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 18-4

Supported by

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THE ROAD TO QUALITY IMPROVEMENT IN RADIATION ONCOLOGY

Radiation oncologists and related scientists in Japan and in the United States share a deep commitment to safeguarding the best interests of cancer patients. We fulfill this professional obligation to patients and to society by voluntarily engaging in detailed self examination to evaluate the structural base and the processes of care actually employed in practice. We then analyze the associated clinical outcomes that are achieved and identify areas for improvement. These important efforts steadily improve cancer treatment quality and have been ongoing in the United States for nearly 40 years and in close collaboration with our colleagues in Japan over the last decade.

Drs. Mitsumori and Teshima, and the contributing members of the Japanese Patterns of Care Study, deserve high commendation for providing such a timely and relevant guidance document describing the basic structural requirements to assure quality in radiotherapy in Japan. The powerful impact of this report will no doubt resonate well beyond the borders of Japan in defining the structural requirements currently required for safe and effective delivery of technologically advanced radiation therapy. As Dr.Hanks, my predecessor as PI of the US Patterns of Care Study, reflected in his preface to a previous JPCS report, progress in radiation oncology "toward one world of quality of care" is a goal that is being achieved as a consequence of this and related investigations.

The Japan-USA Patterns of Care collaboration is a source of pride and personal pleasure for those involved. The results we have achieved together challenge other oncology related professions to also engage in critical self evaluation and practice improvement exercises. Results of our productive collaboration are now positively influencing the development of similar cancer care improvement programs in other countries. To them, we gladly extend our mutual encouragement and support to these international colleagues and offer all possible help.

The road to continuous quality improvement is long and never ending, but optimal cancer care is a noble destination. If the road is never taken, only minimal progress towards quality healthcare can be anticipated. Optimal cancer care in the future entirely depends upon careful assessment of the results of broad based research such as those presented by the Japanese PCS Working Group in this study and
the judicious application of the findings.

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Preface to the 2009 Edition

The preface to the 2005 edition provides a detailed history of the creation of the "Blue Book" in Japan. The publication of this revised edition after a comparatively short time reflects the fact that the physical resources and processes of care involved in radiation treatment in Japan are changing rapidly, as seen in the results from this Patterns of Care Study, and in those of structural surveys carried out by the Japanese Society for Therapeutic Radiology and Oncology (JASTRO).

Specifically:

- Creation of medical care guidelines for individual organ cancers is proceeding rapidly, and specific, standardized radiation treatments for various cancers have been released.
- Intensity modulated radiotherapy (IMRT), stereotactic radiotherapy, and other such precision treatments requiring a high level of skill in practice are now entering wide use.
- In comparison to the availability of physical resources, there is a clear shortage of human resources such as physicians, radiology technicians specialized in radiotherapy, and medical physicists.
- Repeated medical accidents associated with radiotherapy have renewed public awareness of the latent risks of radiotherapy, and in October 2004, a radiotherapy quality controller system was created with the intent to establish additional systems for radiotherapy safety management.
- Enactment of the Fundamental Law for Anti-Cancer Measures (the Cancer Control Act) in April 2007 has led to designation of "cancer care center hospitals" and the creation of subsidies and other policies for the purchase of radiotherapy equipment, a trend toward more intensive cancer treatment, and the introduction of many new models of radiotherapy equipment.
- The worsening of economic conditions and associated policies to restrain health care costs created a need for treatments encompassing both quality and economy.

As in the 2005 edition, the guiding principle of the 2009 edition is to respond to these changes and publicize the basic requirements that all radiotherapy facilities should meet at present.

Major changes in the environment surrounding radiotherapy are also likely to continue, and to avoid obsolescence, we must update the content of this document continually to reflect the results from the Patterns of Care Study and other structural surveys.

Spring, 2010

Michihide Mitsumori, Principal Investigator
Japanese PCS Working Group
Ministry of Health, Labour and Welfare Cancer Research Grant
Planned Research Study (18-4)
"Quality assurance of radiotherapy system and its clinical assessment"

Preface to the 2005 Edition

A Pattern 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 outcomes) in radiation oncology. We have also monitored US-Japan discrepancies. The recent frequency of accidents in the field of radiotherapy is also related to such structural problems. This short report is based on specific medical practice 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, Principal Investigator
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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 guidelines[1] 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 proposed 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, "Our sincere hope is that the US and Japan will continue to work together toward quality assurance to improve care and outcomes for our patients." This phrase summarizes our activities.

The Japanese Society for Therapeutic Radiology and Oncology (JASTRO) has carried out structural surveys of Japanese radiotherapy for the past 15 years.[4-20] 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).[21] The integrated data are statistically adjusted, and nationwide practices in radiotherapy are determined retrospectively[22, 23] 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). With support from a Ministry of Health, Labour and Welfare Cancer Research Grant, the ACR as the center of PCS research in the US,[24, 25] and Drs. Hanks (-2000) and Wilson (2001-) as Principal Investigators in the ACR, from the 1996 inception of PCS in Japan until today, we have completed four surveys and joint US-Japan PCR studies: in 1992-1994,[26, 27] 1995-1997,[28-36] 1999-2001,[37-46] and 2003-2005,[47] and this work has clarified comparative differences between the US and Japan[48-50] and the state of radiotherapy in Japan. These data were essential information for drafting this standard on structure and process. Discrepancies in care according to facility size are still observed frequently in Japan, which is why US-Japan discrepancies were also needed to consider the form radiotherapy truly should achieve in Japan.

Radiotherapy is an important modality of cancer treatment. However, only 20% of cancer patients in Japan undergo radiotherapy, a very low proportion compared to 60% in the US.[50]

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, we believe that 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 protocols are also changing in response to the needs of changing societies. As a result, there is a continual need for updating, and delays in revision are unacceptable.

According to confirmed figures from 2008 demographic statistics, the annual number of cancer deaths is 343,000, accounting for 30% of all causes of death. At the same time, health care costs by disease show that cardiovascular disease accounted for 21%, respiratory diseases 8%, musculoskeletal and connective tissue diseases 7%, and gastrointestinal diseases 7%, while cancer accounted for no more than 12%.

Examination of 2007 health care costs of radiotherapy paid by health insurance for various medical procedures shows that radiotherapy as part of inpatient treatment accounted for no more than 0.4% of costs, versus 13.4% for surgery, and as part of outpatient treatment, radiotherapy accounted for just 0.2%, versus 20.9% for drug

treatment. These figures show that radiotherapy costs are in any event low in comparison to the 14.2% cost for treatment of malignant disease in the overall scheme of health care costs. [51]

Assuming that radiotherapy for cancer increased even by 10%, the increase in health care costs would not even amount to 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?
- How should the increasing specialization of radiotherapy facilities (i.e., regional partnering) be addressed?
- Have adequate baseline surveys been completed on the qualifications, certification, and changing duties of personnel responsible for checking work done at radiotherapy facilities?
- What type of guidance will be necessary to decrease medical accidents at radiotherapy facilities, where precision is increasingly higher?

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.

(1) Based on Japanese Patterns of Care Studies (PCS) and structural surveys by JASTRO, we present standard structures of personnel, equipment, facilities, and operation designed to ensure the quality of safe and effective radiation treatment.

(2) Based on the same research, we present guidelines for appropriate evolution of radiotherapy in the context of integrated cancer treatment in Japan.

Consistent with these goals, this report was prepared as a reference on the items summarized in Table 2-1, for use by physicians, medical physicists, medical radiographers, radiotherapy quality controllers, nurses, graduate and undergraduate students, hospital managers, hospital administrators and policy makers, and all other staff involved in radiotherapy as a cancer treatment or a multidisciplinary treatment for cancer.

Table 2-1 Information provided in this report

1) Essentials for better cancer treatment
2) The clinical role of radiotherapy
3) Method and process of radiotherapy
4) Standards for radiotherapy equipment and facilities
5) Radiotherapy quality assurance
6) Standards for radiotherapy personnel
7) Economic analysis
8) Problems of radiotherapy
9) Future of radiotherapy

The most important goal of cancer treatment 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, materials, and facilities) and best processes (operation and treatment modalities). An iterative cycle of accurate evaluation of results applied to structures and processes will raise treatment to a higher plane.

Best treatment requires ongoing improvements in knowledge and technology among health care personnel, crucial for which is enhanced clinical oncology education and related education programs corresponding to their specialized work. 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 advanced health care structures, 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.

3.1 The Importance of Team Treatment

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), overall condition, and individual background factors. Consequently, surgical oncologists, medical oncologists, and radiation oncologists must confer comprehensively on the mode of treatment. The role of pathologists and diagnostic imaging personnel is also important to an accurate understanding of the stage of disease and scope of cancer. And in addition to physicians, specialists including nurses, pharmacists, social workers, and nutritionists are needed for complete physical and psychological support of cancer patients, and appropriate team treatment providing all these functions is important.

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

When a treatment plan is determined during initial examination, there must be a forum (known as a "multidisciplinary conference" or "cancer board") for each specialist on the team to propose treatment modalities on an equal footing. In locoregional (area of cancer) 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.

3.2 Setting Treatment Objectives

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

3.2.1 Curative 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 (the most advanced level of cancer in cancer progression status classified on 4 levels), 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 (i.e., 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, prostate, and other such areas, curative radiotherapy offers results on a par with surgery.

Treatment modalities also include monotherapy and combination therapy. Combination therapy is carried out when control of local or metastatic foci by a monotherapy is deemed difficult, or when the objective is to reduce adverse events (or adverse effects) resulting from powerful monotherapy. Combination therapy is an effective and efficient combination of treatments from various fields and is first used effectively by a highly educated and experienced team whose members are thoroughly familiar with the ability of each other.

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 protocol requires exactness.

3.2.2 Palliative Treatment

The objects of palliative 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 treatment modalities placing a substantial burden on the patient are 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 advanced cervical cancer, improve ulcerative lesions of skin or breast cancer, improve obstructive lesions of the esophagus or trachea, and assist recovery from pathological fractures.

Representative examples of emergency radiotherapy where urgency is required in palliative 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.

3.3 Informed Consent

Informed consent based on thorough explanation to the patient and/or family is an essential part of determining a treatment plan or modality. What is most crucial is that the patient decide personally upon their own treatment plan and participate actively in treatment. In other words, the patient per se is a crucial member of the team assembled for 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., a second opinion).

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

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 health care providers, and treatment should follow this path. Consequently, each facility must prepare its own radiation treatment guidelines and manuals.

3.3.1 Cancer Treatment Selection Criteria

Therapeutic effect in cancer is often assessed by post-treatment rate of cure or survival period, but treatments with a good rate of cure or survival period are not necessarily the best for individual patients. Apart from these indices, there are various other assessment criteria for cancer treatment outcomes, including invasiveness, post-treatment organ function, aesthetics, and cost. Selection criteria for various treatments should be evaluated and assessed fairly on such indices. Then, based on a thorough explanation and understanding of these indices among patients, individual treatments should be selected according to the assessment criteria of each individual patient.

3.3.2 The Guiding Role of Physicians

In the selection of cancer treatment modalities for individual patients, physicians participating in cancer treatment must have sufficient knowledge to provide an appropriate explanation of the cure rate and survival period, invasiveness, post-treatment organ function, aesthetics, cost, and other such aspects of treatment modalities. They must also maintain a fair and neutral perspective among various treatment modalities at all times.

3.4 The Fundamental Law for Anti-Cancer Measures and Basic Plan for Cancer Treatment Promotion

The Fundamental Law for Anti-Cancer Measures (the Cancer Control Act) was enacted in April 2007 to promote anti-cancer measures in a comprehensive and planned fashion by establishing elements representing fundamental anti-cancer measures. The Act mandated the creation of a system to provide cancer treatment which would allow cancer patients to receive scientifically appropriate cancer-related treatment regardless of the location where such cancer patients live, with complete respect for patient wishes in matters such as selection of cancer treatment modalities. Cancer care center hospitals are obligated to implement the principles of the Cancer Control Act in tangible form. National and local public bodies have a responsibility to adopt and enforce comprehensive anti-cancer measures based on such principles. Physicians and other health care personnel must make efforts to cooperate in the anti-cancer measures

devised by these public bodies, achieve a deep awareness of the situation of cancer patients, and provide quality, appropriate treatment for cancer.

University medical faculties should also devise sufficient measures to achieve the goal of increasing the number of radiation oncologists, as stated clearly in the Basic Anti-Cancer Plan, first among these being the creation of programs in radiation oncology. This report is also intended to spur substantial activity for achievement of the goals of the Basic Anti-Cancer Plan.

(Hiroshi Onishi)

4. The Clinical Role of Radiotherapy

4.1 Characteristics of Radiotherapy

The clinical characteristics of radiotherapy in cancer treatment can be summarized under the following three points.

(1) 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. In most cases, individual treatments can also be performed on an outpatient basis, and treatment is received without major changes in routine activities.

(2) Preservation of organ function and form

Radiotherapy is a treatment to cure cancer without surgical procedure. Consequently, organs in which cancer occurs can be preserved in their original form, and organ 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.

(3) Curative nature

Recent advances in radiation technology allow more intensive administration of higher dosages of radiation to tumors accurately, raising the rate of cure over that in earlier radiotherapy, and increasing the scope of organs where outcomes rival those of surgical results.

