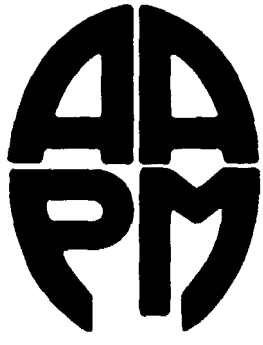
AAPM REPORT NO. 46

COMPREHENSIVE QA FOR RADIATION ONCOLOGY



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COMPREHENSIVE QA FOR RADIATION ONCOLOGY

REPORT OF
TASKGROUP NO.40
RADIATION THERAPY COMMITTEE

AAPM

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Comprehensive QA for radiation oncology: Report of AAPM Radiation Therapy Committee Task Group 40

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PREFACE

This document is the report of a task group of the Radiation Therapy Committee of the American Association of Physicists in Medicine and supersedes the recommendations of AAPM Report 13 (AAPM, 1984). The purpose of the report is twofold. First, the advances in radiation oncology in the decade since AAPM Report 13 (AAPM, 1984) necessitated a new document on quality assurance (QA). Second, developments in the principles of quality assurance and continuing quality improvement necessitated a report framed in this context.

The title "Comprehensive Quality Assurance for Radiation Oncology" may need clarification. While the report emphasizes the physical aspects of QA and does not attempt to discuss issues that are essentially medical (e.g., the decision to treat, the prescription of dose), it by no means neglects issues in which the physical and medical issues intertwine, often in a complex manner. The integrated nature of QA in radiation oncology makes it impossible to consider QA as limited to, for example, checking machine output or calibrating brachytherapy sources. QA activities cover a very broad range, and the work of medical physicists in this regard extends into a number of areas in which the actions of radiation oncologists, radiation therapists,[1] dosimetrists, accelerator engineers, and medical physicists are important. Moreover, this is true for each of the disciplines--each has special knowledge and expertise which affects the quality of treatment, and each discipline overlaps the others in a broad "gray zone." It is important not only to understand each discipline's role in QA, but to clarify this zone so that errors do not "fall between the cracks." This report therefore attempts to cover the physical aspects of QA both in a narrow or traditional sense and in a more integrated sense.

The report comprises 2 parts: Part A is for administrators, and Part B is a code of practice in six sections. The first section of Part B describes a comprehensive quality assurance program in which the importance of a written procedural plan administered by a multidisciplinary committee is stressed. In addition, terms used in quality assurance and quality improvement are given in the Definitions section at the end of the report. The second section of Part B concerns QA of external beam therapy equipment. It relies heavily on AAPM Report 13, with, we hope, some clarification, and adds material on recent innovations in accelerators and measurement equipment. The third section describes QA for treatment planning computers. The fourth covers the treatment planning process and QA procedures for individual patients. The fifth, considers the new specifications of source

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strength and emphasizes the use of redundant systems for source strength calibration and checking. The sixth section is the most clinical and discusses new patient conferences, film review, chart review, and a detailed protocol for chart checking. Appendix A contains descriptions of the roles and responsibilities of the different members of the QA team which reflect the ideas of this interdisciplinary task group comprising dosimetrists, radiation oncologists,, radiation therapy physicists, and radiation therapists. Appendix B defines some terms in quality assurance and quality improvement. In some areas, the recommendations in this report differ from AAPM Report 13: "Physical aspects of quality assurance in radiation therapy," AAPM (1984).

A few comments on terminology are in order. This report distinguishes three levels of imperatives. In order of significance, these are

Shall or must. These terms are applied when the imperative is required by appropriate regulatory agencies.

Recommend. Phrases like "we recommend" are applied to procedures that the task group considers important to follow. While the recommendations reflect the careful considerations of the task group on QA procedures and the tolerance and frequency of QA tests (which are often consistent with other reports), and while it is important that reasonable attempts should be made to follow them, it is also important that they not be followed slavishly. There will be instances where other approaches may prove equal to or better than the recommendations in this report; however, modifications should be instituted only after careful analysis demonstrates that quality would not be compromised.

Should. There are instances where explicit tolerance levels and frequencies are not appropriate, or in which quality of care can clearly be maintained via different avenues. In these instances, which apply to a number of QA, modal words such as "should" are used. The task group recognizes the complexity of the treatment planning and treatment process, and the inadvisability of giving strict directives to every aspect of the processes and procedures touched upon in this report. However, where appropriate, the task group considered it worthwhile to suggest avenues for such QA.

If quality of care is to be improved, enlightened leadership by hospital management and clinical leaders is required. This leadership should instill the desire for improving quality of care and provide the means, both in structure and support, to accomplish that end. Moreover, the process for improved care should be implemented in an atmosphere of mutual support between different medical disciplines and hospital administration. Within radiation oncology itself, coordination is critical among radiation oncology physicists, dosimetrists, accelerator engineers, radiation oncologists, radiation therapists, and administrators. The various groups are brought into coordinated efforts through well-documented QA procedures administered by a multidisciplinary QA committee.

Finally, we should mention that we are aware that a report of this type must come to terms with two conflicting principles, namely that QA should reflect the highest standards, and that those very standards usually lead to increased operational costs to the institution[2]-especially as the standards approach their practical-limits. We have no ready answer to this dilemma. Nevertheless, we have tried to balance these two principles in our recommendations, to report what we consider to be standards of practice in the field, and where none exist, to suggest new standards which we feel are consistent with the principle of balancing quality and cost.

CONTENTS

PART A: INFORMATION FOR RADIATION ONCOLOGY ADMINISTRATORS

In treating patients with radiation, the radiation oncologist prescribes a treatment regimen (including the radiation dose) whose goal is to cure or control the disease while minimizing complications to normal tissues. In general, published clinical and experimental results demonstrate that the response of tumors and normal tissues to radiation is highly variable. Moreover, for some tumors and normal tissues the dose response curves may be very steep in the therapeutic dose range, i.e., a small change in dose can result in a large change in clinical response. In addition, the prescribed radiation dose to the tumor is usually, by necessity, constrained by the tolerance dose of the surrounding normal tissues. Consequently, since the "window" for optimal treatment can be quite narrow, the radiation dose must be delivered accurately and consistently.

Delivery of treatment in an accurate and consistent manner is by no means easy to achieve, since the radiation therapy process is a complex interweaving of a number of related tasks for designing and delivering radiation treatments. The first step in this process occurs during and following the initial consultation, and includes a clinical determination of the extent of the disease and a determination of patient-specific parameters (e.g., surface anatomy, internal organs, and tissues including the tumor) acquired from a number of diagnostic imaging sources such as conventional radiography, CT, sonography, MRI, etc. Once the decision to treat has been made, the plan of treatment requires a synthesis of the patient-specific parameters in order to determine the size, extent, and location of the tumor (target volume) in relation to the normal organs and the external surface anatomy. Special equipment for determining patient-specific contours and for simulating the planned treatment (simulators) are typically used to facilitate the process. The intended distribution of radiation dose to the patient is then determined from a treatment planning system consisting of software algorithms running on computer hardware. These planning systems require entry of radiation machine beam parameters that will result in a precise match between calcu-

lated and measured data (usually obtained following installation and during commissioning of the treatment machines) representing the radiation characteristics of the radiation treatment units. To treat the patient as planned requires accurately calibrated treatment units and the availability of treatment aids and immobilization devices for positioning and maintaining the patient in the planned position. Finally, verifying the correct delivery of treatment may require the use of portal and verification radiographs, in vivo dosimetry, and record-and-verify systems.

The International Commission on Radiation Units and Measurements (ICRU, 1976) has recommended that the dose be delivered to within 5%[3] of the prescribed dose. Considering the many steps involved in delivering dose to a target volume in a patient, each step must be performed with an accuracy much better than 5% to achieve the ICRU recommendation. For example, if only three steps were involved (e.g., tumor localization, dose calculation, and machine calibration)-and the uncertainties in each step were independent of one another-then better than 3% accuracy would be required for each step to attain an overall accuracy of 5%. In reality, more than three steps are involved in the planning and treatment process; this makes an estimate of the accuracy and consistency required in each step much more difficult to evaluate.

To meet such standards requires the availability of the necessary facilities and equipment including treatment and imaging units, radiation measuring devices, computer treatment planning systems and the appropriate staffing levels of qualified radiation oncologists, radiation oncology physicists, dosimetrists, and radiation therapists. It is, therefore, especially important to realistically assess the staffing needs in radiation oncology. Furthermore, the complexity of treatment modalities is increasing. For example, medical linear accelerators contain computer control systems which need careful scrutiny to assure proper and safe operation. Moreover, computerized low and high dose-rate remote afterloaders have sophisticated control systems. Treatment planning systems have become larger and more complex. Several sophisticated options have become standard on commercial and locally developed treatment planning systems (e.g., three-dimensional beam's-eye-view planning, digitally reconstructed radiographs, three-dimensional dose computation and display, dose volume histograms, and so on). The commissioning and quality assurance of such complex systems requires increasing personnel training and time.

Parallel to the difficulties inherent in the more complex software and hardware systems, there have been increasing expectations on the quality of treatment which lead to greater and more complex QA procedures for every aspect of the design and delivery of radiation. These expectations have arisen from a growing appreciation of the importance of QA as described in a number of reports, and from the regulations of national, state, and local authorities and accreditation bodies. While the aim of QA is to improve the care of patients treated with radiation, its increased costs in staff and equipment-which often follows from additional or more refined QA procedures-cannot be ignored. High quality care can result only from careful application of the principles outlined in this report and elsewhere, by well educated and trained staff with the time to apply these principles. We therefore recommend that radiation therapy facilities be staffed at levels that follow the guidelines given in the "Blue Book," the Report of the InterSociety Council for Radiation Oncology (ISCRO, 1992). We further recommend that facilities with one or more multimodality megavoltage medical accelerators have a full-time qualified radiation oncology physicist.

To cope with the ever increasing complexity of the treatment process, it is important that QA processes and procedures emanate from a single body, a QA committee (Sec. I C). This committee usually draws its immediate authority from the chairman of the department of radiation oncology, although in certain areas (e.g., radiation safety) authority may come directly from hospital administration. The members of the QA committee should include a representative from each of the subdisciplines described below. The nature of the QA process for these disciplines is quite varied and intertwined. The roles and responsibilities of the members of four of the subfields, namely radiation oncologists, radiation oncology physicists, dosimetrists, and radiation therapists are therefore discussed below and in Appendix A. However, the QA committee is a much larger entity and should include nurses, the department administrator, a representative of the hospital's QA committee, and others as warranted.

Radiation Oncologist. Only radiation oncologists with delineated hospital privileges may be responsible for consultation, dose prescription, on-treatment supervision and treatment summary reports. They should be certified by one of the recognized boards (the American Board of Radiology or its equivalent). We recommend that the radiation oncology representative in the QA team be certified by one of these boards.

Radiation Oncology Physicist. The radiation oncology physicist is responsible for the calibration of the therapy equipment, directs the determination of radiation dose distributions in patients undergoing treatment (i.e., computerized dosimetry planning or direct radiation measurement), and is responsible for the weekly review of the dose delivered to the patient. The radiation oncology physicist certifies that the treatment machine is performing according to specifications after it is installed, generates the data necessary for accurate treatment planning and delivery of the radiation therapy, outlines written QA procedures which include tests to be performed, tolerances, and frequency of the tests, and understands and appropriately responds to machine malfunctions and related safety issues, Moreover, the radiation oncology physicist should perform a yearly review of the policies and procedures manual of the department of radiation oncology. We recommend that the radiation oncology physicist be certified in radiation oncology physics by the American Board of Radiology, American Board of Medical Physics, or the Canadian College of Physicists in Medicine, and hold an appropriate state license, where applicable.

Radiation Therapist. The radiation therapist is responsible for accurately delivering a planned course of radiation therapy as prescribed by a radiation oncologist. The radiation therapist is also expected to recognize any change in the

patient's condition and determine when treatment should be withheld until a physician is consulted. Additionally, the radiation therapist should be able to detect any equipment deviations or malfunctions, understand the safe operating limits of the equipment, and should be able to judge when, due to equipment malfunctions and problems, or errors in the proposed treatment, to withhold or terminate treatment until the problem has been resolved. We recommend that the radiation therapist have credentials in radiation therapy technology as defined by the American Registry of Radiologic Technologists or possess suitable equivalent qualifications, or hold an unrestricted state license in radiation therapy technology, where applicable.

Medical Radiation Dosimetrist. The medical dosimetrist is responsible for accurate patient data acquisition, radiation treatment design, and manual/computer-assisted calculations of radiation dose distributions (AAMD, 1981). In consultation with the radiation oncology physicist and radiation oncologist, the dosimetrist generates and documents an optimal treatment plan for each patient. The final plan is reviewed by the radiation oncology physicist. The dosimetrist may also assist with machine calibrations and ongoing QA under the supervision of the radiation oncology physicist. We recommend that medical dosimetrists be certified by the Medical Dosimetry Certification Board, or possess the credentials for board eligibility (MDCB, 1991).

In summary, a decision to provide a community with a radiation oncology facility involves a decision to enlist the services of a full radiation oncology team: radiation oncologists, radiation therapists, radiation oncology physicists, and dosimetrists. In addition to providing a radiation oncology facility with space and resources including treatment planning and treatment delivery equipment, it is also important to provide the appropriate dosimetry instrumentation for commissioning and QA of these devices (e.g., ionization chambers, computerized data acquisition dosimetry system, etc.). It is also important to arrange for proper maintenance of this equipment under the supervision of a qualified radiation oncology physicist, and to ensure that the treatment machines, simulators, and computer treatment planning equipment are available during normal working hours for QA tests to verify that they are performing according to specifications. Such QA tests-which are described in detail in the main report-may include spot checks of machine calibration by the therapist prior to initiation of daily treatment, more extensive scheduled QA tests on the treatment units and simulators by the radiation oncology physicist, scheduled machine maintenance by the engineers, scheduled yearly recommissioning of the treatment units, and so on.

It is important to reiterate that QA is required in all areas involved in the radiation therapy process. A comprehensive QA program should not focus just on the analysis of a narrow set of treatment variables, but rather should attempt to understand the cumulative effects of uncertainties in the complete treatment process. Thus the QA program has clinical, physical, and administrative components and its implementation requires the teamwork of all personnel. A separatist approach is no longer tenable (Thompson, 1992); a shared mission is an important feature of the continuing quality improvement (CQI) emphasized by JCAHO, the Joint Commission on Accreditation of Hospital Organizations (JCAHO, 1992). While CQI is very broad based-including not only a representative and varied hospital management team, but patients and third party insurers as well-the following document focuses on the specific processes involved in providing quality care through the concerted and combined efforts of radiation oncology physicians, physicists, therapists, and dosimetrists.

PART B: CODE OF PRACTICE

I. COMPREHENSIVE QA PROGRAM

A. Introduction

"Every patient with cancer deserves to receive the best possible management to achieve cure, long-term tumor control or palliation": this is the major goal of cancer management (ISCRO, 1986). The "quality" of radiation oncology can be defined as the totality of features or characteristics of the radiation oncology service that bear on its ability to satisfy the stated or implied goal of effective patient care [see Definitions section for definitions developed by the international community (ISO, 1986)]. Every radiation oncology department should establish a "quality plan" which states the specific quality practices, resources and activities relevant to the service it provides. This calls for a treatment team that is committed to a policy of quality throughout all activities they perform. The team leaders must establish a "quality system" herein known as the Comprehensive Quality Assurance Program, that provides the organizational structure, responsibilities, procedures, processes and resources for assuring the quality of patient management. (See Definitions).

It is important to mention that quality of care must be an intended goal and exist in practice before procedures to assure it can be developed. "Quality assurance" is all those planned or systematic actions necessary to provide adequate confidence that the radiation oncology service will **satisfy** the given requirements for quality care (see Definitions).

The Joint Commission on the Accreditation of Health Care Organizations (JCAHO) has the role of auditing the quality of patient management. Its publications detail its criteria for documenting the quality of patient care (JCAHO, 1987, 1992). The comprehensive quality assurance program of the radiation oncology service (hereafter called QA program) must fulfill the JCAHO requirements as well as any recommendations set forth in this document as the minimum QA requirements. The American College of Radiology (ACR) also has Standards for Radiation Oncology which specify a QA program including patient chart review (ACR, 1990).

B. Comprehensive QA Program

The physician, physicist, dosimetrist, and therapist, along with other members of the treatment team, should collaborate on developing a written QA program (Quality System) which details the quality control tests and procedures, their frequency, the action criteria, the records required and the

personnel required to perform them. Most importantly, the QA program should have a QA committee (discussed below) and include a feedback mechanism to that committee so that the cause of any shortcomings can be addressed and corrected. The QA program should be comprehensive in that it covers the quality of all aspects of patient care: services (such as taking patient data, making appointments, diagnosis, treatment planning, treatment, and follow-up), products (e.g., customized beam blocks, immobilization devices, individualized compensators), equipment used (accelerators, simulators), psychological well being and the records of all aspects of diagnosis, planning, treatment, and follow-up. The JCAHO states that "the physician director of the radiation oncology department/service is responsible for assuring that the process is implemented" (JCAHO, 1987).

C. QA Committee

The JCAHO requires that quality assurance in radiation oncology be a part of the hospital's QA program (JCAHO, 1987), and more recently, that a program of continuous quality improvement be implemented (JCAHO, 1992). This is discussed in more detail below. In order to assure the many facets of quality in the radiation oncology service, a Quality Assurance Committee (QAC) should represent the many disciplines within radiation oncology. At the least, the QAC should include a member each from the areas of medicine, physics, and treatment. The committee members should be appointed by the senior management of the department (who may also be members of the committee).

