PRACTICAL GUIDELINES FOR THE IMPLEMENTATION OF A QUALITY SYSTEM IN RADIOTHERAPY
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A project of the ESTRO Quality Assurance Committee sponsored by 'Europe against Cancer'

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Chapter 1

INTRODUCTION

Radiotherapy is a multidisciplinary specialty, using complex equipment and procedures for assessment, planning and delivery of treatment. It requires careful and accurate application. The success of radiotherapy, in terms of the probability of local control of the tumour, depends upon an adequately high dose of radiation being delivered to the intended target volume, the latter being selected to provide adequate coverage of the tumour volume and any relevant surrounding margins. At the same time, the limiting factor in radiotherapy treatment is the probability of complications (ie radiation-induced morbidity) in the normal tissues close to the high dose regions. Such complications can occur acutely during or immediately after treatment, but the most serious complications normally occur after a latency period and may develop progressively throughout the rest of the patient’s life (late effects).

Both of these aspects - tumour control and normal tissue complications - make strong demands on the accuracy and precision of the treatment delivered to the patient. This in turn leads to strong demands on quality assurance and quality control on all of the steps, processes and equipment contributing to this. In particular, because of the potential for long-term irreversible damage and because of the delay in its possible onset, there has traditionally been an emphasis on using quality assurance in radiotherapy to prevent, or minimise, such damage and also on establishing careful long term follow-up. Thus quality assurance approaches have long been recognised as important and have been widely applied, but until recently they have often been limited in concept to quality control of the more physical and technical aspects of the treatment process.

It is now widely appreciated that the concept of Quality Assurance in Radiotherapy is broader than a restricted definition of technical maintenance and quality control of equipment and treatment delivery and instead that it should encompass a comprehensive approach to all activities in the radiotherapy department, from the moment a patient enters it until the moment they leave, and also continuing into the follow-up period. The comprehensive approach is favoured because it is recognised that partial organisation of only some of the key steps in the radiotherapy process is not sufficient to guarantee to patients - and to society - that each individual will receive the best available care for their disease.

The principles and structure of a comprehensive radiotherapy quality system have been summarised in the report 'Quality Assurance in Radiotherapy' (QART) of the Quality Assurance Committee of ESTRO [14]. The preparation of that report was supported by 'Europe against Cancer', an initiative of the European Union, which funded the discussion meetings of representatives of the National Societies of Radiotherapy, of Medical Physics and of Radiography from up to 25 countries (from EU, EFTA, Central Europe and Mediterranean). This has ensured that from the outset, although the project has been administratively managed by ESTRO, it has
been run in concert with the National Societies. The final version of the report was formally endorsed by all participating National Societies before its publication in Radiotherapy and Oncology [14]. It is reproduced as Appendix 1 of this document.

The practical implementation of these principles at the departmental level, however, can prove to be difficult in the absence of appropriate guidance. The National Societies and ESTRO therefore decided to seek additional support from 'Europe against Cancer', in order to develop a fuller manual providing local quality project managers with an ad hoc methodology. The present report is the result of this second initiative. It contains practical guidelines on the methodology, covering considerations of documentation, procedures and personnel, and it is illustrated by numerous examples.

The following chapter deals with the core question: why does a radiotherapy centre need a quality system? The aim of this chapter is to provide departmental heads with the necessary arguments they might require to convince themselves of the need to initiate a quality project in their own department. The same arguments will also prove to be of use in their negotiations with their higher management if this is necessary.

The next chapter provides a basic framework for a suitable methodology, outlining the practical aspects of the implementation of a quality system: including how to initiate the whole project in the department, how to structure a project team, how to set up a project timetable, etc. It highlights the way that communication should be organised in the department in order to implement and run a quality project successfully.

The final chapter summarises various items which one should, or could, try to describe and to produce protocols for, and outlines the points which may be considered in carrying this out. This list is not intended to be complete or exhaustive, nor should it be considered as a generally agreed prescription. It follows the structure which has been recommended in The Netherlands by the PACE Foundation and which is currently being implemented in health institutions throughout that country [8]. This structure is largely inspired by the ISO 9000 standards, although it has been adapted to the hospital situation. A similar approach has been taken already in some other countries, eg in the UK recommendations for quality systems for radiotherapy departments [2].

For the sake of clarity a large number of examples have been worked out and are introduced in the text where appropriate. They mostly derive from existing quality systems. However, this document does not contain a fully documented quality manual. Writing one's own manual constitutes one of the most important parts of the project. A full sense of ownership of the manual by all those involved is an important key for the success of the project in the long term. Not writing it in-house means that the manual is not tailored to the way the individual department is structured and the

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1 Austria, Belgium, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Israel, Italy, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, The Netherlands, Turkey, United Kingdom
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way it works, but also loses the enormous benefit of bringing people together in the
department to discuss the organisational aspects of their own work.

The Quality Assurance Committee of ESTRO is pleased to present this work as an
ESTRO publication, with the hope that its use will aid in improving overall quality in
radiotherapy. The Committee wish to thank the Commission of the European Union
and the ‘Europe against Cancer’ administration for the support they have provided
throughout the report’s preparation.
Chapter 2

WHY DOES A RADIOTHERAPY CENTRE NEED A QUALITY SYSTEM?

2.1 INTRODUCTION

Radiotherapy is a multidisciplinary specialty, involving complex equipment and procedures. Many separate but interlinked stages and processes are necessary to progress from the initial clinical decision to undertake treatment through to the treatment delivery itself and subsequent follow-up. It is universally recognised that quality assurance (QA) is vital at all levels of the overall radiotherapy process to ensure the achievement of safe and effective treatment. Historically, QA has long been carried out in many areas of radiotherapy, particularly in the more readily defined physical and technical aspects of equipment, dosimetry and treatment delivery. However, more recently, there has been growing acceptance that QA should be wide in scope, to embrace all aspects in a unified comprehensive manner [17]. Coupled with the increasing complexity of techniques and associated quality control and with the increasing demands on quality of treatment, this has led to the recognition that a systematic approach is both necessary and desirable. In turn this has given rise to recommendations for more formalised quality systems, or comprehensive quality assurance programmes, essentially covering the complete radiotherapy process [2], [1], [14]. Some of these recommendations have arisen following accidents, where the implementation of a quality system is seen as reducing the probability or the consequences of accidents and errors. However, whilst the adoption of a quality system will indeed fulfil this role, the more fundamental reason for following this approach is to help to provide good quality treatment.

2.2 QUALITY SYSTEM

A quality system can be defined as the organisational structure, responsibilities, procedures, processes and resources for implementing quality assurance [1], [14]. The general aim of developing a quality system in a radiotherapy department is to provide a formal written scheme to ensure that all important aspects of quality assurance in the department are defined, documented, understood and put into practice. Thus as one outcome, it should ensure that no area of quality assurance is omitted, for example because it falls on the interface between processes or between professional groups, but rather that all necessary quality procedures are interlinked. It should aid in communication and co-operation of the various groups involved and minimise ambiguity in responsibilities and tasks, which becomes increasingly important as complexity increases. In addition, it enables monitoring of the achievement of quality requirements in practice, as regards compliance with the written system, and provides a method for this to be demonstrated. However, it must be understood that a quality system is essentially a management system. Thus it is not a complete end in itself, in terms of producing scientific, technical or clinical
quality system will give reassurance that such documentation is readily available and may well preclude a case going to court. Indeed, the very possession of a quality system may be said to endow the Radiotherapy Centre with a credibility which will help it to defend itself in the face of such litigation.

2.4.8 Competitors will use a quality system

A somewhat materialistic reason for adopting a quality system, but no less valid, is that it may increase the competitiveness of a Radiotherapy Centre. A similar view has been taken by industry, where the international marque of quality is the ISO 9000 standard [6]. Within a given sector of industry, those who first adopt ISO 9000 seem to do so because of the perceived benefits for their company which are essentially those described above. As rival companies become accredited with the standard, there is a shift of emphasis on the competitive edge which possession of ISO 9000 lends to a company, and, indeed, those without it may begin to feel at a disadvantage. While, clearly, radiotherapy centres should aspire to a quality system for the positive benefits which it brings, there can be no doubt that to be surrounded by neighbouring centres who run quality systems can be a motivating force.

2.5 COSTS AND RESOURCES

In order to implement and maintain an effective quality assurance programme, adequate resources are necessary. This includes three components: personnel, requisite equipment and time to carry out the specific quality-related tasks, including quality audit, and to enable continuing professional education, etc.

Initially, a concentrated effort will be required to establish and put into operation the quality system (see chapter 3). This will involve the appointment of at least one member of the department as a Quality Manager to guide the process and will involve other personnel being given specific defined responsibilities for quality matters. Time will be necessary to develop the quality system, by reviewing the existing quality assurance programme in the department and the existing documentation, by identifying gaps and by writing policies, procedures, etc in a uniform format as required by the system to be implemented. That time will generally be productive in terms of the identification of gaps revealed in existing quality assurance and in the new channels of communication which are opened by the exercise. If all groups of personnel are involved in the preparation of the system, then not only will the system be adopted more readily because of the feeling of mutual ownership, but the process should be faster and may well, itself, raise morale.

After that, a continuing level of resources is required to ensure that the quality system is maintained and continues to be effective. For example, many areas of quality assurance incorporated into a quality system include elements of 'redundant' testing or checking [14], where redundant in this sense means that they build in additional levels of testing safety and performance of the areas involved over and above the basic provision. Many of these are carried out routinely already in radiotherapy departments, for example, independent checks on beam calibration, independent
checks on treatment planning calculations, chart review, etc. However, the establishment of a quality system may identify additional areas where this approach is to be recommended and this may have consequences for resources.

It is the experience of centres who already run established quality systems that once the systems are operating 'in equilibrium', they require little extra time to maintain at least those aspects of quality that would have been carried out in any case, even without a quality system in place. The only extra work may be involved with document control. New quality tasks identified at the initial implementation of the system will require appropriate resources, but as these by definition are to address recognised deficiencies in quality assurance or standards, they ought to be obviously necessary and should produce an immediate and significant improvement in quality of treatment.

Quality systems must include continuing audit. This should encompass the operation of the system itself, as compared with its written definition. In addition, it should test the performance of the system in terms of its effectiveness in providing practical quality, as compared with the quality standards adopted. Quality system audit will be regular and on-going and will require resources to be allocated to carrying it out. It is necessary for the operation of a quality system to build in routine internal audit (within the department). If the quality system is to be accredited, then external audit is also involved. The linked practical audit may be at various levels of the radiotherapy process and could include many types of internal audit, as well as some elements of external audit where available [14].

Section 2.4 draws attention to personnel development and training needs. These activities clearly require resources both in providing appropriate programmes of training and development and in replacing the time lost while personnel participate in these programmes. Although a quality system identifies the need for such programmes and sets in place the mechanisms for monitoring their progress, it would be wrong to attribute this cost in resources to the quality system itself. This is because a well managed organisation will cater for the development and training of its personnel in any case, and, furthermore, there is a growing movement among medical and allied professional groups to require "Continuing Medical Education" and "Continuing Professional Development" for all personnel in the hospital as a prerequisite for maintaining one's name on a register to practice.

One other perceived cost may be the fear that a quality system is bureaucratic and rigid. The level of bureaucracy will increase in the department, essentially to cope with the demands on document control. However, a careful design and implementation of the local quality system can contain this to a level where the benefits gained are recognised to be worth this cost. Systems can and should also be designed to be flexible enough to encompass the department's existing practice and the development of practice, such that innovation and improvement is not suppressed. Indeed, with a well designed quality system, such modifications to practice can be introduced smoothly and safely in a systematic way.

Overall, the costs and benefits must be weighed and balanced. It is possible that some cost savings will be produced by the increase in efficiency and quality at different stages of the radiotherapy process, although these may be difficult to quantify.
However, there should be clear benefits to the patient through better quality treatment and through the minimisation of the incidence and consequences of accidents and errors. It should be noted that the recommendations for the implementation of quality systems are universal, i.e., for all radiotherapy departments and not just for large or well resourced departments. Indeed, it may be that some departments with lack of resources may benefit most from the introduction of a quality system, both from setting up a systematic approach to quality and by identifying and requesting the resources necessary.

2.6 DISCUSSION

We have mentioned ISO 9000 [6] as an example of a quality system. ISO 9000 is essentially a check-list of good practices which a well-run organisation would put into place even if the standard itself did not exist. There are 20 requirements for quality in the standard, most of which are subdivided into more detailed requirements. It is very difficult to argue the case for dropping any one of these requirements without jeopardising the quality of the service provided.

Because of the generality of ISO 9000, it is written in language which does not seem immediately applicable to a radiotherapy service. In the UK, the Bleethen Report ([2]) was an attempt to translate the requirements of ISO 9000 into familiar terms, and all UK centres were asked by the UK government Department of Health to implement the system.

The ESTRO report, "Quality assurance in radiotherapy" (QART) [14] is also written in language appropriate to radiotherapy, but it goes beyond the requirements of ISO 9000. ISO 9000 enables the user to give assurance that standards of service will be met consistently, but the standards are not specified, and they could be sub-optimal. QART, on the other hand, requires that the radiotherapy centre seek to attain the highest standards, for example, by emphasising the need for interdepartmental audit and clinical trials, and the need to match the radiotherapy service with the needs of the geographical region, taking into account neighbouring services.

Being based on the PACE philosophy, QART is flexible, and offers much freedom about what should be regulated and at what detail. While QART contains all of the ingredients of ISO 9000, the wider scope of QART requires a commitment on the part of the Clinical Director and higher management to continuing quality improvement through monitoring of outcomes, a flexible approach and a willingness to pursue excellence.