4.2 Roles of Radiotherapy

In general terms, radiotherapy has the following three roles in cancer treatment.

(1) Selection in initial treatment as standard, curative therapy

Initial consideration of radiotherapy for the objective of curing various cancers at various stages, or incorporation of postoperative irradiation or the like as adjuvant therapy to standard therapy.

(2) Selection as curative therapy for reasons precluding standard therapy

Consideration of radiotherapy when surgery or other standard therapies are available, but patient age or general condition contraindicates surgery, when preservation of organ form or function is a major focus, or when the patient rejects standard therapy.

(3) Selection as palliative therapy

Consideration of radiotherapy for the objective of alleviating various clinical symptoms caused by advanced or recurrent cancer.

4.3 Scientific Characteristics of Radiotherapy as Technique

Unlike surgical therapy, where techniques or procedures often differ among individual surgeons, radiotherapy consistent with the process we advocate in this report is unlikely to differ among practitioners. And unlike chemotherapy, where standard dosing of drug concentrations is difficult for individual organs or tumors, radiotherapy allows precise calculation (standard dosing) of radiation dosage for tumors and marginal organs. Radiotherapy also facilitates detailed recording of treatment procedures and radiation dose distributions for subsequent comparison.

These characteristics are not part of surgery or chemotherapy and are distinctive features of radiotherapy allowing greater scientific recording, analysis, and evaluation of the relationship between treatment details and outcomes or adverse events. Inasmuch as medicine should be evaluated and developed through scientific analysis, these facts present radiotherapy as the most precise modality of treatment.

(Hiroshi Onishi)

5. Radiotherapy Procedures and Current Status in Japan

5.1 The Radiotherapy Process

There is essentially no difference between surgery and radiotherapy of cancer in their significance as a local treatment, though there are major difference in efforts made for qualitative diagnosis and quantitative assessment of tumors. While surgical treatment allows pathological testing for determination of items such as histological diagnosis, infiltration margins, and area of lymph node metastasis, quantitative assessment in radiotherapy is a complete clinical assessment, and it is often the case that treatment includes qualitative diagnosis as a clinical assessment. In other words, radiotherapy does not provide the "pathological disease stage" that always accompanies surgical therapy, and it is an extremely important matter to somehow obtain qualitatively and quantitatively accurate clinical diagnosis. Consequently, effective application of various laboratory data represented primarily by diagnostic imaging is essential for progress in radiotherapy.

Radiotherapy for cancer begins with accurate gathering of information from the tumor and the patient by well trained radiation oncologists, diagnostic radiologists, 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. The 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.[52-62] Such experience and ability must also be assured by fulfillment of the requirements for radiotherapy specialists as prescribed by the Japan Radiological Society and the Japanese Society for Therapeutic Radiology and Oncology (JASTRO). It is also essential that university medical faculties throughout Japan establish courses in radiation oncology to provide a sufficient and continual supply of radiotherapy specialists meeting societal needs.

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 be involved in selection of treatment modalities through explanation to the patient and presentation of alternative therapies. At least in specific areas (e.g., examination of head and neck tumor 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 patient treatment abilities equivalent to those

of a specialist in the respective field. In simulations of real patients and in treatment planning, the radiation oncologist has the ability to set targets 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. Patients undergoing radiotherapy receive proper assessment and management of tumor response and the normal tissue reaction for each dosage used. After radiotherapy is complete, there is an obligation for patient management throughout the clinical course wherever possible, including assessment of local effect, evaluation of adverse effects, and determination as to any recurrence or end-stage failures. Prognostic information on the irradiated patient must also be discerned personally, or through some other method, and we support in-hospital, regional, or national cancer registration. To resolve clinical questions and establish standard treatment protocols at practicing clinics, physicians also have a right or an obligation to participate actively in exploratory clinical studies, and not only retrospective research, concerning treatment of specific patient groups as well as individual patients.

Recent years have seen remarkable progress in the accuracy of information concerning tumors in the consultation phase among various specialists at initial examination. A careful general examination also cannot be overlooked. History-taking and documentation of concomitant illnesses and prior illnesses is important. Examination and testing should also be performed with particular detailed attention to checking of prior radiotherapy.

All this information is compiled to proceed with establishment of a primary monotherapy or a combination of 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 state treatment objectives clearly. The patient and/or family are provided with a thorough explanation of the patient condition and available treatment alternatives, and at this point, informed consent and self-determination are required.

Ideally, this explanation will conform to EBM-based radiotherapy guidelines. This too is a reason why radiotherapy guidelines must be updated constantly. 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 treatment type, 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 appropriate 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, acquire image-based information, obtain information from technicians and nurses, and 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 metastasis of cancer are detected early, cure may once again be achieved by additional treatment. Early discovery and treatment of adverse events (adverse effects) may also prevent severe problems from developing.

Subsequent new treatment designs in a given facility are produced by first reevaluating 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).

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

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

Recent, advanced treatment planning systems use an algorithm for these steps termed inverse planning. This algorithm provides multiple treatment plans. The best mode of treatment is selected from multiple solutions by comparison using a dose-volume histogram (DVH), or by investigation of executable treatment parameters. At this stage, the treatment planning system, connected directly to a multi-leaf collimator (MLC) for the equipment, performs virtual simulation of the irradiated field. 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 begins, a radiotherapy technician positions the patient in the treatment room under direction of the radiation oncologist, according to the virtual simulation parameters, 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 radiotherapy 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. 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 irradiation 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 ultrasound-based verification units.

If the radiation oncologist orders changes to the treatment 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 of treatment implementation is the most important. There is no need for the physician in charge to check the daily treatment setup. However, it is essential that the physician in charge checks each and every setup for treatment in special skin cancer foci, insertion of eyecups during treatment of ocular tumors, pinpoint irradiation cases, and pediatric irradiation cases.

5.2 Importance of Quality Control

A thorough institutional approach to QA/QC is the first step in safe and accurate radiotherapy. Amid recent calls for safety assurance in health care settings, the Japan Association on Radiological Physics was established by related societies and began operation in 2003. At the outset, a series of accidents at radiology treatment facilities came to light, which the organization was pressed to address. The cause of many of these accidents was attributed to users' overreliance on the manufacturer when radiotherapy was introduced and their failure to appropriately carry out testing (commissioning) and other procedures. Technologies such as IMRT, IGRT, and high-precision brachytherapy had also grown in complexity, and more specialized radiophysical or engineering knowledge had become required for performance of safe, high precision radiotherapy. Medical physicists fulfill these roles, and their numbers in the US are substantial. In Japan however, there are extremely few individuals working in a medico-physical capacity in clinical settings. Discrepancies among facilities in the level of QA/QC must be reduced. Mechanisms for certification of medical physicists and radiotherapy quality controllers have been established in Japan. Under the Cancer Control Act, the Ministry of Education, Culture, Sports, Science and Technology has also launched "Cancer Professional Training Plans", and training of medical physicists has expanded rapidly. Individual facilities must now join these developments at an early phase to establish medical physics departments organizationally separate from radiology departments.

Radiotherapy quality control today should also function as more than a simple incorporation of capability for radiotherapy duties (operation of irradiation-related equipment) into the work of medical radiographers. From the perspective of double-checking too, this work should also be performed independently from quality control and the irradiation tasks of radiotherapy technicians, and the minimum requirement for assurance of high-quality, safe radiotherapy is the inception of full-time, dedicated (80% or a greater share of routine work) medical physicists, radiotherapy quality controllers, or other such radiotherapy quality control managers.

Figure 5-3 presents a schematic of personnel involved in radiotherapy as described in Sections 5-1 and 5-2.

Naturally, initiatives should continue to motivate all personnel to provide the maximum possible benefit to patients.

5.3 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 a total of 30 fractions given once per day, 5 times per week, over 6 weeks. This prescription 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 of daily dosage, which increases the total administered dose while suppressing the late effect on normal tissue with a low α/β ratio to a level equivalent to that from a 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 stereotactic radiotherapy further amplify the physical advantages of external irradiation. Intensity-modulated radiotherapy (IMRT) is another technique representing an additional applied development of 3-D CRT. Stereotactic radiotherapy is an irradiation technology in which the establishment of a small difference between the planned target volume and clinical target volume allows a 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). Through application of image-guided technology discussed below, stereotactic radiotherapy can also be performed with a general-purpose linear accelerator, but specialized equipment developed for application to stereotactic radiotherapy includes convergent beam therapy-capable apparatus including a radial array of multiple cobalt radiation sources, and robotic treatment apparatus equipped with a miniature accelerator. Intensity-modulated radiotherapy is an irradiation technology which adjusts beam intensity within a single irradiated surface to provide a unique, target-shaped distribution of dosage

concentrated on an irregularly-shaped target. Its strength is demonstrated particularly when the intent is to concentrate radiation dosage on a tumor while carefully avoiding at-risk organs adjoining the tumor.

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 unaided eye and 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 a large number of treatments have been approved in Japan as advanced treatments. The physical and biological characteristics of these technologies offer advantages over conventional radiotherapy and can sometimes provide a dose distribution and therapeutic effect unobtainable by x-ray therapy. Refractory disease deemed refractory to cure by conventional radiotherapy has been controlled, and development of new indications from a QOL perspective is ongoing. The problem in the future may indeed be insurance reimbursement and a fair location plan for particle-beam therapy facilities in Japan.

A major transformation in sealed brachytherapy has also been achieved in the past 40 years. The use of new nuclides, application of afterloading methods, and the use of computers have provided solutions for high-precision technologies and eliminated exposure among health care workers. Progress in QA and QC has also brought about a reduction in accident rates and treatment outcomes promising high QOL. The emergent technical revolution of high dose-rate brachytherapy has removed the constraint of low dose-rate brachytherapy through the use of fractionation. This development has also been recognized as a safe, high-precision treatment using image-guided technologies discussed below and now promises development of image-guided brachytherapy.

Such image-guided brachytherapy has also opened new avenues in prostate cancer treatment through ultrasound imaging and introduction of I-125 seeds, also approved for use in conventional low-dose rate irradiation 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, ongoing consolidation of facilities able to offer these treatments seems likely to continue in the future.

Total body irradiation is carried out as pretreatment 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 chemoradiotherapy used in peripheral blood stem cell transfusion is also a likely future topic of interest.

IGRT (image-guided radiotherapy)

IGRT is a technology for performance of accurate treatment coupled with correction of spatial errors for body contours and tumor location, based on image information. Specifically, recent years have seen a rapid development of technology and equipment which reduces setup error by checking and correcting tumor location through the use of images in the treatment room, either prior to or during each stereotactic exposure. Examples of image acquisition equipment rendered practical for the treatment room include fluoroscopy equipment, linac-integrated CT equipment, CT imaging equipment in irradiation gantries, and cone-beam CT equipment using flat panels.

Countering respiratory movement

High-precision irradiation technologies seek ways to reduce the gap between planned target volume and clinical target volume. The difference between planned target volume and clinical target volume has two components: setup error occurring in the interval between treatment planning and irradiation, and movement of organs within the body. While setup error has been reduced by the image-guided irradiation technologies described above, measures to counter organ movement in the body are an important issue. In particular, respiratory movement is the largest and most frequently occurring organ movement within the body in radiotherapy, and various measures have been devised to reduce this source of error. Methods in current use include those for controlling respiratory movement such as instruction and practice for shallow breathing; provision of inhaled oxygen; restriction of respiratory movement by means of a body frame, trunk shell, or other such device; and exposure during suspended respiration. Other methods of CT integrating irradiation equipment modify the method of irradiation and leave respiratory movement unaltered, for example, in methods of matching to respiratory phase immediately preceding irradiation, or methods of irradiation and body movement tracking with respiration gating.

Radioisotope (RI) therapy

Treatment of illness using radioisotopes is known as radionuclide therapy or nuclear medicine and has long been practiced. In particular, treatment of thyroid disease (e.g., thyroid cancer, Graves' disease) using radioactive iodine (I-131) has been practiced for more than 50 years. More recently, insurance listing has been extended to treatments for bone metastasis using strontium (Sr-89) and treatment of malignant lymphomas using yttrium (Y-90). However, these treatments require proper medical reimbursement for treatment planning and administration, and not merely the cost of simple drug expenses, and at present, provisions are inadequate.

Chemoradiotherapy

In simultaneous chemoradiotherapy, the intent is to improve treatment results by using the radiation-enhancing effect of concomitant chemotherapy to enhance locoregional effect and at the same time control distant micrometastases. This modality

has been adopted as a standard treatment method in lung cancer, esophageal cancer, and cervical cancer and is also gaining acceptance in head and neck cancer. Now with the appearance of molecular labeled drugs, studies to determine indications and exploration of such concomitant use is beginning.

Teletherapy planning

Teletherapy planning support is defined as efforts to provide assistance, evaluation, guidance, and other support for radiotherapy plan-centered radiotherapy, for example, by digitizing medical information and transferring health care information between radiotherapy systems in different facilities through use of various telecommunication means.

