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National Institute for Occupational Safety and Health

REVIEW AND COMMENTARY ON THE NIOSH WHITE PAPER, "FOLLOW-UP EFFORTS ON SEC-00192 ROCKY FLATS PLANT TRITIUM ISSUES," REVISION 2

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ABBREVIATIONS AND ACRONYMS

ABRWH	Advisory Board on Radiation and Worker Health
Ci	curies
d	day
DOE	(U.S.) Department of Energy
HTO	tritiated water
ICRP	International Commission on Radiation Protection
IMBA	Integrated Modules for Bioassay Analysis
IRF	intake retention fraction
L	liter
mrem	millirem
NCRP	National Council on Radiation Protection & Measurements
NIOSH	National Institute for Occupational Safety and Health
OBT	organically bound tritium
pCi	picocuries
SC&A	S. Cohen and Associates (SC&A, Inc.)
SEC	Special Exposure Cohort
yr	year

INTRODUCTION

During the Rocky Flats Work Group meeting held on March 17, 2015, the Work Group discussed, among a number of other topics, issues related to the reconstruction of doses to workers from tritium. The discussion revolved around previous white papers issued by the National Institute for Occupational Safety and Health (NIOSH) and SC&A related to this matter, and some of the follow-up investigations performed by NIOSH to help close out the white paper issues (ABRWH 2015, p. 7). It is important to acknowledge the context within which the white papers and discussions were held. First, a Special Exposure Cohort (SEC) was granted for Rocky Flats based on the inability to reconstruct internal exposures to uranium, thorium, and neptunium with sufficient accuracy, which means that any exposures to tritium derived in support of a claimant would represent a partial dose reconstruction. If it is determined that doses to tritium cannot be reconstructed with sufficient accuracy, then no tritium doses will be assigned to the workers. Second, if it is determined that tritium doses can be reconstructed and the Work Group agrees on the methods for performing these partial dose reconstructions, these doses will be relatively small.

The discussion of the tritium issues begins on page 105 of the transcript, and can be conveniently divided into issues pertaining to the reconstruction of tritium doses during three time periods: exposures associated with an incident that occurred in April 1973, pre-1973 exposures, and post-1973 exposures. In the sections that follow, each of these time periods is addressed by first summarizing the discussion that occurred during the Work Group meeting, followed by a review of a white paper issued by NIOSH on July 1, 2015 (NIOSH 2015), that addresses many of the issues associated with each of these time periods that emerged during the Work Group meeting. We begin with the 1973 time period, because it is the most complex and helps to set the stage for the discussions on pre-1973 and post-1973 dose reconstruction issues.

1973 Issues

Beginning on page 106 of ABRWH 2015, NIOSH explains that they originally planned to assign all workers a dose of 700 mrem due to exposures to tritium from an incident at Rocky Flats that occurred in April 1973. The methods used by NIOSH are described in great detail in previous white papers and also in the transcript. In addition, SC&A's concerns with the methods used by NIOSH to derive the 1973 tritium intakes and dose commitments are provided in white papers prepared by SC&A and discussed extensively at the March 17, 2015, Work Group meeting.

NIOSH explains in its earlier white papers and at the Work Group meeting that they have revised their original dose estimate down to 84 mrem, based on a more complete review of bioassay data collected from about 250 workers in September and October 1973. Out of the 250 workers, only 5 had results above the Department of Energy (DOE) trigger level of 10,000 pCi/L of urine (based on undistilled urine samples, which gave higher results). These results were analyzed by NIOSH, which concluded that the highest plausible worker dose from the 1973 incident was 84 mrem (ABRWH 2015, p. 115). The white papers issued prior to the NIOSH 2015 white paper, and much of the discussions about the 1973 tritium exposures, centered around the interpretation of the bioassay samples of the five workers and the tritium models that were used to back-calculate the tritium intakes (and associated doses) that might have occurred as a result of the April 1973 incident.

Beginning on page 123 of the transcript, Dr. Joyce Lipsztein (SC&A) explains her concerns regarding the use of the bioassay data from the five individuals and the tritium biokinetic model used by NIOSH to back-extrapolate the tritium intakes associated with the April 1973 incident using the bioassay data from the selected five individuals. NIOSH attributed the highest urine result to an incident that occurred in September. According to NIOSH, only [redact] of the [redact] workers were exposed in the April incident. In reality, all participants agreed that the worst intake occurred in April 1973, and bioassay data from this incident were collected in September and October 1973, a time interval of about 170 to 190 days.

