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RADIATION AND WORKER HEALTH

National Institute for Occupational Safety and Health

SC&A REVIEW OF WHITE PAPER, "NIOSH RESPONSE TO SC&A'S REVIEW OF THE SEC-00109 LANL ADDENDUM"

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1 (Draft)	11/16/2018	Changed some text references to DOE documents at DOE request.
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ABBREVIATIONS AND ACRONYMS

Advisory Board or ABRWH	Advisory Board on Radiation and Worker Health
AL	Albuquerque Operations Office
Ar	argon
CEDE	committed effective dose equivalent
CFR	Code of Federal Regulations
Ci	curie
CsI	cesium iodide
CTW	construction trade worker
DOE	U.S. Department of Energy
DOELAP	DOE Laboratory Accreditation Program
ER	evaluation report
G/MAP	gaseous mixed activation product
HPGe	high purity germanium
keV	kiloelectron volt
LAMPF	Los Alamos Meson Physics Facility
LANSCE	Los Alamos Neutron Science Center
L_C	critical level
MAP	mixed activation product
MDA	minimum detectable activity
MEI	maximally exposed individual
MFP	mixed fission product
mrem	millirem
NaI	sodium iodide
NIOSH	National Institute for Occupational Safety and Health
NOV	Notice of Violation
Np	neptunium
NTS	Noncompliance Tracking System
O	oxygen
ORAUT	Oak Ridge Associated Universities Team
OTIB	ORAUT technical information bulletin
PPE	personnel protective equipment
Pu	plutonium

RPP	radiation protection program
RWP	Radiation Work Permit
SALI	stochastic annual limit on intake
SEC	Special Exposure Cohort
SRDB	Site Research Database
Sv	sievert
TA	technical area
Th	thorium
U	uranium

1 INTRODUCTION AND BACKGROUND

In its September 12, 2018, white paper response (NIOSH 2018) to SC&A's review (2017) of the Los Alamos National Laboratory (LANL) Special Exposure Cohort (SEC)-00109 petition evaluation report (ER) Addendum (NIOSH 2017), the National Institute for Occupational Safety and Health (NIOSH) agrees that use of a 10 CFR Part 835 compliance milestone beginning on January 1, 1996, is not a sufficient basis to presume that "the absence of internal dosimetry records indicates that unmonitored workers were deemed unlikely to have received intakes resulting in a CEDE 0.1 rem or more from all occupational radionuclide intakes in a year" (NIOSH 2017, p. 17), as noted below:

> *NIOSH concurs with SC&A's assessment that program compliance may not be sufficient for demonstrating implementation of the radiation monitoring program. NIOSH also concurs that reliance on oversight findings may not be sufficient for validating that LANL had fully implemented 10 CFR Part 835. This appears particularly evident in the multiple pertinent findings identified in* [a 1999 LANL self-assessment]*, as SC&A points out later in its memorandum.* [NIOSH 2018, p. 6]

However, in acknowledging this agreement, NIOSH noted that it "does not rely solely on 10 CFR 835 compliance for the conclusion that unmonitored workers were unlikely to have received intakes resulting in greater than 100 mrem CEDE" (NIOSH 2018, p. 6). NIOSH contends that there are other evidentiary bases upon which this bounding assumption can be made. As clarified in this recent NIOSH response, these include the following:

1. A **programmatic basis** founded on the conclusion that "the field monitoring and contamination control programs at LANL were well-established and formalized by January 1, 1996," and "intended to ensure that unmonitored individuals were unlikely to receive intakes of 100 mrem CEDE" (NIOSH 2018, pp. 6, 2). In its review, NIOSH notes that "although 10 CFR 835 contains a lot of nuances and implementation guides that may have come out too late to impact RPP development by January 1, 1996, the important question is not overall implementation and compliance with 100 percent of 10 CFR 835, but rather, whether there was a program in place ensuring that unmonitored workers were unlikely to receive intakes resulting in 100 mrem CEDE" (NIOSH 2018, pp. 6). To support its contention about the adequacy of LANL's field monitoring program, NIOSH provides, in its response, a summary listing of numerous procedures, Radiation Work Permits (RWPs), surveys, sampling results, and event reports.

2. A **bioassay data adequacy and completeness basis** founded on a review of the primary LANL radionuclides—tritium, plutonium isotopes, and uranium isotopes—"for which bioassay data are abundant," that demonstrate ER Addendum intake rates are bounding (NIOSH 2018, p. 30). This review was undertaken, in light of "multiple issues regarding LANL's technical ability to monitor for various radionuclides" (p. 22), to answer the question: "Is the assignment of 100 mrem CEDE intakes for unmonitored workers likely to be bounding?" (p. 22). To support its contention about the adequacy of LANL's capability to monitor for radionuclides for which an exposure potential was present at LANL, NIOSH also provides, in its response, a summary of the radionuclide-specific

> *in vivo* intake values, by year, for 1969–2005. NIOSH, likewise, does not find any "significant technical shortfalls" (NIOSH 2018, p. 30) with regard to LANL's *in vivo* program during the period in question.

Based on a "weight of evidence" assessment of these two considerations, and its judgment that 10 CFR Part 835 represented a "paradigm shift" in DOE operations, NIOSH concluded:

> *Based upon its review of existing bioassay results, NIOSH finds that workers who were monitored for the primary radionuclides (uranium, plutonium, and tritium) were unlikely to have received intakes exceeding 2% of the SALI (or intakes that would have resulted in 100 mrem CEDE). NIOSH also believes that intakes to the unmonitored population would have been lower than that of the monitored population. NIOSH therefore concludes that unmonitored workers were unlikely to have received intakes of 2% of the SALI, and the assignment of 2% SALI intakes for unmonitored workers with access to controlled areas is bounding. NIOSH further finds no reason to believe that intakes of exotic radionuclides by unmonitored workers would be substantially different. In summary, NIOSH concludes that the weight of the evidence supports assignment of 2% SALI intakes for unmonitored workers, as proposed in the ER Addendum, is sufficiently bounding and claimant favorable.* [NIOSH 2018, pp. 30–31]

In this evaluation, SC&A addresses this conclusion in terms of its two key supporting bases, with more-specific issues addressed separately.

