Quality in Nuclear Medicine

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Foreword

Historically, nuclear medicine emerged at the end of the nineteenth century. Henri Becquerel and Marie Curie discovered the mysterious rays of uranium and named them radioactivity. From the middle of the last century, the production and application of pharmaceuticals and diagnostic tests developed seriously. During the last decades, imaging by the new developed camera systems such as the single photon emission computed tomography (SPECT) camera and the positron emission tomography (PET) camera, both in the last years often combined with computed tomography (CT) and/or magnetic resonance imaging (MRI), opened new perspectives in the contribution of nuclear medicine towards health care.

With the introduction of high-tech equipment, robotics and process technology new challenges appeared. Application of radioactivity in research (preclinical, in volunteers and in patients) and in a clinical setting require that safety risks and strict rules have to be taken into account. Nuclear disasters in the past have shown us the health damage of radiation and the long-term effects it can have on people and environment. In contrast to the nuclear industry, health-care organizations are not used to applying prospective risk assessment techniques other than as part of their medical assessments. More specifically, medical doctors and research staff may not always be aware of the risks. They perceive regulations as curtailing their opportunities.

The editors of this book have identified this issue. Therefore, the focus of this book covers more than only the scientific successes. The aim of this book is to provide professionals with an integrated approach to quality and quality management aspects concerning nuclear medicine. Nuclear medicine as a mainstream in research and in clinical diagnostics and treatment of metabolic and organ disorders requires the involvement of an interdisciplinary team of experts. Experts in the field of nuclear medicine, physics, radiation safety, good clinical practice (GCP) and good manufacturing practice (GMP), mechanical engineering, quality control, and ICT are needed. All of those themes are covered in this textbook. The contributions are from professionals with many years of experience in the field of nuclear medicine.

Special acknowledgment concerns Prof. Rudi Dierckx, Head of the Department of Nuclear Medicine and Molecular Imaging of the University Medical Center Groningen, as the initiator of this textbook. No one better than Prof. Dierckx knows that, to achieve excellent quality as well as an excellent institute in nuclear medicine, a long and thrilling journey must be taken. Therefore, one could see the chapters in this book as the keystone to this success.

Groningen, The Netherlands
April 2016

Alexander van der Star

Preface

The Department of Nuclear Medicine and the PET center at the University Hospital Groningen obtained their first ISO-9001 certification in the year 2000, actually also a first for the hospital. Using the European Foundation for Quality Management (EFQM) model, in 2015, the newly established department of Nuclear Medicine and Molecular Imaging switched its focus from management domains towards results for different stakeholders. In 2011, the department obtained the Institute for Dutch Quality price 3 stars (INK, Instituut voor Nederlandse Kwaliteit). The formal trajectory towards excellence ended in 2015 with the EFQM recognition 4 stars being awarded. Similar to Japanese arrow shooting the movement, that is, the road towards excellence, was more important than the target. This multi-author textbook wants to share this enthusiasm and expertise from the Groningen network.

Nuclear medicine is a specialty characterized by the use of open sources of radioactivity for diagnosis and therapy. Hence, quality assurance in such an environment may not be considered a luxury. Moreover, from the beginning of the specialty production of radiopharmaceuticals on site and sensitivity of crystal detectors to fluctuations also prompted the need for structured quality controls. In nuclear medicine in Europe, it was Utrecht in the Netherlands under the guidance of Prof. Peter van Rijk being the first to recognize the importance of an umbrella for quality assurance encompassing all processes and to obtain ISO-certification in 1998. Other centers in Belgium such as Gent and later on Leuven, and Groningen in the Netherlands thus in 2000 quickly followed building on this expertise.

Meanwhile the domain changed rapidly, for example, with the breakthrough of informatics, hybrid imaging, and molecular medicine. In the Netherlands and Belgium, the weight of the juridical framework became primarily European, with, the European medical device directory, Euratom directives or, for example, European legislation on good manufacturing practice (GMP), on good clinical practice (GCP), on privacy of patient data, etc. A trend towards harmonization globally further builds upon this layer, as may be seen, for example, in research guidelines (International Commission on Harmonization) or through the efforts of international organizations such as the International Atomic Energy Agency (IAEA).

