



Technical Safety



RADIATION PROCEDURES MANUAL

Procedure Cover Sheet

Procedure Title: Bioassays

Procedure Number: TSO-08-11-REV 1

Effective Date: September 1, 2008

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Technical Safety Office Director



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A. INTRODUCTION

Although the emphasis of radiation protection is primarily on prevention of exposures, measurement and evaluation of exposures is also necessary. Bioassay is the determination of the kind and amount (and possibly the location) of radioactive material in the human body by direct (*in vivo*) measurement or by analysis (*in vitro*) of materials excreted or removed from the body. Bioassay is an important tool for evaluating actual or suspected internal contamination with radioactive materials.

Monitoring and dose assessment must be performed for any individual with an annual intake of all nuclides combined of 0.1 ALI or more. To assure that this requirement is met in all cases, individual intakes of smaller quantities must be detected and evaluated at lower levels. The conditions requiring bioassays, as well as the methods and maximum intervals specified in this procedure are designed to assure that an annual intake exceeding 0.05 ALI, whether as a single intake or as chronic or multiple intakes, is not only detected, but determined quantitatively.

Individuals who handle dispersible radioiodine compounds may be required to obtain *in vivo* measurements of radioiodine in the thyroid, performed by the Radiation Safety Officer (RSO), at specified intervals. Individuals who handle other radionuclides in dispersible forms may be required to perform assays of radioactivity in urine on a routine basis to document the absence of radioactivity in the body or to determine the magnitude of an exposure. Other types of assays may be utilized if, in the judgment of the RSO, such assays will meet the intent of this policy more effectively.

A bioassay is required whenever personal contamination or injury caused by a contaminated object occurs, or if airborne radioactivity may have been inhaled. Routine bioassays, at intervals determined by the nuclides used, are required from each user who handles more than minimal quantities of soluble radionuclides. A routine bioassay may be waived when appropriate surveys for contamination, conducted during and after each use of radioactive material according to recommended procedures,

demonstrate that there was essentially no exposure to unconfined, dispersible radioactive material.

B. PURPOSE

This procedure specifies the requirements, responsibilities and methods for performing and reporting measurements for detecting and verifying the presence of radioactivity in the body.

C. REQUIRED MATERIAL(S)

Minimum counting time calculation sheet
Bioassay guidelines sheet
RPR 10B form
RPR 12A form
RPR 12B form
RPR 12C form

D. PROCEDURE

Conditions Requiring Bioassays

The optimum time for performing a bioassay is within a few days after a potential exposure. Each user should perform a screening assay within a few days after handling any unusually large quantities, or after performing any procedure involving a greater than usual opportunity for exposure. Subsequent routine bioassays would not be required again until the end of another full bioassay interval unless another unusual exposure situation occurred. The RSO will notify users when a bioassay is due, i.e. the expiration of the bioassay interval, but it is the responsibility of the user to complete the bioassay promptly. Since the last bioassay, if no work with radioactive materials was performed, or if survey records verify that there was no exposure to contamination exceeding the levels indicated below, this may be reported by checking the appropriate statement on the "URINALYSIS SCREENING ASSAY" report form (RPR 12A).

1. A bioassay is required within 5 days for each individual having contamination of the skin or hair exceeding 10 Removable Contamination Limit (RCLs). A basic limit for RCLs is specified in "CONTAMINATION LIMITS AND ACTION LEVELS" (RPR 10B).
2. A bioassay is required within the normal bioassay interval for any individual having skin or hair contamination exceeding 1 RCL.
3. A bioassay is required within 5 days for each individual involved in a spill, or other uncontrolled release, of >0.5 ALI of radioactive material outside of a properly functioning fume hood or >5 ALI inside a hood.

4. A bioassay is required within 5 days for each individual who is present in an area during a time when removable contamination exceeding 100 RCL was present on any readily accessible surface.
5. A bioassay is required within the normal bioassay interval for each individual who was present in an area during a time when removable contamination exceeding 10 RCL was present on any readily accessible surface.
6. A bioassay is required within the normal bioassay interval for each “potentially exposed” radiation user. The determination of the cumulative quantity handled will be based primarily on records of receipts and disposals of radioactive materials, with adjustments for individual work assignments as defined by the responsible user. Routine bioassays may be waived at the discretion of the RSO if the records of contamination surveys of both the user and the RSO verify that there was no exposure to unconfined radioactive materials exceeding the levels specified above and no incidents of personal contamination since the last bioassay.