In the above discussion, we have examined the reasons why a radiotherapy centre needs a quality system. Some of the reasons refer to improvements within the centre, such as the central role of a quality system in providing a framework for good management, improving efficiency and raising morale. On the other side of the coin are considerations of the minimisation of the risk of accidents and litigation and the threat of competition. To personnel in centres which have been operating quality systems for several years, it would be unthinkable to abandon their quality system.

For them, the advantages of a quality system are evident, and the question is not: can you afford to run a quality system, but rather, can you afford not to?
Chapter 3

CONSTRUCTION OF THE QUALITY SYSTEM

3.1 INTRODUCTION

The practical implementation of the principles laid out in the report 'Quality Assurance in Radiotherapy' [14] requires patience and persuasion, as well as a clear structured methodology. It is essential, as the very first step, that the Head of Department and the management of the institution whole-heartedly support the project, despite any local and/or temporary problems. They must be absolutely convinced of the benefit which everyone in the department will find in working in an optimally organised structure. This is an important prerequisite for them to be sufficiently persuasive. They must also convince themselves, before convincing their collaborators, that a high level of organisational quality is directly beneficial to each individual patient treated in the department. Otherwise the project will not be taken seriously by the rest of the radiotherapy personnel, but may merely be considered as a passing whim of the Head of Department or alternatively of the Quality Manager. In addition, if the Head of Department is not firmly and obviously committed to supporting the quality project and the quality team, the project will not gain momentum and become established, as it will be clear to personnel that it has no support from above and the Quality Manager, or quality team, will carry no authority in their efforts.

A quality project will usually progress through four consecutive periods: a preparatory phase, a development phase, an implementation phase and a consolidation phase (see Figure 3.1)

3.2 PREPARATION

3.2.1 Involving and informing the department

Implementing a quality system first needs a good understanding of the objectives of the project by the entire personnel in the department. Great care must be taken in delivering clear and complete information on what is going to change and why it needs change or improvement. Consensus at the department level is essential, because the goal is to help personnel to work according to guidelines which everyone understands and has approved. Guidelines which have not been fully discussed in meetings with personnel and approved by all concerned are not likely to be followed appropriately and may, in any case, contain things which are not in line with the way that group of personnel carry out those functions. Approval by the Head of Department alone, whilst essential, is not sufficient.
Phase

1. Preparation
   setting up the team
   informing the department
   inventory of existing structure
   structuring the system

2. Development
   defining policy, (level 1)
   preparing procedures (level 2)
   preparing work instructions (level 3)

3. Implementation
   training
   validation

4. Consolidation
   internal audits
   system review

Figure 3.1: Planning a quality project
It is essential that personnel feel responsible for the system's success and this in itself is one main objective of the project. The quality system belongs to each individual working in the department. One of several pitfalls is that the system is perceived merely as a whim of the Head of Department or of the Quality Manager, rather than practical guidelines for daily work which can improve that work. Each member of personnel must therefore develop a sense of ownership relative to the system and managerial effort must be directed towards this objective.

This is a central step because there is a significant risk that many personnel may consider the project as merely bureaucracy, i.e. paperwork destined to end up on a shelf and divorced from any impact on the daily routine of the department.

3.2.2 The project team

The project team will be appointed by the Head of the Department, taking care that all groups of personnel are appropriately represented. Mutual respect and esteem in this group are essential. Each member must be a respected professional within their own area and personnel group, in order to ensure sufficient credibility of the team as a whole. It must also be clear to everyone that each individual is not participating in a personal capacity, but rather as a representative of their professional group.

The Head of Department would not usually be a team member, partly so that he/she can be detached in judging the team's recommendations. However personnel are likely to model their behaviour in this area on that of the head, who must therefore show steady interest in the progress of the project. Disinterest will kill the project through undermining the motivation of the quality officers.

Three to four people is probably optimal for good flexibility and productivity during the meetings of the project team. Typically this would be a doctor, a physicist and a radiographer, with other personnel representatives co-opted on as appropriate. If it is possible, a short preliminary training of this project team by professionals in quality management is certainly valuable. One or two people may be designated Quality Managers to take responsibility for co-ordinating the activities of the quality team and of the overall quality project.

Frequently, a subgroup of personnel will prove enthusiastic about the project, another subgroup will be very sceptical and the remaining personnel will be largely neutral. The driving force will come from the first group, of course, whilst resistance is to be expected from the second. This resistance can be very irritating to the project team at times, but paradoxically it can help the whole project to keep on a realistic course.

Help from a third party, not directly involved in the department, can be very valuable at the outset. One good approach is to seek support from the hospital administration for the appointment of an external adviser, with experience in quality matters and quality systems, who can monitor the first steps of the project team and help provide its members with elements of appropriate methodology. This adviser can be appointed for a variable period, depending on the size of the department, on the level of quality and experience of quality management already present and, of course, on
the local level of resources. However, limited resources should not prevent any department from developing a quality system since one of the first project outcomes is an increase in quality and productivity (eg reduction in non-quality costs, increase in quality of care and patient satisfaction, reduction of lead times, motivation for continuous improvement, etc).

3.2.3 Structure of the quality system

The quality system consists of three hierarchical levels. Level 1 reflects the quality management policy of the department, ie. the definition of its objectives and the strategies developed to meet these objectives and the responsibilities and the structure of supervision of all functions having an impact on quality. These considerations extend to all parts of the quality system. Level 2 describes procedures referring to all actions which were identified as needing to be formally organised within the framework of the system. Usually, the term 'procedure' in this context is not well understood and requires some explanation. A procedure is a document containing information regarding a particular step in the radiotherapy process, eg opening and managing an administrative file, or establishing an irradiation schedule for a given patient. This document contains a definition of the scope of the procedure (what it covers and is about), of the respective responsibilities of those involved (who is responsible for doing what, who is in charge of which areas) and the outline of the practical actions to be undertaken (what is to be done). Finally Level 3 work instructions explain in detail, for each separate area of practical action contained in a Level 2 document, how this is to be implemented at the practical level (how to do it). Several examples are provided later in this report.

By using the QART document as a source, it is possible to assign to appropriate levels the existing procedures and documentation identified in a given department during this preparatory phase. It helps also to identify areas where there is no clear policy, or where responsibilities are not well defined.

3.2.4 Preparation, planning

Careful planning must be carried out, covering the different phases of the project. The department must be informed of the duration of the different steps. It is important to let personnel understand that the pace of preparation and implementation is slow. It may typically last 1 to 1½ years, although this strongly depends on the local situation and may be a lot faster or rather slower, contingent on the level of structure already present and on the required, targeted level of structure. This timescale concerns the preparatory phase only. The 'end' of the project is a moveable (cyclical) point in time, as the quality system is expected to be regularly audited for possible improvements and therefore continually evolving. An example of a planning chart and timescales is illustrated in Figure 3.2.
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Figure 3.2: Example of a chart for planning a quality project
The timescale planning must be realistic, in order to ensure that it can be followed without major changes. If the planned pace is too fast, delays will immediately begin to build up leading to a fall in motivation of personnel. It is better to plan a slower progress which will be easier to follow. On the other hand it should not be too slow, or personnel will not be sensitive to the need to implement the necessary changes swiftly and vigorously.

From the moment that the planned timescale has been presented to the department, it must be followed as accurately as possible. Delays appearing in the process must be appropriately documented and corrective actions must be implemented quickly so as to regain and maintain the initial timetable as closely as possible. Only major events justify modification of the planned timetable. The Head of Department must consider this with great care. It is one of the major ways by which the head can indicate his/her own interest and motivation in the quality project.

3.2.5 Inventory of the existing elements of the quality system

One good way to begin is to carry out an inventory of the existing structure and procedures. Each department works according to a given set of rules and methods, sometimes written, sometimes not. Most often they are not linked together, as the radiotherapy process is not integrated into a comprehensive system. An inventory of the existing instructions, documentation and rules constitutes a natural basis for further developments and begins to identify where there are gaps in the existing structure. Most often, many work instructions (Level 3 documents) already exist in the department and simply need to be formulated in a consistent manner and circulated properly, although Level 1 and 2 documents will generally be lacking.

The inventory process helps to incorporate into the new system the existing elements of local culture and habits. The inventory of existing procedures is the appropriate time to begin to introduce personnel to the level of requirements of the system, to the strengths and weaknesses of the existing procedures and to the need to work together to improve the overall quality structure. If personnel are fully involved in this inventory then many of these things will grow from their own consideration of the current situation.

The quality system focuses attention on actions which prevent the occurrence of problems, whilst simultaneously laying out corrective actions if some failures are identified during the process. At an early stage during the inventory, priorities need to be identified of those aspects of the quality system which need to be improved first. A careful evaluation of the amount of work to be done and of the resources (time, manpower, budget) required must be carried out at this stage.

3.2.6 Setting up priorities

Important parts of the quality manual deal with the description and "protocolisation" of the patient's progress through the different steps of the radiotherapy process. At the
<table>
<thead>
<tr>
<th>Steps</th>
<th>Actions</th>
<th>Responsible for action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>patient sent to department</td>
<td>external</td>
</tr>
<tr>
<td>2</td>
<td>registration of referral</td>
<td>secretary</td>
</tr>
<tr>
<td>3</td>
<td>date of consultation</td>
<td>secretary</td>
</tr>
<tr>
<td>4</td>
<td>indication for brachy?</td>
<td>doctor</td>
</tr>
<tr>
<td></td>
<td>N other</td>
<td>nurse</td>
</tr>
<tr>
<td></td>
<td>Y brachytherapy protocol</td>
<td>radiographer</td>
</tr>
<tr>
<td>5</td>
<td>booking theatre and room</td>
<td>physicist</td>
</tr>
<tr>
<td>6</td>
<td>booking simulator</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>treatment planning</td>
<td>etc.</td>
</tr>
</tbody>
</table>

Figure 3.3: Example of a flow chart for the brachytherapy process.
outset, this can often appear to be an overwhelming task and it is not uncommon for those in charge of this aspect to experience some discouragement. Quite often, failures may be identified in many steps, some minor, some major, and the project team will find it difficult to select a starting point.

It is clear that everything cannot be considered at once. Some aspects need to be addressed first, logically those where the need for improvement has been identified as urgent, while others can wait to be dealt with later because they are less critical. Setting up priorities is thus an important step. The following method can be used:

(a) The process can first be divided into elementary steps. Figure 2 gives an example for the brachytherapy process. Step 1 is the referral of the patient to the radiation oncology department by a clinician outside the department (and therefore this also covers the entry of the patient into the radiation oncology department's system). This involves recording initial information, etc., which may be identified as a separate step if appropriate. Step 2 is the decision to prescribe brachytherapy and the initial prescription itself; the responsible person is the radiation oncologist. Step 3 is the entry of the patient into the booking system (for theatre time, bed space, etc); again responsibility lies with a clinician. Step 4 is the initial planning of the treatment, to decide sources required, time course, etc; this is the responsibility of the clinician and will involve physics personnel in calculation, source ordering, etc; and so on. The specific steps, their order and the personnel involved may vary depending on the particular local structure. However certain core steps will be common to all departments.

(b) At each step, a description of the problems and actual or potential quality failures should be written, if any are identified. For example step 4 may fail if there is no systematic approach to recording and communicating the decision onwards to subsequent steps; step 6 may fail if sources are not ordered in time to mesh in with later steps, etc.

(c) Each of these problems can be assigned an index of significance (or criticality), with a value between 1 and 10, by each group of personnel involved in the particular step (eg doctors, physicists, radiographers, technicians, nurses) The index value is given according to how critical the failure may be (eg is the patient’s safety compromised) and to how often it happens or is likely to happen (see figure 3.4).

(d) The average value of these indices should then be calculated and all the steps which have been identified as presenting problems can be ranked according to their mean value of the index. This produces a sensibly-based priority list. The work to remedy problems can then begin with the most critical areas, i.e. those with the highest values. Those which occur infrequently will thus not be given priority over those which occur frequently, unless they involve a significant threat to security or safety.

This simple method helps to clarify the sequence of tasks for the project team and to allow it to work in an orderly logical fashion, ensuring that nothing essential or important is omitted, whilst focussing on the details of the process.
<table>
<thead>
<tr>
<th>Steps</th>
<th>Problems</th>
<th>Criticality index</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Booking of operating theatre and of room is not co-ordinated</td>
<td>8</td>
</tr>
<tr>
<td>6</td>
<td>Date and hour of simulation are not planned appropriately</td>
<td>8</td>
</tr>
<tr>
<td>7</td>
<td>Details of dosimetry are not communicated to nursing staff for planning of hospitalisation</td>
<td>2</td>
</tr>
</tbody>
</table>

Figure 3.4: A chart to determine the significance, or criticality, of problems in a process.
3.3 DEVELOPMENT

3.3.1 The quality manual

The quality manual has a double purpose; external and internal. Externally to collaborators in other departments, in management and in other institutions, it helps to indicate that the department is strongly concerned with quality. Internally, it provides the department with a framework for further development of quality and for improvements of existing or new procedures.

Basically, the quality manual will answer two questions for each chapter: what is the standard required (as a particular example: what tolerances are required on treatment unit positioning precision) and how to meet this requirement. Generally agreed, or recommended, standards are already in existence for a number of areas, particularly concerning the more well-defined and more easily measured technical aspects, e.g. beam calibration, beam dosimetry, mechanical stability of equipment, performance of treatment planning systems, patient positioning, dose delivery, etc. In other areas, agreed standards still need to be developed. Finally, some standards will be internal to a given department (e.g. waiting time before treatment) and will have to be developed locally.

It is sensible to begin with standards set at levels which are not too strict, but which can be met in the majority of cases. Setting standards which can not be met routinely is useless and kills the credibility of the quality system. When deviations from these initial levels become exceptional, then a more stringent set can be introduced as a new target to work to.

