ISO 9000 offers many benefits.

In 1995, the Division for Radiology, Radiotherapy and Nuclear Medicine at the University Medical Center, Utrecht, decided to implement a system for quality assurance in accordance with the ISO 9000 standards. Implementation of the quality assurance system was completed in January 1996, and the Division received an ISO 9002 certificate.

Implementation of ISO 9000 depends on certain requirements:
- Management commitment
- Determining objectives
- Assessing current situation
- Identifying needs
- Preparation of an Implementation Plan
- Managing the Implementation Plan.

Providing that these requirements are met, the ISO 9000 system offers many benefits. Firstly, it provides a continuous insight into processes within the organization, enabling changes to be made as required, and in a controlled manner. This also means that, if an examination procedure is changed, it is immediately clear who needs to be informed and what documents must be updated. Furthermore processes are audited periodically by both internal and external auditors. Both audits are obligatory for maintaining a valid ISO 9000 certificate.

Secondly, the ISO quality system includes a strict document control procedure. This makes it possible to create relevant procedures and protocols and to maintain them within the organization. Maintaining relevant technical and working documents is vital for quality control, particularly in departments with a high technology content, such as a radiology department.

Furthermore an ISO 9000 quality system is well adapted to achieving continuous improvement by monitoring performance indicators (Pi’s). The organization decides which Pi’s are relevant for monitoring its processes and output, and sets minimum standards for them. Establishing the method and frequency of the measurements are important factors. After these preparations, the actual monitoring of the Pi’s can begin. If Pi results do not meet the given standards, corrective measures can be taken.

ISO 9000 defines a Quality Management System as the Organizational structure, procedures and resources needed to implement quality management. This comprises all aspects that affect the quality of the product delivered to the customer. ISO only defines what is to be achieved. How it is achieved is up to the individual organization. The requirements are generic, and can be applied to virtually any type of organization.

Implementation of ISO 9000 in our Division has led to a significant improvement in cost effectiveness and efficiency. The department’s 1998 annual quality report was awarded an honorable mention at the 1999 prizegiving of the Nederlandse Vereniging voor Kwaliteit in Zorg (Dutch Association for Quality in Healthcare).

Receiving the honorable mention has had a significant effect on staff morale, and has also led to our being consulted by other healthcare institutions. In our view, practical improvements are the best. The most useful points are built-in quality management and evaluation.

Although implementation of ISO 9000 in our Division can be regarded as a success, by the end of 1998 we had decided that we had reached the limits of the benefits to be expected from the ISO quality system, and began to focus on widening our perspective on quality management. We needed to add a new dimension of
systematic and continuous improvement to the existing quality system.

**Total Quality Management**

We decided to adopt the principles of Total Quality Management (TQM). This is defined by the European Foundation for Quality Management as 'All manners in which an organization meets the needs and expectations of its customers, personnel, financial stakeholders and society in general'. Thus, Total Quality Management can be considered as a philosophy rather than as a model or a method. It is a continuous striving for improvement, covering the complete hospital healthcare process from admission to aftercare.

In order to translate this philosophy into everyday practice, we used a version of the Model for Business Excellence, as developed by the European Foundation for Quality Management (EFQM). The implementation of Total Quality Management in our Division has been described in a previous issue of Medicamundi [1].

ISO 9000 has its shortcomings, but also many excellent features. We have done our best to retain these. The Model for Business Excellence can be considered as complementary to the existing ISO 9000 system for quality assurance.

The EFQM model is in use in most of Europe. In the Netherlands, INK (Instituut Nederlandse Kwaliteit – Netherlands Quality Institute) uses a similar approach. One difference is that the INK version describes implementation in discrete phases (phases 0–5), while the EFQM model uses percentages. We find that, in practice, the discrete phases are easier to use.

The most important feature of the new model is its ability to focus on both organizational and result aspects, and the interaction between the two. The EFQM Model for Business Excellence consists of nine distinct areas, each representing a different aspect of the organization.

These nine areas are subdivided into areas concerned with what results have been achieved (Results) and areas concerned with how these results have been achieved (Enablers). Figure 1 shows the nine areas and how they are related to each other. Table 1 presents the characteristics per area.