The even greater concern expressed by SC&A was whether the biokinetic model used by NIOSH to back-calculate intakes can be used when the time period between the intake and the bioassay sample is greater than 100 days. All participants agree that we are dealing with a situation that reflects an attempt to derive the intakes that occurred in April 1973 from bioassay data collected in September and October 1973, i.e., a time interval of about 170 to 190 days.

Dr. Lipsztein explained that, among the five individuals, NIOSH concluded that perhaps the bioassay data from only [redact] or [redact] of the individuals could be used as representative of possible intakes that occurred shortly after the April incident. More importantly, Dr. Lipsztein explained that there actually is no International Commission on Radiation Protection- (ICRP-) approved tritium biokinetic model that can be used when the bioassay sample is collected more than 100 days after intake. Hence, there is some question whether the doses can be reconstructed without an ICRP-approved model.

The transcript contains considerable discussion regarding this issue, as does the NIOSH 2015 white paper. SC&A believes that we are in a situation where there is ambiguity regarding whether no doses should be assigned to these individuals, or whether there is enough information in the peer-reviewed scientific literature that could support the reconstruction of the doses over a 170- to 187-day time period using models that were not explicitly approved by ICRP for these purposes, given the context within which the models would be used. Further complicating this matter is uncertainty regarding the actual models that NIOSH is employing in this calculation (ABRWH 2015, p. 136). As discussed beginning on page 142, there appears to be a substantial difference in the reconstructed doses depending on which of the various models are used. The differences appear to be due to three problems: the model, the uncertainty on the bioassay results from the five workers, and the uncertainty on dates the exposure occurred. For example, for the first case, the discrepancies on the date of intake made the dose vary from 6,000 mrem (SC&A worst-case scenario, where intake occurs in April and the bioassay sample was collected in September). At the other extreme, NIOSH derived a dose of 2.6 mrem as estimated by using intake and urine collection in September. The bounding dose according to NIOSH was 84 mrem. Using the same intake and urine collection dates and a different model, SC&A calculated a dose of 360 mrem. Because of these uncertainties, Dr. John Mauro (SC&A) suggested abandoning the use of the five case studies and taking advantage of the large number of personnel that were observed to have tritium concentrations in urine of less than 10,000 pCi/L; i.e., the DOE trigger level. In conclusion, Dr. Lipsztein explains that, notwithstanding which model is used, there is a great deal of uncertainty in the derived doses, given the long time period between intake and the bioassay sample, the amount of data, and the bioassay methods employed.

At this point during the Work Group meeting, Dr. James Neton (NIOSH) suggested that NIOSH revisit this issue for further clarification, or perhaps revise their approach for reconstructing the tritium doses associated with the April 1973 incident. That further clarification and reassessment is provided in the NIOSH 2015 white paper.

Our review of NIOSH 2015 found that NIOSH has revised its approach to reconstructing the tritium doses. The new approach assumes that all the Rocky Flats workers that might have been exposed to tritium from the April 1973 incident have tritium concentrations in urine at the trigger level of 10,000 pCi/L from urine samples collected on October 15, 1973, and that these levels were due to acute tritium intakes that occurred on April 9, 1973. Given that the urine of 250 workers was collected in September and October of 1973, and that they all had tritium concentrations that were below the trigger level, SC&A believes that this is a plausible and claimant-favorable strategy.

Given these basic assumptions, NIOSH back-calculated the tritium intake on April 9, 1973; that would result in 10,000 pCi/L in urine on October 15, 1973. In order to perform this calculation, NIOSH used the Integrated Modules for Bioassay Analysis (IMBA) approach to model HTO, described in Part II of the white paper. Part II is titled *Rocky Flats Tritium Dose Assignment for 1973 and Later.*

NIOSH explains that the IMBA approach to model HTO consists of changing the organically bound tritium (OBT) transfer rate constant going from the Transfer Compartment to Total Body 1 from 0.5 to 0.97, and changing the transfer rate constant going from the Transfer Compartment to Total Body 2 from 0.5 to 0.03. NIOSH claims that the introduction of two changes effectively converts the OBT model to the tritiated water model. SC&A has reviewed this model as applied to this problem and found it unacceptable for the following reasons:

