

RADIATION ONCOLOGY
IN
INTEGRATED CANCER MANAGEMENT
REPORT OF THE INTER-SOCIETY COUNCIL
FOR RADIATION ONCOLOGY

Sponsored by the:

American Association of Physicists in Medicine
American College of Medical Physics
American College of Radiology
American Radium Society
American Society for Therapeutic Radiology and
Oncology
North American Hyperthermia Group
Radiation Research Society
Radiological Society of North America
Society of Chairmen of Academic Radiation Oncology
Programs

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PRIOR "BLUEBOOKS"

- 1968 – A Prospect for Radiation Therapy in the United States
- 1972 – A Proposal for Integrated Cancer Management in the United States: The Role of Radiation Therapy
- 1981 – Criteria for Radiation Oncology in Multidisciplinary Cancer Management
- 1986 – Radiation Oncology in Integrated Cancer Management

SUBCOMMITTEE TO WRITE "RADIATION ONCOLOGY IN INTEGRATED CANCER MANAGEMENT"

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August 5, 1991

Gerald Hanks, M.D.
Chairman, Inter-Society Council for Radiation Oncology
Department of Radiation Oncology
Fox Chase Cancer Center
Central and Shelmire Avenues
Philadelphia, PA 19111

Dear Gerry:

The fifth "Blue Book," Radiation Oncology in Integrated Cancer Management, has been completed. This document continues an evolution from, *A Prospect for Radiation Therapy in the United States* (1968), *A Proposal for Integrated Cancer Management in the United States: The Role of Radiation Oncology* (1972), *Criteria for Radiation Oncology in Multidisciplinary Cancer Management* (1981) and *Radiation Oncology in Integrated Cancer Management* (1986).

The sections on Quality Assurance and Criteria for Utilization of Equipment and Facilities have been extensively revised and a section on Economic Issues has been added.

Members representing the professional societies which comprise the Inter-Society Council for Radiation Oncology support this document.

Sincerely,

Robert G. Parker, M.D., Chair
ISCRO Subcommittee for
Revision of the "Blue Book"

August 5, 1991

Eli Glatstein, M.D.
NCI, Department of Radiation Oncology
Building 10, Room B3-B69
9000 Rockville Pike
Bethesda, MD 20892

Dear Eli:

The Inter-Society Council for Radiation Oncology is a group of radiation oncologists, biologists, and physicists who are organized to foster the development of research, education, and the clinical sciences in the field of radiation oncology. We actively review research proposals and undertake projects with the purpose of improving cancer treatment.

I am pleased to present you with a copy of the final draft of the fifth edition of "Radiation Oncology in Multidisciplinary Cancer Management," commonly known as the "Blue Book."

Traditionally, the Blue Book has received the endorsement of the National Cancer Institute and ISCRO now would welcome your endorsement of the 1991 edition.

As you are aware, the Blue Book is extremely important in the planning and staffing of radiation therapy facilities. Perhaps, most importantly, it has become the back bone of quality assurance programs.

This 1991 edition of the Blue Book has two objectives. Reasonable standards for radiation therapy, inclusive of those for personnel, equipment, facilities and operations, are defined, and guidelines for the optimal use of radiation therapy in the integrated management of patients with cancer are suggested.

Thank you for your consideration of our request and I look forward to hearing from you.

Sincerely,

Gerald E. Hanks, M.D.
Chairman

August 27, 1991

Dr. Gerald E. Hanks
Chairman
Inter-Society Council for Radiation Oncology
1101 Market Street
14th Floor
Philadelphia, PA 19107

Dear Dr. Hanks:

I commend you and ISCRO subcommittee members for the 1991 "Blue Book" revision entitled, "Radiation Oncology in Multidisciplinary Cancer Management." This report, the fifth edition prepared by the radiation oncology community, succinctly presents the standards for clinical practice and the objectives for radiation oncology during the remainder of the 1990s. Your evaluation of the criteria for standard radiotherapy practice is particularly important at this time because multi-modality cancer treatment has an increasing number of cancer patients. Your continued effort to provide standards for radiation oncologists as well as guidelines for health care leaders is an excellent example for other oncologic disciplines.

The National Cancer Institute established the Radiation Research Program in 1982, and this program continues to provide a visible and strong focus within the NCI for support of research and related activities in radiation oncology, diagnosis, biology, and physics. Your activities represent an important complement to the research initiatives sponsored by the NCI program.

I am pleased to endorse the 1991 report and once again encourage you and your colleagues in the radiation oncology community to continue your efforts in the conquest of cancer.

Sincerely,

Eli Glatstein, M.D., Acting Director
Radiation Research Program
National Cancer Institute

August 12, 1991

Gerald Hanks, M.D.
Chairman, Inter-Society Council for Radiation Oncology
Department of Radiation Oncology
Fox Chase Cancer Center
Central and Shelmire Avenues
Philadelphia, PA 19111

Dear Dr. Hanks:

On behalf of the Commission on Radiation Oncology of the American College of Radiology, I wish to commend you and your colleagues for the work you have done in revising the "Blue Book." This fifth edition, "Radiation Oncology in Integrated Cancer Management," builds effectively on the strong foundation established by the previous four versions which, since 1968, have placed radiation oncology in a unique position within cancer management by having established criteria for the proper delivery of radiation therapy. This document will serve, as its predecessors have, to provide the most up-to-date elements of the structure and process for providing the most effective radiation therapy. Personnel and equipment requirements, programs for monitoring the quality of patient care, and descriptions of the key interactions with the patients, are well described. It will serve well the needs of cancer patients and those committed to providing the best care for those patients, throughout the last decade of the 20th Century.

Sincerely,

James D. Cox, M.D., Chairman
Commission on Radiation Oncology
American College of Radiology

I. INTRODUCTION

Every patient with cancer should have access to the best possible care regardless of constraints such as geographic separation from adequate facilities and professional competence, economic restrictions, cultural barriers or methods of health care delivery. Suboptimal care is likely to result in an unfavorable outcome for the patient, at greater expense for the patient and for society.

The major components of treatment continue to be surgery, radiation therapy and systemic chemotherapy. Optimal use of these therapeutic modalities requires proper *initial* management decisions. These decisions must be made by health care professionals, who have an understanding of the biology of cancer in the human and the treatment options.

Potential contributions and liabilities of each treatment method must be presented by surgeons, medical oncologists and radiation oncologists as equal members of the patient management team. Essential pretreatment interaction amongst surgeons, medical oncologists and radiation oncologists should continue throughout the course of treatment and the long-term follow-up for every patient.

Patients with cancer, and/or their selected advisors or relatives, must have the opportunity to become fully informed about their medical status, all of the reasonable treatment options and the likely consequences of each management program and even of no treatment. This right of patients to participate in decisions related to their care must be respected at all times.

There are many different approaches to providing *optimal* care. These are tailored to local needs and resources. However, in every circumstance, the integration of highly trained personnel and expensive facilities is required. High quality radiation therapy can be provided most efficiently when the number of patients is large enough to fully utilize the necessary expertise and expensive facilities. Currently, in the United States, at least 50% of facilities have only one

megavoltage radiation treatment unit, and approximately 25% are staffed by a single physician either full-time or part-time¹. It is essential that these limited facilities, whether located in a hospital or free-standing, have the capability for the same high quality patient care available in larger centers. Treatment planning skills, a computer-based treatment planning system, simulation, direct medical radiation physicist involvement, high energy photon and electron beams, skilled brachytherapy and the capability to fabricate treatment aids must be available to the patients in small facilities, either on-site or through arrangements with nearby centers.

Although good radiation therapy programs always have included procedures specifically designed to minimize error and risk and to promote consistent high quality patient care, these activities have become formalized Quality Assurance Programs.

Multiple groups within and outside medical centers now require extensive documentation of compliance with defined standards as a requisite of continued approval of the program and the affiliated medical center.

The costs of health care in general, and for patients with cancer specifically, have come under increased scrutiny. Although the support of radiation therapy in the United States consumes less than 0.5% of health care expenses (Powers, W.E., personal communication, 1989), the expensive facilities and extensively trained personnel are likely targets for cost containment.

Consequently, expanded and updated sections on Quality Assurance and Utilization of Facilities and Equipment are included in this publication.

II. OBJECTIVES OF THIS REPORT

In this report:

- 1) reasonable standards for radiation therapy, inclusive of those for personnel, equipment, facilities and operations, will be defined; and
- 2) guidelines for the optimal use of radiation therapy in the integrated management of patients with cancer will be suggested.