2 SC&A RESPONSES

2.1 SC&A RESPONSE TO NIOSH FINDING OF PROGRAMMATIC ADEQUACY FOR FIELD MONITORING AND CONTAMINATION CONTROL PROGRAMS AT LANL

NIOSH's white paper notes that:

> *The field monitoring and contamination control programs at LANL were well-established and formalized by January 1, 1996. A description of these programs, along with a summary of associated data available to NIOSH, was included in Section 6.1.1 of the SEC-00109 ER Addendum.* [NIOSH 2018, p. 6]

The information provided in support of its finding of programmatic adequacy[1] includes, for 1996–2005, "hundreds of radiological protection documents" from LANL that include RWPs, contamination surveys, area monitoring survey results, air sampling results, and radiological protection checklists (NIOSH 2018, p. 18). With respect to the RWPs reviewed, NIOSH noted that they tended to include required contamination surveys, personnel protective equipment (including respiratory protection), and radiation control technician coverage, but generally, **not**

[1] SC&A uses the term "programmatic adequacy" in this case to mean the adequacy and completeness of the bioassay program, both in terms of its definition, scope, and procedures as well as its demonstrably effective field implementation. It is recognized that this may not be necessarily the same as the bioassay program being "well-established and formalized," as described by NIOSH. However, the question of how adequacy is defined lies at the heart of this particular issue.

bioassay requirements. NIOSH noted that the RWPs reviewed "appear to have been designed to minimize the likelihood of intakes via engineering controls, personnel protective equipment (PPE), and respiratory protection," with elevated surface or airborne contamination presumably triggering "an assessment for the need for bioassay" (NIOSH 2018, p. 20). NIOSH provides two occurrence reports where this scenario played out, i.e., evidence of contamination triggering an assessment that led to bioassays being performed.

SC&A finds that the NIOSH conclusion that "field monitoring and contamination control programs at LANL were well-established and formalized by January 1, 1996" belies whether they were, in fact, being adequately carried out by LANL personnel. In its 2017 report, SC&A raised a concern on this question based on a self-assessment conducted by a team of health physicists in 1999, led by LANL ([redacted]). The assessment team included representatives from Savannah River Site and MJW Corporation/Mound (not so incidentally, these latter two organizations had just dealt with major U.S. Department of Energy [DOE] enforcement actions regarding the implementation of their respective bioassay programs). This LANL self-assessment found 10 key findings regarding inadequate implementation of the LANL bioassay program, including three that directly impaired LANL's ability to monitor individuals "likely to receive a committed effective dose of 0.1 rem (0.001 Sv) or more from all occupational radionuclide intakes in a year" (10 CFR 835.402(c)(1)). These included workers not providing bioassays when required by RWPs and the principal construction trade worker (CTW) subcontractor at LANL not enrolling all workers who were potentially exposed to radionuclides, as required. These findings led to a broad revamp of LANL's bioassay program procedures and processes that was completed in 2000.

NIOSH's response to what is apparently the only comprehensive validation of LANL bioassay program adequacy during 1995–2000 appears not to have been an investigation of whether these major programmatic shortfalls would have implications for the adequacy and completeness of LANL's recorded bioassay data in the late 1990s; instead, NIOSH finds that the self-assessment results are not "sufficient" for validating that LANL had fully implemented 10 CFR Part 835. (NIOSH 2018, p. 6). NIOSH then returns to its apparent thesis that workers were "unlikely to receive intakes of 100 mrem CEDE" because "LANL's field monitoring programs were designed and implemented" for that purpose (NIOSH 2018, pp. 2, 6, 9, 30), and that NIOSH has considerable dosimetry data for 1996–2005 that show doses for monitored workers were generally less than 100 millirem (mrem) committed effective dose equivalent (CEDE) and that "intakes for unmonitored workers would likely be even lower" (NIOSH 2018, p. 10).

SC&A finds this assessment shortsighted, discounting the need to gauge what constituted actual field monitoring practice, i.e., the reality of bioassay practice at LANL in terms of whether workers were appropriately identified for bioassays, whether those bioassays were actually carried out, and to what extent accountability was exercised at the laboratory to ensure such procedures were implemented. The 1999 self-assessment results and corrective actions in 2000 indicate substantial program inadequacies in this regard, undercutting NIOSH's assertion to the otherwise. This is not a question of proving (or not proving) 100 percent compliance with 10 CFR Part 835 as stated by NIOSH, but following a long-established precedent under the Energy Employees Occupational Illness Compensation Program Act to investigate and resolve evidence of inadequacy and incompleteness in worker monitoring data.

In its white paper, NIOSH indicates that the findings identified in a 1999 LANL self-assessment ([redacted]) should not be relied upon because they "may not be sufficient for validating that LANL had fully implemented 10 CFR Part 835"(NIOSH 2018, p. 9), and cites SC&A's support of that position. SC&A disputes that interpretation and finds that NIOSH has taken SC&A's statement out of context. While NIOSH "concurs" with the second part of SC&A's conclusion, below, the qualifying statement that precedes it (regarding the 1999 review) is seemingly overlooked:

> ***SC&A concludes that the 1999 LANL noncompliance notwithstanding (which derived from an independent review with outside reviewers),*** *solely relying on the lack of Notices of Violation (NOVs) and other recorded nonconformances as a benchmark of effective RPP implementation is questionable.* [SC&A 2017; emphasis added]

It needs to be reemphasized, as SC&A did in its 2017 memorandum, that oversight findings—particularly those of external regulatory oversight—are a "blunt instrument" for identifying "often imbedded culture-based workplace safety program gaps and deficiencies" (SC&A 2017, p. 3). However, as SC&A indicated above, LANL's internal self-assessment was **not** that form of oversight and represents one of the few effective means by which field implementation of health physics procedures could be validated. Given the timeframe and team composition of the review, it is clear that LANL was concerned about the implementation of its bioassay program and wanted to ensure that it was in substantive compliance with 10 CFR Part 835 (including § 835.402(c)(1) governing monitoring for individuals "likely to receive a committed effective dose of 0.1 rem (0.001 Sv) or more from all occupational radionuclide intakes in a year)." As an internal self-assessment led by LANL health physicists and advised by independent dosimetrists from other DOE sites, it was uniquely able to review bioassay program implementation for adequacy and completeness. Reporting was done under the aegis of the DOE enforcement program because that was incumbent on all DOE sites following the 120-day moratorium on enforcement actions for bioassay program noncompliances (as noted by SC&A in its 2017 report, self-assessment and self-reporting were cornerstones of the DOE enforcement program).

