

Radiation Oncology in Multidisciplinary Cancer Therapy
- Basic structural requirements for quality assurance of radiotherapy based
on Patterns of Care Study in Japan -

Japanese PCS Working Group
Ministry of Health, Labour and Welfare Cancer Research Grant.
Planned Research Study 14-6

Supported by

Ministry of Health, Labour and Welfare Grant-in-Aid for Scientific Research:
"Third Term Comprehensive Control Research for Cancer (H16-039)"

American College of Radiology

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American College of Radiology

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To patients and families, and all healthcare professionals involved in cancer treatment

We have now reached the completion of "Radiation Oncology in Multidisciplinary Cancer Therapy - Basic structural requirements for quality assurance of radiotherapy based on Patterns of Care Study in Japan -." This is a comprehensive and systematic description of the role of radiation therapy and radiation oncology in current cancer treatment in Japan. Based on results confirmed by Patterns of Care Study in radiation therapy settings over several years, its persuasiveness is unsurpassed. As an individual involved in the group activities of a Patterns of Care Study (PCS) at the beginning, I have been drawn continually to the interesting results from PCS, and I am impressed with their fruition into this book. This publication will no doubt mark a milestone in radiation oncology in Japan. "Disparities" in cancer treatment are said to exist among regions and facilities in Japan, and the procedures of PCS are useful for measuring and assessing such differences. We would be well served if the procedures of PCS were adopted in many other regions, as well as the radiation oncology field.

January, 2005.

Hiroshi Ikeda, MD
Chairman, Division of Radiation Oncology,
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TOWARD ONE WORLD OF QUALITY OF CARE

Radiation Oncologists and collaborating scientists in Japan are dedicated to the goal of providing state of the art treatment to all of their patients. The Japanese Working Group has led this effort over the last nine years by conducting appropriate studies to determine the structure, processes and outcomes of care across all facility types. Differences in these measures of care have been documented, and the influence of facility type noted. Variations in structure and processes have been shown to affect outcome, reinforcing the need to improve in these critical areas.

This report identifies the structure of Rad Onc in Japan and uses the scientific rationale of Patterns of Care Studies (PCS) to identify current and future needs in equipment and treatment technology, staffing, training, certification, information technology, QA and other areas. The costs of the necessary changes are estimated and the government, industry and institutional support necessary to implement these changes over the next decade are estimated.

Japanese scientists have a long history of developing and introducing advanced technology in radiation oncology. These PCS-Japan studies show their leadership in assessing quality of care and using the results of that assessment to improve patient care on a national basis. Other countries in Asia or elsewhere may note the potential of developing similar studies of their cancer care delivery systems. Decades of patients will be grateful.

The Patterns of Care Study in the United States has enjoyed the long collaboration with the entire Japanese Working Group and Prof. Teshima the Principal investigator. Through international collaborations such as these, the world of quality assurance in Radiation Oncology may indeed become small.



Gerald E Hanks MD, FACR
Senior Member Emeritus
Fox Chase Cancer Center
Patterns of Care Study –USA: Principal Investigator 1980-2001

Preface

A Patterns of Care Study (PCS) is a short-term research program investigating retrospectively the three elements of structure, process, and outcome in patterns of nationwide health care. We evaluate the quality of health care, identify problems, and take steps toward improvement. The system was established in the early 1970s, at the same time the Radiation Therapy Oncology Group (RTOG) was founded as a multi-institutional prospective clinical study group in the field of radiation oncology in the US. For the past 30 years, both efforts have worked together to contribute to improvement in the quality of radiotherapy. In Japan, members of our research group nine years ago secured a Ministry of Health, Labour and Welfare cancer research grant and initiated the first PCS. From the first study to the third, we have monitored qualitative discrepancies between facilities in the structure, process, (and some outcome) in radiation oncology. We have also monitored US-Japan discrepancies. The current frequency of accidents in the field of radiotherapy is also related to such structural problems. This short report is based on specific medical data obtained in PCS and offers criteria for specific improvements to inadequate structures in Japan. We hope that this work thereby provides a true public benefit.

We also intend to continue PCS to monitor acceptance of these criteria by health care institutions, medical education institutions, and in regulations, and likewise, to monitor specific improvements in the structure of the radiation oncology field in Japan. Our ultimate goal is to provide safer and more reliable radiotherapy to patients suffering from cancer.

Spring, 2005



Teruki Teshima, MD
Principal Investigator

Japanese PCS Working Group
Ministry of Health, Labor and Welfare Cancer Research Grant;
Planned Research Study (14-6)
"Quality assurance of radiotherapy system and its clinical assessment"

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1. Introduction

1.1 Background

Demand for radiotherapy in Japan is increasing steadily. Now more than ever, it is of urgent importance to create a system that maintains the quality of radiotherapy and reassures the public.

At present, there is demand in a number of areas for radiation oncology guidelines conforming to the actual state of radiotherapy in Japan. This report is an independent Japanese standard for radiotherapy which references the "Blue Book" of US guidelines¹⁾ and uses numerical data obtained from Patterns of Care Studies (PCS)²⁾ in Japan.

The Inter-Society Council for Radiation Oncology (ISCRO), organized primarily around the American College of Radiology (ACR), has contributed greatly to standardization of radiotherapy in the US with the publication of a series of reports, including "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), "Radiation Oncology in Integrated Cancer Management" (1986), and "Radiation Oncology in Integrated Cancer Management" (1991). This series of reports was nicknamed the "Blue Book" for the color of its cover and has come into international use. Inoue et al. received permission from ISCRO Chairman Hanks to translate the last of these reports (1991) and published a Japanese edition in 1993. One objective of this work was to disseminate the concept of clinical quality assurance (QA) in radiation therapy.^{1),3)} This work in turn played an important role in improving QA and quality control (QC) in radiation therapy in Japan. Specifically, the work was useful as a standard for equipment and personnel in radiation therapy facilities, as an operating standard for radiation therapy departments, and as a document for such external negotiations as revision of medical reimbursement. These activities served as a motivation promoting creation of new working standards suited to practice in Japan, and such revision has continued.

Chairman Hanks, writing in the preface to the 1993 Japanese edition, expressed that, "We hope to continue to work with our Japanese colleagues as both of our efforts in Quality Assurance are directed at improved care and outcome for our patients." This phrase summarizes our activities.

The Japanese Society for Therapeutic Radiology and Oncology (JASTRO) has carried out regular structure surveys of Japanese radiotherapy for the past 15 years.⁴⁾⁻¹⁵⁾ These surveys have elaborated radiation therapy facilities throughout Japan, and in PCS, these facilities are stratified by size and nature, PCS subject facilities are selected randomly from each stratum, and research group members audit each facility to ascertain basic information from patients treated previously at each facility, and details of treatment received and prognosis (see Chapter 7).¹⁶⁾ The integrated data were statistically corrected, and nationwide practices in radiotherapy were determined retrospectively with regard to structure (equipment, personnel); patient treatment

processes (diagnosis, treatment) in patients treated for breast cancer, esophageal cancer, cervical cancer, lung cancer, and prostate cancer; and outcome (treatment results).¹⁷⁾ With support from a Ministry of Health, Labour and Welfare Cancer Research Grant, the ACR as the center of PCS research in the US,^{18),19)} and Drs. Hanks (-2000) and Wilson (2001-) as Principal Investigators in the ACR, since the initial introduction of PCS into Japan in 1996, we completed three reports of radiotherapy practices in 1992-1994,²⁰⁾ 1995-1997,^{2),21)-30)} and 1999-2001, and disclosed US-Japan discrepancies^{31),32)} through the US-Japan joint PCS research projects. These data were essential information for making out a draft of this standard concerning structure and process. Discrepancies in care according to facility size are still observed frequently in Japan, and this is the reason why US-Japan discrepancies^{31),32)} were also needed for consideration of the ideal form of radiotherapy.

Radiotherapy is an important modality of cancer management. However, only 20% of cancer patients in Japan undergo radiotherapy, a very low proportion compared to 60% in the US.³²⁾

In stage I and II cervical cancer, for example, while the proportion of patients undergoing radiotherapy with a curative intent is approximately 70% in the US and Europe, the proportion is approximately 10% in Japan. In stage IIIA non-small cell lung cancer, the proportion is 80% in the US and Europe but 20% in Japan. In cases where cancer patients undergo curative radiotherapy in the US and Europe, surgery is often performed in Japan. However, there is little evidence that results from surgical treatment in Japan are better than those in various other countries. Considering even that the distribution of types of cancer is different in Japan versus the US and Europe, the proportion of cancer patients undergoing radiotherapy should be 40% or more at a minimum, even in Japan.

With the advent of the new century, a paradigm shift in cancer management has begun. Standard cancer treatment policies are also changing in response to the requirements of the era and of societies. As a result, there is a continual need for updating, and delays in revision are unacceptable.

According to confirmed figures from 2003 demographic statistics, the annual number of cancer deaths is 309,000, accounting for more than 30% of all causes of death. At the same time, health care costs by disease show that cardiac disease accounted for 22%, respiratory diseases 8%, musculoskeletal and connective tissue diseases 8%, and digestive diseases 7%, while cancer accounted for no more than 11%.

Examination of health care costs paid by health insurance for various medical procedures shows that examination accounted for 18%, diagnostic imaging 9%, drug dispensing 17%, injections 15%, and surgery 22%, while radiotherapy accounted for merely 0.7%.³³⁾

Assuming that radiotherapy for cancer patients increased by 10%, the increase in health care costs would amount to less than 1% of total national health care costs, and the reduction in medical costs incurred for other treatments could decrease total health care costs. Increasing the number of cancer patients undergoing radiation therapy is therefore also important as an efficient use of health care costs.

1.2 Issues in Japanese Radiotherapy

Consideration of the structure of radiotherapy in Japan requires earnest inquiry into the following issues.

Is there a plan to resolve the personnel shortage in radiation oncology?

What is desirable in regional medical cooperation with regard to facilities where specialization of radiotherapy is proceeding?

Have adequate baseline studies been completed on revision of the duties of personnel responsible for checking work done in radiotherapy? Likewise, has certification of the relevant qualifications been adequately studied?

What type of guidance will be necessary to decrease medical accidents at advanced precision radiotherapy?

Expenditures appropriate for maintenance of medical safety are required. The more precision increases, the greater are the costs required for personnel, equipment, and facilities. The practice of sound health care requires more consideration of health care expenditures than ever before. Contents of this report can be used as highly accurate baseline data required for such consideration.

This report is likely to be used very widely. In this respect, we welcome opinions from a variety of perspectives. These responses will certainly affect subsequent publication plans.

2. Purpose of this Report

The purpose of this report is to elaborate the following issues for all health care personnel involved in radiotherapy and for patients and families undergoing treatment.

- (1) Based on Japanese Patterns of Care Studies (PCS), we present standard structures of personnel, equipment, facilities, and operation designed to ensure the quality of radiation treatment.
- (2) Based on the same research, we present guidelines for appropriate evolution of radiotherapy in the context of integrated cancer management in Japan.

The ultimate goal of cancer management is to provide the very best treatment for all cancer patients. The fact that this statement itself appears here again indicates that this goal has not yet been achieved. It is incumbent upon us to advance step by step towards this goal.

Efforts to bring forth the best possible treatment results require best structures (personnel, equipments, facilities, and operation) and best processes (diagnosis and treatment). An iterative cycle of accurate evaluation of results, and application to structures and processes will raise treatment to a higher plane.

Best treatment requires ongoing improvements in knowledge and technology among health care personnel, and what is important for this purpose is education of the clinical oncology corresponding to specialized work and enhancement of related educational programs. Physical and clinical quality assurance and quality control are also essential for implementation of highly accurate treatment.

3. Improving Cancer Treatment

All cancer patients have a right to receive the best treatment available. Best treatment requires an advanced health care structure, and health care providers have an obligation to use such advanced structures to provide such care. If a given patient does not receive best care, the product is an unfortunate outcome for the individual and the family concerned. From the standpoint of health care costs as well, the individual and society incur undue expense.

Current modalities of cancer treatment include surgery, radiotherapy, and chemotherapy. One or a combination of appropriate treatment modalities must be selected with joint consideration given to factors including type of cancer, stage (level of disease progression), performance status, and patient characteristics. Consequently, surgical oncologists, medical oncologists, and radiation oncologists must confer comprehensively on the mode of treatment. Appropriate team treatment is therefore crucial.

Physicians participating on the treatment team must be specialists in their respective fields. Each physician must have a thorough knowledge of tumor properties, an accurate diagnostic ability, and thorough discernment among treatment options.

When a treatment policy is decided upon during initial examination, each specialist on the team must propose types of treatment on an equal footing. In locoregional and systemic evaluation during treatment, or in periodic examination after treatment, the team must also exchange opinions with one another from a basis of individual judgment.

In cancer treatment, the first decision-making is whether to undertake curative treatment, palliative treatment, or symptomatic treatment.

Curative treatment is treatment offering the possibility of a complete cure; palliative treatment is treatment not offering the prospect of cure but pursued to the extent that drawbacks from adverse effects do not exceed the therapeutic effect; symptomatic treatment is treatment without potential for cure but pursued with the objective of alleviating symptoms.

In general, cure is possible in cancer other than Stage IV cancer (when cancer progression status is classified on 4 levels, the most advanced level of cancer), but the potential for successful curative treatment depends on such factors as patient age and physical and psychological status.

In the case of curative treatment, the first effort is achievement of local control that means complete removal or destruction of the mass of confirmed cancer cells. This allows control of regional foci, followed by control of metastatic foci. Local control is accomplished primarily by surgical therapy and radiotherapy.

In early cancer of the cervix, tongue, larynx, lung, and prostate, curative radiotherapy offers results on a par with surgery.

Treatments also include solo treatments and combined treatments. Combined treatments are carried out when control of local or metastatic foci by a sole treatment is deemed difficult, or when the aim is to reduce toxic phenomena (or adverse effects) resulting from powerful solo treatments. Multidisciplinary therapy is an effective and efficient combination of treatments from various fields and is first used effectively by a perfectly educated and experienced team thoroughly familiar with each others' ability.

Palliative radiotherapy is treatment with the objective of long-term tumor control in situations where cure cannot be expected. Palliative radiotherapy must offer an asymptomatic period clearly longer than the period of its adverse effects and a better existence and quality of life (QOL). Consequently, the treatment planning requires greater exactness.

The objects of symptomatic treatment include alleviation of symptoms, psychological relief, and slowing of the progression of illness. Consequently, as in the case of surgery, it is infrequent that a mode of treatment placing a substantial burden on the patient is appropriate, and radiotherapy is pursued most often.

For example, symptomatic radiotherapy is used to relieve pain from bone metastasis and superior vena cava syndrome, provide hemostasis in locally advanced cervical cancer, improve ulcerative lesions of breast cancer, improve obstructive lesions of the esophagus or trachea, assist recovery from pathological fractures, and reduce pleural effusion and ascites.

Representative examples of emergency radiotherapy where urgency is required in symptomatic radiotherapy include compression of the spinal cord or trachea from tumor infiltration (enlargement of cancer and marginal invasion). In these instances, radiation must be initiated at the earliest possible time after occurrence is confirmed.

In determining a treatment policy or type of treatment, it is essential to obtain consent from the patient and/or family after thorough explanation (informed consent). What is most crucial is that the patient himself or herself decide upon their own treatment policy and participate actively in treatment. Informing the patient of his or her cancer is a basic first step that is unavoidable in principle. The patient also has the right to seek an assessment or explanation from another physician i.e., second opinion.

At the same time, the patient should personally bear part of the responsibility for treatment outcomes in appropriate treatment carried out on the basis of a self-determined treatment policy.

At the stage where treatment actually begins, a critical path i.e., standard treatment plan is prepared to ensure easy exchange of information between the patient and the healthcare providers. To this end, in each facility they must prepare their own radiation treatment guidelines and manuals for cancer patients.

4. The Clinical Role of Radiotherapy

4.1 Characteristics of radiotherapy

The characteristics of radiotherapy in cancer management can be summarized under three headings.

Noninvasiveness

Radiation itself does not cause pain to the body. Inflammatory lesions arising after irradiation can be accompanied by pain, but in most cases, the pain is less than that after surgery. The risks to life accompanying surgery and anesthesia are also negligible in radiotherapy. Consequently, patients in poor general condition and patients inoperable for reasons including age or compromised function of various organs can undergo curative radiotherapy without concern.

Preservation of organ and function

Radiotherapy is a treatment to cure cancer without surgical procedure. Consequently, organs in which cancer occurs can be preserved in their original form, and its function can be maintained. For example, surgery for cancer of the larynx results in a loss of voice and creation of a tracheotomy, a hole in the lower neck region, while radiotherapy preserves the voice intact and of course does not wound the surface of the body. In essence, life much like that in the previous, healthy state can be resumed after radiotherapy.

Low cost

The medical expense required for radiotherapy of cancer is on the order of one-half to two-thirds that of surgery for most cancers. Not only is payment by the patient reduced, there are also substantial benefits for health-care economics.

4.2 The role of radiotherapy

Based on these characteristics of radiotherapy, the role of radiotherapy in cancer management can be summarized as follows.

When treatment results akin to those in surgery are obtained in local treatment

Considering the foregoing advantages, there is value in consideration of radiotherapy in principle, regardless of whether or not surgery is possible.

When results from radiotherapy are deemed inferior to those from surgery

Surgery is often pursued in principle among patients for whom surgery is possible, but considering the reduction in quality of life (QOL) due to surgically-induced loss of organ or function, radiotherapy is sometimes selected.

When general condition is poor, or when surgery is not possible for reasons including age or organ function

Radiotherapy is often useful.

5. The Radiotherapy Process

5.1 Performance of radiotherapy

There is essentially no difference between surgery and radiotherapy of cancer in their significance as a local treatment. If there is a difference, it is the measures taken for quantitative assessment prior to treatment. Radiotherapy has no technique equivalent to intraoperative assessment of excised margins through pathological testing during surgical treatment, but remarkable advances have been made in diagnostic imaging as a means for evaluating the extent of tumor infiltration.

Radiotherapy for cancer begins with accurate gathering of information from the tumor and the host by well trained radiation oncologists, surgical oncologists, medical oncologists, gynecologists, head and neck surgeons, pediatricians, pathologists, and specialists in other such fields. Because the radiation oncologist does not participate in intraoperative evaluation, evaluation of the tumor prior to treatment requires advanced clinical abilities. If such abilities are lacking, full participation in deliberations as a team member is difficult.

A radiation oncologist suitable to direct radiotherapy is a physician whose treatment focuses primarily on radiotherapy for cancer patients, or whose work is principally education and research in radiation oncology. This physician should have as much clinical experience and ability as possible to actually and properly determine the suitability of radiotherapy for individual cancer patients with various backgrounds, based on a thorough knowledge of radiation oncology, practice of evidence-based medicine (EBM), and an understanding of various guidelines.³⁴⁾⁻⁴⁴⁾ Such experience and ability must also be assured by fulfillment of the requirements for physicians certified by the Japanese Society for Therapeutic Radiology and Oncology (JASTRO). The radiation oncologist must personally, or in cooperation with a medical oncologist, surgical oncologist, or an oncologist from another such field, assess the medical findings of the individual cancer patient, determine the clinical stage, and present to the patient an explanation and treatment alternatives, including alternate therapies. At least in specific areas (e.g. examination of head and neck cancer patients, breast cancer patients, cervical cancer patients, prostate cancer patients, malignant lymphoma patients, and pediatric cancer patients), it is also preferable that the radiation oncologist has abilities for patient treatment equivalent to those of a specialist in the respective field. In simulations of the patient and treatment planning, the radiation oncologist has the ability to delineate target volume accurately and determine an appropriate radiation field and dosage prescription, based on information including physical findings and image-based findings. Administration of brachytherapy requires yet more advanced technical ability. Proper assessment and management of the response of tumors and the acute reaction of normal tissue subjected to various dosages are carried out for patients undergoing radiotherapy. After radiotherapy is complete, there is an obligation for patient management throughout clinical course, including assessment of tumor response, evaluation of adverse effects, and confirmation of any recurrence or late toxicities. Prognostic information of the irradiated patient must also be discerned personally, or through some method, and we support in-hospital, regional, or national cancer

registration. Additionally, in order to resolve research questions and establish standard treatment methods at practicing clinics, there is also a right or an obligation to participate actively in not only retrospective research but exploratory clinical studies with regard to the treatment of specific patient groups as well as individual patients.

Recent years have seen remarkable progress in the accuracy of information concerning tumors at the tumor board among specialists from various fields at initial examination. A careful general examination also cannot be overlooked. Inquiry and documentation of concomitant illnesses and prior illnesses is important. Examination and testing should also be performed with particularly detailed attention to checking of prior radiotherapy.

All this information is compiled to proceed with establishment of a primary sole treatment or a combined treatment modalities based on surgery, radiotherapy, and chemotherapy. The best treatment must always be selected among the individual treatments compiled. It is also extremely important to indicate the treatment policy clearly. At this point, informed consent and self-determination are required after the patient and/or family is provided with a thorough information of the patient condition and treatment alternatives.

This information must conform to EBM-based radiotherapy guidelines, and consistent updating is needed. In clinical settings, a critical path is used to facilitate communication of intentions between the patient and health-care providers, and risk management must be undertaken to prevent accidents and provide safe treatment. The patient may require time to seek a second opinion and may ask for a referral.

When radiotherapy is selected, decisions are made regarding beam quality, energy, irradiation method, fraction, prescribed dose, and any concomitant treatment. The radiation oncologist has an important responsibility for thorough examination during irradiation for the purpose of systemic management and assessment of tumor and normal tissue reaction. There is also a need to listen to patient and/or family complaints, check treatment records, gather physical and endoscopic findings, image-based information, and information from technicians and nurses, and to consult with specialists in other fields.

