

Contract Oversight Team

NIOSH/OCAS Assessment Report

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OCAS-COT-0015

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Assessment Type: Contract Oversight

Assessment Team: Michael Rafky, Laurie Ishak, Robert Daniels

Assessment Title: Assessment of Potential Conflict of Interest Involving ORAUT-TKBS-0019-5, "Technical Basis Document for Paducah Gaseous Diffusion Plant – Occupational Internal Dose."

Assessment Reviewed By:

<u>Signature on file</u> <i>Signature</i>	<u>10/11/2005</u> <i>Date</i>
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PURPOSE

This assessment was conducted to determine whether a conflict of interest (COI) policy violation occurred in developing the “Technical Basis Document for Paducah Gaseous Diffusion Plant – Occupational Internal Dose” (ORAUT-TKBS-0019-5). The concern that such a policy violation occurred was raised by a claimant advocate.

SCOPE

This assessment focused on two specific questions:

1. Did the involvement of an individual who had previously performed health physics work at the Paducah Gaseous Diffusion Plant, and subsequently served as the Subject Expert on ORAUT-TKBS-0019-5, violate existing conflict of interest policies?
2. Does the “Technical Basis Document for Paducah Gaseous Diffusion Plant – Occupational Internal Dose” developed under the circumstances presented in question 1 above take full advantage of and use the best available data for completing dose reconstructions?

CONCLUSIONS

Did the involvement of an individual who had previously performed health physics work at the Paducah Gaseous Diffusion Plant, and subsequently served as the Subject Expert on the “Technical Basis Document for Paducah Gaseous Diffusion Plant – Occupational Internal Dose,” violate existing conflict of interest policies?

The conflict of interest policy employed during the development and approval of ORAUT-TKBS-0019-5 was unclear and should be revised to better define how Subject Experts may be utilized in developing technical basis documents, in order to indicate what role they perform and what approval authority they have.

The use of site experts to develop ORAUT-TKBS-0019-5 reflects the ORAU management philosophy and intent of the ORAU COI policy.

The use of site experts to develop ORAUT-TKBS-0019-5 was consistent with explanations provided by OCAS to the ABRWH.

The use of the terms “primary author” and “site profile authors” may have resulted in misperceptions regarding the roles of Subject Experts and Technical Basis Document Team Leaders.

A violation of the then-current COI policy did not occur; although the language of the policy was ambiguous, the underlying policy intent was followed.

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The ORAU COI policy must be revised to more clearly define the roles of Technical Basis Document Team Leaders and Subject Experts, and their respective scopes of approval authority.

In that regard, the Technical Basis Document Team Leader has the overall authority and responsibility to determine the content of a Technical Basis Document prior to its submission to OCAS for review. Individuals, regardless of their past work at DOE or AWE facilities, may be used as Subject Experts in preparing Technical Basis Documents. In addition to providing research and data for the Technical Basis Document, Subject Experts may be tasked with drafting the document for which they are designated a Subject Expert. Extensive technical review and multiple required approvals of a Subject Expert’s work, both by the Technical Basis Document Team Leader and thereafter at OCAS, are conducted to ensure that the document is technically accurate and free of bias.

Does the “Technical Basis Document for Paducah Gaseous Diffusion Plant – Occupational Internal Dose,” developed under the circumstances presented in question 1 above, take full advantage of and use the best available data for completing dose reconstructions? Specifically, does ORAUT-TKBS-0019-5 adequately address the information contained in Paper, Allied Industrial, Chemical and Energy Workers (PACE) International Union document “Exposure assessment projects at the Paducah Gaseous Diffusion Plant?”

ORAUT-TKBS-0019-5 relies heavily on the same source documents that are used and referenced in the Paper, Allied Industrial, Chemical and Energy Workers (PACE) International Union document “Exposure assessment projects at the Paducah Gaseous Diffusion Plant,” as well as the PACE document itself.

For both documents, the majority of the recommended contributing isotopes and their distributions within most work locations were abstracted from a 1987 site exposure assessment report conducted by R. C. Baker. However, for these work locations, more conservative assumptions of ²⁴¹Am and uranium enrichment, which would result in higher organ doses, are provided in ORAUT-TKBS-0019-5.

Organ doses calculated from the default values in Table 5-4 of ORAUT-TKBS-0019-5 are higher than organ doses calculated using the average or maximum isotopic distribution values in Table 7.9 of the PACE document for all areas except the ash receivers, pulverizer and converter salvage line.

Organ doses calculated from the default values in Table 5-4 of ORAUT-TKBS-0019-5 are comparable to organ doses calculated using the average isotopic distributions values in Table 7.9 of the PACE document for the ash receivers and pulverizer.

Organ doses calculated using the default values in Table 5-4 of ORAUT-TKBS-0019-5 are less than the organ doses calculated using the average or maximum isotopic distributions values in

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Table 7.9 of the PACE document for the converter salvage line or when using the maximum values cited for the ash receivers and pulverizer.

ORAUT-TKBS-0019-5 should be reviewed and revised as necessary to ensure that the best available data are used. Specifically, the transuranic concentrations documented during operations at the ash receiver and pulverizer, and during the converter salvage line incident, should be evaluated to determine their applicability to the dose reconstruction process.

Based on this review, there is no compelling reason to prefer existing air-sampling data to bioassay information for purposes of PGDP worker dose reconstruction.

