

## QUALITY OF CONTRACT RESEARCH

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### INTRODUCTION

Quality is playing an increasing role in production and manufacturing. With world-wide trade it becomes essential to have well defined quality standards for products, in particular when products are produced in cheap labour countries. Certainly in Europe, with a free market between countries with a differing cultural and economic background, standards are a necessity. In order to cater for this need CEN (Centre European de Normalisation) is rapidly producing standards. Groups of interest are working in Technical Committees (TC) on protection of the eyes (TC 85), skin (TC 122), head (TC 158), hearing (TC 159), against falling (TC 160), of the foot (TC 161) and on protective clothing (TC 162). Where ISO standards exist, these are adopted. ISO has currently TC 94 on protective clothing and equipment and TC 159 on ergonomics. Companies and military will submit products to test agencies for certification. On their turn the agencies need to prove that they are qualified to carry out the test.

This whole procedure is known as output control. However, it is recognized more and more that output control is an insufficient means to assure quality. It is expensive to test all products and moreover, in case of failures the production process has to be improved by a cumbersome feedback procedure. Therefore increasing emphasis is put on the quality of the production process itself: when the process is well controlled the products cannot be wrong. This opens up ways for complete restructuring of production since products that are made under such conditions can be assembled in larger systems without intake inspection or stock supply. This is known as just in time delivery.

Laboratory work, such as testing and research will inevitably be forced to work also with a quality system. An increasing number of clients already require so. The question is whether the experience in manufacturing can be used for laboratory work. A laboratory also produces products but their nature is different from factory products: there is less repetition of the same activity and the product is the work of individuals. Another aspect is that there is no standard test for the quality of a research report.

These aspects suggest that a quality system for a laboratory should focus on the internal procedure rather than on output control. It should also be recognized that the meaning of the word quality depends on the purpose of the laboratory. For TNO, for instance, quality is not the most detailed or the cheapest answer to a problem, but doing what was promised.

### QUALITY STANDARDS

The reference for quality is currently the ISO 9000 series of documents, dealing with guidelines for selection and use, and quality assurance in various environments. ISO 8402 (1) deals with vocabulary and the probably most relevant document for our purpose is ISO 9004 (2), explaining quality management systems. This paper is expanding on the thought that 'the quality system should be organized in such a way that adequate and continuous control is exercised over all activities affecting quality'. The useful aspects are:

4 responsibilities	17 documentation
5 quality systems	18 personnel
6 quality related costs	19 liability
13 test equipment	20 statistical methods
15 corrective actions	

In Good Laboratory Practice (GLP, set up by OESO) or SterLab (\*L, Dutch) implementations heavy emphasis is laid on documentation and responsibilities. For every action, for all data, for all corrections of data, for all use of equipment or software the responsible persons must sign with exact time and date. Also the procedures in the lab, the required qualifications of the staff following the procedures and the management checking the use of the procedures are under strict regulation. Needless to say that this is a heavy financial and operational burden on the lab. Quality system guidelines are completely missing, however, when it comes down to such essential features of research as experimental design, knowledge of literature and statement of falsifiable hypotheses. Attempts are being made to set up a dedicated

standard for research, but this may take a while.

#### QUALITY PROBLEMS OF RESEARCH

A recent investigation to uncover the most frequent mistakes in human factors research (3) shows that some of the typical problems are:

- a- wrong or during the process modified research question
- b- too late reading of literature
- c- exceeding time and budget
- d- insufficient consultation of other experts
- e- problems with internal communication
- f- tunnel vision on investigated problem
- g- inconsistent report and erroneous statistics
- h- unjustified conclusions

Collecting the referee comments on the contributions to this conference (output control) some of these points seem typical for environmental ergonomics work as well. Not all of the above problems were available for observation but frequent problems were b, f, g, and h.

Most of these problems are not prevented by a quality system as described by the standard. The standard and its implementations are useful for testing, where a standard test is repeatedly carried out, but not for unique investigations. However, the principle of control over the process is still applicable.

Another point of consideration is that working under GLP or \*L is an invitation to bureaucracy and enhances the costs considerably. The general comment is that at least part of the costs are returned as less losses due to unnecessary or wrong work, but it is not likely that for research this will provide full compensation. Maybe contractors will be willing to pay more in the future for work under a quality system.

#### QUALITY SYSTEM FOR LABORATORIES

Most contract research organizations have a long history in project management, calibration and output control. There is currently a shift towards process control systems, tailored to the type of work done. The existing procedures are useful as parts of such a new quality system. More emphasis should be laid on the planning phase. Some of the additional topics that should be detailed are:

- problem analysis to extract investigatable research questions and falsifiable hypotheses
- the profit of client and organization from the result of the investigation
- cooperation with other institutes under the same quality system
- predictive analysis of the power of the experimental design
- early documentation of the outcome of consultation and literature analysis
- reproducible data analysis, statistical analysis and filing with standard software
- standard protocols for human use and safety
- demonstration that the problem was solved

The aim of the quality system might -at least initially- be more modest than 'adequate and continuous control'. It is probably not unwise to aim for the 'skilled production of good products'. This means that the complexity of the quality system will be limited to a level, justified by the profits.

#### CONCLUSIONS

Working under a quality system will rapidly become a necessity for research labs. The current standards are not suitable for application but the concept of production process control, as alternative to output control is very useful. By a quality system with limited administrative overhead it must be possible to overcome the most frequently made mistakes in human factors research.

#### REFERENCES

- 1 ISO 8402, Quality - Vocabulary
- 2 ISO 9004, Quality management and quality system elements - Guidelines
- 3 unpublished, performed by staff of the TNO-Institute for Perception