

Summary - Component Level Impact Assessment for Information System Application

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.

A Critical Component can be defined as a physical element or function of a system where operations, contact, data, control, alarm or failure directly impacts product quality or regulatory compliance.

A non-critical component is defined as a physical element or function of a system where the operation, contact, data, control, alarm, or failure will have no impact on product quality or regulatory compliance practices.

However, not all functions that manage Critical Data are critical. The following three questions which supplement the above question may help in determining whether the function is critical. If one of the following questions is answered yes, the component is considered to be a critical component and must be qualified.

Examples:

- A function that generates data
- A function that stores data
- A function that processes data
- A function that manipulates data (calculations)
- A function that outputs data

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