¹Facility Master List Survey, Patterns of Care Study, American College of Radiology

III. GOALS OF CANCER MANAGEMENT

The primary goal of health care personnel and their supporting organizations, and of society generally, is to provide the best possible care to every patient with cancer. The objectives of cure, palliation or long-term tumor control must be clearly defined. Each patient, whether part of an organized study or not, must become a source of information available for continual improvement of therapeutic performance. Concurrently, better methods, equipment and facilities must be developed, and educational programs must be provided for personnel.

IV. THE CLINICAL ROLE OF RADIATION THERAPY

Surgery, radiation therapy and systemic chemotherapy remain the bases of the management of patients with cancer. Hopefully, other methods, such as those modulating the host's immune system, will soon prove useful, at least as adjuvants.

The usual objective of surgery or radiation therapy is local/regional control of tumor. In addition, ionizing radiations may be used as a systemic agent. Chemotherapy usually is used systemically, although it may, on occasion, be used regionally. Surgery, radiation therapy and chemotherapy can be used individually or in various combinations and sequences.

Currently, radiation therapy is used in the management of 50-60% of all patients with cancer. Its use, as for surgery and chemotherapy, must be decided and controlled by specifically trained, competent personnel.

Radiation therapy may be used alone or with other treatments to cure humans with cancers arising in nearly every anatomic site. The inherent advantage of the method is the preservation of anatomic structures and their function. Today, cure should be the objective for approximately 50% of all patients treated. For these patients, cost, inconvenience and iatrogenic morbidity may be of less concern than they are for those unfortunate patients, who are not curable by currently available methods.

Properly used, radiation therapy is a superb palliative agent with a high likelihood of success and easily controlled or avoided morbidity. Examples are: relief of pain from bony metastases; preservation of skeletal integrity; reduction of intracranial pressure with resultant relief of headaches and neurological dysfunction; restoration of the patency of tumor-compromised lumina (esophageal, bronchial, vascular); and control of tumor-induced bleeding.

Conventional, external beam radiation therapy (teletherapy) usually is delivered in single daily increments for several weeks. Currently, there are ongoing trials of the use of multiple increments daily over the same period (hyperfractionation) or over shorter times (accelerated fractionation). The prolonged period of treatment provides an opportunity for all members of the radiation oncology team to provide support to patients.

Intraoperative radiation therapy, using single increments of X-rays or electron beams directed to targets exposed at surgery, is being investigated. The potential advantage is the physical displacement or protection of normal structures from the radiation beam. Inasmuch as a fractionated high total dose is not possible with this approach, it is used to deliver a large "boost" dose.

Brachytherapy, exploiting a variety of radionuclide sources, is used primarily for cancers arising in the head and neck, breast and pelvis. The advantage of this method is delivery of a dose to a tumor, which is relatively higher than that delivered to adjacent normal tissues. In most instances, such interstitial and intracavitary placement of radioactive sources is an operative procedure requiring an anesthetic for the patient.

Particles, both charged (protons, helium ions, heavy ions) and unchanged (neutrons) are being investigated, both as teletherapy beams and brachytherapy agents. Such particles produce more dense ionization in tissues and so theoretically reduce the adverse influence of cellular hypoxia and the effect of position in the cell cycle at the time of irradiation.

Augmentation of the therapeutic effectiveness of ionizing radiations, through the use of adjuvants, is being investigated. Heat applied regionally may be cytotoxic at 42–45°C, and it may augment cell killing by ionizing radiations or chemotherapeutic agents. Selective effectiveness of heat against cancer cells is based on the diminished blood flow in tumors relative to normal tissue with consequent decreased ability to dissipate heat and maintain normal homeostasis. Several systemically administered drugs may increase the sensitivity

of cells to ionizing radiations. Some of these, such as doxorubicin and dactinomycin, unfortunately, may increase the radiation sensitivity of both tumor and normal cells and, consequently, a therapeutic advantage does not result. Electron-affinic compounds may lessen the adverse effects of tumor cell hypoxia on radiosensitivity.

Total body irradiation, long used in multiple small doses as a therapeutic agent in hematopoietic and lymphomatous disorders, is used in larger doses to destroy abnormal (and normal) bone marrow prior to the transplantation of healthy marrow. Total body irradiation, or total nodal irradiation, is used to suppress the immune system in a variety of diseases.

V. THE PROCESS OF RADIATION THERAPY

The clinical use of ionizing radiations is a complex process involving highly trained personnel in a variety of interrelated activities (Tables V-1A and V-1B).

A critical step is the initial evaluation of the patient and an assessment of the tumor. This requires a pertinent history, complete physical examination, a review of all diagnostic studies and reports and discussion with the referring physician.

The radiation oncologist must be aware of the biologic characteristics of the patient's cancer as a basis for estimating its clinical behavior and planning treatment. The documented extent of each cancer must be recorded as a basis for staging. This will support an estimate of the prognosis for each patient and will enable comparison of treatment performances between different medical centers.

Initial decisions about therapy include: an estimate of whether treatment is likely to help the patient; selection of cure or palliation as the objective; and identification of alternative therapies with consideration of their relative merits. If ionizing radiations are to be used, the beam characteristics and/or radionuclide sources, the method and pattern of delivery, doses and sequencing with other treatments must be known.

It is important to discuss these initial tentative decisions with the patient's other physicians, the patient and responsible family members or designees.

Treatment planning requires determination of the tumor site and extent in relation to normal tissues. This assessment is based on physical examination, endoscopy, diagnostic imaging and findings at surgery. The relative contributions of external radiation beams, brachytherapy, intraoperative irradiation and adjuvants need to be considered. The radiation oncologist specifies the doses desired throughout the tumor and sets limits of doses to critical structures. The physician, medical radiation physicist and dosimetrist then

TABLE V-1A
PROCESS OF RADIATION THERAPY (EXTERNAL BEAM)

1. **CLINICAL EVALUATION**
 - Initial multidisciplinary evaluation of patient
 - Decision for radiation therapy
 - Assessment of pathobiology of tumor
 - Staging
2. **THERAPEUTIC DECISION-MAKING**
 - Selection of treatment goals—cure/palliation
 - Choice of modalities of treatment
3. **TARGET VOLUME LOCALIZATION**
 - Definition of tumor extent and potential routes of spread
 - Identification of sensitive organs and tissues
4. **TREATMENT PLANNING**
 - Selection of treatment technique
 - Computation of dose distribution and verification of accuracy
 - Determination of dose/time/volume relationship
5. **SIMULATION OF TREATMENT**
 - Selection of immobilization devices
 - Radiographic documentation of treatment ports
 - Measurement of patient
 - Construction of patient contours
 - Shaping of fields
6. **FABRICATION OF TREATMENT AIDS**
 - Construction of custom blocks, compensating filters
7. **TREATMENT**
 - Initial verification of treatment set-up
 - Verification of accuracy of repeated treatments
 - Continual assessment of equipment performance
 - Periodic checks of dosimetry, record keeping
8. **PATIENT EVALUATION DURING TREATMENT**
 - Evaluation of tumor response
 - Assessment of tolerance to treatment
9. **FOLLOW-UP EVALUATION**
 - Evaluation of tumor control
 - Assessment of complications of treatment

TABLE V-1B
PROCESS OF RADIATION THERAPY (BRACHYTHERAPY)

- 1. CLINICAL EVALUATION**
Initial multidisciplinary evaluation of patient
Decision for radiation therapy
Assessment of pathobiology of tumor
Staging
- 2. THERAPEUTIC DECISION-MAKING**
Selection of treatment goals — cure/palliation
Choice of modalities of treatment
- 3. TARGET VOLUME LOCALIZATION**
Definition of tumor extent and potential routes of spread
Identification of sensitive organs and tissues
- 4. TREATMENT PLANNING**
Selection of volume to be treated
Selection of geometry for application
Computation of doses and dose distributions
Estimation of tolerance to procedure
Check off of equipment
Arrangement for surgical suite and anesthesia
- 5. TREATMENT**
Examination of anesthetized patient
Review of initial treatment plan
Implantation
- 6. VERIFICATION OF IMPLANTATION**
Orthogonal or stereo radiographs
- 7. DOSIMETRY**
Calculation from actual implantation
Establishment of time for removal
- 8. PATIENT EVALUATION DURING TREATMENT**
Assessment of tolerance
Check of position of implant
- 9. REMOVAL OF IMPLANT**
- 10. FOLLOW-UP EVALUATION**
Assessment of early and late sequelae
Evaluation of tumor control

design potential treatment deliveries which satisfy these requirements. The calculation of doses at multiple sites and the mapping of isodose patterns, based on accurately measured doses and other physical characteristics, usually require the use of special computer programs. The physician, upon the advice of the medical radiation physicist and dosimetrist, then selects the best treatment plan for the individual patient.

