Implementation of a Quality Management System according to the UNE-UN-ISO 9001:2008 standard in a Nuclear Medicine Department

V.M. Poblete García a, M.P. Talavera Rubio a, A. Palomar Muñoz a, J.P. Pilkington Woll a, J.M. Cordero García a, A.M. García Vicente a, M. Bellón Guardia a, B. González García a, T. Cañuelo Merino b, A. Núñez García a, V. Peiró Valgañón a, A.M. Soriano Castrejón a

a Servicios de Medicina Nuclear, Hospital General Universitario de Ciudad Real, Ciudad Real, Spain
b Servicios de Radiodiagnóstico, Hospital General Universitario de Ciudad Real, Ciudad Real, Spain

Objective: To describe the process of implementing a Quality Management System according to UNE-EN-ISO 9001:2008 standard in a Nuclear Medicine Department.

Material and method: In February 2008, the committee on internal quality of the department was established, naming a responsible physician. The general operating plan was drawn up, following the requirements established by the ISO 9001:2008 standard. It defined the scope of the standard, defining, preparing and transcribing the various activities of our department. Four training sessions were carried out.

Results: A total of nine general and two specific procedures were documented in which all the activities performed in our department were included. Personnel records of each worker were created, including their profiles and training plan. A record of the equipment and service providers was created, as well as issues with the latter. Satisfaction surveys were obtained from external (patients) and internal customers (faculty applicants). Targets for improvement and activity markers were established. Two audits were performed to complete the process, one internal and one external. The department was accredited in April 2010.

Conclusion: The quality accreditation process is a tool that requires reflection on how we do things and how they can be improved. It makes it possible to measure what we do, to analyze and introduce improvement measures, and therefore, to achieve a higher level of quality in the service we provide our customers. The involvement of the department workers with a commitment to team performance was essential.

© 2011 Elsevier España, S.L. y SEMNIM. All rights reserved.
Introduction

Interest in the quality of health care as it is currently conceived initiated in the last decades of the 20th century. The origin of this interest arose from analysis of the variability observed in the rates of mortality of hospitalized patients. Since then, its development has been unyielding with regard to focus as well as method and reach and involves all health care professionals.

The interest generated by this subject in Spain has shown an important increase in the last years, first within the private health care setting followed by that in the public system. The main objective of Quality Management Systems (QMS) is to reduce the variability in clinical practice at both the time of establishing an indication and at the time of its practice and in the subsequent processes thereof. To do this the availability of methods allowing the establishment of comparisons between the results obtained and the different services rendered as well as the different centers and even different countries has become increasingly more essential.

The ISO 9001:2000 norms emerged as a result of the need to provide the industry with patterns which may be clear, objective references for the production of machinery at an international level. The ISO 9000 norms are a family of standards which describes structures, models, specifications and guidelines related to the QMS. The ultimate aim of these standards is to satisfy both external and internal clients as well as employees, suppliers etc. It is defined as the certification of the process by which an authorized company certifies the fulfillment of the norms defined as the International Norms of Standardization (ISO).

Similar to other models applied within the health care setting such as the EFQM (European Foundation for Quality Management), this model is based on the following principles: orientation to results and the client, leadership and consistency in the achievement of objectives, management by processes and events, implication and participation of personnel, learning and continuous improvement, collaboration and social responsibility. The recommendations of the EFQM model of the ISO have only recently been introduced into the health care system, although in both cases, interesting experiences are of note.\textsuperscript{3-5}

The interest of health care professionals and patients is that the health care provided by the professionals is effective (has a positive effect on the levels of health of the latter), efficient (this effect should be achieved at the lowest possible cost), acceptable (for both the patient as the receptor and in the opinion of the remainder of the profession), accessible (for the patient in terms of distance, waiting, costs, etc.), evaluated as useful by the patients themselves (i.e. in terms of improvement in quality of life) and should be based on evidence, that is, provided on the basis of existing knowledge and not only intuition.