It is important to explain changes and predictions during treatment to the patient and/or family. When treatment begins, patient anxiety can be alleviated by explanation based on the critical path and provision of progress sheets pertaining to the anticipated schedule.

Even after radiotherapy is complete, it is essential to perform periodic examination to assess therapeutic effect and evaluate adverse effects. Feedback from information gained in periodic post-therapy examinations provides essential knowledge on radiotherapy and allows efforts oriented toward optimal treatment.

If signs of cancer recurrence or early metastasis of cancer is detected, cure made once again be obtained by additional treatment. Early discovery and treatment of adverse events effects may also prevent severe problems from developing.

New treatment designs in a facility are produced by reevaluation of treatment apparatus, staff, and modalities of treatment based on data obtained from actual treatment of patients. Best structures and treatment protocols are required to obtain best treatment results, and these emerge from routine practice of treatment (Figure 5-1, Figure 5-2).

The radiation oncologist establishes a gross tumor volume (volume of palpable or visible extent of cancer) and a clinical target volume (volume of area to be irradiated for suspected distribution of cancer, albeit invisible) based on examination findings, image-based information, endoscopic findings, and surgical findings. These parameters demonstrate the experience and knowledge of the radiation oncologist.

CT images taken again in the treatment position are transmitted to a treatment planning system. Prior to this imaging, immobilization device is prepared. A planning target volume (volume of area of actual anticipated exposure to radiation) including a safety zone added to the clinical target volume is designated with consideration given to the treatment policy or the accuracy of the equipment, and the outline of this volume is input. The outline of organs at-risk is also input. The optimal mode of treatment is then selected from multiple treatment plans, based on the prescribed dose proposed by the radiation oncologist and the tolerance dose to organs at-risk.

Recent, advanced treatment planning system uses an algorithm for these steps termed inverse planning. This algorithm provides multiple treatment plans. By comparison to a dose-volume histogram (DVH) or investigation of executable treatment parameters, an optimal treatment is selected from multiple solutions. A treatment planning system connected directly to a multi-leaf collimator (MLC) for the equipment then performs virtual simulation of the irradiated field at this stage. A three-dimensional treatment plan based on CT imaging allows performance of more accurate treatment than a conventional two-dimensional treatment plan derived from an X-ray simulator.

Before the first treatment is begun, a radiation therapy technician carries out positioning in the treatment room according to the virtual simulation parameters and other direction of the radiation oncologist, and the body of the patient is marked (inscribed with markings for application of radiation). A portal film is taken using the treatment beam of a megavoltage treatment unit, and the portal film is checked by comparison to a simulation film or a digital reconstructed radiogram (DRR).

Daily treatment is carried out by a radiotherapy technician under the supervision of a radiation oncologist and a quality controller or a medical physicist. Positioning in each session is carried out using the marks placed on the body surface, and this operation is checked with a portal film produced by the treatment beam. The use of an electronic portal imaging device is more desirable. Integrated CT- and linear accelerator units have been developed, as have verification units operating on the basis of X-ray fluoroscopy of a metal marker inserted in the body, and verification units provided by ultrasound equipment.

If the radiation oncologist provides instructions for a change in plan, the process returns to designation of a target volume, and the series of steps beginning with treatment planning is repeated. Treatment according to plan must be ensured by multiple checking mechanisms. Signatures to checking are required for each step of these processes. Above all, the signature of the physician in charge the implementation of treatment is the most important. There is no need for the physician in charge to check the daily treatment setup. However, it is essential that he checks each setup in treatment of special skin cancer foci, insertion of eyecups during treatment of ocular tumors, pinpoint irradiation cases, and pediatric irradiation cases.

5.2 Various methods in radiotherapy

Fractionated radiotherapy (many repetitions of small amounts of dose) is basic to conventional external radiation protocols. This technique even now has an 80-year history. A representative dose prescription is for 30 fractions, once per day, 5 fractions per week, over 6 weeks. This practice leads to effective death of cancer cells and promises the greatest possible recovery from radiation hazards to normal tissues.

One alteration of this basic protocol is hyperfractionation, which increases the total administered dose while suppressing the late effect on normal tissue with a low α/β ratio to the level of typical single daily dose; another such protocol is accelerated fractionation, an effort to suppress accelerated repopulation by shortening the treatment period.

Three-dimensional conformal radiotherapy (3-D CRT) and intensity-modulated radiotherapy (IMRT) further amplify the physical advantages of external irradiation. Diagnostic imaging technology has played a large part in the dissemination of these advanced radiotherapy techniques. The establishment of a small difference between the planning target volume and clinical target volume allows larger single dose, and the result has been to allow smaller fractionations or single irradiation. The former technique is termed stereotactic radiotherapy (SRT), the latter is termed stereotactic radiosurgery (SRS), and both techniques are collectively termed stereotactic irradiation (STI). Robotic treatment apparatus equipped with miniature accelerator, and tomotherapy apparatus integrating CT equipment and an accelerator have also begun to disseminate. These equipments allow 4-dimensional radiotherapy, which adds a time axis to the other three dimensions.

Operational constraints in the radiotherapy room have been recognized with respect to intraoperative irradiation protocols, the goal of which is to eradicate residual microscopic disease (cancer cells invisible to the naked eye but irremovable by surgery) during surgery, and their use in routine therapy has been slow to take hold. However, a mobile linear accelerator using an intraoperative dedicated electron beam has been developed, and new developments are anticipated.

The equipment, facilities, and operating and maintenance costs of particle-beam radiation therapy are high, but as the appearance of specialized medical equipment and research on miniaturization of equipment continues, proton-beam and carbon ion-beam therapy has begun in earnest, and these technologies have at last been approved in Japan as highly advanced medical technologies. The physical and biological characteristics of these technologies are implemented with an accuracy and efficacy incomparable to that of conventional radiotherapy. Refractory cancer outside the indications of conventional evidence has been controlled, and development of new indications from a QOL perspective is ongoing. The problem in the future may indeed be a fair nation-wide dissemination plan for particle-beam therapy facilities in Japan.

A major revolution in brachytherapy has also been achieved in the past 40 years. The use of new nuclides, application of afterloading method, and the use of computers have provided solutions for high-precision technologies and elimination of exposure to personnel, and progress in QA and QC has brought about a reduction in accident rates and treatment outcomes promising high QOL. High dose rate brachytherapy replacing the merit of low dose rate brachytherapy used in fractionation, has been recognized as a safe, high-precision treatment, and has led to anticipated development of image-guide brachytherapy.

Such image-guide brachytherapy has also opened new avenues in prostate cancer treatment through ultrasound imaging and introduction of I-125 seeds, also approved for use in Japan in 2003. However, the time required for treating physicians to master the technologies is a greater impediment to their dissemination than introduction of the equipment itself. As a result, concentration of facilities able to offer these treatments seems likely to continue in the future.

Ideally, all cancer treatment facilities must be fully equipped with adequate radiotherapy equipment. In reality, though, this is not a likely scenario. Consequently, regional healthcare collaboration with regard to personnel and equipment is important. (6.8) The importance of remote radiotherapy using fiber-optic networks is likely to increase rapidly.

With regard to concomitant chemotherapy, concurrent chemoradiotherapy is growing more common as a standard type of treatment in lung cancer, esophageal cancer, and cervical cancer. This practice is also ongoing for cancers of the head and neck. Additionally, the advent of molecular targeting drugs, has initiated investigations of indication setting and a search for concomitant use. As a result, trial calculation of the total number of anticipated patients and the number of treatment facilities is needed.

Total body irradiation is carried out as a preparation for bone marrow transplantation for its effect of total tumor cell kill and suppression of immune function. The immunosuppressive effect of low dose total body irradiation is also under evaluation in mini-bone marrow transplantation carried out with a view to expanded indication. Intensive chemotherapy used in peripheral blood stem cell transfusion are also a likely future topic of interest.

5.3 The importance of quality control

The first step in performance of accurate radiotherapy is quality assurance (QA) and quality control (QC) within a facility. At the regional and national level, it is important to minimize discrepancies in QA levels among facilities. The evaluation of medical care is a dynamic analysis of the three elements of structure, process, and outcomes, and a search for interrelationships among these three elements. The clinical role of radiotherapy must be continually reevaluated through this process to improve its content.

Active participation in patient care has increased the number of medical lawsuits and encouraged a response to risk management by health care providers. Now, when calls for assurance of safety in health care settings are greater than ever, the Inter-Society Council for Radiological Physics was established in Japan in 2003 primarily by four related societies, and operation has begun (current participants in 2004 are the Japan Radiological Society, Japan Society of Medical Physics, Japan Society of Radiological Technology, Japanese Society for Therapeutic Radiology and Oncology, and Japanese Society of Nuclear Medicine). Its initial work was follow-up of accident response at medical radiation facilities. However, radiotherapy-related societies and associations (the Japan Society of Medical Physics, Japan Radiological Society, Japan Association of Radiological Technologists, Japan Society of Radiological Technology, and Japanese Society for Therapeutic Radiology and Oncology) have since then carried out repeated studies concerning medical accident prevention measures, and the end result has been the new establishment of a Radiation Therapy Quality Controller System.

Periodic QA for equipment performance, performance of standard dose measurement, and data management and its storage are all carried out for the purpose of quality assurance and quality control, and these are important duties of a radiation therapy quality controller, whose affiliation is different from that of a radiation treatment technician. It is therefore necessary to set up positions within a hospital representing a quality control department independent from a radiation department.

5.4 Current status and issues in radiation therapy⁴⁵⁾

Apart from universities and specialized cancer centers, the majority of other hospitals are small-scale facilities, and the reality is that these include facilities unable to perform a thorough examination. Even so, the number of patients treated at small-scale facilities is 14% of the annual number of new radiation treatment patients in Japan (Table 5-1). A certified radiation therapy technician system has just been established. The number of specialized radiation therapy technicians is low, and in many facilities technicians are actually assigned to treatment, diagnosis, and both duties on a rotation system alternating every few months.

Table 5-1 Annual number of patients in Japan in 2001 by facility - Patterns of Care Study (2001)

Facility	Number of facilities	Total number of patients*	(%)
A1	58	40,020	30
A2	59	16,005	12
B1	253	59,739	44
B2	270	18,822	14
Total	640	134,586	

A1: university hospital/cancer center, 430 patients or more treated per year.

A2: university hospital/cancer center, 429 patients or less treated per year.

B1: other national hospital/public hospital, 130 patients or more treated per year.

B2: other national hospital/public hospital, 129 patients or less treated per year.

*Japanese Society for Therapeutic Radiology and Oncology (JASTRO) Regular Structure Survey (2001)

In Japan, with its unique history of development, there is no established system for medical physicists so far.⁴⁶⁾⁻⁴⁸⁾ Currently, a Radiation Therapy Quality Controller System has gradually been prepared. Dosimetrists, regarded as staff members in US facilities, are also unknown in Japan. Radiation oncology nurses are also a topic to be addressed.

In radiation therapy equipment, there is a gradual, ongoing transition in external irradiation equipment from cobalt-60 units to high-energy linear accelerators (Figure 5-3). However, in their current state, the majority of facilities would find it financially problematic to deploy multiple linear accelerators.

Another problem is the number of brachytherapy facilities. Because treatment results for this modality as a curative treatment are not inferior to surgical results, consideration of the quality assurance, quality control, and staff shortage issues accompanying a transition to high-precision brachytherapy equipment makes concentration in large-scale facilities desirable. Efforts must be made to promote effective utilization through regional cooperation (6.8, Figure 5-4, Figure 6-3).

The most problematic issue is the growing societal problem of an increasing incidence of human error as dissemination of high-precision radiotherapy equipment (6.7) proceeds and treatment devices and techniques grow more advanced and more complex. In many of these cases, one aspect of the problem is regarded as the lack of codification in the form of a manual when the equipment is first introduced. To resolve this problem, delivery guidelines for high-energy radiation-generating equipment have been prepared for vendors and users of treatment equipment.^{44),49)}

5.5 Current state of radiation therapy staff

Table 5-2 presents the staff members properly involved in radiation therapy in Japan and their current duties

Table 5-2 Tasks of radiation therapy staff and current status in Japan (responsibilities)

Required post	Tasks	Current status in Japan (responsibilities)
Radiation oncologist	Patient examination, treatment decision-making, treatment planning	Radiation oncologist (some diagnostic radiologists)
Radiotherapy technician	Performance of radiation treatment	Radiation technician
Medical physicist	Radiotherapy quality assurance and control, research and development	Radiation technician (some radiation oncologists)
Quality controller	Radiotherapy quality assurance and control	Radiation technician (some radiation oncologists)
Dosimetrist	Calculation of dose in treatment planning	Radiation oncologist (some radiation technicians)
Mould room technician	Construction of shells, blocks, and other accessories	Radiation technician (some radiation oncologists)
Nurse	Patient nursing, care	Nurse (some radiation technicians/radiation oncologists)
Administrative staff	Administrative work	Administrative staff, nurse, radiation technician

As the table indicates, specialists are generally assigned to their various tasks, but in the current situation, the limited staff in Japan inevitably must fulfill dual roles. To that extent, concentration on their original specialized tasks is not achieved. Examination of essential radiation oncologist manpower (full-time equivalent, FTE) reveals that national hospitals (B facilities) are short 1 staff member, and dual tasks are performed in conjunction with diagnosis, or examination is performed by an adjunct physician from a university (Table 5-3). This is a deplorable problem in the background of medical accident proliferation at radiation treatment sites.

Table 5-3 Equipment and personnel and average annual number of patients by facility in Japan - Patterns of Care Study(2001)

	Stratification of facility			
	A1	A2	B1	B2
Linac (mean number of units)	1.8	1.6	1.1	0.94
<i>Dual energy dissemination (%)</i>	78	62	76	38
CT simulation dissemination (%)	70	50	50	28
High-dose rate brachytherapy(%)	71	72	35	20
Number of radiation oncologists (FTE, median)*	2.7	1.5	0.8	0.3
Number of radiation technologists (FTE, median)*	4.0	3.0	2.0	1.3
Annual number of patients (mean)	630	397	264	101
<i>Annual number of patients / FTE radiation oncologist</i>	233	264	330	336

Shaded data: Index with 20% or greater increase comparing 1995 data; however, staff data is a 1997 and 2001 comparison.

* FTE (full-time equivalent): Essential manpower value after conversion to 40-hour week of exclusive radiation therapy work

Comparative data from 1995 are not available for dissemination of dual energy equipments and annual number of patients/FTE radiation oncologist

The largest objective of this report is to present a plan for solving these problems.

The number of radiation therapy patients is increasing steadily and has doubled in the last 10 years. In 2002, there were 134,000 such individuals, and in the coming decade, a further increase on the order of 2-3-fold is predicted (Figure 10-1). The following facts may explain the accelerating rate of increase. ① An increasing number of elderly individuals: This development not only increases the incidence of cancer (an estimated 900,000 occurrences annually 10 years later); number of patients not indicated for surgery is also increasing, which necessarily increases the number of radiotherapy patients. ② Correct understanding of radiotherapy indications: In Japan, regarded internationally as having a large surgical bias, the proportion of radiotherapy patients with respect to all cancer patients was 20% in 2001; whereas, in the US, where radiotherapy is used effectively, the figure was 60%. After a decade of international standardization based on evidence and increasing demographic aging, it is highly possible that the proportion of patients where radiotherapy is pursued will reach approximately 40% at minimum. ③ Technical advances in radiotherapy: Technology concentrating high radiation dose on tumors is progressing steadily. Radiotherapy results on a par with those of surgery are anticipated in curative treatment for early-stage lung cancer, and the possibility exists that curative radiotherapy will be pursued among patients where performance of surgery was the conventional standard.⁵⁰⁾ From calculation based on these predictions, the prediction number of new radiotherapy patients annually is at least $900,000 \times 0.4 = 360,000$.

In contrast, sufficient human resources have not been secured to respond to the current dissemination of radiotherapy equipment in Japan. According to the 2001 JASTRO Structure Survey, estimated figures were 129,000 new radiotherapy patients, 707 radiotherapy facilities, 1,480 radiation oncologists, 2,060 radiotherapy technicians, and 69 medical physicists.¹⁰⁾ However, currently in November, 2003 there are 422 physicians certified by JASTRO, 86 certified technicians, and a total of 172 certified, quasi-certified, and certification-cooperating facilities.

With regard to proton beam treatment, there are three facilities in Japan where general examination and treatment based on Pharmaceutical Affairs approval had begun by 2003, and one such facility is also approved for Highly Advanced Medical Technology. The carbon ion beam treatment of the National Institute of Radiological Sciences was also recognized as a Highly Advanced Medical Technology in 2003, and particle-beam therapy was included as a clinical radiation treatment. However, this treatment is offered at only six locations in Japan, and the annual number of patients treated is merely 700, indicating a need for further progress in nationally-focused fair distribution as a health care policy. Another important topic is additional and fairly distributed intensity-modulated irradiation facilities and prostate brachytherapy facilities.

5.6 Forecast of irradiation equipment and staff required for radiotherapy (10 years later: 2015)

With an assumed 360,000 radiotherapy patients (addition of 230,000 individuals), numerical predictions are calculated as follows.

- 1,200 radiotherapy units (assuming 300 radiation patients annually per unit): In 2003 there were 750 units, requiring an additional 450 units (45 units/year). Assuming a 10-year mean duration of use for updating of existing equipment, updating requires 75 units/year, for a total 120 units/year new equipment needed.
- 1,800 radiation oncologists (assuming 200 patients annually per physician): In 2003 there were 400 certified physicians (700 treating physicians), requiring an additional 1,400 certified physicians (140/year).
- 900 medical physicists (assuming 400 patients annually per physicists): In 2003 there were 70 medical physicists, requiring an additional 830 physicists (83/year). If research and development by medical physicists as in Europe and the US is desired, approximately half this number again is required.
- 2,400 full-time treatment technicians (assuming 2 technicians per irradiation apparatus): In 2001 there were 1,000 technicians, requiring an additional 1,400 technicians (140/year).
- 1,200 full-time treatment nurses are needed (separate from outpatient treatment; assuming 1 nurse per irradiation apparatus).
- 600 administrative personnel are needed (assuming 1 individual per 2 irradiation apparatuses).

(Toshihiko Inoue, Hiroshi Onishi, Yutaka Takahashi)

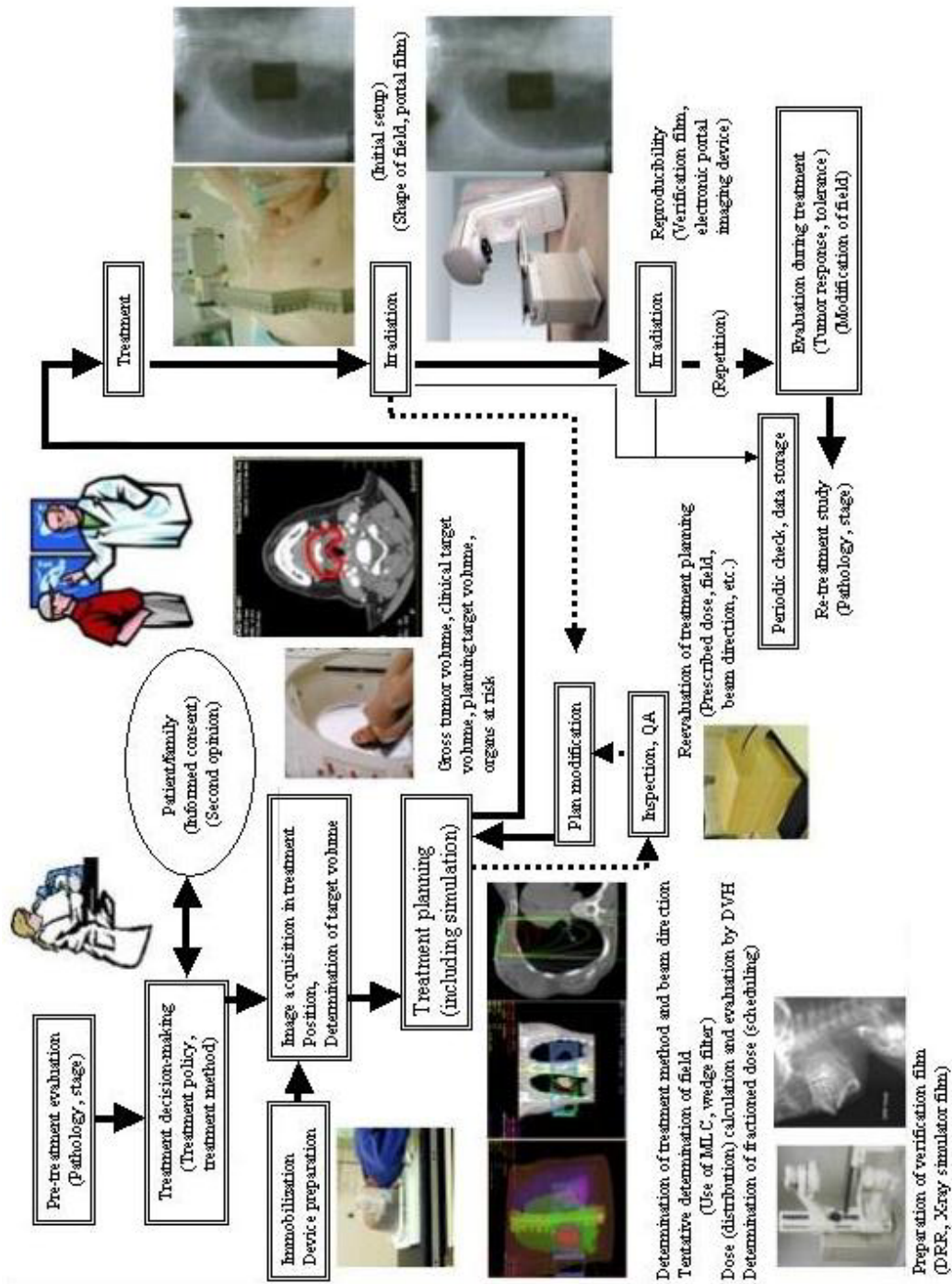


Figure 5-1. The radiotherapy process (external irradiation using CT simulator or similar device).

