

QARC Validation Effort

- **Validation** is the process of checking that a software system meets specifications and that it fulfills its intended purpose.
- The validation effort at QARC was motivated by our participation in several industry trials.
- Industry involvement in Cooperative Group trials has led to increased interest in validation of software used for study analysis.

General Principles of Software Validation; Final Guidance for Industry and FDA Staff (Jan, 2002)

Section 4. Principles of Software Validation

1. Specification of Requirements
2. Defect Prevention – requires a variety of methods
3. Time and effort are required throughout the software life cycle.
4. Software validation takes place within the environment of an established software life cycle.
5. The software validation process is defined and controlled through the use of a plan.

Principles of Software Validation (cont.)

6. The software validation process is executed through the use of procedures that identify the specific actions or sequence of actions that must be taken to complete individual validation activities, tasks, and work items.
7. Software validation after a change – determine the extent to which the change may affect the entire system.
8. Validation coverage (extent of validation) should be based on the software's complexity and safety risk
9. Independent review of validation activities
10. Flexibility and responsibility -- the device manufacturer has flexibility in choosing how to apply these validation principles, but retains ultimate responsibility for demonstrating that the software has been validated.

- Both MAX and CERR were included in the validation process.
- MAX is a legacy system, so a “use case” approach was chosen as the best validation method (software requirements were not formally defined prior to development and implementation).
- CERR was validated as third party software.

The QARC database (MAX) has many functions. It is used by QARC staff to:

- store and manage patient data and information
- view and manage imaging
- view and manage correspondence
- calculate statistics
- import/export data
- run query sets and custom reports
- create and manage the QARC Quality Management System (including QARC SOPs and SOP attestation logs)
- create and manage the QARC knowledge base of resources and information
- enter and manage QARC logs

What needs to be validated?

- Patient data resides in tables, and QARC Staff enter, update, delete and manipulate that data through fields presented to the user on forms.
- Of the 342 tables in MAX, there are 49 tables which are directly associated with the patient record.

What needs to be validated?

- Several reports in the MAX Database are run weekly and are capable of changing data in the Patient Record.
- These reports are part of the validation process.

Risk:

- All active patient tables used for storing patient data are considered to be critically important, and have been assigned as a high risk.
- Tables which contain patient data, but are no longer active have been assigned as a low risk.
- Tables which contain patient data for reports no longer run have been assigned as a low risk.
- The risk level defines validation priority.

Our validation plan details:

- The roles and responsibilities of those involved in the validation of the MAX Database.
- The scope and boundaries of the validation effort.
- What is being validated and how it functions/operates.
- Documentation to be produced.
- What happens should the validation fail to meet the acceptable validation parameters.
- The processes and procedures that are employed to determine the extent to which the Database has succeeded in meeting the needs of the QARC organization.

External review of the validation plan

- The validation plan was reviewed internally.
- The documents outlining the validation plan were also reviewed by an external expert (EduQuest Inc.).
- The validation documents were updated based on feedback received from EduQuest.
- The documents were then approved as specified in the validation plan.

MAX Validation Documentation

One goal of validation is to be able to demonstrate quickly to any potential auditor/inspector (internal or external) that the system is indeed validated. To achieve this goal it is important to know what the validation documents are and where they will be stored and who will be responsible for their maintenance.

- Electronic validation documents are stored in a central repository.
- Test Procedures and reports are published to the QARC Knowledge base.
- All hardcopy documents, such as printed executed test procedures, are stored in the office of the QA Engineer. All folders used to store such documents are clearly labeled and where applicable contain the appropriate MAX build number.
- All approved Validation Reports are published in the QARC Knowledge Base (QKB).

Use Cases

- Use cases were developed to define the steps for each process carried out in the MAX Database.
- Example: use cases pertaining to eMaterial functionality
 - Import a file (eMaterial) into a patients MAX record
 - Delete an eMaterial from a patient's record.
 - Edit the values assigned to an imported eMaterial
 - Provide notes and comments which provide additional information about the linked eMaterial
 - Group eMaterials by category
 - Hide/Show eMaterials by category
 - Remove eMaterial from the view of the Remote Reviewer
 - Print a list of a patient's eMaterials

