

Understanding **Total Compliance Management**

Policy & Procedure Document Control – Staff Certification – Training – Competency Testing

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Total Compliance Management describes an integration of four critical functions including: policy and procedure document control; staff certification; required training; and staff competency testing into a single user-friendly system that empowers staff to manage their own compliance needs. Management can only be assured nothing is slipping through the cracks when every assignment is tracked with a fail-safe system of automated reminders and escalating notices that alert supervisors should any element of a compliance assignment go unanswered—well before a non-compliant condition arises.

Medical laboratories, pharmaceutical manufacturers, and healthcare facilities are under increasing regulatory pressure to effectively manage operational policies, processes, and procedures (PPP). Historically, these documents come into existence as a result of committee review and/or joint authorship—usually via an iterative process, resulting in a series of dated documents that replace pre-existing PPP. Documentation is distributed to staff to read and sign-off with the assumption that they such action indicates compliance. It is not, unusual to see PPPs tacked on a bulletin board with a sign-off sheet or contained in three-ring binders on the top of file cabinets, waiting for staff sign-off.

In the big picture, “signs-off” may be less important than whether staff fully understands and is able to demonstrate specific competencies defined by the PPPs. When that is the case, sign-off sheets provide no such assurance. Any so-called compliance management system should track not only sign-offs but provide for other markers to indicate the fullest possible meaning of compliance, i.e., understanding, required skills, willingness to comply, etc.

Document Control Systems

As far as compliance management, most organizations go no further than Document Control and/or Learning Management Systems. Document Control or Document Management Systems have gained in popularity because they offer a robust authoring system that facilitates the creation of documents for PPPs among a defined group of managers or other key players then “locks” the final documents limiting access to authorized users who have no ability to alter a document’s content. This solves the authoring and control side of the equation, however such systems lack features for effective and efficient deployment to the staff.

The method by which users access electronically controlled documents is more structured than posting to a bulletin board with a sign-up sheet. However, user-access is usually limited to software licenses or “seats” which can be expensive if the document needs to be shared widely among a large population. Moreover, even the tools used to “read” a document are often

unfriendly and can be intimidating to the infrequent reader who is being asked to sign off on an updated policy.

A Document Control system's value proposition is skewed heavily toward the "authors" of a document; generally under ten individuals. Purchasing additional user-licenses to provide staff with access and sign-off functionality only means those licenses may offer a significantly diminished value proposition because they are utilizing only a minuscule sub-set of the license's features. In essence, you are paying for a race car to drive to the super market when a normal car is better suited.

Four-Part Compliance Management Puzzle

Managing PPPs is an easily observable piece of the four-part compliance management puzzle. With a broader perspective three equally pressing issues emerge; they include: **staff certification, staff training, and competency testing.**

Staff certification describes the ability to set staff training and competency requirements for a given staff position; when an individual fulfills the requirements they are "certified" or "qualified" to perform the defined tasks. Likewise, a system should be in place that allows a manager to "search" for certified or qualified staff when staff resources vary or are diminished—not all Learning Management Systems handle this requirement.

Finally, staff competency testing is a critical function that cannot be separated from the other three. Many managers are frustrated with a lack of automation to schedule and manage on-going, hands-on competency testing—yet this too must be fully integrated into a Total Compliance Management System.



Learning Management Systems

Staff training, especially when it is mostly delivered in a classroom or via a teleconference is easy to manage with a simple spreadsheet listing available courses, employees and completion dates. With the advent of more online training, the demand for automated Learning Management System (LMS) has grown, but few, if any Learning Management Systems go so far as to handle **Staff Competency Testing.**

Since orchestrating the interaction of staff, managers, and/or supervisors to review the work or observe the performance of individual staff members for competency testing purposes can be a logistical nightmare, it is no wonder few systems are available to automate the process—certainly not the typical Learning Management System.

Indeed, from a historical perspective, PPPs, staff certification, staff training, and competency testing have been managed separately and viewed as "silos" underneath a vaguely described compliance umbrella. However, the real world demonstrates that each component is not a silo,

but is interconnected and interdependent with each other. Take for example a change in a laboratory procedure. A procedure document is not the same thing as a training program. To be certain, some procedures are straight forward enough that when well written, no additional training may be required. But what happens when additional training IS required? Does it not make sense to be able to link training materials to an updated or new procedure document? Or, consider another example. What happens when a competency test reveals a lack of confidence or lack of skill on the part of an employee? Does it not make sense to have remedial training materials fully integrated with the competency testing?

Total Compliance Management

Total Compliance Management integrates these four, core, compliance functions: **Document management** (policy, process and procedures – PPPs); **staff certification**, **staff training**, and **competency testing**. In addition, any Total Compliance Management solution must offer the following basic functions to its users:

- A comprehensive library of PPP documentation, training assignments, and competency testing criteria and protocols with the ability to add, remove, make inactive or revise any item.
- A system that pro-actively notifies employees of pending compliance assignments while providing easy-access to any, and all, materials necessary to complete the assignment.
- The ability to identify “certified” staff by grouping certification criteria with job codes or job descriptions in order to “qualify” individuals or assist management in the identification of otherwise qualified or nearly-qualified individuals when staffing short falls
- A methodology to monitor the status of each employee’s current and historical compliance status as well as the ability to view any and all compliance assignments, specifically to whom each is assigned, by what criteria and the current status of each.
- Automated notifications to prevent the possibility of non-compliance by providing support for employees whether or not they have regular computer/email access while including supervisors in the notification loop.
- A method for managing sign-offs from multiple approvers who observe, instruct, or qualify employees for various tasks or protocols.
- A fail-safe system to notify management before a non-compliant situation occurs using proactive notifications and regular management reports.

