Draft

ADVISORY BOARD ON
RADIATION AND WORKER HEALTH
National Institute for Occupational Safety and Health

REVIEW OF HANFORD PETITION SEC-00155 AND THE ASSOCIATED NIOSH EVALUATION REPORT

Contract No. 200-2009-28555
SCA-SEC-2012-0058, Revision 0

Prepared by

Joyce Lipsztein, Ph.D.
Arjun Makhijani, Ph.D.
S. Cohen & Associates
1608 Spring Hill Road, Suite 400
Vienna, Virginia 22182

Saliant, Inc.
5579 Catholic Church Road
Jefferson, Maryland 21755

August 2012

Disclaimer

This document is made available in accordance with the unanimous desire of the Advisory Board on Radiation and Worker Health (ABRWH) to maintain all possible openness in its deliberations. However, the ABRWH and its contractor, SC&A, caution the reader that at the time of its release, this report is pre-decisional and has not been reviewed by the Board for factual accuracy or applicability within the requirements of 42 CFR 82. This implies that once reviewed by the ABRWH, the Board's position may differ from the report's conclusions. Thus, the reader should be cautioned that this report is for information only and that premature interpretations regarding its conclusions are unwarranted.

S. Cohen & Associates: ***Technical Support for the Advisory Board on Radiation & Worker Health Review of NIOSH Dose Reconstruction Program***	**Document No.** SCA-SEC-2012-0058 **Effective Date:** Draft – August 7, 2012 **Revision No.** Draft – 0
Review of Hanford Petition SEC-00155 and the Associated NIOSH Evaluation Report	Page 2 of 88
Task Manager: _____ Date: _____ Arjun Makhijani, Ph.D.	**Supersedes:** N/A
Project Manager: _____ Date: _____ John Stiver, CHP	**Reviewer (s):** Robert Bistline, Ph.D.

Record of Revisions

Revision	Effective Date	Description of Revision
0 (Draft)	08/072012	Initial issue

TABLE OF CONTENTS

ACRONYMS AND ABBREVIATIONS

ABRWH or Advisory Board	Advisory Board on Radiation and Worker Health
AEC	Atomic Energy Commission
Am	americium
Bq/L	becquerel per liter
CED	pg. 45 (or does author mean “CEDE?”
CEDE	Committed Effective Dose Equivalent
CLP	Contract Laboratory Program
DOE	U.S. Department of Energy
DOE-RL	U.S. Department of Energy - Richland Operations Office
dpm	disintegrations per minute
EEOICPA	Energy Employees Occupational Illness Program Compensation Act
EML	Environmental Measurements Laboratory
EPA	Environmental Protection Agency
ER	Evaluation Report
FY	fiscal year
g	gram
GM	geometric mean
ICRP	International Commission on Radiological Protection
IG	Inspector General
JAEA	Japan Atomic Energy Agency
L	liter
MDA	minimum detectable activity
mrem	millirem
nCi	nanocurie
NIOSH	National Institute for Occupational Safety and Health
Np	neptunium
OIG	Office of the Inspector General
ORAU	Oak Ridge Associated Universities
pdf	portable document format
PFP	Plutonium Finishing Plant

PNL	Pacific Northwest Laboratories
PNNL	Pacific Northwest National Laboratories
POC	probability of causation
Pu	plutonium
PUREX	Plutonium-Uranium Extraction
QA	quality assurance
QC	quality control
QUS	quick uranium soluble
rem	Roentgen equivalent man
RESL	Radiological and Environmental Sciences Laboratory
RMC	Remote Mechanical C
SC&A	S. Cohen & Associates
SEC	Special Exposure Cohort
SOW	statement of work
Sr	strontium
SRDB	Site Research Database
SWEC	Stone Webster Engineering Corporation
U	uranium
UST	U.S. Testing Company
WHC	Westinghouse Hanford Company

1.0 FINDINGS AND OBSERVATIONS

This report is a review of Special Exposure Cohort (SEC) Petition SEC-00155 (SEC 2009), which concerns the integrity of bioassay data at Hanford from 1987 to 1989, and the associated Evaluation Report (ER) (NIOSH 2011) of the National Institute for Occupational Safety and Health (NIOSH). Specifically, the basis of the petition is that the bioassay data for the Plutonium Finishing Plant (PFP) in the 200 Area generated by U.S. Testing Company (UST), which operated a laboratory on the Hanford Site during this period under a subcontract to Pacific National Laboratory (PNL), are not trustworthy and should not be used for dose reconstruction because of fraud and mishandling of data by the company that was detailed by the U.S. Environmental Protection Agency (EPA), notably in its Action Referral Memorandum dated April 4, 1990 (EPA 1990a).

In reviewing the integrity of the data, NIOSH concluded in its ER that the bioassay data were not affected by the problems detailed by the EPA and could be used in dose reconstruction (NIOSH 2011, p. 35 and p. 38).

SC&A reviewed the SEC petition, NIOSH's ER, associated documents in the Site Research Database (SRDB), and records of the proceedings against UST, including non-public records. SC&A also interviewed the petitioner and the petitioner's representative, and various experts involved in the May 1990 audit of UST's work at its Richland facilities (DOE 1990b) and in the retrospective review of its bioassay program conducted by an outside team in 1991 (Omenn et al. 1991). SC&A also reviewed documents provided by the petitioner and the petitioner's representative. Finally, SC&A also sent questions regarding specific issues that could have been related to the topic of the petition to the [redacted] and the [redacted]. Interview summaries are in Attachments A through D, and the responses of the two PNL experts who oversaw UST's work and contract are in Attachment E.

SC&A investigated the following areas of concern for the 1987–1989 period:

1. Was there any direct evidence of fraud or mishandling of data directly related to the bioassay program?
2. Were there issues of concern that pointed to the potential for fraud or data mishandling?
3. Were there data integrity concerns regarding the bioassay data other than fraud and mishandling of data period?
4. How do the issues raised by EPA relate to the usability of the bioassay data?

In addition, due to a specific issue regarding the use of fecal data in dose reconstruction raised by the petitioner and the petitioner's representative, SC&A also reviewed four completed Hanford dose reconstructions that included the 1987–1989 period and also had fecal data. SC&A did not review the petitioner's dose reconstruction at the direction of the Designated Federal Official for the Advisory Board on Radiation and Worker Health (ABRWH), since there is pending litigation relating to that claim (Katz 2012).

Finding 1: SC&A's review of four cases (not a statistically valid sample) that used fecal data in the dose reconstruction revealed that in one case, the fecal data were not used in accordance with the established procedure. This appears to have resulted in an underestimate of the plutonium intake in that case.

Finding 2: There is less confidence in the fecal sample results, since no Quality Assurance (QA) samples were ever analyzed in the period under review. As one of the May 1990 oversight experts noted in an interview, QA samples are needed "to assure that the results are credible. It does not necessarily mean that results are not credible, but it certainly is a weakness of the program that there were no fecal QA samples" (see Attachment A). The added uncertainty arising from this problem should be addressed in dose reconstruction.

Observation 1: The problems of QA with the work of U.S. Testing (UST) were longstanding ones, stretching back to the 1960s. There is also evidence that both UST and PNL made efforts to correct these problems. However, their persistence does raise a general question about the quality of the UST bioassay program, as well as the oversight of that program by PNL. It must also be noted that the pre-1987 data quality issues have no direct bearing on the usability of the 1987–1989 data. It should also be noted that some of these problems are related to the failure to achieve contractual minimum detectable activities (MDAs), which in some cases (e.g., strontium-90) were more stringent relative to then-prevailing industry norms. The 1987–1989 data appear to be usable for dose reconstruction with appropriate attention to issues such as the MDAs.

Observation 2: Apart from the two issues discussed in Sections 6.1.2 and 6.1.3, there was no direct evidence raising questions about fraud or data manipulation in the UST bioassay program for the period 1987–1989 under review in this report. SC&A investigated these two issues in detail and neither one appears to have been associated with fraud, data manipulation or an intent to hinder external program review. The two issues appear to have reasonable explanations to the extent that can be determined retrospectively after more than two decades; however, some uncertainties remain (see Observations 5 and 6 below).

Observation 3: Despite the presence of problems such as low recoveries and failure to meet contractual MDA requirements, all audits and oversight activities conducted at the time concluded that UST had an acceptable bioassay program overall and that the data were usable. It should be noted that during the interview, the bioassay expert who was part of the May 1990 oversight presented a more nuanced view, saying, "Regarding the usability of data for dose reconstruction, the answer was 'a qualified yes.' There was nothing that was so bad that the data would have to be thrown out" [see Attachment A].

Observation 4: The PNL audits in the 1980s and the 1990 and 1991 oversight activities were not set up to detect sophisticated efforts to manipulate data. Obvious or crude manipulations of data could have been detected; none were found. Further, none of the oversight activities found any issue that would motivate UST to manipulate bioassay data. In fact, the record indicates that UST often caught problems that existed and made efforts to correct them.

Observation 5: The case of the edited Quality Control (QC) file appears to have a reasonable explanation, based on the memory of one of the experts who discovered the edited file in May

1990. There is no paper trail that can verify that only a minor change not involving data was made. However, the fact that the changed QC data file was flagged by the data technician making the change would lend support to the hypothesis that the change was made to correct an error, rather than to manipulate data. This observation depends on the memory of the expert of events over two decades ago for which there is no auditable paper trail.

Observation 6: SC&A believes there is some uncertainty regarding the completeness of the data in the possession of PNL at the time of the retrospective review in 1991; however, there is no evidence that records were withheld to hinder the review or affect it in any way. Any unavailable records appear to have been the result of prior procedures for records transfer between UST and PNL that were set by PNL. The available evidence from the time as well as the extensive interviews and on the record exchanges done by SC&A (see Attachments C and E) indicate that the retrospective review team had the data it needed to do its work and arrive at valid conclusions. The central conclusions were that (1) overall, the team found the bioassay program to be sound, and (2) the team found no evidence of fraud or data manipulation in the bioassay program.

Observation 7: A number of issues that relate to MDA and dose reconstruction, but that do not appear to SC&A to be SEC issues, have been identified in this report.

1.1 OVERALL CONCLUSION REGARDING 1987–1989 BIOASSAY DATA

SC&A did not find any evidence that the bioassay data were affected by fraud or manipulation. When all is said and done, the basic question raised by the petition is a policy issue for the Advisory Board: Should bioassay data, which according to all available evidence are unaffected by fraud, but generated by a company that was dismissed because of data manipulation and fraud in another technically unrelated area (chemicals), be trusted for use in dose reconstruction?

2.0 INTRODUCTION AND SUMMARY OF THE SEC-00155 EVALUATION REPORT

Petition SEC-00155 for a Special Exposure Cohort (SEC) designation concerns Hanford workers in the PFP, 200 Area (SEC 2009, pdf p. 4). In its Evaluation Report (ER) for this petition (NIOSH 2011), the National Institute for Occupational Safety and Health (NIOSH) evaluated the following class:

> *All personnel who were internally monitored (urine or fecal), who worked at the Plutonium Finishing Plant in the 200 Area at the Hanford Site, from January 1, 1987 through December 31, 1989.* [NIOSH 2011, p. 8]

NIOSH describes the scope of its review as follows:

> *The scope of* [the] *SEC-00155 evaluation is limited to determining the usability of bioassay data supplied by UST-Richland during the period 1987–1989.* [NIOSH 2011, p. 16].

This SC&A review is also similarly limited, since the petition is concerned with the usability of bioassay data in the period 1987–1989.

2.1 BASIS FOR EVALUATION

The NIOSH ER describes the basis for evaluation of SEC-00155 as follows:

> *NIOSH deemed the following information and affidavit statements sufficient to qualify SEC-00155 for evaluation on the basis that a report from a health physicist with expertise in radiation dose reconstruction documented limitations of existing U.S. Department of Energy (DOE) records on radiation exposures at the facility:*
>
> > *An audit report, Oversight of U.S. Testing Company Implementation of Analytical Procedures and Protocol, prepared by the U.S. Department of Energy, Richland Operations Office, June 21, 1990 (DOE/Richland Audit Report, 1990).*[1]
> >
> > *The above report was produced as a result of an audit conducted at the U.S. Testing Company (UST) Laboratory in Richland, Washington, during the period May 1–31, 1990. This audit was precipitated by the U.S. Environmental Protection[s] Agency's (EPA's) action to suspend UST from the EPA Contract Laboratory Program, which resulted, at least in part, from accusations by the EPA of purposeful wrongdoing in the analysis of environmental (non-bioassay) samples at the company's*

[1] This document, which is referred to as DOE/Richland Audit Report, 1990 in the NIOSH ER (NIOSH 2011), is referred to as DOE 1990b in this report.

laboratory in Hoboken, New Jersey. The month-long oversight activity included personnel from the EPA Region 10 Laboratory, Washington Department of Ecology Quality Assurance Section, Washington Department of Health Radiation Protection Division, and the DOE Richland Operations Office Quality Assurance Division.

Several potential QA/QC questions and issues were noted in this report, including the following:

- *Inspection of UST QC data showed that low (less than 50%) and extremely low (less than 8%) recoveries were used for some analyses (e.g., total U, Pu in urine/feces, Pu-239/240 and Pu-239, U in urine).*
- *For some Pu-239/240 bioassay analyses in the 1Q90 QC data, the analytical bias range showed extreme variation.*
- *There is a requirement in the Bioassay portion of the Pacific Northwest Laboratory (PNL)-UST contract that requires that inter-comparisons shall be performed with the EPA; although the Environmental Radiochemistry section of UST participates in the QA programs, the Bioassay section does not.*
- *There has been historic inconsistency with the precision of the "less sensitive" uranium analyses for bioassay.*
- *Some radiochemical analyses showed unacceptable results for concentrations near the detection limits. This may be associated with the fact that QC samples are processed with added radionuclides at or near the low-level detection limits.*
- *PNL submitted only 75 unknown samples out of 3,000 radiological bioassay urine samples for QC purposes. No feces QC samples were submitted. This is an inadequate number of QC samples to judge the accuracy of the analyses* [NIOSH 2011, pp. 9–10].

2.2 RELEVANT RADIOLOGICAL OPERATIONS AT THE PLUTONIUM FINISHING PLANT

The NIOSH ER summarizes the PFP radiological operations as follows:

During the period from 1987 through 1989, the major process operations and activities at PFP included [Hoyt and Teal 2004]*:*

- *Weapons Grade Metal production, RMC Line*
- *Plutonium Reclamation Facility*

- *Miscellaneous Treatment system glove box operations*
- *Analytical Laboratory operations*
- *Development Laboratory operations*
- *Polycube processing in Hood 4 of Room 41 (a polycube is a solid mixture of polystyrene and plutonium oxide, typically smaller than a two-inch cube)* [PNNL 2000] [NIOSH 2011, p. 18]

2.3 INTERNAL RADIOLOGICAL EXPOSURE AND MONITORING

The NIOSH ER lists the internal radiological exposure sources:

> *Internal radiological exposure sources at the Plutonium Finishing Plant included plutonium, uranium, neptunium, and americium. Plutonium radionuclides of concern included Pu-238, Pu-239, and Pu-240. Uranium radionuclides of concern included U-233, U-234, U-235, and U-238. Np-237 and Am-241 were also internal exposure sources* [NIOSH 2011, p. 18].

According to NIOSH, "[p]lutonium represented a primary intake source at Hanford, especially for workers in the Area 200 Plutonium Finishing Plant" [NIOSH 2011, p. 19]. After October 1983, Pu was radiochemically extracted through anion exchange column methods and measured using alpha spectrometry (NIOSH 2011, pp. 19-20).

The NIOSH ER describes radiological monitoring that took place at Hanford:

> *Fecal sampling was normally done in response to suspected intakes; however, routine fecal sampling was used for some high-risk plutonium workers, including operators at the Plutonium Finishing Plant from 1986 through June 1989 (ORAUT-TKBS-0006-5, pdf p. 17).*[2] *Fecal samples were usually not analyzed in total (i.e., were aliquoted after muffling, dry ashing, and wet ashing); hence, more than one analysis result for a given sample was possible and will often be found in the database (ORAUT-TKBS-0006-5, pdf p. 16).*
>
> *In-vivo counting equipment and techniques were developed in the late 1950s and have been in routine use since 1960 (ORAUT-TKBS-0006-5, pdf p. 35). Intake determinations for Am-241 and for other gamma-emitting radionuclides for PFP workers often relied on in-vivo measurements* [NIOSH 2011, p. 20].

2.4 SUSPICION OF FRAUD BY U.S. TESTING

The NIOSH ER summarized the situation surrounding EPA suspension of UST from its Contract Laboratory Program (CLP):

> *The EPA suspended UST from its CLP on April 24, 1990, because of alleged fraud by the management of the company. The notice of suspension alleges that*

[2] The document referred to as ORAUT-TKBS-0006-5 in NIOSH 2011 is referenced in this report as ORAUT 2010.

> *the management of UST "conspired, directed, carried out, and otherwise condoned a scheme to defraud the United States Government" in its performance at facilities in Richland, Washington, and Hoboken, New Jersey. The notice also alleges that this scheme "resulted in the submission of false, inaccurate, and unreliable test results and data" (Notice of Suspension, 1990). Furthermore, information contained in EPA Inspector General interviews released in support of the EPA's suspension action suggests that the alleged fraud might very well extend to work performed under the DOE contract with Battelle Memorial Institute's Pacific Northwest Laboratory (Letter from Congress, 1990). In May 1990, PNL conducted two rather intensive, separate, but related activities: (1) a formal audit of past UST activities that included data traceability; and (2) a 3-week onsite, performance-based technical oversight of current UST practices* [NIOSH 2011, p. 22].

2.5 NIOSH EVALUATION REPORT INTERNAL DATA PEDIGREE REVIEW CONCLUSIONS

The NIOSH ER concluded that UST's Bioassay Section was not linked to the alleged fraud cited by EPA:

> *The Bioassay Section of UST-Richland was almost exclusively devoted to performing bioassay analyses that were used to estimate the uptake of radioactive material by Hanford workers (EPA Debarment, 1990).*[3] *In its evaluation and review of available information sources, NIOSH did not find any evidence to link the UST-Richland Radiochemistry Department, or specifically, the Bioassay Division, to any of the alleged acts of wrongdoing that led to the termination of the UST contracts with the EPA or Battelle, PNL. Furthermore…, NIOSH does not find the integrity of the bioassay data produced by UST during the 1987 through 1989 period to have been affected by these allegations* [NIOSH 2011, p. 32].

The NIOSH ER also concluded that the UST bioassay data are reliable for use in dose reconstructions:

> *Based on its research, NIOSH has obtained internal bioassay audit program reports, independent bioassay program audit reports, bioassay data reliability assessment reports, and data from various other program review and personnel interviews indicating that the bioassay analysis results provided by UST-Richland are of sufficient quality to allow their use in development of sufficiently accurate bounding doses for workers in the proposed class. Based on its analysis of these available resources, NIOSH found no part of the class under evaluation for which it cannot estimate radiation doses with sufficient accuracy* [NIOSH 2011, p. 1].

[3] The document referred to as EPA Debarment, 1990 in NIOSH 2011 is referred to as PNL(?) 1990 in the reference list of this report, since it is likely a PNL document, though no author is indicated in the available document itself.

2.6 SCOPE OF THE SC&A REVIEW

The focus of the SEC-00155 petition is the usability of bioassay data generated by UST in Richland, Washington, from 1987 through 1989. NIOSH found no evidence of fraud in the bioassay data and concluded that bioassay data could be used for dose reconstruction with sufficient accuracy for the period 1987–1989. In this review, SC&A has covered only the limited issues of possible fraud; data manipulation; and some other issues, such as quality assurance and quality control related to the audits of the data covered by the petition SEC-00155 and by NIOSH in its ER.

We note here that there is another Hanford SEC petition, SEC-00057-2, for which a number of dose reconstruction issues for the period July 1, 1972, to December 31, 1990, had not been resolved as of the end of May 2012. SC&A had prepared a review of those issues and presented it to the Advisory Board and NIOSH in 2011 (SC&A 2011a and SC&A 2011b). The issues raised in that review were summarized in a matrix (SC&A 2011c). NIOSH reviewed the period from July 1, 1972 to December 31, 1983, and presented its review to the Advisory Board in June 2012 (NIOSH 2012); the Board recommended the addition of this period to the SEC at that time. The period from January 1, 1984 to December 31, 1990, still remains open for SEC consideration as part of SEC-00057-2; SC&A is separately reviewing SEC-00057-2 for this remaining period at the direction of the Board.

SC&A reviewed Petition SEC-00155 (SEC 2009) and the NIOSH ER (NIOSH 2011), as well as documents related to UST analytical performance, as described in the following sections. SC&A also participated in Hanford site visits and reviews of classified and legally protected documents in joint data capture visits with NIOSH.[4] In addition, SC&A conducted interviews with experts who were part of the May 1990 oversight of UST's work at its Richland, Washington, facilities, and also with the petitioner and the petitioner's representative. The summaries of the expert interviews are published with this report as Attachments A, B, and C. The interview with the petitioner and the petitioner's representative is published as Attachment D. Finally, SC&A also sent some questions regarding records transfer from UST to Pacific Northwest Laboratories (PNL)[5] to two people who were employees of PNL during the late 1980s and early 1990s. Their answers are reproduced in Attachment E.

[4] SC&A conducts joint data capture visits in order to enable DOE to pull documents for review just once, instead of twice. This economizes resources. SC&A reviews the materials independently of NIOSH.

[5] PNL is now known as PNNL, which stands for Pacific Northwest National Laboratories. We refer to it throughout this report as PNL, unless the acronym is in a quote.

3.0 AUDITS OF U.S. TESTING'S BIOASSAY PROGRAM

3.1 OVERVIEW

There were a number of audits of UST's work, including its bioassay analysis. These included routine audits by PNL, to which UST was the subcontractor; oversight activities conducted in May 1990, which was the month after EPA filed its report regarding evidence for fraud and data manipulation (Notice of Suspension 1990); and a 1991 independent retrospective review of the UST bioassay program. UST also conducted self-audits of its bioassay program.

3.2 REVIEW OF PNL ANNUAL AUDIT REPORTS

Pacific National Laboratories (PNL), which subcontracted bioassay work to UST at the latter's Richland facilities, conducted audits of UST's work. An annual report was published in the subsequent year, part of which described the results of these audits. In this section, we briefly review the reports for the years 1987 (published in 1988), for 1988 (published in 1989) and for 1989 (published in 1990). It should be noted that the audit program was started well before the period 1987–1989 addressed by SEC-00155. SC&A has discussed some of the earlier audits in its report on SEC-00057 (SC&A 2011a; see, for instance, Sections 4.1 and 10.3). A part of the credibility of the audit program for 1987–1989 is that it was in place well before the 1987–1989 timeframe for which the issue of fraud is examined here.

As stated in the NIOSH ER, a Bioassay Audit Program was implemented by PNL to verify UST's performance. The audit program was conducted every fiscal year to verify compliance with performance criteria established in the statement of work (SOW). A part of the audit was to verify compliance with contractual minimum detectable activities (MDAs). The NIOSH ER report, in item 7.1.1.1, describes the main findings of those audit reports (NIOSH 2011, pp. 23–25). SC&A also reviewed the PNL audit reports for fiscal years 1987, 1988, and 1989.