After the therapeutic approach is selected, the target volume is confirmed and recorded radiographically at simulation. Simulators are specialized units which can reproduce all of the motions of the specific treatment unit to be used. Orthogonal radiographic units are being supplemented by units which display cross-section anatomy. The use of cross-section anatomy (CT scans) supports three-dimensional definition of the target volume. Such use allows immediate treatment planning with later simulation for field marking, identification of treatment unit parameters and radiographic verification of the treatment set-up. The availability of fluoroscopy aids and hastens the process. Simulation, which may be a two-step process, is carried out by a specially trained radiation therapy technologist under the supervision of the radiation oncologist.

Devices to aid in positioning and immobilizing the patient, normal tissue shields, compensating filters and other aids need to be designed and fabricated. This requires access to a specialized preparation room and a machine shop.

Prior to initiation of treatment, radiographs produced by the treatment beam of the teletherapy unit are compared to the simulator films to verify that the beams and targets are identical. Dosimeters may be used, *in vivo*, to measure and record actual doses at specific anatomic sites.

Daily treatments are carried out by radiation therapy technologists who are under the direct supervision of the radiation oncologist and the medical physicist. It is essential that all treatment applications be described in detail (orders) and signed by the responsible physician. Likewise, any changes in the planned treatment by the physician

may require adjustment in immobilization, new calculations and even a new treatment plan. Thus, the technologist, physicist and dosimetrist need to be notified.

Although the daily treatment is set up on the teletherapy unit by technologists, a responsible physician must be available in the department or nearby for confirmation of the treatment, if necessary, and for unscheduled decisions and supervision of personnel. A variety of specific checks to insure conformity to the planned treatment should be in place. Therefore, a physician does not need to visually check each treatment set-up.

The responsible physician monitors the patient's progress by checking the daily entries in the treatment chart and discussing the patient with the technologists, nurses, relatives or friends, and other involved physicians and by periodic examinations. Re-evaluation examinations usually are scheduled at least weekly. Portal verification films, pertinent laboratory and visual imaging studies are periodically ordered and reviewed. The patient, referring physician and responsible friends and/or relatives should be informed of the progress of treatment.

Periodic post-treatment assessment of the accomplishments and possible sequelae of treatment is essential. The radiation oncologist, as the most qualified observer to detect and initiate management of post-irradiation tumor activity or sequelae in normal tissues, must be involved in the post-treatment follow-up program. Early detection of post-treatment tumor activity may permit additional treatment, which may be curative. Early detection and treatment of radiation-induced sequelae may avoid serious problems later.

VI. QUALITY ASSURANCE OF RADIATION THERAPY

The purpose of a Quality Assurance Program is the objective, systematic monitoring of the quality and appropriateness of patient care. Such a program is essential for all activities in Radiation Oncology.

The Quality Assurance Program should be related to structure, process and outcome, all of which can be measured. Structure includes the staff, equipment and facility. Process covers the pre- and post-treatment evaluations and the actual treatment application. Outcome is documented by the frequency of accomplishing stated objectives, usually tumor control, and by the frequency and seriousness of treatment induced sequelae.

The Director of Radiation Oncology is responsible for the organization and supervision of the departmental Quality Assurance Program.

Periodic (at least monthly) audits of recently completed charts by designated reviewers using appropriate screens (check lists) should be reported to the departmental Quality Assurance Committee. All identified problems should be discussed and recorded and a remedial action plan instituted. Requirements of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Nuclear Regulatory Commission (NRC) should be fulfilled.

Components of a Quality Assurance Program for Radiation Oncology are summarized in the following:

6.1 Equipment

Minimal requirements for equipment include: 1) at least one supervoltage/ megavoltage teletherapy unit, with an energy exceeding 1 MV. The distance from the source to the isocenter must be at least 80 cm; 2) access to an electron beam source or a low energy X-

ray unit; 3) appropriate brachytherapy equipment and sources for intracavitary and interstitial treatment; 4) adequate equipment to calibrate and measure dosimetric characteristics of all treatment units in the department; 5) capability to provide appropriate dose distribution information for external beam treatment and brachytherapy; 6) equipment for accurate simulation of the treatment units in the department; 7) field-shaping capability; and 8) access to CT scanning capability (advisable).

6.2 Programs

Minimal programs include: 1) calibration of equipment and measurement of radiation beam characteristics to assure accurate and reliable delivery of the ionizing radiations; 2) charting systems for recording treatment doses; 3) accurate calculation of doses and dose distributions, checks of dose calculations and ongoing reviews of accumulating doses; 4) devices for prevention of mechanical injury of the patients or personnel by the treatment units or accessory equipment; 5) surveillance of the wearing, reading and recording of information from individual film badges; 6) systematic inspection of interlocks; 7) routine leak testing of sealed radioactive sources; 8) availability of safety equipment and use of personnel and patient safety procedures when fluoroscopy and sealed radioactive sources are used; 9) instruction in safe work habits and pertinent new developments; and 10) regular maintenance and repair of equipment.

6.3 Facilities

It is necessary that ramps, doorways, halls and lavatories accommodate wheel chairs, walkers and litters (except for lavatories). There should be holding areas for patients on litters or in beds. The internal environment should provide adequate lighting, ventilation and temperature control. Emergency procedures for fires and other catastrophes should be in place and understood by personnel.

6.4 Patient Evaluation and Treatment

All components of the evaluation of the patient and his/her cancer must be documented in the patient's Radiation Oncology Record. The format, which should facilitate care of the patient in the department, usually includes: a general information sheet listing the names of pertinent relatives, follow-up contacts, referring and family physicians and persons to notify in an emergency; initial history and findings on physical examination; reports of the pathology examinations, laboratory tests, diagnostic imaging studies and pertinent operations; photographs and anatomic drawings; medications currently used; correspondence with physicians and reimbursement organizations; treatment set-up instructions; daily treatment logs; physics, treatment planning and dosimetry data; progress notes during treatment; summaries of treatment; and reports of follow-up examinations.

It is essential that these radiation oncology records be maintained and secured in the department separate from hospital and clinic records to insure ready access at any time for a variety of purposes. Lack of immediate access to patient data can disrupt daily activities in the radiation oncology department. For example, all current and previous treatment data and the treatment plan, with any recent changes, must be available to the radiation therapy technologists each day when the patient is set up for treatment, before the beam is activated. Inasmuch as patients may be treated every 10–15 minutes throughout the day on each megavoltage unit, lack of immediate availability of data on a specific patient would result in chaos. In addition, radiation oncologists, who are on-site and thus "available", frequently receive unscheduled inquiries about patients being treated or those whom have been treated. Copies of pertinent data generated in the department, such as the initial consultation report, the summary of treatment and reports of follow-up visits must be included in each patient's hospital chart to be available to others throughout the medical center.

6.5 Informed Patient Consent

Prior to the initiation of any patient management program, the patient must give valid consent for the actual treatment and related activities such as photography of the face or treatment portals. If the patient is not mentally competent, consent must be obtained from a legally qualified representative. Each radiation oncology center should have a methodology to explain to the patient, or proper representatives, the patient's status, treatment alternatives with their reasonable objectives and possible sequelae and the consequences of no treatment. Informational materials, such as brochures, tape recordings, video presentations and identification of available support services, may help the patient to understand and consequently to comply. If possible, explanations should be in the language preferred and best understood by the patient.

6.6 Treatment Planning Data

All data used in planning the specific treatment for a patient should be immediately available for review. These include: anatomic drawings, copies of appropriate visual imaging examinations, radiographs from simulation of treatment, computation of beams and dose patterns, reasons for the choice of a specific management program, treatment beam verification films, calculation of doses and dose distributions and records of special physical measurements.

6.7 Treatment Data

The centerpiece of the patient's radiation therapy record is the charting of each treatment. These entries, which must be made at the time of each application of ionizing radiations, usually include the daily and cumulative doses through each field to the target and sites of special interest, such as the spinal cord, kidney or eye. For irregular-shaped fields, doses should be calculated at several anatomic sites. Supporting data, such as the actual identifying number and dimensions of each field, maximum dose to each field, consecu-

tive number of the treatment, overall time since initiation of treatment and actual date, usually accompany the dose entries. In addition, there should be positive identification of the equipment used, any treatment aids, the responsible radiation oncologist and referring physician. A written prescription, signed by the responsible radiation oncologist, should include daily and total doses to a specific site (stated depth or isodose contour) in a definite overall time, number of fields to be treated daily and the pattern of application (number of treatments per week). Photographic recording of the position of the patient during treatment, each treatment field and the patient's face help recall.