We recommend that the QAC oversee the QA program, have the responsibility of assisting the entire radiation oncology staff to tailor the recommendations of this and other reports to their radiation oncology practice, monitor and audit the QA program to assure that each component is being performed and documented, and write policies to assure the quality of patient care.

Along with its appointment and assignment of responsibilities, the QAC should be given the authority by the department chairmen-and support by the top hospital administration- to perform its tasks. For example, the QAC should set action levels for treatment team members, and define the actions which are to be taken to correct problems, or to halt any unsafe or unacceptable activity. For example, a typical action level might be 5% for a daily machine output check; a typical action might be that no treatment be given until the discrepancy is resolved. As an example of this process, the QAC can and should assign authority to the radiation oncology physicist to assure accelerator output. Continuing the example, the radiation oncology physicist might then develop the following instructions for the radiation therapist: if the daily accelerator output check is outside the expected value by 3%, then continue to treat, but notify the physicist; if the discrepancy is 5% or more, then stop further treatment and notify the physicist. Moreover, the QAC should carefully review instances wherein action levels are exceeded, errors have been made, procedures are discovered to be faulty, and so on. After such a review, the QAC should formulate their recommendations in writing for improving the QA program. When errors are discovered, the fault often lies in the process (or program) rather than in the action of an individual or individuals. The QAC should meet at a frequency established in writing and should retain for audit the minutes of the meetings, the action recommended and the results attained. Records should be retained for the length of time recommended by JCAHO (1987) or other requirements.

D. Policies and Procedures Manual

A policies and procedures manual is required by JCAHO (1987, 1992). It should contain a concise statement of all the policies and procedures carried out in the department of radiation oncology. This should include, but not be limited to, clinical procedures for evaluating the patient, plan of treatment, follow up, mortality and morbidity review, technical procedures for treatment, treatment planning, machine QA, and radiation safety. it should be updated as procedures change, and should be reviewed once per year and signed and dated by the appropriate section heads. The manual should also be reviewed yearly by the QAC. A listing of the location of the manuals should be maintained to assure that each manual is updated when changes are made.

E. Comprehensive QA Team

The most important component of quality radiation therapy is the commitment of the chief radiation oncologist to Comprehensive Quality Assurance. This is a point reiterated by the JCAHO and the ACR. In addition, the members of the QAC should support members of the QA team.

The tasks of performing quality control and assurance may be delegated to other staff members, including radiation oncologists, radiation oncology physicists, radiation therapists, dosimetrists, nurses, and data entry managers. These individuals; as well as others, are the QA team. Each member of the QA team should know his/her responsibilities, be trained to perform them, and know what actions are to be taken should a test or action give a result outside the limits of established acceptable criteria. Quality records documenting the frequency of performance and the results of a QA program are important, both in retrospective analysis of trends, and in documenting current status.

F. Quality Audit

A Quality Audit (see Definitions) should be performed at a frequency stated in the policies and procedures manual. The JCAHO requires, at the least, an annual reappraisal of the radiation oncology QA program as part of the hospital's QA program annual review (JCAHO, 1987, 1992). Sometimes the audits may be made by persons within the organization according to written procedures, but they should also be periodically performed by an outside group. In all cases, the audit must be performed by persons not responsible for the service under audit. For instance, the ACR Quality Assurance Program recommends a monthly audit by a designated reviewer of an appropriate number of patient charts (ACR, 1989).

External review of the programs, policies, and procedures by qualified experts is an important aspect of a quality audit. For example, the American College of Radiology offers a

program for the Quality Assessment of Radiation Oncology Practices (ACR, 1989) and the Physical Aspects of QA (ACR, 1990a). This program will provide a certificate of compliance to all practices satisfying their criteria.

External monitoring is another example of quality audit. For example, a mailed thermoluminescent dosimeter (TLD) service can be used to verify that the treatment unit calibration is consistent with national and international standards. In all facilities, and especially small ones, where there may be less opportunity for redundant monitoring of the dosimetry systems and treatment units, outside monitoring can provide the necessary redundant verification. Moreover, such audits help to maintain a uniform standard of dose among different treatment facilities; this is important not only for clinical trials research, but for cancer patients treated in different facilities. Furthermore, a uniform standard of dose and a clear indication of treatment techniques, including the method of dose prescription, helps facilitate more accurate dissemination of treatment regimes and results through the literature.

G. Resources

In order to have an effective QA program, the chairman of the radiation oncology department, in concert with administration, should assure that resources are available, including: personnel; QA test tools and equipment; assigned time for performance of QA program (e.g., machine availability for dosimetry QA, auditing of charts); assigned time for in-service educational programs including presentations of the QA program; external review (e.g., external audit of program by outside experts, TLD service for redundant monitoring of the treatment machines).

All three resources-personnel, tools, and time-are necessary for a successful program.

H. Continuous Quality Improvement

Improved methods of cancer patient management are frequently documented by clinical trial reports and peer-reviewed publications. The quality of patient management within the radiation oncology service should improve accordingly. The QA Team and the QAC should keep pace and utilize new information to improve the quality of patient care, and the documented QA program should reflect these improvements. Continuing medical education should be strongly encouraged, and activities such as lectures, workshops, and journal clubs should be available on a regular basis.

Quality Assurance is essential to the safe and effective treatment of the patient, the analysis of data, and the design of prospective research trials at the national and international level. Quality assurance requires that quality be in place. It also requires the time and commitment of the entire staff, and thus is a team effort.

II. QA OF EXTERNAL BEAM RADIATION THERAPY EQUIPMENT

A. General

QA of radiation therapy equipment is primarily an ongoing evaluation of functional performance characteristics. These characteristics ultimately influence the geometrical and dosimetric accuracy of the applied dose to the patients. The functional performance of radiotherapy equipment can change suddenly due to electronic malfunction, component failure or mechanical breakdown, or can change slowly due to deterioration and aging of the components. Therefore, two essential requirements emerge: QA measurements should be performed periodically on all therapy equipment, including the dosimetry and other QA measurement devices themselves: and there should be regular preventive maintenance monitoring and correction of the performance of the therapy machines and measurement equipment. The goal of these procedures is to assure that the performance characteristics, defined by physical parameters and established during commissioning of the equipment, demonstrate no serious deviations.

Although a QA program for radiation therapy equipment is very much a team effort, and the responsibilities of performing various tasks may be divided among physicists, dosimetrists, and therapists, and accelerator engineers, we recommend that the overall responsibility for a machine QA program be assigned to one individual: the radiation oncology physicist.

The QA program should be based on a thorough investigation for baseline standards at the time of the acceptance and commissioning of the equipment for clinical use (AAPM, 1993a). The International Electrotechnical Cornmission (IEC, 1989a,b), American Association of Physicists in Medicine (AAPM, 1984,1993a), and American College of Medical Physics (ACMP, 1986) describe procedures and conditions for acceptance tests. These procedures should be followed to verify the manufacturer's specifications and to establish baseline performance values for new or refurbished equipment, or for equipment following major repair. Once a baseline standard has been established, a protocol for periodic QA tests should be developed for the purpose of monitoring the reference performance values.

This section describes a QA program for commonly used radiation therapy equipment. Specialized units such as cyclotrons and neutron generators are excluded. However, the recommendations of this report can be adapted to these machines with some modifications.

A list of tests for a typical QA program is summarized in Tables I-IV. These tables are arranged according to our recommendations for frequency of tests (daily, weekly, and so on). Tolerance values for each parameter are included in the tables. **We** believe that all of the tests included in the tables are important for ensuring that the equipment is suitable for high quality and safe radiation treatments. The experimental techniques for performing these tests are not discussed, as space is limited and they are described in a number of publications (ACR, 1982, AAPM, 1975, 1984, 1993a; ANSI, 1974, 1978; Essenberg and Koziarsky, 1972; HPA, 1969,

TABLE I. QA of Cobalt-60 units.

Frequency	Procedure	Tolerance[a]
Daily	Safety	
	Door interlock	Functional
	Radiation room monitor	Functional
	Audiovisual monitor	Functional
	Mechanical	
	Lasers	2 mm
	Distance indicator (ODI)	2 mm
Weekly	Check of source positioning	3 mm
Monthly	Dosimetry	
	Output constancy	2%
	Mechanical checks	
	Light/radiation field coincidence	3 mm
	Field size indicator (collimator setting)	2 mm
	Gantry and collimator angle indicator	1 deg.
	Cross-hair centering	1 mm
	Latching of wedges, trays	Functional
	Safety interlocks	
	Emergency off	Functional
	Wedge interlocks	Functional
Annual	Dosimetry	
	Output constancy	2%
	Field size dependence of output constancy	2%
	Central axis dosimetry parameter constancy (PDD/TAR)	2%
	Transmission factor constancy for all standard accessories	2%
	Wedge transmission factor constancy	2%
	Timer linearity and error	1%
	Output constancy vs gantry angle	2%
	Beam uniformity vs gantry angle	3%
	Safety Interlocks	
	Follow test procedures of manufacturers	Functional
	Mechanical Checks	
	Collimator rotation isocenter	2 mm diameter
	Gantry rotation isocenter	2 mm diameter
	Couch rotation isocenter	2 mm diameter
	Coincidence of collim., gantry, couch axis with isocenter	2 mm diameter
	Coincidence of radiation and mechanical isocenter	2 mm diameter
	Table top sag	2 mm
	Vertical travel of table	2 mm
	Field-light intensity	Functional

[a]The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under gantry rotation exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values are ± the deviation of the parameter with respect to its nominal value; distances are referenced to the isocenter or nominal SSD.

1970; IAEA, 1970; IEC, 1989a,b; Lutz et al., 1981; NACP, 1980, NACP, 1981; NCRP, 1981; Purdy et al., 1986; Randall et al., 1977; WHO, 1988). In designing a machine QA program, it is important to explore measurement techniques which are simple, rapid, and reproducible. The test procedures should be able to distinguish parameter changes smaller than tolerance or action levels (for example, the test should be precise enough so that two standard deviations in the measurement of a parameter is less than the action level). Within these limits, the tests should also be developed to minimize the test time.

B. Test Frequency

Performance tests, tolerances, and frequencies are described in Tables I-IV. It should be noted that testing is distributed among daily, monthly, and annual tests: there are no recommended weekly tests (however for Cobalt-60 units we recommend a weekly source position check instead of daily output measurements). For daily tests we include those which could seriously affect patient positioning and therefore the registration of the radiation field and target volume (lasers, ODI); patient dose (output constancy) and safety (door interlock and audiovisual contact). For monthly we include more refined testing of parameters which will either have a smaller impact on the patient (e.g., treatment couch indicators) or have lower likelihood of changing over a month (e.g., light and radiation field or beam flatness). It could be argued that it is possible that a small change, for example, in symmetry could lie outside the tolerance in the table, yet be small enough to elude the machine's interlock system and the daily output measurements. Yet even if such a scenario occurred, it would create an asymmetry in the target volume which would persist on average for 2 weeks out of a typical 6 week treatment course. The overall asymmetry would most likely lie well within clinically acceptable tolerances in target uniformity (e.g., 10%). Thus we believe that daily/monthly tests balance cost and effect judiciously.

We recommend adherence to the program outlined in the tables unless there is demonstrable reason to modify them. For example, parameters which show large deviations from their baseline values should be given special attention and checked more frequently. Alternatively, if careful and extended monitoring demonstrates that a parameter does not change, or hardly changes at all, then the frequency for monitoring this parameter could be reduced. Although it is difficult to recommend how long a parameter should be monitored before decreasing the test frequency (the reverse case is usually obvious), it is prudent that the QA data should be assessed over an appreciable history of equipment performance (e.g., 1 year or more), and the clinical implications of any modification in test frequency should also be assessed. Unfortunately, at this stage there is no accepted method of systematically defining the type and frequency of QA tests that should be performed, based upon machine and dosimetry system performance, the clinical implications of any modification in their performance, and the costs involved. However, there has been some recent work in this area (Schultheiss et al., 1989; Rozenfeld and Jette, 1984). The best guidance we can give at present is that the QA program should be flexible enough to take into account quality, costs, equipment condition, and institutional needs.

C. Guidelines for Tolerance Values

The tolerance values in this section for radiological, geometrical, and mechanical parameters, where applicable, are adopted from AAPM Report 13 (AAPM, 1984). Report 13 used the method of quadratic summation to set tolerance

TABLE II. QA of medical accelerators.

Frequency	Procedure	Tolerance[a]
Daily	Dosimetry	
	X-ray output constancy	3%
	Electron output constancy[b]	3%
	Mechanical	
	Localizing lasers	2 mm
	Distance indicator (ODI)	2 mm
	Safety	
	Door interlock	Functional
	Audiovisual monitor	Functional
Monthly	Dosimetry	
	x-ray output constancy[c]	2%
	Electron output constancy[c]	2%
	Backup monitor constancy	2%
	x-ray central axis dosimetry parameter (PDD, TAR) constancy	2%
	Electron central axis dosimetry parameter constancy (PDD)	2 mm @ therapeutic depth
	x-ray beam flatness constancy	2%
	Electron beam flatness constancy	3%
	x-ray and electron symmetry	3%
	Safety Interlocks	
	Emergency off switches	Functional
	Wedge, electron cone interlocks	Functional
	Mechanical Checks	
	Light/radiation field coincidence	2 mm or 1% on a side[d]
	Gantry/collimator angle indicators	1 deg
	Wedge position	2 mm (or 2% change in transmission factor)
	Tray position	2 mm
	Applicator position	2 mm
	Field size indicators	2 mm
	Cross-hair centering	2 mm diameter
	Treatment couch position indicators	2 mm/1 deg
	Latching of wedges, blocking tray	Functional
	Jaw symmetry[e]	2 mm
	Field light intensity	Functional
Annual	Dosimetry	
	x-ray/electron output calibration constancy	2%
	Field size dependence of x-ray output constancy	2%
	Output factor constancy for electron applicators	2%
	Central axis parameter constancy (PDD, TAR)	2%
	Off-axis factor constancy	2%
	Transmission factor constancy for all treatment accessories	2%
	Wedge transmission factor constancy[f]	2%
	Monitor chamber linearity	1%
	x-ray output constancy vs gantry angle	2%
	Electron output constancy vs gantry angle	2%
	Off-axis factor constancy vs gantry angle	2%
	Arc mode	Mfrs. specs.
	Safety Interlocks	
	Follow manufacturers test procedures	Functional
	Mechanical Checks	
	Collimator rotation isocenter	2 mm diameter
	Gantry rotation isocenter	2 mm diameter
	Couch rotation isocenter	2 mm diameter
	Coincidence of collimetry, gantry, couch axes with isocenter	2 mm diameter
	Coincidence of radiation and mechanical isocenter	2 mm diameter
	Table top sag	2 mm
	Vertical travel of table	2 mm

[a]The tolerances listed in the tables should be interpreted to mean that if a parameter either: (1) exceeds the tabulated value (e.g., the measured isocenter under gantry rotation exceeds 2 mm diameter); or (2) that the change in the parameter exceeds the nominal value (e.g., the output changes by more than 2%), then an action is required. The distinction is emphasized by the use of the term constancy for the latter case. Moreover, for constancy, percent values are ± the deviation of the parameter with respect its nominal value; distances are referenced to the isocenter or nominal SSD.
[b]All electron energies need not be checked daily, but all electron energies are to be checked at least twice weekly.
[c]A constancy check with a field instrument using temperature/pressure corrections.
[d]Whichever is greater. Should also be checked after change in light field source.
[e]Jaw symmetry is defined as difference in distance of each jaw from the isocenter.
[f]Most wedges' transmission factors are field size and depth dependent.

TABLE III. QA of simulators.

Frequency	Procedure	Tolerance[a]
Daily	Localizing lasers	2 mm
	Distance indicator (ODI)	2 mm
Monthly	Field size indicator	2 mm
	Gantry/collimator angle indicators	1 deg
	Cross-hair centering	2 mm diameter
	Focal spot-axis indicator	2 mm
	Fluoroscopic image quality	Baseline
	Emergency/collision avoidance	Functional
	Light/radiation field coincidence	2 mm or 1%
	Film processor sensitometry	Baseline
Annual	Mechanical Checks	
	Collimator rotation isocenter	2 mm diameter
	Gantry rotation isocenter	2 mm diameter
	Couch rotation isocenter	2 mm diameter
	Coincidence of collimator, gantry, couch axes and isocenter	2 mm diameter
	Table top sag	2 mm
	Vertical travel of couch	2 mm
	Radiographic Checks	
	Exposure rate	Baseline
	Table top exposure with fluoroscopy	Baseline
	Kvp and mAs calibration	Baseline
	High and low contrast resolution	Baseline

[a]The tolerances mean that the parameter exceeds the tabulated value (e.g., the measured isocenter under gantry rotation exceeds 2 mm diameter).

values for individual machine parameters. These values are intended to make it possible to achieve an overall dosimetric uncertainty of ±5% and an overall spatial uncertainty of ±5 mm. These uncertainties are generally perceived as clinically acceptable and technically achievable (Herring and Compton, 1971; ICRU, 1976). Further improvements are possible, but only with significant technical innovations and increased cost. The tolerances listed in the tables should be interpreted to mean that if a parameter either exceeds the tabulated value (e.g., the measured isocenter under gantry rotation exceeds 2 mm diameter) or that the change in the parameter exceeds the tabulated value (e.g., the output changes by more than 2%), then an action is required. Therefore, if ongoing QA measurements fall outside the tolerance levels in the tables, the parameters should be adjusted to bring the equipment into compliance: the tolerances are thus action levels. However, if certain parameters barely meet tolerance values repeatedly, an appropriate action should be taken to correct the equipment. It is important to realize that the tolerance levels presented in this document reflects, as best as we can ascertain, standards of practice which have evolved in the practice of radiation oncology physics over the past decades, or even longer. These standards may, and probably will need to be modified as newer techniques are introduced, for example 3D conformal therapy.

