Hanford SEC Review (SEC-00155)
Summary of SC&A Report

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Background to the SC&A Review of Petition SEC-00155

- SEC Petition SEC-00155 is focused on the Hanford 200 Area for the 1987–1989 period.
- Basis of the petition: The bioassay data for the Plutonium Finishing Plant (PFP) in the 200 Area generated by U.S. Testing Company (UST) are not trustworthy and should not be used for dose reconstruction because of fraud and mishandling of data by the company. Among other things, this problem was detailed by the U.S. Environmental Protection Agency (EPA).
- The NIOSH Evaluation Report (April 28, 2011) found that fraud and data mishandling had not affected bioassay data, and that those data were usable for dose reconstruction for the period in question.
- Thereafter, the Board asked SC&A to review the petition and the NIOSH Evaluation Report (ER). The SC&A report was sent to the Hanford Work Group on August 7, 2012.

SC&A Document Review

SC&A reviewed a large volume of documents including

- The petition and the ER
- Documents related to the EPA investigation of UST
- Internal UST and PNL audits of bioassay data
- The 1990 and 1991 external reviews of the UST bioassay program
- Documents supplied by the petitioner and the petitioner's representative
- Non-public documents related to the investigation of UST

SC&A Interviews and Other Research

SC&A interviewed (by teleconference call)

- The petitioner and the petitioner's representative
- The external bioassay expert during the May 1990 external oversight
- One of the two external experts who participated in the May 1990 oversight for the DOE.
- Two of the external experts who conducted the 1991 retrospective overview

Hanford Work Group member Brad Clawson participated in the interviews. Sam Glover from NIOSH and a DOE classification officer were also present during the interviews. All interviews were reviewed by the classification officer and the interviewees.

SC&A also sent questions to two PNL personnel familiar with the bioassay program during the period in question.

Finally, SC&A reviewed data quality issues, including MDAs. SC&A specifically reviewed bioassay data for plutonium, uranium, americium-241, strontium-90, and neptunium, as well as four completed dose reconstructions to examine the use of a certain kind of bioassay data.

Detailed documentation of the above is available in the SC&A report.

Did Fraud Affect UST Bioassay Data?

- SC&A conducted extensive research to locate any evidence of fraud or mishandling of data in the UST bioassay program.
- SC&A asked the petitioner and the petitioner's representative for documentation or personal knowledge of fraud in the UST bioassay program. None of the information provided direct evidence of fraud in that program.
- SC&A conducted detailed interviews regarding two issues potentially related to fraud—one about an edit to a QC file and one regarding potential withholding of data during the 1991 review—but did not find evidence of it.
- No motive for fraud in the bioassay program was found in any of the reviews. Crude levels of fraud could have been detected during the 1990 and 1991 reviews.
- **SC&A concluded that to all available evidence, the UST bioassay data were unaffected by fraud and mishandling of data. However, no definitive finding is possible at this time, since none of the internal or external audits at the time were structured to detect sophisticated fraud.**

Two Views of Data Relating to Fraud

- The petitioner, as well as the DOE, PNL, and the EPA, indicated in various ways that if *any part* of UST data was affected by knowing and willful manipulation of tests or data, then *all data* should be regarded as suspect. This reasoning was explained by the then-DOE Site Manager in a deposition 1991. PNL terminated the UST subcontract, including for the bioassay program, for default in 1990.
- In contrast, the external oversight and retrospective reviews in 1990 and 1991 found the bioassay data to be acceptable, despite some quality assurance and other issues. This view was generally confirmed during SC&A interviews. One expert interviewee said he would give a "qualified yes" to the usability of the data. In other words, these reviews did not conclude that the bioassay data were unusable because of issues relating to fraud that had been raised in the chemical side of the UST program or because of QA problems.
- In 1991, a court stated that the PNL termination of the UST subcontract for default was not warranted, though termination for "convenience" was permissible.

Quality Assurance Issues

- The problems of QA with the work of 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.
- 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.

Quality Control File Editing

- The May 1990 oversight review found an edited Quality Control (QC) file. This edit 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 when it was made 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.

Were Data Withheld from the 1991 Review?

- 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, indicate that the 1991 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.

The Bottom Line: A Policy Question

The bottom line regarding the issue of fraud is a policy question for the 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?**

Other Data Issues, 1987–1989

- The internal audits, external oversight reviews, and SC&A review of the bioassay data all indicated some quality problems with the data, including in particular a failure to meet contractual Minimum Detectable Activity levels in some cases.
- Fecal data had never been subjected to quality assurance sampling.
- SC&A concluded that these problems did not invalidate the bioassay data, but that appropriate adjustments were necessary in some cases prior to the use of the data in dose reconstruction.

Two Findings

- 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." The added uncertainty arising from this problem should be addressed in dose reconstruction.

End of Slides

Questions?