AVOID FAMOUS MISTAKES WITH ISO 9001

CAVENDISH SCOTT
The Standard in Quality and Environmental Consulting Since 1985

www.CavendishScott.com

Avoid Famous Mistakes with ISO 9001

People have been making mistakes for tens of thousands of years. Since the industrial revolution, the impact of certain mistakes has grown immensely. Before the industrial revolution, a dull tool used in machining a part would likely only impact one part—since parts were made one at a time. With the advent of mass production, a dull tool used in machining could impact hundreds of parts.

ISO 9000 is written by quality professionals all over the world, professionals who have had a lot of experience with industrial mistakes and problems caused by poor control over processing. So, ISO 9000 can be viewed as a collection of situations that need to be controlled in order to avoid well-known sources of quality problems. In fact, each and every requirement of ISO 9001 is intended to promote adequate control over organizations' operations and improvement of organizations' processes.

Taking the requirements of ISO 9001 in order and treating them very generally, let's incorporate each of the requirements into the phrase: "If you don't x, you can expect quality problems." (For comedic relief, you might imagine the following list as being akin to Jeff Foxworthy's, "If you x, you might be a redneck.")

- If you don't have a system to manage quality, you can expect quality problems. In other words, if you have no systems in place to ensure quality in processing, processes will become idiosyncratic and dysfunctional. This will cause quality problems.
- If you don't have any documented methods of operations, you can expect quality problems. Word of mouth might work for a while but as time passes, so do memories of what was agreed to be the right way to do it; as product requirements become more plentiful and complicated, processes used to realize such products need to be clearly defined and process documentation (e.g., drawings) is necessary—or else you will have quality problems. Can you imagine a (legal) organization that uses no documentation whatsoever?
- If you don't control your process documentation and records, you can expect quality problems. If you have no controls over your documentation—which almost hard to

imagine—people will make mistakes. Imagine no dates or revision levels on drawings or specifications; imagine random part numbers or order numbers; imagine people finding their work instructions blowing around in the parking lot. No control over records would mean that you could not retrieve any evidence of contractual agreements, no evidence of work completed, no evidence of inspection or test results, etc. Without adequate control over documents and records, you are going to have quality problems.

- If you don't have top managements' interest in quality, you can expect quality problems. If top management doesn't drive it, don't expect autopilot to take over. If management does not provide some mechanism for communicating the importance of quality, the importance of quality will not be communicated; if management does not plan quality assurance, management is effectively planning for quality problems; if management does not periodically review performance and establish goals for improvement, performance will not improve. Without management commitment, you are going to have quality problems.
- If you don't determine and provide resources necessary to assure quality, you can expect quality problems. If incompetent human resources are involved, you will have problems. If the provided work spaces and equipment are inadequate or unreliable, you will have problems. If the work environment is such that it hinders processing or degrades product somehow, you will have problems.
- If you don't plan product realization, you can expect quality problems. Without some idea of what to make, how to make it, how to check it, and how much to produce, you can expect problems.
- If you don't understand what your customers want, you can expect quality problems. Failure to understand customer requirements will not fix itself internally during subsequent order processing. If you make promises to customers that you do not have the ability to fulfill, you will have problems—not just quality problems, but business problems.
- If you don't control the process for designing products, you can expect quality problems.

If inputs to the process are ill-defined and criteria for success are equally ill-defined, you will have design problems. If the outputs of design are not reviewed to determine their acceptability, i.e, they are not verified or validated to meet customer needs, you can expect quality problems. If you have no controls over design changes, you will have problems.

- If you don't exert some control over suppliers or supplied product, you can expect quality problems. If you use unreliable suppliers and/or you don't properly qualify and quantify product to be purchased and/or you do nothing to verify supplied product, you will have quality problems.
- If you don't plan how each order will be processed, you can expect quality problems. If you don't provide information describing the product or instructions to make the product, you will have problems. If suitable equipment is not provided to process work, you will have problems. If you don't have inspection devices and you need them to determine conformity, you are going to have problems.
- If you don't control processes resulting in product that cannot be verified to conform to requirements, you can expect quality problems. If you are building bombs or packing parachutes for a living, and you let just anyone off the street process work using whatever equipment they might be carrying, you are going to have problems. If you have no specified method for processing, you are going to have problems.
- If you don't or can't identify product you are working with, you can expect quality problems. If traceability is required and you cannot maintain it, you are going to have problems.
- If you don't notify the customer that you smashed, lost, or otherwise ruined product they supplied to you, you can expect quality problems—at the very least dissatisfied customers.
- If you don't make efforts to preserve product during processing, storage, and transport, you can expect quality problems. If you ruin product while working with it, allow it to

spoil during storage, or fail to package it properly for shipment, you are going to have problems.

- If you don't establish a par for processing performance, you can expect quality problems. Without measures revealing how well you are performing, you will not know how well you are performing. If you don't know how satisfied your customers are, you don't know how well you are performing; if you don't know the degree to which working practice complies with established methods, you don't know how well you are performing; if you don't establish a par for processing and analyze actual performance against par, you don't know how well you are performing; if you don't measure or monitor your product to determine if it meets requirements, you don't know how well you are performing. In this latter case, you don't know if your product conforms to requirements, which will cause quality problems every time.
- If you don't control nonconforming product, you can expect quality problems. If you continue to add value to product that doesn't conform to requirement in the first place, or if you ship nonconforming product to customers, you can expect big problems.
- If you don't analyze the measurement data you are collecting, you can expect quality problems. Unanalyzed data is not worth collecting.
- If you don't improve upon what you do, you can expect quality problems. As tolerances become tighter and competition grows stiffer, improvement must be a permanent objective of any process—or else you will have problems.
- If you don't take actions to eliminate the root causes of your problems, you can expect quality problems. If you simply correct errors and go on, you can expect the same errors to repeat themselves—resulting in the same old problems.
- If you don't take actions to address potential problems, you can expect quality problems. If you don't avoid them, you will experience them.