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Government Accountability Project

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December 9, 2005

Hon. Michael Leavitt, Secretary
Dept. of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

Dr. John Howard, Director
National Institute for Occupational Safety
and Health (NIOSH)
2000 Independence Ave., SW
Washington, DC 20201

Dear Secretary Leavitt and Dr. Howard:

We are writing to request that you personally review a NIOSH Contract Oversight Assessment Report which (1) blesses a NIOSH subcontractor's conflict of interest who was estimating radiation doses for use in the Energy Employees Occupational Illness Compensation Program (EEOICP), and (2) overlooks how this conflict of interest led to the use of incorrect data and contributed to a loss of credibility in the science used within the NIOSH program.

The "Assessment of Potential Conflict of Interest Involving ORAUT-TKBS-0019-5 Technical Basis Document for Paducah Gaseous Diffusion Plant—Occupational Internal Dose" has prompted NIOSH staff to weaken—rather than strengthen—its governing Conflict of Interest (COI) Policy. This will increase the number of people with conflicts of interest writing key scientific documents on behalf of the federal government, and adversely impact the credibility of the government's radiation risk estimates used to approve or deny compensation claims.

The attached white paper discusses how a NIOSH-funded subcontractor, Carol Berger, was allowed, due to loopholes in the program's conflict of interest restrictions, to review her own previous radiation dose assessments for a DOE contractor (Martin Marietta Energy System) at the Department of Energy's (DOE's) Paducah, Kentucky site. It appears that bias towards her own previous work caused her to use faulty science in preparing a NIOSH site profile at the Paducah site. This caused radiation dose to be underestimated.

NIOSH does not dispute that Ms. Berger reviewed, cut and pasted tables from her 1992 report for Martin Marietta into a September 2004 NIOSH site profile used for reconstructing radiation doses and making compensation decisions. NIOSH found she never considered published data which contradicted her previous work for Martin Marietta. NIOSH did not find a violation of its conflict of interest policy. While NIOSH acknowledges that the Paducah site profile should be reviewed and revised to account for the data overlooked by Ms. Berger, they took the wrong message from this case.

Instead of admitting a mistake and fixing it, NIOSH staff used this oversight report to weaken conflict of interest restrictions nationwide. Given comparable conflict of interests impacting NIOSH site profiles in Hanford (WA), Rocky Flats (CO), Pantex (TX) and Idaho

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National Labs (ID), there is a need for NIOSH to develop a broad and effective remedy.

Attached is a white paper which:

1. Outlines where the NIOSH contractor oversight team report failed to identify three violations of the conflict of interest policy in its report "Assessment of Potential Conflict of Interest Involving ORAUT-TKBS-0019-5 Technical Basis Document for Paducah Gaseous Diffusion Plant—Occupational Internal Dose";
2. Explains that this NIOSH oversight report overlooked the nexus between the appearance of a conflict of interest and potential bias which undermines NIOSH's scientific credibility; and
3. Analyses how the revised NIOSH/ORAU Conflict of Interest Policy (effective October 11, 2005) weakens important safeguards against conflict of interest, expands the number of people writing critical documents who have a conflict of interest, and how the new policy endangers the scientific credibility of the NIOSH program determinations under EEOICPA.

We recommend that you personally review the new COI policy, request the Advisory Board on Radiation and Worker Health to review the technical and policy issues in the Oversight Team Report and report back to you; and in the interim, suspend the revised COI policy pending your assessment. Detailed recommendations on next steps are outlined in the attached white paper.

We would be pleased to brief you in detail. Please contact me at 413-536-3858 or 413-531-5787 (cell) if you have any questions.

Sincerely,



Richard Miller
Senior Policy Analyst

Encl: White Paper Assessing NIOSH Program Conflict of Interest

Cc: Advisory Board on Radiation & Worker Health
Bill Cossler, Vice President, USW Local 5-550 (Paducah)

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**WHITE PAPER ASSESSING NIOSH CONTRACTOR CONFLICTS OF INTEREST AS
THEY IMPACT THE ENERGY EMPLOYEES OCCUPATIONAL ILLNESS
COMPENSATION PROGRAM ACT
GOVERNMENT ACCOUNTABILITY PROJECT (GAP)
DECEMBER 8, 2005**

SUMMARY

This white paper:

1. Outlines how a National Institute for Occupational Safety and Health (NIOSH) oversight report failed to find three violations of the Oak Ridge Associated Universities (ORAU) Conflict of Interest policy in its report "*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);
2. Shows that this NIOSH Oversight Report skirts the essential issue: whether a conflict of interest possessed by a "Subject Expert" has undermined the quality of the science and led to the underestimation of radiation risk from exposure to transuranic (TRU) compounds such as plutonium and neptunium;
3. Analyses how recent revisions to the NIOSH/ORAU Conflict of Interest policy weaken important safeguards against conflict of interest and expand the number of people with a conflict of interest writing critical documents, and explains how these changes threatens the scientific credibility of the NIOSH program determinations; and
4. Recommends interim steps to review and remedy the problems.

