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

A Review of NIOSH's Program Evaluation Report DCAS-PER-039, "Baker Perkins TBD Revision"

Contract No. 75D30124F19451
Document No. SCA-TR-2024-PR039, Revision 0

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September 4, 2024

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Effective date: 9/4/2024 Revision No. 0	(Draft) Document No.: SCA-TR-2024-PR039	Page 2 of 14
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SC&A, Inc. technical support for the Advisory Board on Radiation and Worker Health's review of NIOSH dose reconstruction program

Document title	A Review of NIOSH's Program Evaluation Report DCAS-PER-039, "Baker Perkins TBD Revision"	
Document number	SCA-TR-2024-PR039	
Revision number	0 (Draft)	
Supersedes	NA	
Effective date	September 4, 2024	
Task manager	Kathleen Behling [signature on file]	
Project manager	Bob Barton, CHP [signature on file]	
Document reviewer(s)	Kathleen Behling [signature on file] Bob Barton, CHP [signature on file]	

Record of revisions

Revision number	Effective date	Description of revision
0 (Draft)	9/4/2024	Initial issue

Table of Contents

ΑŁ	bre	viations and Acronyms	4
1	St	atement of Purpose	5
2	Re	elevant Background Information	7
3	Sı	ubtask 1: Identify the Circumstances that Necessitated DCAS-PER-039	8
	3.1	Chronology of events	8
	3.2	SC&A's comments	8
4	Sı	ubtask 2: Assess NIOSH's Specific Methods for Corrective Action	9
	4.1	Internal dose estimate	9
	4.2	External dose estimate	10
	4.3	Occupational medical dose estimate	10
5 Re		ubtask 3: Evaluate the PER's Stated Approach for Identifying the Number of Dring Reevaluation of Dose	
	5.1	NIOSH's selection criteria	12
	5.2	SC&A's comments	12
6 D(ubtask 4: Conduct Audits of a Sample Set of Reevaluated DRs Mandated by -PER-039	13
7	D,	oforonoos	11

Effective date: 9/4/2024 Revision No. 0 (Draft) Document No.: SCA-TR-2024-PR039 Page 4 of 14

Abbreviations and Acronyms

ABRWH, Board Advisory Board on Radiation and Worker Health

BZ breathing zone

DR dose reconstruction

GA general area

MCNPX Monte Carlo N-Particle X

NIOSH National Institute for Occupational Safety and Health

ORAUT Oak Ridge Associated Universities Team

PER program evaluation report

POC probability of causation

TBD technical basis document

1 Statement of Purpose

To support dose reconstruction (DR), the National Institute for Occupational Safety and Health (NIOSH) and the Oak Ridge Associated Universities Team (ORAUT) assembled a large body of guidance documents, workbooks, computer codes, and tools. In recognition of the fact that all of these supporting elements in DR may be subject to revisions, provisions exist for evaluating the effect of such programmatic revisions on the outcome of previously completed DRs. Such revisions may be prompted by document revisions due to new information, misinterpretation of guidance, changes in policy, and/or programmatic improvements.

A program evaluation report (PER) provides a critical evaluation of the effects that a given issue or programmatic change may have on previously completed DRs. This includes a qualitative and quantitative assessment of potential impacts. Most important in this assessment is the potential impact on the probability of causation (POC) of previously completed DRs with POCs less than 50 percent.

During a teleconference by the Advisory Board on Radiation and Worker Health (Board) Subcommittee for Procedure Reviews on March 14, 2024, the Board tasked SC&A to review DCAS-PER-039, revision 0 (NIOSH, 2013; "PER-039"), which was issued to address the impacts on previously completed claims of issuing DCAS-TKBS-0005, revision 01 (NIOSH, 2012), the technical basis document (TBD) for Baker-Perkins. In conducting a PER review, SC&A is committed to perform the following five subtasks, each of which is discussed in this report:

- **Subtask 1:** Assess NIOSH's evaluation and characterization of the issue addressed in the PER and its potential impacts on DR. Our assessment intends to ensure that the issue was fully understood and characterized in the PER.
- **Subtask 2:** Assess NIOSH's specific methods for corrective action. When the PER involves a technical issue that is supported by documents (e.g., white papers, technical information bulletins, procedures) that have not yet been subjected to a formal SC&A review, subtask 2 will include a review of the scientific basis and/or sources of information to ensure the credibility of the corrective action and its consistency with current/consensus science. Conversely, if such technical documentation has been formalized and previously subjected to a review by SC&A, subtask 2 will simply provide a brief summary and conclusion of this review process.
- **Subtask 3:** Evaluate the PER's stated approach for identifying the universe of potentially affected DRs and assess the criteria by which a subset of potentially affected DRs was selected for reevaluation. The second step may have important implications where the universe of previously denied DRs is very large and, for reasons of practicality, NIOSH's reevaluation is confined to a subset of DRs that, based on their scientific judgment, have the potential to be significantly affected by the PER. In behalf of subtask 3, SC&A will also evaluate the timeliness of the completion of the PER.