It should be pointed out that the PNL audit program covered only urine analysis; it did not cover fecal bioassay. Fecal sampling was done for high-risk workers and incidents in the reprocessing and PFP, according to the Hanford Site Profile internal dosimetry volume:

> *Fecal sampling was normally done in response to suspected intakes, but routine fecal sampling was used for some high-risk plutonium workers, mostly operators of Plutonium–Uranium Extraction (PUREX) facility and the Plutonium Finishing Plant, from 1986 through June 1989. The special study showed that, when considered as a group, the mean fecal excretion was statistically significantly different from control. Enhanced air sampling, which was initiated in response to the study, showed frequent but intermittent releases of plutonium in the workplaces, at levels below the detectability of normal air sampling. MDAs are listed for nonroutine plutonium excreta analysis. When modeled as chronic intake, the intakes and doses were low (less than 10 mrem committed effective dose equivalent)…* [ORAUT 2010, pp. 19–20]

The report for 1987 describes a basic assumption about internal exposures:

> *Except for work in the Uranium Oxide Plant (200 W Area), the 306-W Specialty Machine Shop (300 Area), the Fuels Production Facility (300 Area) where uranium with enrichments less than 1.25% ^{235}U are handled, and some laboratory and shop work involving tritium, any internal exposures to radionuclides are assumed to occur only as a result of accidental circumstances.* [Lyon et al. 1988, p. 18]

The 1987, 1988, and 1989 annual reports describe the bioassay analytical services provided by UST. The report for 1987 informs that changes to the Statement of Work (SOW) for UST were introduced in October 1987:

> *The Statement of Work for United States Testing Company, Inc. (UST) was modified effective October 1, 1987 to be consistent with criteria and methods in draft ANSI NI3.30, Bioassay Performance Standards. Specification of minimum detectable amounts, bias, and precision were modified. The changes were based on a review of the draft standard by Internal Dosimetry, a PNL statistician, and UST. The resulting changes are considered to be compatible with the draft ANSI standard, but are not in all cases identical to the formulas and criteria in the standard.* [Lyon et al. 1988, p. 25]

The report summarizes the results of the UST internal QC program, which showed general compliance with contractual requirements, with the exception of uncertainties in the Am-241 and uranium results and increased results on blank samples for Sr-90.

The report for 1987 also describes the external audit made by PNL on UST analytical services.

> *Plutonium-241 was tested for the first time in 1987. The calculated detection level did not meet the 2-dpm/sample requirement because of a high mean blank value and poor precision on blanks and low-level spikes. However, performance was acceptable on samples spiked at about 10 times the contractual detection level.* [Lyon et al. 1988, p. 27]

A pilot study for plutonium involving the analysis of fecal samples of 50 workers was implemented in 1987. However, "initial participation was low and improvements were planned to increase worker acceptance" (Lyon et al. 1988, p. 31). It was continued in 1988.

The report for 1988 discusses bioassay analytical services provided by UST. During 1988, a new SOW was implemented. The main change was the "requirement to subtract the reagent blank value from gross sample results to produce net sample results. This procedure was actually implemented for samples received by UST beginning September 30, 1988" (Lyon et al. 1989, p. 13). The report for 1988 summarizes the results of UST's internal QC program, which showed general compliance with contractual requirements with the exception of the MDAs for Sr-90 analyses, which were greater than the contractual level. In addition, some types of

americium/curium analysis showed low chemical yields and bias outside the allowed uncertainty. The report also describes the results of the PNL external audit program on UST.

The report for 1988 also discusses the results of a pilot routine fecal sampling program:

> *A pilot routine fecal-sampling program… was continued for approximately 100 workers on the Remote Mechanical C (RMC) line at the Plutonium Finishing Plant. Samples from nonexposed persons were also collected as control samples… [T]he worker data, when compared with control sample data, also showed that a large portion of the worker samples (40 to 50%) contained ^{239}Pu at statistically greater levels than the control samples. Special air samples collected by WHC confirmed the presence of low-level airborne plutonium concentrations sufficient to account for the activity observed in the fecal samples.* [Lyon et al. 1989, pp. 16–17].

Since this was only a pilot program, it is unclear how the 1988 fecal data are to be interpreted for the monitoring of high-risk workers in the PFP.

The report for 1989 discusses bioassay analytical services provided by UST. The report summarizes the results of UST's internal QC program, which "showed performance to be satisfactory with respect to contractual requirements, except that 11% of the yields of all samples were below the minimum for the plutonium in urine, using the plutonium-strontium sequential procedure" (Lyon et al. 1990, p. 18).

The results of the PNL external audit program were also summarized. In general, results were similar to the internal UST QC program, except that the PNL audit pointed to "a possible problem with the precision of the ^{241}Am analysis at spike levels near the contractual detection level" (Lyon et al. 1990, p. 19). Furthermore, in 1989, the fecal sampling program that had been a pilot program in the prior year had become a routine program. At this time, "the sampling frequency was changed [from quarterly for the pilot program] to annual" (Lyon et al. 1990, p. 19).

Hence, it may be inferred from the above review of the reports for the years 1987, 1988, and 1989 that routine fecal sampling was begun only in 1989. This appears to be at variance with the statement in the ER, quoted above, that "routine fecal sampling was used for some high-risk plutonium workers, including operators at the Plutonium Finishing Plant from 1986 through June 1989" [NIOSH 2011, p. 20]

These review reports indicate compliance with requirements, but also some non-compliance with contractual requirements. For instance, the report for 1988 states:

- *The MDAs for routine and priority ^{90}Sr analyses, either singly or in sequential analyses, were greater than the contractual detection level. In addition, low chemical yields and bias outside of the allowed uncertainty were obtained for some types of strontium analysis.* ***This problem had carried over from previous years.*** *United States Testing Company, Inc., conducted a thorough*

> *investigation of the procedure and reagents and developed a revised procedure. The revised procedure was in the review and signoff stage at year's end, and was targeted for implementation in January, 1989.*
>
> - *Low chemical yields and bias outside the allowed uncertainty were also obtained for some types of americium/curium analysis. The americium/curium procedure was also revised in FY 1988, and the revised procedure was in the review and signoff stage at year's end, and was targeted for implementation in January, 1989.* [Lyon et al. 1989, p. 13; emphasis added.]

While the report states that the problems were corrected, that would affect samples at dates later than the time of correction. The report does not state what was done to correct the records of prior years.

A problem with failure to meet the contractual MDAs does not necessarily mean that the data cannot be used in dose recontruction, but the actual MDAs have to be known and well-established. Hence, the problem has implications for coworker models. We discuss this issue in more detail in Section 5.0.

3.3 COMPARISON OF PNL QC AUDITS AND U.S. TESTING QC AUDITS

The document, *Summary of Quality Control Information Concerning United States Testing Richland Division Laboratory's Performance on Bioassay Samples*, states that UST was "required to analyze their own quality control (QC) samples (blanks and spiked samples), comprising 10 to 15% of the total throughput… A summary of the results of the QC samples were reported each quarter to the PNL Technical Administrator…." (Bihl 1990, pdf p. 4) In addition to UST's quality control samples, PNL's Internal Dosimetry Program had a program which submitted audit samples of urine blanks and spikes to UST for analysis.

> *The audit program has also included a very few samples of pooled spikes that were split and analyzed both at UST and Mound Laboratory (plutonium and americium) or Radiological and Environmental Sciences Laboratory (RESL) (strontium-90).*
>
> *The audit program is limited in the number of samples and analyses that can be included so the statistical results of the audit program were almost always less robust than UST's QC results. Hence audit results are viewed as only a double check on the UST QC results, not as the definitive indicators of laboratory performance.* [Bihl 1990, pdf p. 4]

UST's and PNL's QC data for radionuclides of primary importance to the bioassay program were compared. Note that the reference below to the "last five years" means 1985–1990 and covers the SEC period under review here (1987–1989).

Plutonium
The audit data and UST's internal QC data show excellent agreement for Pu throughout the last five years. The data also show excellent sensitivity relative to the contractual detection level of 0.02 dpm. Our research indicates that when both sensitivity and number of plutonium analyses per year are considered, UST-Richland is one of the best laboratories in the country, including commercial and DOE contractor labs.

Strontium
The audit data and UST's QC data show excellent agreement throughout the last five years. A major problem surfaced in early FY87 when the mean blank value started to increase. UST spotted the trouble from their own QC data, suspended analysis for strontium-90 on two occasions…, and tried numerous and various approaches to solving the problem. The source of the problem was finally identified in the summer of 1988. During the interval, there were times when the procedure did not meet the contractual detection level… Data obtained since the start of FY89 indicated that the problem is solved.

Uranium
Background uranium in reagents and urine prevented UST from achieving the contractual detection level until reagent background subtraction was implemented in FY89.

…

Americium-241
…Generally, performance at analyzing for americium-241 has been marginal. UST revised the procedure with expectations of improved performance, but a short time later a contamination spread occurred (in FY89) that affected enough of the QC samples (including some audit samples) to muddy the picture. UST discovered the contamination, suspended processing, and cleaned the lab and equipment. Audit data obtained since the cleanup and restart still indicate a detection level that is just above the contractual level and poor precision on spikes near the contractual detection level.

Other Audit Data
The audit program also tests a special uranium procedure referred to as the quick uranium soluble (QUS). Generally the procedure has been within specifications, although there has been a persistently low bias, ranging from -9 to -27%. This was discussed with UST earlier this year, and they are taking steps to reduce the bias.

…

Comparison Study
UST participated in a laboratory intercomparison study for uranium in urine conducted by the Environmental Measurements Laboratory (EML) in FY89… UST… performed well in all categories….

CONCLUSION
Both UST's QC data and Internal Dosimetry's audit data show that… ***UST certainly has not been in compliance with the Statement of Work at all times. Most often, the problems were first detected by UST by their own QC data; UST notified Internal Dosimetry; and a plan for investigation and resolution was negotiated****…*

… There have been two instances where somewhat less than good science has been discovered by Internal Dosimetry. The first was the special treatment being given the americium QC samples. The special treatment (manual analysis of the spectrum) was, in fact, "good science"; the problem was that the improved method was being applied only to QC samples which made the QC data unrepresentative. When this practice was discovered by the UST QC manager, it was swiftly stopped.

The second questionable practice involved recounting of QC spikes when the first count indicated an out-of-tolerance result. The recount was done to confirm whether the out-of-tolerance result was due to an extreme fluctuation in counting statistics or was indicative of actual trouble with the batch of samples (a good practice). The problem was that if the recount showed a within-tolerance result, the first result was discarded and the second result recorded. When Internal Dosimetry discovered and objected to this practice, UST agreed to maintain both results in the database and to use a statistically-based outlier test to decide which results to eliminate from calculations required by the Statement of Work (bias, precision, MDA, etc.)

Overall, UST has provided good service to the Internal Dosimetry Program over the years… Generally, when UST has failed to meet a contractual detection level, the out-of-specification detection level was still as good as any other laboratory in the country. The impact on the Internal Dosimetry Program of the various problems discussed above has been tolerable. [Bihl 1990, pdf pp. 5–7; emphasis added.]

The "marginal" results for Am-241 could be a concern. However, as noted by SC&A in its review of SEC-00057-2, Am-241 monitoring is primarily an issue up to 1976, when the last work with separated Am-241 appears to have been done. In other cases, Am-241 is associated with plutonium-241 and the Am-241 dose can be inferred from plutonium monitoring data. In any case, in the context of this review, it is sufficient to note that any dose reconstruction issues associated with Am-241 would be associated with lung counting, since those were the primary measurements to be used (other than plutonium bioassay and inference of Am-241) for Am-241 dose assignment (SC&A 2011a, Section 13.6). Further, there are far more in-vivo Am-241

measurements than in-vitro measurements available in the period under review here that can be used in dose reconstruction (SC&A 2011b, Tables A-3 and A-4).

It is important to note in the context of SEC-00155 that, according to Bihl 1990, UST often discovered the problems in its bioassay program by its own QC procedures and reported them to PNL (Bihl 1990, pdf pp. 5–6).

3.4 MAY 1990 OVERSIGHT OF U.S. TESTING'S PROGRAM

In May 1990, "in response to the suspension of UST from the U.S. Environmental Protection Agency (EPA) Contract Laboratory Program," an oversight team went over UST's activities to "conduct an overview of ongoing [UST] activities" (DOE 1990b, p. 1-1).

There were three participating organizations: the EPA, the Washington State Department of Ecology, and the Department Energy (Richland Operations Office). PNL "acted as liaison to UST for the oversight organizations" (DOE 1990b, p. 1-1). The DOE also appointed external experts to the oversight team, including a bioassay expert. The Oversight Team conducted meetings, walk-throughs, reviews of laboratory practices, reviews of quality assurance and quality control programs, etc. Daily Reports were written and a final report, which produced and summarized the significant observations in a separate document, was produced (DOE 1990b, pp. 2-1 to 2-3).

Some of the observations from the summaries of the daily reports as they related to the bioassay program are quoted below. The dates not shown in the quotes were May 11 and May 14, 1990. All observations were by the DOE reviewer:

1. *Technical problems encountered during the FY89 PNL audit of UST involving analyses for Am-24l, total U, Pu-24l, and Pm-147 have not been resolved; it was stated in defense that the latter two analyses are rarely required.*

2. *It would be difficult or impossible for UST (as the lab is currently set up) to meet the turnaround time specified in the UST-PNL contract for expedited and/or emergency sample processing if more than a few samples were required.*

3. *There is a requirement in the Bioassay portion of the PNL-UST contract that requires that intercomparisons shall be performed with EML [Environmental Measurements Laboratory] every six months, and that intercomparisons also shall be performed with EPA; although the Environmental Radiochemistry section of UST participates in these QA programs, the Bioassay section does not.*

4. *Inspection of UST QC data for 1Q90 showed that low (less than 50%) and extremely low (less than 8%) recoveries were utilized for some analyses (e.g., total U, Pu in urine/feces, Pu-239/240, Pu-238 & -239, U in urine).*

5. *For some Pu-239/240 bioassay analyses in the 1Q90 QC data, the analytical bias range showed extreme variation.*

6. *The number of blind spike samples submitted to UST for analysis by PNL is inadequate to assess the quality of analytical performance.*

7. *A few of the analytical processes required by the PNL-UST contract Statement of Work are not functional at UST; these processes have not been required for years, but remain in the contract.*

8. *The quarterly QC reports to PNL for radiological analyses do not include explanations for "outliers" (values that fall outside prescribed QC limits) as required by the PNL-UST contract.*

9. *There are no restrictions or limits utilized by UST for QA/QC control of such factors as percent recovery, maximum correction factor, etc.*

10. *It has not been demonstrated the UST version of "process quality control" (also presented by UST as "statistical process control") can provide adequate validity of analytical data as specified in QA measures for each testing parameter or test result.* [DOE 1990b, pdf pp. 53–54]

A number of other problems were also found:

- Blind samples submitted by PNL to UST were not truly blind (DOE 1990b, p. 58).

- "There is evidence that some of the planchets may be counted with a noticeably uneven distribution of solids" [DOE 1990b, pdf p. 79]

- The number of urine QC samples submitted by PNL to UST was too small; no fecal QC samples were submitted (DOE 1990b, pdf p. 82).

In conclusion, the oversight team defined three levels of problems:

- Level 1 problems were the most serious, which the team noted were "commonly referred to as 'show-stoppers'" (DOE 1990b, pdf p. 20).

- Level 2 issues consisted of "[i]tems that must be resolved as soon as feasible" (DOE 1990b, pdf p. 20).

- Level 3 issues were "[i]tems that should be resolved, but do not impact normal processes or activities directly…" (DOE 1990b, pdf p. 20).

The overall finding was as follows:

> *Based on the evaluation of the oversight activities, it was determined that the items observed during the surveillance periods would be accommodated most*

> *accurately by the criteria for Level 2 or Level 3. There were **no evident items** that could easily be attributed to the requirements of a Level 1 finding.* [DOE 1990b, pdf p. 20; emphasis added.]

SC&A interviewed the external expert who was brought in for the oversight of UST's bioassay activities in order to get more insight into the implications of the main conclusions as well as some of the more detailed observations. The summary of that interview is provided in Attachment A to this report.

According to this expert, the oversight team reviewed all aspects of the UST laboratory programs from "cradle to grave," from sample receipt to data entry and management and laboratory procedures and implementation in between. The overall impact of the findings was not considered so serious as to stop the program and implement corrective measures before it could be restarted. For instance, the uneven distribution of material on the planchets was estimated to affect 5% of the samples. Even so, UST should have researched and fixed the problem. The expert, who had decades of experience at the time of the oversight visit to Hanford, had never come across recoveries as low as 12%:

> *There were no limits on the lowest acceptable recovery. Usually, there is a lower limit to recovery of 50% or 60%. They [US Testing] would get recovery as low as 12% and just use that. But if they did get low recoveries, they multiplied the result by the inverse of the recovery fraction to compensate for the low recovery. (Since tracers are added, this enables detection of low recovery.) But it is poor practice to have such low recoveries. The causes of the low recoveries should have been investigated and the problem corrected. The expert had not encountered such low recoveries before and was unsure what the consequences might be for the results of samples affected by low recoveries. In his view, low recoveries did not necessarily mean that results were invalid or that results were not usable* [see Attachment A].

Similarly, the absence of QA samples for the fecal bioassay program was considered a "missing link," but not one that would necessarily cause the data to be invalid:

> *The lack of fecal QA samples is a missing link. That part of the program is just missing. Such samples are for QA, to assure that the results are credible. It does not necessarily mean that results are not credible, but it certainly is a weakness of the program that there were no fecal QA samples* [see Attachment A].

Yet, given the number of QA/QC problems, including the absence of a required intercomparison program with DOE's Environmental Measurements Laboratory (EML) and the lack of sufficiently spiked blind samples, the question arose whether the data were sufficiently robust to be used for a reliable dose reconstruction result. The other bottom line question was whether Battelle or the oversight team could have discovered data manipulation had UST engaged in it.

> *The biggest finding was the lack of blind spikes. All the rest of the difficulties were observations. It was not enough to shut down the analytical procedure until the problems could be fixed. They should have done research on how to*

overcome low radiochemical recoveries. In one instance, they had bad ion exchange resins and they suspended analysis until they got the good resins. If you are clever enough, you could conceal data manipulation. The people on the contract laboratory side were not very clever. They were caught by EPA cooking the books on the chemical side. On the other hand, why do it? The bioassay program was good enough that [US Testing] did not have to have false records to keep it going. It was not that much of a problem. It was obvious that US Testing was not trying to cover up anything. There did not seem to be an effort to falsify things. But if they were clever enough, it would be difficult to detect data falsification.

Regarding the usability of data for dose reconstruction, the answer was "a qualified yes." There was nothing that was so bad that the data would have to be thrown out. It was not like what happened at Mound with the polonium analysis. There was a problem they [Mound] did not realize—it [the polonium] was going into a protein-bound form. So they thought the recoveries were good when in fact they were only 10%. The interviewee did not see anything like that at US Testing. At US Testing, they did not hide the fact of low recoveries. If the recovery was 20%, they multiplied [the result] by five [to correct for the low recovery]. [See Attachment A]

3.4.1 Altered Quality Control Data File

Another report from the oversight activities during the same period was made to the DOE (Morton and Marlette 1990a). One important observation that SC&A did not see in other reports of the May 1990 oversight appears in this document:

The most serious observation of the day appeared in the form of a QC file that had been edited. The hand written note at the top of the page only stated the file had been edited. There was no indication of the changes made to the file. The following discussion with [redacted], [redacted], *suggested restricting the editing of a data file to senior personnel only, and then the new data should be appended to the old, with all data remaining for inspection should the need arise.*

… Since the question of data integrity was questioned the previous day, it was of interest to determine the extent to which the data (raw, intermediate or final) could be edited by UST staff. The [redacted], [redacted], *said* [redacted] *could edit a header file, but did not know how to edit a data file. Subsequent discussions with the* [redacted], [redacted], *confirmed the belief that the* [redacted] *is probably incapable of changing the data. The database is a flat file system rather than the relational type. This would make the modification of data much more difficult to the average operator.* [Morton and Marlette 1990a, pdf p. 6]

The available oversight information does not indicate why the file was edited, whether other files were edited as well, and, if so, how widespread such an activity might have been prior to the

time of the oversight. A special interview with one of the authors of Morton and Marlette 1990a was conducted on this issue.

This expert interview (Attachment B) yielded information indicating that the QC file change was not an instance of data fraud. Rather, to the best of the recollection of the expert, a mistake had been made in the name of a person in the data file containing headers. This kind of error occurred at other times when similar changes were made. There was, however, no auditable trail of who made changes and what changes were made. This is the reason that the oversight team recommended that a procedure that would document the changes and retain the old material be instituted.

According to the expert, the [redacted] who made the changes did not have the expertise to change the data. The [redacted] had both the access to the data and the expertise to change the data. Others may have had both as well. Therefore, there is no absolute guarantee that the data had not been changed. However, the expert did not find evidence for fraudulent manipulation of data. The only data editing example discovered appeared to have an explanation—the change appears to have been made because the original entry of the name was incorrect. Moreover, the fact that the QC file had been changed was flagged by the [redacted]. The expert concluded that the bioassay data could be trusted and used for dose reconstruction.

3.4.2 1991 Retrospective Evaluation

A retrospective review of the UST bioassay program was done in 1991. The evaluation was of data submitted by UST in support of the internal bioassay program. The retrospective evaluation covered the period 1983–1990, and therefore included the 1987–1989 period that is pertinent to SEC-00155. The results were published in Omenn et al. 1991. NIOSH reviewed this examination of UST analytical procedures and data integrity. SC&A also reviewed this document; in addition, SC&A interviewed two of the experts who participated in this review (see Attachment C).

The 1991 retrospective review examined data generated by UST in order to "assure that correct decisions were made regarding the health and safety of workers, and regarding the environmental releases of contaminants, and thus the health and safety of the public" (Omenn et al. 1991, p. 1). The review was extensive; the review team went over analyses of samples that had been analyzed by DOE, including the data in individual files and the QC data associated with batches of samples.

Then the review team went over randomly selected raw data files and verified that in each case the sample existed and had been analyzed (Omenn et al. 1991, p. 1). It selected cases to analyze in detail to examine whether "all the pertinent laboratory records were available, including blanks and spikes;" this was also verified (Omenn et al. 1991, p. 2).

The review team found similar issues as the earlier May 1990 review. For instance, it found that in 1989, there were no blind samples for 6 months during 1989 due to a "funding lapse;" but following that, "the program for blind QC was restored" (Omenn et al. 1991, pp. 13 and 15).

Overall, the review Committee concluded that the bioassay program was apparently reliable. Their review did not find evidence of fabrication of laboratory records or the distortion of laboratory performance through manipulation of QC results:

> *…[I]t appears to be the case that UST performance in the Bioassay Program was, with minor exceptions, in compliance with contractual requirements, and was technically competent according to every measure considered: UST internal QC performance; PNL QA testing; and various audits, inspections, and laboratory intercomparison exercises conducted by PNL, Washington Department of Ecology, US Department of Energy and Washington Department of Health, among others* [Omenn et al. 1991, p. 48].