I. CONTRACT OVERSIGHT TEAM REPORT FAILED TO IDENTIFY THREE VIOLATIONS OF THE ORAU CONFLICT OF INTEREST POLICY:

ORAU, which is under a \$200 million contract to NIOSH to perform radiation dose assessments under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), hired a subcontractor, (Carol Berger), to write "the bulk of" the site profile for the Paducah site, yet this individual was previously employed under contract to Martin Marietta Energy Systems, the DOE's Management and Operating (M&O) contractor at Paducah, Kentucky, to assess worker exposure to transuranic (TRU) compounds from processing over 100,000 tons of "recycled" uranium¹. While consulting for Martin Marietta, the company was a defendant in claims involving worker exposure to radiation. NIOSH concluded there was no violation of the COI Policy, yet several violations were overlooked or were not investigated.

Violation #1: ORAU failed to issue COI disclosure statement for Carol Berger

The ORAU COI Policy (in effect at the time of the Paducah site profile) states:

¹ Personnel Exposure Potential to Transuranic Materials at the PGDP ("IT Report"), Martin Marietta Energy Systems, Inc., September 2, 1992, IT Corporation / Nuclear Sciences, Carol D. Berger, CHP

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“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 reconstruction or SEC petitions on behalf of the EEOICPA program, information about their past and present work at DOE sites.”

When the site profile was released in September 2004, Carol Berger’s conflict of interest disclosure was not made public. She was not listed on the ORAU web site for the team preparing the Paducah site profile. Her COI disclosure only became public after GAP notified ORAU Project Director Dick Toohey in February 2005. Failure to follow the disclosure requirement was not noted in NIOSH’s Oversight Team Report, yet the Report concluded that a “violation of the then-current COI Policy did not occur.” Transparency is a central element in managing the COI, and failure to comply is a *de facto* violation of the COI policy. NIOSH appears to have made no efforts to ensure disclosure of Ms. Berger’s conflicts, and neglected to point out their own failures to carry out adequate oversight in this regard.

Violation #2: Apparent Failure to Maintain Adequate COI Data Base

NIOSH determined that having someone who was part of a Department of Energy (DOE) contractor’s health physics program write “the bulk of” a chapter in a site profile was not a violation of the prohibition in the ORAU policy. However, ORAU’s policy in effect at the time requires that it maintain a database accessible to ORAU’s EEOICPA team, to NIOSH and to the public (subject to privacy act limitation) which identifies:

“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.”

NIOSH’s Oversight Report doesn’t disclose whether the previous work of Ms. Berger was identified in this COI database. Since the Report did not discuss compliance with this disclosure requirement, we presume there was no such examination. If this is in error, NIOSH should clarify. Surely if ORAU was managing its conflicts of interest, and NIOSH was policing the process, a disclosure that Carol Berger was reviewing her own previous work would have put up a red flag to ORAU management, NIOSH and the public, and triggered efforts to mitigate the problem.

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Violation #3: Individuals were allowed to perform, review or approve site profiles at sites where they were previously employed or for contractors for whom they were previously employed.

The ORAU COI Policy states:

“No individual will perform, review or approve radiation dose reconstructions, site profiles or determination 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.”

It is not in dispute that Carol Berger was employed by a DOE contractor at Paducah or that she wrote “the bulk of” the NIOSH site profile for Paducah. NIOSH explains away the evident conflict. They assert that writing the “bulk of” a site profile does not exceed the limited role allowed to “Site Experts” in the COI Policy, which (as cited above) is limited to “advise” on site specific issues “as necessary.” Citing OCAS Senior managers Larry Elliott and Jim Neton (who themselves have a conflict of interest for failing to police conflict of interest and failing to identify technical weaknesses in the Paducah site profile, respectively), the Oversight Report concludes that “Subject Experts may be tasked with drafting the document for which they are designated as the Subject Expert.” What NIOSH has done is make restrictions on those with an undisputed conflict of interest so elastic as to defeat the protections in the COI Policy.

Given the “management philosophy” to allow individuals with a conflict to write site profiles, the NIOSH Oversight Team found that a violation of “the then-current COI Policy did not occur.” The Team concluded that while the “language of the [COI] policy was ambiguous, the underlying policy intent was followed.”