The availability of tools to allow measurement, evaluation and improvement in the health care provided on a daily basis is therefore necessary. It is essential to define clear criteria as to how practice should be acceptable, to be able to measure what is done, with indicators and to define standards of quality (grade of acceptable fulfillment). Monitoring of indicators constitutes a key piece in the programs of continuous improvement in quality.\textsuperscript{6}

The aim of the present article is to describe the process of implementation of a QMS in our department of Nuclear Medicine according to the ISO 9001:2008 norms, with special emphasis on possible conflictive points in order to be of use to other departments which, similar to our department, decide to establish this objective.

Material and method

In February 2009 the QMS was established in our department according to the UNE-EN-ISO 9001:2008 norms. The process of certification was achieved together with 2 other departments in our hospital, those of Radiophysics and Radiologic Protection and Radiodiagnostics, obtaining a single certification including the 3 departments. To do this the department hired a consulting company. The head of the department named a physician to be responsible for quality to direct the process. In addition, the Internal Commission of Department Quality (CIC) was created and was integrated by the head of the department and the person responsible for quality as well as the nursing supervisor and a representative from each section of the department: one nurse, a technical specialist in Nuclear Medicine, an administrative auxiliary and a technical quality collaborator which serve as a unifying link between the 3 departments implementing the QMS.

Meetings among the consulting company, the person responsible for quality and the head of the department were held fortnightly. All the different procedures of department activities as well as the way these are carried out were developed during these meetings. These procedures were then explained in the CIC where they were modified and adapted as appropriate according to the consensus of all the attendees, while also being the vehicle of information for the remaining members of the department.

Once the procedures had been created and approved, the period of implementation was initiated. In addition to adapting and adjusting the activity of the department to that identified in the procedures, format files and registers were created during this period in which all the information of the department was adequately and accessibly identified. One essential point within the documentation of the system was the preparation of the Manual of Quality.

Prior to the implementation, formative sessions were carried out in relation to both the ISO 9001:2008 norms and the repercussion foreseen on department activity.

Once the system had been implemented an internal or preaudit audit was undertaken in which the situation was verified. Thereafter, the last adjustments were made according to the observations or lack of approval declared. To do this, the necessary corrective actions were carried out. Prior to the external or definitive audit a revision of the system by the management was necessary. The management made a general evaluation of the situation of the department to thereafter present its approval to the general management of the hospital as required by the norms. Lastly, the system was submitted to an external or definitive audit which was done in 2 phases and was performed by a expert auditor of AENOR. All the phases of the implementation process over time are shown in Fig. 1.

Results

The Manual of Quality of the Department of Nuclear Medicine was drawn up. This document is the basis of the system of quality which specifies the mission and vision of the department as well as the policy of quality and the objectives to be achieved for the fulfillment of this policy.

A total of 9 general procedures and another 2 specific procedures were established in which all the activity of the department was regulated. To do this, all the processes covered in the QMS had to be recognized and identified (Table 1).

In each of the procedures a format file was created to be applied in each area as was a file of registers generated by these formats:

Procedure 1 (Management of the documentation and registers) describes the way of managing all the documentation of the department. The list of the laws and norms to be applied in our setting are included within the registers included in this procedure in addition to all the internal documents usually used.

Procedure 2 (Revision of the System) includes the norms of the global evaluation of the system of quality itself for correct
Decision-making on QMS implementation

Design the general working plan

Design the plan in detail

Initial work

Implanted QMS

Introduction of adjustments and corrections

Final adjustments

Certificate delivery

Implementation of Quality Management System

Regular review of progress

Pre-audit verification

Initial audit validation

Fig. 1. General scheme of the different phases of implementation of a Quality Management System over time.

Table 1
Processes constituting the Quality Management System of the Department of Nuclear Medicine.