The retrospective review also compared UST QC reports with blind and open audit samples. It concluded that there was no indication "of a large systematic bias or frequent discrepant results" (Omenn et al. 1991, p. 48).

Statistical analysis indicated that, "…false positive results were detected in a systematic manner when they occurred" (Omenn et al. 1991, p. 48).

The conclusion was that, "…the overall performance of UST and the general reliability of data produced were adequate to protect worker safety as part of a reliable basis for decisions regarding occupational protection" (Omenn et al. 1991, p. 49).

We should note here that the Omenn review team stated that some "materials [were] withheld from PNL by UST;" there were also "legal restrictions" (Omenn et al. 1991, p. 49). Nonetheless, the review committee concluded that its procedures as well as assistance from PNL enabled it to arrive at a valid conclusion:

> *Materials withheld by UST did not prevent us from reconstructing cases selected at random from all reported results; the other two limitations were overcome through additional effort and assistance from PNL staff familiar with the PNL filing system. We therefore feel that this constraint is only logistical and does not prevent us from reaching a valid conclusion.* [Omenn et al. 1991, p. 49]

Neither the reason why UST withheld materials from PNL nor the amount of data withheld (if the withheld "materials" contained data) are discussed in the review committee's report. This is notable in view of the fact that the Omenn et al. review did not set out to determine whether or not the data were fraudulent, but rather "focused on the scientific validity of the data:"

> *Our review focused on the scientific validity of the data. The methods we used were not intended to authenticate the laboratory records contained in the data archives. Our conclusions, insofar as they rely on quality control data provided by UST, are limited by our reliance on these records. The purpose of the Review Committee is not to prove the presence or absence of fraud. We are not able to verify that basic laboratory records are genuine, accurate, and unaltered. However, we could have recognized certain aspects of misconduct, such as*

> *obviously altered records, had these been encountered, and we did verify that raw laboratory records existed for results that had been reported.* [Omenn et al. 1991, p. 7]

The above makes clear that the Omenn review team did not set out to do an investigation of fraud in the bioassay program, but would have detected crude forms of fraud, such as "obviously altered records." In light of this, the non-submission by UST of some of the requested records is noteworthy and raises a concern. NIOSH did not discuss this aspect of the Omenn et al. 1991 review in its ER.

SC&A covered these issues in an interview with two of the members of the 1991 retrospective review team. As with other interviews with experts, the interviewees relied on the report they had co-authored and on their memory of events over 20 years ago. A summary of the interview is in Attachment C.

The experts stated that the statements about "materials withheld" by UST were more in the nature of a caveat rather than a statement about specific materials withheld. To the best of their knowledge, the bioassay dataset had been transferred to PNL. The review team had their own criteria to request records; PNL support personnel retrieved the records from an extensive storage location in a warehouse. The review team had no interaction with UST personnel. Some records may not have been found due to a failure to locate them, but there was no evidence of concealment of records. The experts reaffirmed their conclusion about the overall soundness of the bioassay data and opined that they could be used for dose reconstruction.

However, Omenn et al. 1991 explicitly states that, "[l]aboratory records have been maintained by UST and have in part been turned over to PNL" (Omenn et al. 1991, p. 15). SC&A raised a follow-up question with the experts to clarify the interview statement that the "materials withheld" did not refer to any particular records, and the report that states only a part of the UST records were transferred to PNL. The response of one of the experts was as follows:

> *PNNL was in a position to know what UST records were not included when the lab records were provided to it. For a possible example, UST's business records, instrument maintenance records, or other correspondence not part of sample testing work might not have been included. However, we were limited only by what was in the PNNL employee monitoring database. Reports of testing that were omitted from the database (if any) would be invisible to us as we searched for files to review. Any record in the database where the corresponding UST data were unavailable (whether from being withheld, misfiled, or otherwise poorly maintained) would have been potentially detectable, as our report discussed.* [See Attachment C]

SC&A also sent questions to [**redacted**], [**redacted**] for PNL in 1991 when the retrospective review was conducted, and [**redacted**], who was PNL's [**redacted**] at the time. Their responses to SC&A questions are reproduced in full in Attachment E.

[**Redacted**] recollects that all "pertinent records" had been transferred from UST to PNL (see Attachment E). He also noted the following regarding whether any records not present affected the Omenn team review:

> *I do not recall anything from the closeout meeting with the Omenn Committee that implied that they felt that there were significant records that they had not been able to see that affected their conclusion. All the evidence that they saw and other evidence that I saw implied that the issues were with other sectors of the company and that bioassay was not impacted.* [See Attachment E]

[**Redacted**] recollection is reinforced by the team's analysis in regard to a principal question about whether records were being hidden from the retrospective review team or were otherwise missing. The team also looked at the question of whether these samples had actually been analyzed. The team was able to review all the records requested for its analysis of this topic, and came to the following conclusion:

> *The Committee requested raw records for 300 assays (sufficient to detect a 1% occurrence rate of missing data with statistical confidence) randomly selected from the PNL Bioassay File of 51,740 assays of urine and feces specimens between 1983 and 1990. In every case evidence was found that the sample existed and had been analyzed.* [Omenn et al. 1991, p. 1]

The recollection of PNL's [**redacted**] also supports this general conclusion. He also provided an explanation about records that may not have been transferred to PNL by UST:

> *I was not aware of any materials withheld from the review team. However, on Page 49 of their report, the Omenn team stated that with regard to access to raw records, "Any third party seeking to review records of analysis in this matter will experience restrictions and inefficiencies in obtained raw UST records. Access is limited due to (a) materials withheld from PNL by UST; (b) legal restrictions requiring intermediaries to search the files for us; and (c) awkwardness of the file structure itself so that searchers must be very familiar with it. Materials withheld by UST did not prevent us from reconstructing cases selected at random from all reported results; the other two limitations were overcome though* [sic] *additional effort and assistance from PNL staff familiar with the UST filing system. We therefore feel that this constraint is only logistical and does not prevent us from reaching a valid conclusion." From this statement I would conclude the team received all materials they deemed necessary to reach their conclusions. It may be that the reference on Page 4 is to the records still at US Testing that were awaiting submittal to Battelle as discussed above.* [See Attachment E]

From the above statement, it appears that records in the possession of UST were withheld by the process that PNL (referred to as "Battelle" in the above quote) had set up for records transfer for PNL's own convenience. However, the review team itself felt that this constraint did not prevent

it from doing its work and arriving at valid conclusions (Omenn et al. 1991, p. 49). The relevant passage from the report is quoted above in this section.

3.5 OVERALL COMMENTS ON THE OFFICIAL AUDITS AND EVALUATIONS

The audits were not designed as a fully independent check on the integrity of UST's practices and results. Even the independent 1991 review, done after UST lost its contract with the EPA, was not designed to detect fraud though the team could recognize "certain aspects of misconduct." (Omenn et al. 1991, p. 7)

The audits and oversight efforts found a wide array of problems. Still, the bottom line conclusion seems to be that despite these problems, UST's laboratory was, overall, acceptable. No explanation for the "materials" withheld from the 1991 investigation or the edited QC file discovered during the May 1990 oversight activities is evident in the respective reports. However, the interview with one of the experts who wrote about the editing of the QC file indicated that it was not an attempt at fraud or data manipulation, but simply a change made in a header to correct an error. The materials that may have been withheld from PNL by UST did not appear to have hindered the retrospective review. The retrospective review team's attempt to discover missing files or data by examination of 300 randomly selected files did not reveal any missing data.

A second issue is related to the finding of the DOE Inspector General (IG) that there had been manipulation of test equipment at the Richland facilities of UST. The DOE IG noted the following in an e-mail to NIOSH on October 24, 2010 (both the question by NIOSH and the DOE IG's answer are quoted):

> [NIOSH]: *Did the investigation find that the U.S. Testing laboratory in Richland, Washington was involved in any behavior which could be considered fraudulent? If so, please provide a detailed explanation.*
>
> [DOE IG]: *The investigation at Richland found that U. S. testing employees had manipulated test equipment and performed questionable testing. This information was found through witness interviews. The evidence developed by EPA OIG at U.S. Testing, Hoboken, NJ office was more significant and supported with physical evidence. Continued investigation by the EPA OIG in the District of New Jersey did result in U.S. Testing entering a guilty plea agreement on April 17, 1991. U.S. Testing agreed to pay a fine of $100,000, restitution of $913,717.74, and a special assessment of $200.* [Romeo 2010a]

In response to a further query from NIOSH about where bioassay samples were affected by the equipment manipulation, the DOE IG stated that his office's review did not show that:

> *Per my agent's review of the file, I was advised that the reference to test equipment manipulation and questionable testing was related to water and soil sampling, and not associated with bioassay samples.* [Romeo 2010b]

While this exchange indicates that the fraud was related to water and soil samples, the response is not defintive in that regard. At the same time, it does not indicate or allege any fraud in the bioassay data.

4.0 PETITION SEC-00155 AND PETITIONER ISSUES AND DOCUMENTS

4.1 INTERVIEW WITH PETITIONER AND THE PETITIONER'S REPRESENTATIVE

SC&A interviewed both the petitioner and the petitioner's represenative about the issue of possible fraud and misconduct in the radionuclide bioassay program. A summary of the interview is provided in Attachment D to this report. The petitioner also provided a writtten statement, which [**redacted**] read during the interview. It is reproduced in full in the interview summary in Attachment D. During the interview, the petitioner and [**redacted**] representative stated that they would send documents, which SC&A has received and reviewed. They are discussed in the next section. SC&A also reviewed the petition itself, which contained some of the same documents provided to SC&A after the interview.

During the interview, neither the petitioner nor [**redacted**] representative pointed to specific instances of fraud in the bioassay program, such as the drylabbing or backdating and other misconduct they pointed to concerning the chemical sample analysis that caused EPA to terminate the UST contract in 1990. The specific instances of fraudulent activity and misconduct described in the documents provided dealt with toxic chemicals. The petitioner [**redacted**] did not work for a contractor responsible for bioasay and therefore did not have direct knowledge of the procedures involved in bioassay. As a result, [**redacted**] did not have direct personal knowledge of fraud or misconduct specifically relating to the bioassay program.

The petitioner and [**redacted**] representative raised a question about the records that are not available to them from the criminal investigation of UST. Some records from these proceedings are sealed for legal reasons. SC&A notes here that these sealed documents were made available by DOE for closed-door review by NIOSH, which also invited SC&A and the Advisory Board to review the documents at the same time for purposes of efficiency of resource use. The NIOSH reviewer was Sam Glover, the Advisory Board reviewer was Brad Clawson, and the SC&A reviewer was Bob Bistline. All concurred that these documents did not contain evidence of equipment or data manipulation that affected the radionuclide bioassay program. Furthermore, radionuclide bioassay results were not cited by PNL as being among the reasons for contract termination. Only analyses of dioxin and petroleum hydrocarbons are indicated as specific issues leading to contract termination of UST by Battelle (Battelle 1990). Further insight into this question was obtained from one of the documents sent by the petitioner's representative (see Section 4.2.1).

The petitioner's concerns were more general and related to the ethics of the company as a whole. The main question raised by the petitioner in the interview was as follows:

> *The main underlying issue raised by the petitioner was the ethics of UST, which had lost its contract with the EPA due to fraud and manipulation of data. For the petitioner, UST "knowingly and willfully were aware of what they were doing, they just didn't care and in-turn placed my life and my family's livelihood in jeopardy for their own self gain……greed." Both the Hoboken, New Jersey, and*

> *Richland, Washington, laboratories of UST were involved. For the petitioner, this was more important than whether the specific type of sample being analyzed was a chemical or a radionuclide. The results of a company that engaged in fraudulent practices could not be trusted. The petitioner stated that the company had pleaded guilty to a felony. As a result of illegal practices, which were detailed in the EPA Action Referral Memorandum* [EPA 1990a] *and verified by the EPA Office of Inspector General in interviews,* [**redacted**] *and other Hanford employees, who had done hazardous work for the security of the United States, had suffered a betrayal of trust, grievous harm to health, and financial and psychological harm to their families.* [**Redacted**] *stated that "It does not matter whether they were chemicals or radiological samples; it is the lack of ethics that is the problem." Therefore, the petitioner concluded that none of the analytical results of UST during the 1987–1989 period could be trusted or used in a scientific dose reconstruction and that the SEC petition should be granted.* [See Attachment D]

The petitioner listed a number of specific issues associated with the statement that the company "could not be trusted:"

- *Work performed at one site was represented as being done at the other site – even though the UST contract did not permit work to be performed at alternate sites.*
- *There were chain of custody violations.*
- *Two separate logbooks were kept.*
- *There was improper cutting and pasting of results from one sample onto those for another sample.*
- *There was backdating of sample results.*
- *There was doctoring of samples, for instance by dilution.*
- *There was use of illegal drugs in the workplace by management, including when "critical" decisions were being made.* [See Attachment D]

In edits made to the interview when it was sent for corrections to the petitioner and [**redacted**] representative, they also objected to the way that the petitioner's [**redacted**] samples were evaluated for [**redacted**] dose reconstruction. As noted in Attachment D, a copy of the document containing the results was sent to Dr. Jim Melius, Chair of the Hanford Work Group (and Chair of the Advisory Board), who sent it to SC&A.

However, SC&A could not examine any matters related to the dose reconstruction of the petitioner, because there is [**redacted**]. SC&A was advised by the Designated Federal Official for the Board that "you will not be able to review any [**redacted**], nor any cases that have not been fully adjudicated" (Katz 2012). In order to be responsive to the petitioner's concerns regarding potentially incorrect use of [**redacted**] data, SC&A reviewed such use in four completed dose reconstructions (see Section 5.1.1.3 below).

4.2 REVIEW OF PETITIONER MATERIALS

SC&A reviewed the petition and the materials attached to the petition, including the statements made to investigators regarding alleged fraud and manipulation of data and test equipment and results. SC&A also interviewed the petitioner and [redacted] representative and the documents provided subsequent to that interview.

The petition decribes a number of instances of fraudulent activity at both the Richland, Washington, and the Hoboken, New Jersey, facilities of the UST in the 1987–1989 period as described by the EPA, which arrived at the following conclusion:

> *The EPA Office of Inspector General has furnished the Compliance Branch with adequate evidence to believe that UST management, contrary to CLP [Contract Laboratory Program] protocols, and during the performance of Ogranics and Inorganics contracts at the Richland, Washington facility and the Hoboken, New Jersey facility conspired, directed, carried out, and otherwise condoned a scheme to defraud the United States.* [SEC 2009, pdf file p. 31][6]

The evidence, therefore, supports the petitioner's view that there was fraud in testing activities; however, the same evidence also shows that the fraud was related to the testing of organic and inorganic chemical samples. The petition does not cite evidence of fraud in the bioassay analysis program at Richland.

4.2.1 Documents Sent By the Petitioner and [Redacted] Representative

The petitioner initially sent four documents to SC&A for review:

(1) A statement the petitioner had previously made to the Advisory Board: This statement is reproduced in full at the end of the interview record in Attachment C.

(2) The EPA Action Referral Memorandum dated April 4, 1990, describing the misconduct and fraud found by the EPA requiring action. (EPA 1990a)

(3) An interview with a former UST employee conducted by the EPA Office of the IG. This interview is also part of the petition (SEC 2009, starting at pdf page 13).

(4) An interview with another former UST employee conducted by the EPA Office of the IG. This interview is also part of the petition (SEC 2009, starting at pdf page 19.)

These four documents are available on the O-Drive on the SEC viewer. The documents listed in items 2, 3, and 4 above contain information that corroborates the general statements regarding misconduct and problems such as backdating and analyses being done at a location that was not authorized to do them. As noted, they are also part of the SEC petition. This misconduct was described by the petitioner in [redacted] statement (see Attachment D) and is discussed above.

[6] This statement is from the EPA Action Referral Memorandum 1990, which was incorporated into the petition starting at pdf p. 28.

Subsequently, the petitioner's representative also sent nine other documents. The following list of the titles of the documents is reproduced from the cover letter accompaying the documents:[7]

1. *Battelle NW memo re "Problems with US Testing Records and Reports dated 6/30/1969;*
2. *Deposition of Michael J. Lawrence dated 1/15/1991 (excerpted pages only);*
3. *Letter to US Atomic Energy Commission dated 4/22/1968;*
4. *Dept. of Ecology Fact Sheet re US Testing Suspension Impacts on Hanford dated 4/25/1990;*
5. *Battelle NW memo re "Blind Audit Sample Program" dated 1/18/1982;*
6. *Dept. of Energy letter to Dr. Omenn dated 12/4/1990;*
7. *Battelle memo re US Testing dated 5/21/1990;*
8. *Battelle NW memo re Memo with DOE-RL and EPA Region X dated 2/27/1990;*
9. *Daily Report on US Testing 5/9/1990.*

These documents, along with the cover letter (including the marking made on it by the DOE classification officer that some material was Offical Use Only, were sent to NIOSH for posting in the Site Research Database (SRDB).

We describe the issues raised by in these documents, not in the order of the list above, but rather according to the relation of the topic to SEC-00155. Our conclusions, findings and observations are in Section 5.

The older documents from 1968, 1969, and 1982 indicate that the problem of QC with UST's radiochemical work went much farther back than the 1987–1989 period, and even before the 1980s. For instance, the 1968 Battelle memorandum states:

> ...[T]*he reliability and consistency of U.S. Testing's reports to us have deteriorated in recent months. We have speculated as to the reason for this, but the critical aspect is that I could no longer tell the AEC that we are satisfied with the overall quality of U.S. Testing's performance on radiochemical analyses. As you are also perhaps aware, quality control on other aspects of UST work has been a bone of contention for several years and has at times been enough of a problem to cause letters to the Commission to be written.* [Battelle 1969]

The 1968 letter to the Atomic Energy Commission (AEC) from Battelle was one of the letters referred to in the 1969 internal memorandum that stated that Battelle could not "say with assurance that their [UST's] analytical performance meets the contract specifications" (Battelle 1968). The 1982 memorandum lists a number of problems that were revealed by Battelle's audit

[7] These nine documents have been entered into the reference list in the order listed above with the following keys: 1. Battelle 1969, 2. Lawrence 1991, 3. Battelle 1968, 4. Ecology 1990, 5. Battelle 1982, 6. DOE 1990a, 7. Cunningham 1990, 8. Sturgis 1990, and 9. Morton and Marlette 1990b.

program, including "Out-of-Limit Results" and "Lost Samples." More than 30 samples out of almost 370 were "lost" [Battelle 1982].

These problems are along the lines of the problems that have already been discussed for the 1987–1989 period, and that were also revealed in the May 1990 oversight program (DOE 1990b). They do not have a direct significance for the use of the data in the 1987–1989 period, but certainly show that the problems of quality were longstanding ones, raising questions about why they persisted for so long. This point is further discussed in Section 5.0, where SC&A's analysis of the SEC is presented.

The 1990 Daily Report written by Stan Morton and Guy Marlette (Morton and Marlette 1990b), who were part of the May 1990 Oversight team for the DOE, calls attention to the QC file that was found to have been "edited." The Daily Report considers this "a major problem considering the allegations that have been made concerning data alteration" (Morton and Marlette 1990b). This issue is discussed above in Section 3.4. The Daily Report recommends the following procedure:

> *Provisions should be made restricting the editing of a data file. New or revised data should be appended to the current file, leaving the original data intact. Only key personnel should be given delete or replace priviledegs* [sic] *of existing data. This would increase the data integrity* (Morton and Marlette 1990b).

This data file editing issue has been discussed in more detail above in Section 3.4.1. The interview with one of the authors of the daily report quoted just above is in Attachment B. As noted there and in Section 3.4.1, the best that can be determined at the present time is that the edit was not to the data, but to a header; furthermore, the change appears to have been made to correct an error rather than to manipuate data. No definitive finding is possible at the present time, however, since the change made was not accompanied by an auditable trail.

The rest of the documents raise the issue of whether the combination of persistent QC problems in UST's radiochemical work combined with the findings of fraud in the chemical work would cause all of UST's analyses to be suspect. For instance, the issue was briefly raised by the Washington State Department of Ecology (Ecology 1990). In a May 1990 memorandum, PNL noted that "the State [of Washington] has told Westinghouse [the prime contractor for Hanford] that they will not accept any UST results, if there is a way they can refuse to do so." (Cunningham 1990).

The internal Battelle memorandum dated February 27, 1990 (Sturgis 1990) has an attached 1990 EPA draft document (EPA 1990b, pp. 3 and 5) that raises several issues that led up to the central question of whether UST's radiochemical data were usable. The issues included the following:

- PNL did not conduct any audits of UST's work for 35 months during the period 1984–1986, and there was another gap of 19 months between a 1986 audit and a 1988 laboratory survey.

- PNL's audits were "limited in scope" and did not extend its oversight to the "'analytical bench' level of detail."[8]

- PNL did not routinely verify quarterly QC summaries by UST; these reports were therefore "essentially self-monitoring by UST."

As a result, EPA concluded the following:

> *The file review revealed significant periods of time without documented audit activities by PNL. These gaps of time allowed UST's laboratory performance to remain un-checked for a period of two years or more. No surveillance reports were filed during these breaks and on-site verification of laboratory performance was not documented.* [EPA 1990b, p. 5]

The EPA's bottom line joined these concerns to the allegations of fraud as follows:[9]

> *Because of the allegations of fraud, and because of the weaknessses in the historical Quality Assurance program noted above, data produced by UST during the period 1984 to 1989 must be considered suspect.* [EPA 1990b, p. 6]

The EPA recommended that PNL "intiate a data assessment program to evaluate analytical data produced by UST" (EPA 1990b, p. 6).

There are no allegations of fraud in the bioassay program in any of these documents. Instead, the thinking is similar to what has been raised as the central issue by the petitioner: because of the problems on the chemical side of the program, including allegations of fraud, the bioassay data should be "considered suspect."

At about the time the oversight activities of May 1990 ended, Battelle PNL terminated its entire contract with UST, even though no fraud was found in the bioassay program. The contract was terminated for default. A prinicipal reason was that the Richland Division sent dioxin and petrochemcial samples to the Hoboken, New Jersey, laboratory for analysis knowing that the latter was not in compliance with QA requirements:

> *The Richland Division of United States Testing Company, Inc., sent samples to United States Testing Company's Hoboken laboratory to have analytical tests performed for dioxin and total petroleum hydrocarbons, knowing that the quality assurance requirements of Appendix B of the subject contract had not been communicated to the appropriate officials at the Hoboken laboratory.*
>
> …

[8] As noted in Section 3.3, PNL itself had noted that its audits were more in the nature of a "double check" of UST's work, rather than a bottom up, all-encompassing audit.

[9] UST had not yet agreed to a settlement at the time the EPA document was written (February 23, 1990).