Today, Carol Berger is listed on ORAU web site as a “primary author” of the Paducah Site Profile and indicates that she has no conflicts of interest. NIOSH’s new policy, as implemented, allows individuals with a conflict of interest to serve as primary authors and review their previous work without limitation. Rather than fixing the conflict and admitting a mistake, NIOSH has chosen to water down the conflict of interest restrictions.

II. SCOPE OF NIOSH OVERSIGHT REPORT IGNORES THE CORE ISSUE: IS FAILURE TO MANAGE CONFLICT OF INTEREST CREATING FAULTY SCIENCE?

The NIOSH Oversight Report selected only two of the many issues raised in GAP’s February 20, 2005 memo:

- 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 ORUT-TKBS-0019-5, violate existing conflict of interest policies;

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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.

NIOSH's framing of the issues skirts two central questions:

- Did the contractor's conflict of interest in reviewing her previous work for a DOE contractor taint the quality of science that was used in the NIOSH dose reconstruction program? If so, what does this imply about ORAU subcontractors with comparable conflicts of interest at Hanford, Rocky Flats, Idaho, and Pantex?
- How could ORAU's designated "Subject Expert" overlook data in publicly available literature (specifically, the alpha activity ratios used to estimate intakes of transuranics) which indicates that radiation risks were far greater? Why didn't four layers of quality assurance/quality control within ORAU and NIOSH catch Ms. Berger's errors?

NIOSH does not dispute that Carol Berger reviewed and duplicated her own previous work performed for Martin Marietta Energy Systems. She simply cut and pasted alpha activity ratio tables from her 1992 report for Martin Marietta into the NIOSH site profile.

NIOSH acknowledges that the Paducah site profile should be reviewed and revised as necessary to ensure that the best available data is used. Specifically, NIOSH concurs that the transuranic concentrations documented during operations of the ash receiver and pulverizer, and during the converter salvage line incident, should be evaluated to determine their applicability to the dose reconstruction process, because it may not represent expected or bounding.²

One key scientific question rests on whether Ms. Berger properly accounted for air samples at Paducah which had up to 90% alpha activity from neptunium-237 (Np-237) compared with a range of only 6.9%-22.8% in Ms. Berger's tables. Berger's work for NIOSH also underestimated plutonium-239 levels by up to 7-fold. In the face of significant uncertainty, NIOSH procedures require bounding estimates of potential uptakes to avoid underestimating radiation dose to workers.

Carol Berger told NIOSH that "the PACE Report³ was used extensively in the

² NIOSH asserts, without citation, that "converter disassembly work [at Paducah] was infrequent, requiring eight shifts over a two month period" and indicates that only a limited number of workers could have been affected by using the wrong data in the NIOSH site profile. This is inaccurate. Paducah's "CIP-CUP" program required nearly constant converter assembly and disassembly between 1958-1962 and 1974-1982. Worker interviews indicate converter disassembly was also done in the cascade buildings, where exposure to fission products was high. High Np-237 exposures were also found during neptunium refining, cylinder heel cleaning and hydrogenation tower cleaning. Far more than a handful will be impacted by the use of the wrong data, particularly those who have multiple non-SEC primary cancers.

³ NIOSH incorrectly references a "PACE Report" on Paducah as a PACE document. This report was published by
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development of the site profile document at issue," however, she managed to overlook extensive references to monthly health physics reports which, NIOSH now concedes, would have resulted in higher internal doses for certain worker classifications than Berger had used in her previous work for Martin Marietta. She "did not recall a specific assessment of activity fractions or other related reference materials cited in the PACE Report," according to NIOSH, yet the validity her Martin Marietta report was pointedly challenged in a chapter of the PACE report entitled "Prior Radiological and Health Assessments at Gaseous Diffusion Plants⁴." Her use of the PACE report appears to be selective.

In cutting and pasting her 1992 work for Martin Marietta into the NIOSH site profile, Berger underestimated alpha activity fractions for Np-237 by at least 4-fold. If she had not done so, she would have contradicted her previous work for Martin Marietta. This is a case where a scientist is allowed, due to loopholes in the conflict interest protections, to review her previous work, and where, it appears, that bias towards her own work caused her to use faulty science. NIOSH asserts that any bias would have been caught by its multiple tiers of review. But it wasn't, and NIOSH's Oversight Team never asks why.