Standard levels not available in the literature (for example, from EORTC, WHO, IEC, national societies, etc) need to be developed and justified locally to suit the local structure. One approach to defining local levels is to start from observed (measured) performance, or uncertainties, already existing in the department. From these, a maximum deviation must be selected at a level which can be realistically met (e.g. the mean of an inventory value, ± 2 standard deviations, etc). Recording and analysis of observed deviations can teach the department a lot about the ways to improve a given procedure and to help to evolve towards more stringent limits.

For example, a particular department might be concerned by the appearance of a systematic delay between a patient's appointment time and their actual treatment time. In an effort to reduce or eliminate this delay, a new procedure for the delivery of appointment times can be set up and a waiting time standard can be defined as the target being aimed at by the department for the majority of patients. What is considered as an acceptable waiting time is, of course, a matter for local consideration and will depend on staffing, equipment, patient load, and many other factors; national or international standards would be meaningless. The question is how to define a realistic waiting time standard for the local situation.
The following method can be used. For a couple of weeks, or longer as appropriate, the existing delay is monitored as a preliminary step, before any corrective action is taken. It might be found for example that only 20% of patients wait 15 minutes or less. Thus setting up an immediate standard in which 100% of patients wait 5 minutes or less is clearly unrealistic, as it is impossible to meet. It will prove more appropriate to set up as a first target, say, that 80% of patients will not wait for more than 15 minutes. Then later, when this standard is achieved, a new target can be defined in which 90% of patients will not wait for more than 15 minutes, and so on, up to the level which is considered acceptable in this department given its local circumstances. When the ultimately defined standard is achieved, regular checks will be required in order to ensure that there is then no subsequent relaxation and that the waiting time is kept within the limits defined in the local quality system.

3.4 IMPLEMENTATION

3.4.1 Training phase

A few general tips are appropriate: use short, but repeated, training sessions; internal to the department (rather than by external professionals; although external professionals can play a role in initial training of the quality team members); initially oriented towards very practical subjects, concerned with routine daily work, before addressing wider principles; explain the aims, objectives and the rationale for the approach; allow, and provide time for, reaction and discussion, including criticism and proposals for alteration; take account of all these comments.

Initial reactions of personnel will be tempered by the fact that the first result of implementing a quality system is that people will have to change some (a few, or a lot) of their habits. There is an element of loss of comfort which must be taken into account. Persuasion and repeated demonstration of small improvements is the best way to obtain adherence of the majority to the system. A few members of personnel will be sceptical and will need a longer time to convince themselves, or be convinced, of the benefit which they can gain from the project. The best way to overcome this is to involve those personnel as soon as possible in the development of procedures and in the implementation of the quality system.

3.4.2 Validation phase

The objective of this phase is to test the new procedures, as to their appropriateness and feasibility. Advice from the users is important and must be used as a source of improvement. Any suggested improvements at this stage must be carried out rapidly. Care should be taken that any inefficient or unaccepted procedures are not left unchanged, as they will act as sources of generalised de-motivation towards, and criticism of, the whole approach. The Head of Department must be involved and openly interested during this phase.
3.5 CONSOLIDATION

3.5.1 Internal audits

Internal audits constitute a good way to consolidate the quality system. These audits must be presented to the department for what they are; i.e. not a policing operation, but rather a test for possible improvements. The first question that arises when a procedure is not followed appropriately is why do people not follow or use it. Indeed, looking for errors or deviations does not mean looking for the guilty, but rather looking to change things in the system that do not work properly. Internal audit must be an important source of improvements, not of additional stress.

3.5.2 System review

An examination of the contents lists of the Level 1 or Level 2 documentation contained in Appendix 3 will show that the contents are divided into sections with the same headings as the seven sections in the QART document [14] which is reproduced as Appendix 1. It will be seen that there is a sharp distinction between the policies and procedures of section 7 and the rest of the quality manual. All of the policies and procedures up to and including section 6 refer to the radiotherapy service and the infrastructure required to support it. Section 7, on the other hand, describes the internal mechanism of the quality system itself. Without the policies and procedures of section 7, the rest of the quality system would lie unused on the shelf.

The quality system is brought to life - and kept alive - by the system of Management Review which is listed in the Level 2 contents (Appendix 3) as procedure 7.1.4.1. In Management Review, which is chaired regularly by the Clinical Director of the Department, the effectiveness of every part of the quality system is analysed by reviewing its performance since the last meeting, and implementing corrective action which is then fed back into the quality system. This cycle of Management Review is summarised in Figure 3.5.

Because of the special status of the section 7 procedures, and because they are effectively independent of the individual radiotherapy department, a collection of example section 7 procedures is reproduced in Appendix 2 as an aid in producing this section of the quality manual. In addition, many of the forms which appear in the section 7 procedures as required documentation are also included for illustration.
Figure 3.5 The Quality System triggers the recording of measures of quality performance which reflect adversely on the Quality System. These records are analysed regularly at management review meetings and the necessary action for improvement is fed back into the Quality System. Procedures and forms are numbered as in the contents lists in Appendix 3 and many are reproduced in Appendix 2.
3.6 CONCLUSIONS

Several pitfalls, or traps, await the insufficiently prepared department embarking on a quality project such as this. Some of them can be briefly summarised:

(i) there is insufficient involvement of the Head of Department and/or the higher management of the institution;
(ii) the project is, or is seen as, a temporary interest of management, rather than a commitment to a well-prepared and pre-planned strategy;
(iii) the planning and timing is inappropriate to the local situation (particularly during the implementation phase);
(iv) after the preparation of the quality manual, there is insufficient follow-up of its practical implementation. The quality manual is not put into practice;
(v) resistance develops in the department as a result of inappropriate information and communication;
(vi) resistance develops because the manual is considered as hitting people's comfort and imposing bureaucratic rules, whereas a good quality manual ensures flexibility;
(vii) short term results are expected instead of long term improvements;
(viii) there is lack of proper training (supplying people with the written procedures is not sufficient);
(ix) the whole system is too stringent and inappropriate to the size of the department and the level of activities. A subtle equilibrium needs to be found between a quality manual which is too loose and one which is too stringent.

The key messages of this chapter may be summarised:

Construct and formalise a quality system which is sensible, practical, economical and reactive.
Convince the department of the need for a quality system (communicate, seek participation).
Respect the initial planning and timing; encourage confidence of the personnel in the quality system; listen to comments of personnel on it; encourage participation in it, and development of it.
Chapter 4

PRACTICAL GUIDELINES FOR WRITING YOUR OWN QUALITY MANUAL

4.1 INTRODUCTION

The QART report [14] laid the foundations for building what is effectively the Level 1 document (the policy document) of the quality manual, and it is reproduced here as Appendix 1. To help to translate that report into a practical Quality Manual, we provide the following guidance in section 4.2. It comprises action lists, questions and considerations which will help in developing the Quality Manual. The subsection numbers of section 4.2 and the titles of these subsections follow those of the QART report [14].

4.2 PRACTICAL GUIDELINES

4.2.1 Introduction

Describe the background to the role of quality assurance in a radiotherapy centre - a comprehensive introduction is given in the QART report [14] - see Appendix 1.

4.2.2 Aim and Policy of the Organization

With respect to aim and policy several objectives can be chosen and mentioned in the level 1 document eg:

1) To provide sufficient cancer care to the population which the department has to serve;
2) To be the centre for special types of treatments or cancers;
3) To be the training hospital of the region;
4) To be a centre in a network with other cancer centres;
5) To be a high-quality cancer centre.

These objectives should be laid down in a policy document of your department with a long-term vision on the desired development and the general consequences for your budget, infrastructure and staffing.

In order to create such a policy document you need figures to substantiate the position of your department. If you want to know whether your department provides sufficient cancer care you need a description of the population you have to serve.
The following exercises can be helpful:

1) What is the expected number of cancer patients with morbidity and referral pattern?
2) What is the expected number of cancer patients who are candidates for radiotherapy. Knowledge of accepted indications for radiotherapy is needed [12], [13];
3) Develop a scenario of the evolution of these numbers in the next 5-10 years;
4) Describe how the presence or absence of other radiotherapy departments in your own area influences the referral pattern to your own department and whether you can or want to influence this;
5) Describe whether there are agreements on the referral of patients for special treatment eg stereotactic radiotherapy or hyperthermia to your department or whether you would like to see such agreements being made;
6) Describe whether there are agreements for the referral of patients with special types of cancer whose multidisciplinary treatment should be centralized in your hospital eg cancer in children, or bone tumours or whether you would like to see such agreements being made;
7) Describe the official relations you have or would like to have with other departments with respect to training, scientific work etc;
8) Pay attention in your policy document to the general objectives with respect to quality assurance, quality control and quality management;
9) Decide what the consequences of these points are for your budget, infrastructure and staffing.

The level 2 part of your quality manual on aims of the organization will describe and list the procedures you need for the acquisition of the data on which you need to base your level 1 statements. It will also describe and list procedures of negotiation with local, regional and even national authorities about your aims and objectives and their mainly financial consequences.

So, in level 2 you describe for example:

1) Who is responsible for the level 1 policy document and its regular update;
2) How data, eg on numbers of patients, are provided.
   In this respect it is important to elaborate on the need for a good follow-up system, a registry of the treatment results of the department, a complication registry and a registry of accidents and near accidents.
3) With whom should you negotiate, who is responsible, who should be consulted, who can decide.
4) What should be achieved in what time scale and what action should be taken if the goals are not achieved.

4.2.3 Structure of the organization

In Level 1 of this section of your quality manual you have to design several orga-grams eg:
one describing the position of your department in the hospital and showing the hierarchic and functional connection which the head of the department has in this structure (Figure 4.1). Other organograms show how the department is organised into subdivisions and sections with their own tasks and responsibilities. If you have large sections you can decide also to make organograms of these.

The organograms are made according to the following format:

a) Vertically the different levels of responsibility are identified;
b) Horizontally they indicate the number of units (sections) at the same hierarchic level but with different recognizable specific tasks.

The limitations of the structure consist of financial constraints with respect to the possibilities for differentiation in wages and earnings.

Describe the activities of each section and finally indicate within each section, who is responsible for each activity and define the relation between the individuals who bear this responsibility, stating whether they are hierarchic or functional (operational).

It is better to start with listing all of the activities for which you want someone in your department responsible and then to add the names of your co-workers to these responsibilities rather than simply to spread responsibilities among your co-workers.

The job description should follow the function, as a structure also follows function.

Be sure that at the end only one single person is responsible for each activity (task) at each appropriate level.

A comprehensive set of activities can be recognized as being a process. Indicate who is responsible for the whole process. This individual is called the process owner.

Indicate who is implicitly or explicitly the next person responsible with respect to each activity (task).

In level 2 of this section you describe procedures with respect to the organization eg

allocation of responsibilities;
reviewing responsibilities;
assessment of co-workers in the department;
committee membership and its duration;
documentation responsibilities;
describe how sections and co-workers communicate with each other (automation and information infrastructure is extremely important).

Another important point in this respect is meetings.
Make a list of all meetings with co-workers and others in your department and define (Figure 4.2):

1) What is the aim of the meeting;
2) Who should be present;
3) Whether people are representing certain groups;
4) What decisions can be made;
5) What the frequency of the meeting should be;
6) How discussions and decisions are recorded and stored;
7) How information should be transferred to those who are not present in the meeting.

NB 1) Stop useless meetings and create new ones if necessary;
2) Define which qualifications each co-worker should have in order to become a member of the organization. All procedures and organisograms should be in agreement with national law and hospital regulations.

4.2.4 Means and materials

In level 1 you describe the infrastructure of your department and the different responsibilities related to it.

In level 2 you have to describe the procedures with respect to:

- accepting, commissioning and maintaining the infrastructure;
- extending and replacing infrastructure as it becomes necessary (who should be consulted, who pays, who is responsible for the procedure, who decides);
- action in case of unexpected breakdown;
- quality assurance and control related to the infrastructure of your department.

In level 1 again you have to describe the general guidelines related to purchasing, stock keeping and budget responsibility with respect to the consumables in your department.

In level 2 you describe in more detail the procedures and responsibilities with respect to purchasing, stock keeping and budget control, and, in level 3, you list the consumables (e.g., drugs, needles, syringes but also pencils, paper, X-ray films etc) as necessary and appropriate.

4.2.5 Process control

In level 1 the whole process from the moment your department is consulted about a patient until he or she is discharged from follow-up should be described in general
Purpose of the procedure:

To record the different types of meetings and when they take place.

Work terrain of the procedure:

The department of Clinical Oncology, University Hospital Leiden.

Departmental meeting:
frequency: once a month.
aim: to discuss and resolve inter-departmental organisational aspects.
type: informative and conclusive.
minutes: available to all departmental staff.
present: at least one representative from each branch of the department.

Staff meeting (doctors):
frequency: :
aim: :
type: informative and conclusive.
minutes: available to all departmental doctors.
present: the doctors of the department of Clinical Oncology.

Team leaders' meeting (technicians):
frequency: once a month
aim: to discuss and resolve intra-departmental organisational aspects.
type: informative and conclusive.
minutes: none.
present: all team leaders and superintendents.

Technicians' meeting:
frequency: three times a month
aim: to discuss and resolve intra-departmental organisational aspects.
type: informative and conclusive.
minutes: available to all technicians.
present: all technicians.

Technical staff meeting:
frequency: when required
aim: :
type: informative.
minutes: none.
present: all technical staff and the physicist.
terms. As when making the organograms you start with a global description using flow charts (Fig 4.3).

A flow chart is an easy way to describe a process with its actions and decisions based on information or missing information. It is like a decision tree where you can rapidly see what to do at each step of the process. The actions refer to protocols and procedures which are described in more detail in level 2 and to work instructions described in level 3 of your quality document.

For example: level 1 indicates that a patient with T1 N0 M0 breast cancer after referral and confirmation of the diagnosis is a candidate for breast conserving therapy.