> *The Richland Division of United States Testing Company, Inc., continued to send samples to United States Testing Company's Hoboken laboratory to have analytical tests performed for dioxin and total petroleum hydrocarbons after December 6, 1989, knowing that the Hoboken laboratory was not in compliance with the quality assurance requirements of Appendix B of the subject contract.* [Ace 1990, p. 2, pdf file p. 30]

The letter does not contain any allegations or reference to problems such as QA in the work at the Richland facility. The relationship to bioassay and other data not specifically mentioned in the letter of termination was explained in 1991 by Michael Lawrence, Hanford Site Manager for the DOE in 1990, when he testified in the context of a lawsuit by UST against Battelle PNL subsequent to the contract termination:

> *One goes to a testing laboratory for the credibility of their results, and regardless of the percentage number of tests that are done improperly, if any are done knowingly and willfully improperly, then it casts doubt on the credibility of any of the results and, consequently, I don't believe that the Department* [of Energy] *or Battelle can utilize a contractor if there is information which verifies that they knowingly and willfully did not meet the requirements of the contract to provide the credible results that were required by it.*
>
> …
>
> *That they did not have approved quality control or assurance program in place at Hoboken* [NJ]*, and whether or not tests are technically done properly is not in issue. In issue is that quality assurance and quality control programs which ensure the quality of results., the reproducibility of results were not in place and, consequently, whether or not it was done properly in abstract is not the point. The point is that a clear requirement of the contract for quality assurance and quality control program, an approved program at Hoboken was not in place and, therefore, any results coming from that activity are at best questionable and at best worthless.* [Lawrence 1990, pp. 50–51]

The above seems a general statement about the usability of UST data, yet it points only to the specific QA/QC problems at the Hoboken, New Jersey, facility, where only chemical analyses were done. Hence, the thinking appears similar to that of the EPA document of February 23, 1990, quoted above.

In reviewing the contract termination, the court ruled that "the termination of UST for default was not warranted" (United States District Court 1992, pdf file p. 7). The court also ruled that "termination for convenience" would have been appropriate, given the circumstances at the time of termination:

> *…Battelle was clearly under pressure from several entities, the Department of Energy, the Environmental Protection Agency, and the State of Washington. The*

> *very nature of U.S. Testing's work involved matters which would be legitimate concerns of these agencies.* [United States District Court 1992, pdf file p. 8]

Hence, the court did not agree with the substantive reasons given by Battelle for contract termination, but ruled that the contract would have been reasonably terminated anyway, given the circumstances and the concerns of governmental bodies..

Two contradictory trends emerge from the oversight activities of 1990 and 1991 on the one hand and the termination of the UST contract by Battelle PNL and comments and concerns of the EPA regarding the usabililty of the data on the other:

(1) The May 1990 oversight activities found numerous problems but no "show stoppers," and concluded that (1) the data were usable, and (2) UST should improve its procedures, QA/QC, etc., but continue its work despite the deficiencies. Similarly, the overall conclusion of the 1991 retrospective review was that the UST bioassay program was sound.

(2) The trend in thinking of Battelle and the EPA was that EPA findings of wrongdoing on the part of the UST in regard to the CLP, as well as the fact that the Richland facility sent chemical samples to Hoboken, New Jersey, for analysis knowing of QA problems, was sufficient to create a doubt about the reliability of any of the results at either the Hoboken or Richland facilities.

5.0 SC&A REVIEW

5.1 EVALUATION OF PRIMARY RADIONUCLIDE BIOASSAY

According to the NIOSH ER, internal radiological exposure sources at the PFP included plutonium, uranium, neptunium, and americium. Plutonium radionuclides of concern included Pu-238, Pu-239, and Pu-240. Uranium radionuclides of concern included U-233, U-234, U-235, and U-238. Neptunium-237 and Am-241 were also internal exposure sources. A 2004 document reviewing PFP operations confirms this list (Hoyt and Teal 2004). In addition, the PUREX plant operated intermittently through 1990. Hence, mixed fission products would be a concern in the SEC period, 1987–1989, under investigation here. Conditioning of separated cesium-137 and strontium-90 stopped in October 1983 and January 1985, respectively (SC&A 2011a, p. 38), so those two radionuclides would not be issues as separated materials in the period under review in this report.

5.1.1 Plutonium in Excreta Samples

5.1.1.1 Urinalysis

We first looked at the data and the issue of minimum detectable activities (MDAs).

For 1988, 1,502 urine samples from Area 200 were measured. There were 50 positive urine samples from 32 workers. None of those workers had fecal sample data. The ICRP, in its Publication 78 published in 1997, states that the typical detection limit for measurements of Pu-239 in urine samples by radiochemical separation and alpha spectrometry is 0.001 Bq/L, or 0.06 dpm/L (ICRP 1997, Table A.12.12, p. 140). Thus, the MDA used for urine at the 200 Area, 0.02 dpm per sample, is reasonable, even stringent. While SC&A has not compared the results with those from other installations in the 1980s, in SC&A's view, if the samples were analyzed in another laboratory, the results would likely not have been very different in relation to the percent above detection limits. According to [**redacted**], the PNL [**redacted**] at the time, after PNL terminated its contract with UST in 1990 and had to go to other laboratories, it found that "no one could match the 0.2 dpm fecal and 0.02 dpm urine contractual MDAs for both Pu-239 and Pu-238, so we had to settle for less sensitive analyses for awhile. Basically, UST was the most sensitive lab in the nation for Pu-238 and Pu-239 bioassay samples for many years" ([**Redacted**] 2012).

On the other hand, PNL concluded from an experiment with feces samples from 100 workers that intermittent exposures existed at the 200 Area at levels below detectability by normal workplace air monitoring (see Section 3.2 above and Section 5.1.1.2 below). The majority of the

doses of the workers that were monitored had results below detection limits, but a missed dose can be assigned to them at a level corresponding to a urine concentration of 0.02 dpm/L.[10]

In 1987, 1,700 urine samples for Pu analysis were collected, 1,200 samples from the workers from the 200 Area. There were 81 results higher than the MDA. One worker had really high results; this was probably due to an accident. The worker had his urine counted several times, but no fecal samples were collected. The urinalysis results fluctuated a lot. In general, looking at the coworker data, the conclusions are the same as for 1988. As noted above, it is does not appear advisable to rely on the results below detection limits; in such cases, a missed dose based on 0.02 dpm/L should be used.

Setting aside the issue of detection limits, the data collected by NIOSH for their coworker model show that the results from 1987 and 1988 follow the same lognormal distribution as the data for the 1982–1986 period with a similar geometric mean; however, some of the quarterly results in the 1982–1986 period have a higher geometric standard deviation compared to the data for 1987–1988. Thus, the plutonium data do not indicate a conclusion that the results are different in some essential way for the 1987–1989 SEC period than for the earlier 1982–1986 period.

For 1989, there were 1,738 urine samples in the 200 Area. There were 39 positive values, which is a similar situation as for 1988. There were samples with very high results. With the exception of one worker, the workers with the highest results were monitored various times in the year and had repeated high results. Those workers also had high results in 1988. In general, the 1988 results are consistent with the 1989 results. None of the workers with positive urine results had fecal samples. It is interesting to note that NIOSH does not use the 1989 urine results in their coworker model; rather, NIOSH assigns the same result as in 1988, without any technical explanation. However, this is not an SEC issue, but related to making a claimant-favorable choice for dose reconstruction.

As discussed in Section 3.0, the documents related to UST performance indicate a variety of problems regarding QC and meeting contractual MDA requirements, including a wide range of bias for individual low-level spike samples; however, such variation is to be expected at low levels of radioactivity. In addition, UST had very low recoveries for some analyses of Pu-239 and Pu-238 in urine. These problems were reviewed during the audit and oversight activities, as discussed above in Section 3.0. Overall, the plutonium urinalysis results appear usable for the period with an MDA of 0.02 dpm/L for estimating missed dose for the period.

Finally, we note that there were also problems related to the analysis of Pu-241. In the 1987 audit, Pu-241 was tested for the first time. Performance was poor. Plutonium-241 did not meet

[10] While this is not relevant to the SEC review, we note that NIOSH's coworker model for plutonium assigns the same intake rate from January 1, 1982, until 1988, based on all urine excretion rates. From the Excel files, there were 919 samples with volumes higher than 1 liter (which might be used as the full daily excretion). The MDA is 0.02 dpm per sample. The geometric means (GMs) used by NIOSH in 1988 for the four quarters of the year are 0.0008, 0.00052, 0.00064 and 0.00020 dpm/d. Those GMs were derived by using a lognormal distribution using the exact counting results, even the ones below detection limits. This means that NIOSH has used the results below detection limit at face value. This is not appropriate. It is more appropriate to assign a missed dose corresponding to 0.02 dpm/sample, based on the fact that PNL concluded from their investigation collecting feces samples that intermittent exposure could not be detected unless fecal monitoring was done (see Section 5.1.1.2).

the performance requirements in 1987 and in 1988. Since the grades of plutonium, and hence their isotopic composition, at Hanford can be inferred from other isotopic measurements (ORAUT 2010, p. 21), the problems related to Pu-241 should not affect the usability of the urine bioassay data. Plutonium-239 measurements appear to be usable for dose reconstruction, if claimant-favorable assumptions about isotopic composition are made.

5.1.1.2 Fecal Sampling for Plutonium

As noted in Section 2.3, the NIOSH site profile states that fecal samples were used when intakes to monitor some high-risk workers in the PUREX plant and the PFP from 1986 to June 1989 and when intakes were suspected. However, in practice, fecal sampling was more limited. In 1987, only 41 fecal samples were collected from 34 workers. In 1988, 166 workers had 388 fecal samples analyzed. Only 36 were positive results. There were some very high results, but none of the positive fecal results had corresponding positive urine results. The lung Am-241 positive counts were also not matched by positive urine results.

Regarding the reliability of the fecal results, a paper published in the journal Health Physics about a study made using fecal samples from 100 workers (Bihl et al. 1993) provides interesting insights. The study carefully compared the fecal sampling results with air samples, discovering exposures from the results of fecal samples. This study indicates that whenever there are fecal samples, they should be used to derive the worker's exposure.

The analysis of Pu fecal excretion was done mainly as part of a control study, which involved 50 workers in 1987 and 100 workers in 1988. The results of this study were reported in Bihl et al. 1993. We do not know if the fecal samples reported in this paper were analyzed at UST. As discussed in Section 3.0, there were no PNL audits of UST's analysis of feces.

Bihl et al. 1993 considers that all results higher than 0.07 dpm per sample are an indication of Pu exposures. This is because the level of 0.07 dpm per sample was considered the decision level for fecal analysis for plutonium. The database of fecal results uses 0.2 dpm as the MDA. This value of 0.2 dpm/sample is also shown as the MDA in the site profile; it is based on an interview and various statements of work (ORAUT 2010, Table 5-2, p. 19 and note 18, p. 68). According to [**redacted**], 0.2 dpm was the contractual MDA; the actual MDA was less than this, but about twice the decision level of 0.07 dpm. [**Redacted**] noted the reason was that the decision level took only Type I errors into account, while the MDA "is the sum of Type I and II errors plus a few other terms" ([**Redacted**] 2012). ICRP Publication 78 states that the typical detection limit for measurements of Pu-239 in feces samples, by radiochemical separation and alpha spectrometry, is 0.001 Bq, or 0.06 dpm (ICRP 1997, Table A.12.12, p. 140). Therefore, the Bihl et al. 1993 use of 0.07 dpm/sample is consistent with the ICRP Publication 78 value. Presuming that the 100 fecal samples were analyzed at UST with the same care as all the others (that is, no special treatment or care was given to these samples) and using the criterion that results higher than 0.07 dpm/sample are an indication of exposure, the proportion of workers with positive feces in 1988 is similar to that reported in Bihl et al. 1993.

In 1989, 264 fecal samples from 164 workers were collected and analyzed. Thirteen of these samples were >0.2 dpm per sample. Using the criteria in Bihl et al. 1993 of classifying results

>0.07dpm per sample as showing evidence of exposure, 47 samples (17%) showed such evidence. Those samples were presented by 42 workers, represented 26% of the workers who were monitored by fecal samples. Of these 42 workers, 10 workers were not from 200 Area.

SC&A analyzed data from 50% of claimants with POCs >50%. Only [redacted] workers had results of Pu excretion in feces. According to the DOE files, one of the workers in [redacted] gave fecal samples in 1988 and 1989. Another worker was monitored by fecal analysis twice in 1988. The worker was performing [redacted] job at the [redacted], when [redacted] was required to provide fecal samples. Those [redacted] workers were also monitored for Pu excretion in urine in 1987, 1988, and 1989. In addition, SC&A analyzed about 15% of the data from claimants, without looking at the POC. None of the workers randomly selected had fecal sampling results.

5.1.1.3 Case Studies of Fecal Data Used in Dose Reconstruction

The petitioner raised a question about whether [redacted] sample data were being properly used in dose reconstruction (Attachment C). Specifically, the petitioner's representative asked whether the procedure regarding the use of [redacted] samples taken more than 2 months after the intake was being applied to the [redacted]. In order to examine this issue, SC&A examined four completed dose reconstructions that included [redacted] data, but concerning which no claimant issues or litigation was outstanding.[11] Evidently, four cases do not constitute a statistically valid sample and no overall conclusions can be drawn from it. These four cases were done in place of the analysis of [redacted] case, which is [redacted]. A summary of the review of each case is provided below:

1. Case 1

Bioassay Results above the Limit of Detection

To account for potential intakes for Case 1, NIOSH assigned the internal intake based on the two [redacted] samples submitted on [redacted], and [redacted]. A plutonium mixture of weapon-grade plutonium was applied to the plutonium-239 intake to determine the plutonium-238, plutonium-241, and americium-241 intakes. Type M was considered to be the most claimant-favorable solubility type based on [redacted] data. (Solubility Types M, S, and Super S were considered.) Case 1 was also monitored via [redacted] samples and chest counts. However, for this assessment, the [redacted] data and chest count data were not considered on the grounds that this may result in a reduction of dose. For the dose calculation, an acute intake was assumed to occur on [redacted], which is the mid-point between the [redacted] sample on [redacted], and the [redacted] immediately preceding it, provided on [redacted]. This approach provides a more claimant-favorable internal dose than that of assuming a chronic intake started on [redacted], and continued through the date of the [redacted] sample, [redacted]. The resultant intake dates were chosen based on a fit between the projected excretion rates and the bioassay data for Case 1.

[11] There is [redacted] outstanding in the [redacted] case; therefore, it could not be reviewed by SC&A as per the direction provided by NIOSH (Katz 2012).

There are several problems associated with NIOSH's dose reconstruction analysis:

a. The assumption of a [redacted], intake is not substantiated by the bioassay results provided by DOE. There were no [redacted] samples taken before [redacted], and thus [redacted] is not the midpoint between the [redacted], [redacted] sample and a [redacted] sample that preceded it. Rather, the [redacted], midpoint corresponds to the middle of the interval between the date of the [redacted] sample taken ([redacted]) and [redacted], when the [redacted] sample was taken. The excretion rate of Pu in feces is very different from the excretion rate in urine; therefore, the results of urine samples cannot be compared in terms of intakes and exposure with the results of fecal samples. As shown in ICRP 78, the feces excretion rates are about 1 to 2 orders of magnitude higher for Type M Pu. Thus, a negative urine sample does not mean there was no exposure comparable to the one detected through feces analysis (ICRP 1997, Figure A.12.7, p. 144).

b. The [redacted] samples reported in the dose reconstruction were not really positive. The detection limits were 0.2 dpm for the [redacted] samples. All [redacted] samples were below the 0.2 dpm detection limit. [Redacted] of them are also below the Bihl et al. decision level of 0.07dpm/sample discussed above in Section 5.1.1.2.

c. The interval of 86 days from the last exposure, as used in the dose reconstruction, is longer than 2 months. Thus, according to ORAUT-OTIB-0049, the doses to the [redacted] should have been calculated as if they were a 24-hour [redacted] sample and adjusted upward by a factor of 3 (ORAUT 2008, p. 16). Using the highest result (the only one above the decision level reported in Bihl et al. 1993) and using the 86-day interval as suggested by the dose reconstruction (even though SC&A disagrees with the use of this interval), the intake would be 6.2×10^5 multiplied by 3 (the Super S correction, according to OTIB-0049) for a total of 18.6×10^5 dpm (3.1×10^4 Bq). This intake of 18.6×10^5 dpm for Pu-239 is much higher than the intake calculated by the NIOSH dose reconstruction. The corresponding doses would also be higher.

d. The correct way to calculate the Pu doses is to calculate the missed Pu doses using the MDAs for urine, feces and chest measurements.

The main point pertinent to this review and the issue raised by the petitioner is that in this case, the OTIB-0049 procedure of multiplying the intake result by 3 in cases where [redacted] samples were taken over 2 months after the incident does not appear to have been followed.

2. Case 2

Only results from [redacted] samples were reviewed by SC&A.

Available [redacted] samples:

Date	Isotope	Solubility	Mass(g)	Result	Units for result	Error
5/19/1993	Pu-238	F	129	-1.19E-02	dpm/sample	7.56E-03
5/19/1993	Pu-239	F	129	1.56E-01	dpm/sample	9.24E-02
3/18/1993	Pu-238	F	244	2.54E+01	dpm/sample	1.89E+00
3/18/1993	Pu-239	F	244	1.32E+02	dpm/sample	9.09E+00
11/6/1989	Pu-239	F	111	3.25E-02	dpm/sample	2.23E-02
11/6/1989	Pu-238	F	111	4.95E-02	dpm/sample	2.56E-02
3/20/1989	Pu-238	F	158	5.61E-03	dpm/sample	4.94E-03
3/20/1989	Pu-239	F	158	3.26E-02	dpm/sample	1.27E-02
9/12/1988	Pu-238	F	39	4.96E-03	dpm/sample	5.58E-03
9/12/1988	Pu-239	F	39	0	dpm/sample	5.41E-03
6/20/1988	Pu-238	F	27	3.67E-04	dpm/sample	5.22E-03
6/20/1988	Pu-239	F	27	1.10E-03	dpm/sample	3.46E-03

All these results were below the MDA of 0.2 dpm/sample, and also below the decision level of 0.07 dpm/sample suggested in Bihl et al. 1993.

SC&A's review of this data and the use made of it by NIOSH in the dose reconstruction indicates that the dose reconstruction used the [redacted] [redacted] results to calculate the doses from the [redacted] accident. The calculations of the intake were correct. The approach in relation to Super S Pu was also correct.

SC&A notes that the [redacted] results from [redacted] and [redacted], which were all below the MDA, were not used in the dose reconstruction; rather, [redacted] chest counts and [redacted] urinalysis results were used.

3. Case 3

Only results from [redacted] samples were reviewed. The only available [redacted] samples were:

[redacted], [redacted], [redacted]. Result: [redacted] dpm < MDA
[redacted], [redacted], [redacted]. Result: [redacted] dpm < MDA

The dose reconstruction calculated missed doses from Pu, assuming chronic exposures from 1981 to 2002, using half the MDA for urine. In addition, the dose reconstruction calculated another chronic exposure for [redacted] and [redacted] derived from the exact value of Pu-239 [redacted] excretion of [redacted] dpm taken in [redacted], even though this result is below the detection limit. The dose reconstruction justification for this calculation was that a dose assignment of [redacted] rem was made in [redacted] and [redacted] as whole-body dose for the worker in the DOE records. This [redacted] rem dose, though, was not based on the

worker's [redacted] sampling result, but on the geometric mean result of all workers in the 200 Pu Finishing Plant in the last quarter of 1989.

Assuming there was a justification for the use of this [redacted] result for estimating additional doses, the intake calculations are correct. There was no need for Super S corrections. As noted above, consideration should be given to the use of the MDA for missed dose when the result is below the MDA.

4. Case 4

Only results related to [redacted] samples were analyzed.

The worker entered the contaminated area on [redacted]. There is a letter in the DOE files saying that the only time the worker entered the area was on that date. The [redacted] samples were collected on [redacted], and [redacted]. All [redacted] samples were below the detection limit of 0.2 dpm/sample.

The Pu-239 [redacted] sample collected on [redacted], had a result of [redacted] ± [redacted] dpm, in the range of the 0.2 detection limit. In the DOE files relating to this case, there is a document listing the screening level for this sample as [redacted] dpm/sample. The measurement result is clearly above the decision level of 0.07 dpm/sample in Bihl et al. 1993. This sample was used by NIOSH to calculate doses to the [redacted] and the [redacted].

In SC&A's judgment, NIOSH made a correct use of the [redacted] sample data of [redacted] dpm excreted in [redacted] [redacted] days after the intake to calculate the dose due to this incident. NIOSH's assumption of an acute intake is also correct, because the worker was only in the contaminated area [redacted].

As for the result, the calculated intake of [redacted] dpm of Pu-239 ([redacted] Bq, [redacted] nCi) is correct if Type S Pu-239 is assumed. The proportion of Pu-241, Am-241, and Pu-238 in relation to Pu-239 used by the dose reconstruction is higher than the proportion originally used by the PNL health physicist to calculate the worker's dose. The dose calculations are probably correct, as the dose for the [redacted] during 4 years is very low, and the dose to the [redacted] during 2 years is also very low (<[redacted] rem). There is no need for a Type Super S in this particular case.

SC&A considers the assignment of Type S Pu correct, since there are data in the file regarding solubility. We note that if Type M had been assigned (in the absence of solubility data), the intake of Pu-239 would have been very similar; 374 dpm. The doses to the [redacted], on the other hand, would have been about 25 times higher than if Type M had been assumed instead of Type S Pu-239; yet, they would still be less than [redacted] rem. The same applies to the [redacted] dose: Type M would deliver a dose about 40 times higher in 2 years, but still below [redacted] rem.

In summary, SC&A's analysis indicates that the dose reconstruction estimates of [redacted] and [redacted] doses using [redacted] samples results are correct.

5.1.1.4 Summary of Review of [Redacted] Data in Four Dose Reconstruction Cases

In reviewing the four cases above, SC&A found that NIOSH's use of [**redacted**] samples was correct in three out of four cases. In one case, OTIB-0049 was not properly applied in regard to [**redacted**] samples taken more than 2 months after the incident. The corresponding intake appears to be significantly underestimated. It should be noted that SC&A did not review all aspects of the dose reconstructions in these four cases; rather, the focus was on the use of [**redacted**] samples in relation to estimation of Pu-239 intakes.

5.1.2 Americium-241

PNL audits revealed problems with UST performance related to the analysis of Am-241 in urine. The audits minimized the problem, stating that Am-241 was mainly measured by in-vivo methodologies. SC&A analyzed data from 50% of claimants with a POC > 50%. The majority of the workers monitored for Am-241 were monitored through in-vivo chest counting. Only [**redacted**] workers had [**redacted**] analysis for Am-241. Twenty-five workers had Am-241 chest counting. As indicated in the SC&A review of SEC-00057-2 issues, less than 0.4% of the workers at Hanford were monitored by in-vitro urine analysis for Am-241, while 8.3% to 11.4% of the workers were monitored by in-vivo Am-241 chest counts during the period under review here (SC&A 2011b, Tables A-3 and A-4). The [**redacted**] workers who were monitored through [**redacted**] bioassay for Pu were also monitored by in-vivo chest measurements of Am-241; they had no measurements of Am-241 in urine. The fraud investigation did not involve chest counts, which are the principal source of data for Am-241 analysis.

