Draft White Paper

Strategies to Investigate Allegations of Corrupt Bioassay Monitoring at Fernald

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INTRODUCTION

During the Fernald Work Group meeting on January 29, 2010, the concern was raised by petitioner [redacted] and others as to the integrity of the Fernald Feed Materials Production Center (FMPC) bioassay program; specifically, whether the data entered onto log sheets and other hardcopy records reflected the actual uranium sample results, or whether these data were systematically manipulated to avoid recording high internal exposures. SC&A was charged with developing strategies to investigate and analyze the issue, and provide information as to the feasibility and value of each approach. To this end, SC&A has developed three possible strategies to investigate the potential issue of data integrity related to the bioassay program at FMPC.

The three strategies can be summarized as follows:

(1) For a select group of workers, compare the urinalysis results to in-vivo count data to see if large increases in whole-body count results are reflected in the urinalysis records, or if they may have systematically under-reported uranium bioassay results.

(2) For a select group of workers, perform biokinetic analysis of urinalysis records using Integrated Modules for Bioassay Analysis (IMBA) to see if implausibly large decreases in urine concentrations are a common occurrence after a high sample result.

(3) Examine the available Daily Weighted Exposure (DWE) reports to identify the higher risk job titles, plant locations, and years for comparison with bioassay sampling for a group of claimants that can be identified by job title and plant locations by year.

Further descriptions of each of these strategies are included in the following sections, and include the benefits and limitations, feasibility of the strategy, and an example implementation of the strategy (proof of concept).

Given that each strategy requires some interpretation of urinalysis data (and in one strategy, the comparison with in-vivo data), technical considerations for these monitoring types must be considered. Because these technical issues are applicable to all three strategies, they are discussed in detail in Attachment 1 and only briefly summarized in each respective strategy description.

1.0 STRATEGY 1: COMPARISON OF URINALYSIS AND IN-VIVO MONITORING DATA FOR SELECTED WORKERS

1.1 THEORY AND APPROACH

This strategy involves a direct comparison of worker records for individuals involved in both the urinalysis and in-vivo counting programs. It is assumed that significant intakes of uranium would be reflected in both the urinalysis and in-vivo records for an individual. Therefore, it follows that increases in the magnitude of in-vivo samples would likewise be seen as an increase in urine concentration. A significant increase in the in-vivo monitoring results without a comparative increase in urine concentration might indicate the intentional under-reporting of urinalysis data.

1.2 FEASIBILITY/PROOF OF CONCEPT

Strategy 1 is dependent on the number of workers that can be identified who have a significant number of monitoring records for both the in-vivo and urinalysis monitoring programs. SC&A has identified 53 workers who had at least 10 samples in each monitoring category. An example comparison of in-vivo and urinalysis records for two of these workers is shown in Figures 1-1 and 1-2.

