

“Speaking Out”

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Francis Lamm holds an A.A.S. in Electronic Engineering Technology from the Central Technical Institute of Electronics and the American Society for Quality has certified him as a Quality Manager. Mr. Lamm brings over forty-five years of experience to the KAVON team. In that time, he has achieved countless benefits for his clients, including material review and scrap reduction programs for clients. This efficiency has helped them save over \$250,000. Furthermore, he has lead countless clients to ISO 9001:2000 and ISO 13485 certification. He brings the expertise FDA current good manufacturing programs (CGMP) and Quality System Regulations, among many other things, to the KAVON team.



DOCUMENTS

Work Instruction Guidelines

By Francis Lamm

KAVON International, Inc. has assisted and trained hundreds of various sized companies in developing and implementing formal Quality Management Systems (QMS) that meet and/or exceed requirements of the major domestic and international quality standards. These include ISO 9001, AS 9100, ISO/TS 16949, ISO 13485, and the US FDA Good Manufacturing Practices for medical devices.

One of the areas of confusion for medium and mid-sized companies appears to be determining the needed number, content and format for Work Instructions (WI). By definition, a work instruction is a specific guidance or step-by-step instruction on how to perform a specific job task, procedure and/or job function. A work instruction is usually written when a process is too involved or complex to be made part of a general operating or process procedure.

The complexity of a particular company's products and processes also help to determine when and where detailed work instructions are needed in addition to the process procedures in use. Typically, many organizations develop and utilize work instructions for the following purposes:

- as a training instruction for new and transferred employees
- to define and clarify equipment and tools needed, and the sequence on how a job or process must be performed
- to reduce the possibility of mistakes and inconsistencies, generally in a production setting
- to provide a point of reference for jobs or tasks that are not often done over lengthy periods of time
- to provide a basis for reviewing activity if product or process deficiencies and product nonconformances occur. Relevant work instructions can be revised and new methods defined and utilized under document control guidelines to prevent the problem(s) from recurring
- to ensure that procedures and work instructions are clear and concise,

and complement each other

Many organizations tend to overkill the perceived need and develop way too many work instructions for every process. Therefore, organizations should use caution when considering the number and use of work instructions. Often times, repetitive type work instructions are not always necessary when their content is adequately covered in related operating documents, general procedures, or by production equipment manufacturers. This is a common mistake in dozens of organizations, but it can be avoided by knowledgeable, experienced individuals reviewing the needs for existing formal written WIs against other available documentation with a goal to reducing unnecessary or duplicated documentation whenever possible. Referring to the WI definition above (para 2), the use of job routings, flowcharts, photos; actual sample utilization and customer specifications are accepted examples where additional formal WIs may not be necessary. For measurement and production equipment operation, calibration and maintenance, the manufacturer's information and manuals provided usually precludes the need for separate individual work instructions. These should be recorded and brought under the document control system.

Generally, depending on the size of the organization, engineering, supervisory and experienced workers responsible for doing the work review a process in depth, determine the best method(s) to do it and, if and when required, draft the appropriate work instructions in the required format. This can be done on an individual basis or as a team effort. If it is determined there are a number of ways of doing the same process, an acceptable middle ground should be sought to find the best approach that results in meeting the required end results.

It is generally anticipated that most organizations will hire people with some education and related experience specific to the job requirements. The cardinal rule is to make and keep work instructions as simple as possible, with the worker and the task at hand in mind at all times. Work instructions must be easy, understandable and appropriate to the process and the organization's resources.

It is a regulatory requirement that work instructions follow a standardized format and reference procedures and work routings. Procedures and routings must also reference the applicable work instructions as well, and if applicable, the quality standard(s), internal or customer specifications, drawings, etc.

Another useful tool in finalizing drafts of work instructions (or any other type procedure) before formal release for general use, is to test them out by "volunteering" various selected personnel who are not directly involved in the particular job process. Have the volunteers perform the job to the WI, monitor the activities and request their inputs and comments. Review the feedback and evaluate the resulting job for conformity to specifications. As required, revise and repeat the evaluation/try-out until the work instruction can be finalized and released into the document system for general use.

*If your organization needs any assistance writing documents to support your Quality management System, give KAVON International, Inc. a call at 888-637-9598, and let our **Trusted Advisors** help you get started.*

