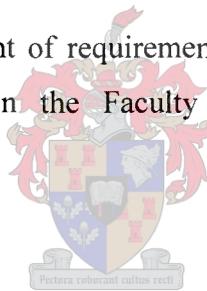


**Working towards the implementation of an international accreditation
programme in a Nuclear Medicine Department of a South African
teaching hospital**

Thea Eiselen

Thesis presented to the fulfilment of requirements for the degree of MSc in Medical Sciences (Nuclear Medicine) in the Faculty of Health Sciences University of Stellenbosch.



Supervisor: Professor A Ellmann

April 2005

DECLARATION

I

Dorothea Eiselen

hereby declare that the work contained in this thesis is my own original work and that I have not previously in its entirety or in part submitted it at any university for a degree.

Signed:

Date:

ABSTRACT

Introduction: Quality assurance in Nuclear Medicine is of utmost importance in order to ensure optimal scintigraphic results and correct patient management. A customised Quality Management System (QMS) should be documented and implemented by following the international guidelines set by the International Standardisation Organization (ISO).

Materials & Methods: A Quality Control Manual (QCM), defining the departmental quality policy, mission, vision and objectives was customised following the framework of a tried and tested design. As ISO focuses on client satisfaction and staff harmony, the following departmental objectives were audited in working towards the accreditation of the Nuclear Medicine Department of Tygerberg Hospital: referring physician satisfaction, patient satisfaction as well as staff satisfaction and harmony. Information was collected by means of questionnaires completed by referring physicians and staff members. One-on-one interviews were executed on patients. An international ISO accredited Nuclear Medicine department was visited to establish the suggested path to follow *en route* to successful ISO accreditation and certification.

Results: Referring physicians indicated overall satisfaction with service provision, but a need for electronic report and image transfers seemed too dominant. The patient satisfaction survey resulted into overall satisfaction with personal service providing, but the provision of written and understandable information, long waiting times and equipment must receive attention. Staff questionnaires indicated a general lack of communication between different professional groups and the need for interpersonal loyalty and team building. Improvement measures were identified to ensure the continuous improvement of the QMS by focusing on these quality parameters.

Conclusion: The department has QA procedures in place, but does not meet all criteria for external accreditation. In order to ensure departmental harmony and sustainability of client and staff satisfaction, the departmental objectives in measured and improved where needed. The successful implementation and continuous improvement of a customised QMS, following the guidelines outlined in the QCM will lead to successful accreditation.

ABSTRAK:

Inleiding: Die belangrikheid van kwaliteit versekering in Kerngeneeskunde vir die versekering van optimale flikkergrafiese resultate en korrekte pasient handtering kan nie onderskat word nie. 'n Klantgerigte Kwaliteitsbeheersisteam (KBS) moet gedokumenteer en geimplimenteer word vir die Kerngeneeskunde Departement deur die riglyne te volg soos uiteengesit deur die Internasionale Standardiserings Organisasie (ISO).

Materiale & Metodes: 'n Kwaliteitskontrol handleiding (KH), wat die departementele kwaliteitsbeleid, die missie en visie asook die departementele doelwitte definieer is ontwerp en saamgestel vir die Kerngeneeskunde departement van Tygerberg Hospitaal. Hierdie ontwerp is gebaseer op die raamwerk van 'n aanvaarde kwaliteitsbeheersisteam. ISO fokus op klante tevredenheid asook personeel harmonie en tevredenheid. Vir hierdie rede is daar 'n tevredenheidpeiling uitgevoer op die klante en personeel in die strewe na ISO akkreditasie en sertifikasie. Inligting was versamel deur vraelyste wat ingevul was deur die verwysende geneeshere, pasiente en personeel.

Resultate: 'n Kwaliteitskontrole handleiding was saamgestel vir gebruik in die Kerngeneeskunde departement. Die interne audit resultate het aangedui dat die verwysende geneeshere tevrede is met die algehele dienslewering. Die behoefde aan elektronies versende verlae en beelde was dominerend. Die pasient tevredenheidspeiling het bevestig dat die pasiente tevrede is met persoonlike dienslewering, maar 'n tekort aan verstaanbare en geskrewe inligting was geidentifiseer. Die lang wagtye en stukkende apparaat is ook gebiede wat verbertering benodig. Algemene gebrek aan kommunikasie tussen die verskillende beroepsgroepe, die behoefte aan interpersoonlike lojaliteit en span werk was die hoof bevindinge van die personeel tevredenheidspeiling. Verbeterings maatreels, gefokus op hierdie departementele doelwitte, was geidentifiseer ten eide te verseker dat die KBS voortdurend verbeter en in stand gehou word.

Samevatting: Alhoewel die departement wel KB prosedures in plek het, voldoen dit nie aan al die kriteria vir eksterne akkreditasie nie. Ten einde departementele harmonie en kliente tevredenheid te verseker, met die oog op ISO sertifikasie, moet die departementele doelwitte deurlopend gemeet en verbeter word.

ACKNOWLEDGEMENTS:

I wish to express my sincere gratitude to Professor Ellmann for her constructive comments and input throughout the duration of this project. I am also indebted to the staff of the Nuclear Medicine Department of Tygerberg Hospital for their continuous support and help.

A special word of thanks and appreciation goes to Professor Dierckx, Filip de Vos and the other staff members of the Nuclear Medicine department of the Ghent University and University Hospital for their advice and contribution towards the documentation used in this project.

Last, but definitely not least, my profound gratitude goes to my husband, Erhard and son, Quintin for their moral and emotional support.

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Chapter 1: Introduction

Similar to the trade industry, the international focus of the health care sector is rapidly moving towards client satisfaction and quality product delivery. Quality assurance and quality management in Nuclear Medicine is of utmost importance to obtain optimal scintigraphic examination results and to ensure consistent client, i.e. patient and referring physician satisfaction. Therefore the Society of Nuclear Medicine (USA)¹, the American College of Nuclear Physicians¹ and the European Association of Nuclear Medicine^{2,3} have designed and implemented procedure guidelines and protocols⁴. These are currently used internationally to identify and develop departmental quality policies and objectives. Different countries and departments, however, have different requirements and needs. Since departmental objectives and quality policies differ and are unique to a specific department, it is necessary to develop and implement tailor made guidelines for a specific department, by following specific guidelines.

Before standardised good practice guidelines can be tested, adapted and implemented in South Africa, and possibly in Africa, it must be evaluated in a smaller environment. This process will lead to the compilation of standard operating procedures (SOPs) applicable to local circumstances. This may then be adopted and implemented by other departments or units on a national and possibly continental level and will eventually lead to greater uniformity of Nuclear Medicine practices. Most of all it should increase the credibility and reliability of Nuclear Medicine services for the patient, the referring physician and health care authorities.

Several factors influence the optimal functioning of any Nuclear Medicine Department. An initial survey of current practices should address all these processes and procedures, with the aim of progressing to a comprehensive quality assurance and management system. It is essential to address and include all departmental aspects involved when formulating a departmental quality policy and in identifying departmental objectives. A standardised programme should be customised and managed according to the quality policy, individual needs, objectives and requirements of a specific department. The successful implementation of a Quality Management System (QMS) represents sound

practices and should be developed using scientific findings and national and international guidelines.

1.1 Aim

This specific project will include the design of a Quality Management System (QMS) in one of the bigger Nuclear Medicine departments in South Africa i.e. Tygerberg Hospital according to the standards set by the International Standardisation Organisations' 9001:2000 document⁵. A custom designed Quality Control Manual (QCM) will discuss the formulated quality policy and identified departmental objectives and key performance areas. This QCM will act as a reference framework to successfully implement the QMS by measuring service quality and the departmental objectives. Although all the departmental objectives form part of the Quality Management System, the main purpose of this study is to determine the degree to which the Department of Nuclear Medicine of Tygerberg Hospital meets departmental objectives regarding client satisfaction and staff satisfaction and harmony *en route* to International Standardisation Organisation (ISO) accreditation. The patients and referring physicians are referred to as clients throughout this document.

1.2 Departmental objectives

In order to meet ISO requirements, several key performance indicators were identified as departmental objectives to assist in the implementation and maintenance of a customised programme with the aim of attaining ISO accreditation and certification.

These are:

- 1) patient satisfaction;
- 2) referring physician satisfaction;
- 3) staff satisfaction and harmony;
- 4) staff development;
- 5) accurate and correct performance of examinations;
- 6) efficient use of available equipment and resources;
- 7) clear and diagnostically valuable reports; and
- 8) accurate and traceable archiving

Although the fundamental focus of this project will be on the first three departmental objectives, they can not be isolated from the others as they all form part of the departmental Quality Management system.

1.3 Problem formulation

The main purpose of this study is to: i) formulate a plan of action to implement a Quality Management System by following guidelines outlined in the QCM, which will lead to ISO accreditation and certification; ii) determine the degree to which the Nuclear Medicine Department (NMD) of Tygerberg Hospital (TBH) meets the identified departmental objectives regarding client satisfaction and staff satisfaction and harmony and iii) set guidelines for future actions regarding ISO requirements not addressed under (ii).

1.4 Study objectives

- 1) To document an outline of ISO requirements
- 2) To formulate and set up an appropriate Quality Management System (QMS), guided by the ISO norm and requirements for the Nuclear Medicine Department of Tygerberg Hospital
- 3) To prepare a Quality Control Manual (QCM) for internal use in the continuous improvement of the Quality Management System within the department
- 4) To determine the current status of the department, regarding client satisfaction and staff satisfaction and harmony, as a baseline for future follow-up internal and external audits
- 5) To identify areas of improvement as a result of the internal audits performed on the referring physicians, patients and staff.

1.5 Future objectives

- 1) Execution of intensive internal audits on the remaining identified departmental objectives as outlined in the QCM in addendum A.
- 2) Identification of areas of improvement according to the results of the internal audits on the remaining departmental objectives
- 3) Implementation and re-auditing of the improvement measurement of all the departmental objectives.

- 4) Using the Nuclear Medicine Department of Tygerberg Hospital a pilot department for the implementation of a Quality Management System, and to test the applicability and relevance of the programme in order to meet international standards set by ISO.
- 5) Attaining ISO certification by approval of the implemented QMS by ISO's external audit team.
- 6) Extension of the programme, after the successful completion of this pilot project to other Nuclear Medicine departments in South Africa and eventually to other African countries. This will result in the standardisation of and effective functioning of Nuclear Medicine departments, with client satisfaction as an end result, on the African continent.
- 7) Utilisation of the successful ISO certification as a stepping stone towards a more clinical accreditation model, for example the European Foundation for Quality Management (EFQM)⁶.

1.6 Why ISO 9001:2000 accreditation and certification?

Although ISO regulations are associated with administrative⁷ procedures rather than clinical procedures and results, it is important to emphasize the specific reasons for ISO accreditation for the Department of Nuclear Medicine of Tygerberg Hospital:

- 1) It will serve as a visual demonstration of the quality policy.
- 2) It will assist in the validation and documentation of processes and procedures currently in use.
- 3) It will ensure good communication between staff.
- 4) It will ensure good communication with the client.
- 5) It will set a high educational standard and continuous development of clinical staff.
- 6) It is in the interest of national and international collaboration to be part of an internationally recognized accreditation body.
- 7) The ISO regulations published in 2000, and used in this study, are moving closer to the European development model EFQM⁶. This transforms the successful ISO accreditation into a stepping stone towards international clinical accreditation.
- 8) Many countries successfully use ISO hand-in-hand with other peer review programmes⁶.

Chapter 2: Quality Management Systems (QMS) and ISO 9001:2000 – An overview

The introduction and successful implementation of an external quality management system depend on the social, political and economical environment within the specific country⁶. The need for improvement within the health sector is an international phenomenon, especially in developing countries. This is due to limited resources and increasing demands from a disease-troubled population. Quality assurance activities not only focus on and deal with local problems, but also serve as a replication framework model for modifications in different settings⁸. A sustainable quality assurance programme depends on the development of a quality assurance structure, continuous standard setting, routine monitoring and quality improvement activities to develop a culture of quality service provision. It is therefore important to choose a QMS which will fit into the socio-economic climate of the department implementing the quality assurance programme.

2.1 What is a quality management system?

The implementation of a quality management system in any department should be a strategic decision. The design, planning and implementation of a QMS will vary from one department to another as it is influenced by a number of factors. These include: various needs; particular objectives; the products; the processes used; the size and structure of the organisation; the complexity of processes and their interactions and the staff competence⁹. It is important to remember that when designing a quality management system, ISO requires a well documented quality management system and not a well managed document system. At the start of the implementation of the quality management system (QMS) the emphasis should therefore be on the standardisation process and not on the set of documents needed to accomplish it. However, ISO stipulates specific criteria for documents associated with the QMS including that it should communicate information, show evidence of conformity and aid in sharing knowledge. Therefore a QMS can be defined as the collection of processes, documents, resources, and monitoring systems that direct the work of an organisation regarding product and service quality⁹. The organisation needs to establish, document, carry out, and maintain this system to meet the requirements of ISO 9001:2000⁵.

The documents required by ISO are listed in clause 4.2.1 of the ISO 9001:2000 document and must include¹⁰:

- 1) Documented statements of a quality policy and quality objectives as defined in clause 5.3 of ISO 9001:2000 document.
- 2) A quality manual, Clause 4.2.2 of the ISO 9001:2000 document specifies the minimum content of a QCM.
- 3) Documented procedures required by this international standard for the following six activities: control of documents, control of records, internal audit, control of nonconforming products, corrective actions and improvement/preventative actions.
- 4) Documents needed by the department to ensure effective planning, preparation and control of departmental processes for example a SOP database and QCM.
- 5) Records required for this international standard; examples include organisational charts, flow charts etc.

When planning a QMS, identified quality assurance principles must be used as quality indicators. The effectiveness of a quality control system is measured by monitoring the quality indicators set by the department as indicated by their clients. This monitoring process can be done by using the well-known Deming circle¹¹ of quality control, i.e. “plan, do, check, adjust”. In 1950, Deming proposed that business processes should be analysed and measured to identify sources of variations that cause products to deviate from client requirements. It was recommended that processes should be placed in a continuous feedback loop to ease the identification of processes that need improvement.

2.2 Quality policy

In order to attain certification and accreditation, the management of the Nuclear Medicine Department of Tygerberg Hospital has identified the need for the design, development and implementation of such a QMS.

Within this custom designed system, all procedures and processes performed within the department will be documented, as required by ISO regulations, to optimize client service as well as staff satisfaction and harmony. This policy will be built on the principle of continuous improvement of identified problem areas.

2.3 Why Quality Control and Accreditation?

The term accreditation refers to the systematic assessment of procedures against defined standards and applied to organisations. It was introduced to the medical field in 1917 in the USA⁶. In the modern world, accreditation and in particular quality assurance aims to make the healthcare sector more responsive to client needs. The implementation of a quality assurance programme, as shown by comprehensive experience, can be a daunting exercise and several guidelines are available in the literature. It is however, emphasised that a flexible and standardised methodology should be adopted when developing a quality assurance and management system. Any department interested in the implementation of a successful quality management system, is strongly advised to gradually develop a custom made programme based on existing systems⁸.

2.4 ISO: A historical perspective

International standards started in 1906 in the electrotechnical field with the organisation named International Electrotechnical Commission (IEC). In 1926, the International Federation of the National Standardising Associations (ISA) undertook a lot of groundbreaking projects in other fields. Delegates from 25 countries, including South Africa, decided to form a new international organisation with the purpose of “facilitating the international coordination and unification of industrial standards”¹³. This new organisation called ISO (International Organisation of Standardisation) is a network of national standards establishments from 148 countries, one per country, coordinated by a central Secretariat situated in Geneva, Switzerland. ISO originated in 1947 in the United Kingdom and was designed to set up standards for the defence, engineering and manufacturing industries. Since then the model has become very popular and is used in 88% of European countries. To date, 230 000 ISO 9000 certificates have been issued to numerous organisations including the health sector^{12,13}. The South African Bureau of Standards (SABS) as the national standardisation body in South Africa has the duty, according to section 3(a) of the Standards Act (1993), to maintain a South African presence in ISO and contribute to the formulation of international standards applicable to the country¹³. Organisations currently in the proud possession of ISO certification include one of the country’s biggest cellular communication networks MTN, Konica Minolta, NTP Radioisotopes (Pty) Ltd. The South African National Accreditation System (SANSA) is recognised by the South African government as the single National

Accreditation body that gives formal recognition that laboratories, certification bodies, inspection bodies and Good Laboratory Practice (GLP) test facilities are competent to carry out specific tasks. This certification is also based on ISO framework regulations¹³.

ISO, derived from the Greek word *isos*, meaning equal, is the International Standardisation Organisation who designed and uses 11 000 international standards, making it one of the worlds' largest developers of standards. ISO specifies very precise requirements for a quality management system. ISO 9000 does not concentrate on what is to be done to improve health care, or the requirements to offer it well. In fact, ISO 9000 is concerned with quality management, or in other words, what the organisation "does" to enhance customer satisfaction by meeting customer and applicable regulatory requirements and to continually improve its performance in this regard. The focus of ISO is on the conformance to specifications, i.e. how successful predetermined objectives and specifications are met¹⁵. The standards set by ISO play a role in the development and supply of products and services. Apart from this, governments are assisted in setting up a technical base for health legislation and to ensure conformity in the assessment of professionals. Any organisation interested in attaining ISO accreditation must demonstrate the ability to consistently provide products that meet client needs as well as adhere to applicable regulatory requirements. The organisation should aim and focus on the enhancement of client satisfaction through the effective implementation and application of a quality management system. Equally important is the fact that this system must be improved continuously to ensure conformity^{9,10}.

2.5 What does international standardisation mean?

According to ISO, a department or institution can measure its degree of successful standardisation if all the involved parties can agree on specifications and criteria in the classification of examinations, preparation and supply of products, testing and analysis processes as well as service provision. In short, it is a reference framework or common technological language between clients and service providers⁹.

The conformity of services and products to ISO standards ensure their quality, safety and reliability and increase the degree of competition among suppliers. Another beneficiary would be the government, as these standards provide the technological and scientific bases underpinning health, safety and environmental legislation.

Important facts on standardisation are¹⁰:

- It involves drawing up necessities and requirements, in other words, in the standardisation process agreements are made and established. The established necessities are called standards.
- These standards give one or more solutions to problems.
- If these problems already exist, standardisation can create order in an existing chaos. Another possibility is that problems would occur in the future if there were no standard.
- The solution is for general use: it is not customised to work for one party, but the same solution can be used by many.
- That solution is not for single use but for repeated use over a certain period (until the standard is revised or withdrawn).
- Standardisation aims to reach the optimum degree of order.

It is for this specific reason that the quality management system should be based on guidelines outlined in the QCM.

2.6 ISO hallmarks

A hallmark can be defined as a mark indicating quality and excellence. Not only does ISO offer a visual emblem certifying just that, but also has very specific guarantees to organisations interested in attaining ISO certification. These are⁹:

- 1) Equal footing – all ISO members reserve the right to develop and implement standards important to their institutions' functioning. Their standards are set and implemented on democratic footing with each participating member having equal input into the development thereof.
- 2) Voluntary – as ISO operates independently no member can be legally forced to implement any of its standards. Many countries adopted ISO standards, especially within the health sector as part of their regulatory framework.
- 3) Market-driven – ISO only develops standards, using experts from the market place, where standards are mandatory.
- 4) Consensus – standards are developed on the basis that an agreement must be reached amongst interested parties in order to ensure extensive applicability of the specific standards. At least every five years, all standards are reviewed to ensure that standards are updated or withdrawn if necessary.

- 5) International – standards should be compatible with worldwide technology and needs. Currently there are approximately 2850 ISO technical groups as well as some 30 000 professionals working on developing standards within ISO regulations.

2.7 Basic principles of ISO

The ISO 9000 regulations address “quality management”. This means that the institution must maintain client satisfaction by meeting client needs and applicable regulatory requirements and the continuous improvement thereof. ISO certification is about designing a quality management system for the development of a product as per client requirements⁵. It must be emphasised that ISO was not developed to specifically evaluate Nuclear Medicine procedures or facilities, or to replace statutory licensing requirements¹⁴, but does require that a basic set of rules are followed.

2.8 Examples of other existing quality management systems

All over the world the interest in accreditation has increased, resulting in a growing number of accrediting bodies. The configuration of each of these accreditation organisations can be linked to chronological and cultural factors as well as the blueprint of the health sector of the involved country. Some of these accreditors focus on accreditation of the entire organisation’s protocols and procedures for example ISO, others like the Council for Health Service Accreditation of Southern Africa (COHSASA)¹⁴ focus on specific geographical regions. The European Foundation for Quality management (EFQM) model, on the other hand, focuses on the accreditation of specific clinical services. It is however, clear that all these accreditation bodies have one specific goal and this is the improvement of service quality¹⁵.

2.8.1 COHSASA

COHSASA was structured as a national collaborating body between the state, private industry, customers and health care professionals. This organisation consulted accreditation bodies in Canada, the UK, Australia and the Joint Commission International Accreditation (JCIA). Two sets of standards were set up namely “General Standards” and “Service-specific Standards”. Their programme is characterised by its integrated, multi-disciplinary, continuous improvement approach and is currently the

“only national accreditation body for health care facilities and is in the process of working towards an international accreditation process to meet Southern Africa’s needs”¹⁶. Contradicting this, however, is the fact that Zambia has developed its own accreditation programme, and set standards, between 1997 and 2000 as “COHSASA was formed earlier but does not yet operate on national scale”¹⁷.

The authors of both these papers emphasised the heavy workload, amount of time and resources needed to design these programmes as well as the budgetary constraints associated with the implementation thereof. The implementation of a QMS, whether nationally or internationally based, involves a heavy workload and many other factors mentioned in the referenced papers. The author of this document has therefore opted to adopt an internationally recognized tried and tested accreditation and certification programme to ensure future expansion of the departmental quality policy and the continuous improvement thereof.

2.8.2 EFQM

The European Foundation for Quality Management model identifies specific domains for clinical results as well as patient and staff satisfaction. It offers a basis model framework which can be used in designing other models making it a unique model to use in conjunction with ISO regulations⁶.

2.8.3 *Visitatie*

The *visitatie* model originated in the Netherlands in the early 1990’s and is still currently used as a tool to ensure quality patient services to increase the degree of public trust and to convince the government and financial institutions of the sustainability of the quality policy of the profession. Similar to ISO audits, the participating departments/practices undergo surveys on a regular basis. The confidential report, composed by the surveyors, is sent to the management of the department/practice. Included in this report are recommendations for improvement. Although no formal follow up visit is arranged with the department/practice, it is expected that the recommended improvement must be implemented. The development of ISO and EFQM were performed by users outside of the health care sector, while *visitatie* focuses

on the clinician and the continuous improvement of the health care sector as seen by the patient^{6,18}.

Chapter 3: Literature review: Client satisfaction and auditing

3.1 Background

An effective way of using internal audit results is by incorporating them into the departmental quality assurance (QA) mechanism. In a QA set-up, client satisfaction survey results are used to identify areas of improvement by using a continuous feedback system. In Australia this incorporation of client satisfaction surveys is widely used in hospital accreditation programmes, while in the UK client satisfaction surveys have been proposed and are routinely used as an audit tool¹⁹. In this study, the international trend was followed, by using the client and staff satisfaction survey results to compare the departmental objectives to the departmental results. By evaluating these results, the areas in need of improvement can be identified. These identified areas must then be incorporated into a continuous feedback system as part of the departmental Quality Assurance and Quality Management programmes *en route* to international ISO 9001:2000 accreditation and certification. Quality assurance can be defined as “all actions directed towards acquiring, conserving and increasing the trust of the client”¹⁹. A clearly stated mission, vision, quality policy and departmental objectives and goals must be imbedded into this departmental quality management programme.

3.2 Client satisfaction

A service triangle theory was designed by Haywood-Farmer²⁰ which is widely used for the analysis of patients’ and staff opinions on service quality as well as to increase the understanding of quality management in different service providing scenarios^{20,21}. It is formulated that an organisation consists of three components, i) “physical and process”; ii) “personal characteristics” and iii) “technical skills”. These are represented by a triangle.

The bottom of the triangle represents the “human capital” component of the tool, with the “technical skills” component on the one side and the “personal characteristics” on the other side.

Technical skills are referred to as those professional qualities, provided by education, of staff to adequately perform their duties. On the other side of the “scale”, however, the “personal characteristic” component refers to qualities unique to the individual.

The third and top angle represents the “physical and process” component and corresponds to all processes, procedures, protocols and systems used in the department (figure 3.2.1)²⁰. Each individual component influences the main objectives and focuses of any department. Depending on the “weight” of every individual component, the balancing point, represented by the diamond in figure 3.2.1, will be closer to either side of the triangle.

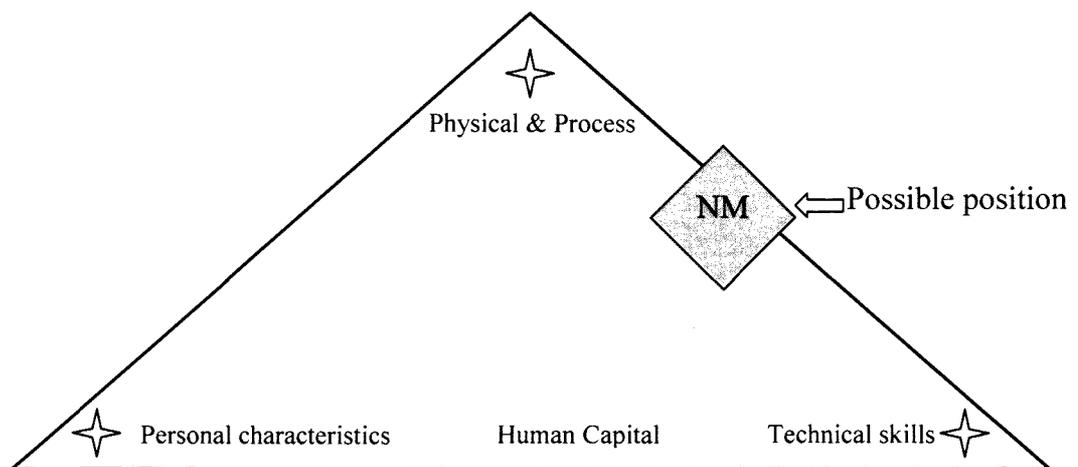


Figure 3.2.1

Due to the nature of nuclear medicine procedures, the objectives and focuses of most nuclear medicine departments will be situated half way between the “physical and process” component and the “technical skills” component of the service triangle. This is due to the fact that specific technical processes and protocols are performed by skilled professionals in order to attain a result. Although most nuclear medicine departments offer the same services, the service quality differs substantially. For this study, client and patient satisfaction were identified as departmental objectives. For this reason, one of the anticipated outcomes, based on the results, is to ensure that this metaphorical “position” moves closer to the “personal characteristics” corner of the service triangle (figure 3.2.2). Balancing the three service components by moving the “centre of gravity” will ensure that the provided service is more client and patient orientated without compromising the technical and physical and process components.

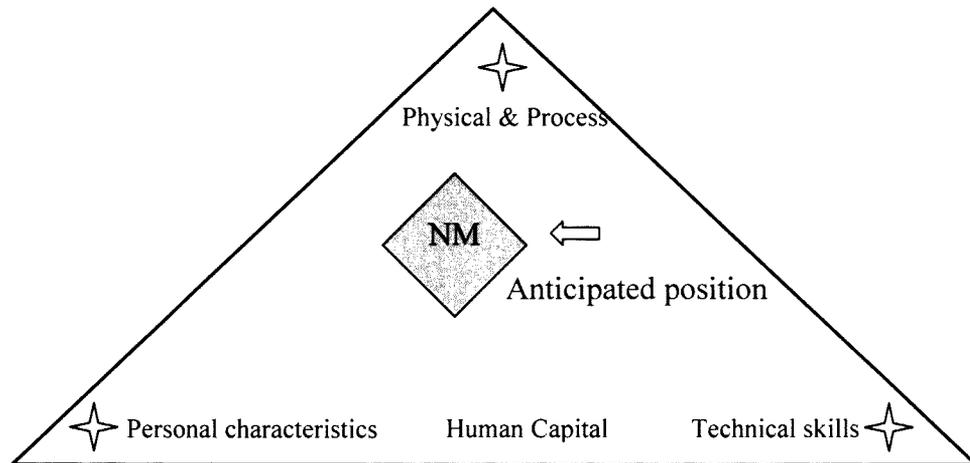


Figure 3.2.2

Literature concludes that service quality within the health sector has a multi-facet configuration, however two facets outshine the rest; i) the technical accuracy of medical diagnostic examinations and ii) the method of service provision to the clients^{22, 23, 24}. It is for this reason that the departmental objectives, apart from the objectives focused on in this study also include: i) accurate and correct performance of examinations; ii) efficient use of available equipment and resources; iii) clear and diagnostically valuable reports; and iv) accurate and traceable archiving²⁵. From the results outlined in the literature^{22,23,40}, it is clear that quality service is closely related, but not equal to client satisfaction, but most of all service quality can not be improved unless it is measured.

Client satisfaction is viewed as a highly desired outcome and goal of the health profession within the modern world. It is probably because of this that the focus of the health care sector is rapidly turning towards client satisfaction, by setting clear objectives regarding client and patient care.

In the retail and business environment, client satisfaction surveys are performed as part of marketing research and used to increase profit. In the health sector this concept can symbolically be adopted, as health service providers are becoming business owners, complete with clients and products, and should show profit. Similar to customers, the referring physicians and patients request information on the provision of diagnostic and treatment services. Should the information be unavailable or not readily understood the clients would highly likely “shop around” until their needs have been satisfied²⁶.

The main method used for determining and monitoring client satisfaction is by random surveys using preset questionnaires¹⁹. Within a competitive environment, those departments seeking international funding and accreditation should show an increased effort to continuously focus on and improve client care. The number of papers published on client satisfaction is enormous. Very little, however, has been said about using the survey results to achieve client satisfaction objectives. In order to successfully achieve these preset objectives, it is important to design the questionnaires or survey tools around the objectives and not to design the objectives around the survey tools or results¹⁹.

The internal audit results, attained for the purpose of this study, represent client needs and demands and are used as an identification tool of problem areas. In order to improve client service it is important to listen to the clients' demands and requests in order to identify their needs and priorities. To identify and successfully address the clients' needs and concerns it is important to prioritise the improvement of the main problem areas. However, care should be taken when prioritising improvement areas. Clients completing satisfaction survey questionnaires are merely asked to give their opinion on a number of specific issues but are not asked to compare different categories. When prioritising improvement measures, one should ensure that the available resources are used optimally²² bearing in mind that the effectiveness of the improvement measurement is dependent on the successful implementation thereof. A lack of the correct resources, be it financial capital or human capital, will result in failing to improve client satisfaction. Regardless of which areas are chosen to be improved, using the resources which are available, will improve the overall satisfaction score. However, it is important to remember that client satisfaction surveys are used to increase and maximize overall client satisfaction and not to prove that the clients are satisfied due to an overall higher score^{19,27}. For this reason, the choice of improvement measures should be realistic and workable within the departmental structure.

According to a study done in the United Kingdom²⁸ the improvements done as a result of internal audit results can be classified as being direct, indirect or none. In the case of direct improvement, the results of the measures taken have a direct influence on the quality management system. On the other hand, indirect improvements are those implemented measures that have no effect on the feedback loop of the quality

management system. No improvements can be defined as those implemented “improvements” that have no effect on increasing client satisfaction as no attempt was made to complete the audit cycle. As outlined by Deming¹¹ and the QCM (Addendum A:7) the only way to effectively manage a QMS is by using a continuous feedback system. It is therefore important to take ownership of and responsibility for the departmental objectives and the completion of the continuous feedback loop. This must be done by implementing improvement measures which will have a visible impact on the service quality and not merely prevent non-conformities.

3.3 Auditing

As we enter an era of increasingly rapid change, the need for client satisfaction and protection is growing just as rapidly. This client protection and confidence in the supplier can be brought about by certification, inspection and testing of products and procedures under a certified quality system. As the client or supplier cannot perform this inspection process themselves, this task is allocated to a recognised accreditation body. Accreditation is the procedure by which an authoritative body gives formal recognition of the competence, impartiality and performance capabilities of a body or a person. It establishes confidence in certificates and reports by implementing internationally accepted criteria set by bodies such as ISO. It is important that service providers are aware of, and understand the benefits of accreditation. All involved parties should be well educated and informed about the preparation, auditing and implementation processes. It must be stressed that the aim of the process is to strive towards perfection, and should not be seen as a threat. However, the results of an audit usually imply change. There are several guidelines for approaching successful change. They are listed below^{10,30}:

- It should be planned and implemented in phases and should be considered in relation to the requirements of the department.
- In order to conduct a successful clinical audit (internal and external) it is important to create a level of trust amongst all involved parties.
- In order to gain commitment to the process, those closely affected should be involved in the planning and implementation thereof.

- By allowing the parties involved to make free and informed choices, they must however also be prepared to alter their behaviour to work as a team towards this goal of perfection.

Auditing has been developed as a tool to measure the service quality against pre-defined standards and objectives as well as a motivation tool to change unacceptable service delivery³⁰. The term internal audit refers to the activity whereby the ISO task team, facilitated by the quality control administrator, arranges an audit. This audit team consists of members working in the department. It is advised that a staff member from an independent department should be included in the audit team. The auditor has to verify how the overall departmental objectives have been met and how these processes are communicated and monitored. For example, if one of the departmental objectives is to improve client satisfaction, the auditor should look for confirmation that the department is monitoring its planned activities to reach the set goal. During the auditing process it is important that the auditor should not lose sight of the overall purpose of the audit, i.e. evaluating the processes within the QMS, and not get side-tracked by unnecessary detail²⁹.

An external audit is performed by an ISO audit team. The ISO team should only be invited to perform the external audit once the departmental ISO task team are confident that all ISO requirements are met by evaluating internal audit reports and activities. According to ISO the auditing technique should include: interviewing the top management to understand their approach, loyalty and involvement in quality, and the departmental quality policy, interviewing staff members to verify their awareness, understanding and knowledge regarding the departmental quality policy and how it relates to their personal activities and seeking evidence of effective propagation of the quality policy by effective communication²⁹.

The United Kingdom government White Paper on “Working for Patients” defines the medical audit as “a systematic, critical analysis of the quality of medical care, including the procedures used for the diagnosis and treatment, the use of resources, and the resulting outcome of the patient³⁰. When performing audits it is important that a specified audit cycle is followed. Audits have specific characteristics which include being logically organised and controlled, aiming to improve client satisfaction, resulting

in changes in processes and following a specific systematic sequence. Auditing should be a continuous process or at the very least contain an element of re-auditing. Monitoring processes and procedures at random, does not adhere to the defined term “systematic” and therefore it is important that a well organised system is in place to ensure the validation of all processes and procedures under audit.

The other characteristic of the analysis, namely that it should be critical, tends to pose a threat and could influence the outcome and details of the audit report. An audit friendly environment holds the success key for auditors, therefore it is important to prepare all the involved parties on audit procedures and the aims thereof. In order to conduct a successful clinical audit (internal and external) it is important to create a level of trust amongst all involved parties³⁰. The importance of the internal and external audit as an identification tool for problematic areas, in need of improvement must be emphasised to ensure that the process does not merely become a cosmetic routine.

The clinical audit cycle (Figure 3.3.1) demonstrates an interesting coherence to the continuous improvement system (Figure 3.3.2) designed and published by Deming in 1986^{28,31}.