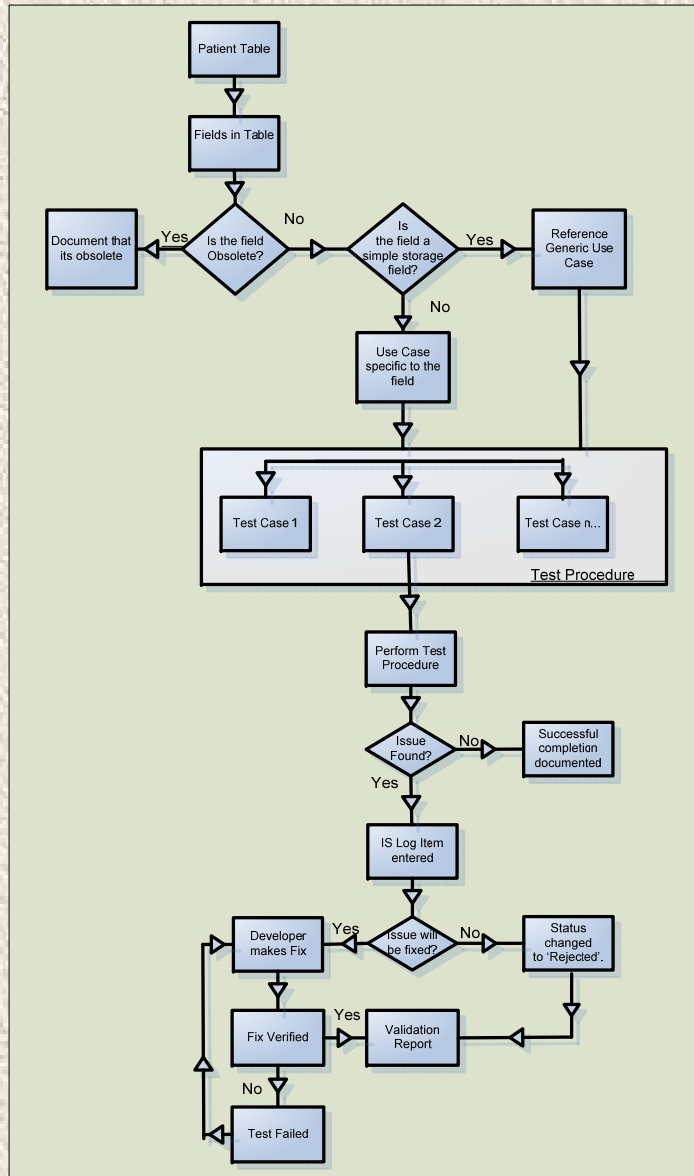
Use Cases/Test Cases

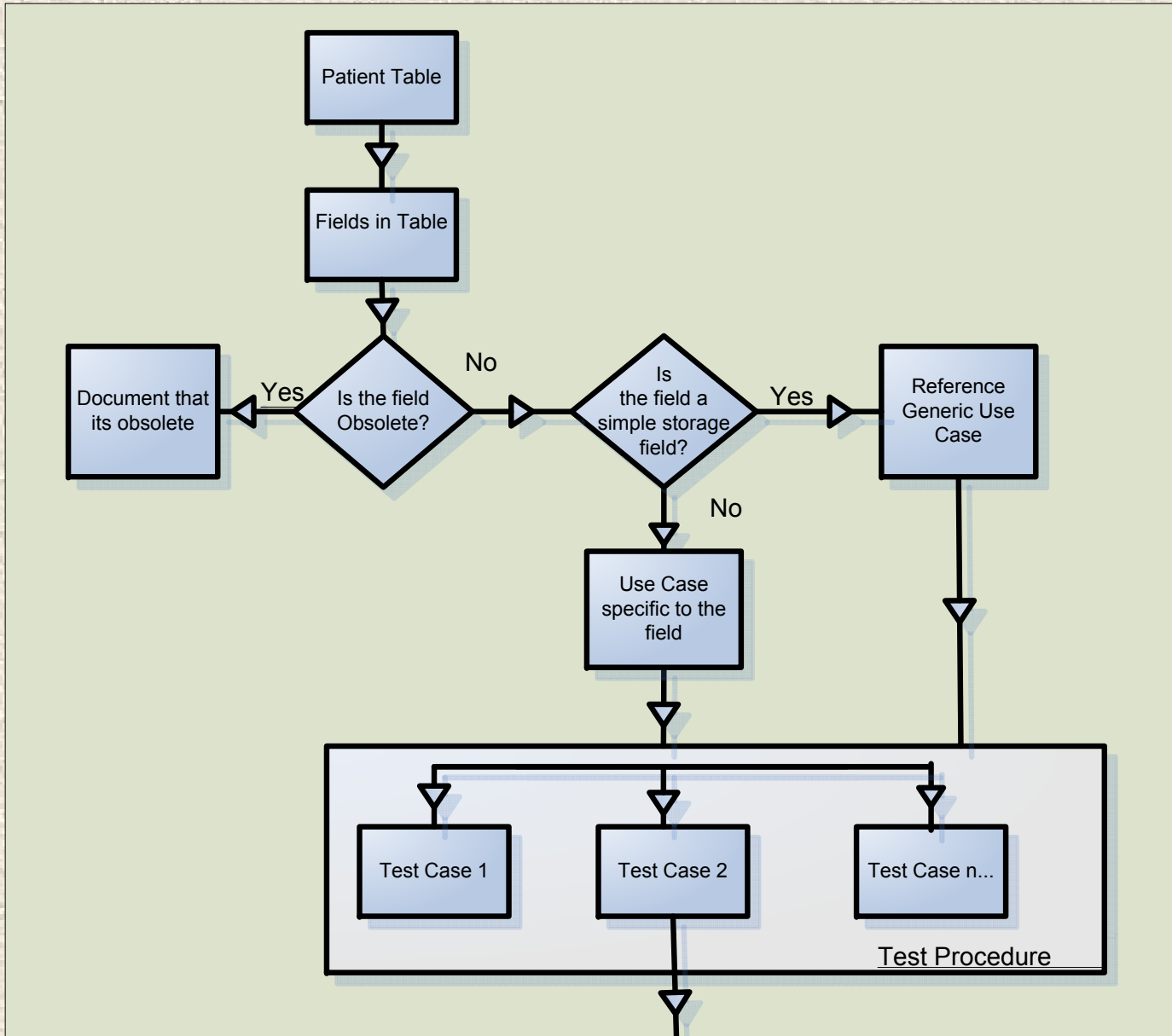
- A member of the QARC staff reviewed each use case to ensure it accurately reflected the reality of how MAX functionality is used.
- A test procedure (consisting of multiple test cases) was developed for each use case.
- All testing took place in non-production builds of the MAX Database.

