

8.0 Quality Assurance

The quality assurance (QA) and quality control (QC) features of the IDP are summarized in this chapter. Details are contained in the program QA plan, *Quality Assurance Plan for the Operation of the Hanford Internal Dosimetry Program* (QA Plan No. LSC-026).

8.1 Quality Assurance and Quality Control for Bioassay Analyses

The quality of analytical results is monitored by the QA and QC programs of the Analytical Services Laboratory (Lab) and the laboratory oversight program of Internal Dosimetry, and the [In Vivo Monitoring Program \(IVMP\)](#).

8.1.1 Analytical Services Laboratory

The Lab measures essentially all indirect bioassay samples and is required by contract to maintain rigorous, extensive, well-documented QA and QC programs.

The Lab is required to maintain a QA manual that outlines responsibilities and provides requirements for data control, document control, calibration and checks of maintenance and test equipment, procedures, training, corrective action in the event of noncompliance, and traceability to standardizing bodies such as the National Institute of Standards and Technology (NIST).

The QC program involves analyzing blanks and spiked samples with each batch of real samples, constantly reviewing data, and publishing quarterly and annual QC reports. No less than 15% of all samples processed are blanks and spikes.

The QC samples are used to demonstrate compliance with requirements specified in the contract between the Lab and PNNL. The requirements in the contract are at least as restrictive as, and in some areas more restrictive than, the recommendations in American National Standard HPS N13.30-1996 ([HPS 1996](#)) and [DOE Standard DOE-STD-1112-98 \(DOE 1998\)](#) on performance criteria for radiobioassay testing. These requirements determine detection levels (MDAs) for each radionuclide and matrix, as well as the allowable bias and required precision of the results. The Lab must demonstrate that actual MDAs are no greater than the levels specified in the contract and that bias and precision are within specified limits.

All routine analyses (i.e., not research and procedure development work) must be done according to written and approved procedures. In addition, all analysts must be trained and certified in each procedure before they can routinely perform the applicable analysis.

8.1.2 Internal Dosimetry Oversight of the Lab's Quality Control Program

Internal Dosimetry conducts an independent oversight program as a check on the validity of the Lab's QC results. The program consists of a combination of blank and spiked samples, which may be submitted for analysis as known audit samples (single blind audits), masked for analysis as authentic worker

samples (double blind audits), or split with another laboratory for simultaneous analytical intercomparison (split samples). The results of the audit samples are used to track Lab performance relative to the contractual detection levels in essentially the same manner as the Lab's own QC program. This procedure serves as an additional check on the Lab's ability to meet HPS N13.30-(HPS 1996) recommendations and contract requirements.

The results of Internal Dosimetry's oversight program are documented annually by means of a letter report that is sent to Field Dosimetry and the Hanford Radiation Protection Historical Files. Any discrepancies between the results of the Lab's and Internal Dosimetry's QC data are investigated, and corrective actions are taken as necessary.

8.1.3 Quality Assurance of In Vivo Measurements

The QA of in vivo measurements is detailed in the *In-Vivo Monitoring Program Manual* (PNL-MA-574), and in the *QA Plan for Operation of the In Vivo Radioassay and Research Facility* (QA Plan LSC-021). In brief, the program consists of daily equipment calibration and background checks using secondary reference sources and periodic calibrations using primary sources (i.e., NIST-traceable sources) in phantoms. In addition, the IVMP participates in laboratory intercomparison studies, in which spiked phantoms are sent to national and international facilities and the results are compared.

The results of workers' counts are tracked on computer by payroll number and name and are transmitted to the REX database weekly. The QA data are temporarily stored in hard-copy form at the IVRRF library and ultimately transferred to the HRRP. Computer codes are validated and verified according to software test plans.

8.2 Quality Assurance and Quality Control for Dose Assessments

The intention of the IDP is for internal dose assessments to meet the DOE requirements as stipulated in 10 CFR 835, and the *Internal Dosimetry Program Guide* (DOE 1999). The methods used to assess internal dose are described briefly in Chapter 3.0 of this manual and are addressed more completely in the Methods & Models of the Hanford Internal Dosimetry Program (PNL-MA-860). Generally, the methods are consistent with those recommended by national and international authorities, such as the ICRP and the NCRP.

All internal dose assessments are performed by the IDP technical-professional staff and include or reference all methods and data used in the evaluation. Documentation of the assessment should be sufficient to enable a technically qualified health physicist to reconstruct the assumptions, methods, and conclusions of the assessment. Computer codes used for dose assessment are verified and validated according to code-specific software test plans.

Before an internal dose evaluation is issued, it undergoes peer review by a second IDP technical professional staff member to verify the technical accuracy and completeness. In addition, the evaluation and summary letter must be approved by the Internal Dosimetry Program Manager before they are issued.

IDP staff responsible for dose assessments have basic knowledge of ionizing radiation and ICRP and NCRP guidance on internal dosimetry through either education or training. In addition, they have been trained in methods described in this manual and on the specific computer codes germane to each dose assessment that they perform. Before new dosimetrists are determined ready to perform dose assessments by the IDP Manager, they undergo a period of apprenticeship commensurate with their experience and education.

8.3 Internal Dosimetry Program Records

The records generated by the IDP are maintained in files within the Radiation Protection Services organization. The IDP manager is responsible for the designation and maintenance of these records. Additional information is provided in Chapter 9.0.

8.4 Audits of the Internal Dosimetry Program

Quality assurance audits and internal audits are part of the IDP and are planned and performed as required by the Program Quality Assurance Plan. These audits are intended to fulfill the requirements of 10 CFR.830.120, but are not intended to fulfill the requirements of 10 CFR 835.102.

The IDP is also subject to quality verification audits by outside organizations in support of their own quality assurance programs and regulatory compliance efforts, such as the 10 CFR 835.102 requirement for contractor radiation program audits. The responsibility for planning and conducting such audits is beyond the scope of the IDP, lying with contractor organization governed by the radiation protection program. The IDP will be responsive to contractor auditing requirements.

8.5 Reference

10 CFR 835. 1999. Department of Energy, *Occupational Radiation Protection*. U.S. Code of Federal Regulations.

Health Physics Society (HPS). 1996. *Performance Criteria for Radiobioassay*. HPS N13.30-1996, McLean, Virginia.

Pacific Northwest National Laboratory (PNNL). *In Vivo Monitoring Program Manual*, PNL-MA-574. Richland, Washington. (Internal manual.)

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U.S. Department of Energy (DOE). 1999. *Internal Dosimetry Program Guide*. DOE G441.1-3, Washington, D.C.