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Advisory Board on Radiation and Worker Health
National Institute for Occupational Safety and Health

Review of NIOSH Response to SC&A Comments on ORAUT-RPRT-0090 re Monitoring Feasibility Evaluation for Exotic Radionuclides Produced by the Oak Ridge National Laboratory Isotopes Division

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Abbreviations and Acronyms

ABRWH, Advisory Board	Advisory Board on Radiation and Worker Health
ATSDR	Agency for Toxic Substances and Disease Registry
Am	americium
Bk	berkelium
Cf	californium
Cm	curium
Ci	curie
Ci/yr	curie per year
DCF	dose conversion factor
D&D	decontamination and decommissioning
DOE	U. S. Department of Energy
dpm	disintegrations per minute
DR	dose reconstruction
EEOICPA	Energy Employees Occupational Illness Compensation Program Act
ER	evaluation report
LANL	Los Alamos National Laboratory
MAPs	mixed activation products
µCi	microcurie
µCi/cm^3	microcurie per cubic centimeter
mCi	millicurie
MFPs	mixed fission products
NIOSH	National Institute for Occupational Safety and Health
NOCTS	NIOSH DCAS Claims Tracking System
ORNL	Oak Ridge National Laboratory
pCi/d	picocurie per day
Pu	plutonium
RaLa	radioactive lanthanum
RPRT	report
RWP	radiation work permit
Ru	ruthenium

SEC	Special Exposure Cohort
SRDB	Site Research Database
SRS	Savannah River Site
TBD	technical basis document
TPO	trans plutonium
WBC	whole body count
X-10	Oak Ridge National Laboratory
Y-12	National Security Complex

1 Introduction and Background

The National Institute for Occupational Safety and Health (NIOSH) evaluated the internal monitoring capability of Oak Ridge National Laboratory (ORNL, X-10) for radionuclides that were produced by the Isotopes Division (termed "exotic radionuclides") and its predecessors from 1955 to 1988 in ORAUT-RPRT-0090, revision 00, "Monitoring Feasibility Evaluation for Exotic Radionuclides Produced by the Oak Ridge National Laboratory Isotopes Division" (NIOSH, 2018; hereafter "RPRT-0090"). In RPRT-0090, NIOSH listed 213 radionuclides in table 6-3, which was presented as the final inventory for the Isotopes Division for the period 1955–1988. Table 7-2 provided a detailed list of each of the 213 radionuclides and the years they were in inventory (representing potential exposure), along with monitoring capability and bioassay data availability. NIOSH found that ORNL had adequate monitoring capabilities for 179 of these 213 radionuclides. Attachment B of RPRT-0090 provided a brief summary of the decay characteristics and bioassay methods for each of these 179 radionuclides. Table 7-4 of RPRT-0090 summarized the 34 remaining radionuclides that needed additional evaluation. Five of these 34 radionuclides were addressed in Attachment C of RPRT-0090 concerning radioiodine. Plutonium-241 was removed from the list of consideration because it was located at the Y-12 National Security Complex (Y-12). In April 2018, the Advisory Board on Radiation and Worker Health (Advisory Board) tasked SC&A to evaluate RPRT-0090.

In October 2018, SC&A issue an evaluation of RPRT-0090. In that report, SC&A identified seven findings and six observations (SC&A, 2018). NIOSH responded to SC&A's evaluation report in a white paper issued in June 2020 (NIOSH, 2020a). The following sections of this report summarize NIOSH's responses and SC&A's evaluation of those responses.

2 SC&A's Findings

2.1 Finding 1: Scope of RPRT-0090 needs to be clearly defined

> SC&A finds that the scope of RPRT-0090 needs to be clarified in terms of whether (and how) it is meant to encompass the "reserved" portion of the ER for "cyclotrons, accelerators, and reactors" and whether NIOSH intends to address the full scope of radionuclides involved in waste management (including D&D), site-wide construction, and maintenance.

2.1.1 NIOSH (2020a) response

> The scope of ORAUT-RPRT-0090 was purposely limited to the production of radioisotopes by the Isotopes Division on both the ORNL and Y-12 footprints. The report evaluated the ability of ORNL to monitor for each radionuclide involved to determine if any represented such a challenge to the in-place monitoring program as to affect the ability to perform dose reconstruction. No such infeasibility was identified. [p. 2]
>
> It should be noted that the entire period requested by the SEC-00189 petitioner (6/17/1943 – 7/31/1955) was qualified by NIOSH and addressed in the ORNL (X-10) evaluation report [NIOSH 2011]. As such, there is no portion related to that petition that remains to be evaluated. The evaluation of the "exotic

> radionuclides" was reserved in the SEC-00189 evaluation report due to the overlap between Y-12 and ORNL with respect to the calutron and cyclotron facilities and their associated operations. NIOSH decided to initiate a combined effort for Y-12 and ORNL to evaluate the isotopes production operations [NIOSH 2012]. Consequently, ORAUT-RPRT-0090 was developed to specifically address the ORNL isotopes production facilities to identify potential infeasibilities in the areas of the reserved section of the SEC-00189 evaluation report (as evidenced by the infeasibility for Pu-241 that was identified and addressed in a separate SEC evaluation). ORAUT-RPRT-0090 was not intended to be an evaluation of whether a co-exposure model type approach could be developed for every single radionuclide. [NIOSH, 2020a, pp. 2–3]

2.1.2 SC&A evaluation of NIOSH response

SC&A accepts NIOSH's clarification regarding the limited scope of RPRT-0090, which would exclude treatment of decontamination and decommissioning (D&D), construction, and maintenance activities that may encompass the facilities in question (this clarification would also be responsive to finding 7, which specifically addressed D&D activities at the Isotope Division facilities). SC&A finds this issue sufficiently addressed and recommends closing this finding.

2.2 Finding 2: Incomplete radionuclide and radioisotope facility inventory

> A sampling of the radionuclides listed in Table 7-2 found a few missing when compared with operational and customer records. Likewise, a few ORNL facilities that historically handled radioisotopes are also not included in those cited and addressed in RPRT-0090. Given the operational diversity of ORNL accelerator and reactor operations, consideration should be given to an inventory scope that encompasses isotopic source terms broader than that of the Isotope Division.

2.2.1 NIOSH (2020a) response

> The discrepancies indicated by SC&A are generally related to the scope of the document, that is, the isotopes produced by the isotopes group versus a more general analysis of the overall radionuclide inventory at ORNL. The facilities listed in ORAUT-RPRT-0090 are the primary facilities used by the isotopes group and are presented for a historical perspective. The inventory listing was developed independently of the facility list and was related to isotope group activities across the site.
>
> Specific discrepancies presented in Table 1 of SC&A's review (within the narrative associated with Finding 2) are addressed in Table 1 [p. 4 of NIOSH, 2020a]. [NIOSH, 2020a, p. 3]

2.2.2 SC&A evaluation of NIOSH response

SC&A accepts the clarifications provided by NIOSH in table 1 of its response and notes that an explanation will be added to the next revision of RPRT-0090 regarding the scope of the radionuclide inventory included. SC&A finds this issue sufficiently addressed and recommends closing this finding.

2.3 Finding 3: Attachment A in vitro bioassay methods lack information about actual implementation

In vitro bioassay methods are outlined in Attachment A, but it does not include any discussion or references regarding their actual field implementation. The exclusion of comparable *in vivo* monitoring methods makes a review of ORNL monitoring capability incomplete.