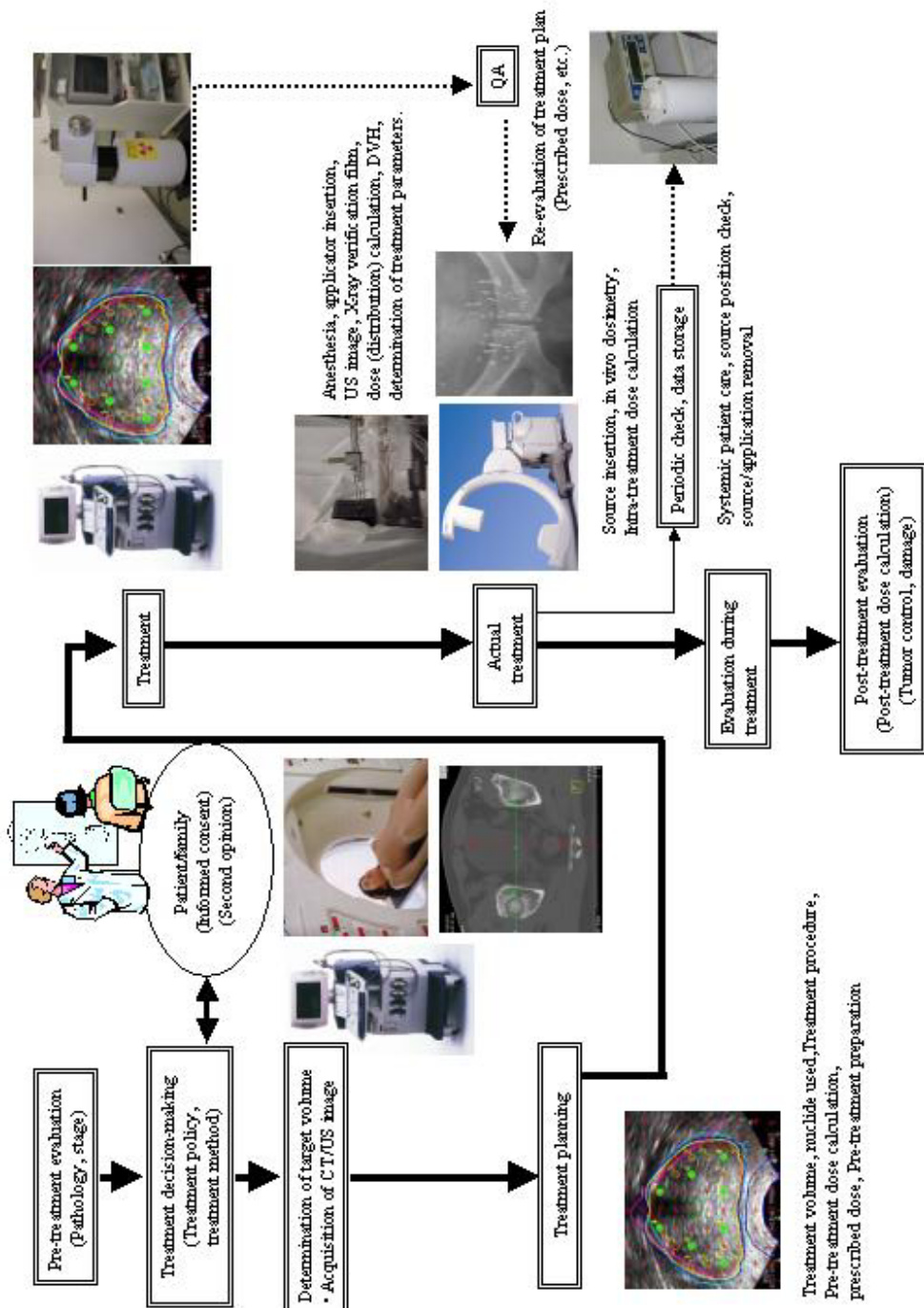


Figure 5-2. The radiotherapy process (image-guide brachytherapy).

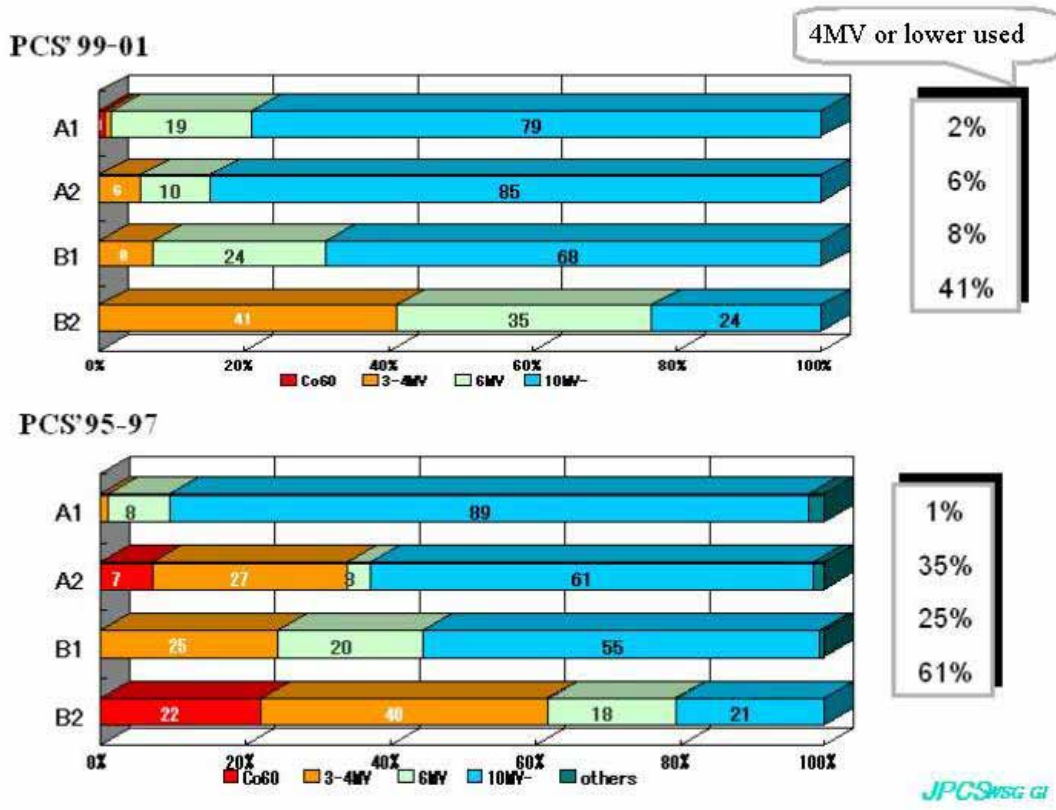


Figure 5-3 Frequency of beam energy used in external radiotherapy for non-surgical cases of esophageal cancer, according to PCS. Facility size results in large differences, with small-scale facilities selecting progressively lower energies. This trend was notably improved in patients treated during 1999-2001 versus patients treated during 1995-1997, but improvement in the smallest (B2) facilities lagged.

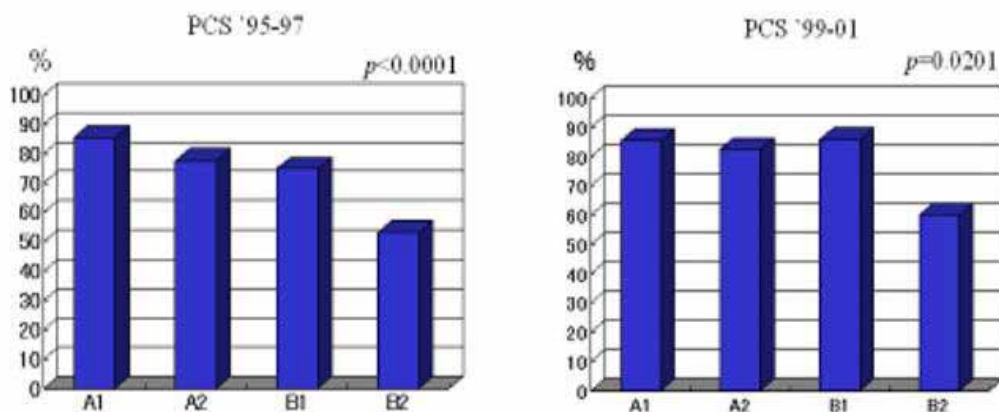


Figure 5-4 Indication rates for intracavitary irradiation in non-surgical cases of cervical cancer. Significant differences according to facility are apparent. Smaller facilities demonstrate progressively lower indication rates. This trend was improved in patients treated during 1999-2001 versus patients treated during 1995-1997, but appropriate therapeutic processes were still not employed at small-scale (B2) facilities.

6. Standards for Equipment and Facilities Utilization

Radiotherapy requires basic equipment comprising an expensive and large external irradiation equipment. Sealed brachytherapy, treatment planning and other treatment-related work require several additional devices. Equipment clearly does not represent all the essential elements. However, at certain facilities the actual radiotherapy treatment is determined mostly by such equipment. As a result, it is essential that facilities have appropriate equipment as determined by thorough study, involving related personnel, from the beginning in the planning stage. Even if standard equipment, which is suitable for the anticipated types of cases is available, cooperative arrangements with other facilities must be settled for instances when the equipment required for a given patient is not available. As discussed in detail in Section 8, excess equipment without provision of adequate human resources is a major drawback. The reader should refer to other publications concerning the requirement and physical and engineering specifications of various equipment, including those by the International Electrotechnical Commission,^{51),52)} and the Japanese Industrial Standards.^{53),54)}

6.1 Facility standards

A radiotherapy facility requires various rooms including examination rooms, patient waiting rooms, external irradiation equipment room, brachytherapy room, radiation source storage room, other radiotherapy rooms, a simulator room, control rooms for each equipment, a treatment planning room, a medical physics and quality assurance/quality control room, and a room for making beam-forming devices and patient immobilization devices. These rooms can also be combined depending on circumstances.

When low-dose-rate brachytherapy or unsealed brachytherapy is carried out, a dedicated treatment room is required. These facilities must be designed with substantial considerations from the perspective of radiation-protection in addition to those for conventional health care facilities. The ingress of equipment during facilities construction and equipment upgrading must also be considered. The external radiation machine room should have a width allowing 180° rotation of the treatment table. The design should also accommodate future increases in patient load and additional commissioning of equipment.

6.2 External irradiation equipment standards

An external irradiation equipment is the basis of a radiotherapy facility, and a minimum of one such unit is essential. The radiation used for external radiation therapy is generated electrically or is produced by a radioactive isotope and obtained with various equipment. Table 6-1 indicates these characteristic features.

A superficial voltage X-ray apparatus is used for treatment of primary or metastatic tumors present on or just below the body surface. However, due to the lack of a skin sparing effect and rapid dose fall off in depth, this apparatus is not suitable for treating deep-seated tumors. Likewise, because an electron beam produced by a linac

or other accelerators is used for treating superficial lesions, this apparatus is currently used very infrequently.

The main external irradiation equipment currently used mostly is a linac (linear accelerator), but telecobalt (Cobalt-60 tele-therapy unit) or other types of accelerators, including microtrons (non-linear accelerator systems) are also used. Modern accelerator systems (liniacs, microtrons) are required to be highly reliable in function, to be used for isocenter treatment, and to obtain an appropriate output for treatment at a 100cm source-patient distance. A cobalt-60 teletherapy unit produces γ -rays through decay of an RI (radioactive isotope) and requires periodic source replacement, typically at a 4-5 year interval. Its structure is simple, and its output is stable as far as the decay is considered, that makes quality assurance and quality control relatively easy. However, the penumbra of the beam is large, and thus it is unsuitable for high-precision treatment. Because of its low energy, these equipments are unsuitable for treatment of deep-seated tumors of the trunk. These equipments are now being replaced rapidly by linac and other accelerators.

Table 6-1 External irradiation equipments

Type of equipment	Maximum beam energy		Characteristics
	X-ray, γ -ray	Electron beam	
Superficial X-ray equipment	0.1MV		High dose at surface X-rays with low penetration
Linac (Linear accelerator)	4-18MV	to 25MeV	Large irradiation field, high dose rate Skin dose sparing due to buildup Sharp beam penumbra Good depth dose curve
Microtron	5-50MV	to 50MeV	Similar to linac, but higher voltage X-rays obtained
RI treatment equipment (Cobalt 60)	1.17 and 1.33MeV		Acceptable radiation field, dose rate, depth dose curve, and large penumbra High-precision treatment is difficult

The radiation produced by the above mentioned equipments includes X-rays, γ -rays, and electron beams. It is desirable to have appropriate multiple energies. Improper adjustment of these equipments is directly related to accidents such as overdose exposure and errors in calibration lead to incorrect irradiation of many patients. Thus, sufficient care and time must be devoted to quality assurance (QA) and quality control (QC). This Section deals with conventional equipments, and Section 6.7 should be referenced for stereotactic radiotherapy, intensity-modulated radiotherapy (IMRT), and other advanced treatment equipment.

Sufficient number of external irradiation equipments is required relative to the patient load, in order to allow enough irradiation time, patient position and field setup time, and the time required for QA/QC.

Table 6-2 shows the minimum required time of an external irradiation equipment for one patient.

Table 6-2 Minimum required time of an external irradiation equipment for one patient

Complexity of irradiation	Example	Time required for a patient
Simple irradiation	1-field or parallel opposing fields Irradiation of 1 site	12(-15) minutes
Moderately complex irradiation	Treatment of 2 or more sites; multi-field irradiation with 3-fields or more Tangential irradiation	20 minutes
Complex irradiation	Complex block such as mantle irradiation	20 minutes or more

*Including time for patient changing cloth and room entry and exit

Additional time on the order of 10 minutes is also required for checking the radiation field during initial treatment or changing fields. Stereotactic radiation of the head and neck region or the trunk requires more time.

The number of treatment portals affects total treatment time (including positioning time), but a larger number of complex irradiations increases the average treatment time. Because the number of fractions differs between curative radiotherapy and palliative/symptomatic radiotherapy, the ratio of these radiotherapy also affects total treatment time. Setup for pediatric patients takes longer time. Whole-body irradiation, intraoperative radiotherapy, stereotactic radiotherapy and other complex techniques occupy equipment for especially longer durations, which must be considered when calculating the number of units needed. Conversely, multi-leaf collimators and electronic portal imaging device discussed below contribute to shortening of total treatment time. The number of technologist operating an external irradiation equipment is another factor that determines treatment time per patient.

The number of external irradiation equipments required must be considered at each facility with consideration of the above mentioned factors. Table 6-3 presents an example of total treatment time calculation. It should be noted that patients do not come at a fixed rate throughout the year, and some allowance is required.

In addition, if the number of treatments per external irradiation equipment is high, it is possible that positioning and other related procedures become inaccurate. Under current conditions in Japan, facilities where the ratio of number of patients per year/number of external irradiation equipments (liniac + telecobalt) is greater than 400 should immediately consider commissioning of new equipment, staff increases, and other necessary improvements taking the foregoing several parameters into account (improvement warning level). This level is the value at 17 percentile of facilities in the order of larger patient loads in facilities selected at random by PCS (data of 2000). The value at 20 percentile of facilities was 350. Because future increases in patient load are forecast at these facilities, preparations for improvement are recommended.

5%	521 patients
10%	450 patients
15%	434 patients
<u>17%</u>	<u>400 patients</u>
20%	350 patients

Given that a 10MV or higher energy is desirable for deep-seated targets in the trunk, while lower energy (5MV or lower) is desirable for shallow lesion such as in the head and neck region or breast, a facility would preferably have the capability for delivering two or more energies. Most models of an external irradiation equipment have multiple energy X-ray-generating functions (dual/triple energy equipment), and these equipments are continually gaining multi-functionality. Such models are particularly useful at small-scale facilities having 1-2 treatment equipments.

Megavoltage radiotherapy equipments include various accessories such as beam compensation devices, beam modification devices (e.g. wedge filters), radiation field-forming devices (e.g. multi-leaf-collimators), electronic portal imaging devices, and position-checking devices such as lasers. These devices are useful for broadening irradiation technique and increasing accuracy, but the use of such advanced devices is complex and requires sufficient skill. A patient treatment table attached to the irradiation equipments relates closely to irradiation accuracy. Patient safety must be assured, particularly with rotating gantries and irradiation equipments with an automatically moving patient table.

Accelerators are desirable to have a multi-leaf collimator (MLC). MLC leaf widths currently used include 2cm (not for new machine), 1cm, 5mm, and micromulti-leaf collimators with a narrower leaf width are also available. The availability of a 5mm or smaller leaf width is desirable for performing high-precision radiotherapy.

Presently there are almost no equipment solely for electron beam; these are combined with X-ray linacs. An electron beam is required for superficial treatment, especially that of the skin, and an electron machine must be equipped with multiple energies for selection of a proper energy depending on the depth of target. It is also used for unique treatment such as intraoperative irradiation.

The operating console is located in a separate room, and the line of movement of the operators to the treatment room must be considered.

Table 6-3 Example of total treatment time calculation

7 hours working time/day

Assuming 50 weeks treatment, 5 days/week, the treatment hours provided by 1 external irradiation equipment is:

$$60 \times 7 \times 5 \times 50 = 105,000 \text{ minutes}$$

Assuming the patient composition is

50% curative irradiation (35 fractionations in average)

50% palliative irradiation (15 fractionations in average).

For simple irradiation, the time required per patient is assumed as 15 minutes (figure includes substantial allowance). It is assumed that irradiation of moderate complexity is carried out in 25% of curative irradiation,⁵⁵⁾ and that irradiation field checking for change of field is carried out one time during all curative irradiation.

In these conditions, the number of hours required for n patients is:

$$\text{(Simple/curative)} \rightarrow 15 \text{ minutes} \times 0.5 \times 0.75\text{-n patients} \times 35 \text{ treatments} + 10 \text{ minutes} \times 0.5 \times 0.75\text{-n patients} \times 2 \text{ times}$$

$$\text{(Moderately complex/curative)} \rightarrow +20 \text{ minutes} \times 0.5 \times 0.25\text{-n patients} \times 35 \text{ treatments} + 12 \text{ minutes} \times 0.5 \times 0.25 \text{ n patients} \times 2 \text{ times}$$

$$\text{(Simple/palliative)} + 12 \text{ minutes} \times 0.5\text{-n patients} \times 15 \text{ treatments} + 12 \text{ minutes} \times 0.5\text{-n patients} \times 1 \text{ time}$$

$$= 412\text{-n minutes}$$

Thus, under these assumed conditions, the number of patients treatable with 1 external

(cont'd)

irradiation equipment is:

$105,000/412 = 254.8 =$ approximately 250 patients.

On the other hand, assuming a required time of 12 minutes per patient (minimum required time) for simple irradiation, the result of the above calculations is 350-n minutes, and 1 external irradiation equipment can treat approximately 300 patients.

The reader should note that these annual treatment capacity figures are at best reference values under the foregoing parameters.

Figure 6-1 presents the annual number of patients treated per external irradiation equipment at various strata of facility. Apart from B2 facilities, 26-75% of A2 and B1 facilities (Q2, Q3) treated approximately 250 patients per unit. At A1 facilities, the figure was approximately 350 patients. At A2 and B1 facilities, greater than 300 patients/unit were treated at the top 25% of facilities (Q4). A1-Q4 facilities treated more than 450 patients/unit. These facilities should consider additional commissioning of equipment and staff increases (warning level).

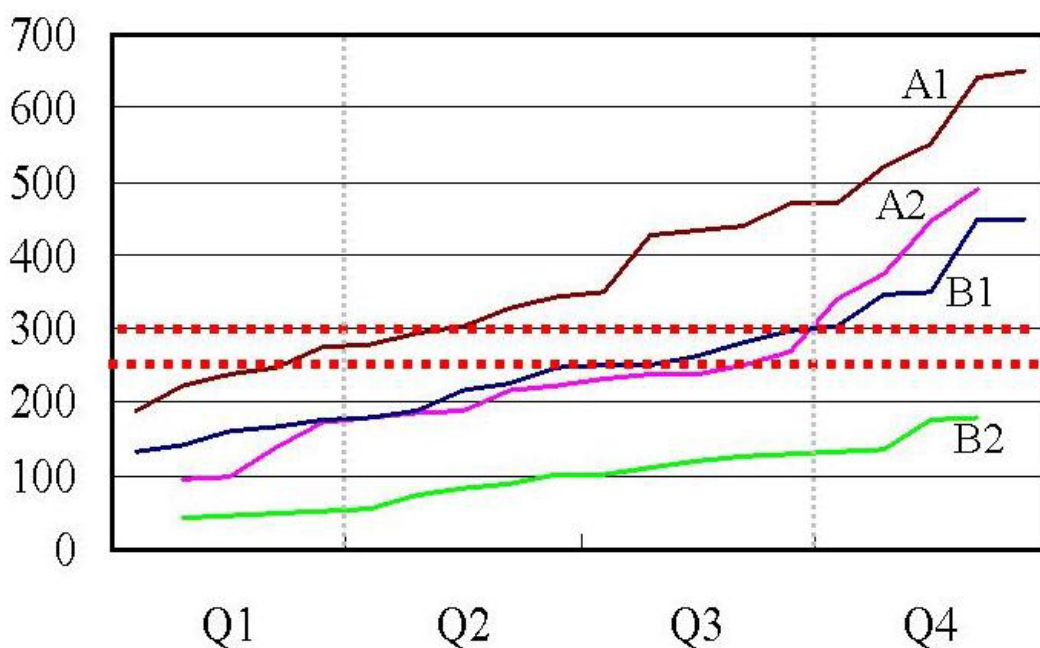


Figure 6-1 Distribution of annual number of patients treated/treatment equipment, by stratification of facility. Horizontal axis represents facilities arranged in order of increasing value of annual number of patients treated/treatment equipment within facilities in each stratum (A1, A2, B1, B2). Q1: 0-25%, Q2: 26-50%, Q3: 51-75%, Q4: 76-100%.