Also stakeholders in health care have become more demanding and more explicit in their expectations. In the Netherlands or Belgium, now certification or

accreditation of the whole hospital is required, no longer as a differentiator, but now as a qualifier only, for example, in order to obtain contracts form health insurance companies. ISO (health) certification, Joint Commission International (JCI), and NIAZ-Qmentum, just to name the top three in the Low Countries, are labels requiring involvement, not only from all clinical departments, but also from all facilitating departments. In a university hospital or university medical center, research, training, and teaching may be included within the scope of quality assurance. In these settings, nuclear medicine may be evaluated no longer only as a department, but rather, for example, in the chain of a care trajectory through "tracing audits" or in the setting of an audit of multidisciplinary investigator-driven research.

Finally, quality may have many faces, but it is clear their number increased and furthermore diversified in a growing demand for clinical governance. Keywords may include transparency, ownership, responsibility, documentation, involvement of stakeholders, cost control, efficiency, and efficacy. Quality instruments nowadays encompass, for example, lean six sigma, Deming circle (PDCA, Plan Do Check Act), prospective risk inventarisation, Prisma analysis, safe incident reporting, evidence base medicine, and clinical guidelines or recommendations, but also retrospective analysis of clinical files of deceased patients, supply chain management, or hostmanship. Personalized medicine not only implies precision medicine, but also, for example, experience-based co-design, attention for the level of understanding of different groups of customers, or medical decision support. Balance scorecards, quality parameters, and other key performance indicators are instruments to keep hold on the growing information on quality, as in the end all is quality related.

Can we deliver quality without the aforementioned tools? Yes, we can. But similar to the aviation industry we have learned that when lives are at stake, safety needs to be assured. Moreover, stakeholders expect more in return for the given societal and individual responsibility and investments. On the other hand, it should be clear that the tools are not the goal, but only the means on the quest for quality and excellence.

This multi-author textbook was written by experts in the field to provide a global view and hopefully at the same time a practical view on quality in nuclear medicine. Moreover, it hopes to provide not only tools, but also an understanding and foster enthusiasm to do better. Ours is a beautiful specialty, but it is in permanent transition as is the outer world. We hope this book would be of help to some in the field at this point in time.

Ars longa, vita brevis.

Groningen, The Netherlands — Andor W.J.M. Glaudemans, Jitze Medema, Annie K. van Zanten, Rudi A.J.O. Dierckx

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Part I

Laws, Standards and Guidelines

The Road to Excellence: A Case Study of the Application of GMP, ISO 9001 and the EFQM Excellence Model in a Nuclear Medicine Department

1

Lidia S. van Huizen and C.T.B. (Kees) Ahaus

Abstract

Definitions are introduced to give insight in the field of work of quality management in relation to responsibilities in NMMI. A relational model visualises the relationships when working on the road to quality excellence. The standards such as GMP, GCP, ISO 9001 and EFQM with examples can help put these models to practise. The road of NMMI in the University Hospital in Groningen presented in boxes gives lessons learned. Additionally the A3 model to prioritise issues on the road to quality excellence is explained.

1.1 Introduction to Quality and Excellence

University hospitals are organisations in which knowledge and innovation regarding cure and care come together in an academic setting. Medical–technical development and high-tech equipment are used in complex multidisciplinary care pathways in centres in which diverse healthcare professionals work together.

This entails responsibility for the ethics, sustainability, reliability and validity of diagnoses and patient treatment, in research and in educating the next generation of healthcare professionals. The field of nuclear medicine assumed this responsibility

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and designed a quality management system (QMS) to ensure the sustainability of its (diagnostic) procedures. European and national societies developed guidelines for most of the diagnostic procedures to guarantee reliable and valid diagnoses. For the most part, this began with establishing procedures related to the risks of using equipment, the safe production of radiopharmaceuticals and the careful evaluation of the imaging process, thereby resulting in a QMS and periodic audits to assess their compliance with the standards. In applying the QMS, the field of nuclear medicine evolved towards excellence in patient care, research and education.

How this evolution unfolded from quality to excellence in quality is explained in this chapter, which includes examples of how this evolution worked for the Department of Nuclear Medicine and Molecular Imaging at the University Medical Centre Groningen (hereafter referred to as NMMI).

1.2 Quality Definitions and Standards in Quality Management

First, it is important to define what is meant by quality in health care and, particularly, in the field of nuclear medicine. Subsequently, the quality improvement cycle and the road to excellence, which is achieved by applying standards and models, will be discussed. It is relevant to describe in a systemic way the roles and responsibilities of professionals and quality staff or supportive staff in health care. Donabedian (Donabedian 1993) argued that we need to agree on (a) the meaning of quality in health care, (b) the relevant actors or players and (c) the configuration of the stage or playing field (Donabedian 1993).