In level 2 the treatment protocol is described with details about target volume dose, aim of treatment, follow-up etc

The level 3 document describes patient position during simulation, the number of simulator films to be taken, dosimetry etc

After you have made general flow charts you make flow charts for different situations eg patients only seen but not treated or patients with special diseases.

Many protocols and procedures of level 2 and 3 normally are already available in the departments. However, they have to be rewritten according to a uniform format (Fig 4.4).

Apart from medical procedures, many other aspects of the process can also point to procedures in level 2 eg

- providing information to the patient (what, when, by whom);
- handling the waiting list;
- handling complaints;
- monitoring and treating side effects (Fig 4.5);
- follow-up;
- rules of consultation;
- etc, etc

This section should also point to procedures for quality control, including checking and counter checking of dose prescription, calculation, control of patient set-up, treatment monitoring etc.

Many of the steps in the process can be provided with a "golden" standard which can then be subject to quality control eg

- waiting time;
- time between different steps of a process;
- number of patients seen or treated in relation to time or staffing levels;

etc.
1. **Target volume (PTV):**
   - the whole breast
   - CTV booster
   - 1 cm margin standard
   - 2 cm margin by risk factors
   - PTV booster minimum size 7x7 cm
     size of the booster increases along with the uncertainty about the tumour bed.
   - Axillary nodes:
     - by spill during operation
     - by linkage of the 2 operation sites
     - by extra capsular extension with questionable margins.
   - Supraclavicular fossa:
     - by suspected or positive infraclavicular nodes.

2. **Dose prescription (non-trial):**
   - whole breast: 50Gy, 25 fractions given in 5 weeks.
   - booster

<table>
<thead>
<tr>
<th>DCIS</th>
<th>&gt; 25%</th>
<th>&lt; 25%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iridium above 45 years *</td>
<td>16 Gy external beams</td>
<td></td>
</tr>
<tr>
<td>Or 20 Gy external beams if Ir. not technically possible</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operative margins positive Iridium</td>
<td>16 Gy external beams</td>
<td></td>
</tr>
<tr>
<td>Operative margins negative 16 Gy external beams</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* under 40 years amputation

- **Supraclavicular fossa:**
  - 50Gy, 25 fractions given in 5 weeks.
  - 95% minimum dose.
  - 60Gy for macroscopic tumour 30 fractions in 6 weeks.
- **Axilla:** see p.3

3. **Critical organs:**
   - Lung and proximal humerus.

4. **Technique:**
   - See loc. protocol 4450

5. **Special considerations:**
   - none

6. **Trials:**
   - EORTC 10882: booster versus no booster.
   - EORTC 22081: high booster versus low booster.

---

Figure 4.4
All serious complications possibly arising from irradiation treatment or from the introduction/use of radioactive sources, such as in brachytherapy, are reviewed during the Friday-afternoon discussion.

The complication form includes the following:
- patient details (hospital sticker)
- name of attending r.o.
- referring hospital.
- date of report.
- registration of organs by number and complication, to be found on a separate list. Official report to be filled in?
- date of the general meeting.

These forms are kept in a special "complications" portfolio.

The less serious complications, grade 1 and 2, are not registered. The graver complications of grade 3, where radical help such as surgery is necessary, are registered, as are the lethal complications of grade 4.

General meeting

The r.o.'s and the physicist discuss these complications during a general 3 monthly meeting. Conclusions can be drawn from recurring problems/situations.
4.2.6 Knowledge and skills

It is extremely important that you lay down in level 1 a policy on the required knowledge of all personnel working in the department and on their continuing professional education. You should also set strict rules with respect to training of persons once a new technology is introduced.

In level 2 you pay attention to the following:

1) A procedure defining the required knowledge of all personnel.
State that you want them to meet criteria of an internationally endorsed curriculum if available (refer to these);

2) A procedure which describes how acquired knowledge and qualifications relate to job description and how training fits in the professional career.

3) A procedure which describes how deficits in training are filled in with tailor-made training programmes for the individual. This part is suitable for quality control with standards and a time scale;

4) The importance of making rules for continuing professional education;

5) The importance of setting rules for congress meetings and describing how all co-workers in the department can profit from the visit of a few.

4.2.7 Control of the quality system

Level 1 describes in general terms what the policy with respect to the quality system is, eg who is responsible for the use of it and its regular updating.

In level 2 all documents (policies, procedures, work instructions, data) which are part of the system are listed with instructions on how to use them and who is responsible (Fig 4.6).

The importance of quality system control was highlighted in section 3.5.2 which refers to examples of procedures for quality system control in Appendix 2.

4.3 CONTENTS OF LEVEL 1 POLICY DOCUMENT

The policies which arise out of consideration of the issues, questions and action lists summarised in section 4.2 should be collected into a policy manual. As an aid to producing this manual, Appendix 3 contains the suggested contents of a Level 1 policy manual. The policy headings and numbering correspond to the above guidance and the QART report [a]. Opposite some of the policies in the contents list appear the requirements of ISO 9000 which correspond to the policies. However, as explained earlier, the scope of the ESTRO quality system extends beyond that of ISO 9000, so that there is not complete correspondence.
Purpose:
Confirmation on:
- how to manage the documentation found in the standard (PACE) manual.
- how update procedures should be dealt with.
- how the documents should be coded.

Procedure terrain:
All documentation contained in the (PACE) manual of the department of Radiotherapy, University Hospital Leiden.

Definitions:
The Pace Manual: the written documentation of a system of procedures for the supervision and enhancement of the quality of work.

Method of work:
The departmental head (DH) and the quality supervisor (QS) play a central role in the maintenance and updating of the documents.

The QS is responsible for:
- making sure that the documents are complete and up to date.
- the availability of the manual, at one central point, on the department.
- periodic checks to see if the documents are used in practice.
- the storage of all original documentation.
- document distribution according to a distribution list.
- removal and eradication of old material.
- index updating in the pace manual.

Written changes on documents are not acceptable.

However, in order not to slow down the updating process, certain members of the department are authorised to make corrections in ink and to date and sign them.

The QS should be informed of all these mutations as soon as possible. The QS is responsible for new updated documents when there is a risk of illegibility.

All changes are documented and authorised before being added to the PACE manual.

The DH supervises the documentation in general and checks all departmental documentation at least once a year. The DH decides which course of corrective action is to be taken by infringement of the rules.

The DH is responsible for the flexible management and administration of the documentation and for modifications in the rules.

Unauthorized copies are not permitted.

When copies are requested by persons not on the distribution list, whether internal or external, it is the DH who decides whether the request is to be honoured or not. As a safeguard, these copies are identified in the following manner:

UNCONTROLLED COPY
INFORMATION ONLY
NO UPDATING

The procedure hereby loses its validity.
Modifications and new documentation.
During departmental gatherings everyone is free to comment on procedures, rules and instructions that need to be included or modified. The DH in collaboration with the QS indicates who should (re)write the new draft. The QS makes sure that the draft is typed and incorporated within the authorised framework and gives it an appropriate code.

The QS is responsible for the distribution of the new drafts. The DH always receives a copy.

Everyone who receives a copy is entitled to write their remarks on the separate form supplied. This should be done within a certain time limit.

When considerable changes need to be made to the contents, then a project group should be assembled with representatives from the related departments.

The QS incorporates the improvements in the draft, which is recirculated until all adjustments are agreed upon.

Once satisfactory, the QS makes the draft into an authorised departmental document to be signed by the DH.

Method of coding documents:
All documents are given a code consisting of a letter combination to be found at the top of the form.

Letter combinations:
General information to be found in the PACE manual begins with one of the 3 letter combinations:
GRN - general
OKG - organisation
PRO - general procedure and methods

The code for the page numbering includes 1 of 2 letter combinations, e.g.:
RS - safety rules and instruction.
OR - occupational rules and instruction.
PR - registration form.
PR - research protocol.

Number combinations:
The rest of the code consists of a combination of at least 3 numbers that show:
1) the paragraph within the chapter.
2) the sub-paragraph within the chapter.
3) the number in the sequence.

Page number:
The page number follows the code. The first number refers to the page and the second to the number in that page sequence. E.g.:
- 1/1 is page one of a one page document sequence.
- 1/5 is the first page of a series of five.
- 3/3 is the last page in a series of three.

The following sub-divisions should be used in a document if applicable:
1) Purpose
2) Procedure
3) Definitions
4) Method of work
5) Forms and other aids.
6) Summary of process in the form of a diagram.

Figure 4.6 (continued)
Ad.1) The purpose and build-up of the procedure is announced.
Ad.2) The validity of the work terrain is shown.
Ad.3) Specific definitions are given.
Ad.4) A description of all the preparation and activities.
Ad.5) A summary of all information, lists, materials, etc., once no. 4) has been completed.
Specific forms, aids and appliances are also mentioned here.
Ad.6) A summary of the processes in the method of work, mentioned in (4).
It can be useful to use a process diagram for this, using various symbols in order to differentiate (see PRO 6/6).

Document framework:
A document consists of one or more pages and can be divided as in the following diagram:

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>D</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>C</td>
<td>E</td>
</tr>
<tr>
<td></td>
<td>F</td>
<td></td>
</tr>
<tr>
<td></td>
<td>G</td>
<td>H</td>
</tr>
</tbody>
</table>

The segments:
A) name or department logo.
B) main title/subject e.g. organisation, documentation.
C) subdivision e.g. quality supervision.
D) codes
E) floppy file name and date of authorisation.
F) text, tables, diagrams etc.
G) make-up of document and initials of the QS.
H) initials of the authoriser (DH).

The following symbols can be used for a schematic summary:
4.4 LEVEL 2 DOCUMENTATION - PROCEDURES

If the quality policies of a department are set out in the Level 1 documentation with due regard to all of the issues considered in section 4.2, then that policy document will form a comprehensive foundation for quality within that department. The means of implementing these policies are the procedures in Level 2 of the Quality Manual. If quality is to be assured, then, as we have discussed in section 3.2.3, for each of these procedures, it is necessary not only to describe the objective and the scope of the procedure as well as the activities referred to by the procedure, but also who is responsible for the activities.

Since a complete quality system will require a large number of procedures, experience has shown that the best way to avoid omitting any important feature of a procedure is to formalise the process of writing procedures. By way of illustration, Fig 4.7 is an example of a procedure as it may appear in Level 2 documentation. The example chosen is self-referential, in that it describes how to write procedures, but there are several features of the procedure which should be noted in addition:

(1) As well as a title ("Procedure writing"), the procedure has a reference number (7.1.2.1). In the system used here (and other systems are available), the digits, apart from the last one, identify the subsection in the level 1 quality manual which points to the procedure. The last digit differentiates the procedure in case more than one is referred to by the Level 1 subsection. In the example given here, the first digit is the same as that of the section on control of the quality system, section 7.

(2) The procedure has an issue number and a date and its computer filename is displayed to facilitate retrieval.

(3) The authority for issue will normally be that of the Clinical Director, and the document will be issued by the Quality Manager.

(4) The style "page n of m" makes it immediately clear if any pages are missing from the procedure.

As a guide to producing a Level 2 procedures document, Appendix 3 includes level 2 procedures in the suggested list of contents. The numbering and headings of the level 2 procedures follow those of the level 1 policy manual. However, the procedure titles can be suggestions only, because individual radiotherapy departments will have fewer or more procedures than in the example illustrated. As in the example of the suggested contents list for the Level 1 document, the corresponding ISO 9000 requirements are indicated opposite the individual procedures.
Procedure 7.1.2.1
Procedure Writing

Scope and Objective
To provide written instructions to all staff so that their assigned tasks are clearly defined. Written instructions are provided only where their absence would carry the risk of error.

Responsibilities
Any member of staff may compile procedures but they will not be issued for use until authorised by the Clinical Director.

Documentation
no list of documents is required for this procedure

Method
1. Each documented procedure will have the following subsections:
   a). Scope and Objective - should state the extent to which the described activity is applied, and the purpose of the activity.
   b). Responsibilities - should specify the job titles of the staff with responsibilities for all or part of the activity described.
   c). Documentation - should specify the titles and/or reference numbers of any documents used in the activity or records created as a result of it.
   d). Method - should describe in a sequence of paragraphs, the individual steps of the activity preferably in chronological order.

2. The compiler and authoriser of procedures should remember that the activity will be audited against the documented procedure and the objective must therefore be achievable in practice, with realistic criteria. It must be sufficiently specific to give unambiguous information and guidance to the user, but no more. It should have regard to the skills of those user(s) defined in the Responsibilities subsection, as specified in the Management Responsibility and Training procedures, and be adequate for their purposes.

3. The procedure will be authorised for issue and distributed according to the Document Control procedure.

<table>
<thead>
<tr>
<th>filename for tracing purposes</th>
<th>this shows if pages are missing</th>
<th>date of issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Filename: PROCWRT.DOC</td>
<td>Page 1 of 1</td>
<td>Last changed: 28-May-97</td>
</tr>
<tr>
<td>Issue No. 1A</td>
<td>Authorised by:</td>
<td>Issued by:</td>
</tr>
</tbody>
</table>

this indicates usually authorised by the Director of the Centre usually issued by the Quality Manager

Figure 4.7 This illustrates one approach to writing procedures
4.5 LEVEL 3 DOCUMENTATION - WORK INSTRUCTIONS

While the procedures in the Level 2 documentation describe how policies are implemented and who is responsible for the activities described, the level of detail contained in a procedure is commonly insufficient to explain enough to a competent newcomer to the department to allow him or her to carry out the procedure unaided. Work instructions are included in Level 3 documentation to meet this need.

It is important to note that work instructions are not intended as a substitute for professional training; rather, they are intended to answer the questions which a competent worker could reasonably be expected to ask during the performance of a procedure: "which of the several possible drugs/SSDs/tumour doses/calculation techniques do you use in this department?"