(1) NIOSH is using a model without validation by experimental data or bioassay results

(2) NIOSH did not present any results that validate its model at 187 days after the intake of tritiated water

(3) NIOSH based its model on a modification of the OBT model, justifying it as being the ICRP 56 (1990) suggested model, when in reality it is not the one for HTO given in ICRP 56 (1990)

(4) The ICRP OBT model has more uncertainties than the HTO model, as it was not based on human results and it varies considerably among the different organic compounds (NCRP 2008)

Appendix A presents a more detailed description of the new model proposed by NIOSH and the reasons why SC&A finds this model unacceptable.

A model that SC&A would find more acceptable for this application[1] is one that assumes a 2-compartment model (A and B), where the fractions excreted in urine from both compartments are about 55%, as described in the National Council on Radiation Protection & Measurements (NCRP) Report 161 (2008) and ICRP Publication 78 (1997). Though this model is not explicitly recommended by ICRP/NCRP for time periods greater than 100 days (in this case, 187 days), it at least has the approval of ICRP/NCRP for up to 100 days. Using this model, a spot urine sample having a concentration of 10,000 pCi/L (14,000 pCi/d excretion rate) collected 187 days after an acute uptake of tritiated water would result in an acute tritium intake of 1.3E9 pCi and an effective dose commitment of 94 mrem.

Pre-1973 Issues

An extended discussion of the issues associated with pre-1973 exposures to tritium begins on ABRWH 2015, page 211. After considerable discussion, it was agreed that this issue should be closed. This decision was acceptable to the Work Group as a bounding approach to reconstructing pre-1973 <u>chronic</u> tritium exposures to all workers. The method used by NIOSH to assign pre-1973 doses was to assume that an August 1974-type event occurred every day pre-1973 and resulted in an effective dose commitment of 37.5 mrem/year to all workers. This value was derived based on the results of bioassay samples collected from workers immediately following the August 30, 1974, release of 1.5 Ci of tritium while opening a shipping container. Specifically, following this incident, the highest concentration of tritium in urine was found to be 36,320 pCi/L, which is associated with a dose commitment of 0.15 mrem. Assuming such an event occurs every day, and assuming that all workers worked 250 days per year, the annual dose for all workers from chronic exposures pre-1973 is assumed to be 37.5 mrem.

The Work Group also acknowledged that there are many questions regarding the degree to which the August 1974 event was actually representative of the types of chronic exposures that might have occurred pre-1973. However, it was also agreed that the assigned exposures were certainly bounding and, given that we are dealing with relatively low exposures (37 mrem/yr), the Work Group felt that the assignment of these doses was acceptable, notwithstanding some of the questions raised regarding the degree to which the conditions under which the August 1974 incident occurred were, in fact, typical or representative of pre-1973 conditions and activities and associated chronic exposures. A key statement by Dr. David Kotelchuck (ABRWH) beginning on page 221 of ABRWH 2015 captures the sentiment of the Work Group regarding this matter:

> *But I'm less worried about overestimating a small quantity, I mean, a small exposure. We're dealing with some very small exposures, and if we're fairly heavily over-estimating where it's not going to affect --- no, we're not doing --- let's just say, I don't worry about over-estimating on a very small quantity on something that is going to result in a very small dose.*

The NIOSH 2015 white paper helps to reinforce the appropriateness of this determination by the Work Group. For example, additional interviews and record searches were performed following the Work Group meeting to determine if there were other incidents (other than the April 1973

[1] For this particular application, the only alternative is to conclude that there is no acceptable model and workers would be assigned no dose from the April 1973 incident.

incident) that were more bounding or representative of pre-1973 conditions and activities than the August 1974 incident. NIOSH reported that no new information was found that could improve on the approach that NIOSH is currently using to reconstruct pre-1973 chronic exposures.

