SC&A S. COHEN & ASSOCIATES
AN EMPLOYEE-OWNED COMPANY

April 11, 2008

Mr. David Staudt
Center for Disease Control and Prevention
Acquisition and Assistance Field Branch
Post Office Box 18070
626 Cochrans Mill Road – B-140
Pittsburgh, PA 15236-0295

Re: Contract No. 200-2004-03805, Task Order 5: Draft Review of the *NIOSH Evaluation Report for the Lawrence Livermore National Laboratory Special Exposure Cohort: In Vivo Counting Time Period Issue*

Dear Mr. Staudt:

S. Cohen & Associates (SC&A) is pleased to submit our draft review of the *NIOSH Evaluation Report for the Lawrence Livermore National Laboratory Special Exposure Cohort: In Vivo Counting Time Period Issue*. This issue-specific review of the LLNL evaluation report was requested by the Advisory Board on Radiation and Worker Health at its January 8–10, 2008, meeting.

SC&A's conclusion from this review is that the NIOSH statement in the LLNL SEC evaluation report that bioassay data prior to 1974 was not sufficient for accurate coworker fission and activation product intake models is valid and can be substantiated. This conclusion is based on the known and reviewed history of the development of in vivo body counting at that time, an in-depth review of the historical LLNL whole-body counter logbooks, key logbooks, and information gained from SC&A interviews with staff familiar with the history of the body counter systems.

Notwithstanding this conclusion and based on our review of whole-body counting logbooks and other records, SC&A is concerned (1) whether specific job titles, occupation, or job locations were adequately known after December 31, 1973, to enable LLNL to identify for routine monitoring all those potentially exposed to these fission and activation product radionuclides; and (2) whether NIOSH can, likewise, identify these individuals for applying an appropriate coworker dose. Comments by the interviewed individuals and Table 5-1 in the SEC Petition Evaluation Report (Petition SEC-00092) lead SC&A to this concern. In addition, based on the number of individuals monitored, the small number of analysis results, and the indeterminate locations for workers noted in Table 5-1, as well as substantiation of these concerns through interviews, SC&A believes that although the capability for appropriate monitoring was in place, identifying the workers that should have been monitored will be difficult. While we believe these issues fall outside of the specific question posed by the Board for evaluation, SC&A believes it should bring it to the Board's attention, due to its relevance to the broader issue of the LLNL SEC.

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We would be pleased to brief the Advisory Board and NIOSH on these results at your convenience. If you have any comments or questions, please contact me at 732-530-0104.

Sincerely,

John Mauro, PhD, CHP
Project Manager

cc: P. Ziemer, PhD, Board Chairperson
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Working Draft

SC&A REVIEW OF THE EVALUATION REPORT FOR THE LAWRENCE LIVERMORE NATIONAL LABORATORY (LLNL) SPECIAL EXPOSURE COHORT: *IN-VIVO COUNTING TIME PERIOD ISSUE*

Prepared by

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April 11, 2008

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.

INTRODUCTION/ISSUE

The National Institute for Occupational Safety and Health (NIOSH) has issued a Special Exposure Cohort (SEC) Petition Evaluation Report for Petition SEC-00092, Revision 0. The proposed class definition for this petition is as follows:

> *All employees of the Department of Energy (DOE), its predecessor agencies, and DOE contractors or subcontractors who were monitored, or should have been monitored, for internal exposure to mixed fission and/or activation product radionuclides while working at the Lawrence Livermore National Laboratory for a number of work days aggregating at least 250 work days from January 1, 1950 through December 31, 1973, or in combination with work days within the parameters established for one or more other classes of employees in the SEC.* (Petition SEC-00092)

The Advisory Board on Radiation and Worker Health (Advisory Board) has requested that SC&A research this class definition to determine if the cut-off date of December 31, 1973, is appropriate, based on the following NIOSH Evaluation Report (ER) statement:

> *NIOSH has access to only limited fission product bioassay data for the period prior to 1974, consisting of data available in NOCTS for less than 30 claimants, 325 gross beta results from MAPPER, and zinc-65 in vivo data for 1965 and 1966 for sixteen cyclotron workers. NIOSH has been unable to obtain additional in vivo counting results adequate for dose reconstruction for the period prior to 1974. The in vivo logbooks examined by NIOSH further indicate that LLNL staff members were routinely modifying the design of the in vivo facility during this timeframe, often operating it from a test scheme rather than from a programmatic bioassay scheme. For reasons stated in Section 5.1 above, NIOSH finds these limited pre-1974 bioassay data insufficient for development of sufficiently accurate co-worker fission product intake models.* (NIOSH 2007)

The ER further states:

> *…the proposed class cannot be restricted to a specific job title or occupation. Further, NIOSH does not have workplace monitoring documentation to demonstrate that fission and activation product were not used or stored in other areas of LLNL involved in radiological activities.*

Accordingly, NIOSH states that, "the NIOSH proposed class definition includes all known LLNL locations that handled or stored radioactive material."

CHARGE OF THE BOARD

The Board requested that SC&A determine whether the NIOSH assessment of the in-vivo counting facility is appropriate for restricting the class definition to the time period of January 1, 1950, to December 31, 1973.

SC&A APPROACH

SC&A reviewed the NIOSH SEC ER (NIOSH 2007), the in-vivo counting system logbooks (Anderson 1964 and 1966, and LLNL 1964 through 1981), the Year By Year History of LLNL document (LLNL 2002), and the draft site profile internal dosimetry technical basis documentation for LLNL (ORAUT 2007). The review of the in-vivo counting system logbooks was especially beneficial in determining the status of the whole-body counter system, its level of confidence and stability, and staff expertise. It is important in providing context to the assessment of the LLNL in-vivo whole-body counting system to review the history of whole-body counting and its development around the country.

The use of in-vivo body counters was in its early stage of development and application for routine use in the early 1960s. Development began with the prototype counter by Robley Evans using G-M tubes for radium measurements in living persons in 1937 (Stannard 1988), followed by Wright Langham in 1958 with his 4π liquid scintillation systems, HUMCO I in 1955 and HUMCO II at Los Alamos (ORAUT 2004 and Stannard 1988), and Martinelli's group at Argonne using a single large NaI(Tl) crystal system in 1961 (Stannard 1988). Other groups were experimenting with whole-body counting systems optimizing sensitivity, resolution, and calibration for various radionuclides, including the following:

- Purdue University, with a 2π system that they converted to a 4π system in 1961 (Kessler et al. 1968)

- Ken Swinth at Pacific Northwest Laboratory, who made progress in plutonium whole-body counting (Swinth 1966)

- Earl Palmer and Bill Roesch's shadow-shield whole-body counter at Hanford (Stannard 1988)

- The Rocky Flats whole-body counter in 1964 (Johnson 1965), with a method for predicting subject background for in-vivo plutonium measurements by Bistline at Rocky Flats (Bistline 1968)

- Plutonium-239 detection in vivo with a germanium-lithium array by Tyree and Bistline at Rocky Flats (Tyree and Bistline 1970)

- John Rundo at Harwell and Argonne and B.T. Taylor at Harwell in 1962 on measurement of plutonium in vivo (Rundo et al. 1968) Taylor and Rundo 1962, and Taylor 1969)

- D. Ramsden and R.G. Speight in England, AEEW-R 494, 1967, on the measurement of plutonium-239 in vivo (Ramsden and Speight 1967)

The LLNL health physics staff's work on their in-vivo monitoring capability took place during this backdrop of rapid advancement of the state-of-the-art in such monitoring technology. The logbooks by Anderson and his LLNL whole-body counter staff were reviewed by SC&A. These logbooks included Anderson 1964 (SRDB 35019), Anderson 1966 (SRDB 14074), and the LLNL whole-body counter logbooks from 1964 through 1981 (SRDB 35017, SRDB 35018, SRDB 35020 through SRDB 35031).