Level 3 documentation is not necessarily restricted to work instructions. In some centres, pages of data such as percentage depth doses and documentation such as forms are allocated to Level 3. In other centres, such documentation is collected together in a fourth Level. There is no particular advantage in either approach, and the choice is simply a matter of taste.

The following example of a work instruction is typical for the detail it contains. Notice also that the same features occur as in the documentation at other levels, namely a reference number, an issue number and date, and spaces for signatures of those authorising and issuing.
Work Instructions 4.7.1.5
Daily Constancy Checks with Diode Dosemeter

<table>
<thead>
<tr>
<th>Machine: SL769/3E</th>
<th>Electrometer: 385</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Diode: 66607</td>
</tr>
</tbody>
</table>

Photons

**Method:**
1. 10 x 10 field centred on PHOTON phantom.
2. 100 cm SSD to surface of phantom.
3. Collimator and gantry at 0°.
4. Check diode is connected to DET A on rear.
5. Set switches to DOSE and DET A.
6. Switch on electrometer.
7. Press RESIST.
8. Set 100 MUs and take diode reading.
9. Repeat three times.
10. Switch off electrometer.

**Results:**
Ensure readings lie within Acceptable Range as recorded in red diode log-books.

*Report any readings outside this range to Physics.*

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**Figure 4.8** This is an example of a format for Work Instructions
APPENDIX 1

The principles and structure of a comprehensive quality system were summarised in a document agreed by members of National Societies of Radiotherapy, Medical Physics and Radiography, supported by the European Union initiative "Europe against Cancer".

This document was published in *Radiotherapy and Oncology* [a] and, as it forms the starting point for the present work, it is reproduced here as an Appendix.
Quality Assurance in Radiotherapy

European Society for Therapeutic Radiology and Oncology Advisory Report to the Commission of the European Union for the "Europe Against Cancer Programme".

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\textsuperscript{------}
\textsuperscript{1}This report was prepared during a meeting of representatives of National Scientific Societies of Radiotherapy and Medical Physics from European countries held in Brussels on 14th and 15th October 1994, on behalf and with the financial support of the Europe Against Cancer Programme of the Commission of the European Union.
Content

1. Introduction
   1.1 Background
   1.2 Quality assurance
   1.3 Basis of recommendations
   1.4 Application of recommendations

2. Aim of the organisation

3. Structure of the organisation
   3.1 Responsibility for quality
   3.2 Organisational relationships
   3.3 Departmental infrastructure
      3.3.1 Qualification of staff

4. Obtaining and maintaining the means and materials for radiotherapy treatment
   4.1 General
   4.2 National and international recommendations
   4.3 Safety and fitness for clinical use
   4.4 Documentation and Records
   4.5 Equipment replacement
   4.6 Quality audit
   4.7 Quality control of external beam treatment units
   4.8 Quality control of simulators and other devices and systems
      providing patient anatomical data
   4.9 Quality Control of Treatment Planning Systems
   4.10 Computer Systems
   4.11 Brachytherapy
   4.12 In-house equipment

5. Process control
   5.1 General
   5.2 Patient Data
   5.3 Treatment Protocols
   5.4 Treatment prescription and treatment planning
   5.5 Treatment Delivery
   5.6 Treatment Verification
   5.7 Treatment Summary and Follow-up
   5.8 Information Flow through the Radiotherapy Process
   5.9 Quality audit

6. Knowledge and Skill

7. Control of the quality system

Appendix 1. Definition of terms

Appendix 2. Quality control of external beam treatment units

References
1. Introduction

1.1 Background

Cancer incidence in Europe is increasing. Currently more than 1.2 million people per year are diagnosed within the European Union with a malignant disease.

It has been estimated that a little less than half of all cancer patients are cured from their disease. Out of a hundred cancer patients, approximately 22 will be cured by surgery, 18 by radiotherapy - alone or combined with other modalities but with radiotherapy as the prominent agent - and 5 by chemotherapy - alone or, more often, combined with other modalities (27). This illustrates that most cancer patients are cured by loco-regional modalities. With increasing efforts towards screening and early diagnosis it must be expected that an increasing number of patients will have cancers which are curable by loco-regional means. At the time of diagnosis approximately 70% of patients will have no detectable distant metastases and will be given loco-regional treatments alone, in which radiotherapy has a very prominent role.

Currently, about half of all cancer patients receive radiotherapy either as part of their primary treatment or in connection with recurrences or palliation. It must be anticipated that radiotherapy will have an increasing role due to the previously mentioned improvements in detection and early diagnosis. Furthermore, there is an increasing use of adjuvant radiotherapy treatments, firstly due to the trend away from radical surgery towards organ conserving surgery combined with radiation (e.g. head and neck cancer, sarcomas, etc) and secondly for patients with high risk of developing loco-regional recurrences (e.g. breast cancer, rectal cancer, etc).

The results of radiotherapy have been substantially improved over the years, but it is still estimated that one third of cancer patients who will die will do so as a consequence of failure to control the loco-regional disease (24). Although some patients will lose control of local failure also will develop distant metastases it is obvious that the minimal aim to achieve cure is tumour control in the loco-regional area. A fundamental requirement for all curative cancer therapy is therefore to achieve this objective.

The effect of radiotherapy depends on the dose applied, whilst the limiting factor is tolerance (e.g. radiation-induced morbidity) of the normal tissues surrounding the tumour. Such complications can occur acutely during (or immediately after) therapy, but the most serious complications normally occur after a latent period and may develop throughout the rest of the patient's life (late effects).
It has been estimated that within the European Union approximately ten million people are alive today after treatment for cancer. Of these, 1-2 million will have recurrent disease and will eventually die of the cancer, whereas the rest are considered cured. Of these cured cancer patients, approximately half have received radiotherapy and, if applied in curative doses, there is a probability that these patients will develop some side-effects to the treatment. The development of radiotherapy is therefore concerned with improving conformation of high dose regions to involved areas with the highest possible precision and at the same time reducing the dose of radiation to the surrounding normal tissue.

Recent developments in radiotherapy technology have created new possibilities for cure, but the superior performance of modern equipment cannot be fully exploited unless a high degree of accuracy and reliability is reached, which is only possible through quality assurance programmes.

Radiation therapy is a multidisciplinary specialty which uses complex equipment for delivery of treatment. This implies that both the parameters related to the patient (diagnosis, decision, indication for treatment, follow-up) and also the procedures related to the technical aspects of providing the therapy should be subjected to careful quality control. Whilst it has long been recognised that Quality Assurance (QA) in radiotherapy is vital to ensure the achievement of safe effective treatment, it has been increasingly acknowledged that a systematic approach to QA is necessary. This entails the establishment and implementation of quality systems, or comprehensive quality assurance programmes covering all aspects of the processes involved through diagnosis, treatment and follow-up.

The need for establishing general guidelines at the European level was identified through a survey of national policies of quality assurance in radiotherapy conducted by ESTRO (European Society for Therapeutic Radiation and Oncology) in 1993 across the European Union and neighbouring countries.

1.2 Quality assurance

Quality Assurance is defined most generally (13) as 'all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality (further definitions are given in Appendix 1). It is concerned with ensuring that the results actually achieved match the stated aims and
that predefined standards are fulfilled. Therefore it requires that aims are clearly defined and that endpoints are measurable in relation to standards.

Although the effectiveness of QA cannot be accurately quantified, it has been repeatedly demonstrated that careful quality control (QC) procedures do detect systematic and random errors which would have gone undetected otherwise. Because it would be unethical to conduct trials comparing treatments with and without QC, an exact measurement of its benefit is not possible. However, given the overall steepness of dose-effect curves, both for tumour control and for normal tissue damage probabilities, it is most likely that the actual implementation of stringent QC procedures has a significant impact on radiotherapy results.

A recent report sponsored by the Europe against Cancer initiative has considered general requirements for quality assurance in cancer treatment (28) and the current document can be viewed as an expansion of the particular recommendations for radiation oncology.

1.3 Basis of recommendations
The basis of the following recommendations is intended to be consistent with two existing general approaches:

(i) the generic approach of the WHO (29) document\(^1\) on Quality Assurance in Radiotherapy is endorsed, as it is based on the distillation of experience from a range of countries. In addition it is wide-ranging, emphasising the interdependence of quality assurance in all areas of radiation oncology. The medical, physical and technical aspects are so closely inter-related that requirements and recommendations must necessarily be included regarding all these aspects and the overall approach to quality assurance in radiotherapy must be multi-disciplinary and co-operative.

(ii) the framework of the recommendations is consistent with the ISO 9001 standards (14) as widely used in industry. The particular approach is based on the general standards for quality assurance in health care as formulated by the Dutch PACE project (20). This took as a starting point the assumption that a good outcome (product) can be expected when a department has good medical, and other, personnel and is well organised. The project then focused on the organisation of hospitals and departments and general standards were drawn up for the different aspects of their

\(^1\) An updated version of this document is currently under review
quality system. The standards produced are in agreement with ISO 9001 but are more appropriate to the situation in health care. A similar approach has been applied in UK recommendations for radiotherapy departments (6). The general philosophy is to indicate what should be regulated and not how it should be done. In this way the standards have greater flexibility than, for instance, the more detailed quality standards in use in the United States, such as AAPM 40 (2). Six standards for the establishment, implementation and maintenance of a quality system within any organisation have been formulated following the PACE approach, and these have then be used as the basis of a quality system for a radiotherapy department (20). They deal with clear definition and documentation of:

- the aims of the organisation;
- the structure of the organisation;
- the procedures for obtaining and maintaining means and materials;
- process control of all relevant activities;
- education and training (knowledge and skill);
- the means by which the quality system itself is controlled.

The recommendations in this document are laid out under six headings corresponding to these requirements.

1.4 Application of recommendations

Individual radiation oncology centres may be utilising very different levels of effort in quality assurance, depending on recommendations and protocols being followed and often reflecting resources available. No one rigid quality assurance programme is suitable in every circumstance. This set of recommendations is intended to provide a flexible framework, laying down principles which must at least emphasise the minimum acceptable standards, but which can incorporate more extensive recommendations in national or local situations where they already exist1. Therefore it is generally applicable to all centres, although it is recognized that local circumstances will influence the pace of implementation.

2. Aim of the organisation

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1 In many countries fragments or full reports have already been published as, f.i. in France (SFPH report, 1992) or in UK (Department of Health, 1991). The present report must then be taken as a complement rather than a new one which would replace the existing protocols.
The main aim of a radiotherapy department is to treat cancer patients (and a minority of non malignant conditions), taking into account available resources, manpower and expertise at the local, regional and national level.

Because the main aim is treatment, it is necessary to establish the definition of a *standard of care* against which a given practice can be audited.

Each radiotherapy department should clearly specify its own breadth of expertise. For example, particular tumours or some clinical situations may be rare or may require specific skill or equipment which may not be locally available. Also, particular regional epidemiology may require that some hospitals develop particular fields of expertise. Only tumour types with a recruitment large enough to ensure the development and maintenance of a good level of technical and medical skill should be included when defining the aims in a given department. Referral to specialized centres may prove more cost-effective and beneficial for the patient for less frequent tumours (retinoblastoma, total body irradiation, etc)\(^1\).

This implies that radiation oncology departments should develop their overall aims within a regional and/or national network and encourage the sharing of responsibility between neighbouring institutions in order to best promote the optimum care and treatment of each patient.

Local aims have to match local resources and the pattern of patient referral. Achieving effective cancer treatment requires a minimum level of staff facilities and equipment. Although there is no single international consensus on the level of these requirements, some initial work has already been carried out, eg. by the EORTC Radiotherapy Cooperative Group (17). In practice, aims and infrastructure are interdependent. The required infrastructure in a given centre can only be discussed when its aims have been clearly stated whilst, on the other hand, aims are impossible to set in detail without consideration of the available infrastructure. Defining the aims of a department should therefore be considered as a dynamic process, continuously influenced by the available infrastructure at any particular time.

\(^1\) For instance, it has been reported that the operative mortality after heart transplantation directly depends on the number of procedures performed each year in a given institution. Less than 9 procedures per year does not guarantee optimal outcome for the patient, probably because the medical and para-medical team do not build up sufficient expertise in this demanding field (JAMA 1994 15; 271: 1844-9).
be linked to any national legislation and to international recommendations (ICRP, IAEA, Euratom, IEC, CENELEC, ICRU).

4.3 Safety and fitness for clinical use
Clear chains of responsibility and communication should be established for equipment, such that there is no ambiguity as to its safety and fitness for clinical use. For example, in the event of equipment faults or suspected abnormal performance, the sequence of events should include: reporting of fault; confirmation and documentation of problem; diagnosis; repair if required; check of function and performance (to include dosimetry if the equipment is a treatment machine); final release for clinical use. The steps between reporting and final release should be carried out by appropriately qualified personnel, for example by engineering and physics personnel where a treatment machine is involved. Formal notification and hand-over procedures should be established between different groups of staff and between radiation oncology centre staff and any outside engineers, etc. to ensure that equipment can only be used clinically when it is positively confirmed as fit for use.

In general it is recommended to carry out hazard assessments where necessary and to include emergency contingency plans in local rules and procedures.

4.4 Documentation and Records
Local manuals for equipment operation and for procedures should be prepared in the local language. Careful documentation is required at all stages throughout equipment life. Records of performance of equipment and all test measurements should be kept. Fault conditions should be carefully documented. Documentation and records for all physical and technical aspects of equipment and treatment should be detailed enough to enable reconstruction of events in the future if required.

4.5 Equipment replacement
Equipment replacement and development programmes should be established and paid for, within the framework of local and national resources. Such programmes should be developed as part of the process of formulating infrastructure recommendations.