CONCERNS, FINDINGS AND RECOMMENDATIONS

Concerns are defined as “systemic breakdowns in programmatic performance supported by one or more findings.” Findings are defined as “deviations from a contractual or programmatic requirement.” Recommendations are defined as “suggestions for program improvement.”

This assessment resulted in two findings and one recommendation:

Finding 1 - The then-controlling conflict of interest policy was not clear and has been revised to better define how Subject Experts may be used in developing technical basis documents.

Finding 2 - ORAUT-TKBS-0019-5 shall be reviewed and revised as necessary to ensure that the best available data are used. Specifically, the transuranic concentrations documented during operations at the ash receiver and pulverizer, and during the converter salvage line incident, should be evaluated to determine their applicability to the dose reconstruction process.

Recommendation 1 – ORAU should conduct an internal assessment of all site profile documents following the approval and adoption of ORAUT-PLCY-0002, “Conflict of Interest.” Documents not meeting the requirements of this new policy should be revised as necessary.

A corrective action plan to address the findings must be submitted by ORAU and approved by OCAS. This plan must include, but is not limited to, a description of the actions that will be taken as well as their projected completion dates.

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SUPPORTING DISCUSSION:

A claimant advocate raised several concerns that are discussed below. These concerns were provided to OCAS through e-mails and were reiterated during an interview conducted on July 14, 2005.

1. The then-current ORAU conflict of interest policy, approved in June of 2004, is included as Attachment 1 and was reviewed. The policy states in part:
 - *No contractor, subcontractor, or employee will be the principle [sic] author, reviewer or give final approval of a dose reconstruction for claimants from a given DOE/AWE site, prepare a site profile for that site, or serve as the primary reviewer for a determination of whether or not to add a class of employees to the SEC from that site, if they have previously performed work that affected or established policies on radiation dosimetry assessments, dosimetry programs or records at that site.*
 - *No Individual will perform, review, or approve radiation dose reconstructions, site profiles or determinations of whether or not to add a class of employees to the SEC for co-workers, DOE facilities at which they were formerly employed, or for contractors by whom they have been employed. Site experts may be employed to advise on site specific issues and incidents as necessary.*
 - The term “Principal Author” is neither defined nor used in Site Profile Documents, Dose Reconstruction Reports, or in the procedures that set forth the requirements for these documents’ preparation. This assessment recognizes that the use of that term may well have resulted in misperceptions regarding the roles and scope of authorities of Subject Experts and Technical Basis Document Team Leaders.
 - The first italicized paragraph above clearly states that individuals who have previously performed work that affected or established policies on radiation dosimetry assessments, dosimetry programs or records at a site may not prepare a site profile for that site.
 - The first sentence in the second italicized paragraph of the COI policy above states that no individual will perform, review, or approve site profiles for DOE facilities at which they were formerly employed. This statement is admittedly not consistent with the first paragraph. Moreover, the last sentence of the second paragraph of the COI policy above states that site experts may be employed to advise on site specific issues and incidents as necessary. This latter statement may be read to allow the employment of site experts as occurred on the Paducah TBD.

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Conclusion:

The conflict of interest policy employed during the development and approval of ORAUT-TKBS-0019-5 was unclear and should be revised to better define how Subject Experts may be utilized in developing technical basis documents, in order to indicate what role they perform and what approval authority they have.

2. In order to determine the intent of the then-current ORAU COI policy, the Associate Director for Science for the Office of Compensation Analysis and Support, and the Director, ORAU Team Dose Reconstruction Project for NIOSH, were interviewed. Given their significant roles in developing the COI policy at issue, they were specifically asked how they believed Subject Experts may be utilized in the development of Technical Basis Documents, what role they perform, and what approval authority they have.
 - The Associate Director for Science for the Office of Compensation Analysis and Support participated in development of the ORAU COI policy as the technical monitor for the contract. He stated his belief that the intent of the policy was to allow individuals who had been employed at facilities at which they were previously involved, or for which they established the radiation control practices, to contribute to Technical Basis Documents but not to allow them to serve as the Technical Basis Document Team Leader or have final approval authority over the document.
 - The Director, ORAU Team Dose Reconstruction Project for NIOSH, was principally involved in the development of the ORAU COI policy. He stated his belief that it was ORAU’s intent to allow individuals with previous employment at facilities to serve as Subject Experts on Technical Basis Documents, precisely because they are often the most knowledgeable about site practices and policies. He also stated that such individuals would not have approval authority over the document.

Conclusion:

The use of site experts to develop ORAUT-TKBS-0019-5 reflects the ORAU management philosophy and intent of the ORAU COI policy.

3. In order to determine if the ORAU COI policy under discussion here is consistent with the explanations provided by NIOSH OCAS to the Advisory Board on Radiation Worker Health (ABRWH), transcripts from meetings of the ABRWH (Attachment 2) were reviewed. Pertinent excerpts of those transcripts are summarized below:
 - April 20, 2004
The speaker is Dr. Melius. Dr. Melius asked if ORAU has created a COI policy for site profile documents. Dr. Neton explained that ORAU was working on a policy for site profile documents that was similar to the COI plan for DRs. Dr. Neton explained that individuals who worked at a site could not be the primary author but could be used as site experts because they are the most knowledgeable about the site.