During the month of February, SC&A conducted telephone interviews with five individuals who either currently work at LLNL or are former LLNL employees. These individuals are knowledgeable of the history of the in-vivo counting systems, and the fission and activation product radionuclides generated and handled at LLNL. The first individual interviewed was a Health Physicist at LLNL working with the in-vivo counting systems during the early days of their development. The second individual interviewed is a Health Physicist currently working in the LLNL in-vivo system. He is very familiar with the history of the systems and is a custodian of most of the historical documentation on the in-vivo systems, including the logbooks of the individual who did much of the original research and calibration work with the systems. The third individual interviewed worked at LLNL as a Radiochemist and then as a Health Physicist from the early 1950s until retirement a few years ago, and as such, spent considerable time working in areas where fission and activation product radionuclides were handled at LLNL. The fourth individual interviewed is employed in the Radiation Safety Section in the Hazards Control Department at LLNL, and the fifth individual interviewed is a retired employee from LLNL with considerable historical knowledge of the handling of fission and activation product radionuclides at the laboratory. Two of the these interviewees were most directly involved and familiar with the history of the whole-body counters over the years.

ANALYSIS

The development of this new evolving technology, i.e., body counters at the various DOE sites, and the invention of new advanced detector systems (sodium iodide detectors, Phoswich detectors, silicon and germanium lithium drifted detectors, hyper-pure germanium detectors, solid state electronics, and computer advancements) out of necessity led to constant changes over the 1960s and early 1970s to keep pace with the improving state-of-the-art. The body-counter and his staff kept detailed logbooks of these changes and problems with sensitivity, resolution, amplifier and pre-amp drifting, calibration, evolution of detectors, etc., that occurred with the LLNL systems. SC&A's review of the body-counter logbooks and discussions with staff verified that evolving changes were being made as new detectors, new electronics, and new calibration phantoms were being developed, and when the new underground system was built, resulting in the normal stability problems that had to be overcome from 1964 through the early 1970s. These problems, likewise, existed at other sites during this same time period, examples of which are referenced in the preceding section, e.g., at Los Alamos, Argonne, Hanford, Rocky Flats, and overseas in some English facilities.

The LLNL logbooks (i.e., LLNL SRDB 35017, 35018, and 35019 [Anderson 1964]) specifically reference calibration and multiple counting of special groups of persons, such as ones exposed at the 90” cyclotron. Radionuclides that were addressed in these logbooks include Zn-65, Na-22, Co-57, Cs-137, Cf-252, Am-241, I-125, I-131, Cm-244, Pu-239, Tc-99m, Te-132, and I-132. In 1966, several termination body counts were performed and interpreted as “normal” or “abnormal.” If they were “abnormal,” there were attempts to positively identify the radioisotopes and at least make an estimate of the quantity, based on the spectra and a calibration; albeit, these are not explained or documented, and could be considered somewhat crude by today’s standards. The use of phantoms is noted in the logbooks of the late 1960s and early 1970s with a “resussie annie,” and in 1969, a REMAB, reportedly used for calibration. In 1968, it is noted that they started using thin crystal, 2” to 5” × 1/16” Be detectors. Prior to this, most of the counting appeared to be done with 5 × 4 and 3 × 3 detectors.

In December of 1967, a program of counting some new employees was started, but it is not clear how routine this was or what the criteria for selection of the subjects may have been (i.e., whether these were select groups of new employees or encompassed all employees). By 1969, it appears that many of the repeat counts performed on some of the special individuals counted from specific groups, such as the cyclotron group, involved use of both the 5 × 4 detector and the 2” to 5” × 1/16” Be detectors. In April of 1969, a group of persons involved in a spill in Building 151 were counted for potential exposure to Cm-244/246, Cf-252, and Am-241/240. The LLNL logbook (LLNL SRDB 35020, 1967–1969) discusses the work stabilizing and calibrating the new underground whole-body counter system. The remaining logbooks (LLNL SRDB 35021 through SRDB 35031) address the use of the system to count other radionuclides, use of SiLi (silicon lithium drifted) detectors (SRDB-35029 1975–1976), counting wounds, counting females, and the use of the new LLNL phantom for calibration. Based upon a review of the increased use of the whole-body counter for counting suspected uptakes in workers in the 1972 through 1973 timeframe (LLNL SRDB 35024 through SRDB 35026), and increased in-vitro bioassay analysis in 1974 for mixed fission products (noted in Table 5-1 of the ER report), it is apparent that by late 1973 or early 1974, LLNL now had better knowledge of the location of these various radionuclides and those workers at risk of exposure, which led to expanding the number of workers monitored and the frequency of sampling.