4.6 Quality audit
Dosimetric intercomparisons, or wider external audits of equipment dosimetry and performance, have been shown to be effective in highlighting problem areas and in
improving quality. It is recommended that each centre should participate regularly in such exercises. The introduction of external quality audit of equipment and dosimetry should be supported, but these activities should be coordinated at the international or national level to prevent unnecessary duplication of effort (7,17,18,26).

4.7 Quality control of external beam treatment units
Quality control of external beam treatment units is widely discussed in many sets of national and international recommendations and is historically the best-developed aspect of QC in radiotherapy (3,15,29). As a minimum, QC programmes for treatment units should include suitable initial and on-going constancy tests of: mechanical/geometric parameters; dosimetric performance; and safety systems. Appendix 2 deals with this in rather more detail, essentially for megavoltage equipment. Test methods, frequencies and tolerances should take into account any national requirements or recommendations. For different types of units, modified programmes are required, taking into account the different characteristics of the equipment and its clinical applications (4).

National legislation and international recommendations on radiation protection of patients, staff and the general public should be a minimum requirement in any radiation safety provisions in the installation and operation of treatment equipment.

4.8 Quality control of simulators and other devices and systems providing patient anatomical data
QC programmes for simulators should include as a minimum a similar set of mechanical/geometric tests as for a megavoltage treatment unit, with similar tolerances and frequencies on the critical parameters. Such a linking of QC requirements between linked pieces of equipment is necessary for consistent quality throughout the whole treatment process. Ideally, couches and scales on simulators should be compatible with those on the treatment units. In addition to these geometric parameters, other specific factors such as field wires and contouring devices should also be included. On the imaging side, the radiation parameters and image quality should be tested in essentially the same way as a diagnostic X-ray set, but taking into account the differences in operation. Film and processor systems should also be included in a similar way.

QC programmes for CT scanners for radiotherapy use, or CT facilities on simulators, and other imaging systems such as MRI or ultrasonography, should include consideration of: the geometric accuracy of the imaging system, couch and lasers; the
data display and data transfer and manipulation; as well as the accuracy and stability of other factors used as input to the treatment planning process, for example CT numbers.

Any other devices used for acquisition of patient anatomical data, e.g. mechanical or optical devices, or related devices such as block-cutters should also be included in compatible QC programmes (4).

4.9 Quality Control of Treatment Planning Systems

Recommendations on QA programmes and consistency of standards for treatment planning systems are currently not as well developed as for treatment units and simulators. There must be sufficient documentation to fully describe the operation of the system and its algorithms, in particular to allow the user to evaluate the accuracy of the beam models and the situations in practice in which they may become limited.

QC programmes, e.g. (2,4,15,16,23) should include initial and periodic tests of: hardware, including all input and output devices; data transfer, including beam data, patient data and image transfer; the integrity and stability of stored beam data; the operation of beam algorithms, for example for wedges, blocks, inhomogeneities, oblique incidence, non-standard treatment distances; and the summation algorithms. The performance of the treatment planning system can be tested by reproducing dose distributions which have been used as initial (measured) input data and then by comparing computations to measurements in beam distributions and plans which represent non-input situations.

An effective periodic check is to run a selection of typical sample plans, using the same 'patient' information and planning parameters and criteria on each occasion. By comparing the results of these standard 'patients' to the results obtained initially, any changes in performance can be identified. These and a sub-set of the acceptance tests should be carried out after any modifications of the hardware and after any new release of software.

Monitor unit calculations should be verified by comparison with manual calculation and by comparison with measurements.

In some geographical areas, quality audit systems are in existence or are under development which have the aim of testing many facets of clinical dosimetry, including
at least some aspects of treatment planning system performance. Participation in these exercises is encouraged, where they are available \(10,17,18,26\).

### 4.10 Computer Systems

Computer systems are now ubiquitous in the whole radiotherapy process: in treatment planning systems; controlling and linking treatment units, simulators and other equipment; in verification systems, patient information systems, and image transfer systems; and in many other applications. Software safety and performance verification is a widely studied topic, but there are not many recommendations for specific QA and QC in the field of radiation oncology computer applications. As a minimum, similar considerations can be applied as have been developed in the field of treatment planning systems, as regards documentation and hardware and software function tests. The methods should be tailored to the particular application. One critical area is that of computer-controlled treatment machines. Some guidance is given in this area in a recent AAPM report 35 \(1\). International recommendations are under development for common approaches to interfacing electronic data exchange between radiotherapy equipment (IEC).

### 4.11 Brachytherapy

Brachytherapy presents its own unique problems \(2,29\). Quality assurance programmes must address: source certification and identification; the calibration of sources, taking into account principles and procedures, quantities and units, and the timing and frequency of re-calibration; the incorporation of decay characteristics into the use of calibration data; the total activity and distribution of activity in particular sources; the selection or preparation of sources of the correct strengths and geometries; the correct insertion of sources; the reconstruction of source arrangements in the patient; the performance and accuracy of dose and time calculations; the safe removal of sources from the patient; and the safe care and custody of sources. QC programmes on remote afterloading systems should include, in addition, consideration of: the accuracy and reproducibility of positioning of sources in the applicator; the safe operation of the equipment; and the accuracy and functioning of the timer.

### 4.12 In-house equipment

The same quality standards should be applied to the supply, specification, performance and maintenance of equipment constructed in-house as to externally obtained equipment.
5. Process control

5.1 General

As a basic principle, the Euratom 84/466 recommendation is endorsed; management of the department should ensure that:

(i) no patient be administered a diagnostic or therapeutic medical exposure unless the exposure is prescribed by a medical practitioner;

(ii) medical practitioners be assigned the primary task and obligation of ensuring overall patient protection and safety when prescribing, and during the delivery, of medical exposure;

(iii) for therapeutic use of radiation (including teletherapy and brachytherapy), the calibration, dosimetry and QA requirements of the standards be conducted by, or under the supervision of, a qualified expert in radiation physics.

All activities, from the moment a patient enters the department until he/she leaves it, should be clearly stated, described and recorded. Departmental protocols and treatment policy documents should be produced and followed. This ensures consistency within the department and guarantees that each individual patient will be treated according to the same high standard of quality.

All procedures and processes must be sufficiently tested before clinical use. QA systems should incorporate checking methods at all possible points. Additional redundant checking and testing should be carried out wherever appropriate, preferably utilising independent approaches, in order to test the methods as well as the end result. Routine checking and counter-checking should be at sufficiently frequent intervals, relative to treatment duration, to detect errors as early as possible in the treatment course and such that any problems encountered can be rectified. Any stage at which numerical data is manipulated or transferred is vulnerable to error and requires stringent checking methods.

5.2 Patient Data

Patients and their record must be unambiguously identified in such a way that they can not be confused, either during treatment or during follow-up.
The following data, not necessarily in order of importance, must be collected and must remain available even after the treatment is finished:

(i) patient history, identification of risk factors, performance status, physical examination, clinical extent of disease.

(ii) If any other treatment has previously been performed, description of technique, immediate outcome and assessment of sequelae (eg. impotence, nerve palsy, leucopenia, etc).

(iii) Diagnostic work-up: additional studies should be performed as appropriate in order to establish the extent of local or distant spread.

(iv) A pathological diagnosis is an absolute requirement. If treatment is delivered without histological confirmation, a justification is required in any individual case (for instance, some brain lesions are not amenable to biopsy).

(v) All the pre-treatment evaluation must be summarized in a disease stage according to UICC or any other internationally agreed classification or staging system (e.g. FIGO).

(vi) Target volumes (using ICRU 38 (11) or ICRU 50 (12) definitions) and organs at risk must be identified and anatomically described in terms of position, shape and dimensions whenever necessary.

(vii) Treatment objectives must be clearly stated and recorded in the patient's file, i.e. radical treatment with curative intent, adjuvant treatment or symptomatic palliation.

(viii) Information regarding disease stage, prognosis and treatment acute and late effects should be given to the patient, taking into account the local cultural background. A record of this discussion should be kept in the medical file (information to the patient, information to the family). It may be useful to develop separate protocols regarding the provision of information to the patient in order to ensure intradepartmental consistency.

(ix) In addition, all details relating to patient measurements, patient calculations and patient treatment should be recorded and included in the patient file (see section 5.4).

5.3 Treatment Protocols

Treatment strategy must follow general guidelines which have been agreed upon, based on the results of clinical, radiobiological or physical studies. Patterns of care studies are also a way to identify areas of consensus in given clinical situations. As a

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1 Many countries have issued regulations regarding the legal minimum period for which medical records must be archived. Ideally, medical records should be kept during the patient's lifetime.

2 This is an important point. When late effects of treatment are assessed, one should be able to track the actual origin of any sequella.
general rule, exposure of normal tissue during radiotherapy should be kept as low as reasonably achievable and organ shielding should be used whenever feasible and appropriate.

(i) In order to ensure local consistency it is necessary to establish treatment protocols in each radiotherapy department.

(ii) The local department of radiotherapy should actively collaborate in, if not promote, multidisciplinary meetings where agreement on treatment protocols can be obtained at the hospital level. Multidisciplinary tumour boards should regularly and frequently take place where such matters as new treatment protocols, individual difficult cases, etc., can be discussed. A written report of decisions should be kept in the patient’s record.

(iii) Protocols are not made to be followed blindly. However, any deviation from local treatment protocols should be documented and the reasons for the deviation carefully recorded.

(iv) Ideally, such protocols should be discussed at the regional, national or international level. Consensus meetings with other specialists should be promoted at the national level.

5.4 Treatment prescription and treatment planning

It is strongly recommended that all treatment prescriptions be written, signed and dated by the radiation oncologist in charge of the case, prior to any treatment. Verbal prescriptions are a source of errors and misinterpretations. The prescription should include information regarding the identification of target volumes and organs or tissues at risk according to the relevant ICRU Report principles1. It should also include the total dose, fractionation schedule, total treatment time, planned interruptions, and a full description of the treatment technique.

The transfer of this information to the physics staff and/or to dosimetrists or radiation technologists for calculations and treatment planning must be organized in a systematic way, so as to limit the possibility of errors or misinterpretations.

Consistent terminology, incorporating the relevant definitions of international bodies such as ICRU, IEC, WHO, is recommended. It is essential to have common clear language for communication between the different professional groups within a centre as well as for the communication of treatment techniques and results between centres.

1 For example ICRU Report 50 for ‘Prescribing, recording and reporting photon beam therapy’ or ICRU Report 38 for ‘Dose and volume specification for reporting intracavitary therapy in gynaecology’.
QA and QC programmes on the treatment planning procedures for individual patients must be tailored to the methods in use in an individual department. As a minimum these should include considerations of: reproducibility of patient positioning; any necessary immobilisation to achieve this, with checks on mechanical and functional stability; unambiguous labelling and confirmation of patient-specific devices; and suitable testing of the application of and the results from the procedures - and criteria - involved in localisation, patient data acquisition, patient marking, simulation, and calculation of dose distribution (physical treatment planning) for each individual patient.

A major part of QC in this area should be concerned with checking and counter-checking measurements and calculations and checking and counter-checking the recording and transfer of data and instructions to and from the various stages of the planning process and to the treatment card or sheet (and to a treatment machine verification system if one is involved). Independence and redundancy in checks of these steps is recommended.

The evaluation of treatment plans, including review of isodose distributions, must be carried out prior to treating the patient and all parameters of these plans should be verified during the first set-up so that any discrepancy can be corrected immediately.

5.5 Treatment Delivery

QA programmes on treatment delivery should include written local protocols covering the techniques and procedures used. In addition there should be a written protocol covering the circumstances under which a treatment may begin. This may include, for example, the required series of planning checks and the requirements for signatures that these stages have all been completed and also that a clinician authorization signature is present.

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1 As a particular example, the treatment planning calculations of dose distribution and monitor units (or time) should be checked by an independent person, including all the parameters used in a manual calculation or entered into a treatment planning system. As an additional counter-check, independent methods can then be used to verify the calculation of the dose at a point, usually the isocentre. These can use manual checks, or checks using an independent computer system. One method of doing this which uses an independent approach is to calculate backwards from the monitor units entered onto the treatment card to the dose expected. Whatever system is used, pre-defined limits should be clearly established, and discrepancies between the two calculations which lie outside this should lead to further investigation of the plan parameters and calculations.
QA and QC programmes on the actual treatment delivery process should as a minimum include consideration of:

checks on correct patient, site and set-up, the latter covering similar requirements on positioning and immobilisation, as in the preceding section, with checks that these are the same as at the simulator or CT planning sessions;

checks on beam set-up, to ensure that all treatment parameters are as prescribed, that any beam modifiers or treatment aids are for that patient and are correctly positioned with respect to the patient and the treatment machine;

checks before and during irradiation, to ensure that the irradiation parameters (eg. modality, monitor units) are correct and that the machine functions and terminates correctly.

Reviews of treatment charts at intervals throughout the treatment have been shown to be useful in identifying problems with data transfer and treatment delivery (30).

5.6 Treatment Verification

Independent treatment verification systems are powerful checks on the achieved quality of the treatment delivered to the patient. Three mutually complementary systems can be used, together or separately. These are computerised record and verify systems, portal imaging and in-vivo dosimetry. Whilst the use of these systems can never replace the standard quality assurance procedures necessary in every radiation oncology department, nevertheless their use as quality assurance tools is strongly encouraged where resources, training and time allow.

Record and verify (RandV) systems can verify treatment parameter selection, and to a certain extent treatment set-up, as long as they are used in a way that satisfies some aspects of independence. A rigorous QA protocol on data input to the system must be established and applied. This should include checks and counter checks on the entered data before treatment begins. For example, if paper treatment charts are in use, these should be used as the primary information source on the first treatment session as an independent check of the information in the RandV system.