6.3 Simulator standards

A simulator is an essential equipment for executing or verifying treatment planning. Modern therapies combining hyperfractionation irradiation and chemotherapy have required higher precision treatment. Regardless of the number of patients, each facility must have, at least, one simulator.

Devices used as simulators are X-ray simulators and CT used for treatment planning. An X-ray simulator has the advantage of providing fluoroscopy in addition to X-ray photography, allowing confirmation of respiratory movement, etc. Equipment capable of taking digital images has an increased utility and improves patient treatment capabilities.

Current treatment planning is carried out mainly by treatment planning CT. Treatment planning CT has two types: One is so-called CT simulators with functions of delineation of targets or organs at-risk and projection of treatment planning results to the patient (shape of irradiation field and isocenter location). Another type is one with only typical diagnostic CT functions (diagnostic CT usage), which project only a treatment planning reference point to the patient; and other functions are carried out by a treatment planning computer. In cases of diagnostic CT usage, large-scale facilities should install dedicated equipment in the radiotherapy department, but in cases where a CT is also used for diagnosis, it is important, for the convenience of treatment planning, that usage time can be secured in the facility. To ensure high precision, the CT should have the flat top table.

It is not necessary for a CT simulator to be installed in all facilities. However, some type of treatment planning CT should be provided in cases of three-dimensional radiotherapy or usage of complex irradiation technologies, and the clinical value of a CT simulator is particularly high in these cases. When installation of a CT simulator is contemplated, determinations must be made individually with consideration of necessary conditions such as regional availability and human resources. Conversely, treatment planning can be accomplished by a CT simulator alone, but even when a CT simulator is available, possession of an X-ray simulator is also desirable.

The procedure time using a simulator for ambulatory, cooperative patients (total time from patient entry of room to patient exit from room, including setup and imaging acquiring time) is approximately 60 minutes. In complex irradiation field set up such as the following instances 1)-3), approximately 50% more time is required.

- 1) Conformal radiotherapy
- 2) Set up of two proximal regions with different beam arrangements (e.g. irradiation of chest wall and supraclavicular fossa region for post operative breast cancer radiotherapy, or irradiation from the oral cavity to the supraclavicular fossa in case of head or neck tumors)
- 3) Set up of large field irradiation such as mantle irradiation.

In the case of children, substantial time and skill are required, for example, to make an immobilization device with ensuring safety and for sedation of the children. Twice the typical time is needed.

Like treatment equipments, simulators must also be renewed or upgraded in cases of deterioration, wear, or decreased safety or precision. Periodic upgrading of equipment is essential not only to maintain treatment quality, but also for the safety of patients and health care providers, and for better economic efficiency.

6.4 Brachytherapy standards

Brachytherapy is grossly classified into high-dose-rate irradiation using a remote after loading system (RALS) and low-dose-rate irradiation involving a manual procedure by a physicians; this explanation concerns primarily the former type.

Brachytherapy is often an important technique in definitive radiotherapy for patients with uterine cancer, head neck cancer, esophageal cancer, prostate cancer, and roentgenographically occult lung cancer, and its therapeutic effect and adverse reactions depend greatly on the treatment process. In Japan, brachytherapy is most commonly used for the treatment of uterine cervical cancer. Reports concerning a PCS in the US⁵⁶⁾ and the Japanese 1995-1997 PCS also indicate that intracavitary brachytherapy plays an important role in the treatment process for cervical cancer. The 1991-2001 PCS demonstrated differences among different classes of facility in the type of devices used, and in the treatment process (Figures 6-2, 6-3).

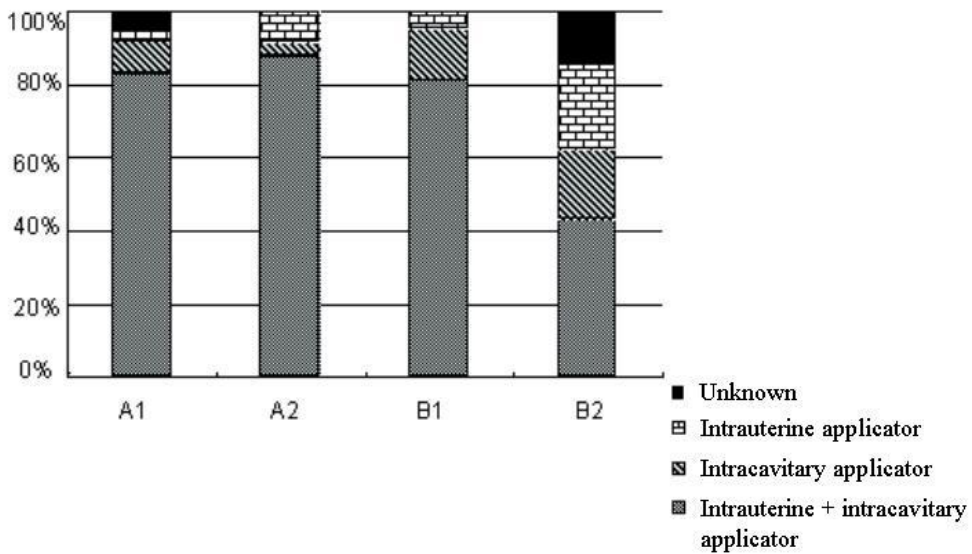


Figure 6-2 Devices used in intracavitary brachytherapy for cervical cancer, by facility (1999-2001 PCS).

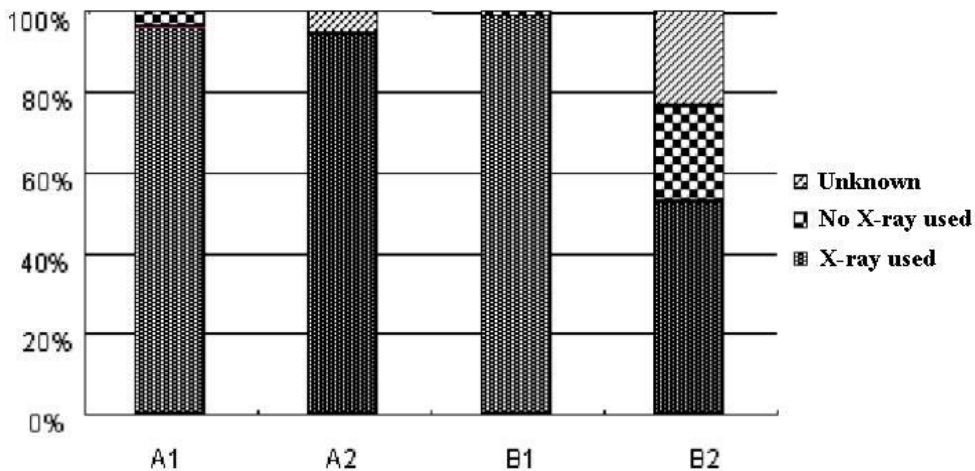


Figure 6-3 Geometrical simulation by radiographs in intracavitary brachytherapy for cervical cancer, by facility (1999-2001 PCS).

Iridium is the popular source used in treatment in recent apparatuses. Radiation source replacement is generally required every three months due to its short half- life of 74 days, and insurance claims are recognized for radiation source cost. Consequently, the condition to maintain operating costs needs 8 cases per replacement period or 32 cases per year. Table 6-4 presents the estimated annual mean number of intracavitary brachytherapy patients in treatment for cervical cancer at facilities of various classes, obtained in 1991-2001 PCS. In practical use, intracavitary brachytherapy is used for postoperative brachytherapy for cervical cancer and esophageal cancer and other diseases. Although considering the number of treatments cases performed at some facilities, referral of intracavitary brachytherapy to associated facilities is advantageous from the standpoint of medical economics (6.8).

Table 6-4 Estimated annual mean number of intracavitary irradiation patients in curative treatment for cervical cancer, by class of facility (1999-2001 PCS)

Facility class (Facility performing intracavitary irradiation)	A1 (19/20)*	A2 (13/16)*	B1 (16/18)*	B2 (7/14)*
Estimated annual mean number of patients (Curative treatment cases only)	33	18	27	8
99-01 total patients (Curative treatment patients only)	99	54	88	24
Estimated annual mean number of patients (Excluding requests to other facilities)	26.3	15.3	19	5.3
99-01 total patients (Excluding requests to other facilities)	79	46	57	16
Number of facilities requesting Intracavitary irradiation in other requests (%)	2 (11)	2 (15)	8 (50)	4 (57)

*(Facilities owning intracavitary irradiation equipment/facilities surveyed)

Commensurate with treatment subject to thorough quality control, it is extremely important to utilize effectively healthcare facilities which meet case-integrating capability and various other standards in keeping with the facilities, equipment, human resources, and medical economics concerned. Consequently, sharing of equipment and association in regional healthcare units should be considered, as discussed in Section 6.8.

A) Equipment

The minimum level required is

- Brachytherapy source storage equipment
- RALS operating equipment
- Dose monitor
- Treatment room monitor
- Bed unit (must also allow examination in gynecological and urological disease)
- X-ray fluoroscopy apparatus/imaging apparatus (in principle, must be installed in the same treatment room)
- Dedicated brachytherapy treatment planning apparatus system
- Various applicators for use in treatment

· Specialized QA/QC tools

The treatment room must meet established construction requirements, recommendations of the International Commission on Radiological Protection, international basic safety standards of the International Atomic Energy Agency, and other such standards pertaining to recommendations for radiation protection. Because interstitial brachytherapy frequently requires anesthetic treatment for placement of the applicator, the use of an operating room should be considered, or the treatment room must have facilities allowing use of medical equipment intended for anesthetic treatment. The treatment room must also be provided with an ultrasonic probe, if such equipment is needed for treatment procedure.

B) Staff

For achievement of standardized treatment, the minimum level of staff required is highly experienced, trained, full-time radiotherapy physicians (must be Japanese Society for Therapeutic Radiology and Oncology-certified physicians), full-time treatment technicians (must be Japanese Society for Therapeutic Radiology and Oncology-certified technicians or technicians having an equivalent qualification), and full-time nurses. Given the need for radiation source handling, loss-prevention, radiation protection, and other safety management, which were thought to be more complex and advanced than that of external beam radiation therapy, a supervisor working exclusively in quality control of radiotherapy should be employed on a full-time basis (the supervisor is ideally a brachytherapy specialist). In addition, persons responsible for safety quality control must be designated clearly.

Intracavitary brachytherapy(uterus, esophagus, and bronchus) requires 1.5-2.5 hours for steps including patient pretreatment preparation, insertion of treatment device (required confirmation and revision assisted by fluoroscopy and radiographs; in case of bronchial cancer bronchial fiberscope examination is needed), imaging, treatment planning, treatment, and post therapeutic treatment. During this session, 2 treatment physicians, 1 technician, and 1 nurse should be involved.

Interstitial brachytherapy requires 2-3 hours for insertion of a treatment device prior to the start of treatment. After device insertion, confirming X-ray/CT imaging, treatment planning, and initial treatment are performed, and this series of procedures requires 2-3 hours. Given the insertion of a medical device directly into the body, minute care is also required to prevent infection. When general anesthesia, lumbar anesthesia, or epidural anesthesia is required, anesthesiologist support is also needed. In many cases, the medical device is left in an indwelling state, and twice daily irradiation is performed over a period of 2-5 days. The second and subsequent irradiations require approximately 30-60 minutes for a single series of processes including preparation for irradiation, checking, and irradiation. Two treatment physicians (which must include one physician with specialized at referred disease), 1 technician, and 1 nurse are needed.

A supervisor responsible exclusively for quality control of radiotherapy should also be involved during treatment planning.

C) Other

When assurance of precision is difficult or safety is reduced for reasons such as deterioration of the apparatus, updating or refurbishment is needed. As described above, the nature of the radiation source used dictates replacement of the radiation source at

intervals suitable to maintain adequate treatment intensity. In light of the handling of highly radioactive (intense), radiation sources requiring minute care, the utmost level of care must be given to management of facilities, equipment, and radiation sources in order to assure the safety of patients and medical staff. Replacement and storage of radiation sources must be carried out according to strict procedures, with checking performed by plural experts.

6.5 Accessory device standards

Irradiation accessories including patient restraints intended to maintain the position of the patient, beam correction devices which modify attributes such as the shape and profile of the beam, and devices used in sealed brachytherapy.

Restraints are often used to maintain the position of the patient and ensure precision and safety. Economizing on materials here eliminates the prospect of safe and highly effective patient treatment. The use of accessories is not required in all cases, but accessories should be used under the following conditions.

a. Patient restraints

- 1) Children (restraints to prevent falling and other such accidents and to improve reproducibility)
- 2) Head and neck tumors/brain tumors (restraints or the like to improve reproducibility)
- 3) Tangential irradiation of chest wall in breast cancer, etc. (accessories to maintain raising of upper arm)
- 4) High-precision treatment (accessories used for stereotactic radiotherapy of the trunk, etc.)

b. Beam correction devices

- 1) High-dose administration to the head or neck region/trunk region (MLC or custom block, etc. preparing shape of irradiation field used in lung cancer, esophageal cancer, prostate cancer, etc.)
- 2) Use of MLC or wedge filter in three-dimensional irradiation
- 3) Whole body irradiation (bolus material to correct for body thickness, or eye block, etc. to avoid irradiation of crystalline lens)
- 4) Intraoperative irradiation (cone or shielding to avoid normal tissue)

c. Devices for sealed brachytherapy

- 1) Applicator for intracavitary irradiation in cervical cancer, esophageal cancer, and lung cancer
- 2) Applicator for interstitial irradiation

6.6 Radiotherapy planning apparatus standards

Calculation of dosage within the irradiated volume of the patient is an essential step in the process of radiotherapy. Ownership of a radiotherapy planning apparatus is essential for performance of safe radiotherapy, and each facility must own a minimum of one treatment planning apparatus. This is an extremely important apparatus particularly in cases of intensive, high-dosage irradiation, and cases where the surrounding area includes at-risk organs. At facilities performing at least calculation of multi-portal irradiation, display of multiplanar isodose distribution, and sealed

brachytherapy, a radiotherapy planning apparatus is needed for such dose calculation. It is also preferable if CT imaging can be performed to carry out three-dimensional treatment planning.

Accurate measurement of beam data and wedge filter data from treatment devices and reliable input of data to a radiotherapy planning apparatus are important tasks in the accurate execution of radiotherapy at each facility. This work is extremely important for protecting patient safety, and users at each facility must accept this responsibility during use. Many calculation algorithms exist, but a highly reliable algorithm must be used.

To ensure patient safety and precise radiotherapy, the use of a radiotherapy planning apparatus must be handled by full-time radiation oncologists, medical physicists, radiotherapy quality controllers, and radiotherapy technicians.

Three-dimensional treatment planning is not essential in all cases, but preparation and evaluation of dose distribution at the center of the irradiated field or beam must be carried out for all patients. For comparatively simple irradiation techniques, (e.g. anterior single portal irradiation or antero-posterior opposing portal irradiation), approximately 30 minutes per site per patient is needed. In the treatment plans presented below, 60 minutes is needed due to the complex calculation and detailed study required.

- 1) Irradiation with three or more portals
- 2) Moving field irradiation
- 3) Irradiation with a beam arrangement at two different contact sites
- 4) Non-opposing two portal irradiation
- 5) Irradiation administering a dosage exceeding the tolerable dosage of adjoining at-risk organs

Additionally, treatment planning for stereotactic irradiation, intensity-modulated radiotherapy, and other such high-precision radiotherapy requires an extremely large amount of time, but the time required differs depending on operating procedures at the facility, and calculation must be made at each facility.

Radiotherapy planning apparatuses also deteriorate, and when a standardized treatment plan has become difficult, or when processing capability has declined, upgrading or refurbishment is needed. Upgrading of an apparatus is essential not only for maintenance and improvement of treatment quality; it also benefits patient and health care provider safety and is advantageous from the operational perspective of economic efficiency.

(Hideo Tatsuzaki, Naoto Shikama, Katsumasa Nakamura, Takafumi Toita,
Takeshi Kodaira)

6.7 Other advanced treatment equipment and facilities

Recently, remarkable progress has been achieved in high-precision treatment methods and planning systems, and clinical application is broadening for such treatments as stereotactic radiotherapy and intensity-modulated radiation therapy (IMRT). These developments have created a need for special-purpose equipment and facilities, and three-dimensional treatment planning equipment in particular has become essential. Here we discuss stereotactic radiotherapy and IMRT using a linac (linear accelerator system).

When performing stereotactic radiotherapy with a linac, the personnel needed included one or more full-time physicians dedicated solely to radiotherapy (limited to individuals with 5 or more years radiotherapy experience), one or more individual responsible solely for precision control of devices involved in radiotherapy (e.g., a medical physicist or radiotherapy quality controller), and one or more radiotherapy technician responsible solely for radiotherapy (limited to individuals with substantial experience in radiotherapy using a linac or microtron). The "radiotherapy technician responsible solely for radiotherapy" and the "individual responsible solely for precision control of devices involved in radiotherapy" mentioned here must in all cases be different individuals. The devices and equipment required for performance of such therapy stated below must also be provided.

- 1) Linac or microtron
- 2) Treatment planning CT apparatus (an apparatus other than a specialized treatment CT is acceptable, but when a diagnostic CT is used, a flat plate is also used).
- 3) Three-dimensional treatment planning system (TPS)
- 4) Equipment restricting patient movement and movement of organs within the body during irradiation.
- 5) Microionization chamber or semiconductor dosimeter (including diamond detector) and concomitantly used water phantom or water-equivalent solid phantom

Recently these high-precision radiotherapy series have also required high-capacity image database servers. It is also desirable to construct a network in the radiotherapy department whereby radiotherapy planning data is linked to patient information, diagnostic imaging data, and treatment implementation data. Where a hospital information system, radiation information system, or other hospital databases or electronic charts exist, linking of the network to such information should also be considered.

Facilities performing such treatment have guidelines regarding precision control of devices involved in radiotherapy, and actual radiation measurement and other such precision control must be carried out according to such guidelines. "Precision control" as used herein includes at a minimum the following elements.

- 1) Calibration of reference dosimeters once or more every 2 years
- 2) Precision control of therapeutic equipment by reference dosimeter once or more each month
- 3) Precision verification and control of micro-irradiation field beam data in each three-dimensional treatment planning apparatus.
- 4) Control of patient restraint accuracy during treatment planning and irradiation once or more every 3 months

In stereotactic radiotherapy of the trunk, patient movement and movement of organs within the body at the focus of irradiation is restricted by the use of devices such a shell, body frame, CT integrated with irradiation apparatus, intra-irradiation fluoroscopy, respiration gating system, and body movement-tracking equipment, but recording of baseline data is needed for assessment of the actual control achieved. Checking is performed during each irradiation treatment to verify that restraint precision at the focus of irradiation is within 5mm; the location of the irradiation focus is determined; and a record is made. Including shell or body frame preparation, treatment

planning requires a minimum of 1 physician and 2 radiotherapy technicians. Treatment planning takes approximately 8 hours. Procedures such as insertion of a metal marker used to check tumor location requires additional time. Irradiation field checking during each irradiation requires a minimum of 1 physician and 1 radiotherapy technician.

In stereotactic radiotherapy for intracranial/head and neck tumors, restraint precision with respect to the focus of irradiation must be within 2mm, and a stereotactic surgical frame or restraint device with equivalent restraint precision must be installed. Depending on the apparatus, anesthesia is required, and surgical provisions are needed. Including personnel for installation of restraints, 3 physicians and 2 radiotherapy technicians are needed. Treatment planning takes approximately 5 hours.

IMRT requires inverse planning, in which a dose distribution method providing complex dose distribution to a tumor or normal tissue is determined by a computer optimization method using a three-dimensional image device. When this method is used for treatment planning, it is not possible to perform redundant checking by manual calculation, as is conventionally the case in dose calculation for administration to a patient. If high precision of location is not maintained, there is also a risk of adverse effects on normal tissue from overdosage, or an inadequate therapeutic effect from underdosage. Special equipment for dose calculation and quality control of each irradiation is needed. The facilities standard needed is also equivalent to or higher than that of stereotactic radiotherapy; specifically, a full-time medical physicist and a radiotherapy quality controller are needed.

Treatment planning also requires the use of restraints corresponding to the treatment site. Treatment planning takes 6-10 hours, depending on the site. A completed treatment plan is tested for each irradiation portal using a phantom.

These therapeutic methods are effective when carried out with thorough control; however, not only is there substantial cost for facilities, personnel with a high level of specialized knowledge and experience are needed for quality control and quality assurance (QC/QA). If a level of thorough control is not ensured, treatment cannot be performed safely. Consequently, rather than having a large number of facilities readily adopt these treatments, introduction by a limited number of facilities fully meeting the criteria is preferable, and such availability should also be shared as a regional and national asset (see Section 6.8).