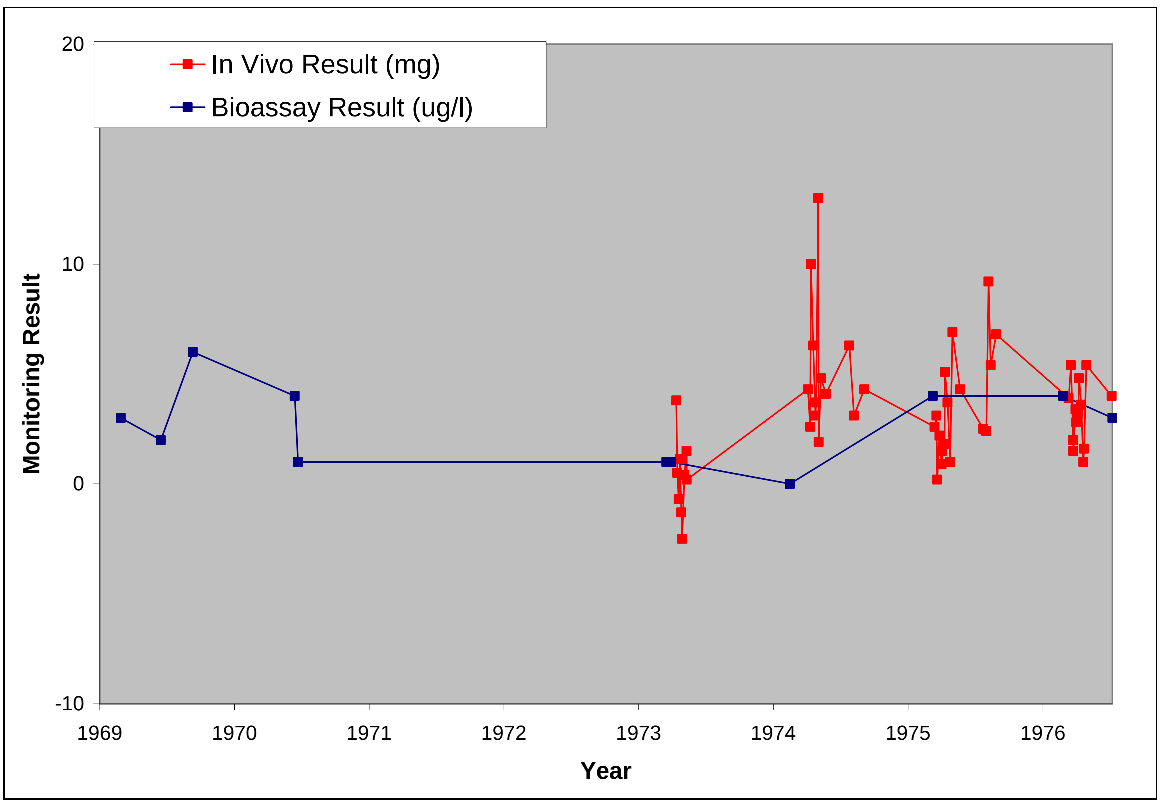

Figure 1-1. Comparison of In-Vivo (mg U Total) and Bioassay Results (ug/l U Total) for a Select Worker

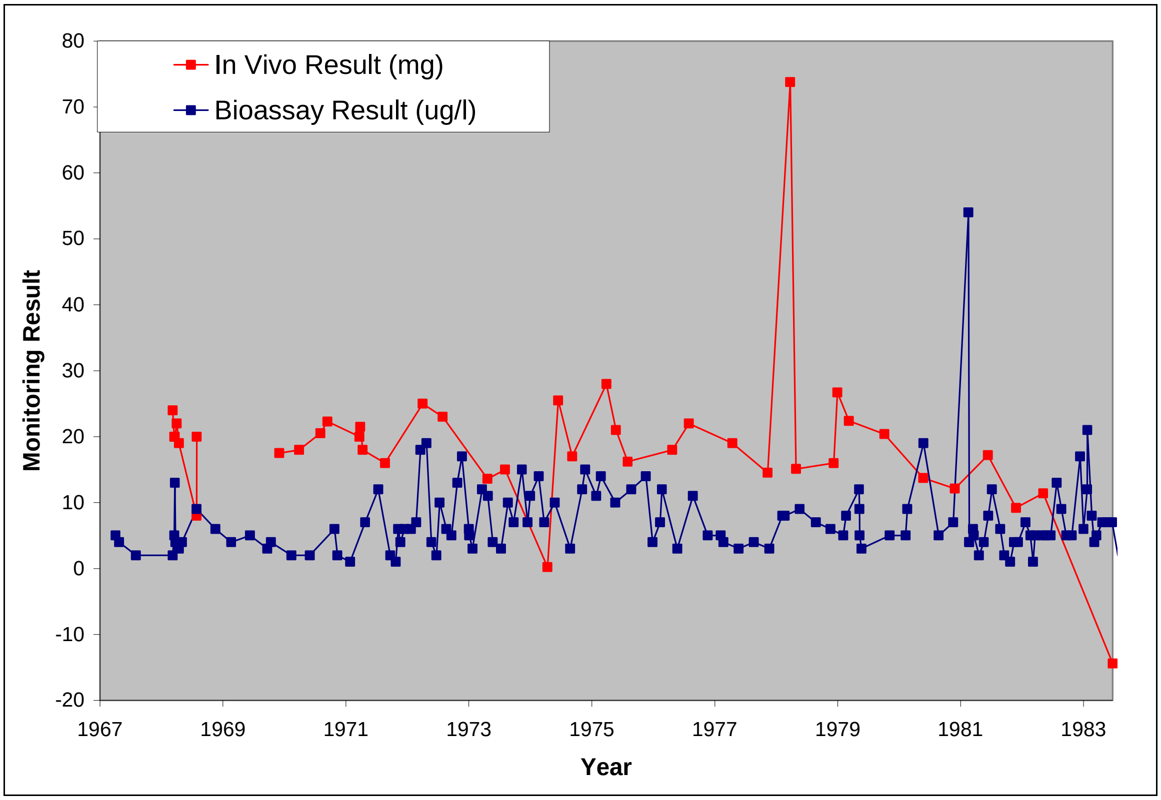

Figure 1-2. Comparison of In-Vivo (mg U Total) and Bioassay Results (ug/l U Total) for a Select Worker

1.3 BENEFITS AND LIMITATIONS OF THE STRATEGY

Benefits:

- Provides a direct comparison of individual worker records to identify any suspect urinalysis results based on the separate in-vivo monitoring program.
- Workers who were targeted for both the urinalysis and in-vivo programs were likely believed to have the highest internal exposure potential for uranium. Because of the high potential for uranium intake, they would also be the likely targets for any under-reporting of urinalysis data.