6.8 Assessment of Treatment

The results of treatment, with documentation of the status of the tumor and sequelae, must be assessed for every patient. Periodic evaluation of patients, in concert with other physicians including oncologists and the primary care provider, is an essential part of management. This is a responsibility shared by the patients and their physicians. A record of outcome by anatomic site, stage and histology should include all patients treated. Other information such as the presence of intercurrent diseases and other treatments is useful. Documenting and keeping these records current is necessary to insure high quality performance. This ever increasing burden of monitoring results should be simplified through the use of an automated data retrieval system.

6.9 Patient-Related Data

The following data should be maintained and kept current at every treatment facility: number of new and former patients seen in consultation; number of new and former patients treated; number of tumors treated at each anatomic site; number of simulations; number of treatment plans; number of treatment portals; whether the treatments were simple, complex or intermediate; number and types of brachytherapy procedures (interstitial implantations, intracavitary

insertions, surface and special applications); and number of post-treatment follow-up examinations.

Annual summaries of these data should be analyzed.

6.10 Assessment of Operations

Each facility should have ongoing programs to monitor operations. Patient flow parameters, such as access to parking, promptness of patient scheduling, intervals from referral to consultation and initiation of treatment, patient treatment throughput per unit time, must be assessed so that deficiencies can be corrected.

6.11 Medical Radiation Physics

The ultimate objective of Medical Radiation Physics activities is to assure the delivery of high quality radiation therapy. These activities include active participation in: treatment planning; consultation and educational activities aiding the radiation oncologists and other staff; decisions on the purchase of equipment; and activities that assure that all radiation equipment and sources are operated and handled safely in order to provide adequate protection of staff, patients and the general public.

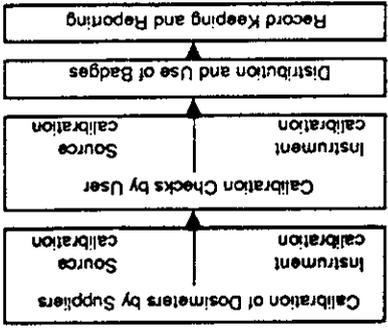
The Quality Assurance Program in Medical Radiation Physics must be developed and monitored by a qualified medical radiation physicist. Necessary quality control of the physical components of radiation therapy includes: 1) assurance of proper, accurate and safe function of all treatment units and simulators; 2) procurement and storage of radioactive sources, and monitoring the proper function of brachytherapy applicators; 3) treatment planning with computer support; 4) monitoring of dosimetry, calibration and beam characteristics; and 5) surveillance safety of patients and personnel. These activities are outlined in Tables VI-1 to VI-4.

The success of radiation therapy is dependent on the accuracy of delivery of specified doses to selected targets, both in tumors and

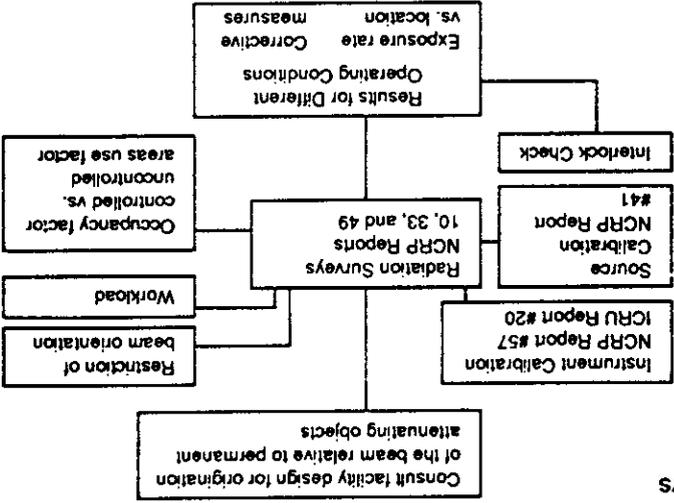
normal tissues. The margin for prevention of serious error may be slight. Therefore, the Medical Radiation Physicist must be provided with adequate personnel and equipment to accomplish these important tasks.

TABLE VI-4
QUALITY ASSURANCE: RADIATION SAFETY

PERSONNEL
DOSIMETRY



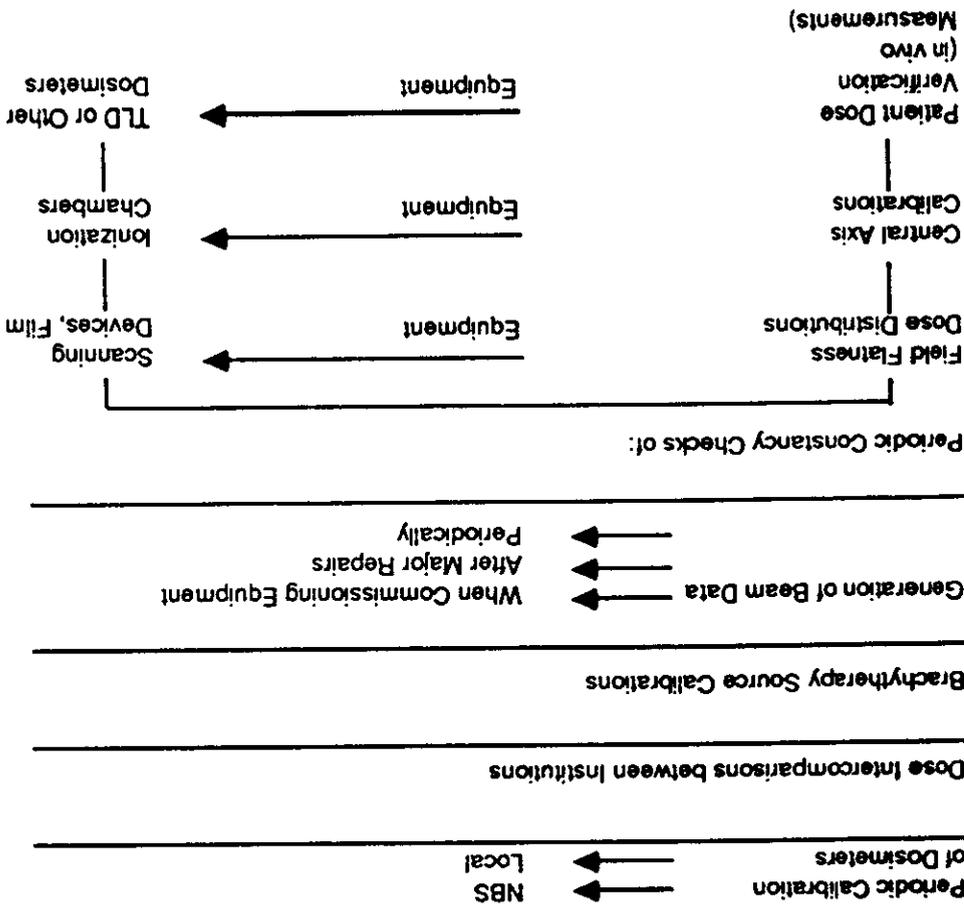
RADIATION SURVEYS



RADIOACTIVE
SOURCE HANDLING

Facility:	Storage: Shielding, inventory Work area: Shielding, handling instruments Transport: Shielding, carrier design
Maintenance:	Cleaning, Sterilization, Leaktests, Disposal Patient rooms: Recovery, transport, ward Insertion: Shielded storage -- transport Removal: Patient survey, source counting, handling instruments Personnel monitoring
Training of Personnel:	M.D.'s, Nurses, Other
Emergencies:	Source Breakage } Procedures, monitors, } call list Loss of source

TABLE VI-3
QUALITY ASSURANCE: DOSIMETRY



VII. CRITERIA FOR UTILIZATION OF EQUIPMENT AND FACILITIES

An analysis of utilization of radiation therapy is the usual basis for documenting the need for additional, new or upgraded facilities and equipment and additional or different personnel. This is a complex process which may be influenced by departmental, institutional, regional, economical and political considerations.

7.1 General Guidelines

Appropriate numerical guidelines relate the numbers and types of patients managed, the complexity of treatments, personnel, equipment and facilities. These guidelines may be modified by affiliations between radiation oncologists and between treatment centers, accessibility of radiation therapy facilities to patients, limitations of existing equipment, transferability of patients between treatment facilities and financial agreements between medical centers. Such guidelines may change in time as technology and practice evolve.