2.3.1 NIOSH (2020a) response

NIOSH intends ORAUT-RPRT-0090 to be a review of the isotopes handled by the isotopes production group in comparison to the available bioassay capability. The report provides a detailed listing of bioassay availability by indicating the number of measurements performed for each method discussed in Attachment A. The available number of bioassay records indicates that the available methods were implemented according to the policies in place at the time. A monitoring method would not be expected to be broadly implemented if the given radionuclide was only produced sporadically. It is not clear what additional information would be needed to rule out a potential dose reconstruction infeasibility. Note that not all available data on sporadically-produced radionuclides will be a sufficient quantity to allow for their use in a co-exposure model. However, this alone is not indicative that a potential exposure could not be bound with sufficient accuracy. [NIOSH, 2020a, p. 5]

2.3.2 SC&A evaluation of NIOSH response

While NIOSH "intends ORAUT-RPRT-0090 to be a review of the isotopes handled by the isotopes production group in comparison to the available bioassay capability," it is clear from the report's stated purpose that any identified monitoring gaps from this comparison would be evaluated to "determine if dose reconstruction for these exotic radionuclides is feasible." (NIOSH, 2018, p. 6). Therefore, the apparent premise of this "monitoring feasibility evaluation" is that availability of bioassay monitoring procedures equates directly to dose reconstruction (DR) feasibility.

While NIOSH contends that "ORAUT-RPRT-0090 was not intended to be an evaluation of whether a co-exposure model type approach could be developed for every single radionuclide" (NIOSH, 2020a, p. 3), its detailed matrix approach to ruling out any "infeasibilities" for DR based on assumed ORNL procedural monitoring capability for each exotic radionuclide handled by the Isotopes Division presumes that distinction and would render a co-exposure model unnecessary.

In RPRT-0090, "when an adequate monitoring method was indicated (i.e., by analytical results for a previous year), it was deemed adequate evidence for concluding there was no gap in monitoring capability" (NIOSH, 2018, p. 24). NIOSH (2018, p. 24) further clarified that "this was the case even when a particular radionuclide was produced in a later year in which no instances of that bioassay method were evident. That is, once a bioassay method was reported, it was assumed to be available each year thereafter." NIOSH's approach, as illustrated in tables 7-2 and 7-3, shows that most radionuclides, therefore, can be labeled as "green" (i.e., the specific radionuclide was present, a bioassay method was available to detect the radionuclide, and sample

results for that particular bioassay method are available, all for the specified year) or "yellow" (i.e., the specific radionuclide was present in inventory, and a bioassay method was available to detect the radionuclide, but no sample results for that particular bioassay method are available, for the specified year based on an applicable prior year bioassay monitoring procedure being documented).

However, as noted in our finding, SC&A's concern is that a review of dosimetry capability, while *necessary* to validate that measurement techniques were technically acceptable and available, is *not sufficient* to address the feasibility of DR. It is also essential, for purposes of data completeness, to validate whether ORNL actually (or, at least, likely) performed the requisite bioassays for workers potentially exposed to exotic radioisotopes over the timeframe in question. This is addressed specifically in DCAS-IG-006, revision 00, "Criteria for the Evaluation and Use of Co-Exposure Datasets" (NIOSH, 2020b, p. 6):

> Once the measurement techniques have been found to be technically acceptable, the amount of available monitoring data must be evaluated to determine if there are sufficient measurements to ensure that the data are either bounding or representative of the exposure potential for each job/exposure category at the facility. This analysis should look, not only at the total amount of data that are available, but also consider any temporal trends in data availability.

If field implementation is not within the scope of RPRT-0090, as noted in NIOSH's response, then RPRT-0090 cannot be the sole basis for a decision regarding feasibility because there is no evident gauging of the sufficiency of measurements to be bounding of potential exposures. Identifying the number of samples or counts alone, including null sampling results, devoid of exposure potential considerations (e.g., the source term being handled) over the 30+ years of Isotope Division production, arguably would not satisfy DCAS-IG-006. At the very least, what is needed is a weight-of-evidence approach to validate that monitoring took place (or was not necessary) for operational time periods that lacked recorded sampling or where sampling was sparse (e.g., one or two samples). Pointing to the sheer presence of samples or the number of ORNL records captured, alone, would not satisfy this need for corroboratory evidence.

The importance and relevance of this point can be found in two recent SEC reviews.

For the Los Alamos National Laboratory (LANL) review, the original Special Exposure Cohort (SEC) petition evaluation report (ER) for petition SEC-00109 for 1976–2005 (NIOSH, 2009) had found that DR of exotic alpha emitters, fission products, and activation products was feasible for 1976–1995 based on the availability and technical adequacy of LANL's state-of-the-art whole body counter. However, subsequent review established that monitoring data for these radionuclides were insufficient or did not exist for the timeframe in question. Interviews with the internal dosimetrists established that while the technological capability was present from at least the early 1970s, it was not applied to routine monitoring of exotics at LANL.

While it is assumed that ORNL bioassays were performed when needed, based on the development of a relevant procedure, how will NIOSH validate whether those procedures were actually followed or whether monitoring of potential exposures took place, as required? NIOSH also appears to presume that, for radionuclides being handled for which no procedures could be

found, it is assumed that ORNL would have had the capability to have developed (and presumably, implemented) such a procedure for the radionuclide, in question. A feasibility determination based on such a *presumption of monitoring* was invalidated during the aforementioned LANL SEC review by the weight of evidence (including a review of actual sampling versus exposure potential over time, as well as interviews with internal dosimetrists). How will NIOSH substantiate the validity of this similar presumption?

For Savannah River Site (SRS), a concern over whether radiation work permit (RWP)-driven, job-specific bioassays were performed adequately was raised by SC&A in its 2017 and 2020 reviews of SRS subcontractor job-specific bioassay data completeness assessments (SC&A, 2017, 2020). Based on compliance findings by U.S. Department of Energy (DOE) headquarters in 1998, it became apparent that, despite detailed, updated procedures for bioassay monitoring, SRS subcontractor workers had not submitted RWP-required bioassays upon completion of work, and contractor management had not held the program accountable for doing so. The DOE enforcement office found this to be a DOE-wide program shortfall and ordered a 90-day stand-down on enforcement actions for all operating contractors to allow site self-assessments and corrective actions to be performed for bioassay programs. How will NIOSH gauge the completeness of such bioassays at ORNL in light of a recognized DOE-wide deficiency in how job-specific bioassays were conducted? This is of particular import given noteworthy bioassay program implementation deficiencies and corrective actions cited in ORNL internal reviews (e.g., MMES (1988)) and later DOE enforcement actions in the 1990s (DOE, 1998a, 1998b).[1]

NIOSH's response to SC&A's finding 3 offers that "it is not clear what additional information would be needed to rule out a potential dose reconstruction infeasibility" (NIOSH, 2020a, p. 5). Based on past and ongoing SEC petition reviews, the following research activities have served to substantiate feasibility for other DOE sites in support of other SEC petition evaluations, in determining whether routine and event-driven bioassays were actually implemented in accordance with site procedures:

- review of programmatic records, including audits, assessments, and quality assurance reviews, both independent and in house
- interviews with operating personnel and health physics staff for the facilities in question
- review of incident occurrence reports and accident investigations
- identifying and reviewing RWPs, including pre-job contamination surveys, particularly for ORNL-wide maintenance and construction workers performing jobs in the isotope production facilities
- establishing field implementation experience with bioassay procedures through review of internal communications and self-assessments (e.g., related to transition to DOE Order 5480.11 in 1989 and Title 10 of the Code of Federal Regulations Part 835 in 1995)

SC&A's cursory review of available ORNL-related Site Research Database (SRDB) records matching these descriptions suggests concerns about lack of operating procedures for internal

[1] The DOE enforcement action surrounding bioassay deficiencies noted in 1996–1997 occurred after the ER time period but can be seen as relevant to the question of historical procedural implementation at ORNL.

dosimetry and inadequate procedures for performing internal dose assessments (MMES, 1988), inadequate implementation of RWPs (MMES, 1988), and the lack of a formal and consistent whole-body counting program until 1994[2] (including the lack of minimum detectable activity procedures until the late 1980s) (ORAU, 2004; MMES, 1988). What is noteworthy from SC&A's review is the lack of corroboratory records—reviews, reports, and interviews—that address the adequacy of how the bioassay program for the ORNL isotope production program was carried out. As reflected in SC&A's finding 6, more information is needed beyond the monitoring data to substantiate that these data are sufficient and complete in the context of DR under the DCAS-IG-006 guidelines.