Limitations:

- Urinalysis sampling and in-vivo monitoring were not carried out on the same days, so peaks and valleys on the magnitude of each monitoring method will not match up exactly on a time scale.
- In-vivo monitoring was not performed at FMPC until 1968, so any comparisons can only be made from this year onward.

- Comparisons are restricted to those workers who were monitored via both urinalysis and in-vivo counting. Workers who were only monitored via urinalysis may also have had their results under-reported, but would not be identified by this strategy.
- Uranium solubility type has a significant effect on the rate of passage of uranium from the lungs into the blood and subsequently the excretion rate observed in urinalysis data. Furthermore, interpretation of in-vivo monitoring requires accurate knowledge of detection methods and procedures, as well as the relative abundance of individual uranium isotopes and daughter products. Without specific knowledge of these aspects, an accurate and reliable comparison of in-vivo results to urinalysis data may be difficult. Further discussion of this issue is found in Attachment 1.

2.0 STRATEGY 2: CONSISTENCY AND RELIABILITY OF URINALYSIS RESULTS FOR SELECTED WORKERS

2.1 THEORY AND APPROACH

This strategy assumes that while integrity issues may have existed, the practice of under-reporting the worker's urinalysis results was not so widespread as to encompass all of the individual's records. Therefore, workers with significant uranium intakes who had a portion of their urinalysis samples under-reported would show implausibly large changes in uranium concentrations reported over time. For example, a worker may have a high urine sample that is a reflection of an actual intake accrued. If this large sample is then followed by implausibly low samples, which cannot be explained by established biokinetic models, then this may indicate that these low samples have been under-reported.

2.2 FEASIBILITY/PROOF OF CONCEPT

One requirement for selecting workers for this strategy is that they must have a reasonable number of urinalysis measurements over a given timeframe. The urinalysis data contained in the HIS-20 database were broken down by decade to determine the pool of workers with a significant number of data points, and the results of this query are shown in Table 2-1. Decades were chosen as the cutoff point for Table 2-1; however, any combination of timeframes could be used to sample the worker records, depending on the timeframes of interest.

Table 2-1. Frequency of Worker Sampling by Decade

Number of Records in Period	Number of Workers with Listed Number of Records by Period			
	1950s	**1960s**	**1970s**	**1980s**
1–10	2442	1342	933	3317
11–20	741	516	263	428
21–30	371	392	64	246
31–40	242	472	40	122
41–50	149	253	88	91
>50	293	369	90	337

Based on the results shown in Table 2-1, there certainly appears to be a sufficient pool of workers to develop a random sample to test via this strategy. An example of the analysis proposed for Strategy 2 is presented in Figures 3 and 4 for a selected worker. For these IMBA calculations, it is assumed the worker sustained an acute intake of enriched uranium approximately halfway between the high sample and the previous sample.

As shown in Figure 2-1, the subsequent bioassay results agree well with the high sample if a Type F absorption is assumed. If Type M absorption is assumed, then there are a couple bioassay samples which do not agree with the high sample. Figure 2-2 shows that even if Type F is assumed, there is one data point that is too low to be compatible with the high sample (data point is highlighted in red).

