

PART II PACKAGE DESIGN APPROVAL APPLICATION

7 Quality Assurance

7.1 Quality Assurance System

- 7.1.1 The Quality Assurance Programmes associated with the design, procurement, manufacture, testing and documentation comply with BS EN ISO 9001:2008.

The adequacy and effectiveness of the quality assurance systems applied are subject to independent audit on a regular basis in accordance with a defined audit programme.

- 7.1.2 The Quality Assurance Programmes associated with the use, maintenance, inspection and transport of these packages shall comply with national and international standards for Quality Assurance that are acceptable to the United Kingdom Competent Authority.

- 7.1.3 See 7.1.1

- 7.1.4 See 7.1.1

7.2 Quality Control in Manufacture and Construction

- 7.2.1 Suppliers are required to submit a production route document for approval prior to work commencing. The production route document details all significant activities for inspection and testing of the package during manufacture.

- i) The containment system is not subject to any specific tests other than visual inspection prior to use. This will be as instructed in FEMCS 2105.
- ii) The neutron absorber will be checked to ensure a homogeneous distribution of boron. This will be done visually during manufacture and by analysis of cast samples at a level to be agreed with the DfT.
- iii) The thermal shielding has been shown to be adequate during regulatory testing and no further testing will be carried out.

- 7.2.2 Manufacturing and test records will be held for the period of time as specified in the relevant component specification. No records will be destroyed without permission, in writing.

7.3 **Maintenance**

All containers will be inspected and maintained as detailed in specification FEMCS 2105.

7.4 **Control and Care of Packages**

Quality assurance in accordance with the relevant Management Control Procedures Suite is applied at all stages of operation and maintenance of packages.