Radioiodine Assays

The preferred bioassay method for gamma-emitting radioiodines is by in vivo measurements of the thyroid gland. These assays are performed by the RSO at preannounced locations on a regular schedule. It is the responsibility of the user to obtain the thyroid assay whenever appropriate. Records of the results of these assays are maintained by the RSO, but are available to the monitored individuals upon request.

Screening Urinalysis

A screening assay is one performed simply to determine whether radioactivity is present in the body, but without precise quantification of activity or dose. For radionuclides other than iodines, routine bioassays are most easily performed by in vivo analyses of urine. The same instruments that are used to measure radioactivity in research samples may be used to detect the same radioisotopes in urine sample. Routine screening assays are to be performed by or for each potentially exposed individual and reported to the RSO on the “URINALYSIS SCREENING ASSAY” form (RPR 12A).

For the nuclides used recently, determine the verification level (dpm/ml of urine) for the elapsed interval. For several commonly-used nuclides, the “BIOASSAY GUIDELINES” that follow list the action levels for various elapsed times up to the maximum elapsed interval. For other nuclides, or for elapsed times not listed, the action levels must be obtained from the RSO.

The sample volume and minimum counting time must be selected so as to achieve a lower limit of detection (LLD) at least equal to the required verification level. The "BIOASSAY GUIDELINES" provide examples for several common nuclides and liquid scintillation counting conditions, and may be used if appropriate. The minimum counting time may be calculated as illustrated later in this procedure or it may also be requested from the RSO.

For urinalysis by liquid scintillation counting, select a fluor that is suitable for large aqueous samples.

For urinalysis by gamma counting, as well as by liquid scintillation counting, proceed as follows:

1. Use the largest vial and sample volume that the system can accommodate to assure adequate sensitivity of the measurement.
2. Prepare urine and distilled water samples of equal volumes. Count both the urine and the distilled water samples for the same times.
3. Record the sample data and results on the "URINALYSIS SCREENING ASSAY" form (RPR 12A). Calculate the activity concentration (dpm/ml) in the urine sample, using a nominal counting efficiency (as provided by the vendor) for the nuclide of greatest concern.
4. Compare the assay result with the verification level for the nuclide(s) of interest, based on the elapsed interval since last use (or last negative bioassay). If the assay result is less than the verification level, send the signed form to the RSO. If the assay result exceeds the verification level, perform a "Verification Assay."

Verification Assay

If the result of a screening assay indicates the possible presence of radioactive material in the body, at least one additional assay must be performed to verify the result. A verification assay for a urine sample involves spiking the urine and distilled water samples with a known amount of activity to obtain the true efficiency of the counting system for the samples. Follow the steps on the "URINALYSIS VERIFICATION ASSAY" form (RPR 12B). If the bioassay result exceeds the investigation level or indicates a potential annual intake exceeding 0.1 ALI, the RSO will determine appropriate corrective measures.

REFERENCES

Radiation Safety Surveys at Medical Institutions, NRC Regulatory Guide 8.23, Rev. 1, Jan. 1981.

General Principles of Monitoring for Radiation Protection of Workers, ICRP Publ. 35, 1982.

Limits for Intakes of Radionuclides by Workers, ICRP Publ. 30, Parts 1, 2 and 3 with Supplements, 1979-82.

Evaluation of Radiation Doses to Body Tissues from Internal Contamination Due to Occupational Exposure, ICRP Publ. 10, 1968.

An Assessment of Internal Contamination Resulting from Recurrent or Prolonged Uptakes, ICRP Publ. 10A, 1971.

General Concepts for the Dosimetry of Internally Deposited Radionuclides, Report No. 84, 1984.

Use of Bioassay Procedures for Assessment of Internal Radionuclide Deposition, NCRP Report No. 87, 1987.

Acceptable Concepts, Models, Equations and Assumptions for a Bioassay Program, Reg. Guide 8.9, 1973.

Applications of Bioassay for I-125 and I-131, Reg. Guide 8.20, Rev. 1, 1979.

Information for Establishing Bioassay Measurements and Evaluations of Tritium Exposure, NUREG-0938, 1983.

ATTACHMENTS

MINIMUM COUNTING TIME CALCULATION

BIOASSAY GUIDELINES

RPR 10B CONTAMINATION LIMITS AND ACTION LEVELS¹

RPR 12A URINALYSIS SCREENING ASSAY

RPR 12B URINALYSIS VERIFICATION ASSAY

RPR 12C THYROID MONITORING REPORT



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REVISION TRACKER

Revision 1	September 1, 2008	Original Procedure
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