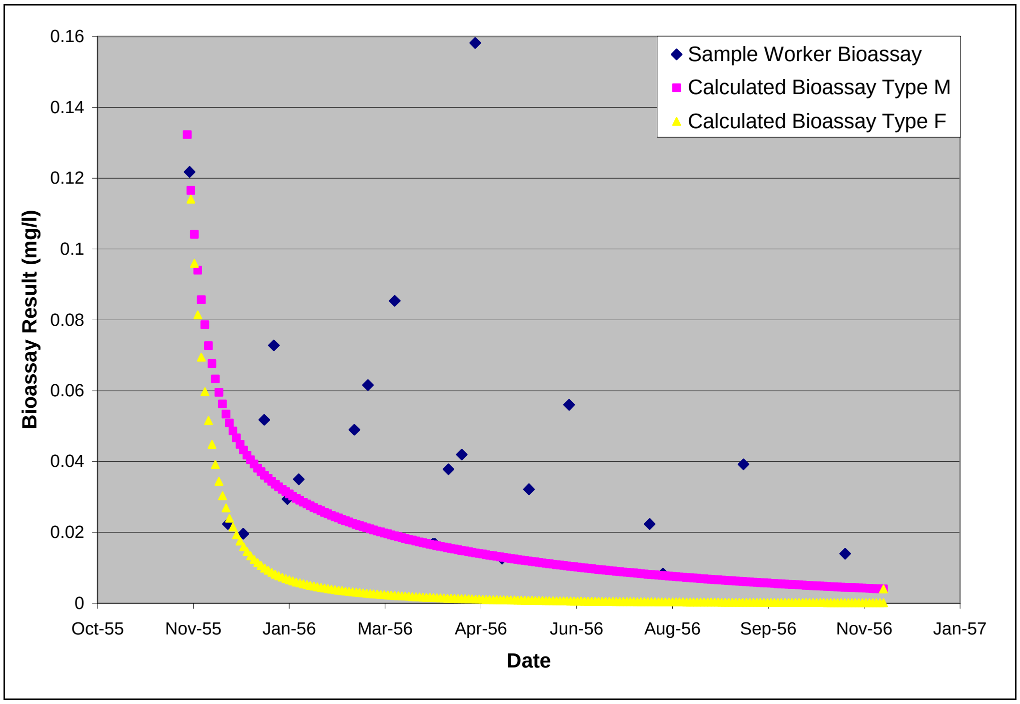

Figure 2-1. IMBA Predicted Bioassay Results Based on First High Sample for Select Worker Compared to Actual Bioassay Results

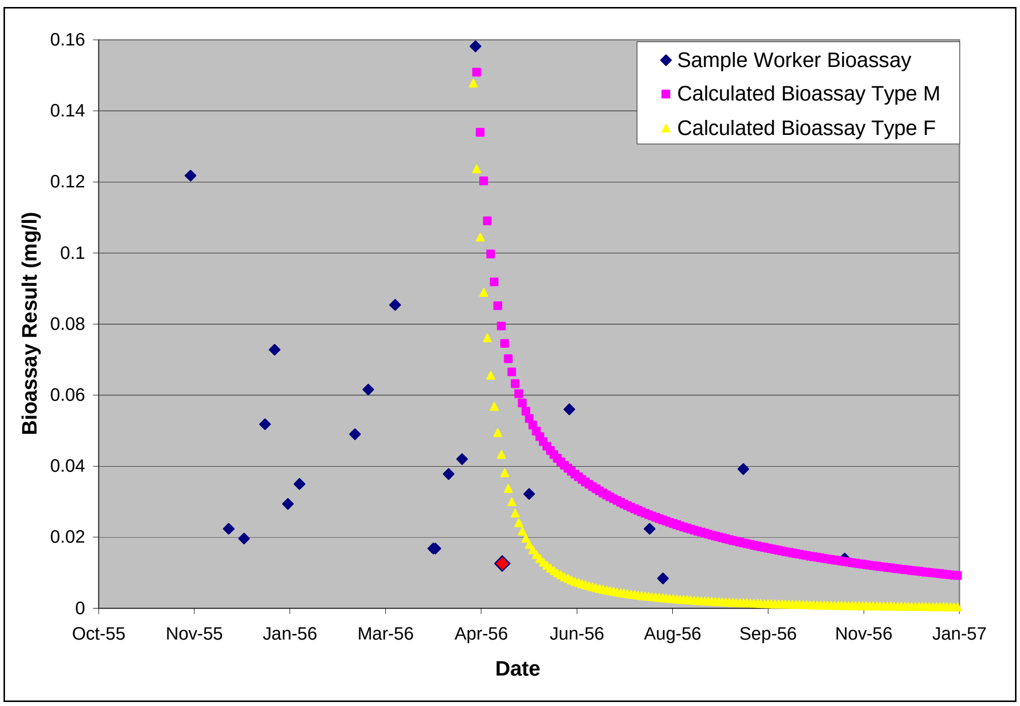

Figure 2-2. IMBA Predicted Bioassay Results Based on Second High Sample for Select Worker Compared to Actual Bioassay Results

2.3 BENEFITS AND LIMITATIONS OF THE STRATEGY

Benefits:

- Directly examines individual bioassay records to identify inconsistencies in reported values that may indicate the practice of under-reporting high samples.
- Strategy is not restricted to any one period during the SEC.

