

SAFETY & HEALTH HAZARDS ALERT

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Bioassay Programs

Background

In December 1994, the Department of Energy (DOE) issued an Environment, Safety and Health (ES&H) Safety and Health Hazards Alert (Issue No. 94-3). The Alert described a situation at a DOE site where bioassay samples for approximately 30 workers involved in a 1989-1991 job, were never properly analyzed until approximately 3 years later.

In March 1996, DOE issued an ES&H Safety and Health Hazards Alert (Issue No. 96-1) describing the need for a quality bioassay program. The Alert described a situation at the same DOE site, which had difficulties obtaining credible bioassay results and timely resolution of positive bioassay samples.

Recent Events

In May 1997, DOE had the opportunity to conduct a limited scope review of the site's bioassay program. During this review, the team documented two concerns that again jeopardize worker's confidence in the site bioassay program. These concerns are that (1) workers are not receiving required bioassays and (2) calculational methods used are inappropriate to identify all positive bioassay samples.

Workers Not Receiving Bioassays

In an effort to reduce unnecessary sample analyses, the site implemented a program where bioassay requirements were specified on the Radiation Work Permit (RWP). Completed RWPs were sent to the initiating work supervisor along with a form on which the supervisor would specify those individuals who would potentially work on the RWP and return the form to the radiation protection organization. This form was not routinely being completed and returned, which resulted in individuals not participating in a bioassay program for radionuclides to which they were potentially exposed.

Inappropriate Calculational Methods

When bioassay sample results are obtained, they must be evaluated against the appropriate criteria to determine whether the sample is positive or negative (i.e., positive meaning an indication that a worker may have had an intake of radioactive material and confirmatory bioassay may be necessary; negative meaning no indication the worker received an

intake). DOE has published guidance in DOE Implementation Guide, *G-10 CFR 835/C1 - Rev 1, Internal Dosimetry Program*, and more recent information is available in Health Physics Society's American National Standard, ANSI/HPS N13.30-1996, *Performance Criteria for Radiobioassay*.

The results of bioassay samples are compared with calculated values to determine whether the sample is a positive or negative indication of an intake. There are two concepts (values) that are critical to the accurate disposition of bioassay results; these are the Minimum Detectable Activity (MDA) and the Decision Level (DL). The DL is typically a lower quantity than the MDA. The specific methods for calculating these quantities are described in ANSI/HPS N13.30 for various laboratory evaluation techniques. Individual bioassay sample results are to be compared against the DL, not the MDA.

The site was routinely using the MDA rather than the DL to evaluate individual bioassay samples. In addition, the MDA value used for ^{238}Pu was last updated in 1992. Since 1992, the site greatly improved the laboratory's ability to detect ^{238}Pu , which resulted in an MDA significantly lower than previously specified. While the technicians in the radiochemistry laboratory were cognizant of the improved MDA, adequate procedures did not exist that would have allowed these changes to be identified and the appropriate changes in evaluation criteria made. The combination of these two errors has resulted in a large number of bioassay samples being reported as negative when in fact they should have been reported as positive.

Inappropriate Response to Workplace Indicators

During a Type B Investigation of a plutonium exposure at another DOE site, weaknesses were identified in their "for cause" or "special" bioassay program. During a work evolution involving four individuals, a Continuous Air Monitor (CAM) monitoring a hallway leading to the work area alarmed with an indication of approximately 3900 times the Derived Air Concentration (DAC). Three individuals were working in respiratory protection and one individual had previously left the work location, exiting through the affected hallway without

respiratory protection. Subsequent to the alarm, the four individuals reentered the work area in respiratory protection. The CAM again alarmed indicating approximately 1800 DAC. Although the individuals were on a semi-annual routine bioassay program, the series of CAM alarms and knowledge that at least one individual had earlier been present without respiratory protection, no "for cause" or "special bioassay samples" were initiated to determine if an intake had occurred.

Guidance on the participation in a Special Bioassay Program is published in DOE Implementation Guide, G-10 CFR 835/C1 - Rev 1, Internal Dosimetry Program.

Implications

The inability to ensure that workers participate in the necessary bioassay programs could result in a worker who actually receives an intake of radioactive material not being identified. Not evaluating individual bioassay samples against the appropriate criteria could result in undetected low-level intakes. For many of the transuranic radionuclides, the doses associated with these low-level exposures are not insignificant. These recent events could hinder the site's ability to resolve ongoing worker health and safety concerns associated with the bioassay program.

The lack of participation in a special bioassay program could complicate the determination of when an intake occurs, potentially prevent the identification of low-level intakes near the detection limit and delay the prompt application of medical intervention rendering it essentially ineffective for transuranics.

Actions Recommended

All sites are required to be in full compliance with the provisions of Title 10 Code of Federal Regulations, Part 835, *Occupational Radiation Protection*. Failure to comply with these provisions could result in a contractor being assessed a civil penalty or could result in criminal penalties being taken against the contractor.

It is imperative that sites ensure that an effective program exists for identification of individuals who need to be on a bioassay program and that the individuals identified actually participate in the program (provide bioassay samples).

Each site should evaluate the adequacy of their bioassay programs with an additional focus on the technical basis for the participation in the special bioassay program and the evaluation of bioassay results. In making this evaluation, it will be beneficial to refer to guidance that DOE issued for implementing an acceptable bioassay program. This guidance is contained in DOE Implementation Guide, G-10 CFR 835/C1 - Rev 1, Internal Dosimetry Program. The implementation guide is available at <http://tis.eh.doe.gov/docs/ig/int/>.

Radiobioassay Accreditation Program

The Department is concluding development of a Radiobioassay Accreditation Program, which is based upon the Health Physics Society's American National Standard, ANSI/HPS N13.30-1996, *Performance Criteria for Radiobioassay*. Comments on the proposed amendment to Title 10, Code of Federal Regulations, Part 835, *Occupational Radiation Protection*, are being resolved along with comments on the draft DOE Technical Standard, *The Department of Energy Laboratory Accreditation Program for Radiobioassay*. It is anticipated that the documents will be published in final form by the end of 1997. The proposed amendment would require all site bioassay programs to be accredited within 3 years of the effective date of the revised Part 835. To assist sites in being proactive, the Department is currently accrediting sites on a voluntary basis.

For more information, contact Robert Loesch, Office of Worker Protection Programs and Hazards Management, EH-52, on 301-903-4443.



This Safety & Health Hazards Alert is one in a series of publications issued by EH to share occupational safety and health information throughout the DOE complex. To be added to the Distribution List or to obtain copies of the publication, call 1-800-473-4375 or (301) 903-0449. For additional information regarding the publications, call Mary Cunningham at (301) 903-2072.