(Chikako Yamauchi)

6.8 Facility discrepancies and inter-facility sharing of equipment and patient referral

Progress in the technical aspects of radiotherapy has brought high-precision radiotherapy¹ into general clinical use in place of conventional two-dimensional radiotherapy. The introduction of such technologies typically requires expensive initial investment, as well as running costs. In addition to the staff needed for treatment delivery, well trained personnel are also necessary for treatment planning and quality assurance activities. As also discussed in Section 5.2, it is not efficient for all facilities

¹"High-precision radiotherapy" used here includes the following: Three-dimensional conformal radiation therapy, intensity-modulated radiation therapy, stereotactic radiosurgery, and brachytherapy (remote afterloading systems and permanent implant brachytherapy).

to acquire such facilities and human resources uniformly. As also discussed in Section 6.2, a treatment facility should ideally own a minimum of two treatment apparatuses in order to avoid radiotherapy downtime due to machine failure or periodic inspection. In addition, a dual-energy linear accelerator is preferable for providing the optimal dose distribution at all treatment sites, however, in terms of health care economics, it is not necessarily appropriate for all facilities to own such equipments.

Factors pertaining to the patients undergoing treatment must also be considered. High-precision radiotherapy is often used for initial treatment of cancer for curative intent. The overall condition of many patients is thus good, and there are few problems in traveling long way for radiotherapy. In contrast, there is little need for high-precision radiotherapy in palliative and symptomatic treatment. The overall condition of patients is generally poor, and treatment at a facility near the home area is desirable.

Given the foregoing issues, radiotherapy facilities should pursue group-level optimization of functions in regional health care by stratifying on the basis of their equipment and human resources, and by forming groups based on population density and commuting distance/time to the hospital (Table 6-5). Specifically, a desirable structure includes a core facility devoted exclusively to high-precision radiotherapy (university hospital, cancer center, etc.) which owns several accelerators and has sufficient staff, and a number of general facilities giving consideration to compatibility and complementary treatment equipment/treatment planning equipment; wherein these facilities refer patients to each other depending on their condition. It is also desirable for such facilities to supplement the functions of each other, for example, when a breakdown of treatment equipment arise, thereby fulfilling the functions needed in regional health care (Figure 6-4).

(Michihide Mitsumori)

The following table presents the amount of resources appropriate for the specifications and population (administrative units) of a specific facility

Table 6-5 Optimization of functions in regional health care by stratification of radiotherapy facilities based on equipment and human resources and by grouping based on population density and commuting distance/time to hospital (example)

Type of facility	Role	Human resources (example)	Technical resources (example)	Installation standard (example)
Radiotherapy center facility A	Development of a new treatment technology ²	3 or more JASTRO-certified physicians	2 or more dual energy linacs	1 facility per 2 million people, or 1 facility within 2 hours commuting time
	Establishment of a standard procedure for the state-of-art treatment technologies. Technical support for affiliate hospitals	5 or more full-time treatment technicians 1 or more radiotherapy quality controller 3 or more full-time treatment nurses	High dose rate RALS treatment apparatus CT simulator Three-dimensional treatment planning apparatus	
Radiotherapy center facility B	Implementation of the state-of-art treatment according to standardized procedure ³	2 or more full-time physicians 1 or more JASTRO-certified physician 3 or more full-time treatment technicians 1 or more radiotherapy quality controller 2 or more full-time treatment nurses	1 or more dual energy linac High dose rate RALS treatment apparatus CT simulator Three-dimensional treatment planning apparatus	1 facility per 1 million people, or 1 facility within 1 hour commuting time
	Implementation of standard treatment ⁴	1 or more full-time physician 1 or more full-time treatment technician 1 or more full-time treatment nurse	1 or more single or dual energy linac CT or X-ray simulator	1 facility per 300,000 people, or 1 facility within 30-minute commuting time
Radiotherapy regional health care facility	Implementation of palliative/symptomatic treatment			

²Example as of end-2004: IMRT for prostate cancer, ¹²⁵I seed permanent implantation for prostate cancer, stereotactic radiation treatment for lung cancer

³Example as of end-2004: 3DCRT (70Gy or higher) for prostate cancer, 3DCRT (multiportal irradiation for other organs), SRS, SRT for brain tumors

⁴Example as of end-2004: whole brass irradiation as breast-conserving treatment, 60Gy antero-posterior opposing portal radiation for lung cancer with complications, 66Gy curative irradiation for cancer of the larynx.

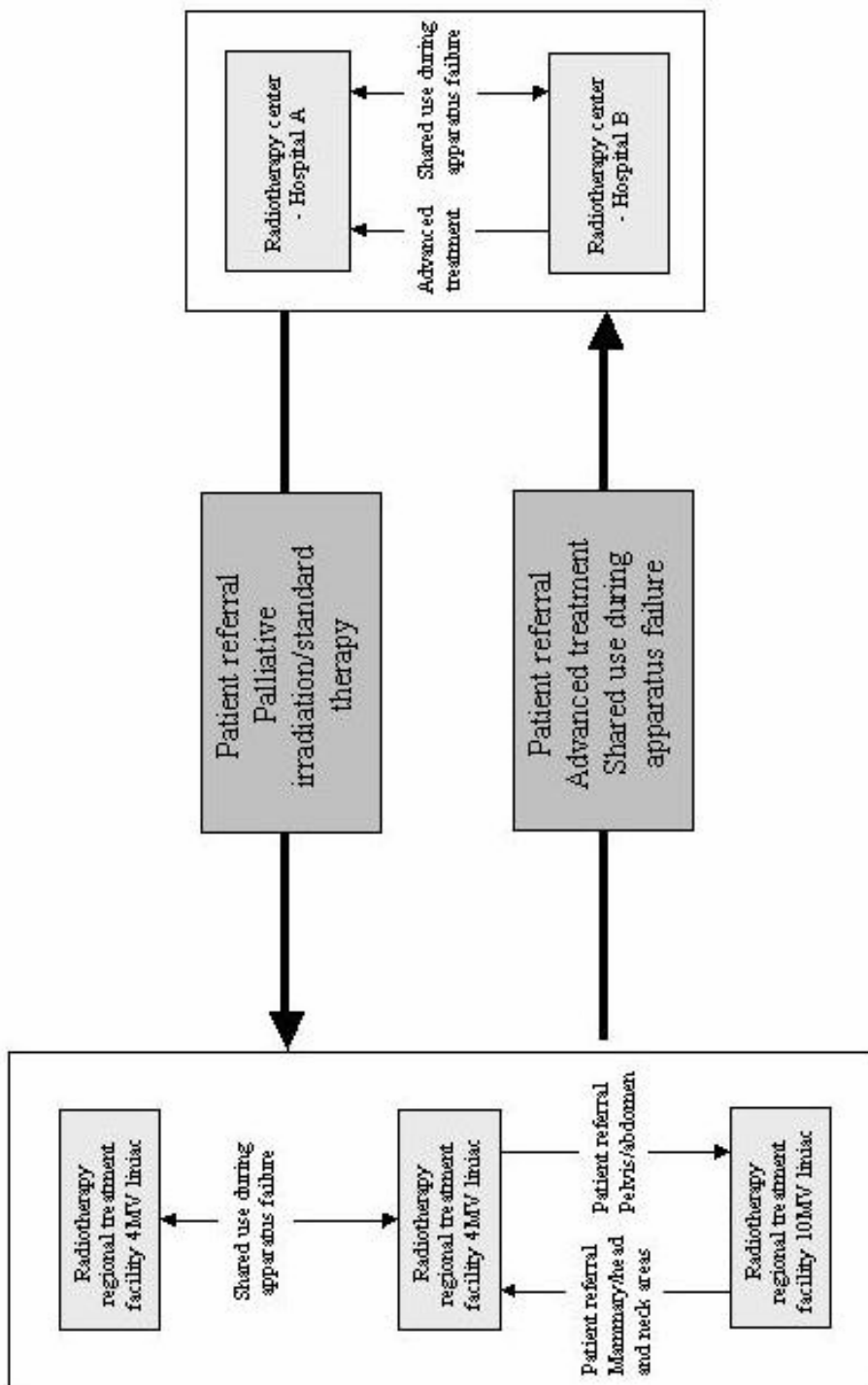


Figure 6-4 Shared use of equipment and patient referral among facilities in regional treatment (example).

7. Radiotherapy Quality Assurance

The object of quality assurance and quality control (QA/QC) programs is to monitor the quality of medical care and its appropriateness objectively and systematically. This is an essential program for all activities of a radiotherapy department. Since a quality assurance program involves structures, processes, and outcomes, each of these areas can be evaluated. Section 6 discusses standards for facilities and equipment, and Section 8 discusses standards concerning personnel. This Section discusses standards relating primarily to processes and systems that should be prepared for analysis of outcomes. A "process" includes patient assessment before and after treatment and actual treatment methods and refers to examination and treatment itself. A cycle is required in which processes are documented and their outcomes are analyzed routinely and returned to the site. Active steps should be taken to establish such an assessment system in the radiation oncology area of each facility, and information management systems should be set up with the premise that all data can be disclosed to patients at any time.

7.1 Documentation of radiotherapy-related consultation and treatment

Information concerning the consultation and treatment of patients undergoing radiotherapy must be recorded and stored in the form of documents conforming to the Medical Care Law and the Medical Practitioners Law, the Laws concerning the Prevention from Radiation Hazards, and the relevant implementing regulations. Table 7-1 presents the standard information to be noted in medical records.

Table 7-1 Basic information noted in medical records

1) Identification number (ID; hospital and RT departmental)
2) First and last name / phonetic reading*
3) Sex
4) Date of birth / Age at initial consultation
5) Address and postal code / Telephone number
6) Date of initial consultation
7) Referring hospital / Department / Physician
8) Height / Weight
9) Chief complaint
10) Current history / Prior history / Family history / Allergic history / Infectious diseases / Complications / Medication status

*Japanese names have multiple possible readings. –tr

When radiotherapy is planned, the items in Table 7-2 are also noted.

Table 7-2 Documentation for radiotherapy planning

-
- | |
|---|
| 1) Disease targeted by radiotherapy (localization and histology), TNM stage, site, and extent of disease. |
| 2) When lesions are measurable, size and measurement method used. |
| 3) Examination findings by radiation oncologist (history taking and physical findings). |
| 4) General condition (Performance status). |

(cont'd)

- 5) Tumor marker or endocrine receptor information.
 - 6) Diagnostic imaging report, surgical records, pathology reports, summary of clinical course in admission, and correspondence with referring physician.
 - 7) Prior radiotherapy records.
 - 8) Integrated treatment policy (curative, symptomatic, etc.), including surgery and chemotherapy, etc.
 - 9) Purpose of radiotherapy and selection rationale.
 - 10) Combined therapy (surgery, chemotherapy, endocrine therapy, etc.).
 - 11) Informed consent.
 - 12) Target volume and basis for establishment, prescribed dose, fractionation, anticipated number of days for treatment, and irradiation method.
 - 13) In case of clinical trials or protocol treatment, summary of the protocol.
-

In cases where the site of the lesion can be determined visually, it is useful for review and therapeutic progress if a sketch or photograph is added to the medical record. When there are several types for stage classification, the classification used should be indicated. For many malignant tumors, when a measurable lesion is present, the size of the lesion is used to assess therapeutic effect, it is therefore important to evaluate and note the size of the lesion before treatment. Because the general condition of the patient and tumor status change over time, documentation must include the purpose and the method of radiotherapy in association with physical finding and imaging not only at initial consultation but at the time when treatment is considered. General condition (performance status) is an important prognostic factor in cancer patients but later assessment by a third person is difficult, and evaluation at the initial consultation is essential.

Periodic examination should be carried out during the radiotherapy, and information about irradiation sites and cumulative dose is recorded, as are items such as physical findings, response of the lesion, the occurrence of any adverse effects and the details, and the treatment undertaken. The Medical Law also dictates that examination by a physician is required on the day treatment is performed, and details of the examination at such time must be noted in the medical record. When the target volume or irradiation method is changed during the treatment interval, such fact is also noted.

Because most of the work between creation and confirmation of a radiotherapy plan is not carried out in the presence of the patient, staff in the radiation oncology department should always be able to refer to and document radiotherapy information. A radiotherapy-related records separate from the medical chart must be prepared for this purpose and must be kept in the radiotherapy department at least during the interval from plan drafting to the completion of treatment. While the progress of treatment, records of examination and prescription by the attending physician, evaluation of therapeutic effect and adverse effects, diagnostic imaging reports completed during treatment, and other such information is noted in medical record, the record should be shared within the medical facility including staff outside the radiotherapy department.

When radiotherapy is complete, a summary of treatment is prepared and includes information such as irradiation site, total radiation dose, number of fractionation, and the initial and final treatment dates. Information on therapeutic effect and adverse effects must also be noted. The term for retention of medical records is legally 5 years, but inasmuch as the benefits and adverse effects of radiotherapy can

extend throughout the life of the patient, records and images relating to therapy must be stored on a semi-permanent basis.

7.2 Informed consent

When radiotherapy is initiated, the symptoms and available treatments must be explained to the patient in detail, and consent for implementation (informed consent) must be obtained. When a patient is in a condition not allowing voluntary decision-making, consent must be obtained from a guardian or other such individual. Specific procedures for obtaining informed consent at the radiotherapy facility must be established in advance. Preparation of pamphlets, videos, or other such explanatory materials is regarded as useful for communicating information on radiotherapy and imparting understanding. Informed consent to radiotherapy should be handled by the radiation oncologist with responsibility for treatment. The information to be explained to patients during the informed consent process includes the items in Table 7-3.

Table 7-3 Content of informed consent

1) Name of disease, symptoms, and cause of symptoms
2) Standard treatment and the role of radiotherapy
3) Anticipated effects: Potential for cure, life-extending benefit, symptomatic relief, etc.
4) Radiotherapy method, total dose, number of fractions, total treatment time, etc.
5) Potential adverse events and treatment
6) Alternative treatments: Effects and adverse events, etc., advantages and disadvantages in selection of other treatments
7) Possibility for presentation of treatment results and other such treatment-related information in conference or literature.
8) Strict confidentiality of name and other personal information and utmost efforts made for protection of human rights
9) Ability to ask questions freely
10) Seeking of a second opinion other than that of the attending radiation oncologist
11) Freedom not to select the treatment(s) explained, and ability to withdraw consent at any time

This information is explained in detail, the documents used for explanation are given to the patient, and a copy is placed in the medical record. In the case of a protocol treatment or clinical trial, that fact must be explained, and consent must be obtained in advance. To confirm consent, the attending physician providing the explanation and the patient should each sign a document.

7.3 Information to be given to the patient

At the start of treatment, in addition to medical particulars, the patient must be given an explanation of the schedule to completion of treatment, an estimate of medical costs, instructions for contacting the radiotherapy department, and various other particulars regarding communication. Any changes due to circumstances or other such information must also be communicated at such time. It is preferable for the radiology department to prepare in advance a pamphlet noting such particulars, a radiotherapy record card brought to treatment, and other such materials given to the patient. For

example, providing the patient with a record card stamped or signed when treatment is performed is useful for reconfirming the number of treatments performed.

Other details to confirm include a mobile telephone number to allow the radiotherapy department to contact the patient quickly. It is important to confirm family or other such telephone numbers as emergency contacts. The patient should also be asked in advance about special requests regarding treatment.

(Masahiro Kenjo)

7.4 Treatment planning data

Data used in radiotherapy planning (RTP) must all be accessible for rechecking. Planning data include the following records and other such materials.

Essential items include the required data in Table 7-4, divided into irradiation parameters; equipment, immobilization, and accessories; and imaging data; likewise, the required data in Table 7-5 represented as auxiliary items, and the items in Table 7-6 noted during three-dimensional treatment planning.

Table 7-4 Essential treatment planning data

- A) Irradiation parameters
 - 1) Name and signature of treatment planners (physicians, radiotherapy technicians, quality controllers, medical physicists)
 - 2) Irradiation site
 - 3) Irradiation method, irradiation field, irradiation energy
 - 4) Dose reference point
 - 5) Prescribed dose
 - 6) Single dose, fraction numbers, number of treatments per day
 - 7) Total dose, scheduled overall time
 - 8) Number of beam per day, fractionation (number of treatments per week)
 - 9) Identified number and sizes of irradiation field
 - 10) Use of lead block / MLC (Y/N) and type
 - 11) Use of wedge filter (Y/N) and angle/orientation
 - 12) Use of bolus or compensating filter (Y/N) and type
 - 13) Input value of individual beam dose
 - 14) Dose calculation and dose distribution
 - B) Equipment, immobilization, and accessories
 - 1) Equipments used
 - 2) Patient position during treatment (supine, prone, lateral, sitting, etc.)
 - 3) Treatment accessories (shell, ring, immobilization device, etc.)
 - C) Data to be saved as images
 - 1) Simulation film or, in CT simulation, digitally reconstructed radiographs (DRR)
 - 2) Verification film (liniography/portal film)
-

Table 7-5 Auxiliary treatment planning data

- 1) Irradiation purpose (radical, symptomatic, palliative, etc.)
- 2) Selection rationale for irradiation method
- 3) Body sketch
- 4) Maximum dose at each irradiation field
- 5) Single dose at specific sites (note depth or percentage of maximum dose)
- 6) Diagnostic imaging results (planning CT, etc.)

(cont'd)

- 7) Required body measurements
 - 8) Photographs of treatment site
 - 9) Facial portrait of patient.
-

Table 7-6 Data noted during three-dimensional treatment planning

- 1) Notation of target volume GTV, CTV, ITV, PTV, etc.
 - 2) Target volume (TV) dose (single/total)
 - 3) Dose (single/total) of at-risk organs (spinal cord, kidneys, eyes, etc.)
 - 4) Beam's Eye View (BEV)
 - 5) DVH (dose-volume histogram), etc.
-

Image data should be stored as digital data far as possible, in DICOM or other such protocol having a commonality. Allowing network transmission to other facilities is preferable from the standpoint of protecting personal information.⁵⁷⁾⁻⁵⁹⁾

7.5 Treatment data

At the center of patient radiotherapy records are irradiation record entries of treatments performed. During actual radiotherapy, the data shown in Table 7-7 must be recorded as a daily irradiation record. Table 7-8 shows cumulative data that must be recorded when treatment is completed, and Table 7-9 shows data recorded when treatment is completed in a three-dimensional treatment plan.

Table 7-7 Data to be recorded as a daily irradiation record

- 1) Number of treatments
 - 2) Treatment date
 - 3) Cumulative dose
 - 4) Number of days from treatment start date
 - 5) MU value and dose value of each beam
 - 6) Checking/approval of check film
 - 7) Signature of therapist
 - 8) Signature of radiation oncologist (signature on medical record/chart acceptable)
-

Table 7-8 Cumulative data at completion of treatment

- 1) Total dose
 - 2) Total number of treatments
 - 3) Overall treatment time
-

Table 7-9 Data recorded at completion of treatment in three-dimensional treatment plan

- 1) Cumulative dose of target lesion
 - 2) Cumulative dose of organs at risk (OR)
-

When a hospital information system (HIS), radiographic information system (RIS), hospital cancer registry, or electronic chart exist, these series of radiotherapy (RT) databases should be linked to such databases. Figure 7-1 presents a schematic relating to the RT database process, based on such links.

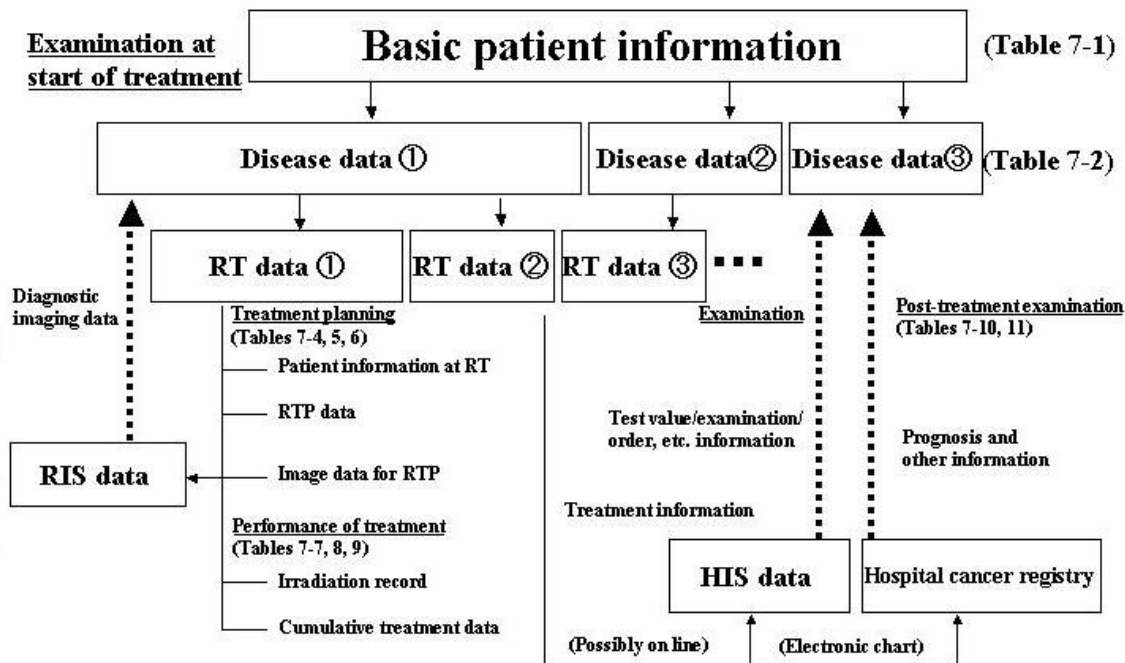


Figure 7-1 Radiotherapy (RT) database process.

7.6 Follow-up and evaluation of therapeutic effects and adverse effects

The radiation oncologist should follow up and evaluate all patients with regard to therapeutic effect on tumors and the state of adverse effects caused by radiotherapy.

