Acceptance Testing

Overview

Acceptance testing verifies that the eRT software has been correctly installed and is functioning as intended within the Licensee's computing environment prior to clinical commissioning or use. Acceptance testing confirms proper operation of core application functions using manufacturer-supplied reference data and expected results.

Manufacturer-Supplied Test Materials

The following datasets will be used for acceptance testing.

- Phantom "Patient" Dataset (reference ct image set with predefined structures) Fix Me! Need Link
- Reference Organization Configuration (reference file containing fully defined organization, site, and machine data) Fix Me! Need Link
- Test Plan Definition (document defining the plan that should be created for the provided dataset) Fix Me! Need Link
- Results (charts, files, and descriptions of the expected results for the test plan)

These materials are intended solely for verification of system functionality and shall not be used for clinical purposes.

Acceptance Testing Procedure

1. Install the eRT software according to the Installation Instructions Fix Me! Link.
2. Login to the eRT software as a user with Organization Configuration permissions, then import the provided Reference Organization Configuration.
3. Import the provided Phantom Patient Dataset
4. Create the Acceptance Test Treatment Plan as defined in the provided Test Plan Definition
5. Verify successful completion of the following operations by comparing to the provided Acceptance Test Results:
    1. Import of imaging and associated data without errors.
    2. Correct display of image orientation and geometry.
    3. Visualization of structures consistent with provided documentation.
    4. Execution of dose calculation using default settings.

5. Display of calculated dose distribution.
6. Export of test data using supported interfaces.

Compare system outputs with the provided reference results, including:

- visual comparison of geometry and overlays;
- confirmation of calculated numerical values where specified;
- confirmation that no calculation or system errors occur.

Verifying Data Transfer Accuracy

In addition to the calculation acceptance testing, the QMP shall verify the accuracy and completeness of data transferred between the eRT software and external systems prior to clinical use. This procedure confirms correct configuration of data exchange interfaces and helps ensure treatment information integrity.

Scope

This verification applies to all supported data exchange interfaces, including but not limited to:

- DICOM image import
- structure set import/export
- treatment plan data transfer
- dose data transfer

Verification Procedure

1. Import representative datasets from each connected external system, that include a CT image set with corresponding structure set
2. Confirm the following after import:
    1. patient identifiers match the source system
    2. image orientation and spatial alignment are correct
    3. structure geometry and labeling are preserved
    4. referenced coordinate systems are consistent
3. Export data generated by the eRT software to the receiving system
4. Verify in the receiving system that:
    1. geometry and positioning remain unchanged
    2. dose distributions align with source images
    3. plan parameters are transferred without unintended modification

Recommended Checks

Verification should include (at a minimum):

- visual overlay comparison
- coordinate consistency checks
- confirmation of Frame of Reference alignment
- verification of referenced object relationships

Acceptance & Documentation

Acceptance criteria shall be defined by the clinical institution based on applicable professional guidelines and institutional procedures.

The user shall document successful verification for each connected system prior to clinical deployment.

Reverification

Data transfer verification should be repeated following:

- Software upgrades affecting interoperability
- configuration changes
- addition or replacement of connected systems

Acceptance Testing Sign-Off

After completion of acceptance testing, the Qualified Medical Physicist will sign off on the

Acceptance Test Form

indicating that this step has been satisfactorily completed.