D. QA of Cobalt-6-Units

Some aspects of QA testing of Cobalt-60 teletherapy units are mandated by the Nuclear Regulatory Commission (NRC, 1989), or by state regulations. Therefore, in states where such regulations are in force, the specified frequency of the tests for Cobalt-60 must not be modified. These and other recommended test frequencies are summarized in Table I. A complete discussion of QA of Cobalt-60 teletherapy equipment is provided in documents produced by the American National Standard Institute (ANSI, 1974, 1978). In addition to regulatory requirements, this task group recommends that a weekly test should be performed to assure that the source is properly positioned on the radiation axis. This may be confirmed either by measuring light and radiation field coincidence or via beam output measurements. Commercially available beam output check devices or film should be sufficient to perform this test. It should be noted that the tolerance value in Table I for the monthly radiation output measurement is 2%, which is more stringent than the one required by NRC. This recommendation is based upon the fact that the monthly output check is performed by. a physicist with an ionometric dosimetry system that has a calibration traceable to NIST, so that the required accuracy of 2% is readily achievable. Moreover, the tolerance level for monthly output measurement for Cobalt units is thus brought into agreement with accelerators.

E. QA of Medical Electron Accelerators

Medical electron linear accelerators presently constitute the majority of radiation therapy treatment units. They certainly require greater and more careful scrutiny of test parameters than do Cobalt-60 units. Moreover, the newer generation of medical accelerators, which increasingly are monitored and controlled by computers, has added to the

TABLE IV. QA of measurement equipment. I, initial use for each mode used or following malfunction and repairs; E, each use (measurement sequence) or ongoing evaluation; B, each batch or box at appropriate energy (dosimeter element position should also be considered); D, documented and correction applied or noted in report of measurement; M, monthly.

Instrument type	Test	Frequency	Tolerance[a]
Local standard[b]	ADCL calibration	2y[c]	D
	Linearity	2y[c]	0.5%
	Venting	2y[c]	D
	Extra-cameral signal (stem effect)	I	0.5%
	Leakage	E	0.1%
	Redundancy check[d]	E	2%
	Recombination	I	D
	Collecting potential	E	D
Field instruments	Local std. comparison	2y	1%
	Linearity	2y	D
	Venting	2y	D
	Extra-cameral signal	2y	D
	Leakage	E	0.1%
	Recombination	I	D
	Collecting potential	E	D
Output check	Local std. comparison	M	1%
Relative dose			
TLD	Calibration	E	D
	Linearity	I	D
Film	Dose response	B	D
	Densitometer linearity	1y	D
	Processor uniformity/reproducibility	E	D
Ion chamber	Linearity	1y	D
	Extra-cameral signal	I	1%
Diodes	Energy dependence	I	D
	Extra-cameral signal	I	D
	Linearity	I	D
Positioning	Accuracy	E	2 mm
	Hysteresis	E	2 mm
Automated Scanners	Mechanical	I	2 mm
	Positional accuracy	E	1 mm
	Collecting potential of detector	E	D
	Detector linearity	I	0.5%
	Extra-cameral signal	I	0.5%
	Detector leakage	E	0.5%
	Accuracy of data analysis	I	1%
	Accuracy of printouts	I	1 mm
Accessories	Thermometer Calibration	I	0.1 deg/C
	Barometer Calibration	3 mo	1 mm/Hg
	Linear rule Calibration	I	0.3%

[a]Percent values are ± the deviation of the parameter with respect to the nominal, and distances are referred to the isocenter or nominal SSD.
[b]Local standard instrument has a calibration directly traceable to NIST and should be reserved for calibration of radiation beams, field instruments, and intercomparisons.
[c]Two years required by NRC. Without a redundancy program, this may be inadequate; with a redundancy program, dosimetry systems maintain calibration factors for significantly longer periods of time.
[d]With a radionuclide (e.g., SR-90) or chamber intercomparison.

complexity of these units. The introduction of more specialized treatment units such as microtrons and specialized intraoperative accelerators presents different and often more challenging problems in acceptance testing, commissioning, and ongoing QA. The safe operation of computer controlled radiation machines requires extensive and repetitive checking of interlock chains (Weinhous et al., 1990). Recent reports (EC, 1990; AAPM, 1993b) describe special testing requirements for computer controlled accelerators. However, since the design philosophies of the interlock chains vary among manufacturers, it is very difficult to recommend standard interlock check procedures for all accelerators. This task group suggests that the manufacturer's recommended guidelines and test procedures should be strictly followed to check the safety interlocks.

The machine parameters and tolerance values in Table II,

grouped by the recommended frequency of measurements, includes ail the parameters described in AAPM Report 13 (AAPM, 1984) and some additional parameters appropriate to the newer-generation equipment. For example, it is now recommended that beam uniformity and dose stability should be checked at different angular positions of the gantry, since recent reports (Padikal et al., 1981; Loyd et al., 1989) indicate that accelerator beam characteristics can vary with gantry position. Failure to monitor these can produce errors in the dose delivered to the patient. Commercially available beam scanners which mount directly on the treatment head of the machine are useful in measuring beam output and symmetry as a function of gantry angle.

A variety of other instruments now commercially available are very useful and time saving for routine quality assurance. For example: for daily "spot checks" there are devices which use arrays of ionization chambers or solid state detectors which can perform multiple tests with one radiation exposure (e.g., output and symmetry). Although these instruments may be calibrated against local standard instruments, this is not required when they are used for constancy checks. The use of computer driven scanners is also encouraged in periodic quality assurance testing. These scanners allow a comprehensive set of measurements to be obtained in a reasonably short time. Instruments for dosimetry checks are further discussed in the previous report (AAPM, 1984).

The tolerance values for radiation output in Table II are 3% and 2% for daily and monthly checks, respectively. We recommend that the tolerance values be more stringent for monthly output checks because these are performed by a physicist with an ionometric dosimetry system that is acceptable for calibration by an Accredited Dosimetry Calibration Laboratory. The daily output checks, however, may be performed with any device which has a precision adequate to verify that the therapy unit is performing within tolerance limits. The daily output check device is often operated by a therapist for daily output measurements.

Daily output measurements are often performed using a device inherently less precise than the ionometric system used for monthly calibration, and the measurements may be performed under less controlled conditions. These daily measurements are often performed under time constraints, and sometimes without temperature and pressure corrections. For these reasons, we recommend an additional clinical action level of 5% for daily radiation output checks. If this level is exceeded, no further treatment should be given until a radiation oncology physicist has assessed the problem. If the output difference is in the range of 3% and 5%, then treatment may continue and the radiation oncology physicist is notified. Although treatment is allowed to continue for the short term, the cause of the discrepancy should be investigated at the first opportunity by the radiation oncology physicist. The daily output measurements should be recorded in a bound volume which is maintained at the treatment unit. It is essential that the physicist review these daily measurements and keep the output under surveillance.

The techniques for mechanical checks are described in various publications (AAPM, 1975, 1984; ANSI, 1974, 1978; Essenberg and Koziarsky, 1972; HPA, 1970; IEC, 1989; Lutz et al., 1981; Randall et al., 1977). Some newer-generation accelerators allow independent motion of collimator jaws. For these units, the mechanical alignment of each jaw should be evaluated independently.

1. QA of Newer Innovations on Medical Accelerators

Some of the more recent innovations in medical accelerator technology include computer controlled and monitored operation; motorized autowedge; dynamic wedge; multileaf collimators; record and verify systems; portal imaging devices; stereotactic radiosurgery; and intraoperative radiotherapy. QA procedures for these systems are beyond the scope of this report. It is the recommendation of this task group that the guidelines established by the manufacturers for safe operation should be strictly followed. If such information is not available from the manufacturers, they should be encouraged to provide it. As experience with these innovations increases, the universal guidelines for their quality assurance should be forthcoming. Several task group reports of AAPM (1993a-e) should be consulted.

F. QA of Simulators

Simulators are designed to reproduce the geometric conditions of the radiation therapy equipment (BJR, 1989). Therefore, they should be subjected to the same mechanical checks as accelerators. In addition, the simulator should be checked for image quality according to established guidelines for diagnostic radiography units (AAPM, 1984; ACMP, 1986). QA tests for simulators are summarized in Table III.

G. QA of CT Scanners

CT scanners which are used commonly in radiation therapy treatment planning should be an integral part of the QA program. CT scans for treatment planning are often done with a flat top insert on the CT table to reproduce the radiation therapy treatment couch top. In addition, a laser system mimicking that used on the simulation and treatment units should be mounted in the CT suite and the alignment of the lasers should be checked daily. Such a system is an integral component for relating the patient's position during CT with that on the simulation and treatment machines. Moreover, the location on CT scans of the intersection of the lasers with patient's skin is usually determined by placing radio-opaque catheters on the laser-skin intersection prior to the initiation of scanning. The correlation of CT numbers with electron densities and the variation of CT numbers with position and phantom size should be determined. Since this correlation is a function of the quality of the x-ray beam, it should be checked yearly. In addition, the CT scanner should be checked for image quality and other parameters described in the QA protocol provided by the manufacturer. Further details can be found in an AAPM report on performance standards and QA of CT scanners (AAPM, 1977).

H. QA of Measurement Equipment

The QA of measurement equipment is as important as that of the radiation treatment equipment and should be part of a

QA program. The recommended QA tests, their frequency, and the tolerance limits are given in Tabel IV. While this table is reproduced in part from the previous report (AAPM, 1984)-where more details can be found-additional tests for automated scanning water phantoms are now included. These systems are being widely used for dosimetry data collection and routine QA measurements. A detailed protocol for testing these scanners may be found in the published literature (Mellenberg et al., 1990) and the manufacturer's recommended test procedures. For densitometers see (Holmes and Mc Cullough, 1983).

Redundancy in dose calibration equipment is recommended to assure that instruments are holding their calibration. A redundant system can be established by comparing the response of the measurements equipment with an appropriate long-lived radioactive source (Strontium-90). We strongly recommend that if access to a Strontium-90 check source is unavailable, then at least two independent dosimetry systems be maintained. A Cobalt-60 teletherapy machine cannot substitute for a Strontium source as part of a redundant measuring system unless it is not used to treat patients. These systems should be intercompared at least quarterly. A two-system redundancy method provides better accuracy than one system with check sources (Rozenfeld and Jette, 1984). If only one dosimetry system is available, we recommend that a redundant system be formed with a dosimetry system at another institution, with quarterly intercomparisons.

I. Documentation and Records of QA

It is very important that test procedures are well documented for all units under the QA program. We recommend that the results of initial baseline testing (commissioning) and future periodic testing be recorded and dated. These results should be periodically evaluated to determine the performance level of each piece of equipment. Control charts are sometimes useful, particularly in representing long-term drifts that may not be obvious otherwise. In addition, clear documentation can prove to be useful when communicating with the manufacturers for modification and improvement of the equipment. Some states mandate that all QA records must be kept on file for a minimum specified time (typically 5 years, although sometimes longer).

III. TREATMENT PLANNING COMPUTER SYSTEM

The treatment planning computer is a crucial component of the entire treatment process in that a significant portion of patient treatments are designed and dose distributions calculated with these systems. Treatment planning systems cover a wide range of applications. Commissioning and QA for these systems raise a number of concerns because of their range and complexity. For example, external beam treatment planning systems include, but are not limited to: the calculation Of relative dose distributions for each machine, energy, and modality; the summation of relative doses from different beams; the calculation of monitor units (minutes) for a given prescribed dose if the appropriate calibration data has been entered into the planning system; and production of clear and accurate output data, including graphical isodose distributions. Furthermore, there are independent computer "monitor-unit" programs which calculate the number of monitor units for a single field given the prescribed dose and depth, usually along the central axis. In addition, there are so-called "irregular field" computer programs which are capable of calculating the dose at different depths and locations in irregularly shaped fields [generally these programs are used for such treatments as Hodgkins disease (mantle fields) and head and neck]. Finally, several major concerns for brachytherapy exist (and to some extent for external-beam treatment planning systems as well): that the dose distribution is correct for the source type in use, that the spatial reproduction of the implant is appropriate; that dose summations are calculated correctly; that the above are invariant following rotational and translational operations.

We recommend that these systems undergo rigorous acceptance tests and commissioning, and that a QA program be established and implemented. Moreover, it is important that these treatment planning computer systems come with complete and clear documentation. One should appreciate that all possible sources of error can never be tested, nor can the manufacturer assure the user of a "bug-free" system. Therefore, a treatment planning system should be tested over a range of parameters which would be typical of those used in the clinic, and the system should be tested on a periodic basis. General recommendations for these systems can be found in ICRU 42 (ICRU, 1987) and in more detail in a recent report on commissioning and QA of treatment planning computers (Van Dyke et al., 1993). In this chapter the major components of a QA program will be discussed with recognition that QA for treatment planning systems is an evolving subject (see e.g., Van Dyke et al., 1993; AAPM, 1993f).

A. Program Documentation

Program documentation is one of the most basic elements in a treatment planning system. The user of any new system should expect that the manufacturer will provide full documentation on the treatment planning system's hardware and software components. The following comprises a minimum set of documentation.

1. Beam Data Library

The manufacturer should provide clear documentation on the procedures for acquiring and transferring beam and other necessary data to the treatment planning system's data library. We recommend that users acquire their own basic beam data sets. We further recommend that these data be acquired by a qualified radiation oncology physicist using a water tank with an automated dose acquisition system.

2. Dose Calculation Models

It is important that the manufacturer provide a complete description of the physical models used for all of the dosimetric calculations. The documentation should describe the required dosimetric input data set and the expected accuracy of the dosimetric calculations for various treatment planning conditions, and should discuss the limitations of the dose

calculation models. The user should have access to the source programs and model parameters (ICRU, 1987).

3. Operating Instructions and Data I/O

There should be complete operating instructions, including procedures for entering individual patient data and machine parameters into the system in order to carry out a treatment plan. Equally important is a description of the definition of the output parameters, such as field size, gantry angle, etc. The manufacturer should also provide clear, detailed, and unambiguous examples illustrating the use of the system. For example, it should be evident how beam weighting procedures operate (e.g., weighting by "tumor-dose" or by "given-dose"), how wedge factors are used (e.g., whether they are applied internally by the computer algorithms or externally by the user), how brachytherapy source Strengths are specified, and so on.

B. Test Procedures

1. Initial Manufacturer's Tests

The manufacturer should make available documentation of their program of software testing of the treatment planning system. The manufacturer should also supply information on the error rate and type of errors discovered in field operation of the system. Furthermore, manufacturers should specify their procedures for documenting and correcting software "bugs" discovered in the field, and provide error logs for the user. Finally, the schedule for software upgrades should also be provided.

2. Initial User Test Procedures

We recommend that computer software be commissioned for each treatment machine, energy, modality and for each isotope at the time of purchase of the software, annually, and every time a software upgrade is installed. The treatment planning system, in these respects, is no different from other medical devices. Detailed procedures for testing treatment planning systems have been described in the literature (Masterson et al., 1991; McCullough and Kruger, 1980; Rosenow et al., 1987; Jacky and White, 1990; Shui et al., 1992; Van Dyke et al., 1993).

We further recommend that as part of acceptance testing procedures, the calculated dose distributions for a select set of treatment conditions in standard phantoms be compared to measured dose distributions for the same phantoms. Such tests-which should include examples typical of those used in the clinic (e.g., breast tangent fields with wedges)-are recommended because they compare the calculated and measured dose distributions for conditions which are meant to mimic those in use on patients. In addition, it is worthwhile to independently calculate the dose in the phantoms at selected points, using either the dose calculation algorithms documented by the manufacturer or an alternate algorithm. This latter method could reveal errors in coding of the algorithms that may not be obtained directly from dosimetric measurements (Jacky and White, 1990).

A reference set of treatment planning test cases should be established. Typical test cases should include dose distributions for each energy and mode for external beam therapy and for each source for brachytherapy, and typical treatment plan arrangements. This set should be used for yearly recommissioning of the treatment planning system. A subset of this reference set can be used for monthly QA, comparing the reproducibility of the calculations, where checksums (or other indicators that verify that the data and applications files have not changed) are not available (see below).

Single field or single source dose distribution. The dose distribution and the absolute dose at, at least, one point from a single external beam field or brachytherapy source should be calculated with the treatment planning computer in simple geometries (e.g., rectangular slab phantom) and compared with measurements. These comparisons should cover all sources, field energies, and modalities and should cover a clinically relevant range in parameters (e.g., field sizes, depths, calculation planes, etc.). It is also worthwhile to perform an independent calculation of the dose at selected points and compare those to the computer calculations.

Monitor unit calculations. In addition to the absolute dose measurements, the computer-calculated monitor units for all energies and modalities should be compared with an independent calculation.

Test cases. After the single field or source distributions and monitor unit calculations have been verified, simple test cases using multiple fields or sources in well-defined geometries should be generated. These tests cases should verify the ability of the software to sum the dose from multiple fields and sources, incorporate inhomogeneity corrections to the accuracy stated by the manufacturer, produce accurate output including isodose distributions and dose volume histograms, and calculate correctly the monitor units for a given prescription, In addition, for brachytherapy the tests should confirm the ability of the software to magnify and demagnify input and output to properly localize sources in three-dimensional space from the input information, identify proper calculational planes, and reproduce dose distributions after translational and rotational operations. For 3D systems, the tests should also confirm the spatial accuracy of beam-eye-view, digitally reconstructed radiographs, and other spatial displays.

3. Tests After Program Modification

We recommend that QA tests always be performed on the treatment planning system after program modification. The tests should use a reference set of QA treatment plans (a subset of the reference set used at commissioning) and the results should be compared to the initial acceptance test results. It is important that the operation of the treatment planning system as a whole be tested, even if only one module is modified, since changes in one part of the code can lead to unexpected results elsewhere.