7.2 Guidelines for Equipment Utilization

- a. A realistic load for a megavoltage unit is about 6,500 standard treatments (equivalent simple treatment visits or ESTVs)* per year. This approximation is based upon an average of four patients treated hourly for 7 hours daily, 5 days per week, 51 weeks per year with allowances for double time for initial set-ups of five patients starting treatment per week, for verification films and other checks once weekly on 50% of patients being treated and for equipment maintenance or repair one day per month.

*Equivalent Simple Treatment Visit (ESTV)—The time required, usually about 15 minutes, for the uncomplicated set-up and treatment of a patient on a modern megavoltage unit.

This can be calculated as follows:

4 standard treatments/hr x 7 hr/day x 5 days/wk		
x 51 wks/year	=	7,140
less double time for initial treatment		
of 5 patients/week.....	=	260
less one day per month down time for equipment		
maintenance and repair (28 patients x 12 days)	=	<u>336</u>
patient treatments per year per unit	=	6,544

The 7-hour-daily patient treatment schedule allows for equipment quality assurance procedures, warm-up time for a linear accelerator, room preparation and clean-up, and other support activities, which in total with actual treatment comprise an 8-hour work day.

As the proportion of patients requiring multiple treatments per day (hyperfractionation) or complicated treatment techniques, such as total body irradiation, total nodal irradiation or irradiation while bedfast or anesthetized increases, the number of patients treated per unit time and the total number of treatments on each apparatus will decrease. Thus, at many major referral and university medical centers, the number of treatments per megavoltage unit may be closer to 5,000 per year.

- b. If it is assumed that approximately 50% of patients will be treated for cure (30–40 increments) and 50% for palliation (10–20 increments), then about 250 patients can be treated on each megavoltage unit annually.

Patients treated for cure:		
125 patients x 35 Rx (average)	=	4,375
Patients treated for palliation:		
125 patients x 15 Rx (average)	=	<u>1,875</u>
Total		<u>6,250</u>

However, if the ratio changed to 60% of patients treated for cure and 40% treated for palliation, only 200 patients could be treated per megavoltage unit annually. Therefore, the percentage of patients treated for cure at a given institution is a major determinant in the capacity of each treatment unit.

A treated patient refers to a single course of treatment for a specific disease. If a patient returns for additional courses of treatment for new problems related to the initial cancer or to a different cancer, this is considered an additional work unit (number of patients treated). Inasmuch as the effort per patient varies widely, it may be of value to subclassify the patients by the complexity of treatment. (See Section 7.2 d.)

- c. One megavoltage radiation therapy unit should serve a population of approximately 120,000 people. This is based on the assumption that 4.1 newly diagnosed cancers will be detected per year per 1,000 people. This frequency should be adjusted for regional factors. For example, in one state the reported frequency of newly diagnosed cancers has been 4.9 per 1,000, while in another it has been 1.9 per 1,000. If 50% of all patients with cancer receive radiation therapy, then a population of 120,000, which will produce about 492 newly diagnosed cancers at 4.1 per 1,000, will provide about 245-250 patients with cancers who will receive radiation therapy.
- d. Adjustments to the above criteria must be made for: 1) dedicated special- purpose treatment units, such as for particle radiation therapy; 2) specialized procedures of limited but important application, such as total body irradiation (TBI), stereotaxic radiosurgery and intraoperative radiation therapy; and 3) patients who are difficult to handle such as infants and those in beds.

Allowances for the complexity of treatment can be based on current CPT-4 data. Simple, intermediate and complex radiation treatments are defined as follows:

Simple – single treatment site, single treatment field or parallel opposed fields with no more than simple blocks;

Intermediate – two separate treatment sites, three or more fields to a single treatment site, use of special blocking;

Complex – three or more treatment sites, tangential fields with wedges, rotational or arc techniques or other special arrangements, complex blocking (i.e., mantle and inverted Y fields).

The basic unit, one Equivalent Simple Treatment Visit (1 ESTV), requires up to 15 minutes on a modern megavoltage teletherapy unit. This includes time for portal filming. An Intermediate Treatment Visit can equal 1.1 ESTVs and most Complex Treatment Visits can equal 1.25 ESTVs.

Special consideration is required for patients needing more time than usual and for use of highly specialized treatment techniques. Thus, for children under 5 years of age, the ESTV can be multiplied by 2, and for most patients in beds the ESTV can be multiplied by 1.2.

For the increased time required for special techniques, supplemental ESTVs can be added for each visit:

Total body irradiation (photons or electrons)....	Add 4.0 ESTVs
Hemi-body irradiation	Add 2.0 ESTVs
Intraoperative radiation therapy	Add 10.0 ESTVs
Particle radiation therapy	Add 2.0 ESTVs
Dynamic conformational radiation therapy with moving gantry, collimators and couch	Add 1.5 ESTVs
Limb salvage irradiation at lengthened SSD	Add 1.0 ESTV
Additional field check radiographs	Add 0.5 ESTV
Stereotaxic radiosurgery	Add 3.0 ESTVs

e. Types of Equipment Required

Patients treated in facilities, which are utilized for curative treatment, should have access to at least two megavoltage units, either on-site or through working agreements. One of these megavoltage units should provide photons of low energy (^{60}Co or 1–6 MV X-rays) and the other, photons, of at least 10 MV and electron energies to at least 12 MeV. Alternatively, a dual-modality, dual-energy accelerator might be sufficient if the lower X-ray energy is 4–6 MV and the highest electron energy is at least 12 MeV. In larger facilities, there should be at least one high energy (10 MV or above) unit to every 2 or 3 lower energy (Co-60 teletherapy, 4–6 MV linear accelerator) units depending on work load, types of patients and tumors treated and availability of expertise and supporting resources.

The increasing use of high energy electron beams as a component of treatment, such as for “boosting” the excision site in the intact breast, reducing the dose to the heart when treating the internal mammary nodes, irradiating the chest wall following mastectomy, treating posterior cervical nodes over the spinal cord or “boosting” the dose to intraoral and pharyngeal tumor sites, requires access to this capability in each facility where curative treatment is attempted. It is unreasonable, and possibly dangerous, to transfer patients between unrelated facilities in order to provide access to electron beam therapy because the necessary coordination of the several components of radiation therapy of a specific patient becomes unlikely. It is unrealistic to assume that all patients needing electron beam therapy will be specifically referred to an “outside” facility for that purpose. For the same reason, brachytherapy must be available so that all components of a patient’s treatment can be integrated by the responsible radiation oncologist. Transfer of a patient from one facility to another during a course of radiation therapy is ill-considered because the chances for error and mismanagement are increased. Also, such disruption of care increases the cost to the patient because of duplication of effort, such as resimulation, additional reviews of records and creation of new records. In order to reduce the need to transfer patients or the temptation to treat patients with a less-than-optimal modality, the

purchase of a dual-energy, dual-modality treatment unit should be considered. Despite the above concerns, in rare cases it may still be necessary to provide part of a patient’s treatment at a remote facility, where expensive special-purpose treatment equipment is available.

Dislocation of a patient from an organized continuum of care for other reasons, such as an arbitrary geographical or institutional distribution of equipment, should be resisted by both patient and physician. In the past, the use of ill-conceived formulas to geographically distribute facilities and radiation treatment units fostered mediocrity at the expense of programs successful because of high quality performance. Referral of patients to facilities demonstrating high quality service should be supported. Administrative allocation of patients to facilities because they are under utilized promotes neither good care nor cost effectiveness.

f. Efficient Use of Resources

The high cost of an adequate radiation oncology facility generates interest in efficient use. One possibility is operation for more than a single standard work shift. Such an extension of the current conventional period of operation can be supported only if the quality of patient care is uniform throughout the entire work period. This implies comparable availability to all patients of personnel, including physicians, medical radiation physicists, nurses, technologists, receptionists and other support staff and of all services throughout the medical center, including patient billing, laboratories and administrative support. It must be realized, however, that any cost savings are likely to be less than apparent, since the equipment will wear out more rapidly and need to be replaced sooner.

7.3 Criteria for Equipment Replacement

Radiation treatment units require replacement when they become technologically obsolete or worn out. The average life of a modern megavoltage unit (linear accelerator, Co teletherapy unit) has

been 8–12 years if: the equipment has been properly maintained; replacement parts have been readily and economically available; and the operational characteristics and mechanical integrity have met performance and safety standards.

Beyond its useful working life, a megavoltage therapy unit needs to be withdrawn from clinical service unless it can be upgraded to warranty status and is not technologically obsolete. This periodic replacement and renovation of equipment is necessary not only for quality care, but for patient and personnel safety and efficient economical operation. Equipment replacement must be justified on departmental and institutional, not geographical or political, needs.