Problems associated with radiotherapy in Japan include a rapid increase in numbers of cancer patients due to demographic aging, and a shortage of radiation oncologists. Teletherapy planning support using information technology (IT) is a useful method with potential to improve the quality of radiotherapy and equalize cancer treatment across facilities with too few radiation oncologists, and further adoption is anticipated. However, radiotherapy is essentially a treatment made safe and efficient by coordination among the medical staff in a given facility to function as a single treatment team, a basic requirement for which is that a full-time radiation oncologist is affiliated with the facility, and until more radiation oncologists are available, teletherapy planning will be a complementary treatment measure. Appropriate facility and personnel environments, well-functioning systems, and evaluation for medical reimbursement are also highly important for pursuit of safe, high-quality radiotherapy through teletherapy planning support.

5.4 Best Practices for Interruption of Radiation

From biological principles, it is desirable that radiotherapy be accomplished without a period of interruption during irradiation, whenever possible. Particularly in cases of curative exposure for fast-growing tumors and squamous epithelial cancer, the effect of a interruption is regarded as substantial, and according to the JASTRO guidelines proposed by Nagata et al., it is generally preferable that there be no interruption of irradiation for a period of 4 days or longer, including weekends and holidays.[63] Consequently, clinical irradiation on vacation days is necessary during major holiday periods. In this respect, specific consideration must be given to create economically and logistically appropriate working conditions and compensation for staff routinely involved in such vacation day irradiation.

5.5 Best Practices for Outpatient Radiotherapy

The availability of radiotherapy for outpatient treatment is a major advantage, but waiting times for outpatients readily tend to exceed those for inpatients. Waiting time and the periods before and after irradiation often cause changes in condition, and likewise, i.v. therapy, nutrition management, and physical treatment are frequently needed during outpatient visits. These circumstances require structural preparations allowing appropriate response, for example (i) amenities for waiting, (ii) provision of i.v., rest, and treatment areas, and (iii) resident nurses with substantial experience in radiotherapy. Corresponding medical reimbursement must also be secured.

5.6 Current Status and Issues in Radiotherapy in Japan

5.6.1 Facility size and present conditions

Apart from universities and specialized cancer hospitals, the near-majority of other hospitals with radiotherapy capacity are small-scale facilities seeing less than 130 new treatment patients annually, and the reality is that these hospitals include facilities unable even to perform a thorough examination. Even so, the number of patients treated at small-scale facilities is 16% of the annual number of new radiotherapy patients in Japan (Table 5-1).

Table 5-1 Annual patient numbers and categories at radiotherapy facilities in Japan, by facility size - Patterns of Care Study (2003)[15]

Facility class	Annual number of new treatment patients	No. of facilities	No. of new patients	(%)
A1: University hospitals, cancer centers	410 or more	61	39,471	26%
A2: University hospitals, cancer centers	Less than 410	61	16,087	11%
B1: Other hospitals	130 or more	298	70,633	47%
B2: Other hospitals	Less than 130	306	23,313	16%
Total		726	149,504	

Table 5-2 presents a summary of equipment and staff and annual average number of radiotherapy patients at radiotherapy facilities in Japan, by size, according to the 2007 JASTRO Structural Survey.

Table 5-2 Summary of equipment and staff and annual average number of radiotherapy patients at radiotherapy facilities in Japan, by size[9, 10]

	Facility class			
	A1	A2	B1	B2
Linac (mean number of units)	2.1	1.3	1.0	0.9
Dual energy penetration (%)	76.8	70.3	73.0	53.2
CT simulation penetration (%)	93.0	77.5	69.1	52.6
High-dose rate RALS penetration (%)	88.7	45.1	22.6	2.7
Number of radiation oncologists (FTE, median)*	3.3	1.0	1.0	0.3
Number of radiotherapy technicians (FTE, median)*	5.0	2.4	2.0	1.3
Annual actual number of patients (mean)	850.7	308.0	327.0	98.4
Annual actual number of patients / FTE radiation oncologist	200.1	218.2	327.3	209.9

* FTE (full-time equivalent): Number of actual man-hours converted to radiotherapy-only, 40-hour weeks

High-energy linacs have come to account for most of the external radiation apparatus used in radiotherapy (Figure 5-4). Cobalt-60 external radiation equipment also complicates preparation of a detailed radiation dose distribution, and with the reduction of insurance compensation for the use of this equipment in Fiscal 2008, the number of these units is declining.

As the precision of radiotherapy-related equipment increases and treatment devices and techniques grow more advanced and complex, an increasing incidence of human error presents a growing societal problem.[64] In many of these cases, one aspect of the problem is regarded as a lack of documentation previously provided as 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.[52, 65]

A decreasing number of facilities performing low-dose rate brachytherapy is also a problem in the area of sealed brachytherapy. Because treatment results for low-dose rate brachytherapy as a curative treatment are not inferior to surgical results, and considering the QA/QC and personnel shortage accompanying increasing precision of brachytherapy equipment, consolidation to large-scale facilities is desirable. Efforts must be made to increase utilization through greater regional cooperation (Section 6.8, Figure 5-5, Figure 6-3).

5.6.2 Status of radiotherapy staff

Table 5-3 summarizes the state in Japan of staff qualified to participate in radiotherapy and their tasks.

Table 5-3 Radiotherapy staff tasks and current status in Japan (providers)

Tasks	Provider in US	Provider in Japan
Patient examination, treatment determination, treatment planning	Radiation oncologist	Radiation oncologist
Performance of radiotherapy	Radiotherapy technician	Radiotherapy technician
Radiotherapy quality assurance and control, research and development, treatment planning assistance, chart management	Medical physicist	Radiotherapy technician (some medical physicists or quality controllers)
Calculation of dose in treatment planning	Dosimetrist	Radiation oncologist (some radiotherapy technicians, medical physicists, quality controllers)
Construction of shells, blocks, and other accessories	Medical physics technician	Radiotherapy technician (some radiation oncologists)
Patient nursing, care	Nurse	Nurse (some radiotherapy technicians/radiation oncologists)
Administrative work	Administrative staff	Administrative staff, nurse, radiotherapy technician, radiation oncologist

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) fall short of 1 staff member, and dual tasks are performed in conjunction with diagnosis, or examination is performed by an adjunct physician from a university (Table 5-2). This situation should be of great concern for its potential to cause medical accidents at radiotherapy sites. The most important objective of this report is to outline guidelines for solving these problems.

Table 5-4 below presents the most recent status of radiotherapy in Japan and numbers of personnel involved in radiotherapy.

Table 5-4 Status of radiotherapy in Japan – 2007 JASTRO Structural Survey[9,10]

Item	Number
Number of radiotherapy patients	170,229
Number of radiotherapy facilities	721
Physician radiotherapy providers (full-time, actual number)	1007
JASTRO-certified physicians	477
Physician radiotherapy providers (FTE)	826.3
Technician radiotherapy providers (full-time, actual number)	2617
Specialist radiotherapy technicians	432
Technician radiotherapy providers (FTE)	1634.1
Radiotherapy quality controllers (full-time, actual number)	528
Radiotherapy quality controllers (FTE)	106.6
Medical physicists (full-time, actual number)	268
Medical physicists (FTE)	68.4
Nurse radiotherapy providers (full-time, actual number)	1064
Nurse radiotherapy providers (FTE)	494.4
JASTRO-certified facilities	114
JASTRO provisionally-certified facilities	20
JASTRO-certified cooperating facilities	108
Facilities employing full-time physician radiotherapy provider	511
Facilities performing stereotactic radiotherapy using linac	123
Facilities performing intensity-modulated radiotherapy	58
Facilities equipped with image-guided apparatus	93
Facilities performing teletherapy planning	37
Facilities performing iodine therapy for prostate cancer	78
Facilities providing proton beam therapy	5
Facilities providing carbon ion-beam therapy	2

Japan currently has not secured sufficient personnel even to expand the availability of radiotherapy equipment and satisfy the number of patients indicated for radiotherapy. There is particularly a shortage of radiation oncologists, and as the basic plan enacted in 2007 states clearly, their training will become a national issue.

The number of technicians dedicated to radiotherapy is also low, and it is a major problem that at many facilities, technicians are actually on a rotation system involving exchange every several months and are tasked with both treatment and diagnosis.

Radiotherapy in Japan has also developed through a process unique in the world, and as yet there is no established system for medical physicists.[66-68] A radiotherapy quality controller system was established by five radiotherapy-related societies and organizations in 2005, but the functional role of medical physicists therein has not been

fully determined. Japan also lacks the dosimetrists routinely present as staff in US facilities.

Other issues concern safety management for medical devices and stereotactic radiotherapy and intensity-modulated radiotherapy technology for the body trunk. Specifically, despite the fact that facility standards for providers of medical physicist and quality control functions have been established under medical reimbursement provisions, the fact that national qualification of medical physicists and occupational, wage, and other systems have still not been established at radiotherapy facilities is a major impediment to development of radiotherapy in Japan, one in need of early resolution.

Creation of radiotherapy certification and specialist nurse systems is another pending issue (see Section 8).

5.7 Forecast of irradiation equipment and staff required for radiotherapy (10-year outlook: 2020)

The number of radiotherapy patients is forecast to increase as shown in Figure 10-1, based on the factors shown in Table 5-5.

Table 5-5 Factors increasing future demand for radiotherapy

Increased number of cancer patients from demographic aging and need for minimally-invasive treatment
Increased practice of evidence-based medicine and self-selection of treatment modality
Treatment plans emphasizing QOL
Health care cost advantage of radiotherapy
Radiotherapy support through health care policy (Anti-Cancer Act)
Further progress in irradiation technologies
Changes in disease structure of cancer (increase in radiotherapy-indicated cancer)

Table 5-6 presents predicted needs for radiotherapy-related personnel, based on predicted numbers of radiotherapy patients as shown in Figure 10-1. The number of radiotherapy patients has increased steadily, approximately doubling in the last decade. The 2007 figure of approximately 181,000 is predicted nearly to double again in the next 10 years (Figure10-1). The rate of indication for radiotherapy has also increased among all cancer patients (26.1% in 2007) and may reach the level of 40% in 10 years. Based on these predictions, the annual number of new radiotherapy patients 10 years from now is estimated as 854,000[(69)]×0.4 = 342,000. Assuming 342,000 radiotherapy patients, the number of radiotherapy units needed will be 1,140 (assuming 300 patients treated/unit/year).

Table 5-6 Predicted numbers of radiotherapy-related personnel needed in 2020

Position	Personnel required 10 years from present	Current number of personnel (FTE)*
Radiation oncologist	1,710 (Assuming 200 patients/physician/year)	826.3
Indicated as medical physicists / Radiotherapy quality controller	1,140 (Assuming 300 patients/controller/year)	175.0
Medical physicist	570 (Assuming 1 physicist / 2 treatment units needed)	68.4
Radiotherapy technician	2,280 or more (Assuming 2 or more technicians / 1 treatment unit)	1634.1
Nurse	1,140 (Assuming 1 nurse / 1 irradiation unit)	494.4

* JASTRO 2007 Structural Survey

(Hiroshi Onishi, Yutaka Takahashi)

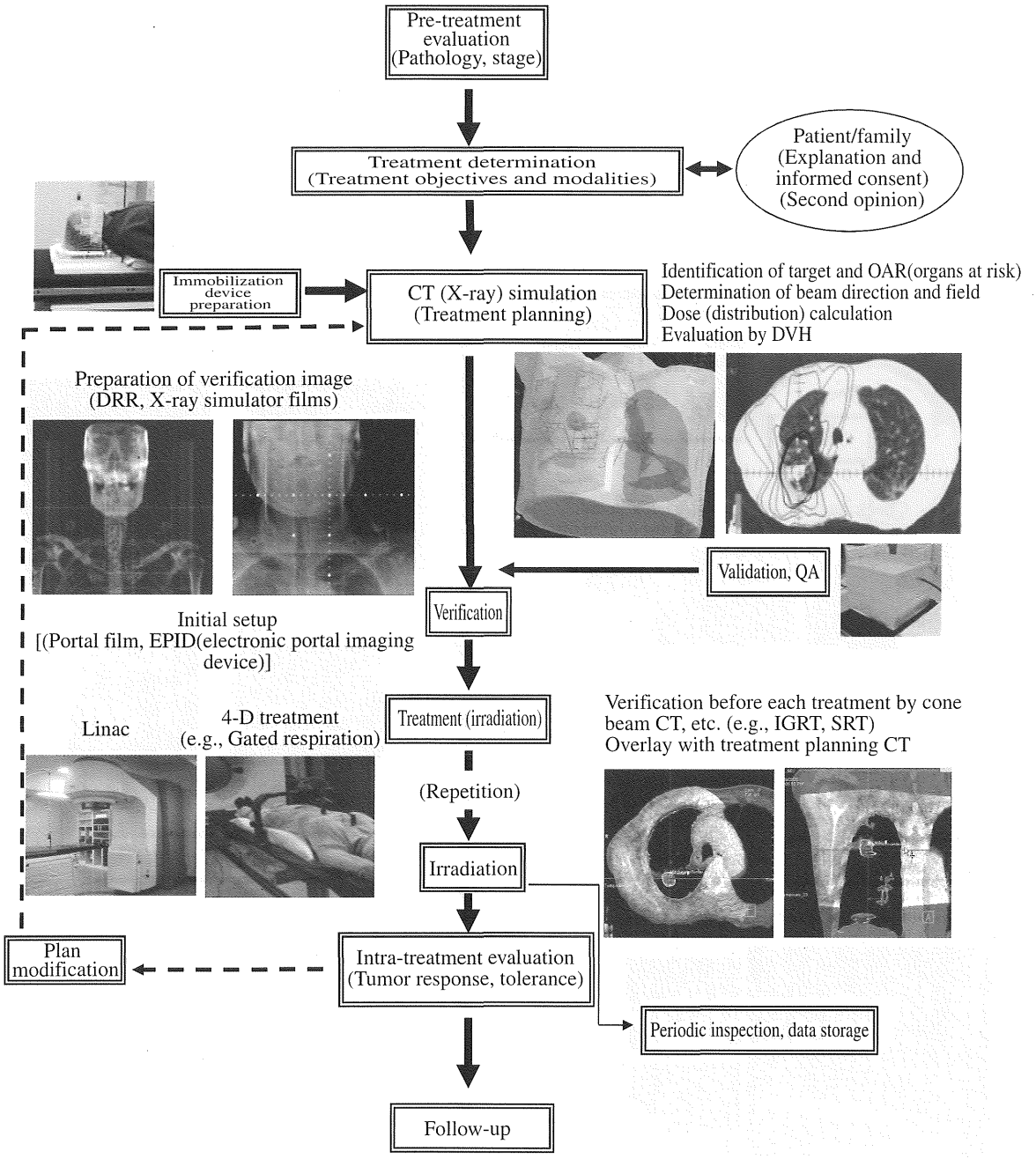

Figure 5-1 The radiotherapy process (external irradiation)