Balanced against these programmatic concerns are what radionuclide-specific bioassay samples were identified by NIOSH for 1955–1988. But can these be considered complete without any validation that required sampling was performed for the isotope production program? How can bioassay sampling be inferred, when recorded data are lacking or sparse, on the basis of a preexisting bioassay monitoring procedure? Were job-specific bioassays a requisite part of RWPs in use at isotope production facilities? How can radionuclide-specific monitoring procedures and their implementation be presumed based on a judgment of ORNL laboratory dosimetry capability without any corroboration based on records or interviews?

SC&A would accept NIOSH's clarification that, in response to this finding, the scope of RPRT-0090 does not include such implementation questions. However, SC&A finds that the report's intended purpose to determine DR feasibility clouds this issue. If RPRT-0090 is solely a survey of monitoring feasibility or bioassay capability for 1955–1988, SC&A recommends closure of this finding with the expectation that DR feasibility will be addressed later.

If RPRT-0090 is intended as the key basis for ascertaining DR feasibility for ORNL exotics, SC&A recommends to the ORNL work group that that this finding be held open until the question of data completeness and other field implementation questions can be settled. SC&A further recommends that joint NIOSH/SC&A/Advisory Board interviews be conducted with former ORNL dosimetrists and health physics personnel, along with data captures focused on clarifying actual field implementation of historic bioassay procedures cited by NIOSH for the Isotopes Division during the years of SEC relevance. Notwithstanding NIOSH's invitation to SC&A to canvass its estimated 15,000 documents related to ORNL, SC&A's searches of the SRDB (using keywords such as "bioassay," "procedures," "assessments," and "isotopes"), have not turned up noteworthy and sufficient corroboratory information regarding actual field implementation. Speaking with knowledgeable site experts on this question will serve to support NIOSH's *presumption of monitoring* consistent with how this issue has been typically addressed for SEC reviews at other DOE sites. This finding remains open.

[2] In the ORNL internal dose technical basis document (TBD), ORAUT-TKBS-0012-5, revision 02 (NIOSH, 2013), NIOSH acknowledges that listed ORNL whole-body frequencies were not consistently followed and that no formal counting frequency was used at ORNL until the late 1980s. The TBD also notes that although a routine in vivo monitoring program for all site radiological workers began in 1965, a formal program was not instituted until the late 1980s. An interview with the in vivo dosimetrist of that time indicated that reliance on area health physicists to select workers for monitoring led to inconsistencies until the central health physics program assumed that responsibility in 1994. While this is noted in RPRT-0090, no further assessment of these implementation considerations for their implications to dose reconstruction feasibility is provided.

2.4 Finding 4: Feasibility of monitoring 28 radionuclides not adequately addressed

> While the 28 radionuclides were discussed in Section 7.2 and some of their characteristics were listed in Tables 7-4, 7-5, and 7-6 of RPRT-0090, the feasibility of monitoring for intakes for DR purposes was not completely addressed, particularly given the lack of routine bioassays in the earlier years. Methods for accounting for the lack of monitoring of these radionuclides need to be addressed in more detail, and an acceptable resolution derived. SC&A finds that it is not possible at this time to validate implementation without further onsite review, including document review and interviews with health physicists of the time period involved.

2.4.1 NIOSH (2020a) response

> The implementation of the monitoring program is indicated by the availability of the bioassay cards showing results for the respective methods. Any available bioassay data could be used to assign doses to a claimant using an individual dose reconstruction approach and the methods established in the site profile. Additional review of available records and monitoring procedures will be on-going using the data available in the Site Research Data Base (SRDB); SC&A is invited to do the same (current holdings for ORNL are close to 15,000 documents). NIOSH did not intend to include a formal review of program implementation in ORAUT-RPRT-0090 because that was not the objective of the report (see also the response to Finding 3). [NIOSH, 2020a, pp. 5–6]

2.4.2 SC&A evaluation of NIOSH response

NIOSH stated on page 25 of RPRT-0090 that the red-colored data cells in tables 7-2 and 7-3 mean:

> A specific radionuclide was present in inventory in the specified year, but an additional analysis was necessary to determine if the nuclide represented an infeasibility from a monitoring perspective.

The use of derived air concentrations (table 7-5) to illustrate the maximum organ dose for a hypothetical intake is summarized in table 7-6 of RPRT-0090. Supplemental information to address some of the gaps in the data in table 7-6 is provided in table 3 of NIOSH's response paper (NIOSH, 2020a, p. 12).

Although the resulting organ doses in table 7-6 from a hypothetical intake are not alarming, they do not appear insignificant for a potential unmonitored exposure, and the derived doses do not directly address the monitoring feasibility question. Therefore, SC&A finds that the question of "if the nuclide represented an infeasibility from a monitoring perspective" remains relevant and that it was not specifically and completely addressed in sections 7.2 or 8.0 of RPRT-0090. SC&A recommends that this finding remains open.

2.5 Finding 5: 1955 and 1956 intakes may not be bound by earlier coworker data

> Assessment of RaLa [radioactive lanthanum] radioiodine releases at X-10 indicates the highest annual releases occurred during the campaign to process Hanford slugs during 1956. Therefore, the radioiodine production and releases during the years used for coworker development (1947–1949) do not appear to bound the production throughput, at least during 1956 and possibly 1955.

2.5.1 NIOSH (2020a) response

> NOTE: NIOSH now uses the term "co-exposure" for coworker or co-worker. Verbatim quotes from documents issued by other organizations retain their terminology.

There is no doubt that the incidental release of iodine during RaLa production and releases during the production of iodine are different. The salient point is that an individual who received no thyroid monitoring from 1955 to 1962 would not likely have been exposed to a higher level of radioiodine than that determined by a chronic intake using the 95th percentile of routine monitoring data for 1947 to 1949. This conclusion is supported by the fact that during the earlier period (1947–1949) much larger quantities of iodine were processed than during the 1955–1962 activities of the isotopes group (1,000 ci – 3,600 Ci). The minimum annual inventory during the 1947 to 1949 period (8,800 Ci/yr) is based on the range of 8,800 Ci/yr to 42,600 Ci/yr [ATSDR 2008, PDF p. 16]. The fact that the cited quantity might only represent the quantity released through stack emissions provides further support since the stack emissions would be much smaller than the quantity of material being processed.

The assertion that the intake calculated at the 95th percentile based on monitoring performed from 1947 to 1949 is somehow not sufficiently claimant favorable fails to consider the intended use of the co-exposure (formerly coworker) data to address potentially unmonitored exposure to isotopes group workers. Moreover, to accept this one would have to conclude that the release quantity tabulated for 1956 (66,700 Ci) is sufficiently higher than the value cited for 1947 (64,200 Ci) to not be within the uncertainty inherent in the data itself and not addressed by the use of the 95th percentile of the intake calculated using the 1947 – 1949 data. In fact, these values differ by less than 4% [ATSDR 2008, PDF p. 12].