Portal Imaging can be used to verify relative positional aspects of treatment between patient and beam and between patient/beam and beam modifiers, such as blocks.
(shields). These systems, whether film or electronic, should be used at the initial treatment session to demonstrate correct coverage of the target volume and that organs at risk are not in the treatment field. Repeated portal imaging has been shown to decrease the incidence of treatment field placement errors (9).

In vivo dosimetry can verify the overall dosimetry of treatment delivery. Entrance doses can provide check information on a combination of the positioning of the patient, the calculation of monitor units, the selection of some treatment parameters and beam modifiers and the performance of the treatment unit throughout that particular treatment (21). Combined with exit doses, they can provide check information on some of the acquired patient data and on the performance of the treatment planning procedures (22). The careful use of measurements of this type can identify systematic uncertainties in the radiotherapy process, and can detect individual errors for particular patients or treatment fractions. The use of at least a minimum level of in-vivo dosimetry as a QA tool is encouraged.

Although these systems are useful QA tools, as already mentioned, their use implies the implementation of additional stringent QA programmes on their performance and utilisation.

5.7 Treatment Summary and Follow-up

Treatment sheets and radiotherapeutic forms should comply with minimum requirements aiming at helping physicians in retrieving and keeping trace of all clinical data and techniques relevant to treatments; facilitating exchange of information and statistical data processing and providing legal guarantees, to the extent that radiation oncologists can provide complete files.

Treatment reporting must follow ICRU Report 38 and 50 guidelines (11,12).

In addition to the absorbed dose distribution it should be noted that the biological dosimetry may involve other parameters relevant both to the probability of obtaining tumour control (cure) and the risk of developing morbidity. The most important parameters are:

(i) Tumour: total dose, dose per fraction, dose rate, overall treatment time, homogeneity of dose, tumour volume, oxygenation, histopathological origin and differentiation, tumour site.

(ii) Normal tissue: dose, dose per fraction, dose rate, overall treatment time, field size and volume treated, extent of organ involved in field, number of fields, position, dose heterogeneity, patient age,
individual (genetic) variation. It should be noted that normal tissue morbidity is still a very loosely defined parameter. This, therefore, demands an unambiguous description of symptoms and severity in addition to the organ involved.

Since the normal tissue tolerance is a limiting parameter in most situations in radiotherapy, it is the responsibility of the radiotherapist to assess and record the acute and late treatment-related morbidity. Because the occurrence of complications is delayed and may develop at any stage during the patient's life, all patients given radiotherapy for curative purposes should have regular follow-up by the radiotherapist or another qualified clinician to whom he may delegate this task. This requires a knowledge of the patterns and symptoms of the potential side-effects. The recording should preferably be performed by using scoring systems which have been established for various organs and tissues. The information collected should be used by the radiation oncologist to evaluate the quality of the delivered treatment and used to modify the therapy if necessary. It is the responsibility of each department to collect the necessary information on treatment outcome and to ensure that this is evaluated on a regular basis, i.e. organise its own internal clinical audit.

5.8 Information Flow through the Radiotherapy Process
Correct information flow (e.g., of data, images, instructions) through a department of radiation oncology is critical to the quality of the radiotherapy treatment and the importance of systematic QA and rigorous QC on this has been stressed in a number of the preceding sections, where particular instances arise. However information flow is such a fundamentally important consideration in all treatment- and associated- procedures, that it is deemed worthwhile to further reemphasise the necessity of checking and counter-checking, with redundant independent checking wherever possible. This is necessary at all points where information is transferred from one stage of the process to another, from one person to another, or from one information medium (e.g., paper, computer screen, instrument reading) to another.

5.9 Quality audit
Whenever possible, consideration should be given to the implementation of quality audit of the process. Internal audit exercises can be organised with the department whilst external audit can be effected by participation in multi-centre or wider programmes. One particular example is discussed in section 4.6.
6. Knowledge and Skill

The department as a whole, and its management in particular, should assume the responsibility of ensuring that the knowledge and skills of its various staff groups are maintained in a planned way. This requires a formal departmental policy on continuing education and necessitates the availability of resources.

It is the responsibility of each individual to ensure that he/she keeps informed of developments in the subject throughout his whole career but it is the responsibility of the head of department to ensure that there are sufficient opportunities for staff in all relevant groups to follow continuous education programmes. Particular training should be provided when new items of equipment and/or new procedures are introduced. Specific training in quality issues is required.

As regards equipment of various types, participation in users groups is encouraged, where particular problems and solutions can be discussed with other users and through which details of malfunctions and other problems or points of common interest can be circulated.

A scientific library where literature such as journals, textbooks, conference abstract books are available is useful. It allows free access of information to any department member.

Active or passive participation in scientific meetings, both in the hospital itself and at the regional, national, and when appropriate the international level should be encouraged and facilitated.

Attendance at meetings must be organised on a departmental basis to ensure that all collaborators have equal opportunities to follow educational programs. In particular, one has to take care that those people who are not involved in research are given the opportunity to go to congresses and seminars on a regular basis.

7. Control of the quality system

Procedures should be implemented by which the quality system itself is controlled. These include:

(i) establishing responsibility for quality in the department (section 3.1);
compromised. A minimum programme may be one in which the test frequencies are relaxed, but only by a limited amount (5,25). Any such minimum approach must be developed towards an optimum programme as time and resources allow.

A QC programme must be implemented on all dosimeters, to include regular calibration and stability checks, and on any support equipment, such as thermometers, barometers, etc. Any other test and measurement equipment should also be included in tailored QC programmes, for example phantoms, beam data acquisition systems, etc.

As a particular critical part of a commissioning and QC programme, special mention can be given to the initial and periodic dose calibration of treatment beams. The absorbed dose must be measured following the recommendations laid out in a modern dosimetry protocol (code of practice) based on a coherent set of the accepted physical data (eg. IAEA TRS 277, 1987). The protocol must be followed in detail to ensure consistency in dosimetry. Measurements must be carried out using an ionisation chamber having a calibration traceable to a primary or secondary standards laboratory. Independent verification of beam calibration is strongly recommended (8).
References


8. Dutreix, A., Hanson, W.F., Jarvinen, H., Johansson, K-a., and Thwaites, D.I. Recommendations for an independent verification of the initial output calibration of megavoltage radiotherapy units. in: Radiation dose in radiotherapy from prescription to delivery, IAEA TECDOC 734, IAEA, Vienna, pp 385-386.


APPENDIX 2

In general, the detailed contents of procedures, work instructions and forms depend on the practices of individual centres. For controlling the quality system, however, many departments will identify common core features, and these are contained in the following set of example procedures and forms.

Detailed examination of the procedures and forms in this Appendix will show that they form a complete, self-consistent set. That is, they refer to each other using the number system of the contents list in Appendix 3 and all of the procedures listed in section 7 of the contents list appear here (apart from procedure 7.1.2.1 which appears earlier, as Figure 4.7). Furthermore, the set of forms and procedures in this Appendix is consistent with those which are referenced in the flow diagram of the Management Review Cycle in Figure 3.x.
EUROPEAN RADIOTHERAPY CENTRE

Procedure 7.1.1.1
Document and Data Control

Scope and Objective

All documents that give instructions or information to personnel are controlled so that they are always available, relevant and up to date. They include documents generated within the European Radiotherapy Centre (ERC), such as Quality Manuals, as well as documents sourced externally such as statutory requirements, codes of practice, guidelines and national and international standards.

Responsibility

The Director of ERC authorises the issue of all controlled documents generated within the ERC. The Quality Manager distributes the documents. For documents sourced externally the nominated holder will be responsible for receiving amendments, modifying his or her copy and notifying all personnel affected by the change.

The Quality Manager will hold Distribution Lists of copies of documents, detailing individual copy holders. The nominated holder of each document will receive amendments, modify their copy as instructed, record the change on the Revision History page of the Manual if appropriate, and destroy superseded copies.

Documentation

Master List (Form 7.1.1.1(a))
Distribution List (Form 7.1.1.1(b))
Documentation Transmittal Form (Form 7.1.1.1(c)).
Wi 7.1.1.1

Method

1. The Quality Manager will maintain a Master List, itself a controlled document, that lists all controlled documents held in the ERC. Each entry will state the authority for issue of the documents and its issue number and/or date. In case of externally sourced references, the list will also state the holder and/or location.

2. The Quality Manager will hold the Reference Master copy of all ERC controlled documents as a reference for audit, comparing all copies with the Master.

Figure A2.1 Example of a procedure for controlling documents and data
3. The Master of each Manual will contain a Revision History page, amended appropriately, and authorised by the Director of ERC to record all changes.

4. New documents or amendments to old documents will be issued by the Quality Manager who will amend the Distribution List or Revision History sheet respectively, to record the issue. The nature of the changes to documents will, where possible, be highlighted by margin marks.

5. Changes to documents can only be authorised by the person who authorised the original issue, or specified in the relevant procedure.

6. Superseded pages of Master copies will be retained by the Quality Manager in a Superseded Document File. Superseded copies will be destroyed.

7. Each QA Procedure will be authorised for issue by signature(s) on the front page of each procedure. Each page will be uniquely identified by a "Page n of m" legend. QA procedures can be issued individually but only as complete procedures. Sets of procedures held by individuals will be contained within a QA Manual Cover Sheet, Revision History page and Policy Statement.

8. Externally sourced reference material such as manufacturers' manuals for equipment, statutory regulations and codes of practice, which relate to the requirements of the quality system, are recorded in the ERC Manuals Database. This database provides a master list and unique numbering system for these documents. (See WI 7.1.1.1)

9. Minor changes to documents may be written by hand, in ink, provided they are authorised (ie. initialled) by the individual who authorised the original document. Such handwritten minor amendments to contents lists and document control master lists may be authorised by the Quality Manager.
EUROPEAN RADIOTHERAPY CENTRE

Procedure 7.1.3.1
Quality Records

Scope and Objective
Records will be retained to prove conformance with the Quality System and procedures. Records will be retained for a specific period, maintained by a designated authority and held in protective environmental conditions.

Responsibility
The final user of each record is defined in the operational procedure that describes the use of the record. The guardian of the record in storage is defined in the List of Quality Records (Form 7.1.3.1(a)).

Documentation
List of Quality Records (Form 7.1.3.1(a)).

Method
1. Each Operational procedure that describes the use of a quality record also specifies the identification, collection and indexing of the document. The filing, storage and maintenance of each record are the responsibility of the guardian identified in the Schedule. All records will be legible and traceable to the relevant activity and readily retrievable if required for future use.

2. If the volume of records of a particular type in the office filing cabinets becomes excessive, the older records will be archived. The siting and method will be identified for each record. The period of retention of these archived records is included in the Schedule.

3. Where specified in service contracts/agreements, relevant records will be made available for inspection by customers for an agreed period.

4. At the end of the retention period the guardian will destroy the record.

Figure A2.2 Example of a procedure for maintaining quality records
EUROPEAN RADIOThERAPY CENTRE

Procedure 7.1.4.1
Management Review of Quality Standards

Scope and Objective
The effectiveness of the European Radiotherapy Centre’s (ERC) quality system is subject to regular review to ensure that it is appropriate to the services being provided and continues to support the Quality Policy. The Review is a forum for analysing all the measures of performance for the Quality System, assessing the information conveyed by these measures, and taking effective remedial action. All personnel with key responsibilities for quality are involved in the review process.

Responsibility
The Director of ERC will call the Review Meeting at the specified interval or when dictated by exceptional circumstances. The Quality Manager minutes the meeting and reports the findings from performance reviews, audits and corrective and preventive action analyses.

Documentation
Management Review Report (Form 7.1.4.1a))
Minutes of Management Review
Analysis of Quality Performance (Form 7.1.4.2a))

Method
1. At intervals not exceeding six months, a Management Review Meeting is held and chaired by the Director of ERC. The following are invited to attend: the Quality Manager and members of ERC as appropriate. The results of audits from the preceding six months are reported by the Quality Manager. All aspects of the Quality System are discussed including the Quality Policy and the need for Statistical Techniques. Key performance measures are reported to assess the effectiveness of Quality procedures. Where the need for a change in any element of the system or procedure is identified and agreed by the meeting, formal notification of the change follows the Document and Data Control procedures (QAP 7.1.1.1).

2. The meeting will consider expected service trends within ERC, statutory changes dictated by current ECC or national government legislation and best radiotherapy practice, and adjust the quality arrangements as necessary to cater for the expected service environment.

3. Future training needs will be assessed and arrangements made and resources applied to provide training and retraining where necessary.

Figure A2.3  The Management Review procedure, which is at the core of the Management Review Cycle
EUROPEAN RADIOThERAPY CENTRE

Procedure 7.1.4.2
Analysis of Quality Performance

Scope and Objective
In order that the Management Review can take appropriate corrective action to ensure the Quality System is always appropriate and effective and continues to serve the Quality Policy, it requires accurate and relevant data on the performance of the system. This procedure covers data collection, processing and reporting.

Responsibility
The Quality Manager collects data from selected operational areas and reports it in summary form to the Management Review.

Documentation
The Analysis of Quality Performance Report (Form 7.1.4.2(a)) is the key document, which is based on an analysis of selected indicators of quality. The sources are:

1. Complaints, direct or via a referring agent
2. Failures by Suppliers or Sub-Contractors
3. Failures within the European Radiotherapy Centre (ERC) to supply agreed treatment
4. Incidents
5. Delays in starting treatment
6. Patient Questionnaire problems
7. Audit Reports - Internal and External
8. Quality System/Procedural Failures
9. Concessions

Method
1. Every six months the Quality Manager will retrieve and scan the selected documents. He will summaries the data on the Analysis of Quality Performance Report (Form 7.1.4.2(a)).
2. The number of incidents in each period and cumulative totals will be compared with past performance. The Management Review will set targets for reduction of failures and authorize corrective action following increases in failure rates.