4. Ongoing Tests

We recommend that ongoing QA should be regularly performed on the treatment planning system as described in Table V. In particular, yearly recommissioning in standard geometries and beam arrangements that were used during

TABLE V. QA for treatment planning systems and monitor unit calculations.

Frequency	Test	Tolerance[a]
Commissioning and following software update	Understand algorithm	Functional
	Single field or source isodose distributions	2%[a] or 2 mm[b]
	MU calculations	2%
	Test cases	2% or 2 mm
	I/O system	1 mm
Daily	I/O devices	1 mm
Monthly	Checksum	No change
	Subset of reference QA test set (when checksums not avilable)	2% or 2 mm[c]
	I/O system	1 mm
Annual	MU calculations	2%
	Reference QA test set	2% or 2 mm[d]
	I/O system	1 mm

[a]% difference between calculation of the computer treatment planning system and measurement (or independent calculation).
[b]In the region of high dose gradients the distance between isodose lines is more appropriate than % difference. In addition, less accuracy may be obtained near the end of single sources.
[c]These limits refer to the comparison of dose calculations at commissioning to the same calculations subsequently.
[d]These limits refer to comparison of calculations with measurement in a water tank.

acceptance tests may reveal changes in the way the system is used by the dosimetrists and physicists, and may also reveal inadvertent modifications in the treatment planning programs or beam library. A monthly checksum of data and object files, if available, should be compared against previous checksums since any change would reflect inadvertent alterations. If checksums are not available, then they can be replaced by monthly spotchecks on a subset of the initial planning reference set. A daily QA procedure to test the input-output, including digitizer and plotter reproducibility, should also be established.

IV. EXTERNAL BEAM TREATMENT PLANNING

In this section, QA for the treatment planning process is discussed, followed by a discussion of QA for individual patients. QA in treatment planning may refer to any of three distinct processes. (1) Nongraphical planning is often used for single or parallel opposed fields. In this approach, the monitor units (minutes) for the prescribed dose to a point on the central axis is usually calculated using central axis depth dose, tissue phantom ratios (TPRs) or tissue maximum ratios (TMRs), and beam output calibration tables. Furthermore, the field apertures, which define the treatment volume, are usually designed on radiographs obtained during simulation. (2) Traditional graphical planning is used for many patients. In this method, a target volume is defined from a or orthogonal simulation films, and the patient's contour is either obtained using a mechanical device (e.g., lead solder wire) or from CT. The field arrangements are designed and dose distributions calculated on one or a limited number of axial cross sections using a computerized treatment planning system. The radiation oncologist then prescribes the dose to a point or an isodose curve, and the field apertures are usually defined, as in procedure 1, from simulation films. (3) 3D treatment planning differs from the above in that target volumes, normal tissue volumes, and surface contours are obtained directly from CT. More significantly, in addition to field design, the field apertures are defined using beam's-eye-view (BEV) rather than from simulation radiographs. Moreover, 3D systems may produce digitally reconstructed radiographs (DRRs) from the CT data set. It is possible to prescribe dose to a point, isodose curve, isodose surface, or dose level on a dose volume histogram (DVH).

A. Treatment Planning Process

Treatment planning[4] is a process that begins with patient data acquisition and continues through graphical planning, plan implementation and treatment verification. It entails interactions between the radiation oncology physicists, dosimetrists, radiation oncologists, residents, and radiation therapists, and the use of a large number of software programs and hardware devices for graphical treatment planning. Each step of the complex treatment planning process involves a number of issues relevant to quality assurance. The process is represented schematically in Table VI and described in the following sections.

7. Prescription

We strongly recommend that the prescription be written, signed, and dated by the radiation oncologist prior to treating the patient. Verbal prescriptions are poor practice and are a potential source of misinterpretation and error. The prescrip tion should include the dose per fraction, total dose, number of fractions, number of fractions per day, and the prescription point or isodose curve (or surface). The dose for each component of a multiphase treatment, as well as the total dose, should also be clearly documented. In addition, the tolerance doses for critical structures should be written into the pre-

TABLE VI. Treatment planning process.

Process	Related QA procedures
Positioning and immobilization	Port films. Laser alignment.
Simulation	Simulator QA including image quality and mechanical integrity (see Sec. II F)
Patient data acquisition (CT, MRI, manual contouring)	CT, MRI QA including image quality and mechanical integrity (Sec. II G). Accuracy of mechanical contouring (Sec. IV A 3)
Data transfer to treatment planning system	QA of the entire data transfer process, including digitizers, digital data transfer, etc. (Sec. III B 3)
Definitions of target volumes	Peer review, e.g., new patient planning conference, chart rounds (Sec. VI)
Aperture design	Independent check of delivery (e.g., port films), and peer review (Sec. VI D 4)
Computation of dose distributions	Machine data from commissioning and QA of treatment machines (Sec. II E). Accuracy and QA of treatment planning system (Sec. III).
Plan evaluation	Peer review of plan, e.g., during chart rounds (Sec. VI). Independent check by radiation oncology physicist (Sec. IV A 9)
Prescription	Written, signed, and dated (Sec. IV A 1).
Computation of monitor units	Treatment planning system QA (Sec. III B 4). Independent check within 48 h (Secs. IV A 10 and IV B 2)
Production of blocks, beam modifiers	QA for block cutting and compensator systems (Sec. IV A 11). Port film review (Sec. VI D 4).
Plan implementation	Review of set-up by treatment planning team (Secs. IV A 12 and IV B 3). Chart review (Sec. VI).
Patient QA	Treatment plan review (Sec. IV B 1). Chart review after new or modified field, weekly chart review, port film review (Sec. VI). *In vivo* dosimetry for unusual fields, critical organ doses (e.g., gonadal dose) (Sec. IV B 4). Status check, follow up (Sec. VI)

scription when it differs from departmental policy (as documented in the procedures manual). The prescription should also include a definition of the target volume, which may be explicit (as is common in graphical planning) or implicit (as is common when designing field apertures for single and opposed fields). We further recommend that the target volume and field apertures be signed and dated by the radiation oncologist.

2. Positioning and Immobilization

It is important to position patients comfortably and reproducibly on the simulator, CT, MRI, and treatment units, and to maintain them in a fixed position during the course of imaging and treatment. A number of techniques may be used for immobilization, e.g., tape, casts, and bite block systems. It should be possible to immobilize head and neck patients to the order of 2 to 3 mm (Hunt et al., 1993; Rabinowitz et al., 1985) and to a lesser degree in other sites. Internal organ motion, particularly in the thorax (Svensson, 1989) and the pelvis (Ten Haken, 1991), can be appreciable.

3. Data Acquisition

Diagnostic units including simulators, CT, MRI, and ultrasound are used for acquiring patient contours and target and normal organ volumes. Details on diagnostic QA can be found in various protocols (see, e.g., AAPM, 1977, 1989, 1990, 1991, 1993g). However, there are a number of additional demands placed on diagnostic units which are specific to treatment planning. Special couch attachments simulating the treatment machines and imaging devices are useful. Immobilizing devices should be constructed so that they can be attached to the diagnostic and treatment couches and imaged with CT, MRI, and ultrasound without artifacts. Patient motion can distort MRI and CT images and change linear attenuation coefficients derived from CT. Furthermore, the position of the patient in the CT scanning ring can lead to errors due to beam hardening in the CT numbers (Masterson et al., 1981) used to derive the linear attenuation coefficients of the patient. Nonlinearities in the video chain can cause magnification and distortion errors in hard copy CT output. And the size of contours obtained from CT may be affected by the contrast setting.

The registration of patient data between CT, MRI, other diagnostic devices, simulators, and treatment units should be checked. This can be accomplished by imaging phantoms on the different imaging and treatment units. Special care should be given to MRI units which may suffer from spatial distortions (Fraass et al., 1987). In addition, for CT it is necessary to obtain or confirm the relationship between CT number and electron density (Masterson et al., 1981).

4. Contouring

The most common method of obtaining body outlines is to contour a strip of solder wire or plaster of paris to the body of the patient, transfer the contouring device to a sheet of paper, and trace the patient's contour. With this method, it is important to measure the distance between at least three points which have been marked on the contour. The calipers used to measure this distance should be checked regularly, since offset errors are not uncommon. Specialized mechanical devices such as pantographs, which may have better accuracy and reproducibility, may also be used to obtain patient contours (Day and Harrison, 1983). In addition, Moire photography, other optical techniques and ultrasound are also used (Boyer and Goitein, 1980; Clayton and Thompson, 1970; Carson et al., 1975a; Carson et al., 1975b). If CT is used, geometrical accuracy should be checked as discussed in the previous subsection. It is recommended that contour-

ing accuracy be within 0.5 cm (AAPM, 1984). While not used for contouring per se, other specialized tools may be useful in field alignment (Buck et al., 1985).

5. Data Transfer

One method of entering patient data into the treatment planning computer is to digitize plane film or hard copy CT. Since data transfer errors can occur because of digitizer nonlinearities and malfunctions, digitizers should be checked daily. Alternatively, data can be transferred more directly via tape, floppy discs, or computer network. Data transfer routines should be designed to check the integrity of the transfer.

6. Target Volume and Normal Organ Definition

Uncertainties in the target volume are related to uncertainties in the size of the tumor mass and the extent of microscopic spread of the disease (ICRU, 1978). Therefore, high quality imaging on treatment simulators and other imaging devices is important. With CT for example, the contrast setting can affect the size of the target volume. CT-defined target volumes defined on-line at a video monitor are preferable to those obtained from hard-copy images. In designing target volumes, an additional margin should be included to compensate for organ motion, set-up errors, and other technical uncertainties. The sizes of these margins are based upon experience.

Usually CT is used to define normal organs (e.g., small bowel, kidney), since it is difficult to localize them on plane films. Procedures should be in place to assure that contrast agents are used, when appropriate, to localize critical organs. Although most organs are imaged on CT with high contrast, it is possible to define normal organs improperly due to faulty or incomplete CT procedures.

7. Aperture Design

In treatment planning, field apertures are often defined from simulation films; therefore, accurate specification of the magnification factors is important. Three-dimensional treatment planning systems are more complex, in that apertures can be defined interactively using beam's-eye-view (BEV) computer displays in which volumes are projected onto a plane along ray lines that emanate from the source. Errors in the BEV algorithm can lead to systematic misregistration of the treatment fields with respect to the target volume and normal organs. BEV accuracy as a function of gantry angle, collimator angle, field size and isocenter distance should be confirmed prior to use, after software modifications, and checked as part of ongoing QA (see Secs. III B 2-111 B 3).

8. Computation of Dose Distributions

The accuracy of dose distribution calculations depends upon machine input data, approximations made in dose calculation algorithms, patient data including inhomogeneities, and the accuracy with which treatment machine parameters such as flatness and symmetry are maintained. The dose computation algorithms should be checked as part of the commissioning and ongoing QA of the treatment planning system (see Secs. III B 2-111 B 3).

9. Plan Evaluation

The evaluation of treatment plans usually includes review of isodose distributions as displayed on a video monitor or hard copy. With 3D treatment planning systems, dose volume histograms (DVHs) are often added to the plan review process. The accuracy of the isodose distributions may depend upon factors other than the accuracy of the dose calculation algorithms. For example, nonlinearities in the plotter can lead to distortions in the dose distributions and patient anatomy. These can be checked by printing out electronically defined scales of fixed length. Furthermore, the dose distribution calculations can be sensitive to the grid size, and dose volume histograms can additionally be sensitive to the dose bin size (Drzymala et al., 1991). All output data, including those presented in graphical format, should be included in ongoing QA of the treatment planning system (see Sec. III B 3).

10. Computation of Monitor Units (minutes)

The number of monitor units (or minutes) required to fulfill the prescription is obtained either directly from the treatment planning system, by an independent computerized monitor unit calculation routine, or by "hand calculations" using percent depth dose (PDD), TPRs, TMRs, and machine calibration tables (AAPM, 1993h). The accuracy of these calculations is affected by a number of factors, which are listed in Table VII.

11. Beam Modifiers

Beam shaping is most often accomplished using low melting alloy blocks and hot wire block cutting devices. Errors can occur because of incorrect specification of the magnification factor inaccuracies in the block cutting system and human error. Grid plates which, when inserted in the radiation field, produce regularly spaced marks on port films (Van de Geijn et al., 1982) are useful in distinguishing between patient positioning problems and block cutting errors. The latter are identified by comparing the distances between the block boundaries and the projected grid points on simulation and beam films. The accurate centering of the grid plate on the radiation axis is critical when using such a device.

We recommend that the block cutting system be checked monthly by fabricating a standard block outline and comparing the projected aperture with that intended on a simulator or treatment machine.

We also recommend that systems for fabricating compensators be checked monthly by fabricating a standard compensator (e.g., a step wedge) and verifying the accuracy with mechanical and radiographic measurements.

12. Plan Implementation

Once the patient has been correctly set-up, a record-and-verify (R&V) system should be used to assure that the same parameters (within tolerance limits) are used each day. Typically, these systems verify key machine parameters such as monitor units, gantry angle, collimator angle, collimator settings, beam modifiers (wedge number, blocking tray number), couch parameters, etc. (Mohan et al., 1984). R&V sys-

TABLE VII. Factors affecting monitor unit (minute) calculations.

Parameter	Related QA
Patient surface contour	Periodic checks of caliper accuracy. Redundant patient measurements. Treatment planning system monthly QA.
Collimator setting	Monthly simulator & treatment machine QA (Tables I–III)
Dose per monitor unit (minute) on the central axis as a function of collimator settings	Part of daily & monthly machine QA for a 10×10 field (Tables I and II) and annual recommissioning for output vs field size
Depth of the calculation (prescription) point	Periodic checks of caliper accuracy. Use of both lasers and ODI during patient setup to verify depth. Repeat patient measurements during course of treatment.
Target-to-patient-surface or target-to-isocenter distance	Monthly QA on simulators and treatment machines (Tables I–III)
Relative dose factors (PDD, TPR, TMR, etc.)	Monthly x-ray and electron energy constancy checks (Table II)
Aperture size and shape	Redundant check of magnification factor.
Wedge and compensator transmission	Annual machine recommissioning. Monthly check of latches and positioning of accessories (Table II)
Blocking tray transmission	Annual machine recommissioning. Monthly check of latches and positioning of accessories (Table II)

terns have identified "significant" errors at a rate of about 1% (Podmaniczky et al., 1985). These systems are especially useful in their ability to detect certain potentially serious systematic errors, for example in monitor unit setting, and wedge angle and direction. However, R&V systems should be used with care; if an error is made on the first day and not detected (e.g., incorrect wedge angle or direction), the R&V system will verify the incorrect parameter from day to day. To reduce the possibility of an error on the first setup, an independent verification of the treatment parameters should be made. To further reduce the risk of such systematic errors, at each subsequent fraction the patient should be setup using the treatment plan and setup instructions in the patient's chart (rather than using the treatment parameters as recorded and displayed by the R&V system). The R&V system should be used to verify the parameters only after the set-up is complete.

B. Treatment Planning QA for Individual Patients

1. Treatment Plan Review

We recommend that all graphical treatment plans should be signed and dated by the individual who formulated the treatment plan, and by the radiation oncologist-with the dose prescription clearly written on the plan, and reviewed by the radiation oncology physicist. We further recommend that this review should occur prior to treatment. When this is not possible, it should occur prior to the third fraction or before 10% of the dose has been delivered, whichever occurs first. The independent plan review should assure that the monitor units are correct, that all machine parameters used for patient setup are correct (e.g., field size, gantry angle, etc.), that additional setup instructions are correct (e.g., patient supine or prone), that the quality of the plan meets department standards, and that all signatures, prescriptions, etc. are recorded. In addition, we recommend an independent calculation of the dose at one point in the plan, preferably at the isocenter or at a point near the center of the tumor. We further recommend that if the independent calculation differs by more than 5%[5] from the treatment plan, the disparity should be resolved before commencing or continuing treatment.

2. Monitor Unit Calculation Review

There should be a monitor unit check when there is no graphical plan. We recommend that the initial calculation be signed and dated by the individual who performs it (irrespective of whether it is done with the aid of a computer program or by "hand calculation"), and then reviewed by another authorized individual, preferably a radiation oncology physicist. We further recommend that this review occur prior to treatment; where this is not possible (e.g., emergency treatment), then it should be done before the third fraction or before 10% of the dose has been delivered, whichever occurs first.

3. Plan implementation

All parameters in the treatment plan should be verified during first setup so that any ambiguities or problems can be corrected immediately. Special care should be taken to assure that all beam modifying devices (blocks, wedges, compensators) are correctly positioned. Although errors in block fabrication and mounting are often discovered during the review of port films, wedge or compensator misalignment is much more insidious, and may remain throughout the course of treatment if not discovered during initial patient setup.

We recommend that the radiation oncologist be present at the treatment machine for first setup and for major changes

TABLE VIII. Summary of QA recommendations for individual patients.