SC&A is not disputing that NIOSH has captured a considerable number of radiological control documents that illustrate a functioning field monitoring program, just that the number and scope of such documents do not necessarily equate, without some form of validation, to adequate **implementation** in the context of the data completeness necessary for dose reconstruction with sufficient accuracy.

SC&A recommends that the Work Group has NIOSH follow up on the 1999 LANL self-assessment results ([redacted]) and substantiate whether and how these reported program deficiencies impact the adequacy and completeness of bioassay results for 1995–2000.[2] A pertinent question is whether bioassay data are sufficiently complete, given evidence of incomplete worker bioassay program enrollments, inadequate use of checklists to identify radionuclides being handled, and nonparticipation of workers in required bioassays (particularly,

[2] At the August 23, 2017, Advisory Board meeting, NIOSH had indicated it would obtain more information on this assessment from LANL and make that information available to the Work Group and SC&A, but there is no mention of such a follow-up or its results in their white paper (ABRWH 2017, pp. 249–250).

transient CTWs). This question is particularly relevant given LANL's apparent reliance on engineering controls, PPE, and respiratory protection, backed up by RWP-driven surveillance of job contamination levels, to trigger an assessment for the need for bioassay.

2.2 SC&A Response to NIOSH Finding of Bioassay Data Adequacy and Completeness

In its response, NIOSH outlines the radiation dosimetry requirements for LANL before promulgation of 10 CFR Part 835 and notes that they were well-established and included action levels for monitoring of workers with a potential to receive 100 mrem CEDE from internal sources. However, as emphasized in SC&A's 2017 response, the DOE validation review in 1995 of LANL's radiation protection program (RPP) (DOE/AL 1995) likewise found that the radiation protection program, including radiation dosimetry, satisfied all 10 programmatic requirements of 10 CFR Part 835, including an onsite review of procedural implementation. However, without any uniform acceptance criteria[3] for what was needed in these procedures and how they were to be implemented, their actual use and implementation would remain in question. This was later illustrated, for LANL's bioassay program, in the results of the self-assessment conducted in 1999 (DOE/AL 2017).

In response to this concern, NIOSH makes the following point:

> *In SC&A's review of the SEC-00109 LANL ER Addendum, SC&A pointed out multiple issues regarding LANL's technical ability to monitor for various radionuclides and example of oversight findings where perhaps workers should have been monitored for internal dose according to the 10 CFR 835 rule, but apparently were not. NIOSH shares some of the concerns from the oversight findings, as discussed above in this document. In light of these concerns, the primary question still remains. Is the assignment of 100 mrem CEDE intakes for unmonitored workers likely to be bounding?* [NIOSH 2018, p. 22]

To answer this question, NIOSH looks to the primary LANL radionuclides—tritium, plutonium, and uranium—where there are over 450,000 *in vitro* records and over 100,000 *in vivo* records. Included in NIOSH's white paper are six tables, excerpted from ORAUT-OTIB-0062, *Internal Dosimetry Coworker Data for Los Alamos National Laboratory* (NIOSH 2009), that give intake values to be used in dose reconstruction for unmonitored LANL workers for any given year. From these data, NIOSH concludes that 100 mrem CEDE would be bounding of intakes for the primary radionuclides. NIOSH also "finds no reason to believe that intakes of exotic radionuclides by unmonitored workers would be substantially different" (NIOSH 2018, p. 30).

However, NIOSH offers no substantiation for this last finding about exotic radionuclides. As noted earlier in its white paper:

> *A class of LANL workers has been added to the Special Exposure Cohort* ***due to a lack of available bioassay data for "exotic" radionuclides.*** *This class includes all workers from the beginning of site operations in 1942 through 1995.* ***This lack of***

[3] The lack of uniform DOE-wide acceptance criteria was highlighted and referenced in SC&A's 2017 memorandum.

> ***bioassay data for "exotic" radionuclides has continued to persist to the present time.*** [NIOSH 2018, p. 22; emphasis added]

If bioassay data for exotic radionuclides are lacking and continue to be lacking, and were the central basis for the preceding SEC class, it would seem important for NIOSH to provide substantiation grounded in actual monitoring data, dose modeling, or even source term assessment (using the hierarchy of objective dose reconstruction methods) to demonstrate that the acknowledged conditions for the SEC class through December 31, 1995, had clearly changed by 1996.[4] While there are considerable bioassay data associated with the primary radionuclides, particularly plutonium, uranium, and tritium, this has always been the case for LANL and was determined by NIOSH and the Work Group not to be a valid consideration in determining the adequacy of bounding doses for exotic radionuclides in the SEC years prior to 1996 (ABRWH 2012a, pp. 5–12; NIOSH 2012, pp. 47–53).

NIOSH recognized, then, that the application or extension of bioassay results for plutonium and the other actinides would not be appropriate as a means to bound intakes of exotic radionuclides to unmonitored workers at LANL because of the following reasons:

- *Exposure for many exotics might be on an intermittent, experimental basis leading to episodic exposures that are not adaptable to chronic-exposure models.*
- *The controls in place for smaller bench-top-type operations might not have been as well-engineered as the controls in place for larger routine operations.*
- *The operations involving these exotics might have been of a sufficiently different nature as to preclude a direct comparison to those of U and Pu.* [NIOSH 2012, p. 48]

On this basis, a response to the central question posed in the NIOSH white paper—*Is the assignment of 100 mrem CEDE intakes for unmonitored workers likely to be bounding?*—would be clearly affirmative for the primary radionuclides and would remain uncertain for the exotic radionuclides. While NIOSH finds that there is no "evidence" suggesting that the exposure experience with exotics, in this case (i.e., 100 mrem CEDE), would be otherwise for unmonitored workers, such a comparison is flawed for the reasons stated without any new data or analysis to the contrary.