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Although an official policy was not in place, ORAU was following such a policy voluntarily. Dr. Melius believed there needed to be transparency to that process. Mr. Elliott stated that anyone who works on the document will be referenced and their biographical sketch will be provided on the web. [p. 130, ln. 6-25, & pp. 131-133]

- June 2, 2004 (Volume D):
The speaker is Mr. Elliott. Mr. Elliott explained that there was a COI policy in place for site profile authors that mirrored the policy for dose reconstructors—*i.e.*, that the person who worked at a facility could not be the primary author of a site profile document. [p. 48, ln. 1-25, & p. 49]
- August 24, 2004 (Volume D):
The speaker is Dr. Melius. Dr. Melius asked if the new COI plan that was signed applied the same COI plan to individuals who work on site profile documents that was being used for individuals that complete dose reconstructions. Dr. Neton explained that the language paralleled the language of the COI plan for DRs. Copies of the modified COI plan were given to the Board. [p. 47, ln. 15-25, & p. 48]

Conclusions:

The use of site experts to develop ORAUT-TKBS-0019-5 was consistent with explanations provided by OCAS to the ABRWH.

The use of the terms “primary author” and “site profile authors” may have resulted in misperceptions regarding the roles of Subject Experts and technical basis document team leaders.

A violation of the then-current COI policy did not occur; although the language of the policy was ambiguous, the underlying policy intent was followed.

4. The individual approving ORAUT-TKBS-0019-5 as the Technical Basis Document Team Leader was then employed by the company owned by the individual listed as the Subject Expert. A concern was raised by a claimant advocate that this too was a violation of the conflict of interest policy.
 - Upon review, the then-current COI policy was found not to address such arrangements.
 - The Technical Basis Document Team Leader was interviewed to determine what he believed his level of authority was, considering his organizational position relative to the Subject Expert. He stated that although the Subject Expert on ORAUT-TKBS-0019-5 wrote the bulk of the document, that individual still had to submit the document to the ORAU team for internal peer review. He further explained that he

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had the ultimate authority to approve and disapprove any and all information to be put into the document. Following this internal review, the document was submitted to OCAS for further review and approval. The OCAS review involved multiple iterations of comments between ORAU and OCAS.

Conclusions:

The ORAU COI policy must be revised to more clearly define the roles of Technical Basis Document Team Leaders and Subject Experts, and their respective scopes of approval authority.

In that regard, the Technical Basis Document Team Leader has the overall authority and responsibility to determine the content of a Technical Basis Document prior to its submission to OCAS for review. Individuals, regardless of their past work at DOE or AWE facilities, may be used as Subject Experts in preparing Technical Basis Documents. In addition to providing research and data for the Technical Basis Document, Subject Experts may be tasked with drafting the document for which they are designated a Subject Expert. Extensive technical review and multiple required approvals of a Subject Expert’s work, both by the Technical Basis Document Team Leader and thereafter at OCAS, are conducted to ensure that the document is technically accurate and free of bias.

5. Questions were raised regarding the Subject Expert’s previous involvement with the site in writing the 1992 document “Personnel exposure potential to transuranic materials at the Paducah Gaseous Diffusion Plant” published by IT Corporation/Nuclear Sciences, and specifically whether or not source documents other than the above-mentioned IT document were used in developing ORAUT-TKBS-0019-5.
 - Interviews were conducted to gather background information concerning document development. Based on discussions with the Subject Expert for ORAUT-TKBS-0019-5, the default activity fractions were chosen using the following general criteria: 1) Resulting dose estimates would be reasonable and claimant favorable; and 2) The values would promote consistency across similar DOE facilities (*e.g.*, K25 Site and Portsmouth Gaseous Diffusion Plant). The Subject Expert stated that the contributors and the Technical Basis Document Team Leader agreed to activity fractions that were consistent with the available literature (including the PACE Report) and provided claimant favorable estimates based on generic work descriptions across the related sites. Although the Subject Expert did not recall a specific assessment of the activity fractions or other related reference materials cited by the PACE Report, the Subject Expert stated the PACE Report was used extensively during the development of the site profile document at issue. The Subject Expert also acknowledged that ORAUT-TKBS-0019-5 should be revised if additional information is identified that may be useful in dose reconstruction.

Conclusion:

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ORAUT-TKBS-0019-5 relies heavily on the same source documents that are used and referenced in the Paper, Allied Industrial, Chemical and Energy Workers (PACE) International Union document *Exposure assessment projects at the Paducah Gaseous Diffusion Plant*, as well as the PACE document itself.

