

SAMPLE PAGES

FOR

ISO 13485:2016
POCKET GUIDE

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WORK ENVIRONMENT AND CONTAMINATION CONTROL

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Work environment



In this clause, the standard states that requirements for the work environment must be provided. Monitoring and control of the work environment is needed when the possible variation can affect product quality.

Further related requirements include:

- When personnel, product and work environment interact in a way that safety and performance are at risk, requirements and procedures for the following are necessary:
 - health of personnel.
 - cleanliness of personnel.
 - clothing of personnel.
- Personnel temporarily assigned to work under special environmental conditions must be trained or monitored by someone trained. (6.4.1)

Other issues of the work environment that could be addressed include:

- considerations related to safety and health (e.g. the available means to simultaneously wear corrective lenses and eye protection should not be so awkward as to cause an individual to choose one over the other)
- the methods for doing work (work cells or teams could diminish chances for errors)
- ethics on the job (defining ethical behavior requirements can discourage individuals from concealing the use of de-

- the conditions in and around the work area (comfortable workers in a clean and clutter free environment make fewer mistakes).

Management's Role – Auditors will be expecting that the requirements for work environment have been clarified and that practice reflects everyone's compliance with the statements of clarification. That practice, of course, will be derived from examples set by management. If your company has defined work environment issues as bulleted above, your diligence in adhering to safety rules, functioning as team players, maintaining professional work habits and a reasonably neat personal work space will not go unnoticed by other employees.

There are other subtle ways in which managers can contribute to better quality. We all have heard of managers who only want to hear good news. "There were no defects....., all shipments were on time, etc." Employees reluctant to deliver bad news could fail to identify defects because of the way they perceive messages transmitted by management. Be on guard against sending messages that can negatively affect the quality of products or services.

Each Employee's Role – Your role in work environment related policy issues is to understand and abide by the policy. In your effort to do your best work, you may be motivated to ignore an issue related to safety and health. Take the time to do what is necessary so that there is no compromise to health and safety or quality. The methods provided should be embraced and a positive effort should be put forth to make them work. If you are asked to work in teams, share your knowledge and listen well so that the quality of product or service is optimized. Always be very aware of the company policy for ethical behavior. Resist

crossing the line regardless of what you think you may have heard. Strive to maintain the area that you work in, especially your own personal space, as neat as possible in order to avoid conditions that could contribute to defects

IS013485:2016 has been much more definitive than other standards about work environment requirements. This fact enables auditors to write undeniable nonconformities. Auditors will look closely for compliance to the yellow highlighted requirements in the discussion on sub-clause 6.4.1.

CAUTION

**PRODUCT
QUARANTINE
AREA**

Contamination control

Obviously, medical devices, especially those that are implantable, need to be provided to end users with no contamination. To that end, the standard has the following requirements:

- When product is or is suspected to be contaminated, documentation must be provided for contamination control as appropriate. That control to avoid unwanted particulates, harmful microorganisms, etc. could include:
 - quarantine of product
 - decontamination of product
 - other appropriate disposition of product, etc.
- Maintenance of this control must be sustained throughout production and packaging. (6.4.2)

Management's Role – Auditors will be expecting that the requirements for contamination control have been clarified and that practice reflects everyone's compliance with the statements of clarification. Managers should always be reluctant to economize on budget line items earmarked for contamination control. Constantly show all employees that contamination

avoidance and decontamination processes are extremely important.

Each Employee's Role – Your role with regard to contamination control related QMS requirements is to understand and abide by them. Do not compromise contamination safeguards. Shortcutting to meet schedule is risky enough that the schedule is more likely to be harmed than helped. Take the time to do what is necessary so that uncontaminated product or service is routine.