While SC&A acknowledges releases of, and occupational exposures to, airborne radionuclides, including exotics, had declined at LANL by the mid-1990s, SC&A does not share NIOSH's apparent support of LANL's contention that bioassay data are scarce for exotic radionuclides

[4] The white paper notes that "the ER Addendum presents a methodology for performing dose reconstructions for exotic radionuclides for LANL workers in the absence of bioassay during the 10 CFR 835 era" (NIOSH 2018, p. 12). However, as noted by NIOSH, "the primary basis for this proposed method was the legal requirements set forth in 10 CFR 835 that went into effect on January 1, 1996" (NIOSH 2018, p. 22). The Addendum also cites ORAUT-OTIB-0054 (NIOSH 2015) methodologies that are only applicable to reactor or reactor fuel mixed fission product (MFP) and MAP source terms (i.e., not MAPs from accelerators such as the Los Alamos Neutron Science Center [LANSCE]). Without a presumption of compliance, these Addendum methodologies would need to be re-justified by NIOSH.

because "workers were not required to have been monitored for them" (NIOSH 2018, p. 22). As noted in Work Group meetings and reports, LANL responses, and DOE oversight reviews,[5] LANL's *in vivo* program did not focus on exotic radionuclide monitoring, a circumstance that predated 10 CFR Part 835. What heretofore has been lacking is a bounding LANL (or NIOSH) dose assessment for exotic radionuclide exposure that shows occupational doses would be below the threshold of 100 mrem CEDE per year by 1996.

On what is the assumed 100 mrem CEDE bounding dose for exotic radionuclides to be based if the following are true: (1) the compliance basis of 10 CFR Part 835 is no longer a sufficient basis for benchmarking 100 mrem CEDE, (2) the use of primary radionuclide bioassay results to bound or compare those of exotic radionuclides is inappropriate, (3) bioassay data are found to be likely incomplete and program implementation inadequate from the 1999 LANL self-assessment, and (4) bioassay data for exotic radionuclides remain unavailable, as acknowledged in the ER and NIOSH white paper? A NIOSH judgement based solely on what is taken to be apparent program improvement in the 1990s would not seem to be enough, considering the substantial evidence to the contrary.

2.3 SPECIFIC ISSUES

2.3.1 10 CFR Part 835 as a Paradigm Shift

The white paper indicates that "NIOSH believes that the 10 CFR 835 era represents a paradigm shift in DOE operations" (NIOSH 2018, p. 6). SC&A agrees that the 10 CFR Part 835 implementation period brought about greater accountability to safety and health requirements. However, as emphasized in SC&A's 2017 memorandum, that accountability did not necessarily begin on January 1, 1996. Self-assessments performed by Los Alamos in 1999 ([redacted]), SRS in 1998 (Kornacki et al. 1998), and Mound in 1997 (DOE 1998a) for their respective sites under the aegis of the Price-Anderson enforcement program found significant deficiencies in the implementation of occupational bioassay programs that impaired field monitoring, including "ensuring that unmonitored workers were unlikely to receive intakes resulting in 100 mrem CEDE" (NIOSH 2018, pp. 6–7). The latter two were of sufficient concern to DOE (combined with similar findings at three other DOE sites) to prompt a 120-day "moratorium" for DOE-wide enforcement actions related to bioassay program deficiencies beginning in December 1998 to enable **all** DOE operating contractors to self-assess their bioassay programs, take necessary corrective actions, and report program status to DOE (DOE 1998b, DOE 2000).

As noted in this DOE directive, the need for DOE-wide self-assessments during the moratorium was found necessary given the "commonality" of bioassay program deficiencies that included lack of formalized and approved procedures, failure to implement program requirements, non-collection of and participation in job-specific and special bioassays, and failure to maintain accurate worker dose records (DOE 1998b, pp. 1–3). For LANL, it is particularly noteworthy that the 1999 bioassay program deficiencies (10 corrective actions to be completed by 2000) ([redacted]), were preceded by bioassay program deficiencies from another self-assessment in 1997 (10 corrective actions to be completed by 1998) ([redacted]). This

[5] For example, ABRWH 2012b, NIOSH 2012, LANL 2013, and DOE 2001.

corroborates DOE's further finding, as contained in its moratorium directive, that even when bioassay program deficiencies were identified by contractor self-assessments, "corrective actions taken have been inadequate to prevent recurrence of identical [bioassay and dose assessment] problems" (DOE 1998b, p. 3).

Whether "there was a program in place ensuring that unmonitored workers were unlikely to receive intakes resulting in 100 mrem CEDE," as noted by NIOSH (2018, pp. 6–7), is a condition that needs to be critically reviewed and established on a site-by-site basis as a function of available information about program adequacy and completeness. It should not be a standing assumption, regardless of whether 10 CFR Part 835 compliance is, or is not, its basis.

2.3.2 Technological Limitations of *in vivo* Capability

NIOSH does not share many of the concerns identified by SC&A about historical technological limitations of the LANL *in vivo* program, as noted in its white paper response (NIOSH 2018, p. 12). The comments summarized by SC&A in its 2017 memorandum regarding these technology-based concerns were taken directly from interviews with LANL internal dosimetrists and were originally cited in SC&A's 2010 review of the ER (SC&A 2010). SC&A is, indeed, aware of the use of germanium detectors at LANL during the period in question. The following is the preface to the same LANL interview comments, as provided in SC&A 2010, which, in turn, had been drawn from an earlier edition of ORAUT-TKBS-0010-5, *Los Alamos National Laboratory – Occupational Internal Dose* (NIOSH 2004a):

> *In 1970, an* in-vivo *counter capable of measuring four separate regions of the body began operation…. Twin Phoswich (CsI and NaI) detectors were placed over the lungs. The two layers of the detector were capable of simultaneously, yet separately, monitoring chest burdens for 10–250-keV photons (NaI), and 250–2,000-keV photons (CsI) for a qualitative assessment of a variety of fission and activation radionuclides. A planar High Purity Germanium (HPGe) detector monitored the region between 10 keV and 250 keV with excellent energy resolution, and could be positioned over the liver or thyroid as needed. Finally, an HPGe (previously a GeLi) detector was positioned under the prone subject. This detector was primarily for whole-body assessment and has good photon energy resolution in the range of 10–2,000 keV. This system could both identify radionuclides and quantify the body burden.* [SC&A 2010, p. 11]

SC&A provided the excerpted comments in its 2010 report (SC&A 2010) based on the LANL interviews to illustrate that the technology available to LANL for monitoring exotic radionuclides paced the implementation of that technology. This was often dependent on judgments about whether mixed activation products (MAPs) or MFPs figured in a worker's exposure potential, whether a dosimetrist was actually focused on source terms beyond the primary radionuclides, and whether one could discriminate a corresponding spectrum peak for a these exotic radionuclides when available detectors of the time may not have been sufficiently sensitive, particularly at the lower energy regions.