<table>
<thead>
<tr>
<th>Process</th>
<th>Entry</th>
<th>Exit</th>
<th>Proprietor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documentation of the system</td>
<td>Need to document a process</td>
<td>Process documented</td>
<td>Responsible for quality</td>
</tr>
<tr>
<td>Data analysis</td>
<td>Taking of data of indexes</td>
<td>Follow up reports</td>
<td>Heads of departments</td>
</tr>
<tr>
<td>Revision by the management</td>
<td>Data of system follow up</td>
<td>Report of system revision by the management</td>
<td>Heads of departments</td>
</tr>
<tr>
<td>Continuous improvement</td>
<td>Analysis of complaints, ca, nc, pa, reports of follow up of indexes and revision report</td>
<td>Decisions established as part of the system</td>
<td>Heads of departments</td>
</tr>
<tr>
<td>Diagnosis in Nuclear Medicine</td>
<td>Request for test by physician</td>
<td>Test report in the hands of the petitioning physician</td>
<td>Head of NM Department</td>
</tr>
<tr>
<td>Treatment in Nuclear Medicine</td>
<td>Request for treatment by physician</td>
<td>Patient treated</td>
<td>Head of NM Department</td>
</tr>
<tr>
<td>Control of equipment</td>
<td>Information of equipment installation</td>
<td>Equipment controlled</td>
<td>Head of RP Department</td>
</tr>
<tr>
<td>Homologation of suppliers</td>
<td>Offer from supplier</td>
<td>Homologated supplier</td>
<td>Hospital management</td>
</tr>
<tr>
<td>Purchasing</td>
<td>Detection of need for purchase</td>
<td>Receipt of product</td>
<td>Supervisor</td>
</tr>
<tr>
<td>Equipment maintenance</td>
<td>Detection of need for maintenance</td>
<td>Equipment serviced</td>
<td>Hospital Maintenance Department</td>
</tr>
<tr>
<td>Calibration of equipment</td>
<td>Detection of need for calibration</td>
<td>Equipment calibrated</td>
<td>Head of RP Department</td>
</tr>
<tr>
<td>Training</td>
<td>Detection of need for training</td>
<td>Training activity evaluated</td>
<td>Heads of department</td>
</tr>
</tbody>
</table>

Abbreviations: ca: corrective actions; pa: preventive actions; nc: no consent; NM: Nuclear Medicine; RP: Radiophysics.

maintenance. The document of revision of the situation which is performed annually (revision of the system by the Management) is included among the registers embodied by this procedure as are the minutes of the periodic meetings held by the Internal Commission of Quality and the references of these meetings.

Procedure 3 (Management of human resources) regulates the management of the personnel working in the Department of Nuclear Medicine, including the list of employees, the requisites of the respective profiles, the welcome plan for new employees as well as the plan of formation and the document of evaluation of educational activities. In addition, the plan of department formation was developed reporting all the educational activities (courses, educational sessions, congresses, etc.) in which the members of the department participate throughout the year. All the certificates of participation to these courses were collected. Moreover, the head of the department made a personalized evaluation of the exploitation of these activities.

Procedure 4 (Management of maintenance of installations and equipment) regulates the methodology to be followed to achieve optimum functioning of the installations and equipment of the department. The registers include the list of the equipment in the department as well as its location and the annual plans of preventive maintenance of each.

Procedure 5 (Purchasing and homologation of suppliers) describes the system to use for the supply of all types of materials and processes which affect, in any way, the provision of the
departments of nuclear medicine. It also establishes the system of supplier homologation and follow up. This procedure has two registers: the list of suppliers of the Department of Nuclear Medicine and an annual register of its follow up reflecting the incidences produced with these suppliers.

Procedure 6 (Control of equipment, inspection, measurement and trial) has the objective of describing the methodology to follow to ensure the reliability of the measurements provided by the inspection and measurement teams in the department. This procedure includes collection of the registry of equipment requiring calibration or verification (area detectors, gamma cameras, etc.), the foreseen calendar to carry out these activities as well as the register indicating that this has been adequately done.

