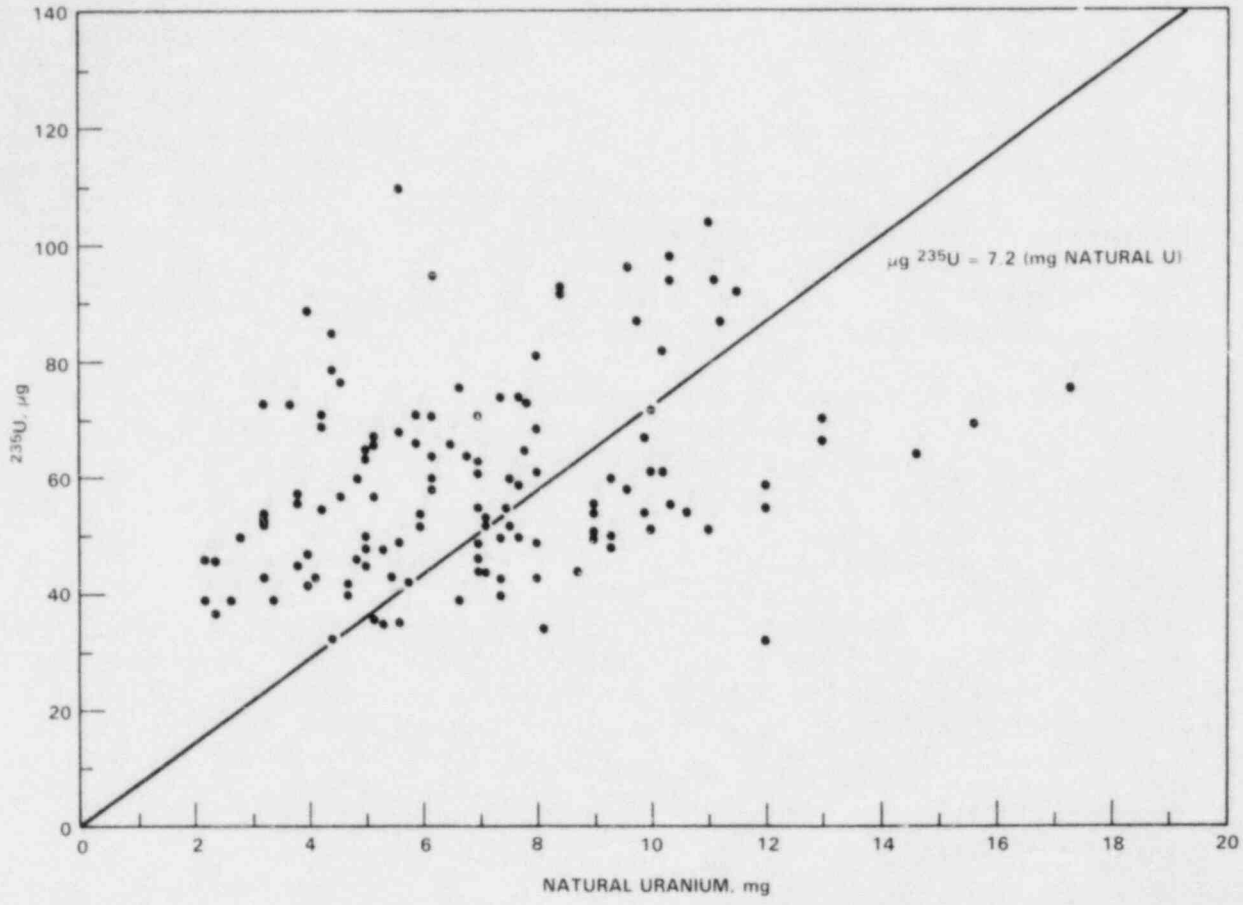

FIGURE 9. Amounts of Natural Uranium in mg Versus Amounts of ^{235}U in µg

Mill 2, which performed routine uranium urinalyses on a monthly basis, also submitted a total of 243 results of personnel air samplers obtained for several individuals. Figure 10 indicates that, for this set of data, no correlation between uranium urinalyses and air sampler results could be found. Measurements of uranium in vivo were also available for these same workers.

The relationship between results of in vivo uranium examinations and a worker's urinalyses or air sampler results was investigated by calculating the correlation coefficient for the in vivo examination result. Six parameters were used:

- mean urinalysis result during previous six months
- highest urinalysis result during previous six months
- urinalysis result nearest the in vivo examination date
- mean air sampler result during previous six months
- highest air sampler result during previous six months
- air sampler result nearest the in vivo examination date.

Table 16 shows the correlation coefficients between the whole body counter examination results and the above parameters for 1978, 1979, and 1980 individually and for all three years combined. For the years individually, only the

