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Document Management for Life Science

INTEGRATED MANAGEMENT SYSTEM IMPLEMENTATION PROJECT

(WHITE PAPER)



There are several ISO management system standards. Until 2012 they had slightly different requirements on the management system framework in very different document structures. At that time ISO/IEC have published a directive on how ISO management system standards shall be written. This made life much easier for organizations aiming to establish management systems that comply with multiple standards. But still, compliance with the requirements must be harmonized. The purpose of this paper is not to provide a comprehensive and detailed description of implementing a management system but to focus on integrated implementation and highlight experiences of a given integrated implementation project, providing useful hints for the reader.

The Client

Our client was a small IT service company that provides mainly IT operations and support services. They wanted to extend their certified QMS (Quality Management System) to implement an ISMS for the whole of their operations and an SMS (Service Management System) for their services in one step.

Operating the Project

The meaning of the term "integrated management system" is that multiple management subsystems are documented and operated in a single framework and common requirements are documented only once. When starting the project, our client had two reasonable requirements: integrate new management subsystems into the existing QMS documentation and have the certification audit integrated with the renewal audit of the QMS. To have an integrated audit you need a single certification body, but this has the advantage that common management system requirements are audited only once, and all the subsystems are audited in one visit.

The very first task is always to set up the implementation project. This time we had an experienced project manager with a well-founded knowledge of the business processes. We agreed on a commonly acceptable schedule, identified stakeholders, and set up communication channels.

The preference for carrying out the QMS renewal audit possibly integrated with the ISMS and SMS certification meant that we had about seven months for the project (until the QMS audit was due). It was immediately clear that this was not much time to establish two relatively complex subsystems, considering that during this time the internal audit and the management review also needed to take place. This put pressure on both the client and us.

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To control progress, we followed a somewhat different logic from the usual and a strict schedule. **As part of the gap analysis, we developed a list of documents that contained the current and planned documents as well and seemed to be practical for the organization to cover all three standard requirements.** This list was then sorted in a logical creation/update order, and these planned outputs were assigned to seven biweekly periods. This list was a live document, updated weekly, which gave both parties immediate feedback on the progress. Shorter periods wouldn't have been feasible, as it is not trivial to estimate how much time will be required to draft a given document for that particular client and we simply had no time reserves for longer periods.

Creating the Documentation

Normally a top-down approach is the best when creating management system documents. In this case however – due to the time constraints – two additional aspects had also been considered:

- Documents that required the most additional work from interested parties of the client had to be prepared first. Finalizing and approving these kept them busy while the consultant was drafting other documents.
- Preparation of certain forms had to be brought forward to take them into immediate use so that the collection of operational evidence could begin.

DACHS is always providing custom services; we are not selling pre-written management system documentation sets, as they tend to be lengthy (to support all sizes and types of organizations) and never fit perfectly. In the current project we could and had to build on the existing QMS, which clearly made the use of these document sets impossible anyway.

If an organization uses a consultant, it is important to expect the consultant to be proficient in all management system standards involved. In fact, if management subsystems are developed with the involvement of different consultants, the synergies between the standards may not be optimally exploited. The result – according to the old joke – can easily be a camel, which was originally intended to be a horse but was designed by a committee.

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Documenting the Management System

There is a logical order in which subject-specific requirements should be documented, as these are related to each other:

- If there is no quality management system, it is advisable to start with the SMS, as the requirements of the more general QMS will automatically be met. So, the establishment of the QMS can be limited to those processes that fall outside the scope of the SMS.

- In the case of an existing quality management system (and this was the situation in our present project), the QMS procedures and policies shall be reviewed and, if necessary (and typically it is), supplemented to meet all SMS requirements. While implementing the SMS, the information security–related requirements can be omitted, as these will be covered when implementing the ISMS.

- It is a good practice to leave the ISMS to the end, because by the time one starts establishing it, it has already been documented what processes need to be operated and what assets are used for them in the other subsystem(s). This is fundamental to document security controls effectively without omitting important processes and assets.

Earlier versions of ISO management system standards required the existence of a management system manual. There is no longer such a requirement, **but the traditional and in most of the cases practical approach is to have a manual for the management system framework elements.** Our client also had an ISO 9001-compliant manual that needed to be extended by the specifics of the two other standards in a single step. Due to the unified requirements, it was expected to be a pretty straightforward process, so we left it to the end of the management system establishment process. While we were putting the SMS- and the ISMS-specific requirements into the integrated management framework, we also actually did a review of the existing QMS.

The Outcome

Strictly following the original plan, we were able to work out the planned documents with no delay. After implementing a complex management system like this, where many new procedures/policies are documented and organizational practice has to comply with plenty of new requirements, it is no wonder that nonconformities will possibly be documented on the certification audit. It is not really worthwhile to plan for zero nonconformities. **An effort to ensure that the audit should not find any non-compliance at all would prolong the project, and there is no guarantee of reaching this objective.** The realistic goal is to avoid major nonconformities, which means the certificate will be issued, but corrective actions will have to be executed.

On the certification audit there were two minor nonconformities identified, so both certificates could be issued. The organization had a successful certification audit, but they know that **a management system needs to be operated and changes followed up, and there are always possibilities for improvement.**

If your organization aims to implement just an ISMS, without an existing management system framework, you can read about it in **this paper.**

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