Part I of the white paper specifically addresses information that might be relevant to the assessment of pre-1973 exposures. The report acknowledges that, "Bounding tritium exposures for the pre-1973 period are more difficult to develop as a result of this lack of measurement data." Reference is made to tritium releases of 600 Ci of elemental tritium in 1968, 57 Ci of tritium in April 1969, 40 Ci in March 1971, and 29 Ci in November 1971. However, NIOSH explains that it selected the August 1974 release of 1.5 Ci of tritium as a surrogate for chronic tritium releases pre-1973, because it is judged to be most representative of undocumented chronic releases from shipping containers prior to 1973. <u>The NIOSH white paper would benefit from additional discussion of why the other large pre-1973 releases were not considered when developing the approach for reconstructing pre-1973 releases and doses</u>.

Part 1 of the white paper provides detailed information on the airborne concentration of tritium in the vicinity of the contaminated shipping container (also referred to as a pressure cooker) that was associated with the 1.5 Ci release of tritium on August 30, 1974. It also provides a detailed compendium of the swipe and bioassay data collected after the incident. NIOSH's analysis of the data indicated that the highest tritium concentration in urine associated with this incident was 36,320 pCi/L and resulted in a dose commitment of 0.15 mrem to the exposed individual; thus, the assumed 37.5 mrem/yr chronic exposure to tritium pre-1973.

Post-1973 Exposures

This topic is introduced on page 122 of ABRWH 2015 and then discussed in detail beginning on page 177. The transcript provides the rationale for selecting 0 mrem per year as the chronic dose to be assigned to post-1973 exposures. In addition, on page 179 of the transcript, reference is made to an SC&A report dated September 18, 2014 (SC&A 2014), and a May 30, 2014, NIOSH report (NIOSH 2014) on this subject. The transcript refers to the nine findings related to this issue as described in SC&A 2014, and then goes on to summarize the basic concerns that SC&A has with the data used by NIOSH that establish the basis for assigning 0 mrem/yr to workers as the chronic exposures post-1973.

Following considerable discussion, SC&A identified a number of fundamental concerns with the data and approach used by NIOSH for selecting 0 mrem/yr as the chronic tritium exposures at Rocky Flats post-1973. The first concern is that the bubblers used to determine the airborne concentration of tritium associated with opening many shipping containers might not have been located where the workers opened the containers (specifically the inner containers), and thereby missed tritium that might have escaped when the inner containers were opened. The second concern was that the bioassay data that were routinely collected were too infrequent (e.g., one urine sample per worker per year) to capture spikes in tritium concentrations in urine that might have occurred from time to time. Another concern was the efficiency of the bubblers, and finally, some concern was expressed regarding exposures to insoluble tritides, which appear to have been present at the facility but were never discussed.

During the meeting, it was agreed that NIOSH would look into these matters. However, some preliminary perspectives on these issues were discussed. Specifically, beginning on page 189 of ABRWH 2015, NIOSH personnel explained that the bubblers were located not only where the large 55-gallon drums were opened, but also where the smaller 10-gallon drums (that were inside the 55-gallon drums) were opened. Hence, NIOSH believes that the bubblers were located where there was potential for workers to be exposed to tritium. In addition, NIOSH explained that, before the large shipping containers were opened, air was sucked from the containers to determine if there was any tritium inside the containers.

There was also some discussion of the bioassay program, where it was acknowledged that the sampling was infrequent, but there was a total 75 urine samples, and all had tritium concentrations that would indicate exposures well below 1 mrem/yr. It was agreed that, though the individual sampling frequency was limited to one sample per person per year, taken in its totality, the fact that none of the 75 samples had elevated levels of tritium would help to argue that there was, in fact, very little likelihood that workers were experiencing exposures to spikes that could result in exposures in excess of 1 mrem/yr. However, on page 200 of ABRWH 2015, an SC&A representative pointed out that there was, in fact, one bioassay measurement in 1978 that was elevated (117,000 pCi/L), but it was acknowledged that this was a special case where an incident occurred that warranted a special sampling; this was not part of the cohort sampling program.

With respect to metal tritides, a discussion begins on page 206 of the transcript indicating that the presence of metal tritides at the facility had a very specific purpose (they were sealed), and there was very little likelihood that there were any exposures to metal tritides as they were used at Rocky Flats.

The outcome of these discussions was that Dr. Mauro requested that NIOSH look a little further into the locations of the bubblers, their efficiency, possible tritide issues, and perhaps discuss the implications of the collective results of the cohort sampling program (also referred to as the one-in-ten program) as an argument that spikes were very unlikely (ABRWH 2015, p. 205).

