

**WASTE PACKAGE SPECIFICATION AND
GUIDANCE DOCUMENTATION**

**WPS/210: Waste Package Quality
Management Specification:
Guidance Material**

**January 2008
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Bibliography

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WASTE PACKAGE SPECIFICATION AND GUIDANCE DOCUMENTATION

**WASTE PACKAGE QUALITY MANAGEMENT SPECIFICATION: GUIDANCE
MATERIAL**

This document forms part of a suite of documents prepared and issued by the Radioactive Waste Management Directorate (RWMD) of the Nuclear Decommissioning Authority (NDA).

The Waste Package Specification and Guidance Documentation (WPSGD) provide specifications and guidance for waste packages, containing Intermediate Level Waste and certain Low Level Wastes, which meet the transport and disposability requirements of geological disposal in the UK. They are based on, and are compatible with, the Generic Waste Package Specification (GWPS).

The WPSGD are intended to provide a 'user-level' interpretation of the GWPS to assist Site License Companies (SLCs) in the early development of plans and strategies for the management of radioactive wastes. To aid in the interpretation of the criteria defined by the WPSGD, and in their application to proposals for the packaging of wastes, SLCs are advised to contact RWMD at an early stage.

The WPSGD will be subject to periodic enhancement and revision. SLCs are therefore advised to contact RWMD to confirm that they are in possession of the latest version of any documentation used.

WPSGD DOCUMENT NUMBER WPS/210 - VERSION HISTORY		
VERSION	DATE	COMMENTS
WPS/210/01	August 2005	Aligns with GWPS (Nirex Report N/104) as published June 2005
WPS/210/02	January 2008	Responsibility for the WPSGD passed to the NDA RWMD. Aligns with Issue 2 of GWPS (Nirex Report N/104) as published March 2007.

This document has been compiled on the basis of information obtained by Nirex and latterly by the NDA. The document was verified in accordance with arrangements established by the NDA that meet the requirements of ISO 9001. The document has been fully verified and approved for publication by the NDA.

1 INTRODUCTION

The Radioactive Waste Management Directorate (RWMD) of the Nuclear Decommissioning Authority (NDA) has been established with the remit to implement the geological disposal option for the UK's higher activity radioactive wastes. The NDA is currently working with Government and stakeholders through the *Managing Radioactive Waste Safely* (MRWS) consultation process to plan the development of a Geological Disposal Facility (GDF).

As the ultimate receiver of wastes, RWMD, acting as GDF implementer and future operator, has established waste packaging standards and defined package specifications to enable the industry to condition radioactive wastes in a form that will be compatible with future transport and disposal. In this respect RWMD is taking forward waste packaging standards and specifications which were originally developed by United Kingdom Nirex Ltd, which ceased trading on 1st April 2007 and whose work has been integrated into the NDA.

The primary document which defines the packaging standards and specifications for Intermediate Level Waste (ILW), and certain Low Level Wastes (LLW) not suitable for disposal in other LLW facilities is the Generic Waste Package Specification (GWPS) [1]. The GWPS is supported by the Waste Package Specification and Guidance Documentation (WPSGD) which comprises a suite of documentation primarily aimed at SLCs, its intention being to present the generic packaging standards and specifications at the user level. The WPSGD also includes explanatory material and guidance that users will find helpful when it comes to application of the specification to practical packaging projects. For further information on the extent and the role of the WPSGD, reference should be made to the *Introduction to the Waste Package Specification and Guidance Documentation, WPS/100*¹.

Quality Assurance is an essential part of an effective management system. It provides a disciplined approach which ensures that arrangements are in place covering all safety related aspects throughout the lifetime of a waste package.

The accepted standard for Quality Assurance promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a Quality Management System (QMS), to enhance customer satisfaction by meeting customer requirements. In particular, RWMD requires assurance that the packaged waste will perform as specified against the appropriate safety criteria for transport, operation and disposal.

The purpose of this guidance document is to provide advice and interpretation on the requirements detailed in the *Waste Package Quality Management Specification, WPS/200*.

2 GUIDANCE

2.1 Quality Management for Waste Packaging

The purpose of Quality Management is to provide confidence that the packaged waste has the characteristics ascribed to it, and complies with the agreed specifications. This

¹ Specific references to individual documents within the WPSGD are made in this document in *italic script*, followed by the relevant WPS number.

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will enable RWMD to be assured that the declared characteristics of every individual waste package can be reliably used in safety assessments for transport and operations at a GDF.

The waste package is an engineered safety barrier that forms one of the barriers to the release of radionuclides from a GDF and therefore needs to be developed and produced under appropriate QMS. In order to give further confidence, it is important that the part of the organisation responsible for monitoring the implementation of the arrangements have sufficient authority and is independent from commercial pressures.

The QMS as described in the requirements of BS EN ISO 9001 [2] (ISO 9001) is considered to be the minimum standard for the packaging of waste for handling, transport, storage and eventual disposal.

