

- Restrictions on the system (if any)
- Deliverables
- Conclusion

For simple analytical instruments, a simple table to summarize the qualification testing, acceptance criteria, results, and pass/fail decision of the tests will be sufficient since there are fewer tests that are required and the tests are usually relatively simple. For complex analytical systems, a more complex table often referred to as a traceability matrix which traces the requirements, testing, acceptance criteria, test results, and storage locations of the validation documents, test data, and other supporting documents is usually included in the summary report for easy reviewing and quick references.

After the actual qualification testing and regular performance verification testing, the documents and the related test data are the only proof that the instrument has gone through such testing and has been properly installed and maintained to support its intended applications. The document should be stored systematically in a centralized location and maintained with care in order to prevent any losses. A good recordkeeping system can be extremely useful in audit preparation and help to speed up the turnaround time for documents during an inspection.

4.3 Operational Phase

After an instrument has been qualified, it is ready for production use. The activities in the operational phase support the day-to-day use and maintain the instrument in a validated state.

Standard Operating Procedure A SOP has to be written to provide instructions for the operation, maintenance, and calibration of the new instrument. A typical SOP should include:

- A general system description
- Operation instructions
- Responsibilities of the system users and system administrators
- Calibration or performance verification requirements, acceptance criteria, frequency of testing, and the actions required if the instrument does not meet the performance verification requirements.
- Maintenance requirements
- Service, major and minor repairs, and parts replacement that will necessitate a requalification of the instrument. For example, the replacement of a UV lamp in a UV detector does not require a full requalification, whereas a replacement of circuitry board will warrant full requalification.

Maintenance Normal wear and tear as well as aging of various components may compromise the performance of the instrument or lead to operation failure. The instrument needs to be maintained in order to function consistently and reliably. A preventive maintenance program which identifies and replaces the consumable parts will likely save time and money in the long run. The usage and service records