7.4 Criteria for Additional Equipment

The need for additional radiation therapy equipment in a specific facility should be based upon an increasing number of patients requiring treatment, the changing complexity of treatment or addition of a new specialized service.

Additional megavoltage equipment needs to be considered when:

1. utilization consistently exceeds the level of patient service defined in Section 7.2 (250 new patients treated or 6,500 equivalent simple treatment visits (ESTVs) annually per megavoltage unit);
2. the patient characteristics or tumor types require an increased complexity of treatment, i.e., electron beam “boosts” in breast conservation programs;
3. new techniques requiring more time per patient, i.e., total nodal or whole body irradiation, intraoperative irradiation and multifractionation of the usual daily dose increments, are introduced; and
4. there is an increased commitment to clinical research and teaching.

7.5 Simulators

- a. All modern radiation therapy facilities should have access to at least one simulator, regardless of the number of patients being treated. The need for more than one simulator in a facility can be estimated from the following:

If a simulation, which requires about 60 minutes for an ambulatory, cooperative patient, is designated as an Equivalent Simple Simulation Visit (1 ESSV), the relative values of other simulation procedures can be allocated as follows:

Mantle field	Add 0.5 ESSV
Limb salvage techniques	Add 0.5 ESSV
Intact breast techniques with 3 fields	Add 0.5 ESSV
Extended fields at increased SSD	Add 0.5 ESSV
Conformal techniques	
for each set-up in excess of 3 fields	Add 0.3 ESSV
for dynamic motion	
(collimator, gantry, couch)	Add 1.0 ESSV

In general, one simulator can service 2–3 megavoltage treatment units.

- b. Simulators, like megavoltage treatment units, need to be replaced or renovated when they become technologically obsolete, worn out, unsafe or inaccurate. Currently, simulators based on cross-section anatomy, rather than conventional orthogonal projections, are proving very useful and may become an important component of simulation.

7.6 Dedicated Special-Purpose Units

Recent development of sophisticated treatment delivery and planning systems have required the availability of special-purpose

equipment. For example, three-dimensional treatment planning and CT simulation require direct access to CT units.

Certain treatment capabilities are not needed in every radiation therapy facility but should be available to all patients. Such units, which can be considered regional and sometimes national resources, should be considered separately when assessing equipment and personnel requirements.

Examples are heavy particle accelerators, intraoperative radiation therapy units, stereotaxic radiation devices and special hyperthermia equipment.

Inasmuch as the proper clinical use of these technologies is uncertain, equipment and personnel needs have not been determined.

VIII. Characteristics of Clinical Programs

To enable the best possible management, patients must have convenient access to radiation oncologists and facilities where there are an adequate complement of qualified personnel and state-of-the-art equipment. Decisions about the care of patients should be based on clinical need and not compromised by the lack of immediately available resources.

To provide adequate management of patients, radiation oncology programs may include more than a single facility, several physicians and physicists and a range of skilled personnel. Necessary cooperation between personnel at separate facilities may be based on formal or informal relationships.

8.1 Program Structure

The structure of any radiation oncology program is based on a complex interaction of factors such as: needs of the patient population; demographic characteristics of the regional population; geographic relationships; scientific, educational and service needs; and community and special interests. A single type of organization will not function optimally in all situations; therefore, alternatives are necessary.

Possible structures include:

- 1) independent, self-contained centers;
- 2) conjoint centers with affiliated units of varying autonomy contributing to the overall function; and
- 3) regional networks of units organized for special purposes such as clinical research and education.

8.2 Personnel

The most important component of any program is the personnel. Requirements for various skills will vary with requirements for

patient service, education programs, research and community interests. (See definitions in Glossary XI).

8.2.1 Guidelines for Patient Service

Guidelines for minimum personnel necessary for good patient care are listed in Tables VIII-1 and VIII-2. Personnel requirements may vary somewhat related to specific needs of the treatment program.

8.2.2 Guidelines for Academic Programs

In addition to personnel for patient management, academic programs have additional needs commensurate with requirements for teaching, research and development of advanced technology. For example, a full-time academic radiation oncologist may have less than a 50% time commitment to patient management. Therefore, the ratio of physicians to patients treated would become one for 125 patients irradiated annually. Similar academic commitments increase the number of physicists required. For teaching, research, technology development and ever increasing quality assurance responsibilities, the compliment of physicists could easily be at least double the numbers listed in Table VIII-1.

In addition, administrative requirements further reduce the ratio of physicians and physicists to patients treated.

Research and education activities need to be financially supported by means others than direct patient revenues. However, many of the administrative activities relate to patient care, particularly as outside regulatory and reimbursement agencies become involved.

Personnel, other than physicians, physicists, radiation therapy technologists, nurses and dosimetrists, required for the effective operation of a radiation oncology clinic include: an administrator; specially trained secretaries; medically trained transcriptionists; a receptionist; special duty clerks; an orderly; financial and personnel supervisors; a maintenance engineer and/or electronics technician;

block/mold room technologist; a data manager; a dedicated social worker; and a dietitian. Personnel capable of maintaining complex radiation therapy units, such as linear accelerators and simulators, and physics equipment, must have skills usually not found in general biomedical electronics groups. Therefore, these people need to be specifically recruited and assigned to the radiation oncology facility. Programs with 2 or more megavoltage accelerators may require dedicated maintenance personnel.

8.3 Equipment

8.3.1. External Beam Treatment Units

A variety of equipment produces beams of ionizing radiations for therapy. These sources are electronic and radioisotopic. Their characteristics are summarized in Table VIII-3.

Superficial and orthovoltage X-ray therapy units are used to treat primary and secondary tumors on or near the body surface. These include cancers of the skin, eyelid, oral mucosa (per oral application through a cone) and uterine cervix (transvaginal application through a cone). The desired characteristic is maximal dose distribution on the surface with rapid fall off of dose with increasing depth in underlying tissue. For these reasons (lack of skin sparing and rapid fall off of dose), these X-rays are not suitable for treating deep seated tumors.

Accelerators (linear accelerators and microtrons) of varying energies and configurations have different clinical uses. All modern accelerators should be functionally reliable with an X-ray source that is isocentrically movable about a patient and should have an output adequate for treatment with the source at a distance of 80-100 cm from the patient. Low energy accelerators produce 4-6 MV photons, but usually do not have electron beam treatment capability. They have uses similar to those of ⁶⁰Co teletherapy units. High energy accelerators produce photons above 10 MV and usually have the

capacity to produce a range of therapeutically useful electron beams. Some of these high energy accelerators also have a second photon beam of lower energy (dual-energy unit), thus increasing the versatility of the equipment. This is particularly useful in small facilities with 1–2 megavoltage units. As noted previously, large clinics may have one high energy accelerator for every 2–3 low energy units. This distribution may be more cost effective than using only dual-energy accelerators. However, if electron beams are frequently used, it is advisable to have access to at least two sources in case of equipment breakdown.

Medical betatrons provide high energy photon and electron beams. Although these generators are reliable, low dose output, limited field size and cumbersome motions of the treatment head limit the number of patients treated daily. These units are no longer manufactured.

Microtrons are electric generators similar in principle to linear accelerators but with magnetic bending of the electron paths into circular orbits. The microwave power source is either a klystron or a magnetron. The beam transport system is relatively simple. A single microtron may supply beams to several treatment rooms. Although the first clinical microtron was described in 1972, few have been used.

Cobalt–60 teletherapy units generate photons from the decay of a radioactive isotope. A modern isotope source, with a diameter of 2.0 cm or less, can produce an output of more than 150 cGy per minute at a source to axis distance (SAD) of 80 cm, the *minimum* acceptable distance for clinical teletherapy. The artificially activated ⁶⁰Co source, which has a half-life of 5.3 years, requires periodic (usually about every 4 years) replacement in a busy clinic.

Teletherapy has been attempted with Cesium–137 sources. Because of the low specific activity of this isotope, the sources often have been larger than 2.0 cm in diameter, leading to an unacceptable beam penumbra. The source-to-patient distance often has been reduced to less than 80 cm in order to increase the radiation output at the site of interest. For these reasons, Cesium–137 teletherapy is *not* acceptable for modern clinical radiation therapy.

It is important that Cesium–137 teletherapy units, Cobalt–60 teletherapy units designed for use at less than 80 cm SAD, old betatrons and other electronic units, i.e., van de Graaf generators, unsuitable for modern clinical use, *not* be counted in any regional clinical radiation therapy equipment survey.