Given these perspectives, as summarized from the transcript, the following presents a summary of the material in the NIOSH 2015 white paper that helps to bring closure to these concerns regarding the post-1973 exposure assignment of 0 mrem/yr.

Part II of the white paper is titled, *Rocky Flats Tritium Dose Assignment for 1973 and Later*. The subsection titled, "Dose Assessment for 1974–1975 and Post 1975" reiterates the review of the cohort bioassay sampling (one-in-ten program), stating that 38 individuals were sampled in 1974 and 37 in 1975, and that each of these individuals were sampled only once. This is consistent with previous descriptions of this program. There appears to be very little new information, but the data, taken collectively, indicate that it is unlikely that workers experienced spikes during this time period.

Appendix 2 of the NIOSH 2015 white paper is titled, *Response to Work Group/SC&A Comments on the Rocky Flats Plant Tritium White Paper*. The appendix provides a timeline of Work Group activities and provides a response to the issues raised during the Work Group meeting that relate to post-1973 exposures (as summarized above). It appears that the bubblers (and cold traps) were located in hoods and at downdraft tables where containers were opened, confirming that bubblers were generally located where workers might have been exposed to tritium. This is consistent with statements made during the Work Group meeting.

Appendix 3, titled, *Workplace Air Monitoring at Rocky Flats, 1977–1981*, also addresses some issues raised by SC&A. The section indicates that there were 107 bubbler log entries beginning in 1977 that represented airborne tritium concentrations at locations other than plenums and exhaust ducts. These log entries represent 17 different locations where workers may have been located and where there was the potential for elevated tritium concentrations. These data help to provide further information on the concentration of tritium in air, at least for time periods post-1977, at locations where workers might be present. The data from these bubblers are consistent with the assumption that the annual exposures to workers post-1977 were less than 1 mrem/yr.

This section does not provide information regarding the efficiency of the bubblers. However, this does not detract from the weight of evidence that worker exposures post-1973 were likely extremely small.

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APPENDIX A: CRITIQUE OF THE NEW TRITIUM BIOKINETIC MODEL PROVIDED IN NIOSH 2015

NIOSH proposes to use the ICRP 88 model for OBT (ICRP 2002a), described in Figure A1-1 of the NIOSH 2015 white paper, to evaluate intakes of HTO by introducing two changes into the OBT model. The first change is the transfer rate constant going from the Transfer Compartment to Total Body 1 from 50% in the OBT model to 97% in the HTO model. The second change is the transfer rate constant going from the Transfer Compartment to Total Body 2 from 50% in the OBT model to 3% in the HTO model.

In introducing those two modifications, NIOSH is changing the ICRP model for HTO. This is especially problematic in relation to the fractions excreted in urine (14/30 from the short-term compartment and all the activity of the long-term compartment). As explained in ICRP 78 (ICRP 1997), about 50% of the total daily loss of water is excreted via urine. NCRP Report 161 (NCRP 2008) suggests 55% excretion in urine.

Thus, the model proposed by NIOSH includes a higher excretion rate in urine than the one proposed in ICRP 78 (1997) and NCRP 161 (2008). Since the dose is being calculated from an excretion rate result, the higher the fraction excreted in urine, the lower the calculated intake and dose. Thus, this modification introduced by NIOSH, without support from the ICRP, is not claimant favorable. In addition, NIOSH has not presented any experimental data or bioassay results that justify the proposed excretion rates. In addition, NIOSH is using the urinary bladder compartment, which is not recommended by the ICRP. Although the delay caused by the urinary bladder is irrelevant for the time period of the calculation of intakes, doses to the urinary bladder should be the same as to other tissues [per ICRP 67 (ICRP 1993)].