Limitations:

- The strategy relies on workers with multiple urine samples taken frequently over a given time period, and would not detect under-reported sampling for workers with sparse monitoring.
- High urinalysis records may not have been the result of a significant uranium intake, but rather of alternate factors, such as the contamination of the sample. Therefore, subsequent records that show implausibly large drops in concentration may not be the result of under-reporting of the later samples, but rather the overestimation of the original high sample.
- As mentioned in Strategy 1 and discussed in detail in Attachment 1, uranium solubility type has a significant effect on the excretion rate observed in urine. Without knowledge of the solubility type encountered by an individual worker, an accurate biokinetic assessment of urinalysis results becomes difficult. Further discussion of this issue is found in Attachment 1.

3.0 STRATEGY 3: COMPARISON OF DAILY WEIGHTED EXPOSURE DATA TO URINALYSIS RECORDS FOR KNOWN PLANT AREAS, JOB TYPES, AND TIME PERIODS

3.1 THEORY AND APPROACH

Daily weighted exposure (DWE) reports are provided for various facilities, job types, and periods of exposure at FMPC. The DWE reports provide a comparison of the intake potential for various job types and plant areas. It is assumed that those job types and areas with the highest intake potential would also have a higher-than-average concentration of uranium in urine. Job title and work location data will be extracted from HIS-20 (when available) and compared with DWE reports to determine if there were consistently low bioassay results reported for workers with a high intake potential. If the higher-risk job titles consistently show below-average concentrations of uranium in urine, this might indicate that there was a systematic under-reporting of high urine samples.

3.2 FEASIBILITY/PROOF OF CONCEPT

Table 3-1 provides a listing of DWE reports for FMPC by plant and year that SC&A was able to identify on the Site Research Database (SRDB). The identification of specific job titles is derived from the NIOSH DCAS Claims Tracking System (NOCTS), so only claimants can be used for comparison. Further restricting the pool of available workers is the fact that plant location is only reported in the HIS-20 database for select workers, and generally only from 1953–1958 (and to a lesser extent, 1959–1961).

Table 3-1. Availability of DWE Reports by Plant Area at Fernald

Plant Area	Identified DWE Reports
Pilot Plant	1953, 1956–1957
Plant 1	1955–1963, 1965–1967
Plant 2	1955–1961
Plant 2-3	1962, 1965–1968
Plant 3	1956–1961
Plant 4	1954–1965, 1967–1969
Plant 5	1953–1963, 1965–1969
Plant 6	1953–1959
Plant 6 Inspection and Machining	1960–1968
Plant 6 Rolling Mill	1960–1968
Plant 7	1955–1956
Plant 8	1955–1968
Plant 9	1954–1955, 1957, 1959–1960, 1962–1966, 1968

Table 3-2 shows the plants and years in which SC&A was able to identify a DWE report, as well as a group of claimants that are identified with that particular plant and year. One difficulty in matching up specific claimants to the DWE data is the fact that job titles listed in the DWE reports are much more specific than typically contained in NOCTS. The vast majority of claimants identified with specific plants have the rather generic job title of 'operator' or 'technician,' whereas the DWE reports will specifically state what type of operator or technician is being examined (such as 'medart straightener operator' or 'sample preparation technician'). Furthermore, the DWE report often contains multiple instances of a given job title with drastically different air sampling data. For example, the DWE report for Plant [[redacted]] in 1961 shows [[redacted]] different DWE values for the 'mill man.' Depending on where in the plant the worker was stationed and what the specific duties were as a 'mill man,' the DWE values could range from 21 dpm/m^3 (~0.3 × MAC) to 1,750 dpm/m^3 (~25 × MAC).

However, one trend that holds true throughout nearly all of the DWE reports is that administrative personnel, such as clerks, recorders and foreman-type job titles, repeatedly had lower DWE air sample results than the various types of 'operators,' which consistently had a higher exposure potential. Therefore, in a general sense, the plant-specific urinalysis data can be examined to see if the operator job categories consistently have higher urinalysis results than the lower-risk jobs, such as the administrative categories. As an example analysis, the bioassay and DWE data are analyzed for the Pilot Plant in 1957 and provided in Attachment 2.