> In the narrative preceding Finding 5, a number of concerns were documented. To assist in the understanding of the ORAUT approach, additional clarification specific to each concern is provided in table 2 [on p. 7 of NIOSH (2020a)]. [NIOSH, 2020a, p. 6]

2.5.2 SC&A evaluation of NIOSH response

The fundamental question is whether internal monitoring data from one era (1947–1949) can be used as substitute co-exposure intake estimate for another era (1955–1962). It is SC&A's opinion that adequate information and evidence must be available to establish that operations were sufficiently similar to, or bounding of, the radiological operations during the period for which no

internal monitoring records are available. To this end, NIOSH proposes use of the 95th percentile of derived co-exposure intake estimates from 1947–1949 and provides three primary comparisons to postulate that the derived intake rates are bounding. The magnitude of co-exposure estimate comparisons can best be summarized as comparisons to available urinalysis data taken in 1966, in vivo estimates of body burdens measured in 1962, and site technical guidelines regarding allowable airborne contamination limits.

As described by SC&A (2018), there were a number of concerns and/or requests for clarification on the underlying evidence intended to support the position that derived co-exposure intake rates appropriately reflect and bound potential exposures during the unmonitored period. NIOSH (2020a) summarized each of these concerns and provided additional information in table 2. This information, with SC&A's current technical position, is provided in table 1 below.

Finally, NIOSH acknowledges that while stack releases from RaLa operations were higher in 1956 than in 1947, the difference is relatively insignificant (~4 percent). SC&A is inclined to agree; however, SC&A would also note that in situations where uncertainty exists in claimant dose estimates, it is often accepted practice in the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) program to apply adjustment factors to account for such uncertainty. For example, the methodology described in section 7.2 of NIOSH (2018) applies the somewhat arbitrary adjustment factor of 10 to the intake rate to account for uncertainty in reconstructing dose to 28 individual radionuclides. RPRT-0090 states:

> The factor of 1×10^{-5} was selected based on the guidance in NUREG-1400, which postulates that 1×10^{-6} times the material handled could serve as a reasonable estimate of the quantity that could be inhaled ([NRC] 1993). A factor of 10 was added to ensure a conservative evaluation. [NIOSH, 2018, p. 40]

SC&A notes that this factor of 10 is in addition to other claimant-favorable assumptions concerning release fractions and confinement factors that SC&A presumes were made to address uncertainties in dose assignment.

Whether such uncertainty is sufficiently accounted for by the use of the 95th percentile based on routine monitoring is a matter of professional judgment and should be weighed by the work group.

Table 1. Summary of issues concerning radioiodine co-exposure model (expansion of NIOSH (2020a), table 2)

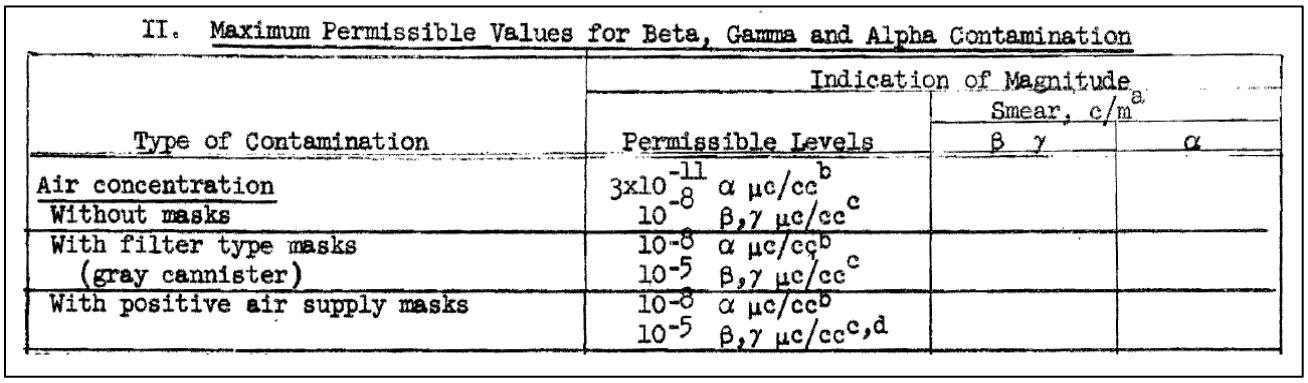
No.	Original SC&A concern (as stated in NIOSH (2020a), table 2	NIOSH clarification (as stated in NIOSH (2020a), table 2	Current SC&A position
1	Of the 168 bioassay samples evaluated in RPRT-0090, only 8 were taken prior to 1963 and only 2 were taken prior to the first use of the whole body counter in 1961.	As stated in section C.4, the evaluation of iodine exposure prior to 1962 was primarily done using thyroid monitoring. A total of 230 such measurements are available spanning the period 1945 through 1957.	SC&A concurs that the co-exposure model is not based on the urinalysis data cited. SC&A notes that while there are 230 thyroid measurements from 1945 through 1957, only 112 such measurements were made during the period 1947–1949 when co-exposure intakes were developed. However, SC&A's concern is related to the use of the urinalysis data as evidence to validate the proposed co-exposure intakes based on thyroid monitoring data as bounding. SC&A does not believe it has been thoroughly established that operational conditions are sufficiently similar to use such data as evidence that calculated co-exposure intakes are bounding. However, as SC&A notes in the next table entry (no. 2), SC&A has not identified any indication that conditions were such that urinalysis results would be an order of magnitude higher during the unmonitored period than later periods when urinalysis data are available.

No.	Original SC&A concern (as stated in NIOSH (2020a), table 2	NIOSH clarification (as stated in NIOSH (2020a), table 2	Current SC&A position
2	Although RPRT-0090 notes that the projected urinary excretion rate is more than an order of magnitude higher than the maximum observed routine sample, no information or references are provided to indicate when that routine sample was taken. The analysis in Section C.7 of RPRT-0090 indicates that the evaluated urinalysis results spanned all the way to 1988.	The maximum observed routine sample cited was collected on 11/4/1966 [ORNL 1986, PDF p. 3]. This sample was one of the 115 iodine urine samples coded as type '000' in the ORNL bioassay records (see ORAUT-RPRT-0090, Table 4-3).	SC&A acknowledges and appreciates the additional information provided by NIOSH. SC&A notes that the sample is outside the period in which the co-exposure model is intended to assign intakes of radioiodine. It is generally appropriate to establish that operations, and associated exposure potential, are appropriately similar or bounding during this period for the comparison of urinalysis results to have significance. However, SC&A also recognizes that there is no indication that operations and exposure potential during the unmonitored period were an order of magnitude higher than the operations in which the highest observed urinalysis sample was obtained.
3	Per Table C-8 of RPRT-0090, the highest observed radioiodine urinalysis sample was 2.2×10^7 picocuries per day (pCi/d), which is a factor of 130 higher than the projected urinary excretion rate using the chronic co-exposure model. NIOSH indicates this sample was categorized as "incident/follow-up/resample" but does not elaborate on the timeframe or conditions.	The referenced sample was collected on 6/22/1967. The sample is related to an event that occurred on 6/21/1967 and is detailed in section C-11 of ORAUT-RPRT-0090 in the subsection pertaining to that incident date.	SC&A acknowledges the clarification provided by NIOSH. The incident in question involved disassembly of contaminated equipment, and potassium iodide was administered shortly following the incident to limit uptake of the radioiodine to the thyroid. Logically, this would also result in increased excretion rates of radioiodine in subsequent urinalysis samples similar to other chelation techniques. The magnitude of such increases relative to the potential intake have not been evaluated; however, SC&A notes that internal monitoring involving chelation techniques are not utilized in co-exposure modeling due to the biological variation in excretion patterns. Therefore, this sample is likely not relevant to evaluating co-exposure intake estimates.