As noted in ORAUT-TKBS-0010-5:

> *An* in vivo *count spectrum is not analyzed for a fission or activation product radionuclide unless a peak that is associated with that nuclide is visible in the spectrum. When that peak is visible, the suspected nuclide is added to the library and the spectrum is reanalyzed. Visual or non-library-driven software recognition of a peak can be subjective and not directly correlated to MDA or L_C calculations, especially with the broad peaks that are associated with scintillation detectors. For whole-body counts, it is not reasonable to assume that a worker was exposed to or is being monitored for all radionuclides potentially reportable simply because an MDA was determined and listed on the report.* [NIOSH 2013, p. 47]

Given NIOSH's and SC&A's original concerns about the lack of available *in vivo* results for MAPs and MFPs, despite the availability of state-of-the-art counter technology, SC&A had interviewed internal dosimetrists to better ascertain actual practice in this regard. Our summary of comments, as presented in SC&A's 2017 report, was consistent with NIOSH 2013, with one clarification needed.

It needs to be clarified that LANL's twin Phoswich detectors were replaced by twin three-detector arrays of HPGe detectors in 1999, with the Phoswich and germanium systems being operated concurrently during the 1998–1999 period. The HPGe lung counter has 10–300 kiloelectron volt (keV) and 80–3,000 keV ranges, so a lower sensitivity for certain fission and activation products can be obtained (NIOSH 2013). SC&A agrees that Phoswich detectors were used in conjunction with germanium detectors, but when the former detectors were replaced with HPGe lung counters in 1998, it opened up the lower energy spectrum common for a number of MAPs and MFPs to improved peak discrimination and therefore, better detection.

2.3.3 DOE Oversight Finding in 2001 about Mixed Activation Product Monitoring for LANSCE and Thorium-232

Regarding the 2001 DOE oversight finding, NIOSH indicates that it does not share SC&A's concern over the exclusion of thorium-232 (Th-232) monitoring capability in monitoring matrices and the absence of MAPs radionuclides for LANSCE in the *in vivo* program library. In its supporting explanation, it appears that NIOSH is conflating LANL's *in vivo* technical capability to detect Th-232 and MAPs using germanium detector technology with actual practice. While the technology existed at LANL at the time of the DOE audit, an agreement was lacking between the *in vivo* laboratory and the internal dosimetry program to ensure ready capabilities to monitor for incident or non-routine exposures. As DOE pointed out, the "*in-vivo* monitoring matrices should include the capability to monitor for Th-232" and that "without [the library of radionuclides of concern from LANSCE], the *in vivo* laboratory cannot identify monitoring strategies or ensure adequate energy calibrations" for LANSCE emissions (DOE 2001, p. 9). However, it is also clear that LANL could deploy its *in vivo* monitoring for Th-232 for special bioassays, if necessary, as in the case of the international traveler cited by NIOSH (NIOSH 2018, p. 16).

NIOSH discussed this specific issue at the April 29, 2010, LANL Work Group meeting:

> *DR. NETON: Yes. I guess what I'm concerned about in talking to the dosimetrists at Los Alamos, anybody you talk to probably, is that, yes, you're a plutonium lab essentially. This is an accelerator over here with a short life…*
>
> *I think just walking down and validating whether or not this new robust system was actually being applied uniformly, beyond the primaries, to things that certainly the HPs may have considered not a big deal would be very important because I think it's possible that because of the nature of the source terms at a glance, even though they were an exposure pathway, they might not have been sort of front and center to those kinds of controls and that kind of responsiveness.*
>
> *And certainly one review as late as 2001 seems to suggest that it took DOE whacking the bioassay program and the in vivo program on the head to get their attention that they weren't doing what was prescribed in terms of monitoring LANSCE, being able to monitor LANSCE.* [ABRWH 2010, pp. 83–84]

With regard to LANL monitoring capabilities for Th-232, the DOE assessment in 2001 indicated that a "review of the internal dosimetry monitoring matrices for internal dosimetry evaluation program indicated that this program might be required to analyze for thorium-232 (Th-232) on a routine basis and for an accident scenario since this source term is present at LANL" (DOE 2001, p. 9). DOE was clear that "at this time there are no personnel who have been identified as requiring routine monitoring for Th-232" (p. 9). However, the issue was the need for LANL to include the capability to monitor Th-232 in its *in vivo* monitoring matrices. As noted by DOE, an apparent gap existed in LANL capabilities:

> *Interviews with the* in-vivo *laboratory staff indicated that they were not aware of the need for this capability. The* in-vivo *laboratory does have a phantom for thorium calibration; however, the* in-vivo *procedures call for thorium monitoring to be performed by the phoswich system. This system is currently not in use. While the system could be brought into operation if needed, the* in-vivo *staff indicated that there were no immediate plans to do so. Their plan was to use the newer germanium system for all routine analysis. To provide the thorium capability in case of incidents, the* in-vivo *laboratory should maintain the phoswich system consistent with this need or update their procedure and/or calibrations to permit thorium monitoring on the germanium system.* [DOE 2001, p. 9]

On this basis, while SC&A agrees with NIOSH's claim that LANL had the "technical capability" to monitor for Th-232 (and other MAPs), SC&A finds, as did DOE, that the exclusion of Th-232 from LANL *in vivo* monitoring matrices and MAPs from the *in vivo* monitoring library would make it problematic for this monitoring to be accomplished adequately.

