NIOSH Response to NTS Report NC ID 484 (LANL)

Response Paper

National Institute for Occupational Safety and Health

March 26, 2019

Chris Miles
Oak Ridge Associated Universities Team

Reviewed by LaVon Rutherford
Division of Compensation Analysis and Support

PURPOSE

This white paper responds to Noncompliance Tracking System (NTS) report NC ID 484 (DOE, 1999) that resulted from a 1999 LANL self-assessment (Brackett and La Bone, 1999). This paper:

- Discusses the background details that drove the self-assessment
- Lists the findings and observations identified in the self-assessment
- Addresses the resulting deficiencies identified in the NC ID 484 report
- Discusses the corrective actions taken by LANL to address the deficiencies
- Addresses how these deficiencies and remedies impact the ability to bound dose

BACKGROUND

In the SEC-00109 Petition Evaluation Report, Rev. 1, dated August 13, 2012 (NIOSH, 2012), NIOSH defined a single class of employees for which NIOSH cannot estimate radiation doses with sufficient accuracy. The class included all employees of the Department of Energy, its predecessor agencies, and their contractors and subcontractors who worked at the Los Alamos National Laboratory (LANL) in Los Alamos, New Mexico from January 1, 1976, through December 31, 1995. The dose reconstruction limitations identified during the specified class period included the inability to bound unmonitored intakes of exotic alpha-emitters, fission products, and activation products.

NIOSH selected the December 31, 1995 end date for the class based on its presumption that by January 1, 1996, LANL would have been in full compliance with 10 C.F.R. pt. 835, *Occupational Radiation Protection,* paragraphs 402 and 702 (10 C.F.R. pt. 835, 2018), which state:

> ***§835.402 Individual monitoring.***
>
> *(c) For the purpose of monitoring individual exposures to internal radiation, internal dosimetry programs (including routine bioassay programs) shall be conducted for: (1) Radiological workers who, under typical conditions, are likely to receive a committed effective dose equivalent of 0.1 rem (0.001 sievert) or more from all occupational radionuclide intakes in a year.* (10 C.F.R. 835.702)
>
> ***§835.702 Individual monitoring records.***
>
> *(a)Records shall be maintained to document doses received by all individuals for whom monitoring was required pursuant to §835.402 and doses received during planned special exposures, accidents, and emergency conditions* (10 C.F.R. 835.702).

The 10 C.F.R. pt. 835 rule became effective on January 13, 1994 and required full compliance by January 1, 1996 (DOE/EH-0575, 1997).

In the SEC-00109 Petition Evaluation Report Addendum, dated April 24, 2017 (NIOSH, 2017), NIOSH relied heavily on a presumption of compliance with 10 C.F.R. pt. 835 to conclude that, during the period from January 1, 1996 through December 31, 2005, unmonitored workers were unlikely to have received intakes of radioactive materials that would have resulted in 100 mrem CEDE per year.

In its review of the SEC-00109 petition evaluation report addendum (SC&A, 2017), SC&A questioned the use of a presumption of compliance with 10 C.F.R. pt. 835, stating:

> *Program compliance with 10 CFR Part 835, while necessary under DOE's Price-Anderson regulatory framework, is not sufficient for demonstrating that actual radiation program practice is adequate.*

In support of this position, SC&A cited Noncompliance Report NC ID 484. NC ID 484 was based on a self-assessment of the LANL Internal Dose Evaluation Program (IDEP) conducted on March 22–25, 1999 by representatives from Savannah River Site (SRS), MJW Corporation, LANL's Radiation Protection Services Group (ESH-12) and Quality Assurance Group (ESH-14).

In the response paper (NIOSH, 2018) to SC&A's review of the SEC-00109 evaluation report addendum, NIOSH concurred with SC&A's assessment that compliance with the 10 C.F.R. pt. 835 milestone may not be sufficient for demonstrating actual implementation of the corresponding radiation monitoring program requirements. NIOSH also concurred that reliance on oversight findings may not be sufficient for validating that LANL had fully implemented 10 C.F.R. pt. 835.

However, NIOSH did indicate in its response paper that it does not rely solely on 10 C.F.R. 835 compliance for the conclusion that unmonitored workers were unlikely to have received intakes resulting in greater than 100 mrem CEDE. LANL's field monitoring programs were designed and implemented for the purpose of ensuring that unmonitored individuals were unlikely to receive intakes of 100 mrem CEDE. Also, NIOSH has a substantial amount of internal dosimetry data for LANL workers. These data show that intakes for monitored workers during the 1996-2005 time period were generally less than 100 mrem CEDE and NIOSH believes that intakes for unmonitored workers would likely have been even lower.

In spite of these NIOSH conclusions, concerns persist over how the deficiencies identified in NC ID 484 could potentially affect NIOSH's ability to bound unmonitored worker intakes. This issue was discussed at length at the December 13, 2018 LANL Work Group meeting. This white paper more fully evaluates Noncompliance Report NC ID 484, including what led to the deficiencies being identified, how they were resolved, and what potential impact they may have had on NIOSH's efforts. Each NC ID 484 deficiency is listed followed by LANL's response and

any corrective action implemented. This list is followed by NIOSH's assessment of the impact that these deficiencies may have had on its ability to bound dose.

DOE 120-day Moratorium

Over the 1997 and 1998 calendar years, the DOE Office of Enforcement and Investigation had taken enforcement action at five DOE-contractor facilities with regard to deficiencies in their IDEPs. The commonality of the deficiencies of the IDEPs at these facilities, as well as possibly others throughout the DOE complex, led the Office of Enforcement and Investigation to the conclusion that the DOE contractors needed to review their own IDEPs to determine whether similar deficiencies existed and to take corrective actions. The IDEP concerns identified by the Office of Enforcement and Investigation included:

1. Workers not always being included in bioassay programs when required
2. Minimum detectable activities and decision levels not calculated or used properly
3. Failure to properly evaluate bioassay results (e.g., positive results not being recognized)
4. Quality assurance

On November 24, 1998, the Office of Enforcement and Investigation issued a 120-day moratorium on Price-Anderson Amendments Act (PAAA) enforcement actions related to DOE-contractor IDEPs. The moratorium period extended from November 24, 1998 through March 31, 1999. It was enacted by Director R. Keith Christopher via a letter to DOE and Contractor PAAA Coordinators titled "Price-Anderson Amendments Act Enforcement Actions Related to Internal Dose Evaluation Programs (Radiobioassay and Dose Assessment) for Contractors in the Department of Energy Complex." During the moratorium, DOE contractors were required to review their IDEPs, identify deficiencies, and propose corrective actions (DOE, 1998).

1999 LANL SELF-ASSESSMENT

To accomplish DOE's required review of their IDEPs, LANL utilized representatives from SRS, MJW Corporation, LANL's Radiation Protection Services Group (ESH-12), and Quality Assurance Group (ESH-14). Beginning March 22, 1999, a four-day self-assessment of the LANL IDEP was performed to identify program deficiencies prior to increased investigation and enforcement activities by the Office of Enforcement and Investigation (DOE/EH-10). ESH-12 was the primary focus of the self-assessment; individuals from ESH-1 and ESH-4 were also interviewed. The scope of the self-assessment included:

- Identification of workers who are required to participate in bioassay programs
- Performance of routine, job-specific, special, and follow-up bioassays on identified workers
- Evaluation, assessment, and assignment of dose to workers based on bioassay results
- Recording and reporting of dose to workers
- Performance of *in vivo* and *in vitro* analyses to include radioanalytical laboratory analyses and radioactivity determinations of collected bioassay samples

The self-assessment resulted in four findings and ten observations. Three of the four findings were related to the identification of individuals required to submit bioassay samples and the subsequent submittal of those samples. The remaining finding and several observations were related to the general lack of approved procedures. The report indicated that the LANL staff was extremely technically competent and that none of the findings or observations were issues of adequately protecting workers, but rather, were associated with regulatory compliance (Brackett and La Bone, 1999). NIOSH has been unable to locate any formal responses from LANL to the individual findings and observations in the self-assessment report. The self-assessment led to Noncompliance Report NC ID 484 being filed in DOE's Noncompliance Tracking System (NTS), which was formally responded to by LANL. LANL's response to the deficiencies identified in NC ID 484, along with NIOSH's assessments, are discussed in subsequent sections of this document.