There was no Am-241 separation in the period 1987–1989, which is the period relevant to SEC-00155. Since plutonium composition can be inferred from isotopic data, a claimant-favorable assumption about the age and composition of plutonium can also be used to infer Am-241 dose.

5.1.3 Uranium

There were some issues with uranium analysis regarding MDA:

> *Background uranium in reagents and urine prevented UST from achieving the contractual detection level until reagent background subtraction was implemented in FY89.* [Bihl 1990, pdf p. 5]

This problem is common, because natural uranium is ubiquitous. The next year, UST participated in an EML intercomparison study (Bihl 1990, pdf p. 6); UST performed well. In addition, in-vivo monitoring of uranium through chest counts of U-235 and Th-234 were regularly performed. Hence, there does not appear to be an SEC issue that is specific to uranium in the period 1987–1989.

5.1.4 Neptunium

SC&A did not find any record of Np monitoring or any mention of this nuclide in any of the UST reviews; hence, this radionuclide does not appear in the evaluation of data manipulation or

fraud. This is not surprising, since there was no neptunium separation in the period 1987–1989. NIOSH proposes to estimate neptunium intakes in the context of mixtures with recycled uranium (ORAUT 2010, p. 29) and with plutonium (ORAUT 2010, p. 60). This is reasonable in principle, but SC&A has suggested a re-examination of the specifics of the procedures proposed by NIOSH (SC&A 2011a, pp. 31–32). However, this issue is not related to fraud or to data quality. It will be addressed in SC&A's review of SEC-00057-2 for the 1984–1990 period.

5.1.5 Strontium-90

Handling of separated Sr-90 ended when the production of Sr-90 capsules stopped in January 1985 (SC&A 2011a, p. 38); hence, Sr-90 bioassay data are not a central issue for dose reconstruction in the 1987–1989 period under review. However, Hanford analyzed large numbers of urine samples for Sr-90 in the 1987–1989 period, and the data reveal some exposure potential to Sr-90 among 200 Area workers. Since some issues regarding meeting the contractual MDA came up in the audits, we address the Sr-90 bioassay quality issue in the context of SEC-00155.

The NIOSH site profile for Hanford describes various MDAs for Sr-90 for the period 1972–1990. Those MDAs, listed in Table 5-19, are unusual. In general, MDAs tend to decrease with time, because of the advent of new better techniques. However, the listed Sr-90 MDAs do not show this behaviour. The MDA for the period September 1990 to November 1991 is listed as 30 dpm, while the MDA for the earlier period of 1983 to 1990 is listed as 2 dpm/sample (ORAUT 2010, Table 5-19, p. 36).

According to a PNL memorandum, UST indicated to PNL that for 1981, it had "serious problems…with current procedures for analysis of strontium," but UST had not "provided any supporting data" (Hickman 1982). PNL's audit data indicates that UST was meeting the contractual detection level of 5 dpm per sample, so UST's request for new analytical procedures was denied.

As noted above, the MDA was just 2 dpm/sample between 1983 and 1990. This contractual detection limit of 2 dpm is very low. Some of the best laboratories have reported an achievable MDA of 3 dpm/L in recent years (Lopez Ponte et al. 2004).[12] JAEA (Japan) reported that the MDA is 3.5 dpm/L (JAEA 2009). For the time period in question, one can refer to ICRP Publication 54 (ICRP 1988, p. 98), which reports 24 dpm/L (0.4 Bq/L) as the typical detection limit for measuring Sr-90 in urine by beta counting following chemical separation.

UST's frequent failure to meet the Sr-90 contractual MDA also indicates that the contractual MDA was too low. For instance, the audit for 1988 found that the MDA in 1988 was 3.1 dpm, as opposed to the contractual limit of 2.0 dpm (Bioassay Audit for FY 88, Table 3, pdf p. 15). The contractual MDA was later raised. According to the site profile, the MDA for Sr-90 was raised to 10 dpm per sample in 1992 (ORAUT 2010, p. 35).

[12] One laboratory in Lithuania did report an MDA of 0.035 Bq/sample, which is 2.1 dpm/sample. The counting time was 12,000 seconds (3 hours and 20 minutes) (Lopez Ponte et al. 2004, p. 94).

In 1987, 951 samples from 851 workers from the 200 Area were collected for Sr-90 analysis. Of these, 158 were above the reported detection limit. In the first 6 months of 1987, "strontium-90 processing was suspended twice" due to increasing activity in UST's blanks. The increase persisted, but was shown to be due to "chemical processing and was not in the urine itself." But the audit concluded that despite the increase in the mean blank value, "both PNL and UST data demonstrate compliance – barely – with the contractual detection level" (Bioassay Audit for FY 1987, pdf p. 14).

In 1988, 1,184 samples were collected from 1,047 workers from the 200 Area for Sr-90 analysis. Of these, 220 samples were above the reported and contractual detection limit of 2 dpm. Sixty-two (62) samples from 59 workers had results higher than 3.1 dpm, which was the MDA for 1988, as noted above. The only follow-up was from a worker who had an extremely high result of [**redacted**] dpm in [**redacted**] L urine sample (probably 24-hour sample). In 5 days, the activity in a [**redacted**] L urine sample dropped to [**redacted**] dpm.

In 1989, 1,297 samples were collected from 1,123 workers from the 200 Area for Sr-90 analysis. Of these, 588 workers were monitored for Sr-90 in both 1988 and in 1989. Only 9 results were reported above the contractual MDA of 2 dpm. High results like 12.9 dpm (probably a 24-hour sample, volume = 1.23 L), 30.4 dpm (probably a 24-hour sample, volume = 2.3 L), 6.7 dpm (probably 24-hour sample, volume = 2.894 L), and 10.6 dpm in a partial-day sample (0.67 L) had no follow-up. Only one high result of [**redacted**] dpm had a follow-up. The [**redacted**] sample was measured 28 days later and the result was [**redacted**] times lower ([**redacted**] dpm). Both [**redacted**] samples were probably 24-hour samples, as their volumes were about [**redacted**] L each.

The results of the Bioassay Audit Program for FY 1989 report that in 1989, the MDA returned to an acceptable value, which is listed as 1.2 dpm (Bioassay Audit for FY 89, Table 3, pdf p. 14). This MDA is too low, compared to present results, as discussed above.

In summary, the contractual MDAs for Sr-90 in the period under review were too low to be accepted as being actually achieved consistently. It is not surprising that UST at first did not achieve such MDA. It is surprising, though, that an MDA even lower than 2.0 dpm was achieved in 1989. The failure to meet the Sr-90 contractual MDA limits was essentially a problem of the way the contract was written, since the MDA was too low for the methods available. In SC&A's judgment, all values below 3.1 dpm, which was the MDA for 1988, should not be used, as they carry too many uncertainties to be reliable. Rather, the MDA of 3.1 dpm should be applied in these cases to estimate missed dose. Finally, since a suitably chosen MDA can be applied, UST's failure to meet the contractual MDA for Sr-90 from time to time during the 1987 to 1989 period is not an SEC issue.

6.0 OVERALL SC&A ANALYSIS

The main issue in SEC-00155 relates to whether the bioassay results generated by UST in the 1987–1989 period can be used in dose reconstruction, as NIOSH concludes in its ER (NIOSH 2011), or whether they should be discarded because of data manipulation and fraud, the central claim of the petitioner.

There are two aspects to the issue of fraud and data manipulation that relate to the reliability of bioassay data for use in dose reconstruction:

(1) Direct evidence of fraud or data manipulation in some of the analyses produced by UST in the period 1987–1989

(2) An inference that the bioassay data are unreliable and cannot be trusted, because there was data manipulation and fraud on the chemical side of UST's program

In addition to these issues, there are issues arising out of failure to meet contractual MDA limits and other QC issues that arose out of the various audits. We review each of these aspects in light of the analysis and evidence in Sections 3.0 to 5.0, starting with the question of data quality.

6.1 QUALITY OF THE DATA

Apart from any issues of data manipulation that we review separately below, the various issues found in the annual audits by PNL, the May 1990 oversight activities, and the 1991 independent audit have been discussed above. There were a number of instances of failure to meet the MDA, and also efforts to correct these problems. SC&A's view is that the MDA issues are not SEC issues, because an appropriate MDA can be chosen for dose reconstruction that is supported by the data and the literature.

6.2 DIRECT EVIDENCE

Overall, apart from two very specific instances discussed below that raise concerns, there is no direct evidence of fraud or data manipulation of UST bioassay results. There were routine audits done by PNL, which subcontracted bioassay to UST; a special oversight program that was done in May 1990 by three agencies (EPA, Washington Department of Ecology, and DOE), which involved an external bioassay expert that reviewed ongoing work at the time of the oversight; and an external review of the entire bioassay program from 1983 to 1990. These audits found a number of problems with UST, such as low recoveries and failure to meet contractual MDAs. However, at the time these were done, all concluded that the UST bioassay results were sound enough to be used. For instance, the 1991 external oversight that examined the data from 1983–1990, which includes the 1987–1989 period under review here, found as follows:

> *It appears to be the case that UST performance in the Bioassay Program was, with minor exceptions, in compliance with contractual requirements, and was technically competent according to every measure considered: UST internal QC performance, PNL QA testing, and various audits, inspections, and laboratory intercomparison exercises conducted by PNL, Washington Department of*

> *Ecology, US Department of Energy and Washington Department of Health, among others* [Omenn et al. 1991, p. 48].

The external bioassay expert who was part of the May 1990 oversight expressed a similar view in an interview with SC&A:

> *There were a lot of positive things observed during oversight activities. The technicians knew what to do, and they were doing it properly. Overall, it was a very good program. The deficiencies that were noted would create some doubts, but it would not be enough to shut them* [UST] *down.* [See Attachment A]

When questioned directly as to the usability of the data, the expert expressed a more nuanced conclusion:

> *Regarding the usability of data for dose reconstruction, the answer was "a qualified yes." There was nothing that was so bad that the data would have to be thrown out.* [See Attachment A]

It should be noted that neither the routine audits conducted by PNL, which were only double-checks of UST's self-audits, nor the 1990 and 1991 oversight activities were designed to detect outright fraud done in a sophisticated manner. However, crude manipulation of data could have been detected. The conclusions were that there were no reasons for fraud and that no fraud was detected during the oversight, but that there were no guarantees that fraud had not been committed.

The conclusion of the 1991 oversight report regarding the possibility of fraudulent bioassay data was as follows:

> *Our review focused on the scientific validity of the data. The methods we used were not intended to authenticate the laboratory records contained in the data archives. Our conclusions, insofar as they rely on quality control data provided by UST, are limited by our reliance on these records. The purpose of the Review Committee is not to prove the presence or absence of fraud. We are not able to verify that basic laboratory records are genuine, accurate, and unaltered. However, we could have recognized certain aspects of misconduct, such as obviously altered records, had these been encountered, and we did verify that raw laboratory records existed for results that had been reported.* [Omenn et al. 1991, p. 7]

One of the external bioassay experts who participated in the May 1990 oversight activities put it as follows in his interview with SC&A:

> *If you are clever enough, you could conceal data manipulation. The people on the contract laboratory side were not very clever. They were caught by EPA cooking the books on the chemical side. On the other hand, why do it? The bioassay program was good enough that* [UST] *did not have to have false records*

> *to keep it going. It was not that much of a problem. It was obvious that US Testing was not trying to cover up anything. There did not seem to be an effort to falsify things. But if they were clever enough, it would be difficult to detect data falsification.* [See Attachment A]

The two experts who participated in the 1991 retrospective review expressed similar conclusions:

> *The experts reaffirmed their conclusions regarding the overall competence of the bioassay program. They also reaffirmed the report's statement that they could not entirely rule out the possibility of something fraudulent having occurred outside the scope of the review. Omenn et al., 1991 notes that the review team did not "verify that basic laboratory records are genuine, accurate, and unaltered" (p. 7). However, given allegations about what may have happened "elsewhere in the country," the team was alert to the possibility of fraud and did not find any evidence of fraud.*
>
> *The experts reaffirmed the report's overall conclusion that the bioassay data are sound. They also answered in the affirmative in response to a specific question about whether they were sound enough to be used in dose reconstruction.* [See Attachment C]

SC&A also reviewed the petition and the associated documents for direct evidence of fraud in the bioassay program and found none; the only such direct evidence related to the chemical analysis side of UST's work. Similarly, as described above, SC&A interviewed the petitioner and his representative. Neither the interview nor the documents provided to SC&A by them contained direct evidence of fraud or data manipulation of radionuclide bioassay data.

SC&A also reviewed the documents that are not public concerning the criminal investigation of UST in 1989 and 1990. These documents were made available to NIOSH for review when it was preparing its ER. An SC&A representative as well as an Advisory Board member were present and participated in the document review. All parties concur that these non-public documents do not contain direct evidence of fraud or data manipulation in UST's bioassay program.

Finally, SC&A reviewed a number of documents in the Site Research Database (SRDB) on the "O-Drive," including the annual reports produced by PNL that contain reviews of UST's bioassay program. This review also did not produce any direct evidence of data manipulation or fraud in the UST bioassay program.

6.2.1 Two Specific Concerns

There were two very specific concerns, one direct and one indirect, that raised the possibility that the integrity of some of the data may be in question. SC&A conducted an interview for each of these concerns with one of the authors of the reports that had raised the issues in question (see Attachment B and Attachment C). We discuss each of these in turn.

6.2.2 Edited Qualty Control File

The May 1990 oversight found that a QC file had been "edited:"

> *The most serious observation of the day appeared in the form of a QC file that had been edited. The hand written note at the top of the page only stated the file had been edited. There was no indication of the changes made to the file. The following discussion with* [redacted], [redacted], *suggested restricting the editing of a data file to senior personnel only, and then the new data should be appended to the old, with all data remaining for inspection should the need arise.*
>
> *… Since the question of data integrity was questioned the previous day, it was of interest to determine the extent to which the data (raw, intermediate or final) could be edited by UST staff. The* [redacted], [redacted], *said* [redacted] *could edit a header file, but did not know how to edit a data file. Subsequent discussions with the* [redacted], [redacted], *confirmed the belief that the* [redacted] *is probably incapable of changing the data. The database is a flat file system rather than the relational type. This would make the modification of data much more difficult to the average operator.* [Morton and Marlette 1990a, pdf p. 6]

As is clear from the above that the 1990 report found this to be a serious enough matter to make a recommendation about how to carry out changes to a data file, should changes be needed for a legitimate reason. It also recommended a procedure for maintaining a record of the changes to assure any future reviewer that data had not been manipulated in any illegitimate or unscientific way. But the 1990 report did not contain a description of the edits to the file, how extensive the changes had been, or whether there were other cases of such edits. SC&A conducted an interview about this issue with one of the authors of the 1990 report quoted above (Attachment B). It is discussed above in Section 3.4.1.

The best available evidence, based on memory of events long ago, indicates that there was a reasonable explanation for the change in the QC file. It was apparently a change in the header of the file and the name of the person in the header was changed. There is no hard evidence that other parts of the file were not changed, but the [redacted] was judged to not have the expertise needed to make changes in the data itself. SC&A cannot make an independent judgment on this point. However, the interview with the expert was frank and open and provides the best available judgment on the matter. This judgment is supported by the fact that no evidence of fraud or data manipulation in bioassay data was discovered despite extensive review. In addition, the fact that the changed QC data file was flagged by the [redacted] making the change would lend support to the hypothesis that the change was made to correct an error rather than to manipulate data.

Furthermore, no direct evidence of data manipulation or fraud regarding bioassay data was provided by the petitioner. SC&A's research also did not reveal any material reason for UST to manipulate bioassay data, such as those described by the EPA for chemical data (Notice of Suspension 1990).

It is to be noted that some uncertainty exists in this conclusion for three reasons:

- The audits and oversight activities were not designed to detect outright fraud.
- There was no auditable trail for the QC file edits that were made.
- To some extent, the reconstruction of the QC file edits depends on memory of events over two decades ago, and some issues did arise in this regard (see Attachment B).

6.2.3 Materials Withheld from 1991 Retrospective Review

As described in Section 3.4.2, the 1991 retrospective review stated that its access to data was limited in part by "materials withheld from PNL by UST" (Omenn et al. 1991, p. 4). The review team only dealt with PNL personnel who retrieved files from storage for them according to the latter's search criteria.

SC&A interviewed two of the authors of the retrospective review (see Attachment C). In hindsight, they felt that no materials were withheld and that the statement was in the nature of a caveat, because they did not deal with UST directly, only with PNL. They had the records they needed to do their review. They stood by their conclusion that, overall, the bioassay data for the period the team reviewed, 1983 to 1990, which includes the SEC-00155 period of 1987–1989, were sound and could be used for dose reconstruction.

Given that the team did not have any interaction with UST and did not directly retrieve records, it is not possible to know if any records were withheld. Moreover, contrary to the recollection of the experts during the interview (when they said all records had been transferred to PNL), the report states that UST records "have *in part* been turned over to PNL" (Omenn et al. 1991, p. 15, emphasis added).

SC&A sought clarification from the interviewees. One interviewee responded as follows:

> *PNNL was in a position to know what UST records were not included when the lab records were provided to it. For a possible example, UST's business records, instrument maintenance records, or other correspondence not part of sample testing work might not have been included. However, we were limited only by what was in the PNNL employee monitoring database. Reports of testing that were omitted from the database (if any) would be invisible to us as we searched for files to review. Any record in the database where the corresponding UST data were unavailable (whether from being withheld, misfiled, or otherwise poorly maintained) would have been potentially detectable, as our report discussed.* [See Attachment C]

Since some uncertainty remained as to the completeness of the review team's access to the records, SC&A sought further clarification from PNL's [**redacted**] at the time of the retrospective review and the PNL [**redacted**].

Their responses are discussed in Section 3.4.2 above and reproduced in full in Attachment E. Basically, these responses support the recollections of the review team that the retrospective review team had access to the records they needed to arrive at valid conclusions.

The experts stated that they found no evidence of concealment. The retrospective review appears to be thorough and well done. There is no reason to second guess that review. The experts selected which records they were going to review and PNL retrieved them for the review team.

The extensive and statistically structured review went into considerable detail, including examination of raw data files; it did not find any evidence of fraud or manipulation of bioassay data. This is consistent with the other audits, the May 1990 oversight findings, SC&A's review of documents, and the review of the non-public files relating to the criminal investigation. None of these showed evidence of bioassay data having been tampered with or manipulated in a fraudulent manner. The one case of the QC file that had been changed had an explanation—it was apparently made to correct a mistake in a header file (see Section 3.4.1).

Finally, the 1991 retrospective review team requested a random sample of 300 assays for review. They were able to review all of them, and found that the samples "existed and had been analyzed" (Omenn et al. 1991, p. 1). The sample size was selected so as to be able to detect "a 1% occurrence rate of missing data with statistical confidence" (Omenn et al. 1991, p. 1).

In reviewing all of these materials and statements, SC&A concludes that some uncertainty remains as to the completeness of the records in PNL's possession at the time of the retrospective review. The best available explanation, provided by the [**redacted**], is that some records were kept by UST and only transferred to PNL at the latter's request. This arrangement was for the convenience of PNL (see Attachment E). Any records that were not available do not appear to have affected the ability of the retrospective review team to review the program and arrive at a reliable and valid conclusion about UST's bioassay program. The retrospective review team was explicit about this in its report (Omenn et al. 1991, p. 49) and in the interview conducted with two of its members by SC&A (Attachment C). This conclusion is also supported by the negative finding regarding missing records when the review team tried to determine whether records were missing by requesting 300 records at random from PNL's database of more than 50,000 bioassay records (see Section 3.4.2).

Therefore, SC&A concludes that it is highly unlikely that bioassay data were being hidden from the retrospective review team. Most likely the review team's main conclusions were not affected by any unavailable records that may not have been transferred to PNL prior to the retrospective review.

6.3 INFERRING UNSUITABILITY

The central argument made by the petitioner is that the issue of whether there was fraud or data manipulation in the bioassay program is not relevant. The central issue is that UST did have such problems in some part of its program, even if it was on the chemical side. As a result, UST's bioassay data should be rejected as untrustworthy for use in dose reconstruction:

> *The main underlying issue raised by the petitioner was the ethics of UST, which had lost its contract with the EPA due to fraud and manipulation of data. For the petitioner, UST "knowingly and willfully were aware of what they were doing, they just didn't care and in-turn placed my life and my family's livelihood in jeopardy for their own self gain……greed." Both the Hoboken, New Jersey, and Richland, Washington, laboratories of UST were involved. For the petitioner, this was more important than whether the specific type of sample being analyzed was a chemical or a radionuclide. The results of a company that engaged in fraudulent practices could not be trusted… or used in a scientific dose reconstruction....* [See Attachment D]

This same argument appears to have been used by PNL when it terminated the UST contract in June 1990. The DOE Manager of the Hanford Site at the time of the termination pointed to UST's problems with data manipulation in relation to analyses for dioxin and petroleum chemicals, and that only the Hoboken facility of UST, where no radionuclide bioassays for Hanford were performed, was involved. But he argued that the credibility of all results would be in question if there were any willful manipulation of data:

> *One goes to a testing laboratory for the credibility of their results, and regardless of the percentage number of tests that are done improperly, if any are done knowingly and willfully improperly, then it casts doubt on the credibility of any of the results and, consequently, I don't believe that the Department* [of Energy] *or Battelle can utilize a contractor if there is information which verifies that they knowlingly and willfully did not meet the requirements of the contract to provide the credible results that were required by it.*
>
> …
>
> *That they did not have approved quality control or assurance program in place at Hoboken* [NJ], *and whether or not tests are technically done properly is not in issue. In issue is that quality assurance and quality control programs which ensure the quality of results., the reproducibility of results were not in place and, consequently, whether or not it was done properly in abstract is not the point. The point is that a clear requirement of the contract for quality assurance and quality control program, an approved program at Hoboken was not in place and, therefore any results coming from that activity are at best questionable and at best worthless.* [Lawrence 1990, pp. 50–51]

The termination of UST's contract, despite the findings of the May 1990 oversight activities, indicates that DOE and PNL found substance in the indirect argument that willful manipulation of some of the data cast doubt on all of it, even though there was no direct finding of fraud in the bioassay data. The termination of the contract for this reason is similar to the position of the petitioner, as quoted above and as is detailed in Attachment D.

In this context, it is also pertinent to note that the U.S. District Court ruling in the case filed by UST against PNL found that termination for default was not warranted, though a termination for convenience was permissible (see Section 4.2.1).

6.4 POLICY ISSUES

Despite extensive research and investigation, including interviews with experts and the petitioner and his representative, SC&A found no direct evidence of fraud or manipulation of bioassay data. Moreover, the problems with the quality of the data are not of a nature to prevent their use in dose reconstruction with some adjustment, notably to some MDAs. The oversight activities of May 1990 and the retrospective review of 1991 did not find evidence of fraud in the bioassay program; rather, despite some deficiencies, these reviews concluded that the overall bioassay program was sound.