6. Questions were raised regarding the data contained in ORAUT-TKBS-0019-5, specifically as compared to the PACE/University of Utah document, “Exposure assessment projects at the Paducah Gaseous Diffusion Plant.”
 - These two documents were evaluated by an independent certified Health Physicist to determine if the best available data were used in ORAUT-TKBS-0019-5. Specifically, the isotopic fractions of transuranic elements prescribed in ORAUT-TKBS-0019-5 were compared to those contained in the PACE document. Both documents rely heavily on the “Exposure assessment - uranium recycle materials in the Paducah Feed Plant” published by R.C. Baker in 1987 for isotopic fractions in all areas with the exception of the ash receivers, pulverizer, and converter salvage line. The isotopic fractions listed in ORAUT-TKBS-0019-5 and the PACE document are therefore comparable for all areas other than the ash receivers, pulverizer, and converter salvage line.
 - The converter salvage line isotopic fractions for ^{237}Np , ^{239}Pu , ^{230}Th and uranium used by PACE and the University of Utah were extracted from a 1979 radiation survey of the C-400 Converter Bundle Salvage Line. The values represent the arithmetic mean and maximum results of a series of air samples taken during “unusually high concentrations of airborne radioactivity”. The high airborne results were observed during the disassembly of contaminated converter bundles that had been placed in storage. Further analysis of converter disassembly work revealed that the high airborne activities were “unusual” and were attributed to poor decontamination of the bundle prior to salvaging and working dry surfaces. The report documenting this event states that the appropriate radiological control practices had not been followed. The individuals involved with this incident were wearing external radiation dosimetry at the time and received follow-up monitoring including urinalysis, whole body counts and external contamination monitoring.
 - The basis for activity fractions assumed for workers at the pulverizer and ash receivers could not be directly determined from the referenced information. However, available information indicated that activity fractions higher than those reported by ORAUT-TKBS-0019-5 may be common to certain plant processes. For example, the Report of the Joint Task Force on Uranium Recycle Material Processing indicates residual ash materials shipped to the Feed Materials Production Center (FMPC) from PGDP in 1980 contained plutonium levels ranging from 67 ppb to 7,757 ppb (average 1,123 ppb) compared to the 1,000 ppb Pu used by Baker and

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subsequently cited by ORAUT-TKBS-0019-5. Likewise, a 1962 health physics inspection report indicated 90% “trace” alpha activity (*e.g.*, 10% uranium) in dust from C-337, U-3, or C-6 that was vacuumed from a disassembled converter. This assessment assumes that “trace” activity refers to transuranic materials, which were primarily ²³⁷Np. However, it is important to note that the converter disassembly work was infrequent, requiring approximately eight shifts over more than a two month period. Based on a brief review of existing records, some of which are cited in ORAUT-TKBS-0019-5 and the Exposure Assessment Project at the Paducah Gaseous Diffusion Plant, the default values in ORAUT-TKBS-0019-5 may not represent expected or bounding values for certain work locations.

Conclusions:

For both documents, the majority of the recommended contributing isotopes and their distributions within most work locations were abstracted from a 1987 site exposure assessment report conducted by R. C. Baker. However, for these work locations, more conservative assumptions of ²⁴¹Am and uranium enrichment, which would result in higher organ doses, are provided in ORAUT-TKBS-0019-5.

Organ doses calculated from the default values in Table 5-4 of ORAUT-TKBS-0019-5 are higher than organ doses calculated using the average or maximum isotopic distribution values in Table 7.9 of the PACE document for all areas except the ash receivers, pulverizer and converter salvage line.

Organ doses calculated from the default values in Table 5-4 of ORAUT-TKBS-0019-5 are comparable to organ doses calculated using the average isotopic distributions values in Table 7.9 of the PACE document for the ash receivers and pulverizer.

Organ doses calculated using the default values in Table 5-4 of ORAUT-TKBS-0019-5 are less than the organ doses calculated using the average or maximum isotopic distributions values in Table 7.9 of the PACE document for the converter salvage line or when using the maximum values cited for the ash receivers and pulverizer.

ORAUT-TKBS-0019-5 should be reviewed and revised as necessary to ensure that the best available data are used. Specifically, the transuranic concentrations documented during operations at the ash receiver and pulverizer, and during the converter salvage line incident, should be evaluated to determine their applicability to the dose reconstruction process.

7. The claimant advocate raised another question regarding whether bioassay data should be preferred to air-sampling data for reconstructing doses of PGDP workers. The primary program governing procedures, contained in 42 C.F.R. Part 82, “Methods for Radiation Dose Reconstruction under the Energy Employees Occupational Illness Compensation

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Program Act of 2000 (EEOICPA),” were reviewed to determine the hierarchy of data to be used.

- As noted immediately above, OCAS conduct of occupational radiation dose reconstruction is governed by 42 C.F.R. Part 82, “Methods for Radiation Dose Reconstruction under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA).” In accordance with 42 C.F.R. § 82.2, a hierarchy of methods establishes individual worker monitoring data (when complete and adequate) as the highest priority for internal and external dose reconstruction methods. Guidance for assessing internal exposures recognizes workplace area monitoring data as a viable source of information for dose reconstruction in the absence of adequate or available bioassay data. Air-sampling data are commonly relied upon for dose reconstruction during time periods prior to established bioassay programs, or for unmonitored workers with likely exposure. However, PGDP workers have participated in a uranium bioassay program at frequencies based on exposure potential since the beginning of enrichment operations, and the resulting bioassay data are available to dose reconstruction staff. Although few available data directly provide detailed results for TRU-contaminated materials, the uranium data can be related to potential TRU uptakes using default assumptions of isotopic concentrations. It must be noted that these same assumptions, in addition to others, are also necessary when using uranium air-sampling data for dose reconstruction.

Conclusion:

Based on this review, there is no compelling reason to prefer existing air-sampling data to bioassay information for purposes of PGDP worker dose reconstruction.