As noted by NIOSH in the ER, there were numerous counts made on individuals, some of which were for testing the background and stability of the system, and others for testing potential uptakes in workers involved in special projects. SC&A would hesitate to call these special whole-body counts as “testing” for uptakes in the experimental or developmental sense, but they also cannot be called “routine” or programmatic. Likewise, it cannot be determined from the logbooks if they monitored all individuals working around the fission and activation product radionuclides on a routine basis. The special counts of groups or individual workers appear to have been done more as a “yes or no” verification of uptakes. Accurate quantification and calibration data are not provided to be able to verify the values noted in the notebooks. It does appear that by 1974, the in-vivo counting systems were stabilized and calibrated with industry-recognized standard phantoms for in-vivo measurement of many of the different radionuclides they were monitoring for, and the monitoring of workers was becoming more routine and programmatic.

In the telephone interviews conducted with two of the interviewees, they stated that the counters were undergoing the normal changes that occurred at all the other sites during this time of advancing detector systems and electronics, but Anderson and his staff were monitoring workers frequently for suspected exposures while making improvements to the systems. They did admit that maybe not everyone who had the potential for exposure was necessarily being monitored routinely in those early years of the late 1960s and early 1970s, but that workers having suspected uptakes were monitored to confirm or deny uptakes had occurred. It was suggested that SC&A talk with an individual who had worked as a Radiochemist and a Health Physicist in many of those areas where fission and activation products were known to exist onsite. In locating this individual, discussions were held with two of the other interviewees (one who likewise had a long history at the national laboratories) that had handled fission and activation product radionuclides. These two individuals stated that fission and activation products were located at various locations around the site and not necessarily in specific locations, such as the radiochemistry and cyclotron areas, although one individual did note several specific designated buildings. They recalled fission and activation products existing in some of the following buildings: Buildings 231, 151, 251, and 101 (which later became 222 and 212).

It should be noted that in discussions with the individuals SC&A interviewed, concern was expressed over the fact that even after 1974, fission and activation product radionuclides were not necessarily used or stored in specific designated or segregated locations, and persons coming in contact with these radionuclides for monitoring purposes may not have been identifiable by job title, occupation, or their primary assigned job location in areas where these radionuclides might have been located.

FINDINGS AND CONCLUSIONS

It is SC&A's conclusion that the NIOSH statement in the LLNL SEC ER that bioassay data prior to 1974 were not sufficient for accurate coworker fission and activation product intake models is valid and can be substantiated. This conclusion is based on the known and reviewed history of the development of in-vivo body-counting at that time, an in-depth review of the historical LLNL whole-body counter logbooks, the Anderson logbooks, and information gained from SC&A interviews with staff familiar with the history of the body-counter systems.

SC&A finds that based on these stated facts, the in-vivo counting systems were sufficiently developed, calibrated, and stabilized by 1974 for routine monitoring use. SC&A further finds that the calculations performed for determining resolution, the use of state-of-the-art calibration phantoms, the calibrations for various radionuclides, the apparent stability of subject background counts, and system background counts recorded in the LLNL whole-body counter logbooks serve to verify that the system was capable of routine monitoring by 1974. Based on the information provided in the logbooks, SC&As believes that the expertise of the staff was adequate, and the sensitivity and resolution gave the systems sufficient capability and stability to be used for special case-by-case individual counts and for screening small groups for verification of uptakes from exposure incidents involving certain specific radionuclides in the late 1960s.

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