7.6.1 Post-treatment follow-up and evaluation

Patients should continue to be followed-up even after treatment. It is important to cooperate with physicians in other departments or the general practitioner (family physician) for periodic examination of the patient. Suggested medical information appears below. If death is confirmed, such information should also be noted.

Table 7-10 presents items to be recorded as post-treatment medical information, and Table 7-11 presents information to be noted at death.

Table 7-10 Post-treatment medical information

-
- 1) Follow-up examination date
 - 2) Performance status of patient
 - 3) Assessment of therapeutic effect
 - 4) Tests and dates forming basis of assessment
 - 5) Adverse effects
 - 6) If recurrence: site, date, basis
- Other treatment information, regular physician information
-

Table 7-11 Information noted at death

-
- 1) Date of death
 - 2) Cause of death (death from primary cancer/death from other cancer/death from intercurrent disease)
 - 3) State of tumor at death, recurrence (Y/N)
 - 4) Autopsy (Y/N) and findings
 - 5) Individual certifying death or name of hospital
-

7.6.2 Clinical outcomes and evaluation of results

The following records should be tabulated with inclusion of all patients, based on treatment results and follow-up information obtained as described above. Continual addition to, and updating of this series of records is essential for maintenance of high-quality treatment. Clinical results and outcomes should be produced, and the relevant results should be evaluated continually. Table 7-12 presents specific items.

Table 7-12 Clinical outcomes to be evaluated

-
- 1) Treatment results by site
 - 2) Therapeutic effect by stage of cancer
 - 3) Therapeutic effect by histological type
 - 4) Evaluation of adverse effects
 - 5) Other treatment method-related information
-

These clinical results and outcomes should be prepared to allow presentation or publication at any time.

7.7 Tabulation and statistics of treatment-related data

The series of treatment-related data should be stored at all treatment facilities and updated continually. The use of a database with automatic searching system facilitates management of these records. When database of other departments, a hospital cancer registry, or a regional cancer registry, etc. exist, a link to such databases should be established to give feedback to treatment, or prognostic information. Figure 7-2 presents a scheme relating to this process. Table 7-13 presents items pertaining to treatment-related data. These data must be tabulated for production of statistics.

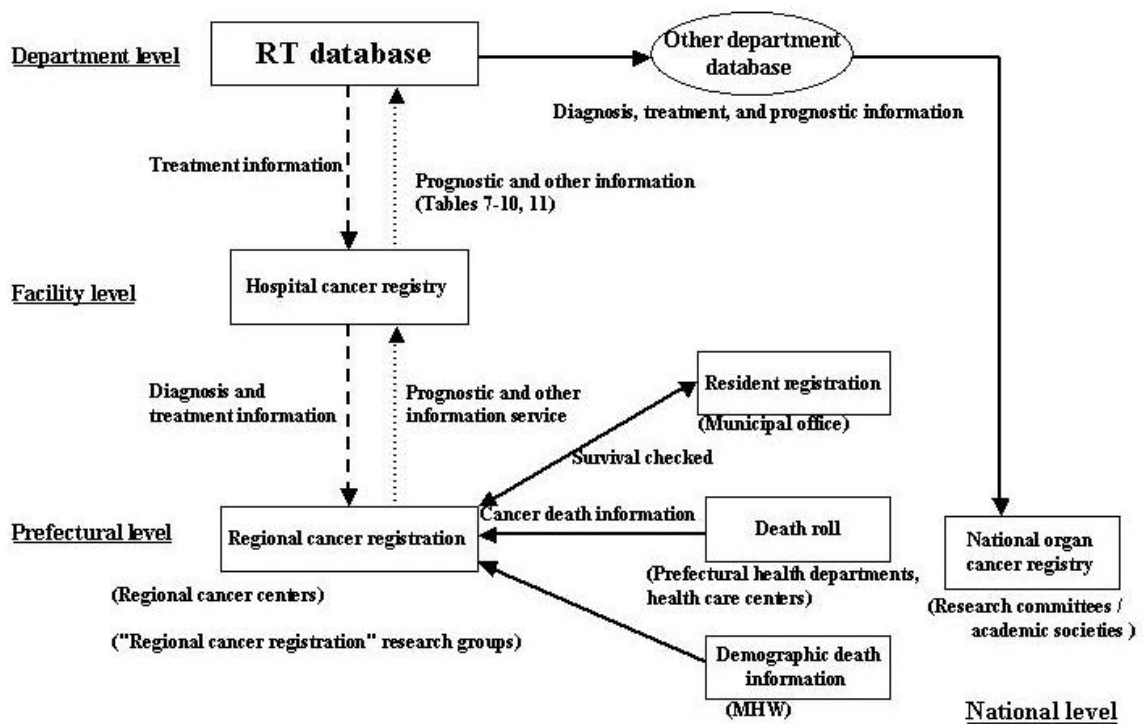


Figure 7-2 Relationship between radiotherapy (RT) database and cancer registration/other databases.

Table 7-13 Treatment-related data

- 1) Number of new patients examined and number of patients re-examined
- 2) Number of newly treated patients and number of re-treated patients
- 3) Number of patients treated by disease/site
- 4) Number of simulations
- 5) Number of treatment planning
- 6) Total number of treatments
- 7) Number of treatment portals
- 8) Complexity of treatment (simple, complex, specified), number of restraints, etc. countable
- 9) Number of stereotactic irradiations, number of IMRT
- 10) Operating time of treatment equipment, irradiation time
- 11) Type and number of brachytherapy (interstitial, intracavitary, superficial, other)
- 12) Number of examinations for post-treatment follow-up

Tabulated results and summaries for these data for one to several years should be analyzed. Analysis of the operating state of each department should also be required. All data should be prepared based on the premise that it can be disclosed to patients at any time.

7.8 Evaluation of operations

A program should be in place to monitor the operation of each facility of treating departments. The items relating to operations shown in Table 7-14 should be monitored.

Table 7-14 Operation-related items

-
- 1) Ease of access to treatment department
 - 2) Time required for telephone response and other appointments for examination
 - 3) Number of days required from referral to examination and to start of treatment
 - 4) Total time from reception to examination and to completion of treatment
 - 5) Number of patients treated per unit time (throughput)
-

These parameters relating to the flow of patients should be evaluated to improve the efficiency of operations in the treating department

(Masahiko Koizumi)

7.9 Radiotherapy quality control unit (medical physics unit)

7.9.1 Importance of QA/QC

The importance of QA/QC has been indicated in the research concerning dose-response curves.⁶⁰⁾⁻⁶²⁾ Figure 7-3 presents dose-response curves for tumor tissue and normal tissue. The relationship between dose and effect describes an S-shaped curve with a steep slope. In reality, many reports have shown that differences in dose on the order of 5-15% contribute greatly to increasing tumor recurrence and toxicity of normal tissue (Figure 7-4).⁶²⁾ Spatial errors in irradiated volume also cause undesired irradiation to normal tissue as well as inadequate irradiation to tumors, resulting in increasing normal tissue toxicity and reducing tumor cure rate (Figure 7-5). Radiotherapy is thus a treatment making use of extremely subtle differences in dose effect in normal tissue and tumors; in this respect, radiotherapy differs greatly from surgical treatment or chemotherapy. Consequently, ensuring several % in dose accuracy and millimeter units in spatial accuracy is essential.

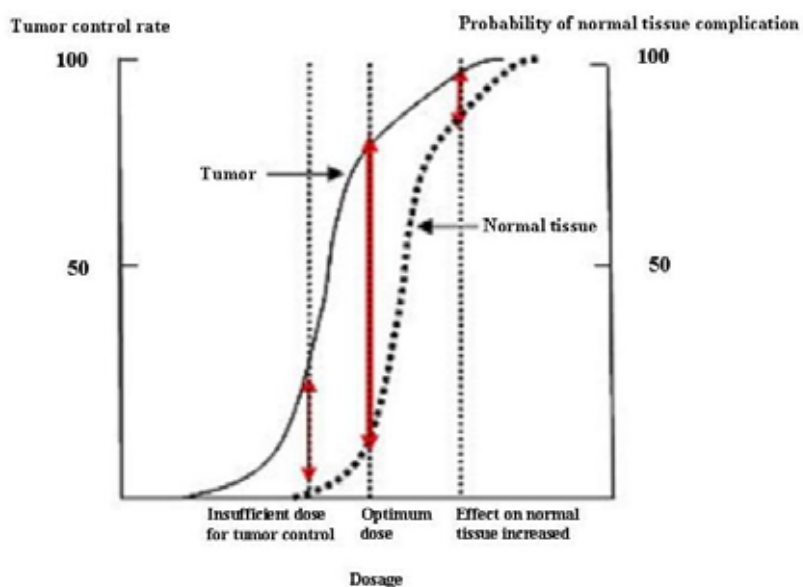


Figure 7-3 Dose-response curve (conceptual drawing). Bidirectional arrows indicate difference between tumor control and toxicity of normal tissue

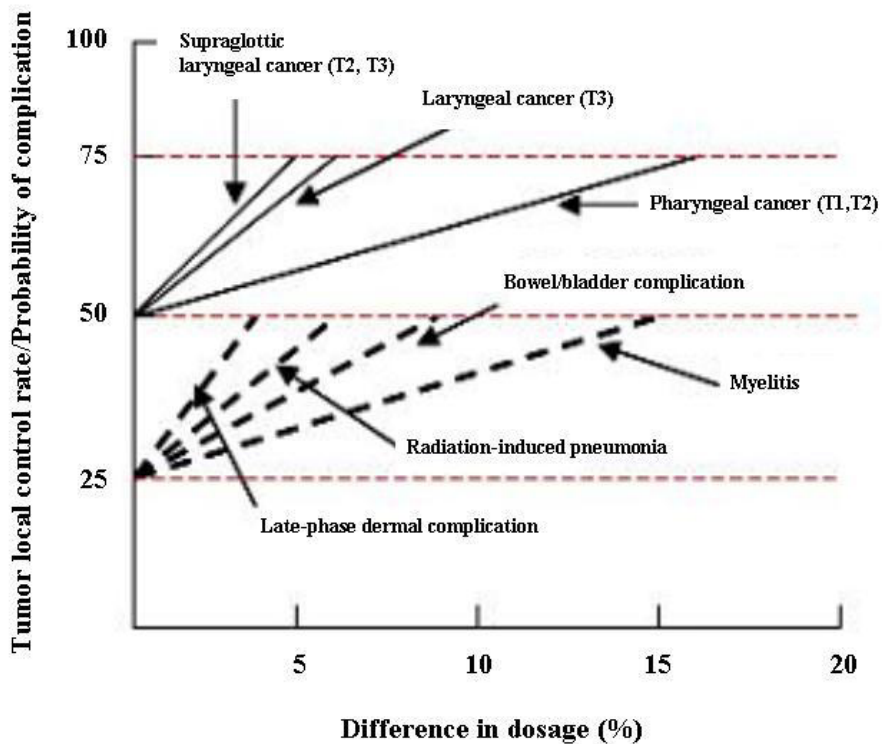


Figure 7-4 Tumor local control (solid lines) increases from 50% to 75%. Probability of normal tissue complication (broken lines) also increases from 25% to 50% with increasing dose.

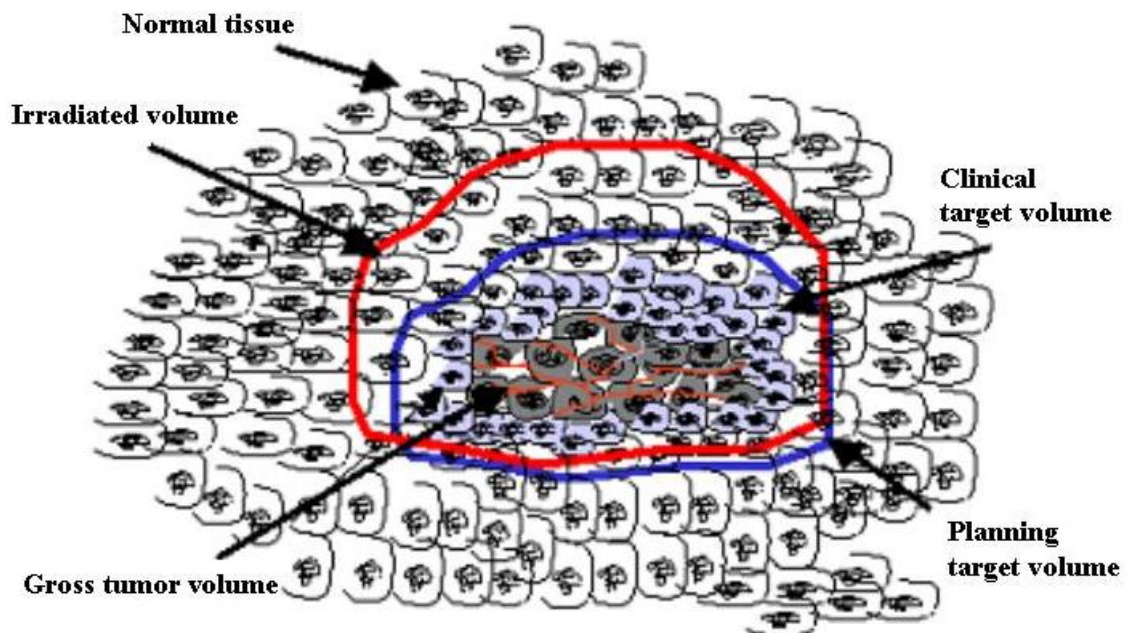


Figure 7-5 Schema of irradiated volume. Spatial errors in irradiation field lead to undesired irradiation to normal tissue and inadequate dose in tumor tissue.

Recent clinical or radiobiological studies have indicated that the absorbed dose to tumors should be delivered at least 7-10% accuracy in radiotherapy. Therefore, considering various errors, the systematic error of the absorbed dose delivered to a reference point must be as low as 3-5%.⁶³⁾ Achieving such strict accuracy throughout all the processes illustrated in Figures 5-1 and 5-2 is not easy. However, development of radiation technologies in US and thorough QA/QC in their use has led to achieving the high accuracy and improving treatment results even for refractory tumors. Thorough physical QA/QC by radiotherapy quality controllers (medical physics) are also essential in Japan.

7.9.2 Differences in QA/QC implementation between Japan and the US

Recently in Japan, a series of medical accidents in radiotherapy has come to light. Some of the accident reports showed that the biggest dose error was 35%.⁶⁴⁾⁻⁶⁶⁾ It has been concluded that one cause of these incidence is a lack of appropriate QA/QC. Radiotherapy in Japan is thus enmeshed in the lack of more fundamental QA rather than ensuring the 7-10% accuracy required in radiotherapy.

Figure 7.6 shows the mean time per year required for commissioning, calibration, and periodic QA in 50 facilities (approximately half core cancer treatment hospitals and half university hospital cancer centers) in the US in 2003.⁶⁷⁾ It becomes apparent that in comparison to Japan, substantially more time is spent on these activities in the US. These are standard times for ensuring high accuracy. QA/QC services performed by medical physicists are also added to insurance ratings.⁶⁷⁾ Japan also needs QA/QC programs implemented by quality controllers (medical physicists).

7.9.3 QA/QC programs

Programs to achieve accuracy within the acceptable error and to prevent accidents in all radiotherapy processes must be created, monitored, and implemented by radiotherapy quality controllers (medical physicists). The items of QA/QC are shown in Table 7-14.

Radiotherapy quality controllers (medical physicists) must create QA/QC programs based at a minimum on the JASTRO QA guidelines.^{38), 41)} When high-accuracy treatment is performed, the radiotherapy quality controller (medical physicist) should create an individualized program based on the detailed, practical guidelines, etc. (Table 7-15) published in the US, Europe, and Japan. The medical physicists must also understand physical limitations of accuracy of all radiotherapy systems and should play a role in research by developing new treatment technologies designed to increase accuracy.

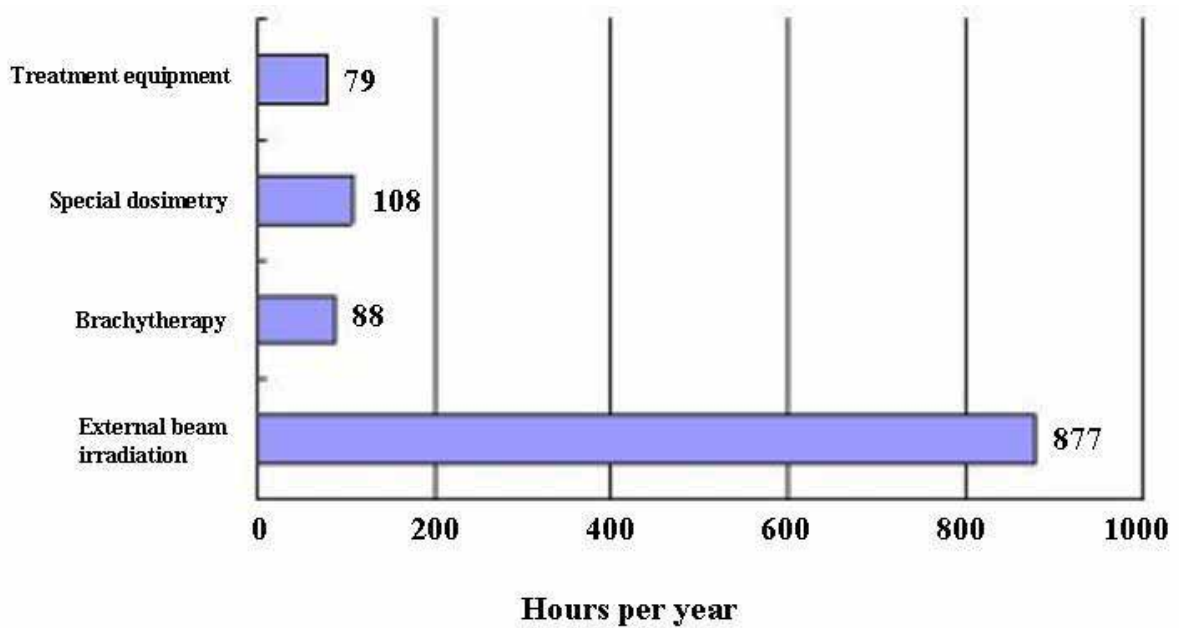


Figure 7.6 Time using QA/QC in the US (median values)

Improvements in accuracy in recent technologies from the US and Europe by QA/QC have led to cure of even refractory tumors. To achieve such results in Japan, there is an essential need for QA/QC by radiotherapy quality control units (medical physics units) and for research, development, and education by medical physicists. Since the technologies of radiotherapy have rapidly advanced, these activities can never be provided only by radiation oncologists or therapist. Consequently, radiotherapy quality control units (medical physics units) must be provided with suitable staff, terms of employment, and facilities.

Table 7-15 Items included in quality control

Acceptance testing and commissioning of all treatment unit, treatment planning systems, and simulators prior to clinical use
Periodic QA of all treatment unit, treatment planning systems, and simulators
Ordering and storage of radiotherapy sources and monitoring for appropriate function of sealed brachytherapy applicators
Treatment planning using computers
Dosimetry, calibration and monitoring of beam characteristics
Design of optimal patient immobilization devices and their assurance of safe functioning, and monitoring of production
Radiation protection survey for patient and staffs
Research and education enabling improvement in quality and high-accuracy treatment
Creation and revision of QA/QC programs

Table 7-16 Representative references on QA/QC in medical physics

Item	Publishing organization
Linear accelerators	AAPM TG 45 ⁶⁸⁾ Japan Industries Association of Radiological Systems ⁴⁹⁾
Multi-leaf collimators	AAPM TG 50 ⁶⁹⁾
Treatment planning system	AAPM TG53 ⁷⁰⁾ MHLW Grant-in-Aid for Scientific Research, Ikeda Group (AAPM TG 53, translation) ⁴⁴⁾ ESTRO QA Booklet No7 ⁶³⁾ Japan Society of Medical Physics, Topical Research Committee, Task Group 01 ⁷¹⁾
RALS	AAPM TG 41 ⁷²⁾ Japan Society of Medical Physics ³⁷⁾
Permanent implan	AAPM TG 64 ⁷³⁾
CT simulator	AAPM TG 66 ⁷⁴⁾
Electron portal imaging (EPID)	AAPM TG 58 ⁷⁵⁾
Intensity-modulated radiation therapy	AAPM IMRT subcommittee ⁷⁶⁾
Sterotactic radiosurgery	AAPM TG 42 ⁷⁷⁾ Japan Society of Medical Physics ³⁹⁾
Heterogeneity correction	AAPM TG 65 ⁷⁸⁾
General external irradiation	Japan Society of Radiological Technology ⁷⁹⁾
Radiation source calibration	NCRP Report 41 ⁸⁰⁾
Instrument measurement	ICRU Report 20 ⁸¹⁾
Radiation protection	ICRU Report 47 ⁸²⁾

(Yutaka Takahashi)

8. Standards for Staff Required in Radiotherapy

Provision of the best possible care to patients requires that medical facilities have a thoroughly knowledgeable staff including a radiation oncologist, have equipment prepared on the basis of a well-studied QA/QC program, and are kept in a state allowing use at all times. Performance of appropriate radiotherapy requires multiple facilities, multiple radiation oncologists, various required staff, and cooperative relationships with other facilities maintained through public or private relations.⁸³⁾⁻⁸⁸⁾

8.1 Radiation oncologists

As discussed in Section 5.1, a radiation oncologist is a physician whose treatment focuses primarily on radiotherapy for cancer patients, or whose work is principally education and research in radiation oncology. The Japanese Society for Therapeutic Radiology and Oncology (JASTRO) has established a certified physician system.