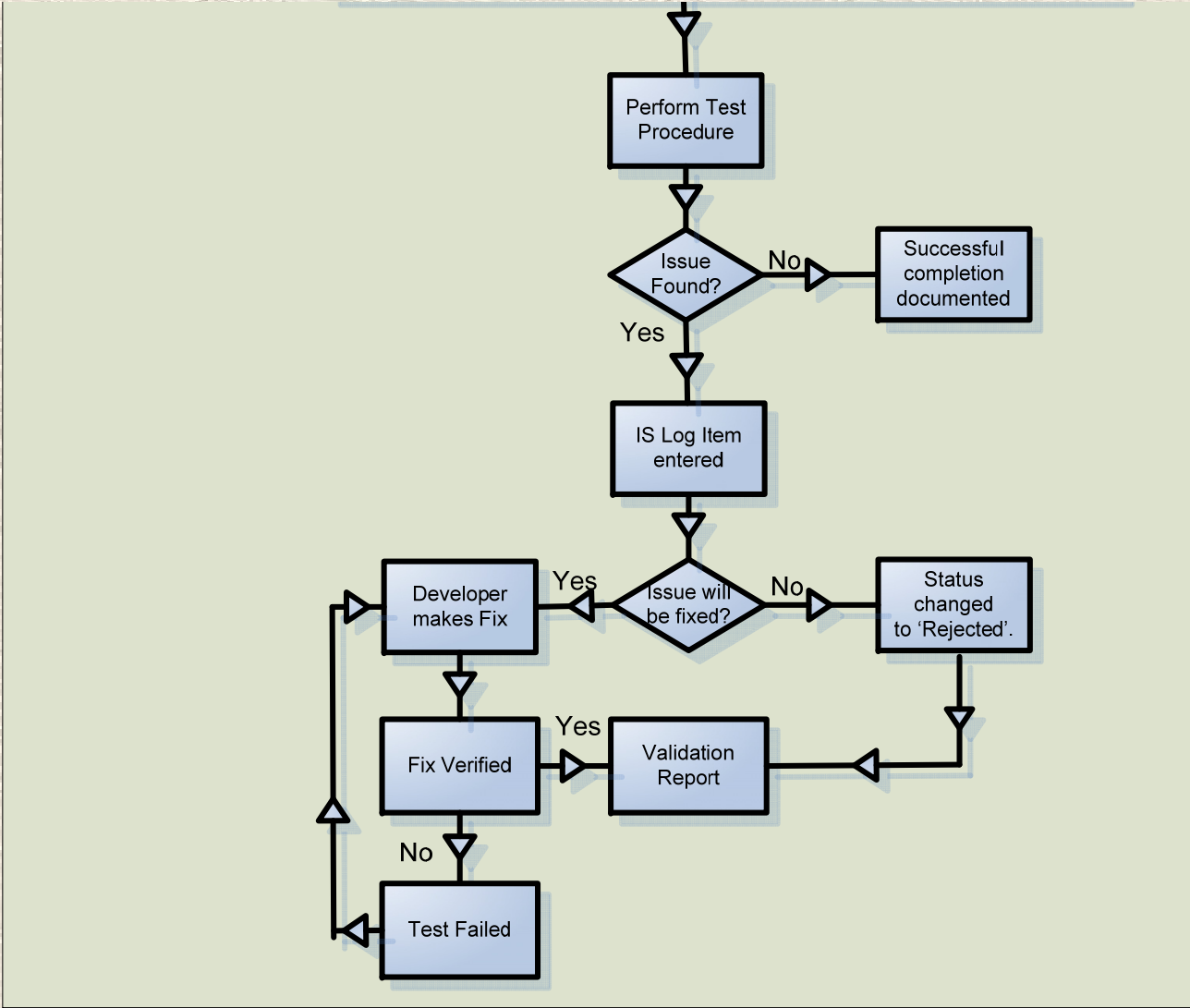
Test Cases

The Test Cases in each Test Procedure verify:

- that 'good values' are correctly accepted by the Database.
- that 'bad values' are handled gracefully by the Database.
- that reasonable and predictable mistakes are handled gracefully by the database.







Change Control of MAX Database

Procedures:

1. All change requests are submitted as IS Dept Log Items.
2. Members of the IS Dept review the request for potential issues and risks.
3. Submitter has the right to appeal a negative decision to the Director of IS and then to the QARC Management Team.
4. IS Dept evaluates the level of risk, which determines the level of approval required for the change.
5. Key QARC staff meet twice per month to assist in prioritization of development.
6. The developer makes changes to the code in the developer environment and does preliminary testing.

Change Control of MAX Database

Procedures (cont):

7. A test build is delivered to the QA Engineer, who tests the changes.
8. If testing is successful, the QA Engineer sets the IS Dept Log Item to “Resolved.” If not successful, failure is documented in the IS Dept Log and QA Engineer works with Programmer to make necessary corrections.
9. When change is ready to be released, systems programmer publishes a new version to the production server.
10. Email is distributed to the QARC staff outlining the changes in the new build.

CERR Validation

- Validation approach and requirements assume that CERR is 3rd party software.
- Testing is less stringent than what would be required for the software developer.
- Sufficient testing is required to establish that the software meets "user needs and intended uses."
- A use case/test case approach was used, similar to the approach used for validating MAX.

CERR Validation

- First step was to specify our functional requirements (essential and non-essential) for a QA review application
- Required functionality was divided into six broad categories:
 - Import functionality (RTOG and DICOM RT)
 - Viewer functionality
 - Plan tools (renaming, summing, beam data display, etc)
 - Structure tools (contouring, expanding, combining, etc)
 - DVH tools
 - Study tools (anonymization, import log display, etc)

CERR Validation

- Eight data sets were identified to be used for testing CERR functionality.
- 3 data sets were in RTOG Format, 5 data sets were DICOM RT.
- Planning systems represented were Eclipse, Pinnacle, and XiO.
- Studies were chosen that contained features relevant to the tests to be performed.
- For some of the studies planning system output in electronic format was available for comparison with CERR.

CERR Validation

- 72 tests were performed, covering each area of the required functionality.

Example: Structure Tools

Test cases 30-35 assess the capability of the application to perform structure operations. This capability can be useful if certain required structures have not been submitted. For these test cases use RTOG data set, Case #1. Before performing these test cases, DVH's for the CTV and PTV should be recalculated in order to minimize the effects of small discrepancies in the volume calculation between the planning system and CERR. The discrepancy in the volume calculation will be assessed later as part of the dose volume histogram tests.

Test Case	Test Procedure	Result (pass/fail)	Comments
30	Expand the CTV by 1.0 cm. The expanded CTV should approximately coincide with the PTV in all three dimensions, and their volumes should agree within 5%.		
31	Shrink the expanded CTV by 1.0 cm. The resulting structure should approximately coincide with the original CTV, and their volumes should agree within 5%.		
32	Subtract the CTV from the PTV. Verify visually in three dimensions that the new structure is a shell surrounding the CTV. Verify that the volume of the new structure is the difference between the PTV and CTV volumes (+/-3%).		

Test Case	Test Procedure	Result (pass/fail)	Comments
33	Create the union of the CTV and the structure created in the previous test case. Verify visually that the resulting structure is the same as the PTV and their volumes are equal (+/-3%).		
34	Create a structure that is the intersection of the CTV and the PTV. Verify that it is identical to the CTV and their volumes are equal (+/-3%).		
35	Contour the spinal cord for a length of 6.0 cm, skipping every other slice. Calculate the volume of the resulting structure. Use the "Fill Slice Gaps" function to fill in the missing contours. Calculate the new volume, which should be larger by a factor of approximately 1.90 (+/-5%).		

CERR Validation

Results: The only area in which some of the test cases did not meet our criteria was the DVH tools.

- For one of the data sets DVH's could not be calculated. This was remedied by updating one file with the corresponding file from a later version of CERR.
- Two test cases had discrepancies because one structure was partially outside the dose grid.
- Four test cases had discrepancies when comparing very low doses.
- One test case had a discrepancy for a structure with a small volume.