Appendix 6

QUALITY CONTROL AND VALIDATION DONE IN THE AEC LABORATORY

The AEC's Radioanalytical Laboratories has fully documented validated procedures compiled in a Quality Management System (QMS). The Quality System designed and implemented by Radioanalysis complies with all the requirements of ISO Guide 25 (SABS 0259). This means, inter alia, that only properly documented and validated analytical methods are used, that these methods are applied by technically trained and competent personnel, that systems are available and used to maintain the performance of facilities and methods, and that a programme of continuous quality improvement is actively pursued. Audits and surveillance programmes by clients are encouraged within the constraints of security, safety and proprietary rights of the other clients. The QMS is regularly updated with new and revised analytical procedures. Of the analytical procedures have been approved upon by the Council for Nuclear Safety (CNS). The Quality System is audited annually by Corporate Quality Services of the AEC for compliance with ISO Guide 25. Some of the larger clients also prefer to perform their own independent audits. Application for accreditation by the National Laboratory Accreditation Service (NLA) is pending and expected during 1998.

The following independent audits have been carried out on the quality systems. Uncontrolled copies of these audit reports are available on request.

- RA-AUD-002 (02): Audit by the Council for Nuclear Safety on methods for analysis of U and Ra in water (November 1996) (1997-01-13).
- RA-AUD-005 (02): Audit of Radioanalysis Quality System by AEC Corporate Quality Services on 1997-08-19 (1997-10-27)
- RA-AUD-006 (02):Audit (1997) by the USA Food and Drug Administration on the purity certification of fission molybdenum by Radioanalysis (1997-11-10).
- RA-AUD-007 (02): Inspection by the Council for Nuclear Safety on the implementation of gamma spectrometry procedures (97-10-29) (1997-11-14).
- RA-AUD-008 (02): Inspection by the Council for Nuclear Safety on the implementation of procedures for gross α/β -counting for EET (98-12-12) (1998-03-02).

The RA laboratories participate in national and international inter laboratory performance studies. The results are fully documented in the QMS. The RA laboratories are part of the IAEA's world wide network of recognised radioanalytical laboratories (ALMERA) and of the International Comprehensive Nuclear-Test Ban Treaty Organisation (CTBTO). Information on the most recent interlaboratory performance studies that demonstrate the ability of the laboratory to provide an acceptable analytical service, are contained in the following documents. Uncontrolled copies of these are available on request:

- RA-PFT-001 (01): Council for Nuclear Safety intercomparison study on the determination of uranium and radium in aqueous samples (1996-08-01).
- RA-PFT-002 (01): PROCORAD intercomparison study on the determination of radionuclides in urine samples (1997-01-13).
- RA-PFT-005 (01): IAEA: ALMERA intercomparison study on the determination of radionuclides in environmental samples SOIL-1 (soil) and SED-1 (sediment) (1998-05-11).
- RA-PFT-007 (01): International study of essential and toxic elements in bread flours: P-RBF and P-WBF (1997-04-07).
- RA-PFT-008 (01): International study on major and trace elements in IAEA-331 (spinach) and -336 (lichen) (1997-04-21).
- RA-PFT-010 (01): Council for Nuclear Safety intercomparison exercise on the determination of radium and uranium in environmental water (1998-05-11).
- RA-PFT-012 (01): Intercomparison by the Department of Water Affairs and Forestry on the measurement of naturally occurring radionuclides (1998-02-23).

To supply full documentation of the QMS and the analytical procedures is not practical due to the vast amount of paper involved. However, the QMS can be reviewed and/or audited by the Department of Water Affairs and Forestry (DWAF) whenever required. The main topics dealt with are:
The quality policy statement inferring the mission and commitment of all personnel to comply with the policies and procedures laid down.

The normative references based on SABS 0259 (ISO/IEC 25 equivalent), and internal documents describing:

- the management system to generate, implement and control documents,
- the management system for the validation of the analytical methods used by the laboratories,
- the management system for training and qualification of analytical personnel,
- the management system for registration, handling and closing of non-conformance affecting quality,
- the management system to regulate the production of quality products and services by the laboratories,
- the list of controlled documents and forms issued by the laboratories,
- the definition of terms and abbreviations used by the laboratories, and
- the list of designated personnel with particular responsibility and authority.

The quality system describing:

- the strategy for achieving quality at the laboratories, and the objective of the system,
- the organisation, responsibilities and authority to manage the system,
- the controlled quality assurance documents and records of technical information,
- the quality audit, review and surveillance of the system,
- the secure storage of operational records, the confidentiality of proprietary information of the client and the access regulations to the laboratories,
- the selection, appointment, training and qualification of personnel.

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The operational system describing:

- the client's liaison, promotion, advertising, and marketing administration,
- the client interface to manage, set services, non-routine services, ad hoc services and projects,
- facilities used in the laboratories, the monitoring of their performance, their calibration and the control and use of standards and certified reference materials,
- the execution of analysis like sampling, sample receipt, processing using validated and non-established methods,
- the reporting of results and record keeping,
- the capabilities of the analytical methods through validation and inter-laboratory comparisons,
- the type of nonconformance like incidents, deviations and complaints, and the handling of this nonconformance, and
- other aspects affecting quality like the resources of materials used in the laboratories, and the use of subcontractors.

Instruments are calibrated regularly with internationally traceable reference standards according to the procedures laid down in the QMS. In-house reference samples are analysed at regular intervals to evaluate the performance of the analytical procedures. Storage of data and samples is prescribed by the QMS. All raw data are stored for 3 years or more. The work is performed by and under supervision of competent staff registered as professional natural scientists with the SA Council for Natural Scientific Professions. The radioanalytical laboratory currently employs 31 staff members. The qualifications of the key personnel are available on request.