USACHPPM
Readiness thru Health

79-002-0406

Just the Facts...

Depleted Uranium (DU) Urine Bioassay and Fragment Analysis Programs and the USACHPPM Laboratory Quality System

1. **Purpose**. To provide information about the United States Army Center for Health Promotion and Preventive Medicine (USACHPPM) Directorate of Laboratory Sciences (DLS) Quality Assurance and Quality Control Programs for the analysis of DU in urine specimens and in metal fragments removed from patients.

2. **Key Points**.

a. *Laboratory Quality System*. All analyses performed by DLS are performed under a Quality System that is certified as compliant to ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration." Elements of the DLS Quality System include documented processes for analyst training and competency, method validation, document control, control of records and data, purchasing and ensuring the quality of supplies, measurement traceability and report requirements. Conformance to established internal processes and the ISO Standard is ensured by internal audits performed through out the year, periodic audits by external certification bodies and an annual review of the Quality System by management. All elements of the DLS Quality System are documented in our Quality Assurance Manual (QAM) and Standing Operating Procedures (SOP).

b. *Technical Requirements and Certifications*. The DLS meets all of the requirements for and maintains the following technical certifications: Commission on Laboratory Accreditation (COLA) and Clinical Laboratory Improvement Program (CLIP) for all radiobioassay measurements for uranium. These certifications provide validation of the DLS quality processes through external third party review by trained expert auditors.

c. *Proficiency Testing*. All analytical certifications require laboratory participation in a proficiency evaluation (PE) study, if available. To meet this requirement for the bioassay work, DLS participates in the Oak Ridge PE program for uranium concentration in natural urine matrix. Oak Ridge submits blind samples for analysis and for the last nine sets of audit samples, DLS has achieved successful results. DLS also participated in an Intercomparison of Isotopic Uranium at ultra-low concentrations in synthetic urine study. Isotopic ratios were slightly enriched, natural and depleted. Results of this study are still preliminary and have only been released to the participating laboratories.

d. *Continual Improvement*. Continual improvement is an integral part of the DLS Quality System. As part of the process, monitoring of control results, corrective and preventive actions, and internal and external audits are performed to identify trends and areas requiring improvement.

e. *Quality Control Procedures for the Analytical Techniques.*

(1) Quality control for the current uranium in urine method includes laboratory control samples at two concentration levels, reagent prep blanks, matrix spikes, matrix spike duplicates, sample prep duplicates, and instrument duplicates. The standards used for the laboratory control samples are custom-made, synthetic urine matrix certified for both uranium concentrations and uranium-235/uranium-238 isotopic ratios ranging from natural to depleted uranium. These standards are NIST traceable through DOE.

(2) Quality assurance and control procedures are also in place for the current USACHPPM [and Aberdeen Test Center (ATC)] methods for fragment analysis. This includes procedures for both the radioactivity measurements and the fragment identification (done jointly with the Aberdeen Test Center). All detected chemical elements are reported, but the focus of the analysis is on uranium and tungsten.

Directorate of Laboratory Sciences
U.S. Army Center for Health Promotion and Preventive Medicine
5158 Blackhawk Road
Aberdeen Proving Ground, MD 21010-5403
410-436-3639 or DSN 584-3639