REQUIREMENTS DOCUMENT

No	TITLE	Rev
RD-005	QUALITY MANAGEMENT REQUIREMENT FOR ACTIVITIES INVOLVING RADIOACTIVE MATERIAL: MINING AND MINERALS PROCESSING	0

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1. PURPOSE

1.1 This document details the National Nuclear Regulator (NNR) requirements for quality management that are of direct significance in assuring the radiation protection of holders personnel and the public.

2.1 This document applies to all organisational functions which could, radiologically, influence or affect the quality of the environment or of items, equipment, activities and services related to radiation protection. The requirements of this document support the principles related to radiation protection already detailed in the appropriate Nuclear Authorisation.

3. RESPONSIBILITY

3.1 The Holder has overall responsibility for the establishment and implementation of an appropriate quality management programme consistent with the requirements of this document.

4. MANAGEMENT

4.1 A written policy shall be prepared and issued by the Holder stating the quality objectives to be met during all phases of operation, shutdown and decommissioning. The policy shall be supported by a quality management programme which shall be implemented to enable these objectives to be achieved and verified. It shall be binding on all levels of management and shall establish and provide authority for the quality management programme and the discharge of the programme responsibilities.

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5. MANAGEMENT REVIEW

5.1 The Quality Management Programme shall be reviewed at defined intervals by Executive Management to assess the status and adequacy of the programme. During this review, audit and surveillance findings, system deficiencies, document discrepancies, non-conformance reports, corrective action requests and any other performance related reporting mechanism shall be evaluated to determine the extent and consequences of the deviations and their effect on the programme.

5.2 The review process shall assess the effectiveness of the inspection, verification and audit functions in monitoring the achievement of the programme objectives.

6. ORGANIZATION

6.1 The organizational structure, functional responsibilities, levels of authority, lines of internal and external communication for management and the execution of activities related to radiation protection shall be clearly documented by the Holder.

6.2 The Executive Management shall identify, in the organizational structure, the persons responsible for the performance of inspections, verifications, auditing and reviewing the quality management programme.

7. QUALITY MANAGEMENT DOCUMENT

7.1 The quality management programme shall be detailed in a written, authorised document approved by the NNR.

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8. DOCUMENT CONTROL

8.1 The quality management programme shall include administrative and functional controls which shall be carried out in accordance with written, authorised procedures. Activities related to radiation protection shall be accomplished by written, authorised procedures, instructions, specifications or drawings, as appropriate.

8.2 Documents related to radiation protection shall be prepared, reviewed and verified for feasibility by technically competent personnel. Preparation shall be performed by designated personnel, and reviews and verifications shall be carried out by personnel independent of any direct responsibility for the original document preparation. Documents related to radiation protection shall be authorised for implementation by designated individuals.

8.3 Where procedures and instructions relating to radiation protection are not pertinent or available, temporary procedures and instructions may be utilised. The compilation and authorisation of these temporary documents shall be in accordance with written, authorised procedures.

8.4 All procedures and instructions relating to radiation protection shall be periodically reviewed. Revisions and changes to procedures, instructions and drawings shall be processed in the same manner as the original.

8.5 An approved document control system, for ensuring the correct utilisation of document revision, shall be established, documented, authorised, and implemented.

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8.6 Procedures, where relevant, shall include appropriate quantitative or qualitative acceptance criteria for determining that important radiation protection activities have been satisfactorily accomplished.

9. DESIGN

9.1 Design and design changes for all equipment, items and activities impacting on radiation protection shall be controlled by written, authorised procedures. Designs and design changes related to radiation protection shall be executed by adequately trained, competent, authorised personnel.

9.2 Adequacy of designs impacting on radiation protection shall be verified by design review, alternative calculations or by testing of the designated item. Verification of designs related to radiation protection shall be undertaken by personnel who are independent of any direct responsibility for the original design process and who are at least as competent as the designer.

9.3 The impact on radiation protection due to changes in equipment configuration, modifications and operational procedures, including their schedules, shall be assessed in terms of acceptable risk to a degree and in a manner commensurate with the requirements of the NNR.

10. PROCESS CONTROL

10.1 The provisions set out in 10.2 below apply, inter alia, to the following functions and areas of activity:

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Operational Radiation Protection, Effluent Control, Environmental Surveillance, Radioactive Waste Management, Training and Qualification of Staff, Normal and Abnormal Operation, Routine and Special Maintenance, Fire Protection, Housekeeping, Physical Security, Emergency Planning.

In addition to the above, other areas of activity related to radiation protection may be identified and shall also be subject to the provisions in 10.2.

10.2 The following shall be addressed by those personnel designated by Management as responsible:

10.2.1 A broad description of the purpose, objectives, functions, responsibilities and procedure(s) defining the modus operandi, acceptance criteria and applicable quality standards for the associated tasks in each area of activity, shall be set down in writing.

This is Management's responsibility and must meet the requirements of the NNR.

10.2.2 The means by which radiation protection requirements are to be met shall be ascertained from written, authorised procedures and work instructions.

11. INSPECTION AND TESTING

11.1 To verify conformance with the documented instructions, procedures and drawings, a programme for inspection of items, services and activities shall be established, authorised and implemented.

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11.2 A surveillance testing and periodic inspection programme shall be implemented to ensure that systems and equipment related to radiation protection will continue to operate, parameters being kept within prescribed limits, or will act to ensure safe conditions if these prescribed limits are exceeded.

11.3 Provision shall be made within the operating schedule to permit the performance of such surveillance, testing and periodic inspection in a timely manner. Deficiencies shall be promptly and appropriately documented and evaluated for their effect on conformance to requirements.

11.4 Measures shall be established to identify the inspection and test status of individual items and for indicating the operating status of systems and components to prevent their inadvertent operation and use.

11.5 All inspection, measuring and test equipment in use shall be calibrated and adjusted against certificated equipment having traceability to nationally recognised standards.

12. CORRECTIVE ACTION

12.1 Measures shall be established, documented and authorised to ensure that conditions adverse to quality, which have caused or may cause a problem, such as failures, malfunctions, deficiencies, deviations, defective equipment, together with procedural and system non-conformances, are promptly identified, corrected and recorded. The root cause of the problem shall be determined and appropriate corrective action implemented to prevent repetition.

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13. RECORDS

13.1 Procedures shall be established and authorised for identifying, collecting, indexing, filing, storing, maintaining and dispositioning of quality management records.

13.2 Quality management records shall be maintained to demonstrate achievement of the required quality and the effective operation of the quality system in accordance with the requirements of the NNR.

13.3 All quality management records shall be legible and traceable to the item, equipment or activity involved. Quality management records shall be stored and maintained in such a way that they are readily retrievable in facilities that provide a suitable environment to minimise deterioration or damage and to prevent loss. Retention times of quality records shall be established in writing.

14. AUDITS AND SURVEILLANCE

14.1 Measures shall be undertaken to monitor the implementation and effectiveness of, and compliance with, the Quality Management Programme. Scheduled periodic audits and surveillance shall be performed in accordance with written authorised procedures. Audits and surveillance shall be performed by qualified personnel having direct access to that level of management necessary to ensure that, if necessary, appropriate corrective actions are identified. Personnel performing audit and surveillance functions shall be independent of any direct responsibility for the activities which they perform. Results of audits and surveillance shall be documented by the auditors/surveyors and reviewed by those organizations having responsibility in the area monitored.

Corrective action shall be taken by the responsible organization and the organization's management shall verify that deficiencies noted have been corrected.

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