8.2 Radiotherapy technicians and specialist radiotherapy technicians (tentative title)

A radiotherapy technician involved in radiotherapy has a thorough knowledge of radiotherapy-related equipment, beginning with radiotherapy apparatuses, and works in conjunction with a radiotherapy quality controller to perform appropriate radiotherapy and precision control. This work requires an ability to perform individual therapeutic processes properly, carry out thorough verification, and create and store implementation records, and in performance of treatment, the safety of the patient must be fully assured. This work is carried out in concert with radiation oncologists, radiotherapy nurses, and other such radiotherapy staff to provide appropriate radiotherapy to patients.

A specialist radiotherapy technician (tentative title) has fulfilled the requirements for certification by the Organization for Specialist Radiotherapy Technician Certification (tentative title), has predetermined experience and advanced knowledge of radiotherapy, and works exclusively in radiotherapy. The Organization for Specialist Radiotherapy Technician Certification (tentative title), established in 2005, is anticipated to provide standardization. A specialist radiotherapy technician must be engaged in acquisition of the latest knowledge concerning radiotherapy technology, study concerning precision control, and efforts to learn information relevant to development of new treatments and advances in devices. A specialist radiotherapy technician should also be in a leadership position with respect to education of treating radiation technicians involved in radiotherapy and technology acquisition and should offer appropriate advice.

8.3 Radiotherapy quality controllers (from the Organization for Radiotherapy Quality Control "Code on Radiotherapy Quality Controller System")⁸³⁾

A radiotherapy quality controller has personal responsibility for work relating to radiotherapy quality control. Other important duties include monitoring of general hospital work from a quality control perspective, communications and dissemination of

contacts and instructions, and proposal of revisions to managing departments. The work of the controller also includes voluntary quality improvement activities at individual sites (not simply "quality control" in a narrow sense, a wide range of activities intended to improve the "quality of radiotherapy" itself).

The main tasks in such work include

- Setup and implementation of a QA program for radiotherapy apparatuses
- Setup and implementation of a QA program for radiotherapy planning apparatuses
- Preparation and designation of data input to treatment planning systems and checking of all computer dose measurement planning
- Determination of QA programs for treatment planning facilities, including tests to be run, tolerances, and test frequencies
- Understanding of contradictions and problems assessed through QA programs, and implementation of appropriate response
- Cooperation with other individuals involved in radiotherapy quality control in various aspects of treatment apparatus/treatment planning apparatus QA programs
- Creation of programs in conjunction with device introduction from a radiotherapy apparatus and planning apparatus quality control perspective
- Establishment and implementation of quality control after completion of nonfunctioning device repair

8.4 Medical physicists

The medical physicist plays a leading role in physical and technical issues relating to radiation medicine. This individual contributes to medical and health care development through efforts to improve and maintain quality. The role is broad, extending from clinical to research work.

- Implementation of all work performed by the radiotherapy quality controller
- Setup and implementation of external radiation and brachytherapy treatment plans
- Physical consulting with radiation oncologists
- Research and development
- Education (young physicists/radiotherapy quality controllers, treating radiation technicians, residents, students)

Certification and testing systems are operated by the Japan Radiological Society and the Japan Society of Medical Physics.

8.5 Radiotherapy nurses

Nurses involved in radiotherapy must have specialized knowledge of radiotherapy and the ability to establish and implement a nursing plan for patients during or after treatment; such nurses must also be assigned solely to a radiotherapy department as specialist radiotherapy nurses. At present, there is no qualification and certification system for (specialist) radiotherapy-certified nurses, and such a system must be established. Such nurses must also function as a member of a health care team, cooperating with ward nurses with regard to inpatients and with outpatient physicians and nurses with regard to outpatients, in order to provide patients with the nursing required. Radiotherapy nurses ascertain the potential for various adverse events depending on the condition of each patient and factors such as treatment site/treatment

method, provide necessary information to the patient and family, and provide explanations that impart understanding. In routine activities before and after treatment, radiotherapy nurses provide appropriate explanation of issues of concern and responsive measures and provide or make reference to literature or materials as needed. Radiotherapy nurses also have the role of ascertaining changes in patient status in concert with the radiation oncologist and communicating information the treatment staff must consider.

8.6 Administrative staff

These individuals take charge of identifying incoming patients appropriately and providing information consistent with appointments and instructions. Administrative staff identify patients based on treatment cards, appointments slips, or the name as written by the individual and check the hospital information system screen display or appointment list, etc. to see that the incoming patient has an appointment (according to plans for radiotherapy accident prevention, adoption of checking through forms and representations differing in each case in multiple departments is better than adoption of uniform checking procedures for all departments and is regarded to have the effect of obviating incorrect responses resulting from familiarity on the part of the individuals being checked). Administrative staff monitor the movements of waiting patients and ensure that they do not enter radiation control areas or other such areas where entry is restricted. Administrative staff monitor patient safety, and if problems are suspected, initiate cooperation with radiation oncologists, radiotherapy technicians, or radiotherapy nurses as appropriate.

8.7 Radiotherapy information managers

These individuals manage and control records relating to radiotherapy and have knowledge of how to protect personal information appropriately. Radiotherapy information managers have completed information management training designated by the facility. Radiotherapy information managers control radiotherapy-related statistics and various other information required in reports. Radiotherapy information managers collect and manage information required for treatment and research according to appropriate regulations. These individuals also perform computer system and network management.

8.8 Other staff required on the radiotherapy team

A system is needed to accommodate the requests of radiotherapy staff and provide information or skills needed by patients through assistance from social workers, nutritionists, physiotherapists, or various other occupations with specialized knowledge.

A team of construction, plumbing, electrical, and other technicians must include designated individuals with a thorough knowledge of the structure and layout of the radiotherapy department who also have the ability to respond to problems.

Table 8-1 presents the professional relationship among the radiotherapy department staff for 1) work prior to the start of treatment, 2) treatment, 3) brachytherapy, and 4) quality control and maintenance of system and equipment.

Table8-1 Professional relationship among radiotherapy department staff

Task	Performed by
1. Work prior to start of treatment	
<p>The goal of treatment and treatment procedure should be discussed with treatment team involved in the patient’s care. The clinical information required for radiotherapy must be recorded appropriately in the patient’s chart.</p>	<ul style="list-style-type: none"> • Treatment team • Radiation oncologist • Radiotherapy nurse
<p>Physicians have a legal and ethical duty to obtain informed consent from the patient and/or family. Informed consent shall be obtained and should be appropriately documented prior to the treatment including treatment sites, goal, procedure, benefits and side effects (7.2). The radiotherapy nurse may provide information using standardized information materials such as the treatment schedule and daily activities.</p>	<ul style="list-style-type: none"> • Radiation oncologist • Radiotherapy nurse
<p>Informed consent shall be obtained enough time and the patient and, when appropriate, the family must have adequate information to understand the treatment and procedure. The informed consent document should contain adequate statement and the signature of the patient or patient’s representative. A copy of all pertinent consent documentation should be kept in the patient’s chart (7.2).</p>	<ul style="list-style-type: none"> • Radiation oncologist
<p>The appropriate treatment planning process should be provided. Devices to aid in positioning and immobilizing the patient are to be used where appropriate and should be kept in each patient. Adequate information for treatment planning must be obtained and documented.</p>	<ul style="list-style-type: none"> • Radiation oncologist • Medical physicist • Radiation therapist
<p>Takes photographs and documents of alignment states, and devices to aid in positioning and immobilizing the patient during treatment planning (when patient photographs are taken, consent is obtained).</p>	<ul style="list-style-type: none"> • Radiation oncologist • Medical physicist • Radiotherapy nurse • Radiation therapist
<p>Documents parameters needed for individual treatment in the radiotherapy chart. The parameters must be checked by independent person or method before the first treatment. The beam delivery parameters must be correctly transferred to treatment unit and the parameters must be checked by independent staff or method before the first treatment. The date and time of parameters input shall be documented. Particularly when parameters are transferred from treatment planning system to a treatment unit, each parameter should be checked by independent person. Treatment parameters undergo appropriate control by the radiotherapy quality controller.</p>	<ul style="list-style-type: none"> • Radiation oncologist • Medical physicist • Radiotherapy quality controller • Radiation therapist
<p>Appropriate quality control must be perform and documented before treatment. To permit proper delivery of therapy, radiographs or portal images produced by each treatment beam unit with the patient in the treatment position are compared and documented with the simulator films or digitally reconstructed radiographs (DRR) to verify that the treatment beams and fields planned at simulation are well matched.</p>	<ul style="list-style-type: none"> • Radiation oncologist • Medical physicist • Radiotherapy quality controller • Radiation therapist

(cont'd)

Records additional identifying information on facial photographs or photographs for patient identification and attaches to medical records or irradiation records to allow checking during treatment implementation (when patient photographs are taken, consent is obtained). Make system for recognition for the patient by ID or name, etc. to avoid erroneous irradiation.	<ul style="list-style-type: none">• Radiation oncologist• Radiotherapy nurse• Radiation therapist• Information manager
Holds periodic conferences of radiotherapy staff to check questionable issues and solve problems, and confirms recognition in common with staffs.	<ul style="list-style-type: none">• All staff
2. Treatment	
It is essential that all treatment parameters be described in detail and orders be signed or initialed by the radiation oncologist prior to treatment.	<ul style="list-style-type: none">• Radiation oncologist
The beam delivery parameters must be checked by radiation therapist operating treatment. If the therapist is replaced, appropriate checking of treatment parameters should be performed prior to treatment.	<ul style="list-style-type: none">• Radiation therapist
Two or more therapists should perform treatment.	<ul style="list-style-type: none">• Radiation therapist
Uses auxiliary stairs as appropriate to move the treatment table and provides assistance as needed to prevent falling by the patient. If necessary, explain to the patient using immobilization devices during irradiation. Enforces checking by ID card or checking by name, etc. to avoid incorrect irradiation.	<ul style="list-style-type: none">• Radiotherapy nurse• Radiation therapist
Uses appropriate immobilization devices, utilizes skin markings, and prevents improper alignment by checking same.	<ul style="list-style-type: none">• Radiation therapist
Notes adequate information to keep reproducibility of patient's position during treatment and others in the radiotherapy chart, and shares information with the radiotherapy staff.	<ul style="list-style-type: none">• Radiation therapist• Radiotherapy nurse
The important information includes consciousness levels, risks of infection and fracture, and external catheters should be shared among radiation staffs and staffs in ward and out patient clinic during treatment.	<ul style="list-style-type: none">• Radiotherapy nurse• Radiation therapist• Radiation oncologist• Treatment team
Creates the safety manual for patient's safety, such as place or remove wedge filters, shielding lead, or treatment cones, and performs alignment checked by another therapist.	<ul style="list-style-type: none">• Radiotherapy technician
The treatment parameters must be checked appropriately before the treatment. Therapists should confirm in radiation chart to prevent errors with regard to any items not checked automatically, such as wedge filters, boluses and blocks.	<ul style="list-style-type: none">• Radiotherapy technician
Performed treatment must be recorded and signed by the therapist. Any changes in the planned treatment must be	<ul style="list-style-type: none">• Radiation therapist• Radiotherapy quality

(cont'd) documented on the radiotherapy chart verifiably. The radiotherapy chart needs the periodically check by the radiation oncologist and a radiotherapy quality controller.	controller • Radiation oncologist
Radiographs or portal images should be produced prior to the initiation of radiation therapy and any changes appropriately. These images are compared and documented with the simulator films or digitally reconstructed radiographs (DRR) to verify that the treatment beams and fields planned at simulation are well matched by the radiation oncologist. The radiotherapy quality controller should be managed appropriate quality control for these images.	• Radiation therapist • Radiotherapy quality controller • Radiation oncologist • Medical physicist
During the treatment, the patient should be kept watch by the therapist using monitoring system from the control room during treatment.	• Radiation therapist
Assessment by the radiation oncologist and radiotherapy nurse of sequelae of treatment is recommended periodically during and after treatment. Appropriately any changes in patient during treatment shall be notes in the medical record.	• Radiation oncologist • Radiotherapy nurse
3. Brachytherapy	
Pays special attention to handling of low dose-rate sealed brachytherapy.	• Radiation oncologist • Radiotherapy quality controller • Medical physicist
QA is required to assure individual radiation source output and integrity.	• Radiation oncologist • Medical physicist • Radiotherapy quality controller
The facility shall perform management of sources as appropriate to prevent radiation source loss accidents.	• Radiation oncologist • Radiotherapy quality controller • Medical physicist • Radiation therapist
Records documenting appropriate description of each radioactive source and its usage are necessary	• Radiation oncologist • Radiotherapy quality controller • Medical physicist • Radiation therapist
The facility shall have manual to perform periodic sealed-source leak testing or arrange to have this service provided in compliance with applicable federal regulation.	• Radiation oncologist • Radiotherapy quality controller • Medical physicist • Radiation therapist

(cont'd)	<ul style="list-style-type: none"> • Specialist radiotherapy nurse • Treatment team
Patient must explain to stay the appropriately shielded treatment room as necessary. The record documenting for shielded treatment room about all persons who coming and going is necessary	<ul style="list-style-type: none"> • Radiation oncologist • Radiotherapy quality controller • Radiotherapy nurse • Treatment team
4. Quality control and maintenance of system and equipment	
Medical physicist and/or radiotherapy quality controller must be developing and implementing a quality assurance (QA) program for radiotherapy equipments, treatment planning systems or treatment planning CT, or other such radiotherapy-related process. The information content of the QA should be documented and verified as necessary.	<ul style="list-style-type: none"> • Medical physicist • Radiotherapy quality controller
Documentation must exist indicating that the medical physicist and/or radiotherapy quality controller has authorized the system for clinical use and has established a QA program to monitor the treatment planning system's performance as it relates to the planning process.	<ul style="list-style-type: none"> • Medical physicist • Radiotherapy quality controller
Medical physicist and/or radiotherapy quality controller should perform acceptance testing, commissioning, and implementation of the radiotherapy equipments, treatment planning systems or treatment planning CT, or other such radiotherapy-related process.	<ul style="list-style-type: none"> • Medical physicist • Radiotherapy quality controller
Medical physicist and/or radiotherapy quality controller should establish and manage a QA program for the radiotherapy equipments, treatment planning systems or treatment planning CT, or other such radiotherapy-related process	<ul style="list-style-type: none"> • Radiation therapist • Radiotherapy quality controller • Medical physicist
Prepares records of malfunctions and problems for individual systems and other such radiotherapy-related equipments, and records details and response. Makes predetermined reports to the managing organization as necessary.	<ul style="list-style-type: none"> • Radiation therapist • Radiation oncologist
The medical physicist and/or the radiotherapy quality controller must be developing and implementing a QA program for radiotherapy equipments, treatment planning systems or treatment planning CT, or other such radiotherapy-related process for malfunction.	<ul style="list-style-type: none"> • Radiotherapy quality controller • Medical physicist • Radiation therapist • Medical physicist
Perform and documents periodic calibration for radiation dose measurement system.	<ul style="list-style-type: none"> • Radiation therapist • Medical physicist • Radiotherapy quality controller
Enters into service contracts with manufacturers for treatment	<ul style="list-style-type: none"> • Installer

(cont'd)
 apparatus, treatment planning apparatus, and other such radiotherapy-related equipment; carries out periodic inspection, and creates records.

- Radiotherapy technician
- Radiotherapy quality controller
- Medical physicist
- Radiation oncologist

Table 8-2 presents the number of individuals required as radiotherapy department staff. The figures shown are estimated based on “Blue Book” of US guidelines and PCS 1999-2001 data in Japan (Figures 8-1, 8-2). Treatment of 200 patients per year by one FTE radiation oncologist is regarded as standard; instances of treatment of 300 or more patients per year can lead to a decline in the quality of care, and increases in staff should be considered (warning level). For one FTE Radiation therapist, treatment of 120 patients per year is regarded as standard; instances of treatment of 200 or more patients per year can lead to a decline in quality, and in similar fashion, increases in staff should be considered (warning level).

Table 8-2 Number of individuals required as radiotherapy department staff

Position	Minimum level	Ideal level
Radiation oncologist (Staff)	1 per facility Add 1 for each 300 patients per year (Minimum level allowing operation)	Add 1 for each 200 patients per year Do not assign 300 or more patients per year to 1 radiation oncologist. (Do not assign 20 or more/day to 1 individual.)
Radiotherapy quality controller	1 per facility	Add 1 for each 300 patients per year
Medical physicist	1 among cooperating facilities	1 per facility Add 1 for each 2 irradiation equipments Or add 1 for each 400 patients per year
Radiation therapist	2 for each 1 treatment equipment Staffing also possible when using treatment planning CT or simulator Add 1 for each 120 patients per year	Add 1 for each 120 patients per year Do not assign 200 or more patients per year to 1 radiotherapy technician. Staff 2 per accelerator at all times when performing treatment. Add 1 for each 50 patients/treatment equipment/day. Staffing also possible when using treatment planning CT or simulator
Certified Radiation therapist	1 per facility	Staffing of 1 specialist Radiation therapist per treatment apparatus also possible
Radiotherapy nurse	1 per facility	Add 1 for each 300 patients per year
Administrative staff	1 per facility in dual role as radiotherapy information manager	Add 1 for each 500 patients per year
Radiotherapy information manager	1 per facility in dual role as receptionist	Add 1 for each 500 patients per year

(Minako Sumi, Takashi Uno, Katsumasa Nakamura)

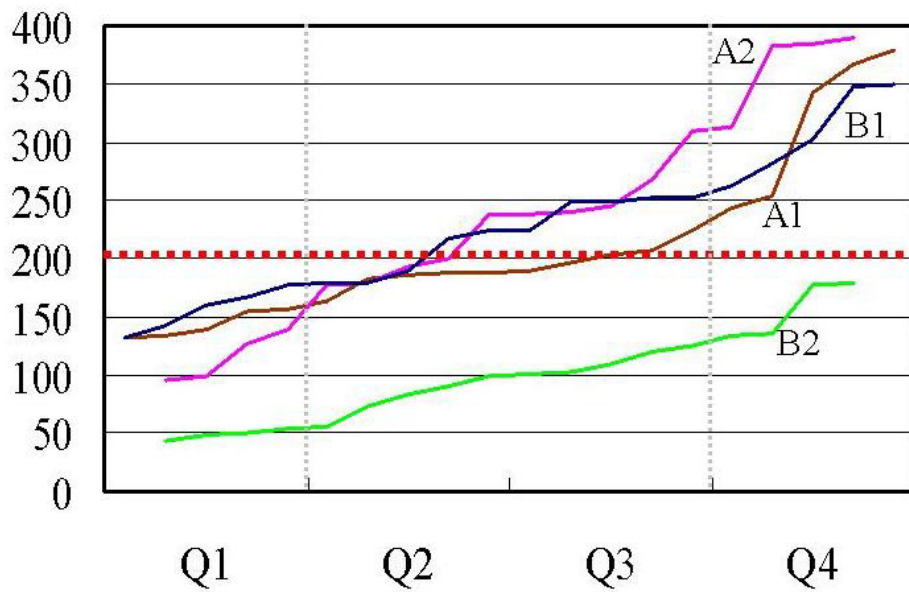


Figure 8-1 Distribution of number of patients per year/number of FTE radiation oncologists at PCS 1999-2001 survey facilities. To avoid overestimation, facilities with FTE<1 were calculated as FTE=1. Horizontal axis is arranged in order of increasing value for each facility stratum (A1, A2, B1, B2). Q1: 0-25%, Q2: 26-50%, Q3: 51-75%, Q4: 76-100%. Apart from B2 facilities, approximately 200 patients/FTE individual were treated at 26-75% of facilities. In Q4 facilities (highest 25%), 300 or more patients were treated (warning level). In B2 facilities, the value was low, at < 150, but treatment was performed by non-full-time radiation oncologist (median value FTE 0.3, Table 5-3).

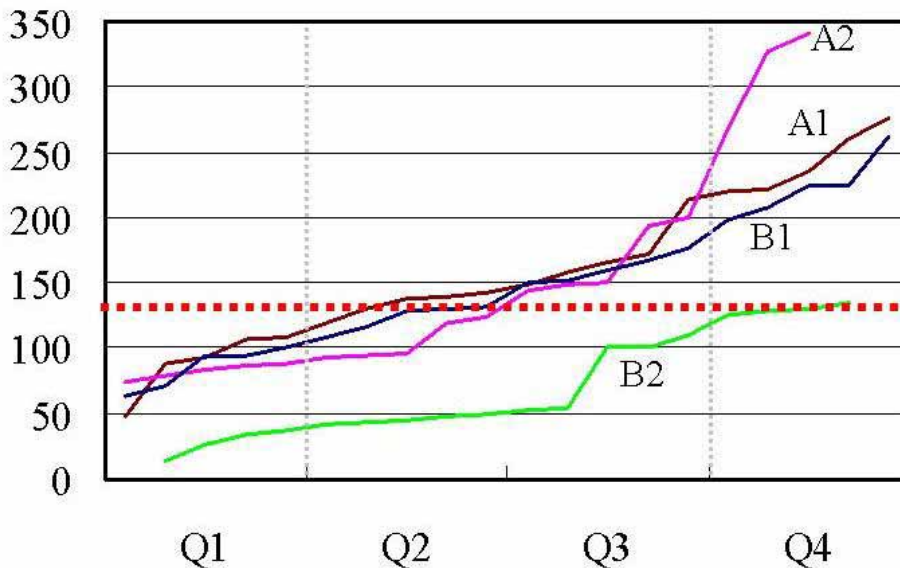


Figure 8-2 Distribution of number of patients per year/number of FTE radiotherapy technologists at PCS 1999-2001 survey facilities. As above, apart from B2 facilities, 100-150 patients/FTE individual were treated at 26-75% of facilities. In Q4 facilities (highest 25%), 200 or more patients were treated (warning level).

