

ISO 9001:2000 - You Might Be In Trouble If... (Part 1)

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There are some questions, the answers to which I am unsure...what exactly happened at the end of the TV-series *The Sopranos*? “Who let the dogs out”? If “it’s not about winning or losing, but how you play the game” - then why bother showing up?

On ISO 9001-related issues, there *are* answers I am sure of. Several of these relate to ways to tell if there’s going to be a problem during your next ISO 9001 audit.

I’ve decided to make a list of the first 10 of issues that I could think of - not a “Top 10” list, but just the first that come to mind. Since this is being written primarily for companies that have already achieved ISO 9001 certification, I’m leaving out some of the more obvious issues (e.g. missing the six procedures required by the ISO 9001 standard), however, most of these could still apply to an organization attempting certification for the first time.

The first 10 issues I could think of are shown below, presented in the order of the standard (their related clause is shown in parenthesis):

1. Document Control (4.2.3) - You have multiple versions (revisions) of the same document in use in the work area, or “stray” documents in use without the proper approvals and that haven’t been recorded in the system.
2. Control of Records (4.2.4) - You can’t find the records you’re looking for, or records that you need when requested. Someone has taken your records and you don’t know who and/or when. If you’re lucky enough to find the records you’re looking for, they’re covered in coffee stains, cigarette burns, and/or food.
3. Customer Focus (5.2) – You have no customer feedback collected on how you’re performing. If you receive a complaint, it’s taken care of on-the-spot and not documented. You may send out customer surveys or questionnaires, but nobody ever responds.
4. Quality Policy (5.3) - You don’t have a quality policy posted. It may have fallen off the wall, been taken down, or you may have moved to a new location and forgotten to put it back up.
5. Quality Objectives (5.4.1) - You have no quality objectives established for the current period, or you have partially developed objectives that use words like “more”, “less”, “fewer”, “better”, instead of using quantitative terms. You may have failed to meet your last objectives and didn’t take any subsequent corrective action.
6. Management Representative (5.5.2) - You don’t have a management representative. Your management representative may have quit, been fired or re-assigned. Worse yet,

you may have a management representative that doesn't know they are the management representative.

7. Management Review (5.6) - You haven't performed a management review in over a year. You may have had meetings, but you're unable to demonstrate anything that comes close to meeting the criteria of the standard.
8. Competence, Awareness and Training (6.2.2) - You can't prove the competency of the personnel performing tasks that affect product (or service) quality. You have no established job requirements, and/or you have personnel working and you can't demonstrate how they're qualified to do so.
9. Determination of Requirements related to the product (7.2.1) - You can't prove any evidence of contract review. Orders may be taken verbally without being documented, or even if taken in writing and there's no evidence of review.
10. Design Control (7.3) - Your design controls have lapsed, and now your engineers are free to indulge in their creative pursuits without constraint. Design output isn't defined, reviews are nonexistent, validation isn't performed and/or you have no working process to control design changes.

Needless to say, the above is just a sample of the problems that may exist with your Quality Management System (QMS), and it isn't intended to be an all inclusive list by any means. Since the above list only covers up to clause 7.3 of the ISO 9001 standard, there's still a lot more that will need to be addressed. You'll need to perform your own internal assessment prior to your next ISO 9001 certification audit, to identify any other concerns that may exist.

I still don't know "who let the dogs out?", but hopefully these answers will help you with your next ISO 9001 audit.

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