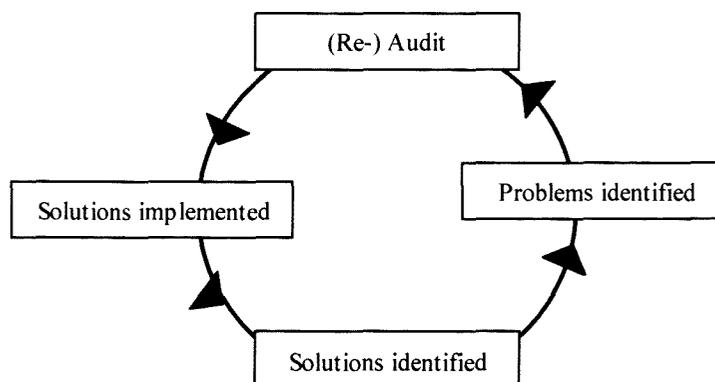


Figure 3.3.1

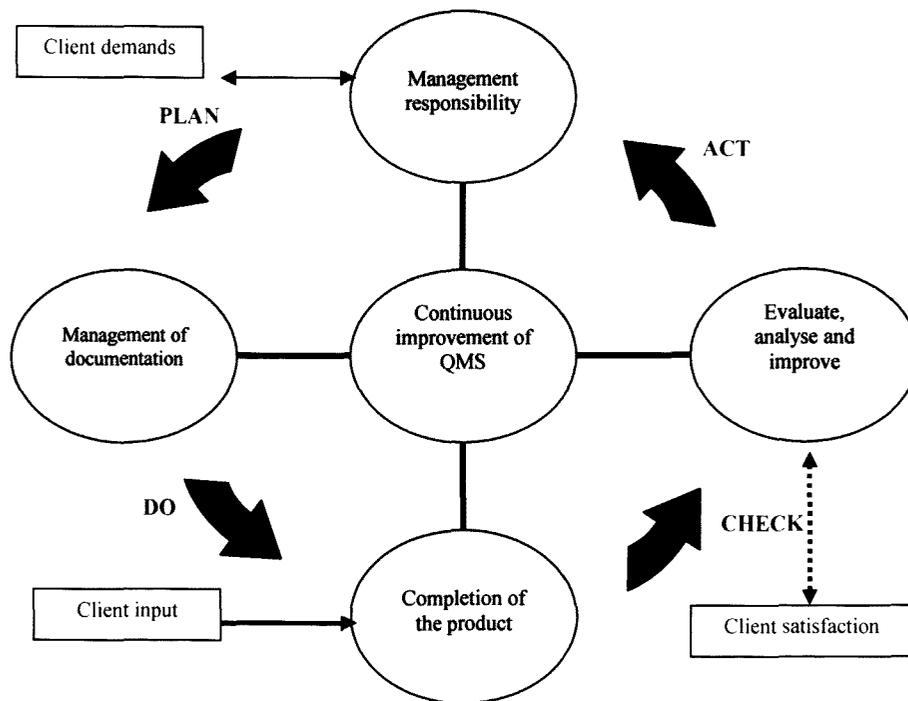


Figure 3.3.2

From these diagrams it is clear that the audit cycle consists of different stages including³⁰:

- i) identifying the issues to be audited
- ii) setting standards and/or objectives
- iii) measuring the quality and checking the results against the standards set
- iv) identifying improvement measurements
- v) deciding on strategies for change
- vi) implementing necessary improvement measures
- vii) monitoring the effect of changes against the standards/objectives set

The process can start at any stage and will continue until the standards/objectives have been met, or new standards have been set.

Using the guidelines provided by the literature, a baseline internal audit was performed to evaluate the current status of the Nuclear Medicine Department of Tygerberg Hospital regarding client, patient and staff satisfaction. In future the performance scale of the NMD will be determined by re-auditing satisfaction parameters as outlined in the PRIA.01 document in addendum B. An analysis, to compare results obtained from follow-up audits with the baseline audit, will be performed in accordance with article 8.4 of the ISO 9001:2000 document as outlined in the QC.STAT.01 document found in addendum B.

Chapter 4: Literature review: Staff satisfaction

Although differences in job satisfaction have already been identified and formulated in 1930, research on job satisfaction has only started in the 1980's³². Therefore literature on staff satisfaction within the working environment, and especially in the Nuclear Medicine environment is limited. However, several theories on factors influencing job satisfaction were formulated by various researchers. More important is the fact that job satisfaction has a direct influence on client satisfaction. Some of these theories will be explained to emphasise the significance of staff satisfaction and harmony in a successful organisation.

The biggest constraint that the health care sector faces is the lack of human resources. Staff shortages within the Nuclear Medicine Department, as in many other departments, are a reality. It is therefore important to address and resolve staff issues internally. Communication and commitment are probably two of the main building blocks to ensure staff satisfaction. The efficiency of hospital management, relationships with managers, knowledge and communication regarding departmental goals, plans and service quality as well as being part of the departmental team are closely related to job satisfaction. Factors having a negative influence on job satisfaction include stress, unrealistic performance expectations, workload, role conflict and conflict with other medical professionals^{33,34}.

Millions of rands and dollars are spent on purchasing expensive equipment and on upgrading the working environment, but managers are reluctant to invest money, time and effort in human relations. Inevitably, it is the people working for the organisation that ensure its success and not the equipment; therefore the organisation can only be as "good" as its employees. The first question one should ask is whether good workers, who form the backbone of a "good business", are born or made. A study performed in 1989³², revealed that there is a strong correlation between job satisfaction and the genetic composition of individuals. These findings perfectly fitted the definition of job satisfaction being "an emotional state"³².

The five factor model for defining the dimensions of personality, otherwise known as the "Big Five" factor structure has been developed in 1990 by LR Goldberg. This model

describes that inherited characteristics such as neuroticism, extraversion or being interested in behaviour towards others or one's environment rather than oneself, openness to experience, thoughtfulness and conscientiousness or giving attention to detail, can be related to job satisfaction³². By making use of this model, intensive research has been performed on measuring the influence of specific personality qualities on job satisfaction. It was found that only four of the five identified personality qualities namely neuroticism, extraversion, consideration and conscientiousness have a significant influence on job satisfaction. As all of these characteristics are part of an individual's genetic composition this theory correlates and complements the finding of the study performed in 1989³². This probably answers the question whether "good workers" are born or made by stating that job satisfaction is influenced by genetic compositions and is therefore inherited. However, even though individual characteristics are mostly determined by genetic composition, environmental influences can change certain characteristics and behaviour³².

Apart from inheritance, human nature also influences job satisfaction. However, there seems to be a lack of understanding of human nature and values. The differences in fundamental human nature can be described by the XY theory developed by DT McGregor in 1960³⁵. The negative assumption of human nature, theory X, stipulated that the average person dislikes work and is lazy. This theory also describes X persons as people who only work if compelled and lack a sense of responsibility. They display minimal concern with departmental protocols and objectives but demand job security. Managers operating on the X factor basis tend to be autocratic and are not interested in improving job satisfaction and loyalty or achieving their personal goals. Staff are merely seen as "tools" used to perform the task. In contrast, the Y theory incorporates a more positive assumption, namely that work is human nature and external powers and threats do not act as motivation. The Y theory assumes that people are committed to departmental objectives as it contributes to their personal life fulfilment and creativity. In practising this theory staff naturally accepts responsibility and job security never seems to be a concern. The Y theory would be the most effective theory to adopt in the management of any department. This is an all encompassing management style that can ensure good staff morale, mutual respect, realisation of objectives and overall efficiency.

Fulfilment of fundamental needs is an inherent human characteristic. In 1960, David McClelland^{35,36} identified three fundamental needs. Individuals developed these fundamental needs over time and they are dependent on the environment in which individuals find themselves. These fundamental personal needs can have a positive or negative effect on the friendliness of the working environment. The three needs are³⁶:

- 1) Achievement by performing according to standards and to resolve problems by excelling professionalism.
- 2) Power or the desire to control and influence others through authority.
- 3) Affiliation by avoiding conflict and form professional work relationships with colleagues.

In achieving one's goals and objectives it is important to have a systematic approach as well as receive feedback on performance. The second identified need, having power and control, is an area of concern. The positive side of power is the fact that power reflects commitment and success as part of an individuals' self fulfilment; this is an asset to the management of the department. However, care should be taken not to confuse power with control as "control freaks" are a detriment to the department. The third need, manifested as a desire to be part of a group and to be popular amongst the group, can improve departmental relations and teamwork if applied positively³⁶.

In the working environment, motivation and needs are metaphoric synonyms. Understanding one's needs does not simplify motivation. Being motivated involves making decisions. To make decisions, people must believe that the amount of effort put in is equal to the level of performance. Subsequently by reaching an acceptable level of performance, achieving goals is easier, but the individual must value these goals or outcomes. There are two outcome levels, namely performance and reward. Performance includes parameters such as the quantity and quality of work, work attendance and creativity. Reward on the other hand includes earning respect from colleagues, praise for satisfactory performance, promotions and contributing significantly to the work environment. Valance describes the amount of value added to a goal or outcome. People's values differ and therefore it is important to focus on the outcomes which add value to the individual staff member's motivation and satisfaction and departmental harmony^{36,37}. To assume that all staff members have the same expectations, values and goals is incorrect³⁶.

It is therefore important to respect individualism and to identify staff orientated managerial strategies in order to generate satisfied staff and subsequently a successful “business”.

Another theory addressing motivation of staff is the Herzberg theory³⁷. He stipulated that, in the work environment motivation can be defined as “an individual’s degree of willingness to exert and maintain an effort towards organisational goals”. He agreed that although motivation is a difficult concept it can be determined at two levels; i) personal such as job expectations, self esteem, personal goals in comparison to organisational goals and ii) organisational level. The Herzberg theory describes “dissatisfiers or demotivators” and “satisfiers or motivators” within the working environment. The main difference between the two is the fact that the one is extrinsic and regulated, such as salaries while the other is intrinsic and unregulated. Intrinsic factors include self-fulfilment, achieving goals, recognition and interpersonal relationships and are self regulated and independent of outside influence. Herzberg emphasises that job satisfaction and job dissatisfaction are not antonyms. This is due to the fact that the “dissatisfiers” have very little influence on job satisfaction while “satisfiers” have a significant influence on job satisfaction. For this reason it is important to improve motivation and therefore increase staff performance by focussing on the “motivators” rather than extrinsic demotivators. Another important motivational tool could be feedback from patients visiting the department, as it can play a significant role with respect to recognition and achievement³⁷. It is for this reason that the patient satisfaction questionnaire used in this study contains questions dealing with staff approachability, empathy, competency and friendliness.

There has been a growing interest amongst academics and practitioners in maintaining a balance between work and life. This draws individuals into situations where they work extended hours and therefore experience an increasingly unsatisfactory relationship between home and work. Subsequently, this has a negative effect on human relationships both at home and at the work place resulting in conflict³⁸. It has been shown that a supportive working environment reduces work and family conflict and enhances the individual workers’ perspectives on their value to the department. In a working environment where teamwork is emphasised, burnout due to an unbalanced

lifestyle not only has an effect on individual job performance, commitment and satisfaction but also on patient satisfaction^{21,38}.

A study performed in the USA³⁹ demonstrated that staff satisfaction directly influences client satisfaction. Intrinsic job satisfaction indicators could be significantly correlated to client satisfaction while extrinsic indicators showed low correlation abilities to client satisfaction. The authors of this article designed a “hypothesised model” to demonstrate the effects of intrinsic job indicators on service quality. After rigorous testing of several different hypotheses, their model confirmed that job satisfaction can have a significant influence on customer service and ultimately on departmental effectiveness. Not only did this correlate with other literature³⁹ but also demonstrated the fact that extrinsic motivation, such as salaries and benefits, are not the key to staff satisfaction. Motivation and job satisfaction lies in the art of making work enjoyable and fulfilling. In contrast to money, the basis of intrinsic job satisfaction is psychological awards which can be controlled by individual employees and departmental managers. Although extrinsics are important in maintaining a quality life, efforts should be made to improve those factors that can be controlled, or intrinsics, to improve staff satisfaction and ultimately client satisfaction³⁹.

In achieving the proposed departmental objective of staff satisfaction and harmony, a staff satisfaction survey questionnaire should be divided into categories addressing the working environment, imbursement, working hours, recognition, team work and departmental communication. The results should assist in identifying staff orientated outcomes to enhance staff satisfaction and harmony.

Chapter 5: Materials and Methods

5.1. Introduction

The aim of the study was to design a Quality Management System (QMS) for the Nuclear Medicine Department of Tygerberg Hospital, according to the standards set by the International Standardisation Organisations' 9001:2000 document⁹. In order to achieve this, a quality policy had to be formulated and key performance areas or departmental objectives identified. The successful implementation of this QMS, as well as the continuous improvement thereof will be dependent on the adoption of the Deming approach¹¹. Hereby, departmental processes and procedures will be analysed and measured to identify sources of variations that cause these processes and products to deviate from client and staff requirements. These requirements will be identified by listening to the clients' demands and by evaluating the questionnaires completed by the clients. The identified requirements will form the basis used to develop and manage the QMS. A custom designed documentation system, called a quality control manual (QCM), will be adopted for use in the Nuclear Medicine department.

The re-evaluation, analyses and improvement of the system will be done by periodic client and staff satisfaction surveys and by measuring the departmental objectives against the departmental results obtained in intensive internal audits. These aspects will not be covered in the research presented in this thesis.

5.2. The Quality Control Manual and affiliated documents

The quality control manual currently in use in the Nuclear Medicine Department of the University of Ghent was used as a framework to design a QCM suitable for the needs of the Nuclear Medicine Department of Tygerberg Hospital. After considering the current working environment, departmental protocols and documentation of the Tygerberg Nuclear Medicine Department the Ghent framework formed the foundation of a specially designed and practically applicable manual for this particular department. This QCM, together with the documents required by ISO, will act as a reference framework to successfully implement the QMS by measuring service quality and the departmental objectives. The document will include general sections on quality management and ISO requirements as well as the departmental objectives attained in the

departmental quality management system. The mission and vision of the Nuclear Medicine Department of Tygerberg Hospital will also form part of the document. Guidelines for conducting internal audits, as well as the implementation and maintenance of a quality management system will be described.

Several appendices and documents listed below, as required by ISO must form part of this manual. This manual together with its affiliated documents will be the core of the successful implementation of a QMS within the Nuclear Medicine Department of Tygerberg Hospital *en route* to ISO certification.

It is not the aim of ISO to evaluate Nuclear Medicine procedures and facilities but they firmly set basic rules. These rules will be adhered to by incorporating them into the custom designed documents as applicable to the needs of the NMD of TBH and described in and referred to in the QCM. These rules and applicable documents are⁹:

- 1) Documentation of all processes and procedures within the department,
- 2) System for changing any existing documentation,
- 3) System handling complaints from clients; these include corrective and improvement measures,
- 4) Annual evaluation and validation of suppliers,
- 5) Structured documentation of all processes and protocols,
- 6) Good communication between department and clients,
- 7) Good interdepartmental communication,
- 8) Traceability of events,
- 9) Traceability of patients,
- 10) Focus on client satisfaction and continuous improvement

It is not the intention of ISO to prescribe international or national standards to a specific organisation or department. For this reason the system currently in use can be updated / streamlined to adhere to the recommendations without having to make major adjustments.

5.3. Clients

Throughout this document the referring physicians and patients will be referred to as clients. As the core of ISO regulations revolve around client satisfaction and staff harmony⁹, it was opted to use participatory research. Participatory research encourages

active participation of the individuals to whom the research is applicable and intended to assist. A structured method of data collection was used by means of a non-personal data collection, using preset questionnaires. The aim of the data collection exercise was to convert the information received by the participants into analogous data to be used in follow up audits¹⁰.

5.3.1 Referring physicians

A structured method of data collection was used by means of non-personal data collection. The format of the interview was a self-administered (SA) questionnaire especially designed to evaluate the referring physicians' needs as well as satisfaction levels⁴⁰. As the identified departmental objectives to ensure referring physician satisfaction include telephone etiquette and producing clear and diagnostically valuable reports, questions addressing these issues were included in the questionnaire. The acceptable report format, electronically or in paper format as well as the value of clinical information booklets were also questioned. An example of the questionnaire can be found in addendum C. The questionnaire consisted of a set of 24 questions presented in a specific sequence requiring a positive or a negative answer. The sample group represented the current referral base of the Nuclear Medicine Department of Tygerberg Hospital, including the private practices and secondary hospitals.

Questionnaires were sent out by fax, e-mail, mail and by internal mail or by including the questionnaire in the report envelope.

Only fully completed questionnaires were included in the statistical analysis, 40 questionnaires were distributed and 31 completed documents were returned. A section for comments was included in the questionnaires; the comments received together with suggested improvement measures will be discussed in chapter 7.

5.3.2 Patients

The word "patient" is derived from the Latin root *patior*, which means to suffer or bear. This supports the traditional myth that patients are passive objects who subject themselves to treatment by experts²⁶. Currently many patients arrive at the service provider with high expectations and knowledge regarding their own health and the outcome of the examination requested by their referring physicians. Historically

decision making regarding personal health and the treatment of diseases were dominated by health care professionals. This has changed due to the easy accessibility of medical information, both electronically and in other published media. However, in South Africa, there is still a tendency that patients make informed decisions under the guidance of their preferred medical practitioner.

According to ISO regulations a departmental Quality Management System (QMS) should evolve around client satisfaction and the continuous improvement thereof. As patient satisfaction is one of the focuses of the study, a need was identified for more specific and detailed information, which can facilitate comparison of the reactions of different patients. The most structured way of getting information from participants is by means of a personal interview. As the interviewer had a specific goal in mind and objectives set, an established questionnaire was used⁴⁰. The sample group consisted of randomly chosen patients visiting the Nuclear Medicine Department of Tygerberg Hospital between March 2003 and October 2004. Only fully completed questionnaires were included in the statistical analysis.

The questionnaire consisted of a set of questions presented in a specific sequence with an indication of possible answers. The 4 point Linkert²¹ response format (ranging from fully agree = 1 to fully disagree = 4 or very satisfied =1 to very dissatisfied = 4) was used. The patient's response is qualitatively measured on a scale of choices from for example "fully agree" to "fully disagree"^{19,21}. Due to the large number of questions included in the questionnaire both positively and negatively worded questions were used in order to ensure reliable results⁴⁰. This interview method can be defined as being a Non Scheduled Structured Interview (NSSI)⁴⁰. An example of this questionnaire, with the numeric values of patients' responses, can be found in addendum D. All the remarks stated by the participant were recorded by the interviewer. Questions and answers were categorized in order to simplify statistical analysis. During a visit to the Department of Nuclear Medicine at the Universitaire Ziekenhuis Ghent, Belgium and intensive personal communication with colleagues at this facility, the following categories were identified and adopted for the purpose of this study:

- Number of times the patient visits the department for follow up examinations
- Amount of information given regarding the examination

- Degree of friendliness and respect with which the patient had been treated in the department by all staff members
- The time the patient had to wait in the waiting room
- Consultation with a doctor in the department
- Tidiness and hygiene of the department

5.4. Staff

A structured method of data collection was used to obtain information from staff members. This was done by conducting a Scheduled Structured Interview (SSI) session⁴⁰, prior to a staff meeting. The sample group consisted of all the staff members of the Nuclear Medicine Department excluding the head of the department. The questionnaires were presented to each participant at the same time to minimise the effect of influencing each other, enabling a more objective comparison of results. The questionnaires were handed to the clinical staff individually, due to the fact that most of them could not attend the meeting. These participants were asked to respect the importance of the objectivity of the provided information. It is therefore assumed that their opinions can be accepted as objective. As the information was gathered by asking the participants an array of questions instead of observing them, some basic principles applied. The participant had to be co-operative and had to express what they experience in reality and not what they anticipated the reality to be.

The questionnaires contained demographic questions with a choice of possible positive or negative answers. The design of the questionnaire was based on the questionnaire used in the SERVQUAL²¹ perception scale to measure patient and staff perceptions of service quality and customised for the appropriate use in the Nuclear Medicine Department of Tygerberg Hospital. An example of this questionnaire with the numeric values of the staffs' responses can be found in Addendum E.

Included in all questionnaires were areas for comments regarding the specific question as well as a general comment section. All of these comments together with suggested improvement measures will be discussed in chapter 7.

5.5 Areas of improvement

The results obtained from the questionnaires as well as the comments from all the participating groups were used to measure the current departmental status in relation to

the departmental objectives. These initial measurements were used to identify areas of improvement to be implemented and continuously monitored, as required by ISO.

Chapter 6: Results

A Quality Management System (QMS) was formulated for implementation, monitoring and continuous improvement in the Nuclear Medicine Department of Tygerberg Hospital. Incorporated into this customised QMS are identified departmental objectives, a quality policy as well as a mission and a vision. In order to implement, maintain, manage and continuously improved the QMS a Quality Control Manual (QCM) was prepared. This manual explains the QMS and was customised following the guidelines set by ISO. This manual, together with the affiliated documents will be used as a reference guide towards ISO accreditation and certification.

6.1 Quality Control Manual

The QCM, adapted from the QCM used at Ghent, Belgium, can be found in Addendum A. The departmental quality policy as well as its mission and vision have been formulated and the departmental objectives listed in this document. The focus of this study is on client satisfaction and staff satisfaction and harmony. For this reason custom designed documents addressing these objectives, form part of this document and are listed below:

- 1) Documentation of all processes and procedures within the department [QCM];
- 2) System for changing any existing documentation [Addendum B:CDOC.01];
- 3) System handling complaints from clients. These include corrective and improvement measures [Addendum B: ICD.EXAM.01, ICD.PAT.01, ICD.REFP.01];
- 4) Annual evaluation and validation of suppliers;
- 5) Structured documentation of all processes and protocols;
- 6) Good communication between department and clients [Addendum B: MT.ECOM.01];
- 7) Good departmental communication [Addendum B: MT.ICOM.01];
- 8) Traceability of patients and events [Addendum B: TRACE.01];
- 9) Focus on client satisfaction and continuous improvement

Since it is not the intention of ISO to prescribe international or national standards to a specific organisation or department, these documents have been customised in accordance with the system currently in use. The aim is to update or streamline this system, to adhere to the recommendations without having to make major adjustments.

Not only does ISO set rules but also requires specific documents to be used in the design, implementation and management of a successful QMS *en route* to certification. These required documents are listed in clause 4.2.1 of the ISO 9001:2000 document and must include¹⁰:

- 1) Documented statements of a quality policy and quality objectives as defined in clause 5.3 of ISO 9001:2000 document [Addendum A page 4 and 8]
- 2) A quality control manual, clause 4.2.2 of the ISO 9001:2000 document specifies the minimum content of a QCM
- 3) Documented procedures required by this international ISO standard for the following six activities: control of documents [Addendum B: QCD.01], control of records [Addendum B: QR.01], internal audit [Addendum B:PRIA.01], control of nonconforming products [Addendum B:QC.EXAM.ICA, QC.PAT.ICA, QC.REFP.ICA]
- 4) Documentation of corrective actions [Addendum B: QC.EXAM.ICA.M1, QC.PAT.ICA.M1, QC.REFP.ICA.M1]
- 5) Documentation of improvement/preventative actions [Addendum B: QC.EXAM.ICA.M2, QC.PAT.ICA.M2, QC.REFP.ICA.M2]
- 6) Documents needed by the department to ensure effective planning, preparation and control of departmental processes (confined in a SOP database and QCM)
- 7) Records required for this international ISO standard; examples include organisational charts, flow charts etc.

6.2 Results of the baseline internal audit on clients

The internal audit was performed on the different sample groups in order to set baseline parameters. These attained values will in future be statistically compared to the follow-up internal and external audits in order to identify improvement measures as well as to measure the improvement or deterioration of overall client and staff satisfaction. This

comparative analysis will be a reflection of the effectiveness of the implemented quality management system. These comparisons do not form part of this study.

For the purpose of this study participation responses higher than 90% were regarded as very good, those between 50% and 90% as unacceptable while figures lower than 50% were indicative of areas in need of urgent attention and improvement.

6.2.1 Referring Physicians Satisfaction

Although 40 questionnaires were distributed, only 31 completed forms were returned and included in the satisfaction survey (overall response rate of 78%). An outline of the answers received on the 24 questions asked, is available in Addendum C. Of the 31 participants 12 (38%) were stationed at Tygerberg Hospital, 3 (10%) at secondary hospitals, and 16 (52%) at private practices. Although patient referrals are received from the day hospitals and 2 Military Hospital, none of the questionnaires sent to these hospitals were received back, and therefore these groups were excluded from the survey. The majority of the participants 18 (60%) were consultants, while the rest of the group consisted of registrars and general practitioners.

The sample group represented most of the common clinical fields with 7 (23%) of the participants working in general private practice, 8 (27%) from the internal medicine department, 5 (17%) oncologists and 3 (10%) orthopaedic surgeons. The remainder of the group consisted of one representative each from sports medicine, cardiology, haematology, casualty, rheumatology, paediatrics and cardiothoracic surgery respectively.

Only 2 (7%) of the participants referred patients on a daily basis while 10 (33%) referred patients on a weekly basis. The majority of the referring physicians (11 (37%)) only requested Nuclear Medicine examinations a few times per year.

Only 1 (3%) participant indicated that patients were expected to make their own appointments. Patients' appointments were personally made by 16 (57%) of the participants, while 11 (39%) of the participants indicated that their patients' appointments were made by either their receptionists or the ward sister.

Specific quality parameters, to ensure referring physician satisfaction, form part of the QMS designed for the Nuclear Medicine Department of Tygerberg Hospital. These are professional telephone etiquette; acceptable telephonic answering of clinical questions; ensuring the availability of a nuclear physician; ensuring an acceptable waiting period between requesting an examination and the actual examination date and sending out a clear, comprehensive and clinically valuable report in good time (see Addendum A page 9). Figure 6.1 and table 6.1 below, describe how the NMD of TBH is currently measuring up against these departmental objectives.

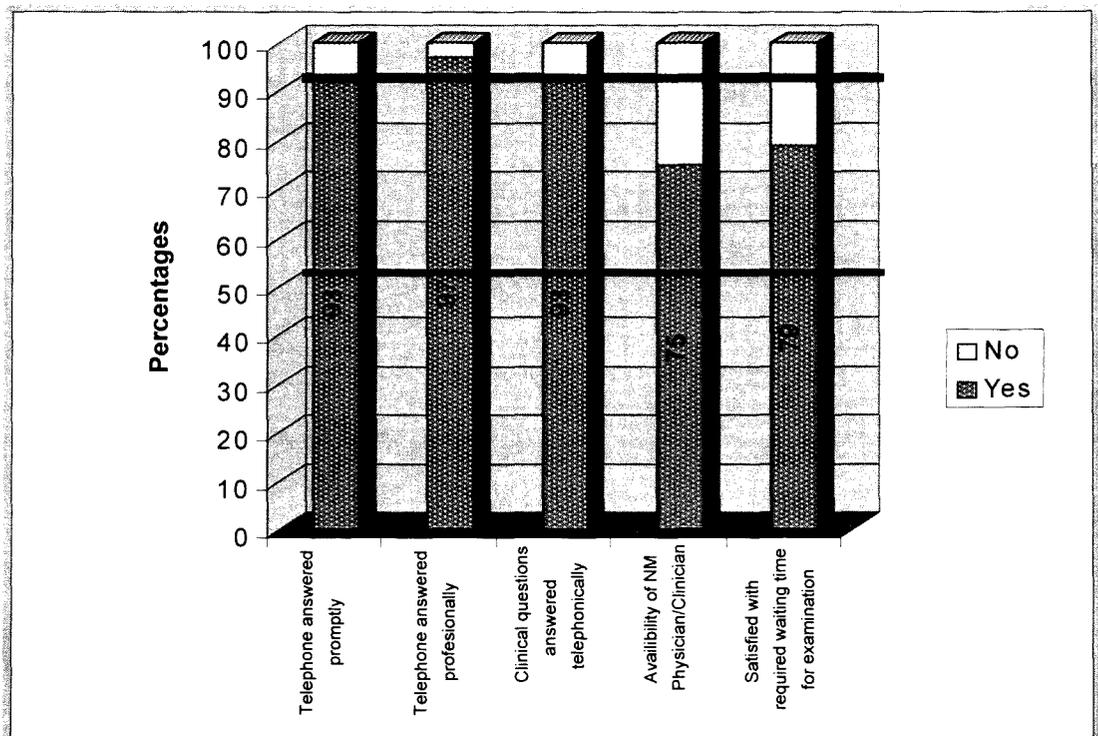


Figure 6.1 Telephone etiquette

Availability	Fast	21(67%)
	Slow	10 (33%)
Media used	Fax	16 (50%)
	Mail	17 (57%)
	Both	2 (7%)
	email	1 (3%)
Electronic reports	Acceptable	22 (79%)
	Unacceptable	6 (21%)
Report & images	Yes	14 (43%)
	No	17 (57%)
Necessity of images	Yes	18 (60%)
	No	13 (40%)
Report clear and clinically valuable	Yes	29 (94%)
	No	2 (6%)

Table 6.1 Handling of reports

Of all the participants, 28 (90%) indicated that clinical information booklets/media would be helpful and valuable, while 23 (77%) requested patient information booklets to answer their patients questions regarding the requested examination.

An extremely positive and complimenting result is the fact that all the participants agreed that the overall service quality is high.

6.2.2 Patient Satisfaction

The patient group comprised 50 (37%) males and 80 (63%) females with ages varying from 3 months to 86 years (mean age = 49.8 years). The questionnaires were completed by the parent or guardian of all children under the age of 10 years. A summary of the answers received on the 94 questions asked, is available in Addendum D. Although 155 interviews were conducted, only 130 questionnaires were included in the study due to the fact that 25 were incomplete (overall response rate of 84%).

Of all the participants 100 (77%) were referred to TBH as out-patients while the remaining 30 (33%) were in-patients.

The majority of the patients did not complete grade 12. The distribution of educational levels is outlined in table 6.2.

EDUCATIONAL LEVEL	NUMBER OF PARTICIPANTS
Grade 5	36 (30%)
Grade 8 or 9	27 (22%)
Grade 10 or 11	26 (21%)
Grade 12	6 (5%)
Higher education	26 (21%)

Table 6.2 Educational level

A variety of investigations demonstrated by figure 6.2, requiring different protocols and waiting times, are performed in a Nuclear Medicine department. Within the sample group 25% of the patients were booked for myocardial perfusion studies, 14% for examination of the thyroid gland, 13% for gallium scans, 11% for renograms and 10% for bone scans and gastro-intestinal track studies respectively. The largest portion of the 10% GIT group was infants.

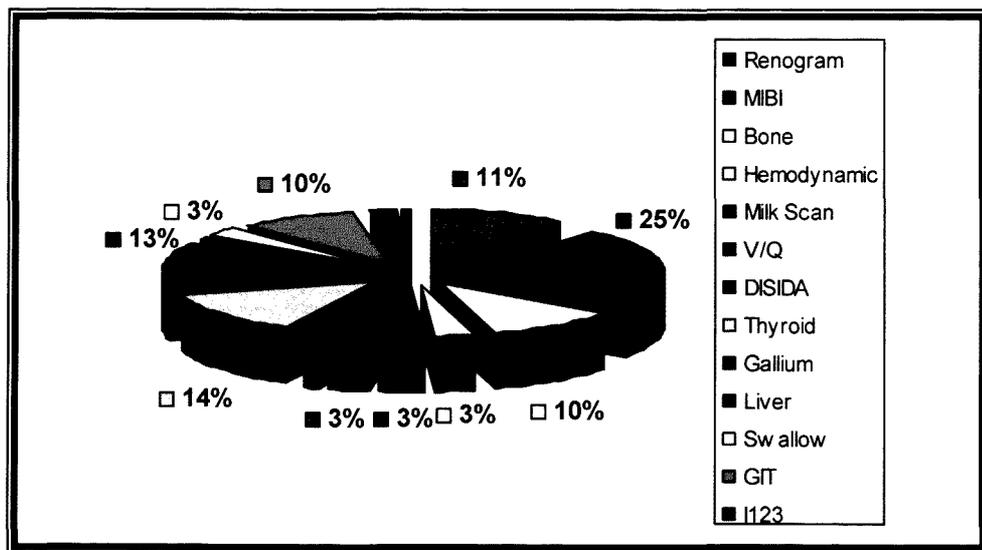


Figure 6.2 Examination distribution

The patients indicated that most of the appointments were made by the referring physicians personally. This was also indicated in the referring physician survey.

The QMS for the Nuclear Medicine department also contains specific quality parameters to ensure patient satisfaction. These include the amount of information given

to the patient regarding the investigation and regarding the waiting time. Figure 6.3 gives a clear indication of the enormous gap in providing information to the patients about the reason for the investigation, the investigation procedure and the reason for the injection of radiopharmaceuticals.

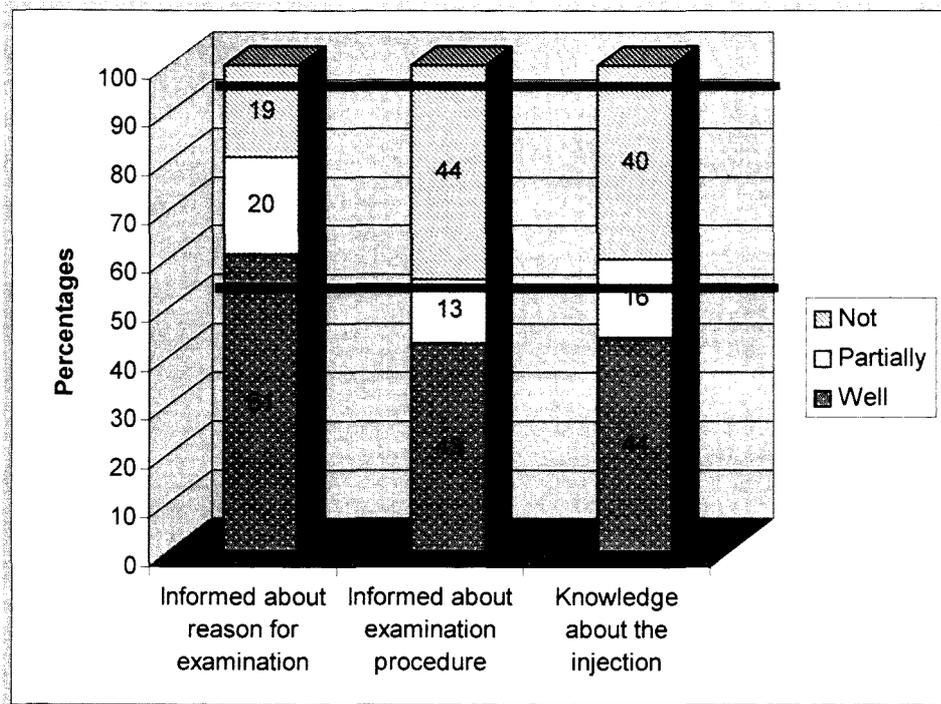


Figure 6.3 Information received

Although 83 (76%) participants indicated that they were informed about the waiting time between receiving the injection and being scanned, the majority only learned this on their arrival in the department. Most of the patients (53 (41%)) waited between 11 and 30 minutes before they received the radioactive injection but a substantial number of patients (49 (38%)) waited for long periods of time before the administration of the injection as outlined in figure 6.4.

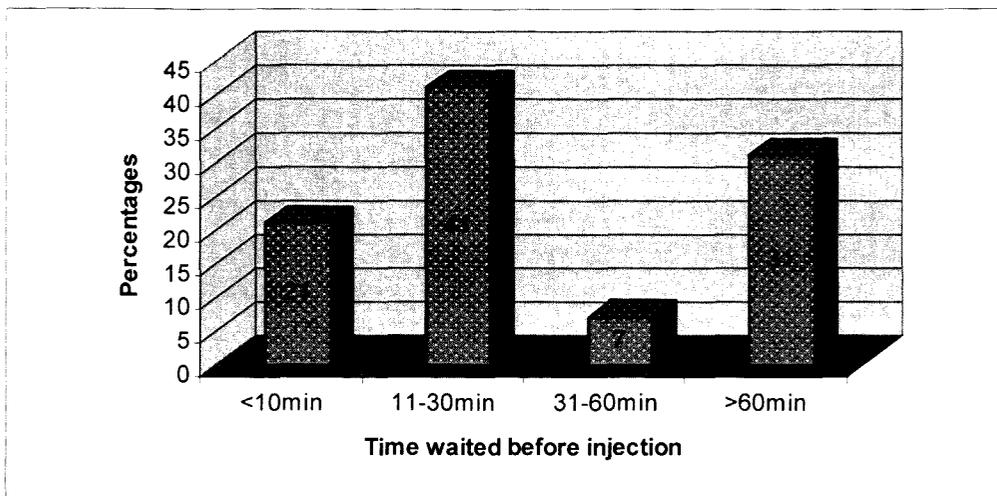


Figure 6.4 Time waited before injection

Adverse reactions due to the administration of radiopharmaceuticals are rare but it is in the interest of both the patient and the staff member performing the procedure, to be familiar with the recipients' known allergy history. Only 73 (56%) of the participants were asked about their known allergies prior to injection.

One of the contradicting results found in this study, is the fact that even though most patients indicated that they anticipated spending the whole day at the hospital only 41 (33%) of the participants brought something to occupy themselves with during the waiting period. This is indicative of the anticipation that something will be provided. The majority of the participants (105 (80%)) indicated that they could find something to do in the waiting room, they did however complain that the reading material was old and in a bad shape. Responses to what activities patients would prefer while waiting varied. Table 6.3 lists these preferences.