Compliance & Learning Management System

The Compliance Management System (CLMS) is the fourth generation of the system initially developed by Knowledge-Forge over five years ago. The new system draws upon the strengths

of the original Knowledge Tracking System (KTS) that is currently installed in a wide variety of healthcare venues where it is managing over 1,000,000 compliance assignments per year.

Questions:

Surely it is not possible to manage every aspect of compliance from a single interface?

Obviously Joint-Commission compliance is different than meeting FDA or CLIA requirements, so a single interface would probably be so generic as to be functionally useless. However, because of the open architecture of the Knowledge-Forge Compliance & Learning Management System™ it **IS** easy to apply the CLMS tool to any of the above scenarios so the answer is yes, the CLMS will handle every aspect of compliance. The simple rule of thumb is that if it is someone's responsibility to complete an action, then that action can be setup as an assignment for the CLMS to make sure the action is completed by the designated person, on-time, and meeting all required specifications—only with the CLMS, there will also be an easy-to-follow audit trail for confirmation and inspection.

How many policy or procedure documents can the CLMS system handle?

There is no limit to the number of source documents the CLMS system manages. Once a document is in the system, the CLMS automates (with the help of a user-friendly wizard) the process of updating and revising as well as assigning or re-assigning the updated documents to only affected individuals.

How does the CLMS differ from a Document Management System?

The CLMS' strong suite is in how easy it makes editing, updating, and revising a document already in the system. Even stronger is CLMS' ability to automate the distribution of documents across even the largest organization so that **ONLY** the individuals affected by a document are involved in the process.

The CLMS does not have a fully integrated authoring tool—we recommend the Adobe® suite of Acrobat tools in conjunction with Microsoft® WORD® or your authoring program of choice. Any text editor that supports multi-user editing will work—especially if the output is saved as a non-editable Acrobat® PDF document.

The CLMS will work with virtually any existing Document Management System so if you have already made the investment, do not worry, CLMS will not make it obsolete because the CLMS will greatly extend the existing system's value by extending its functionality.

Can I do more than merely have a policy or procedure document read and signed-off? Can I add a test or require some other action that assures me my staff actually understands the document in question?

Yes, unlike most Document Management Systems, the CLMS allows you to add a host of completion items to any Policy, Process and Procedure (PPP) document or training module. Sometimes a simple sign-off is ok; sometimes it is just not enough. In addition to an electronic sign-off, the CLMS allows you (and/or your legal council) to edit the wording of a unique affirming sign-off statement. You may also add a multiple choice quiz, multi-step, trainer, peer

or supervisor reviews that may involve one-on-one conferences or even a demonstration of skills. Finally, you may add a survey to assess the user's understanding, attitude, and intentions.

Is the system smart enough to know who is affected by a specific Policy, Process, or Procedure document—in other words who needs to review and sign off?

Yes. PPPs and other items can be associated with a Group (department, cost center, etc.), a Job Description and/or specific individuals. New versions of these items are automatically assigned to replace older versions. A versioning 'wizard' takes into account the type and criticality of change when determining how and when new versions are assigned. Similarly, if new requirements are made of a cost center or job definition the people assigned to those will automatically receive the new requirement.

What if a PPP change is minor and I don't want to force people familiar with it to review it again?

When a new version of a PPP or other item is activated you have a number of options on how the distribution occurs. For example, critical updates can be rolled out to everyone immediately while less significant updates can be phased in with new assignees and annual renewal requirements. Other intermediate options let you determine how the new version circulation occurs, based on its importance.

Some of our items are required annually, some are required only once or as needed, yet others are required bi-annually. Can an automated system really keep up?

Although the above scenario sounds complicated, it is exactly what the CLMS is designed to handle – without any guess work. Managing this with a spreadsheet or other methods requires considerable time and effort and is prone to errors. The rules, relationships and scheduling options in the CLMS make these types of assignments simple and automatic. Layering the roll-out of new versions on top of this is also straight forward and easily automated in the CLMS. Exception reports and an audit trail provide a second level of assurance that no non-complying events ever occur.

We have a large number of presentations and paper-based tests that we currently use. How would that work with an automated system like the Compliance & Learning Management System?

The CLMS can handle this in a number of ways. If the presentation content is electronic-media based; it can be assigned and delivered directly to the appropriate people. If the content involves overheads, videos, or live presentation/demonstrations then the content can be presented in a classroom setting—time and location notifications are handled by the CLMS. Either way the paper-based test should be imported to the CLMS and administered electronically eliminating the manual grading process and providing a central location for all test results.

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