

### 4 Responsibilities

The Project Leader and/or System Owner have responsibility for ensuring that a risk-managed approach for the development and maintenance of computerized systems is utilized. A multi-disciplined team should be assembled to support this approach and should include representation from some or all of these as applicable:

- Technical Staff
- System owner
- Key User
- Quality Assurance
- Computer Validation
- IS Quality Manager

It is the responsibility of this multi-disciplined Team to carry out risk assessment activities & make informed decisions about the validation processes & deliverables that will be required to adequately address validation or change control.

### 5 Guideline

A risk-managed approach to the system life cycle is necessary for an efficient and effective way of working. Utilizing risk management methodologies allows validation activities to be appropriately scaled to meet business and regulatory needs without creating unnecessary work. Documentation and testing are focused in appropriate areas to mitigate risk. In some cases this may require additional testing in high-risk areas.

This approach also benefits the change control process because areas of regulatory impact and risk will have been identified prior to initiating the change. Thus the impact of a change can be more easily identified and appropriately handled.

A number of assessments are carried out and decisions documented to support a risk-managed approach. It is important to recognize that these assessments are tools to aid the team in the decision making process. The output of an assessment should be carefully weighed against the team's knowledge of the computerized system in order to make informed decisions. The team's subjectivity will be instrumental in many cases throughout the process. Decisions should be appropriately documented to capture the rationale.

The scope and amount of validation or qualification is determined by assessing the business requirement, the associated activities and the level of risk this represents to business. This is described in the following sections.

The following diagram provides an overview of the risk management process and The detail of these activities is described in sections 5.1 through 5.7