2.3.4 Exposure from Unevaluated Neptunium-237 Sources

Despite SC&A's identification of other neptunium-237 (Np-237) source terms that would bear a review for exposure potential, NIOSH contends that LANL would have limited unmonitored

doses to 100 mrem CEDE and therefore, NIOSH's proposed bounding dose would be appropriate for any such exposures. SC&A has already addressed its concern about NIOSH reliance on the design and implementation of the LANL field monitoring program after 1995 as the basis for applying a 100 mrem CEDE bounding dose. NIOSH should evaluate the exposure potential for all identified Np-237 sources and show that they can be bounded.

2.3.5 Relevancy of DOELAP Accreditation Milestone

NIOSH indicates that it "does not agree that DOELAP accreditation is relevant for full compliance with 835.402 and 835.702" and notes that "DOELAP is not a dosimetry standard," but rather, a performance standard (NIOSH 2018, p. 7). SC&A believes that NIOSH misunderstands its comment, and the context in which it was being made, which is reproduced below:

> *If anything, core requirements for and change to how DOE internal dosimetry programs were implemented did not come until the internal dosimetry technical standard of 10 CFR Part 835 was coupled with an accreditation requirement (for overall dosimetry* ***program functionality****) under DOELAP in the 1998 amendments to the rule, which required all sites to achieve accreditation by January 1, 2002.* [SC&A 2017, p. 4; emphasis added]

As noted, SC&A acknowledges that the DOE Laboratory Accreditation Program (DOELAP) addresses the functionality of key elements of the dosimetry program, not the dosimetry, itself. However, based on experience at other DOE sites (e.g., Sandia National Laboratory and Brookhaven National Laboratory), full compliance with 10 CFR Part 835 was not achieved for internal dose assessment and recordkeeping for some sites until the DOELAP accreditation process was well underway.

In fact, for LANL, in response to an earlier (1997) 10 CFR Part 835-based compliance finding regarding bioassay program deficiencies, expedited action was initiated to "meet the requirements of the *Department of Energy Laboratory Accreditation Program for Radiobioassay" (DOELAP)*" ([redacted]). LANL noted that "an assessment of current operations and the development of a Plan/Program that will meet the DOELAP accreditation standards" would be undertaken and that this assessment would be used "to identify and eliminate any weakness found in the [bioassay] program." This additional compliance finding of weaknesses in the LANL bioassay program and the 10 action items (including DOELAP accreditation) for which LANL made a subsequent, formal commitment to DOE under the enforcement program further underscore that the LANL bioassay program was not "well-established and formalized" by 1996, and that both LANL and DOE considered DOELAP accreditation to be relevant for ensuring 10 CFR Part 835 compliance.

2.3.6 Mixed Activation Products and Dose Assessment

In response to a NIOSH inquiry, LANL noted that its internal dosimetry monitoring programs are established on an "as-needed basis" and that monitoring is only required if a given radionuclide "represents a significant internal exposure hazard" and if "workers are likely to receive 100 mrem [annually] from internal exposure" (LANL 2013, p. 2). However, as noted

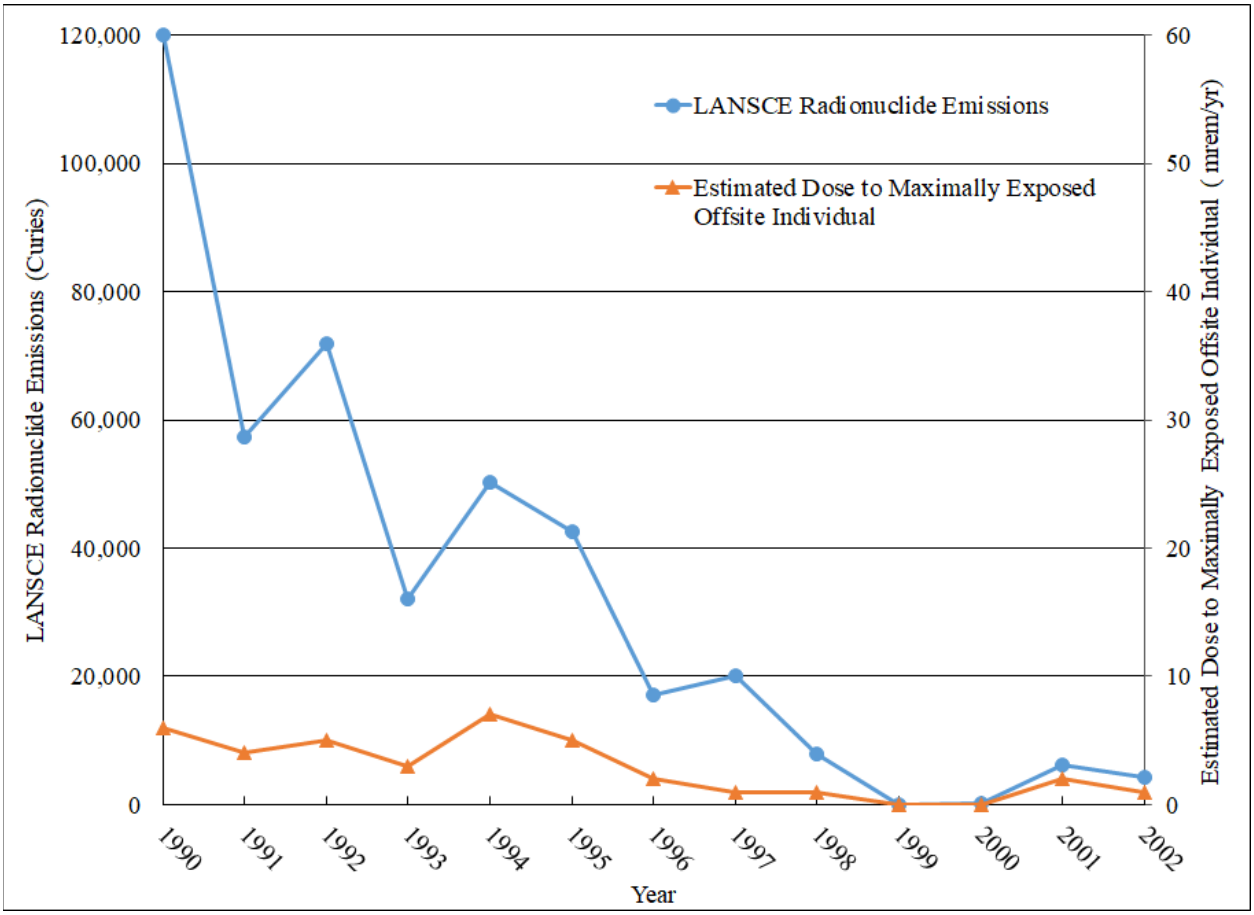
elsewhere in this report, and as discussed at length in previous Work Group meetings, LANL had the *in vivo* program and technological capability since the 1970s to monitor for many MAPs and MFPs but clearly did not address exotic radionuclides as a priority, instead focusing on plutonium, uranium, tritium, and other primary exposure sources.

