of supplier materials, such as user or technical manuals for functionality that is critical to a business operation or directly impacts validated applications. The primary value of such mapping is that staff can more easily locate detailed guidance regarding correct operation, configuration, and maintenance of software.

**Build and Test**

Since layered software is rarely built, this phase consists of developing work instructions to ensure local staff can install and configure the software in a test environment (if possible) and testing to determine if the requirements will be achieved. Generic installation instructions are usually provided with layered software, so these need only be referenced, not repeated, with incorporation of local information or amendments needed to setup the software in your environment. The goal is a process that will be readily understood by the staff that will use the instructions.

Once successfully installed and configured, the software should be tested to determine if the requirements identified in the planning phase are satisfied.

**Installation Phase**

Verification of proper installation can be as simple as a quick version check on a splash screen, or as complicated as a daily backup integrity check spanning multiple weeks for mission critical or high-risk validated applications that includes completion of a detailed checklist each day. The detail and extent of the final installation verification should be commensurate with the potential impact of failure of the software to perform as required. Pay particular attention to layered software requiring configuration changes, as either applications or hardware is deleted or added to ensure all required service needs are covered (e.g., ensuring all disks are included in the nightly backup script, etc.).

**Ongoing Operation**

Layered software is often implemented to provide a service for multiple applications (e.g., backup for LIMS and MRP systems, etc.). Implement processes that will keep configuration and operation of the layered software synchronized with future changes to applications and hardware that can be affected by the layered software.

**Retirement**

As layered software is retired or replaced, consider the possible need for later restoration. Copies of retired software and associated support materials, such as internal documentation and supplier materials, should be retained when that software would be needed to process or restore archived data. The software and documentation should adhere to the same retention schedule as the pertinent archived data.

**Infrastructure Applications**

Certain application software is used by infrastructure organizations to manage various business processes within the infrastructure environment (see Figure 5). Examples of software that might fall into this category would include:

- Inventory/Asset/License management systems
- Problem and change management systems
- General document management applications supporting the creation, approval, and control of items, such as
  - Standard Operating Procedures
  - Installation guidelines and checklists
  - Network diagrams

While the information managed within these types of applications does not directly impact the development, manufacture, and distribution of pharmaceutical products, some of this information may be subject to review during audits by regulatory agencies, e.g., change records that show the controlled change history of a qualified server. As a result, they may be viewed in the same validation context as business applications supporting regulated areas. Such considerations are outside the scope of this paper, which focuses on infrastructure equipment qualification, but such applications should be reviewed with the company’s business Quality Unit for potential applicability of internal validation requirements.

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**About the Authors**

The full IVT NIQ committee is responsible for authorship of this proposed standard. The opinions expressed are their own, and not necessarily those of their employers. Comments and questions should be directed to Warren Campbel. He can be reached at (610) 715-4741, by fax (610) 933-9413, and by email at campbmw@attglobal.net

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**Suggested Reading**

IVT Network Infrastructure Qualification Proposed Standard

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