2.2 Quality Management System

The international standard, ISO 9001 [2] provides a widely recognised benchmark or minimum standard for waste packagers' QMS. This standard defines the elements of a comprehensive QMS, based on the following principles:

- Principle 1: Customer focus;
- Principle 2: Leadership;
- Principle 3: Involvement of people;
- Principle 4: Process approach;
- Principle 5: System approach to management;
- Principle 6: Continual improvement;
- Principle 7: Factual approach to decision making;
- Principle 8: Mutually beneficial supplier relationships.

ISO 9001 [2] promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a QMS, to enhance customer satisfaction by meeting customer requirements. As the organisation that may ultimately be responsible for disposing of the waste packages (or at the very least, the organisation that currently has responsibility for representing those interests) RWMD should be recognised as a customer of the waste packaging process, and its requirements taken into account accordingly.

The QMS should cover all stages of the waste packaging process that can affect the quality of the waste package throughout its lifetime. As stated in *Waste Package Quality Management Specification, WPS/200* these include:

- waste characterisation;
- container design;
- container manufacture;
- wasteform development;
- process development;
- plant specification and design;
- LoC submissions and advice actions;
- plant commissioning and operations;
- raw materials storage;

- waste package interim storage and monitoring;
- control of non-conforming packages;
- change control and continual improvement of waste package design, processing plant and interim storage;
- package records and their long-term retention.

The QMS should be established and implemented at the earliest practicable time, and must keep pace with progress in establishing the processes for packaging waste, through to interim storage.

2.3 Waste Product Specification

The purpose of a Waste Product Specification (WPrS) is to specify the properties, composition and performance characteristics for each type of waste package. In order to adequately define a waste product, the scope of the WPrS needs to specify the waste container and associated items, properties, waste composition, inactive feed materials, formulation, process condition and product storage conditions.

The WPrS should be submitted in its various stages of development with the submissions for a LoC, this might be an outline with the Conceptual stage, a draft at the Interim stage and a final with the Final stage submission.

It is considered good practice to undertake a periodic review of the WPrS, to ensure that its effectiveness is maintained. Continual improvement and advances in technology require that controlling documentation is updated in systematic and regular manner. It is important that RWMD are informed of any changes to the WPrS.

Guidance on the preparation of a WPrS is provided in *Guidance on the Structure and Format of Waste Product Specifications, WPS/620*.

2.4 Demonstration of Effectiveness and Verification

RWMD looks for objective evidence that all work from the start of the project has been carried out under the control of a QMS and that future activities will likewise be carried out under the control of a QMS. Objective evidence may be in the form of records and planning documents included with submissions, supplied separately or demonstrated to RWMD during a site audit. As stated in *Waste Package Quality Management Specification, WPS/200* the objective evidence should demonstrate that:

- the QMS applies to all stages of the process from initial design through to and including final packaging and interim storage;
- the waste is being packaged in compliance with the QMS and with the WPrS, and;
- that the QMS implementation and WPrS compliance are verified by independent internal audit.

The waste packager shall establish a system of verification for all activities that have a bearing on the quality of the packaged waste, independent of the personnel directly responsible for or involved in those activities.

Waste packagers will be responsible for demonstrating that a QMS for waste packaging, consistent with the requirements of the specification, is in place and that these arrangements are being implemented.

2.5 Assessment by RWMD

In order to demonstrate the quality of products, the waste packager must facilitate access for RWMD to undertake verification through audit of the QMS. The audit should verify all activities that have a bearing on the quality of the packaged waste.

The purpose of the assessment(s) is to enable RWMD, as the ultimate receiver of waste packages, to establish independently that the QMS is in place for all activities affecting packaged waste quality, and that these activities comply with the specified requirements. The nature, extent and scope of the assessments must be sufficient to provide RWMD with the necessary assurance.

In the event of a waste packager choosing to pursue Third Party certification of their QMS, this will reduce the level of assessments carried out by RWMD, provided that it is carried out by a certification body that is accredited by the United Kingdom Accreditation Service (UKAS) whose scope is extended to include radioactive waste management.

2.6 Submission to RWMD for LoC

It is expected that the waste packagers QMS will include procedures that will control the preparation of submissions to RWMD for assessment and control the fulfilment of any actions arising from the issue of a LoC and/or Advice Report.

It is expected that submissions to RWMD will include statements of intent along with appropriate objective evidence that QMSs have been applied in earlier stages of the work and will continue to be applied throughout the lifetime of the waste package.

The content of the submission, with respect to quality arrangements, will depend upon the stage of the submission. The content should develop to be more extensive and comprehensive as the submission progresses between the three stages (Conceptual, Interim and Final). Each submission is assessed for completeness and adequacy, Appendix A contains an extract from the RWMD internal guidance document for assessing waste package QMSs. Where an audit of the project has been carried out by RWMD then the findings of the audit and the objective evidence seen during the audit are also taken into consideration.