Effective date: 9/4/2024 Revision No. 0 (Draft) Document No.: SCA-TR-2024-PR039 Page 6 of 14

• **Subtask 4:** Conduct audits of DRs affected by the PER under review. The number of DRs selected for audit for a given PER will vary. (It is assumed that the Board will select the DRs and the total number of DR audits for each PER.)

• **Subtask 5:** Prepare a written report that contains the results of DR audits under subtask 4, along with our review conclusions.

Effective date: 9/4/2024 Revision No. 0 (Draft) Document No.: SCA-TR-2024-PR039 Page 7 of 14

2 Relevant Background Information

Baker-Perkins Company formed as the result of a merger of two companies in the early 1900s. The company developed industrial mixing machines that were initially intended for the food industry, but later transitioned to chemical industry processing. The first "Universal" mixer was produced in the Saginaw, Michigan, factory, which was a key piece of machinery for the processing of chemical pharmaceutical products, colors, paints, varnishes, paper pulp, cellulose, foundry sands and loams, rubber materials, etc. Baker-Perkins offered heavy-duty mixers for industrial operations in the 1950s. One line of continuous heavy-duty mixer produced by Baker-Perkins was called the "Ko-Kneader." In 1956, this line of mixer was tested for its use in mixing uranium compounds for National Lead of Ohio (Fernald). These tests were performed from May 14 to 16, 1956, at Baker-Perkins in Saginaw, Michigan. Equipment used during the test was decontaminated and cleaned from May 15 to 18, 1956.

Effective date: 9/4/2024 Revision No. 0 (Draft) Document No.: SCA-TR-2024-PR039 Page 8 of 14

3 Subtask 1: Identify the Circumstances that Necessitated DCAS-PER-039

3.1 Chronology of events

NIOSH issued revision 00 of DCAS-TKBS-0005 on February 17, 2011, the TBD for Baker-Perkins (NIOSH, 2011). As a result of SC&A's review of revision 00 of DCAS-TKBS-0005, revision 01 of DCAS-TKBS-0005 was issued on May 1, 2012 (NIOSH, 2012). SC&A's review of revision 00 of DCAS-TKBS-0005 had four findings and six observations (SC&A, 2011).

PER-039 evaluated the effects of using revision 01 of the TBD on all previously completed Baker-Perkins claims.

3.2 SC&A's comments

Programmatic revisions that may affect the outcome of previously completed DRs and mandate the need for a PER include any revisions to guidance documents that may result in the assignment of a higher dose.

SC&A believes that the issuance of a revision to the TBD for Baker-Perkins dose estimates is justification for reevaluating worker doses, as defined in PER-039. SC&A concurs with NIOSH's decision to issue PER-039 and has no findings.

4 Subtask 2: Assess NIOSH's Specific Methods for Corrective Action

Several changes in the methods used to reconstruct doses at Baker-Perkins were incorporated in revision 01 of DCAS-TKBS-0005, resulting in the inhalation and external doses being higher for some job categories compared to previous methods. Since SC&A has previously reviewed revision 00 of DCAS-TKBS-0005 in November 2011 (SC&A, 2011), this review of PER-039 focuses only on the changes in revision 01.

4.1 Internal dose estimate

The internal dose estimate uses alpha air sampling data that was collected at Baker-Perkins during all phases of the testing in 1956. The data consist of breathing zone (BZ) and general area (GA) air samples collected during scooping of the uranium material into the feeder, decontaminating the equipment, and all other tasks. The main change to the internal dose approach in revision 01 of DCAS-TKBS-0005 (NIOSH, 2012) from revision 00 (NIOSH, 2011), is that the four initial job categories (operator, laborer, supervisor, and clerical) were condensed into three different categories (operator/laborer, supervisor, and other), and a more detailed timeline of the test was used to calculate doses. NIOSH designated the operator/laborer category for workers involved in the hands-on tasks, including scooping the uranium and decontaminating the equipment. NIOSH used the BZ air samples to calculate dose for this category. The supervisor category was designated for workers who were likely in the vicinity of the activities but did not participate in a hands-on fashion. NIOSH used the GA air samples to calculate dose for this category. The other category was designated for workers who would not have routinely been in the area during the test but could have entered the area infrequently. For this category, NIOSH assigns 10 percent of the supervisor dose. NIOSH calculated the inhalation and ingestion uranium intake rates for each of the three job categories, shown in tables 1 and 2 of DCAS-TKBS-0005 (NIOSH, 2012).

4.1.1 SC&A's comments

In the 2011 review of revision 00 of DCAS-TKBS-0005 (NIOSH, 2011), SC&A had two findings associated with internal dose estimates:

Finding 1: Air concentration assignments may not have been claimant favorable or bounding.

Finding 2: The use of the 50th percentile values is not adequate (SC&A, 2011).

NIOSH responded to these findings in a white paper and detailed the internal dose approach that is currently employed in revision 01 of DCAS-TKBS-0005 (NIOSH, 2012).