No.	Original SC&A concern (as stated in NIOSH (2020a), table 2	NIOSH clarification (as stated in NIOSH (2020a), table 2	Current SC&A position
4	Conclusion 2 notes that the projected whole-body accumulation is a factor of 4 larger than the highest whole-body accumulation recorded (0.28 microcuries [µCi]). However, this whole-body measurement was made in 1962, and no whole-body measurements were made until 1961. It has not been established that these data can be back-extrapolated to represent prior exposure conditions.	The intention of the cited comparison (i.e., "factor of 4 larger than the highest whole-body accumulation recorded") is to contrast the expected accumulation (based on the claimant-favorable proposed intake quantity during the period in which it would be applied) to the magnitude of the actual measured quantity during the period during which that proposed claimant favorable intake would be applied. This is done to indicate that the proposed intake is bounding. That is, projections based on the proposed intake are much higher than anything actually observed in the exposed population.	SC&A acknowledges NIOSH's clarification of the intent behind the comparison to available in vivo counting data. However, SC&A notes that the operations in 1962 may not be reflective of operations occurring in prior years. This may be particularly important for 1956, when the highest estimates of radioiodine releases related to RaLa operations were documented to have occurred.
5	Conclusion 3 notes that the projected chronic air concentration (1.8×10^{-8} µCi/cm^3) was nearly a factor of 2 higher than the maximum operating level used to control facility air concentrations. However, the air sampling data are only available in summary form, and neither the quantitative results nor the locations of these air samples are currently known.	The comparison was to the operating limits (tolerance values) enforced during the time period, not the actually observed air concentrations. The point made is that the air concentrations above what would be allowed for routine occupancy would be associated with the magnitude of intakes proposed for assignment to unmonitored individuals.	SC&A agrees with NIOSH that the projected air concentration based on the proposed co-exposure intake rates bounds what was established as the maximum operating level for the facility if it is indeed 1×10^{-8} µCi/cm^3 (refer to subsequent discussion under table item no. 6). However, SC&A believes it is important to establish what the actual measured air concentrations were at the facility, whether and when they were exceeded, and the frequency of such events. Such information would establish that the chronic exposure levels at the projected air concentration are in fact bounding for all operations involving radioiodine.

No.	Original SC&A concern (as stated in NIOSH (2020a), table 2	NIOSH clarification (as stated in NIOSH (2020a), table 2	Current SC&A position
6	The ORNL site profile (NIOSH 2007, p. 34) notes that the tolerance-level air concentration during 1954 (the year just prior to the unmonitored period of interest) was actually 3×10^{-8} µCi/cm^3, 50% higher than the projected air concentration calculated in RPRT-0090 (1.8×10^{-8} µCi/cm^3).	The documents associated with the citation in NIOSH 2007, p 34 referred to the 'tolerance level' anecdotally without specifying the actual tolerance value. The tolerance value applicable to beta/gamma air concentration data is 1×10^{-8} µCi/cm^3 as indicated in the 5/1/1951 compilation of maximum permissible operating levels [Sadowski 1953, PDF p. 7]. The cited value of 3×10^{-8} is in error and will be corrected in the next revision of the ORNL site profile	SC&A reviewed the indicated reference and acknowledges NIOSH's interpretation of the record. However, it is not as clear to SC&A that the original cited value of 3×10^{-8} µCi/cm^3 is necessarily in error. A screenshot of the record is provided in figure 1 below. It is unclear if the "3x" was meant to be applicable to all entries describing the air concentration limits. SC&A believes that it would be unusual to have different respiratory protection factors for alpha and beta/gamma contamination. In general, the protection factor for respirators is based on the particle filtration characteristics of the respirator rather than the radiation type. In this case, NIOSH's interpretation of the record would indicate a respiratory protection factor of 333 for alpha and 1,000 for beta-gamma using the same respirator.

Figure 1. Excerpt from Sadowski (1953) documenting tolerance levels for airborne contamination cited in NIOSH (2020a)



II. Maximum Permissible Values for Beta, Gamma and Alpha Contamination

Type of Contamination	Indication of Magnitude Smear, c/m[a] Permissible Levels	β γ	α
Air concentration	3×10^{-11} α μc/cc[b]		
Without masks	10^{-8} β,γ μc/cc[c]		
With filter type masks (gray cannister)	10^{-8} α μc/cc[b]		
	10^{-5} β,γ μc/cc[c]		
With positive air supply masks	10^{-8} α μc/cc[b]		
	10^{-5} β,γ μc/cc[c,d]		

2.6 Finding 6: Adequacy and implementation of in vivo bioassay program not addressed

Information is lacking for the actual implementation of the ORNL in vivo program, including what and how radionuclides were monitored in practice, what and how workers were identified and included for counting, and how capability to monitor for MAPs [mixed activation products], MFPs [mixed fission products], and exotic radionuclides paced both technology developments and onsite monitoring practice (e.g., routine vs. nonroutine monitoring). SC&A recommends that the Work Group request a review of available records, particularly internal dosimetry program records and WBC [whole body count] nuclide libraries, and scheduling of interviews with appropriate ORNL dosimetry staff.

2.6.1 NIOSH (2020a) response

NIOSH believes that the volume of available monitoring data, including analysis for non-routine radionuclides, as shown in ORAUT-RPRT-0090, Table 4.3 (Bioassay code 000 with monitored nuclide, 1955 – 1988), demonstrates the capability to monitor exposure to the wide range of materials present. However, NIOSH did not intend to include a review of program implementation in ORAUT-RPRT-0090.

There are numerous internal dosimetry related documents already available in the SRDB that SC&A may review prior to additional data captures and interviews (the current SRDB holdings for ORNL amount to almost 15000 documents). These include excerpts from radiological control personnel logbooks, which demonstrate the level of control and monitoring performed. [NIOSH, 2020a, p. 8]

2.6.2 SC&A evaluation of NIOSH response

SC&A considers this finding subsumed under finding 3 and recommends closure of finding 6.

2.7 Finding 7: Unclear treatment of post-1988 monitoring capability during abandonment, deactivation, and decontamination and decommissioning phases

After radionuclide production ended, the adequacy of monitoring and feasibility of assigning intakes from the storage, disposal, and D&D of the facilities has not been addressed. This issue is especially important for the ORNL Isotopes Division because it processed and concentrated unusual radionuclides that would not be encountered during the normal D&D process.

2.7.1 NIOSH (2020a) response

The point of ORAUT-RPRT-0090 was to assess the feasibility of monitoring nuclides produced by the isotopes group during production operations. While such analysis is outside the scope of the document, it would seem credible that it would be feasible to bound exposures to the same set of radionuclides during D&D periods after 1988 with modern dosimetry methods.

2.7.2 SC&A evaluation of NIOSH response

SC&A finds this issue sufficiently addressed in finding 1 and recommends closing finding 7.

3 SC&A's Observations

3.1 Observation 1: Inventory discrepancy

A sampling of some of the inventory of the radionuclides for the early years indicated some discrepancies in inventory between Table 7-2 in RPRT-0090 and NIOSH's X-10 Inventory spreadsheet.[3]

3.1.1 NIOSH (2020a) response

As stated in section 6.0 of ORAUT-RPRT-0090, an inventory of radionuclides processed by the ORNL X-10 isotopes group was developed through a review of published sales records. The spreadsheet that SC&A refers to in their comment represents the compilation of that document review. However, as also indicated in section 6.0, NIOSH updated the radionuclide inventory based on a review of logbooks. This review resulted in the addition of additional radionuclides, and additional inventory years for existing radionuclides.