The subsection of Part II of the NIOSH 2015 white paper, named "Calculations," has a definition of the biokinetic model that was explained in the introduction to the white paper. The subsection explains the steps used to solve the differential equations of the model. At the end of the subsection, on page 28, NIOSH states:

> *The ICRP 88 model predicts a higher excretion rate than the IMBA model at all times after intake… The tritium concentrations predicted by the two models differ by ~9% at t = 30 days, which is an insignificant difference when modeling intakes of tritiated water in an operational radiation protection program. However, at t = 200 days post-intake, the excretion rates differ by ~90%. It is our opinion that the ICRP 88 approximation is not applicable at such extremely long times post-intake and that the ICRP 56 model, as implemented in IMBA, should be used.*

SC&A does not agree that the ICRP 56 model (ICRP 1990) was used in the IMBA implementation of the HTO model. ICRP 56 suggests a three-exponential function to represent the whole-body retention of tritium after intakes of tritiated water. For calculating the dose from tritium, which has entered the body as tritiated water, a simplified two-component exponential function is suggested by ICRP 56 (ICRP 1990). This equation represents the retention in compartments A and B, with half-lives of 10 and 40 days, respectively. ICRP 56 does not mention the fractions excreted in urine from the two compartments in the HTO model. In addition, ICRP 56 does not mention the fractions excreted in urine from the two compartments in the OBT model.

NIOSH has introduced a modification into the ICRP HTO model without showing that it reproduces bioassay results or experimental data at later times after intake. The issue of a tritium model that can be used to calculate intakes at long time periods after intake has not yet been resolved. Even the model for OBT cannot be applied to all OBT compounds. (ICRP 1997).

NIOSH compares its intake retention fraction (IRF) in urine results with the ones from Radiological Toolbox V3.00[2] to justify the values obtained. Although it agrees with NIOSH's IRF in urine for H-3 vapor, the Radiological Toolbox V3.0 explicitly defines that for tritiated water:

> *The tritium concentration in urine is assumed to be the same as in body water. Urinary excretion will not result in a significant additional dose to the bladder wall which is assumed to receive the same dose as other tissues (ICRP Publication 67).* (Radiological Toolbox: Biological data, display systemic model H-3).

The model that NIOSH is proposing to use, the ICRP Publication 56 (1990) model, is actually used in NCRP Report 161 (NCRP 2008), but it only shows urine results up to 100 days after the intake. NCRP 161 (2008) defines the systemic biokinetics of tritium as follows:

> *In the ICRP biokinetic model for ^{3}H taken into the body as HTO, whole-body retention at t days after injection is described by a sum of two exponential terms:*
>
> $R(t) = 0.97exp(-0.693t/T1) + 0.03exp(-0.693t/T2)$
>
> *For the adult, T1 = 10 d and T2 = 40 d.*
>
> *The model is based on measurements of whole-body retention of ^{3}H in adult humans exposed to HTO, together with relatively detailed studies of the behavior of HTO in laboratory animals. The dominant, short-term component closely approximates the turnover of body water. The longer-term component appears to represent tritium incorporated into tissues (ICRP, 1989; Trivedi et al., 1997)* …….
>
> *Model predictions of retention and excretion of ^{3}H following acute ingestion or inhalation of HTO by a worker are given in Table 20.50. The predictions are based on the ICRP retention model for HTO described earlier. It is assumed that absorbed ^{3}H is in equilibrium with body water and that 55% of daily water loss is*

[2] The User's Manual for this software can be accessed at http://www.nrc.gov/about-nrc/regulatory/research/radiological-toolbox.html. The software can be downloaded from http://crpk.ornl.gov/software/.

> *in urine and 3.8% is in feces, based on water balance data from ICRP Publication 89 (ICRP, 2002b). It is further assumed that:*
>
> - *100% of inhaled HTO deposits in the respiratory tract and passes immediately to blood;*
> - *100% of ingested HTO is immediately absorbed to blood; and*
> - *tritium entering blood immediately equilibrates with body water.*
>
> *Delays in excretion pathways before removal from the body are not included in this simplistic model.*

In relation to the model applied to OBT, which is used by NIOSH as a standard to implement the model for HTO, NCRP 161 (2008) states:

> *Because available data on the biokinetics of organically-bound tritium vary considerably with the compound administered, and because the ICRP model for organically-bound tritium is based mainly on observations of the behavior of selected compounds in laboratory animals, dose estimates for intake of organically-bound tritium involve greater uncertainty than estimates for intake of HTO.*

In conclusion, there are significant uncertainties on the HTO excretion rates at long time periods after intake. Those uncertainties cannot be solved using as a basis a model that involves even greater uncertainties.