The main issue in SEC-00155 is whether any of UST's data can be trusted since some was found to be fraudulent. The petitioner was explicit that it did not matter whether bioassay data were directly affected by fraud, so long as some data were fraudulent or manipulated. This position was supported in 1990 by the reasoning of the EPA and the DOE.

In conclusion, the issue of whether the bioassay data, that in themselves appear to be usable, should be discarded due to fraud in another area of analysis is not a technical question for SC&A to address, but rather a policy question for the Advisory Board.

A second issue that is important for the petitioner is the use of [**redacted**] data. The problems found in one case (Case 1 above) indicate that in one out of four cases reviewed, [**redacted**] data were not used according to the established procedure. SC&A did not review the petitioner's dose reconstruction at the direction of NIOSH (Katz 2012), since that is the [**redacted**]. Since SC&A has not reviewed a statistically valid sample concerning the use of [**redacted**] data to estimate plutonium intakes, the matter might be further addressed by the Advisory Board or the Board's Hanford Work Group.

6.5 FINDINGS AND OBSERVATIONS

Finding 1: SC&A's review of four cases (not a statistically valid sample) that used fecal data in the dose reconstruction revealed that in one case, the fecal data were not used in accordance with the established procedure. This appears to have resulted in an underestimate of the plutonium intake in that case.

Finding 2: There is less confidence in the fecal sample results, since no Quality Assurance (QA) samples were ever analyzed in the period under review. As one of the May 1990 oversight experts noted in an interview, QA samples are needed "to assure that the results are credible. It does not necessarily mean that results are not credible, but it certainly is a weakness of the program that there were no fecal QA samples" (see Attachment A). The added uncertainty arising from this problem should be addressed in dose reconstruction.

Observation 1: The problems of QA with the work of U.S. Testing (UST) were longstanding ones, stretching back to the 1960s. There is also evidence that both UST and PNL made efforts to correct these problems. However, their persistence does raise a general question about the quality of the UST bioassay program, as well as the oversight of that program by PNL. It must also be noted that the pre-1987 data quality issues have no direct bearing on the usability of the 1987–1989 data. It should also be noted that some of these problems are related to the failure to achieve contractual minimum detectable activities (MDAs), which in some cases (e.g., strontium-90) were more stringent relative to then-prevailing industry norms. The 1987–1989 data appear to be usable for dose reconstruction with appropriate attention to issues such as the MDAs.

Observation 2: Apart from the two issues discussed in Sections 6.1.2 and 6.1.3, there was no direct evidence raising questions about fraud or data manipulation in the UST bioassay program for the period 1987–1989 under review in this report. SC&A investigated these two issues in detail and neither one appears to have been associated with fraud, data manipulation or an intent to hinder external program review. The two issues appear to have reasonable explanations to the extent that can be determined retrospectively after more than two decades; however, some uncertainties remain (see Observations 5 and 6 below).

Observation 3: Despite the presence of problems such as low recoveries and failure to meet contractual MDA requirements, all audits and oversight activities conducted at the time concluded that UST had an acceptable bioassay program overall and that the data were usable. It should be noted that during the interview, the bioassay expert who was part of the May 1990 oversight presented a more nuanced view, saying, "Regarding the usability of data for dose reconstruction, the answer was 'a qualified yes.' There was nothing that was so bad that the data would have to be thrown out" [see Attachment A].

Observation 4: The PNL audits in the 1980s and the 1990 and 1991 oversight activities were not set up to detect sophisticated efforts to manipulate data. Obvious or crude manipulations of data could have been detected; none were found. Further, none of the oversight activities found any issue that would motivate UST to manipulate bioassay data. In fact, the record indicates that UST often caught problems that existed and made efforts to correct them.

Observation 5: The case of the edited Quality Control (QC) file appears to have a reasonable explanation, based on the memory of one of the experts who discovered the edited file in May 1990. There is no paper trail that can verify that only a minor change not involving data was made. However, the fact that the changed QC data file was flagged by the [**redacted**] making the change would lend support to the hypothesis that the change was made to correct an error, rather than to manipulate data. This observation depends on the memory of the expert of events over two decades ago for which there is no auditable paper trail.

Observation 6: SC&A believes there is some uncertainty regarding the completeness of the data in the possession of PNL at the time of the retrospective review in 1991; however, there is no evidence that records were withheld to hinder the review or affect it in any way. Any unavailable records appear to have been the result of prior procedures for records transfer between UST and PNL that were set by PNL. The available evidence from the time as well as the extensive interviews and on-the-record exchanges done by SC&A (see Attachments C and E)

indicate that the retrospective review team had the data it needed to do its work and arrive at valid conclusions. The central conclusions were that (1) overall, the team found the bioassay program to be sound, and (2) the team found no evidence of fraud or data manipulation in the bioassay program.

Observation 7: A number of issues that relate to MDA and dose reconstruction, but that do not appear to SC&A to be SEC issues, have been identified in this report.

Overall conclusion regarding 1987–1989 bioassay data: SC&A did not find any evidence that the bioassay data were affected by fraud or manipulation. When all is said and done, the basic question raised by the petition is a policy issue for the Advisory Board: Should bioassay data, which to all available evidence are unaffected by fraud, but generated by a company that was dismissed because of data manipulation and fraud in another technically unrelated area (chemicals), be trusted for use in dose reconstruction?

7.0 REFERENCES

Ace, J.K., 1990. Letter from Jeffrey K. Ace, Manager Subcontract, Battelle Pacific Northwest Laboratories, to Van H. Pettey, Vice President and General Manager, United States Testing Company, Inc., "Termination for Default of Contract No. 005145-A-M1 (formerly No. B-Q5145-AM1)," Battelle Pacific Northwest Laboratories, Richland, Washington. No date: Receipt acknowledgment signature is June 1, 1990. SRDB 94354, pdf pages 29 to 32.

Battelle 1968. Letter from the Manager, Environmental Studies Section [no company name, but evidently Battelle] to C. L. Robinson, Director, Laboratory University Division, U.S. Atomic Energy Commission, "Summary Analysis of U.S. Testing Company's Performance of Environment Sample Analyses Through December 1967." April 22, 1968.

Battelle 1969. Battelle Northwest memo from J.P. Corley to Environmental Evaluations Staff, "Subject: Problems with US Testing Records and Reports," Battelle Northwest, Richland Washington. June 30, 1969.

Battelle 1982. K R. Price to M. J. Sula, "Subject: Blind Audit Sample Program." Battelle Pacific Northwest Laboratories, January 18, 1982

Battelle 1990. Letter from W. R. Wiley, Director, Battelle Pacific Northwest Laboratories, to Michael J. Lawrence, Manager, Richland Operations Office, Department of Energy, "Ref. United States Testing Company, Inc. – Subcontract No. 005145-A-M1," with attached draft letter from Jeffrey K. Ace, Manager Subcontract, Battelle Pacific Northwest Laboratories, to Van H. Pettey, Vice President and General Manager, United States Testing Company, Inc., "Termination for Default of Contract No. 005145-A-M1 (formerly No. B-Q5145-AM1)," Battelle Pacific Northwest Laboratories, Richland, Washington, May 31, 1990. Concurrence by Michael J. Lawrence, dated June 1, 1990 is shown on the letter. SRDB 91055.

Bihl, D., 1990. "Summary of Quality Control Information Concerning United States Testing Richland Division Laboratory's Performance on Bioassay Samples." May 11, 1990. SRDB Ref ID: 82464.

[**Redacted**], 2012. E-mail from [**redacted**], [**redacted**] of the PNL [**redacted**], to Robert Bistline and Arjun Makhijani, SC&A, "RE: Questions for [**Redacted**]," May 30, 2012.

Bihl, D.E., R.L. Buschbom, and M.J. Sula, 1993. "Experience with a Routine Fecal Sampling Program for Plutonium Workers." *Health Physics* 65(5), SRDB Ref ID: 13396.

Bioassay Audit for FY 1987. *Results of the PNL Bioassay Audit Program for FY 1987*, Battelle Pacific Northwest Laboratory. February 18, 1988. SRDB Ref ID: 82223.

Bioassay Audit for FY 1988. *Results of the PNL Bioassay Audit Program for FY 1988*, Battelle Pacific Northwest Laboratory. January 30, 1989 SRDB Ref ID: 82243.

Bioassay Audit for FY 1989. *Results of the PNL Bioassay Audit Program for FY 1989*, Battelle Pacific Northwest Laboratory. February 15, 1990. SRDB Ref ID: 82244.

Cunningham, G.H., 1990. Memo from Guy H. Cunningham, Director, Legal and Contracts, with attachment to Bill Wiley, Director, PNL "Re: U.S. Testing" Battelle Pacific Northwest Laboratories, May 21, 1990.

DOE 1990a. Letter from J.J. Sutey, Director, Research and Development Division, Department of Energy, to Dr. Gilbert S. Omenn, DOE Richland Operations Office, Richland, Washington. December 4, 1990.

DOE 1990b. "Oversight of U.S. Testing Company Implementation of Analytical Procedures and Protocol Oversight Results of Daily Activities at the U.S. Testing Company Laboratory, Richland, Washington During the Period of May 1–31, 1990." Department of Energy, Richland Operations Office, Richland, Washington, June 21, 1990, SRDB Ref ID: 91101.

Ecology 1990. *Fact Sheet: U.S. Testing Suspension Impacts on Hanford*, Washington State Department of Ecology. April 25, 1990.

EPA 1990a. *Action Referral Memorandum, Subject: Request for Suspension of United States Testing, Co., Inc., (EPA No. 89-0021-00); Nationwide Consumer Testing, Inc., EPA No. 89-0021-1; Research & Testing Co., Inc., EPA No. 89-0021-02; and Qualitest, Inc., EPA No. 89-0021-03*, from Sharon O. Mitchell (Compliance Specialist, EPA), Jeanne Pascal (Assistant Regional Counsel, EPA), and Frank Dawkins (Compliance Specialist, EPA), "THRU" Robert F. Meunier (Chief, Compliance Branch, EPA) and David J. O'Connor (Director, Procurement and Contracts Management Division, EPA), U.S. Environmental Protection Agency, Washington, DC. April 4, 1990.

EPA 1990b. "Administrative File Review Report: Battelle Pacific Northwest Laboratories (PNL): PNL Quality Programs Data Quality Oversight of United States Testing Company, Inc. (UST), Richland, Washington," U.S. EPA Region X, Environmental Services Division, Regional Quality Assurance Management Office, February 23, 1990 (handwritten date). (Attachment to Sturgis 1990.)

[**Redacted**], 2012. Letter from [**redacted**], petitioner's representative for SEC-00155, letter to Lynn Ayers, SC&A. March 28, 2012. Reviewed by J. D. Briggs, DOE, with handwritten notes by Mr. Briggs.

Hickman, D.P., 1982. Internal Memorandum from D.P. Hickman to T.M. Braniecki, "US Testing's Performance for CY 1981," Battelle Pacific Northwest Laboratories. May 18, 1982. SRDB 91012.

Hoyt, R.C., and J.A. Teal, 2004. "Plutonium Finishing Plant Operations Overview (1949–2004), Contamination Events and Plutonium Isotope Distributions of Legacy Holdup Material in Process System," HNF-22064. Fluor, Richland, Washington. 2004. SRDB 65485.

ICRP 1988. International Commission on Radiological Protection, *Individual Monitoring for Intakes of Radionuclides by Workers: Design and Interpretation*, ICRP Publication 54, Annals of the ICRP, Vol. 19, Nos. 1–3, Pergamon, Tarrytown, New York. 1988.

ICRP 1997. International Commission on Radiological Protection, *Individual Monitoring for Individual Exposure of Workers*, ICRP Publication 78, Annals of the ICRP, Vol. 27, No. 3/4, Pergamon, Tarrytown, New York. May 1997.

JAEA 2009. Japan Atomic Energy Agency, e-mail communication to ICRP Committee 2; 2009.

Katz, T., 2012. E-mail from Ted Katz, Designated Federal Official for the Advisory Board on Radiation and Worker Health, to Arjun Makhijani, SC&A, "RE: SEC-00155 question." April 19, 2012, 4:39 pm.

Lawrence, M.J., 1991. Deposition of Michael J. Lawrence, Civil Action No CS-90-212-RJM, U.S. Testing Company, Inc., v. Battelle Memorial Institute, Pacific Northwest Laboratory, United States District Court for the Eastern District of Washington, January 15, 1991 (excerpted pages only).

Letter from Congress, 1990. *Letter from U.S. House of Representatives to Secretary of Energy regarding United States Testing Co., Inc.*, letter from Rep. John D. Dingell et al., to James D. Watkins, Secretary of Energy, May 31, 1990. SRDB Ref ID: 91126.

Lopez Ponte, M.A., C.M. Castellani, L. Currivan, R. Falk, P. Olko, and C. Wernli, 2004. "Individual Monitoring for Internal Exposure in Europe and the Integration of Dosimetric Data," *Radiation Protection Dosimetry*, Vol. 112, No. 1, pp. 69–119, 2004.

Lyon, M., J.J. Fix, J.L. Kenoyer, J.A. Leonowich, H.E. Palmer, and M.J. Sula, 1988. *Hanford Radiological Protection Support Services Annual Report for 1987*, PNL-6624/UC-14. August 1988. SRDB Ref ID: 015198.

Lyon, M., J.J. Fix, J.L. Kenoyer, J.A. Leonowich, H.E. Palmer, and M.J. Sula, 1989. *Hanford Radiological Protection Support Services Annual Report for 1988*, PNL-6952/UC-41. June 1989. SRDB Ref ID: 015197.

Lyon, M., D.E. Bihl, J.J. Fix, J.L. Kenoyer, J.A. Leonowich, and H.E. Palmer, *Hanford Radiological Protection Support Services Annual Report for 1989*, PNL -7417/UC-607. July 1990. SRDB Ref ID: 013423.

Morton, J.S., and G. Marlette, 1990a. *Final Report on the Radiochemistry Operations of U.S. Testing Laboratory*, The Radiological and Environmental Sciences Laboratory, U.S. Department of Energy. June 1, 1990. SRDB Ref ID: 91065.

Morton, S. and G. Marlette, 1990b. "Daily Report on U.S. Testing, for May 9, 1990." DOE-ID-RESL. [No other date or titles indicated.]

NIOSH 2011. *SEC Petition Evaluation Report: SEC Petition SEC-00155*, National Institute for Occupational Safety and Health, Cincinnati, Ohio. April 28, 2011.

NIOSH 2012. *SEC Petition Evaluation Report: SEC Petition SEC-00201*, National Institute for Occupational Safety and Health, Cincinnati, Ohio. May 31, 2012.

Notice of Suspension, 1990. Harvey G Pippen, Jr., Director, Grants Administration Division, U.S. EPA, letter to Lawrence S. Lazar, President and CEO, U.S. Testing, Co., *Re: United States Testing Co., Inc.; EPA Case No. 8900021-00*, with accompanying attachment, *Action Referral Memorandum, U.S. Environmental Protection Agency*, dated April 4, 1990. April 24, 1990. SRDB Ref ID: 91102.

Omenn, G.S., G. van Belle, D.A. Kaman, and M. O'Brien, 1991. *Retrospective Evaluation of Data Submitted by U.S. Testing in Support of the Internal Bioassay Program Operated by Battelle Pacific Northwest Laboratories 1983–1990*. October 10, 1991. SRDB Ref ID: 82224.

ORAUT 2008. *Estimating Doses for Plutonium Strongly Retained in the Lung*, Rev. 01, PC-1, ORAUT-OTIB-0049. Oak Ridge Associated Universities Team, Cincinnati, Ohio. September 26, 2008.

ORAUT 2010. *Hanford Site – Occupational Internal Dose*, Rev. 04, ORAUT-TKBS-0006-5. Oak Ridge Associated Universities Team, Cincinnati, Ohio. October 20, 2010. SRDB Ref ID: 89283.

PNL(?) 1990. *U.S. Testing/EPA Debarment*, appears to be a partial document with technical background on the U.S. Testing program, author likely Pacific Northwest Laboratory, 1990, SRDB Ref ID: 91100. (Referenced in NIOSH 2011 as EPA Debarment, 1990.)

PNNL 2000. *Polycube Oxidation and Factors Affecting the Concentrations of Gaseous Products*, J. Abrefah et al., Pacific Northwest National Laboratory. April 2000. SRDB Ref ID: 94154.

Romeo, C. 2010a. E-mail from Charles Romeo, DOE Inspector General's Office of Investigations, to Sam Glover, National Institute for Occupational Safety and Health, Subject: "RE: Travel to dc," October 26, 2010, 10:45 AM, SRDB 94111, pdf pages 6 and 7.

Romeo, C. 2010b. E-mail from Charles Romeo, DOE Inspector General's Office of Investigations, to Sam Glover, National Institute for Occupational Safety and Health, Subject: "RE: Travel to dc," October 27, 2010, 11:06 AM, SRDB 94111, pdf page 5.

SC&A 2011a. *Review of Special Exposure Cohort Issues for the Hanford Site for the Period July 1, 1972, to December 31, 1990*, Vol. I, S. Cohen & Associates, Vienna, Virginia. July 28, 2011.

SC&A 2011b. *Review of Special Exposure Cohort Issues for the Hanford Site for the Period July 1, 1972, to December 31, 1990*, Vol. II, S. Cohen & Associates, Vienna, Virginia. July 28, 2011.

SC&A 2011c. "Remaining Hanford SEC Issues for SEC Petition 0057-2 and 00152," S. Cohen & Associates, Vienna, Virginia. August 19, 2011

SEC 2009. *Special Exposure Cohort Petition SEC-00155*, Hanford Site Petition Document dated October 26, 2009.

Sturgis, G.A., 1990. Internal memorandum from G.A. Sturgis to F.C. Hood, "Subject: Meeting with DOE-RL and EPA Region X," Battelle Pacific Northwest Laboratories, February 27, 1990.

United States District Court 1992. *United States Testing, Inc. Plaintiff -vs- Battelle Memorial Institute Pacific Northwest Laboratories, Order No. CS-90-212 RJM*, United States District Court, Eastern District of Washington. January 3, 1992. SRDB 94354 (pdf file pages 7 and 8).

ATTACHMENT A: INTERVIEW REGARDING MAY 1990 OVERSIGHT ACTIVITIES

SUMMARY OF TELECONFERENCE INTERVIEW REGARDING MAY 1990 OVERSIGHT OF U.S. TESTING'S BIOASSAY PROGRAM

SC&A's Task Manager for the review of Special Exposure Cohort (SEC) Petition SEC-00155, Arjun Makhijani, interviewed a bioassay expert, [Redacted], who participated in the oversight of U.S. Testing's (UST's) activities in May 1990. Also present during the call were Sam Glover (NIOSH), Bob Bistline (SC&A), Brad Clawson (Advisory Board member), and Dave Briggs [DOE Richland Operations (DOE-RL) classification officer, host of the call]. The interview was conducted on May 2, 2012.

As a technical support contractor supporting the Advisory Board on Radiation and Worker Health (Advisory Board), S. Cohen & Associates (SC&A) has been tasked with reviewing the National Institute for Occupational Health and Safety (NIOSH's) Evaluation Report on the SEC Petition for Hanford site workers. One component of SC&A's review is a series of interviews with site experts, including current and former site workers, petitioners, and worker representatives. The purpose of these interviews is to hear first-hand accounts of past radiological control and personnel monitoring practices, and to better understand how operations and safety programs were implemented at the site over time.

The expert was briefed on the interview process, which was unclassified. As a precaution, it was moderated by a U.S. Department of Energy (DOE) classification officer. After consultation with DOE-RL to ensure there were no issues regarding public release, the expert was provided with two of the reports prepared by the Oversight Team so he could refresh his memory. He was given the following context on Petition SEC-00155.

SEC-00155 is a petition to add workers in the Plutonium Finishing Plant and the 200 Area at Hanford during the period 1987–1989 to the SEC under the Energy Employees Occupational Illness Program Compensation Act (EEOICPA). The petitioner claims that bioassay data are untrustworthy and cannot be used for reliable dose reconstruction. The specific data in question are bioassay data for the period 1987–1989. SC&A, which provides technical support to the Advisory Board on Radiation and Worker Health (Advisory Board or Board), is reviewing the petition and NIOSH's evaluation of that petition for the Board. The interview was about the oversight activities conducted during May 1990. The expert was brought into the oversight team as an independent consultant with expertise in reviewing bioassay programs.

A.1 ACCURACY OF U.S. TESTING'S PROGRAM

The areas of activity observed included sample receiving and storage areas, sample receiving procedures, sample collection instructions, analytical data reduction procedures and database management, sample logging, sample reports, and review of the quality assurance (QA) manual. Laboratory procedures and activities in analyzing samples were observed from cradle to grave—from receiving the samples to the end of the analysis and data entry. There was also a general review of procedures used to analyze samples.

A.1.1 Effect of Low Recoveries and Noticeably Uneven Distribution of Solids on Some Planchets

Less than 5% of the samples were affected by uneven distribution of solids on planchets. It might result in lower radiochemical recovery.

There were no limits on the lowest acceptable recovery. Usually, there is a lower limit to recovery of 50% or 60%. They [UST] would get recovery as low as 12% and just use that. But if they did get low recoveries, they multiplied the result by the inverse of the recovery fraction to compensate for the low recovery. Since tracers are added, this enables detection of low recovery. But it is poor practice to have such low recoveries. The causes of the low recoveries should have been investigated and the problem corrected. The expert had not encountered such low recoveries before and was unsure what the consequences might be for the results of samples affected by low recoveries. In his view, low recoveries did not necessarily mean that results were invalid or that results were not usable.

A.1.2 Lack of Intercomparisons

It was normal procedure for laboratories that worked with DOE contractors to do intercomparisons with the DOE Environmental Measurements Laboratory (EML). While the failure of the bioassay program to participate in routine intercomparisons with EML (DOE 1990b, pdf p. 53) is not necessarily disqualifying, it was not clear how UST was able to avoid the required intercomparisons.

A.1.3 Problems Noted in the Oversight Report that Might Affect Confidence in the Validity of the Data

There were a lot of positive things observed during oversight activities. The technicians knew what to do, and they were doing it properly. Overall, it was a very good program. The deficiencies that were noted[13] would create some doubts, but it would not be enough to shut them [UST] down.

A.2 PNL'S OVERSIGHT OF U.S. TESTING

The U.S. Environmental Protection Agency (EPA) audits were for the Contract Laboratory Program and covered chemical analyses. There was no comparable surveillance of the radiochemistry program. Battelle could have done a better job of oversight. One problem was that they submitted too few QA samples. Specifically, there were 3,000 urine samples, and Battelle submitted only 75 QA samples and no fecal samples. They should have done closer to 5% to 10%. There should have been between 150 and 300 urine samples. Also, the blind spikes were right at the detection limit. So the statistics were terrible, like 4 +/- 3. The blind spikes should have been at least 10 times that.

[13] The deficiencies referred to at this point in the interview were "inadequacy of analytical data outputs," "inadequacy of the established quality control process," and "lack of a QA/QC program that demonstrates the validity of specific analyses and data points" (DOE 1990b, pdf p. 17).

