

Name: Eyad Salman  
Course: QAS515 - Human Factors in Quality Assurance  
Topic: Impact of ISO9000 on human factors in quality system environment.  
Date: 7/16/03

## Impact of ISO9000 on human factors in quality system environment.

Quality in a pharmaceutical environment, or others is a characteristic of those products and services which; (a) meet or exceed the express or implied functional, delivery, and value expectations of the customer, (b) meet or exceed statutory, social, or regulatory requirements, and (c) provide cost and performance benefit to the customer in the execution of his business.

There are few studies concerning effects following the implementation of the quality standard ISO 9000 regarding working conditions. How do the process characteristics relate to working conditions and other desired effects?.

Quality can be assured through a process of continuous improvement which is an integral part of all functional disciplines, beginning at the earliest stages of product development and continuing through final installation and use by the customer. Assessments, preventive actions, effective feedback, and timely corrective actions are essential elements of continuous quality improvement activities. Continuous improvement is a core theme in ISO 9000:2000, and is inherent in the model's structure. Continually improving defect rates, with consequent increased customer satisfaction, is a core value of Deming and total quality management (TQM). Although many, including the authors of this article, believe that continual improvement was always implied in ISO 9000, continual improvement is now a clearly defined requirement. In regards to resource management, the 1994 standard contained a paragraph that required management to provide all necessary resources. These provisions are expanded in the 2000 revision.

Every employee is responsible for quality in the performance of his/her work, and will measure his/her performance against established quality objectives. The resources, tools, and training required to meet these objective have been provided, and are periodically assessed for effectiveness. How those resources and tools and training provided is the heart and the focus of human factors and their impact on the quality of the work.

Ergonomics has a strong human focus and success lies in integrating the effort to the goals of business. It is suggested in this that ergonomics has a strong contribution to business in any continuous improvement effort. This strength lies in the focus on the human as an employee or participant in business ventures and as a customer or a recipient of the product or service. A customer satisfaction model is suggested that pulls together customer and employee oriented quality initiatives that are occurring across industries. The various initiatives of National Quality Awards and productivity improvements through the Lean Enterprise focus have made major changes in business processes. For the human factors and ergonomics message to be part of these current business trends it must be phrased in the language of business.

Name: Eyad Salman  
Course: QAS515 - Human Factors in Quality Assurance  
Topic: Impact of ISO9000 on human factors in quality system environment.  
Date: 7/16/03

The reality of business is that it must make a profit. Although ergonomics has a strong human focus, success lies in integrating the effort to the goals of business. Recently, many studies have occurred which have emphasized ergonomics as good economics. From a dollar and cents vantage point, a strong case can be made for justifying ergonomics improvements. ISO 9001:2000 has brought some of those core quality aspects of the system that include some of the need to pay attention to human factors in the workplace and work environment and brought greater indirect attention to ergonomics by including a Work Environment clause that points out the importance of human factors on the quality of work produced. It is suggested ISO 9001:2000 that ergonomics has a strong contribution to business in any continuous improvement effort that is pursued. This strength lies in the focus on the human as an employee or participant in business ventures and as a customer or a recipient of the product or service.

ISO 9001:2000 which has a focus on human resources requires that personnel be "competent" rather than "qualified" and states that competence may be based on appropriate education, training, skills and experience. These changes are described under section 6.2.2. Competence, awareness and training requirement difference which includes five requirements in this section, and those requirements are a) determine the necessary competence for personnel performing work affecting product quality, b) provide training or take other actions to satisfy these needs, and e) maintain appropriate records of education, training, skills and experience. The two new requirements are c) evaluate the effectiveness of the actions taken, and d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

The intent of this section is to ensure that properly skilled people are performing the activities as defined in the quality system. Evidence of the effectiveness of the training or other means of providing competent employees must be available. Employees must be aware of the impact that they have on the overall quality system. The training of people and its effect on the quality system is invaluable, when people are trained. Design factors, which contribute to human errors, include aspects of the system hardware, software, procedures, environment and training, which affect human error likelihood. Design factors encompass such aspects of the system as equipment design features; information characteristics (availability, access, readability, currency, accuracy and meaningfulness); workspace arrangement; procedures and processes; environments; and training. Together the situational factors and the design factors constitute the human-systems interfaces. Hence training is critical to insure that those factors are covered, and to overall produce higher quality of work (<http://carlow.com/hpresearch.html>).

Name: Eyad Salman

Course: QAS515 - Human Factors in Quality Assurance

Topic: Impact of ISO9000 on human factors in quality system environment.

Date: 7/16/03

This aspect of training people is critical, by training personnel, you are allowing them to perform jobs at a higher level and by providing training you are giving them a set of new capabilities to perform the job by which you are also reducing overloading, the concept of overloading is critical to human factors because when someone is overloaded, they are not going to perform the best job, and may result with poor quality of work, hence effecting the overall health of the person performing the job. Training is essential to give people the motivation to performs the job, and making them feel valuable and stay motivate because they are better equipped to perform the tasks.