1.2.1 Quality Definitions

In quality management and certification, the ISO 9000 family of standards is widely used as a reference for QMSs. The terms and definitions related to quality and quality management are listed in ISO 9000, whilst ISO 9001 comprises the requirements of the QMS. For health care, a translation of specific terms is undertaken, and these are then added to facilitate their implementation in healthcare organisations (NEN-EN-15224, Health care services – quality management systems 2012a).

The quality of a product or service is not easily defined as various definitions can be found in the literature. Reeves and Bednar (Reeves and Bednar 1994) typify the different definitions of quality. The rather internally or manufacturing-focused definition of ISO emphasises the specified or expected characteristics of a product or service. Other definitions are more externally focused and marketing-based ("Quality is meeting and/or exceeding customers' expectations" (Reeves and Bednar 1994)) or can be considered value-based ("Quality is related to both the actual use and the price of the product" (Reeves and Bednar 1994)). Quality can even be seen as "the highest form", as we can all recognise excellent quality when we see it.

1.2.1.1 Quality

Quality refers to the degree to which a set of inherent characteristics fulfils requirements (ISO 9000) (ISO 9000:2005).

The term "quality" can be used with adjectives such as poor, good or excellent, which makes it a relative and not an absolute concept. In the second definition, "inherent" can be seen as opposed to "assigned", which means that quality exists in something, especially as a permanent characteristic.

These definitions do not consider the different perspectives of stakeholders in the field in which an organisation is working. Within the nuclear medicine field, stakeholders—for example, the patient, the referring healthcare professional, the organisation or the government—may have expectations of different qualities.

1.2.1.2 Quality in Health Care

In our work, we use quality defined as the "degree to which a set of inherent characteristics fulfils requirements" (ISO 9000:2005). To make quality in health care measurable and controllable, the quality characteristics of clinical processes must be identified and described. In the healthcare-specific NEN-EN 15224 (ISO 9001 for Healthcare) standard, the patients' or customers' requirements for healthcare services must be specified according to effectiveness, safety, availability, timeliness/accessibility, continuity of care, respect for patient values and preferences, and appropriateness, aspects of efficiency, fair distribution and evidence must be considered.(NEN-EN-15224, Health care services – quality management systems 2012a) These requirements or expectations are similar to the six aims for improvement mentioned by the Institute of Medicine in its well-known report titled "Crossing the Quality Chasm: Safe, Effective, Efficient, Personalized, Timely and Equitable" (Institute of Medicine 2001).

A precondition for delivering a high quality of products and services is the quality of an organisation. All activities that aim to strengthen the quality of the organisation can be considered quality management.

1.2.1.3 Quality Management

This refers to the coordinated activities that aim to direct and control an organisation with regard to quality (ISO 9000:2005).

The direction and control of an organisation with regard to quality generally include the establishment of a quality policy and quality objectives, quality planning, quality control, quality assurance and quality improvement. Based on these quality management activities, the organisation provides a "justified trust" related to the quality that is delivered, and it views the improvement of the organisation's performance as a permanent objective.

In the primary process of a nuclear medicine organisation, different types of standards need to be fulfilled on the production floor. By implementing a QMS, the learning or self-cleansing ability of the organisation becomes important. Subsequently, standards of excellence take this a step further. The relationships between quality control, quality assurance and total quality management are visualised in Fig. 1.1. In the primary process, quality control provides trust; in the QMS,

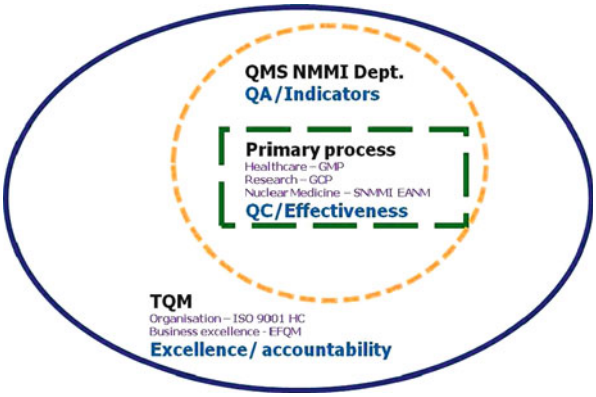

Fig. 1.1 Visualisation of the relationships between different standards and quality focus at different levels (*QMS* quality management system, *NMMI Dept.* Department of Nuclear Medicine and Molecular Imaging, *QA* quality assurance, *GMP* good manufacturing practice, *GCP* good clinical practice, *SNMMI* Society of Nuclear Medicine and Molecular Imaging, *EANM* European Association of Nuclear Medicine, *QC* quality control, *HC* health care, *EFQM* European Foundation of Quality Management)

quality assurance and quality improvement using performance indicators are embedded; and in total quality management, the expectations of all stakeholders are important. At each level, a focus on quality improvement brings the organisation to the level of excellence. This requires leadership and a strategy of striving for excellence.