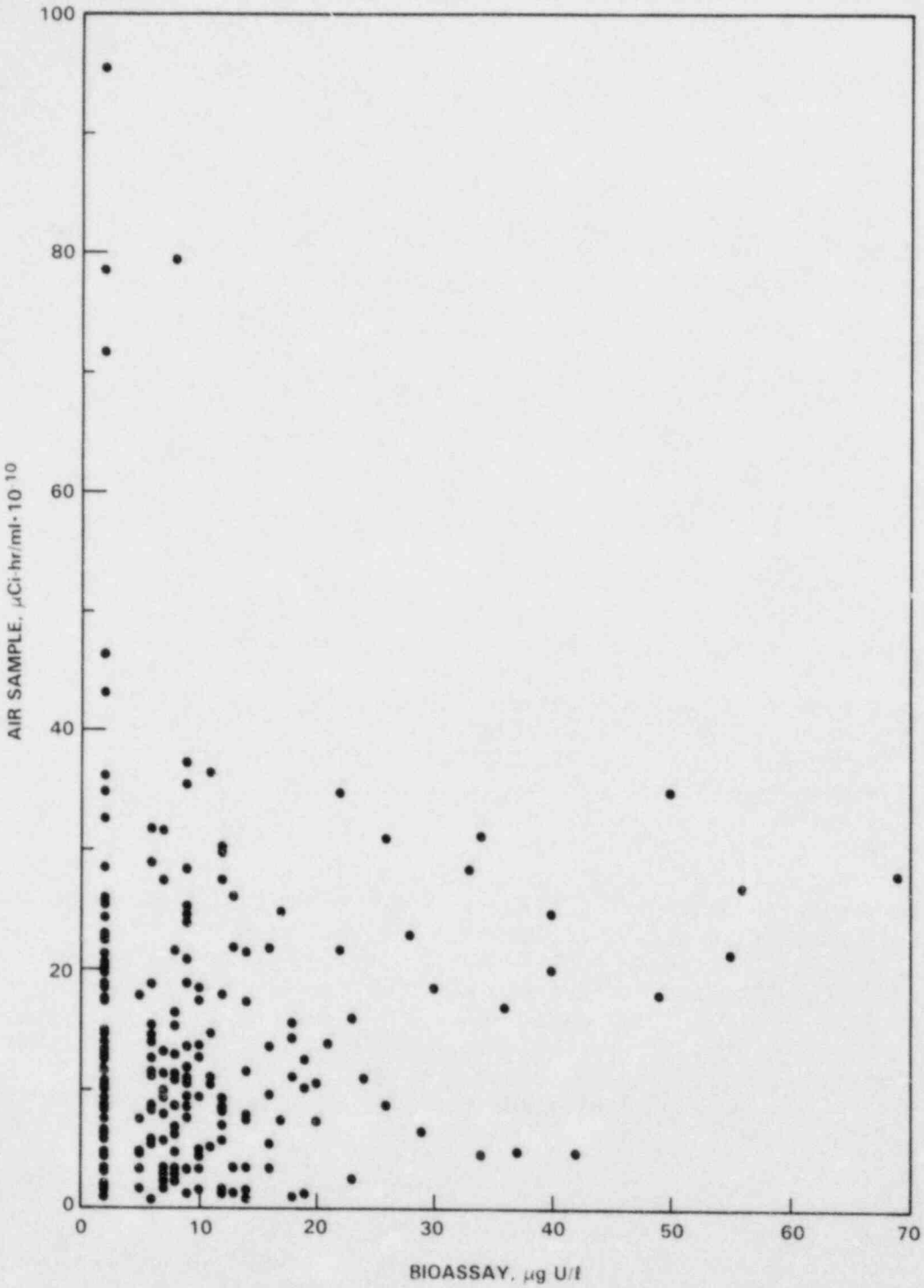

FIGURE 10. Correlation Between Urinalysis and Air Sampler Results for Mill 2

TABLE 16. Correlation of In Vivo Examinations with Urinalysis and Air Sampler Results for the Previous Six Months (Mill 2)

Parameter	1978	1979	1980	All Years
Mean urinalysis	-0.322	0.392	0.302	0.074
Highest urinalysis	-0.321	0.265	0.078	0.026
Urinalysis nearest in vivo examination	0.008	0.473(a)	0.276	0.046
Mean air sample	0.345	-0.005	0.318	0.379(a)
Highest air sample	0.360	0.047	0.574	0.401(a)
Air sample nearest in vivo examination	0.228	-0.030	0.129	0.390(a)
Sample size	20	21	11	52

(a) Correlation is significantly different from zero at a 95% confidence level

bioassay result nearest the examination in 1979 had a correlation with the in vivo examination results that was significantly different from zero. When the three years were combined, all three of the parameters relating to the air sample results were significantly correlated with the in vivo examination results. Although the correlations were significantly different from zero, a correlation of 0.401 between the highest air sample result and the in vivo examination result does not indicate a causal relationship between the variability of uranium measured in vivo and airborne uranium at the mill measured with air samplers. In fact, all the results presented in this section of the report show a great deal of unexplained variability so that the lack of high correlation in the several parameters discussed above should not be surprising. In general, the objectives of a reliable routine health physics monitoring program could not be met with this data because the uncertainty, as explicitly evaluated with BW plots using the urinalyses data, was very large. Furthermore, the NRC objective of using routine uranium urinalyses results to insure the adequacy of the air sampling program is apparently not being met in this case, as illustrated by the lack of any significant correlation between this set of air sampler and urinalysis results.

DISCUSSION

Uranium presents both a radiological and chemical hazard to man when it is deposited in the body (Hodge 1956; Eisenbud 1956; Butterworth 1958); therefore, exposure limits are established so that uranium work can be conducted with the risk of health effects kept acceptably low. Once an exposure has occurred, the amount of uranium deposited in the body can be estimated from measurements of uranium in excreta and from *in vivo* examinations (Scott 1967; Cofield 1960; Alexander 1974; King 1979). Urine and fecal analyses measure the amount of inhaled uranium that has translocated from the lungs and passed through the body. *In vivo* examinations can determine the amount of uranium deposited in the lungs, kidney, and skeleton. Together, these measurements can be used to determine the amount of uranium initially inhaled and the amount expected to remain in the body as a long-term deposition (Quastel 1970).

PERFORMANCE CRITERIA

In general, a routine bioassay program should detect uranium with a high degree of confidence so that millworkers who may have unknowingly been exposed on the job are reliably identified by a high urinalysis or an *in vivo* examination result. No single criterion exists for identifying unknowingly exposed workers; however, the most reliable method is the analysis of excreta from workers who occupy areas of uranium mills where intake is possible (Hursh 1958; Dolphin 1972).

Whenever NRC action levels for bioassay measurement results are exceeded, the mills must respond (100% of the time) with an appropriate action such as investigating the cause of the elevated result or by removing the worker from the area where the exposure likely occurred (USNRC 1978). If bioassay measurements are unreliable, then false positive results may initiate an unnecessary response from the mill and place unnecessary concern upon the worker. On the other hand, false negative results may allow a real uranium intake to go undetected. Both of these should be avoided as much as possible, and the probability of each occurring should be known to those responsible for the monitoring program.

Eliminating all false results is nearly impossible, would place a significant financial burden upon the mill, and would be an inconvenience to the worker because of the type and number of bioassay measurements necessary to achieve perfect reliability (i.e., accurate 100% of the time). Therefore, within realistic constraints, a known, limited degree of false results may be accepted so long as the probability of missing a serious exposure is zero.

When performance criteria are established, such as the NRC has recommended in a limited fashion in its draft regulatory guidance, guidelines for measurement reliability should be included along with accuracy in terms of bias, precision, and detection limits. The NRC has not considered measurement confidence or reliability in the regulatory guide for bioassay measurements at uranium mills. The required level of confidence depends upon how well the uranium content in the lungs or excreta must be known. The draft NRC

regulatory guidance implies that uranium mill bioassay programs detect 15 μg of U/ℓ in urine and 8 mg of U in the lungs with perfect confidence (i.e., 100% of the time) since there is no guidance to the contrary.

The cost of a bioassay monitoring program depends on sampling or measurements frequency and the laboratory performance. Highly sensitive, highly reliable bioassay measurements are usually more costly. However, fewer samples need be collected relative to a less sensitive, less reliable bioassay measurement to achieve the programmatic objective. In other words, because one procedure is twice as sensitive as another, the mill may be able to satisfy monitoring requirements with one measurement a month rather than two or more, thereby gaining some offsetting cost savings. Another impact resulting from use of bioassay analyses with poor performance may be the number of follow-up analyses necessary because of the high frequency of false positive results. The impact arising from the number of false negative results is unmeasureable.

Thus, there is a trade-off between level of performance (including accuracy in terms of bias, precision, and reliability) and monitoring frequency. Once suitable performance criteria are achieved, the credibility of the monitoring program, for the mills, its employees, and the NRC, is well established.

URINALYSIS RESULTS

The large variability observed in the urinalyses data may be a result of collecting single void urine samples which, after analysis, are adjusted in volume to represent that amount of urine excreted by reference man in one day (ICRP 1975). This adjustment is not necessarily the correct approach since metabolism varies significantly from worker to worker. Furthermore, excretion of internally deposited radioactive materials fluctuates widely with time. For example, urine excreted after arising from sleep usually contains the highest content of metabolites, including uranium (Dolphin 1972).