In regards to the comparison of radionuclides identified through the summary of monitoring data contained in ORAUT-TKBS-0012 and the inventory data contained in ORAUT-RPRT-0090, it should be noted that the scopes of these documents are different and that ORAUT-RPRT-0090 is limited to the inventory of materials processed by the isotopes group and not the inventory of all radionuclides potentially present at ORNL. [NIOSH, 2020a, p. 9]

[3] NIOSH supplied Microsoft Excel "X-10 Exotics Workbook_022015 kwv" under the tab "Master Summary Data" (hereafter "X-10 Inventory").

3.1.2 SC&A evaluation of NIOSH response

Instances of discrepancies that SC&A identified were additional radionuclides and/or years appearing in table 7-2 of RPRT-0090; therefore, SC&A concurs that additional radionuclides and/or inventory years from logbooks added to the original X-10 inventory spreadsheet would explain the discrepancies in inventory between table 7-2 in RPRT-0090 and NIOSH's X-10 Inventory spreadsheet. SC&A finds this observation clarified and recommends closure.

3.2 Observation 2: Specific alpha-emitting radionuclide needs to be identified for DR

> The specific radioisotope monitored is not always presented in NIOSH's X-10 Database as it generally is in the NOCTS [NIOSH DCAS Claims Tracking System] files. Gross alpha results could be applied to many radionuclides. Is the information on the original bioassay cards available in the X-10 Database, and will the X-10 Database be used in DR or coworker model development?

3.2.1 NIOSH (2020a) response

> The original X-10 bioassay cards are provided by ORNL for individual claimants and are the basis for dose reconstruction. The X-10 database is not used for dose reconstruction purposes. Any notations as to the specific radionuclide being monitored are available for use in the claimant-specific dose reconstruction report. [NIOSH, 2020a, p. 10]

3.2.2 SC&A evaluation of NIOSH response

Considering NIOSH's clarification that the X-10 database will not be used for individual DR, SC&A concurs with NIOSH's response. Additionally, if the X-10 database will not be use in co-exposure intake modeling without further consideration of specific alpha-emitting radionuclides, then SC&A finds this observation has been sufficiently clarified.

3.3 Observation 3: Trans-plutonium radionuclides may need further analyses

> SC&A is concerned that assigning trans-plutonium gross alpha counting results as Am-241 intakes without consideration of other potential trivalent alpha-emitting actinides (such as Bk-249, Cf-252, Cm-242, Cm-244, etc.) and their individual radiotoxicity could result in underestimating the internal dose. It could be beneficial to determine if assigning the intake as Am-241 is claimant favorable, considering the exotic trans-plutonium radionuclides at ORNL.

3.3.1 NIOSH (2020a) response

> ORAUT-TKBS-0012-5 (Oak Ridge National Laboratory – Occupational Internal Dose) [NIOSH, 2013] identifies Am-241 as the default assumption for the interpretation of trans-plutonium (TPO) bioassay results. However, individual dose assessments are completed considering all available claimant-specific information, including any data. This includes the original bioassay cards, which, along with other information contained in the claimant records, may contain identifying information on the nuclides of interest. Of the 20 radionuclides that are called out in ORAUT-RPRT-0090 as detectable by the TPO method, only two

> have a higher organ dose conversion factor (DCF, dose to a particular organ/unit activity). These are Cm-248 and Cf-249 with maximum organ DCF ratio to Am-241 of 3.7 and 1.55, respectively. However, Am-241 is a reasonable default assumption considering that the maximum annual inventory for these two radionuclides (64 mCi and 56 mCi, respectively) is a factor of 10^5 lower than that of Am-241. [NIOSH, 2020a, p. 10]

3.3.2 SC&A evaluation of NIOSH response

SC&A evaluated NIOSH's response. Considering that NIOSH has analyzed the DCFs and inventory amounts of the TPOs, SC&A finds that using Am-241 as the default radionuclide (if other information is not available) would be a reasonable assumption. SC&A finds this observation clarified and recommends closing it.

3.4 Observation 4: Use of gross beta or gamma count data could result in underestimate of assigned dose

> Using gross beta or gamma count data without knowledge of the radionuclide the counter was calibrated with and the radionuclides in the bioassay sample could result in assigning the incorrect radionuclide and radioactivity content because of different counting efficiencies for the different energy of beta particles and gamma photons. Has this issue been addressed for DR for ORNL claimants? Additionally, bioassay data for at least one beta-emitting radionuclide (Ru-106) could not be located for several years that Table 7-2 indicated it was available.

3.4.1 NIOSH (2020a) response

> In regards to the issue with Ru-106, bioassay methods assigned to Ru-106 are type 000 (Ru-106), 013/GB0 [gross beta in urine sample], and RU6 [Ru-106]. SC&A is correct in that, although Table 7-3 [p. 34] shading is 'green' indicating the presence of bioassay data, no results for these methods were present in 1975, 1978, and 1986-1988. An editing mistake happened during the final document preparation for 508 compliance. In the next revision to ORAUT-RPRT-0090, Table 7-3 will be shaded 'yellow' for the indicated years.
>
> The original X-10 bioassay cards are provided by ORNL for individual claimants and are the basis for dose reconstruction. Any notations as to the specific radionuclide being monitored are available for use in the claimant-specific dose reconstruction report. Specific adjustments based on individual radionuclides would be outside the scope of ORAUT-RPRT-0090 and would be addressed within individual dose reconstruction reports, if appropriate. [NIOSH, 2020a, p. 11]

3.4.2 SC&A evaluation of NIOSH response

SC&A concurs with NIOSH's response to the ruthenium-106 (Ru-106) issue and agrees that the issue can be resolved by NIOSH making changes in the next revision of RPRT-0090.

However, the issue of the appropriate radionuclide and counting efficiency to be used in a given DR when the bioassay card lists gross beta or gamma counts (if this occurs), or the appropriate

radionuclide to assign when the bioassay card lists results in disintegrations per minute (dpm) or microcurie without a specific radionuclide, does not appear to have been completely addressed. Although RPRT-0090 is not intended to be a guide for DR, addressing the information that will be needed for DR for radionuclides from isotope production is appropriate when evaluating RPRT-0090. SC&A recommends that this observation remain open.

3.5 Observation 5: The results in table 7-6 depend on inventory used

> As outlined in Observation 1, there appear to be some discrepancies in the inventory used by NIOSH compared to those provided to SC&A for evaluation of RPRT-0090. These discrepancies change a few of the results of Table 7-6, as illustrated in Table 3 of this report [SC&A, 2018].

3.5.1 Summary of NIOSH (2020a) response

NIOSH (2020a, p. 12) states:

> As indicated in the response to Observation 1, the spreadsheet upon which SC&A's comparison is based contained only the results of the review of Isotope Group sales/inventory data.
>
> Additional research was conducted for radionuclides contained in Table 7-6 when for one or more years are 'unknown'. Additional information on the identified radionuclide inventory discrepancies is provided in Table 3 [p. 12].

NIOSH will correct the error for tellurium-121 in table 7.6 in the next ORAUT-TKBS-0012-5 revision.