In Fig. 1.1, we depict the relationships between different standards regarding quality control, assurance, improvement and excellence. The inner rectangle represents the primary process with the quality control checks and guidelines which are specific to the field of work. The middle circle is about the quality assurance of the primary and supporting processes and about quality improvement based on the Deming cycle: plan–do–check–act. Finally, in the outer circle, the business is led by total quality management with clear accountability and a focus on excellence.

1.2.2 Standards and Models

The Department of NMMI at UMCG produces its radiopharmaceuticals in close collaboration with, and under the supervision of, the hospital pharmacy, and it has not only a good manufacturing practice (GMP) licence but also ISO 9001 certification and an INK/EFQM recognition. In this section, we discuss different standards which can be used in quality control and (total) quality management: GMP, GCP, ISO 9001 (for health care) and the EFQM excellence model.

Radiopharmaceutical production can be executed according to GMP in relation to the European Pharmacopoeia. NMMI works collaboratively with the Society of

Nuclear Medicine and Molecular Imaging (SNMMI) and the European Association of Nuclear Medicine (EANM). NMMI advocates the use of standardised procedures for diagnoses and patient treatment in order to create a sustainable QMS. For the protection of the patients, personnel and environment, NMMI adheres to the Radiation Protection Act. For basic research and development of new radiopharmaceuticals and nuclear medicine procedures, compliance with good clinical practice (GCP)/the Helsinki Rules, which govern research on humans and legislation related to research on animals, is mandatory.

1.2.2.1 Good Manufacturing Practice (GMP) (De Vos et al. 2005)

Radiopharmaceuticals must be manufactured in accordance with GMP guidelines; strict adherence to these guidelines is mandatory and is monitored by agencies that control authorisation and licencing for the manufacture and sale of pharmaceutical products, for example. These guidelines provide minimum requirements that a pharmaceutical product manufacturer must meet to ensure that the products are of a high quality and do not pose any risk to the consumer or public. Table 1.1 provides examples of the GMP criteria in a nuclear medicine field.

Table 1.1 GMP criteria and examples for applying these in a nuclear medicine field

GMP	Examples
Environmental requirement	Production is in clean areas with required air characteristics
Personnel	Personnel are trained in disciplines relevant to the manufacturing of sterile and radioactive products
	High standards of personal hygiene are applied
	Authorities and responsibilities are clearly defined (e.g. the release of a batch)
	Safety rules of radiation control are respected
Premises and equipment	The design of laboratories fulfils all requirements regarding radiation protection, cleanliness and sterility
	Cross-contamination of radioactive air with nonradioactive air is prevented
	Critical equipment is listed, calibrated, tested and maintained
Production	Standard operating procedures (SOPs) are available, reviewed and kept up to date
	Quality control and (double) checks are applied in addition to release procedures
	The dispensation, packaging and transportation of radiopharmaceuticals comply with national and international regulations
Labelling	Products are identified by permanently attached labels
Production and distribution records	Records of production batches provide a complete account of the manufacturing history
Quality assurance and quality control	Quality control requires detailed instructions for testing and analysis
	Quality assurance includes the review of the production process

1.2.2.2 Good Clinical Practice (GCP)

GCP follows the International Conference on Harmonisation (ICH) of GCP guidelines. GCP is an international quality standard that is provided by the ICH, which is an international body that defines the standards which governments can transpose into regulations for clinical trials involving human subjects. GCP enforces stringent guidelines on ethical aspects of a clinical study. High standards are required in terms of comprehensive documentation for clinical protocol, record keeping, training and equipment, including computers and software. Quality assurance and inspections ensure that these standards are achieved. GCP aims to ensure that the studies are scientifically authentic and that the clinical properties of the investigational product are properly documented. GCP also provides researchers and their study teams with the tools to protect human subjects and collect quality data.

As can be concluded from Table 1.2, GCP guidelines focus on the clear responsibilities of those who are involved in clinical research.