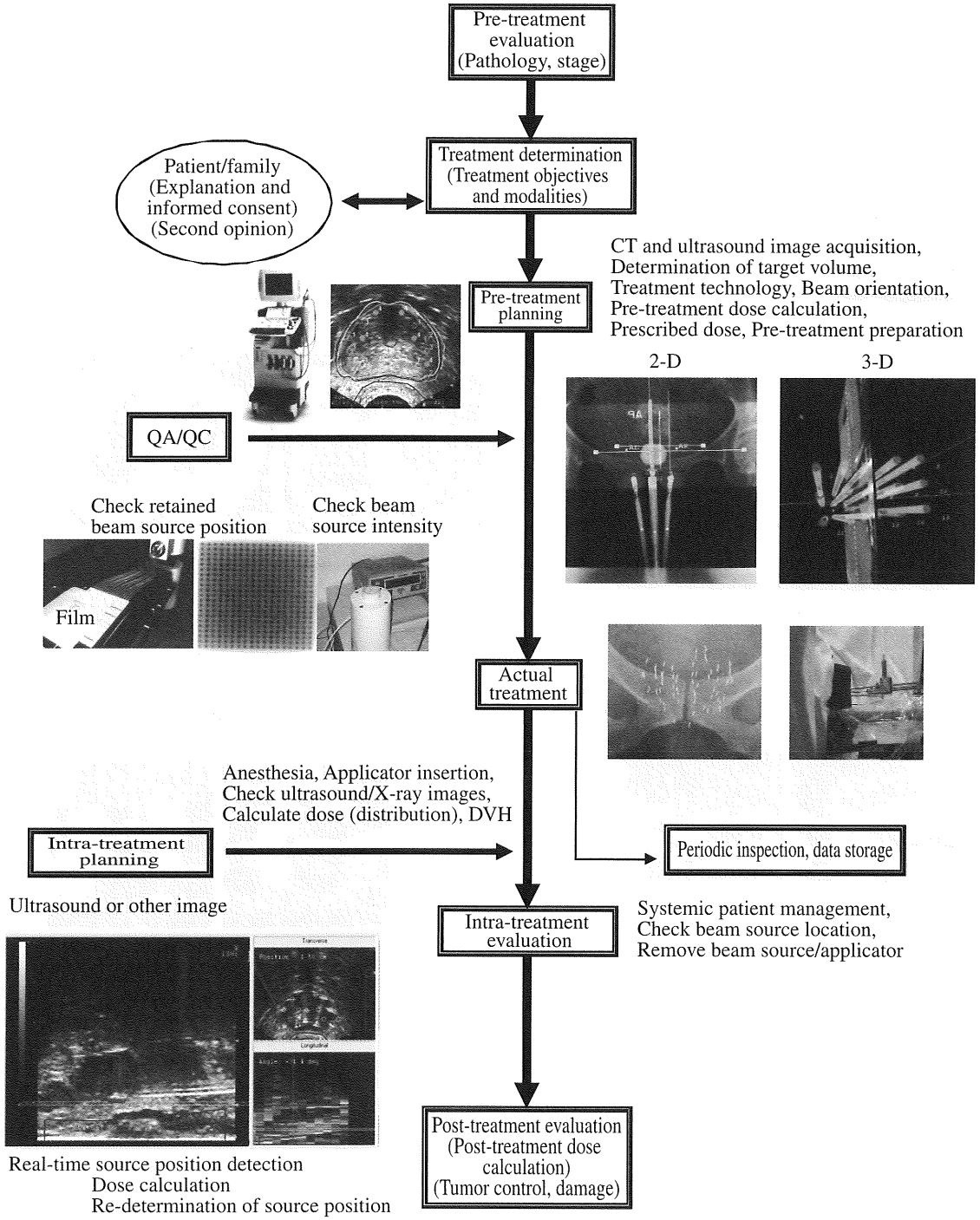

Figure 5-2 The radiotherapy process (image-guided brachytherapy)

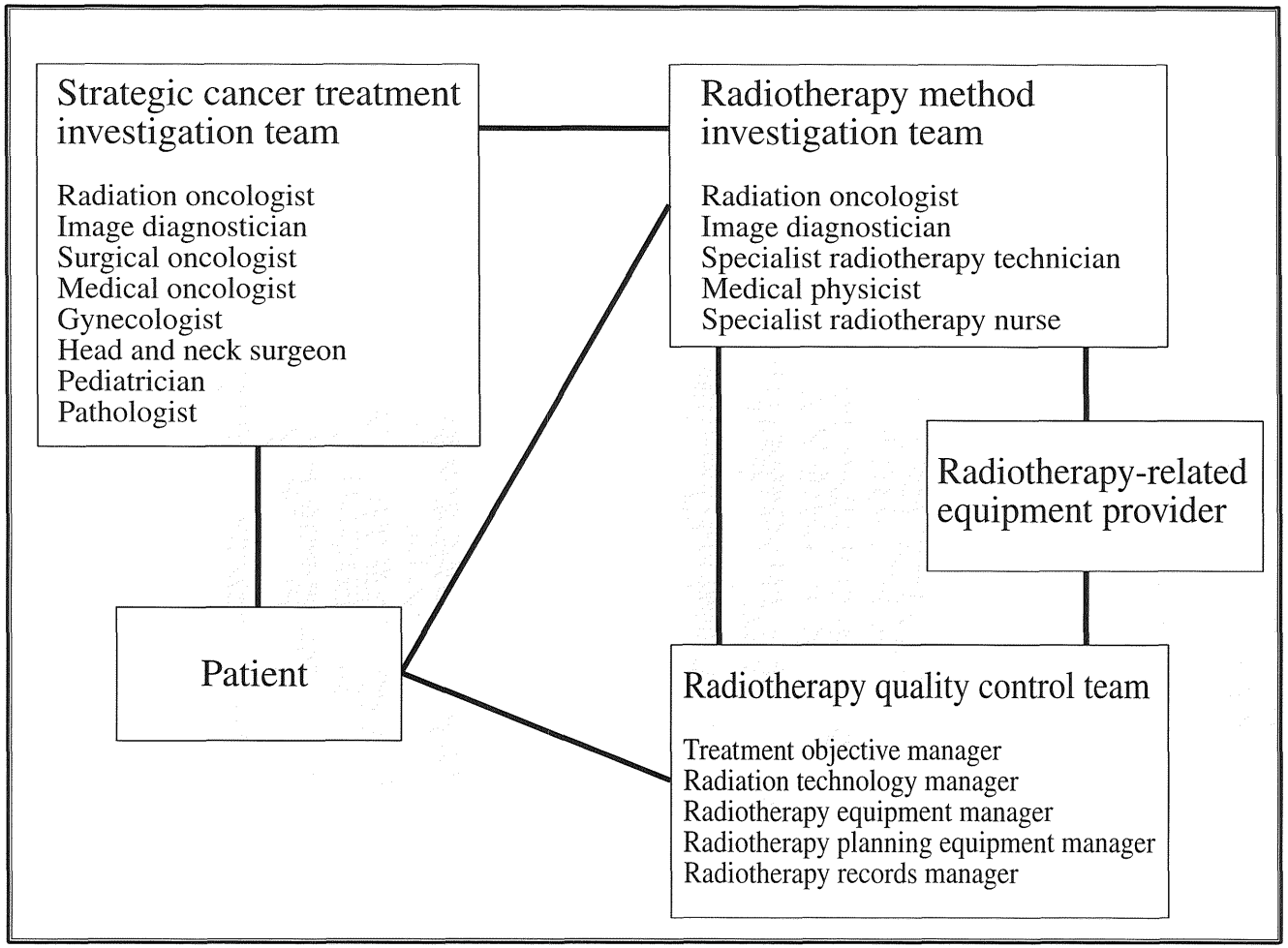

Figure 5-3 Schematic of radiotherapy-related personnel

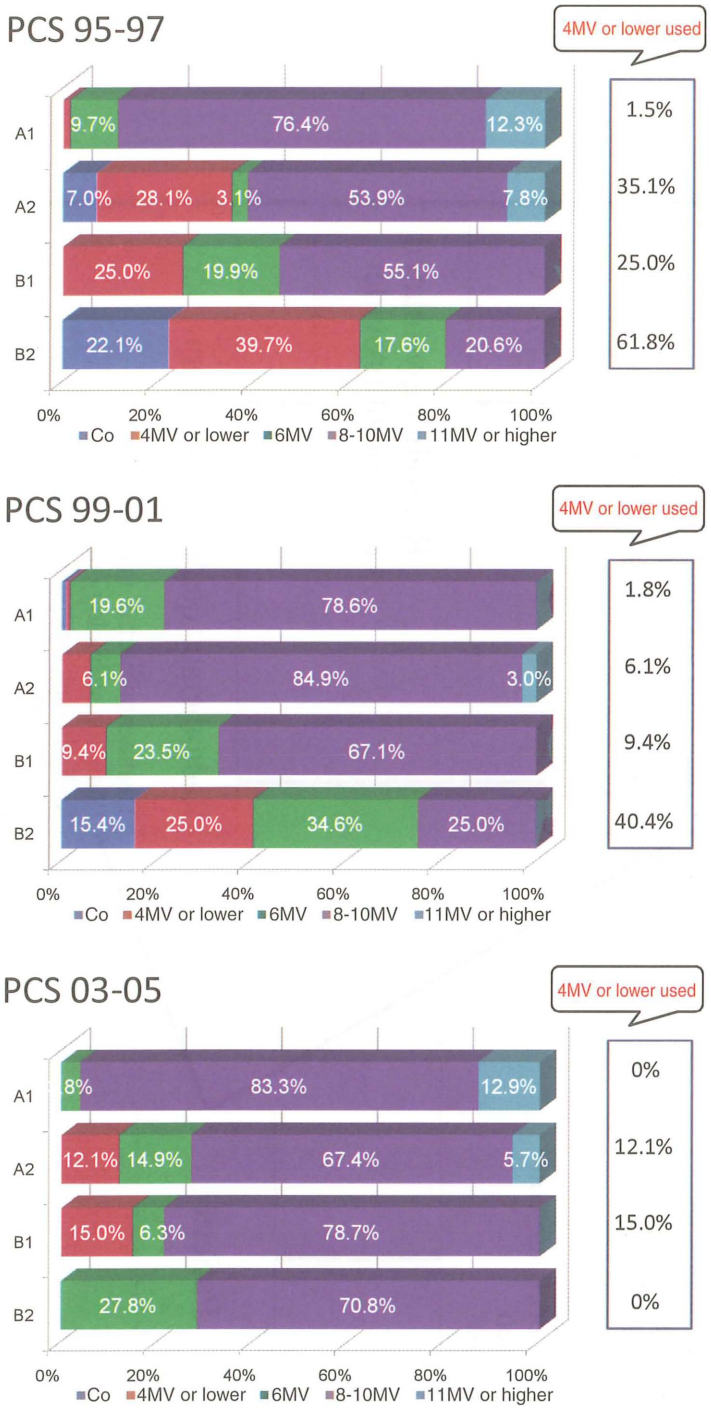

Figure 5-4 Frequency of beam energy used in external radiotherapy for non-surgical cases of esophageal cancer, according to PCS. Facility size results in large differences, with small-scale facilities selecting progressively lower energies. This trend improved notably over time.