The urinalysis quality control programs conducted at a few mills involved a practice that might have introduced a bias to our analysis of test urine sample results. Some spiked test samples were produced by adding a known amount of uranium activity to an aliquot of urine obtained from a worker's actual routine sample rather than using urine from a person known to have no exposure to uranium at the mill. Whenever such urine was used for a spiked test sample, the results had to be "adjusted" by subtracting the amount of known added activity from the measured result. This practice would have an impact on this mill's quality control program by significantly increasing the uncertainty of the spiked test sample results whenever the urine used as a blank was contaminated with uranium. We do not know whether data submitted for our analysis was adjusted whenever necessary.

Recognizing that the uranium urinalysis data in this report were unreliable, the result records were examined to determine whether the retention of uranium in mill workers could be determined from a graph of uranium excretion with time. Since urinalysis test data indicate that no mill should fail to detect 30 μg of U/ℓ, individuals with at least one result exceeding this value were identified using a computer search of the data records. There were

256 workers out of 1369 with at least one urinalysis result exceeding 30 μg of U/ℓ. However, only 12 workers had adequate follow-up sampling from which retention could be evaluated. Apparently, this lack of diagnostic sampling was due, in part, to the delay between sample collection, analysis, and notification to the mill.

Figures 11 and 12 show uranium urinalysis data for two workers with at least one result greater than 35 μg of U/ℓ. The urinalysis results are plotted against consecutive days starting with the first available result in the record. Results below 5 μg of U/ℓ, the dashed line on the plot, are not shown. The mean observed half-time for uranium in twelve different workers was 14.6 ± 4.3 days. It is not known what systemic retention compartment this represents or whether there is more than one compartment represented by this data. However, according to ICRP 30 (ICRP 1979), three compartments are expected (viz., bone, kidney, and soft tissue). These are in addition to deposition sites in the respiratory system.

Graphical analysis is a useful technique for identifying and evaluating trends. For example, Figures 13 and 14 illustrate an unusual trend in the results of routine urinalyses for two workers at Mill 10. Apparently near day 450, something happened at Mill 10 to reduce the amount of uranium inhaled by these workers as demonstrated by reduction of uranium excreted in urine. The variability of the results also appears significantly reduced. Although no explanation for the change was available in the records, the management at Mill 10 may have changed the urinalyses laboratory or procedure, improved a milling process, or implemented a respirator program. It is unusual that results and their variability could experience a change of this magnitude without a concurrent action from management. Had the urinalysis results been examined for trends, management would have noticed the change and could have taken steps to document its findings for the records. This documentation would be essential if the observed trend proved to represent a possible increase in worker exposure rather than a diminution, as illustrated in Figures 13 and 14.

Figure 15 illustrates an unexpected event at a uranium mill processing yellowcake that is dried at high temperatures and, therefore, expected to exhibit insoluble characteristics in the lung and a long, effective clearance half-time in the respiratory tract. The first and last peaks in the figure represent uranium concentrations of 285 μg of U/ℓ and 680 μg of U/ℓ, respectively with clearance half-times equal to 3.3 days and 1.8 days, respectively. The observed peaks may not be due to uranium intakes, but rather contamination of the sample. Sample contamination would be likely if the monitoring program required sample collection during the work day when the millworkers were on the job. No explanation was available in this worker's records to describe the occurrence.

IN VIVO EXAMINATION RESULTS

Analysis of *in vivo* examination results determined that variations observed between sequential measurements were significantly greater than expected. In addition, the fact that the highest *in vivo* lung measurement