Table 1.2 GCP criteria and examples for applying these in a nuclear medicine field

GCP	Examples
Institutional review board/ethics committee	The responsibilities of the ethics committee are to
	Safeguard the rights, safety and well-being of trial subjects
	Review the qualifications of the investigator
	Review ongoing trials related to risk
Investigator	The investigator is responsible for
	Communication with the ethics committee regarding protocol, amendments and trial review
	Informed consent of trial subjects
	Records and reports, including safety and premature terminations or suspension of the trial
	Adequate resources for research
	Written procedures for generating data and keeping records
Sponsor	The sponsor is responsible for
	Access to records and safety information
	Adverse drug reaction reporting
	Monitoring and (internal) audit
	Having qualified individuals to make the trial design
	Investigator selection based on appropriate qualifications, knowledge and experience
Clinical trial protocol	The protocol contains general and background information, trial objectives and purpose, trial design, selection and withdrawal of subjects, treatment of subjects, assessment of efficacy and safety, use of statistics, direct access to source data and documents, QC and QA, ethics, data handling and record keeping, financing and insurance, as well as publication policy
	The protocol shall include compliance issues with legislations, e.g. reliable patient dosimetry according to the 2013/59 EURATOM Directive
Essential documents	Documents: trial protocol, informed consent, procedures, information, contracts or agreements, etc.
	Records are retained for at least 3 years after completion of the trial

1.2.2.3 ISO 9000 Family of Quality Management Systems Standards and ISO 9001

The ISO 9001 standards and business excellence models have similar purposes:

- To provide a model for the internal and external evaluation of the QMS
- To enable an organisation to identify its strengths and weaknesses and, thus, provide a basis for continuous improvement
- To obtain external recognition

The ISO 9000 family of QMS standards is designed to help organisations to ensure that they meet the needs of customers and other stakeholders by meeting the requirements related to a product or service. ISO 9001 provides the requirements for the QMS of organisations that wish to meet the standard.

ISO 9000 is based on eight quality management principles, all of which are fundamental to good business practices: customer focus, leadership, involvement of people, process approach, system approach to management, continual improvement, fact-based decision-making and mutually beneficial supplier relationships.

In 2012, a specific ISO 9001 for Healthcare Services (NEN-EN 15224) was released to translate the general terms of QMSs to the field of healthcare services, especially to the hospital environment. The ISO 9001 for Healthcare Services promotes a focus on the patient by emphasising patient centredness. Everything starts with the patient and the professional perspective, and real quality stems from the contact between the healthcare professional and the patient. In addition, this standard promotes the implementation of a risk-based approach to patient safety, which should be embedded in the QMS.

The 11 criteria of quality (appropriate, correct care; availability; continuity of care; effectiveness; efficiency; equity; evidence-/knowledge-based care; patient-centred care, including physical and psychological integrity; patient involvement; patient safety; and timeliness/accessibility) are suggested for use as tools for the organisation to describe the measurable quality characteristics of products and services delivered by the three primary processes of care, education and research, as Donabedian has suggested.(Donabedian 2005) By using the indicators associated with these quality characteristics and (clinical) risks, the QMS enables measurable improvement (Table 1.3).

1.2.2.4 EFQM Excellence Model

In 1988, 14 presidents of European multinationals took the initiative to launch a business excellence model: the European Foundation for Quality Management (EFQM) excellence model. National equivalents, such as the Dutch INK management model, are derived from the EFQM model. The EFQM model (see Fig. 1.2) shows that business results, customer results, people results and society results depend on actions taken in the five enabler areas: processes, products and services, partnerships and resources, people, and strategy and leadership.

Note that the results are framed more broadly than financial results, such as return on investment, profitability and sustainable financial growth. Excellent

Table 1.3 ISO criteria and examples for applying these in a nuclear medicine field

ISO criteria	Examples
The management and the QMS ("Act")	ThQMS is documented in a quality manual
	A quality policy with quality objectives is available
	Responsibilities, authorities and tasks are clearly defined
	(Top) Management reviews the QMS on a regular basis
The resources and the QMS ("Plan")	It is clear what resources (including infrastructure, work environment and personnel with the required competences) are needed to implement the QMS, to deliver quality products and services and to enhance customer satisfaction
The realisation of products and services ("Do")	Processes are planned, and risk assessments of clinical processes are worked out
	Requirements that apply to products/services are clear and are communicated with the customer
	The design of products and services meets the defined requirements
	Purchased, outsourced or subcontracted products are controlled, and suppliers are monitored
	Production and service provision are carried out under controlled conditions
	Measuring equipment is suitable and provides accurate data.
The measurement, analysis and improvement of quality ("Check")	Customer satisfaction is monitored
	An internal audit programme is implemented
	An approach to prevent or correct nonconformity (e.g. complaints) is applied