The lack of fecal QA samples is a missing link. That part of the program is just missing. Such samples are for QA, to assure that the results are credible. It does not necessarily mean that results are not credible, but it certainly is a weakness of the program that there were no fecal QA samples.

The Oversight Report noted that "[t]he system for submitting blank, duplicate, and spiked samples to UST by PNL should be modified so that the numbering system does not identify the samples as such, and the samples can be considered to be 'blind'" (DOE 1990b, pdf p. 58).

The interviewee's observation was that the sample ID was different and might suggest [to UST] that it was a blind sample. But even if it was not truly blind, that would not invalidate the result, though if the analysts knew, they might have exercised more care than normal in doing the work.

A.3 CONCLUSIONS REGARDING DATA USABILITY

Beside the oversight during May 1990, the team also looked at records from 1990 and the last half of 1989. No material difference was noticed between the 1989 and 1990 work.

The Oversight Report concluded that, "There were no evident items that could easily be attributed to the requirements of a Level 1 finding" (DOE 1990b, pdf p. 20). The report defined "Level 1" problems as "show-stoppers." SC&A asked the site expert to clarify the caveats and conclusions drawn by the investigators.

The biggest finding was the lack of blind spikes. All the rest of the difficulties were observations. It was not enough to shut down the analytical procedure until the problems could be fixed. They should have done research on how to overcome low radiochemical recoveries. In one instance, they had bad ion exchange resins and they suspended analysis until they got the good resins.

If you are clever enough, you could conceal data manipulation. The people on the contract laboratory side were not very clever. They were caught by EPA cooking the books on the chemical side. On the other hand, why do it? The bioassay program was good enough that [UST] did not have to falsify records to keep it going. It was not that much of a problem. It was obvious that [UST] was not trying to cover up anything. There did not seem to be an effort to falsify things. But if they were clever enough, it would be difficult to detect data falsification.

Regarding the usability of data for dose reconstruction, the answer was "a qualified yes." There was nothing that was so bad that the data would have to be thrown out. It was not like what happened at Mound with the polonium analysis. There was a problem they [Mound] did not realize—it [the polonium] was going into a protein-bound form. So they thought the recoveries were good when in fact they were only 10%. The interviewee did not see anything like that at UST. At UST, they did not hide the fact of low recoveries. If the recovery was 20%, they multiplied [the result] by five [to correct for the low recovery].

The team observed the editing of data in one specific instance, but the site expert was not aware of the details. Another interview was arranged to address this particular point. The expert noted that it would be very difficult to change the data after the fact.

A fair summary would be that the oversight did not see any outright manipulations of the data. The questions were about level of performance. That is, the report made observations as opposed to findings. A lot of their analyses were perfectly fine.

ATTACHMENT B: SUMMARY OF TELECONFERENCE INTERVIEW REGARDING MAY 1990 OVERSIGHT OF U.S. TESTING'S BIOASSAY PROGRAM

SC&A's Task Manager for the review of Special Exposure Cohort (SEC) Petition SEC-00155, Arjun Makhijani, interviewed Stanley Morton, who participated in the oversight of U.S. Testing's (UST's) activities in May 1990. Also present during the call were Sam Glover (NIOSH) and Dave Briggs (DOE-RL classification officer, host of the call). Sam Glover and Brad Clawson (ABRWH) also made some comments and had some questions. The interview was conducted on May 22, 2012.

As a technical support contractor supporting the Advisory Board on Radiation and Worker Health (Advisory Board), S. Cohen & Associates (SC&A) has been tasked with reviewing the National Institute for Occupational Health and Safety (NIOSH's) Evaluation Report on the Special Exposure Cohort (SEC) Petition for Hanford site workers. One component of SC&A's review is a series of interviews with site experts, including current and former site workers, petitioners, and worker representatives. The purpose of these interviews is to hear first-hand accounts of past radiological control and personnel monitoring practices, and to better understand how operations and safety programs were implemented at the site over time.

The expert was briefed on the interview process, which was unclassified. As a precaution, it was moderated by a U.S. Department of Energy (DOE) classification officer. After consultation with DOE Richland Operations (DOE-RL) to ensure there were no issues regarding public release, the expert was provided with the report he co-authored (Morton and Marlette 1990a), so he could refresh his memory. He was given the following context on Petition SEC-00155.

SEC-00155 is a petition to add workers in the Plutonium Finishing Plant and the 200 Area at Hanford during the period 1987–1989 to the SEC under the Energy Employees Occupational Illness Program Compensation Act (EEOICPA). The petitioner claims that bioassay data are untrustworthy and cannot be used for reliable dose reconstruction. The specific data in question are bioassay data for the period 1987–1989. SC&A, which provides technical support to the Advisory Board on Radiation and Worker Health (Advisory Board or Board), is reviewing the petition and NIOSH's evaluation of that petition for the Board. The interview was about the oversight activities conducted during May 1990. Specifically, this interview was focused on a QC data file that had been edited, according to the report.

B.1 INTRODUCTION

Morton and Marlette 1990a was prepared at the behest of the DOE. The basic concern to be addressed was whether UST's bioassay program was reliable—whether it provided results based on analysis of data and whether the results accurately reflected the content of the bioassay samples.

The oversight included review of ongoing work during the oversight period in May 1990. It also included review of laboratory operations for at least 2 years prior to that, probably from mid-1987 to 1990.

B.2 ALTERED QUALITY CONTROL FILE

Morton and Marlette 1990a stated the following regarding the editing of a QC file:

> *The most serious observation of the day appeared in the form of a QC file that had been edited. The hand written note at the top of the page only stated the file had been edited. There was no indication of the changes made to the file. The following discussion with* [**Redacted**], [**redacted**], *suggested restricting the editing of a data file to senior personnel only, and then the new data should be appended to the old, with all data remaining for inspection should the need arise.*
>
> *…Since the question of data integrity was questioned the previous day, it was of interest to determine the extent to which the data (raw, intermediate or final) could be edited by UST staff. The* [**redacted**], [**redacted**], *said* [**redacted**] *could edit a header file, but did not know how to edit a data file. Subsequent discussions with the* [**redacted**], [**redacted**], *confirmed the belief that the* [**redacted**] *is probably incapable of changing the data. The database is a flat file system rather than the relational type. This would make the modification of data much more difficult to the average operator.* [Morton and Marlette 1990a, pdf p. 2]

B.2.1 Description of the Edits

There was a note attached to the [edited] file on a yellow sticky that said [**redacted**] [[**redacted**]] had made a change to the header of the file. If the note had not been there, it would not have been possible to know that the header had been changed. There was no routine established procedure to indicate whether a header file in the database had been changed. Header information would include items like identifying information for workers, dates of the samples, etc. Other fields would contain the requested analysis and results as they are completed.

To the best of the expert's recollection, the change that had been made had to do with who performed the analysis. So the modification was the name of the person who performed the analysis. There was no indication in the note of all the changes that were made to the header. There was no notation of what the header was prior to the change.

There had been similar changes to header files at other times; however, the [**redacted**] had not changed data files. There were no records as to how frequently this happened. The expert cannot offer a qualitative impression even about how often that might have occurred.

The [**redacted**] said [**redacted**] did not know how to change the data. The oversight team concluded that [**redacted**] probably did not have the expertise to modify the data file.

Based on the interviews and examination of the file and a judgment about the level of expertise of the [**redacted**], the conclusion was that no data had been changed.

B.3 POTENTIAL FOR CHANGES TO DATA

There was both direct entry of data into the computer, such as gamma and alpha spectrometry, as well as some manual data entry. The system was a combination of both. The [redacted] was entering data from some handwritten report. But there is a difference between making a mistake and fraudulently changing the data. Someone has to approve that data. Unless there is stringent software that precludes data being changed, such a person could have changed the data. No one could say with complete assurance that data had not been changed.

There was no clear audit trail regarding who had access to initiate changes to the database. Databases are complex. The person making the changes would have to have special knowledge to edit the raw data. It would take some skill and knowledge to be able to that.

The [redacted] had access to the data. [Redacted] also had the knowledge of the database structure to be able to change the data. So at this level, only the [redacted] would have the expertise and the access to change the data. Management had to approve the tables, but the expert did not know whether they had access to the data so as to be able to change the tables. There were probably others who had both the expertise and the access.

Changing data is part of doing business, but there should be an auditable trail: Who made the changes? What was changed? What was there before the change? In principle, it would be nice to have two people to sign off on that change. That requires some scheduling and is difficult for a commercial lab, but the expert recommended that the change be made. Unfortunately, UST never got to make the recommended change, since their contract was terminated.

B.4 EVIDENCE FOR DATA MANIPULATION

The report noted the following regarding data integrity:

> *We cannot, however, address the main issues concerning overall data integrity. A real-time surveillance and general examination of current quality control measures does not provide information pertaining to intentional data manipulation or fraudulent activities. As mentioned above, an intelligent user in a key position at UST (or virtually any commercial or government laboratory) can manipulate data. Measures can be taken to minimize this possibility, but some potential will always exist. The necessity to analyze large numbers of samples per unit time may affect the integrity of the analyst or an intelligent user in a key position. A Statement of Work that reflects realistic performance criteria and incentives for quality as well as quantity is critical.* [Morton and Marlette 1990a, pdf p. 10]

This passage was written because the oversight activities could not preclude someone with the proper knowledge from changing data. This could happen, even today with the four-sign-offs requirement mentioned by Advisory Board member Clawson as current Idaho National Laboratory practice. The oversight team did not have the ability to be sure no data were manipulated; that would stretch it too far. But no evidence other than that one QC file that had been edited was found, and in that case, no data had been modified; only the header had been

changed. The best recollection of the expert was that the file header was changed because they needed to change the name of the person who performed the analysis because it had been entered wrong, so it was a justifiable change.

B.5 EMERGENCY PROCESSING CONTRACT ISSUE

Question: The contract required emergency processing within hours of "up to 25 samples at once…" (Morton and Marlette 1990a, p. 9). UST indicated that such a large number was not likely to be required. Was there any indication of a risk of "dry-labbing" under pressure on the radiological side, given the contractual pressures that may have been brought to bear?

The expert's impression was that the 8-hour turnaround time specified in the PNL contract for the emergency sample requirement was, in his opinion, unreasonable and could not have been accomplished, especially with a nuclide such as radium. It seems that PNL did not test that part of the contract. The oversight team believed that if this was a real need, then there should be some method in place to test it. If it is not tested, then there will not be assurance that the capability will be there if it is needed.

The discussion on this point did not center on dry-labbing. Dry-labbing is especially to be avoided in an emergency situation, because the results are very important [at such a time]. The oversight focused on how UST would respond in an emergency to produce the analyses in the time specified in the contract. If the requirement would have been tested by PNL with single blind samples, then, and only then, would PNL have had the confirmation of UST's ability to meet the contractual requirement. There would have been no question about capability or data integrity.

An untested requirement does not necessarily result in falsified data. The 25-sample emergency sample requirement could have compromised quality of THAT data if the clause had been invoked and there were that many samples for analysis on an emergency basis. But the clause was never tested in practice.

B.6 CONCLUSIONS

The expert did not find that the charges on the non-radiological side applied to the bioassay program. He saw no evidence of data being changed. The change to the QC file header, which did not affect test results, was a legitimate correction and was flagged by the [**redacted**]. Although it illustrates a weakness in change tracking and controls (by modern standards), it was not done in a deceptive or hidden manner that would indicate fraudulent intent.
During the interview, the expert said he was not sure why UST was not participating in the DOE Laboratory Accreditation Program. Upon reflection, he determined that accreditation for bioassay laboratories did not begin until sometime after 1998.

The expert did not feel that what he observed justified a termination of the contract; it was guilt by association. The expert communicated that personally to the DOE headquarters manager who requested the review. The expert believes the bioassay results have sufficient integrity to be used in a dose reconstruction program.

ATTACHMENT C: SUMMARY OF TELECONFERENCE INTERVIEW REGARDING THE 1991 RETROSPECTIVE REVIEW OF U.S. TESTING'S BIOASSAY WORK

SC&A's Task Manager for the review of Special Exposure Cohort (SEC) Petition SEC-00155, Arjun Makhijani, interviewed Dr. Gilbert S. Omenn and Dr. David A. Kalman, who were two of the experts who conducted a retrospective review of U.S. Testing's (UST's) work for the 1983–1990 period (Omenn et al. 1991). Also present during the call were Brad Clawson (Advisory Board member), Sam Glover (NIOSH), and Dave Briggs (DOE-RL classification officer, host of the call). The interview was conducted on June 14, 2012, by teleconference call.

As a technical support contractor supporting the Advisory Board on Radiation and Worker Health (Advisory Board), S. Cohen & Associates (SC&A) has been tasked with reviewing the National Institute for Occupational Health and Safety (NIOSH's) Evaluation Report on the Special Exposure Cohort (SEC) Petition for Hanford site workers. One component of SC&A's review is a series of interviews with site experts, including current and former site workers, petitioners, and worker representatives. The purpose of these interviews is to hear first-hand accounts of past radiological control and personnel monitoring practices, and to better understand how operations and safety programs were implemented at the site over time.

The experts were briefed on the interview process, which was unclassified. As a precaution, it was moderated by a U.S. Department of Energy (DOE) classification officer. After consultation with DOE Richland Operations (DOE-RL) to ensure there were no issues regarding public release, the experts were provided with the report they co-authored (along with two others), so that they could refresh their memories about the review (Omenn et al. 1991). They were also given the following context on Petition SEC-00155.

SEC-00155 is a petition to add workers in the Plutonium Finishing Plant and the 200 Area at Hanford during the period 1987–1989 to the SEC under the Energy Employees Occupational Illness Program Compensation Act (EEOICPA). The petitioner claims that bioassay data are untrustworthy and cannot be used for reliable dose reconstruction. The specific data in question are bioassay data for the period 1987–1989. SC&A, which provides technical support to the Advisory Board, is reviewing the petition and NIOSH's evaluation of that petition for the Board. The interview was about the retrospective review of UST's work conducted in 1991. One concern is regarding data or other materials that may have been withheld.

C.1 INTRODUCTION

The interviewees had reviewed the report, but did not have the raw notes or other notes, so this interview is based on a review of the report and their memory.

The data reviewed included data that were present in the PNL databases that described employee testing, as well as laboratory records, including raw records that were produced by UST and provided to the reviewers by PNL. One or two people from PNL were principal support personnel; they assisted in accessing information from the PNL database and helped retrieve information from UST files that the review team identified and requested. The reviewers

interrogated the databases and identified files for follow-up. They identified sample submissions and [the PNL support personnel] would go to the repository of UST data and come back with what they could find.

The review team did not directly access the raw data or comb the files. Rather, the team received those parts of the files that they requested from the PNL support personnel. These were laboratory records. Laboratory samples were identified with a person's name and with employee numbers. The review team generated a target list of things for review based on the PNL dataset; the PNL support personnel had the task of identifying the corresponding files and also of protecting privacy. The success rate was high. They found pretty much everything that was requested.

No UST personnel had contact with the review team, whose dealings were entirely with PNL. The review team did not go into UST's facilities. The best recollection of one of the experts interviewed was that all of the raw data was in the custody of PNL. As they understood it, PNL took over the entire set of laboratory records from UST. There was a warehouse with rack after rack of archived records. The data were in archive boxes in a warehouse, but there is no documentation of that in the review report (Omenn et al. 1991). PNL was aware of what the state of the data was, so there was no need to document that in the report. UST was not in a position to remove or redact anything based on the review team's requests.

C.2 ACCESS TO DATA

The experts felt they had free access to the data, though they did not go and browse in the warehouse. The review team framed the queries as a means of identifying which folders they were interested in. They requested these folders, and the PNL support personnel retrieved them for review. The requests were made based on searches of the PNL database; the team constructed search terms as they saw fit. The application of these terms was a transparent process. The resulting target list of documents was developed by the team, and they received all the materials they asked for.

A part of the process for selecting folders for review was to focus on where there might be poor quality work and where there might have been tampering with the samples.

C.3 POSSIBLE WITHHOLDING OF MATERIALS

The report, under the heading "Constraints on Our Analysis," noted that access to raw records was limited in part due to "materials withheld from PNL by UST…" (Omenn et al. 1991, p. 4).

In response to a question about what materials were withheld, one of the experts stated that it was his belief that this statement was more in the nature of a hypothetical. It was not the intent to say that something was actually withheld. However, the team was not asked to make a forensic assessment of availability or non-availability of data, and did not have access to or interaction with UST personnel. The team was not aware that materials were withheld, but was not in a position to verify that; the statement in the report was intended to make that point.

In regards to the statement in the report that "Materials withheld by UST did not prevent us from reconstructing cases selected at random from all reported results" (Omenn et al. 1991, p. 49), one of the experts stated that this was a generic caution. He stated that a better phrasing would have been to say it in the conditional: "if materials were withheld…" Any material that was not available related to support for sample data, rather than the sample data itself. The experts stated that their report did not omit any opportunities to address implications of data withheld. Had they felt that data were being withheld, they would have addressed that directly. The experts stated that nothing was withheld and nothing could have been withheld by UST, because PNL took over the entire set of laboratory records.

[A post-interview question was sent to the interviewees on the completeness of the records in the possession of PNL. SC&A sent the following questions to the interviewees:

> *The Omenn et al. 1991 report states that "Laboratory records have been maintained by UST and have in part been turned over to PNL." This seems at variance with the recollection in the interview statement that the entire set of records had been transferred to PNL. Did the statement about withheld records perhaps refer to the records that had not been transferred? Did you restrict your sampling to the records that were in PNL's possession? A clarification would be deeply appreciated. The same clarification will be made in the summary.*

One of the interviewees responded as follows:

> *PNNL was in a position to know what UST records were not included when the lab records were provided to it. For a possible example, UST's business records, instrument maintenance records, or other correspondence not part of sample testing work might not have been included. However, we were limited only by what was in the PNNL employee monitoring database. Reports of testing that were omitted from the database (if any) would be invisible to us as we searched for files to review. Any record in the database where the corresponding UST data were unavailable (whether from being withheld, misfiled, or otherwise poorly maintained) would have been potentially detectable, as our report discussed.*]

The review was a quite original and appropriate statistical analysis of the data. A file folder was a unit of analysis. This folder concerned a particular analysis of a particular sample. The information in the records is specific to that sample. The assessment of the quality of data applies to a batch of samples. Quality-related documents are not in those individual sample files; they are assigned to a batch of samples and are supporting information. For subsequent analysis, the reviewers had to reconstruct this supporting information, since it was not maintained on a sample-by-sample basis. There is a real possibility that some of these supporting documents were not retrieved because they could not be located, but concealment was not an issue. There was no evidence of concealment.

C.4 USABILITY OF THE DATA FOR DOSE RECONSTRUCTION

Omenn et al. 1991 (p.48) concluded that:

> *…. [I]t appears to be the case that UST performance in the Bioassay Program was, with minor exceptions, in compliance with contractual requirements, and was technically competent according to every measure considered: UST internal QC performance; PNL QA testing; and various audits, inspections, and laboratory intercomparisons exercises conducted by PNL, Washington Department of Ecology, US Department of Energy and Washington Department of Health, among others.*

The experts reaffirmed their conclusions regarding the overall competence of the bioassay program. They also reaffirmed the report's statement that they could not entirely rule out the possibility of something fraudulent having occurred outside the scope of the review. Omenn et al. 1991 notes that the review team was not "able to verify that basic laboratory records are genuine, accurate, and unaltered" (p. 7). However, given allegations about what may have happened "elsewhere in the country," the team was alert to the possibility of fraud and did not find any evidence of fraud.

The experts reaffirmed the report's overall conclusion that the bioassay data are sound. They also answered in the affirmative in response to a specific question about whether they were sound enough to be used in dose reconstruction.

ATTACHMENT D: INTERVIEW WITH PETITIONER AND [REDACTED] REPRESENTATIVE

SUMMARY OF INTERVIEW WITH PETITIONER AND THE PETITIONER'S REPRESENTATIVE REGARDING HANFORD PETITION SEC-00155

Conducted by SC&A on February 3, 2012

D.1 INTRODUCTION

As a technical support contractor supporting the Advisory Board on Radiation and Worker Health (Advisory Board), S. Cohen & Associates (SC&A) has been tasked with reviewing National Institute for Occupational Safety and Health's (NIOSH's) Evaluation Report on the Special Exposure Cohort (SEC) Petition for Hanford, SEC-00155. Part of SC&A's procedure is to interview petitioners and their representatives to hear their first-hand accounts, including any matters relating to past radiological control and personnel monitoring practices, and to better understand the petition and/or how operations and safety programs were implemented at the site over time. In the present instance, SEC-00155 was restricted to the 1987–1989 timeframe, as was the interview with the petitioner and the petitioner's representative. The interview was focused on the issue of bioassay data manipulation or fraud, which are the issues at the center of Petition SEC-00155. There is another Hanford petition that is simultaneously under review, SEC-00057, which covers the period from July 1, 1972, to December 31, 1990. Hence, it includes the 1987–1989 period covered by Petition SEC-00155. SEC-00057 also covers all Hanford facilities, including the Plutonium Finishing Plant in the 200 Area that is the subject of Petition SEC-00155. SC&A noted this during the interview. However, the petitioner and the petitioner's representative were invited to comment on any topic they felt might be relevant.

The interview was conducted by teleconference call on February 3, 2012, by Arjun Makhijani (SC&A). Besides the petitioner and the petitioner's legal representative, others present were:

Sam Glover for NIOSH
Chris Miles as an observer for ORAUT
Dave Briggs, DOE classification officer and host of the call
Brad Clawson, ABRWH, for the latter part of the interview

The parties were informed in the usual manner that the interview was voluntary and unclassified. They were also informed about the review procedure: that DOE would do a classification review of the draft, subsequent to which the draft would be sent to the participants for corrections, additions, and edits of their parts. This is an important safeguard against missing key issues or misinterpreting some vital piece of information.

Since SEC-00155 is focused on bioassay data, a definition of bioassay data in the context of the petition was discussed. The data in question are urine and fecal sampling and analyses for radionuclides. The analyses in question were those done by U.S. Testing Company (UST) in the period 1987–1989.

D.2 ETHICS

The main underlying issue raised by the petitioner was the ethics of UST, which had lost its contract with the U.S. Environmental Protection Agency (EPA) due to fraud and manipulation of data. For the petitioner, UST "knowingly and willfully were aware of what they were doing, *they just didn't care* and in-turn placed my life and my family's livelihood in jeopardy for their own self gain……greed." Both the Hoboken, New Jersey, and Richland, Washington, laboratories of UST were involved. For the petitioner, this was more important than whether the specific type of sample being analyzed was a chemical or a radionuclide. The results of a company that engaged in fraudulent practices could not be trusted. The petitioner stated that the company had pleaded guilty to a felony. As a result of illegal practices, which were detailed in the EPA Action Referral Memorandum and verified by the EPA Office of Inspector General in interviews, [redacted] and other Hanford employees, who had done hazardous work for the security of the United States, had suffered a betrayal of trust, grievous harm to health, and financial and psychological harm to their families. [Redacted] stated that, "It does not matter whether they were chemicals or radiological samples; it is the lack of ethics that is the problem." Therefore, the petitioner concluded that none of the analytical results of UST during the 1987–1989 period could be trusted or used in a scientific dose reconstruction, and that the SEC petition should be granted.