Procedure	Recommendation
Monitor unit (minutes) calculations	1. Reviewed prior to treatment by an authorized individual who did not perform initial calculation, or when not possible (e.g., emergency treatment), then prior to 3rd fraction or before 10% of the dose has been delivered, whichever occurs first.
Graphical treatment plan review	1. Reviewed prior to treatment, or when not possible, then prior to 3rd fraction or before 10% of the dose has been delivered, whichever occurs first. 2. Reviewed by a radiation oncology physicist who did not formulate treatment plan. Where only one physicist and that person performed the plan, then reviewed by another authorized individual. 3. Review includes calculated monitor units, input-output and plan quality. 4. Independent calculation of dose at a point: Compare for each field—with an independent calculation of dose to a point using the calculated monitor units—the prescribed and calculated dose. 5. If these differ by more than 5%, then the discrepancy should be resolved before continuing treatment.
Plan set-up	Radiation oncologist present at first setup or for major changes in treatment.
Beam (portal) films—curative and high morbidity risk palliative patients	Initial films reviewed by radiation oncologist prior to first treatment. In addition, ongoing portal films (the standard is weekly) also reviewed by the radiation oncologist.
Beam (portal) films—palliative patients	Films reviewed prior to second fraction.
In-vivo dosimetry	1. All institutions should have access to TLD or other *in vivo* dosimetry systems. 2. Should be used to measure dose to critical structures (e.g., lens, gonads). 3. May be used to record dose for unusual treatment conditions.

of definitive treatment procedures. In addition, a check of the setup by the physicist will minimize errors that may be undetected due to misunderstanding of the physical concepts and details. We further recommend that beam films be reviewed by the radiation oncologist before the first treatment for curative procedures or special complex palliative procedures that involve a high risk of morbidity, and before the second fraction for other palliative procedures. A summary of QA recommendations for individual patients is given in Table VIII.

4. In Vivo Dosimetry

In vivo dosimetry can be used to identify major deviations in the delivery of treatment and to verify and document the dose to critical structures. Institutions should have access to TLD or other in vivo systems. Thermoluminescent dosimetry (TLD) is often used because the device is small and relatively easy to calibrate, while diodes have the advantage of instantaneous readout. These in vivo systems can have relatively large uncertainties, which should be assessed before using them (Leunens et al., 1990). While in vivo systems are useful for individual patient measurements, they should not substitute for an adequate QA program.

V. BRACHYTHERAPY

Brachytherapy is the use of encapsulated radioactive sources to deliver radiation dose within a distance of a few centimeters by surface, intracavitary, interstitial or intraluminal applications. Brachytherapy has potential spatial and temporal advantages over external beam therapy (Barendsen, 1982; Turesson, 1990). The development of new techniques and radionuclides, and improvements in remote afterloading devices, including the use of high activity sources, have stimulated renewed interest in brachytherapy.

A brachytherapy treatment plan is more difficult to implement than an external beam therapy plan, particularly in interstitial brachytherapy, and to a lesser extent in intracavitary, intraluminal, and plaque therapy. In addition, the difficulty of determining source location and the presence of high dose gradients make the calculation of the dose distribution and the specification of dose-either at a point or throughout a volume-less precise than in external beam therapy. For these and other reasons, quality assurance practices are in general less rigorously defined in brachytherapy than in conventional external beam therapy.

One goal of QA is to achieve a desired level of accuracy and precision in the delivery of dose. As previously discussed, for external beam therapy it is generally accepted that dose should be delivered within 5% limits. For intracavitary and plaque brachytherapy, an uncertainty of ±15% in the delivery of prescribed dose is a more realistic level; and larger uncertainties may be present in multiplane interstitial implants (Hanson et al., 1991).

While QA of source calibration, the first component in dose rate accuracy, has been discussed in several documents (AAPM, 1984; Williamson, 1983; Williamson et al., 1985; Nath et al., 1990; Weaver et al., 1990b), relatively little has been written on comprehensive brachytherapy QA (Williamson, 1991). Therefore, this chapter is more detailed in places than the corresponding discussion of external beam therapy. After reviewing source description, the chapter addresses QA

of source calibrators, including a discussion of redundant systems. The section on treatment planning and dosimetry includes procedures for QA of dose calculation algorithms as well as the multiple steps to assure quality in the intended delivery of treatment. Procedures specific to remote afterloading devices are also discussed. The chapter concludes with a discussion of safety.

A. Sealed Sources

1. Description of Sources

The radiation characteristics of an encapsulated source are strongly dependent upon the distribution of the activity within the source and the details of the source encapsulation. Therefore, it is incumbent on the user to obtain the following information, and to evaluate its potential implications for clinical dosimetry.

Physical and chemical form. The chemical composition of the radionuclide and inert filler material (e.g., Cs-137 absorbed into ceramic microspheres, I-125 absorbed onto silver rods, etc.) should be provided by the manufacturer. This information is important because attenuation in the source and filler may significantly alter the dose distribution about the source (Ling et al., 1983; Schell et al., 1987). In addition, the presence of radioactive impurities may require a storage period after initial production to allow the decay of short-half-life isotopes (Stephens, 1981). If the source should rupture, knowledge of the chemical form may aid in radiation safety considerations. Finally, the possibility of chemical or physical changes and the potential effects on patient treatments during the useful life of a source should not be ignored.

Source encapsulation. Source encapsulation can influence the source calibration, the dose distribution, and the physical integrity of the source. This information should be available from the manufacturer. Encapsulation designs will vary for different radionuclides, and may vary for the same radionuclide from different manufacturers. Most long half-life sources (Ra-226, Cs-137) are doubly encapsulated; some sources have a unique capsule design (I-125, Pd-103) while others may consist of wires or seeds with a radioactive core and inactive cladding (Au-198, Ir-192) (Weaver et al., 1990; Shalek and Stovall, 1990). A number of authors have investigated the effect of the encapsulation on dose distributions of various sources (Horsler et al., 1964; Krishnaswamy, 1972; Ling et al., 1979; Schell et al., 1987; Shalek and Stovall, 1990; Meli et al., 1990; Weaver et al., 1990a).

Radionuclide distribution and source uniformity. The radioactive material may be continuously distributed within the encapsulation or divided among compartments or cells (Shalek and Stovall, 1990). The loading of the radionuclide along a source may be uniform or nonuniform, by design or otherwise. The active length may or may not be centrally located along the source, may be a uniform or nonuniform, by design or otherwise. The active length may or may not be centrally located along the source (Sharma et al., 1981), and the wall thickness of the casing or adsorption onto the matrix may not be uniform (Weaver et al., 1990a). For each type of source, these intricacies and their implications for source calibration and the dose distribution should be carefully assessed. Autoradiography and transmission x rays of a source are simple and informative tests for gross nonuniformity of the radionuclide within the source (Hendee, 1970; Khan, 1984). The uniformity of activity among radioactive seeds should be assessed (Ling and Gromadzki, 1981). The spacing of seeds in ribbons as provided by the manufacturer may require visual inspection or autoradiography.

Source identification. It is essential to be able to distinguish between sources that have the same radionuclide and capsule design but different activities. For shorter half-life sources, a simple reliable inventory system is necessary (see Sec. VA5). For long half-life sources, a rapid and reliable system for verification of source strength will prevent errors and reduce the level of personnel exposure and anxiety. None of the present methods of marking long half-life sources is universally accepted. Engraved codes are frequently difficult to read and thus result in unnecessary personnel exposure. Color coding tends to fade in time or flake off, and colored sutures fade and become disconnected. We recommend that sources be color coded and that the color be replenished as needed.

2. Calibration of Sources

Although commercial suppliers of brachytherapy sources provide a measure of source strength, it is unwise to rely solely on this value for patient dose calculations. Each institution planning to provide brachytherapy should have the ability to independently verify the source strength provided by the manufacturer. Source calibrators will be discussed in Sec. VA 3. Details of source calibration can also be found in various publications (AAPM, 1984; Williamson, 1983,1985; Weaver et al., 1990).

a. Specification of Source Strength. We recommend, as does AAPM Report 21 (AAPM, 1987), that the quantity of radiation emanating from a source be expressed as "air-kerma strength," which is the product of the air-kerma rate in free space and the square of the distance of the calibration point from the source center along the perpendicular bisector of the source. ICRU Report 38 (ICRU, 1985) defines a similar quantity as "reference air-kerma rate." The typical units are $\mu Gy\ m^2 h^{-1}$. The "reference air-kerma rate" is defined specifically at 1 m, while "air kerma strength" must be determined at a distance where the source approximates a point source.

b. Traceability of Source Calibration. The calibration of sources is traceable to national or international standards at several levels.

Direct traceability is established when a source or calibrator has been calibrated either at NIST or an AAPM-Accredited Dosimetry Calibration Laboratory (ADCL) accredited for brachytherapy calibrations.

Secondary traceability is established when the source is calibrated in comparison with a source of the same design and comparable strength which has direct traceability or when the source is calibrated using an instrument with direct traceability.

Secondary traceability by statistical inference is estab-

TABLE 1.X. QA tests for brachytherapy sources. I, initial purchase; D. documented; and E, at every use.

Type of source	Test	Frequency	Tolerance
Long half-life: description	Physical/chemical form	I	D
	Source encapsulation	I	D
	Radionuclide distribution and source uniformity	I	D
	Location of radionuclide	I	1 mm
Long half-life: calibration	Mean of batch	I	3%
	Deviation from mean	I	5%, D
	Calibration verification	E	[a]
Short half-life: description	Physical/chemical form	I	D
	Source encapsulation	I	D
Short half-life: calibration	Mean of batch	E	3%
	Deviation from mean[b]	E	5%
	Radionuclide distribution and source uniformity	E	V[c]

[a]Visual check of source color code or measurement in a calibrator.
[b]For short half-life sources this may not always be practical (see Sec. V A 2 c).
[c]V, visual check, autoradiograph, or ionometric check.

lished for a group of sources from which a suitable random sample has been calibrated with secondary traceability (AAPM, 1987).

Remote traceability occurs if the institution relies on the manufacturer's calibration as its only standard. This calibration may or may not be traceable to a national or international standard.

c. Recommendations. We recommend that brachytherapy sources used in radiation therapy have calibrations with direct or secondary traceability to national standards (AAPM, 1987). For newly developed isotopes for which no national or international standard exists, remote traceability may be used to establish a local standard.

Ideally, every radioactive source that is to be implanted in a patient should be calibrated. In practice, however, limitations of time, personnel exposure, or other physical constraints may preclude this level of thoroughness. We recommend that all long half-life sources be calibrated. Traceability by statistical inference may be appropriate for short half-life sources, depending upon the number of ribbons or seeds in the designated strength groupings under consideration. If the grouping contains only a few seeds or ribbons, we recommend the calibration of all seeds. For groupings with a large number of loose seeds, we recommend that a random sample containing at least 10% of the seeds be calibrated; for a large number of seeds in ribbons, a minimum of 10% or 2 ribbons (whichever is larger) should be calibrated. For sources purchased in a sterile configuration, we recommend purchasing and calibrating a single (nonsterile) seed for each designated-strength grouping.

Brachytherapy sources are assigned a "calibration" by the manufacturer. It is not uncommon for an institution to accept the manufacturer's calibration. However, it is the responsibility of the institution to verify that this calibration is correct. The institution should compare the manufacturer's stated value with the institution's standard. If the two are within acceptable limits (see Table IX), either the manufacturer's or institution's value may be used. We recommend that if the institution's verification of source strength disagrees with the manufacturer's data by more than 3%, the source of the disagreement should be investigated. We further recommend that an unresolved disparity exceeding 5% should be reported to the manufacturer. It is always advisable to ask the manufacturer to review its calibration of the sources to help resolve these discrepancies. With a proper redundancy program to verify that the institution's dosimetry system has not changed with time (see Sec. VA3b), there remains a small risk of error when the institution's calibration value is used but differs from the manufacturer's data.

Source QA tests and their frequency and tolerances are presented in Table IX. It should be noted that the recommended 3% tolerance between manufacturer and institution calibrations discussed above applies to the mean of a batch of sources. Since individual sources may differ from the mean by a greater amount, we recommend a deviation from the mean of 5% for individual sources.

For long half-life sources, the uniformity of each source should be verified during the initial calibration procedure. All seed ribbons should be verified during the initial calibration procedure and visually inspected to assure correct spacing of the seeds and the correct number of seeds. Differentially loaded ribbons require special consideration.

3. Brachytherapy Source Calibrators

In principle, source strength can be measured with a variety of detectors. Well ionization or reentrant chambers are preferred for conventional strength brachytherapy sources (Berkley et al., 1981; Weaver et al., 1990b), and thimble chambers measuring radiation intensity at a distance are preferred for high dose rate sources (Goetsch et al., 1991). However, thimble chambers have been used successfully for conventional dose rate sources (Loftus, 1980,1984; Berkley et al., 1981; Weaver et al., 1988), and Goetsch reports on a reentrant chamber designed for high dose rate sources (Goetsch et al., 1991). The radiation oncology physicist

TABLE X. QA tests for brachytherapy source calibrator. I, initial use or following malfunction and repairs,[a] instrument or sources have a calibration directly traceable to NIST. See further discussion in Secs. V A 2 b and V A 3 b, S, isotope/source specific, D, documented and correction applied or noted in report of measurement, when appropriate, and E, each use (measurement sequence) or ongoing evaluation.

Instrument type	Test	Frequency	Tolerance
Well ionization chamber	ADCL calibration	I,S[a]	D
	Precision	I	2%
	Linearity	I, 2 year	1%
	Collection Efficiency	I	1%
	Geometrical/length dependence	I	D
	Energy dependence	I	D
	Source wall dependence	I	D
	Venting	I	D
	Redundant check	E	2%
	Leakage	E	D
In-air calibration chamber and external source holder	ADCL calibration	I,S[a]	D
	Accuracy of source chamber distance	1 yr, S	1%, D
	Redundancy	E	D
	See Table IV for other tests		

[a]Instrument or sources have a calibration directly traceable to NIST. See further discussion in Secs. V A 2 b and V A 3 b.

should identify a single dosimetry system that will be used for brachytherapy calibration-although this need not be the sole use of the system. The QA tests for this calibrator are listed in Table X.

a. Commissioning a Calibrator.

Precision. The reproducibility of the source calibrator should be better than 2% and the signal-to-noise ratio greater than 100:l. For measurement with a thimble chamber at a distance, the orientation of the source and the distance from the source to chamber is very critical. For re-entrant chambers, the response is dependent on the orientation of the source and its position in the well (Williamson, 1983; Weaver et al., 1990a). Therefore, it is essential to devise a source holder which will reproduce the source positioning.

Scale factors and linearity. We recommend that the scale factor and linearity of each scale used on the electrometer be determined and monitored. If possible, a single scale and/or a single radionuclide setting (in the clinical range) should be used at all times on a nuclear medicine type dose calibrator, irrespective of the number and types of radionuclides measured. If the scale linearity cannot be determined independently, a short half-life source may be measured as it decays (Weaver et al, 1990).

Ion collection efficiency. Collection efficiency should typically be better than 99% for commercial well chambers and conventional brachytherapy sources. This should be verified using the highest intensity source expected to be calibrated. 'Measurements at two or more polarizing potentials can be used to obtain the collection efficiency (Almond, 1981), keeping in mind that these are continuous radiation sources. A correction for ion recombination losses may need to be measured and applied to the calibration, particularly for high dose rate sources.

Geometry and length dependence. Because of dose anisotropy about a source, the relative orientation of the source axis is important for any calibrator (Berkley et al., 1981). A positioning device should be used, to assure reproducible positioning. For re-entrant chambers, the sensitivity of the chamber changes with the position of the source within the chamber. Therefore, a source should be moved through the active volume of the chamber to verify and quantitate the extent of the change in sensitivity with source position. Two techniques have been described for determining the response of the calibrator with source length (Berkley et al., 1981). The source-length dependence may also be a function of the radionuclide (Weaver et al., 1990).

Energy dependence. The sensitivity of well ionization chambers depends on the energy of the photons, even in "air-equivalent" or "tissue-equivalent" chambers (Berkley et al., 1981; Weaver et al., 1990a). Thus a calibrated source of one radionuclide cannot be used to determine the source strength of another radionuclide. For thimble chambers, the calibration may also change with the photon energy.

Dependence on the wall of the source. Because well chambers approach $4-\pi$ geometry, their sensitivity will depend upon the anisotropy of the source (Williamson, 1983). Thus a calibrated source of one encapsulation may not be reliable for determining the strength of a source of the same radionuclide but different encapsulation.

6. Redundancy. Rozenfeld and Jette (1984) have discussed the principles of redundancy used to verify the reliability of a thimble chamber and maintain its calibration for external beam dosimetry. Well ionization chambers, if properly maintained, should retain their electrical and radiological characteristics as well as thimble chambers (Berkley et al., 1981). The principles outlined by Rozenfeld should apply equally well to brachytherapy and are outlined below.

A redundant system is a collection of radiation sources and detectors whose radiologic characteristics are predictable with a high degree of reproducibility. These sources and de-

TABLE .X1. QA tests for brachytherapy applicators. I. initial use or following malfunction and repairs; D, documented and correction applied or noted in report of measurement, when appropriate; and E, as a minimum, a visual inspection to verify that the dummy sources fairly represent the active source distribution.

Type of applicator	Test	Frequency	Tolerance
Intracavitary	Source location	I, yearly	D
	Coincidence of dummy and active sources	I	1 mm
	Location of shields	I[b]	D
Interstitial	Coincidence of dummy and active sources	I,E	1 mm

[a]To reduce personnel exposure, the dummy source location may be checked in place of the active source, if it is established that the dummy and active source locations are coincident.
[b]Location of shields should be verified by radiograph before the first use. Before every use, the applicator may be shaken to listen for loose parts.

tectors are intercompared periodically to verify whether one has changed its radiologic characteristics with time. The components of a brachytherapy source calibration redundant system are:

- Isotope calibrator (well ionization chamber or thimble chamber with a precise positioning mechanism);
- A long half-life encapsulated radioactive source whose mechanical integrity is reliable and whose decay is well known;
- The manufacturer's source specification, which is assumed unlikely to change with time. A major disadvantage of this component of the system is that the user does not know the reliability of the manufacturer's specification.