3 REFERENCES

- 1 Nirex, *Generic Waste Package Specification*, Nirex Report N/104 Issue 2, 2007.
- 2 BSI, *Quality Management Systems – Requirements*, BS EN ISO 9001.

Appendix A - Guidance used by RWMD for Assessment of Waste Package Quality Management Systems in Submissions

A.1 INTRODUCTION

RWMD requires waste producers operate an effective QMS to all activities which can affect the quality of packaged waste including; waste characterisation, design, development, commissioning and operation of waste packaging plants, and storage. The aim is to ensure the following:

- packaged waste has the properties ascribed to it;
- packaged waste complies with agreed specifications; and that
- adequate records are maintained.

As part of the Letter of Compliance process, waste producers are required to submit objective evidence to demonstrate compliance with this requirement. This Appendix provides guidance on the assessment process for these QMSs.

A.2 SCOPE

RWMD need assurances and objective evidence from the waste packager that they intend to comply with the requirements of the WPSGD, which include a requirement to comply with the requirements of the international standard BS EN ISO 9001 *Quality management systems - Requirements*.

The waste packager can provide objective evidence via assessment or documentation. Such assessments of activities that may affect product quality include plant and waste container design activities, waste characterisation, research and development, commissioning, packaging operations and storage of packaged waste. Documents submitted will be subject to review by appropriately qualified personnel.

A.3 ASSESSMENT

The requirements of a QMS are dependent on the submission stage. The particular objectives of the assessment at each submission stage, together with the information required, are detailed below.

A3.1 Conceptual Stage Submission

The objectives of the assessment at this submission stage are to seek confirmation that:

- the design and development of the waste package and the waste packaging plant will take place within an effective QMS complying with ISO 9001;
- RWMD's requirements have been identified and embodied within the development plans.

Essential evidence that is required at this stage is:

- A clear statement of intent to comply with the *Waste Package Quality Management Specification, WPS/200*.

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Other evidence that is desirable at this stage includes:

- A Quality Programme, Project Plan or equivalent which clearly describes the following:
 1. the project objectives and scope, which should include obtaining and complying with the RWMD Letter of Compliance;
 2. an outline project plan identifying and describing the key stages of the project such as; waste characterisation; container design; process development; testing; and, commissioning;
 3. a programme of design and development review stages, which include independent verification;
 4. the key hold points and milestones of the project, including submissions to RWMD;
 5. a description of the key roles and responsibilities involved in the project;
- Evidence that the organisation responsible for the project and major sub-contractors operate QMSs complying with ISO 9001, this can be demonstrated either by submission of appropriate quality system certificates or quality system documentation, e.g. manuals, procedures;
- Evidence that the interface with RWMD has been clearly identified and built into the project plan;
- An outline WPrS;
- A copy of the Best Practical Environmental Option (BPEO) justification for the project.

A3.2 Interim Stage Submission

The objectives of the assessment at this submission stage are to:

- confirm that waste package and packaging plant development activities have been undertaken under appropriate quality assurance arrangements;
- confirm any recommendations arising from the Conceptual stage assessment have been addressed;
- to ensure the quality programme or project plan for the remainder of the project is adequate, i.e., for commissioning and operation of the plant.

Essential evidence that is required at this stage is:

- records of the completion of the independent reviews of research, design and development identified in the project plan;
- a draft WPrS, identifying the key parameters for product quality and supported by appropriate R & D.

Other evidence that is desirable at this stage includes:

- an updated quality programme or project plan;
- records that demonstrate an adequate system is place to control advice, action points or LoC caveats arising from the Conceptual stage submission;
- copies of independent audits of the project;
- detailed plans for plant installation, commissioning and acceptance testing;

- selection criteria; specifications and requirements for key suppliers;
- outline quality plans or operating procedures for the plant that demonstrate how compliance with the WPrS will be assured.

A3.3 Final Stage Submission

The objectives of the assessment at this submission stage are to:

- confirm that commissioning and testing of the waste packaging plant was undertaken under a verified QMS;
- confirm that recommendations from the Interim stage assessment have been addressed;
- ensure that quality assurance and control arrangements for the routine operation of the plant are adequate and address RWMD's requirements, including the arrangements for non-conforming product.

Essential evidence that is required at this stage is:

- a final WPrS;
- a draft quality plan or equivalent for packaging process which defines the process control measures that will be in place and identifies the tests, measurements or inspections will be undertaken and what acceptance criteria will be applied;
- a procedure for the identification, assessment, and disposition of non-conforming product.

Other evidence that is desirable at this stage includes:

- an updated quality programme or project plan;
- records of the commissioning and testing of the plant;
- records of independent review of testing and commissioning;
- copies of any independent audits of the project;
- draft operating procedures for the plant;
- details (or samples) of the records that will be generated and retained for the process and the waste packages produced;
- a procedure for change control of the WPrS;
- an internal audit programme for the process;
- risk register for the process;
- evidence of third party assessment of the process, e.g. copy of ISO 9001 certificate covering plant.