The lack of *in vivo* bioassay results belies the historic presence of airborne exposure pathways for workers due to MAPs from sources such as LANSCE (or LAMPF, the Los Alamos Meson Physics Facility, as it was originally called). LAMPF/LANSCE has been the dominant source of airborne radionuclides at LANL since the late 1970s (NIOSH 2004b, p. 43). In the 1970s–1980s, MAPs, while relatively short-lived, historically accounted for the largest boundary dose and individual dose from all of LANL operations, with reported doses "among the highest nationwide among DOE operations in 1979" (NIOSH 2004b, p. 43). The estimated maximum site boundary dose levels varied according to beam energy, operational workload, and stack holdup controls, which affected the total MAP emission activity levels. These have declined steadily over time with improved emission controls and operational changes from 734,000 curies (Ci) in 1984, to 120,000 Ci in 1990, to 50,200 Ci in 1994, to 20,000 Ci in 1997, and to almost zero (43 Ci) in 1999 (Bowen et al. 1986, p. 1; NIOSH 2004b, p. 43; LANL 1994, p. 5; LANL 2002). For 1978, with an annual MAPs radionuclide release of 117,000 Ci from LAMPF (at 40% to 50% of design beam time), a maximally exposed individual (MEI) dose of 126 mrem was calculated at the site boundary based on "conservative plume diffusion models," with a corresponding measured dose of 14 mrem (NIOSH 2004b, p. 43).

While it is true that the "use of exotic radionuclides at LANL was relatively rare, not nearly as prevalent as the use of the primary radionuclides (plutonium, uranium, and tritium), for which there is an abundance of bioassay data" (NIOSH 2018, p. 12), the exposure potential for unmonitored workers to intakes of airborne emissions of MAPs was clearly of some significance given the historical boundary doses that were modeled and monitored. Without substantiation that upper-bound doses from these sources did not exceed 100 mrem per year for the maximally exposed unmonitored onsite worker after 1995, LANL's (and NIOSH's) assertion about monitoring appears to have no objective basis.

To gain some perspective in this regard, SC&A reviewed LANL environmental surveillance reports for the period 1990–2000 and found that (as noted previously) total MAPs emissions from LANSCE had declined from 120,000 Ci to almost zero by 2000, with a corresponding offsite MEI drop of 6 mrem to 0.4 mrem in that same period (LANL 2018). This is shown graphically in Figure 1.

Figure 1. Annual LANSCE Radionuclide (G/MAPs) Emissions and Offsite MEI, 1990–2002 (adapted from LANL 2003, 2018)



SC&A also reviewed the technical basis document for occupational environmental dose, ORAUT-TKBS-0010-4, Revision 01 (2010), and found that NIOSH had modeled occupational skin and whole-body dose immersion doses for "gaseous/mixed activation products" (G/MAPs) for LANSCE (NIOSH 2010, p. 23–24). This was done for Technical Area (TA) 53 (LANSCE), and two nearby work locations, TA-21 (Defense Programs East; 2,000 meters south-southeast of TA-53) and TA-72 (700 meters south-southeast of TA-53) that were predominantly downwind (NIOSH 2010, p. 24). Using Gaussian equations to model dispersion from the LANSCE stack (assuming no adjustment for dispersion factors and a ground-level release for claimant favorability), the estimated average external dose (immersion) from G/MAPs released from LANSCE were as shown in Table 1 for the 1990–2000 period. (NIOSH 2010, p. 47). In Table 1, the estimates assume the receptor is at 500 m from the source for 2,000 hr/yr, with no plume depletion, and no plume rise (stack height is zero).

Table 1. Estimated Average Occupational External Doses from G/MAPs released from LANSCE (TA-53) (mrem/yr) (excerpted from NIOSH 2010, Table 4-29)

Year	Skin [(a)]	Whole Body [(b)]
1990	190 mrem	120 mrem
1991	90 mrem	57 mrem
1992	110 mrem	71 mrem
1993	51 mrem	32 mrem
1994	79 mrem	49 mrem
1995	69 mrem	43 mrem
1996	17 mrem	11 mrem
1997	32 mrem	20 mrem
1998	12 mrem	7.7 mrem
1999	0.047 mrem	0.3 mrem
2000	1.1 mrem	0.68 mrem

a. Calculated using skin dose factor for O-15 from Eckerman and Ryman (1993).
b. Calculated using whole-body dose factor for Ar-41 from Eckerman and Ryman (1993).

As Table 1 shows, average whole-body dose declined from an estimated 120 mrem per year in 1990 to 0.68 mrem per year by 2000, with a range of 0.3 to 20 mrem during the 1996–2000 period (of relevance to this SC&A review[6]). For occupational environmental exposures at the adjacent facilities at TA-21 and TA-72, the respective average whole-body dose ranges during this same period were 0.02 to 7.6 mrem, and 0.06 to 4.2 mrem (NIOSH 2010, Table 4-30).

While these constituted **average** estimated occupational doses from G/MAPs emissions for workers at LANSCE and nearby facilities, the decline of LANSCE emissions from the 1990–1995 period through to 1999 is marked and, upon further review, may warrant further attention as a starting point to characterize maximum annual occupational exposure to G/MAPs and other airborne exotics.