ACTIVITY	NUMBER OF PARTICIPANTS
Read a book or magazine	45 (41%)
Watch television	25 (23%)
Chat to other patients	15 (13%)
Listen to music	5 (7%)
Play	8 (6%)
Chat about the gospel	4 (3%)
Sleep	4 (3%)
Drink coffee	3 (2%)
Have a massage	1 (1%)
Needlework	1 (1%)

Table 6.3 List of preferred activities

Most of the patients made use of public transport and 81 (64%) patients indicated that they could find their way around the hospital terrain easily. This could be explained by the fact that both the bus and taxi depots are located at the hospital entrances. A small number of patients 20 (15%) found it difficult to locate the Nuclear Medicine Department within the hospital.

Although many (110 (85%)) of the participants found the waiting time acceptable, many indicated that the time spent waiting would be more acceptable if they were informed about the reasons thereof. This information can be supplied by handing out information booklets. Even though these booklets are available, 81 (62%) did not receive any written or verbal information regarding the examination process and procedure. A positive parameter is the fact that the majority of the patients found the service acceptable (figure 6.5).

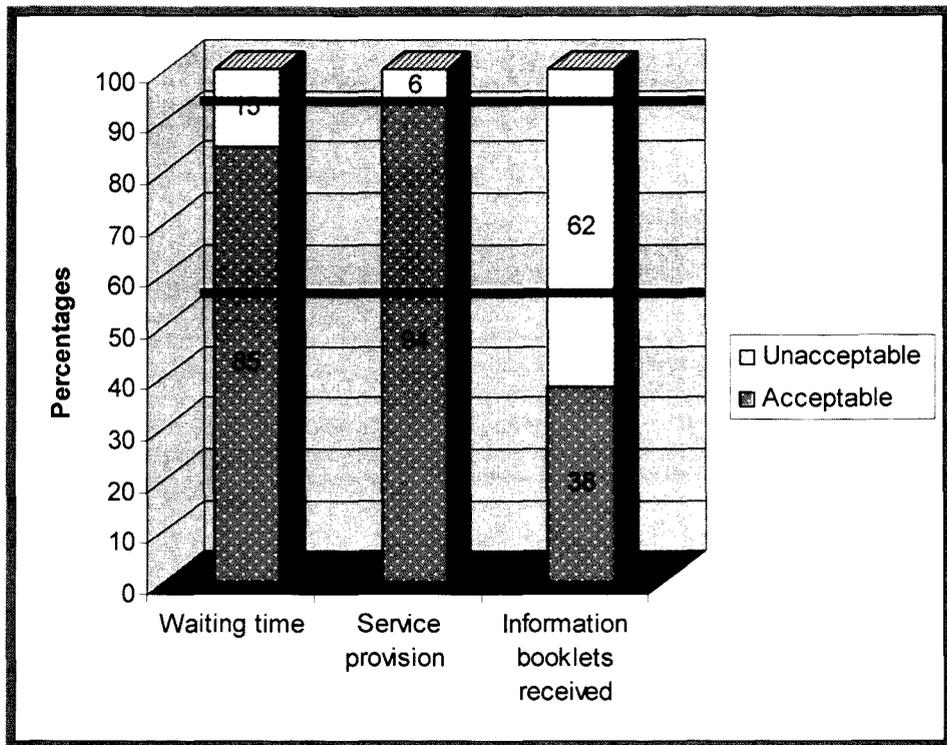


Figure 6.5 Acceptability of services

Patient satisfaction is dependent on the way patients are treated and respected by staff. The degree of friendliness and respect with which the patients were treated in the department by all staff members was also identified as a quality parameter. The responses of how individual patients experienced the way in which they were treated by departmental staff members are summarised in table 6.4. The results indicate that this particular departmental objective measures up well with the results, proving that the patients are satisfied with the way they were treated by staff members.

	Agree	Disagree
Staff is professional	130 (100%)	0 (0%)
Staff is helpful	127 (98%)	3 (2%)
Staff treats patients with respect	129 (99%)	1(1%)
Take time to explain examinations	118 (91%)	12 (9%)
Staff keep patients informed	118 (91%)	12 (9%)
Staff keep to their word and are trustworthy	110 (85%)	20 (15%)

Table 6.4 Way in which patients are treated by staff

Table 6.5 summarises the environmental friendliness of the department as well as the convenience of the service hours. The majority of the patients found the department neat and tidy although most of the complaints received were about the cleanliness of the restrooms.

	Agree	Disagree
Department is well equipped	121 (93%)	9 (7%)
Staff well groomed and neat	125 (96%)	5 (4%)
Department neat and tidy	122 (94%)	8 (6%)
Service times convenient	126 (97%)	4 (3%)

Table 6.5 Environmental friendliness of the department

6.3 Staff satisfaction.

The sample group consisted of 31 participants, representing the staff categories within the department, referred to as the combined staff group throughout this study. These include clinical staff (9), radiographers (10), nursing staff (4), administrative staff (3), radiography students (9) and the support staff (2).

To ensure that the departmental objectives of staff satisfaction and harmony as well as staff development are met, specific quality parameters that were identified include; improving and maintaining the working environment, ensuring a variety of responsibilities, tasks and work contents as well as continuous development and training of all staff members. Similar to the responses of the referring physicians and the patients, responses higher than 90% were regarded as very good, those between 50% and 90% as unacceptable while figures lower than 50% were indicative of areas in need of urgent attention and improvement. Figure 6.6 illustrates how the department measures up to these parameters. From this graph it is clear that the radiographer group felt they lacked adequate post school education and are unfamiliar with their duties.

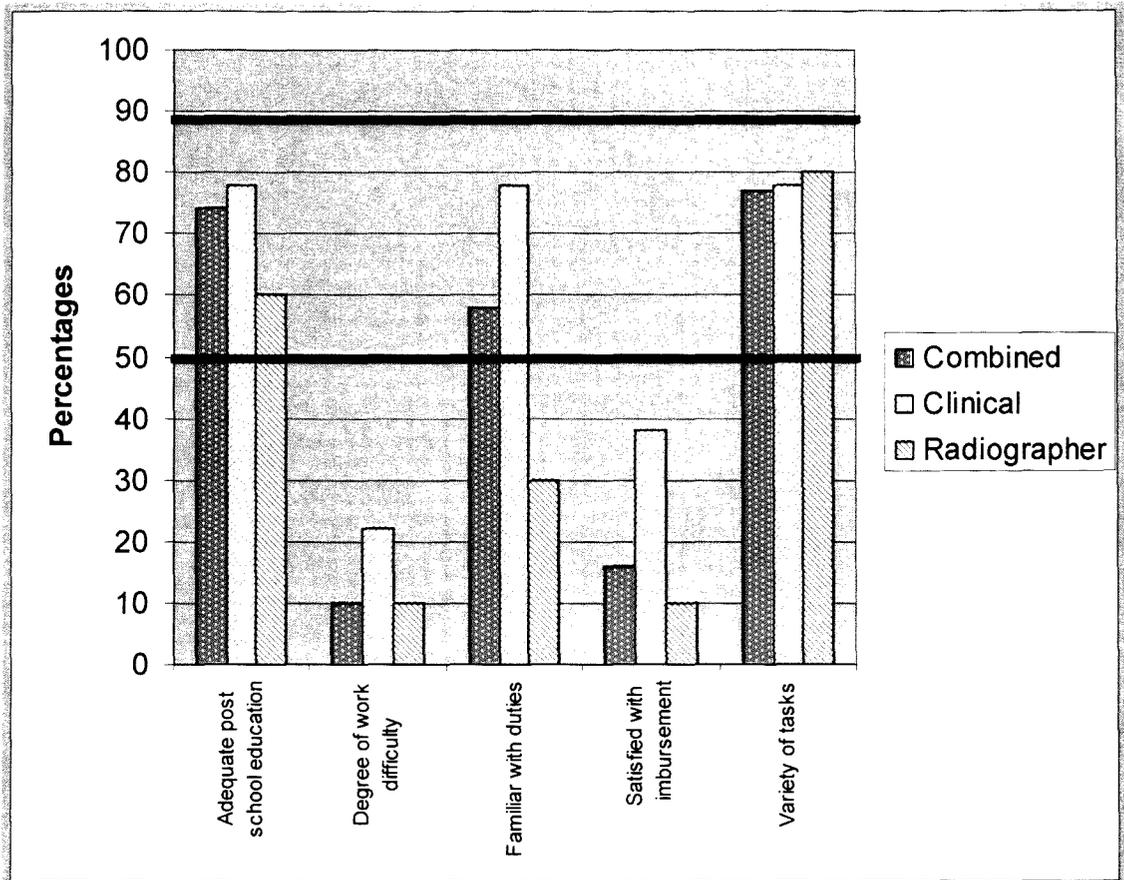


Figure 6.6 Work environment

In order to develop within the working environment, individual staff members must appreciate the necessity of participation in continuous development programmes. Even though the participation in Continuous Professional Development (CPD) programmes is compulsory for all clinical staff members, radiographers and nursing staff, it was interesting but alarming to see how little of them did participate in such programmes (figure 6.7). It is however very positive that the majority of staff members strove to develop their own future.

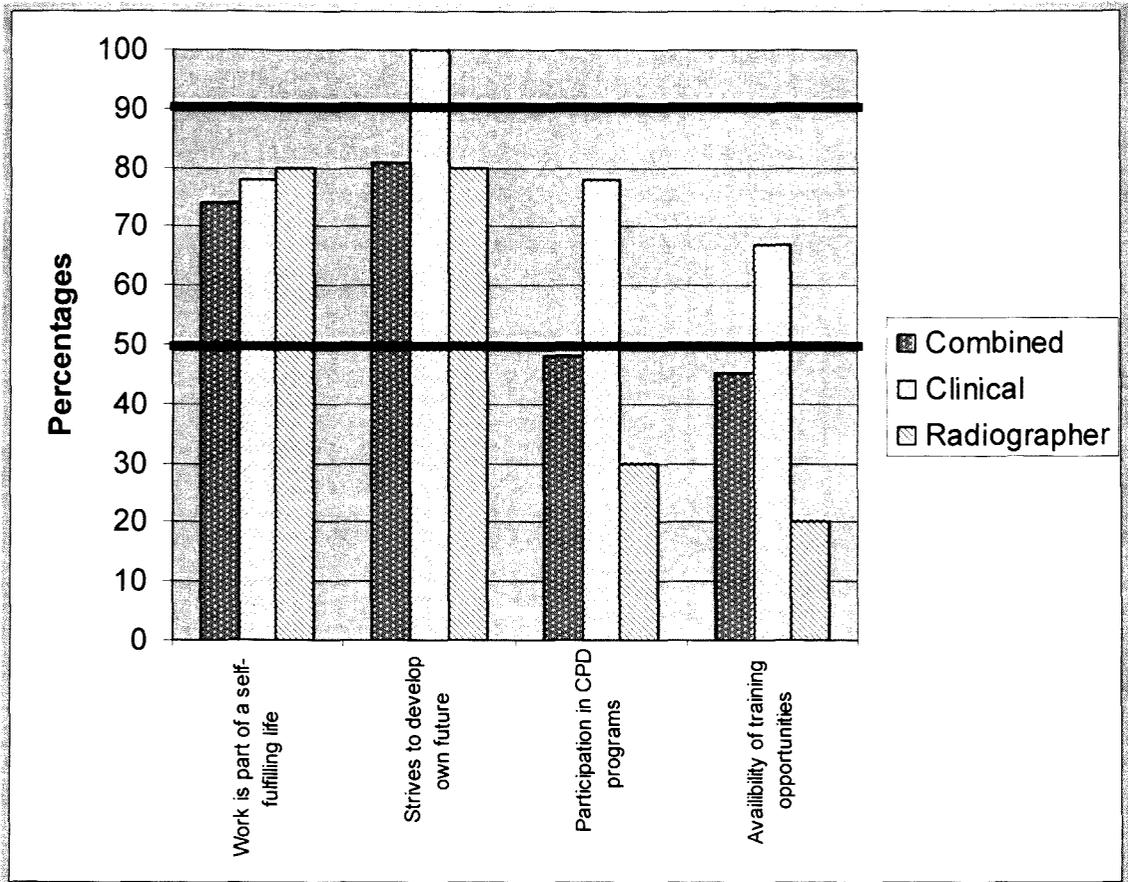


Figure 6.7 Continuous development

A major concern within the state hospital is the shortage of human resources resulting in extended working hours. Although most of the participants indicated that they are not coping with their allocated workload and are overworked due to not having control over their workload, many indicated that they still have time to be idle as illustrated in figure 6.8.

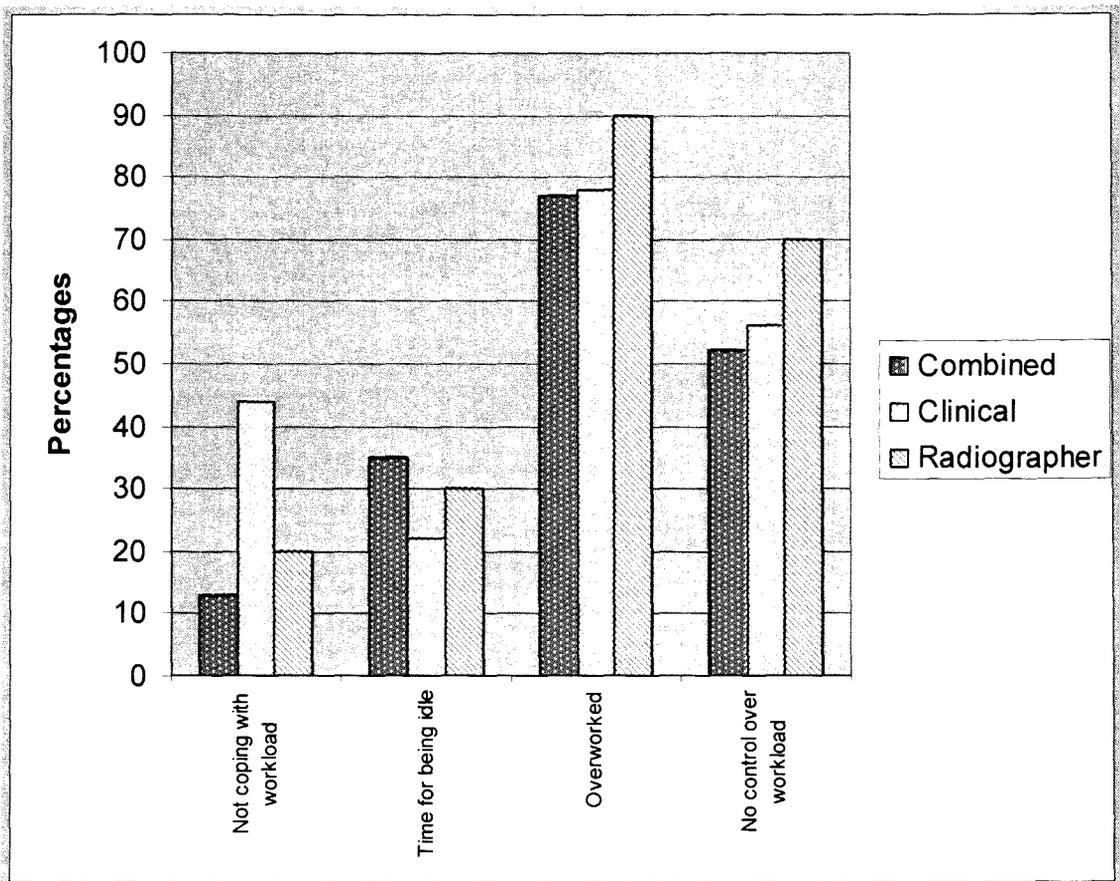


Figure 6.8 Workload

As reviewed in the literature^{36,39}, humans need to be rewarded in order to be satisfied. Imbursement is one form of reward. Most of the participants indicated that they are dissatisfied with their salaries (figure 6.6). This is an extrinsic factor over which the department has little control. Reward, on the other hand, include things like earning respect from colleagues, praise for good work, promotions and the ability to structure the work environment. Figure 6.9 illustrates the amount of “intrinsic rewards” received from management by the participants. All the groups indicated that they receive very little motivation and positive criticism from their peers and management. A positive finding however is the fact that most participants see themselves as being an asset to the department.

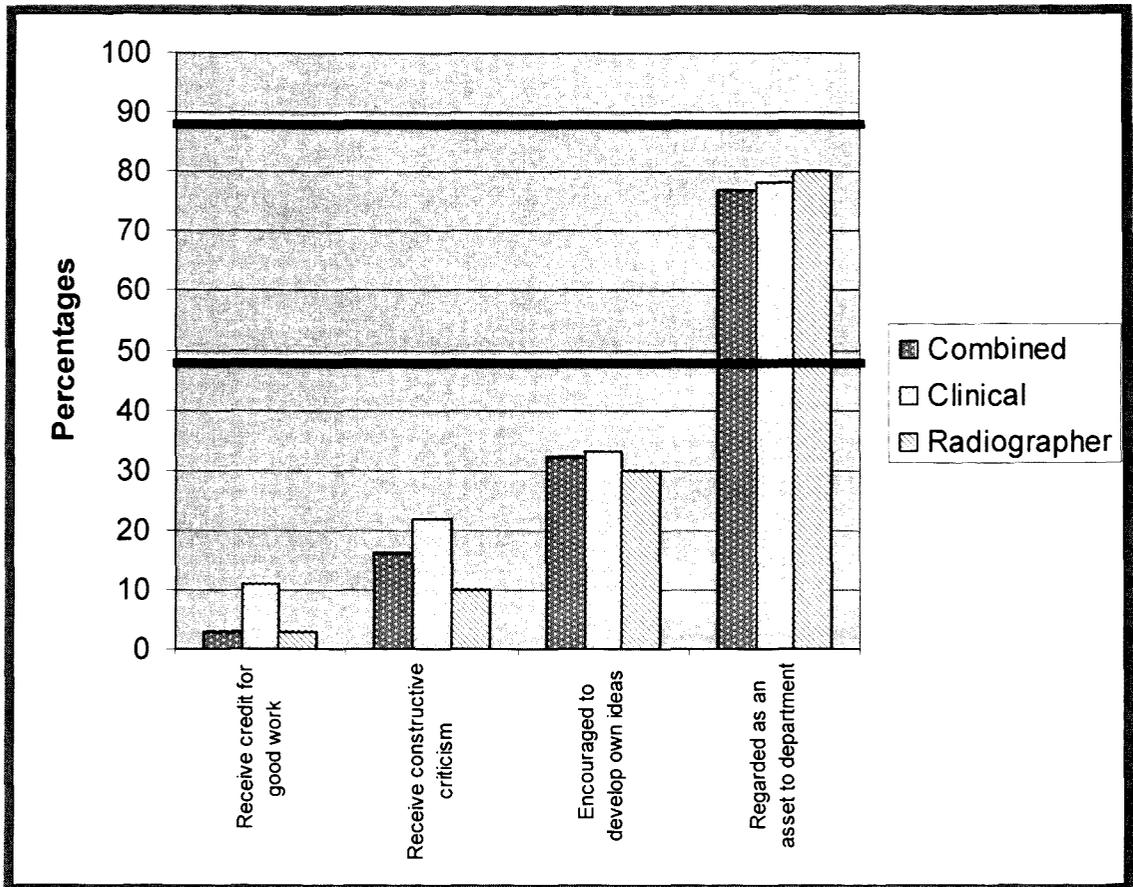


Figure 6.9 Feedback on job performance

Other theories addressing motivation of staff is the Herzberg theory³⁷. He stipulated that, in the work environment motivation can be defined as “an individual’s degree of willingness to exert and maintain an effort towards organisational goals”. He agreed that although motivation is a difficult concept it can be determined at two levels; i) personal such as job expectations, self respect, personal goals in comparison to organisational goals and ii) organisational level. The Herzberg theory describes “dissatisfiers or demotivators” and “satisfiers or motivators” within the working environment. If the working environment is unpleasant due to a lack of team spirit and inapproachability of management, staff members will be demotivated and dissatisfied. Communication is the key to setting personal goals in accordance to organisational goals. It is impossible to follow departmental procedures and protocols if these are not known or changes not communicated to staff members. Figure 6.10 illustrates that there is a serious lack of team spirit and departmental communication.

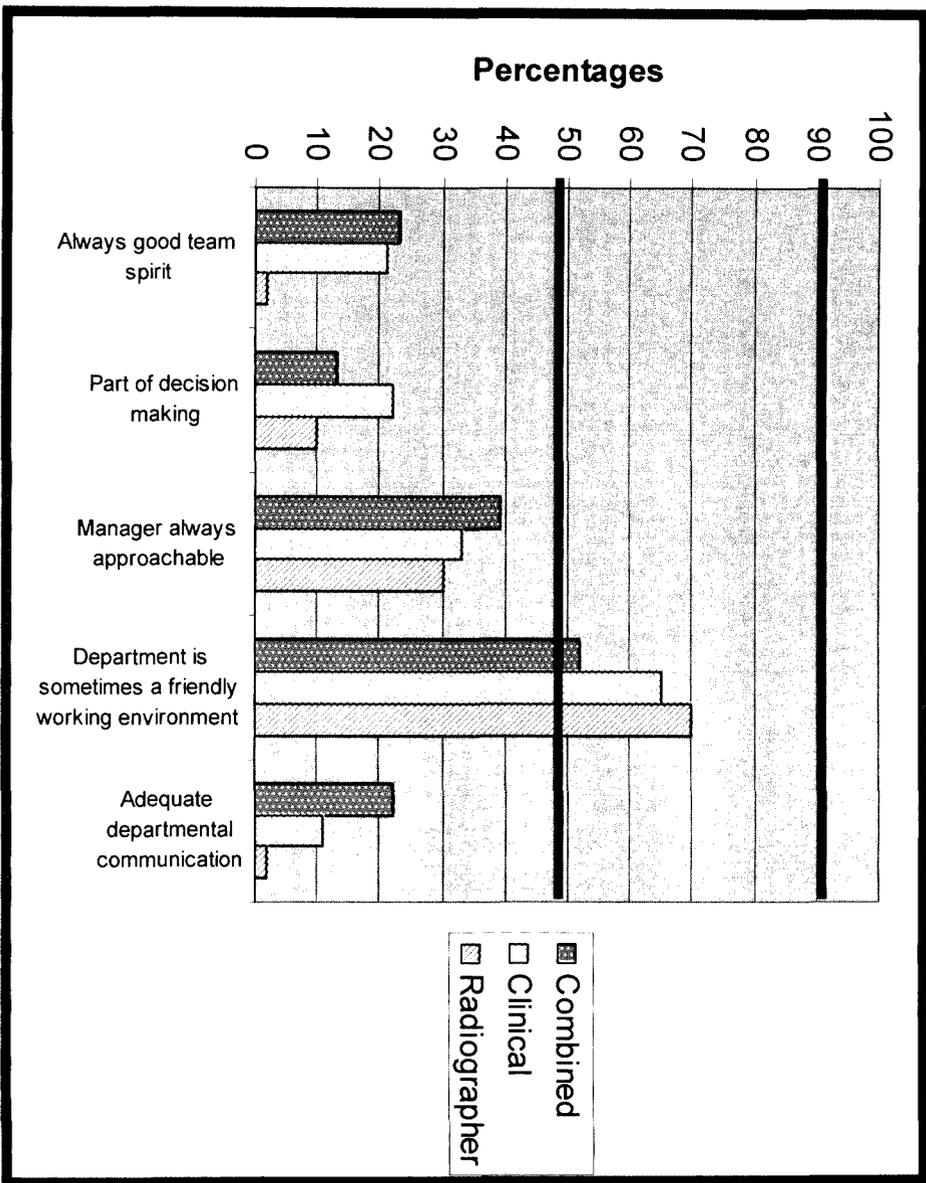


Figure 6.10 Departmental collaboration

Chapter 7: Discussion

ISO defines effectiveness as “the extent to which planned activities are realized and planned results achieved”⁹. In order to effectively manage and improve the custom designed QMS it is necessary to continuously identify and implement improvement measures. ISO stipulates that improvement should take place in three phases by means of specific measures. These are corrective, preventative and improvement measures which must be implemented in this sequence⁹.

Areas for improvement have been identified purely by evaluating the answers received from the questionnaires and by interpreting the comments made by the participants of all the different represented groups. Some suggested improvement measures are noted but as the implementation and maintenance of a successful Quality Management Programme is a continuous team effort, more suggestions will probably develop and be implemented.

7.1 The Quality Control Manual

The QCM has been designed according to ISO regulations. Determining whether this document is suitable for the Nuclear Medicine Department of Tygerberg Hospital, remains to be seen when it is fully implemented and is beyond the scope of this thesis. The successful implementation of the QMS and QCM in the department forms part of the future plans.

7.2 Identified client problem areas and suggested improvement measures

ISO focuses on client satisfaction and the continuous improvement thereof. Throughout the study the referring physicians and the patients are referred to as clients.

7.2.1 Referring Physicians

7.2.1.1 Although referrals are regularly received from 2 Military Hospital none of the questionnaires sent out to the physicians were returned. Therefore this group of referring physicians were excluded from the sample group.

Suggested improvement measures:

- ❖ Investigating a better method of distributing and collecting of referring physicians questionnaires.

7.2.1.2 Numerous patients arrived at the department uninformed. As 57% of the referring physicians personally made appointment for their patients, the informative phase should ideally start there. The majority of the referring physicians (77%) also indicated that they would find patient information brochures helpful. This indicates an uncertainty or a lack of knowledge regarding the examination procedures, making it difficult to explain the procedure to the patient.

Suggested improvement measures:

- ❖ Familiarising referring physicians with the examination procedures
- ❖ Distributing patient information booklets to referring physicians.
- ❖ Encouraging the referring physicians to inform and educate the patients on the examination procedures.

7.2.1.3 Professional telephone etiquette is one of the referring physicians' satisfaction quality parameters. The fact that 7% (Figure 6.1) of the referring physicians indicated that the telephone was not answered promptly and that their clinical questions were not answered adequately, as well as 3% being dissatisfied with the way the telephone was answered (Figure 6.1), needs attention.

Suggested improvement measures:

- ❖ Telephone etiquette training for staff members responsible for managing the patient booking area.
- ❖ Educating non-clinical staff members on the principles, indications and procedures of routine investigations performed on patients.
- ❖ Continuing the use of the telephone information booklet.

7.2.1.4 A waiting list for examinations is common in the state hospital environment. Although the majority of referring physicians have become accustomed to it, the 21% (Figure 6.1.) who found the waiting time unacceptably long should be decreased.

Suggested improvement measures:

- ❖ Educating the administrative clerk on examination protocols and procedures to ensure better planning and organisation of the daily programme.
- ❖ A radiographer should assist in synchronising the patient appointments, in order to maximise workflow.
- ❖ Purchasing more gamma cameras.
- ❖ Meeting with suppliers of all consumables on a routine basis, to stress the importance of regular and timely delivery.

7.2.1.5 Another quality parameter requiring improvement is the availability of a nuclear physician to answer clinical questions regarding examination indications and procedures. Only 75% of the referring physicians (figure 6.1) indicated that a nuclear physician was always available.

Suggested improvement measures:

- ❖ Informing referring physicians, on a regular basis, about the methods to contact the nuclear physicians, for example by using the hospital radio system and/or cell phones.
- ❖ Ensuring that the staff members at the booking area are well informed about which nuclear physician is rostered to answer clinical questions.
- ❖ Ensuring easy access to electronic resources to enable the nuclear physicians to deal with queries via email or other electronic media.
- ❖ Having a radiographer at the appointment book. He / she can assist the clinicians by answering technical questions, currently not within the ability of the administrative staff.
- ❖ Employing more clinical staff; this will ensure that a nuclear physician is always available to answer queries and discuss results with the clients.

7.2.1.6 The immediate availability of final reports is one of the areas needing serious and priority attention. Only 67% of referring physicians (table 6.1) were satisfied with the waiting time for reports.

Suggested improvement measures:

- ❖ Having more computers available, to allow nuclear physicians to edit, print and/or send their reports. This will not only speed up the process

but also decrease errors, the duplication of work as well as the amount of paper used.

- ❖ Availability of that the relevant clinical information and X-rays when the examination is performed.
- ❖ Implementing an effective system for the electronic transfer of reports and images to referring physicians outside Tygerberg Hospital.
- ❖ Employing more clinical staff members.

7.2.1.7 During the study period only 3% (table 6.1) of the clients received reports via email. This method of distributing reports was not routine practise in the Nuclear Medicine Department of Tygerberg Hospital. The traditional way of sending reports via the ordinary mailing system may be one of the reasons for the delay before referring physicians received the reports.

Suggested improvement measures:

- ❖ Implementing an email database to send electronic reports and/or images to all referring physicians, as 79% (table 6.1) indicated that electronic media would be acceptable.
- ❖ Introducing a campaign targeting referring physicians to educate them about the advantages of electronic media. This would decrease the 21% (table 6.1) of referring physicians who found it unacceptable to receive electronic results.
- ❖ Establishing an effective filing system, especially in Tygerberg Hospital, to ensure that even though electronic reports are sent to the referring physicians, paper copies are placed in patient files.

7.2.1.8 Even though 60% (table 6.1) of the participants indicated that the images should accompany the reports, only 43% (table 6.1) received both the report and images.

Suggested improvement measures:

- ❖ Ensure that all reports sent out, electronically or through the existing methods, include a copy of the images.
- ❖ Developing a computerised electronic tool to automate the attachment of images to emailed reports.

7.2.1.9 Duplicate reports were received by 7% (table 6.1) of the participants as reports were faxed and mailed to them. This method was mainly used for sending reports to referring physicians outside Tygerberg Hospital. This duplication is not cost effective, but has been implemented due to the unreliability of the South African mailing system.

Suggested improvement measures:

- ❖ Implementing a reliable cost effective report distribution system by utilising electronic media.

7.2.1.10 The fact that 90% of the referring physicians indicated that clinical information booklets and media will be valuable may reflect their insufficient knowledge about Nuclear Medicine procedures. This could probably also be an indication of the total lack of knowledge of those physicians who seldom or never refer patients to the Nuclear Medicine department.

Suggested improvement measures:

- ❖ Launching an awareness campaign by sending out clinical information brochures to all clinical colleagues.
- ❖ Inviting referring physicians and colleagues to clinical information sessions and workshops. This could potentially increase the number of patient referrals and ensure closer collaboration with clinical colleagues.
- ❖ Organising regular joint meetings with clinical disciplines where interesting or difficult cases can be discussed.

Even though all referring physicians indicated that they were satisfied with the current service provision, a number of pitfalls have been identified. It is in the interest of ISO regulations that the processes must be monitored and improved continuously. For this reason an annual internal re-evaluation audit must be performed, by following ISO audit regulations.

7.2.2 Patients

7.2.2.1 From the questionnaires completed by the patients, it was clear that they did not receive adequate information prior to arriving in the department (figure 6.3). Most of the patients (61%) were uninformed about the reason for the investigation, the examination procedure (43%) and that they will receive an injection (44%). Providing sufficient information to the patient was identified as one of the departmental objectives; therefore it is the responsibility of the ISO task team to seriously address this issue.

Suggested improvement measures:

- ❖ Ensuring that information booklets are distributed to referring physicians on a regular basis.
- ❖ Requesting that all patients receive the appropriate information booklet from the referring physician. The fact that a dose of radioactivity will be administered and that several examinations require a physiological circulation time before imaging must be emphasised.
- ❖ Implementing pre-examination measures such as follow-up phone calls to patients and introducing user friendly posters in the reception and waiting room areas. These measures may have financial and time constraint implications.
- ❖ Executing a system where outpatients referred from Tygerberg Hospital must visit the Nuclear Medicine Department to book their appointments. This may ensure that all patients receive information booklets and are familiarised with the examination they are referred for.

7.2.2.2 Although the average dose preparation time is 25 minutes a substantial number of patients (38%) waited for longer than 30 minutes before the radiopharmaceutical was administered. Several patients indicated that they waited for more than 4 hours before being attended to. Included in this group were patients booked for renograms. The waiting times were even longer on Fridays. Although this is alarming, 85% of patients indicated that they were aware that they would have to wait for a long time and accepted this as they felt they had no other choice. During the interview process, many patients

commented that the waiting time would be more acceptable and bearable if they were informed about the reason for extended waiting times.

Suggested improvement measures:

- ❖ Executing a specific investigation to determine the reasons for the extended waiting times before the administration of radiopharmaceuticals.
- ❖ Using these findings to activate solutions, for example motivating the acquisition of more gamma cameras.
- ❖ Re-evaluating the patient scheduling system i.e. booking and injecting patients at different intervals.
- ❖ Utilising of the available staff and gamma cameras optimally by putting a different patient-to-camera allocation strategy into practice.
- ❖ Communicating with patients regarding the reasons for waiting times, as some examinations do require longer physiological circulation times.
- ❖ Designing and implementing a SOP for informing and rescheduling patients in the event of isotope delivery problems and camera down times by following the ICA procedures as outlined in the QCM (Addendum A page 8).

7.2.2.3 It is in the interest of Good Clinical Practice (GCP) to prevent and document adverse reactions due to the administration of radiopharmaceuticals or any other medication to a patient. Therefore the fact that not all the patients (56%) were questioned about their known allergies should be addressed.

Suggested improvement measures:

- ❖ Writing a SOP for radiopharmaceutical administration.
- ❖ Including a record block on the TRACE.001 (Addendum B) to remind staff members to ask patients about their known allergies.

7.2.2.4 By law, it is the responsibility of radiation workers to inform and protect members of the public against radiation. An effort should be made to improve the knowledge of patients regarding their exposure to radioactivity during their visit to the Nuclear Medicine department. Only 51% of the patients indicated that they were conscious of being exposed to radioactivity and had seen radioactivity signs displayed in the department.

Suggested improvement measures:

- ❖ Drafting posters with information on the safe use of radioactivity without causing unnecessary fear.
- ❖ Informing the patient verbally before administration of the radioactivity about the radioactive component of the injection and the safety thereof.

7.2.2.5 Some of the patients (25%) indicated that they were unaware that they would have to pay a fee at the hospital. Even though several patients indicated that they felt uncomfortable, it had not discouraged them to have the examination done.

Suggested improvement measures:

- ❖ Requesting the referring physician or his/her secretary to inform the patient of any financial responsibility.
- ❖ Including this information within the patient information brochure.
- ❖ In the case of private patients, where an itemised billing system is applied, the information on the possible cost for the requested examination should be available. It is preferred that a printed statement is handed to the patient on the arrival in the department.

7.2.2.6 Due to the location of Tygerberg Hospital and the lack of a reliable public transport system, most of the patients spent the required waiting time in the department. Although 80% of the patients indicated that they could find something to occupy themselves with during the waiting period, most patients complained about the age and condition of the available magazines.

Suggested improvement measures:

- ❖ Starting a magazine library requesting the donation of magazines from staff members, patients and voluntary organisations such as church groups. This will facilitate the rotation and replacement of magazines on a regular basis.
- ❖ Designing and implementing a SOP for effective and practical time schedules to accommodate ward patients to minimise their time spent in the department.

7.2.2.7 The inpatient waiting room was found to be cold, dirty and unfriendly. All the inpatients complained that they spent many hours in this waiting room “staring at the ceiling”.

Suggested improvement measures:

- ❖ Purchasing a TV and supplying magazines to this waiting room could assist in turning it into a patient friendly environment.
- ❖ Designing and implementing a SOP for effective and practical time schedules to minimise the time ward patients spent in the department.
- ❖ Explaining to patients why they were kept in the Nuclear Medicine Department between receiving the radiopharmaceutical and being scanned. This is due to the unavailability of enough porters and the distances patients must be transported between wards and the department.

7.2.2.8 A high percentage of participants (41%) indicated that they would prefer reading a book or magazine, and 23% of the patients would enjoy watching television. During the patient satisfaction survey process, a television set was placed in the out-patient waiting room. The majority of the children’s parents indicated a playroom will ease the stress of the hospital environment for both themselves and the children. One of the patients indicated that she would like to be massaged while waiting, which would probably result in more patients opting for this luxury (perhaps some staff members too).

Suggested improvement measures:

- ❖ Identifying a suitable area in the department to change into a childrens’ playroom stocked with toys and books.
- ❖ Ensuring that sufficient good quality magazines are available in the waiting rooms.

7.2.2.9 Although 85% of the participants indicated that they could easily locate the Nuclear Medicine Department, most of them acknowledged that they had to ask for directions.

Suggested improvement measures include:

- ❖ Assembling visible sign posts and route indicators on the hospital terrain and from the main entrances of the hospital.

- ❖ Requesting that patients referred from clinics within Tygerberg Hospital are sent to the Nuclear Medicine Department to book the requested examination. This will ensure that the patient will be familiar with the location of the department on his/her return and have received the necessary clinical and procedural information on the examination.
- ❖ Ensuring that patients referred from other locations receive a route map, suggested to be added to the information leaflet, from the referring physician with directions to the department.