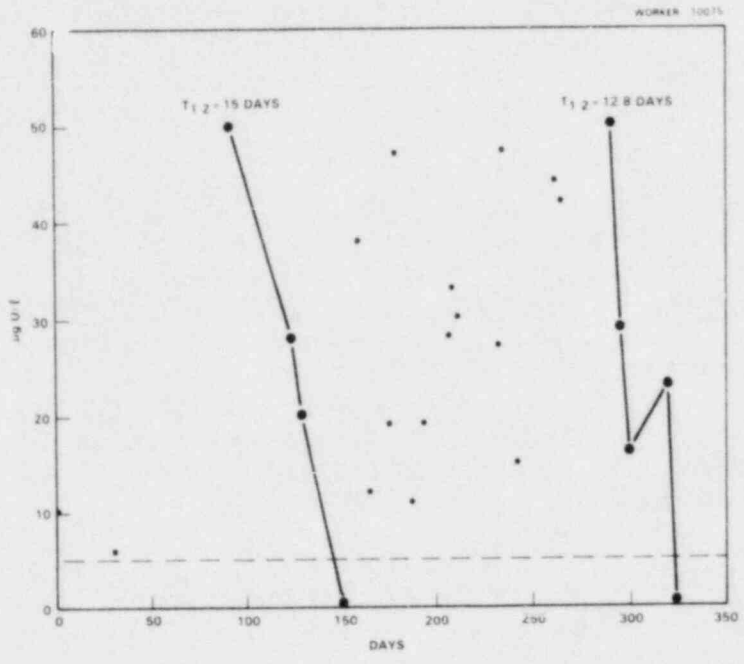

FIGURE 11. Detailed Routine Results for Uranium in Urine of Worker A

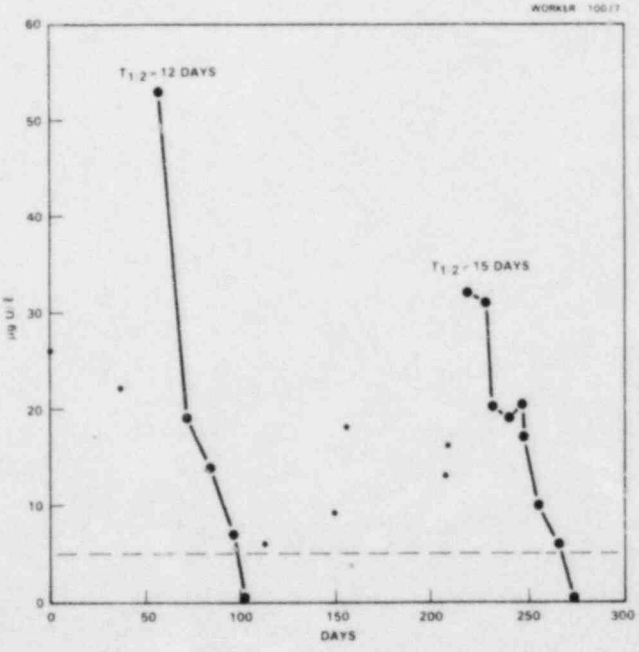

FIGURE 12. Detailed Routine Results for Uranium in Urine of Worker B

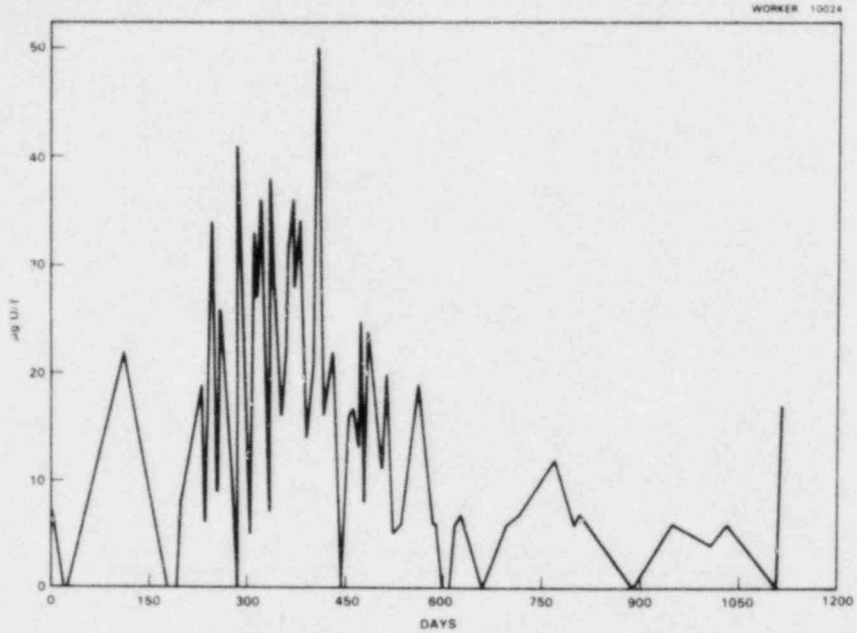

FIGURE 13. Routine Results for Uranium in Urine of Worker C

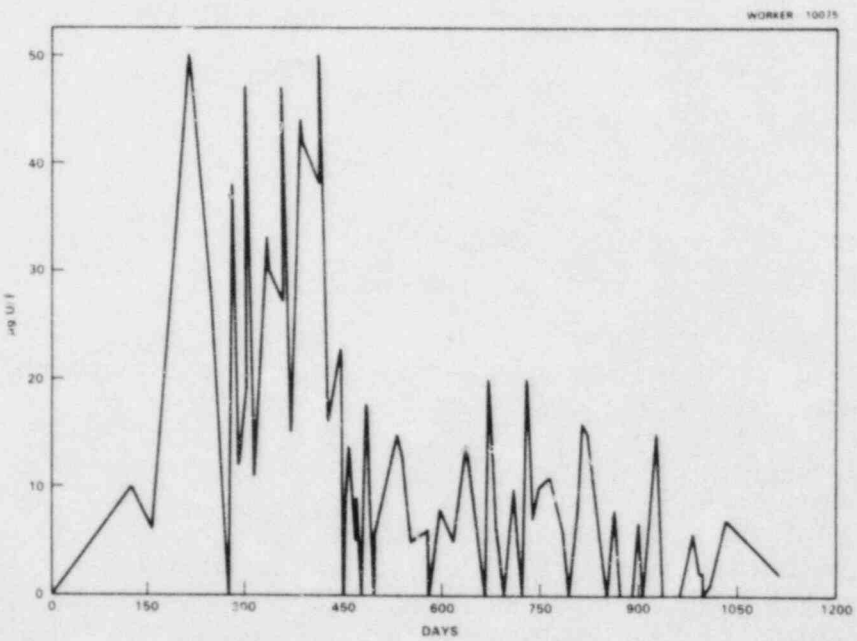

FIGURE 14. Routine Results for Uranium in Urine of Worker A

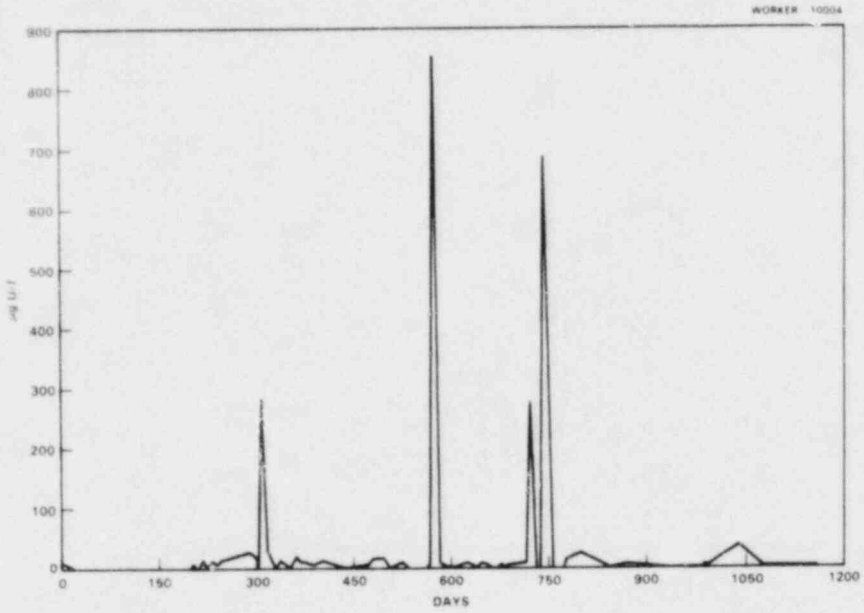

FIGURE 15. Routine Results for Uranium in Urine of Worker D

results were found in workers at the mill producing highly soluble, low-temperature-dried yellowcake indicate that in vivo measurements are probably not indicative of internally deposited activity but may represent surface or some other source of contamination.

The correlation of natural uranium and ^{235}U measured in vivo indicated that ^{235}U was detected only 18% of the time when, in fact, it was present in amounts significantly above the detection limit. That is to say, ^{235}U was not reliably detected during the onsite in vivo examination.

Difficulties associated with performing reliable in vivo examinations at mill sites should not discourage these measurements from being included in a routine uranium monitoring program. In vivo examinations are the only means of determining whether mill workers have received an internal deposition of insoluble uranium. However, if the health physicist is to have any confidence in the in vivo examination results, adequate performance criteria must be adopted by mill management, met by the vendor, and include techniques to account for uranium skin contamination. Furthermore, the WBC unit should not be located near uranium or other natural or technologically enhanced radioactive materials that cause the instrument background to fluctuate or become elevated (Spitz et al. 1980; Shapiro 1974; Helgeson 1979).

A comparison of uranium urinalyses and in vivo examination results was made by ranking the results according to the percentage at each mill that exceed the NRC action levels. Mills with the highest percentage of urinalysis results above action limits did not have the highest percentage of in vivo examination results above the action limits. There were no significant correlations between uranium urinalysis or in vivo examination results for any

mill. In fact, expected differences in bioassay monitoring results between mills producing high- and low-temperature-dried yellowcake were not observed.

CONCLUSIONS

The bioassay results in our study, involving the period from 1978 through 1980, were highly variable and thus unreliable as a monitoring tool for determining whether millworkers have been exposed to airborne uranium. Health physicists at these mills during this period were apparently unaware of this variability and its impact upon reliability because, heretofore, the bioassay data had never been analyzed to determine its quality. Furthermore, the manner in which bioassay result records were maintained on file at the uranium mills was not conducive to any type of trend analysis.