A two-component redundant system consists of a calibrator and one long half-life source or a calibrator and the manufacturer's source specification. A three-component redundant system is a major improvement, since the third component of the system can be utilized to resolve discrepancies between the other two. Several three-component systems are:

- a radionuclide calibrator, a standard source of the radionuclide in question, a second long half-life reference source of another radionuclide;
- a standard radionuclide calibrator, a reference long half-life source, a second radionuclide calibrator (preferably of different design from the standard);
- a radionuclide calibrator, a reference long half-life source, the manufacturer's source specification.

Four-component (or more) systems can be established by adding more calibrators or more sources (preferably of different radionuclides).

When a redundant system is first established, all components are intercompared. Afterwards, whenever sources are to be measured, the calibrator and one source are intercompared and the calibrator response is compared with decay of the source (as a minimum). If the two components do not agree, a third and possibly fourth component is included in the intercomparison to resolve the discrepancy. All components of the redundant system are intercompared at least annually. AARM Report 13 (AAPM, 1984) lists detailed procedures for establishing and using a redundant system to calibrate long half-life and short half-life sources.

We recommend that an institution maintain at least a two-component redundant system. A three-component redundant system is preferred, since it is easier to identify the origin of a discrepancy. We recommend establishing and maintaining a three-component redundancy system for newly developed isotopes for which no standards exist.

4. Brachytherapy Applicators

Table XI lists QA tests to be performed for brachytherapy applicators. Of major concern is that the applicators position the sources where they are intended to be localized, and that any part of the structures which are used to attenuate the radiation (e.g., rectal and bladder shields) have not shifted.

5. Source Inventories

Both long half-life and short half-life sources require both an active inventory and a permanent file. Because the information and procedures differ, each is considered separately.

a. Long Half-life Sources.

- Active inventory (updated quarterly). The active inventory should be posted in the hot lab, and maintained in the dosimetry section for calculation purposes. The inventory should include:
  - -radionuclide and source type,
  - -total number of sources and total source strength,
  - -for each batch of equivalent sources:
    - +number of sources of that source strength,
    - +mean source strength/spread in source strengths,
    - +date appropriate/time period in use clinically,
    - +institution's identification (e.g., "green," "10-mg tube," etc.),
    - +location in safe.
- Permanent file. A permanent file should be maintained containing the following information:
  - -radionuclide, source type, manufacturer, model number or other description,
  - -diagrams illustrating all materials and dimensions of the source,
  - -for each source or batch of equivalent sources:
    - +institution's verification of manufacturer's calibration/date,
    - +leak test results,
    - +location in institution.

b. Short Half-life Sources.

• Active inventory. In most cases the shipping container and/or storage drawer are labeled with:
-radionuclide,
-batch identification,
-source strength, total source strength, and source strength per seed/wire/source train.

If the institution performs a large volume of brachytherapy, a log of sources in active inventory may be needed.

• Permanent File. The following information should be maintained in a permanent file for the same period of time required for the patient's treatment records:
-radionuclide, source type, manufacturer, model number or other identification,
-batch number, date of shipment, number of seeds or wires,
-manufacturer's source strength specification (calibration) and date appropriate,
-number of wires or seed ribbons/number of seeds per ribbon,
-seed spacing/weighting,
-institution's verification of manufacturer's calibration,
-wipe test record,
-disposal: Date returned to the manufacturer or location in long term storage and ultimate disposal.

c. In-use Inventory. There should also exist a log for both long and short half-life sources currently in therapeutic use. This log should contain:
• patient's name, room number, procedure and date,
• responsible person and phone number,
• attending physician,
• number of sources and total source strength,
• source disposal.

After an implant, sources should be immediately returned to their appropriate storage position in the safe. Sources used on only one patient should be held until decay is sufficient or returned to the supplier, if appropriate.

B. Treatment Planning and Dosimety

In brachytherapy, with the exception of surface plaques and other implants with fixed geometries, the execution of the treatment can deviate substantially from the treatment plan. Therefore, two calculations are often required: planning calculations to determine the distribution and activity of the sources, and verification calculations to determine the treatment time from the actual distribution of sources.

Permanent implants require careful planning, since the number and strength of the sources are determined by the volume of the implant. Furthermore, the implant, once achieved, cannot be modified. For very short half-life sources, timing is also very critical (e.g., Au-198 decays 1% per hour, while I-125 decays at 1% per day).

1. Planning

The basic goal of planning is to achieve a dose distribution that will treat the target volume without exceeding normal tissue tolerance. From this plan, basic implant parameters are obtained, such as source type, length, number of sources, spacing, and special devices needed (e.g., templates). All implants should be planned, at least to the extent of determining an ideal implant configuration.

Traditional systems such as Manchester (Meredith, 1967), Quimby (Quimby and Castro, 1953), Paris (Pierquin et al., 1978), and Stockholm (Walstam, 1954) consist of rules for implanting the target so as to produce an acceptable dose distribution to the target volume, i.e., a known minimum dose, an acceptably uniform dose to the bulk of the target, and absence of excessive dose to large volumes. Although computerized calculations are now relatively standard in planning brachytherapy procedures, these traditional systems can still be very useful as a planning tool. They also provide a basis of continuity with prior clinical experience.

In certain situations it is possible to perform detailed preimplant calculations for the planned source configuration for a patient. This approach is most useful when source position is constrained by templates, eye plaques or other applicators. An alternative approach involves performing calculations and dose evaluations for a wide range of idealized implants defined by systematic variations in dimensional and source strength parameters. Dose as a function of these parameters can be presented in the form of a table, graph, or nomograph for individual treatment planning (Anderson et al., 1985; Pierquin et al., 1978; Henschke and Ceve, 1968).

For intracavitary brachytherapy, source locations are generally determined by the geometry of the applicator, and planning includes selection of an applicator and source-strength configuration to deliver doses to specified treatment locations. Treatment time depends on the actual implant and clinical judgment.

2. Localization

With the possible exception of radioactive eye plaques and other surface plaques, the position of all intracavitary, intraluminal, and interstitial implants, including vaginal applicators, should be verified by radiography or CT. Special problems with remote afterloading devices, particularly those with moving sources, will be discussed in Sec. V C.

Dosimetry personnel should be present during the localization of the implant to assure that the proper geometry is maintained (e.g., that the localization films are orthogonal), that fiducial markers and magnification rings are properly positioned and imaged, that the patient does not move during the study and that the quality of the films is adequate to localize the sources accurately. Dummy sources used for these studies should simulate source position and spacing accurately. As a minimum, a visual inspection is recommended to verify that the dummy sources fairly represent the active source distribution.

Orthogonal and stereo-shift x-ray techniques represent the most conventional methods for source and tissue localization. Various authors discuss these techniques [Shalek and Stovall, 1969; Khan, 1984; Glasgow and Perez, 1987 (Figs. 10.9 and 10.10); Smith et al., 1990; Anderson, 1975]. Three-film techniques (Amols and Rosen, 1981; Rosenthal and Nath, 1983; Altschuler et al., 1983; Biggs and Kelley, 1983) and CT scan techniques are also being used (Weaver et al., 1990b).

TABLE XII. Procedure specific parameter verification.

Endpoint	Procedure	When
Accuracy of OR implant description	Direct observation	During procedure
Prescription accuracy and consistency	Consistency of loading and prescription with disease stage, therapy chart treatment plan, department treatment policies	First half of treatment
Verify correct sources chosen	Spot calibration check and visual verification	Source preparation and source loading
Sources correctly loaded	Therapist or physicist (or individual knowledgeable in source loading) always assists physician	Source loading
Treatment plan	Calculation of plan and check for accuracy/consistency	First half of treatment
Implant removal	Physicist present or contact nursing staff to verify	Expected removal time
Sources all removed	Patient survey source count Final source inventory	At removal Next working day
Review treatment	Verify treatment time	After completion of procedure
Record, QA audit	All QA, treatment, and radiation safety records complete	After completion of procedure

3. Dose Calculation Algorithms

This document and others (AAPM, 1987; ICRU, 1985; Weaver et al., 1990a) recommend that the source strength be specified as air kerma rate at a large distance (typically one meter) from the source measured on the perpendicular bisector of the source. Most treatment planning programs however require source strength specifications in terms of older quantities such as exposure rate at a distance; equivalent mass of radium, apparent activity, etc. It is important to understand the assumptions of the calculational algorithm, and to convert air-kerma rate into the appropriate unit of source strength required for the treatment planning programs.

Since source calibration is air kerma rate at a point far from the source, it is important to verify that the calculational algorithm properly converts this source calibration into the appropriate dose distribution near the source where target and critical structure doses must be known. The algorithm must not only properly convert source strength to dose rates on the perpendicular bisector, but also correct for anisotropy along the axis of the source. Traditional methods of calculation include point source approximation with or without anisotropic corrections, unfiltered line source approximation, "along" and "away tables" and Sievert integrals (see e.g., Shalek and Stovall, 1969, 1990). An alternative, and perhaps improved, approach is one in which the dose rate is calculated from source strengths and doses (per unit source strength) measured in the medium (Meli et al., 1990).

4. Patient Dose Calculation

Post-implant dose distributions should be calculated in a timely fashion. For temporary implants, the calculated dose distribution is needed to schedule removal of the sources, or to modify the implant if necessary or desirable. For permanent implants, the calculation documents the dose delivered and may be used in the planning of further therapy. The dose distribution should be calculated in multiple planes so that the three-dimensional nature of the distribution can be established. A minimum of three planes is recommended. Dose distributions in planes through suspected high or low dose regions should also be calculated.

As with external beam dosimetry, all patient dose calculations should be reviewed to verify that no gross errors have occurred. We recommend that this be done in a timely fashion so errors can be corrected before treatment is complete. As a minimum, an independent dose calculation to at least one critical point is recommended for each implant (AAPM, 1984). Comparison with mg-hr tables from a classical implant system may also be used to check many clinical implants. We recommend agreement within 15% between the independent check and the dose calculation. (Hanson et al., 1991). If the treatment was custom planned, the check should verify that the final result was consistent with the plan. The geometrical configuration of the computer generated implant should be compared with radiographs and an assessment of the isodose distribution compared with the written prescrip tion.

5. Delivery of Treatment

The final consideration for quality assurance is to assure the delivery of the treatment to the patient. One aspect of this QA is documentation of the physical parameters that specify how the implant is to be loaded (e.g., source strength, applicator, dimensions of implant, dose prescription, implant time, etc.). Secondly, unambiguous lines of communication should be established to convey the necessary information among members of the implant team (e.g., the description of the implant as executed in the operating room must be communicated to the treatment planning staff). Frequently it is the physicist who provides the continuity necessary to assure all steps are properly executed.

Table XII outlines a number of steps in the execution of a brachytherapy treatment. Physics representatives should be

TABLE XIII. QA of remote afterloading brachytherapy units.

Frequency	Test	Tolerance
Each treatment day	Room safety door interlocks, lights, and alarms	Functional
	Console functions, switches, batteries, printer	Functional
	Visual inspection of source guides	Free of kinks and firmly attached
	Verify accuracy of ribbon preparation	Autoradiograph
Weekly	Accuracy of source and dummy loading (dummies used for spacing and/or simulation/verification)	1 mm
	Source positioning	1 mm
At each source change or quarterly	Calibration[a]	3%
	Timer function	1%
	Check accuracy of source guides and connectors	1 mm
	Mechanical integrity of applicators (by x ray if appropriate)	Functional
Annual	Dose calculation algorithm (at least one standard source configuration for each isotope)	3%, 1 mm
	Simulate emergency conditions	
	Verify source inventory	

[a]It is worthwhile at source change to calibrate both new and old sources to establish and document reproducibility of calibration method.

present in the operating room during custom-planned interstitial procedures and/or challenging dosimetric problems.

6. Documentation

We recommend that a written dosimetry report for each brachytherapy procedure be inserted in patient charts. The report should include the following (ICRU, 1992):

- Description of the sources (including calibration methods).
- Description of technique and source pattern used, including the separation between the sources and source lines, relationship of sources to each other in a plane passing through the center of the implant, general description of the pattern, such as curved plane, etc.
- Time of dose delivery.
- The total air kerma strength.
- Description of the dose to include the prescribed dose, dose at the periphery of the target volume, a central dose, and regions of high dose or low dose. Dose rate and/or total dose isodose distributions in appropriate planes.
- Isodose distributions.
- Other information such as dose volume histograms, quality indices, etc.

C. Remote Afterloading

Remote afterloading systems consist of conventional low dose rate (LDR) as well as high dose rate (HDR) devices; Because they present special considerations, they are discussed in an independent report (AAPM, 1993c). Although details can be found in that report, we present a discussion of the three principal QA end points: accuracy of source selection, spatial positioning, and control of treatment time. Other considerations pertain mostly to radiation safety. Table XIII is a list of the QA procedures and frequency.

1. Calibration

The source strength of low dose rate (LDR) devices should be determined in the same manner as that discussed in Sec. VA. For devices with multiple sources, the strength of each source should be determined to assure that all sources are within acceptable intervals from the mean. Procedures for the calibration of HDR sources are only recently becoming standardized. The accuracy and precision of well ionization chambers for HDR sources has limitations due to the low collection efficiency and high signal currents. However, at least two well ionization chambers specifically designed for HDR are presently commercially available, and two Accredited Dosimetry Laboratories are presently accredited to calibrate these chambers. The accuracy and precision of calibration at a distance using a thimble chamber also has limitations, which include scatter and effective distance from the source (effective measurement point of the chamber). Although there is no directly traceable calibration for Ir-192, an air kerma (or exposure) calibration factor can be obtained by interpolation between factors at 250 kVp and Cesium-137 or Cobalt-60 (Goetsch et al., 1991). A buildup cap thickness of 3 mm of waterlike plastic is recommended for Ir-192. Goetsch (1991) described a technique for minimizing uncertainties due to scatter and chamber position.

A spot-check of source activity can be performed using a thimble ionization- chamber with the source/applicator and chamber held rigidly in a plastic phantom, or with a well ionization chamber.

2. Verification of Source Position

Verification of correct source positioning and sequencing can be achieved by autoradiography supplemented by external markings (e.g., pin pricks). The relative optical density may be useful in qualitatively distinguishing between different sources. A standard source configuration utilizing all sources in the unit can be autoradiographed periodically to

jointly verify source localization and inventory. Some useful verification techniques are described by Williamson (1991).

3. End Effects

External beam units are calibrated against an internal timer or monitor unit. However, remote afterloading units are frequently calibrated against an independent clock. One technique for measuring end effects (Williamson, 1991) is to fasten a Farmer chamber in close contact with the applicator to obtain a high signal. A plot of the integrated signal versus the time of application gives the linearity of the timer and end effects. Calibration parameters should be chosen so that end effects do not contribute more than 1% to the uncertainty.

D. Safety

The principle of keeping exposures as low as is reasonably achievable (ALARA) applies to individuals working with patients who have received internally distributed radioactive sources. Radiation safety in brachytherapy is discussed in a number of reports (NCRP, 1972, 1974; AAPM, 1984; ICRP, 1985; NCRP, 1989). All efforts should be taken by the staff to reduce the risk to personnel and maximize the benefit to the patient and each facility must consult the agency regulations (Nuclear Regulatory Commission or State) for specific requirements regarding the possession and use of radioactive materials and radiation equipment. Special precautions should be taken in caring for patients receiving brachytherapy, since the sources may contain photon emitters of relatively high intensities and may emit significant dose rates near the patient.

One potential advantage of remote afterloading devices is that they minimize dose to hospital personnel and family. Other common methods for reducing radiation exposure to personnel are (1) limiting the time of contact with patients, (2) increasing the distance from the patient, and (3) the use of protective barriers.

Categories requiring radiation safety measures in brachytherapy.

- Facility
  - -receipt and inventory of sources,
  - -storage and work areas (shielding, carrier design),
  - -transportation (shielding, carrier design).
- Maintenance
  - -inventory,
  - -source identification,
  - -cleaning (especially safety aspects),
  - -leak tests,
  - -disposal.
- Clinical application
  - -preparation, sterilization, and transfer of sources and source applicator,
  - -application to patient,
  - -removal of sources from patient (patient and room surveys),
  - -return of sources to storage area,
  - -personnel monitoring,
  - -patient discharge.
- Emergencies and special precautions
  - -source breakage and contamination,
  - -loss of source,
  - -cardiac or respiratory arrest,
  - -emergency surgery,
  - -death of patient (autopsy, cremation, embalming),
  - -notification of the location of radioactive sources to local fire department.
- l Education and training of personnel
  - -physician and nursing staff,
  - -ancillary personnel (including housekeeping).

VI. QA OF CLINICAL ASPECTS

"Clinical aspects" refers in this report to those areas which link together the work of radiation oncologists, radiation therapists, dosimetrists, and medical physicists. Peer review is an essential feature of clinical QA. in this chapter we describe the important components of such peer review: new patient planning conference, chart review, and film review. Sometimes these are combined into one or more conferences, and often the latter two are combined into one conference–usually called chart rounds. In addition to a number of recommendations about clinical QA, we also present, in the section on chart review, a suggested detailed protocol for chart checking. Since a clear delineation of the roles and responsibilities of each member of the planning team is critical for a well functioning QA program, we present roles and responsibilities in Appendix A.

A. New Patient Planning Conference

New patient planning conference should be attended by radiation oncologists, radiation therapists, dosimetrists, and medical physicists. The pertinent medical history, physical and diagnostic findings, tumor staging, and treatment strategy (including the prescription and considerations of normal organ dose limits) should be presented by the attending radiation oncologists and residents. Ideally, all patients seen in consultation should be discussed, although this is not always practical. The background information presented in planning conference is important for the treatment planning team, since significant medical problems, prior radiotherapy, and past or intended surgery or chemotherapy will have an influence on the design of the treatment plan. In addition, this information is important for the radiation therapist, since it may influence scheduling and special care given during setup, and may alert the radiation therapist to be aware of changes in the patient during the course of treatment. The time needed to plan the therapy and prepare accessory devices and blocks should be discussed so that there is a realistic schedule.