7.2.2.10 The fact that the staff abstained from explaining examination procedures to 9% of the patients (table 6.4) should receive attention. Explaining procedures to patients should become protocol, as the completion of a successful and high quality study is dependent on patient collaboration. Some of the patients requested that the results and images of the examination should be explained and discussed with them.

Suggested improvement measures:

- ❖ Adding a tick box to the TRACE.001 and TRACE.002 document to act as a reminder to staff members regarding the explanation of procedures.
- ❖ Schooling and educating of existing and new staff members on departmental protocol and procedures regarding communication with patients.
- ❖ Explaining the departmental policy regarding the discussion of results with patients.

7.2.2.11 As outlined in the QCM, one of the patient orientated quality parameters is the amount of information given to patients before and during their visit to the Nuclear Medicine Department. According to the internal audit results only 38% of patients received adequate information. Included in the remaining 62% group of patients who received inadequate information, an alarming 34% indicated that they had not received any information at all. During the interview process patients indicated that even though they have not received any information, they did not ask any questions either. As many of the staff members seemed to be very busy, patients were reluctant to ask questions in fear of delaying staff members.

Suggested improvement measures include:

- ❖ Drafting and assembling patient friendly information posters in both waiting rooms.
- ❖ Hosting a patient awareness campaign targeting all staff members.
- ❖ Revising and re-introducing the existing patient information brochures.
- ❖ Encouraging patients to ask questions, by adopting an approachable attitude.

7.2.2.12 A positive finding however, is the fact that only 6% of the patients (figure 6.5) found the service they received from the department as well as the general appearance of the department unacceptable. Some comments received from the participants include:

- ❖ Some patients complained about the cleanliness and unhygienic status of the restrooms, waiting room and injection area.
- ❖ Although the majority of patients found the paintings against the walls beautiful, some patients found them childish and non-clinical.
- ❖ The museum items received lots of attention and were found to be attractive, unique and interesting.
- ❖ Many patients complained about the state of the white coats worn by the staff and found them to be dirty and unprofessional.
- ❖ An urgent need for a children's playroom was identified.
- ❖ Several complaints were lodged regarding the availability, age and user friendliness of the wheelchairs.
- ❖ Patients booked for myocardial perfusion studies appreciated and praised the fact that they received personal phone calls in preparation for the examination.
- ❖ Patients booked for radioactive iodine treatment praised the medical staff for "going that extra mile" regarding the explanation of the procedures and follow up process.
- ❖ A number of patients indicated that they felt uncomfortable and uneasy when the equipment did not function optimally and that they have sympathy with the clinical staff members who have to perform their duties under such circumstances.

- ❖ Some patients complained that their personal rights were violated as they were asked personal questions and received injections in the presence of other people.
Suggested improvement measures:
- ❖ Implementing a patient complaints system for the documentation and handling of complaints received from patients as outlined in die QCM (Addendum A page 8) and ICA document (Addendum B).
- ❖ Putting the identified corrective, preventative and improvement measures for all received complaints into practise as outlined in the ICD.PAT.01 document.
- ❖ Maintaining the patient and staff restrooms, on a regular basis by an appointed member of the cleaning staff team.
- ❖ Setting up a playroom for children with toys and books.
- ❖ Educating staff members on patient rights and communication skills.
- ❖ Ruling that staff members wearing white coats change their coats on a daily basis or as needed.

7.3 Identified staff problem areas and suggested improvement measures

Due to the variety of staff categories the suggested improvement measures were separately analysed for the combined group, clinical staff and radiographers.

7.3.1 Combined staff

7.3.1.1 An interesting, yet concerning finding is the fact that 87% (figure 6.8) of staff members experienced a degree of work-burnout, but 35% (figure 6.8) indicated that there were times that they found themselves doing nothing.

Suggested improvement measures include:

- ❖ Re-evaluating duty lists.
- ❖ Using idle times for participation in quality assurance or self-development activities.

7.3.1.2 One of the identified staff satisfaction quality parameters is staff harmonisation and communication. The keys to the optimisation of staff co-operation and harmony are communication and team work. A need was identified for better co-operation and communication between staff members

regardless of what staff category they belonged to. This insufficient collaboration and communication was highly commented on and emphasised by the doctors and radiographers. Staff members also requested that there should be visible differences in responsibilities between junior and senior staff members. These could influence departmental team spirit and team work as well as departmental communication (figure 6.10). In order to ensure mutual collaboration it is important to communicate all changes regarding schedules, protocols and processes to all staff members.

Suggested improvement measures include:

- ❖ Familiarising individual staff members with tasks and responsibilities. These task and responsibility lists are outlined in the MT.RESPONS.01 document and should be accessible to all members.
- ❖ Making the attendance of and participation in regular staff meetings compulsory.

7.3.1.3 Knowledge and competency are valuable attributes of individuals within a professional work group set-up. In a health care environment a balance is needed between clinical and managerial expertise as well as a good understanding of the departmental procedures and processes. Twenty two percent of the clinical staff group members and 40% of the radiographers (figure 6.6) indicated that they found their post school education inadequate to perform their duties. This emphasises the need for continuous development and field orientated education. The fact that 81% of the participants indicated that they always strive to develop their own future (figure 6.7) was a positive attitude, but unfortunately the lower figures of participation in continuous professional development programmes (figure 6.7) did not support this statement. Despite the fact that the Nuclear Medicine department is part of an academic environment, and offers regular well-structured academic programmes, 55% (figure 6.7) of the staff members indicated that training opportunities are not always available to them.

Suggested improvement measures:

- ❖ Implementing an effective, easy accessible communication system to inform staff members of planned training sessions.

- ❖ Identifying staff members interested in attending continuous development and training sessions.
- ❖ Announcing planned training sessions at staff meetings.
- ❖ Educating radiographers on the use of the existing record keeping system for the attendance of training sessions as documented in the staff competency reports requested by ISO.
- ❖ Issuing departmental certificates as an acknowledgement of participation in CPD programmes to each individual staff member as outlined in the QCM.
- ❖ Adding a specific section on the duty roster for attendance of academic sessions and freeing staff members from their duties in accordance with this roster.

7.3.1.4 Imbursement packages in Government departments are not comparable with the private sector, often leading to professionals leaving the state hospitals to work in private practices. Even though this is a reality, it is an extrinsic factor and is not the only cause of overall dissatisfaction and negativity.

Suggested improvement measures:

- ❖ Improving the working environment by elevating the team spirit and increasing mutual collaboration through team building exercises.
- ❖ Changing overall attitude and respecting the unique characteristics of individual staff members.
- ❖ Taking each radiographer's specific interest areas into consideration and incorporating it into the duty roster.
- ❖ Easing individual work loads by the re-evaluation of rostering, even distribution of tasks and effective use of resources.

7.3.1.5 Work satisfaction and productivity are dependent on acknowledgement, positive feedback and constructive criticism. Of the combined staff group and radiography group 26% and 22% respectively indicated that they always received constructive feedback from their peers (figure 6.9). Contrary to this, 44% of the clinical staff indicated that they never received any constructive criticism. Adding to these concerning indicators is the fact that only 3% of

the participants (figure 6.9) felt that they were acknowledged when performing good work.

Suggested improvement measures:

- ❖ Using the annual competency evaluation feedback sessions to communicate on an individual basis regarding work performance and acknowledgement of achievements and progress made.
- ❖ Acknowledging good work and progress of individual staff members at the staff meetings.

7.3.1.6 Communication in any professional set-up is vital. For this reason the fact that on average only 22% of the staff members (figure 6.10) indicated that the communication in the department is adequate, was alarming.

Suggested improvement measures:

- ❖ Implementing and maintaining an effective computerised local area network (LAN) communication system with personalised login codes.
- ❖ Monitoring the frequency of individual staff members logging in, to access and read departmental memos, meeting agendas and minutes.

7.3.2 Clinical staff

7.3.2.1 Included in the comments made by the clinical staff, are their concerns regarding the amount of administrative duties. Most of the participants indicated that their clinical and educational duties and research opportunities were slowed down by administrative duties.

Suggestions for improvement include:

- ❖ Canalising administrative duties to responsible administrative clerks and staff.

7.3.2.2 A number of clinical staff members indicated that requests for additional scans to be performed on patients, were interpreted by some of the radiographers as a personal vendetta towards individual radiographers. According to these clinical staff members the priorities of all staff members should be in the interest of the patient. Requests for additional views and/or examinations should be seen as part of quality patient care and examinations

as well as service provision. This patient orientated mind shift would probably occur when the staff's competencies are improved through measures previously discussed and by ensuring a good understanding of the departmental procedures and processes.

- 7.3.2.3. One of the duties and responsibilities of the management team is to make decisions regarding departmental protocols. Therefore it should be noted that the 12% of the combined staff members, the 10% of the radiographers and 22% of the clinical staff members who indicated that they are involved in making decisions regarding departmental protocols are members of the management team (figure 6.10). To ensure the acceptance of the ISO certification process the input from all members of all staff categories is mandatory. In order to gain commitment to the quality management system, those closely affected should be involved in the planning and implementation thereof.

Suggested improvement measures:

- ❖ Including representatives of all staff categories in the ISO-TT. Each of these representatives should meet with their respective groups prior to and after all ISO-TT meetings in order to communicate all input and decisions made.
- ❖ Circulating all ISO-TT meeting agendas and minutes to all staff members, whose responsibility would be to acknowledge having received and read them.
- ❖ Allocation single editing rights to the QCA for changing of protocols or processes after following the correct procedure as outline in die QCM.

7.3.3 Radiographers:

7.3.3.1 The majority of the participants (80%) indicated that their work always consisted of a variety of tasks, while 20% felt they performed routine work (figure 6.6).

Suggested improvement measures:

- ❖ Rotating staff members through the various areas in the department will decrease the possibility of engaging in routine work. This will also increase the degree of expertise in the entire field of the profession.
- ❖ Encouraging the participation in continuous professional development programmes on different fields in the profession. Improved knowledge and competencies could make dealing with difficult and challenging tasks easier.

7.3.3.2 In order to adhere to the requirement set by the health professionals council of South Africa (HPCSA) all registered radiographers should undergo Continuous Professional Development (CPD) by attending accredited educational and information sessions. The fact that only 30% of the radiographers (figure 6.7) participated in this programme raises concern and should be addressed as soon as possible.

Suggested improvement measures:

- ❖ Updating the LAN communication system on a regular basis to ensure that all radiographers are well informed about all available CPD programmes.
- ❖ Organising CPD programmes focussing on technical rather than clinical aspects of the profession.
- ❖ Monitoring the participation of CPD activities.
- ❖ Issuing departmental certificates as acknowledgement of the participation in CPD activities to each individual staff member as outlined in the QCM (Addendum A page 10).

7.3.3.3 The lack of important skills could be the cause for the high number of radiographers (figure 6.8) finding it difficult to cope with their allocated workload.

Suggested improvement measures:

- ❖ Establishing and ensuring the attendance of a compulsory orientation programme for all new staff members as outlined in the QCM.
- ❖ Implementing regular departmental training session to staff members to increase overall staff competency.
- ❖ Spreading the workload evenly and fairly to ensure that staff members are exposed to all work areas.

7.3.3.4 A high percentage of radiographers (80%) indicated that they experience difficulty in coping with their allocated workload. However, 30% of them also indicated that they found time to be idle (figure 6.8). This is a symbol of non-productivity and the causes, as well as implications should be investigated.

Suggested improvement measures:

- ❖ Using idle time for personal professional development, for example participation in research, attending and/or presenting academic sessions and reading journals.
- ❖ Re-evaluating the rostering process.

7.3.3.5 The majority of radiographers were dissatisfied with the reimbursement of overtime. Due to the departmental workload staff members seldom had the opportunity to take extra time off. Reimbursement for overtime worked had recently been granted by the provincial administration, which may address the problem.

Suggested improvement measures:

- ❖ Keeping to preset working shifts with the incorporation of over time payment.
- ❖ Re-evaluating the rostering process.
- ❖ Implementing daily shifts.

7.3.3.6 The lack of praise, acknowledgement of progress and receiving constructive criticism (figure 6.9), emphasised the need for improvement.

Suggested improvement measures:

- ❖ Performing annual staff evaluations and competency assessments as outlined in the QCM.
- ❖ Implementing an agenda point at the staff meetings to announce special achievements or accomplishing personal goals.

7.3.3.7 In working towards the departmental objective of harmonising staff, the survey identified that 90% of the radiographers sometimes worked together as a team and sometimes found it easy to communicate with colleagues both on work related issues as well as personal issues. In the medical environment teamwork is an important facet and therefore it is important that the team members should always work together as a team regardless of the circumstances.

Suggested improvement measures:

- ❖ Organising and ensuring the compulsory attendance of team building events twice a year.

7.3.3.8 The workload should be restricted in the event of camera down time.

Suggested improvement measures:

- ❖ Changing to work shifts to accommodate patients and make optimal use of the available resources.
- ❖ Re-evaluating daily patient list and planning to attend to ward patients after hours.
- ❖ Stressing the importance to communicate with all the involved parties, especially the patients, explaining the reasons for possible extended waiting times.

7.4 Identified pitfalls of this study

- ❖ Length and extent of the referring physician and patient satisfaction questionnaires made the surveillance process time consuming, for this reason shortened, user friendly self administered questionnaires have been designed for future use [Addendum B: REFPQ.003, PSQ.003 and SSQ.003]. Questions contained within this questionnaire are similar to those used in the base line survey, assuring comparative analysis of the results.
- ❖ The response rate of the referring physician satisfaction survey was low due to an insufficient distribution and return system.

Chapter 8: The way forward

John Maxwell said that the “Depth of your Mythology is the Extent of your Effectiveness”. On the way to ISO accreditation and certification it is important that a well defined route map must be followed with clear route markers and designated stopovers. Route markers include staff training and motivation, encouraging staff to be creative in initiating improvement, setting departmental and personal goals and implementing improvement measures. By following these route markers the continuous improvement of the quality management system must form the basis of comparing the departmental objectives with the departmental audit results. These results will indicate the effectiveness of the implemented QMS. The accreditation process should be seen as an improvement and harmonising tool and not as a war against existing processes.

8.1 Getting used to change and structure

The effective implementation, management and continuous improvement of a Quality Management System in any department is a challenge and long term goal. Due to the professional bureaucracy within the department, the setting up of a Quality Management system can sometimes cause conflict as a result of change. In a study performed in France⁴¹ some obstacles and problems were identified during the implementation of a QMS. Staff members, especially those working with a long service history, found it difficult to change their habits. On top of this, extra time must be freed to participate in quality management activities such as training sessions, meetings and documentation of SOP. The activities in this department demotivated certain staff members who could not see the value of quality management and feared the increase in paperwork. Many of the staff members also indicated that the successful implementation of a quality policy and programme without an increase in the available resources is an unrealistic exercise and concept. Some suggestions made by this French group to ensure active staff participation included: (1) focussing on the emphasis on improving the departmental processes and procedures rather than blaming individuals, (2) adopting structured problem solving strategies, (3) using multidisciplinary groups and (4) giving staff members specific responsibilities.

Therefore it is important to start at the beginning, i.e. getting all staff members on board in adopting a professional lifestyle revolving around clients and quality service

provision under the leadership of an enthusiastic, energetic and motivated QCA. Although it will take time to get used to the “new” quality policy, this process starts on personal level and should ideally cross all boundaries currently defining different professions and internal structure, procedures and processes.

8.2 Primary aims - *en route* to certification

In order to successfully develop, implement, monitor and adopt an effective quality management system specific aims should be in place. These include:

- i) adopting quality consciousness to a point of no return
- ii) prioritising safety - in a speciality characterised by the use of open sources of radioactivity, it is important that procedures must be performed by following uniformly documented working protocols.
- iii) detecting small errors in order to prevent the big ones
- iv) encapsulating and developing knowledge amongst staff to ensure job satisfaction
- v) increase industrial collaboration
- vi) anticipation of legal obligations and social requests
- vii) increase efficiency and efficacy
- viii) working towards field specific accreditation (GCP and EFQM); this will require ISO 9001:2000 certification, adequately trained staff and evidence based guidelines

8.3 The next steps *en route* to ISO certification for the Nuclear Medicine Department of Tygerberg Hospital

Stepping stones in preparation for the first ISO audit (realistic timeframe: 12-18 months):

- ❖ Evaluating and validating the QCM.
- ❖ Validating current departmental SOP and the conversion thereof into electronic format.
- ❖ Correlating documentation currently in use with the requirements outlined in the QCM.
- ❖ Designing a clinical competency report for nuclear physicians.
- ❖ Setting up an ICA database for the management of non-conformities.

- ❖ Preparation, education and training of staff members regarding ISO 9001:2000, focusing on the benefits of the successful implementation of standardisation as well as an effective QMS.
- ❖ Designing a user friendly internal audit checklist.
- ❖ Scheduling the first formal internal audit of the QMS with the following objectives;
 - identifying an energetic and enthusiastic quality control administrator (QCA);
 - identifying suitable members for the internal audit team;
 - training of the internal audit team;
 - evaluating and validating the SOP currently used within the working environment;
 - getting staff members accustomed to the idea of internal- and external auditing;
 - adoption the statistical analysis protocol as outlined in the QCSTATS.01 document;
 - formulating a baseline audit report to use as a reference framework in preparation for an external ISO audit.
- ❖ Informal communication with the ISO authorities.

8.4 On the horizon, following the international Nuclear Medicine trend

The European health sector has adopted several techniques for the peer review of quality assurance and the improvement of service quality. These include ISO 9000 standards, the European Foundation of Quality Management's (EFQM) Excellence model and *visitatie*¹⁸. Both the models have been discussed in chapter 2.

Although the *visitatie* programme was originally aimed at surgeons, gynaecologists and paediatricians, several European Nuclear Medicine departments are in the process of attaining *visitatie* recommendations^{6,18}. It would be in the interest of strengthening the ties and current close collaboration between the European- and South African Nuclear Medicine communities to follow the European trend.

Chapter 9: Conclusion

ISO defines the effectiveness of a departmental quality management system as “The extent to which planned activities are realized and planned results achieved”⁵.

This effectiveness can be measured by comparing the departmental objectives with the results attained from audits. The metaphoric “gap” between these two measuring blocks should be as small as possible. The only way to achieve a perfect balance between the two is by the successful identification, implementation and continuous monitoring of improvement measures. The conclusions drawn from this research are important to define the current status of the Nuclear Medicine Department of Tygerberg Hospital regarding client satisfaction and staff harmony and satisfaction. ISO focuses on client and staff satisfaction as well as the continuous improvement thereof. This study added to the understanding of the importance of client and staff satisfaction and its relation to quality service.

Apart from the fact that the appropriateness of the customised QCM remains to be seen, it is important that all identified departmental objectives must be audited. These objectives can not be separated from each other. Results from these audits will be used in the continuous improvement and management of the QMS of the Nuclear Medicine department of Tygerberg Hospital. Within a time period of 18-24 months ISO will be contacted in order to schedule the first external audit.

The department has QA procedures in place, but does not meet all criteria for external accreditation. In order to ensure departmental harmony and sustainability of client and staff satisfaction, the departmental objectives are measured and improved where needed. The successful implementation and continuous improvement of a customised QMS, following the guidelines outlined in the QCM will lead to successful accreditation.

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Addendum A

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		Name		Signature	
	Author	Thea Eiselen			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

Department of Nuclear Medicine
Tygerberg Hospital / University of Stellenbosch



Quality Control Manual 2004
According to ES ISO 9001:2000



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1 Introduction

As we enter an era of increasingly rapid change, the need for client satisfaction and protection is growing just as rapidly. This client protection and confidence in the supplier can be brought about by certification, inspection and testing of products and procedures under a certified quality system. As the client or supplier cannot perform this inspection process themselves, this task is allocated to a recognised accreditation body. Accreditation is the procedure by which an authoritative body gives formal recognition of the competence, impartiality and performance capabilities of a body or a person. It establishes confidence in certificates and reports by implementing internationally accepted criteria set by bodies such as ISO (International Standardisation Organisation). It is important that service providers are aware of, and understand the benefits of accreditation. All involved parties should be well educated and informed about the preparation, auditing and implementation processes. It must be stressed that the aim of the process is to strive towards perfection, and should not be seen as a threat. However, the results of an audit usually boil down to change. There are several guidelines for approaching successful change. These are:

- It should be planned and implemented in phases and should be considered in relation to the requirements of the department.
- In order to gain commitment to the process, those closely affected should be involved in the planning and implementation thereof.
- By allowing the parties involved to make free and informed choices, they must however also be prepared to alter their behaviour to work as a team towards this goal of perfection.

2. Aim

The intended result of this study is to attain ISO 9001:2000 certification for the processes and procedures involved in diagnostic examinations performed, and therapeutic treatments given at the Nuclear Medicine Department (NMD) of Tygerberg Hospital (TBH) in Cape Town. The referring physician and the patient are seen as clients, and the written report is classified as the product.

Standard operating procedures, hereafter called SOPs, will be documented for all processes within the department. These SOPs will be validated by the Head of the Department (HOD). All examinations still in a developmental stage as well as SOPs and/or procedures not validated by the HOD will be excluded from this document. These procedures will thus also be excluded from the certified activities, unless a new audit takes place. Should it be necessary to make changes to existing SOPs due to newly validated scientific data, the specified system procedure must be used as outlined in the QC.CWP.1 document.

All SOPs are listed in the SOP TBH database on the in-house computer based in room 49 of the Nuclear Medicine department.

This database will contain folders for procedures performed in the radiopharmaceutical laboratory; procedures within the working environment;

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all quality control procedures; and examinations performed on, and treatment of patients.

Ensuring the correctness of these SOP documents is the responsibility of the HOD. All examinations performed in the NMD should comply with specific parameters, which are outlined in an outline in Appendix D (page 26) of this document and form the basis of the quality management system (QMS).

3. Quality policy

In order to attain certification and accreditation, the management of the NMD of TBH has identified the need for the design, development and implementation of a QMS.

The main focus of this system will be:

- to document all procedures and processes performed within the department; and
- to optimise services and products to referring physicians and patients.

This policy will be built on the principle of continuous improvement of identified problem areas.

The objectives will be incorporated into a QMS in accordance with the ES ISO 9001:2000 document. The guidelines of the QMS are documented in a quality control manual. Legal aspects regarding radiation control, safety and hygiene are taken into consideration.

Adequate time and resources should be made available to ensure successful implementation, continuous evaluation and improvement of the QMS. This should include dedicated staff, an ISO task team (ISO-TT) and regular internal audits. The core factors in bringing about improvement are knowledge and communication. Therefore it is important that all staff members are well informed of ISO related topics and should participate in continuous professional development (CPD) programmes. It would be the responsibility of the quality control administrator (QCA) to communicate all relevant information to members of staff and maintain an accredited, relevant and meaningful educational programme.

The QCA, in close collaboration with the directorate of the NMD of TBH, will also be responsible for the continuous evaluation, maintenance and improvement of the QMS. He/she will chair the ISO-TT meeting and communicate information regarding planned audits, internal and external, to members of the TT as well as staff members. Audit reports will be analysed and acted upon under the close supervision of the QCA.

4. What is standardisation?

In practice, standardisation is understood as the process during which agreements are reached and established between interested parties. They are

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often of a technical nature. These agreements are established with the intention and expectation that they will be continuously used.

Standardisation therefore:

- involves drawing up provisions and requirements, called a standard, which offers one or more solutions to problems;
- can create order in existing chaos and prevent the possible recurrence of problems;
- involves designing solutions which can be continuously used over a certain period (until the standard is revised or withdrawn); and
- aims to reach the optimum degree of order, by which the interested parties can reach consensus. It is therefore necessary to weigh up interests.

5. What is a quality management system?

A QMS is the collection of processes, documents, resources, and monitoring systems that direct the work of an organisation regarding product and service quality. The organisation needs to establish, document, carry out, and maintain this system to meet the requirements of ISO 9001:2000.

5.1 Documentation requirements

5.1.1 General

The organisation needs to document – either electronically or in hard copy – the quality policy, objectives and manual. Written procedure, plans and operations need to describe how product and service quality are attained. Certain records, providing evidence of activities that were carried out (i.e. purchase orders, sales contracts, inspection records, design review notes, etc.), have to be retained.

The quantity, detail and form of the documentation may differ from one organisation to another, depending on size, type of activities, or complexity of processes.

5.1.2 Quality manual

The quality manual describes the extent of the QMS and may exclude certain sections of the standard, as outline by ISO, that are not relevant to the organisation. All of the quality procedures are either included in the quality manual or are referred to in it. The interaction between processes constituting the QMS is also described.

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5.2 Control of documents

All of the documents in your QMS must be legible, identified, reviewed, authorised, up-to-date, issued, distributed, and periodically updated. Obsolete documents have to be identified and protected from unintended use. Documents that come from outside the organisation also have to be identified and controlled.

5.3 Control of records

Certain records need to be kept to demonstrate how the QMS operates. These records must be legible, and easy to identify and retrieve. A written procedure must describe how they are identified, stored, protected, retrieved, and must define their retention and disposal times.

6. Why is a quality management system necessary?

The implementation of a quality system in any department should be a strategic decision. The design, planning and implementation of a QMS will vary from one department to another as it is influenced by a number of factors.

These include:

- various needs;
- particular objectives;
- the products;
- the processes used; and
- the size and structure of the organisation.

7. Planning of the quality management system

Identified quality assurance principles will be used as quality indicators. The effectiveness of a quality control system is measured by monitoring the quality indicators set by the department as indicated by their clients. This monitoring process can be done by using the well-known Deming circle of quality control, i.e. "plan, do, check, adjust". In 1950, Deming proposed that business processes should be analysed and measured to identify sources of variations that cause products to deviate from client requirements. It was recommended that processes should be placed in a continuous feedback loop to ease the identification of processes that need improvement. This is illustrated by the following outline (Figure 1.1):

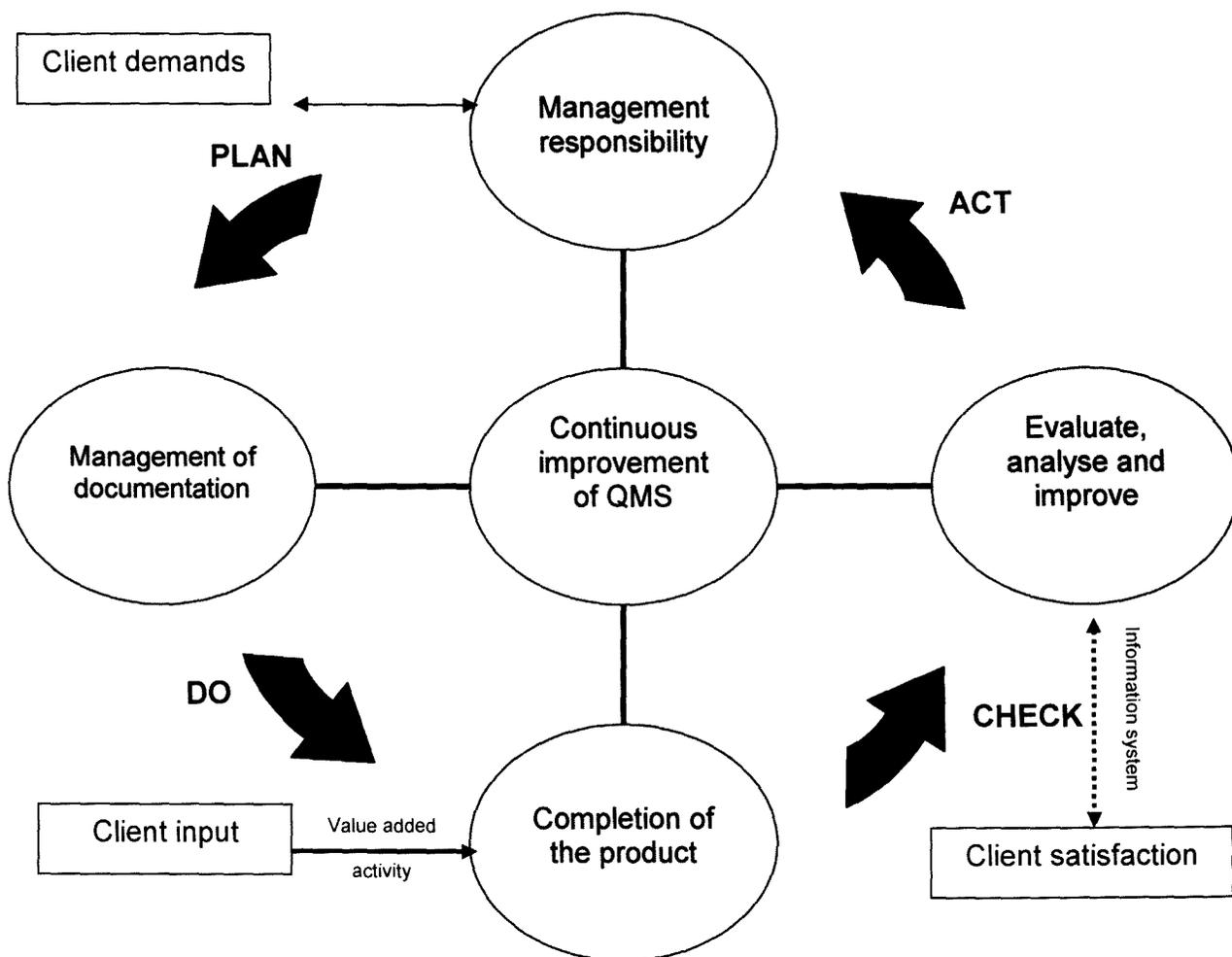


Figure 1.1

These basic principles will be communicated to all staff members at regular staff meetings. It is important that staff members are motivated to practise the principles as a team, and do not see the process as a threat.

Comments on the diagram:

Plan:

It is the responsibility of management to listen to the clients' demands and establish the objectives and processes needed to deliver results in accordance with client requirements and the department's policies.ⁱ Design or revise current processes and departmental components to improve results.

Do:

Implement the quality management system, and measure its performance. Again the clients' input should be seen as a value added activity to ensure the completion of the planned product.

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Check:

Assess the measurements by conducting an internal re-audit using patient and client satisfaction surveys, document all results and report to the management team.

Act:

Take actions to practise the identified and chosen improvement measurements. Restart the improvement process if found to be necessary.

8. Objectives of quality control

The objectives of quality control are to implement and maintain a customised programme with the aim to attain ISO accreditation and certification.

The following important basic principles were identified:

- patient satisfaction;
- referring physician satisfaction;
- staff satisfaction and harmony
- staff development;
- accurate and correct performance of examination;
- efficient use of available equipment and resources;
- clear and diagnostically valuable reports; and
- accurate and traceable archiving.

8.1 Patient satisfaction

Important quality parameters include:

- how many times the patient visits the department for follow-up examinations;
- amount of information given regarding the examination;
- amount of information given regarding the waiting time;
- degree of friendliness and respect with which the patient is treated in the department by all staff members;
- waiting time in the waiting room;
- consultation with a doctor in the department; and
- tidiness and hygiene of the department.

All criteria will be measured by:

- an initial audit performed using original patient satisfaction questionnaires (PSQ 001& PSQ 002);
- a weekly analysis of ICD.PAT.01 documents by QCA;
- a monthly evaluation of ICA.PAT.01 at the ISO-TT meeting by following the guidelines in document QC.PAT.ICA;

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- discussing the preventative and improvement measurements at the monthly ISO-TT meeting by following the guidelines in the QC.PAT.ICA.M1 and QC.PAT.ICA.M2 documents;
- implementation and monitoring of improvement measurements as outlined in the QC.PAT.ICA.M2 document;
- an annual audit, as organised by the QCA by using the revised and shortened questionnaires (PSQ 003 & PSQ 004); and
- comparative analyses, as outlined in the QC.STAT.01 document, of patient satisfaction data by using the quality management database (QMDB).

8.2 Referring physician satisfaction

Important quality parameters include:

- professional telephone etiquette;
- telephonic answering of clinical questions;
- availability of Nuclear Medicine physician;
- value of written clinical information provided by the department;
- waiting period between requesting an examination and the actual examination date;
- the time elapsed between the examinations and receiving the report;
- clarity and comprehension of the report; and
- clinical value of the report.

All criteria will be measured by:

- an initial audit performed using original referring physician satisfaction questionnaire (REFPQ 001 & REFPQ 002);
- a weekly analysis of ICD.REFP.01 documents by QCA;
- a monthly analysis of ICD.REFP.01 documents at the ISO-TT meeting by following the guidelines in document QC.REFP.ICA;
- discussing the improvement measurements at the monthly ISO-TT meeting by following the guidelines in documents QC.REFP.ICA.M1 and QC.REFP.ICA.M2;
- the implementation and monitoring of improvement measurements as outlined in the QC.REFP.ICA.M2 document;
- an annual audit, as organised by the QCA, using the shortened and revised questionnaires REFPQ 003 and REFPQ 004; and
- a comparative analysis, as outlined in the QC.STAT.01 document, of referring physician satisfaction data by making use of the RREFPSAT.01 document.

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8.3 Staff harmony and development

Important quality parameters include:

- interaction and teamwork;
- effective, continuous, interdepartmental communication;
- improving and maintaining the working environment;
- a variety of responsibilities, tasks and work contents;
- amount of recognition given; and
- participation in a CPD programme.

All criteria will be measured by:

- an initial audit performed using original staff satisfaction questionnaire (SSQ 001 & SSQ 002);
- monitoring monthly staff meeting attendance by making use of the MT.MATT.01 document;
- half yearly team building and/or social events as organised by the QCA in cooperation with the management team;
- the implementation, training and maintenance of an effective computerised LAN communication system with personalised log-in codes. Log-in codes will be used to monitor the access to departmental memos, meeting agendas and minutes;
- a roster based on rotation in order to ensure that staff members are exposed to all work aspects within the department;
- an annual satisfaction audit, as organised by the QCA, using the shortened and revised questionnaire SSQ 003;
- annual clinical performance evaluations by using the MT.PEFTEVAL.01 document; and
- a comparative analysis, as outlined in the QC.STAT.01 document, of staff satisfaction data by making use of the RSTAFFSAT.01 document.

8.4 Following a correct and standardised examination protocol

Important quality parameters include:

- number of incorrect examinations:
 - wrong injection type;
 - incorrect injection dosage; and
 - injecting the wrong patient.
- number of incorrect specified examination parameters:
 - wrong acquisition;
 - useless acquisitions performed;
 - incorrect image processing; and
 - irrelevant information in report.

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All criteria will be measured by:

- a weekly analysis of ICD.EXAM.01 documents by QCA;
- a monthly analysis of ICD.EXAM.01 documents at the ISO-TT meeting by following the guidelines in document QC.EXAM.ICA;
- discussing the preventative and improvement measurements at the monthly ISO-TT meeting by following the guidelines in documents QC.EXAM.ICA.M1 and QC.EXAM.ICA.M2;
- the implementation and monitoring of preventative and improvement measurements as outlined in the QC.EXAM.ICA.M1 and QC.EXAM.ICA.M2 documents;
- annual evaluations of all examination SOPs;
- annual evaluations of all data processing SOPs; and
- annual evaluation of report format.

8.5 Effective use of available resources

Important quality parameters include:

- optimal use of the existing staff;
- optimal use of financial resources;
- effective handling of patient accounts/invoicing;
- optimal use of existing equipment;
- efficiency of individual staff members;
- training and orientation of all new staff members;
- participation in CPD for all clinical staff;
- teamwork amongst staff members;
- inter-hospital collaboration with other departments; and
- collaboration with other hospitals/institutions.

All criteria will be measured using specific indicators:

- All staff-related documentation should be available to all members of staff. These include MT.RESPONS.1, individual staff members' evaluation files and ISO-TT reports.
- An effective internal communication system must be set up between all members of staff as stipulated in section 5.5.3 of ISO 9001:2000 regulations.
- CPD certificates (MT.CPDS.1) must be awarded annually as part of a staff development programme.
- The optimal use of the staff component is calculated by dividing the number of examinations performed per annum by FTEs. The aim is to keep this ratio as high as possible.
- When drafting the budget, the average operational cost per examination, as in the previous financial year, is calculated. The intention should be to keep this ratio as low as possible, without compromising quality.

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- A capacity utilisation of all gamma cameras is performed on a quarterly basis. This is done by counting the number of examinations performed on each gamma camera. The aim is to keep this ratio as high as possible without compromising image quality. Correct management of camera downtime will receive special attention.
- The efficiency of all staff members is evaluated annually by allocation of a subjective score (very bad, bad, good, very good, and excellent). This score allocation will be done by the particular staff member's direct head by means of an evaluation interview and accumulated incidents (positive or negative). These 'score sheets' will be kept in the individual staff member's EF. The accepted average score for all staff members should be 'good' in order to maintain quality.