The Model for Business Excellence provides a useful framework for structuring quality improvement efforts, because it has an integrated cycle for continuous improvement. The cycle begins

**Table 1. EFQM model: description of the nine areas**

<table>
<thead>
<tr>
<th>Enablers</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Leadership</td>
<td>Results of employee satisfaction survey,</td>
</tr>
<tr>
<td></td>
<td>absenteeism</td>
</tr>
<tr>
<td>Resources</td>
<td>Patients: complaints</td>
</tr>
<tr>
<td>Policy &amp; strategy</td>
<td>Policy deployment, policy is more than just a</td>
</tr>
<tr>
<td></td>
<td>plan to purchase equipment</td>
</tr>
<tr>
<td>People management</td>
<td>Management by objectives, standards and values</td>
</tr>
<tr>
<td></td>
<td>Use of process-related performance indicators, patient throughput</td>
</tr>
</tbody>
</table>

**Results**

- **People satisfaction**
- **Customer satisfaction**
- **Impact on society**
- **Business results**

**Fig. 1. EFQM model for business excellence.**
There is an integrated cycle of continuous improvement. With carrying out a self-assessment to see what results have been achieved so far. On the basis of these findings, organizations can decide what improving actions must be taken to strengthen one or several Enablers, in order to achieve better results next time. For example: if an organization wants to improve People (employee) satisfaction, it has to strengthen People Management and also perhaps Leadership, and Policy and Strategy. This can be realized by improvement actions in these particular areas.

After such improvement actions have been implemented, the organization again carries out a self-assessment in order to see if the improvement actions have resulted in a better overall performance. Based on this second assessment, new Result areas can be selected for improvement, and so the cycle begins again.

At the end of 1998 the management of the Department of Radiology launched a long-term project to implement the TQM principles, by using the EFQM Model. The project commenced with a meeting with all our employees, to inform them about TQM, the EFQM Model and the self-assessment.

The EFQM Model makes it easy to enlarge the scope of quality management, and to take an objective look at the organization and the results it achieves. Furthermore, it helps to set priorities in the improvement projects, and it is an adequate model for evaluation of the achieved improvements.

In our Division, implementation of the principles of Total Quality Management began with a meeting in which all our employees were informed about the aims of the project, followed by a strategic planning process, culminating in a 5-year Strategic Plan and a long-term Investment Plan. In the meantime, a patient satisfaction survey was carried out to provide a basis for assessment, and a workflow management system has been implemented.

At the end of the planning phase, a special task force was set up to perform a self-assessment according to the EFQM Model for Business Excellence. The outcome of this self-assessment will be discussed in several meetings with groups of employees.

Based on these discussions, a final conclusion will be drawn concerning the present position of the department on the areas of the EFQM Model. The management team will then decide which areas will be the focal point for the next two years so that specific improvement projects can be developed.

However, the EFQM Model is not only useful for future improvement initiatives. Current improvement projects can also be (re) prioritized and evaluated on the basis of the self-assessment.

It is important to emphasize that the role of the ISO 9000 system remains unchanged. It will still be used to control all the critical processes within our department. The ISO 9000 system can be regarded as a solid basis for all future TQM efforts.

The INK Model

There are certain overlaps between the ISO 9000 system and the INK Model (Fig. 2).

Implementation of the Self-Assessment Model

Implementation of the INK self-assessment model takes place in 5 phases, corresponding to the percentages of the EFQM Model.

Phase 1: Activity oriented
In the first phase the main emphasis is on orientation with respect to the various activities. The main aim is the provision of good professional care. There is no common approach to care, and care is provided in relatively independent components. Care workers function as autonomous professionals, and there is a strongly personal approach. Problems tend to be solved after they arise. There is a wide gap between management and the work floor: everyone does his or her ‘own thing’.

Phase 2: Processes oriented
In the second phase, the organization is mainly directed towards management and improvement of the primary processes. Processes are controlled and improved on the basis of identification, measurement and insight. Attention is also paid to the relationships between the various care processes, and there is collegial cooperation and agreement between the professionals. Critical moments and risks are identified.
Phase 3: System oriented
In this phase, process control and customer orientation are central. The relationship between primary processes and supporting processes becomes increasingly important. Interdisciplinary cooperation and harmonization of primary and supporting activities become self-evident. The policy penetrates to all levels in the organization. Staff are aware of the aims of the organization, and are aware of their own individual contribution. Periodic evaluation of care and services is directed towards improvement and renewal. The ‘plan-do-check-act’ cycle is evident in all processes. There is systematic and purposeful recording of information, so that trend analyses can be made. Those responsible for the processes can take preventive measures, based on the observed trends. The necessary organizational changes are often made in this phase (less hierarchy, greater independence, adequate information, supporting leadership, more training etc.) and internal and external results are continuously evaluated. This phase is certainly the most difficult to complete, but when it has been completed it becomes relatively easy to increase the quality level.

Phase 4: Chain oriented
In this phase, process control and improvement reach over the ‘walls’ of the organization. The organization also concerns itself with processes and relationships with external partners, and works towards the creation of a ‘quality chain’. The organization seeks continuously for optimum relationships and the realization of partnership and win-win relations.