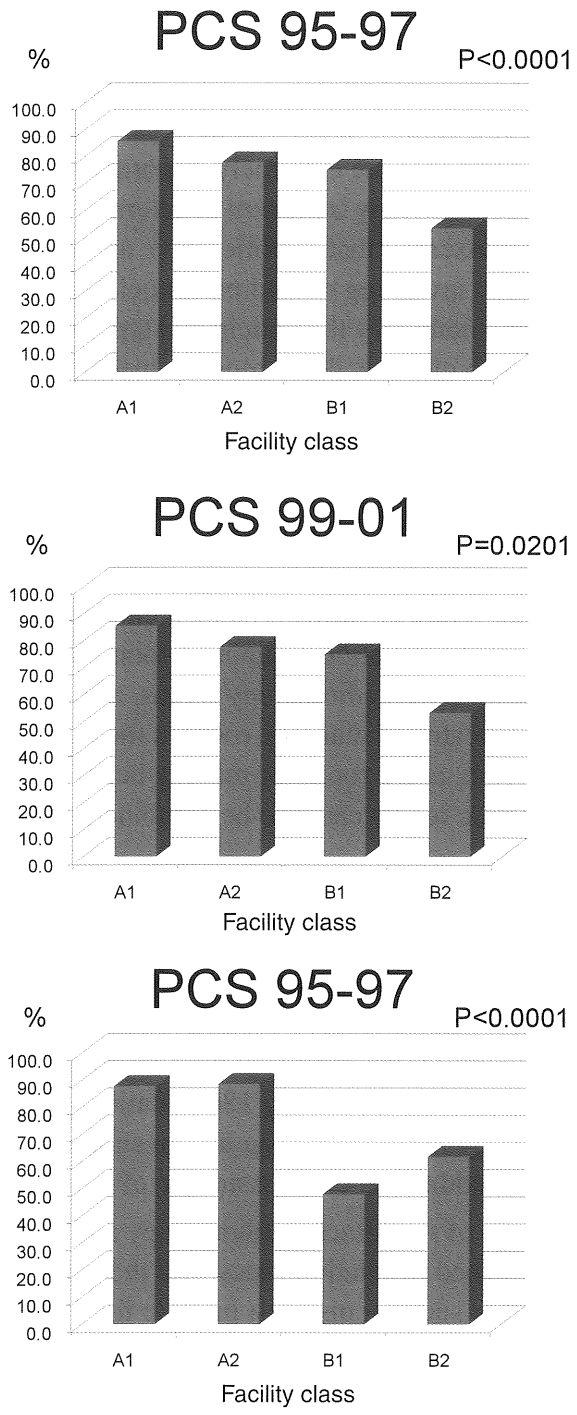

Figure 5-5 Indication rates for intracavitary irradiation in non-surgical cases of cervical cancer. Differences by facility size are apparent. Smaller facilities demonstrate progressively lower indication rates. Appropriate therapeutic processes may not have been employed at Class B facilities.

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. The type of therapeutic equipment used and its performance are extremely important in radiotherapy, and 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 planning stage. Even if standard equipment suitable for the anticipated types of cases is available, cooperative arrangements with other facilities must be made 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.

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, individual equipment control rooms, a treatment planning room, a medical physics and quality assurance/quality control room, and a room for making beam molds 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. Methods for intake of equipment during facilities construction and equipment upgrading must also be considered. The external radiation equipment room should have a width allowing 180° rotation of the treatment table and accommodation of whole-body irradiation. The design should also accommodate future increases in patient load and additional commissioning of equipment.

Recent, wider adoption of stereotactic radiotherapy and intensity-modulated radiotherapy has also lengthened irradiation times, and the shielding design for external radiation equipment and other such rooms must provide for a sufficient duration of use.

6.2 External irradiation equipment standards

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

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 reduction with depth, this apparatus is not

suitable for treating deep-seated tumors. Likewise, because the electron beam produced by a linac or other accelerator is also used for treating superficial lesions, this apparatus is currently used very infrequently.

The main external irradiation equipment currently in wide use is a linac (linear accelerator), but telecobalt (Cobalt-60 teletherapy unit) or other types of accelerators, including microtrons (non-linear accelerator systems) are also used. Modern accelerator systems (linacs, microtrons) must be highly reliable in function, and systems used for isocenter treatment must provide an appropriate output dose for treatment at a 100 cm 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, which makes quality assurance and quality control relatively easy. However, the penumbra of the beam is large, and it is thus unsuitable for high-precision treatment. And because of its low energy, this equipment is unsuitable for treatment of deep-seated tumors of the trunk. This equipment is now being replaced rapidly by linac and other accelerators.

Table 6-1 Types of external irradiation equipment

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

The radiation produced by the above-mentioned equipment includes X-rays, γ-rays, and electron beams, and it is desirable to have appropriate multiple energies. Improper adjustment of this equipment is related directly 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 equipment, and Section 6.7 should be

referenced for stereotactic radiotherapy, intensity-modulated radiotherapy (IMRT), and other advanced treatment equipment.

A sufficient number of external irradiation units relative to patient load is needed to allow sufficient irradiation time, patient position and field setup time, and the time required for QA/QC.

Table 6-2 shows the minimum time required for treatment of 1 patient by external radiotherapy equipment.

Table 6-2 Minimum time required for treatment of 1 patient by external radiotherapy equipment.

Complexity of irradiation	Example	Time required for 1 patient*
Simple irradiation	Irradiation of 1 portal or 2 opposing portals at 1 site	10 (to 15) minutes
Complex irradiation	Irradiation of 2 non-opposing or 3 portals	15-20 minutes
Specialized irradiation	4 or more irradiations moving radiotherapy or conformal radiotherapy	20 minutes or more
Very specialized irradiation	Intensity-modulated radiotherapy Image-guided radiotherapy	20-30 minutes or more

* Including time for patient changing and room entry and exit
* Additional treatment time is required for treatments such as stereotactic radiotherapy of the trunk and intraoperative irradiation.

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

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

These factors must all be taken into account when considering the number of external irradiation units required at each facility. Table 6-3 presents an example of

total treatment time calculation. It should be noted that patients are not treated at a fixed rate throughout the year, and some extra allowance is required.

In addition, if the number of treatments per external irradiation unit is high, positioning and other related procedures may become inaccurate. As shown in Table 6-3, assumptions of a 7-hour day, 5-day/week schedule, and 250 workdays/year will allow treatment of approximately 250 patients per external irradiation unit. On this basis, a warning level has been set whereat commissioning of new equipment, staff increases, and other necessary improvements are recommended when the ratio of number of patients per year/number of external irradiation units is greater than 400. In case of a large anticipated increase in the proportion of complex, specialized irradiations, even more treatment time will be needed, and commissioning of additional equipment or increases in personnel will be needed even below this warning level. The number of facilities exceeding the improvement warning level in the 1999-2001 PCS was 12/76 (16%), but in the 2003-2005 PCS the figure increased to 11/61 (18%), suggesting that some action will be needed.

Regarding X-ray energy levels, given that a 10MV or higher energy is desirable for deep-seated foci in the trunk, while lower energy (6 MV or lower) is desirable for shallow lesions such as those in the head and neck region or the breast, facilities should have the capability to deliver two or more energies. Most models of external irradiation equipment have multiple low energy X-ray-generating functions (dual/triple energy equipment), and the multi-functionality of equipment is increasing. Such models are particularly useful at small-scale facilities having 1-2 treatment units.

Megavoltage radiotherapy equipment includes 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. Some of the newest models include position detectors equipped with flat-panel detector devices. These devices are useful for expanding irradiation technique options and increasing accuracy, but the use of such advanced devices is complex and requires complete mastery. The patient treatment table included with the irradiation equipment is also an element connected intimately with irradiation accuracy. Patient safety must be assured, particularly with irradiation equipment in which rotating irradiation mechanisms or patient tables move automatically.

Accelerators should have a multi-leaf collimator (MLC). MLC leaf widths currently used include 2 cm (currently not used in new equipment), 1 cm, 5 mm, and micromulti-leaf collimators with even narrower leaf widths. A 1 cm or smaller leaf width is needed for performing high-precision radiotherapy.

Recently, respiratory motion-monitoring equipment has come into wider use. This equipment is used to treat lung, liver, or other such tumors characterized by respiratory motion, and the equipment is useful for decreasing adverse events but must be verified for precision thoroughly at each facility.

Apart from specialized intraoperative electron beam equipment, there is almost no stand-alone electron beam units, and this equipment is typically combined with X-ray linacs. An electron beam is required for superficial treatment, especially that of the skin, and this equipment must be equipped with multiple energies for selection of proper energy for the depth distribution of the target foci.

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

Table 6-3 Example of total treatment time calculation

Assuming a 7-hour day, 5-day/week schedule, and 250 workdays/year, the number of treatment hours provided by 1 external irradiation unit is:
60×7×5×50 = 105,000 minutes.
Patient composition is assumed as:
50% curative irradiation (35 fractionations on average) and 50% palliative irradiation (15 fractionations on average).
For simple irradiation, the time required per patient is assumed as 15 minutes (figure includes substantial allowance). Other assumptions are complex irradiation performed in 25% of curative irradiation (20 minutes required), [55] and irradiation field checking for change of field performed one time during all curative irradiation (10-12 minutes required).
With these parameters, the number of hours required for n patients annually is:
(Simple/curative) → 15 minutes × 0.5 × 0.75 n patients × 35 treatments + 10 minutes × 0.5 × 0.75 n patients × 2 times
(Complex/curative) → +20 minutes × 0.5 × 0.25 n patients × 35 treatments + 12 minutes × 0.5 × 0.25 n patients × 2 times
(Simple/palliative) → + 12 minutes × 0.5 n patients × 15 treatments + 12 minutes × 0.5 n patients × 1 time
= 412 n minutes
Thus, under these assumptions, the number of patients treatable with 1 external irradiation unit is:
105,000/412 = 254.8 = approximately 250 patients.

However, assuming 12 minutes per patient required for simple irradiation (the minimum required time), the result of the above calculations is 350 n minutes, and 1 external irradiation unit can treat approximately 300 patients.
In any event, 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 unit at various facility classes. At A2 and B1 facilities, the median value is approximately 250 patients per unit, but at A1 facilities, the median value is approximately 350 patients. At A2 and B1 facilities, more than 300 patients/unit were treated at the top 25% of facilities (Q4). A1-Q4 facilities treated more than 450 patients/unit. These facilities are at risk for a decreased quality of treatment due to

overloading and should consider additional commissioning of equipment and staff increases (improvement warning level).

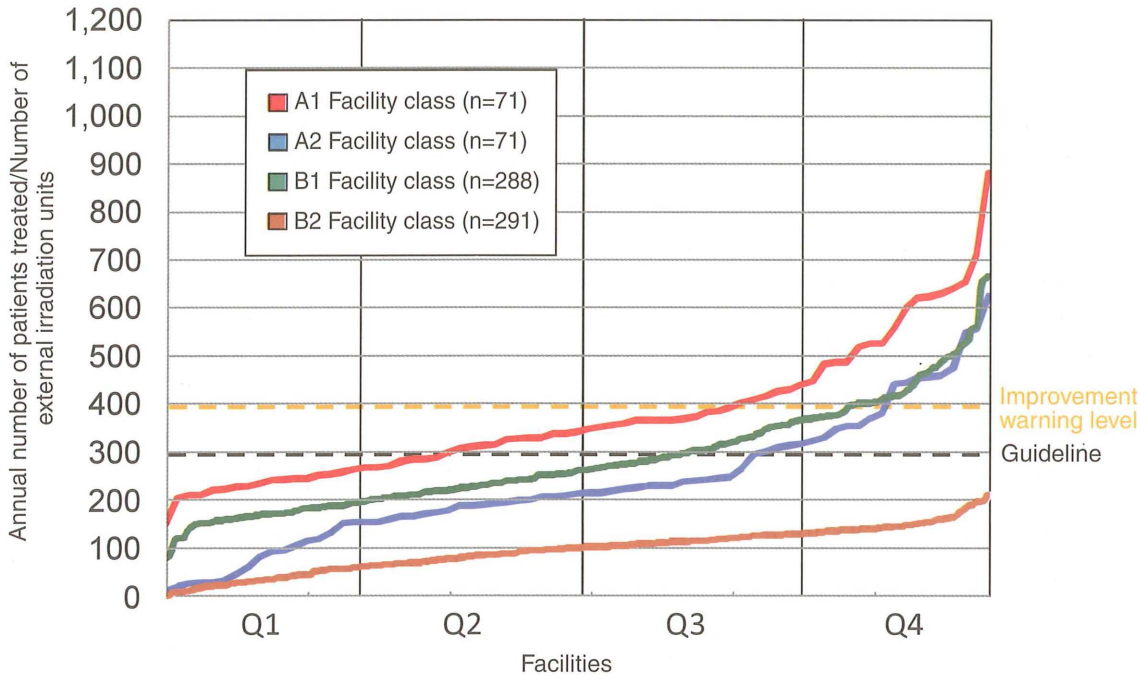

Figure 6-1 Distribution of annual number of patients treated/treatment equipment (2007 JASTRO Structural Survey data)

6.3 Simulator standards

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

Current treatment planning is carried out mainly by treatment planning CT. Treatment planning CT include "CT simulators" with functions including delineation of targets and at-risk organs and projection of treatment planning results (shape of irradiation field and isocenter location) onto the patient. There are also diagnostic CT units equipped with only diagnostic CT functions, and these units project only treatment planning reference points onto the patient, while a treatment planning computer performs other functions (use of diagnostic CT). When diagnostic CT is used, large-scale facilities should install dedicated equipment in the radiotherapy department, but in cases where CT is used for diagnosis as well as other functions, it is important to facilitate treatment planning by securing usage time in advance within the facility. To ensure high precision, the equipment should have a table able to lie flat.