In 2000, Carol Berger's work for Martin Marietta was critiqued in the PACE report, but these critiques were not addressed in the September 2004 NIOSH Site Profile, nor were they spotted in 3 ORAU reviews by Jay Maisler, the "ORAU Team Lead" (who is employed by Carol Berger), Judson Kenoyer, Dick Toohey, or in NIOSH's review by Jim Neton (Science Director).

The NIOSH's Oversight Report glosses over the troubling conclusion that conflicts of interest have tainted the quality of science developed by the NIOSH Office of Compensation and Analysis Support (OCAS). The NIOSH staff had a chance to root out these conflicts, but chose instead to recommend changes that will institutionalize these conflicts. Regrettably, this will taint

the DOE's Office of Environment, Safety and Health, not by the PACE Union, and is entitled "Exposure Assessment Project at the Paducah Gaseous Diffusion Plant" (December 2000), which was prepared under contract by PACE and University of Utah, Division of Radiobiology. Since this is a DOE document, which was subject to DOE-HQ and DOE-Oak Ridge review, as well as a peer review by John Till and Eula Bingham, prior to DOE-HQ publication in 2000, NIOSH should properly cite it as DOE 2000. It appears that repeated reference to this as a "PACE document" is a not-so-subtle effort to label it as an advocacy document produced by a labor union, instead of a peer-reviewed radiation exposure assessment developed by a university-labor consortium for a government agency whose past performance they were auditing.

⁴ *Exposure Assessment Project at the Paducah Gaseous Diffusion Plant* states with regards to Berger's previous study for Martin Marietta: "Some serious concerns were noted regarding the study methodology including: 1) the use of average values of statistically insignificant numbers (including negative bioassay results) to determine doses, 2) the determination of dose assuming an acute intake 1, 5 and 10 years before the bioassay sample does not address the question of what transuranic intakes might have been 16-39 years earlier, 3) the workers selected for inclusion within the fecal bioassay study were hired in the mid-1970s however, the majority of the reactor return work was conducted from 1953 through 1977, 4) dose estimates based on uranium urinalysis results were based on only two years of uranium urine data, and 5) dose estimates based on air sampling were based on air sampling data collected from 1989-1991. It is unlikely that samples collected during this time period represent air concentrations from 1953 to the late 1970s. The items noted above contributed to the limited value of this report for the current exposure assessment."

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the scientific credibility of site profiles and SEC determinations.

III. THE ORAU CONFLICT OF INTEREST POLICY, AS RECENTLY AMENDED, IS SEVERELY WEAKENED AND THREATENS NIOSH'S SCIENTIFIC CREDIBILITY:

NIOSH amended its Conflict of Interest Policy governing the conduct of ORAU and its subcontractors on October 11, 2005. Several changes are noteworthy:

New Policy: "Site experts may be employed to advise on site specific issues and incidents as necessary. Site or Subject experts may be employed in the preparation of key Project functions documents such as Site Profiles or draft SEC petition Evaluations."

Old Policy: "No individual will perform, review or approve radiation dose reconstructions, site profiles or determination 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."

Analysis: Allowing "subject experts" with conflicts of interest to write site profiles or perform SEC evaluations infects the program with avoidable bias. When individuals are employed by NIOSH and have to review their previous work, or that of their co-workers, they are naturally going to be inclined to stick by what they have said previously—right or wrong. It is a human response, and a point of professional pride, not to want to contradict one's previous work. This potential bias has to be fire-walled out, not built in. These modifications effectively paper over the Berger conflict of interest, and legitimize the plethora of conflicts of interest which have infected OCAS. Instead of gutting its COI Policy, NIOSH should have brightened the lines to preclude those with conflicts from writing key documents used to make compensation decisions. NIOSH set up a system where experts with obvious conflicts are holding the pen, and waiting for others to catch their biases in the review process. This is akin to letting influenza infected nurses to work in hospitals with face masks, and waiting for others to find out and remove them.

New Policy: "TBD (Site Profile) team members may contribute to documents prepared for sites where they or their employer may be conflicted, but cannot serve as document owner."

Old Policy: None

Analysis: This loophole facilitates evasion of the conflict of interest policy. Non-conflicted team leaders can be bystanders while conflicted team members "hold the pen" and

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carry out the bulk of the writing and research.

New Policy: "Routine access to completed forms ORAUT-FORM-0051 (corporate conflict of interest) will be limited to ORAU employees with an established need to know the information and who have agreed not to disclose the contents of the completed forms to other individuals who do not have a need to know. Upon request, access to the completed forms may also be granted to certain NIOSH personnel, but only to individuals who have also agreed not to disclose the information to other parties not having an established need to know. As described above, information concerning specific sites where it has been established that an ORAU Team subcontractor has an active COI will be provided in the Website Disclosure Statements of the individual employees of that subcontractor. No distinction will be made, however, between sites where the employee has a personal conflict and those where the employee's company is conflicted."