Listed below are the findings and observations identified in the self-assessment report followed by NIOSH comments:

Finding 1: *Radiation workers are not consistently placed on the appropriate routine bioassay program.*

NIOSH Comment: The issues discussed in this finding included ineffective HP checklists, workers failing to submit bioassay samples per RWP requirements, and JCNNM personnel not fully participating in required bioassay programs. This finding resulted in NC ID 484 Deficiencies 1, 2, and 3, which are addressed later in this document.

Finding 2: *Visitors may not receive appropriate monitoring.*

NIOSH Comment: This finding led to NC ID 484 Deficiency 4, addressed later in this document.

Finding 3: *Termination samples are not consistently collected.*

NIOSH Comment: This finding led to NC ID 484 Deficiency 7, addressed later in this document.

Finding 4: *ESH-12 does not have all applicable procedures formalized to administer the IDEP program in accordance with quality assurance requirements.*

NIOSH Comment: This finding led to NC ID 484 Deficiency 10, addressed later in this document.

Observation 1: *Total effective dose equivalent is not used in ALARA determinations or comparisons of dose to the administrative control levels.*

NIOSH Comment: This observation, while potentially important for ALARA purposes, is not relevant to NIOSH's ability to reconstruct dose.

Observation 2: *Significant changes in calculated internal dose may occur without notification of the affected individual.*

NIOSH Comment: This observation could potentially impact the dose of record calculated by LANL. However, NIOSH does not use the dose record calculated by LANL for dose reconstruction purposes; NIOSH uses the actual bioassay results to calculate specific organ doses. Therefore, this observation is not relevant to NIOSH dose reconstruction.

Observation 3: *Some automated intake evaluations do not receive proper review by the dosimetrists.*

NIOSH Comment: This observation could potentially impact the dose of record calculated by LANL. However, NIOSH does not use the dose record calculated by LANL for dose reconstruction purposes; NIOSH uses the actual bioassay results to calculate specific organ doses. Therefore, this observation is not relevant to NIOSH dose reconstruction.

Observation 4: *The internal dosimetrists do not routinely interpret exposures to airborne radioactive materials in terms of DAC-hr.*

NIOSH Comment: This observation is primarily a concern that nasal smears are relied upon for determining the need for bioassay (rather than tracking DAC-hrs), which is inconsistent with the guidance given in technical basis documents. From NIOSH's perspective, this is a situation that could potentially result in workers not being monitored, as required by procedure. For such cases, unmonitored intakes could be estimated using co-worker data.

Observation 5: *Special urine samples may not be collected within the specified time frame following an incident.*

NIOSH Comment: The primary concern with this observation is that following an incident, the site needs to collect urine samples as soon as possible in order to determine the severity of an event and mitigate it accordingly. The potential delay in corrective action could lead to additional intakes, but would not necessarily impact NIOSH's ability to reconstruct dose. NIOSH can generally bound an intake with a sample taken well after the intake occurred, provided it is not a short-lived radionuclide.

Observation 6: *The internal dosimetrists do not apply protection factors to respiratory protection used by workers exposed to radioactive materials.*

NIOSH Comment: The discussion associated with this observation in the self-assessment report indicates that dosimetrists rely on nasal smears to determine if bioassay is necessary following respirator use, rather than using air monitoring data with a respirator protection factor. This approach may have been in violation of LANL procedures and could have potentially resulted in some workers not submitting bioassay samples following respirator use, as may have been required by procedure. For such cases, NIOSH would use the data that are available and would use co-worker data to estimate unmonitored intakes involving the primary radionuclides of concern at LANL.

Observation 7: *Actions taken to obtain delinquent urine samples from workers may not be adequate.*

NIOSH Comment: LANL found this issue to be limited to one employee. This is another example of a worker perhaps not being monitored as required by procedure, potentially resulting in a lack of available bioassay data. For such cases, co-worker data may be used to estimate intakes.

Observation 8: *The availability of a bioassay method influences the determination of whether or not to place a worker on a routine bioassay program.*

NIOSH Comment: This observation describes two instances in which workers potentially exposed to Np-237 were apparently not monitored. The concern here is that bioassay methods for Np-237 were unavailable and that cost was a significant consideration for the decision not to use an off-site vendor. The self-assessment report did indicate that: "…*reasonable technical arguments were made in both cases for not sampling for Np-237*…" In response to numerous NIOSH requests, LANL has always maintained the position that the reason that bioassay data are rare for the exotic radionuclides (e.g., Np-237) is because monitoring was rarely deemed necessary for those radionuclides (i.e., workers were unlikely to have received 100 mrem CEDE intakes from such nuclides).

Evaluation of intakes of exotic radionuclides such as Np-237 is ongoing with NIOSH and the LANL Work Group. NIOSH's current position is that unmonitored intakes of exotic radionuclides at LANL were unlikely to have resulted in doses exceeding 100 mrem CEDE. Observation 8 does not appear to conflict with this position.

Observation 9: *Internal doses from intakes of short-lived emitters at LANSCE may not be accurately assessed and reported.*

NIOSH Comment: The concern here is that the annual *in vivo* counts being used at the time were not adequate to evaluate intakes of the short-lived radionuclides at LANSCE. Discussion of this topic has been ongoing with NIOSH and the LANL Work Group. The discussion in the self-assessment report states: "*…we feel that the doses received by these workers are not a large fraction of the legal limit…*" This statement is consistent with NIOSH's position that unmonitored intakes of airborne radionuclides associated with LANSE operations were unlikely to have resulted in doses exceeding 100 mrem CEDE. Evaluation of intakes of short-lived radionuclides at LANSCE continues within NIOSH and the LANL Work Group.

Observation 10: *There are intakes of regulatory concern that are not being evaluated in a timely fashion.*

NIOSH Comment: This observation appears to have led to NC ID 484 Deficiency 6, which is addressed later in this document. The concern is with a few cases in which bioassay results had not yet been fully evaluated to produce the final dose of record. The primary concern here is that the lag in assigning the dose of record could potentially result in not controlling doses to applicable limits and ALARA requirements. Although the doses of record were eventually finalized and recorded, NIOSH does not use the site's doses of record to assess doses, but rather uses the actual bioassay results. Therefore, this observation is not relevant to NIOSH dose reconstruction.

The findings and observations from the self-assessment led to Noncompliance Report NC ID 484 being filed in the DOE's Noncompliance Tracking System (NTS), as discussed below.

NONCOMPLIANCE REPORT NC ID 484

To address the deficiencies identified in the NC ID 484 (DOE, 1999), LANL developed 18 corrective actions. Some of the deficiencies were addressed by more than one corrective action and some corrective actions were relevant to more than one deficiency. Each of the NC ID 484 deficiencies are listed below, followed by LANL's response to each. The LANL Response/Corrective Actions for each deficiency are presented verbatim from Noncompliance Report NC ID 484. The text therefore includes dates and shows the evolution of some corrective actions. The corrective actions are incorporated under their associated deficiency. All corrective actions were completed by November 30, 2000. As noted, NIOSH provides additional commentary where deemed helpful.