8.3.2 Simulators

Any program in which curative radiation therapy is offered must have access to a modern simulator capable of precisely reproducing the geometric relationships of the treatment equipment to a patient. This simulator must produce high quality diagnostic radiographs. The availability of fluoroscopy increases the usefulness and the patient throughput. Use of fluoroscopy requires special personnel training and careful use because of the radiation hazards. Photon beams of megavoltage therapy units are unsuitable for good quality imaging of anatomic structures within the treatment volume and so do not adequately substitute for a simulator. If there are additional simulators in a department, these may be adequate with only the radiographic, and not the fluoroscopic, capability.

Computerized tomography and magnetic resonance imaging are being used increasingly in radiation treatment planning. If there are no dedicated scanners in the radiation oncology department, it is essential that there be a definite time allotment on the CT and MR scanners in the medical center or clinic to facilitate treatment planning. In a large department, such time requirements become the equivalent of a dedicated imaging unit.

8.3.3 Treatment Planning/Dose Computation Equipment

The calculation of doses at points within the irradiated volume of the patient is an integral part of the delivery of radiation treatments. Curative treatments require careful planning, including an evaluation of several alternate treatment approaches. Thus, it is essential that all radiation therapy facilities have access to modern computerized treatment planning systems. While for small facilities (i.e., < 300

patients/year) it might be adequate to subscribe to a time-sharing system located in a large medical center, having a dedicated system within the department has proven very valuable for providing high quality care. A computerized treatment planning system should, as a minimum, provide the capability of simulation of multiple external beams, display isodose distributions in more than one plane and perform dose calculations for brachytherapy implants. It is highly desirable that the system has the capability of performing CT based treatment planning.

8.4 Support Services

Radiation oncology is a clinical service which, to be effective, must be a full participant in cancer activities in the medical center or the private office complex.

8.4.1 Hospitalization of Patients

Although about 85–90% of patients treated daily in a radiation oncology facility are outpatients, more than 10–15% require hospitalization at some time for a variety of reasons. Many must be in the hospital while implanted radioactive material is in place, because of both public safety concerns and the need for close medical observation and provision of relief of symptoms. Others are hospitalized because of the adverse effects of treatment or the tumor itself. Occasionally, a concurrent illness forces hospitalization. When hospitalization becomes necessary during or after radiation therapy, the radiation oncologist may be the admitting and attending physician, supervising the medical aspects of inpatient care and involving consultants as necessary. In this capacity, the radiation oncologist serves in the same role, and should meet the same standards, as any other admitting/attending physician. This requires admitting privileges and hospital staff membership.

8.4.2 Access to Operating Room

The radiation oncologist must have access to the operating room for a range of brachytherapy procedures. The radioactive materials for interstitial or intracavitary applications need to be placed in appropriate applicators either by or under the direct supervision of radiation oncologists and medical radiation physicists. Inasmuch as this preparation usually is done in a special room in the radiation oncology department, safe transport of the radioactive materials to and from the operating room or patient's room also is their responsibility. Inasmuch as radiation oncologists are responsible for patient selection, applicator selection and preparation and results and sequelae of brachytherapy, it is essential that they participate in each procedure.

8.4.3 Hospitalization of Patients During Brachytherapy

During hospitalization for brachytherapy, patients must be under the control of the responsible radiation oncologist. Procedures, which might alter the position of the applicators, and medications and diet, which may influence the patient's tolerance to the procedure, must be closely controlled and monitored. Patient and personnel radiation safety measures must be firmly established, controlled and monitored by the responsible radiation oncologist, the medical radiation physicist and the radiation protection organization of the medical center.

8.4.4 Clinical Facilities

The clinical facility must be designed to accommodate a large number of outpatients and a limited number of inpatients, many of whom are in hospital beds or wheelchairs. Inasmuch as 85–90% of the patients are outpatients, who may have appointments 5 days per week for several weeks during treatment, it is important that the clinical radiation oncology facility be close to a parking area.

Reception and waiting areas may be designed to separately accommodate the patients being treated and the patients scheduled for consultation and follow-up examination.

An adequate number of examination rooms must be equipped for complete physical examinations, to include the head and neck and female pelvis.

It is useful to have a comfortable room where the physician may discuss the findings and the proposed management program with the patient and relatives.

A physician's work room, adjacent to the clinic examination rooms, allows review of charts and visual aids, discussion, dictation and phone use outside the immediate range of the patients.

A securable medication room for small quantities of narcotics may be useful.

A procedure room for the biopsy of a surface lesion, endoscopy, thoracentesis, and even intracavitary placement of applicators or interstitial sources of radioactive isotopes, extends the range of activities in the department.

The treatment planning area should be near the treatment rooms to promote necessary interchange between the physicians, physicists, technologists and dosimetrists.

A physics laboratory to support dosimetry and equipment calibration needs to be near the treatment units.

Access to a machine shop, for fabrication of unique items of equipment, and to an electronics shop, for maintenance of electronic equipment, saves time and money.

A room for fabrication of treatment aids and immobilization devices is necessary.

Facilities for the secure storage of radioactive brachytherapy sources are essential.

TABLE VIII-1
MINIMUM* PERSONNEL REQUIREMENTS FOR
CLINICAL RADIATION THERAPY

Category	Staffing
Radiation Oncologist-in-Chief	One per program
Staff Radiation Oncologist	One additional for each 200-250 patients treated annually. No more than 25-30 patients under treatment by a single physician.
Radiation Physicist	One per center for up to 400 patients annually. Additional in ratio of 1 per 400 patients treated annually
Treatment Planning Staff	
Dosimetrist or Physics Assistant	One per 300 patients treated annually
Physics Technologist (Mold Room)	One per 600 patients treated annually
Radiation Therapy Technologist	
Supervisor	One per center
Staff (Treatment)	2 per megavoltage unit up to 25 patients treated daily per unit 4 per megavoltage unit up to 50 patients treated daily per unit
Staff (Simulation)	2 for every 500 patients simulated annually
Staff (Brachytherapy)	As needed
Treatment Aid	As needed, usually one per 300-400 patients treated annually
Nurse**	One per center for up to 300 patients treated annually and an additional one per 300 patients treated annually
Social Worker	As needed to provide service
Dietitian	As needed to provide service
Physical Therapist	As needed to provide service
Maintenance Engineer/Electronics Technician	One per 2 megavoltage units or 1 megavoltage unit and a simulator if equipment serviced "in-house"

*Additional personnel will be required for research, education and administration. For example, if 800 patients are treated annually with 3 accelerators, one ⁶⁰Co teletherapy unit, a superficial x-ray machine, one treatment planning computer, the clinical allotment for physicists would be 2-3. A training program with 8 residents, 2 technology students and a graduate student would require another 1-1.5 FTEs. Administration of this group would require 0.5 FTE. If the faculty had 20% time for research, a total of 5-6 physicists would be required.

**For direct patient care. Other activities supported by LVNs and nurses aides.

TABLE VIII-2
KEY STAFF FUNCTIONS IN CLINICAL RADIATION THERAPY

	KEY STAFF	SUPPORTIVE ROLE
1. CLINICAL EVALUATION.....	Radiation Oncologist	
2. THERAPEUTIC DECISION.....	Radiation Oncologist	
3. TARGET VOLUME LOCALIZATION		
Tumor Volume.....	Rad. Oncologist & Physicist	Sim. Tech/Dosimetrist
Sensitive Critical Organs.....	Radiation Oncologist	Sim. Tech/Dosimetrist
Patient Contour.....	Physicist	Sim. Tech/Dosimetrist
4. TREATMENT PLANNING		
Beam Data-Computerization.....	Physicist	
Computation of Beams.....	Physicist	Dosimetrist
Shielding Blocks,	Dosimetrist/	Radiation Oncologist/
Treatment Aids, etc.....	Mold Room Tech	Physicist
Analysis of Alternate	Radiation Oncologist/	
Plans.....	Physicist	Dosimetrist
Selection of Treatment	Radiation Oncologist/	
Plan.....	Physicist/Dosimetrist	
Dose Calculation.....	Dosimetrist	Physicist
5. SIMULATION/VERIFICATION	Radiation Oncologist/	Dosimetrist/
OF TREATMENT PLAN.....	Sim. Tech	Physicist
6. TREATMENT		
First Day Set-Up.....	Radiation Oncologist/ Dosimetrist	Dosimetrist/ Physicist
Localization Films.....	Radiation Oncologist/ Therapy Techs	Dosimetrist/ Physicist
Daily Treatment.....	Radiation Therapy Tech	
7. EVALUATION DURING TREATMENT...	Radiation Oncologist	Radiation Therapy Tech
Nurse.....		Social Worker
		Dietician
8. FOLLOW-UP EXAMS.....	Radiation Oncologist	Data Manager
Nurse.....		Social Worker
		Dietician

TABLE VIII-3
RADIATION THERAPY UNITS

Type of Equipment	Maximum Beam Energy MeV		Characteristics
	X or Gamma Rays	Electrons	
Superficial X-ray Units	0.1	—	High dose at surface Shallow penetration of X-rays
Orthovoltage X-ray Units	0.3	—	High dose at surface Moderate penetration of X-rays
Linear Accelerators			
Low Energy	4-6		Large field sizes High dose rates, skin sparing Sharp beam margins
High Energy	> 10	to 25	Good depth dose characteristics
Betatron	25-45	to 45	Small field sizes Low dose rates Good depth dose characteristics
Microtron	5-50	to 50	Similar to those of linear accelerator
Radioactive Isotope Unit			
Cobalt-60	1.2		Acceptable field sizes, dose rates and depth dose characteristics if SSD ≥ 80 cm Large penumbra

IX. ECONOMIC ISSUES

Until recently, the environment for reimbursement for radiation oncology was acceptance of "usual and customary" charges based on patterns developed over many years. This resulted in wide variations locally and nationally.