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ATTACHMENT 1
ORAU TEAM CONFLICT OF INTEREST POLICY

A. Overview

In any situation that involves compensation for injury, whether a tort claim, a worker’s compensation case, or a claim made under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), the integrity of the process must be unimpeachable. This is particularly true under the EEOICPA, because one branch of the U.S. government (i.e., DOE) was responsible for the exposures to ionizing radiation and hazardous substances and is also charged with providing data to assist in adjudicating claims, while other branches of the government (i.e., NIOSH, DOL) are responsible for administering and operating the program. Many of the persons working for the government on this program, whether as federal or contractor employees, have had previous involvement in the conduct of radiation protection programs at Department of Energy (DOE) facilities; or they may have previously received or are currently receiving financial support or compensation from DOE.

The ORAU Team is extremely sensitive to the concerns in the stakeholder community regarding perceived or actual conflicts of interest (COI). We understand why the bar on perceived and actual conflicts of interest must be set higher for this project than is established by the COI provisions of the Federal Acquisition Regulations (FAR).

The critical consideration is not whether the potential for COI exists – it does. The most important factors are that the contractor have a rigorous and precise plan for identifying potential COI situations and avoiding them; and that NIOSH be assured the contractor will carry out that process with absolute integrity. Although some may view it as not desirable that persons with any sort of DOE affiliation be involved in dose reconstruction, preparation of site profiles, or Special Exposure Cohort (SEC) petition review, it is almost inevitable that many such persons must be involved, especially in the process of research. For example, health physicists who have expertise in the internal radiation dosimetry of plutonium must have learned their trade at DOE facilities simply because that is where the plutonium is. Similarly, the research effort to develop Site Profiles and process SEC petitions for the various sites will necessarily involve persons with expert knowledge of the sites, and that knowledge will usually have been gained from having worked there. Therefore, given these inherent potential conflicts, the contractor selected for the dose reconstruction project, along with NIOSH, must do everything possible to prevent or manage actual and perceived conflicts of interest and to disclose all potential conflicts of interest.

ORAU, a non-profit association of universities, was chartered in 1946. In the ensuing five decades, we have gained unparalleled experience in maintaining the integrity of technical processes while working with many issues of public concern. Lessons learned from those experiences have been woven into the culture and structures of ORAU.

Providing objective science-based studies and analyses that withstand the COI challenge is more than something we do – it’s a part of who we are.

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ORAU and its employees are committed to the highest ethical standards. All ORAU employees receive mandatory initial and refresher training in ethical issues. This training is mandatory not only for ORAU employees, but for all persons working on this project, including subcontractors, and was conducted during the start-up phase, with annual refreshers thereafter. Copies of the training materials can be provided to NIOSH for the project files. ORAU will maintain documentation of the successful completion of this (and other) training for all personnel working on this project, whether ORAU or subcontractor employees.

B. COI Policy

ORAU is committed to full and open disclosure as the best way to prevent conflicts of interest. ORAU agrees completely that “sunshine is the best disinfectant.”

The ORAU Team will disclose, for each company and for each individual involved in dose reconstruction, preparation of Site Profiles, research supporting determinations of whether or not to add a class of employees to the SEC, or any other work done by primary authors or reviewers for NIOSH on dose reconstructions or SEC petitions on behalf of the EEOICPA program, information about their past and present work at DOE sites. In addition, the ORAU Team members will inform NIOSH of any new DOE work that they are awarded. ORAU and its subcontractors will be proactive in making its processes for avoiding COI available to all stakeholders.

There are three aspects to effective disclosure/avoidance of conflict of interest:

- Planning of the work by the contractor;
- Oversight by NIOSH of COI performance; and
- Disclosure of information sufficient to let the public reach its own conclusions concerning the resolution of potential concerns about conflict of interest.

ORAU will construct a database that lists all DOE sites where EEOICPA team members have worked, and outlines all potential areas of conflict of interest. This database will be used by the Project Director and Task Managers in making and checking work assignments for dose reconstruction, preparation of site profiles, research supporting determinations of whether or not to add a class of employees to the SEC, or any other work done by primary authors or reviewers for NIOSH on dose reconstructions or SEC petitions on behalf of the EEOICPA program. All individuals and companies on the

ORAU EEOICPA team will provide the necessary information to populate the database initially, and will promptly update it as necessary.

Access to the database will be provided to NIOSH for oversight of this contract.

Printouts about the persons (and their companies) performing individual dose reconstructions, preparation of site profiles, research supporting determinations of whether or not to add a class of employees to the SEC, or any other work done by primary authors or reviewers for NIOSH on dose reconstructions or SEC petitions on behalf of the EEOICPA program will be available upon

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request, subject to legal requirements concerning the protection of privacy interests. ORAU will continue to make disclosure statements available to the public via ORAU’s website.