Table 3-2. Plants and Years in which Claimant Urinalysis can be Matched and DWE Data Exists

FEMP Location	# of Claimants (# of Samples)*								
	1953	1954	1955	1956	1957	1958	1959	1960	1961
Pilot Plant	-	-	-	20 (184)	11 (53)	-	-	-	-
Plant 1	-	-	14 (42)	39 (140)	22 (49)	-	-	-	-
Plant 2	-	-	21 (85)	42 (127)	32 (67)	1 (1)	-	-	-
Plant 2-3	-	-	-	-	-	-	-	-	-
Plant 3	-	-	31 (93)	23 (43)	27 (64)	1 (1)	-	-	18 (18)
Plant 4	-	5 (13)	16 (30)	26 (112)	27 (148)	4 (4)	-	-	-
Plant 5	8 (11)	5 (11)	48 (343)	61 (135)	69 (257)	9 (9)	-	-	1 (1)
Plant 6	6 (6)	7 (21)	48 (167)	73 (444)	121 (822)	7 (7)	-	-	-
Plant 7	-	-	42 (629)	25 (154)	-	-	-	-	-
Plant 8	-	-	15 (66)	35 (197)	42 (387)	2 (2)	-	-	-
Plant 9	-	-	5 (8)	-	21 (58)	-	-	-	-

* Dashes indicate that either no claimant samples could be identified or no DWE report is available for that plant and year.

In addition, a handful of DWE reports contain an appendix that provides urinalysis data by job title. The benefit of this information is that the appendices use many of the same specific job titles as the DWE report; therefore, a much clearer connection can be made between the urinalysis and the DWE data. This additional urinalysis data can be checked for consistency with the exposure potential outlined in the given report. An example of this secondary approach is found in Attachment 3 for Plant 1 in 1967.

3.3 BENEFITS AND LIMITATIONS OF THE STRATEGY

Benefits:

- Specifically investigates the highest risk jobs and plant locations, which would likely be the target of any purposeful under-reporting of urine concentrations.
- A handful of DWE reports list average urine concentration results by job category for the given plant as an appendix. These data can be used to expand the pool of workers examined for that plant beyond available claimant data, and also provide a more direct comparison of the DWE and urinalysis data by job category.

Limitations:

- Daily weighted exposure reports identified are limited to the years and plants shown in Table 3-1.
- Job title data for urinalysis sampling is limited to the claimant job categories on NOCTS. This pool is further restricted by the practice of reporting the plant location in the HIS-20 records themselves (generally 1953–1958 and, to a lesser extent, 1959–1961).
- Direct comparison of an individual worker's urinalysis records to those workers analyzed in the DWE study is not possible, because of a lack of information on the specific workers sampled in the DWE study. This is further clouded by the same job title appearing multiple times in a given DWE report with drastically different air sampling results (i.e., the mill man in Plant [redacted], 1961).
- It is not clear to what extent respiratory protection was used for high-risk jobs and specific workers. Therefore, even a worker who had the highest DWE assessment in a given plant and year may not have had significantly higher urine concentrations, due to the use of respirator or other personal protective equipment.
- As stated in the previous strategies and further described in Attachment 1, uranium solubility type significantly affects the rate of passage of uranium into the urine. Therefore, if workers were exposed to a very insoluble form of uranium, it may not be reflected in the urinalysis records, even though that worker may have been subject to a high DWE to uranium. The inverse may also be true, in which a worker with a low DWE inhales a highly soluble form of uranium, which would result in a comparatively large urinalysis result. Further discussion of this issue is presented in Attachment 1.

ATTACHMENT 1: TECHNICAL LIMITATIONS OF URINALYSIS AND IN VIVO METHODS IN DETERMINING URANIUM EXPOSURES

This attachment describes the technical limitations of in-vivo and urinalysis monitoring methods in the context of their possible effect on the accuracy and conclusiveness of Strategies 1–3.

Difficulties in Determining the Lung Content of Uranium from In-Vivo Monitoring Data:

The uranium content in the lungs usually is estimated by in-vivo counting of 186 keV photon emissions from U-235. Depending on the sensitivity of the counting system, it may also be feasible to estimate the U-238 activity in the lungs by counting 63 keV and 93 keV emissions from the U-238 daughter Th-234, assuming Th-234 is in equilibrium with U-238. The accuracy of in-vivo lung measurements of uranium is limited by the weak photon energies (particularly from Th-234), the low yield of photon emissions, and uncertainty in the calibration associated with individual differences in chest wall thickness and location of internally deposited uranium in the chest. For Th-234 counting, an additional uncertainty is introduced by the assumption of its equilibrium with U-238. For the more common method of counting U-235 photon emissions, interpretation of the data depends on knowledge of the isotopic composition of the inhaled uranium. That is, one needs to know the relative amounts of U-234, U-235, and U-238 in the inhaled material in order to estimate the total uranium in the lungs. For example, the estimated total uranium content based on the U-235 content will be much different for depleted uranium, natural uranium, and uranium at various levels of U-235 enrichment, because of the large differences in the percentage of total mass represented by U-235.