Major changes have recently occurred. In July, 1985, it became mandatory that Medicare billing utilize Current Procedural Terminology (CPT) for reporting medical services performed by physicians. Soon thereafter, the Health Care Finance Administration (HCFA) issued Transmittal 1200 redefining the concept of daily and weekly patient management. Shortly afterwards, a Resource Based Relative Value Scale (RBRVS), designed in the Harvard School of Public Health, was introduced for Diagnostic Radiology. This has been extended to Radiation Oncology.

A consequence of the use of RBRVS is that reimbursement levels for radiation oncology units will be similar whether hospital-based or free-standing. Likewise geographic variations will be reduced and eventually eliminated.

These changes are not designed to reduce high quality patient care, but they will require documented justification for new equipment, programs and personnel. Innovation and research necessary to improve the radiation treatment of patients with cancer may become more difficult to support.

In the immediate future, billing and reimbursement must be updated to current practices, and CPT and RVS codes must be properly related (a users guide has been issued by the American College of Radiology).

X. CONCLUSIONS

The primary goal of cancer management is to provide every patient with the best possible management regardless of constraints. Secondary goals include continuing improvement of treatment through the development of better methods and the training of personnel.

Radiation therapy is an integral component of the management of 50-60% of patients with cancer in the United States. To ensure maximum effectiveness and minimal treatment induced morbidity, the modality must be used as well as current knowledge and technology permit.

In this report, guidelines are proposed for optimal use based on standards for personnel, equipment, facilities and operations.

XI. GLOSSARY

Accelerated Fractionation—The use of multiple daily increments, each equal to or less than a standard daily increment (i.e., 180–200 cGy), for an overall time which is shorter than standard.

Betatron—An accelerator first used for radiotherapy in the 1950s prior to the introduction of linear accelerators. Although X-ray and electron beams can be provided over a wide range of energies, the low dose rates and limited field sizes result in an unfavorable comparison with modern linear accelerators.

Brachytherapy—A method of treatment using sealed radioactive sources to deliver radiations at short distances by interstitial, intracavitary or surface applications.

Cancer—A term inclusive of a variety of malignant neoplasms; derived from the Latin word for crab.

Cesium-137—A radioactive isotope with a half-life of 30 years; emits gamma radiations with an energy of 660 keV most commonly used in intracavitary sources; found early use as teletherapy sources and in interstitial needle sources; sometimes used in remote afterloading brachytherapy.

Cobalt-60—A radioactive isotope with a half-life of 5.3 years; emits gamma radiations (1.17 and 1.33 MeV); used as a teletherapy source; found early use in interstitial and intracavitary needle sources; sometimes used in remote afterloading brachytherapy.

Cure—Actually implies complete restitution to predisease status; may be used for that situation when, after a disease-free, post-treatment interval, the survivors have a progressive death rate from *all* causes similar to that of a normal population of the same age and sex.

Dosimetrist—A member of the radiation therapy planning team who must be familiar with the physical characteristics of the radiation generators and radioactive sources used to treat patients; training and expertise necessary to generate and calculate radiation dose distributions, under the direction of the medical physicist and radiation oncologist, are necessary.

Electron—An atomic particle with a negative electric charge which may be accelerated to strike a target and produce X-rays or used collectively as a beam for treatment.

Gamma Rays—Electromagnetic (photon) radiations which are emitted from an unstable atomic nucleus; for example, gamma rays are emitted from Cesium-137, Cobalt-60 and Radium-226.

Hyperfractionation—The use of multiple daily increments, each considerably smaller than a standard daily increment, over a conventional period.

Hyperthermia—Elevation of the body temperature regionally (i.e., 42–45°C) or systemically (i.e., 41.8°C) resulting in direct cell killing and augmentation of the effects of other cytotoxic agents.

Interstitial Radiation Therapy—Sealed radioactive sources within special applicators placed in tissue in a preconceived pattern.

Intracavitary Radiation Therapy—Radioactive sources in closed containers placed in body cavities, i.e., uterus, vagina.

Ionizing Radiations—Radiant energy which is absorbed by a process of imparting its energy to atoms through the removal of orbital electrons.

Iridium-192—A radioactive isotope with a half-life of 74 days; emits gamma (300–600 keV) radiations; used in interstitial therapy; sometimes used in remote afterloading brachytherapy.

Linear Accelerator—A device in which particles (i.e., electrons, protons) can be accelerated to high energies along a straight path using microwave technology.

Linear Energy Transfer (L.E.T.)—A measure of the average rate of energy loss along the track of a charged particle, expressed as energy units per unit track length.

Medical Radiation Physicist—A professional with at least a master's degree and usually a Ph.D. in physics plus additional training and experience in diagnostic and/or therapeutic radiologic physics; most are certified by the American Board of Radiology or its equivalent.

Megavoltage Radiations—An ill-defined, frequently used term for ionizing radiations with energies equal to or greater than 1 MV.

Microtron—An electronic generator similar in principle to a linear accelerator but with magnetic bending of the electron paths into circular orbits; a single generator may supply beams to several treatment rooms.

Oncology—The study of tumors; no specific relationship to a medical discipline; applies to surgery, radiology, internal medicine, pediatrics and gynecology.

Orthovoltage X-rays—A term which applies to X-rays of insufficient energy to be “skin-sparing” or to avoid preferential absorption in bone; usually generated at 150–400 kVp; may be divided into superficial and deep X-rays, although often used interchangeably with deep X-ray.

Palliation—Relief or prevention of symptoms or signs caused by disease.

Penumbra—Those radiations just outside and adjacent to the full beam including components from incomplete beam collimation and scatter from the primary beam.

Radiation Dose—Energy imparted per unit mass of absorber at a specific site under certain conditions (absorbed d., threshold d., tumor d., depth d., permissible d.).

Radiation Oncologist—A physician with a special interest and competence in managing patients with cancer; minimal requirements include an M.D. degree, a year of general clinical training, three to four years of specialized training and certification by the American Board of Radiology or its equivalent.

Radiation Oncology—A clinical medical specialty with a specific involvement with tumors, particularly as they relate to treatment with ionizing radiations.

Radiation Oncology Nurse—A registered professional nurse who, as part of the radiation oncology team, provides appropriate direct intervention to aid the patient and family with problems related to the disease, treatment and follow-up evaluation; recommended minimal qualifications include a baccalaureate degree in nursing, two years experience in medical-surgical nursing and at least one year’s experience in oncology nursing.

Radiation Therapy—Treatment of tumors and a few specific non-neoplastic diseases with ionizing radiations.

Radiation Therapy Technologist—A highly skilled professional who is qualified by training and experience to provide treatment with ionizing radiations under the supervision of a radiation oncologist.

Radioactivity—Emission of radiations from the breakdown of unstable nuclei which occurs naturally or is artificially produced.

Radionuclide—A radioactive form of a nuclide, which is any nuclear species of a chemical element capable of existing for a measurable time; often an isotope, with the same number of protons but a different number of neutrons, is referred to as a nuclide.

Simulation—Meaning to pretend; in radiation therapy, the precise mock-up of a patient treatment with radiographic documentation of the treatment portals.

Stereotactic Radiation Therapy—A method using three-dimensional target localization, which enables precise irradiation of small intracranial lesions.

Superficial X-rays—Minimally penetrating X-rays of low peak energy, generated by voltages in the range of 85–140 kV; used to treat lesions on the body surface.