The database will be constructed to provide the following information to the ORAU EEOICPA Team, to NIOSH, and, as described above, to others:

- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor is, was or will be (in the next 12 months) involved in managing or directing DOE radiation protection and health physics program policies, practices and /or procedures.
- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor is, was or will be supporting, directly or indirectly, decision making in a radiation dosimetry program. This includes a contractor/subcontractor that is a management and operations / management and integration (M&O/M&I), team member of an M&O/M&I, or a program manager of such a program.
- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor has broad technical support contracts or task-based contracts in place at DOE sites whose Statement of Work permits them to currently complete or be broadened to include the above radiation dosimetry work.
- Whether and where ORAU, a subcontractor, or individual employees of ORAU or a subcontractor has an active interest in bidding for the above DOE work activities and such “interest” has been properly disclosed elsewhere publicly (through public announcements, media or other disclosures).
- Whether and where any individual employees of ORAU or a subcontractor for the ORAU EEOICPA team have acted as expert witnesses on behalf of DOE or a DOE contractor with respect to worker compensation claims or law suits involving the question of whether radiation exposure was responsible in whole or in part for an alleged injury.
- Whether any individual employees of ORAU or a subcontractor for the ORAU EEOICPA team have former colleagues or co-workers whose claims they may receive for dose reconstruction by virtue of the DOE facilities or sites assigned to them.
- Whether ORAU and its subcontractors and their employees are reviewing reports, assessments, surveys, documents and records that they organizationally or individually have been responsible for authoring, developing, or submitting to DOE or its contractors. ORAU will further indicate if ORAU, a subcontractor, or individual employees of ORAU or a subcontractor was an unidentified contributor to any such reports, assessments, surveys, documents or records.

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Assessment of Potential Conflict of Interest Involving ORAUT-TKBS-0019-5, “Technical Basis Document for Paducah Gaseous Diffusion Plant – Occupational Internal Dose.”	OCAS-COT-0015	October 11, 2005

To avoid potential for actual or perceived conflicts of interest in dose reconstructions or other activities under this contract, ORAU, its subcontractors, and the individual employees of ORAU or a subcontractor will subscribe to the following restrictions:

- No contractor, subcontractor, or employee will be the principle author, reviewer or give final approval of a dose reconstruction for claimants from a given DOE/AWE site, prepare a site profile for that site, or serve as the primary reviewer for a determination of whether or not to add a class of employees to the SEC from that site, if they have previously performed work that affected or established policies on radiation dosimetry assessments, dosimetry programs or records at that site.
- No contractor, subcontractor, or employee will be the principle author, reviewer or give final approval of a dose reconstruction for claimants from a given DOE/AWE site if they have previously been involved with DOE-funded dose assessments or reconstructions for workers from that site.
- No contractor element will participate in or review dose reconstructions or participate in research supporting site profiles or determinations of whether or not to add a class of employees to the SEC for those DOE sites or activities where it is the prime contractor (i.e., M&O/M&I), team member to a prime contractor, program manager or subcontractor managing dosimetry programs, or otherwise intends to be employed as such within 12 months of starting this contract.
- No individual will perform, review, or approve radiation dose reconstructions, prepare site profiles, or conduct research supporting determinations of whether or not to add a class of employees to the SEC, if he or she has voluntarily acted as an expert witness (including a non-testifying expert) on behalf of DOE or a DOE contractor in defense of radiation dose claims or suits. Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.
- No individual will perform, review, or approve radiation dose reconstructions, site profiles, or determinations of whether or not to add a class of employees to the SEC for co-workers, DOE facilities at which they were formerly employed, or for contractors by whom they have been employed. Site experts may be employed to advise on site specific issues and incidents as necessary.
- No contractor or subcontractor element will be permitted to perform or bid for collateral work on DOE radiation dosimetry program support for those sites where it is conducting dose reconstructions, preparing a site profile (or scheduled to prepare a site profile), or performing work supporting a determination of whether or not to add a class of employees to the SEC.

Assessment Title	Assessment ID	Date Completed
Assessment of Potential Conflict of Interest Involving ORAUT-TKBS-0019-5, “Technical Basis Document for Paducah Gaseous Diffusion Plant – Occupational Internal Dose.”	OCAS-COT-0015	October 11, 2005

- Key personnel of the ORAU team will not have a conflict of interest with respect to managing this project or carrying out or marketing radiation protection/health physics services elsewhere in DOE.
- Each supervisor, dosimetrist, and reviewer, and each professional performing, reviewing or approving a dose reconstruction, preparing a site profile or performing work supporting a determination of whether or not to add a class of employees to the SEC, will be required to complete and sign the attached form agreeing to abide by the above requirements. The forms will be maintained as auditable records of this project.
- No contractor, subcontractor, or individual will perform, review, or approve radiation dose reconstructions, prepare site profiles, or conduct research supporting determinations of whether or not to add a class of employees to the SEC if the company or individual has voluntarily provided expert witness services (including a non-testifying expert) on behalf of DOE or a contractor in defense of any claim filed under the EEOICPA. Restrictions for an individual who acts under subpoena will be determined on a case-by-case basis.
- A form identifying the dosimetrist who performed the dose reconstruction and the reviewer who approved it will be attached to each dose reconstruction and SEC determination, and provided to the claimant or petitioner(s) as appropriate, along with short biographical sketches.

All subcontracts issued to support ORAU in EEOICPA will contain a clause to ensure that the subcontractor complies with ORAU policy (stated here) regarding conflict of interest.

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Attachment 2 (April 20, 2004)

THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

convenes the

TWENTY-THIRD MEETING

ADVISORY BOARD ON
RADIATION AND WORKER HEALTH

The verbatim transcript of the Meeting of the Advisory Board on Radiation and Worker Health held at the Red Lion Hotel, 802 George Washington Way, Richland, Washington, on April 20, 2004.