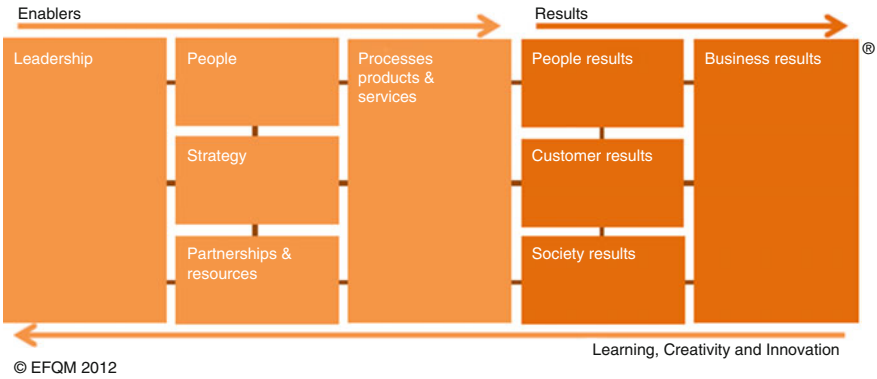

Fig. 1.2 EFQM excellence model. Actions in enabler areas lead to results and reviewing the results leads to learning, creativity and innovation

organisations have good customer results (e.g. value-added products and service excellence), people results (e.g. opportunities to grow, work–life balance and pride) and society results (e.g. brand reputation, ethical behaviour and transparent communication with the society). Hence, excellent organisations perform exceptionally well from a multistakeholder perspective. Furthermore, the model advocates a long-term focus and condemns a short-term focus on only bottom-line financial results.

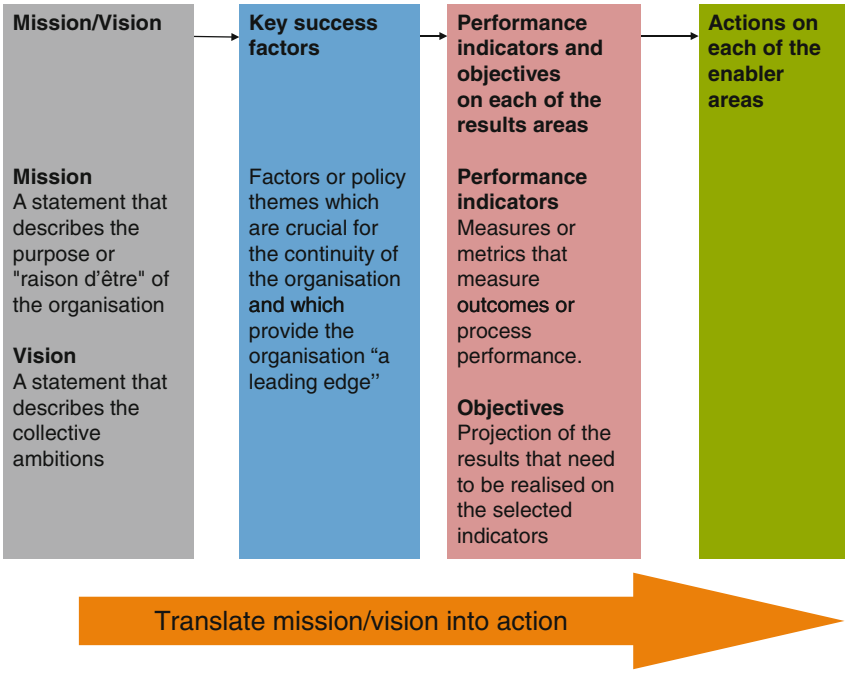

Fig. 1.3 Key concepts in performance management

There are two fundamentally different approaches to applying the EFQM excellence model. First, the model can be used for *continuous improvement*; this starts with elaborating on an analysis of improvement issues and actions in the enabler areas that have an impact on the results areas of the model and may end in writing a self-assessment application of 30–50 pages to apply for and be awarded with a three-, four- or five-star EFQM recognition. On average, two Dutch organisations per year are awarded with such a recognition (three, four or five stars). This implies that organisations that receive the recognition can be considered excellent organisations. In 2011, NMMI received a three-star recognition and is currently preparing a self-assessment document to apply for a four-star EFQM recognition. In the following section, we will reveal an outline of the EFQM criteria and provide examples of the evidence that NMMI applies these criteria.