Deficiency 1 (derived from Self-assessment Finding 1)

Some workers and their supervisors are not accurately completing the "health physics checklist" (utilized for enrolling workers into dosimetry programs) to the extent that these checklists may not identify those radionuclides actually handled by the worker. Thus, some workers are not being assigned to the appropriate routine bioassay program in accordance with site requirements. [835.402(c)(1)]

LANL Response/Corrective Actions to Deficiency 1

Reference Deficiency #1:
The Laboratory policy for completion of the health physics checklist is defined in the LIR 402-706-01.1, Personnel Dosimetry, dated May 8, 1998. This LIR states that the "Line manager will: Ensure that the following dosimetry elements are implemented: ... Proper completion and submittal of health physics checklist." In addition the LIR states that "Radiological workers are responsible for ...Completing and submitting the health physics checklist."

The Laboratory General Employee Radiological Training (GERT), Course Number 15503 and the Radiological Worker II Training (RWII), Course Number 12909 was reviewed by the LANL PAAA Coordinator. The course content was determined to be adequate as it related to the completion of the Health Physics Checklist.

Reference Deficiency #1 AND #2:
Other tools to be used for the accurate completion of the health physics checklist and to assure compliance with RWP requirements will be evaluated. These tools may include an on-line-health-physics matrix, bioassay card, or LANL dosimetry monitoring card. Responsible Group: ESH-12

[Name redacted] *has changed the target date on 10/18/1999 from: 09/30/1999 to: 10/01/2000 with the following justification: A LANL dosimetry card will be developed. This card will identify the routine bioassay program(s) that individuals are enrolled in, and will include both the In Vivo and In Vitro bioassay programs. The dosimetry card will provide ESH-1 RCT's, line*

managers, and facility managers' current bioassay enrollment to identify the bioassay status of workers in the field, and provide ESH-1 RCT's information regarding the current bioassay status of individuals working under an RWP.

The LANL dosimetry card will require information from multiple dosimetry systems, which is not yet linked into one system. The dosimetry card system will be implemented for beta testing by June 1, 2000 and is slated for lab wide implementation by October 1, 2000.

In lieu of a dosimetry card system, a web-based Dosimetry Participation Verification Program (DPVP) has been developed and implemented. This allows those individuals with appropriate authority (e.g., group leaders and Health Physics Operations [ESH-1] personnel) to view current dosimetry program enrollment information for workers. This information can be obtained by entering the worker(s) Z numbers or by requesting the information for an entire group. The dosimetry program enrollment information is presented in tabular format for each individual such that it can ascertained as to what dosimetry programs the individual is currently enrolled in.

Deficiency 2 (derived from Self-assessment Finding 1)

Some radiological workers are not complying with specific RWPs that require them to participate in a bioassay program. As an example, two out of five workers who performed work under a specific RWP did not participate in the bioassay program in accordance with requirements of the RWP. [835.402(c)(1)]

LANL Response/Corrective Actions to Deficiency 2

NIOSH Comment: LANL addressed Deficiencies 1 and 2 together; see the discussion above, as noted.

Deficiency 3 (derived from Self-assessment Finding 1)

Johnson Controls of Northern New Mexico (JCNNM), the principle subcontractor to Los Alamos National Laboratory, may not be enrolling all workers who are potentially exposed to radionuclides into the appropriate bioassay program in accordance with site requirements. [835.402(c)(1)]

LANL Response/Corrective Actions to Deficiency 3

Reference Deficiency #3:
Representatives from ESH-12, ESH-1, Johnson Controls Northern New Mexico (JCNNM) and the respective facilities where radiological work is being conducted, will meet and ensure that appropriate JCNNM workers are enrolled in the appropriate Laboratory monitoring program. Responsible Group: ESH-12

Representatives from ESH-1, ESH-12 and Johnson Controls Northern New Mexico (JCNNM) met on July 21, 1999 to address the issue of ensuring workers are enrolled in appropriate Laboratory bioassay programs. Although the corrective action mentioned JCNNM workers as those requiring attention, it was determined that a new, robust program could help ensure proper enrollment of workers from both the Laboratory and its subcontractors. This program will be described in detail as part of the closure to corrective action #3 above.

The LANL RPP Manager will ensure that the appropriate guidance for enrolling subcontractors in the appropriate bioassay program has been developed. Responsible Group: LANL RPP Manager

[Name redacted] *has changed the target date on 09/08/1999 from: 08/31/1999 to: 01/07/2000 with the following justification: In lieu of issuing guidance specific to subcontractors based on the current dosimetry enrollment process, it has been decided to issue guidance for all types of workers, including subcontractors, based on the new, more robust program that is currently under development. The schedule for implementing this new program is as follows:*

Commence implementation of new dosimetry enrollment process, including issuance of enrollment (for all workers, including subcontractors) process documentation to the Laboratory. Milestone: 2/28/2000

Updates will be provided as each of the milestones noted above are completed.

[Name redacted] *has changed the target date on 01/07/2000 from: 01/07/2000 to: 01/31/2000 with the following justification: The section of this corrective action dealing with finalization of generic dosimetry enrollment criteria was completed on January 7, 2000.*

[Name redacted] *has changed the target date on 02/02/2000 from: 01/31/2000 to: 02/28/2000 with the following justification: The facility-/activity-specific dosimetry matrices was completed by ESH-1 on 02/02/2000. The enrollment process is still planned to be initiated by 02/28/2000.*

[Name redacted] *has changed the target date on 02/29/2000 from: 02/28/2000 to: 10/02/2000 with the following justification: The realization that a pilot implementation process at selected facilities would be appropriate prior to rolling the process out to the entire Laboratory at once. Implementing the process at selected facilities as a pilot would allow for the identification and correction of process deficiencies with minimal impact to overall Laboratory operations.*

[Name redacted] *has changed the target date on 10/11/2000 from: 10/02/2000 to: 10/20/2000 with the following justification: The responsible party for implementing this corrective action requested an extension due to technical issues associated with archiving dosimetry assignments.*

The on-line system is completed and available for Lab-wide use on Monday, 10/23/2000.

NIOSH Comment: In an email correspondence regarding this issue dated April 16, 1999, the JCNNM Health and Safety Manager, a Certified Health Physicist, made the following statements (LANL, 2000, PDF pp. 151 and 157):

> *The need for placing someone on the bioassay program, as specified in 10 CFR 835.402 (c) (1) is: "Radiological workers who, under typical conditions, are likely to receive a committed effective dose equivalent of 0.1 rem or more from all occupational radionuclide intakes in a year." Based upon our years of sampling, JCNNM workers ARE NOT LIKELY to receive any dose from radionuclide intakes. We are required to have personnel on the program as a condition of entry into some facilities and for some RWP's. If we are in violation, it is with facility procedures and not with the CFR.*
>
> *Planned actions:*
>
> 1. *I will meet with the LANL team addressing this issue and developing the necessary fixes.*
> 2. *We will begin to explore ways to obtain the required bioassay samples from employees after they have been terminated.*
> 3. *I will, once again, look to see if there are ways to reduce the number of JCNNM personnel who are included on the various bioassay programs.*

The letter also states:

> *…this cannot be fixed by JCNNM, we are required by contract to use their* [LANL's] *service and it must be a site wide fix. As you also may be aware, we rely very heavily on LANL for radiation protection services, including their RCT's who fill out the RWP and supervise almost all radiation protection aspects of all our work.*

To address this issue, JCNNM proposed the following actions:

1. Review current workers to assure that all JCNNM personnel, borrowed personnel, and onsite subcontractors are enrolled in the appropriate internal dose programs.
2. Establish procedural guidelines and processes to assure that JCNNM personnel, borrowed personnel, and onsite subcontractors are enrolled in the appropriate internal dose programs when they are hired, transferred, or when their work assignments are changed.