Procedure 7 (Feedback) specifies the methods of communication used on our department to communicate with both external (patients) and internal (physicians requesting tests) clients. This procedure has 3 main sources of information: claims directed to the department through the Customer Service Department (CSD) of the hospital, which are collected, analyzed and filed annually. Another source is that of oral complaints made by either our external or internal clients which are noted in a specific register. The last sources are questionnaires given to patients and professionals which obtain different points for evaluation in relation to the activity of the department. These questionnaires are given to those who are interested, collecting and analyzing the results.

Procedure 8 (Audits) describes how to identify, solve and verify the areas with a lack of consent found, the corrective actions and the preventive actions of the department. This procedure includes the results obtained in the audits performed in the department whether by the internal audit carried out by the consulting company hired for the implementation of the system or the external audit undertaken by an expert auditor of AENOR, which is the point at which certification is achieved. This external audit is done in 2 phases. A total of 7 areas of lack of consent were found, all of which were minor, in addition to various other observations. Five of the areas of lack of consent referred to the point related to equipment maintenance and calibration and the other 2 referred to correct fulfillment of the registries generated in the health care activity of the department. All of these areas were solved by the implementation of adequate corrective actions in each case.

Procedure 9 (Lack of consent, preventive actions and corrective actions) describes how to identify, solve and verify the areas of no consent found, as well as carry out actions to correct previous undesirable situations (corrective actions) or avoid potential undesirable situations (preventive actions). This procedure includes the format to follow to undertake the above mentioned actions as well as a register of the actions performed whether these were those which are now closed (solved situations) or those which remain open (situations to be solved).

The last 2 procedures, Procedure 10 (Procedure of planning and control of metabolic treatments in the Department of Nuclear Medicine) and Procedure 11 (Procedure of planning and control of clinical diagnostics in Nuclear Medicine) describe the methodology to follow for planning, carrying out and controlling the health care activity of the department with respect to both activities related to diagnostic tests and those involved in the application of ambulatory and non ambulatory metabolic treatments. In these procedures the maps of management by processes of health care activity of the department are registered.

Lastly, and according to the norms, 3 objectives of improvement and 3 indicators to evaluate the activity of the department were established.

The process of implementation finalized in April 2010 when our department was granted accreditation.

Discussion

The concept of quality should be defined as client satisfaction, that is, the degree to which the expectations of a client are achieved. In our case this refers to when a client attends our department as either a patient (external client) or as a petitioning physician (internal client). This is not an unfamiliar term to specialists in Departments of Nuclear Medicine since it has prevailed legally in the working of our specialty for years, even before the QMS specifically entered in the health care systems.

The Royal Decree (RD) 1841 of December 5, 1997 established the criteria of quality in Nuclear Medicine, completing previous Royal Decrees such as RD 1132 of September 14, 1990 which established fundamental measures of radiological protection to persons undergoing medical examinations and treatment and which incorporated the directive of the Council 84/466/EURATOM under Spanish law. This decree also complemented what was stipulated in the RD 479/1993 of April 2 which regulated the use of radiotracers in humans. Article 1 of the RD 1841/1997, states the objective to establish the criteria of quality in Nuclear Medicine with the aim of optimizing the administration of radiotracers and radiologic protection to patients. Article 2 is of note in that it specifically indicates the obligation of implementing a program to guarantee quality in health care units of Nuclear Medicine which would regulate correct clinical practice in our departments with respect to the dose absorbed, management of radiotracers information to the patient, clinical or control investigation and acceptance of equipment in accordance with national and international norms. All of these points are specifically stated in the QMS according to the ISO 9001:2008 norms. The application of these QMS in the Departments of Nuclear Medicine is of special interest considering the complexity of the activity developed in these departments: the high number of diagnostic and therapeutic tests performed, the use and preparation of radioactive elements, and their administration to patients, the need for extraordinary safety measures and the use of high technology tools (calibrations, repairs, etc.). Nonetheless, the introduction of these management systems in a Department of Nuclear Medicine should not be totally new but rather should be continuous and update the usual health care that has been provided in our centers for years. However, all of these norms have become obsolete and lack the focus provided by the QMS for directing the practice of management by processes and include the concept of self-evaluation with the aim of achieving continuous improvement and the ultimate objective of the concept of total quality. Thus, as other authors have concluded, before implementing this system in our departments we should consider that this implementation, should not be an essential change in the usual work methods in a department. Our objective should be to establish a method of systematization and standardization on how the different activities, whether health care-related or not, are developed, registering everything that is important for the organization. This will make it easier to evaluate what and how we are doing something, to find defects and errors and thereby be able to apply corrective actions which will progressively bring us closer to the, perhaps utopian, concept of total quality.

