DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/ Quality, Safety & Oversight Group

October 09, 2018

David J. Allard, CHP
CRCPD Chairperson

David Tuberville
OAS Chair
Conference of Radiation Control Program Directors, Inc.
Office of Executive Director
1030 Burlington Lane, Suite 4B
Frankfort, KY 40601

Dear Mr. Allard and Tuberville:

I am writing on behalf of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), Division of Clinical Laboratory Improvement & Quality. CMS is a federal agency which has, as one of its responsibilities, the administration of the Clinical Laboratory Improvement Amendment program (CLIA).

Based on the information you provided in your previous email and on our conference call on April 17, 2018, we understand that the type of bioassay testing for radioactivity on urine or other human specimens conducted by your program is for the sole purpose of monitoring radioactive exposure limits to determine whether a bioassay licensee is in compliance with 10 CFR20.1204 determination of internal exposure, i.e. has not exceeded allowable exposure limits. The only test result reported and shared with the licensee is the individual's radioactive exposure measurements to meet the regulatory compliance. Therefore, a facility that performs such a test is not required to obtain a CLIA certificate.

However, if a patient specific test result, which can be used for the assessment of an individual's health or to refer the individual for treatment, is reported back to the patient or reported to a provider/physician, a CLIA certificate would be required for that testing facility. CMS defines a CLIA laboratory at 42 CFR §493.2, as a facility that examines specimens derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

This determination is applicable to the specific scenario that you and your colleagues presented to us. CMS would like to continue to review these types of inquiries on a case-by-case basis to determine if CLIA certification is applicable.

If you have any questions, please contact us at the following email address: LabExcellence@cms.hhs.gov.

Sincerely,

Karen W. Dyer

Karen Dyer, MT (ASCP), DLM
Director, Division of Clinical Laboratory Improvement and Quality,
Centers for Medicare & Medicaid Services