8.6 Clear and diagnostically valuable reports

Important quality parameters include:

- standardisation of report format;
- ensuring clinical value in the management of the referring physician's patient;
- optimal use of existing resources;
- development and implementation of e-commerce system;
- optimising report release time to two days; and
- ensuring the availability of Nuclear Medicine physicians to discuss results either telephonically or via email.

All criteria will be measured by:

- using the appropriate report template as listed in the ADD.LIST. The typing of the reports is the responsibility of the administration clerk;
- an annual audit using the referring physician questionnaire (RPQ 003) to evaluate the clinical value of reports received in the clinical management of patients;
- the successful implementation of a computerised reporting workstation. This will enable Nuclear Medicine physicians to process and send reports directly;
- educating the referring physicians in using e-commerce resources for the receiving and archiving of reports and/or images;
- educating referring physicians and Nuclear Medicine physicians to make use of email facilities to answer clinical queries and clarify report results;
- three monthly analyses of sections 7 and 8 of the traceability formula documents (TRACE.001 and TRACE.002);
- the registration of all non-conformities by completing an ICD.EXAM.01 document;
- a comparative analysis of statistical data by using the QMDB;
- an annual evaluation of report formats; and

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- the implementation and monitoring of preventative and improvement measurements as outlined in the QC.EXAM.ICA.M1 and QC.EXAM.ICA.M2 documents.

8.7 Accurate and traceable archiving

Important quality parameters

- Ensuring accurate and traceable archiving of patient reports and data as legally required
- Optimal use of existing resource
- Development and implementation of a user-friendly system

All criteria will be measured by using:

- three monthly analyses of section 9 of the traceability formula documents (TRACE.001 and TRACE.002), to determine consistency of the archiving process.

The initial evaluation results serve as standard for the years to come. The aim is to improve these results gradually but continuously by adhering to the requests and expectations of our clients. Special attention will be given to client service, efficiency and appropriateness. Client service can be defined as the adjustment of departmental operation to adhere to the client's needs and desires. Effectiveness is the degree in which the goal is achieved. Appropriateness indicates whether the qualitative results have been achieved with as little effort as possible.

9. Exclusions

All the requirements stated in the ES ISO 9001:2000 are discussed and applied to the activities within the NMD of TBH.

10. The Nuclear Medicine Department

10.1 Mission

Our mission is:

- to provide professional service to the patient by making the correct diagnosis and giving the correct treatment with friendliness and empathy;
- to achieve work satisfaction through mutual respect and dedicated teamwork, taking interest in our profession but also in each other;
- to strive towards new developments within the Nuclear Medicine field and adopt techniques to improve patient care on a continuous basis;

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- to provide top quality education to all staff, students and colleagues in order to grow with the changing needs and developments of the medical and scientific profession; and
- to contribute to the scientific environment by conducting relevant and appropriate research.

10.2 Vision

Our vision is to be a department that provides quality service to our patients and a high standard of training to all staff, and to nurture the academic environment on a continuous basis by conducting world-class research.

The organogram of TBH is found in Appendix A of this document.

The organogram of the NMD is found in Appendix B of this document. From this it is clear that the department functions in six units, i.e. clinical, scientific, radiographers, nursing, administration and support. These units are clinically managed by the HOD supported by the management team. Further information can be found in the MT.DOC.1 document.

11. Why ISO 9001:2000?

The motivations for being awarded an ISO certification include:

- to demonstrate the NMD of TBH's priority attention to quality client care visually;
- to provide confidence to clients about the consistent performance of the department;
- to ensure the validation and correct documentation of processes and procedures currently used;
- the validation of SOPs currently used as well as SOPs being developed;
- to ensure good communication between all staff members regarding departmental activities and SOPs;
- to implement the requirements set by ISO to ensure good communication with the client, in this case with the patient and the referring physician. This includes handling, correction and improvement of their requests and/or complaints;
- to build a good QMS, from the crawling stage to the sprinting stage, by offering a clear structure;

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- using a definite and clear description of tasks, responsibilities and abilities of all staff members (as required by ISO standard) as a tool to cultivate optimal staff collaboration and teamwork;
- ensuring participation in a CPD programmes
- employing highly skilled staff, through the ISO standard requirement of a high standard education and continuous schooling for all clinical staff;
- to secure market related prices and service quality from all suppliers as a result of annual evaluation and comparison of companies and products;
- to lower costs through the effective use of available resources;
- to open up possible collaboration with other African countries in order to standardise all processes and procedures within the different NM facilities, as well as the documentation thereof;
- to be part of an internationally recognised quality system and accreditation body, in the interest of international and national collaboration.

12. Outline of a standard examination

The aim of the department is to be awarded with ISO 9001:2000 certification for nuclear medicine diagnostic and therapeutic procedures and processes. In Appendix C of this document, an outline of a standard examination can be found; most of the examinations performed in the NMD follow this pattern. In explanation of the diagram, a short description of a classic examination will be given. Note that slight deviations might occur in some examinations. These differences will be described in die SOP of that specific examination. These SOPs can be found in the examination SOP folder of the SOP TBH database.

A. Planning

Bookings for requested examinations are done either telephonically or when the request form is received. All request form will be evaluated by a clinical staff member for validation of the appropriateness of the requested examination. All bookings are documented in the PT.LOG.01 book. The telephone information booklet (TQB.01) can be used to answer any telephonic queries regarding examination types and patient preparation. Should the requested examination require ordering a specific product, follow step C. In the case of unavailability of ordered products or any other reasons for not performing the requested procedure, follow step D. This is classified as the planning phase. Responsibility for the booking of all diagnostic procedures lies with the clerk and radiographer manning the

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book. Therapeutic procedures are the responsibility of the Nuclear Medicine specialist.

B. Receive request form

Request forms (EXAM.REQUEST), completed in duplicate, are received via internal post or fax. The following information must appear on the request form:

- patient name;
- hospital file number;
- date of birth;
- examination requested;
- date of request;
- date of booking;
- clinical history; and
- name and signature of the referring physician.

The clerk must make telephonic contact with the ward or referring physician should any of this information be incomplete. In the case of incomplete clinical information, the registrar should contact the referring physician. Forms are filed in boxes labelled for the specific day of the week. Lists of the week's bookings are sent to the clerk at the administration office on the western side of the NMD. It is the responsibility of the clerk to obtain all patient records and X-rays from the medical records department prior to the arrival of the patient.

C. Order product

All non-stock items should be ordered by using the PAWC Department of Health general requisition document.

D. Contact referring physician

The referring physician should be contacted telephonically in cases where it is not possible to perform the requested examination. This communication is the responsibility of the Assistant Director radiography or any clinical staff member of the NMD, and should be documented by using the NOEXAM.01 document. This document must be sent to the QCA, who will be responsible for the implementation of preventative and improvement measurements, if possible.

E. Examination type

For diagnostic examinations, follow steps F and G. For therapeutic procedures, follow steps K and L.

F. Patient registration

Out patients arriving at the department should be in possession of an appointment card. The clerk at the reception area will issue an appointment

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card to patients visiting the TBH for the first time. This appointment card is placed in a box at the reception office on the western side of the NMD. Patients are computer registered by the administration clerk and receive their patient file, their X-rays and stickers. From here, the patient proceeds to the central booking and administration desk, and hands the file and X-rays to the clerk or radiographer. The particular patients' request form is taken from the filing box and attached to the TRACE.01/TRACE.02 document. This document is for future use by the radiographer scanning the patient as well as the doctor reporting the examination. At this stage the corresponding patient sticker must be stuck to the "stick the patient sticker here" block in section 2 of the TRACE.01/TRACE.02 document. The patient's name and examination type is added/ticked on the daily examination list (PATIENT.LIST) and the request form is sent to the hot lab. Patients receiving a bone scan are asked to complete the BONE.QUES.1 document, which is attached to the request form bundle on completion.

G. Preparation of radiopharmaceuticals

Patients should be in possession of a completed request form (see B) before any radiopharmaceutical is administered. Individual patient request forms are sent to the hot lab after the registration of patients.

All radioactive administered dosages are prepared in the hot lab under the supervision of the Radiopharmacist. Section 1 of the TRACE.01/TRACE.02 document must be completed by the person physically performing the preparation process. Quality control of preparations should be performed as outlined in the SOPs, and documented accordingly. The preparation SOP, as compiled by the Radiopharmacist, should be followed at all times. These SOPs are documented within the hot lab folder of the SOP TBH database. Should a student prepare radiopharmaceuticals, it remains the responsibility of the person in charge of the hot lab to ensure the correctness of the process. Individual patient dosages are labelled for identification purposes with a sticker containing the following information: preparation type, patient name, patient number, activity, date and time. The final product is collected by a radiographer or the nursing sister and placed in the injection room.

H. Product administration

The nursing sister in charge calls the patient from the waiting room to the consultation/injection room.

Patient identification is confirmed by asking the patient to state his/her name and date of birth.

It is the responsibility of the person injecting the patient to ensure that the details appearing on the injection detail document correspond with the patient details and examination type. He/she should complete section 3 of the TRACE.01/TRACE.02 document.

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I. Consultation and scan

Section 4 as well as the clinical history section of the TRACE.01/TRACE.02 document should be completed by the radiographer responsible for scanning the patient. The particular examination protocol should be followed. All these protocols can be found in the examination folder in the SOP TBH database.

All out patients should be consulted by a medical doctor, whose responsibility it would be to complete section 5 of the TRACE.01/TRACE.02 document.

Should any special or additional views be required, this should be clearly stated in section 5 of the TRACE.01/TRACE.02 document. This document must then be sent back to the radiographer originally responsible for scanning the patient, whose responsibility it remains to adhere to the requests.

J. Processing

As some diagnoses are made after computerized processing of raw data, several investigations require post-imaging processing. The Nuclear Medicine doctor reporting on the examination performs most of the processing. He/she must complete section 5 of the TRACE.01/TRACE.02 document. Processing protocols are documented in the processing folder of the SOP TBH database. The correctness of the processing protocols is the responsibility of the Physicist under supervision of the HOD.

K. Patient registration

All patients receiving a thyroid scan and who are diagnosed as needing radioactive iodine (RAI) treatment, must be discussed with the referring physician to confirm whether the patient must be treated or not. All female patients of reproductive age undergo a pregnancy test before they may enter the thyroid therapy room. At the Nuclear Medicine thyroid clinic the patient receives an information sheet (THYINFO.01/THYINFO.02) answering all frequently asked questions. It is the responsibility of the Nuclear Medicine specialist or registrar to explain the procedure to the patient in understandable terminology. The patient is also given the opportunity to ask more questions if any uncertainties still exist. Each patient, prior to receiving therapy, must sign a consent form. For each patient receiving RAI, a letter is written to the referring physician/day hospital containing applicable information on the therapy e.g. beta blockers, steroids, etc.

L. Preparation of tablet

Individual dosages are ordered for each booked patient using the prescribed document. The patient's personal details should be correlated with the details appearing on the dosage description.

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M. Therapy

Each patient's folder, thyroid clinic envelope, the letter to the referring doctor and two envelopes must be in the treatment room before the capsule can be administered. ¹³¹I therapy capsules are given to the patient by the Nuclear Medicine specialist, who completes a traceability formula document (RAITF.01) for each patient. The name, address, telephone number, referring doctor and clinic or hospital where the patient usually goes for treatment, plan of treatment, current and previous medication, etc. should always be filled in, even if it is a second or third dose.

Patients working in the catering business, on fruit or vegetable farms, day care personnel and nursing staff, or medical doctors (especially those working closely with babies/children) should be booked off for at least three days.

N. Follow-up

A follow-up examination is scheduled for each patient for two to three months after receiving treatment. During this visit the Nuclear Medicine specialist completes the THYFOLLOW.01 document. Guidelines and rules regarding RAI treatment are outlined in the THY.RULES document.

O. Reporting

The referring physician receives a written report on all examinations and/or treatments performed on referred patients. A doctor of the NMD of TBH dictates this report onto an audio-cassette. After reviewing the final typed report, and finding it to be correct, he/she must sign the original report. If corrections must be made, they must be indicated clearly and the report sent back to the typist.

By completing and signing section 6 of the TRACE.01/TRACE.02 document, the doctor indicates that he/she agrees that the examination/treatment process has been completed according to the preset protocols. The end responsibility to approve reports lies with the HOD. Before the report is sent for typing, the doctor must complete section 10 of the TYRACE.01/TRACE.01 document regarding the statistics.

P. Typing of reports

Together with the sending and archiving of reports, this is the responsibility of the medical secretary and can be summarised as follows:

The dictated report is typed into the report template. All reports follow a specific pattern as outlined in the relevant prescriptive document. The typed document is sent back to the doctor of the NMD to be reviewed. Once the revised and corrected/signed report has been received back, the responsible typist must complete section 7 of the TRACE.01/TRACE.02 document. In cases where a provisional report is requested, it is the responsibility of the doctor who reported the specific study to make contact with the referring physician. The end responsibility for correctness and timely distribution remains that of the HOD.

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Q. Sending of reports

Sending the original report to the referring physician is the responsibility of the administration clerk. This can be done using email, fax, mail or internal mail.

R. Archiving

A copy of the typed report together with the TRACE.01/TRACE.02 document is stored in the administration office for a period of 5 years. This is the responsibility of the administration clerk. Patient reports are kept within the patient file and then sent to the records department of TBH where it is kept for 10 years as stipulated by law. Images are saved onto the Hermes computer system and are the responsibility of the medical technical officer. Regular backups are made onto electronic storage media.

13. The internal audit procedure

An internal audit will be performed every six months, in preparation for the external audit performed by ISO. ISO perform external audits on an annual basis after certification has been approved. Scheduling and planning of these audits is the responsibility of the QCA. The planning document (PIA.01) should be presented at the preceding ISO-TT meeting. The audit procedure is outlined in the PIA.01 document. An audit can be described as a cycle or spiral, as illustrated in the following diagram:

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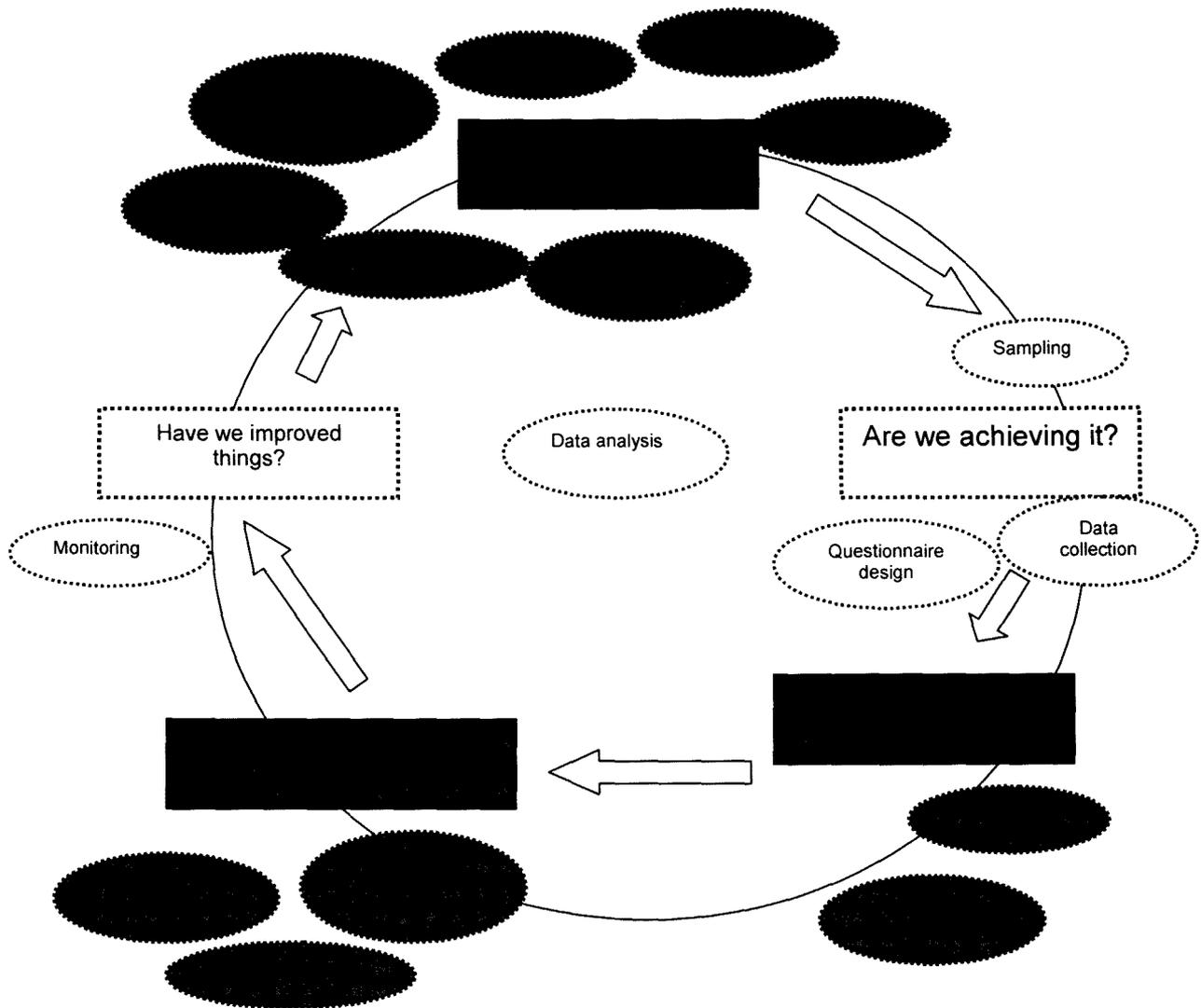


Figure 13.1

13.1 Using an audit checklist

The auditor or audit team should review information relevant to their assignment and prepare working documents to achieve this. Therefore the auditor 'tool box' may include a checklist. It is important to note that the checklist should not restrict the extent of the auditing activities, as this may have a negative influence on audit results.

13.2 Example of the auditing process

It is beneficial and advised to measure the department's QMS according to the ISO 9001:2000 requirements. For this reason a checklist will ensure that all relevant ISO requirements are addressed.

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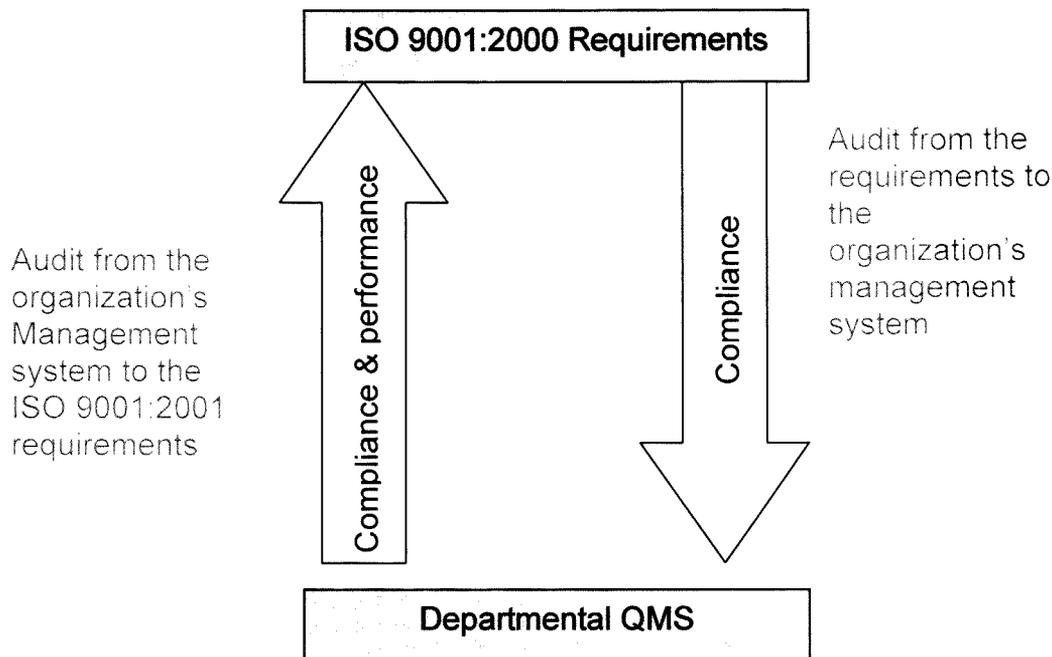


Figure 13.2

It is beneficial to audit from the organization's quality management system up to the requirements to ensure that all the relevant ISO requirements are addressed.

13.3 Audit reporting

Audit reports should be prepared and presented to the top management of the department. It would be appropriate to present an executive summary of the audit report. This report should emphasise key findings, both positive and negative, as well as identify areas of improvement.

14. Guidelines in preparation for the implementation of a quality management system which would meet ISO 9001:2000 requirements

ISO emphasises an approach that includes:

- identification of processes that will aid in the effective implementation of a QMS;
- having a clear understanding of process interactions;
- ensuring the effective monitoring and operation of all processes by using a user friendly documentation system; and
- ensuring that the driving force behind successful implementation of the QMS lies within the continuous analysis and improvement of processes, and not in the documentation thereof.

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15. Documents of the quality management system

The core of the QMS is outlined in the quality control manual. The requirements of the ISO 9001:2000 norm for system procedures are discussed, which discussion in turn refers to all working procedures, lists, processes and formulas. These can be defined as documents needed by the organisation to ensure the effective planning, operation and control of its processes.

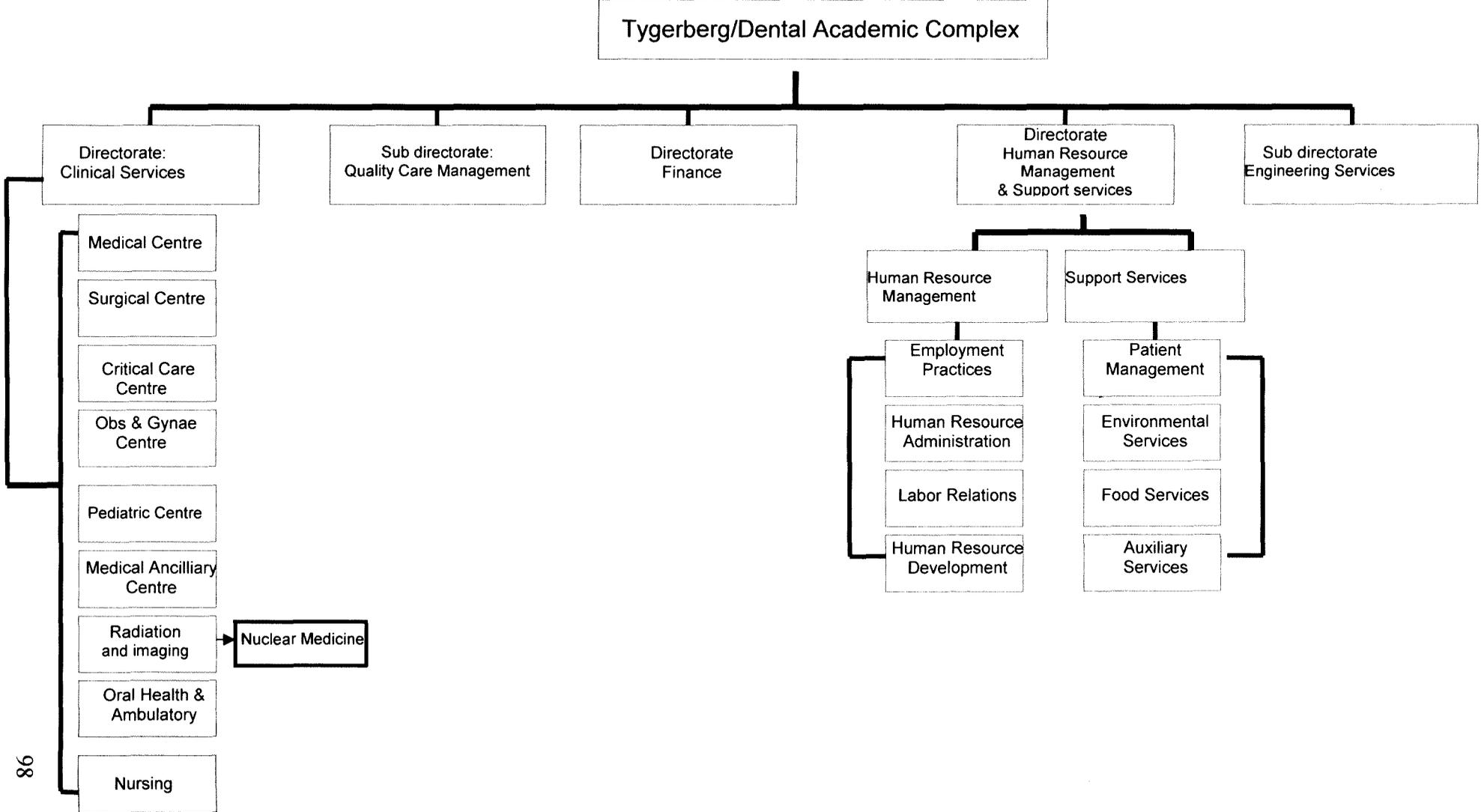
Each document has a specific code in the right-hand corner for easy identification. The document title is in the top left-hand corner of the first page of each document. Electronic hyperlinks have been created to make the manual user-friendly. Lists of all documents referred to in this manual can be found in the summary below (Table 20.1, 21.1, 22.1, 23.1, 24.1, 25.1)

All documents of the quality system (quality manual and system procedures), where references have been made to chapters in the ISO 9001:2000 norm document, are listed below (Table 15.1):

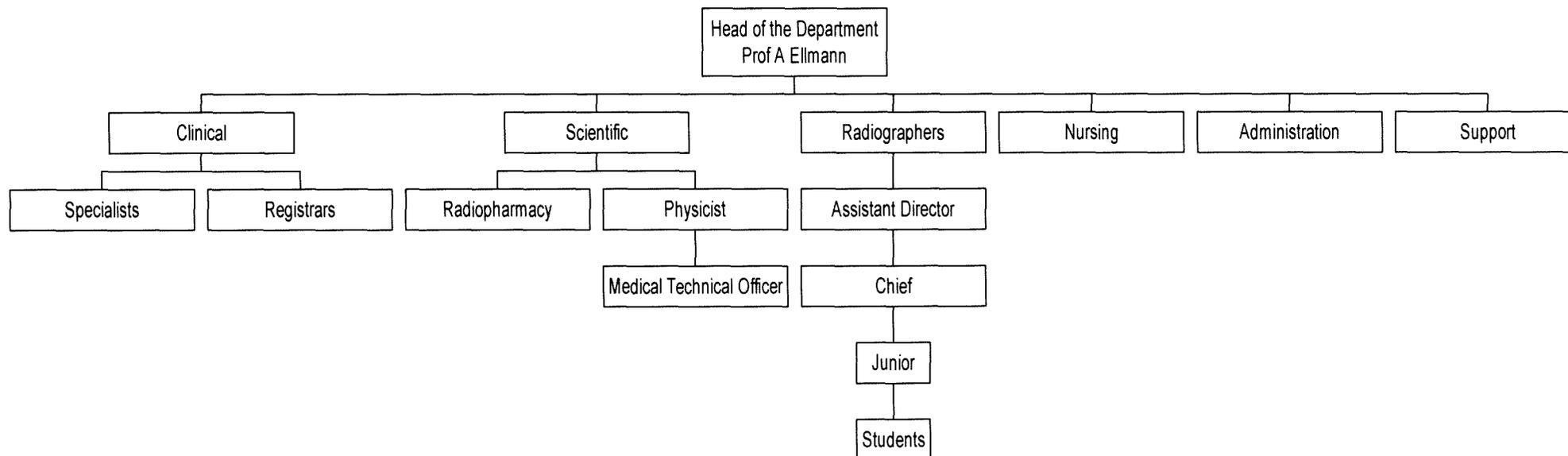
Document	Abbreviation	Reference in ISO document
Quality control manual	QCM Man	4.2.1, 4.2.2, 5.3, 5.4, 5.5.3, 7.1, 7.5.3
Document control	QCD.01 QC.CWP.01	4.2.3 7.3
Quality registration	QR.01	4.2.4, 7.1,7.2, 7.4.1,7.5.3, 7.5.4,7.5.5
Internal audit	PRIA.01	8.2.2
Non-conformities	QC.EXAM.ICA QC.PAT.ICA QC.REFP.ICA	8.3
Preventative measurements	QC.EXAM.ICA.M1 QC.PAT.ICA.M1 QC.REFP.ICA.M1	8.5.3
Improvement measurements	QC.EXAM.ICA.M2 QC.PAT.ICA.M2 QC.REFP.ICA.M2	8.5.2
Statistical techniques	QC.STATS.01	8.4
Client relations	C.REL.01	5.2,7.2.1,7.2.2,7.5.2, 7.5.4, 7.5.5, 8.2.1, 8.2.3, 8.2.4
Staff documents	MT.RESPONS.01	5.5.1, 5.5.2
Internal communication	MT.ICOM.01	5.5.3
External communication	MT.ECOM.01	7.2.3
Evaluation and continuous improvement of the QMS	MT.EQMS.01	5.6, 8.5.1
Availability of resources	MT.RES.01	6.1, 6.3, 6.4
Staff development	MT.SDEV.01	6.2

Table 15.1

16. Appendix A : Organogram of Tygerberg Hospital, Cape Town

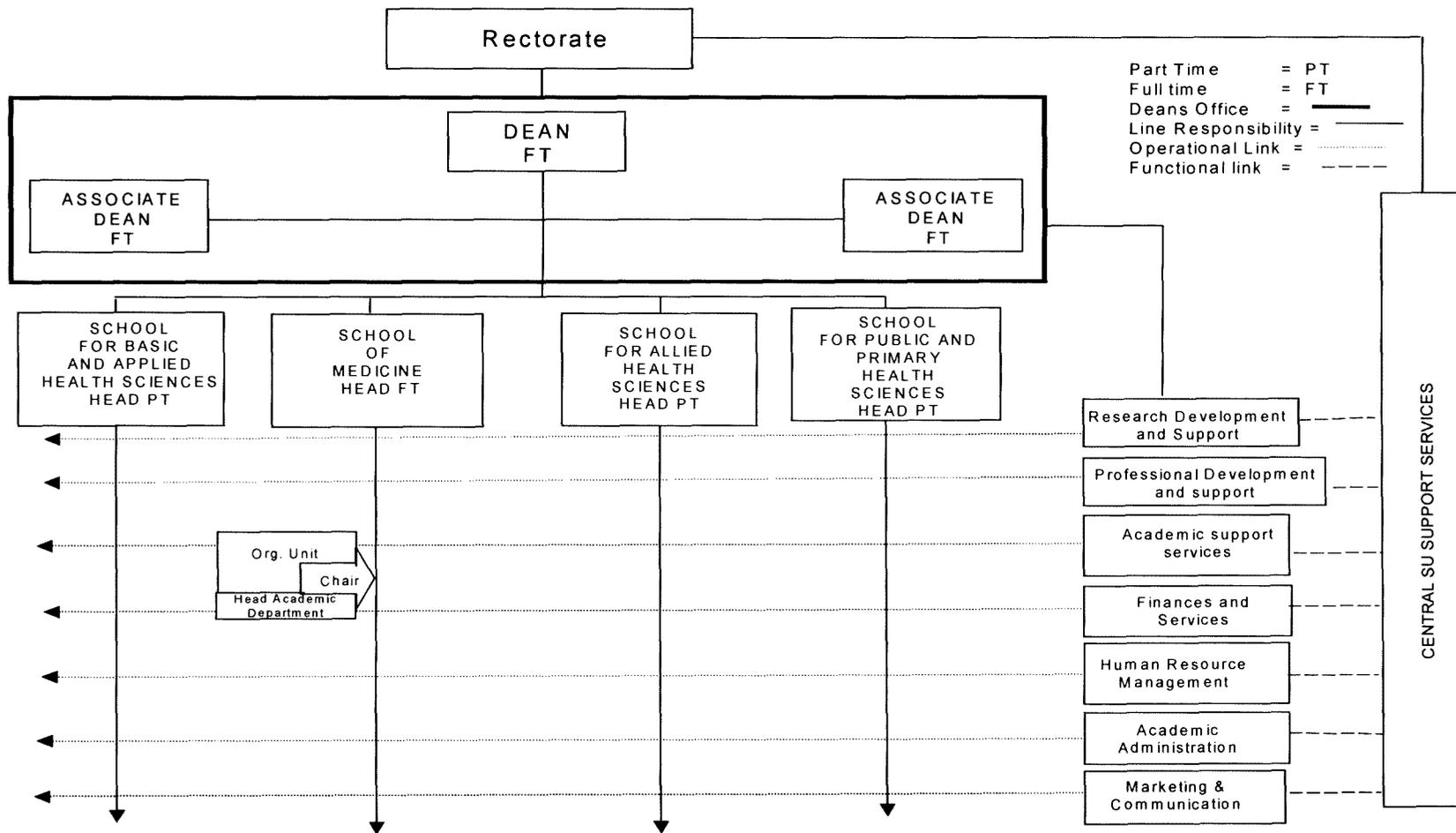


17. Appendix B: Organogram of the Nuclear Medicine Department

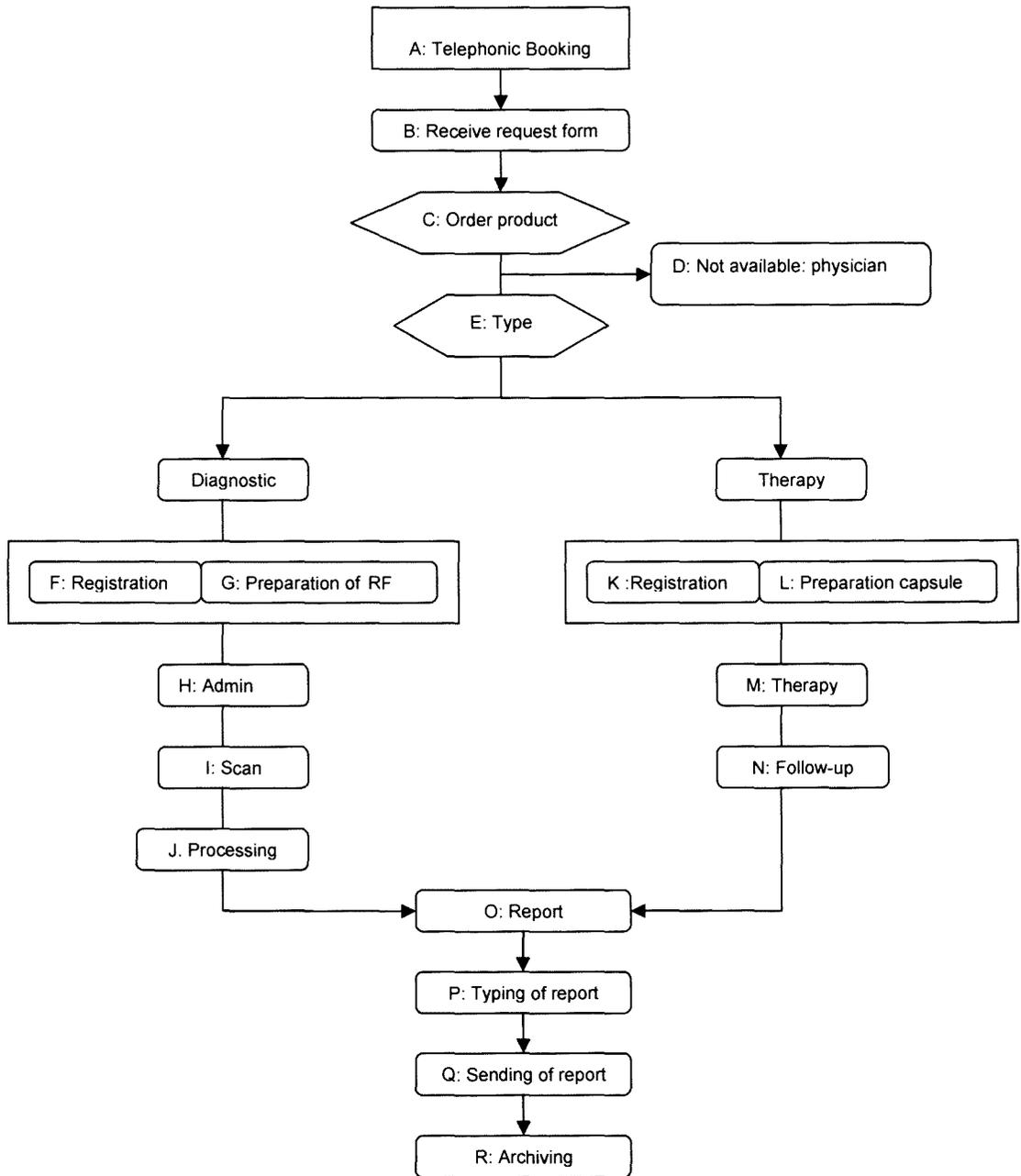


Departmental sections:
A = Clinical and Scientific
B = Radiography
C = Nursing
D = Administrative
E = Support