Figure A2.4 Procedure for the regular analysis of quality performance
EUROPEAN RADIOTHERAPY CENTRE

Procedure 7.1.5.4 Complaints

Scope and Objective

To ensure that both internal and patient complaints are responded to promptly, appropriately and by applying corrective action to rectify the immediate problem. There is also a subsequent analysis of the incident to identify trends and systemic failures that require changes to the Quality System and Operational Procedures. The aim is to prevent recurrence of the problem or error.

Responsibility

Complaints can be received verbally, by telephone or by letter, by any member of staff. The recipient applies prompt corrective action to solve the immediate difficulty and notifies the appropriate Section Manager (Clinicians, Physicists, Radiographers, Nurses) so that they can complete their part of the procedure.

Documentation

The Non-Conformity Report (Form 7.1.5.1(a)) is both an actioning document and record.

The Compliment Monitoring Record (Form 7.1.5.4(b)) records compliments from patients/carers.

Method

Patient Complaints

1. Patient complaints can be received orally by any member of staff during treatment within the European Radiotherapy Centre, and these are reported to the senior member of staff on duty.

2. After taking the appropriate action to rectify the complaint, a Non-Conformity Report will be completed and a copy sent to the Quality Assurance Manager for subsequent analysis purposes.

3. A written acknowledgement of letters of complaint is sent within three days, and, if investigation into the complaint is needed, the response should be within one week whenever possible.
4. The Quality Manager checks the progress of the complaint, in order to close off the Non-Conformity Report. The recipient of a patient complaint is responsible for undertaking its satisfactory resolution and informing the patient of the outcome.

5. The Quality Manager reports to the Management Review Meeting the number of complaints and the analysis of the reasons in accordance with QAP 7.1.4.1 and 7.1.4.2.

6. Patient Satisfaction Survey Forms are distributed on a periodic sample basis and the results of these will be considered and analysed as part of the Management Review process by the Quality Assurance Manager. Compliments are recorded by the Director or the Quality Manager on Form 7.1.2.4(8).

Internal Complaints

1. Any member of staff may raise a complaint if any part of the Quality System or Operational Procedures are defective. This includes failures by suppliers.

2. The complainant will take the appropriate corrective action immediately and then notify their Section Manager, who will raise a Non-Conformity Report, and who will send a copy to the Quality Assurance Manager.

3. The Non-Conformity Report will include full details of the problem and specify the required corrective action. The Quality Manager will confirm that corrective action has been effective, analyse the statistics of failure for reporting to the Management Review Meeting, and file the Report.

4. The Non-Conformity Report will specify the required corrective action, including individual responsibilities and time scales for action. The Report will then be passed to the Quality Manager who will confirm with the number of staff that the corrective action has been effective. The Quality Manager may test this effectiveness himself. He will then file the Report for routine corrective action analysis.
Procedure 7.1.6.1
Internal Quality Audit

Scope and Objective
The Quality System and Operational Procedures will be audited formally to obtain objective evidence of the effective functioning of each aspect of the intended controls. Audits will be performed to a plan agreed internally in the European Radiotherapy Centre (ERC) and the records will include specification of all corrective actions necessary to maintain compliance. Further audits will be performed at the discretion of the Quality Manager, or in response to particular problems.

Responsibility
The Quality Manager will plan and organise the audit schedule in conjunction with local arrangements for conducting the audit. The Director of ERC will audit those activities for which the Quality Manager has direct functional responsibility, to maintain independence.

The Quality Manager will accompany visiting auditors and will maintain records of all audits. He will be trained formally in Internal Quality Auditing and his Training Record so endorsed.

The Head of the function being audited is responsible for rectifying non-compliance by application of the agreed corrective action, through the staff concerned, which is subsequently monitored by the Quality Manager.

Documentation
Audits and subsequent re-audits will be recorded on a schedule (Form 7.1.6.1(c)). Individual audit results will be recorded and verified on the Audit Forms (Form 7.1.6.1(b)). Corrective Action Following Audit will be recorded on Form 7.1.6.1(a). The audit reports will be summarised on Form 7.1.6.1(d). The forms will be retained to provide a historical record of systems compliance.

Method
1. Each element of the Quality System is audited at intervals not exceeding six months. The schedule for each Section or activity is shown overleaf (paragraph 3).
2. The Quality Manager will prepare an audit checklist for each Section or activity, including the following elements:
   - Naming the auditor (especially for cross-audit for independence);
   - Liaison for auditing;
   - Access to relevant procedures;

Figure A2.9 Example of a procedure for internal quality audit
3. The audit of the Section or activity will include the following steps:

- Confirm that the operator performs the activity as specified, by comparison with the written procedure, to ensure the procedures, documents, tools, training and environment are appropriate to support the quality aim.
- Take sample documents and confirm that they are correctly written, distributed, actioned and filed.
- Check the task was completed correctly on previous occasions, by reviewing records.
- Bring discrepancies to the notice of the operator and departmental supervisor.
- Record the results of the audit on Form 7.1.6.1(b).
- Agree the course of corrective action and the deadline for the action to be completed.
- Record the findings and the agreed action on Form 7.1.6.1(a).
- Re-audit to confirm the effectiveness of the corrective action.
- Record the results on Form 7.1.6.1(a).
- File Form 7.1.6.1(a).

4. The auditor will retain unclered Audit Reports for the purposes of Re-audits, which will be included in the Audit Schedule.

5. Successful audits will also be recorded so that the basis of the conformance is known. This will enable the auditor of the audit to re-confirm the audit technique.

6. The statistics of successful and non-conforming audits will be analysed and presented to the Management Review on Form 7.1.6.1(d). Consistent failures and trends will be identified for corrective action.
FORM 7.1.6.1(a)

EUROPEAN RADIOThERAPY CENTRE

CORRECTIVE ACTION FORM (following audit)

Auditor's Name: Form Number:

Sections Audited: Audit Reference:

1. Procedure audited:

2. Variations Noted:

3. Above Variation Accepted: (Signature Section Head)

4. Corrective Actions Required:

   Deadline:

5. Above Variations Now Clear: Signature Date

6. Possible System Modifications:

7. Audit Closed Signature Date

Figure A2.16 Example of a form for recording corrective action following audit
APPENDIX 3

This Appendix illustrates one suggested format for the contents of Level 1 and Level 2 of a quality manual. The illustration is given with some reservations, because it might lead to a misunderstanding that this is the definitive approach. This supposition would be wrong. The format of the quality manual should develop naturally from the way each individual centre implements the principles set out in this Report according to its own particular circumstances. The scope of the quality system may be wider or narrower than we have suggested here, and will depend upon the requirements of the centre. The illustration should therefore be considered merely as an example of one possible starting point for constructing one's own, individual manual.

In the following example, the section headings and numbers in bold type are those of QART [a] which is reproduced in Appendix 1. Two of these sections may be considered to set out policy without necessarily requiring supporting procedures, and so they only appear in the contents of the Level 1 manual. In order to illustrate the correspondence with ISO 9000, the relevant section numbers from that standard are shown opposite the appropriate policy sections and procedures.

Level 1 - Policy Document

Corresponding section of ISO 9000

1. Introduction
   1.1 Background
   1.2 Quality assurance
   1.3 Basis of recommendations
   1.4 Application of recommendations

2. Aim of the organisation
   2.1 Aim of the organisation

3. Structure of the organisation
   3.1 Responsibility for quality 4.1.1, 4.1.2.3
3.2 Organisational relationships
3.3 Departmental infrastructure
  3.3.1 Qualification of personnel
  3.3.2 Equipment and infrastructure

4. Obtaining the means and materials for radiotherapy treatment

4.1 General
  4.1.1 Evaluation of suppliers
  4.1.2 Purchasing data
  4.1.3 Acceptance inspection and testing
  4.1.4 In-process inspection and testing
  4.1.5 Final inspection before release for clinical use
  4.1.6 Documentation and records
  4.1.7 Control, calibration and maintenance of inspection, measuring
       and test equipment
  4.1.8 Inspection and test status of equipment
  4.1.9 Handling and storage of equipment

4.2 National and international recommendations
4.3 Safety and fitness for clinical use
4.4 Documentation and records
4.5 Equipment replacement
4.6 External quality audit
4.7 Quality control of radiotherapy equipment

5. Process control

5.1 General
  5.1.1 General patient care
5.2 Patient data
5.3 Treatment protocols
5.4 Treatment prescription and treatment planning
5.5 Treatment delivery
5.6 Treatment verification
5.7 Treatment summary and follow-up
5.8 Information flow through the radiotherapy process
5.9 Quality audit

6. Knowledge and skill

6.1 Knowledge and skill
7. Control of the quality system

7.1 Control of the quality system
7.1.1 Document and data control 4.5
7.1.2 Quality system 4.2
7.1.3 Quality records 4.16
7.1.4 Review of quality performance 4.1
7.1.5 Corrective and preventive action 4.14
7.1.6 Internal quality audit 4.17
7.1.7 Statistical analysis of service 4.20
In the following list of procedures, the procedure numbers are sequential, and each is prefaced with the number of the level 1 policy section which points to the procedure. The procedures which appear in section 7 - Control of the Quality System - appear as examples in Appendix 2, along with associated forms.

Many of the following procedures point to work instructions. For example, procedure 4.7 should point to work instructions for radiation dose measuring equipment, linear accelerators, KV X-ray units, Grenz-ray sets, treatment planning computers, dedicated CT scanners, dedicated MRI scanners, afterloading units, brachytherapy sources, etc.

Again, it must be emphasised that this list is illustrative only, and certainly not exhaustive or complete.

**Level 2 - Procedures Document**

**Section 3 - Structure of the organisation**

3.3.2.1 Contract review and resource assessment 4.3, 4.1.2.2

**Section 4 - Obtaining and maintaining the means and materials for radiotherapy treatment**

4.1.1 Preventive maintenance 4.9, 4.10, 4.11
4.1.2 Decommissioning of cobalt units 4.9
4.1.1.1 Supplier control 4.6
4.1.2.1 Tendering process 4.6
4.1.2.2 Specifying and ordering equipment 4.6
4.1.3.1 Acceptance testing of equipment 4.9, 4.10, 4.11
4.1.4.1 Dosimetry 4.9, 4.10, 4.11
4.1.5.1 Commissioning equipment for clinical use 4.9, 4.10, 4.11
4.1.9.1 Handling and storage of equipment 4.15
4.3.1 Permit-to-Work on radiotherapy equipment 4.9
4.3.2 Radiation safety 4.9
4.5.1 Equipment replacement 4.1.2.2
4.6.1 External quality audit none
4.7.1 Quality control of radiotherapy equipment 4.9, 4.10, 4.11
Section 5 - Process Control

5.1.1.1 Provision of cleaning and catering facilities 4.7
5.1.1.2 Portering 4.7
5.1.1.3 Car parking 4.7
5.1.1.4 Reception 4.7
5.1.1.5 In-patient care and monitoring for patients receiving radiotherapy (nurses) 4.7
5.1.1.6 Patient care (radiographers) 4.7
5.1.1.7 Patient care (isotope suite) 4.7
5.1.1.8 Patient referral from radiographers to nurses 4.7
5.1.1.9 Radiotherapy safety aspects of caring for patients receiving brachytherapy and unsealed sources 4.7
5.1.1.10 Nursing care for patients in brachytherapy suite 4.7
5.1.1.11 Nursing care for children undergoing radiotherapy under general anaesthetic 4.7
5.1.1.12 Out-patients clinic 4.7
5.1.1.13 Administration of blood transfusions by nursing personnel in the Oncology Clinic 4.7
5.1.1.14 Patient hostel 4.7
5.2.1 Patient data 4.8
5.3.1 Patient referred for consideration for radiotherapy (doctors) 4.9
5.3.2 External-beam radiotherapy (doctors) 4.9
5.3.3 Brachytherapy (doctors) 4.9
5.3.4 Unsealed sources (doctors) 4.9
5.4.1 Simulator (radiographers) 4.9
5.4.2 CT scanning (radiographers) 4.9
5.4.3 Ultrasound (radiographers) 4.9
5.4.5 External beam treatment planning (physicists) 4.9
5.4.6 Brachytherapy planning (physicists) 4.9
5.4.7 Unsealed sources (physicists) 4.9
5.4.8 Total-body irradiation - planning and treatment delivery (physicists) 4.9
5.4.9 Mould room activities 4.9
5.4.10 Preparation and storage of sealed radioactive sources by mould room staff 4.9
5.5.1 Remote after-loading (radiographers) 4.9
5.5.2 Treatment delivery (radiographers) 4.9
5.5.3 Handling of unsealed radioactive sources (radiographers) 4.9
5.5.4 Incidents in the isotopes department (radiographers) 4.9
5.6.1 Treatment verification (radiographers) 4.9
5.7.1 Treatment summary and follow-up 4.8
5.8.1 Patient referrals 4.8
5.8.2 Admitting and discharging patients 4.8
5.8.3 Identification and traceability of patient registration documents, notes, X-rays and treatment accessor 4.8
5.8.4 Archiving patients' notes 4.8
5.8.5 Gatekeeping and contract monitoring - extra-contractual referrals 4.8
5.8.6 Secretarial activities 4.8
Section 6 - Knowledge and skill

6.1.1 Training records 4.18
6.1.2 Personnel development 4.18

Section 7 - Control of the quality system

7.1.1.1 Document and data control 4.5
7.1.2.1 Procedure writing 4.2
7.1.3.1 Quality records 4.16
7.1.4.1 Management review of quality standards 4.1
7.1.4.2 Analysis of quality performance 4.20, 4.1
7.1.5.1 Corrective and preventive action 4.14
7.1.5.2 Incidents 4.14
7.1.5.3 Concessions 4.14
7.1.5.4 Complaints 4.14
7.1.6.1 Internal quality audit 4.17
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