For each patient, the prescribed dose, critical organ doses, possible patient positioning, possible field arrangements, and special instructions should also be discussed. Interaction of all participants at the planning conference may be helpful in resolving technical issues, which otherwise could potentially lead to delays and errors during subsequent simulation and planning. For example, incorrect initial immobilization of the patient due to uncertainty about the treatment technique can lead to limitations in the possible beam arrangements, or might possibly lead to the need for additional simulation and

replanning of the patient. Other areas which should be discussed among the participants of the planning conference are: the need for special point dose calculations, such as the dose to critical organs and predefined anatomical reference points; the need for in vivo (or special in phantom) dosimetry for situations where there is uncertainty in the calculational methods (e.g., surface dose, junction between fields, exit dose, out-of-field dose, etc.); and the need for designated points where the cumulative dose is required, for example, in regions of overlap among fields or where there has been previous radiotherapy.

In many cases, discussions of the type outlined above may not occur in a formal planning session, but it is important that these issues be resolved prior to simulation. Moreover, planning is an ongoing process; a continuing dialogue between members of the planning team is always useful and often required.

B. Chart Review

1. Basic Components of a Chart

The patient's chart should consist of at least the following components

- Patient identification
  - -patient name, ID, photograph.
- Initial physical evaluation of patient and pertinent clinical information
  - -diagnosis of disease,
  - -stage of disease,
  - history and physical,
  - -pertinent pathology report,
- Treatment planning
  - -simulator and setup instructions containing all relevant beam and patient parameters,
  - -MU (minutes) calculation work sheet,
  - -graphical plans,
  - -in viva dosimetry results,
  - -special physics consultations (e.g., nonroutine field abutment, dose to critical organs, etc.).
  - Signed and witnessed consent form
  - Treatment execution
  - -Prescription page with adequate space to fully specify the prescription (dose, tune, and fractionation) and modications to the prescription for each treatment site and space to sign and date.
  - -Daily record documenting the daily and cumulative doses to all prescription, critical organ, and anatomical reference points.
  - -Daily record documenting treatment aids (e.g., compensating filter, wedge) and portal and verification films.
  - -Chronology of treatment changes and remarks.
  - -Treatment field documentation including a graphical indication of each treatment portal and photographs of the field marking on the patient.
  - -Descriptions of patient setup position, location of treatment field relative to external patient anatomy, special treatment devices, beam modifiers, etc., including a photograph of the patient in the setup position.
  - -All relevant field setup parameters (e.g., gantry angle, collimator angle, etc.).
- Clinical assessment during treatment
  - -weight, blood count, dose to date.
- Treatment summary and follow-up
  - -summary of clinical problem,
  - -summary of treatment delivery,
  - -summary of patient's tolerance to treatment,
  - -summary of tumor response,
  - -follow up plan,
  - -ongoing follow-up reports.
- QA checklists
  - -for example the ACR 15 point checklist (ACR, 1989).
- Key to all abbreviations used throughout the treatment chart (JCAHO, 1987)
  - -File of initials of all individuals who initial the chart.

2. Overview of Chart Checking

The items recording in the radiation chart are reviewed by a number of individuals at different times during the patient's treatment. For example, the radiation therapist uses the chart on a daily basis and may discover errors. Radiation oncologists also refer to the chart frequently, at initial setup and during routine medical examinations throughout the course of treatment. Given the complexity of modem day radiotherapy, and significant differences in the functioning of departments, it is not possible to define when and where each item in a chart should be reviewed. We do, however, recommend that:

- Charts be reviewed
  - -at least weekly,
  - -before the third fraction following the start of each new treatment field or field modification,
  - -at the completion of treatment.
- The review be signed and dated by the reviewer
- Each department's QA committee oversee the implementation of a program which clearly and unambiguously defines:
  - -which items are to be reviewed,
  - -who is to review them,
  - -when are they to be reviewed,
  - -the definition of minor errors (discrepancy, technical deviation) and major errors,
  - -what actions are to be taken, and by whom, in the event of such errors.
- All errors be reviewed and discussed by the QA committee. The review should seek to discern whether the error was simply a human mistake or whether it reflects a problem or weakness in departmental policies and procedures. The exact nature of the analysis of such systematic errors will vary, but should include documentation by all personnel involved in the issue. The document should contain an explanation of the error as well as a plan to avoid errors of this type in the future. It should also be reviewed by a designated staff member (often the clinical director or chairman of the QA committee) and presented with appropriate recommendations for policy changes (if warranted) at the next meeting of the departmental QA committee.

- A random sample of charts be audited at intervals prescribed by the QA committee.

A proposed detailed protocol for treatment chart checking is described in the next section.

C. Chart Check Protocol

In this section we outline a suggested procedure for chart checking of the technical parameters of treatment. Although each institution should develop its own schedule and procedures, this outline may be of help in developing such a protocol for reviewing treatment delivery. We do not discuss a chart check protocol for clinical information, which should be carried out by a radiation oncologist according to a documented schedule delineated in the department policy and procedures manual.

1. Review of New or Modified Treatment Field

The first task of the chart reviewer is to identify any changes in the treatment (e.g., change in field size, dose per fraction, etc.) or new treatment fields since the previous weekly chart review. The chart reviewer should check and search for:

- new prescriptions,
- new fields or field parameter modifications (field size, gantry angle, etc.) indicated on, for example, the simulator/setup sheet,
- an indication of modified fields on the monitor unit (minutes) calculation work sheets, isodose distributions, etc.,
- MU changes under a particular field indicated in the daily record,
- simulator and/or portal films and prints (Polaroids) of the field markings to identify new fields or field modifications,
- an indication of a change in, for example, a "changes or remarks" section of the treatment chart.

The recurrent chart checking theme is to verify that all parameters are consistent from prescription to treatment plan to simulator sheet to MU (minutes) calculation to the daily treatment record. Moreover, the chart reviewer should be especially alert to the parameters listed below; a discrepancy in any of these would cause a serious error in dose delivery:

- wedge or wedge angle,
- source surface distance (SSD) vs source axis distance (SAD),
- interfield separation (e.g., using separation instead of depth for monitor unit calculations),
- number of fields per fraction,
- treatment unit and modality,
- dose prescription.

Having determined the new or modified fields, which is the reason the chart is under review, the following specific areas of the chart should be reviewed.

a. Treatment Prescription. The treatment prescription for each site and field should be reviewed to determine whether:

- The prescription has been signed and dated.
- All prescription changes have been signed and dated.
- All treatment techniques are indicated (AP/PA, arc rotation, etc.).
- The treatment machine, mode, and energy is identified.
- The treatment prescription points or isodose levels are defined and conform to departmental guidelines for prescribed technique and modality.
- The prescription indicates the daily dose, total dose, and fractionation scheme.
- There is a treatment plan narrative contained in each chart which is consistent with the prescription on the dose prescription page.
- The prescription dose is "reasonable" (this is a filter for gross errors such as prescribing 15000 cGy instead of 1500 cGy).
- There are previously treated or concurrently treated volumes in which dose would overlap with the current treatment volume. If so:
  - -the simulator films should be reviewed to locate such potential overlap,
  - -the past isodose distributions should be reviewed to locate such potential overlap and obtain the maximum cumulative dose in the overlap region.
- The separation between adjacent fields has been calculated.
- The cumulative dose to all standard points defined by department policy (e.g., dose maximum, critical organ doses, etc.) has been calculated.
- The cumulative dose to any other special points has been calculated.
- In vivo measurements have been requested, where ap propriate.

b. Simulator Instructions. The simulator/setup page should be reviewed for each field to determine whether the following information is accurately and clearly indicated:

- all physical beam parameters (e.g., length, width, field offset for asymmetric collimators, gantry angle, collimator angle, attenuator device, wedges, modality, beam energy, SSD),
- source surface distance or isocentric treatment technique,
- patient treatment position,
- patient support and immobilization devices,
- patient separation and/or prescription depth.

The reviewer should also determine whether the chart has been initialed by the therapist, indicating agreement between the simulator setup parameters and those on the first day of treatment. The reviewer should also evaluate whether the patient separation for the treatment and site is "reasonable" (e.g., a separation of 7.5 cm for a lateral brain is not reasonable and should alert the reviewer that something is wrong).

c. Isodose Distributions, Special Dose Calculations and Measurements. The reviewer should determine whether:

- An isodose distribution was calculated as requested or specified by department policy.
- Special calculations were performed as requested or specified by department policy (e.g., specific dose calculations, irregular fields, special equivalent square calculations, etc.).
- Patient data and beam parameters used for isodose cal-

culations, irregular field dose or point dose calculations are consistent with those specified in the simulator/setup section of the chart. For such calculations the reviewer should evaluate whether:

-The beam weight for each field agrees with the MU (minutes) calculation for that particular field.

-Hot spots, critical organ doses, are consistent between the calculation sheet (isodose distribution) and the treatment record, and that all parameters used in the calculation reflect those stated in the simulator/setup section (e.g., field size, gantry angles, wedge number, blocking, bolus, etc.).

-The contours used for calculating isodose distributions are consistent with the separation and depth indicated on the simulator/setup sheet and used for the MU calculation.

-The algorithm used for each calculation is appropriate to the modality and particular geometry of the treatment technique.

d. MU (minutes) Calculation. The reviewer should determine whether:

- The daily dose calculated for each field is consistent with the total dose and fractionation scheme for that site according to the prescription and treatment plan.
- All beam and patient parameters used for the calculation are consistent with those listed on the simulator/setup sheet and treatment plan. Special care should be given to: wedge type (if any), SSD vs SAD treatment, patient separation, and treatment machine (modality, energy).
- Beam weighting (dose per fraction for the particular field) is consistent with the treatment plan (isodose distribution).
- MU calculations have been reviewed. If not, they should be checked immediately.
- All factors and parameters used for the calculation of MU (minutes) are correct according to the data tables (e.g., PDD, TMR, field size factor, tray transmission factor, wedge transmission factor, etc.).
- Beam blocking is extensive, and if so, whether appropriate equivalent square (or equivalent) calculations have been made.
- Patient separation varies significantly within the treatment area, and if so, whether the separation used for the calculation corresponds to the separation at the actual clinical point of interest.
- Significant areas of high dose (hot spots) have been calculated and documented in the chart.
- For a multifield treatment, the MU (minutes) setting indicated on the daily record for a particular field corresponds to the correct MU calculation for that particular field.
- Special dose modifying devices have been used (to be ascertained by review of daily treatment record, isodose distributions, or simulator/setup sheet). Such devices include tissue compensators, special trays, transmission blocks, and occasionally a customized patient support system. If so, the reviewer should check that dose calculations have been appropriately modified.
- In the case of electron beam treatments, special block cutouts were used, and whether treatment is at extended SSD, and whether appropriate measurements (or tabulated data) were used to account for these special cases.

e. In vivo Measurements. The reviewer should determine whether:

- In vivo measurements (TLD, diode, etc.) were requested or specified by department policy (e.g., when treating under conditions outside the range of the actual tabulated data measurements).
- The summary reports of these measurements, which should be located in the patient's chart, lie within expected limits and have been fully documented.

f. Daily Treatment Record. The reviewer should determine whether:

- The MU (minutes) settings indicated for each field are consistent with both the calculation work sheet and the data in the simulator/setup parameters sheet.
- Correct treatment machine, modality, and beam energy are used for each field and correctly indicated on the daily record.
- Each field treated has been signed after treatment by the radiation therapist.
- There is definitive documentation in the treatment record (using codes, abbreviations, etc.) that the planned modifying devices (blocks, wedges, bolus, compensators, etc.) are being used.
- Cumulative total dose for each site has been correctly recorded, taking into consideration the appropriate contributions from each field in the treatment plan.
- Cumulative doses to the special calculation points (points of interest), critical organs, etc. have been correctly recorded.
- The dose delivered by portal films has been added to the cumulative dose (according to the department policy).

2. Weekly Chart Review

As part of the weekly chart review, the reviewer should determine for each patient whether any new fields have been created or any previously treated fields modified. This can be ascertained using the methods described in the previous section (VI C 1). All modified and new treatment fields should be carefully reviewed as described in the previous section (VI c 1).

a. Review of Previous Fields. For each patient, the reviewer should determine:

- The date of the previous weekly chart review.
- Whether the interval between chart reviews has been appropriate according to departmental policy.
- Whether the chart and the calculations have been reviewed by more than one physicist or dosimetrist. If not, every effort should be made to have a "second pair of eyes" review the chart at least once during the course of therapy.
- Whether the monitor unit calculations have been reviewed by a person other than the one who performed the original calculation.

b. Cumulative Dose. The chart reviewer should determine whether:

- All doses have been correctly summed since the previous chart review. This should include the dose to the prescription site and all additional sites such as critical organs, dose to d_{max} etc.
- The total dose to the prescription point will reach the total prescribed dose prior to the next weekly chart review (if so, a note to the radiation therapist should be written in the chart noting the last treatment).
- The total dose to the prescription point (and critical structures) exceeds the prescribed value.

3. Review at Completion of Treatment

As a final review before the chart is placed in a file, the following items should be checked:

- prescribed dose delivered,
- chart properly documented according to department policy,
- treatment summary included.

D. Film Review

1. Types of Films

In addition to simulation films, two imaging techniques are used to assess radiation field position and target volume, namely localization using portal (portal localization) images and localization using verification (verification-localization) images. A portal image is obtained using a relatively sensitive x-ray film exposed to only a small fraction of the daily treatment dose (Reinstein et al., 1987). A subcategory of a portal image is a "double-exposure" image, in which one exposure is obtained with the treatment field aperture in place [i.e., with blocks or multileaf collimator (MLC)] and a second exposure is taken with the cerrobend blocks removed (or MLC retracted) and the x-ray jaws opened to image some of the patient's surrounding anatomy. One virtue of this method is that field placement is easier to assess when the surrounding anatomy is imaged than when only the treatment volume is imaged. One problem with double-exposure portal imaging is that the patient is imaged under setup rather than treatment conditions, that is, portal images provide a brief "snapshot." Another difficulty is that the dose per portal image, while low (usually less than 5 cGy), still delivers additional dose to the patient outside the treatment volume-and this becomes more significant as the number of treatment fields increases. Furthermore, since portal imaging assesses the position of the patient over a short time interval prior to treatment, it does not include the effect of patient motion during treatment. In contrast, verification images are single-exposure images which record the delivery of the entire dose for each fraction from each field. These images record what occurred during treatment, including the motion of the patient and the presence of radiation beam modifiers.

On-line imaging devices (also known as electronic portal imaging) may play an important role in improving patient imaging before and during treatment (Shalev et al., 1989; Munro et al., 1990; Boyer et al., 1992). Since the image is available on a video monitor, the radiation fields may be reviewed within seconds. Perhaps more important, the relative ease of capturing and processing images may facilitate more frequent imaging. These devices are also capable of enhancing images, and possibly improving the contrast of internal anatomical landmarks. It should be noted, however, that more frequent double-exposure imaging will present additional problems with out-of-field dose.

2. Initial Portal Imaging

The purpose of portal images is twofold: to verify that the radiation field isocenter (or other reference point) is correctly registered with respect to the patient's anatomy, and that the aperture (blocks or MLC) has been properly produced and registered with respect to the radiation field isocenter. We recommend that portal films be obtained for all treatment fields prior to first treatment. Where oblique or noncoplanar fields are used: orthogonal films imaging the isocenter should be obtained, in addition to images of the treatment fields. This recommendation is based upon the fact that larger setup errors are observed in transferring a plan from the simulator to the treatment machine than in day-to-day use of the treatment machine (Rabinowitz et al., 1985). If first day setup modifications are not made, positioning errors may persist as systematic deviation throughout the course of treatment.

In some instances (for example, vertex fields in the brain), a useful image of the radiation field may be difficult to obtain. Moreover, for rotational treatments it is not practical to obtain images at all gantry angles. In these instances, orthogonal images of the isocenter should be substituted. We further recommend that all beam films be reviewed, signed, and dated by the radiation oncologist before the first treatment for curative or special palliative procedures, and before the second fraction for palliative procedures.

3. Ongoing Portal and Verification Images

Day-to-day variations in patient setup are likely to be random and smaller in magnitude than first-day variations (Rabinowitz et al., 1985). However, large and systematic deviations can still occur due to a number of factors, including an error in interpreting the films on the first day, a modification in the setup procedure, a change in the radiation therapist(s) involved in the treatment, an unrecorded change in the blocks, etc. Furthermore, changes in patient anatomy due to weight fluctuation or disease status can also cause systematic deviations in the registration of radiation fields. Therefore, the recording and review of ongoing portal and verification images for each site is an important aspect of the comprehensive QA program. It is important to realize that a small change in patient position observed on one day may be simply a random error which cannot be controlled, and that an immediate correction of the patient's position could "overcorrect" and lead to a larger, subsequent systematic error. Therefore, such potential setup errors, when they are observed, should be monitored for a few consecutive days and the patient's position should be modified only if they persist.

Several studies (Rabinowitz et al., 1985; Marks et al., 1976; Byhardt et al., 1978; Lam et al., 1987; Marks et al., 1982; Hunt et al., 1993) have demonstrated that clinically significant localization errors (of the order of 1 cm) occur relatively frequently (that is of the order of 10%-36% of the

time depending upon treatment site). However, Marks et al. (1976) have reported that the relative frequency of localization errors diminishes as the frequency of portal and localization films increases. For example, the number of cases with errors greater than 1 cm decreased from 36% to 15% when the number of portal films was increased from 9 to 24 during a course of treatment. These results suggest that more frequent portal imaging is needed, with the ideal being, perhaps, once daily. Unfortunately, given the time and cost of current conventional imaging with film, practical considerations preclude daily imaging. Instead, it is recognized that the frequency with which portal and verification films should be obtained depends upon the site treated, the immobilization device used, the individual patient's condition, and the intended degree of reproducibility that is sought. Nevertheless, we recommend that portal or verification films of all fields be obtained at least once per week.