18. Appendix C: Organogram of the Faculty of Health Sciences, University of Stellenbosch



19. Appendix D: Outline of a standard examination



RF = radiopharmaceutical
Admin = administration

Nuclear Medicine - Tygerberg Hospital/University of Stellenbosch	Code:QC Man	P 28/34
QUALITY CONTROL MANUAL ISO 9001:2000	Edition 1	Drafted on 25/06/2004

20. Appendix E: List of management team and staff documents

MT.COMR.01	Staff competency report
MT.CPDC.01	CPD certificate
MT.DOC.01	Departmental profile
MT.DORG.01	Fill out organogram
MT.ECOM.01	External communication
MT.EQMS.01	Evaluation and continuous improvement of the QMS
MT.ICOM.01	Internal communication
MT.MATT.01	Staff meeting attendance record
MT.PERFEVAL.01	Staff performance evaluation
MT.RES.01	Availability of resources
MT.RESPONS.01	Staff responsibilities
MT.STRAIN.01	Staff training

Table 20.1

21. Appendix F: List of quality control documents

QC.CWP.01	Changing of work procedure according to current scientific information
QC.EXAM.ICA	Non-conformity – examinations
QC.EXAM.ICA.M1	Preventative measurements – examinations
QC.EXAM.ICA.M2	Improvement measurements – examinations
QC.PAT.ICA	Non-conformity – patients
QC.PAT.ICA.M1	Preventative measurements – patients
QC.PAT.ICA.M2	Improvement measurements – patients
QC.REFP.ICA	Non-conformity – referring physicians
QC.REFP.ICA.M1	Preventative measurements – referring physicians
QC.REFP.ICA.M2	Improvement measurements – referring physicians
QC.STATS.01	Statistical techniques
QC.SUGGLOG.01	Suggestion log book for improvement measurements

Table 21.1

Nuclear Medicine - Tygerberg Hospital/University of Stellenbosch	Code:QC Man	P 29/34
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22. Appendix G: List of administration documents

ABB.LIST	Abbreviation list
ASSET.LIST	List of departmental assets
BONE.QUES.01	Bone scan patient questionnaire
C.REL.01	Patient relations
CDOC.01	Changing of documents
EXAM.REQUEST	Examination request form
ICD.EXAM.01	ICA formula – examination
ICD.PAT.01	ICA formula – patient
ICD.REFP.01	ICA formula – referring physicians
NOEXAM.01	Non-performance of requested examination
PATIENT.LIST	Daily patient list
PSQ 001	Patient questionnaire
PSQ 002	Patient questionnaire
PSQ 003	Patient questionnaire
PSQ 004	Patient questionnaire
QCD.01	Control of quality documents
QR.01	Quality registration
RP.FMP.01	Dobutamine Myocardial perfusion report template (AFR)
RP.FMP.02	Dobutamine Myocardial perfusion report template (ENG)
RP.FMP.03	Persantin Myocardial perfusion report template (ENG)
RP.FMP.04	Persantin Myocardial perfusion report template (AFR)
RP.MP.01	Myocardial perfusion report template (ENG)
RP.MP.02	Myocardial perfusion template/Bruce report template (ENG)
RP.MP.03	Myocardial perfusion template/Bruce report template (AFR)
RP.THY.01	Thyroid report template
RP.VQ.01	V/Q report template
RPQ 001	Referring physician questionnaire
RPQ 002	Referring physician questionnaire
RPQ 003	Referring physician questionnaire
RPQ 004	Referring physician questionnaire
RPSAT.01	Results patient satisfaction surveys
RREFPSAT.01	Results referring physician satisfaction surveys
RSTAFFSAT.01	Results staff satisfaction surveys
SSQ 001	Staff satisfaction questionnaire
SSQ 002	Staff satisfaction questionnaire
SSQ 003	Staff satisfaction questionnaire
TQB.01	Telephone query booklet
TRACE 001	Traceability formula
TRACE 002	Traceability formula

Table 22.1

Nuclear Medicine - Tygerberg Hospital/University of Stellenbosch	Code:QC Man	P 30/34
QUALITY CONTROL MANUAL ISO 9001:2000	Edition 1	Drafted on 25/06/2004

23. Appendix H: List of SOP documents

RAITF.01	Radioactive iodine treatment traceability formula
THYFOLLOW.01	Thyroid follow-up table
THYINFO 001	Thyroid information leaflet
THYINFO 002	Thyroid information leaflet
THYRULES.01	Thyroid clinic rules

Table 23.1

24. Appendix I: List of Hot lab documents

HL.ADOSE.01	Adult radioactive dosages
HL.BLOOD.01	Platelet labelling
HL.BREASTF.01	Breastfeeding recommendations
HL.CAPINTEC.01	Capintec dose calibrator factors
HL.CDOSE.01	Children radioactive dosages
HL.KITS.01	Kits used in TBH
HL.LTRACE.01	Labelled Leukocyte traceability formula
HL.MO99.01	^{99m} Mo Assay on Capintec
HL.PROCINFO.01	Hot lab process information (Afr)
HL.PROCINFO.02	Hot lab process information (Eng)
HL.RAW.01	Radioactive waste disposal
HL.RBCVOL.01	Red blood cell volume studies
HL.SPILL.01	Hot lab spillage protocol (Afr)
HL.SPILL.02	Hot lab spillage protocol (Eng)
HL.STOCK.01	Hot lab refrigerator stock
HL.STOCK.02	Hot lab stock
HL.STOCK.03	Hot lab freezer stock
HL.STOCK.04	Hot lab consumables stock
HL.STOCK.05	Hot lab consumables stock – white blood cell labelling
HL.SUPP.01	Supplier address list
HL.TcCHOROMO.01	^{99m} Tc Chromatography
HL.VINTEN.01	Vinten dose calibrator factors
HL.WKITS.LIST.01	Weekly received kits
HL.WRN.LIST.01	Weekly received radionuclides
HL.BLOOD.01	Platelet labelling
HL.BREASTF.01	Breastfeeding recommendations
HL.CHOROMO.01	Chromatography preparation
HL.KITS.01	Kits used in TBH
HL.PROCINFO.01	Hot lab process information
HL.RAW.01	Radioactive waste disposal
HL.SPILL.01	Hot lab spillage protocol
HL.STOCK.01	Hot lab refrigerator stock
HL.STOCK.02	Hot lab stock
HL.STOCK.03	Hot lab freezer stock
HL.STOCK.04	Hot lab consumables stock
HL.STOCK.05	Hot lab consumables stock – white blood cell labelling
HL.SUPP.01	Supplier address list

Nuclear Medicine - Tygerberg Hospital/University of Stellenbosch	Code:QC Man	P 31/34
QUALITY CONTROL MANUAL ISO 9001:2000	Edition 1	Drafted on 25/06/2004

HL.WKITS.LIST.01	Weekly received kits
HL.WRN.LIST.01	Weekly received radionuclides

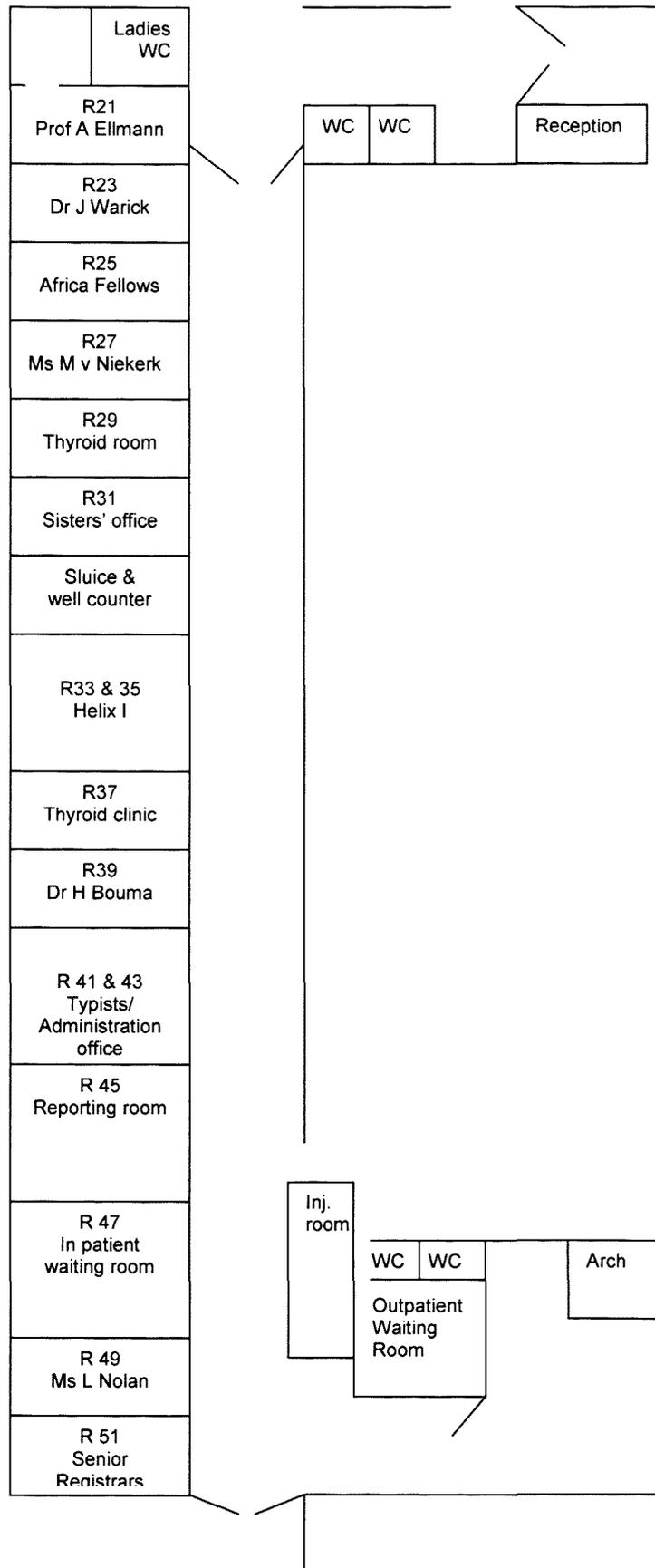
Table 24.1**25. Appendix J: List of audit documents**

PIA .01	Internal audit planning
PRIA.01	Internal audit procedure

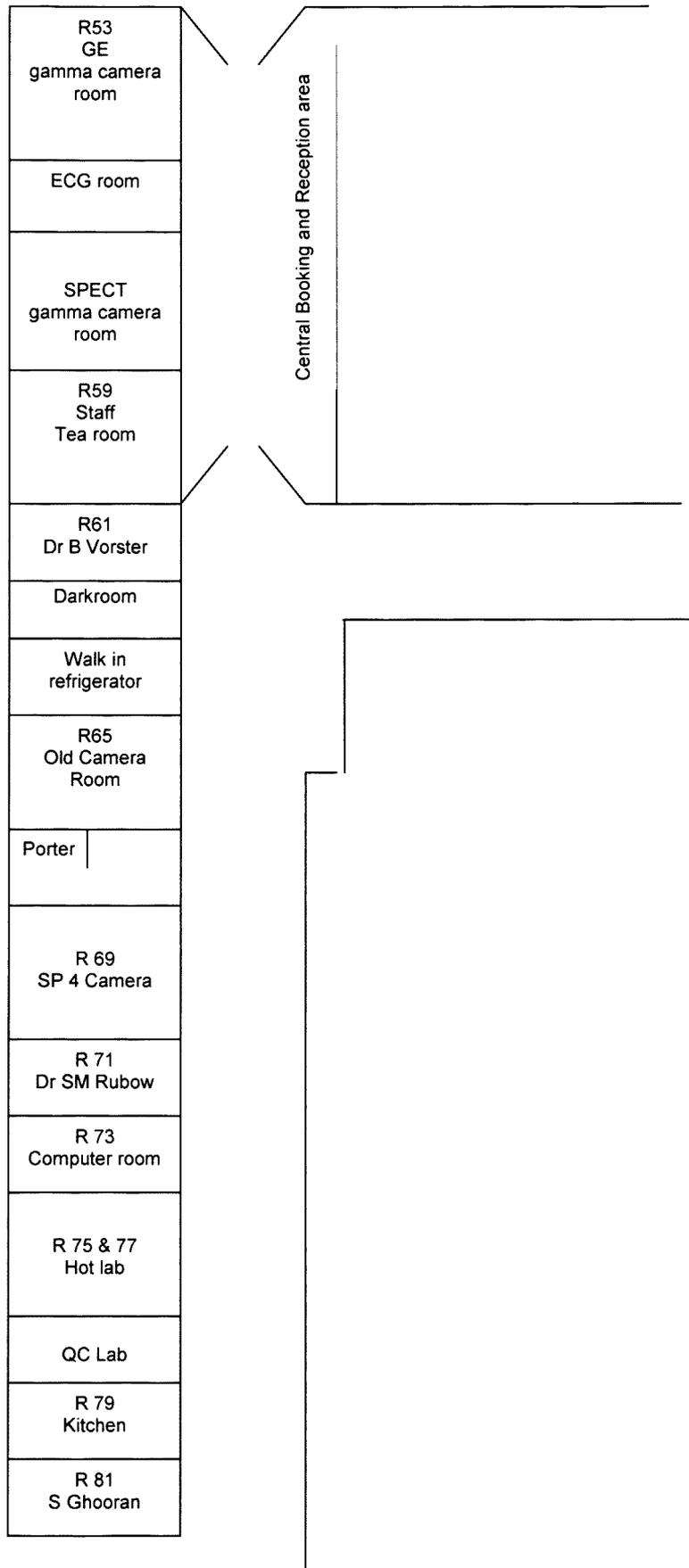
Table 25.1

Nuclear Medicine - Tygerberg Hospital/University of Stellenbosch	Code:QC Man	P 32/34
QUALITY CONTROL MANUAL ISO 9001:2000	Edition 1	Drafted on 25/06/2004

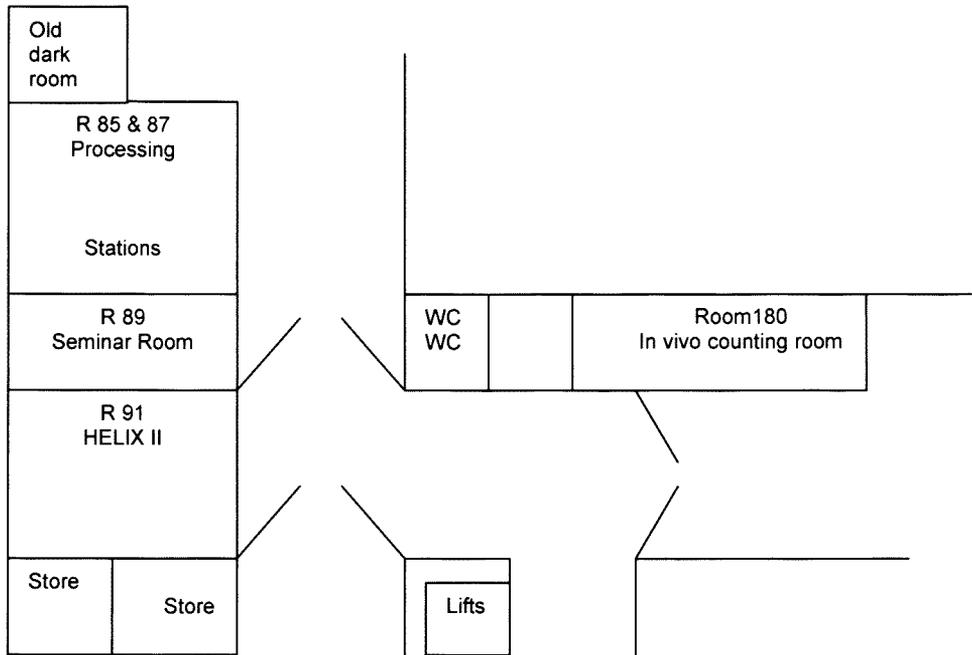
26. Appendix K: Departmental Floorplan



Nuclear Medicine - Tygerberg Hospital/University of Stellenbosch	Code:QC Man	P 33/34
QUALITY CONTROL MANUAL ISO 9001:2000	Edition 1	Drafted on 25/06/2004



Nuclear Medicine - Tygerberg Hospital/University of Stellenbosch	Code:QC Man	P 34/34
QUALITY CONTROL MANUAL ISO 9001:2000	Edition 1	Drafted on 25/06/2004



ⁱ ISO 9000 introduction and support package <http://www.iso.org>

Addendum B

Document name	Description	Page number
CDOC.01	Changing of documents	111
ICD.EXAM.01	ICA formula – examination	112
ICD.PAT.01	ICA formula – patient	112
ICD.REFP.01	ICA formula – referring physicians	112
MT.ICOM.01	Internal communication	113
MT.ECOM.01	External communication	117
TRACE 001	Traceability formula	118
QCD.01	Control of documents	121
QR.01	Quality registration	125
PRIA.01	Internal audit	127
QC.STAT.01	Statistical techniques	131
QC.EXAM.ICA	Non-conformity – examination	134
QC.PAT.ICA	Non-conformity – patient	139
QC.REFP.ICA	Non-conformity – referring physician	142
QC.EXAM.ICA.M1	Preventative measurements - examination	146
QC.EXAM.ICA.M2	Improvement measurements - examination	149
QC.PAT.ICA.M1	Preventative measurements - patients	151
QC.PAT.ICA.M2	Improvement measurements - patients	154
QC.REFP.ICA.M1	Preventative measurements - referring physicians	156
QC.REFP.ICA.M2	Improvement measurements - referring physician	158
REFPQ.003	Shortened referring physician questionnaire	160
PSQ.003	Shortened patient satisfaction questionnaire	161
SSQ.003	Shortened staff satisfaction questionnaire	162

		Name	CDOC.01	Signature	
	Author	P. du Bondt			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

REQUEST FOR CHANGING A DOCUMENT
Requested by:

Current code & title:	
Current edition:	

New code & title:	
New edition:	

Applicable as from (date):	
----------------------------	--

REASON FOR CHANGING THE DOCUMENT:

DECISIONS MADE:	

SIGNATURE AND DATE:	
Person requesting change:	QCA:

		Name	ICA Formula	Signature	
	Author	Thea Eiselen			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

Number:

Received:

Person sending in complaint:

Person completing ICA formula:

Patient file number:

Date received:

Date received by QCA:

Date discussed at ISO-TT meeting:

Description of incident:

Planned corrective, preventative and improvement measurements:

a. Corrective measurements:

b. Preventative measurements:

c. Improvement measurements:

Signatures:

Person completing ICA formula:

Quality controller:

		Name	MT.ICOM.01	Signature	
	Author	F. Jacobs			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

In this system procedure, article 5.5.3 of the ISO 9001:2000 norm will be discussed. This article addresses internal communication. For each internal meeting, the composition, meeting frequency, chairmanship and his/her tasks and responsibilities, as well as the minutes are discussed.

The following is discussed:

1. The **management team** mainly reviews the departmental policy.
2. At the **staff meetings**, the HOD communicates important and relevant information to all members of staff. Staff members have the opportunity to discuss their problems and suggestions.
3. The **medical staff meeting** is the harmonising tool for collaboration between doctors. Alterations to medical processes and the implementation of new medical examinations are discussed.
4. The **ISO-TT** is responsible for the effective continuous evaluation of the QMS.

Meeting dates and records of minutes are contained within the QMDB.

1. Management team

1.1 Composition

- Head of Department
- Senior Nuclear Medicine physicians
- Physicist
- Radiopharmacist
- Assistant Director

1.2 Meeting frequency

- Weekly, if plenary

1.3 Chairperson

- Head of the Department

1.4 Tasks and responsibilities

- Report to senior staff members
- Monitor the effective use of the available budget
- Monitor the effective use of the infrastructure
- Optimise the harmonious collaboration within the department
- Discuss staff issues

- Monitor the correct use of the QCM
- Monitor, discuss and develop interdepartmental relationships
- Monitor service quality
- Optimise a safe working environment
- Monitor correct patient care
- Ensure that the referring physicians' questions are answered

1.5 Records

- Decisions are discussed at staff meeting.
- Documentation are archived for five years.

2. Staff meeting

2.1 Composition

- All members of staff

2.2 Meeting frequency

- Every 6-8 weeks, on the condition that at least one medical staff member is present

2.3 Chairperson

- Head of the Department

2.4 Tasks and responsibilities

- Inform the staff of all the important topics discussed at the management team meeting
- Inform staff of all measurements to be implemented; evolution of the department, as well as any external activity which might affect the department
- Inform the staff of all the important topics discussed at the ISO-TT meeting
- Discussion of problems and questions

2.5 Records

- An agenda of this meeting is circulated via internal mail or email to allow for the adding of discussion points.
- The minutes of the meeting are sent out via email or internal mail to all staff members and archived for five years.

3. Medical staff meeting

3.1 Composition

- All doctors of the NMD

3.2 Meeting frequency

- Monthly, on the condition that the HOD is present

3.3 Chairperson

- Head of the Department

3.4 Tasks and responsibilities

- Promote collaboration between colleagues
- Discuss clinical problems
- Coordinate work distribution
- Follow up on the progress of fellows
- Discuss interesting in-house clinical findings

3.5 Records

- An agenda of this meeting is circulated via internal mail or email to allow for the adding of discussion points.
- The minutes of the meeting is sent out via email or internal mail to all staff members and archived for five years.

4. ISO task team

4.1 Composition

- Quality control administrator (QCA)
- Head of the Department
- Assistant director Radiography
- Representative from nursing staff
- Internal auditors

4.2 Meeting frequency

- Monthly

4.3 Chairperson

- QCA

4.4 Tasks and responsibilities

- Before the ISO certification, the most important task is the implementation of an effective QMS and the customising documentation.
- After the ISO certification, the most important task is the management and evaluation of the QMS for its appropriateness and effectiveness.

Other tasks include:

- the identification and implementation of corrective, preventative and improvement measurements;
- the re-evaluation of improvements for their effectiveness; and
- continuous improvement of the QMS.

4.5 Records

- An agenda of this meeting is circulated via internal mail or email to allow for the adding of discussion points.

- The minutes of the meeting are sent out via email or internal mail to all staff members and archived for five years.

		Name	MT.ECOM.01	Signature	
	Author	F. Jacobs			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

In this system procedure, article 7.2.3 of the ISO 9001:2000 norm is discussed. This article addresses communication with the client. Client communication and communication with external colleagues will be discussed in this document.

1. Communication with the client (patient and referring physician)

During their visit, patients receive a consultation by either a doctor of the NMD or a radiographer. During such a consultation session, the patient will be given the opportunity to express any dissatisfaction or complaints regarding the department. Should this be a clear complaint, the person conducting the consultation will complete the ICA.PAT.01 or ICA.REFP.01 documents. The clients, whether they are patients or referring physicians, can also lodge complaints, comments and suggestions, either telephonically, in writing or via email. Again this will instigate the opening of the appropriate ICA document.

In order to optimise client satisfaction, it is important to identify the client's needs. For this reason, the QCA undertakes annual client satisfaction surveys by using the preset questionnaires REFPQ 003 and REFPQ 004, and PSQ 003 and PSQ 004 respectively. The results of the surveys are statistically analysed as described in the QC.STATS.01 document. This is the responsibility of the QCA. On the one hand, this analysis represents the current client requirements, and on the other hand, the degree of client satisfaction. These results should be mentioned in the annual QC report set up by the QCA, and presented to the management team. It is important to communicate these results to all involved staff members to increase motivation, and as a token of appreciation and recognition for dedicated participation in the QA programme.

2. Communication with external colleagues

- Apart from communication with the client, the NMD continuously communicates with its external partners. No formal records of these events are kept, but this communication plays an important role to assist the staff members concerned in performing their tasks and in founded decision-making.

		Name	TRACE. 001	Signature	
	Author	Thea Eiselen			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

1. Radiopharmaceutical		Prepared by:	
ISOTOPE:		Date:	
		Time:	
Product name:	Serial number:	Activity:	±(10%)
		MBq	

2. Patient ID:		Date of birth:	
Examination:			
Stick patient sticker here:			
Pregnancy Test: <input type="checkbox"/> Pos. <input type="checkbox"/> Neg. <input type="checkbox"/> N/A Signature:			
3. Injection details:		Injected by:	
Time:	Cubi fossa	LEFT	RIGHT
	Wrist	LEFT	RIGHT
Comments:	Hand	LEFT	RIGHT
	Foot	LEFT	RIGHT
		Other	

4. Imaging details:				Scanned by:			
Camera	Date	Type	Time	Type	Time	Type	Time
		<input type="radio"/> dyn		<input type="radio"/> stat		<input type="radio"/> WB	
		<input type="radio"/> dyn		<input type="radio"/> stat		<input type="radio"/> WB	<input type="radio"/> SPECT
		<input type="radio"/> dyn		<input type="radio"/> stat		<input type="radio"/> WB	<input type="radio"/> SPECT
		<input type="radio"/> dyn		<input type="radio"/> stat		<input type="radio"/> WB	<input type="radio"/> SPECT
Clinical history:							

Water given:	<input type="radio"/> Yes	<input type="radio"/> No	Time:
Other comments:			

Additional info:	Length:	cm	Weight:	kg
Comments:				

X-rays available:	<input type="radio"/> Yes	<input type="radio"/> No	Date:
If not, where are the X-rays?			

Data sent to Hermes:	<input type="radio"/> Yes	<input type="radio"/> No	Date:
Sent by:			
5. Consultation:	<input type="radio"/> N/A	Doctor:	
		Date:	
Comments:			
Additional views needed:			
<input type="radio"/> Processed		By:	
<input type="radio"/> Hard copies made		By:	
<input type="radio"/> Ready for reporting		Time:	Date:
6. Report:	Doctor:		
	<input type="radio"/> Dictated	Time:	Date:
	<input type="radio"/> Reviewed	Time:	Date:
Signature:			
Provisional report needed:		<input type="radio"/> Yes	<input type="radio"/> No
7. Typing of report:	Typed by:		
	Date:		
	Time:		
	Sent for revision:	Time:	Date:

O Provisional report phoned through:		Date:		Time:	
8. Sending of report:					
			Sent by:		
			Date:		
Images included:		<input type="radio"/> Yes		<input type="radio"/> No	
Copy made:		<input type="radio"/> Yes		<input type="radio"/> No	
<input type="radio"/> Fax	<input type="radio"/> Mail	<input type="radio"/> Internal mail		<input type="radio"/> email	
9. Archiving:					
Report:	By:	Source:			Date:
Images:	By:	Source:			Date:
10. Statistics:					
Referred from:					
TBH	GSH	RXH	DAYHOSP	2MIL	SEC PRIVATE ABROAD
Pre-test diagnosis:					
Study code	Nuclide	Compound		Dose	
Diagnosis codes:					
Training:		<input type="radio"/> Yes		<input type="radio"/> No	
Comments:					

		Name	QCD.01	Signature	
	Author	P. du Bondt			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

1. Subject and application area

Requirement 4.2.3 on “control of documents” (ISO 9001:2000) applies. The purpose of the document control procedure is to ensure that valid documents are available at applicable areas (rooms) within the department.

For a description of the type of documents used within the quality management system, please refer to the quality manual.

Every staff member affiliated to the NMD of TBH has access to all documents. This excludes staff files other than personal files. All external persons (non-staff members) can get access to documents by prior arrangement with the Head of the Department.

2. Important duties, authorities and responsibilities

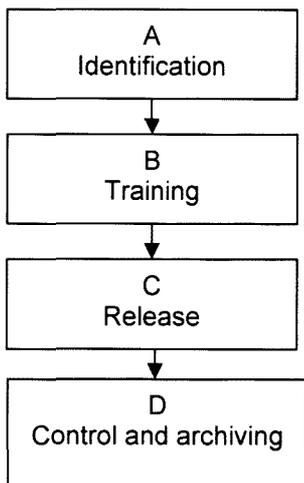
The quality control administrator is:

in overall control of all documents;

entitled to make editorial changes;
 responsible for all amendments;
 responsible for distribution; and
 responsible to notify all parties concerned.

The management team authorises and publishes all quality documents.

3. Flow diagram



4. Comments on flow diagram

A. Identification

Microsoft WORD-document:

i) The following header appears on each page of all working documents:

¹ Department of Nuclear Medicine - Tygerberg Hospital/University of Stellenbosch		² Code:	³ p 1/55
⁴ DOCUMENT TITLE	⁵ Edition nr	⁶ Drafted on: date	

Key:

- 1: name of department, hospital and associated university;
- 2: document code, abbreviated as outlined in the QCM;
- 3: current page/number of pages in document;
- 4: document title;
- 5: edition number; and
- 6: draft date.

ii) The following logo appears on the first page of all documents:

		Name		Signature	
	Author	xxxxxxxxxx			
	Editor	xxxxxxxxxx			
	Approved by	xxxxxxxxxx			

B. Training

If the document indicates an unknown specific practical act in the NMD, it is the responsibility of the responsible section head to provide training to all staff members involved before implementing such document.

C. Publishing

All new documents should be circulated to all staff members and be readily available, either in hard copy format or on the intranet. A register for the acknowledgement of receiving and reading of documents should be kept.

D. Control and archiving

The quality control manual can be found at: C: ISO/QCM
 Quality control documents can be found at: C: ISO/DOCUMENTS
 Administration documents: C: ISO/DOCUMENTS/ADMIN
 Hot lab documents: C: ISO/SOP/HOTLAB
 Document management team: C: ISO/DOCUMENTS
 Patient care documents: C: ISO/DOCUMENTS

Working procedures/SOPs: C: ISO/SOP/GENERAL

In the event of the need to change a document, this should be requested from the QCA. This procedure is outlined in the QC.CWP.01 document.

5. SOP review

In order to ensure that all documents and procedures are kept up to date, all SOPs must be evaluated and verified. This verification process will assist in the identification of corrective and improvement measurements.

The QCA is responsible for the correctness and appropriateness of all SOP documents.

In cases where no modifications to documents are identified, the edition number as well as the drafted date should be changed to the date of verification. These evaluation dates should be documented in the on-board table.

The date of the reviews is noted in the QCDB.

		Name	QR.01	Signature	
	Author	P. du Bondt			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

1. Subject and application area

Requirement 4.2.4 on “control of quality registrations” (ISO 9001:2000) applies. The purpose of this document is to ensure the control of quality registration. All staff members have access to these documents for quality assurance purposes.

2. Important duties, authorities and responsibilities

These are outlined in the table below.

3. Table

Norm	Identification	Code	Where	Responsible	Storage time
1 Registration of the production processes					
	a. Request form and report	Patient file	Room 41& 43	HOD	30 years
	b. Appointment book	PT.LOG.01	Room 41 & 43	HOD	10 years
7.5.3	c. Traceability formula	TRACE 01/02	Room 41 & 43	QCA	10 years
	d. Acquisition data (raw data)	Hermes	Room 45	HOD	10 years
7.1 7.2.2	e. Assessment of client demands	PSQ.003 PSQ 004 RPSAT.01 RPSAT.01	Room 41 & 43	QCA	10 years
	f. Used radio-pharmaceuticals		Room 75 & 77	RF	10 years
2 Purchase registrations					
	a. Order invoices & delivery notes – hot lab		Room 71	RF	10 years
	b. Order invoices & delivery notes - consumables		Room 71	RF	10 years
7.4.1	c. Evaluation of suppliers		Room 71	RF	10 years

3 Electronic registration

7.1 7.5.4	a. Report	Templates on PC of secretary	Room 41 & 43	HOD	30 years
--------------	-----------	------------------------------	--------------	-----	----------

4 Other registrations

5.6.1	a. Management evaluation		Room 21	HOD	10 years
6.2.2	b. Education report	Staff file	Room 49	HOD	10 years
6.2.2	c. Evaluation report	Staff file	Room 49	HOD	10 years
8.3	d. Non-conformity	QC.EXAM.ICA QC.PAT.ICA QC.REFP.ICA	Room 41 & 43	QCA	10 years
8.5.2	e. Improvement measurements	QC.EXAM.ICA.M2 QC.PAT.ICA.M2 QC.REDP.ICA.M2	Room	QCA	10 years
8.5.3	f. Preventive measurements	QC.EXAM.ICA.M1 QC.PAT.ICA.M1 QC.REDP.ICA.M1	Room	QCA	10 years
8.2.2	g. Internal audit report		Room	QCA	10 years
	h. Records of patients receiving diagnostic examinations		Room	ADR	10 years
	i. Records of patients receiving therapy.		Room	ADR	10 years
8.2.4	j. Staff lists and competencies	Staff file	Room	HOD	10 years
7.6	k. Evaluation of measuring equipment - hotlab		Room	MF	10 years
7.6	l. Evaluation of camera's	SOP database	Room	Assist Dir	10 years
	m. Expired and replaced quality documents and change formula	SOP & CDOC	Room	QCA	10 years
	n. Continues improvement	QCM – ICA documents		QCA	10 years

	Action	Name	PRIA.01	Signature	
	Author	P. du Bondt			
	Editor	Thea Eiselen			
	Approved	Prof. A. Ellmann	Head of Department		

1. Topic and applicable areas

Requirement 8.2.2 on the “internal audit” (ISO 9001:2000) applies. The purpose of the internal audit is to determine whether the QMS is still functioning effectively. The assessment will evaluate the correctness of prescribed documentation of processes and procedures within the QMS, as well as monitor the effect of continuous improvement as implemented by the responsible parties.

What do we want to achieve?

- Verification of the comparability of described procedures within the norm;
- verification of the comparability of described procedures practised;
- a determination of the effectiveness of the implemented QMS;
- identification of shortfalls in the QMS;
- identification of improvement and corrective measurements; and
- a determination of the effectiveness of the corrective, preventative and improvement measurements.

The internal audit is performed twice a year.

2. Most important tasks, authorities and responsibilities

The internal audit is scheduled and coordinated by the QCA. An internal audit team (IAT) will perform the audit and report all findings to the QCA. This report will be discussed at the ISO-TT meeting. The aim is to include an external expert in the IAT after a workable audit system has been implemented.

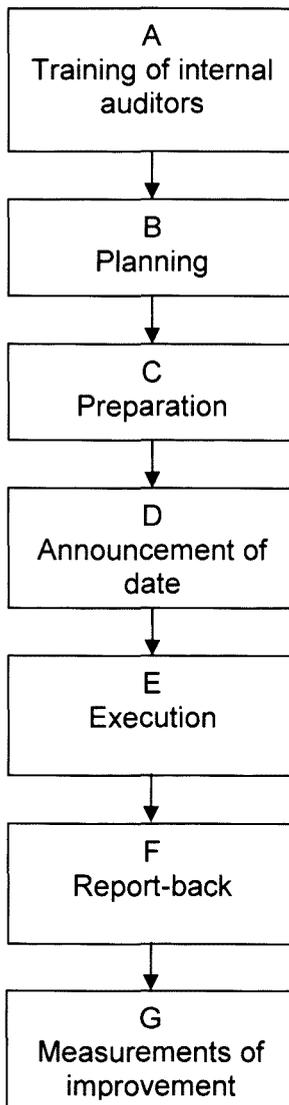
The IAT consists of departmental staff members with extensive knowledge of the current procedures and protocols within the department. Training sessions for all IAT members should be conducted by the QCA, before the internal audit.

Internal auditor profile:

- knowledge and understanding of the QMS;
- understanding of the role of each individual section in the department as a whole;
- a realistic and objective evaluator;
- a purposeful and neutral approach to the auditing process;
- ability to form a conclusion; and

- respect for confidentiality.

3. Flow Diagram



4. Comments on flow diagram

A. Training of internal auditor

Training

To qualify as an internal auditor, each candidate should complete a recommended course. This should be presented by the QCA or by an external institution, and should include:

- the ISO 9001:2000 norm;
- Amelior course; and
- practical tracking of an internal audit procedure.

Skills regarding all the aspects of the QMS and the evaluation thereof are part of the course curriculum. This includes planning, organisation,

communication, evaluation of examination procedure, interviewing and report evaluation.