3.5.2 SC&A evaluation of NIOSH response

SC&A evaluated NIOSH's response and the additional information provided in table 3 (NIOSH, 2020a, p. 12). SC&A analyzed the additional data and references and concurs with NIOSH's response that addresses the issues that SC&A previously summarized in table 3 of SC&A (2018) concerning table 7-6 of RPRT-0090. SC&A agrees with NIOSH's plans to correct the tellurium-121 entry in table 7-6 in the next revision of RPRT-0090. SC&A finds that this observation has been addressed and recommends closing it.

3.6 Observation 6: Additional RaLa production information should be provided

> NIOSH should provide an evaluation and discussion of any potential differences in exposure potential between commercial radioiodine production and the radioiodine produced via the RaLa operation to justify the extrapolation of exposures occurring during the years 1947–1949 to the unmonitored period (1955–1962).

3.6.1 NIOSH (2020a) response

> NIOSH believes that the exposure routes from RaLa processing and commercial iodine production are not relevant to the analysis presented. Both sets of activities were subject to the same radiological protection and monitoring programs. It is not likely that unmonitored individuals working from 1955 to 1962 would be

> exposed to levels of activity that would have triggered the monitoring program, as demonstrated by the fact that individuals exposed to such levels were in fact monitored during the period for which monitoring data are available (1947–1949). [NIOSH, 2020a, p. 13]

3.6.2 SC&A evaluation of NIOSH response

SC&A respectfully disagrees. In a general programmatic view, it is SC&A's opinion that the question of representativeness of co-exposure models includes an evaluation of the operational conditions at the time. This is of particular importance when data are extrapolated from one operational period to another. SC&A's interpretation of the guidance in DCAS-IG-006, "Criteria for the Evaluation and Use of Co-Exposure Datasets" (NIOSH, 2020b), requires even stricter evaluation of such operational conditions when combining data from contiguous years. Specifically, NIOSH (2020b, p. 11) states:

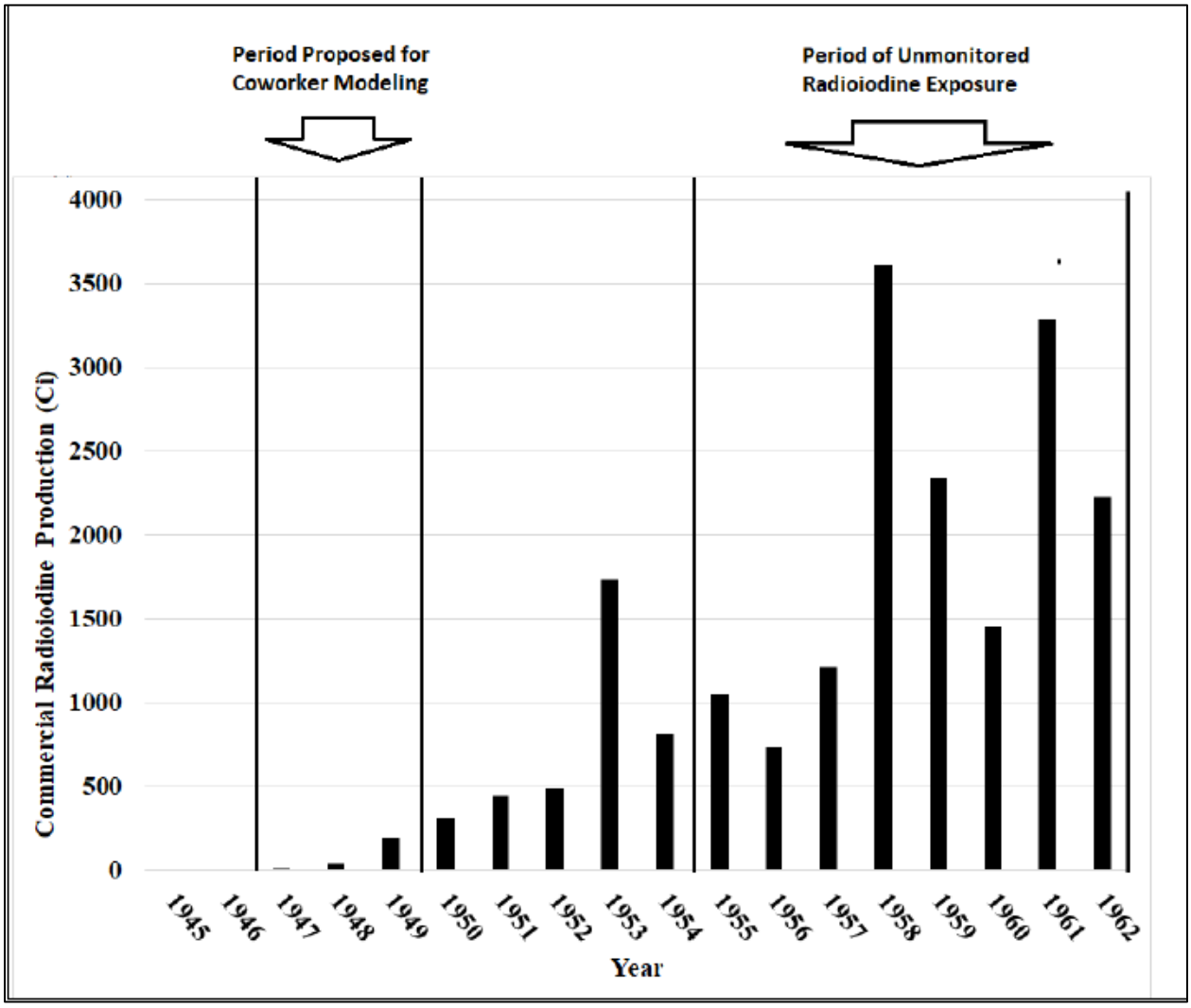
> If, because of data limitations, it is necessary to consider time intervals beyond one year in the co-exposure model, any changes in site practices or operations should be evaluated to ensure that the data can be validly combined.

SC&A believes such an evaluation is especially applicable when extrapolating data from one period to another.

The contention that workers were not "exposed to levels of activity that would have triggered the monitoring program" is not currently able to be evaluated because sufficient monitoring data from this period have not been located. SC&A believes the claimant-favorable assumption is that the lack of monitoring data during the period of interest is not due to a lack of exposure potential, but rather a lack of available records.

Specific to the co-exposure period in question, the major difference in campaigns appears to be related to the commercial production of radioiodine. It is SC&A's understanding that, while such commercial operations are not necessarily included in EEOICPA DRs, if it is not possible to differentiate between Atomic Weapons Employer/DOE operations and commercial operations, they must be considered for DR. Therefore, it is unclear to SC&A whether the difference in commercial operations as demonstrated in figure 2 of SC&A (2018) (shown below in figure 2) is relevant in an SEC context. A clarification of the statutory requirements concerning "commercial" versus "government" work may render this observation moot for the purposes of developing DR methods.

Figure 2. Commercial radioiodine production (1945–1962) (reproduced from SC&A (2018), figure 2)



4 Summary and Conclusions

This section summarizes SC&A's evaluation of the NIOSH (2020a) response paper.

Finding 1: Scope of RPRT-0090 needs to be clearly defined

- NIOSH (2020a) responded that the scope of ORAUT-RPRT-0090 was purposely limited to the production of radioisotopes by the Isotopes Division on both the ORNL and Y-12 footprints. ORAUT-RPRT-0090 was not intended to be an evaluation of whether a co-exposure model type approach could be developed for every single radionuclide.

- SC&A accepts NIOSH's clarification regarding the limited scope of RPRT-0090, which would exclude treatment of D&D, construction, and maintenance activities that may encompass the facilities in question. SC&A recommends closure.