Second, the model can be used for *management control* by applying the A3 approach (Doeleman et al. 2014). The A3 approach can be applied by drawing up an annual plan for the organisation on one A3-sized page. In such an annual plan, the mission, vision and key success factors are depicted. In addition, the organisation elaborates on the performance indicators of each of the results areas and on the actions in each enabler area that may impact the results. In Fig. 1.3, the meaning of and relationship between the key concepts in management control and performance management are depicted (Ahaus and Diepman 1998). In the following section, we will provide an example of the NMMI A3 annual plan, which illustrates examples of the mission, vision, key success factors, performance indicators and actions.

1.3 Quality Management at NMMI in UMCG

1.3.1 The Evolving Role of the Quality Management System

A QMS helps management to control the quality performance of the organisation. The system approach is simple: Say what you do, do what you say, show that you do what you say, and improve on it. This quality management philosophy is widely used—for example, the Deming quality improvement circle (plan–do–check–act).

The purpose of setting up and implementing a QMS can be to improve products or services; strengthen leadership, competences and working conditions of staff; harmonise management systems; reduce costs due to poor quality; and reduce the risk of adverse events (NEN-EN 15224, Health care services – quality management systems 2012b). When the quality improvement cycle is followed, the sustainability of what has been improved needs to be ensured within the organisation. An important precondition is the quality awareness of the healthcare worker, which is expressed by showing ownership and taking initiative and responsibility. The organisation should support this by defining standards and procedures to guide and support the working teams of the primary process and by implementing clear reporting relations.

In this section, we will show examples of the implementation of the QMS at NMMI. First, we will discuss what ISO 9001 (and its healthcare version) has brought. In addition, using examples, we will show how the EFQM excellence model is applied.

1.3.2 What Has ISO 9001 Brought?

ISO 9001 certification for quality management is a voluntary assessment that is regulated internationally and nationally. As discussed earlier, the ISO criteria focus specifically on the management cycle for quality improvement (plan, measure, analyse and report data).

Whilst the benefits of ISO 9001 are numerous, they can be categorised into one of three areas, which are also known as the 3 "C's" of ISO 9001: consistent service, customer satisfaction and continuous improvement (Metzcar). In the box below, we will discuss NMMI's journey in implementing ISO 9001. The box includes best practices and some lessons learned.

NMMI and ISO 9001

In 1997, NMMI in UMCG launched a project to implement a QMS to describe the processes of four service centres—the clinical laboratories, the hospital pharmacy, the Positron Emission Tomography (PET) Centre and the Department of Nuclear Medicine—and to accomplish the quality aims and sustain a method of working which meets the risks assessed. The search for a standard for QMSs and for implementation strategies offered several options: Dutch variants, such as the INK management model (the Dutch equivalent of the EFQM excellence model), the standards of the Netherlands Institute for

Accreditation in Health Care (NIAZ standards) and an international standard—the ISO 9001.

NMMI chose ISO 9001, and in 2000, NMMI was ISO 9001 certified. Quality improvement was accomplished based on data measured by key performance indicators. This required resources which were devoted to improvement, openness and collaboration. NMMI succeeded in engaging the professionals and motivating commitment to high standards of quality and continuous quality improvement.

In addition to patient care, scientific research and the education of healthcare professionals are also incorporated into the QMS. Explicitly, the "risks" associated with patient care and information security as aspects of the QMS are taken into account.

Best Practices of NMMI

- Quality policy with clear and measurable quality objectives related to key indicators
- Primary process of NMMI, which is "in control" by applying a set of indicators and conducting a regular management review
- A quality manual with protocols and SOPs
- List of risks with priority and the control of critical safety issues
- Patient centeredness within all primary processes, measured by patient satisfaction surveys
- Internal audits on the process of patient care

Lessons Learned

1. Before the start of the project, the QMS for the primary process was a book with instructions of which each person had his or her own interpretation. "SOPs" were implemented after the evaluation of the different interpretations. Now, the processes in the QMS handbook to direct the organisation and control the detailed primary processes fit perfectly. At first, the acceptance of the processes amongst the nuclear professionals was difficult, but their motivation improved when the effect was seen in process performance. A prospective risk assessment helped to include patient safety priorities in the improvement plans.
2. The combination of the different standards after harmonisation in the workplace helped the department to grow, developing a culture that focused on quality improvement.
3. Audits on chains of (care) pathways helped with getting the organisation to focus on patients and referring physicians.
4. Communication and collaboration with third parties regarding quality assurance/quality control was stimulating but also time-consuming.
5. The head of NMMI was a role model in this process of organisation development. However, including quality on the agenda of the board of directors was challenging in the beginning. This is a success factor, as the literature shows that it is positively associated with the effects of the certification and accreditation of the organisation's QMS (Shaw et al. 2014).