Phase 5: Total quality
In the last phase, the total quality phase, continuous improvement has become an integral part of all processes and relationships in the organization. The organization can compare itself with the very best of national and international organizations.

Identifying the phases
Identification of phases is both confusing and illuminating. It is confusing because no organization is ever completely in one specific phase. There are always various activities, projects and measures at various places within the organization which, taken together, ensure and improve quality. Each of the activities or projects goes through its own phases, and it may well happen that department A is in a different phase from department B.

The identification of phases is illuminating, because it helps in determining the management strategy. In each phase of the development, a realistic estimate must be made of the usefulness and achievability of the various activities for monitoring and improving quality. It is also necessary to determine, in each phase, what the most effective manner will be for achieving the desired results.

The more advanced the organization is in the implementation of total quality, the clearer the feedback loops in all processes will be. As the organization progresses, ‘policy deployment’ increases: a policy is translated into working

Identification of phases is confusing and illuminating.
processes, and there is no difference in principle between the ideas at the top and the ideas and working methods on the work floor. A third important characteristic of a ‘ripe’ institution is that the institution does not obtain its legitimacy from individual care and service alone, but also from its role within society.

Quality Indicators

Several quality indicators have been identified. These include:
- report turn-around time
- availability of folders
- waiting lists
- waiting times
- examination times

Report turn-around time
The report turn-around times are recorded weekly, and reported quarterly. Failure to meet the norm can generally be traced to one or both of two causes. The radiologist may be late in making the report, or there may be a backlog in the typing room. The results are discussed with both the radiologists and the file room staff. For polyclinical examinations, all modalities are above the norm of 70% within 2 working days (Fig. 3). In the clinical examinations, only the angio reports are above the set norm (95% within 2 working days). For the other modalities, the reporting times are slightly below the norm (Fig. 4).

Availability of folders
Most examinations are made by appointment. The administration ensures that the patient folders are retrieved one day before the examination. The ‘availability of folders’ quality indicator shows how many folders are actually available at the time of the examination. The results are obtained from quarterly spot checks. The availability of folders is relatively stable, between 80 and 90% (Fig. 5). There has recently been a slight drop in availability, due to staff shortages.

Waiting lists
The waiting lists for the various types of radiological examination are reviewed monthly. The waiting lists are strongly dependent on the pattern of referrals. Time slots for the various specialized modalities are allocated annually. If the allocation is exceeded, the waiting lists become
longer. This gives the various divisions control over their own waiting lists. The waiting lists per division show considerable variation (Fig. 6). The waiting lists for MRI in the neurology division are particularly long because the number of examinations exceeded the allocation (Fig. 7).

Waiting times
The waiting times are measured from the time between the appointment and the moment that the examination begins. The waiting times are reported quarterly, and those for each modality are discussed in meetings with representatives of the modality concerned. If any irregularities occur, they can be corrected per modality. The average waiting times for CT, MRI and angio have remained stable at around 4 minutes. Those for conventional examinations are around 12 minutes, with some variation, due to the fact that no appointments are made for these examinations (Fig. 8).

Average examination time per modality
This quality indicator is measured weekly, based on data from the hospital information system (HIS). The examination time is defined as the time from the moment the patient arrives in the examination room to the moment when he or she leaves it. The figures are reported annually, broken down per modality. Due to technical advances and greater experience, the duration

Fig. 6. Average waiting lists for CT in the Neurology Division (1998/99).

Fig. 7. Average waiting lists for MRI in the Neurology Division (1998/99).

Fig. 8. Average waiting time before examination per modality (1995–1999).
Improvement projects play an important role in the quality policy. The organization is expected to adapt itself to changing conditions, and to provide improved results. This can be achieved, on one hand, through the academic environment, which ensures a constant stream of technical innovations and new medical insights. On the other hand, the budget structure demands an efficient and effective use of the means available.

The initiative for an improvement project can be taken at either the operational or the management level. The projects can range from small-scale projects, which can be carried out relatively rapidly, to major projects, which may take several years. For the larger projects, a project organization is set up. The time scale and the expected results are explicitly mentioned in the project plan. Special attention is also paid to ensuring that the expected results are achieved, and evaluating them.

The smaller improvement projects are discussed in the various types of meeting organized with the professional groups, and also in the weekly interdisciplinary operational discussions. Many operational improvement projects have originated in these discussions.

The most important improvement projects are:
- structuring requests for examinations
- improving the quality of information on the patient
- improving the technical quality of the medical images
- improving the organizational structure.

Structuring requests for examinations
In the past, it occasionally happened that appointments were not correctly booked, and that request forms for examinations were lost. Incorrectly planned examinations are very annoying for the patient, while the administration lost many hours in tracing missing request forms. In order to improve the stream of appointments (130 000 annually), an improvement project was begun.