Finding 2: Incomplete radionuclide and radioisotope facility inventory

- NIOSH (2020a) responded that the discrepancies indicated by SC&A are generally related to the scope of the document, that is, the isotopes produced by the isotopes group versus a more general analysis of the overall radionuclide inventory at ORNL. The inventory listing was developed independently of the facility list and was related to isotope group activities across the site.

- SC&A accepts the clarifications provided by NIOSH in table 1 of its response and notes that an explanation will be added to the next revision of RPRT-0090 regarding the scope of the radionuclide inventory included. SC&A recommends closure.

Finding 3: Attachment A in vitro bioassay methods lack information about actual implementation

- NIOSH (2020a) state that it intends ORAUT-RPRT-0090 to be a review of the isotopes handled by the isotopes production group in comparison to the available bioassay capability. Note that not all available data on sporadically produced radionuclides will be a sufficient quantity to allow for their use in a co-exposure model. However, this alone is not indicative that a potential exposure could not be bound with sufficient accuracy.

- SC&A's concern is that a review of dosimetry capability, while necessary to validate that measurement techniques were technically acceptable and available, is not sufficient to address the feasibility of dose reconstruction. Identifying the number of samples or counts, alone, including null sampling results, devoid of exposure potential considerations (e.g., source term being handled) over the 30+ years of Isotope Division production, arguably would not satisfy DCAS-IG-006. At the very least, what is needed is a weight-of-evidence approach to validate that monitoring took place (or was not necessary) for operational time periods that lacked recorded sampling or where sampling was sparse (e.g., one or two samples). SC&A recommends that this finding remain open.

Finding 4: Feasibility of monitoring 28 radionuclides not adequately addressed

- NIOSH (2020a) responded that the implementation of the monitoring program is indicated by the bioassay cards and will be used in individual DR. Additional review of monitoring procedures on the SRDB will be ongoing, and SC&A can review the documents also.

- SC&A did not find that sections 7.2 and 8.0 of RPRT-0090 specifically and completely address the question of "if the nuclide represented an infeasibility from a monitoring perspective" posed of page 25 of RPRT-0090, nor did the recent response (NIOSH, 2020a). SC&A recommends that this finding remain open.

Finding 5: 1955 and 1956 intakes may not be bound by earlier coworker data

- NIOSH (2020a) responded that the difference is insignificant (~4 percent) and that application of the 95th percentile is sufficiently bounding.

- SC&A agrees that the difference between stack releases in 1947 and 1956 is relatively small (~4 percent). However, when uncertainty exists regarding the development of co-exposure intakes, adjustment factors (often arbitrary in nature) are applied to assure a bounding dose assignment. In this case, co-exposure estimates are extrapolated from one period to another, and so the uncertainty is significant in SC&A's opinion. Whether utilization of the 95th percentile is a bounding dose estimate is a matter of professional judgment, and an additional adjustment may be warranted.

Finding 6: Adequacy and implementation of in vivo bioassay program not addressed

- NIOSH (2020a) believes that the volume of available monitoring data, including analysis for non-routine radionuclides, as shown in ORAUT-RPRT-0090, table 4.3 (Bioassay code 000 with monitored nuclide, 1955–1988), demonstrates the capability to monitor exposure to the wide range of materials present. However, NIOSH did not intend to include a review of program implementation in ORAUT-RPRT-0090.

- SC&A considers this finding subsumed under finding 3 and recommends closure of this issue.

Finding 7: Unclear treatment of post-1988 monitoring capability during abandonment, deactivation, and decontamination and decommissioning phases

- NIOSH (2020a) states that the point of ORAUT-RPRT-0090 was to assess the feasibility of monitoring nuclides produced by the isotopes group during production operations. While such analysis is outside the scope of the document, it would seem credible that it would be feasible to bound exposures to the same set of radionuclides during D&D periods after 1988 with modern dosimetry methods.

- SC&A accepts this clarification, as noted in the response to finding 1. SC&A recommends closure of this finding.

Observation 1: Inventory discrepancy

- NIOSH (2020a) clarified the additional radionuclide inventory based on a review of logbooks. The review of the logbooks resulted in the addition of radionuclides and additional inventory years for existing radionuclides.

- SC&A concurs that additional radionuclides and/or inventory years from logbooks added to the original X-10 inventory spreadsheet would explain the discrepancies in inventory between table 7-2 in RPRT-0090 and NIOSH's X-10 Inventory spreadsheet. SC&A finds this observation clarified and recommends closing it.

Observation 2: Specific alpha-emitting radionuclide needs to be identified for DR

- NIOSH (2020a) responded that the X-10 database is not used for DR purposes.

- SC&A concurs with NIOSH's response. Additionally, if the X-10 database will not be use in co-exposure intake modeling without further consideration of specific alpha-emitting radionuclides, then SC&A finds this observation clarified and recommends closing it.

Observation 3: Trans-plutonium radionuclides may need further analyses

- NIOSH (2020a) responded that curium-248 (Cm-248) and californium (Cf-249) with a maximum organ DCF ratio to americium-241 (Am-241) of 3.7 and 1.55, respectively, are the only radionuclides with larger DCFs than Am-241. However, Am-241 is a reasonable default assumption considering that the maximum annual inventory for these two radionuclides (64 millicurie (mCi) and 56 mCi, respectively) is a factor of 105 lower than that of Am-241.

- SC&A evaluated NIOSH's response. Considering that NIOSH has analyzed the DCFs and inventory amounts of the TPOs, SC&A finds that using Am-241 as the default radionuclide (if other information is not available) would be a reasonable assumption. SC&A finds this observation clarified and recommends closing it.

Observation 4: Use of gross beta or gamma count data could result in underestimate of assigned dose

- NIOSH (2020a) responded that an editing mistake happened during the final document preparation for Section 508 compliance for Ru-106. In the next revision to ORAUT-RPRT-0090, table 7-2 will be shaded "yellow" for the indicated years. NIOSH also responded that the original X-10 bioassay cards are provided by ORNL for individual claimants and are the basis for DR. Any notations as to the specific radionuclide being monitored are available for use in the claimant-specific DR report.

- SC&A concurs with NIOSH's response to the Ru-106 issue by changes in the next revision of RPRT-0090. However, the issue of the appropriate radionuclide and counting efficiency to be used in a given DR when the bioassay card lists gross beta or gamma counts (if this occurs), or the appropriate radionuclide to assign when the bioassay card lists results in dpm or microcurie without a specific radionuclide, does not appear to have been completely addressed. SC&A recommends that this observation remain open.

Observation 5: The results in table 7-6 depend on inventory used

- NIOSH (2020a) responded that, as indicated previously, the spreadsheet upon which SC&A's comparison is based contained only the results of the review of isotope group sales/inventory data.

- SC&A evaluated NIOSH's response and the additional information provided in table 3 (NIOSH, 2020a, p. 12). SC&A analyzed the additional data and references and concurs with NIOSH's response that addresses the issues that SC&A previously summarized in table 3 of SC&A (2018), concerning table 7-6 of RPRT-0090. SC&A finds that this observation has been addressed and recommends closing it.

Observation 6: Additional RaLa production information should be provided

- NIOSH (2020a) responded that evaluation of the commercial radioiodine operations are not relevant to the ability to demonstrate co-exposure feasibility.

- It is SC&A's opinion that the proper evaluation of operational activities, campaigns, and conditions is a key factor in the determination that extrapolation of dose estimates from one period is appropriate for another period. Guidance in NIOSH (2020b) is even more restrictive in that it requires similar evaluations when contiguous years are combined for data evaluation. A clarification of the statutory requirements concerning "commercial" versus "government" work may render this observation moot for the purposes of developing DR methods.

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