- **Evaluation:** All units must be evaluated to determine the degree of compliance to the guidelines of the QCM. Existing documents must be evaluated to determine adherence to requirements and whether the document is implemented correctly. In summary, this stage is an evaluation of existing documents and their use.
- **Interviewing:** Skills for the conducting of interviews (practical, natural and informative) will be covered.
- **Feedback reports:** The internal audit report is sent to the QCA, where after a summary is prepared. A list of corrective and improvement measurements is presented at the ISO-TT meeting. Measurements are discussed, approved and implemented under the supervision of the QCA. Areas requiring improvement measurements should be re-audited during the next scheduled internal audit.

Practical guidelines for the internal auditor

The idea of being audited naturally evokes tension between the auditors and the department's staff members; this tension can be kept to a minimum by:

- communicating the importance of standardisation to staff members;
- informing all staff members about the audit procedure;
- discussing areas of shortfalls with the staff members concerned; and
- not imposing solutions, but asking staff members for their input.

Objectivity and independence of the internal auditors

To ensure the objectivity and neutrality of the internal auditors, they should be personally selected by the QCA. By regularly rotating individuals, the risk of auditors imposing a personal input on the results of the audit is reduced. The QCA should at all times act in a professional and independent manner.

Role of the internal auditor

- Always act in a diplomatic and professional manner.
- Keep the atmosphere clear and win trust.
- Always respect the reactions of the auditee.
- Convince the auditee of the need for improvement.

B. Planning

It is the responsibility of the QCA to plan audits for each academic year. The format of this plan is documented in (PIA.01). By using this three-year plan, all aspects of the QMS should be audited within this period.

The audit date as well as the audit agenda must be sent to the directorate of the NMD of TBH one (1) month before the scheduled date.

C. Preparation

The internal audit team is selected and trained by the QCA. It is suggested that a checklist or questionnaire be designed and used for every audit performed within the department.

Advantages of using a checklist and/or questionnaire

- It ensures a complete process.
- It increases efficiency.
- It acts as a guideline to the internal auditors.
- It makes it easy to reconstruct the audit process.
- One can make use of a score system.

D. Announcement of date

It is the responsibility of the QCA to inform all staff members about the date and protocol of the planned internal audit.

E. Conducting of programme

The programme should include the following:

- a meeting on arrival to explain the aims, the programme to be followed as well as identifying the processes to be evaluated;
- an evaluation of the main focus points and knowledge of the QCM by using a question session, either verbally or written;
- scan type evaluation of each chapter of the QCM;
- verifying the identity codes for all existing procedures;
- verifying procedures, log books and maintenance records;
- interviewing staff members performing different procedures and processes;
- visual inspection of equipment, tidiness of the working environment and practicality of lay-out and design;
- verification of environmental safety, temperature control and adequate signage; and
- evaluation of corrective and improvement measurements as implemented in reaction to the previous audit report. Should all measurements be in place, it should be included in the report in order to finalise the necessary documentation.

Audit techniques

- Interview: asking open questions to staff members
- Listen and understand
- Observe
- Perform random spot checks

Documents of the internal auditors

Each individual auditor should compile a written report of all audit results. The report should include and highlight the shortfalls as identified by using the checklist. This report, containing the auditors' personal details, should be sent to the QCA, either electronically, by fax or mail.

F. Reporting

The report should include the following:

- name of auditors;
- overview of results;
- categorising of shortfalls as discussed and decided upon by the IAT;
These are defined as:

- **major** – a shortfall that has a direct influence on the service quality. It is recommended that these processes and/or procedures be stopped until corrective and improvement measurements have been implemented and re-evaluation has been performed;
- **minor** – important, normally a systematic shortfall which has no direct influence on service quality. This should be corrected and/or improved under the supervision of the QCA, within a three-month period from the report date. The correct documentation process should be followed as outlined in the documentation section of the QME. A report of the successful implementation of the measurements taken should be compiled by the QCA in order to re-categorise the incident;
- **observation and comments** – small or single incidents that should be corrected by the next internal audit date;
- **correct** – no shortfalls noted; and
- **suggestions** - for corrective and improvement measurements.

G. Follow-up of improvement measurements

The ISO-TT, under supervision of the QCA, ensures that the improvement measurements taken are implemented correctly and effectively.

		Name	QC.STAT.01	Signature	
	Author	P. du Bondt			
	Editor	Thea Eiselen			
Approved by	Prof. A. Ellmann	Head of Department			

In this quality plan, article 8.4 of the ISO 9001:2000 norm is discussed. This article deals with data analysis. Within the framework of the QMS, some data with relation to client satisfaction is processed statistically. The data is captured from the completed PSQ 003, PSQ 004, REFP 003 and REFP 004 documents. Currently all data is used, but the age and gender of both groups are left out of the equation.

1. Determining the five most important requirements of our clients

Each patient indicated his or her five most important criteria. These are calculated by determining an index. Referring physician questionnaires are evaluated and indexes calculated in order to identify areas of good and bad departmental performance. If the results of 40 patients and referring physicians are used, the sum of the scores indicated by the participants is logged into column B, while the sum of potentially full scores is logged into column A. By dividing the results of column B by those in column A, the index is identified, as outlined in the RPSAT.01 and RREFPSAT.01 documents. Those criteria with the highest indexes, as well as the new criteria, are defined as the patient's five most important requirements.

In the case of referring physicians, the areas with the highest indexes are identified as areas of good performance, while those areas with low scores are identified as areas of bad performance.

2. The role of these five requirements in the follow-up evaluation

The criteria selected less than three times are removed from the list, since they were incorrectly identified as important by management. The new criteria, which appear more than two times, are added to the list, since more than one patient identified them as important requirements.

3. Determining the performance scale of the NMD in relation to the different criteria

An unpaired t-test is performed on all criteria, using the old and new evaluation data. This t-value, including the corresponding criteria, is summarised in a descending sequence. A big positive t-value indicates that the department's performance has improved. Contrary to this, a big negative t-value is indicative of a poorer performance. Each t-value can be associated with a p-value. Criteria with a negative t-value and a p-value smaller than 0.05 are considered as a significantly weaker performance. Criteria with a positive t-value and a p-value smaller than 0.05 are considered a significant improvement in performance.

4. Determining the general performance of the NMD

For this purpose, the average t-value of the "most important requirements", as indicated by the clients, is used. A p-value is again associated with this t-value. A negative t-value and a p-value smaller than 0.05 imply that the client satisfaction has declined significantly. Contrary to this, a positive t-value and a p-value smaller than 0.05 imply that the client satisfaction has increased significantly.

5. Identify areas of improvement

Areas with the lowest indexes, calculated as in (1), are identified as areas in need of improvement. Improvement measurements should be implemented through documentation using the appropriate QC.ICA.M2 document.

6. Results of the evaluation

- The five most important patient requirements as stated in (1)
- The highest and lowest scored questions of the referring physician questionnaires as stated in (1)
- An adapted list of criteria to be used in the follow-up evaluation as stated in (2)
- An orderly list of criteria, including the t- and p-values calculated in (3)
- The average t-values and p-values calculated in (4)
- Identified areas of improvement as calculated in (5)

		Name	QC.EXAM.ICA	Signature	
	Author	P. du Bondt			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

1. Topic and applicable areas

Requirement 8.3 on control of diverging products (ISO 9001:2000) applies. The purpose of this procedure is to describe the measurements to be followed in the event of non-conformity related to patients.

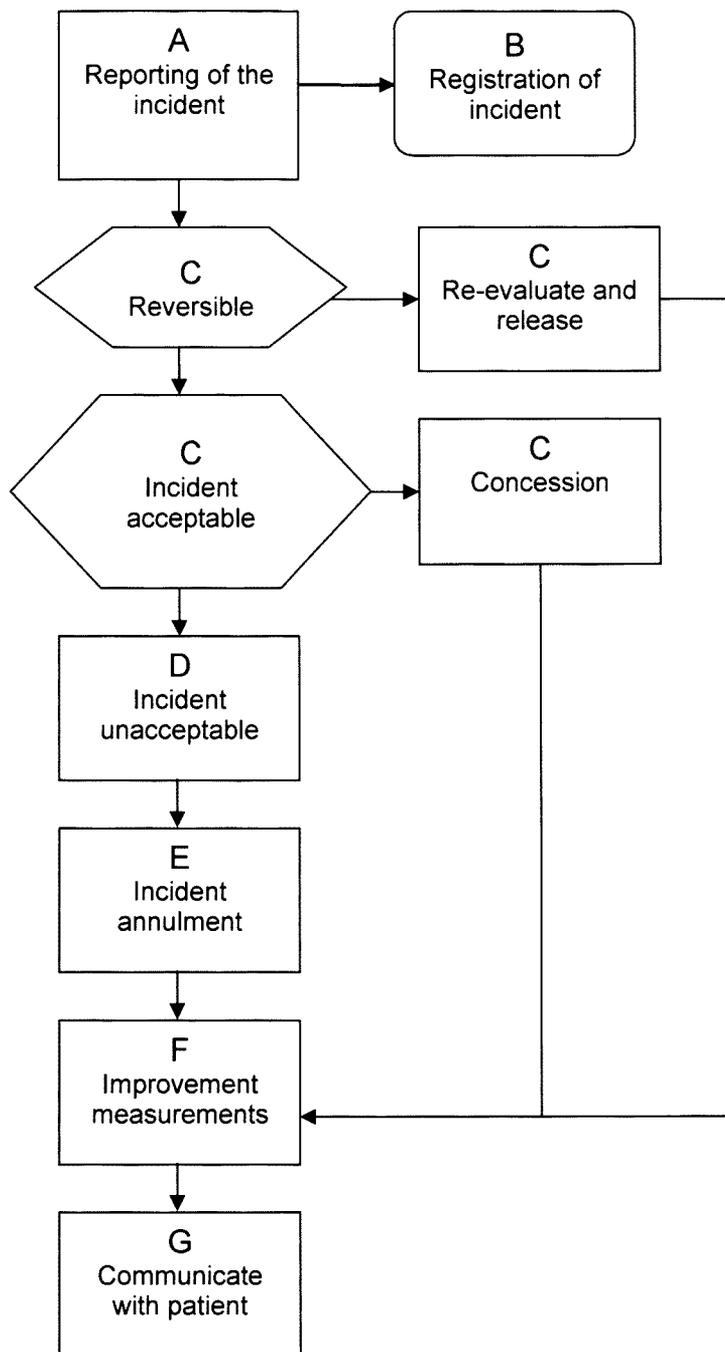
Types of non-conformity are:

- violation of rights;
- complaint: expression of discontent; and
- deviation: failure to adhere to normal procedures.

2. Most important tasks, authorities and responsibilities

The QCA is responsible for the processing of all non-conformities.

3. Flow chart



4. Comments on flow chart

A. Reporting of the incident

Any member of staff can report the violation of rights, or any complaints and deviations to the QCA. Reporting can be done verbally, by email or by making use of the ICD.EXAM.01 document. Staff incidents are not categorised in sections, although opportunities for improvement can be identified. All staff members, regardless of their position and authority, should apply emergency measurements, although these actions should motivate concession. These measurements should be reported to the

specific staff member's head, who will decide whether any further action is needed.

In the case of smaller incidents, which are resolved immediately, the staff member together with his/her direct head should decide whether an ICA procedure should be initiated. The next step would be to open an ICD.EXAM.01 document, after which the procedure will follow the correct protocol, as directed by the QCA.

B. Registration and substance of incident

The staff member supplies the QCA with the ICD.EXAM.01 document. The staff member(s) involved should also complete the corrective, improvement and prevention sections on the ICD.EXAM.01 document. The QCA will allocate an ICA number to all new ICD.EXAM.01 documents according to the QM database.

Should the relevant staff member or the QCA regard it necessary to change the format of the original ICD.EXAM.01 document, this should be done by using the CDOC.01 document.

The QCA will present all reported incidents at the monthly ISO-TT meeting. The corrective, improvement and preventative measurements will be discussed at this meeting, and follow-up measurements will be noted. Following the advice of the ISO-TT, the departmental head will decide on the substance of the incident. Should it be regarded as unsubstantiated, the incident will be classified as null. Substantiated incidents will be followed up by the ISO-TT.

C. Re-evaluation and release

Any incident involving the client (in this case the patient) is regarded as high priority and urgently dealt with. The ISO-TT will seek the best possible solution.

All reported incidents would be evaluated by the ISO-TT to determine whether concession should be granted.

Should the incident be re-evaluated and the process resumed, the client will be notified of the reasons and the anticipated steps to be followed.

The ISO-TT decides what form of communication will be sent to the client, i.e. specifying improvement and preventative measurements.

D. Defect

Deviation refers to any incident violating normal protocol with possible legal implications. For this reason, any incident categorised as a deviation will implicate that the client as well as the hospital Superintendent should be informed.

E. Annulment

All documentation should be kept in the patient's medical file.

F. Taking improvement measurements

The relevant procedures, as prescribed in the QC.EXAM.ICA.M1 and QC.EXAM.ICA.M2 documents, should be followed.

G. Communication with patient

The patient should be informed in writing of the measurements taken.

		Name	QC.PAT.ICA	Signature	
	Author	P. du Bondt			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

1. Topic and applicable areas

Requirement 8.3 on control of diverging products (ISO 9001:2000) applies.
 The purpose of this procedure is to describe the measurements to be followed in the event of non-conformity relating to patients.

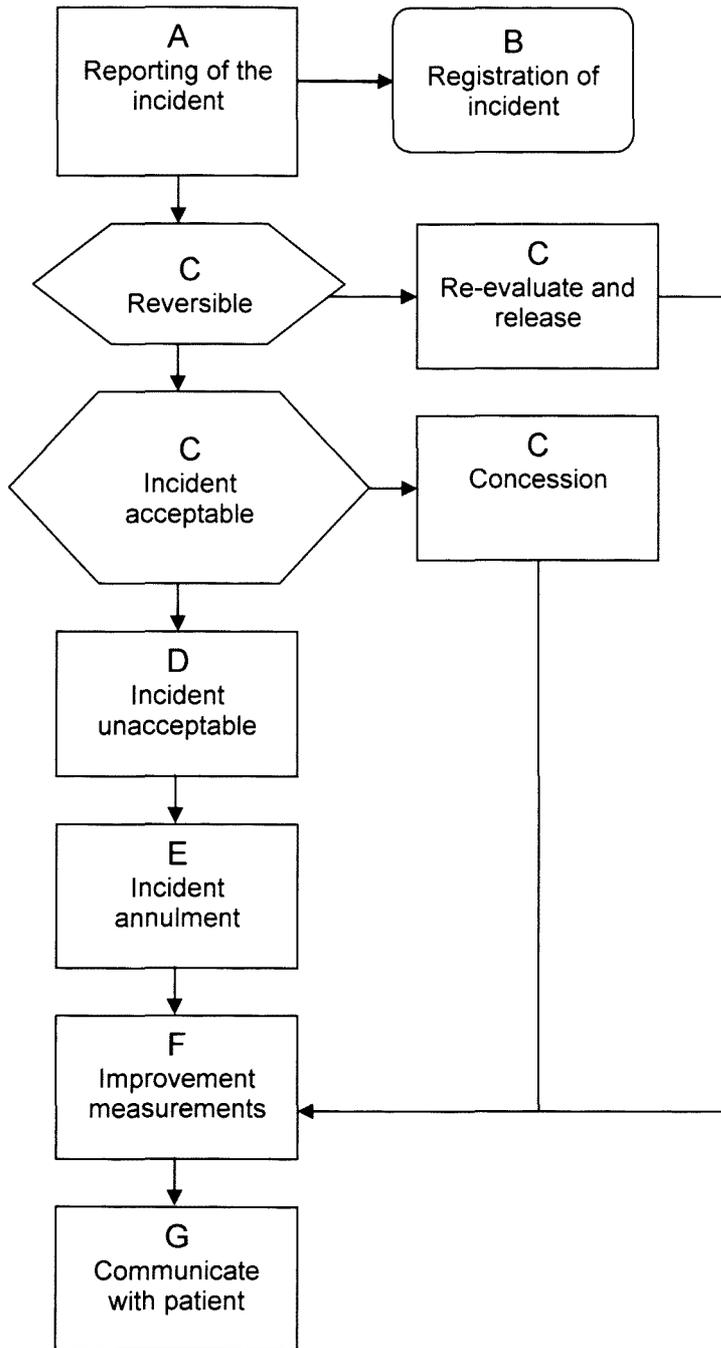
Types of non-conformity are:

- violation of rights;
- complaint: expression of discontent; and
- deviation: failure to adhere to normal procedures.

2. Most important tasks, authorities and responsibilities

The QCA is responsible for the processing of all non-conformities.

3. Flow chart



4. Comments on flow chart

A. Reporting of the incident

Any member of staff can report the violation of rights, or any complaints and deviations to the QCA. Reporting can be done verbally, by email or by making use of the ICD.PAT.01 document. Staff incidents are not categorised in sections, although opportunities for improvement can be identified. All staff members, regardless of their position and authority, should apply emergency measurements although these actions should motivate concession. These measurements should be reported to the

specific staff member's head, who will decide whether any further action is needed.

In the case of smaller incidents which are resolved immediately, the staff member together with his/her direct head should decide whether an ICA procedure should be initiated. The next step would be to open an ICD.PAT.01 document, after which the procedure will follow the correct protocol, as directed by the QCA.

B. Registration and substance of the incident

- The staff member supplies the QCA with the ICD.PAT.01 document.
- The staff member(s) involved should also complete the corrective and improvement sections on the ICD.PAT.01 document.
- The QCA will allocate an ICA number to all new ICD.PAT.01 documents according to the QM database.
- Should the involved staff member or the QCA regard it necessary to change the format of the original ICD.PAT.01 document, this should be done by using the CDOC.01 document.
- The QCA will present all reported incidents to the TT at the monthly meeting.
- The corrective, preventative and improvement measurements will be discussed at this meeting; follow-up measurements will be noted.
- Following the advice of the TT, the departmental head will decide on the substance of the incident. Should it be regarded as unsubstantiated, the incident will be classified as null. The TT will follow up substantiated incidents.

C. Re-evaluation and release

- Any incident involving the client (in this case the patient) is regarded as high priority and urgently dealt with. The TT will seek the best possible solution.
- All reported incidents would be evaluated by the TT to determine whether concession should be granted.
- Should the incident be re-evaluated and the process resumed, the client will be notified of the reasons thereof and the anticipated steps to be followed.
- The TT decides what format of communication will be sent to the client, i.e. specifying improvement and preventative measurements.

D. Defect

- Deviation refers to any incident violating normal protocol with possible legal implications. For this reason, any incident categorised as a deviation will implicate that the client and the hospital Superintendent should be informed.

E. Annulment

- All documentation should be kept in the patient's medical file.

F. Taking improvement measurements

- The relevant procedures as described in the QC.PAT.ICA.IM document should be followed.

G. Communication with patient

- The patient should be informed in writing of the measurements taken.

	Action	Name	QC.REFP.ICA	Signature	
	Author	P. du Bondt			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

1. Topic and applicable areas

Requirement 8.3 on control of diverging products (ISO 9001:2000) applies. The purpose of this procedure is to describe the measurements to be followed in the event of non-conformity relating to referring physicians.

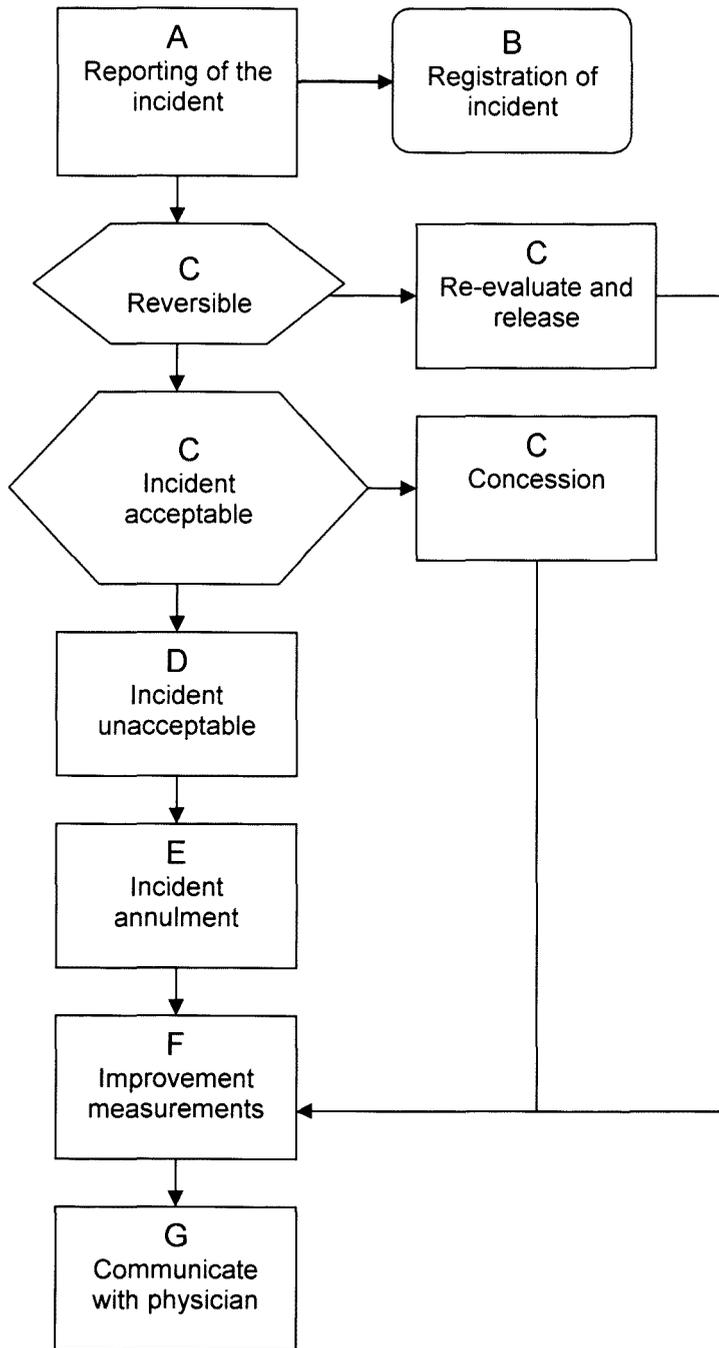
Types of non-conformity are:

- violation of rights;
- complaint: expression of discontent; and
- deviation: failure to adhere to normal procedures.

2. Most important tasks, authorities and responsibilities

The QCA is responsible for the processing of all non-conformities.

3. Flow chart



4. Comments on flow chart

1. Reporting of incident

Any member of staff can report the violation of rights, or any complaints and deviations to the QCA. Reporting can be done verbally, by email or by making use of the ICD.REFP.01 document. Staff incidents are not categorised in sections, although opportunities for improvement can be identified. All staff members, regardless of their position and authority, should apply emergency measurements, although these actions should

motivate concession. These measurements should be reported to the specific staff member's head, who will decide whether any further action is needed.

In the case of smaller incidents which are resolved immediately, the staff member together with his/her direct head should decide whether an ICA procedure should be initiated. The next step would be to open an ICD.REFP.01 document, after which the procedure will follow the correct protocol, as directed by the QCA.

2. Registration and substance of incident

- The staff member supplies the QCA with the ICD.REFP.01 document.
- The staff member(s) involved should also complete the corrective and improvement sections on the ICD.REFP.01 document.
- The QCA will allocate an ICA number to all new ICD.REFP.01 documents according to the ICA database.
- Should the involved staff member or the QCA regard it necessary to change the format of the original ICD.REFP.01 document, this should be done by using the CDOC.01 document.
- The QCA will present all reported incidents to the TT at the monthly meeting.
- The corrective, improvement and preventative measurements will be discussed at this meeting; follow-up measurements will be noted.
- Following the advice of the TT, the departmental head will decide on the substance of incident. Should it be regarded as unsubstantiated, the incident will be classified as null. The TT will follow up substantiated incidents.

3. Re-evaluation and release

- Any incident involving the client (in this case the referring physician) is regarded as high priority and urgently dealt with. The TT will seek the best possible solution.
- All reported incidents would be evaluated by the TT to determine whether concession should be granted.
- Should the incident be re-evaluated and the process resumed, the client will be notified of the reasons therefore and the anticipated steps to be followed.
- The TT decides what form of communication will be sent to the client, i.e. specifying improvement and preventative measurements.

4. Deviation

- Deviation refers to any incident violating normal protocol with possible legal implications. For this reason, any incident categorised as a deviation will implicate that the client and the hospital Superintendent should be informed.

5. Annulment

- All documentation should be filed.

6. Taking improvement measurements

- The relevant procedures, as described in the QC.REFP.ICA.M1, should be followed.

7. Communication with referring physician

- The physician should be informed in writing of the measurements taken.

		Name	QC.EXAM.ICA.M1	Signature	
	Author	P. du Bondt			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

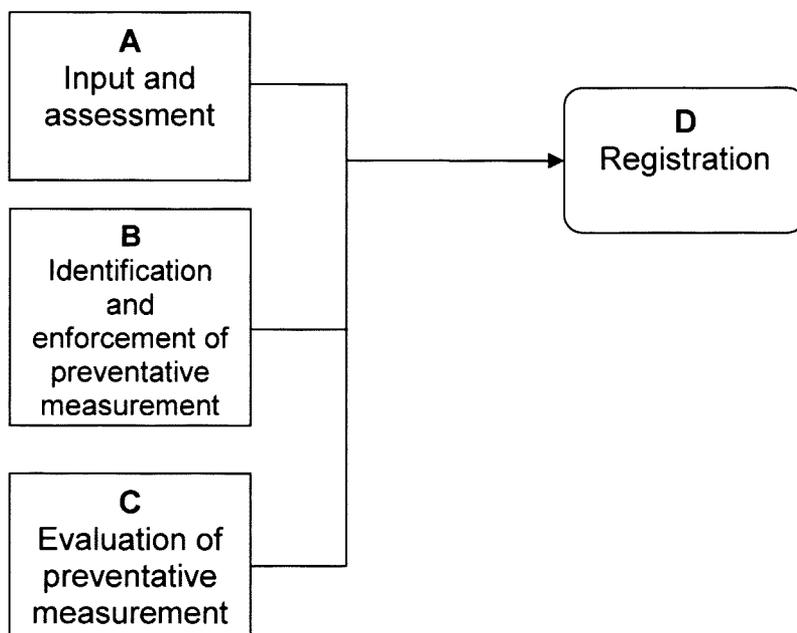
1. Topic and application area

Requirement 8.5.3 on preventative measurements (ISO 9001:2000) applies. The purpose of this procedure is to describe the measurements to be taken to prevent potential incidents, by removing the possible cause of the error or misconduct.

2. Important duties, authorities and responsibilities

The quality control administrator (QCA) is responsible for processing the preventative measurements in terms of all complaints received.

3. Flow chart



4. Comments on flow chart

A. Input and assessment

Possible future non-conformities can be identified by:

- **trend analysis of the traceability formula** - every three months, a random sample survey is performed on 40 formulas. It is required that this formula is completed in full. Non-compliance to this must be documented and the necessary suggestions must be made;
- **trend analysis of the time elapsed between completing the examination and distributing the report** – every three months, a random sample survey is performed on 40 formulas. It is required that the report is sent out within two days. In the event of exceeding this timeframe, the causes should be identified and documented. All previous analysis results should be taken into consideration in the planning of the preventative measurement;
- **analysis of the audit reports** – as outlined in the PRIA.01 document;
- **risk analysis** - should be performed annually and non-conformities should be documented;
- **SOP review** - every three years, all SOP documents should be checked for their correctness and changed accordingly, as outlined in the QCD document;
- **satisfaction surveys** - annual satisfaction enquiries should be performed on patients and referring physicians, by using the questionnaires PSQ03, PSQ04, RPQ03 and RPQ04; and
- **staff harmony and development** - annual satisfaction evaluations should be performed on all departmental staff members by using the questionnaires SSQ01 and SSQ02.

B. Identification and enforcement of preventative measurements

Relevant measurements should be identified by the ISO-TT, and enforced as soon as possible.

C. Evaluating the measurements taken

ISO is about continuous improvement, and for this reason the evaluation of the measurements should be done on a regular basis by the ISO-TT. Should additional measurements be needed, these should be discussed and enforced. All the measurements should be documented and communicated to the staff.

D. Registration

Preventative measurements, and the results thereof, should be documented in the reports issued by the ISO-TT.

		Name	QC.EXAM.ICA.M2	Signature	
	Author	P. du Bondt			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

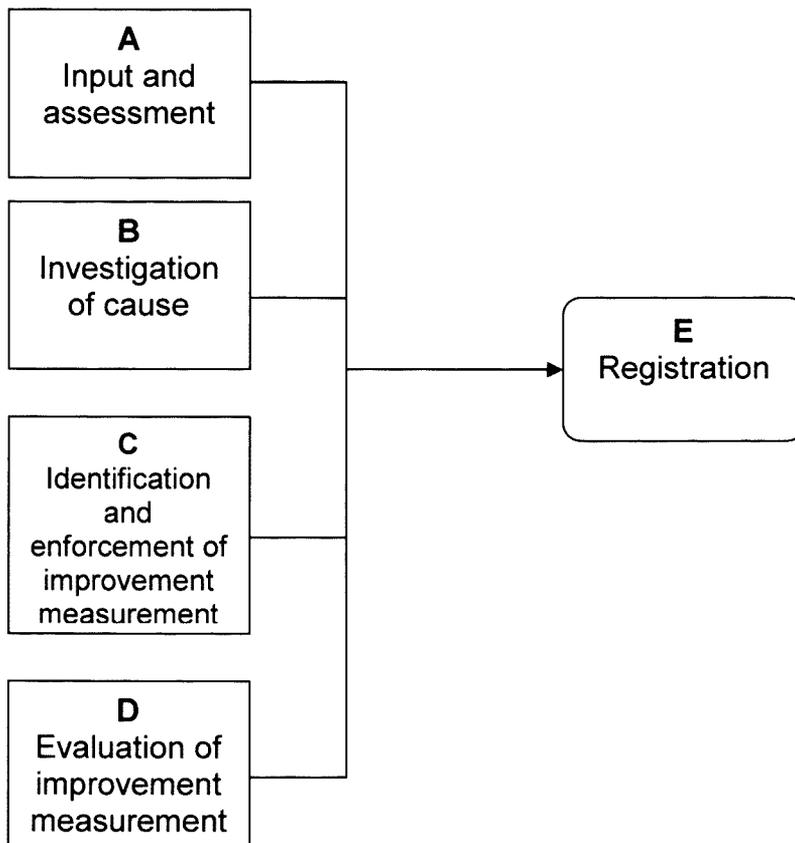
1. Subject and application area

Requirement 8.5.2 on improvement measurements (ISO 9001:2000) applies. The purpose of this procedure is to describe the measurements to be taken to avoid the recurrence of the complaint laid by the victim, by removing the cause of the error or misconduct or improving the situation.

2. Important duties, authorities and responsibilities

The quality control administrator (QCA) is responsible for processing the improvement measurements for all complaints received.

3. Flow chart



4. Comments on flow chart

A. Input and assessment

The input includes complaints and/or irregularities. All input received by any member of the staff must be reported to the QCA. The QCA discusses the input according to its substance and the necessary improvement measurements to be taken at the next monthly ISO-TT meeting.

B. Investigating the cause

The QCA will contact the head of the specific unit. Together with the ISO-TT, they will identify the cause of the incident.

C. Identification and enforcement of improvement measurements

The relevant measurements should be identified by the ISO-TT and enforced as soon as possible.

D. Evaluating the measurements taken

Evaluation of the measurements should be done at the following ISO-TT meeting. Should additional measurements be needed, these should be discussed and enforced. All the measurements should be documented and communicated to the client.

E. Registration

Improvement and preventative measurements should be documented in the report issued by the ISO-TT.

		Name	QC.PAT.ICA.M1	Signature	
	Author	P. du Bondt			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

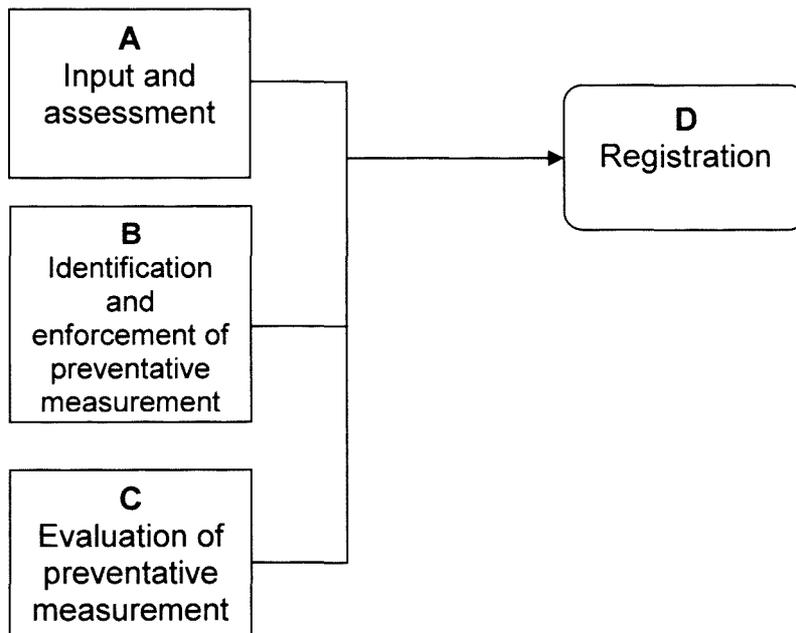
1. Topic and application area

Requirement 8.5.3 on preventative measurements (ISO 9001:2000) applies. The purpose of this procedure is to describe the measurements to be taken to prevent potential incidents, by removing the possible cause of the error or misconduct.

2. Important duties, authorities and responsibilities

The quality control administrator (QCA) is responsible for processing the preventative measurements in terms of all complaints received.

3. Flow chart



4. Comments on flow chart

A. Input and assessment

Possible future non-conformities can be identified by:

- **trend analysis of the traceability formula** - every three months, a random sample survey is performed on 40 formulas. It is required that this formula is completed in full. Non-compliance to this must be documented and the necessary suggestions must be made;
- **trend analysis of the time elapsed between completing the examination and distributing the report** – every three months, a random sample survey is performed on 40 formulas. It is required that the report is sent out within two days. In the event of exceeding this timeframe, the causes should be identified and documented. All previous analysis results should be taken into consideration in the planning of the preventative measurement;
- **analysis of the audit reports** – as outlined in the PRIA.01 document;
- **risk analysis** - should be performed annually and non-conformities should be documented;
- **SOP review** - every three years, all SOP documents should be checked for their correctness and changed accordingly, as outlined in the QCD document;
- **satisfaction surveys** - annual satisfaction enquiries should be performed on patients and referring physicians, by using the questionnaires PSQ03, PSQ04, RPQ03 and RPQ04; and
- **staff harmony and development** - annual satisfaction evaluations should be performed on all departmental staff members by using the questionnaires SSQ01 and SSQ02.

B. Identification and enforcement of preventative measurements

Relevant measurements should be identified by the ISO-TT, and enforced as soon as possible.

C. Evaluating the measurements taken

ISO is about continuous improvement, and for this reason the evaluation of the measurements should be done on a regular basis by the ISO-TT. Should additional measurements be needed, these should be discussed and enforced. All the measurements should be documented and communicated to the staff.

D. Registration

Preventative measurements, and the results thereof, should be documented in the reports issued by the ISO-TT.