Deficiency 4 (derived from Self-assessment Finding 2)

There are no provisions within existing documents to address whether visitors (members of the public) should be assigned to bioassay programs. Because visitor monitoring is required at half the level of worker monitoring, separate guidelines are necessary for reviewing the potential for intake. [835.402(c)(3), 835.402(d)]

LANL Response/Corrective Actions to Deficiency 4

Reference Deficiency #4:
The LANL RPP Manager will review the guidance for assigning visitors to bioassay programs and make any appropriate changes. Responsible Group: LANL RPP Manager

[Name redacted] *has changed the target date on 09/08/1999 from: 08/31/1999 to: 02/28/2000 with the following justification: In lieu of issuing guidance specific to visitors based on the current dosimetry enrollment process, it has been decided to issue guidance for all types of workers, including visitors, based on the new, more robust program that is currently under development. The schedule for implementing this new program is as follows:*

Complete finalization of generic dosimetry enrollment criteria by ESH-12. Milestone: 1/7/2000

Complete finalization of facility-/activity-specific dosimetry matrices by ESH-1.Milestone: 1/31/2000

Commence implementation of new dosimetry enrollment process, including issuance of enrollment (for all workers, including visitors) process documentation to the Laboratory. Milestone: 2/28/2000

This corrective action will be updated as each milestone noted above is completed.

The section of this corrective action dealing with the finalization of generic dosimetry enrollment criteria was completed on 01/07/2000.

The section of this corrective action dealing with the facility-/activity-specific dosimetry matrices was completed by ESH-1 on 02/02/2000.

[Name redacted] *has changed the target date on 02/29/2000 from: 02/28/2000 to: 10/02/2000 with the following justification: Refer to corrective action #5. The pilot implementation process will also apply to this corrective action.*

[Name redacted] *has changed the target date on 10/11/2000 from: 10/02/2000 to: 10/20/2000 with the following justification: The responsible party for implementing this corrective action requested an extension due to technical issues associated with archiving dosimetry assignments.*

10/19/2000: The on-line system is completed and available for Lab-wide use on Monday, 10/23/2000.

Target date changed FROM: 08/31/1999 TO: 02/28/2000 JUSTIFICATION: In lieu of issuing guidance specific to visitors based on the current dosimetry enrollment process, it has been decided to issue guidance for all types of workers, including visitors, based on the new, more robust program that is currently under development. The schedule for implementing this new program is as follows:

Target date changed FROM: 02/28/2000 TO: 10/02/2000 JUSTIFICATION: Refer to corrective action #5. The pilot implementation process will also apply to this corrective action.

Target date changed FROM: 10/02/2000 TO: 10/20/2000 JUSTIFICATION: The responsible party for implementing this corrective action requested an extension due to technical issues associated with archiving dosimetry assignments.

Deficiency 5

The annual report to individuals did not include a field for reporting the dose equivalent to the embryo/fetus of declared pregnant workers for calendar years 1996, 1997, and 1998. [835.801(a)]

LANL Response/Corrective Actions to Deficiency 5

Reference Deficiency #5:
The database was modified on April 30, 1999, to collect and report fetal dose for declared pregnant workers for the 1998 reporting year. The fetal doses for 1998 were then received and entered into the database. The 1998 individual dose reports with fetal doses included as a separate field are being generated this month. Future individual dose reports will include fetal dose as a separate field. Adding the fetal dose field was completed on April 30, 1999.

Deficiency 6 (derived from Self-assessment Observation 10)

In a few cases (< 1%), the dose of record has not been finalized because of the difficulty in obtaining the necessary historical information related to the time of intake. These doses have been identified through the routine bioassay program and the interviews required for gathering this information have not been completed yet. This lag in assigning the dose of record could potentially result in not controlling doses to applicable regulatory limits and ALARA requirements. [835.101(c), 835.202(a)(1), 835.202(a)(2), 835.402(d)]

LANL Response/Corrective Actions to Deficiency 6

Reference Deficiency #6:
The process for evaluating these potential doses with unknown times of intake, over the time period 1980 1997, is underway. These potential intakes were identified by a more sensitive

bioassay system (TIMS) than is used elsewhere in the DOE complex. The total number of identified individuals is 15. ESH-12 is scheduling appointments with the individuals and line managers to determine the date and probability of intake. Given the potential intakes were identified years after the completion of regulatory cycles, ALARA and dose limitation cannot be controlled for the year of intake. The data will continue to be collected and evaluations will be performed. Responsible Groups: ESH-12 and ESH-1

[Name redacted] *has changed the target date on 01/06/2000 from: 01/01/2000 to: 03/01/2000 with the following justification: Eleven of the cases have been completed. The remaining four will be completed March 1, 2000.*

Target date changed FROM: 01/01/2000 TO: 03/01/2000 JUSTIFICATION: Eleven of the cases have been completed. The remaining four will be completed March 1, 2000.

NIOSH Comment: Per an email correspondence on February 29, 2000 (LANL, 2000, PDF p. 30), all of the plutonium-239/240 cases that were identified had been resolved. In looking into this issue, LANL also identified three other cases involving americium-241. These cases were still pending at the time of the email correspondence.

Deficiency 7 (derived from Self-assessment Finding 3)

Termination bioassay samples are not being collected in all cases. [835.202(b), 835.402(d)]

LANL Response/Corrective Actions to Deficiency 7

Reference Deficiency #7:
The LANL "Procedures for Arranging Final Paycheck" for terminating employees requires the completion of a "Termination Clearing Form." ESH-12 and the Dosimetry Office are required to sign-off on this form before the employee can receive their final paycheck.

ESH-12 and the Dosimetry Office will review the ESH termination process in support of the LANL Termination Clearing Form, make any appropriate changes, and formally document the process in a procedure. Responsible Group: ESH-12

[Name redacted] *has changed the target date on 10/18/1999 from: 09/30/1999 to: 12/17/1999 with the following justification: ESH-12 is currently reviewing the ESH termination process for bioassay, making appropriate changes, and documenting the process in a draft procedure. However, this draft procedure deals exclusively with UC employees. The review and finalization of this procedure will be completed as outlined in Corrective Action #12.*

The LANL IDEP assessment identified the subcontractor termination bioassay process as being deficient in that there are no assurances that all subcontractors enrolled in bioassay programs are receiving termination bioassays. This has not yet been addressed in the termination process and draft procedure because of the complexity and multi-organizational aspect of this issue. To resolve this complex, multi-organizational deficiency, involved organizations have been

identified (ESH-12, BUS-5 (Procurement), JCNNM, PTLA, and HR-5 (Contract/Staffing Alternatives)) to work the issue. An evaluation focused on identifying the issues and resolving these issues will be scheduled for no later than 11/30/99. Follow-on corrective actions developed from this evaluation will be developed and posted to the NTS no later than 12/17/99.

The corrective actions were developed on December 16, 1999 and added to this report on December 23, 1999. See 13 through 17 below.