Old Policy: "The critical consideration is not whether COI exists, it does.....Therefore, given these inherent potential conflicts, the contractor selected for the dose reconstruction project, along with NIOSH, must do everything possible to prevent of manage actual and perceived conflicts of interest and disclose all potential conflicts of interest."

"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 reconstruction or SEC petitions on behalf of the EEOICPA program, information about their past and present work at DOE sites."

"Printouts about the persons (and their companies) performing dose reconstructions, preparation of site profiles, research supporting determination 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 request, subject to legal requirements concerning the protection of privacy interests."

Analysis: Without full disclosure (subject to Privacy Act restrictions), there is no way for the public to verify whether a corporate conflict exists or not. Transparency used to be a guiding NIOSH principle, but this principle has been downgraded without clear justification. NIOSH and ORAU will police themselves without any mechanism for accountability.

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New Policy: "In addition to specific responsibilities delineated for Team Leaders in ORAUT-PROC-0031, DOE Site Profile Development, Review and Approval Process, also ensure that data and information provided by team members (including persons designated as site or subject experts) is not biased due to previous work at or for the site in question."

Old Policy: None on "bias".

Analysis: To the extent "bias" is identified, it should be rooted out. However, this new policy does nothing to close the loopholes that were opened up in the revised COI policy. The term "bias" is not defined, and it is not clear what type of bias is unacceptable (stated bias vs. unstated bias? Dislikes Special Exposure Cohorts vs favors Special Exposure Cohorts?). There are no metrics prescribed or objective criteria specified to determine bias. NIOSH removed the objective limitations on Subject Experts and Primary Authors which helped control conflicts and replaced it with subjective judgments. Health physics professionals, like most people, resent inferences that because they worked for a DOE contractor, they must have biases towards their previous work at a site or that of their employer. NIOSH provides no practical means for Team Leaders to objectively identify and manage bias. NIOSH has no mechanism to ensure that Team Leaders don't bring a preconceived bias of their own to the task. NIOSH has no mechanism to screen out bias on its own staff of federal employees, nor does it take action when contractor bias is brought to their attention. There are also practical limits: will a team leader (who is a subordinate to the corporate management), preclude their superior from working on a project because the subordinate has deemed him/her as "biased"?

IV. RECOMMENDED ACTIONS FOR THE DIRECTOR OF NIOSH:

1. NIOSH should obtain and release a redlined version of its new COI policy which shows what has been added and removed compared with its previous COI policy. This will more clearly reveal the degree and extent to which NIOSH/ORAU has:
 - a) watered down the protections against conflict of interest,
 - b) increased the degree of secrecy governing disclosures about corporate conflict of interest, and
 - c) expanded the numbers people with of conflicts of interest involved in undertaking radiation dose assessments.
2. NIOSH should prepare an accounting of the number of people by site who are preparing/revising site profiles, or have previously prepared site profiles, and who have COIs but are exempted from COI restrictions under NIOSH's newly articulated policy. NIOSH should identify which individuals on each site profile team who must conform to the COI restrictions.

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3. Provide the Advisory Board on Radiation and Worker Health (ABRWH) with a redlined copy of the COI policy. Ask the ABRWH to convene a working group and provide recommendations to your office within 60 days on the modified Conflict of Interest Policy.
4. Ask the ABRWH to review the technical issues raised in the NIOSH Oversight Team Report, and assess whether TRU exposures should be reassessed across the Paducah plant site.⁵ The assessment should also address whether site profiles at Oak Ridge K-25 and Portsmouth GDP will have to be changed as a result of changes made at Paducah.
5. Suspend the revised COI policy pending a review by the NIOSH Director to determine its potential impact on scientific credibility and bias.
6. Request NIOSH Program staff respond to GAP's February 20, 2005 memo regarding the Paducah site profile and provide the requested information. NIOSH has not responded to this memo for 9 months.

⁵ NIOSH's Oversight Team Report suggests only limited revisions are needed to the Paducah internal dose site profile, and declares that the Berger ratios for most of the Paducah plant are acceptable, based on comparison with the PACE report. This is an incorrect application of the PACE report. The PACE report only looked at TRU exposures for a few areas (presumed to be the highest), and did not perform a plant wide TRU assessment. NIOSH's recommended revisions are too narrow. NIOSH failed to assess the 0.5 micron particle size for Np-237 cited in the 1960 AEC memo by Dunham and Brunner and whether this would lead to greater dose consequences.