Appointments are now only made when a request form is available. For this purpose, all clinical and polyclinical departments within the hospital have been given a fax machine. It has been agreed that appointments for an examination will now only be made when a request form has been faxed. Table 1 shows the situation before the improvement project (1997) and afterwards (1998). The percentage of available request forms has increased drastically, while the total tracing time has been reduced by 64 %. The increase in the average tracing time is due to the fact that missing request forms are now more difficult to trace, and may even be non-existent.

Improving the quality of information on the patient
This improvement project was an initiative of the technical assistants. In some cases, essential data on patients was missing at the moment when the examination was to be made. This problem was particularly serious in the MR units. For this reason, the head of one of the MR units developed a screening form in which the patient was asked a number of questions that were important for the examination. The form was sent together with the patient information letter. If one of the questions was answered with 'yes' the referring specialist was contacted. This new procedure reduced the chance of an examination being canceled due to unforeseen circumstances, such as the presence of a metal prosthesis. At the same time, it was decided to include a map showing how to get to the university medical center, because many MRI patients come from outside the region.

Improving the technical quality of the medical images
There is an improvement project to increase the quality of conventional radiographs. Every radiologist can use the 'quality pager'. If a radiologist finds that the quality of an image is unsatisfactory, he or she can use this pager to contact
a technician who will come and investigate the problem. A reporting form has been developed, which provides a feedback on these problems, so that the responsible head of unit can carry out any necessary adaptations of the protocols. The reporting forms are discussed with technicians on a weekly basis and Radiologists are invited to attend these meetings, so that they can provide direct feedback on their requirements.

Digitization. A start has been made on providing a digital central archive with the appropriate workflow manager. It is expected that the introduction of digitization will have an enormous impact on the working methods of the various sections, so that it is important to have a clear insight into the new situation.

The selection process is being carried out in four stages. In stage 1, the six most important suppliers of digital systems were invited to provide a written information package with answers to eight questions. The six suppliers were then invited to make a presentation of their products. After the presentation, the suppliers were asked to answer six functional questions, and the selection commission and the technical advisory group were able to ask further questions. On the basis of the information provided, a decision was made to visit four sites, in order to see the products in practical application. The selection commission and the technical advisory group were able to ask further questions. On the basis of the information provided, a decision was made to visit four sites, in order to see the products in practical application. The results are assessed on the basis of previously determined critical points. Stage 4 will be the commercial activity, with the purchase decision and the drawing up of contracts.

Improving the organizational structure
Because the head of the file room is responsible for more than 30 staff, there is little time available for direct contact and discussions. For this reason, three team leaders were appointed, who are available for discussion with the staff, and who spend as much time as possible on the work floor. This means that there is far better direct control of the activities of the staff, and that the threshold for consultation with a more senior member of staff has been significantly lowered. This reduces the workload on the head of administration. An additional advantage of the appointment of team leaders is that they can be involved in improvement projects, such as improving the logistics of image handling, and staff training.

Infusions by nursing staff. It has been decided that the infusions should be given by doctors’ assistants rather than by the radiologists themselves. This solves several problems. It helps to compensate for the shortage of radiologists, who can now concentrate on the actual examinations, and also saves costs.

Internal Audits

In order to determine whether the quality system is functioning efficiently, periodic internal audits are carried out in the department. Each audit is based on a procedure in the quality system. The procedures to be examined are listed in an annual plan, in such a way that all procedures in the quality system are examined at least once every two years. Specially trained members of the departmental staff carry out the internal audits. Interdepartmental audits have also been started on an experimental basis.

The experiment can be regarded as successful, because it appears that the unprejudiced view of an auditor from another department can lead to questions which would not occur to somebody who was involved in the day-to-day running. For this reason, the interdepartmental audits have now been made permanent.

Visitations

As mentioned, our department has completed an initial self-assessment. Another important aspect is that of visitation. It is not always possible to be objective about one’s own organization. We

Visitations allow organizations to share information.
Total Quality Management improves cost effectiveness, efficiency and patient satisfaction. Therefore visit other organizations on a regular basis, and representatives of other organizations visit us, so that we can compare our results and experience. Visitations are organized and implemented by the Nederlandse Vereniging voor Radiologie (Netherlands Radiology Association). The visitations are done with a ‘visitation tool’, in the form of a computer with a special database developed in cooperation with Philips Healthcare Consultancy. Each year about six visitations are carried out. The documentation is also assessed.

Conclusion

Implementation of Total Quality Management has resulted in a continuing upward trend in cost effectiveness, efficiency and patient satisfaction.

References