The NRC should consider establishing uniform performance criteria for uranium bioassay monitoring results and recommending explicit levels of accuracy in terms of bias, precision, and confidence that should be achieved by these routine measurements. Application of uniform bioassay performance criteria at all mills would simplify interpretation of results from mill to mill. In lieu of new recommendations, the only performance criteria currently recognized by the mills or their in-plant or vendor laboratories are those recommendations cited in the draft NRC Regulatory Guide 8.22 (USNRC 1978) which sets 5 μg U/l as the measurement sensitivity. Lacking such regulatory guidance, bioassay results may continue to be unreliable. Therefore, the draft NRC regulatory guidance should be revised and issued to include as performance criteria, explicit recommendations for the levels of accuracy in terms of bias, precision, and confidence expected from bioassay monitoring results.

Once performance criteria for accuracy, precision, and confidence are adopted and implemented, a routine procedure for uranium mill health physicists to test bioassay processors will be required to insure that the performance criteria are reliably being met. The recommended procedure involves preparation of urine samples that contain known quantities of uranium and blanks that the health physicist would submit routinely as blinds. Results of these tests would enable health physicists at each mill to calculate decision limits (L_c) and detection limits (L_d) and determine how well bioassay performance criteria are being met. Recommendations for bioassay performance criteria and a program to test the laboratory are given in Appendix B.

The observed retention half time of uranium in the body of exposed millworkers in this study is approximately 14 days. Urine samples collected less frequently than twice a month may fail to detect an unknowingly exposed worker because of the apparent rapid clearance of uranium from the body. Furthermore, if bioassay results continue to be unreliable, the sampling frequency may need to be greater than semimonthly. On the other hand, a bioassay monitoring program with sensitive, highly reliable procedures might enable samples to be collected less frequently than twice a month.

The quality of *in vivo* examination results could not be determined directly as it was for results of urinalyses. However, measurement variability was found to be very large, limiting *in vivo* examinations as a useful bioassay monitoring tool. Some of the measurement variability was likely due to the influence of large quantities of radioactive milling by-products in close

proximity to the mobile WBC, uranium dust in the air, and uranium contamination on the skin or hair of the workers being examined. Although significant environmental factors present at the mill apparently caused the in vivo examination results to be unreliable, in vivo examinations should not be abandoned as a monitoring tool for uranium mill workers. Improved, and potentially useful, results can likely be obtained by minimizing the effects of environmental factors.

Two recommendations are proffered to improve the in vivo results. First, uranium contamination on the skin can be quantitatively determined by measuring the low-energy uranium x-rays emitted by activity on the surface of the body and eliminating that uranium from the total measured in vivo. Examinations performed with thin, dual-crystal scintillation detectors or high resolution, solid state, planar, germanium detectors can simultaneously measure the uranium x-ray as photons and uranium to determine the amount deposited in the lungs. Secondly, regional WBC examination centers could be established in areas close to uranium milling areas. These permanent centers would be able to control ambient conditions and interferences, such as contaminated surface dust on workers, more consistently than is apparently possible with onsite measurements. A combination of these two recommendations would best suit requirements for in vivo examination of uranium mill workers.

The way in which the uranium mills keep and maintain their records needs to be improved. Each mill had its own method for storing bioassay data which in no case was in a form suitable for performing statistical analyses. Furthermore, what data were stored typically were incomplete and lacked explicit information about the sample collection date, the processing date, who performed the analyses, and whether the result was valid. A sample copy of data from each mill is provided in Appendix A. Revisions to the draft NRC regulatory guidance should provide guidance relative to the minimum data elements for retention in permanent records and the manner in which data should be saved. The only way in which the mills and the NRC can determine whether regulations concerning uranium exposure have been met is to evaluate the records containing bioassay results. These records must be complete and in a format such that the data are easily retrievable.

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APPENDIX A

EXAMPLES OF RAW DATA SUBMITTED BY THE URANIUM MILLS

BIO ASSAY PROGRAM

NAME _____ S.S. No _____ DATE OF BIRTH: 10-3-43 WORK No: 00272

DATE OF SAMPLE	TIME OF SAMPLE	RESULTS µg/l "U"	COMMENTS
4-15-80	4-2 5:30 P	<5	
4-30-80	4-18 7:00 A	8	
MAY 15 1980	5-7 7:20 A	<5	
MAY 31 1980	5-27 7:15 A	10	
JUN. 15 1980	6-2 7:45 A		NO SAMPLE/LOST BY SPILLAGE
JUN. 30 1980	6-18 7:45 A	<5	

APPROVED BY _____

EXPOSURE HISTORY FOR PERIOD 01/04/81 - 07/25/81

EMPLOYEE NAME EMP ID	WEEK OF	EXP HRS	TOTAL ORE CONC*	TOTAL YC CONC*	% MPC	URINE SAMPLE#	GAMMA EXP**	Y-T-D GAMMA*	L-T-D GAMMA*
F ;	01/04/81 - 01/10/81	51.5	44.252	.297	22.20	18			.012
)	01/11/81 - 01/17/81	60.3	27.194	.375	13.69				
	01/18/81 - 01/24/81	55.5	45.624	3.037	23.57				
	01/25/81 - 01/31/81	31.5	19.817	.246	9.96				
	02/01/81 - 02/07/81	46.0	15.220	1.560	8.00	15			
	02/08/81 - 02/14/81	33.0	16.466	.000	8.23				
	02/22/81 - 02/28/81	9.0	3.357	.702	1.85				
	03/01/81 - 03/07/81	48.0	51.089	.162	25.58	16			
	03/08/81 - 03/14/81	36.7	20.380	.204	10.24				
	03/15/81 - 03/21/81	46.5	49.992	13.525	28.37	< 5			
	03/22/81 - 03/28/81	45.0	30.676	1.383	15.68		25	.025	.037
	03/29/81 - 04/04/81	31.0	14.352	.063	7.19	15			
	04/05/81 - 04/11/81	18.0	6.775	.072	3.40				
	04/12/81 - 04/18/81	47.5	12.543	.000	6.27	< 5			
	04/19/81 - 04/25/81	55.0	24.023	1.263	12.32				
	04/26/81 - 05/02/81	46.0	17.350	9.381	11.02	12			
	05/03/81 - 05/09/81	62.0	43.627	1.908	22.29				
	05/10/81 - 05/16/81	51.5	29.097	.583	14.69	< 5			
	05/17/81 - 05/23/81	41.5	29.340	.260	14.73				
	05/24/81 - 05/30/81	45.0	27.081	6.294	15.11	7			
	05/31/81 - 06/06/81	55.0	21.209	3.760	11.54				
	06/07/81 - 06/13/81	27.0	19.544	.011	9.77	6			
	06/14/81 - 06/20/81	60.5	25.421	5.328	14.04				
	06/21/81 - 06/27/81	51.5	31.729	.532	15.99	7			
	06/28/81 - 07/04/81	38.0	15.339	.000	7.66				
	07/05/81 - 07/11/81	45.0	28.190	.867	14.31	8			
	07/19/81 - 07/25/81	31.5	9.210	3.751	5.54	4			

