Regulatory Basis:
FDA Quality Systems Regulations

Reference: FDA CFR - Code of Federal Regulations Title 21

General Discussion
This document explains how the Commissioning and Qualification System Level Impact Assessment template can be used for Information Systems.

To classify Information Systems as Direct, Indirect or No impact systems, only one question is applicable for Information Systems. By means of three typical examples, this document explains how system classification could be performed, based on the use of the system and its data.

Systems Validation, all new systems shall be considered to be 'direct impact' systems, unless there is documented rationale based on a System Level Impact Assessment (SLIA), for classifying systems as either "indirect impact" systems or "no impact" systems, based on the system's potential to impact product quality or regulatory compliance-practices.

It is recommended to base the system level impact assessment on the URS (User Requirement Specification) or other document(s) describing the system and system boundaries. 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 SLIA questions and to provide supporting rationale.

The System Level Impact Assessment template should lists a set of questions used to determine whether the system has Direct Impact or not. Typically, the only question that directly applies to Information Systems is the following question:

"Does the system produce, monitor, evaluate, store or report data used to accept or reject product or material or data used to support Regulatory Compliance – Practices?"

This question will be answered **yes** if: The system generates, manages, transmits or prints primary records and/or signatures that are required by regulation (predicate rules);

Examples:
___ The system 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.

___ The system manages records that support the process of annual reviews or batch yield calculations.

___ The system manages data that is used to create labels that identify a drug substance, intermediate, commercial product, clinical material or drug product.

___ Data from the system are part of the batch record or used to support lot release.

when it manages Indirect/Non Impact Data and interfaces with a Direct Impact System. A No Impact System is determined as a system that manages Indirect/Non Impact Data and does not interface with a Direct Impact System.

This type of evaluation may seem obvious for systems with clear boundaries and one way of intended use, like a LIMS (Laboratory Information Management System) system managing data that will lead to decisions to accept or reject product based on lab results. But in some cases, the answer requires some thinking as the classification depends on how the system actually is used.

Therefore, the documentation of narrative rationales for the Y/N decisions of the system level impact assessment is essential.

Below are some examples of information systems that often raise questions in determining the direct, indirect or no impact.

Card Access Reader Software
The system used at a center location to restrict access to people entering offices would not be considered as a Direct Impact system. Where people in the building work with compliance-supporting information systems, access to these systems is restricted with logical security. The same rationale applies if the card access reader software is only used to restrict entrance to offices on a site.

Different situations could arise when the system is used for restricting people access to manufacturing premises. Whether the system is direct impact and needs to be qualified depends entirely upon how the system is used. If it is the intention to act on the data that are generated and managed in the system and that action supports regulatory compliance-practices, then this system is a direct impact system and would require validation.

If the electronic log entry is used to automatically block access to people who haven't entered the aseptic area in 6 months (and thus need retraining), this would be considered a GMP-decision and thus the system would be considered direct impact.

__ If the system restricts access to specific areas based on data of the person's training status and these data are maintained and managed by the system, this would be considered as a GMP decision and a direct impact system.

__ If it is merely a passive system that only controls access based on general HR data and does not deter who gets access based on quality or GMP training attributes, then it would be considered an indirect or no impact system, dependent on whether it interfaces a direct impact system. It would not be a direct impact systems because the data managed by the system are not used as the primary method of verification, that only trained personnel are granted access to critical processing areas; the data are Indirect or Non impact

Training Record System
The training record management system is a system that often raises questions around impact and the need for qualification. GMP regulations such as FDA 210 and 211 require the need for