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 use of complex irradiation technologies. Treatment planning can be accomplished by a treatment planning CT unit alone, but concurrent availability of an X-ray simulator is 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, preparation of immobilization devices, and imaging time) is approximately 30-45 minutes.

In the case of children, substantial time and skill are required, for example, to prepare immobilization devices with adequate consideration of safety, or for sedation of sick children, and twice the typical time is needed. In addition to the simulator-based treatment planning work, computer-based radiotherapy treatment planning is also performed.

In the US, treatment planning as described above is performed mainly by radiation dosimetrists, but in Japan the work is often performed by radiation oncologists, which is one factor negatively affecting the work environment of radiation oncologists. Like treatment equipment, simulators must also be upgraded or improved due to 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 from an operational perspective, 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 direct handling of the radioactive source by a technician. Brachytherapy is often an important technique in

curative radiotherapy for patients with diseases such as uterine cancer, head or neck cancer, esophageal cancer, prostate cancer, and hilar lung cancer, and its therapeutic effect and adverse reactions depend greatly on the treatment process. In Japan, brachytherapy is most commonly used for treatment of uterine cervical cancer. The 2003-2005 PCS report also showed that intracavitary brachytherapy plays an important role in the treatment process for cervical cancer. The 2003-2005 PCS demonstrated differences among different classes of facility in the type of devices used, and in the treatment process (Figures 6-2, 6-3).

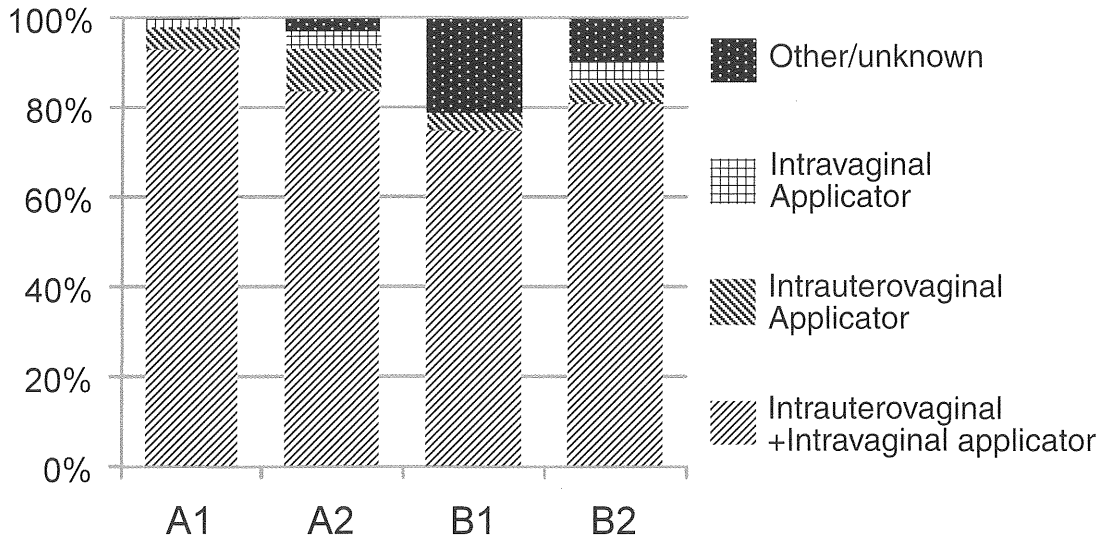

Figure 6-2 Devices used in intracavitary brachytherapy for cervical cancer, by facility (2003-2005 PCS)

Class B facilities demonstrate a pattern of low proportionate use of guideline-compliant

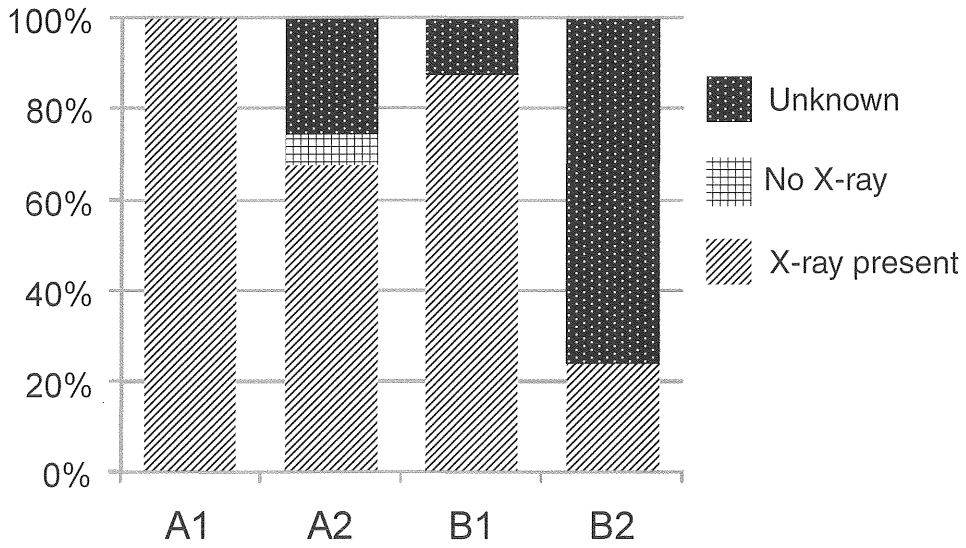

Figure 6-3 Radiographs made for intracavitary brachytherapy planning for cervical cancer, by facility (2003-2005 PCS)

Imaging of planning films is recommended for each instance of planning when brachytherapy is performed, but the data presented show that facility structure may preclude adherence to correct treatment procedures.

Iridium is the main radiation source used for treatment in recent apparatuses. Replacement of the radiation source is generally required every 3-4 months due to its short half-life of 74 days, and insurance claims are recognized for radiation source cost. Consequently, the minimum requirement to maintain operating costs under the insurance system is to perform 7 or more treatments in each replacement period, and the cost criterion for radiation source expenses is thus 21-28 patients per year. Table 6-4 presents the estimated annual mean number of intracavitary brachytherapy patients in curative treatment for cervical cancer at facilities of various classes, obtained in the 2003-2005 PCS. With a cobalt radiation source however, there is no addition guaranteeing replacement of the radiation source. And when the amortized cost of the equipment used in RALS, personnel costs for physicians and other medical staff, and periodic maintenance expense are all included, assurance of profitability is at present very uncertain, even at A1 facilities with numerous cases. Insurance point revision or other changes are needed to support operation of clinically profitable brachytherapy.

According to a JASTRO Brachytherapy Committee survey report on sealed brachytherapy, the number of brachytherapy cases is greatest in cervical cancer, but secondarily there are also many low dose-rate treatments for prostate cancer, which has an important position in brachytherapy in Japan.[70] (Figure 6-4)

Table 6-4 Estimated annual number of intracavitary irradiation cases for cervical cancer, by facility class (2003-2005 PCS)

Facility class (Facility performing intracavitary irradiation)	A1 (15/17)*	A2 (17/17)*	B1 (6/15)*	B2 (5/12)*
Estimated annual mean number of cases (Curative treatment cases only)	23.6	6.8	2.8	1.7

* (Facilities owning intracavitary irradiation equipment/facilities surveyed)

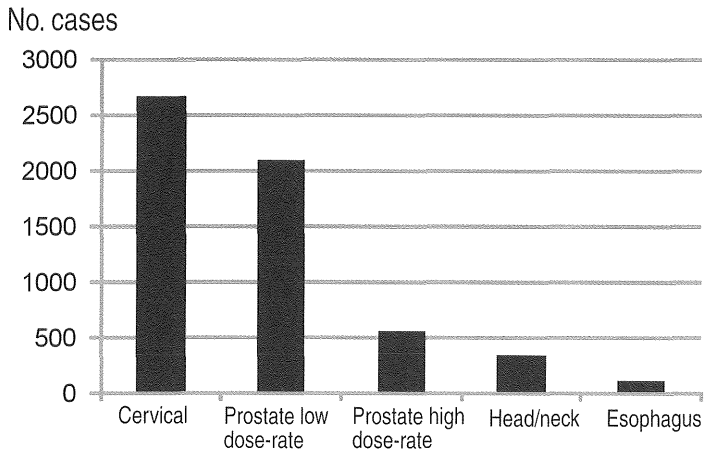

Figure 6-4 Number of brachytherapy treatments performed in Japan in 2006, by site[70]

An extremely important aspect of treatment subject to thorough quality control is effective utilization of health care 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 health care units should be considered, as discussed in Section 6.8.

Equipment

The minimum level of equipment required for reliable safety in brachytherapy is:

1) RALS source storage equipment
2) RALS source operating equipment
3) Dose monitor
4) Treatment room monitor
5) Bed unit (must also allow examination in gynecological and urological disease)
6) X-ray fluoroscopy apparatus/imaging apparatus (in principle, must be installed in the same treatment room)
7) Dedicated brachytherapy treatment planning system
8) Applicators for use in intracavitary irradiation in cervical cancer, esophageal cancer, and lung cancer
9) Applicators for use in interstitial irradiation
10) Specialized QA/QC tools

Recent years also seem to have brought a greater use of treatment planning using CT or MRI as adjunct equipment for treatment planning in intracavitary radiation, and consideration should be given to locating CT or MRI equipment in the treatment room or devising partnerships for patient transport. Treatment rooms must meet construction requirements established in health care law, 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 or source insertion equipment, if treatment will include low dose-rate interstitial irradiation by isotope permanent insertion. Equipment is also needed to allow dosimetry or radiation measurement in urine, feces, and other substances to monitor for drop out or loss of isotopic radiation sources.

Staff

For achievement of standardized treatment, the minimum level of staff required is highly experienced, trained, full-time radiotherapy physicians (Japanese Society for Therapeutic Radiology and Oncology-certified physicians required), full-time treatment technicians (Japanese Society for Therapeutic Radiology and Oncology-certified

technicians, or technicians with equivalent qualification required), and full-time nurses. Radiation source handling, loss-prevention, radiation protection, and other safety management are more complex than tasks in external irradiation therapy and require a high level of safety management, and the quality controller should be a full-time individual working exclusively in radiotherapy quality control. Persons responsible for safety quality control must also be designated clearly.

Intracavitary brachytherapy (uterus, esophagus, and bronchial tubes) requires 1.5-2.5 hours for steps including patient preparation, insertion of treatment device (requires confirmation and revision by X-ray fluoroscopy; bronchial treatment is guided by bronchial fiberscope), imaging, treatment planning, treatment, and post-therapeutic treatment. During this interval, 2 treatment physicians, 1 technician, and 1 nurse are 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 or equivalent physician 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 processes including preparation for irradiation, checking, and irradiation. Two treatment physicians (which must include one gynecologist, urologist, or other physician with specialized knowledge of the disease concerned), 1 technician, and 1 nurse are needed. Performance of low dose-rate interstitial irradiation is completed in one day, and the series of treatments requires 2-5 hours. Specifically in cases of low dose-rate interstitial irradiation for prostate cancer, detailed standards of practice, standards for removal, and other such issues are available in the "Guidelines for Safety Management in Permanent Insertion Sealed Brachytherapy of the Prostate by Seed Radiation Source" prepared jointly by the Japanese Society for Therapeutic Radiology and Oncology, the Japanese Urological Association, and the Japan Radiological Society, and these standards should be referenced.[71]

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

Other

When assurance of precision is difficult or safety is reduced for reasons such as deterioration of the apparatus, upgrading or refurbishing 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 multiple individuals.

6.5 Irradiation accessory standards

Irradiation accessories include 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, equipment for monitoring and control of respiratory motion, and devices used in sealed brachytherapy. Restraints are often needed to maintain the position of the patient and ensure precision and safety. Economizing on materials here precludes highly safe and 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. Respiratory motion monitoring devices (e.g., for stereotactic radiotherapy of the trunk)
    1) Respiratory gaiting CT/irradiation systems
    2) Simple respiratory exchange volume indicator
c. 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)
d. Devices for sealed brachytherapy
    1) Applicator for intracavitary irradiation in cervical cancer, esophageal cancer, or 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 the very least, a radiotherapy planning apparatus should allow capture of CT images used for treatment planning, independently of that for diagnostic purposes, not to mention multi-portal irradiation calculations and display multiplanar isodose distribution, as well as capability to perform three-dimensional treatment planning. Facilities performing sealed brachytherapy also need the capability for such dose calculation. 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. But this work is also 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 managed 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.

Complex irradiation procedures require greater amounts of labor and time, and the following figures are a guide to the time needed not only for treatment planning, but also for tasks aside from those using CT imaging and simulator equipment for treatment planning; i.e., tasks including checking of plan details, verification, data transfer to treatment equipment, and independent verification.

