Regulatory Basis:
FDA Quality Systems Regulations

Reference: FDA CFR - Code of Federal Regulations Title 21

General Discussion
This document explains how Component Level Impact Assessment can be performed for Information System Applications. This document only applies to Information Systems and it does not apply to any Process Control systems.

The classification of Information System components as critical or non critical can be performed using a Component Level Impact Assessment in order to determine which components need qualification. This document also gives document on how to identify components in applications and includes examples of component level impact assessments for three typical software applications.

In the absence of a component level impact assessment, all components of new direct impact systems must be considered as critical components and need to be qualified. However, if there is a documented rationale based on a Component Level Impact Assessment, components might be classified as non-critical based on their lack of potential to impact product quality or regulatory Compliance Practices.

It is recommended to base the component level impact assessment on the specifications that define the functions of the system (e.g., Functional Requirement Specification) or other document(s) describing the system functionalities. An application profile (system description addressing the key functionality and how the functionality is used) may also be used to provide unambiguous information that is needed to answer the CLIA questions and to provide supporting rationale.

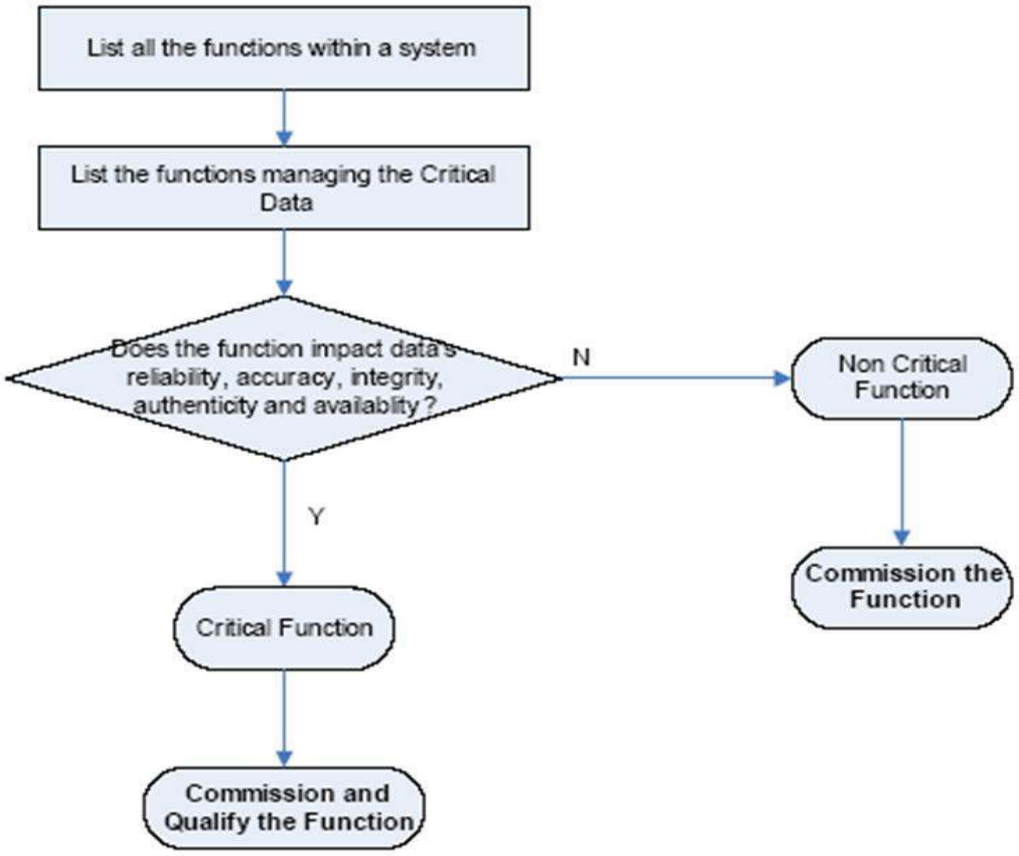
The Component Level Impact Assessment templates should be created to list a set of questions used to determine whether the component/function is critical or not. Typically, the only question that directly applies to Information Systems is the following question:

"Does the component produce, monitor, evaluate, store or report Critical data1?
This question will be answered ***yes*** if:

- The component/function is used to print primary2 records and/or signatures that are required by regulation (predicate rules);

Examples:

- The component/function generates, stores or transmits training records, calibration records, change control records, deviation resolution records, batch records, laboratory data, validation documentation, annual product reviews, cleaning records, and GMP documents (e.g., SOPs).
- The component/function manages records that support the process of annual reviews or batch yield calculations.
- The component/function manages data that are used to create labels that identify a drug substance, intermediate, commercial product, clinical material or drug product.
- The component/function manages data that are part of the batch record or used to support lot release.



Identification of Components

One of the challenges in performing Component Level Impact Assessment is identifying individual components (functions) in software products. An approach for identifying components includes identifying each (numbered) Specification item (e.g. Functional Specification) as a component.

1. Example for a LIMS system (Note: This is just an example only. Not all the functions within a LIMS system are listed below):

	Component (Function)	Critical	Rationale
1)	Certificate of analysis (CoA) report functionality	Y	C of A report functionality outputs Critical Data.
2)	Sample analysis report functionality	Y	Sample analysis report functionality outputs Critical Data (used to accept/reject product)
3)	Stability summary report functionality	Y	Stability summary report functionality outputs Critical Data that support regulatory compliance practices