In evaluating the workability and relative merits of Strategy 1, it is important to assess the reliability of the in-vivo lung counting procedure at Fernald, including knowledge of the isotopic composition of the airborne uranium at times and locations of interest. Without specific knowledge of the counting procedure, methods, and types of uranium encountered, a comparison between in-vivo counting and urinalysis data may become difficult.

Difficulties Arising from the Behavior of Inhaled and Absorbed Uranium:

Inhaled uranium-containing materials show a wide range of dissolution properties in the lungs. The portion of inhaled uranium that is absorbed to blood shows a high level of urinary excretion soon after absorption.

The more soluble uranium compounds show rapid removal from the lungs and rapid absorption to blood. Roughly two-thirds of the absorbed uranium is excreted in urine during the first 24 hours. Thereafter, the urinary excretion rate declines rapidly. Only about 2% is excreted in urine during the next 24 hours, and the urinary excretion rate continues to decline thereafter. Since it is likely that relatively soluble uranium compounds were commonly handled at Fernald, large decreases in urinary uranium over a short period might be expected. This limits the usefulness of Strategy 2 for uranium workers at Fernald (i.e., a check for implausibly large decreases in urine concentrations after a high sample result).

Urinary measurements generally are not a good way to monitor intake of relatively insoluble uranium compounds, such as uranium dioxide, because little of the inhaled activity reaches blood and hence little is excreted in urine. This would be a particular problem for Strategy 1, in that high in-vivo counts would not correspond to high urinary uranium, and perhaps not even to measurable urinary uranium in many cases. This would also be an issue for Strategy 3 if a worker with a high daily exposure was subject to an insoluble form of uranium.

Given these considerations, reliable information about the uranium solubility type becomes very important. Although the HIS-20 database does provide a solubility type designation along with each urinalysis result, the origin and reliability of these solubility designations has not yet been established, so it is not clear to what extent they can be used for comparison with in-vivo counts (Strategy 1), biokinetic analysis (Strategy 2), or comparison with DWE reports.

ATTACHMENT 2: EXAMPLE OF STRATEGY 3 ANALYSIS FOR THE PILOT PLANT IN 1957 USING CLAIMANT DATA

The daily weighted exposure (DWE) data by job category for the Pilot Plant in 1957 is provided in Table A2-1. As one would expect, the higher DWE results are for the various types of operators, while the administrative job categories such as the supervisors were much lower.

Table A2-1. Job Specific DWE Data Collected in December of 1957

Job Title	Area	DWE Result ($d/m/m^3$)
Remelt and Burnout Operators	3037	1,136.4
Centrifugal Casting Operators	3037	942.5
Reduction Operators	3037	346.3
Chief Technicians	3037, 3620	313
Roving Operators	General Plant	210.8
Saw Operators	3037	123.2
All Personnel	3620	115.8
Breakout Operators	3037	114.7
General Operators	3013	71.7
Chief Technicians	3013	66.2
Superintendant, Administrative Assistant, Clerks	Administrative	53.3
Area Supervisor, Technologist	3037, 3620	46
Area Supervisor	3013	27.5

As was shown in Table 3-2, urinalysis data for 11 claimants (53 total samples) could be identified with the Pilot Plant in 1957. All but [redacted] of these 11 claimants had the job title of [redacted], while the [redacted] had the listed job titles of [redacted], which would clearly fall into that administrative category. By rank ordering the claimant data, it was found that this [redacted] bioassay sample fell at about the 16th percentile, which is in excellent agreement with the DWE data.

In addition to this, the rank-ordered data for chemical operators were compared with the data for all workers (not just claimants) who could be identified with the Pilot Plant in 1957. The results can be seen in Figure A2-1, which shows that the uranium concentrations for chemical workers are very similar to the overall population of identified Pilot Plant workers for 1957. However, Figure A2-1 also shows that from the 20th percentile to approximately the 80th percentile, the uranium concentrations for chemical workers are just slightly higher than the Pilot Plant worker population as a whole. While the difference is not overly large, there is nothing that indicates that individuals in a seemingly higher-risk job category, such as the chemical workers, were having their urinalysis results systematically under-reported.

