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5: MANAGEMENT RESPONSIBILITY
5.6: MANAGEMENT REVIEW
5.6.2 AND 5.6.3: REVIEW INPUT AND OUTPUT

This map doesn't meet the clause specification.

Suggested Process Map

Process Map showing how product realization processes and the interaction of the QMS are reviewed. Show what triggers a review (input), the review activities, how action items are assigned (output), and how changes are reviewed and approved.

In 5.6, there is a list of what should be reviewed (5.6.1, quality policy and quality objectives and 5.6.2, listed inputs), how it should be reviewed (5.6.1, assure continuing suitability, adequacy, and effectiveness of the QMS; look for improvement opportunities; look for changes to the QMS), and what the possible results should look like (5.6.3, decisions and actions related to improvement of process, improvement of product, resource needs).

The revised Conversion Checklist suggests a Management Meeting Template that includes all the items to be reviewed. The process map should address how they are reviewed (compared to baselines, compared to previous month's data, reviewed for corrective action implementation and evaluation, such as in the case of previous audits, etc.

The map also must address the results of the review--if its an improvement opportunity or change to the QMA, how is the action item assigned, tracked, and considered closed?

Basically, the map drawn here says that some unidentified person or group reviews the QMS annually by looking at some unidentified data and if the data indicates the system is effective (with an undefined standard of effectiveness) the review is over and if the data indicates the system is not effective (again with an undefined standard of effectiveness) the system is reviewed again the next year. There's no indication of what is done if the system is deemed ineffective.

If you have a procedure that details all that is done in the management review and meets the requirements of 5.6, this can stand-in for much of the detail in the process map. However, the map still needs to have more information so an auditor or registrar can at least understand the basic premise of your process. (What is the source of the data? How do you use the data to compare, contrast, and identify problems? How do you assign responsibility for analysis and improvement? How do you follow-up on action items?).

Nothing is said about suitability or adequacy (you may not have many defects because the system is too inadequate to identify them). Also missing are audit results, actions from other management reviews needing follow up, the status of preventive and corrective actions, proposed changes that could affect the QMS, the subjective aspects of customer feedback, or process efficiency and effectiveness. While this may appear to be a lot of detail, your handling of audit results will be different than what you do about SPC out of tolerance data.

If the map truly reflects your process, then the process needs rethinking to meet the standard.