One question may be considered prior to implementation and that is why choose a QMS according to the ISO versus other norms, such as the EFQM model. Both models present analogies since the focus of the ISO 9001 norms and the EFQM model is that of the Total Quality Management and includes contributions of models of management excellence in the last years. Thus, the requisites of the ISO norms are included in the EFQM model, both being client-oriented and requiring commitment at an executive level. However, the EFQM model goes further, with in depth contemplation of the direction of the processes. Thus, the ISO 9001 norms may be considered as a subset of the EFQM model, being more directed to recognition.
of the processes in search of weak points and establishing areas of improvement. The EFQM model is used as a second phase of the QMS when the advantages provided by the ISO 9001 system have been achieved to carry out more extensive and in depth self-evaluation. This is why we, similar to other groups, have chosen a QMS following the ISO norms, leaving, perhaps, achievement of Total Quality as perceived by the EFQM system for a second phase.

Prior to initiating the process, we should consider that the implementation of a QMS should represent the desire to take an important qualitative step in our daily practice; it should make us think about what we do, how we do it, and how we can improve our work. The person designated as the coordinator of the process should have a clear spirit of leadership, and, especially, commitment of collaboration from the remaining members of the team, since a system is formed by each and every one of the workers, and all should have a real feeling of integration and be an active part of the system. There should be a participative attitude, with involvement and responsibility of all of those integrated in the department. This point is very important as it may become an added obstacle in the introduction process since, in general, feelings of resistance to change occur when there is a new challenge, and this may be the downfall of such a process, or at least, distort the true objective of the system. To avoid this undesired situation, we created the CIC in the department in which all the different sections of the department are represented, reviewing and approving the advances together, and posteriorly, participating in the changes in the system, promoting participation, and moreover, being spokespersons and sources of communication among co-workers.

Another difficulty which may arise is that derived from the lack of knowledge of the ISO 9001:2008 norms. We should, therefore, take into account that the basic structure of the standards is that shown in Fig. 2, that is, continuous analysis of the activity carried out to improve our product and thereby increase the satisfaction of our users. This is the final objective of all the system. This is the point toward which we should direct all our efforts. In our system, one procedure, that of feedback, is aimed at measuring the satisfaction of our users. Feedback is a specific requirement of the norms, having the aim of improving our services. In our experience, feedback has been very useful, allowing evaluation of the claims to the CSD and the information obtained in the questionnaires as well as the creation of a system for collecting direct oral complaints. With this system any member of personnel in our department may report any complaint made by a patient. In our opinion, the information obtained in this registry is of special interest since it provides more direct and sincere information than that provided by the complaints department of the CSD. With regard to this point, as in other departments, our department has always been interested in evaluating the opinions of both our external (patients) and internal (petitioning physicians) users. Thus, for some years we have given questionnaires to our patients, as well as to the physicians with greater demand of the services of our hospital.