	Name	QC.PAT.ICA.M2	Signature	
	Author	P. du Bondt		
	Editor	Thea Eiselen		
	Approved by	Prof. A. Ellmann	Head of Department	

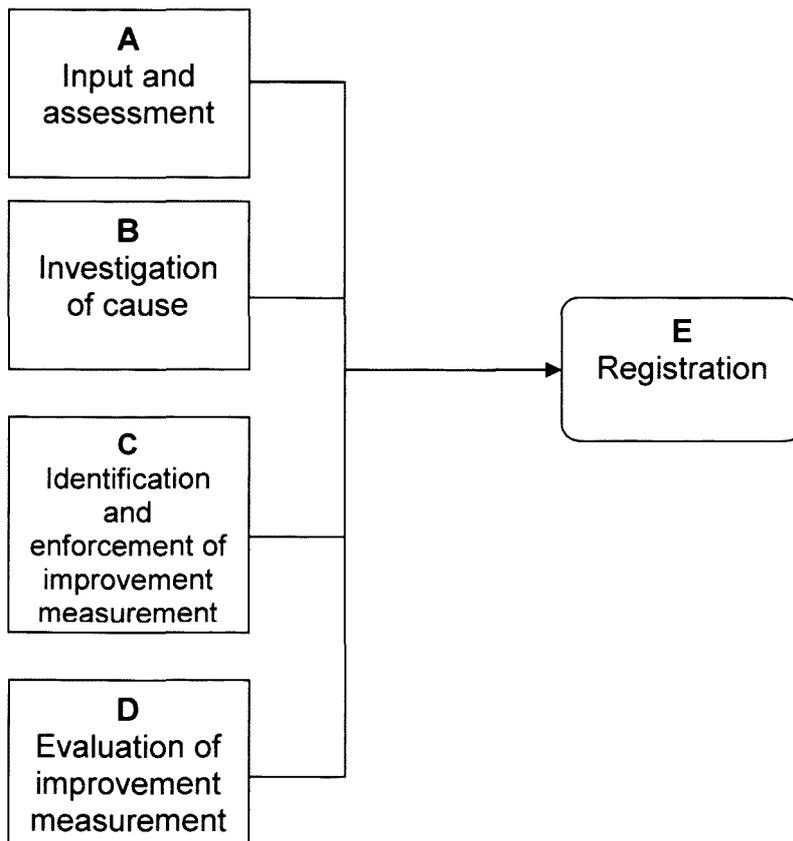
1. Topic and application area

Requirement 8.5.2 on improvement measurements (ISO 9001:2000) applies. The purpose of this procedure is to describe the measurements to be taken to avoid the recurrence of the complaint laid by the victim, by removing the cause of the problem, or improving the situation.

2. Important duties, authorities and responsibilities

The quality control administrator (QCA) is responsible for processing the improvement measurements for all complaints received.

3. Flow chart



4. Comments on flow chart

A. Input and assessment

The input includes complaints and/or irregularities. All input received by any member of staff must be reported to the QCA. The QCA discusses the input according to its susceptibility and the necessary improvement measurements to be taken at the next monthly ISO-TT meeting.

B. Investigating the cause

The QCA will contact the head of the specific unit. Together with the ISO-TT, they will identify the cause of the incident.

C. Identification and enforcement of improvement measurements

Relevant measurements should be identified by the ISO-TT and enforced as soon as possible.

D. Evaluating the measurements taken

Evaluation of the measurements should be done at the following ISO-TT meeting. Should additional measurements be needed, these should be discussed and enforced. All the measurements should be documented and communicated to the client.

E. Registration

Improvement measurements and the results thereof should be documented in the report issued by the ISO-TT.

5. References and additions

		Name	QC.REFP.ICA.M1	Signature	
	Author	P. du Bondt			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

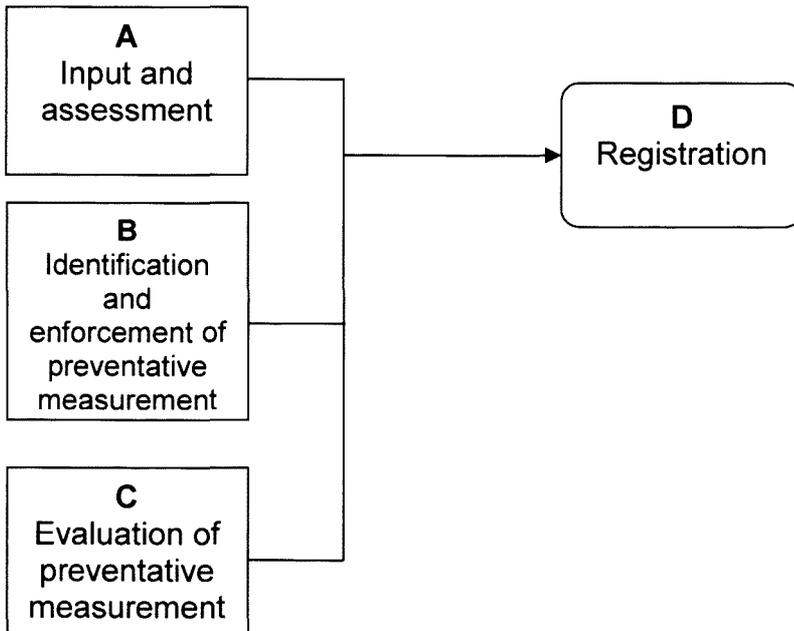
1. Topic and application area

Requirement 8.5.3 on preventative measurements (ISO 9001:2000) applies. The purpose of this procedure is to describe the measurements to be taken to prevent potential incidents by removing the possible cause of the problem.

2. Important duties, authorities and responsibilities

The quality control administrator (QCA) is responsible for processing the preventative measurements for all complaints received.

3. Flow chart



4. Comments on flow chart

A. Input and assessment

Possible future non-conformities can be identified by:

- **trend analysis of the traceability formula** - every three months, a random sample survey is performed on 40 formulas. It is required that

this formula is completed in full. Non-compliance to this must be documented and the necessary suggestions made;

- **trend analysis of the time elapsed between completing the examination and distributing the report** - every three months, a random sample survey is performed on 40 formulas. It is required that the report is sent out within two days. In the event of exceeding this timeframe, the causes should be identified and documented. All previous analysis results should be taken into consideration in the planning of the preventative measurement;
- **analysis of the audit reports** - as outlined in the PRIA.01 document;
- **risk analysis** - should be performed annually and non-conformities should be documented;
- **SOP review** - every three years, all SOP documents should be checked for correctness and changed accordingly, as outlined in the QCD document;
- **satisfaction surveys** - annual satisfaction enquiries should be performed on referring physicians, by using the questionnaires RPQ03 and RPQ04; and

B. Identification and enforcement of preventative measurements

Relevant measurements should be identified by the ISO-TT and enforced as soon as possible.

C. Evaluating the measurements taken

ISO is about continuous improvement, and for this reason the evaluation of the measurements should be done on a regular basis by the ISO-TT. Should additional measurements be needed, these should be discussed and enforced. All the measurements should be documented and communicated to the staff.

D. Registration

Preventative measurements and the results thereof should be documented in the report issued by the ISO-TT.

5. References and additions

	Action	Name	QC.REFP.ICA.M2	Signature	
	Author	P. du Bondt			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

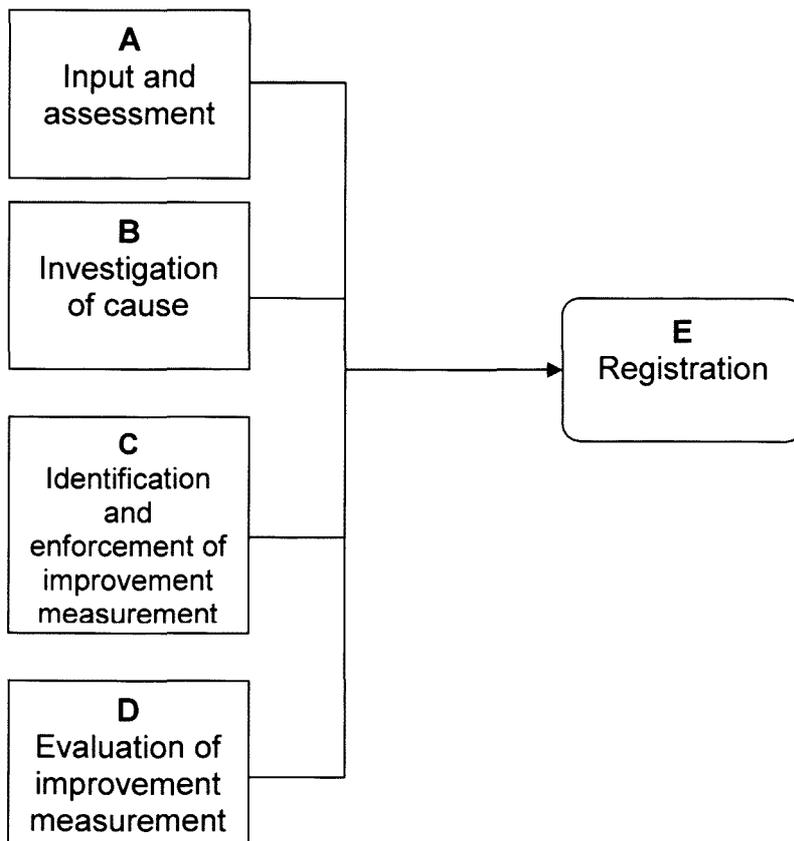
1. Subject and application area

Requirement 8.5.2 on improvement measurements (ISO 9001:2000) applies. The purpose of this procedure is to describe the measurements to be taken to avoid the recurrence of the complaint laid by the victim by removing the cause of the problem.

2. Important duties, authorities and responsibilities

The quality control administrator (QCA) is responsible for processing the improvement measurements for all complaints received.

3. Flow chart



4. **Comments on flow chart**

A. Input and assessment

The input includes complaints and/or irregularities. All input received by any member of staff must be reported to the QCA. The QCA discusses the input according to its substance and the necessary improvement measurements to be taken at the next monthly ISO-TT meeting.

B. Investigating the cause

The QCA will contact the head of the specific unit. Together with the ISO-TT, they will identify the cause of the incident.

C. Identification and enforcement of improvement measurements

A relevant measurement should be identified by the ISO-TT and enforced as soon as possible.

D. Evaluating the measurements taken

Evaluation of the measurement should be done at the following ISO-TT meeting. Should additional measurements be needed, these should be discussed and enforced. All the measurements should be documented and communicated to the client.

E. Registration

Improvement and preventative measurements should be documented in the report issued by the ISO-TT.

		Name	RFPQ.003	Signature	
	Author	P. du Bondt			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

Dear colleague

In the interest of our quality system (ISO 9001:2000) and in order to ensure even better service delivery in future, you are asked to answer the following few questions regarding issues that are important to us. It would take only a few minutes of your time to answer these, and on completion you could hand it to one of the departmental secretaries, who will forward it to the Department of Nuclear Medicine. Should you have any questions, please do not hesitate to contact the department on 938-4265.

Thank you for your cooperation.

Cross out your number of choice by using an X, thereby allocating a mark out of 10.



Does the report answer your questions as stated in the request form?		1 2 3 4 5 6 7 8 9 10
Is the report understandable and clear?		1 2 3 4 5 6 7 8 9 10
Is the waiting period between the telephonic request and actual examination date acceptable?		1 2 3 4 5 6 7 8 9 10
Are you satisfied with a preliminary/telephonic report?		1 2 3 4 5 6 7 8 9 10
Would electronically transferred reports be acceptable to you?		1 2 3 4 5 6 7 8 9 10
Would electronically transferred images be acceptable to you?		1 2 3 4 5 6 7 8 9 10
Do you receive the report in good time?		1 2 3 4 5 6 7 8 9 10
Is good telephone etiquette practised in the department?		1 2 3 4 5 6 7 8 9 10
Is a Nuclear Medicine physician always available to answer your clinical questions?		1 2 3 4 5 6 7 8 9 10
Would clinical information booklets be of value to you?		1 2 3 4 5 6 7 8 9 10
Do you get positive feedback from your patients on their return?		1 2 3 4 5 6 7 8 9 10
Do your patients keep to appointments?		1 2 3 4 5 6 7 8 9 10
<input type="radio"/> Male <input type="radio"/> Female	<input type="radio"/> 20-29 years <input type="radio"/> 30-39 years <input type="radio"/> 40-49 years <input type="radio"/> 50-59 years <input type="radio"/> > 59 years	Is there something specific you would like to bring to our attention?

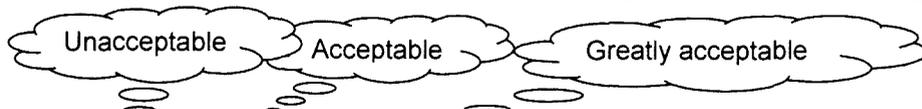
		Name	PSQ.003	Signature	
	Author	P. du Bondt			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

Dear patient

In the interest of our quality system (ISO 9001:2000) and in order to ensure even better service delivery in future, you are asked to answer the following few questions regarding issues important to us. It would take only a few minutes of your time to answer these, and on completion you could hand it to one of the Radiographers. Should you have any difficulty in answering any of the questions, please do not hesitate to consult one of the Radiographers. The last four questions are only applicable to ward patients.

Thank you for your cooperation.

Cross out the number you choose by using an X, thereby allocating a mark out of 10.



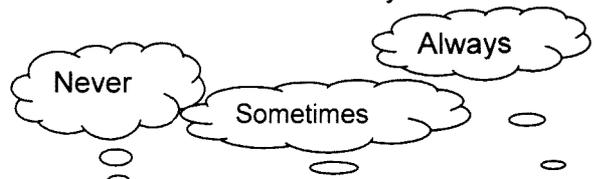
1 2 3 4 5 6 7 8 9 10	How was the waiting time at your arrival in the department?	
1 2 3 4 5 6 7 8 9 10	Was the waiting time between the injection and the scan too long?	
1 2 3 4 5 6 7 8 9 10	<i>Do you understand the necessity of the waiting time?</i>	
1 2 3 4 5 6 7 8 9 10	Were your questions answered?	
1 2 3 4 5 6 7 8 9 10	Did you receive adequate information from the staff?	
1 2 3 4 5 6 7 8 9 10	<i>Did you find the information supplied by staff and brochures useful?</i>	
1 2 3 4 5 6 7 8 9 10	Are the staff friendly?	
1 2 3 4 5 6 7 8 9 10	<i>Is friendliness important to you?</i>	
1 2 3 4 5 6 7 8 9 10	Is the department neat and tidy?	
1 2 3 4 5 6 7 8 9 10	Is the interior modern and comfortable?	
1 2 3 4 5 6 7 8 9 10	<i>Is the interior decorating of the department important to you?</i>	
1 2 3 4 5 6 7 8 9 10	Do you think the staff are professional and competent?	
1 2 3 4 5 6 7 8 9 10	<i>Is the competency of the staff important to you?</i>	
1 2 3 4 5 6 7 8 9 10	Is the department child-friendly?	
1 2 3 4 5 6 7 8 9 10	Is enough information given to the parents of siblings?	
1 2 3 4 5 6 7 8 9 10	Have you received adequate attention during the time you spent waiting in the in-patient waiting room?	
1 2 3 4 5 6 7 8 9 10	Is the information you received prior to your visit, from the nursing staff and physician regarding the examination adequate?	
1 2 3 4 5 6 7 8 9 10	Is the waiting time in the Department of Nuclear Medicine prior to your examination acceptable?	
1 2 3 4 5 6 7 8 9 10	Is the waiting time in the Department of Nuclear Medicine after your examination acceptable?	
<input type="radio"/> Male <input type="radio"/> Female	<input type="radio"/> < 20 years <input type="radio"/> 20-29 years <input type="radio"/> 30-39 years <input type="radio"/> 40 – 49 <input type="radio"/> 50 – 59 <input type="radio"/> > 59 years	What would you like to improve or change within the department? Feel free to make suggestions.

		Name	SSQ.003	Signature	
	Author	Thea Eiselen			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

WORK SITUATION and MOTIVATION QUESTIONNAIRE

CONFIDENTIAL

It is obvious that people differ from one another in what they need and expect to get from different areas of their lives. Please think about the work you do and, because no job is perfect, consider what would make it better from your point of view.



Work contents:

I am interested in my work.	1	2	3	4	5	6	7	8	9	10
My work consists of a variety of tasks.	1	2	3	4	5	6	7	8	9	10
I approach my work as an expert. Whatever my job, I want to provide high-quality work and exercise my skills and competence.	1	2	3	4	5	6	7	8	9	10
Opportunities for development and training are available to everybody.	1	2	3	4	5	6	7	8	9	10
I approach my work as a means to a self-fulfilling life. I want to further my own development.	1	2	3	4	5	6	7	8	9	10
I regard the contents of my work as responsible.	1	2	3	4	5	6	7	8	9	10
I know exactly what my tasks are.	1	2	3	4	5	6	7	8	9	10
I am proud to say what kind of work I do.	1	2	3	4	5	6	7	8	9	10
My work is the way to future success.	1	2	3	4	5	6	7	8	9	10
I feel that my work is of value to the department.	1	2	3	4	5	6	7	8	9	10
There is no time for idleness.	1	2	3	4	5	6	7	8	9	10
I set my own performance standards for my work.	1	2	3	4	5	6	7	8	9	10

Recognition:

I am praised regularly for my work.	1	2	3	4	5	6	7	8	9	10
I receive constructive criticism about my work.	1	2	3	4	5	6	7	8	9	10
The only time I hear about my performance, is when I do something wrong.	1	2	3	4	5	6	7	8	9	10
I get credit for what I do.	1	2	3	4	5	6	7	8	9	10
I am told that I am making progress.	1	2	3	4	5	6	7	8	9	10

Working environment, communication and teamwork:

My working hours are reasonable.	1 2 3 4 5 6 7 8 9 10
I get the opportunity to mix with my colleagues and to communicate on work related aspects.	1 2 3 4 5 6 7 8 9 10
The department's staff members pitch in to help each other out.	1 2 3 4 5 6 7 8 9 10
There is a good team spirit among the department's staff members.	1 2 3 4 5 6 7 8 9 10
The team building sessions are fun and useful in building better team spirit.	1 2 3 4 5 6 7 8 9 10
The department's staff members take a personal interest in one another.	1 2 3 4 5 6 7 8 9 10
I am seen as part of the team.	1 2 3 4 5 6 7 8 9 10
I can count on my manager to keep things I tell him/her confidential.	1 2 3 4 5 6 7 8 9 10
My manager has a lot of personal integrity.	1 2 3 4 5 6 7 8 9 10
The department is a relaxed working environment.	1 2 3 4 5 6 7 8 9 10
It is easy to talk to my manager about work related problems.	1 2 3 4 5 6 7 8 9 10
My manager encourages me to develop my own ideas.	1 2 3 4 5 6 7 8 9 10
When I have a break during work time, I find the tearoom to be an employee friendly environment.	1 2 3 4 5 6 7 8 9 10
Interdepartmental communication regarding protocols and changes thereof is adequate.	1 2 3 4 5 6 7 8 9 10
When I have a personal problem my colleagues are understanding and accommodating.	1 2 3 4 5 6 7 8 9 10
Rostering is done fairly.	1 2 3 4 5 6 7 8 9 10
Communication on all levels of the department is up to standard.	1 2 3 4 5 6 7 8 9 10

Comments:

.....

.....

.....

.....

.....

.....

.....

Thank you kindly for your valuable input.

Addendum C

Nuclear Medicine Department - Tygerberg Hospital/University of Stellenbosch		Code: RPQ 001	P 1/4
REFERRING PHYSICIAN SATISFACTION		Edition 1	Drafted on 22/06/2004

	Action	Name		Signature	
	Author	Thea Eiselen			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

❖ Referring physician questionnaire ❖

The purpose of this questionnaire is to determine the general satisfaction of physicians referring patients to the Nuclear Medicine Department of Tygerberg Hospital.

The questionnaire is anonymous, therefore your name will not be asked anywhere. The researchers undertake not to reveal your identity under any circumstances.

Your response is important in order to make this survey a success. There are no correct or incorrect answers. We are only interested in your honest opinion.

The results of this project will be published in scientific publications without compromising confidentiality.

To complete the questionnaire:

Circle the number or answer in the blocks that correlate with your details or opinion.

Please write your answer where a dotted line appears.

Completed on:.....(day)

Date:.....

Examination done:.....

Number: VGQ..... (Office use)

Nuclear Medicine Department - Tygerberg Hospital/University of Stellenbosch		Code: RPQ 001	P 2/4
REFERRING PHYSICIAN SATISFACTION		Edition 1	Drafted on 22/06/2004

1. Where are you stationed?

Stationed	
Tygerberg Hospital	12
Secondary Hospital	3
Day hospital/clinic	
2 Military Hospital	
Private practice	16

2. What is your rank in the department (if applicable)?

Rank	
Consultant	18
Clinical registrar	6
Medical officer	
General practitioner	7
Other	

3. From which department are you?

.....

4. How often do you refer patients to the department?

References:	
Daily	2
More than once a week	7
Once a week	3
Every second week	3
Once a month	2
A few times a year	11
Once a year	1

Nuclear Medicine Department - Tygerberg Hospital/University of Stellenbosch		Code: RPQ 001	P 3/4
REFERRING PHYSICIAN SATISFACTION		Edition 1	Drafted on 22/06/2004

5. Who usually makes the appointment?

Appointment made	
Myself	16
Receptionist	11
Sister in the ward	
The patient	2

6. Please answer the following questions:

Question	Yes	No
When you phone to make an appointment, is the telephone answered promptly?	27	2
When you phone to make an appointment, is the telephone answered professionally?	28	2
Are your clinical questions answered to your satisfaction?	26	3
If there is a waiting period for the examination you requested, is it acceptable to you?	24	7
If there is a long waiting period for the examination you requested, are your grievances attended to and are you referred to the Nuclear Medicine physician?	19	6
Are the scintigram reports in your opinion made available promptly?	21	10
Do you receive the scintigram reports by fax?	16	15
Do you receive the scintigram reports by mail?	17	13
Do you receive the scintigram reports electronically?	1	30
Do you receive the scintigram images together with the report?	13	17
Would you prefer that the scintigraphic images are sent with the report?	14	17
Are the scintigram reports clear?	29	2
Does the scintigram report answer your clinical questions?	30	1
Is the Nuclear Medicine physician readily available to answer your questions?	28	0
Will electronically transferred reports and images be acceptable to you?	22	6
Would general and clinical information for referring physicians on specific examinations be of value?	26	3
Would patient information brochures be of value?	24	7

Nuclear Medicine Department - Tygerberg Hospital/University of Stellenbosch		Code: RPQ 001	P 4/4
REFERRING PHYSICIAN SATISFACTION	Edition 1	Drafted on 22/06/2004	

Are the reports and feedback you receive from the Nuclear Medicine Department of value in the management of your patients?	29	2	
Do you think that the Nuclear Medicine examinations your patients undergo in Tygerberg Hospital are of excellent quality?	30	0	

Is there something specific you would like to bring to our attention?

.....

.....

.....

.....

.....

Thank you for you co-operation!

Addendum D

Department of Nuclear Medicine - Tygerberg Hospital/University of Stellenbosch		Code: PQS 001	P 1/7
PATIENT SATISFACTION		Edition 1	Drafted on 21/06/2004

	Action	Name		Signature	
	Author	Thea Eiselen			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

❖ PATIENT QUESTIONNAIRE/OPINION POLL ❖

The purpose of this questionnaire is to determine the general satisfaction of patients visiting the Nuclear Medicine Department of Tygerberg Hospital.

The questionnaire is anonymous, therefore you will not be asked to state your name anywhere. The researchers undertake not to reveal your identity under any circumstances.

Your response is important in order to make this survey a success. There are no correct or incorrect answers. We are only interested in your honest opinion.

The results of this project will be published in scientific publications without compromising confidentiality.

To complete the questionnaire:

Circle the number in the blocks that correlates with your details or opinion. Please write your answer on the dotted line.

Completed on:.....(day)

Date:.....

Examination done:.....

Number: PQ.....

Department of Nuclear Medicine - Tygerberg Hospital/University of Stellenbosch		Code: PQS 001	P 2/7
PATIENT SATISFACTION		Edition 1	Drafted on 21/06/2004

1. Patient's sex

Male	50	1
Female	80	2

2. Patient's age

mean = 49.8	3
-------------	---

3. What is your highest qualification?

Qualification		
Standard 5/grade 7 or lower		37
Standard 6 or 7/grade 8 or 9		27
Standard 8 or 9/grade 10 or 11		26
Standard 10/grade 12		6
Standard 10/grade 12 plus diploma or degree		26

4

4. How many times have you visited the following departments:

Department	Times visited	
the Nuclear Medicine Department at Tygerberg Hospital; or	mean = 1.5.	5
any other Nuclear Medicine Department (Tygerberg excluded)?0.....	6

5. Are you currently a ward patient at Tygerberg Hospital?

No	100	
Yes	30	7

6. Who made your appointment?

Appointment made by:		
yourself;		1
referring doctor;		120
referring doctor's receptionist;		5
sister in the ward; or		4
other.....		5

8

Department of Nuclear Medicine - Tygerberg Hospital/University of Stellenbosch		Code: PQS 001	P 3/7
PATIENT SATISFACTION		Edition 1	Drafted on 21/06/2004

7. How well have you been informed regarding the following:

	Well informed	Partially informed	Not informed	
the reason for being sent for this specific examination;	78	26	26	9
the course of the examination before you came to the Nuclear Medicine Department; and	55	17	58	10
the reason for the injection?	57	19	51	11

8. Please answer each of the following questions:

Question	Yes	No	
Have you been asked whether you have any allergies before receiving the injection?	73	57	12
Has the fact that you will be exposed to harmless radioactivity been explained to you?	66	64	13
Have you been asked whether you are pregnant?	25	12	14
Have you been asked whether you are currently breastfeeding?	25	12	15
Are you aware of any financial responsibilities you may have towards the hospital administration?	80	30	16
Were you aware of the fact that there will be a waiting period between the injection and the scan?	85	22	17
Were you aware of the fact that you might have to wait long before your scan will be performed?	74	39	18
Did you wait alone or did someone keep you company?	88	42	19
Did you bring something to do while you were waiting?	41	89	20
Was there adequate seating in the waiting room?	122	8	21
Have you been informed why you had to wait?	108	22	22
Did you feel that the order in which patients were called for their examinations was fair?	106	24	23
Was there something available in the waiting room to keep you busy?	100	30	24

Department of Nuclear Medicine - Tygerberg Hospital/University of Stellenbosch		Code: PQS 001	P 4/7
PATIENT SATISFACTION		Edition 1	Drafted on 21/06/2004

9. What did you do during the waiting period?

Action	Yes	No	
Read magazines	40	90	25
Had conversations with other patients	60	70	26
Studied	2	128	27
Listened to music	9	121	28
Read the paper	10	120	29
Read a book	10	120	30
Other	1	2	31

10. What would you prefer to do during the waiting period?

.....	32
-------	----

11. How long did you wait in the waiting room before receiving your injection?

10 min	11-15 min	16-20 min	21-25 min	26-30 min	31-60 min	1 hour+	
26	5	22	7	17	8	37	33

12. How long did you wait in the waiting room before your scan was done?

10 min	11-15 min	16-20 min	21-25 min	26-30 min	31-60 min	1 hour+	
25	5	22	8	16	9	45	34

13. How long did you anticipate to wait for the full examination, i.e. injection and scan time?

10 min	11-15 min	16-20 min	21-25 min	26-30 min	31-60 min	1 hour+	
3	0	1	3	3	10	110	35

Department of Nuclear Medicine - Tygerberg Hospital/University of Stellenbosch		Code: PQS 001	P 5/7
PATIENT SATISFACTION		Edition 1	Drafted on 21/06/2004

14. Circle the correct number that, according to your experience, represents your opinion of the Nuclear Medicine Department of Tygerberg Hospital.

Statement	Fully agree	Agree	Disagree	Fully disagree	
The department is adequately equipped.	4	110	4	2	36
The facilities of the department are attractive.	9	110	7	4	37
The staff members of the department look neat and well-groomed.	13	108	5	4	38
When staff undertake to do something at a specific time, they keep to their promise.	10	100	12	8	39
The staff are helpful when I have a problem.	13	110	4	3	40
The service times are convenient.	7	119	4	0	41
The staff keep me informed of when my scan will be done.	6	114	7	3	42
The department is arranged comfortably, and it is easy to find your way.	8	99	19	4	43
The staff are reluctant to help me.	0	3	118	7	44
The staff are too busy to attend to my requests immediately.	0	12	108	10	45
The staff are trustworthy.	3	127	0	0	46
I feel safe in the hands of the staff.	3	127	0	0	47
The staff are polite.	9	121	3	4	48
The staff receive enough support from their colleagues to perform their work.	4	126	0	0	49
I received personal attention from the staff.	3	123	4	0	50
I did not receive personal attention from the staff.	2	0	123	5	51
The staff know what my needs are.	0	123	7	0	52
The Nuclear Medicine Department of Tygerberg Hospital has weaknesses.	0	4	116	10	53
The department's hours suit me.	1	129	0	0	54
The service delivery is good.	7	123	0	0	55
The department is hygienic.	5	126	9	0	56

Department of Nuclear Medicine - Tygerberg Hospital/University of Stellenbosch		Code: PQS 001	P 6/7
PATIENT SATISFACTION		Edition 1	Drafted on 21/06/2004

Statement	Fully agree	Agree	Disagree	Fully disagree	
The information leaflets on all the examinations are comprehensive.	5	44	22	59	57
The doctors and staff are professional.	7	123	0	0	58
The doctors and staff are competent.	1	2	3	4	59
Patients are treated with respect.	7	119	4	0	60
The information on the operation of the department is adequate.	4	40	26	60	61
The information on caretaking and treatment is inadequate.	5	40	3	60	62
My questions are answered in full.	1	2	3	4	63
The information supplied by the department is easy to understand.	1	2	3	4	64
The staff takes time to explain anything, if needed.	7	112	8	3	65
It is easy to reach the department.	4	106	12	8	66
It is difficult to find your way around the grounds and buildings.	4	39	82	5	67
There is ample parking for visitors and patients.	6	106	9	9	68
The working hours are adequate.	7	119	3	1	69
The time in which the service is offered is convenient.	7	119	3	1	70
The staff treat me with expertise.	5	124	3	1	71
The staff are friendly.	6	124	0	0	72
I am being treated with respect by the staff .	6	124	0	0	73
The staff spend enough time with me.	5	125	0	0	74
The way in which the staff treat me creates trust.	5	124	0	1	75
The staff are impatient with me.	0	0	120	10	76
The staff understand me.	4	124	2	0	77
The staff treat me sincerely.	4	122	2	2	78
The staff members are helpful.	11	110	9	0	79

Department of Nuclear Medicine - Tygerberg Hospital/University of Stellenbosch		Code: PQS 001	P 7/7
PATIENT SATISFACTION		Edition 1	Drafted on 21/06/2004

15. Indicate how satisfied or dissatisfied you are in general about the following aspects of the Nuclear Medicine Department of Tygerberg Hospital:

Aspect	Very satisfied	Satisfied	Dissatisfied	Very dissatisfied	
the time I had to wait;	5	111	10	4	80
the amount of information given;	5	88	28	9	81
the information given was understandable;	7	111	4	8	82
the directions and signage in the department;	5	115	6	4	83
the general appearance of the facilities of the department;	15	108	4	3	84
the security of die department;	5	122	0	3	85
the expertise of the staff;	5	124	1	0	86
the mutual collaboration of the staff;	9	118	0	3	87
the way in which the staff treat me;	15	113	0	2	88
the way in which the staff understand my needs as a patient;	10	114	4	2	89
the helpfulness of the staff;	12	118	0	0	90
the caretaking of the staff;	12	116	2	0	91
the correctness of the administration;	11	110	8	1	92
the way in which the staff listen to my complaints and/or remarks;	8	120	2	0	93
the department in general.	10	112	5	3	94

Thank you for your co-operation!

Addendum E

Department of Nuclear Medicine - Tygerberg Hospital/University of Stellenbosch	Code: SSQ.02	P 1/4
STAFF SATISFACTION QUESTIONNAIRE	Edition 1	Drafted on 18/11/2003

		Name		Signature	
	Author	Thea Eiselen			
	Editor	Thea Eiselen			
	Approved by	Prof. A. Ellmann	Head of Department		

WORK SITUATION and MOTIVATION QUESTIONNAIRE

CONFIDENTIAL

It is obvious that people differ from one another in what they need and expect to get from different areas of their lives. Please think about the work you do and, because no job is perfect, consider what would make it better from your point of view.

For each question, you have a choice of three answers:

A= Always

T = True

S = Sometimes

U = Unsure

N = Never

F = False

Work contents:

	A	S	N	A	S	N	A	S	N	
The post school education I received is adequate to enable me to perform my duties.	23	6	2	6	3	0	6	4	0	1
I am interested in my work.	25	5	1	4	5	0	9	1	0	2
My work consists of a variety of tasks.	24	7	0	8	1	0	8	2	0	3
I approach my work as an expert	22	9	0	6	3	0	7	3	0	4
Whatever my job, I want to provide high-quality work and exercise my skills and competence.	30	0	1	9	0	0	10	0	0	5
I receive training on a regular basis.	15	11	5	8	1	0	3	5	2	6
My work is easy.	6	22	3	0	6	3	1	8	1	7
The workload is easy to handle.	5	22	4	0	5	4	0	8	2	8
I approach my work as a means to a self-fulfilling life.	23	8	0	6	2	1	8	2	0	9
I want to further my own development.	25	5	1	8	1	0	8	2	0	10
I have control over the amount of work I do.	4	11	16	0	4	5	0	3	7	11
I am completely independent of others.	3	22	6	0	9	0	0	6	4	12
I came to work with a positive approach, but have found that the system and its leaders keep me from staying positive.	8	19	4	3	3	3	4	6	0	13

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	A	S	N	A	S	N	A	S	N	
I regard the contents of my work as responsible.	30	1	0	9	0	0	9	1	0	14
I know exactly what my tasks are.	18	11	2	6	3	0	3	6	1	15
I am allowed to decide my own working methods.	18	5	8	1	8	0	1	7	2	16
I am proud to say what kind of work I do.	23	7	1	6	3	0	8	2	0	17
My work is the way to future success.	21	8	2	6	2	1	5	4	1	18
I have the opportunity to take part in decision-making.	4	20	7	2	6	1	1	6	3	19
I feel that my work is of value to the department.	24	6	1	6	3	0	9	1	0	20
There is no time for idleness.	11	15	5	3	4	1	3	6	1	21
I set my own performance standards for my work.	23	6	2	6	3	0	7	3	0	22
I have a certain degree of authority in my work.	14	9	8	4	4	1	4	3	3	23

Payment:

T = True U = Unsure F = False

	T	U	F	T	U	F	T	U	F	
My salary is satisfactory in relation to what I do.	5	20	6	3	3	3	1	7	2	24
I earn the same as, or more than other people in a similar job.	10	7	14	1	6	2	4	2	4	25
The basis of payment, for example overtime/bonuses, is reasonable.	7	11	13	1	5	3	1	6	3	26

Recognition:

	A	S	N	A	S	N	A	S	N	
I am praised regularly for my work.	3	19	9	0	5	4	0	7	3	27
I receive constructive criticism about my work.	5	18	8	2	3	4	1	7	2	28
The only time I hear about my performance, is when I do something wrong.	7	14	10	3	2	4	2	7	1	29
I get credit for what I do.	1	20	10	1	6	2	0	7	3	30
I am told that I am making progress.	2	12	17	1	3	5	0	4	6	31
I am seen as part of the team.	14	14	3	4	5	0	1	8	1	32

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Working climate:

	A	S	N	A	S	N	A	S	N	
My working hours are reasonable.	19	10	2	3	5	1	5	4	1	33
I am overworked.	3	24	3	1	7	1	1	9	0	34
I get the opportunity to mix with my colleagues and to communicate on work related aspects.	15	26	0	4	5	0	3	7	0	35
The department's staff pitches in to help each other out.	5	18	8	3	4	2	0	5	5	36
There is a good team spirit among the department's staff.	7	20	4	2	5	2	0	9	1	37
The department's staff members tend to get along with each other.	6	20	5	0	8	1	0	9	1	38
The department's staff members take a personal interest in one another.	8	18	5	0	8	1	0	8	2	39
I feel I have a lot in common with my colleagues.	6	21	4	0	5	4	0	9	1	40
I can count on my manager to keep things I tell him/her confidential.	13	15	3	3	3	3	3	6	1	41
My manager has a lot of personal integrity.	12	17	2	6	2	1	4	5	1	42
My manager is the kind of person I can relate to.	8	18	5	2	6	1	2	7	1	43
The department is a relaxed working environment.	7	17	7	0	7	2	0	7	3	44
It is easy to talk to my manager about work related problems.	12	13	6	3	3	3	3	6	1	45
My manager does not play favorites.	9	7	14	2	2	5	0	2	7	46
My manager encourages me to develop my own ideas.	10	16	5	3	4	2	3	7	0	47
When I have a break during work time, I find the tearoom to be an employee friendly environment.	15	12	4	3	4	2	4	5	1	48
Rostering is done fairly.	17	12	2	7	2	0	2	7	1	49

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	A	S	N	A	S	N	A	S	N	
When I have a personal problem, my colleagues are understanding and accommodating.	15	13	3	5	4	0	3	6	1	50
Interdepartmental communication regarding protocols and changes thereof is adequate.	7	16	8	2	4	3	0	8	2	51
Communication on all levels of the department is up to standard.	5	21	5	3	4	2	0	8	2	52
Opportunities for development and training are available to everybody.	14	13	4	6	3	0	2	5	3	53

What would you like to change/develop in the department?

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Thank you kindly for your valuable input.

Key:



Combined staff (all participating staff members)



Clinical staff



Radiographers