Target date changed FROM: 09/30/1999 TO: 12/17/1999 JUSTIFICATION: ESH-12 is currently reviewing the ESH termination process for bioassay, making appropriate changes, and documenting the process in a draft procedure. However, this draft procedure deals exclusively with UC employees. The review and finalization of this procedure will be completed as outlined in Corrective Action #12.

NIOSH Comment: Upon review of the subcontractor termination process, the following issues were addressed to improve the process (LANL, 2000, PDF pp. 43-44):

1. *Improve education of UC and subcontractor employees regarding termination issues by working with ESH-13 to review the General Employee Training to identify and emphasize termination requirements. In addition, bioassay kit instructions will be updated to notify participants of the requirement for submitting a termination bioassay sample through the termination process. Target completion date: October 1, 2000.*

2. *Evaluate the Employee Information System (EIS) in conjunction with the Bioassay database (BEST) for identifying personnel who have terminated without completing the Termination Clearing Form and require a termination bioassay sample. These individuals would then receive a certified letter informing them of the need to submit a termination bioassay sample and instructions to follow. Target completion date: July 28, 2000.*

3. *Meet with BUS-5 and ESH-5 personnel to evaluate sub-contractor ES&H requirements with regard to completing the LANL termination clearing form. Follow on corrective action will be complete on October 1, 2000 once this meeting takes place.*

4. *Meet with the LANL badge office to determine the role of the badge office in assisting ESH in identifying terminating personnel who have not completed the LANL termination process. Follow on corrective actions will be complete on October 1, 2000 once this meeting place.*

5. *Review all termination procedures and forms for JCNNM, PTLA, HR-5, and BUS-5 for accuracy and ability to effectively ensure that personnel are evaluated for termination bioassay samples. Target completion date: July 28, 2000.*

Deficiency 8

Routine and special in vitro bioassay samples are not being submitted as required by a small percentage of bioassay program participants (< 2%). [835.101(c), 835.202(b), 835.402(d)]

LANL Response/Corrective Actions to Deficiency 8

Reference Deficiency #8:
This issue was limited to one employee. The current Policy is that a formal memo is sent to the individual, his line manager, Group Leader, and Division Director if the employee does not submit the in vitro samples as required. Management is responsible to ensure employees comply with the requirements. No corrective actions are required.

Deficiency 9

During 1998, in vivo measurements were not obtained for some workers on the required frequency. [835.101(c), 835.202(b), 835.402(d)]

LANL Response/Corrective Actions to Deficiency 9

Reference Deficiency #9:
Personnel were not able to complete the in vivo counts as scheduled due to construction of the facility housing the in vivo equipment. All personnel are now current on their measurements. No corrective actions are required.

Deficiency 10 (derived from Self-assessment Finding 4)

ESH-12 does not have applicable procedures formalized to administer the IDEP program in accordance with quality assurance requirements. [830.120, Criterion 4]

LANL Response/Corrective Actions to Deficiency 10

Reference Deficiency #10:
Working documents within the IDEP will be reviewed and formalized as required. The first step will be to determine the documents that need to be formalized. Target completion dates for the writing and approval of these documents will be determined after the list of documents that require formalization are identified. Responsible Group: ESH-12

[Name redacted] *has changed the target date on 10/18/1999 from: 09/30/1999 to: 10/01/2000 with the following justification: Formalization of the IDEP procedures requires discussions between the RPP manager, ESH-12 group leader, and the IDEP team leaders in ESH-12 to define the objectives and content of the LANL IDEP procedures. Once the objectives and content have been agreed upon, the IDEP procedures will be developed. These discussions and the resulting agreement will be completed by December 17, 1999.*

The following list of operations has been initially identified for formalization into procedures. Based on the discussion identified above, certain procedures may be combined or separated into new procedures.

1. *Health physics checklist procedure*
2. *Bioassay enrollment procedure*
3. *Bioassay kit circuit procedure*
4. *Radiological dose assessment process and examples*
5. *Internal dosimetry and bioassay requirements for LANL operations*
6. *Special internal dosimetry and bioassay process*
7. *Terminations*
8. *Annual report card to workers*
9. *REIRS (Radiation Exposure Information Reporting System)*

The IDEP procedures will be completed and formalized by October 1, 2000.

12/23/1999:
The RPP manager, ESH-12 group leader, and IDEP team leaders in ESH-12 met on December 16, 1999 to further define the objectives and content of the LANL IDEP procedures. It was decided in this meeting to develop and publish the following IDEP procedures by 10/1/2000:

1. *Health physics checklist procedure*
2. *Bioassay enrollment procedure*
3. *Bioassay kit circuit procedure*
4. *Internal dose assessment process*
5. *Terminations*
6. *Annual report card to workers*
7. *REIRS*

All procedures except the internal dose assessment process procedure were completed by 10/1/00. The internal dose assessment process procedure was completed on 10/5/00.

Target date changed FROM: 09/30/1999 TO: 10/01/2000 JUSTIFICATION: Formalization of the IDEP procedures requires discussions between the RPP manager, ESH-12 group leader, and the IDEP team leaders in ESH-12 to define the objectives and content of the LANL IDEP procedures. Once the objectives and content have been agreed upon, the IDEP procedures will be developed. These discussions and the resulting agreement will be completed by December 17, 1999.

Evaluate the Employee Information System

Evaluate the Employee Information System (EIS) in conjunction with the Bioassay database (BEST) for identifying personnel who have terminated without completing the Termination Clearing Form and require a termination bioassay sample . These individuals would then receive a certified letter informing them of the need to submit a termination bioassay sample and instructions to follow.

ESH-12, S-6, and CIC-13 personnel met on 2/24/00 to evaluate the EIS and options to ensure that personnel terminating complete required termination bioassay samples. See CA #18 below for implementation of process described above.

Review all termination procedures and forms

Review all termination procedures and forms for JCNNM, PTLA, HR-5, and BUS-5 for accuracy and ability to effectively ensure that personnel are evaluated for termination bioassay samples.

Improve education of UC and subcontractor employees

Improve education of UC and subcontractor employees regarding termination issues by working with ESH-13 to review the General Employee Training to identify and emphasize termination requirements. Additionally, bioassay kit instructions will be updated to notify participants of the requirement for submitting a termination bioassay sample through the termination process.

The bioassay kit instructions have been updated to notify participants of the termination requirements and need for termination bioassay samples.

[Name redacted] *has changed the target date on 10/11/2000 from: 10/01/2000 to: 10/13/2000 with the following justification: The responsible party for this corrective action requested an extension until 10/13 for revision of both General Employee and Rad Worker training materials. The revision will include termination bioassay requirements. The revision awaits information that will be developed as part of completing CAs 05 and 06. Bioassay kit instructions were revised on 10/01/2000 to notify participants of the requirement for submitting termination bioassay samples.*

Target date changed FROM: 10/01/2000 TO: 10/13/2000 JUSTIFICATION: The responsible party for this corrective action requested an extension until 10/13 for revision of both General Employee and Rad Worker training materials. The revision will include termination bioassay requirements. The revision awaits information that will be developed as part of completing CAs 05 and 06. Bioassay kit instructions were revised on 10/01/2000 to notify participants of the requirement for submitting termination bioassay samples.

Meet with BUS-5 and ESH-5 personnel

Meet with BUS-5 and ESH-5 personnel to evaluate sub-contractor ES&H requirements with regard to completing the LANL termination clearing form. Follow on corrective actions will be complete on October 1, 2000 once this meeting takes place. Corrective actions identified at this meeting will be met by closure of CA 18

Meet with the LANL badge office

Meet with the LANL badge office to determine the role of the badge office in assisting ESH in identifying terminating personnel who have not completed the LANL termination process. Follow on corrective actions will be complete on October 1, 2000 once this meeting takes place.