2.4 APPENDIX A: SEC-00109 LANL PETITIONER ISSUES AND RESOLUTIONS

This appendix provides a compilation of all the issues identified over the years by the SEC-00109 LANL petitioner, along with corresponding resolutions; this review was requested by the Advisory Board on Radiation and Worker Health (Advisory Board) LANL Work Group. This compilation is provided in the form of a table that identifies the following for each issue: the petitioner issue, the forum or document source, date, supporting documents, and NIOSH resolution. SC&A reviewed this Appendix following the initial issuance of the NIOSH response (issuance of a revised Appendix was delayed until after issuance of the NIOSH response).

Beyond SC&A's general comments in its draft report (SC&A 2018) about the assumption of 100 mrem CEDE/year for any unmonitored exposures after 1995 (an assumption that figures in

[6] SC&A selected this subset of the SEC evaluation period as one of relevance to 10 CFR Part 835 program implementation.

many of the responses in Appendix A), SC&A has one specific comment on Appendix A that requests a clarification from NIOSH regarding how it would bound occupational doses from mixed activation and fission products for the post-1995 period. As a function of NIOSH's intended reassessment of such exotic internal exposures (ABRWH 2018), this concern may also be resolved in the course of that planned review.

This request for clarification was forwarded to NIOSH and the Work Group in a January 4, 2019, transmittal (SC&A 2019).

3 CONCLUSIONS

NIOSH has agreed that compliance alone with 10 CFR Part 835 may not be a sufficient basis for validating that unmonitored workers at LANL would not have been likely to receive 100 mrem CEDE intakes. In its white paper, NIOSH has provided what it considers additional substantiation as it pertains to exposures to both primary and exotic radionuclides (e.g., MAPs and MFPs), including a review of bioassay results for primary radionuclides (plutonium, uranium, and tritium) monitored at LANL and a summary of available radiological control documents that are considered exemplary of the overall strength of the LANL field monitoring program. NIOSH also stresses its belief "that the 10 CFR 835 era represents a paradigm shift in DOE operations" (NIOSH 2018, p. 6). In its conclusion, NIOSH finds that this "weight of the evidence" continues to support the premise that unmonitored LANL workers were unlikely to have received intakes greater than 100 mrem CEDE per year.

SC&A respectfully disagrees that NIOSH has provided any new evidence that is sufficiently persuasive to contribute to the weight of evidence for this SEC-related evaluation, other than for the LANL primary radionuclides. As noted earlier in this response, a comparison of exposure results for these primary radionuclides as a means to compare or bound those of exotic radionuclides was discussed extensively in Work Group sessions and has already been deemed inappropriate. Likewise, any review of LANL field monitoring program performance would need to consider the implications of the 1999 LANL self-assessment of its bioassay program, which found not only broad noncompliances with 10 CFR Part 835, but also evidence of likely bioassay data incompleteness due to improper bioassay enrollments by the principal CTW contractor and nonparticipation by workers in the bioassay program. Without objective evidence to substantiate it, this assumption of a 100 mrem CEDE intake per year benchmark is no different than the former presumption based on regulatory compliance.

It would seem that two central questions remain to be resolved. First, what is the adequacy and completeness of the LANL bioassay program in light of the 1999 findings? Second, can potential doses to unmonitored workers be bounded for exposures to exotic radionuclides?

For the first question, there is a need to follow up on the findings of the 1999 LANL self-assessment and ascertain whether those findings are indicative of a serious programmatic deficiency that would impair the completeness of bioassay results and records for workers through 2000 (when corrective actions were put into place). If there is evidence that a substantial number of workers were not enrolled in bioassay programs as required or that many workers did not provide required bioassays, NIOSH would need to consider whether that would render

bioassay records inadequate and incomplete for purposes of dose reconstruction with sufficient accuracy.

For the second question, NIOSH has already modeled occupational skin and whole-body immersion doses for "gaseous/mixed activation products" from LANSCE, using Gaussian dispersion models and conservative dose assessment factors, and found average worker whole-body doses (but not maximum exposed worker doses) to decline from 20 mrem per year to 0.6 mrem per year during the 1995–2000 period. It would seem that these modeled dose estimates may provide a starting point for further review of how potential occupational exposures to G/MAPs can be characterized during the time period of interest after January 1, 1996. It is unclear how the other radionuclide constituents ("exotic alpha-emitters" and "fission products") (NIOSH 2017, p. 3) would be addressed, but similar source-term or air sampling-based modeling estimates would seem feasible.[7]

Finally, the fundamental question for the Work Group comes back to the established basis for the preceding SEC class for LANL. If compliance with 10 CFR Part 835 is no longer a valid reason for applying a 100 mrem CEDE for unmonitored workers, on what basis is the acknowledged pre-1996 "inability to bound unmonitored intakes of exotic alpha-emitters, fission products, and activation products" (NIOSH 2017, p. 3) to be resolved such that those potential exposures can now be bounded in dose reconstruction? The lack of bioassay data for exotic radionuclides confounded dose reconstruction before 1996, and there is no new evidence presented by NIOSH of any demonstrable changes in field monitoring, *in vivo* analysis results, or recordkeeping beginning on January 1, 1996, that would resolve the issue other than the implementation of 10 CFR Part 835, which has now been discounted as a sole deciding factor.

The NIOSH weight-of-evidence conclusion that the same 100 mrem CEDE benchmark can now be based on LANL's "well-established" field monitoring and contamination control programs coupled with "state-of-the-art counting equipment…staffed with competent professionals" (NIOSH 2018, p. 30) is reminiscent of past Work Group deliberations contrasting LANL's recognized technical capability versus its actual practice, in this regard. These were ultimately decided by both NIOSH and the Advisory Board, in terms of recommending an SEC class through 1995, on actual data unavailability, i.e., the lack of bioassay data for exotic radionuclides and lack of applicable dose reconstruction methods, **not** the extensive bioassay program requirements, procedures, technology, and professional expertise that made such field monitoring feasible at LANL but ultimately not realized in a way that dose reconstruction could be accomplished with sufficient accuracy.

[7] SC&A provides this additional perspective for the Work Group and NIOSH based on its broader review, in this case, of relevant data and documentation not addressed in the ER Addendum or NIOSH's white paper. However, SC&A's findings and conclusions as contained in this response paper only address the issues, findings, and conclusions presented by NIOSH in these two aforementioned evaluation documents for Petition SEC-00109.

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