ISO 9001:2000 applied to a research oncology laboratory: which problems? The experience of National Cancer Institute-Bari

Quality assurance of health care services has become a crucial issue in the last years.

Compliance with UNI EN ISO 9001:2000 standard was adopted by many oncology institutes worldwide, with the aim to provide high-quality patient-focused performances [1].

Here we provide a description of implementation of a Quality Management Systems carried out in the Clinical and Experimental Oncology Laboratory (CEOL) of the National Cancer Institute of Bari, drawing attention to critical points of 'Certification Process' in a research laboratory where procedures and results are rapidly changing and hardly standardizable.

The whole process lasted ~15 months and was realized with the advice and the consulting support of TQM Consult S.p.A. (Bari, Italy). The commitment was based on ~30 men per day among operating consultancy, training and back-office activity; furthermore, a dedicated permanent team, consisting of a project manager, manager consultants and supervision of a quality manager, was involved at all levels of the organization.

The declared end points of quality certification for CEOL have been the achievement of several key objectives.

1 The realization of a ‘quality path’ inside the organization.
2 The realization of a common platform of ‘knowledge management’ among all managers.
3 The creation of a ‘common team spirit’ based on team job and on the direct participation of their results.
4 The development of special attention to customer expectations with special regards to the scientific community.
5 The development of interffunctional activities through a process approach.

The process approach, characteristic of ISO 9001, establishes two important goals: the satisfaction of all stakeholders and continuous improvement [2]. It has been necessary to identify and analyze the ‘primary’ processes of the laboratory and those defined ‘secondary’ or ‘of support’, defining for each process the appropriate procedures, the involved functions and the competences. Contextual to the described activities, the involvement of the internal staff by means of training and information had an unavoidable role in the whole process.

For each process, opportune ‘quality indicators’, which are ‘objectively measurable’ and useful in monitoring the course of the processes, controlling the activities and promoting improvement actions, have been identified. The concept of ‘measurement’ is a carrying element of the Quality Management Systems, clearly expressed in Clause 8 of the UNI EN ISO 9001:2000 standard, ‘Measurements, analysis and improvement’ [3].

A peculiarity of the process of certification of a research laboratory with specific competences in oncological field is represented by the setup of ‘consolidated’ indicators in innovative processes. In fact, considering the experimental attitude of the laboratory, the choice of ‘indicators of efficiency’ for procedures such as those experimental ones, turned out rather delicate. An important contribution in such sense is given by the use of ‘temporal’ indicators able to measure and to estimate the time of execution of the different steps of a research project and indicators able to evaluate the results and the data obtained in order to verify how much these fit with what is expected or planned.

According to the requirements given in Clause 7.3 ‘Design and Development’, the organization has to determine design stages, review, verify and validate activities that are appropriate to each design. These activities are an important tool to control the design and the development of product and also to evaluate and ensure that the ‘design outputs’ have met the ‘design inputs requirements’. The research project outputs do not always meet the input requirements. In fact, sometimes the researcher on the basis of preliminary results can modify the design of project in terms of activities, methods and biological models. In conformity to ISO 9001:2000, the researcher can identify design changes and review, verify and validate them appropriately before their application.

A second critical point was to characterize ‘the Customer’ of an experimental laboratory and the right indicators for monitoring his ‘satisfaction’, as requested by the standard [4]. An experimental laboratory is mainly committed to producing scientific turns out (the product) to be qualitatively valued (efficiency indicators) by the national and international scientific community (the customer). As ‘product’, we must also include the research projects coming or financed by third-parties’ subjects, either institutional or extrainstitutional, private or public, national or international, etc.
Finding ‘objective’ indicators for the evaluation the quality of scientific research is under continuous debate. Useful indicators for the ‘quality’ estimation of the project plan process can be represented, for instance, by the number of the approved and financed research projects and by indicators for the estimation of the total impact of the projects on the production and scientific spreading (impact factor). Even though impact factor has been largely criticized, it is still the more reliable measure of the citations to science and social science journals. It is used as a proxy for the importance of a journal to its field and is used, largely, by scientific community to ‘evaluate’ the researcher.

The use of impact factor alone as indicator of quality is not adequate. As the procedure ‘Customer Satisfaction’ describes, a particular consideration has the comment expressed by a qualified scientist on publication (peer review).

The outcome of the planned activities was the achievement of the UNI EN ISO 9001:2000 certification by a third-party Sincert-accredited body/registrar DNV (Det Norske Veritas) on October 2006; field of application of the certificate: ‘Design and provision of clinical laboratory research activities, experimental development and medical and scientific spreading in the oncological fields of Applied Molecular Biology, Functional Biomorphology and Preclinical and Clinical Pharmacology. Management of Oncological Biobank.’

The certification of the CEOL according to ISO 9001:2000 standard allowed us to constitute a continuous improvement of the research program’s effectiveness, of the operating activities efficiency and of the resource management optimization, both technical and human.

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