Assessment Title	Assessment ID	Date Completed
Assessment of Potential Conflict of Interest Involving ORAUT-TKBS-0019-5, "Technical Basis Document for Paducah Gaseous Diffusion Plant – Occupational Internal Dose."	OCAS-COT-0015	October 11, 2005

Attachment 2 (April 20, 2004)

1 people -- I think we did one interview at Rocky Flats
2 for a person who we had discovered had some knowledge
3 and was getting ready to retire, but you know, our
4 involvement there has been limited. We need to -- we
5 need to aggressively pursue that more.

6 **DR. MELIUS:** Yeah, I have a few questions.
7 The first is an item from last meeting -- actually
8 several meetings ago, also, but from my understanding
9 from last meeting was that ORAU was -- and NIOSH were
10 developing a conflict of interest policy regarding --

11 **DR. NETON:** Right, right, I'm glad you
12 brought that up because it was in my notes and I
13 skipped right over it. Thank you.

14 ORAU has drafted a conflict of interest
15 policy. We are -- we are still in the process of
16 reviewing it, but I will say that the revisions that
17 they've made to their conflict of interest plan are
18 very similar to the concepts that are included in their
19 dose reconstruction conflict of interest policy, so
20 that any worker who had worked at the site -- currently
21 works or previously worked at that site could not be a
22 principal author of one of those Technical Basis
23 Document chapters. That doesn't preclude, though, them
24 from using resources, site subject matter experts as
25 resources to help flesh out and author those chapters,

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Attachment 2 (April 20, 2004 continued)

1 because we really frankly believe that they have to.
2 Those people are the most knowledgeable. But the
3 person who puts pen to paper or whatever you want to
4 say is -- cannot be -- you know, have that conflict of
5 interest. And for the new profiles being developed,
6 ORAU -- even though the official policy is not approved
7 -- is following that voluntarily at this point until we
8 review and approve their completed conflict of interest
9 modification.

10 **DR. MELIUS:** I don't know how to ask this.
11 It would be helpful to see it and -- I mean you say
12 you're following it, and yet we can't see it.

13 **DR. NETON:** I understand, Dr. Mel-- yeah,
14 it's -- until we get the final form out, I can't -- I
15 can't authori-- or issue it, but it's extremely close.
16 I mean I imagine this will be within a matter of weeks
17 that we can get this thing issued.

18 **DR. MELIUS:** Well, if we can get a -- 'cause
19 I think it's a significant problem and frankly people
20 are going to be skeptical until they -- they see it and
21 see how it's being implemented.

22 And just a comment on what you have briefly
23 described is I think one of the major issues is going
24 to be transparency if there are -- you're going to
25 access or use people with potential conflicts of

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Attachment 2 (April 20, 2004 continued)

1 interest or whatever you want to call that as a
2 resource, at least there ought to -- there should be
3 some transparency to that, and I think it's really
4 transparency for all your references for this 'cause I
5 think that would be --

6 **DR. NETON:** I agree.

7 **DR. MELIUS:** -- very helpful and --

8 **DR. NETON:** Yeah, anyone who works on the
9 profile as a member of the team needs to file a
10 biographical sketch -- you know, they will have a
11 signed biographical sketch indicating that conflict of
12 interest and what their role was. But you're right,
13 until we get that formal policy issued, it's -- you
14 know, you can't tell.

15 **MR. ELLIOTT:** Can I comment here on that
16 issue? We agree, I think, very strongly that whoever
17 contributes to these documents needs to be so
18 referenced. And I think you'll see this conflict of
19 interest plan come out, as Jim has described it, that
20 will make sure that the principal authors -- who
21 interpret what is provided to them, what resources they
22 have -- are not conflicted. And as soon as we have
23 this conflict of interest plan approved, I assure you
24 we'll give it to the Board the day it happens.

25 **DR. MELIUS:** We'll give you a day or two.

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Attachment 2 (April 20, 2004 continued)

1 **MR. ELLIOTT:** I'm committed on the record,
2 the day it happens.

3 **DR. MELIUS:** Okay, okay. Appreciate that.
4 And I think also -- I mean references to people who are
5 at these outreach meetings you're having, the so-called
6 "old timers" that Gen mentioned I think would be -- are
7 also -- I think it's helpful to the credibility of the
8 process to see who was accessed. And as people go back
9 and look at how this site profile that was -- you know,
10 may have been used for their dose reconstruction, I
11 think it really adds to the process.

12 **DR. NETON:** We are committed to putting the
13 minutes of those meetings on our web site, as well as
14 the attendance sheets. And I think we make it clear at
15 the meetings that we plan on doing so, so if anyone has
16 a problem with that, they can -- they can withdraw
17 their name.

18 **DR. MELIUS:** You have me a little confused on
19 another point, some of the clarifications you did at
20 the beginning -- and this has I think some implications
21 on what the Board's going to be doing in terms of
22 review process. And you mentioned I think three
23 different -- you have sort of the site profile
24 technical document which you describe in a chapter, so
25 forth. You have these implementation guides which I

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Attachment 2 (June 2, 2004)

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THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND
HEALTH

convenes the

TWENTY-FIFTH MEETING

ADVISORY BOARD ON

RADIATION AND WORKER HEALTH

VOL. I

The verbatim transcript of the
Meeting of the Advisory Board on
Radiation and Worker Health held at the
Hyatt Regency Buffalo, Two Fountain
Plaza, Buffalo, New York, on June 2,
2004.