1.3.3 How EFQM Brought NMMI Further Along the Road to Excellence

The implementation of the ISO 9001 criteria has assisted NMMI to move to the next stage by helping it to improve and demonstrate its capabilities in a widely accepted framework. The embedding of the ISO 9001 framework in the NMMI QMS has assisted in its efforts to improve the organisation's effectiveness and efficiency. The next stage was applying a business excellence model such as the EFQM excellence model (or the Dutch equivalent, the INK management model).

In Sect. 1.2.2, the enabler and results areas of the EFQM excellence model were introduced. Moreover, we highlighted two different applications of the EFQM excellence model:

- By helping to improve organisational practices, capabilities and results, based on a self-assessment on the EFQM criteria
- By serving as a working tool for understanding and managing performance and for guiding annual planning—for instance, with the A3 approach.

As the quality management of an organisation matures, even if it is on the level of "sustainable success" and "excellent" performance, it remains important for the organisation to continue seeking ever-increasing effectiveness and efficiency gains.

First, we will discuss NMMI's journey with regard to applying the EFQM excellence model. Then, we will set out the EFQM criteria in a table and provide examples of the evidence NMMI reported in its 2015 self-assessment application. Finally, we will provide an example of NMMI's A3 annual plan.

NMMI and Business Excellence, Quality Improvement and EFQM

The business excellence models contain criteria that enable the comparative evaluation of organisational performance, and these are applicable to all activities and all interested parties ("stakeholders") of an organisation. Assessment criteria in business excellence models provide a basis for an organisation to compare its performance with that of other organisations. The combined use of the ISO 9001 standards and a business excellence model such as EFQM will give organisations the opportunity to broaden the application of the QMS as the scope of application of EFQM includes not only patients but also staff (including PhD students), referring physicians, hospital pharmacy, society and the board of directors.

The NMMI started a project to apply EFQM to improve its service level to the medical departments, to ensure that its reports were trustworthy and received in a timely manner and to ensure that its personnel were working in a safe environment and undertaking even more efficient processes.

Best Practices of NMMI

- An analysis of the expectations, needs and wishes of all stakeholders and the measurement of stakeholders' experiences in separate surveys amongst patients, referring physicians, employees, PhD students and the management of trends in stakeholder satisfaction
- The collaboration with other universities, hospitals and strategic partners, such as Siemens, which put NMMI in a leading position in the nuclear medicine field
- The contribution to society by writing books to disseminate scientific output, delivering presentations to congresses and educating students in the medical sciences

Lessons Learned

1. The role of the department manager is very important because he is personally involved in creating a culture of quality excellence.
2. The QMS (including safety management) of NMMI has been certified in all kinds of standards, and NMMI applies these criteria for many years. In addition, NMMI applies a quick yearly scan in the EFQM areas, followed by the application for EFQM recognition in 2011 and in the summer of 2015. By applying quality thinking for many years, it is in the "genes" of the NMMI.
3. The implementation of total quality management requires a vast investment in information technology (a documentation programme), extra equipment, personnel and education. It was important to think about the maintenance of up-to-date documentation, the maintenance of equipment, the measurement of stakeholders' experiences with questionnaires and the education needed to work with instruments such as internal auditing.
4. UMCG started a hospital-wide ISO 9001 initiative whilst NMMI started the application of the EFQM excellence model. There was a symbiosis of NMMI striving for excellence and UMCG as a whole striving for ISO 9001 certification.

In the following table, we list the main EFQM criteria and provide examples of the evidence derived from NMMI's self-assessment report. The EFQM self-assessment report is the source document for the external EFQM audit, which is an assessment that is done by EFQM auditors. It can be assessed whether NMMI can be awarded with a three-, four- or five-star recognition based on the score on a scale of 1–1,000 points. As discussed, NNMI received a three-star recognition in 2011 and is currently (2015) applying for a four-star recognition (Table 1.4).