The petitioner provided a written statement, which had previously been given to the Advisory Board. It is reproduced in full at the end of this summary.

D.3 SPECIFIC ISSUES

Among the practices cited by the petitioner were:

- Work performed at one site was represented as being done at the other site, even though the UST contract did not permit work to be performed at alternate sites.
- There were chain-of-custody violations.
- Two separate logbooks were kept.
- There was improper cutting and pasting of results from one sample onto those for another sample.
- There was back-dating of sample results.
- There was doctoring of samples, for instance by dilution.
- There was use of illegal drugs in the workplace by management, including when "critical" decisions were being made.

The petitioner provided supporting documentation in the form of the records of two interviews conducted by the EPA Office of Inspector General and the April 4, 1989, Action Referral Memorandum. These documents are part of SEC-00155. Key parts of the EPA Action Referral Memorandum are reproduced below, since they were a principal part of the interview.

Quotations from the April 4, 1989, EPA Action Referral Memorandum:

> *14. The EPA Office of Inspector General has furnished the Compliance Branch with adequate evidence to believe that UST management, contrary to CLP protocols, and during performance of Organics and Inorganics contracts at the Richland, Washington facility and the Hoboken, New Jersey facility conspired, directed, carried out, and otherwise condoned a scheme to defraud the United States.*
>
> *15. With the knowledge and participation of management in both the Hoboken & Richland laboratories, initials of personnel who met the required qualifications and work experience criteria were forged onto logbooks and analysis sheets to conceal the fact that work had actually been done by unqualified personnel. Alterations of log book pages and destruction of worksheets and pages of log books were also committed at least between December, 1987 and August, 1988…*
>
> *16. Contrary to CLP protocol and contract requirements, the required chain of custody was breached frequently by UST personnel and management by the carrying of samples and data from Richland for analysis in the Hoboken laboratory and vice versa….*
>
> *17. At least during 1987 and 1988 data was fraudulently reported as being analyzed on certain types of equipment. For determinations of pH readings, UST reported results to a degree of accuracy which could only have been done on a pH meter. UST also indicated the use of an automatic sampling machine. Neither a pH meter nor an automatic sampler was present or used at the times this equipment was represented as having been used….*
>
> *18. EPA standards require a clearly defined analytical sequence of standards and samples for PCB/Pesticides during which standards are to be dispersed throughout the analytical sequence. Instead, UST analyzed the samples as a group and the standards as second group and indicated in the logbooks by the letter "A" that the standards and samples were injected in the required sequence by an automatic sampler. This was done solely to conceal the fact that neither the standards nor the samples were performed according to contract requirements. This practice is believed to have taken place between May, 1987 and January, 1989….*
>
> *19. Each sample received by a CLP must be analyzed within contract time requirements depending on the nature and volatility of the substance. UST developed a pervasive practice of analyzing samples past their expiration date but reporting the sample preparation and analysis as being within contractual requirements. This is commonly referred to as backdating. Since at least 1987, this practice was used by UST in all analyses done under both Organics and Inorganics contracts. Some 70%–80% of EPA work has been estimated to have been affected at the Hoboken laboratory. Supervisory personnel left written*

instructions for technicians to run samples while entering into the computer and/or log a time and date which would indicate that the sample had been run earlier. These written instructions were then destroyed. Backdating was also accomplished through another method known as "cut and paste." This is the technique of pasting a false date which meets contract requirements in place of the actual late date on the generated data, photocopying the falsified document and submitting the finished product for payment to the EPA as the "original."….

20. CLP protocols require the use of specified standards for the purpose of calibrating (checking the accuracy) the equipment used during analyses. The improper calibration of equipment and the failure to use standards required by CLP protocols affected work done under Organics and Inorganics contracts…. UST also failed to use the mediums or standards required by the EPA…. These practices make it impossible to determine if the analyses results are reliable. These practices are believed to have taken place at least in 1987 and 1988.

21. CLP protocols also require that each time a sample is prepared a method blank (reagent water which measures contamination from a source other than the sample) is also prepared, and these results are analyzed and reported along with the sample analyses results… Method blanks and samples are prepared in the Extraction laboratory and then sent to the correct laboratory for analysis. Instead, UST management would misrepresent that the proper blanks had been used when, in fact, they had not. These practices are believed to have existed at least in 1987 and 1988….

22. Analyses results are often produced on a computer print out as a graph in the form of peaks which indicate where the proper standard was used. "Peak shaving" consists of manual manipulation of a computer to bring the peak within the required range. This appears to have been common business practice throughout the Hoboken and Richland facilities where equipment producing computer printouts was used…. Data produced from such practices is unreliable.

23. From at least May 1987 to January 1989, with the knowledge and acquiescence of management, hazardous wastes were apparently discarded into city dumpsters present on UST property, improperly handled and stored on UST premises and poured down laboratory drains which discharged into local sewer systems and the waters of the United States, a potential violation of 33 USC §1331 and 42 USC §6928 (d) (2) (A)….

24. The allegations set out supra in paragraphs 14–24 not only took place during the time periods denoted in each allegation but involved management and employees who were employed at the Hoboken facility at the time the Interim Agreement was signed….

…

> *32. There is adequate evidence to believe that UST is, until proven otherwise, a company that conspired, directed, and condoned a scheme in at least the Richland facility and the Hoboken facility to defraud the United States Government. This resulted in the submission of false, inaccurate and unreliable test results and data submitted to the EPA for payment under its contracts. This was apparently done with knowing, willful and flagrant disregard for state and federal laws, contract requirements and CLP protocols. The potential impact upon Federal programs, public health and the environment at this time, cannot be measured.*

In addition to the above from the EPA Action Referral Memorandum, the petitioner also pointed to corroborating evidence from the interviews conducted by the EPA Office of Inspector General, Office of Investigations.

SC&A is reviewing these documents as part of its review of SEC-00155.

D.3.1 Evidence Specific to Radionuclide Bioassays

SC&A inquired about evidence and documents relating specifically to data manipulation and fraud in the way radionuclide bioassays were done. SC&A also inquired whether the petitioner had personal knowledge of testing procedures, calibration, and other practices. The petitioner stated that [**redacted**] did not work for UST, but for another contractor, and did not have personal knowledge of practices relating to bioassay analysis or of the audits that were done.

D.3.2 Other Documents

SC&A asked the petitioner for any and all documents that [**redacted**] believed were relevant to the petition, independently of whether SC&A otherwise had access to them. Four documents were received by SC&A from the petitioner and the petitioner's representative:

- A statement by the petitioner (which [**redacted**] read during the interview and which is reproduced below in full)
- The April 4, 1989, EPA Action Referral Memorandum
- Two interviews conducted by the EPA Office of Inspector General, Office of Investigation

Two other documents were sent to SC&A via Advisory Board member Brad Clawson and the Hanford Work Group Chair, Dr. Jim Melius:

- "Evaluation of the Significant Observations Resulting from the U.S. Testing Oversight Program: Daily Reports Producing During Surveillance Period of 5/01/90 to 5/31/90," in *Final Report – Oversight of U.S. Testing Company Implementation of Analytical Procedures and Protocol*. June 7, 1990.
- Petitioner's [**redacted**] and [**redacted**] data from various dates starting in [**redacted**], along with page 16 from Technical Information Bulletin ORAUT-OTIB-0049 showing

Table 4-7. This table shows the Type S and Type SS (also called Super S) doses to the liver from Pu-239 and the intake adjustment factors to be used to go from Type S dose to Type SS dose in years 1 through 10 "after a 5-year chronic intake of ^{239}Pu calculated from urinary excretion data." The adjustment factor shown is one for years 1 through 7 and four for years 8, 9, and 10. It also shows Section 4.1.4 from ORAUT-OTIB-0049, which states that dose calculated from fecal samples taken more than 2 months after an incident should be multiplied by a factor of 3.

[A post-interview statement from the petitioner is included, verbatim, below. The documents referenced as "attached" were received as attachments to the statement. SC&A is making the attached documents available to NIOSH and ABRWH.]

Regarding Section 4.1.4 "Doses Based on Fecal Bioassay Data" of Bulletin ORAUT-OTIB-0049. Under Section D of the Interview Summary in the paragraph on Petitioner's [redacted] *and* [redacted] *data is a misapplication showing Table 4-7 and quoting adjustment factors for PU239 urinary excretion data. But what should be applied is the provision in the second paragraph of 4.1.4 concerning fecal samples collected* ***more than 2 months*** *after the an acute intake, providing: "Once the dose to the organ of interest is calculated, it is adjusted upward by a factor of 3."*

Petitioner's [redacted] *was on* [redacted]*, see attached bioassay. Note there were* [redacted] *samples taken* [redacted] *and* [redacted]*, well beyond* [redacted] *months after the* [redacted]*. When this issue was raised in Petitioner's first interview with NIOSH, it was disregarded on the basis that the subsequent sample measurements were unreliable. This is the very issue in this petition SEC-00155, that the underlying data provided by UST was unreliable and corrupt to the point that no reasonably accurate dose reconstruction could have been performed. Also attached are pages from Final Report of DOE Quality Assurance Division of the UST Analytical Procedures and Protocol showing UST incapable and unequipped for accurate radiological measurements. Respectfully submitted: April 4th, 2012* [redacted] *as Authorized Representative and Attorney of Record on behalf of Petitioner,* [redacted].

SC&A will review the document, *Evaluation of the Significant Observations Resulting from the U.S. Testing Oversight Program: Daily Reports Producing During Surveillance Period of 5/01/90 to 5/31/90,* as part of this SEC review. SC&A will await guidance from the Advisory Board on the review of the dose reconstruction of the petitioner relating to the [redacted] and [redacted] sample data provided.

Subsequently, the petitioner's representative also sent nine other documents. The following list of the titles of the documents is reproduced verbatim from the cover letter accompanying the documents:

1. *Battelle NW memo re "Problems with US Testing Records and Reports dated 6/30/1969;*

2. *Deposition of Michael J. Lawrence dated 1/15/1991 (excerpted pages only);*
3. *Letter to US Atomic Energy Commission dated 4/22/1968;*
4. *Dept. of Ecology Fact Sheet re US Testing Suspension Impacts on Hanford dated 4/25/1990;*
5. *Battelle NW memo re "Blind Audit Sample Program" dated 1/18/1982;*
6. *Dept. of Energy letter to Dr. Omenn dated 12/4/1990;*
7. *Battelle NW memo re US Testing dated 5/21/1990;*
8. *Battelle NW memo re Memo with DOE-RL and EPA Region X dated 2/27/1990;*
9. *Daily Report on US Testing 5/9/1990.* [Foulds 2012]

The above documents, as well as the cover letter accompanying them, were provided to NIOSH for posting in the Site Research Database (SRDB).

A number of documents relating to the EPA case against UST are not available on the SRDB; they are also not available to the petitioner. The matter apparently relates to whistleblower protections in a criminal investigation. They have been reviewed as part of the review of the petition in a confidential setting at the DOE by Sam Glover (NIOSH), Brad Clawson (ABRWH), and Bob Bistline (SC&A). The notes from these interviews relevant to bioassay data are in the SRDB. The petitioner and the petitioner's legal representative discussed how they may get access to them.

The written statement below, sent by [**redacted**], starts with the phrase "Employment dates" and ends with the signature line:

[**redacted**] *dates:*

- [**redacted**] [**redacted**]
- [**redacted**] *to* [**redacted**] [**redacted**] [**redacted**]
- [**redacted**] *to* [**redacted**] [**redacted**] [**redacted**]
- [**redacted**] *to* [**redacted**] [**redacted**] [**redacted**]
- [**redacted**] *to* [**redacted**] [**redacted**] [**redacted**]
- [**redacted**] *dates* [**redacted**] *to* [**redacted**]
- [**redacted**]

Let me first say, thank you for providing me with this opportunity.

I understand this is scientific based information but let me also appeal to the sentiments of your heart in that you will do the righteous thing and your actions will right a wrong.

The actions of deceit and ultimate betrayal, in trust, due to the unethical acts, for personal gain, have never been so blatant, with true disregard for my wellbeing and threatening my life and the livelihood of my family and numerous other victims of this tragedy. We, the courageous Americans, paid a high price for our service, incurring disabling and or fatal illnesses as a result of exposure to

radiation, chemicals other hazards that are unique to nuclear weapons production and testing.

I ask that you adopt this SEC petition and justify (award) full medical and monetary compensation for the victims of this tragedy due to the neglectful actions, again, for personal gain, by US Testing, of which none of this should have occurred if the company had not been engulfed by greed.

The evidence you seek has been previously outlined in various documents (ref, EPA referral memorandum dated April 4, 1989) which is further substantiated by supporting data based on interviews of numerous US Testing personnel conducted by the Office of Inspector General, Office of Investigation dated June 6, 1989.

The facts are many, but for the sake of time, here are two:

1) *SEC report – pg 32 of 58 states;*
    - *NIOSH did not find bioassay data produced by UST to have been affected, however;*
        - *the* ***Action Referral Memorandum-item #9 states;***

          Contract was Lab specific; neither lab was listed as an alternate site to perform work on a contract basis.
        - ***Based on the Office of Inspector General – interviews, also site numerous Chain Of Custody protocol violations***
2) *SEC Report – pg 29 of 58 states;*
    - *Sample card/final results were not found and,*
    - *Incomplete record of one sample/result*

      This lends credence to incomplete/inaccurate record keeping and cast doubt on accuracy of samples recording; the 2 above statements are from NIOSH themselves.

      Office of Inspector General – interviews, states, two separate logbooks were kept.

Other facts still remain:

- *Cut and Paste activities*
- *Maintain 2 separate log books*
- *Backdating sample results*
- *Doctoring Samples*
- *Use of illegal drugs by management*

These are the facts, and many more can be found in the Office of the Inspector General Report dated June 6, 1989

These interviews are first hand witness accounts conducted by creditable people (Inspector General Office) who took an oath to uphold the law. The outcome of their investigation substantiates the facts that create and establish reasonable doubt and questions the creditability of US Testing which is further supported by the EPA referral memorandum facts section. Because of the unscrupulous actions of US Testing many people have endured unjust suffering.

To rely on an organization, complete strangers, that have the responsibility to analyze samples and you entrust them to be honest because they have the educational knowledge and experience is where my trust was.

Ladies and Gentlemen, you say you want facts, here then are some undisputable facts:

- [**redacted**].
- [**redacted**]
- [**redacted**]
- [**redacted**]
- [**redacted**].
- [**redacted**].
- [**redacted**].
- [**redacted**].

*All are facts that have been **forcibly and permanently** etched **into** my life.*

One can chose, to dispute the evidence before you, but science only presumes facts based on data analyses that can be manipulated to support the desired outcome.

No data analyses or computer programs can dispute the above mentioned facts.

*But, one main ingredient is missing, one, that we tend to sometimes overlook, and its called **ethics**. In this case it is economics over ethics. These people, whom I entrusted to analysis samples and provide honest results, failed in their ethics, because they knowingly and willfully were aware of what they were doing, <u>they just didn't care</u> and in-turn placed my life and my family's livelihood in jeopardy for their own self gain……greed.*

NIOSH states, pg 46 of the handout, "NIOSH found no part of the class which it can not estimate radiation doses with sufficient accuracy"…..

I must ask? How can an estimate be accurate when I myself have three (3) different dose reconstructions ….with three (3) different results?

I question US Testing protocols, ethics, and methodology…which is why they were terminated….such as Higher Management's use of illegal drugs on company time and premises. These people were tasked in making major decision but were under the influence at the time certain critical decisions were made.

Again I must ask, where is the creditability in this? Where are the ethics?

Ladies and gentlemen,

The decay of the human spirit, for personal and company gain, has never been so evident as it is with this company that I once trusted.

In essence, as in my case, I have been left ***"raped" stripped*** *from my being.* ***Betrayed*** *by those I once trusted.*

I ask:

That you, right a wrong

This is your opportunity to make a positive difference in people's lives.

The power to do the righteous thing is, in the name of humanity and justice, in…..your…..hands.

Don't turn your backs on these courageous Americans who defended our national security for the freedoms we enjoy. We didn't use bullets and missiles but worked in gloveboxes and in high hazard environments such as chemical and radiological process.

In closing let me just reiterate;

I appeal to your consciousness and sentiments of your heart because no-one should go through what these families and I have gone through and to approve this SEC Petition to compensate those of us, those courageous Americans, who have unnecessarily suffered and those who have died.

This would be the righteous thing to do.

Thank you"
//signed [**redacted**]*//*

End of [**redacted**] written statement sent to SC&A.

ATTACHMENT E: QUESTIONS TO TWO PNL EMPLOYEES (ONE PRESENT AND ONE FORMER) REGARDING RECORDS TRANSFER FROM U.S. TESTING TO PNL AND THEIR RESPONSES

SC&A sent four questions via e-mail to [**Interviewee 1**], who was the [**redacted**] for PNL at the time of the 1991 retrospective review, and to [**Interviewee 2**], who was the [**redacted**] at that time. The questions and their answers as sent by them (in two separate documents on July 1, 2012, and July 10, 2012, respectively) are reproduced below.

E.1 [**Interviewee 1**] Responses

Question 1: P. 15 of the Omenn et al. report states that "Laboratory records have been maintained by UST and have in part been turned over to PNL." The wording seems to imply that the transfer of records from UST to PNL was incomplete at the time of the report. Is this correct? Were some of the records still with UST at the time of the review in 1991? If so, what part(s) of the records were held back by UST, and why were they held back?

> [**Interviewee 1**]: *I have no recollection that there were records not transferred. By contract, UST was required to turn over all pertinent records. As* [**redacted**]*, I was more focused on overseeing an interim in vitro bioassay program that was using a number of different labs across the country, and on getting a new permanent contract in place with a new lab.* [**Interviewee 2**] *was our staff member in charge of* [**redacted**] *at that time.* [**Interviewee 2**] *oversaw* [**redacted**]*, coordinating with the* [**redacted**]*.* [**Interviewee 2**] *reported to me and kept me abreast of what was happening.* [**Interviewee 2**] *also was the* [**redacted**]*,* [**redacted**]*. I do recall there were many boxes of record transferred; I do not recall* [**Interviewee 2**] *saying that there were significant records withheld by UST. Because UST had several clients there may have been some QA results that were relevant to bioassay in general but were associated with batches of other clients' samples that would not have been turned over to PNL. Similarly results of onsite inspections/audits by other clients would not have been turned over to PNL.*

Question 2: P. 4 of the Omenn et al. report states that the access to raw records of the review team was limited in part due to "materials withheld from PNL by UST…." What materials were withheld? Why were they withheld?

> [**Interviewee 1**]: *I have no recollection of what was withheld or why. I'm surprised that the Omenn Committee didn't state exactly what they were. I do not recall from the closeout meeting that they felt anything significant was missing from their review. Of course they did not have time to read every single record that had been transferred. There is a small chance that a mention was made of missing records in my weekly reports to my management circa 1991. Things like that may be saved in my letterbook. PNL has determined that letterbooks are not official records but the Radiological Records Group at PNNL has saved a number of managers' letterbooks. A request to see if they saved my letterbooks from that*

period can be made to Gail Splett at DOE-RL. Be sure to mention hard copy letterbooks because, to the best of my memory, the letterbooks were never converted to electronic copy. The letterbooks hold every single letter as well as the weekly reports so many of the letters will not be of interest. Make your request specific for my weekly reports (probably would have Internal Dosimetry Group or Internal Dosimetry Program in the title) or for any letter that discusses topics associated with UST or the Omenn Committee. The letterbooks are organized by calendar year so 1991 would be the relevant year.

Question 3: Do you think the materials not transferred to PNL or withheld from PNL affected the review in any way? For instance, were the materials reviewed by Omenn et al. representative of the bioassay records overall in the 1983–1990 period? If yes, what is the basis for coming to this conclusion?

[**Interviewee 1**]**:** *I do not recall anything from the closeout meeting with the Omenn Committee that implied that they felt that there were significant records that they had not been able to see that affected their conclusion. All the evidence that they saw and other evidence that I saw implied that the issues were with other sectors of the company and that bioassay was not impacted.*

Question 4: Was PNL able to provide the Omenn et al. team with all the materials they requested?

[**Interviewee 1**]**:** *All I recall is that they had access to all the boxes that PNL had and this was a large number of boxes of records that covered the contract period.* [**Interviewee 2**] *may have a more detailed memory.*

E.2 [Interviewee 2] Responses

Question 1: P. 15 of the Omenn et al. report states that "Laboratory records have been maintained by UST and have in part been turned over to PNL." The wording seems to imply that the transfer of records from UST to PNL was incomplete at the time of the report. Is this correct? Were some of the records still with UST at the time of the review in 1991? If so, what part(s) of the records were held back by UST, and why were they held back?

[**Interviewee 2**]**:** *To the best of my recollection, the subcontract statement of work required US Testing to maintain records of the analytical raw data and other associated quality assurance records for an unspecified time after the analytical reports were submitted to Battelle, and then submit them in batches as requested by Battelle. This was specified as a convenience to Battelle. When the "held back" records were eventually received by Battelle, they were sent to archival records storage.*

Question 2: P. 4 of the Omenn et al. report states that the access to raw records of the review team was limited in part due to "materials withheld from PNL by UST…." What materials were withheld? Why were they withheld?

> [**Interviewee 2**]: *I was not aware of any materials withheld from the review team. However, on Page 49 of their report, the Omenn team stated that with regard to access to raw records, "Any third party seeking to review records of analysis in this matter will experience restrictions and inefficiencies in obtaining raw UST records. Access is limited due to (a) materials withheld from PNL by UST; (b) legal restrictions requiring intermediaries to search the files for us; and (c) awkwardness of the file structure itself so that searchers must be very familiar with it. Materials withheld by UST did not prevent us from reconstructing cases selected at random from all reported results; the other two limitations were overcome though additional effort and assistance from PNL staff familiar with the UST filing system. We therefore feel that this constraint is only logistical and does not prevent us from reaching a valid conclusion." From this statement I would conclude the team received all materials they deemed necessary to reach their conclusions. It may be that the reference on Page 4 is to the records still at US Testing that were awaiting submittal to Battelle as discussed above.*

Question 3: Do you think the materials not transferred to PNL or withheld from PNL affected the review in any way? For instance, were the materials reviewed by Omenn et al. representative of the bioassay records overall in the 1983–1990 period? If yes, what is the basis for coming to this conclusion?

> [**Interviewee 2**]: *To the best of my recollection, annual assessments of US Testing compliance with the subcontract statement of work did not identify any findings regarding lack of supportive quality assurance records.*

Question 4: Was PNL able to provide the Omenn et al. team with all the materials they requested?

> [**Interviewee 2**]: *The Omenn report states on Page 49, "We therefore feel this constraint is only logistical and does not prevent us from reaching a valid conclusion." From this statement I would conclude the team received all materials they deemed necessary to reach their conclusions.*