Assessment Title	Assessment ID	Date Completed
Assessment of Potential Conflict of Interest Involving ORAUT-TKBS-0019-5, "Technical Basis Document for Paducah Gaseous Diffusion Plant – Occupational Internal Dose."	OCAS-COT-0015	October 11, 2005

Attachment 2 (June 2, 2004 continued)

1 There is a policy that is being adhered to
2 right now at ORAU that we agree with and we
3 -- and has been articulated in previous
4 Board meetings, and that is that -- and it's
5 very similar to the conflict of interest
6 policy for dose reconstructors, that they --
7 a person working on a site profile cannot be
8 the principal author if they've had
9 expertise in management of a dose reconst--
10 of a dose monitoring program at a -- at a
11 given site -- at -- for the site where the
12 site profile's being developed from.

13 **DR. NETON:** There are also provisions
14 for organizational conflict of interest, as
15 well. If the company --

16 **MR. ELLIOTT:** Right.

17 **DR. NETON:** -- had done a substantial -
18 - any work at all related to dose
19 reconstruction, dosimetry, radiation
20 protection programs practices, they could
21 not be working on that profile.

22 **DR. MELIUS:** I mean just -- needless to
23 say, it's sort of absurd to have -- not have
24 a policy and yet follow a policy and award
25 contracts under it and -- does not generate

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Attachment 2 (June 2, 2004 continued)

1 a lot of confidence in the process.

2 I have two questions that arise out of

3 the minutes. One --

4 **DR. ZIEMER:** Would you like Larry to

5 ask these next two questions?

6 **DR. MELIUS:** No, no, I don't think

7 that's -- he's welcome to.

8 The -- one is, did we ever get the --

9 the memo we sent up to -- through Secretary

10 Thompson to Department of Energy, I don't

11 ever remember -- recall receiving a final

12 copy of that.

13 **DR. ZIEMER:** That --

14 **DR. MELIUS:** I may have.

15 **DR. ZIEMER:** -- was sent and it may be

16 in this -- is it in this packet?

17 **DR. MELIUS:** Okay. Okay.

18 **DR. ZIEMER:** It is there.

19 **DR. MELIUS:** And it has gone over to

20 the Department of Energy?

21 **MR. ELLIOTT:** I don't know that it has

22 made its way to the Department of Energy.

23 It's on its way --

24 **DR. ZIEMER:** It had to go to Secretary

25 Thompson's office.

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Attachment 2 (August 24, 2004)

THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION
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convenes the

TWENTY-SIXTH MEETING

ADVISORY BOARD ON
RADIATION AND WORKER HEALTH

VOL. I

The verbatim transcript of the Meeting of the Advisory Board on Radiation and Worker Health held at the Shilo Inn Suites, 780 Lindsay Boulevard, Idaho Falls, Idaho, on August 24, 2004.

NANCY LEE & ASSOCIATES
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Assessment Title	Assessment ID	Date Completed
Assessment of Potential Conflict of Interest Involving ORAUT-TKBS-0019-5, "Technical Basis Document for Paducah Gaseous Diffusion Plant – Occupational Internal Dose."	OCAS-COT-0015	October 11, 2005

Attachment 2 (August 24, 2004 continued)

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1 application -- or is it premature to even begin
2 to ask that question at this point?

3 MS. ISHAK: My -- Jim, did you want to answer
4 this question or...

5 DR. NETON: Yeah. I don't recall the
6 specifics, but it's more than likely related to
7 covered exposure outside of certain time periods.

8 I mean I think K-25 had -- you know, the SE--
9 the original SEC sites had certain prescribed
10 time constraints, and I think it is either
11 outside of that -- it must be related to that.
12 That's the only condition I can think of that
13 would...

14 DR. ZIEMER: Jim?

15 DR. MELIUS: Yeah, I have two questions. One
16 quickly, the conflict of interest on the site
17 profiles for ORAU, is that the same conflict of
18 interest policy as exists for the other -- for
19 the -- you sort of described it briefly, but is
20 it the same as for the other dose
21 reconstructions?

22 DR. ZIEMER: I think Jim Neton can --

23 DR. NETON: Yes, I'll answer that. This was
24 just signed I believe Friday, very timely. It
25 took some going back and forth, and -- you know,

NANCY LEE & ASSOCIATES

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Attachment 2 (August 24, 2004 continued)

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1 legal --

2 DR. ZIEMER: Incentivized.

3 DR. NETON: -- folks involved, but in essence

4 what we've done is it's exactly -- ORAU has

5 placed language in their conflict of interest

6 policy that is -- parallels almost exactly the

7 exact language for the dose reconstructions. And

8 in fact, we took the opportunity at this time,

9 since we had it opened up, to add the same type

10 of provisions for evaluation of SEC petitions.

11 So you know, we were trying to be a little

12 proactive there and be ahead of the curve, so

13 principal reviewers on SEC petitions cannot have

14 previously been employed at the site and that

15 sort of thing. It's out there on our web site.

16 I have copies that --

17 MR. ELLIOTT: Aren't the copies in the

18 Board's book?

19 DR. NETON: They should be in your book under

20 my site profile presentation.

21 MR. ELLIOTT: Okay.

22 DR. MELIUS: Second question has to do with

23 the SEC petitions. Are those going to be -- do

24 you have a task order with ORAU for doing the

25 technical work on those or are those being done

NANCY LEE & ASSOCIATES