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MEMORANDUM FOR DOE PAAA COORDINATORS
CONTRACTOR PAAA COORDINATORS

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SUBJECT: Compilation of Bioassay Issues Reported During the 120-Day Suspension of PAAA Enforcement Actions Related to Internal Dose Evaluation Programs by Contractors in the Department of Energy Complex

BACKGROUND - The DOE Office of Enforcement and Investigation (EH Enforcement) invoked a 120-day suspension of PAAA enforcement actions for issues associated with contractor Internal Dose Evaluation Programs (IDEP). Prior to initiation of the suspension, EH Enforcement had identified deficiencies in DOE-contractor implemented bioassay programs at numerous sites within the DOE complex. The commonality of the IDEP deficiencies at the various sites, as well as the possibility of the existence of similar deficiencies at other DOE sites, led EH Enforcement to the conclusion that a suspension of enforcement actions would be appropriate to provide DOE-contractors an opportunity to review their own IDEPs to determine whether similar or other program deficiencies existed, and, if so, to take appropriate corrective action.

Contractors were alerted to review their IDEP during the 120-day suspension period. If program deficiencies were identified, and if they met the Noncompliance Tracking System (NTS) criteria, these issues were to be reported into the NTS, along with proposed corrective actions and the anticipated target completion dates. EH Enforcement did not plan to take enforcement action against the contractor for identified IDEP problems if bioassay program deficiencies were identified and reported and if corrective actions, as identified by the contractor, were implemented. However, failure of the contractor to implement proposed corrective actions would permit EH Enforcement to re-open PAAA enforcement action for any of these issues in the future.

The suspension period for PAAA enforcement actions related to IDEPs terminated on April 1, 1999. After a review of the bioassay program deficiencies that were reported into the NTS during the suspension period, EH Enforcement determined

that a compilation of the reported deficiencies might be of further use to the DOE-contractor community for purposes of review of respective IDEPs. A total of eleven DOE sites reported deficiencies into the NTS during the suspension period. For ease of summary the reported issues have been broken down into the following three primary categories: (1) inadequate IDEP documentation; (2) inadequate field implementation of formal IDEP programs; and (3) inadequate quality assurance (QA) programs for identification of IDEP deficiencies. A summary of the technical issues reported into the NTS by the DOE-contractors is compiled in the remainder of this memorandum.

IDEP DOCUMENTATION - The most commonly reported issues were related to deficiencies in IDEP documentation. The reported documentation inadequacies included (1) outdated Technical Basis Documents (TBDs); (2) TBDs that inadequately defined the technical bases for the IDEP; (3) TBDs that contained inaccuracies and fundamental methodology errors; (4) formal procedures lacking sufficient detail to ensure bioassay program implementation, and (5) in some cases, failure to develop formal procedures or other program directives to ensure that all aspects of the IDEP, i.e., TBD, were implemented. The effects of the documentation deficiencies resulted in the following program weaknesses:

1. Bioassay program participation not adequately defined.
2. Bioassay scheduling not consistently defined across a contractor site.
3. Bioassay program requirements not consistently identified over all facilities at a single contractor site.
4. Subcontractor participation in bioassay program not assured.
5. Visitor bioassay issues not addressed.
6. Chain-of-Custody program for onsite, as well as offsite, bioassay samples not addressed.
7. Technical guidance at the field level inadequate to ensure dose detection, evaluation and control.
8. Formal documentation inadequate to ensure and define the re-evaluative process to be used when activities and their associated radiological hazards change.

FIELD IMPLEMENTATION - A result of IDEP documentation weaknesses is that bioassay program requirements are not implemented in the field as intended or as necessary to meet regulatory requirements. Evaluation and assignment of worker doses are, consequently, inadequately and/or inaccurately performed such that compliance with annual DOE limits for personnel exposures may not be assured. Examples of deficiencies in field implementation of the IDEPs that were reported into NTS are listed below.

1. Annual reports to workers documenting their exposures to radiation incomplete.
2. Repeated failures to perform *in vivo* bioassays as required.
3. Failure to perform special, follow-up bioassays in a timely manner.
4. Radiological worker restrictions not implemented in a timely manner.
5. Failure to perform termination bioassays and, subsequently, failure to issue reports of terminated worker exposures.
6. Collection of routine bioassay samples incomplete.
7. Analysis of bioassay samples not performed for all radionuclides to which workers were exposed.
8. Workers enrolled in incorrect routine bioassay program.
9. Job-specific Radiation Work Permit (RWP) required bioassay samples not collected and processed.
10. Routine and special bioassay samples not collected and processed as required.
11. Dose assessments and subsequent dose assignment for workers with intakes of radioactive material not completed.
12. Bioassay program not consistently implemented across a contractor site.
13. Decision Levels in use did not appropriately reflect current quantitative capability of the site laboratory.
14. Inconsistent application of bioassay requirements for similar work activities.
15. Untimely performance of worker dose assessments.
16. Untimely radioanalytical processing of bioassay samples.
17. Internal dose assessments not accurate.
18. IDEP procedure reviews and subsequent revisions not performed.
19. Bioassay sample submission not verified as required.

QUALITY ASSURANCE (QA) - Some bioassay program deficiencies exist at DOE-contractor sites because procedures adequate to implement the site QA Plan, as its requirements apply to IDEP, have not been developed and/or adequately implemented. As a result, bioassay program deficiencies that may exist remain unidentified, corrective actions to remedy these deficiencies are not developed and implemented, and, field verification of the adequacy of proposed corrective actions is not performed. Examples of QA issues reported into the NTS are listed below.

1. Self-assessments for appraisal of the IDEP not performed.
2. Assessments of IDEP compliance not comprehensive.
3. IDEP assessment frequency not established.
4. Procedures needed to administer the IDEP in accordance with the QA Plan not available.

SUMMARY- It is recommended the contractors review their IDEP programs to ensure that bioassay program deficiencies as identified above are not existent within their site's IDEP.