

Summary - Periodic Review of Processes and Systems

Validated processes and qualified systems (from this point forward refers to equipment & computer systems) are required to be periodically evaluated to verify that they remain in a validated state. High risk processes (e.g. sterile or aseptic) may also require routine re-qualification and/or revalidation. The application of a risk-based approach allows:

- The prioritization of PR and routine re-qualification/revalidations activities.
- The scientific justification of the PR frequency and routine re-qualification /revalidation frequency (if applicable)

Routine revalidation is only required for high risk processes (e.g. sterile/aseptic). The types of processes that are typically involved in routine revalidation include sterilization and aseptic processing (e.g. autoclaves, de-pyrogenation tunnels, steam-in-place systems, aseptic filling lines).

If Routine revalidation is required, it is typically conducted using a concurrent validation approach. The testing is executed on a preset frequency against a standardized pre-approved protocol or SOP.

Refer to Appendix 1, step 1, “Identification of system criticality” for guidance on when PR applies or does not apply according to the qualification approach used.

Unless a re-qualification is required for a specific system, where no significant changes have been made to the direct impact /indirect impact systems (that require qualification) /critical system, a PR (with evidence that the system is consistently performing and is fit for use) fulfils the need for re-qualification.

Where applicable, a review of system security, including appropriateness of user access and addition/removal of users is often carried out as a routine activity. If this is the case, then security would not need to be included in the PR. However, if there is no separate management system in place for these activities then they must be included in the PR. For example:

- Security access and privilege review
- Security log review; System log review
- System Backup review;
- Data integrity review, including archived and old data

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