9. Economic Issues

Recent progress in technology has led to a diversification of cancer treatment methods from simple to complex, depending on the site and form of cancer and the treatment planning involved. Until FY1995, compensation for treatment was uniform, without regard to irradiation technology (method of irradiation), but beginning in FY1996, the administrative cost for creation of treatment plans was divided into three levels termed simple, complex, and unique, and beginning in FY2002, the cost of irradiation was also segregated on three levels.

These developments have led to an environment allowing frequent use of multiportal irradiation (a treatment method applying radiation from multiple directions). While this technique increases the amount of radiation applied to a tumor, it has also allowed a reduction in the amount of radiation applied to the surrounding, normal tissue. Tumor control rates (rates of tumor growth suppression) have increased, and the incidence of adverse events (rate of adverse effects produced) has also declined, leading to major benefits for patients undergoing treatment.

In light of the unique nature of radiation therapy, higher scores have also been established for facilities employing full-time, highly experienced specialist radiotherapy oncologists. Reductions have also been established for facilities insufficiently prepared to provide substantial radiotherapy, and a policy has emerged of distinguishing advanced radiotherapy facilities from others.

Such health-care compensation policies allow facilities with substantial numbers of radiotherapy patients and substantial radiotherapy infrastructure (treatment devices and staff) to secure health-care compensation that recovers expensive equipment investments.

Nonetheless, current health care compensation cannot be termed adequate. The more that radiotherapy technologies advance, the more important quality control becomes to guarantee patient safety and reliable treatment. In addition to radiologists and radiotherapy technicians, there has always been an essential need for specialist staff to manage treatment devices and perform other functions such as calculation of patient radiation dosages. The health care compensation currently provided has only created hospital operations in which the majority of hospitals are understaffed in this respect and physicians work in dual roles. Assuming that sufficient staff were retained, a cursory calculation of personnel and other such costs would show that profits are difficult to secure. In addition, a shortage of radiation oncologists has led to remote radiotherapy allowing handling of multiple radiation treatments, which has in turn allowed development of information technologies (IT), but there is no health care compensation system corresponding to these technologies. In other words, health care compensation still does not provide an economic basis guaranteeing employment of specialist staff and application of the most advanced IT.

What follows is an example calculating expenses required for equipment and staff to provide advanced radiotherapy at present, and the income from such operations, assuming 250 radiotherapy patients per year.

The initial investment for equipment is ¥290 million, staff employment costs are ¥43.2 million, and annual maintenance and service costs are ¥13 million; whereas, annual health care compensation is ¥86.2 million.

Consequently, approximately 10 years is required just to recoup equipment costs, but with ongoing progress in radiotherapy devices, device upgrading is reportedly needed approximately every five years.

At the same time, small-scale facilities (less than 100 patients annually) disadvantaged by health care compensation do contribute to regional health care by focusing on treatment plans and disease groups treatable by simple irradiation techniques, but operations at these facilities are often simply unprofitable.

At a small-scale facility performing simple irradiation, assuming 100 radiotherapy patients per year, the initial investment for devices is ¥111 million, annual staff employment costs are approximately ¥28.6 million, and annual maintenance and service costs are approximately ¥7.3 million; whereas annual health care compensation is approximately ¥30 million. If the equipment is depreciated over 10 years, operating expenses alone produce an annual ¥16 million deficit.

Details for the basis of these calculations are shown in the appendices. However, due attention should be paid to the fact that these calculations do not include expenses such as real estate and construction costs and insurance for employees.

The results of these calculations show that support for all small-scale facilities is inefficient, but to assure the presence of hospitals close to patients, complete elimination is undesirable. All patients benefit from radiotherapy, regardless of region, disease group, or treatment plan, so what is again needed to realize and maintain these benefits is the creation of facilities standards and a health care compensation system consistent with the radiotherapy infrastructure.

Progress in radiotherapy techniques and IT is supported by progress in science and technology and therefore subject to constant change; however, health care compensation should be reevaluated continually to create a response to such technical progress.

Finally, as indicated in the forecasts in Section 5.6 and in Figure 10-1, the number of radiotherapy patients is forecast to increase to at least 200,000 in five years and to 300,000 in 10 years. Since the number of patients treatable by a standard infrastructure like that presented in Section 6 is fixed, a health care compensation system able to support a standard infrastructure must be put in place in order to assure staff and devices sufficient to respond to future increases in the number of patients. Specifically, the basis for such a system will be increased funding for basic radiotherapy costs, establishment of health care compensation for radiotherapy quality control, and establishment of new health care compensation for high-precision radiotherapy technologies, remote radiotherapy, and other advanced technologies.

(Yasuo Ashino, Hiroshi Onishi)

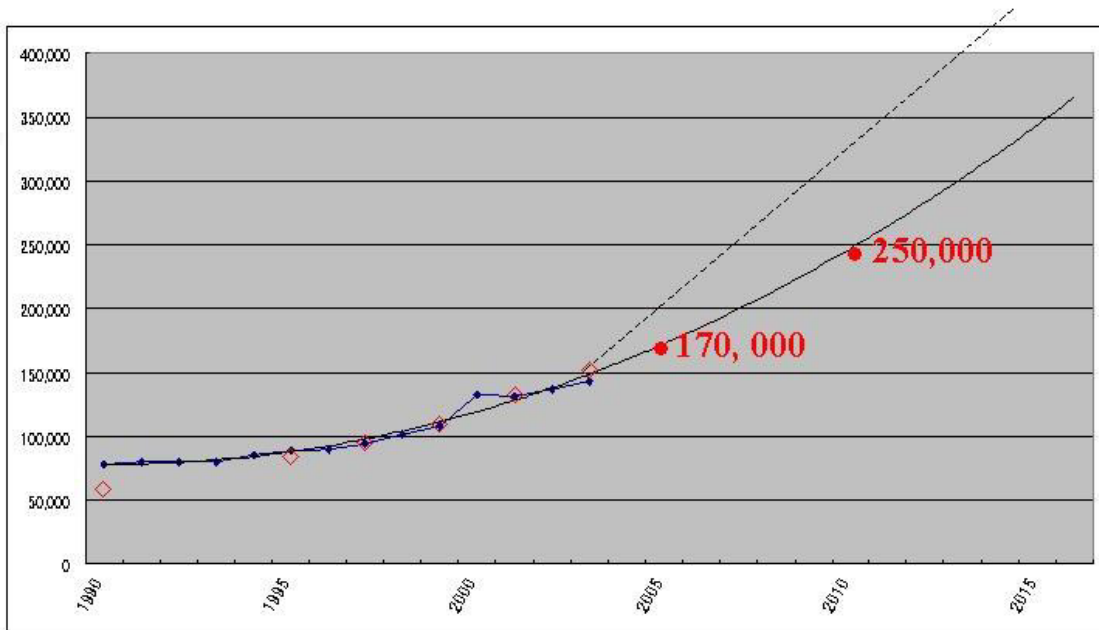
10. Conclusion

The first goal of cancer treatment is to assure the best possible treatment outcomes for all patients at present time. This goal is secured on provision of the best possible treatment process. Additionally, the universal point of departure for this goal is the preparation of the best possible infrastructure (facilities, equipment, and personnel). The second goal of cancer treatment is to construct a system for continuous improvement allowing routine provision of the best quality care even as time passes, through development of better treatment plans and through ongoing preparation of infrastructure and education of personnel.

Even at present, 20% of cancer patients in Japan undergo radiotherapy, which plays an important role in cancer treatment. The number of patients undergoing radiation treatment is increasing rapidly, and a maturation process resulting in numbers of 50-60%, on a par with those in the US, is anticipated (Section 5.6, Figure 10-1). There is a need for a general mobilization of current knowledge and technologies in efforts to maximize therapeutic effect and minimize adverse effects in a more active utilization of radiotherapy.

This report designates and presents standards for personnel, equipment, and facilities unique to Japan, standards for their use, and guidelines on their optimal utilization. The report is based on data from three national "Patterns of Care Studies" (PCS) carried out with support by the Grant-in-Aid for Cancer Research from Ministry of Health, Labour and Welfare (Nos. 8-27, 8-29, 10-17, and 14-6), and the standards herein are primarily the work of PCS research group members and research collaborators.

(Teruki Teshima)



◇ : JASTRO Structure Survey

JPCS WG

Figure 10-1 Estimate of increase in demand for radiotherapy in Japan, based on statistical correction of annual change in the number of new patients per year at PCS survey facilities supported in part by the Grant-in-Aid for Cancer Research (No. 14-6) from the Ministry of Health, Labour and Welfare . ◇ denotes the total number of survey results in regular structure surveys by the Japanese Society for Therapeutic Radiology and Oncology (JASTRO). Recent data from surveys with high response rates are highly consistent with the PCS estimates. The broken line indicates the increasing trend in a case assuming achievement in 2015 of radiotherapy application in approximately 50% of all cancer patients, on a par with the US.

11. Glossary of Terms¹¹⁾

- Accelerated fractionation
A type of irradiation involving multiple, fractional exposure during a day. The total course of treatment is shortened relative to that in standard fractionation by an equivalent or lower daily dose (1.8-2 Gy) than in standard fractionation.
- Adverse effect
Any unfavorable and unintended sign, symptom, or disease observed during therapy or treatment, without regard to a causal relationship to therapy or treatment.
- Beam's eye view
Image viewed apparently from the location of a radiation beam source, devised by computer reconstruction of a target outline and an at-risk organ outline input by a radiation therapist.
- Biologically equivalent dose, BED
Conversion of absorbed dose distribution into biologically equivalent dose distribution based on factors such as radiation quality, irradiation time-pattern, and irradiation volume.
- Bolus
A device made from a material similar in composition to the body which is placed on the surface of the body to transfer a buildup of dose distribution to the body surface and enhance dose at the body surface.
- Brachytherapy
Divisible into sealed brachytherapy and non-sealed brachytherapy. See "Sealed brachytherapy".
- Cancer
In a broad sense, the term cancer refers to all malignant neoplasms, and in a narrow sense, cancer refers to epidermal malignant neoplasms. Non-epithelial malignant neoplasms are termed sarcomas.
- Carbon ion beam
Ionization of carbon atoms to produce heavy ion particles and acceleration of such heavy ions. Superior to a proton beam in relative biological effectiveness and concentration of dose, but construction costs for facilities are higher than those for proton beam.
- Cesium-137
Radioisotope with a half-life of 30 years. Emits 660keV γ -rays; used primarily for procedures such as intracavitary and interstitial radiation.
- Clinical target volume (CTV)
The volume of an area to be subjected to radiation based on suspicion of progression of microscopic cancer not visible to the unaided eye or through diagnostic imaging.
- Cobalt-60
Radioactive isotope with a half-life of 5.3 years. Emits 1.17 and 1.33 MeV γ -rays. Used primarily for external irradiation.

- Commissioning
Adjustment carried out after intake inspection at an individual facility to ensure accuracy suited to treatment plans and methods and to establish a baseline of performance data. Carried out primarily by a user prior to clinical use.
- Compensating filter
A device which compensates for irregular body surfaces to create a uniform radiation dose distribution within the body, and which, in contrast to a wedge filter, is placed on the surface of the body or at an emission aperture.
- Conformal radiotherapy, CRT
Irradiation method involving multi-directional irradiation using photon or particle beams, in which the shape of the irradiated field and the target coincide when viewed from any direction of irradiation.
- Critical path
Standard treatment plan.
- CT simulator
Used in three-dimensional radiotherapy planning as a substitute for an x-ray simulator; functions include projection onto patients of planning results for X-ray, CT-, and dose distribution calculating systems.
- Cure
Completion of treatment in the status prior to onset of illness. Also used to indicate a rate of death after treatment equivalent to the rate of death from various causes in a sex- and age-matched standard population.
- Definitive irradiation
Radiotherapy carried out with the objective of cure.
- Dose volume histogram, DVH
Illustrates the relationship between the radiation dose in a target or other critical risk organ and the dose and volume in various organs; allows comparison of multiple treatment plans.
- Radiotherapy quality controller, dosimetrist
A member of a radiotherapy team with training in the physics of radiotherapy equipment and radiation sources used to treat patients, and one with responsibility only for work concerning radiotherapy quality control.
- EBM (evidence based medicine)
Medical treatment grounded in a scientific basis.
- Electron
Elementary particle carrying a negative charge. X-rays are produced by accelerating and smashing electrons into a target. Also used in therapy as an electron beam.
- Gamma ray
Electromagnetic radiation (photon beam) emitted from an unstable atomic nucleus. Examples include emission from cesium-137, cobalt-60, and radium-226.
- Gross tumor volume, GTV
Volume of cancer to the extent visible to the unaided eye or by diagnostic imaging.

- Hyperfractionation
A method entailing multiple exposures during a day using a single dose lower than the standard daily dose (1.8-2Gy) in a standard total course of treatment.
- I-125 (Iodine-125)
Used in permanent implantation brachytherapy for prostate cancer. In Japan, treatment using I-125 has been pursued since 2003.
- Informed consent
In determination of a treatment plan or method, obtainment of consent after thorough explanation to the patient/family.
- Inspection on receipt (Intake inspection)
Testing carried out primarily by a manufacturer together with a user to check whether the precision of device performance characteristics matches specifications and whether operation is normal.
- Intensity-modulated radiotherapy (IMRT)
A treatment method in which a single irradiated field is divided into multiple areas, and an optimal beam intensity is administered to each divided area.
- Interstitial radiotherapy
A treatment method in which a sealed radiation source is applied interstitially within a specialized applicator positioned in a predetermined pattern.
- Intracavitary radiotherapy, ICRT
Therapeutic method involving application of a brachytherapeutic source in an applicator (device) inserted in the uterus, vagina, or other such body cavity.
- Intraoperative irradiation
Visually-guided electron beam irradiation of a focus in patients of inoperable or incompletely excised cancer.
- Inverse planning
An inverted treatment plan in which dose and administration in tumors and normal tissue are determined by computer optimization by a 3-dimensional diagnostic imaging equipments in order to implement complex dose distribution
- Ionizing radiation
Radiation produced by absorption of that portion of energy imparted to an atom when orbital electrons of the atom are released; considered photons carrying the classic electron bond energy of 10eV or more.
- Iridium-192
Radioactive isotope with a half-life of 74 days. Emits 300-600keV γ -rays. Used in interstitial radiation and remote afterloading.
- Linacgraphy
A check film used to verify an irradiated region.
- Linear accelerator
Also known as a linac. A linear electron accelerator using electromagnetic microwave technology to generate a high-energy x-ray or electron beam.
- Medical radiation physicist
Specialist with a masters or doctorate degree in physics and education and training in radiation physics for radiological diagnosis or treatment.
- Megavoltage radiation
Ionizing radiation with energy equivalent to or greater than 1MV.

- Microtron
External irradiation equipments which uses a circular accelerator to rotate electrons in a uniform DC field in a circular path.
- Molecular targeted drug
Differences in the structure of cancer cells and normal cells are understood, as are mechanisms of cancer cell proliferation and metastasis, and it is believed that treatment can be provided with a minimal effect on normal cells if the properties representing distinct features of cancerous cells are attacked. A molecular targeted drug is one produced for this purpose.
- Multi-leaf collimator, MLC
A column designed to produce an irregular irradiation field conforming to the shape of a target to be irradiated.
- Oncology
The research area relating to tumors.
- Symptomatic radiation therapy
Radiation therapy to prevent or alleviate symptoms caused by an illness.
- Palliative radiotherapy
Radiotherapy with an objective of long-term tumor control in cases where cure is not anticipated.
- Proton beam
Accelerated protons, the particles that form a hydrogen nucleus or a hydrogen positive ion. Concentration of dose is superior to that of x-rays, but the cost of facilities construction is high.
- PTV, planning target volume
Volume of region where actual contact by radiation is anticipated.
- Quality assurance
System-wide activities carried out to assure provision of adequate quality.
- Quality control
Operational technologies and activities used to assure provision of requisite quality in a subsystem of a larger system.
- Quality of life
Quality in living.
- Radiation dose
The absorbed dose, threshold dose, tumor dose, deep dose, transmitted dose, or other amount of irradiated energy per unit mass in an absorbing structure under certain predetermined conditions.
- Radiation oncologist
Physician specialized in tumors, and particularly treatment of tumors by radiation.
- Radiotherapy
A therapeutic technique for treating tumorous illnesses and some non-tumorous illnesses with ionizing radiation.
- Remote afterloading system (RALS)
Device and after loading technique for carrying out remote high-dose intracavitary irradiation.

- Risk management
Risk management.
- Sealed brachytherapy
Therapeutic technique using a sealed radioactive substance to provide radiation at a near-contact distance. Used in interstitial, intracavitary, and surface irradiation.
- Second opinion
Assessment and explanation by another physician.
- Simulation
In radiotherapy, precise determination of the location of an irradiation field for patient treatment by X-ray or CT exposure.
- Stereotactic irradiation, STI
Therapeutic method allowing accurate irradiation of small foci by three-dimensional localization of targets. Includes stereotactic radiotherapy (SRT) involving fractionated irradiation and stereotactic radiosurgery (SRS) effected by a single irradiation.
- Total body irradiation, TBI
A treatment method irradiating the entire body; used as a pretreatment in bone marrow transplant therapy to eradicate tumor cells and suppress immune reactions.
- Wedge filter
Device used to increase the uniformity of dose in the irradiated volume by compensating for dose-distribution caused by irregular body surfaces, or by correcting maldistribution in a high dose area caused by factors such as two perpendicular beams.
- X-ray simulator
Device used to check the incident direction and irradiated field of an external radiation beam by equating an external radiotherapy equipments and a number of theoretical conditions.

(Kazuhiko Ogawa)

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Appended Tables

) The required expenses in case that 250 patients are treated by radiation in one year in terms of mainly standardized modality.

A) The required equipments & tools to provide radiation treatment.

	Equipments & Tools	Units	An estimated purchase price
1	Radiation treatment machine (dual energy with MLC)	1	
2	Dedicated CT simulator for radiation treatment	1	
3	Conventional X-ray simulator	1	
4	Radiation treatment planning system	1	¥290,000,000
5	Radiation treatment aids	Possess	
6	Measurement equipments for QA/QA (Dosimeter, Waterphantom, etc.)	Possess	
7	Network for IT	Possess	

Remarks) The period of amortization is 6 years and ¥48,335,000 is amortized per year.

B) The required human resources to perform radiation treatment.

	Occupation	Persons	An estimated expenses
1	Radiation oncologist	1	
2	Radiation therapist	2	
3	Radiation treatment QA/QC manager	1	¥43,200,000
4	Dedicated nurse for radiation treatment	1	
5	Medical secretary for radiation treatment	1	

C) The annual maintenance fees and utilities' expenses for radiation treatment equipments & tools

	Equipments & tools	Units	An annual maintenance fee, etc.
1	Radiation treatment machine (dual energy with MLC)	1	
2	Dedicated CT simulator for radiation treatment	1	
3	Conventional X-ray simulator	1	
4	Radiation treatment planning system	1	¥9,000,000
5	Radiation treatment aids	Possess	
6	Measurement equipments for QA/QC (Dosimeter, waterphantom, etc.)	Possess	
7	Network for IT	Possess	
8	Electricity, water, etc.		¥1,000,000

9	(cont'd) Consumable items, etc.	¥3,000,000
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) The annual income paid by reimbursement in case that 250 patients are treated by Radiation in one year in terms of mainly standardized modality.

	Treatment modality	Patients	An estimated annual income
1	One port or two opposite ports treatment	90	
	Second target treated by one or two opposite ports	20	
2	Non two opposite ports or three ports treatment	90	
3	four ports or more, arc or dynamic conformal treatment	45	¥86,200,000
4	Stereotactic treatment	20	
5	Total body irradiation	5	

) The required expenses in case that 100 patients are treated by Radiation in one year in terms of mainly simple modality.

A) The required equipments & tools to provide radiation treatment.

	Equipments & tools	Units	An estimated purchase price
1	Radiation treatment machine (single energy without MLC)	1	
2	Dedicated CT simulator for radiation treatment	None	
3	Conventional X-ray simulator	1	
4	Radiation treatment planning system	1	¥111,000,000
5	Radiation treatment aids	None	
6	Measurement equipments for QA/QA (Dosimeter, waterphantom, etc.)	None	
7	Network for IT	None	

Remarks) The period of amortization is 6 years and ¥18,500,000 is amortized per year

B) The required human resources to perform radiation treatment.

	Occupation	Persons	An estimated expenses
1	Radiation oncologist: One temporally,(twice a week equivalents 0.4 of full-time)	0.4	¥28,600,000
2	Radiation therapist; 2 persons (0.5 of full-time per person)	1.0	
3	Radiation treatment QA/QC manager; one full-time person	1.0	

(cont'd)

4	Dedicated nurse for radiation treatment; one person (0.5 of full-time)	0.5
5	Medical secretary for radiation treatment; none	0.0

C) The annual maintenance fees and utilities' expences for Radiation Treatment equipments & tools

	Equipments & tools	Units	An annual maintenance fee, etc.
1	Radiation treatment machine (single energy without MLC)	1	
2	Dedicated CT simulator for radiation treatment	None	
3	Conventional X-ray simulator	1	
4	Radiation treatment planning system	1	¥4,750,000
5	Radiation treatment aids	None	
6	Measurement equipments for QA/QA (Dosimeter, waterphantom, etc.)	None	
7	Network for IT	None	
8	Electricity, water, etc.		¥750,000
9	Consumable items, etc.		¥1,800,000

) The annual income paid by reimbursement in case that 100 patients are treated by radiation in one year in terms of mainly simple modality.

	Treatment modality	Patients	An estimated annual income
1	One port or two opposite ports treatment	80	
	Second target treated by one or two opposite ports	20	
2	Non two opposite ports or three ports treatment	15	
3	four ports or more, arc or dynamic conformal treatment	5	¥29,820,000
4	Stereotactic treatment	0	
5	Total body irradiation	0	

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