Another concept mentioned in the ISO standard is found in Clause 6.4, Work Environment Requirement Difference, this requirement emphasizes the organization's responsibility to manage the work environment needed to achieve conformity to product requirements. Which means that the organization must identify and manage all those factors of the work environment that are needed to supply a conforming product. These factors may include among others:

- **Human Factors**

- Creative work methods;
- Opportunities for greater involvement of personnel;
- Safety rules and guidance;
- **Ergonomics**;
- Special facilities for people.

- **Physical Factors**

- Heat; Noise; Light; Hygiene; Humidity; Cleanliness; Vibration; Pollution; Airflow.

This requirement has just touched a great deal on the basic concept of ergonomics, and Human factors. As mentioned above, in order to meet its objectives, the organization should ensure that the technical, administrative, and human factors affecting the quality of its products will be under control, whether hardware, software, processed materials, or services. All such control should be oriented towards the reduction, elimination, and, most importantly, prevention of quality nonconformities.

This requirement relates only to those factors, which need to be, managed in order to achieve conforming products and does not relate to any legislative requirements related to Occupational Health and Safety, protection of the environment etc, except as required by section 7.2. Obviously, different types of businesses and industry sectors may vary dramatically with regard to an acceptable work environment, and so it is the organization's management who determines the adequacy of the work environment provided by an organization. A training provider may need to ensure the training area is adequately lighted and contains appropriate seating and visual aid capabilities, some manufacturing facilities may require "clean rooms" or humidity controlled areas, companies handling items easily damaged by electrostatic discharge may require special

Name: Eyad Salman  
Course: QAS515 - Human Factors in Quality Assurance  
Topic: Impact of ISO9000 on human factors in quality system environment.  
Date: 7/16/03

flooring or equipment, and chemical storage areas may require special protective barriers.

As a further example, an employee might perform a particular function that required repetitive wrist movements (e.g., tightening a screw). As the day wore on, it is possible that the overuse of the wrist could result in poorly torqued screws resulting in a possible quality defect. The company should identify such a situation and provide a means of eliminating the potential defect (e.g., air-driven screwdrivers). Evidence could consist of records of decreased quality defects and/or medical problems related to that activity.

The key to achieving continuous improvement is to blend together work processes with the improvement effort. Improvement cannot be an add-on to normal process work, but must be one in the same (<http://www-sv.cict.fr/cotcos/pjs/TheoreticalApproaches/CogErgonomics/CogErgpaperBannon.htm>). This is the thrust of the ISO 9000 Quality Systems approach. This is also the key to bringing together ergonomics and quality. Ergonomics requires the same management focus and problem solving techniques. Quality goals can be realized by using the essentials of ergonomics. In fact, ergonomics puts in human terms many of the quality objectives. For example, task analysis of a manufacturing process will provide input to the design function in concurrent engineering.

Ergonomics with its emphasis on human capability meets the needs of the worker who is the essential resource for successfully implementing continuous improvement in any organization. This involvement at the working level has set a habit pattern that is the foundation for continuous improvement of all company processes. These foundations will ensure the processes within the company achieve quality results, both in the goals that each person within the company has, and in the verification by customers. The future changes to the ISO 9000 standard will help organizations establish continuous improvement management processes similar to the Baldrige Award criteria (Mroz, 1998).

Human factors and ergonomics professionals have the potential for major contribution to the customer satisfaction objectives of business. This is to say that good business practices must incorporate human factors and ergonomics concepts. In order for this message to be made known outside of the meeting rooms of ergonomics professionals, it must be presented as a vital part of strategic planning and as a major resource for achieving customer satisfaction continuous improvement initiatives. For acceptance of the link between ergonomics and business management, the target audiences must be chief executives of business and their organizations. The various initiatives of National Quality Awards and productivity improvements through the Lean Enterprise focus have made major changes in business processes. For the human factors and ergonomics message to be part of these current business trends it must be phrased in the language of business.

Name: Eyad Salman  
Course: QAS515 - Human Factors in Quality Assurance  
Topic: Impact of ISO9000 on human factors in quality system environment.  
Date: 7/16/03

## REFERENCES

K. H. E. Kroemer, H. B. Kroemer, K. E. Kroemer-Elbert: Ergonomics how to design for ease and efficiency, second edition, Prentice Hall, NJ, 2002.

Booher, H, 1990, *MANPRINT: An Approach to Systems Integration*, Van Nostrand Reinhold, NY.

Mroz, J, 1998, ISO 9000 in 2000, *Quality Digest*, October, 1998

Robert W. Peach, Robert Peach : The ISO 9000 Handbook Fourth Edition

ISO 9001:2000 Guidelines and standard.