Single portal irradiation, opposing two portal irradiation:	45 minutes
Non-opposing two portal irradiation, three portal irradiation:	60 minutes
Four or more portal irradiation, moving field irradiation or conformation irradiation:	60 minutes
Intensity-modulated radiotherapy (IMRT):	Several to 10 days

Radiotherapy planning apparatuses also deteriorate, and when standardized treatment planning is difficult, or when processing capability has declined, upgrading or refurbishing is needed. Upgrading of an apparatus is essential not only for maintenance and improvement of treatment quality, but also for the safety of patients and health care providers, and from an operational perspective, for improving economic efficiency.

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

6.7 Other advanced treatment facilities and standards

Recently, remarkable progress has been made 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).

The personnel needed to perform stereotactic radiotherapy with a linac include one or more full-time physician dedicated solely to radiotherapy (limited to individuals with 5 or more years radiotherapy experience), and one or more radiotherapy technician responsible solely for radiotherapy (limited to individuals with substantial experience in radiotherapy using a linac or microtron). One or more individual responsible solely for precision control of devices involved in radiotherapy, irradiation plan verification, assistance with the irradiation plan, and other such roles (e.g., a radiotherapy or other technician*) must also be available. Here, the "radiotherapy technician responsible solely for radiotherapy" and the "individual responsible solely for precision control of devices involved in radiotherapy" must in all cases be different individuals. The following devices and equipment required for performance of such therapy must also be provided.

1) Linear accelerator
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 radiotherapy planning system
4) Equipment restricting patient movement and movement of organs within the body relative to the focus of irradiation.
5) Micro-ionization chamber or semiconductor dosimeter (including diamond dosimeter) and accompanying water phantom or water-equivalent solid phantom

Such recent 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 (HIS), radiology information system (RIS), 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 are 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 5 hours. Procedures such as bodily insertion of a metal marker used to check tumor location require 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, 2 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 treatment planning 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 dose-calculation equipment and quality control of each irradiation is needed.

The facilities standards are as follows:

1) Linear accelerator
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 radiotherapy planning system capable of inverse planning (inverse treatment planning)

4) Equipment restricting patient movement and movement of organs within the body relative to the focus of irradiation
5) Micro-ionization chamber or semiconductor dosimeter (including diamond dosimeter) and accompanying water phantom or water-equivalent solid phantom

In addition to the foregoing standards, construction of the following personnel and facilities systems is recommended.

1) Full-time physician dedicated solely to radiotherapy: A radiation oncologist with five or more years of radiotherapy experience, including 3 or more years of experience with conventional three-dimensional conformational irradiation of the head and neck/trunk regions.
2) Full-time radiotherapy technician dedicated solely to radiotherapy: An individual with five or more years of radiotherapy experience, including 1 or more years of experience with conventional three-dimensional conformational irradiation of the head and neck/trunk regions.
3) Individual responsible solely for precision control of devices involved in radiotherapy, irradiation plan verification, assistance with the irradiation plan, and other such roles (e.g., a radiotherapy or other technician): An individual with one or more years of experience in a clinical setting with precision control of devices, irradiation plan verification, assistance with irradiation plans, and other such roles. Finally, in addition to physicians and to radiotherapy technicians involved directly in exposure, the perspective of medical device safety management suggests that IMRT staff should also include one or more full-time individuals dedicated solely to functions such as precision control of devices involved in radiotherapy (radiotherapy technician or radiotherapy quality control technician) and one or more full-time medical physicist technicians.

Treatment planning also requires the use of restraints corresponding to the treatment site. Treatment planning takes 5-8 hours, depending on the site. A completed treatment plan must be examined for target validity and validity of target and at-risk organ dosage, with the findings of such examination kept in writing. Treatment plans for which findings have been determined must also be investigated in advance, and the findings of such investigation must be kept in writing or in image/table form, and such findings must be kept in a form available for external audit or other such request for disclosure as needed.

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 the methods should also be shared as a regional and national asset (see Section 6.8).

(Chikako Yamauchi)

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

Progress in radiotherapy technologies has brought high-precision radiotherapy[1] into general clinical use in place of conventional two-dimensional radiotherapy. The introduction of such technologies typically requires expensive initial investment, as well as maintenance costs. In addition to the staff needed for treatment delivery, personnel with a high level of specialized knowledge and experience are also necessary to create treatment plans and for quality assurance activities supporting precision. As also discussed in Section 5.2, it is not efficient for all facilities performing radiotherapy to acquire such facilities and human resources. As also discussed in Section 6.2, a treatment facility should ideally own a minimum of two interchangeable treatment apparatuses in order to avoid radiotherapy downtime due to periodic inspection or upgrading of treatment equipment, which is nevertheless impractical for small-scale facilities. Similarly, 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 acquire a dual-energy linac irradiation apparatus.

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 beyond home environs to receive treatment. In contrast, there is little need for high-precision radiotherapy in palliative and symptomatic treatment, but the overall condition of patients is poor, and treatment at a facility near the home environs is desirable.

Given the foregoing issues, radiotherapy facilities should stratify on the basis of their equipment and human resources, form groups based on health care regions, and pursue optimization of regional health care functions at such a group level (Table 6-5).[2] Specifically, a desirable structure has a number of general facilities, as well as a core center (university hospital, cancer center, etc.) which is devoted exclusively to high-precision radiotherapy, owns several treatment units, including the most advanced units, and has sufficient staff. These facilities would refer patients to each other depending on their condition and would complement the functions of the other in cases such as downtime due to equipment upgrading, thereby fulfilling the functions needed in regional health care (Figure 6-5). Refer to Table 6-5 below for details on equipment specifications and the optimal number of units required per health care region.

(Michihide Mitsumori)

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

[2] Free-standing facilities owning only high-precision treatment equipment and performing treatment regardless of its indication for health maintenance have also appeared in recent years. Though such facilities do not fall into the health care system categories considered in this report, the quality assurance standards discussed in this report do of course apply. The same is true with respect to particle beam facilities (proton beam, heavy ion beam) currently in operation or planned.

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)

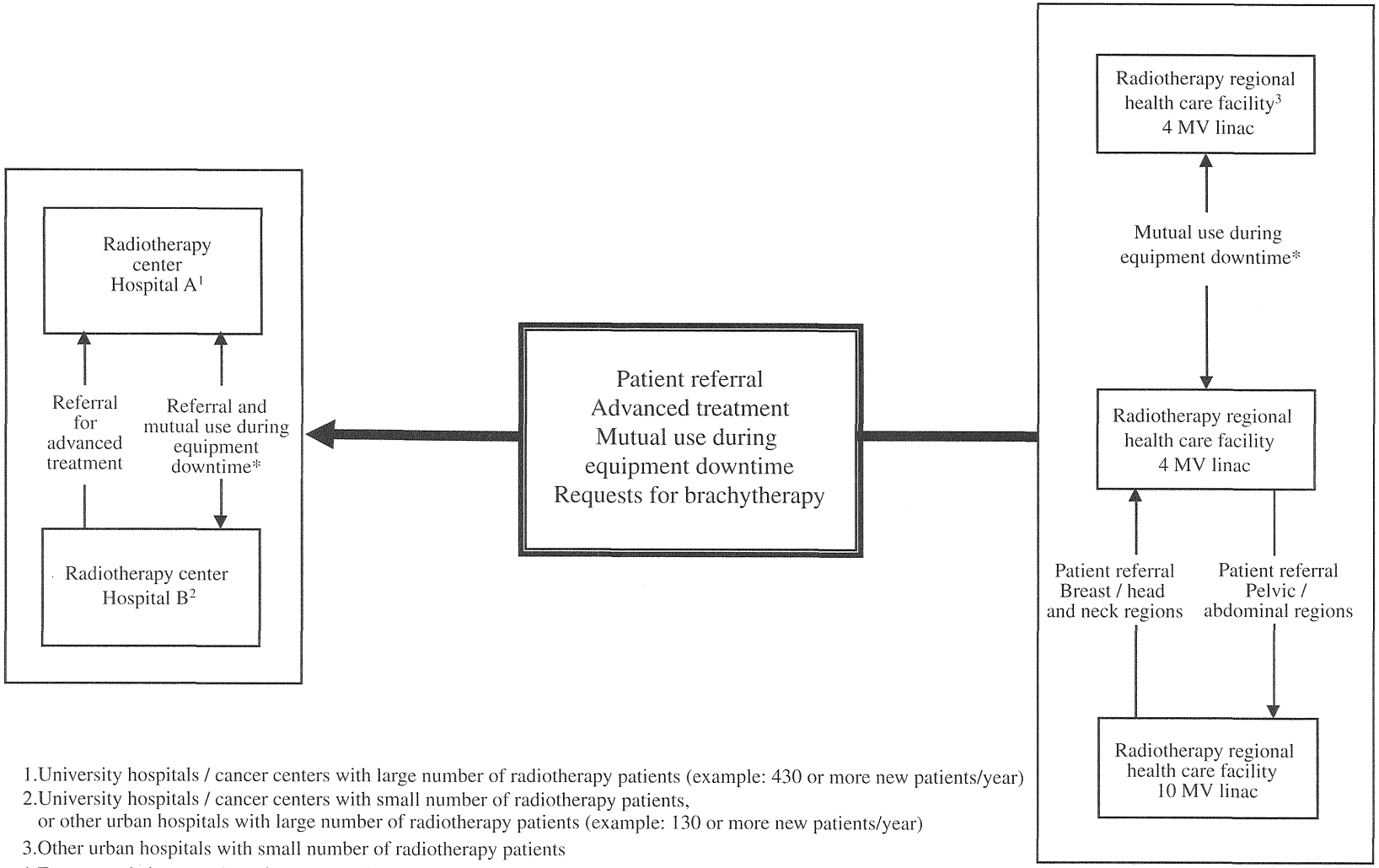
Type of facility	Role	Human resources (example)	Technical resources (example)	Equipment standard (example)
Radiotherapy regional health care facility	Implementation of standard treatments[1] Implementation of palliative/symptomatic treatment	1 or more full-time physician 1 or more full-time treatment technician 1 or more full-time treatment nurse	1 or more single or dual energy linac CT or X-ray simulator 3-D treatment planning unit	1 facility or more per primary health care region
Radiotherapy center facility B	In addition to the above, implementation of advanced treatments[2]	2 or more full-time physicians 1 or more JASTRO-certified physician 3 or more full-time treatment technicians 1 or more medical physicist/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 or more per secondary health care region
Radiotherapy center facility A	In addition to the above, Development and introduction of advanced treatments[3] Establishment of guidelines for generalization of advanced treatments Technical support for group-affiliate hospitals Education	3 or more JASTRO-certified physicians 5 or more full-time treatment technicians 1 or more medical physicist/radiotherapy quality controller 3 or more full-time treatment nurses	2 or more dual energy linacs High dose rate RALS treatment apparatus CT simulator Three-dimensional treatment planning apparatus	1 facility or more per tertiary health care region

[1]Example as of end-2008: whole breast irradiation as breast-conserving treatment, 60Gy antero-posterior opposing portal radiation for lung cancer with complications, 66Gy curative irradiation for cancer of the larynx.

[2]Example as of end-2008: 3DCRT (70Gy or higher) for prostate cancer, 3DCRT (multiportal irradiation) for other organs, SRS, SRT for brain tumors, ^{125}I seed permanent implantation for prostate cancer

[3]Example as of end-2008: IMRT for prostate cancer, stereotactic radiotherapy for lung cancer (SRT), and image-guided radiotherapy in these therapies incorporating treatment position correction, movement tracking, or other such features through on-board imaging

Figure 6-5 Shared use of equipment and patient referral among facilities in regional treatment (example).



1.University hospitals / cancer centers with large number of radiotherapy patients (example: 430 or more new patients/year)
2.University hospitals / cancer centers with small number of radiotherapy patients,
or other urban hospitals with large number of radiotherapy patients (example: 130 or more new patients/year)
3.Other urban hospitals with small number of radiotherapy patients
* E.g., extended suspension of treatment due to upgrading of equipment

7. Radiotherapy Quality Assurance

7.1 Medical records related to radiotherapy

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 Act and the Medical Practitioners Act, the Radiology Technicians Act, and the relevant implementing regulations. Table 7-1 presents the basic information to be noted in medical records.

Table 7-1 Basic information noted in medical records

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

This basic information must be shared as such in the medical institution where the radiotherapy department is affiliated. When performance of radiotherapy is examined, the information shown in Table 7-2 is then recorded.

Table 7-2 Information required when examining performance of radiotherapy

1) Disease targeted by radiotherapy, stage of disease, histologic type, site of involvement, 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)
5) Tumor marker or endocrine receptor information
6) Diagnostic imaging report, surgical records, pathology reports, summary of inpatient care, and correspondence with referring physician
7) Prior radiotherapy records
8) Comprehensive treatment plan (curative, palliative, etc.), including surgery and chemotherapy, etc.
9) Object of radiotherapy and selection rationale
10) Concomitant therapy (surgery, chemotherapy, endocrine therapy, etc.) and specific details, if any
11) Explanation and informed consent-related information
12) Individual target volumes and basis for establishment, prescribed dose, fractionation, planned treatment days, and irradiation method
13) Clinical trial or protocol treatment details, if any

In cases where 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. In cases where there can be more than one stage classification for the target disease, the classification used should be clarified. For many malignant tumors, if a measurable lesion is present, the size of the lesion is used to assess the therapeutic effect; the target lesion to be measured should thus be defined, measured, and recorded before starting the treatment. Because the general condition of the patient and/or tumor status change over time, the object and the method of radiotherapy also change accordingly, and a treatment plan should not be made solely on the basis of findings in examination at the medical facility. The object and the method of radiotherapy must be determined by re-evaluating patient and tumor condition when execution of radiotherapy treatment is studied. Note, however, that general condition (performance status) remains an important factor in determining the therapeutic plan and prognosis and because third-party assessment at a later stage is difficult, documentation by the examining physician is essential.