* UCI/ML X 10 E-11 ** MILLIREMS L LOST FILM BADGE
\# UG/L * REMS

3RD QUARTER 1979

I.D.#	Dates of Urine	Urinalysis U(μg/l)	9/23/79-9/29/79 YC(mghr/m^3)	9/16/79-9/22/79 YC(mghr/m^3)
2	9/24/79	5.0	0.04	0.10
182	9/24/79	3.6	0.03	0.02
160	9/24/79	6.1	0.00	0.00
17	9/24/79	<1.8	0.02	0.03
219	9/24/79	<2.2	0.03	0.02
31	9/24/79	6.2	0.07	0.32
155	9/24/79	2.1	0.03	0.03
163	9/24/79	3.2	0.00	0.00
121	9/24/79	<1.9	0.00	0.00
177	9/24/79	5.9	0.06	0.11
152	9/24/79	2.3	0.00	0.00
172	9/24/79	2.6	0.03	0.03
171	9/24/79	<2.1	0.03	0.16
151	9/24/79	<2.2	0.00	0.00
170	9/24/79	2.3	0.04	0.13
71	9/24/79	<3.1	0.03	0.02
82	9/24/79	<3.1	0.03	0.03
173	9/24/79	<3.1	0.00	0.00
84	9/24/79	4.4	0.01	0.12
167	9/24/79	<1.8	0.02	0.04
102	9/24/79	<1.8	0.00	0.00
221	9/24/79	<1.8	0.00	0.00

		NATURAL URANIUM NANOCURIES	U-235 MICROGRAMS
-7486	07/26/81 AT 1955	5.2 ± 1.5	0 ± 42
-6932	07/29/81 AT 1045	8.5 ± 1.9	0 ± 50
-4937	07/26/81 AT 0605	5.2 ± 1.5	0 ± 39
-9717	07/28/81 AT 1020	0.0 ± 1.2	0 ± 34
-3779	07/28/81 AT 0741	9.8 ± 1.8	0 ± 50
-3749	07/26/81 AT 2130	8.0 ± 1.5	0 ± 48
-8228	07/26/81 AT 1105	7.0 ± 1.5	0 ± 45
-5263	07/28/81 AT 1350	2.0 ± 1.5	0 ± 45
-4815	07/26/81 AT 0627	6.5 ± 1.9	0 ± 56
-2380	07/27/81 AT 1133	2.9 ± 1.6	0 ± 41
-5967	07/26/81 AT 0521	8.7 ± 1.6	0 ± 48
-0763	07/27/81 AT 0751	4.6 ± 1.6	0 ± 44
-6599	07/26/81 AT 0819	4.8 ± 1.7	0 ± 57
-2852	07/27/81 AT 1440	0.0 ± 1.5	0 ± 39

		RADIUM B,C NANOCURIES
)-5340	07/28/81 AT 1359	3 ± 3
)-3779	07/28/81 AT 1303	3 ± 2
)-3749	07/29/81 AT 1024	5 ± 3

Bioassay Date	Vendor Report Date	Urinalysis Result - ug/l	In-Vivo Analysis Results	
			U-nat nCi	U-235 ug
3-13-78		<5		
2-23-78			2 ± 3	<13
9-25-78		<5		
9-25-78		10 ± 5		
8-79		3.6		
7-11-79			4.2 ± 1.6	0 ± 50
7-11-79			2.7 ± 1.4	0 ± 47
3-80		8		
7-29-80			2.3 ± 1.6	0 ± 41

PERSON #36 — SOLUBLE URANIUM AREAS

IN VIVO COUNTING

1980 2.9 ± 1.2 NCI U-NAT
0 ± 29 MICROGRAMS U-235

URINE ANALYSIS

1-2-79	<.5 UG/L	U-NAT	2-6-80	9.33 UG/L	U-NAT
1-15-79	<.5		2-21-80	2.79	
1-30-79	<.5		3-4-80	6.15	
2-14-79	3.64		3-19-80	5.51	
3-8-79	.76		4-2-80	6.53	
4-4-79	5.00		4-24-80	5.26	
4-16-79	<5		4-29-80	.76	
5-15-79	.76		5-22-80	<.5	
5-21-79	2.20		5-28-80	<.5	
6-4-79	6.53		6-20-80	1.14	
6-25-79	2.92		7-9-80	5.26	
7-11-79	8.90		7-28-80	2.80	
8-6-79	4.46		8-4-80	1.40	
8-21-79	1.16		8-19-80	<.5	
10-4-79	<.5		9-10-80	2.16	
10-10-79	<.5		10-7-80	<.5	
10-26-79	4.66		10-17-80	<.5	
11-8-79	2.63		11-11-80	<.5	
11-21-79	<.5		11-25-80	<.5	
12-6-79	1.44		12-16-80	7.20	
12-27-79	<.5				
1-14-80	3.98				
1-22-80	<.5				

URINE ANALYSIS

May 1979

NAME		DATE	AREA	Nat/ ugm U / l
Ti	2	5/3	Shifter	2.33
He	055	5/4	Precip.	1.74
Dr	050	5/3	FilterO.	3.62
Ca	058	5/3	BallMill	4.64
St	022	5/3	Crush.O	6.20
Ch	060	5/3	Crush.H	2.59
Me	054	5/4	Dryer	1.93
Me	054	5/21	Dryer	3.44
Ch	060	5/31	Crush H	5.12
St	022		Crush O	Term.5/13
Mo			Labor	No Samples
F	002		Filter H	"
Fr	013	5/7	Shifter	2.30
Je	017	5/7	Precip	6.61
Ev	016	5/7	Filter O.	4.31
La	020	5/7	BallMill	1.15
Mc	014	5/17	FilterH.	1.45
Ca	037	5/7	Labor	2.30
Ru	021	5/7	Crush O	.86
Sh	002	5/7	Crush H	2.87
Pe	032	5/8	Dryer	1.73
Ru	021	5/17	Crush O	1.03
Sh	002	5/18	Crush H	7.31
P	032	5/17	Dryer	1.03

NAME		DATE	AREA	Nat/ ugm U / l
		5/10	Shifter	.79
	055	5/10	Precip.	1.57
	050	5/10	FilterH.	.63
	058	5/10	BallMill	.63
	022	5/10	Labor	1.26
	060	5/10	Filter O.	.94
	054	5/10	Crush.H	1.57
s	054	5/10	Dryer	1.26
	060	5/10	Crush.O	1.57
s	022	5/29	Dryer	3.53
	060	5/31	Crush H.	4.53
	002	5/31	Crush O.	6.30
	013	5/14	Shifter	1.76
	017	5/14	Precip	3.93
	016	5/14	Filter O.	1.32
s	020	5/14	BallMill	6.32
	014	5/14	FilterH.	.88
	037	5/14	Labor	3.82
	021	5/15	Crush O	3.10
	002	5/15	Crush H	3.52
	032	5/14	Dryer	3.97
	021	5/29	Crush O	2.87
	002	5/29	Crush H	.66
	032	5/29	Dryer	2.21