The meeting with the LANL Badge Office took place on 10/05/2000. Follow-on corrective actions identified at this meeting will be met by closure of CA 18. As indicated in CA 18, individuals, especially subcontractors, within the bioassay program who terminate employment without providing termination samples will be notified via certified mail of the need to submit a termination sample. As a result of the meeting that took place on 10/05/2000, it was decided that notifications will also be made to the subcontractor company, the requester of the subcontract, and the BUS-5 contract administrator.

A process/procedure will be developed

A process/procedure will be developed and implemented for identifying individuals, especially subcontractors, within the bioassay program who terminate employment without providing termination bioassay samples. A certified letter requesting a termination bioassay sample will be sent to those individuals identified through this process. The specific document will be added to this CA for closure.

NIOSH DISCUSSION OF THE LISTED DEFICIENCIES AND THEIR POTENTIAL IMPACT ON ITS ABILITY TO BOUND DOSE

When the ten deficiencies identified in NC ID 484 are viewed overall, Deficiencies 1, 2, and 3 are arguably the most important in terms of how they could potentially impact NIOSH's ability to bound intakes. All three of these deficiencies are in regard to workers not fully participating in the appropriate routine bioassay programs. Given the lack of available bioassay data for exotic radionuclides, it appears that there were no "routine" bioassay programs in place for "exotic" radionuclides at LANL at the time of the 1999 self-assessment. This suggests that the deficiencies identified were all concerns with the routine bioassay programs for the primary radionuclides handled at LANL (i.e., americium, uranium, plutonium, tritium, and Cs-137). The term "exotics" was defined in the SEC-00109 Petition Evaluation Reports, Rev. 0 (NIOSH 2009) and Rev. 1 (NIOSH 2012), dated January 22, 2009 and August 13, 2012, respectively. The definition included everything other than U-234/235/238, Pu-238/239, tritium, Am-241, and Cs-137. This would include Sr-90, Th-232, Cm-244, Ac-227, Pa-231, Np-237, and others.

1. **Deficiency 1** is a concern that some workers and their supervisors were not accurately completing health physics checklists, and therefore, were not being assigned to the appropriate routine bioassay programs. The obvious concern with Deficiency 1 is that, prior to the implementation of the web-based Dosimetry Participation Verification Program (DPVP) on October 1, 2000, the health physics checklist may not have been an effective tool for ensuring that workers participated in the appropriate routine bioassay programs.

   NIOSH has previously determined that there are no dose reconstruction infeasibilities for the primary radionuclides at LANL. This is because there are extensive co-worker data available for the primary radionuclides (ORAUT-OTIB-0062; ORAUT-OTIB-0063). Tables 1 and 2 below show the number of *in vitro* records that were available to derive the LANL co-worker models for the 1996-2005 period.

Table 1: Total Urinalyses Records by Calendar Year

Analyte	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	Total
Am-241	3	85	218	245	228	190	284	208	287	153	1901
H-3	1649	1681	1691	1673	1624	1471	1406	1427	1260	1353	15235
Pu-238	1906	3720	4668	4166	4374	4177	4412	4670	4281	3274	39648
Pu-239	1924	4666	5310	4902	4902	5530	6581	7879	7506	5633	54833
Pu-239+Pu-240	12	506	328	370	276	679	1086	1607	1626	1861	8351
Pu-240	0	227	231	122	133	368	426	2378	3237	1371	8493
Th-228	0	0	0	0	0	0	0	0	0	7	7
Th-229	0	0	0	0	0	0	0	0	0	7	7
U-234	1026	825	829	740	905	1272	748	772	1065	844	9026
U-235	1026	825	829	740	905	1272	748	772	1065	844	9026
U-238	1026	825	829	740	905	1272	748	772	1065	844	9026

Table 2: Total Fecal Analyses Records by Calendar Year

Analyte	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	Total
Am-241	41	8	2	0	19	0	0	0	0	9	79
H-3	0	0	0	0	0	0	0	0	0	0	0
Pu-238	41	8	2	0	19	0	0	10	0	6	86
Pu-239	41	8	2	0	19	0	0	10	0	6	86
Pu-239+Pu-240	0	0	0	0	0	0	0	0	0	0	0
Pu-240	0	0	0	0	0	0	0	0	0	0	0
Th-228	0	0	0	0	0	0	0	0	0	0	0
Th-229	0	0	0	0	0	0	0	0	0	0	0
U-234	0	0	0	0	0	0	0	0	0	6	6
U-235	0	0	0	0	0	0	0	0	0	6	6
U-238	0	0	0	0	0	0	0	0	0	6	6

Routine *in vivo* monitoring programs for fission products, activation products, and other gamma-emitting radionuclides were also in place at LANL throughout the period under evaluation. The LANL Bioassay Repository Database includes 106,950 *in vivo* records (ORAUT-OTIB-0063) that were also used for the co-worker models, of which 31,160 are from the period from 1996-2005, encompassing 37 different radionuclides. A summary of available *in vivo* records for the 1996-2005 period are presented in Table 3 below.

Table 3: Total *In Vivo* Records by Calendar Year

Analyte	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	Total
Am-241	1250	1087	1172	1181	1138	994	1558	1091	1329	1284	12084
Be-7	45	28	27	23	1	0	0	0	0	5	129
Bi-213	0	0	0	0	0	0	0	0	3	11	14
Br-76	0	0	1	0	0	0	0	0	0	0	1
Br-77	0	0	1	0	0	0	0	0	0	0	1
C-11/N-13	60	57	59	71	107	66	74	56	0	0	550
Cd-109	0	0	1	0	0	0	0	0	0	0	1
Ce-141	0	0	1	0	0	0	0	0	0	0	1
Cm-244	0	0	0	0	0	0	0	1	0	0	1
Co-60	0	2	6	2	1	0	7	11	0	1	30
Cs-137	1	2	6	6	3	15	18	9	9	14	83
Eu-152	12	27	35	48	106	66	74	56	0	0	424
Hf-173	0	2	0	1	0	0	0	0	0	0	3
Hf-175	0	0	0	0	0	0	0	0	0	5	5
Hg-195m	0	0	1	0	0	0	0	0	0	0	1
Hg-197	0	0	1	0	0	0	0	0	0	0	1
Hg-197m	0	0	1	0	0	0	0	0	0	0	1
Hg-203	0	0	1	0	0	0	0	0	0	0	1
Mn-54	45	28	27	23	1	0	0	0	0	0	124
Na-22	54	55	59	71	107	66	74	56	0	0	542
Nd-147	0	0	1	0	0	0	0	0	0	0	1

Analyte	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	Total
Os-185	0	0	1	0	0	0	0	0	0	0	1
Pb-212	0	0	0	0	0	0	0	0	3	11	14
Pb-214	0	0	0	0	0	0	0	0	3	11	14
Pu-239	1239	1069	1163	1175	1126	986	1548	1085	1339	1255	11985
Ra-226	0	0	0	0	0	0	0	0	0	1	1
Rb-83	0	0	1	0	0	0	0	0	0	0	1
Rb-84	0	0	1	0	0	0	0	0	0	0	1
Sb-124	0	0	1	0	0	0	0	0	0	0	1
Se-75	0	0	1	0	0	0	0	0	0	0	1
Sm-145	0	0	1	0	0	0	0	0	0	0	1
Ta-179	0	0	1	0	0	0	0	0	0	0	1
Th-234	0	0	0	0	0	0	0	0	1313	1254	2567
Tl-201	0	0	1	0	0	0	0	0	0	0	1
Tl-202	0	0	1	0	0	0	0	0	0	0	1
U-235	0	0	0	1	1	0	2	0	1313	1254	2571
U-238	0	0	0	0	1	0	0	0	0	0	1

The routine bioassay programs in place during the 1996-2005 time period are described in the LANL document, *Laboratory Standard: Radiation Dosimetry Monitoring*, LS107-11.0 (LANL, 1994, PDF pp. 15-58), dated December 12, 1994, and in a document entitled *Internal Dosimetry and Bioassay Requirements for LANL Operations*, revised January 7, 2000 (LANL, 2000, PDF pp. 34-40).