4. Film Review Conference

Weekly treatment film review conferences should be attended by the entire planning team and the nursing staff. Such interdisciplinary representation has several advantages:

- Inconsistences between actual and intended treatment (e.g., between simulation images and portal images) may be more easily identified when different observers from different disciplines review the films. It is also useful to indicate the number of repeat films on the final portal film presented at the film review conference. For example, at many institutions weekly portal films are immediately reviewed by the radiation therapists, who make minor adjustments in patient setup as needed until the repeated port film indicates agreement with the approved simulator image. Awareness of the number of repeat films will focus attention on particular problems in treatment setup, which can lead to corrective actions such as improved patient marking, clearer instructions, and immobilization devices where needed.
- When a disrepancy is identified, it may be possible to determine its cause (e.g., a block cutting error, a patient positioning error, etc.).
- The action needed to correct the discrepancy can be discussed and directly communicated to the appropriate staff member. Written notes of the recommended corrective actions should be obtained.
- Treatment plans and graphical dose distributions should be reviewed. It is useful to discuss the rationale for the current approach and alternate techniques, field arrangements, patient positioning, etc.

APPENDIX A: ROLES AND RESPONSIBILITIES

1. Responsibilities of the Radiation Oncologist

The director of the Radiation Oncology department is responsible for implementation of a comprehensive QA program. As indicated earlier, only radiation oncologists with delineated hospital privileges are responsible for consultation, dose prescription, on-treatment supervision, and treatment summary reports. In addition to these functions, which are further described below, the radiation oncologist should be responsible for the chart review of any patient who dies during the course of treatment or any patient with an unusually severe or unexpected reaction to treatment. This can often be accomplished by regularly scheduled Mortality and Morbidity Conference. In addition, all physicians should follow each patient to the greatest possible extent and document the outcome of therapy. Such follow-up should include an evaluation of the success of treatment in terms of tumor control and complications. In addition, a review of patient outcome studies must be presented twice yearly to the entire department (JCAHO, 1987). Such outcome studies should be designed to facilitate examination of the success or failure of a department in a specific disease site. Comparisons with outcomes available through Patterns of Care (PCS) studies (Hanks, 1989; Coia, 1991) or through literature review should be made so that remedial action can be taken if success falls short of expected outcomes.

The previously mentioned responsibilities are further delineated below.

Consultation. A consultative report must be provided for hospital medical records (JCAHO, 1987). The clinical evaluation of a patient for consideration of radiation therapy and the institution of that therapy requires the following:

-determination of patient suitability for treatment,
-history and physical exam by a physician,
-laboratory investigations to help determine patient medical status and tumor extent,
-radiologic investigations, as required, for determining medical status and tumor stage,
-pathologic confirmation of a malignancy or statement of benign condition (except in rare instances such as emergencies or surgically inaccessible sites),
-establishment of tumor stage or extent and tumor location,
-statement of options for treatment with a general statement regarding total dose and time,
-informed consent to be obtained prior to initiation of treatment.

Establishment of Plan. The elements of the overall plan of treatment[6] are developed by the radiation oncologist with delineated hospital privileges (JCAHO, 1987). Ideally, a discussion of consultative findings including diagnosis and stage should be presented along with a plan of treatment that establishes dose, fractionation, and technique. Input from other radiation oncologists and radiation oncology physicists is recommended in establishing the plan of treatment, to provide peer review and analysis of technique. Prior to initiation of therapy, a dose prescription and plan of treatment must be written on the patient's chart.

Treatment Execution. The radiation oncologist should be involved on a regular basis in the treatment delivery process, as outlined extensively in the sections on film and chart review.

On-treatment Evaluations. Patients should be monitored at least once weekly during treatment to evaluate changes in clinical status, tumor response, and treatment toxicity. These evaluations should include:

-pertinent symptom elucidation and relevant physical findings,

-monitoring of weight and nutritional status,
-ordering and monitoring of pertinent radiologic investigations,
-institution of therapies, for treatment-related toxicities,
-alterations in the plan of treatment such as a change in dose per fraction, total dose, technique, use of bolus, treatment break, etc.,
-appropriate consultations for medical and surgical problems.

Treatment Summary. A statement summarizing the course of treatment must be provided for hospital medical records. This summary should include dose administered, description of the treatment technique, time period of treatment, patient tolerance, tumor response, and follow-up plan.

Follow-up Evaluation. Following completion of treatment, a plan for follow-up is made. The frequency of post-treatment monitoring is individualized depending on rumor stage, patient clinical status, intent of treatment, and existence of other treatment modalities. A system for evaluating tumor response and assessing treatment morbidity must be in place (JCAHO, 1987).

2. Responsibilities of the Radiation Oncology Physicist

Radiation oncology physicists are primarily and professionally engaged in the evaluation, delivery, and optimization of radiation therapy. Their role has clinical, research, and educational components. In addition to their advanced degree (in a relevant field), these individuals will have received instruction in the concepts and techniques of applying physics to medicine and practical training in radiation oncology physics. A major responsibility of the radiation oncology physicist is to provide a high standard of clinical physics service and supervision. The roles and responsibilities of the radiation oncology physicist in QA are outlined below.

Calibration of Radiation Oncology Equipment. One of the primary responsibilities of the radiation oncology physicist is to assure that all treatment machines and radiation sources are correctly calibrated according to accepted protocols.

Specifications of Therapy Equipment. The radiation oncology physicist should help define the specifications for the purchase of treatment unit(s), including external beam and brachytherapy units, therapy simulator(s), CT and ultrasound units, other therapy imaging systems (e.g., on-line portal imaging systems), and treatment planning system. The radiation oncology physicist is involved in the design of the facility and must assure that all radiation safety requirements are met.

Acceptance Testing, Commissioning & QA. The radiation oncology physicist is responsible for acceptance testing, commissioning, calibration, and periodic QA of therapy equipment. In particular, the physicist must certify that the therapy units and planning systems are performing according to specifications, generate beam data, and outline written QA procedures which include tests to be performed, tolerances, and frequency of the tests.

Measurement and Analysis of Beam Data. Important components of the commissioning phase include not only the generation of beam data for all energies, modes, and isotope sources, but also evaluation of the quality of the data and its appropriateness for treating different disease sites. Such evaluation may lead to the initiation of further measurements and refinements for different treatment techniques.

Tabulation of Beam Data for Clinical Use. It is the responsibility of the radiation oncology physicist to assure that the beam and source data are correctly entered into the treatment planning system. Furthermore, the beam data should be tabulated in a form that is usable by the radiation therapists, dosimetrists, and radiation oncologists.

Establishment of Dose Calculation Procedures. A major responsibility of the radiation oncology physicist is to establish the dose calculation procedures that are used throughout the department-and to assure their accuracy.

Establishment of Treatment-planning and Treatment Procedures. Along with the radiation oncologist and other members of the treatment planning team, the radiation oncology physicist is responsible for establishing treatment-planning and treatment procedures. This includes both the technical aspects of the process (e.g., how block cutting is to performed) and the flow of procedures entailed in the process (e.g., when different steps in the process of planning are to be performed).

Treatment Planning. As already stated, the radiation oncology physicist is responsible for the specification, acceptance testing, commissioning, and QA of treatment planning systems. In addition, the physicist performs or oversees the determination of radiation dose distributions in patients undergoing treatment (i.e., computerized treatment planning or direct radiation measurements). This includes consultation with the radiation oncologist and the evaluation and optimization of radiation therapy for specific patients.

Establishment of QA Procedures. The radiation oncology physicist is required to be available to the department of radiation oncology according to JCAHO (1987). The physicist can ensure that the policies and procedures "contain proper elements of good radiation oncology practice, delivery of treatment, radiation safety, quality control, and regulatory compliance" (AAPM, 1987). Moreover, the radiation oncology physicist should perform a yearly review of the appropriate sections of the policies and procedures manual (JCAHO, 1992).

Supervision of Therapy Equipment Maintenance. Regular maintenance of the treatment machines is required. We recommend that this be overseen by the radiation oncology physicist. While the supervising radiation oncology physicist does not usually perform the actual machine maintenance, he or she is responsible for releasing a treatment machine into clinical service after maintenance, and for documenting that any alteration caused by the maintenance and repair schedule does not affect the accelerator performance or calibration.

Education. The radiation oncology physicist has a responsibility to provide education and training in medical physics for physicians, radiation therapists, dosimetrists nurses, medical technical assistants, as well as student physicists and technical staff.

3. Responsibilities of the Medical Radiation Dosimetrist

The medical radiation dosimetrist is professionally engaged at the interfaces between: (1) the clinical requirements of patient treatment prescribed by the radiation oncologist; (2) the physical requirements specified by the radiation oncology physicist for calibrating, designing, and executing the patient's prescription; and (3) the simulation and treatment delivery procedures implemented by the radiation therapist.

The medical radiation dosimetrist occupies a unique specialized position, responsible for the efficient translation of these clinical and physical requirements, calibrations, and procedures into a coherent individually planned course of radiation for the cancer patient. The medical radiation dosimetrist has a major responsibility for the accurate documentation and communication of all phases of this process for the entire oncology team and the patient chart.

Treatment Planning. Following consultation with the radiation oncologist and/or radiation oncology physicist, the medical radiation dosimetrist coordinates the necessary procedures to initiate the planning process. The dosimetrist may be involved in simulation procedures. Utilizing the data acquired during the planning process (CT, MRI, and simulation), the dosimetrist generates two-dimensional or three-dimensional isodose plans following the specifications of the radiation oncologist. The final plan is reviewed by the radiation oncology physicist and approved by the radiation oncologist. The dosimetrist then documents and communicates all facets of the treatment plan to the oncology team, and assures that a copy of the treatment plan is placed in the patient's chart.

Dose Calculations. Manual or computer-generated dose calculations are performed by the dosimetrist and placed in the patient's chart. The dosimetrist will participate in regular chart review.

Radiation Measurement. Utilizing ion chambers, TLD, or film, the medical dosimetrist may aid the radiation oncology physicist with special clinical measurements. The dosimetrist, as a member of the QA team, also assists with machine calibrations and ongoing QA under the supervision of the radiation oncology physicist. In assisting with brachytherapy procedures, the dosimetrist may perform source loadings, isodose computations, and radiation surveys.

Education. Dosimetrists may conduct formal didactic lectures or technical in-service training for radiation oncology staff and other personnel (dosimetry students, therapy students, residents). Dosimetrists may attend, plan, or conduct educational workshops. In addition, as new techniques are developed and implemented, dosimetrists may be involved in clinical research with the oncology team.

Supervision. Acting in a supervisory role, the dosimetrist records and audits services rendered for reimbursement. Ordering clinical supplies and equipment and scheduling preventive maintenance are tasks performed by the dosimetrist at the discretion of the treatment facility.

4. Responsibilities of the Radiation Therapist

Radiation therapists are highly skilled professionals qualified by education to provide radiation therapy-related patient services under the supervision of a radiation oncologist or, where appropriate, a medical radiation oncology physicist. The radiation therapist is capable of and responsible for the following functions (ACR, 1988):

- Delivery of Radiation
  - -Deliver a planned course of radiation therapy.
  - -Verify prescription.
  - -Maintain daily records and document technical details of the treatment administered.
  - -Observe the clinical progress of the patient undergoing radiation therapy, observe the first signs of any complication, and determine when treatment should be withheld until a physician can be consulted.
  - -Provide patient care and comfort essential to radiation therapy procedures.
- Treatment Machines
  - -Detect equipment malfunctions, report same to the proper authority, and know the safe limits of equipment operation.
  - -Apply the rules and regulations for radiation safety, detect any radiation hazards, and provide for appropriate public safety in the event of a radiation accident.
  - -Understand the function and utilization of equipment.
  - -Understand the use of all treatment accessories.
- Treatment Planning
  - -Understand treatment methods and protocols.
  - -Simulate and plan a prescribed course of treatment.
  - -Construct immobilization and beam-directional devices and prepare brachytherapy molds.
  - -Calculate and/or review monitor unit (minutes) calculations for nongraphical plans under supervision of physicist.
- Brachytherapy
  - -Assist in the preparation of brachytherapy sources.
- Machine QA
  - -Assist the physicist in calibration of QA of treatment machines.
  - -Assist in maintaining records.
- Follow-Up
  - -Participate in the patient follow-up program.
  - -Assist in recording statistical data.
- Education
  - -Participate in patient education procedures.

APPENDIX B: QA DEFINITIONS

The QA definitions in this section were developed by the International Standards Organization (IS0 8402-1986), and reprinted and accepted by the American National Standards Institute, Inc. and the American Society for Quality Control as an American National Standard (ANSI/ASQC A3-1987); they have been adapted for Radiation Oncology QCA.

Throughout these definitions, reference is made to "product" or "service." These words are intended in a broad sense. Examples of products are custom beam blocks and custom treatment aids. Examples of services are physical examination, treatment planning, and treatment administration.

Quality. The totality of features and characteristics of a radiation therapy process that bear on its ability to satisfy stated or implied needs of the patient.

Comment: In order to assure, control, or improve quality, it is necessary that it be evaluable. This definition calls for the identification of those characteristics and features bearing upon the "fitness-for-use" of a product or service. The "ability to satisfy stated or implied needs" reflects value to the patient and includes economics as well as safety, availability, maintainability, reliability, design, and all other characteristics that the need for the product or service involves. The phrase "stated or implied needs" includes defining a price as well as stating what must be achieved, since it is usually possible to improve use characteristics if price is not a limitation.

Quality Assurance. All those planned or systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.

Comment: Quality assurance involves making sure that quality is what it should be. This includes a continuing evaluation of adequacy and effectiveness with a view to timely corrective measures and feedback initiated where necessary. For a specific product or service, quality assurance involves the necessary plans and actions to provide confidence through verifications, audits and the evaluation of the quality factors that affect the adequacy of the design for intended applications, specification, production, installation, inspection, and use of the product or service. Providing assurance may involve producing evidence.

- When quality assurance is used in the total system sense, as it normally is when the term is not modified by a restrictive adjective, it has to do with all aspects of quality.
- For effectiveness, quality assurance usually requires a continuing evaluation of factors that affect the adequacy of the design or specification for intended applications as well as verifications and audits of production, installation, and inspection operations. Providing confidence may involve producing evidence.
- Unless given requirements fully reflect the needs of the patient, quality assurance will not be complete.
- Within an organization, quality assurance serves as a management tool.

Quality Audit. A systematic and independent examination and evaluation to determine whether quality activities and results comply with planned arrangements and whether the arrangements are implemented effectively and are suitable to achieve objectives.

Comments:

- Quality audits are performed by personnel not directly responsible for the areas being audited, preferably in cooperation with the responsible personnel.
- One purpose of a quality audit is to evaluate the need for improvement or corrective action. An audit should not be confused with "surveillance" or "inspection" activities performed for sole purposes of process control or product acceptance.
- Quality audit can be conducted for internal or external purposes.

Quality Control. The operational techniques and activities used to fulfill requirements of quality.

Comments: Quality control involves operational techniques and activities aimed at both monitoring a process and eliminating causes of unsatisfactory performance at relevant stages in order to achieve economic effectiveness.

The aim of quality control is to provide quality that is satisfactory (e.g., safe, adequate, dependable, and economical). The overall system involves integrating quality aspects of several related steps, including the proper specification of what is wanted, design of the product or service to meet requirements, production or installation to meet the full intent of specifications, inspection to determine whether the resulting product or service conforms to the applicable specification, and review of usage to provide revision of the specifications. Effective utilization of these technologies and activities is an essential element in the economic control of quality.

Quality System (Comprehensive Quality Assurance Program). The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Comments:

- The quality system should be only as comprehensive as needed to meet the quality objectives.
- For regulatory compliance and assessment purposes, demonstration of the implementation of identified elements in the system may be required.

Quality System Audit (Comprehensive Quality Assurance Program Audit). A documented activity performed to verify, by examination and evaluation of objective evidence, that applicable elements of the quality 'system are suitable and have been developed, documented, and effectively implemented in accordance with specified requirements.

Comments: In general, a quality system audit is an independent (unbiased) assessment of the effectiveness of an organization's quality system. The findings should be clearly reported so that the operation being audited can implement any required corrective action.

[1]The term radiation therapist is used throughout rather than the older ap pellation radiation therapy technologist.

[2]By cost, we generally mean the time and effort involved in carrying out the recommendations. However, there may be other costs due to the need for additional equipment or the loss of treatment time.

[3]While 5% appears to be achievable in many instances with external beam treatments, we consider 15% more reasonable for brachytherapy procedures (see also Sec. V).

[4]The term treatment planning is used in a wide variety of contexts and with different meaning. It sometimes refers to the narrower process of obtaining isodose distributions, or it may refer to the planned treatment regime (for example, the "plan" of treating a patient with combined chemotherapy and radiation). Since there is no universal agreement, treatment planning here refers to the technical process from data acquisition to treatment verification, while the terms graphical treatment planning or graphical planning apply to the use of computers to design a treatment and produce isodose distributions. In Sec. VI we must deal with the broader view of patient treatment; in that context, the term plan of treatment is used.

[5]In many cases, a tighter limit of 2% is practical. However, in some instances where sophisticated dose calculation algorithms are used and there are significant inhomogeneities, and/or substantial blocking of the field, and/or electrons, a 2% limit may be too tight. Under these conditions, 5% may be more realistic.

[6]See footnote 4 for the distinction between treatment plan and plan of treatment.

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