MPC=15 ugm U Nat/ l

DATE OF SAMPLE

WORK NUMBER	CEP 6-15-77	PALS 6-15-77	6-30-77	7-15-79	7-30-79	PALS	E.A.	8-15-77	8-31-77	9-15-79	9-30-79	10-15-79	10-30-77	11-15-79	PALS	Epidemiology	11-30-79	12-15	12-31
03441			25	<5	10	17	11	16	11	6	13	11	27	6			<5	<5	18
04022																	11-29-79		
04480			<5	<5	6			<5	5		27	<5	T	RANSFERED			10-9-79		
05118			9	10	9	12	11	7	<5		6	15		15	7.8 9.2	Lost	19	7	15
05274								11-28-79		<5	6	23	8	24	9.8 11.6	10	8	<5 9.5	11
04987				<5	14	8	11		21	10	6	28		18			5	<5	5
05029	<5	36.4	13	7	9			6	11	9	8		10	<5				<5	5
05517	<5	16.6	<5	<5	7			<5	5	<5	7	16	<5	6			7	15	15
05541								8-23-79		<5	14	44	12	<5			5	8	15 1-3-80
05547	<5	18.9	<5	<5	6			9	<5	<5	<5	<5	<5	<5			5	<5	<5
05568			10	<5	10	16	12	5	7		9	14	<5	8	RETIRED		11-16-79		

CUSTOMER
ADDRESS
CITY
ATTENTION
INVOICE NO

Received 08-13-79

SAMPLES RECEIVED 7-23-79	CUSTOMER ORDER NUMBER
TYPE OF ANALYSIS Urine	

Sample Identification		Date Collected	Total Uranium ug/liter
# 406	Double distilled water		4
# 407	68 ugU/l standard		53
# 408	spiked to 15 ugU/l		20
# 409	" " 30 "		37
# 410	er" " " "		6
# 411	" " " "		33
# 412	" " " "		37
# 41[illegible]	" " " "		34
✓ Ma[illegible]		7-9-79	8
+ Bo		7-12-79	13
+ Bur		7-12-79	14
Car		7-9-79	< 5
Dal		7-9-79	5
Dav		7-9-79	8
Gra		7-9-79	12
+ Her		7-10-79	5
+ Jac		7-12-79	7
+ Jam		7-12-79	11
Joh		7-9-79	8
Kau		7-9-79	14
Kir		7-9-79	6
Lam		7-9-79	7
Mil		7-9-79	< 5
Sac		7-9-79	7
Sa[illegible]		7-9-79	5

APPROVED BY

8-8-79

1978

NAME		DATE	Exposure Week before MPC	Exposure During Samples MPC	Bioassay ugU/l 1st Day Back	Bioassay ugU/l Last Day of Week	REMARKS
Bar	1	3/3/78	2.32	.036	3rd 5.3	6th 4.74	
Bow	2	3/6/78	.039	.095	6th 7th 8th 11.62 9.96 <1	9th 10th 13th 1.82 <1 <1	working in dryer
Col	3	3/6/78	.024	.258	4.28 9.96 7.46	3.14 4.49	working on Lute
Col		3/15/78	.258	.361	15th 16th 17th 3.77 12.34 14.16	20th 5.81	Cup in # 8 hearth
Con	4	3/6/78	0	.136	6th 7th 8th 2.71 3.82 1.74	9th 10th 3.35 <1	
Con		3/13/78	.136	.191	1.54		
De	5	3/6/78	.017	.136	6th 7th 8th 1.82 5.34 4.37	9th 10th 8.10 <1	
De		3/13/78	.136	.372	13th 16th 6.78 2.16	17th 1.01	Lute cup
De		3/20/78	.372	.564	<1		
De		4/5/78	.006	.277	5th 6th 9.29 2.63	7th <1	Scrubber fan & bearings
De		5/1/78	.013	.018	1.65	<1	
Faz	6	3/6/78	.015	.141	6th 7th 8th <1 <1 7.25	9th 10th 5.26 7.76	Lute Cup #8 hearth
Faz		3/13/78	.141	.354	13th 15th 16th 9.41 8.65 22.39	17th 21st 8.56 2.50	
Bow	2	5/12/78	.0 V	.024	4.28	<1	
Bro	7	5/12/78	.007	.015	8.61	1.65	
Mar	8	5/12/78	0	.017	3.14	8.69	
Roo	9	5/12/78	.049	.030	<1	<1	
Sho	0	5/12/78	.038	.057	2.33	37.3	Contamination very likely
Set	1	5/12/78	.054	.023	1.06	7.04	

ATS Period	Pos. Code	Hours	Calculated Exposure µc/ml x 10^-12	% MPC	[illegible] Hours	CALCULATED EXPOSURE	% MPC	Hours	ACCUMULATED EXPOSURE	% MPC
11/19/79	13,4,5	40	210.3045	52.574						
11/26	2,3,4,5	40	341.9393	85.485						
12/3		0								
12/10	2,3,5	32	14.5861	3.645						
12/17	3,4,5	40	17.3375	4.333						
12/24	3,4,5	40	15.3784	3.843						
12/31	2,3,4,5	48	16.9396	4.233			1978	2030	8093.8398	33.413
1/7	3,4	39	4.2322	1.057			total	2439	9562.4254	33.97
1/14	3,4,5	48	5.6779	1.418						
1/21	2,3,4,5	40	5.7163	1.423						
1/28	3,4,5	48	5.6779	1.418						
2/4	2,3,4,5	40	18.6272	4.655						
2/11	2,3,4,5	40	11.4847	2.870						
2/18	3,4,5	40	18.6044	4.650						
2/25	3,4,5	48	19.3813	4.844						
3/4	3,4,5	40	7.0350	1.757						
3/11	3,4,5	40	7.0350	1.757						
3/18	2,3,4,5	40	7.0899	1.770						
3/25	3,4,5	48	7.5654	1.890						
4/1	3,4,5	40	5.6302	1.406						
4/8	3,5	40	5.5551	1.388						
4/15	4,5	32	3.7939	0.947						
4/22	3,4,5	48	6.2327	1.557						
4/29	4,5	40	5.3432	1.335						
5/6	3,4,5	40	5.2944	1.322						
5/13	3,4,5	40	5.1479	1.285						
5/20	3,4,5	48	5.6552	1.412						
5/27	3,4,5	40	3.9512	0.986						
6/3	2,3,5	39	2.1643	0.539						
6/10	3,5	40	3.4229	0.855						
6/17	3,4,5	48	4.1906	1.046						
6/24	3,4,5	40	32.2983	8.073						
7/1	3,4,5	41	18.0523	4.512						
7/8	3,4,5	40	31.6960	7.923						
7/15	2,3,4,5	48	47.6054	11.899						
7/22	2,3,4,5	38	5.5779	1.393						
7/29	3,4,5	40	5.6487	1.409						
8/5	2,3,4,5	32	5.2071	1.299						
8/12	4,5	40	5.7003	1.424						
8/19	3,4,5	32	3.9010	0.974						
8/26	3,4,5	16	1.9935	0.497						
9/2	3,4,5	40	4.2299	1.056						
9/9	2,3,4,5	48	4.6145	1.152						
9/16	3,4,5	47.5	4.1492	1.036						
9/23	3,4,5	32	2.6297	0.656						
9/30	3,4,5	40	4.5426	1.134						
10/6	2,3,4,5	48	3.8463	0.960						