The quantities of available bioassay records presented above illustrate that, even though some workers may not have participated in the appropriate routine bioassay program due to ineffective health physics checklists, there was nevertheless sufficient overall worker participation in the various routine bioassay programs that statistically-valid co-worker models could be generated from the resulting data. NIOSH's biggest concern with the potential lack of worker participation in bioassay programs is that the available data could be biased in a non-claimant-favorable manner, or biased low. This would only be the case if the unmonitored worker population actually received higher intakes than the monitored worker population. NIOSH has found no reason to believe this to be the case. The co-worker data may therefore be used to assign intakes to unmonitored workers for the primary radionuclides. This is the case even for those unmonitored workers who should have been monitored. This deficiency does not have any effect on the pedigree of the existing data that are available for monitored workers, data from which the co-worker models were derived.

As mentioned previously, this deficiency appears to pertain to the routine bioassay programs for the primary radionuclides of concern at LANL. Although NIOSH does not find this deficiency to impact its ability to bound unmonitored intakes to the primary radionuclides, it remains a concern with regard to bounding intakes of exotic radionuclides, nuclides for which there is a lack of available bioassay data. At the time of this writing, NIOSH is continuing to evaluate the feasibility of bounding unmonitored intakes for the exotic radionuclides.

2. **Deficiency 2** is a concern that radiological workers were not participating in bioassay programs as required by specific RWPs. LANL responded to Deficiencies 1 and 2 with the same corrective actions, namely the development and implementation of the web-based DPVP. Although Deficiency 2 does not specifically refer to "routine" bioassay, it can be assumed that, like Deficiency 1, it is in reference to the primary radionuclides given the lack of bioassay programs for exotics. The impact of Deficiency 2 on NIOSH's ability to bound unmonitored intakes is essentially the same as the impact of Deficiency 1. The issue or concern in both cases is that some workers may not have participated in routine bioassay programs in violation of LANL procedures. As discussed under Deficiency 1, for such individuals, dose reconstruction for the primary radionuclides may be completed by applying the co-worker models presented in ORAUT-OTIB-0062.

   Although NIOSH does not find this deficiency to impact its ability to bound unmonitored intakes to the primary radionuclides, it remains a concern with regard to bounding intakes of exotic radionuclides. NIOSH is currently evaluating the feasibility of bounding unmonitored intakes for the exotic radionuclides.

3. **Deficiency 3** is a concern that Johnson Controls of Northern New Mexico (JCNNM) may not have been enrolling workers into the appropriate bioassay programs. Although Deficiency 3 was specific to JCNNM, the corrective actions applied to all LANL workers, including Laboratory workers. Again, as with the Deficiencies 1 and 2, the primary corrective action was the development and implementation of the web-based DPVP.

It is interesting to note that, in the initial informal email correspondence in response to Deficiency 3, the JCNNM Health and Safety Manager, a CHP, stated:

> *Based upon our years of sampling, JCNNM workers ARE NOT LIKELY to receive any dose from radionuclide intakes. We are required to have personnel on the program as a condition of entry into some facilities and for some RWP's. If we are in violation, it is with facility procedures and not with the CFR.* (LANL, 1999)

It should be stressed here that NIOSH has not reviewed the specific sampling data which the JCNNM Health and Safety Manager appears to be referring to in the statement above. NIOSH therefore does not accept the Safety Manager's conclusion about workers not being likely to receive any dose from radionuclide intakes. The statement is included here only to illustrate the viewpoint of the Safety Manager at the time of the 1999 self-assessment. It is also interesting to note that one of the initial planned actions was to:

> *…look to see if there are ways to reduce the number of JCNNM personnel who are included on the various bioassay programs.* (LANL, 1999)

Together, these two statements suggest that, from the point of view of the JCNNM Health and Safety Manager at the time, the reason that JCNNM workers are in violation of procedures is not because workers are not being monitored appropriately, but rather, because workers are unnecessarily being placed on bioassay programs when there is little or no potential for intakes. Again, NIOSH does not accept what appears to be the Safety Manager's opinion in these statements without having reviewed the supporting data. This discussion is only included here to illustrate the thinking of the Safety Manager at the time of the 1999 self-assessment.

As with Deficiencies 1 and 2, the concern here is a lack of participation in the various routine bioassay programs in violation of LANL procedures. As discussed for Deficiencies 1 and 2, for such unmonitored individuals, dose reconstruction for the primary radionuclides may be completed by applying the co-worker models presented in ORAUT-OTIB-0062.

Although NIOSH does not find this deficiency to impact its ability to bound unmonitored intakes to the primary radionuclides, it remains a concern with regard to bounding intakes of exotic radionuclides. NIOSH is currently evaluating the feasibility of bounding unmonitored intakes for the exotic radionuclides.

4. **Deficiency 4** has to do with the lack of documentation to address whether visitors (members of the public) should be assigned to bioassay programs. The corrective action for this issue was also the development and implementation of the web-based DPVP. This issue is not relevant to NIOSH's ability to bound intakes to LANL workers.

5. **Deficiency 5** has to do with the annual report to individuals, which did not include a field for reporting dose to the fetus of a declared pregnant worker. This issue is not relevant to NIOSH's ability to bound intakes to LANL workers.

6. **Deficiency 6** is concerned with a few cases in which bioassay results had not yet been fully evaluated to produce the final dose of record. The primary concern here is that the lag in assigning the dose of record could potentially result in not controlling doses to applicable limits and ALARA requirements, a legitimate health physics concern. This deficiency does not affect NIOSH's ability to reconstruct dose because NIOSH does not use the site's doses of record to assess doses; NIOSH uses the actual bioassay results, which are available.

7. **Deficiency 7** is a concern that termination bioassay samples were not being collected in all cases. This issue could alter the methodology of dose reconstruction. For such cases, after the last bioassay result, the person is considered unmonitored and NIOSH would estimate intakes based on co-worker data for the specific radionuclides and periods of interest.

8. **Deficiency 8** had to do with an *in vitro* bioassay sample not being submitted as required. LANL determined that this issue was limited to a single employee. As with other examples of missing or nonexistent bioassay data for the primary radionuclides, NIOSH can use co-worker data to bound intakes.

9. **Deficiency 9** had to do with a period in 1998 where *in vivo* measurements were not obtained for some workers on the required frequency. In its response, LANL indicated that personnel were not able to complete the *in vivo* counts as scheduled due to construction of the facility that housed the *in vivo* equipment at that time. LANL also indicated in their response that all personnel are now current on their measurements. This deficiency would not affect NIOSH's ability to bound intakes for the affected workers using the available bioassay data.

10. **Deficiency 10** had to do with a lack of formalized procedures for the IDEP program. LANL's corrective action for this deficiency was the development and issuance of multiple procedures. All of the new procedures were effective by October 5, 2000. NIOSH does not find this lack of formalized procedures to be an invalidation of LANL's prior internal dosimetry data. Data collected and analyzed prior to the implementation of these new procedures are usable for NIOSH dose reconstruction.