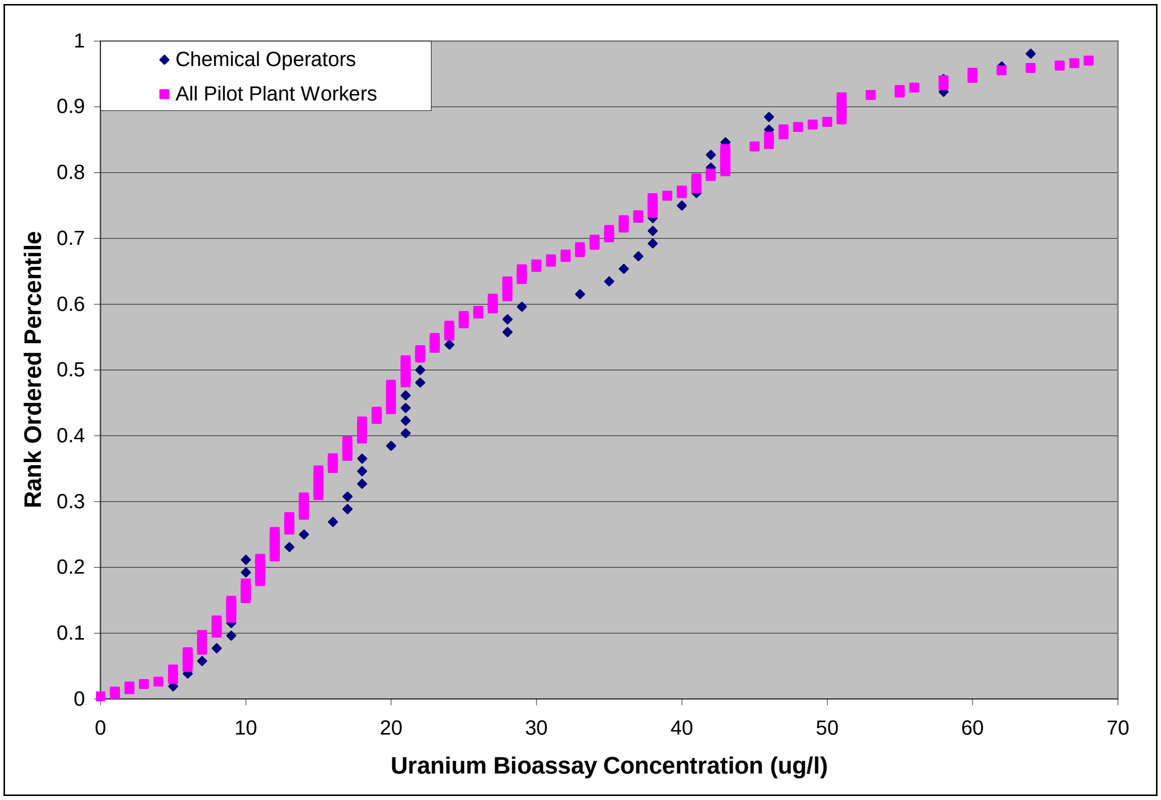

Figure A2-1. Rank-Ordered Plot of Chemical Operator Uranium Concentrations versus All Identifiable Pilot Plant Workers

ATTACHMENT 3: EXAMPLE OF STRATEGY 3 ANALYSIS FOR PLANT 1 IN 1967 USING DWE URINALYSIS DATA

Table A3-1 shows the DWE data for Plant 1 in 1967, as well as the plant average urine concentrations reported in an appendix to the DWE report. This table does not show very good agreement between the DWE assessments and plant average urine concentrations. For example, the job title of ‘Wheelabrator’ had by far the highest DWE; however, that job category had one of the lowest average urine concentrations. Meanwhile, the job title of ‘Williams Mill Operator’ had one of the highest average urine concentrations, yet had a comparatively low DWE.

One possibility is that the jobs with the high DWEs all wore respiratory equipment during the highest risk activities. In fact, the DWE report does recommend that the ‘Wheelabrator Operator’ wear a dust-type respirator during the dustiest activity performed (operating the wheelabrator itself). However, the same recommendation is made for the ‘Williams Mill Operator’ during the dustiest activity for that job type (changing drums at the sampling station). So it is not clear why the DWE and urinalysis data for this plant and year do not seem to mirror each other.

Table A3-1. Comparison of Job Specific DWE Data and Plant Average Urine Concentrations

Job Title	DWE Result (d/m/m^3)	Plant Average Urine Concentration (mg/l)
[Redacted] Operator	120	0.006
[Redacted] Operator	50	0.012
[Redacted] Technician	50	0.007
[Redacted] Operator	50	0.005
[Redacted] Foreman	20	0.003
[Redacted] Clerk	20	0.003
[Redacted] Operator	20	0.014
[Redacted]	20	0.004
[Redacted] Operator	20	0.021
[Redacted] Operator	20	0.009
[Redacted] Operator	20	0.006
[Redacted] Clerk	10	Not Available
[Redacted] Technician	10	0.002
[Redacted] Operator	10	0.008
[Redacted] Operator	10	0.011
[Redacted] Operator	10	0.002
[Redacted]	10	Not Available