APPENDIX B

RECOMMENDATIONS FOR BIOASSAY PERFORMANCE CRITERIA AND AN AUDIT PROGRAM TO TEST THE LABORATORY

APPENDIX B

RECOMMENDATIONS FOR BIOASSAY PERFORMANCE CRITERIA AND AN AUDIT PROGRAM TO TEST THE LABORATORY

Analysis of uranium in urine is a common radiochemical procedure in which uranium is removed from the sample matrix and quantitatively measured. Evaluation of bioassay results can determine whether a worker may have incurred internal uranium exposure at the mill, estimate the rate of elimination of uranium from the body in urine at various times after intake, and determine the amount of uranium remaining in the body. Although natural uranium is toxic, it is not believed hazardous until the intake exceeds 2.7 mg (ICRP 1968). Bioassay measurements must, therefore, be highly reliable so that the health physicist can take precautions whenever a worker is found to excrete uranium at or near hazardous levels.

The reliability of the bioassay analysis can be assured if performance criteria include *a priori* requirements for accuracy (bias) precision, and confidence. These performance criteria are established depending upon how well you need to identify the intake of uranium and control the potential for further exposure. For example, an internal dosimetry bioassay program could be established with performance criteria such that the probability is greater than 95% that all internal depositions exceeding 1% of the maximum permissible limits on dose will be identified from a routine bioassay sample.

Performance criteria for a uranium mill bioassay program should require a high degree of confidence (e.g., $P > 95\%$) that all bioassay results greater than 5 µg of U/ℓ are detected. Three major performance criteria that should be considered are:

- Type I (a) and Type II (b) errors must not exceed 0.05 at the detection limit. That is, no more than 5% of the samples should be judged to contain no activity when, in fact, the true activity was L_d or greater (Type II error). Additionally, no more than 5% of the samples containing no activity should be judged as containing activity (Type I error).

- Results should be unbiased.

- All results including negative values and those below the L_d should be reported (i.e., no data censoring).

Two special levels that should be considered when establishing lower limits for the bioassay measurement are:

- The "decision limit" (L_c) is the activity level at which a decision is made as to whether or not the sample contains activity. That is, if the reported activity of a sample is below L_c, the sample is

judged to contain no activity and if the reported activity of a sample is at or above L_c, the sample is judged to contain activity.

- The "detection limit" (L_d) is defined in relationship to L_c such that the smallest true signal will be detected 95% of the time, i.e., a measurement result equal to L_d may be relied upon (95% of the time) to lead to detection. This is what is usually considered the detection limit at the 95% confidence level.

Once bioassay performance criteria for accuracy (bias), precision, and confidence are established, the health physicist should be responsible for auditing or testing the bioassay laboratory or vendor to ensure that the performance criteria are met. An audit program consists of submitting blank and spiked samples to the laboratory with the same characteristics as the actual samples collected in the routine bioassay program. Audit samples should be submitted to the laboratory in a manner such that they cannot be differentiated from typical routine samples. In other words, audit samples should be submitted as blind and open tests in an amount up to approximately 10% to 15% of the total number of routine samples.

To test laboratory performance at the decision limit (L_c), enough blank samples must be submitted so that the standard deviation (S_o) of the net activity can be determined when the sample contains no activity. If the distribution of the blank urine results are assumed Gaussian, then:

$$L_c = \bar{X}_o + K_\alpha S_o$$

where

$$X_o = \sum_i (X_i/n)$$

$$S_o = \sum_i (X_i - \bar{x})^2/ (n-1)$$

n = number of available audit samples

K_α = the upper percentile from the standard Gaussian distribution corresponding to the size of the desired Type I error (e.g., if $\alpha = 0.05$, the $K_\alpha = 1.645$)

and

$$L_d = L_c + K_\beta S_d$$

where

K_β = the upper percentile from the standard Gaussian distribution corresponding to the size of the desired Type II (e.g., if $\beta = 0.05$, the $K_\beta = 1.645$)

S_d = standard deviation of the net activity determined from measurements of spiked samples.

The health physicist should maintain a running table and chart of the data, $\bar{X}_o$, S_o, and L_c. The chart, along with the table, is convenient so that any trends with time can be easily observed. Table B.1 illustrates some of the relevant parameters for a few blank urine samples submitted for uranium analysis. The table contains columns for date, audit results, $\bar{X}_o$, S_o, L_c and the results from any outlier test. The table also indicates what results were deleted because they were outliers and what results were subsequently reinstated when future data indicated that a deleted result probably was not an outlier.

Whenever a new set of results are obtained, the table is updated. Before a new $\bar{X}_o$, S_o, and L_c are calculated, the data needs to be inspected for outliers. This can be done by first visually inspecting the chart or table and then testing any suspicious data. After any outliers have been removed from the data, the new $\bar{X}_o$, S_o, and L_c are determined. Test sample results determined to be outliers are considered failures when laboratory performance is being evaluated.

TABLE B.1. Bioassay Data for Natural Uranium Blank Audit Samples

Date	Audit Results, µg of U	$\bar{X}_o$	S_o	L_c	Outlier Test
1	0.23				
	0.03				
	0.00				
	0.19				
	0.21	0.13	0.11	0.31	
2	0.03				
	0.035				
3	0.85(a)	significant outlier (<0.01)			$R_{11} = 0.756$

(a) This audit result has been determined to be an outlier according to the Dixon Criterion (Natrella 1966). Calculation of L_c should not include outliers.

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Uranium urinalysis and in vivo examination results obtained from workers at eleven uranium mills between 1978 and 1980 were evaluated by Pacific Northwest Laboratory at the request of the U.S. Nuclear Regulatory Commission. The main purpose of this evaluation was to determine the degree of the mills' compliance with bioassay monitoring recommendations given in the draft NRC Regulatory Guide 8.22. The effect of anticipated changes in the draft guidance, as expressed to PNL in May 1982, was also studied. Statistical analyses of the data showed that the bioassay results did not reliably meet the limited performance criteria given in the draft regulatory guide. Furthermore, quality control measurements of uranium in urine indicated that detection limits at $\alpha = \beta = 0.05$ ranged from 13 µg/ to 29 µg/ℓ, whereas the draft regulatory guidance suggests 5 µg/ℓ as the detection limit. Recommendations for monitoring frequencies given in the draft guide were not followed consistently from mill to mill. The results of these statistical analyses indicate a need to include performance criteria for accuracy, precision, and confidence in revisions of the draft regulatory guide. Revised guidance should also emphasize the need for each mill to continually test the laboratory performing urinalyses by submitting quality control samples to insure that the performance criteria are being met.

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