CONCLUSIONS

As stated in the Background section of this document, NIOSH no longer holds the view, presented in the SEC-00109 LANL ER Addendum, that it can rely on compliance with 10 C.F.R. pt. 835 for its conclusion that unmonitored workers were unlikely to have received intakes resulting in greater than 100 mrem CEDE. This change in viewpoint was largely due to the deficiencies cited in Noncompliance Report NC ID 484, the subject of this evaluation.

In its white paper responding to SC&A's concerns (NIOSH, 2018), NIOSH acknowledged that it could not rely solely on the lack of Notices of Violation (NOVs) and other recorded non-conformances as a benchmark of effective RPP implementation. The white paper emphasized four points:

1. LANL is under a legal requirement to monitor workers likely to receive intakes of 100 mrem CEDE;

2. NIOSH has accumulated a large quantity of bioassay records for the period under evaluation that clearly indicate that monitored workers were unlikely to receive intakes greater than 100 mrem CEDE (ORAUT-OTIB 0062 and ORAUT-OTIB-0063);

3. LANL has robust field-monitoring programs designed and implemented to ensure that unmonitored individuals are unlikely to receive intakes of 100 mrem CEDE; and

4. Because it is evident from the available bioassay data that monitored workers were unlikely to receive intakes greater than 100 mrem CEDE, NIOSH concluded in the paper that unmonitored workers were also unlikely to receive intakes greater than 100 mrem CEDE.

As stated in the preceding section, NIOSH has not identified any dose reconstruction infeasibilities for the primary radionuclides at LANL. LANL has had effective routine bioassay programs in place for these radionuclides throughout the period under evaluation and sufficient bioassay data are available to NIOSH. The primary focus of the self-assessment was clearly the routine bioassay programs (i.e., Am, Pu, U, and tritium).

Nevertheless, it is important to remember that the 1999 LANL self-assessment (which led to NC ID 484) was an evaluation of the IDEPs existing at LANL at that time. Significant flaws were highlighted in NC ID 484, which led to significant improvements to LANL's IDEPs. However, in its review of all of the available documentation associated with NC ID 484 and the corrective actions that followed, NIOSH did not find any reason to abandon the use of the ORAUT-OTIB-0062 co-worker models to bound unmonitored worker intakes for the primary radionuclides.

In closing, it is worth reiterating that the issues and concerns identified in Nonconformance Report NC ID 484 were associated with the routine bioassay programs being implemented at that time, and these routine bioassay programs were for LANL's primary radionuclides of concern. At the time of this writing, as it relates to the SEC-00109 petition evaluation, NIOSH is continuing to evaluate the feasibility of bounding intakes of the "exotic" radionuclides at LANL - those nuclides for which there were no active routine bioassay programs, and for which very little bioassay data exists. NC ID 484 has little relevance to NIOSH's ability to bound intakes for these exotic radionuclides. There were no findings or deficiencies identified in the 1999 LANL self-assessment or in NC ID 484 suggesting that LANL lacked the capability, or that it needed to develop and implement, additional routine bioassay programs for other radionuclides. In response to numerous NIOSH requests, LANL has always maintained the position that the reason that bioassay data are rare for the exotic radionuclides is because monitoring was rarely deemed necessary for those radionuclides (i.e., workers were unlikely to have received 100 mrem CEDE intakes from such nuclides). In its review of all of the available documentation associated with NC ID 484 and the corrective actions that followed, NIOSH did not find any reason to abandon its position that unmonitored workers at LANL were unlikely to have received intakes exceeding 100 mrem CEDE from any radionuclides during the period in question (1996 - 2005).

REFERENCES

10 C.F.R. pt. 835, 2018, *10 C.F.R. 835*, Electronic Code of Federal Regulations; U.S. Federal Government; gpo.gov; current as of September 12, 2018; SRDB Ref ID: 173737

Brackett and La Bone, 1999, *Assessment of the Los Alamos National Laboratory Internal Dose Evaluation Program*, E. M. Brackett (MJW Corp.) and T. R. La Bone (Westinghouse Savannah River Company); April 22, 1999; SRDB Ref ID: 175134

DOE, 1998, *Price-Anderson Amendments Act Enforcement Actions Related to Internal Dose Evaluation Programs (Radiobioassay and Dose Assessment) for Contractors in the Department of Energy Complex*, U.S. Department of Energy, Office of Enforcement and Investigation; November 24, 1998; SRDB Ref ID: 168448 - OUO and CUI

DOE, 1999, *Noncompliance Tracking System (NTS) Report NC ID 484*, NTS-ALO-LA-LANL-LANL-1999-0004, U.S. Department of Energy; submitted 03/31/1999; completed 12/18/2000; closed 02/27/2001; SRDB Ref ID: 164555

DOE/EH-0575, 1997, *DOE Occupational Radiation Exposure – 1997 Report*, U.S. Department of Energy, Office of Worker Safety and Health; DOE/EH-0575; 1997; SRDB Ref ID: 64900, PDF p. 15

LANL, 1994, *Laboratory Standard: Radiation Dosimetry Monitoring*, LS107-11.0, Los Alamos National Laboratory; December 23, 1994; SRDB Ref ID: 133601

LANL, 1999, *Internal Dosimetry Program*, internal memo from J. L. Bliss (Safety Manager, Johnson Controls Northern New Mexico) to G. W. Woodson (LANL); April 21, 1999; SRDB Ref ID: 168446, PDF pp. 151 and 157

LANL, 2000, *LANL Corrective Actions Taken in Response to NC ID 484*, Los Alamos National Laboratory; documents related to closeout of NTS report NTS-ALO-LA-LANL-LANL-1999-0004; SRDB Ref ID: 168446

NIOSH 2009, *SEC Petition Evaluation Report for Petition SEC-00109, Los Alamos National Laboratory*; Rev. 0, National Institute for Occupational Safety and Health (NIOSH); January 22, 2009; SRDB Ref ID: 79895

NIOSH, 2012, *SEC Petition Evaluation Report for Petition SEC-00109, Los Alamos National Laboratory*; Rev. 1; National Institute for Occupational Safety and Health (NIOSH); August 13, 2012; SRDB Ref ID: 165232

NIOSH, 2017, *SEC Petition Evaluation Report for Petition SEC-00109, Addendum*, Los Alamos National Laboratory; National Institute for Occupational Safety and Health (NIOSH); April 24, 2017; SRDB Ref ID: 173741

NIOSH, 2018, *NIOSH Response to SC&A's Review of the SEC-00109 LANL Addendum, with Revised References Section and Appendix*, National Institute for Occupational Safety and Health (NIOSH); October 23, 2018; SRDB Ref ID: 174356

ORAUT-OTIB-0062, *Internal Dosimetry Coworker Data for Los Alamos National Laboratory*, Rev. 00, Oak Ridge Associated Universities; October 15, 2009; SRDB Ref ID: 75028

ORAUT-OTIB-0063, *Los Alamos National Laboratory Bioassay Repository Database*, Rev. 00, Oak Ridge Associated Universities; August 24, 2009; SRDB Ref ID: 73101

SC&A, 2017, *Review of SEC Petition Evaluation Report Addendum (SEC-00109) for Los Alamos National Laboratory*, SC&A, Inc.; July 27, 2017; SRDB Ref ID: 173740

SC&A, 2018, *SC&A Review of White Paper, "NIOSH Response to SC&A's Review of the SEC-00109 LANL Addendum"*, SC&A, Inc.; November 16, 2018; SRDB Ref ID: 175421