The degree of satisfaction shown by the external and internal clients was curiously similar to that obtained on repeating these questionnaires in the process of the implementation of our QMS. This returns us to the previously mentioned idea of continuity in the department in the time before and after the introduction of the QMS.

The basic mechanism of the certification process may be summarized in 4 steps: the first, and most laborious is that of adequately documenting what should be and is done, taking the drawing up of procedures and other documents such as work instructions as results. The second is compliance with the procedures since non compliance leads to lack of concordance in the system. The third point is to provide evidence that the procedures are fulfilled, making a series of registers which report all our activity mandatory. These registers should be associated with each procedure as described in Results. Lastly, all this process should be verified by an external source, synonymous with audit, with which an external auditor certifies that the norms are being adequately fulfilled as required.

Several key points should be taken into account in the process of documenting the system: only what is essential and to be performed in the simplest way possible. This documentation must be revised and approved by an authorized person, normally the head of the department. This documentation should be available for use and correctly identified. It should undergo continuous revision and updating, with identification of the changes made.
Within the documentation of the system the standards require that the registers obtained from our activity be controlled. A register is the proof that a process has been performed and a result has been obtained. This register should not be modified since this document provides evidence of the activities undertaken to an external observer. These registers should be adequately preserved and be easily identifiable and recoverable.

Another vital point in the introduction of the system, which may have certain difficulties, is the elaboration of the Manual of Quality. This manual should include 5 points: (1) describe the Policy of Quality of the system, that is, make a written declaration of the guidelines and lines of conduct to be followed by the members of the organization, (2) establish the reach of the system, that is, to what activities our QMS applies, (3) describe the processes affecting our activity (strategic processes, key processes and support processes) (Fig. 3), (4) describe the responsibilities, authority and interrelationships of the different sections of the department personnel (functional organigram), and (5) include the processes established for the working of our QMS.

One principal requisite of the norms, which is an important basis for correct implementation of a QMS, is that of the responsibilities of the management of the system which is usually assumed by the head of the department. This person has the role of leadership which must demonstrate with evidence, ensure possession of knowledge of the requisites of the clients and satisfy these needs and establish objectives and how to perform these to achieve the continuous improvement required by the norms. To do this it is important to establish a functional and organizational hierarchal structure. In addition, this person must ensure an appropriate circuit of communication within the system to guarantee adequate collaboration from all the personnel.

Another important question which may generate doubts and difficulties is linked with this point. This is the establishment of annual objectives to achieve improvements within our QMS as well as determine indicators. An indicator is the method to measure both our processes and the resulting product. Indicators are a way of obtaining precise, timely information on the functioning of our processes and the quality of the services rendered. They allow recognition of errors within the system and the subsequent possibility of investigating the cause and thereafter correct the situation.

The last reference is related to the last phase of certification, that is, the audit. The ISO 9001:2008 norms define the audit as a methodical, independent examination undertaken to determine whether the activities and the relative results of quality comply with the previously established standards and whether these standards are carried out effectively and are adequate to achieve the objectives established. To do this, the audit should be considered as an occasion to find weaknesses in our systems and thus, to determine occasions to improve. The audit should not be considered as an examination of the personal work of an employee(s), a dispute or a search for guilty parties. This phase should be faced with naturalness, with the idea that the faults found are opportunities for improvement which will help to achieve the objective sought with the implementation of a management system.

In conclusion, the intention which a department should have on initiating the process of implementation of a QMS is that of taking an important qualitative step in the daily routine, with the conviction that, in the near future, these systems will be an essential tool in the organization and the functioning of central hospital departments in general and particularly in the Departments of Nuclear Medicine. This system establishes a tool which allows recognition of what we are doing and how we are doing it, thereby allowing analysis of faults and inducing continuous improvement. Total involvement of the personnel is essential, being, perhaps, the most difficult, albeit essential, point to achieve, since without this involvement we will never achieve the aims which are expected of these systems.

**Conflict of interests**

The authors declare no conflict of interests.

**References**