In SC&A's response to NIOSH's white paper, SC&A found the revised approach to internal dose estimates to adequately address the original concern (SC&A, 2012). SC&A also believed that NIOSH's revised approach adequately addressed the concern regarding the 50th percentile values, since the new approach considers the 50th and 95th percentile intakes (SC&A, 2012). SC&A verified that the methods used in NIOSH's white paper were incorporated into revision 01 of DCAS-TKBS-0005 (NIOSH, 2012). SC&A also confirmed that the resulting

internal dose estimates in revision 01 of DCAS-TKBS-0005 (NIOSH, 2012) are higher for all job categories, compared to the doses in revision 0.

SC&A has no findings on internal dose.

4.2 External dose estimate

No external dose readings were collected during the test at Baker-Perkins. The highest exposure potential is from the drummed uranium. Therefore, NIOSH calculated external dose assuming workers were one foot away from a drum of uranium for the entire day. Additionally, all three worker categories identified in the internal dose section received the same external dose estimate. Given the information available from the test, NIOSH estimated that all the uranium used during the test could have fit into one 55-gallon drum. NIOSH used MCNPX to model the dose rates from a drum of uranium-238 and used these results to calculate external photon dose, skin dose, and dose to the hands and forearms, given in table 5 of DCAS-TKBS-0005 (NIOSH, 2012).

4.2.1 SC&A's comments

In the 2011 review of revision 00 of DCAS-TKBS-0005 (NIOSH, 2011), SC&A has two findings and an inconsistency observation associated with external dose estimates:

Finding 3: No submersion dose considered.

Finding 4: Two drums of uranium were not considered.

Observation: Inconsistency with the defined labor categories between internal and external dose estimates.

NIOSH responded in a white paper and clarified that the estimated dose rates from a drum of uranium were more claimant-favorable than the doses from surface contamination. NIOSH also determined that the amount of uranium used during the test could have fit into a single drum. SC&A reviewed revision 01 of DCAS-TKBS-0005 (NIOSH, 2012) and found that no changes were made to the approach for calculating external dose or to the estimated doses from revision 0, since NIOSH demonstrated that SC&A's two findings were appropriately addressed in the TBD. With regard to the observation, NIOSH indicated that clarifying language would be added to the next revision of the TBD stating that operators, supervisors, and others would receive the same external dose estimate.

SC&A has no findings on external dose.

4.3 Occupational medical dose estimate

No site-specific guidance for Baker-Perkins occupational medical dose exists; therefore, the guidance in revision 06 of ORAUT-OTIB-0006 (ORAUT, 2019) should be used for assigning occupational medical dose in DRs. It is assumed that employees received one posterior-anterior chest x-ray for the year 1956. Organ doses due to occupational medical exposure are entered into the Interactive RadioEpidemiological Program as 30–250 keV photons as a normal distribution with a standard deviation of 30 percent.

Effective date: 9/4/2024 Revision No. 0 (Draft) Document No.: SCA-TR-2024-PR039 Page 11 of 14

4.3.1 SC&A's comments

SC&A agrees with the guidance of using ORAUT-OTIB-0006 and the assumed x-ray frequency to calculate occupational medical doses.

Effective date: 9/4/2024 Revision No. 0 (Draft) Document No.: SCA-TR-2024-PR039 Page 12 of 14

5 Subtask 3: Evaluate the PER's Stated Approach for Identifying the Number of DRs Requiring Reevaluation of Dose

5.1 NIOSH's selection criteria

Section 3.0 of DCAS-PER-039 (NIOSH, 2013) described the following criteria NIOSH used to identify previously completed claims requiring reevaluation using revision 01 of DCAS-TKBS-0005 (NIOSH, 2012). NIOSH identified all previously completed claims with verified employment at Baker-Perkins, which was eight claims. Since all eight claims had a POC less than 50 percent, they were all reevaluated by NIOSH using revision 01 of DCAS-TKBS-0005 (NIOSH, 2012). NIOSH determined that the resulting POC for each of the eight claims was below 45 percent, and the highest POC was below 15 percent. The POC increased for three of the claims and decreased for the remaining five claims.

5.2 SC&A's comments

SC&A finds NIOSH's selection criteria for defining the eight claims requiring reevaluation of dose to be sufficient to identify all impacted claims. Additionally, SC&A believes the PER was conducted in a timely manner, as revision 01 of DCAS-TKBS-0005 (NIOSH, 2012) was issued in May 2012, and DCAS-PER-039 was issued in January 2013 (NIOSH, 2013). There are no findings associated with subtask 3.

Effective date: 9/4/2024 Revision No. 0 (Draft) Document No.: SCA-TR-2024-PR039 Page 13 of 14

6 Subtask 4: Conduct Audits of a Sample Set of Reevaluated DRs Mandated by DCAS-PER-039

Previous sections of this report described the issuance of revision 01 of DCAS-TKBS-0005 (NIOSH, 2012), the TBD for Baker-Perkins. SC&A recommends that the Board select two cases from the cases evaluated by NIOSH. SC&A believes a claim whose POC increased and a claim whose POC decreased would be appropriate for evaluation.

Effective date: 9/4/2024 Revision No. 0 (Draft) Document No.: SCA-TR-2024-PR039 Page 14 of 14

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