At every radiotherapy session, the irradiation site, radiation dosage, and irradiation method are described as legally required, and the name of the instructing physician and the radiotherapy technician performing treatment are recorded. Periodic examination should be carried out throughout radiotherapy, and the medical records must document such items as progress, including cumulative dosage; physical findings; lesion site evaluations; occurrence, details, and treatment for any adverse response; and further plans. Section 20 of the Medical Practitioners Act also states that examination by a physician is required on days when treatment is performed. Specific details of any change in target volume, irradiation method, irradiation dosage, or other such parameters during treatment are also noted. Information such as treatment progress, records of examination and prescription by the attending physician, evaluations of therapeutic effect and adverse events, and reports for diagnostic imaging during treatment must be entered in medical records as appropriate, and this information must be shared within the medical institution, to include 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 fractionations, and initial and final treatment dates. Information on therapeutic effect and adverse events must also be noted. Section 24 of the Medical Practitioners Act states that the term for retention of medical records is 5 years, but inasmuch as the treatment benefits and the effect of adverse events can extend throughout patient lifetime,[72] radiotherapy-related records should be stored on a semi-permanent basis.

Many tasks in the radiotherapy department such as drafting of treatment plans, data entry in treatment equipment, and performance checking take place out of patient view. Vast amounts of information, including parameters for controlling equipment, are generated while performing tasks related to preparation and performance of radiotherapy. Although it is not necessary to record all of this information in the medical records, such information should be made accessible for review at any time, at least within the department, just as in the case of medical records. As the precision of

radiotherapy has improved, departmental information systems have come to play an important role, thus creating a need to construct and manage a radiotherapy-related information system separate from that for medical records.

Recently, introduction of and migration to electronic medical records (electronic charts) at health care sites has been promoted throughout Japan. Introduction of electronic chart systems, which guarantee authenticity, legibility, and preservation, also has the potential to bring significant advantages to management and sharing of information within radiotherapy departments. The advantage of electronic charts is also substantial for continual updating and sharing of information relating to progress, and not only target volume setting, radiation dose distribution graphs, and dose prescription. Electronic charts also allow the radiotherapy department to immediately check the patient's treatment status in each treating department and ward, and facilitate reflection of such information in treatment planning and execution. When electronic medical charts and information management systems in the radiotherapy department are linked, the information to be shared between the systems must be clarified, and the content and quality of information exchanged between the radiotherapy department and electronic medical charts must be assured. The department must therefore include a manager thoroughly familiar with information management for network construction and administration of both information systems.

Medical care databases linked with electronic medical charts are under development, and the hope is not limited to recording treatment information for individual patients; it is also to link within departments and within and between facilities for databases covering medical departments, diseases and organs, academic societies, and regional cancer registration, in order to accumulate and analyze information on diseases and treatments.

7.2 Explanation and Informed Consent

When radiotherapy is initiated, the medical condition and planned treatment must be explained to the actual patient in detail, and consent regarding implementation (informed consent) must be obtained just as when performing surgeries and other courses of medical treatment. In cases where the patient is not in a condition capable of voluntary decision-making, consent must be obtained from a guardian or other such individual in advance. Radiotherapy departments must establish specific procedures for explanation and acquisition of informed consent in advance. Preparation of pamphlets, videos, or other audiovisual explanatory materials is useful for communicating information on radiotherapy and imparting understanding. Explanation on and acquisition of consent related to radiotherapy should be handled by the radiation oncologist responsible for treatment, with the aid of the medical team. Table 7-3 lists some of the information to be explained to patients.

Table 7-3 Items to be explained to patient at the initiation of radiotherapy

1) Name of disease, cause of the medical condition and current symptoms, stage of disease, etc.
2) Treatment considered standard for the aforementioned circumstances and the role of radiotherapy in same
3) Anticipated effects: Potential for cure, life-extending benefit, symptomatic relief, etc.
4) Radiotherapy method, radiation dose, number of fractionations, treatment interval, etc.
5) Potential adverse events and treatment for same
6) Alternative treatments: Advantages and disadvantages in selection of alterative treatments
7) Anticipated events if treatment is not performed
8) Precautions during performance of radiotherapy and requests by the medical institution
9) Treatment results or other treatment-related information may be presented in conferences or in the literature
10) Name and other personal information is kept strictly confidential, and utmost efforts are made for protection of human rights
11) Questions may be asked freely
12) A second opinion other than that of the attending physician may be sought inside or outside the medical institution
13) There is freedom not to select the treatment(s) explained, and the ability to withdraw consent at any time
14) Name and contact information of the physician providing the foregoing explanation

This information is explained in detail before consent to performance of the planned treatment is obtained. If individual medical institutions have designated specific forms for explanation and informed consent, such forms are used. Moreover, if treatment is performed as part of a clinical study or advanced treatment, such fact must be explained,

and informed consent must be obtained per protocol. Details explained are provided to the patient in writing, with sufficient time given for examination and decision-making. The details of any special requests made by the patient and the response by the medical institution are also documented. When consent to performance of treatment is obtained, signing of the informed consent form by the physician providing the explanation and the patient receiving the treatment are judged to represent that confirmation of consent was obtained. Copies of the explanatory documents and consent documents are provided to the patient, and the originals are attached to the medical records. If electronic medical charts are used in the medical institution, the originals are converted to electronic documents and made accessible as needed. At the start of radiotherapy, it must be confirmed that the consent documents have been created properly.

7.3 Information to be communicated

At the start of radiotherapy, in addition to medical particulars such as the name of the disease, medical condition, and other treatment details, the patient must be given an explanation of various items including the schedule up to completion of the treatment, a rough estimate of the overall medical costs, medical cost payment and other paperwork, and instructions for contacting the radiotherapy department. It is also stated that these items may change due to various circumstances. The radiology department should prepare in advance a pamphlet noting such particulars, a record card to be brought to daily treatment sessions, and other materials given to the patient. Providing the patient with a record card stamped or signed when treatment is performed is useful for keeping count of the number of treatments performed. Other details to confirm include a mobile telephone number or other means to allow the radiotherapy department to contact the patient quickly. It is important to confirm telephone numbers of family members or other persons serving as emergency contacts. The patient should also be asked in advance about the preferred method of contact.

7.4 Treatment planning data

Data used in radiotherapy planning (RTP) must all be readily 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 methods, and accessories; and imaging data. The data in Table 7-5 represent auxiliary items, and Table 7-6 presents items noted during three-dimensional treatment planning.

Table 7-4 Essential treatment planning data

A) Irradiation parameters
   1) Name and signature of treatment planner (physicians, radiotherapy technicians, quality controllers, medical physicists) data checker
   2) Irradiation site
   3) Irradiation method, irradiation field, irradiation energy
   4) Calculation method (algorithm), dose reference point
   5) Prescribed dose, total dose
   6) Single dose, number of doses, number of treatments per day
   7) Number of exposures per day, fractionation (number of treatments per week)
   8) Planned treatment interval
   9) Number and size of each 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 method, and accessories
   1) Equipment used
   2) Patient position during treatment (supine, prone, lateral, sitting, etc.)
   3) Treatment accessories (shell, ring, immobilization device, etc.)
C) Data saved as images
   1) Digitally reconstructed radiographs (DRR) from CT simulator, or positioning radiograms (simulation films)
   2) Verification film (liniacgraphy/portal film), EPID images
   3) Conebeam-CT images

Table 7-5 Auxiliary treatment planning data

1) Irradiation goal (curative, symptomatic, palliative, etc.)
2) Body sketch
3) Maximum dose at each irradiation field
4) Daily dose at specific sites (note depth or percentage of area)
5) Diagnostic imaging results (planning CT, etc.)
6) Required body measurements
7) Photographs of treatment site
8) Facial photograph of patient.

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

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

Whenever possible, image data should be stored as digital data, by common protocol (e.g., DICOM format), and capability for network transmission to other facilities is preferable from the standpoint of protecting personal information.[73-75]

7.5 Treatment data

The core of patient radiotherapy records is 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 complete, and Table 7-9 shows data recorded when irradiation is completed in a three-dimensional treatment plan.

Table 7-7 Mandatory data 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 portal 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 (OTT)

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 (OAR)

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

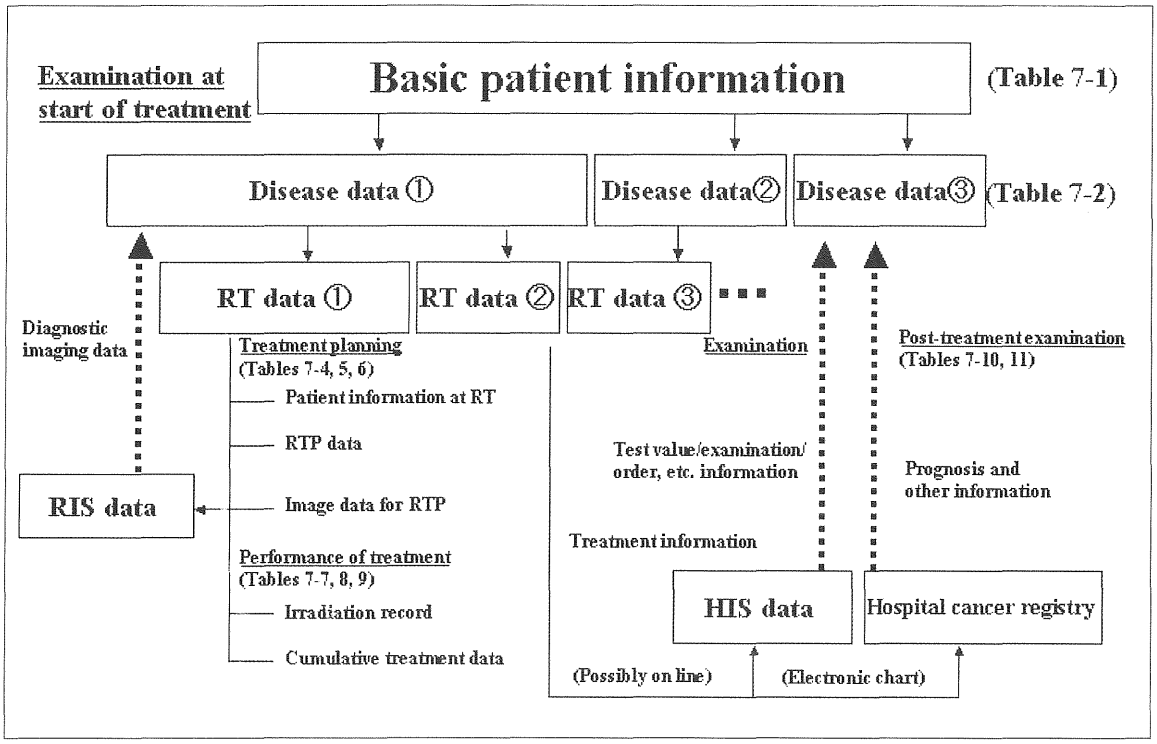


Figure 7-1 Radiotherapy (RT) database process.

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

Patients should continue in follow-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) Patient general condition
3) Assessment of therapeutic effect
4) Tests and dates forming basis of assessment
5) Adverse events
6) If recurrence: site, date, basis
7) Other treatment information, family physician information

Table 7-11 Information noted at death

1) Date of death
2) Cause of death (as death from primary cancer / death from other cancer / death from other 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 illness/site
2) Therapeutic effect by stage of cancer
3) Therapeutic effect by histological type
4) Evaluation of adverse events
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

Series of treatment-related data should be stored at all treatment facilities and updated continually. The use of a database with automatic search capability facilitates management of these records. Though adoption of HIS and/or electronic medical chart systems has grown substantially in recent times, it is important to link such systems to treatment systems and databases in a coordinated fashion. Electronic medical charts and treatment systems should be constructed at the outset to allow cross-cutting use of treatment-related data across patients and treatment modalities, not simply for individual patients. To provide treatment information, prognostic information, or other feedback, links should also be established to any other available databases of treating departments, hospital cancer registries, or regional cancer registries. Figure 7-2 presents a flowchart of this process, and Table 7-13 presents items pertaining to treatment-related data. These data must be tabulated for production of statistics.

Table 7-13 Treatment-related statistical 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 positionings
5) Number of treatment plans
6) Total number of treatments
7) Number of treatment portals
8) Number of countable immobilization and other devices, by applicable insurance type (e.g., opposing, non-opposing, simple, multi-portal)
9) Number of stereotactic irradiations, number of IMRT treatments, total-body irradiation
10) Operating time of treatment equipment, irradiation time
11) Type and number of sealed brachytherapy treatments (interstitial, intracavitary, superficial, other)
12) Number of examinations for post-treatment follow-up

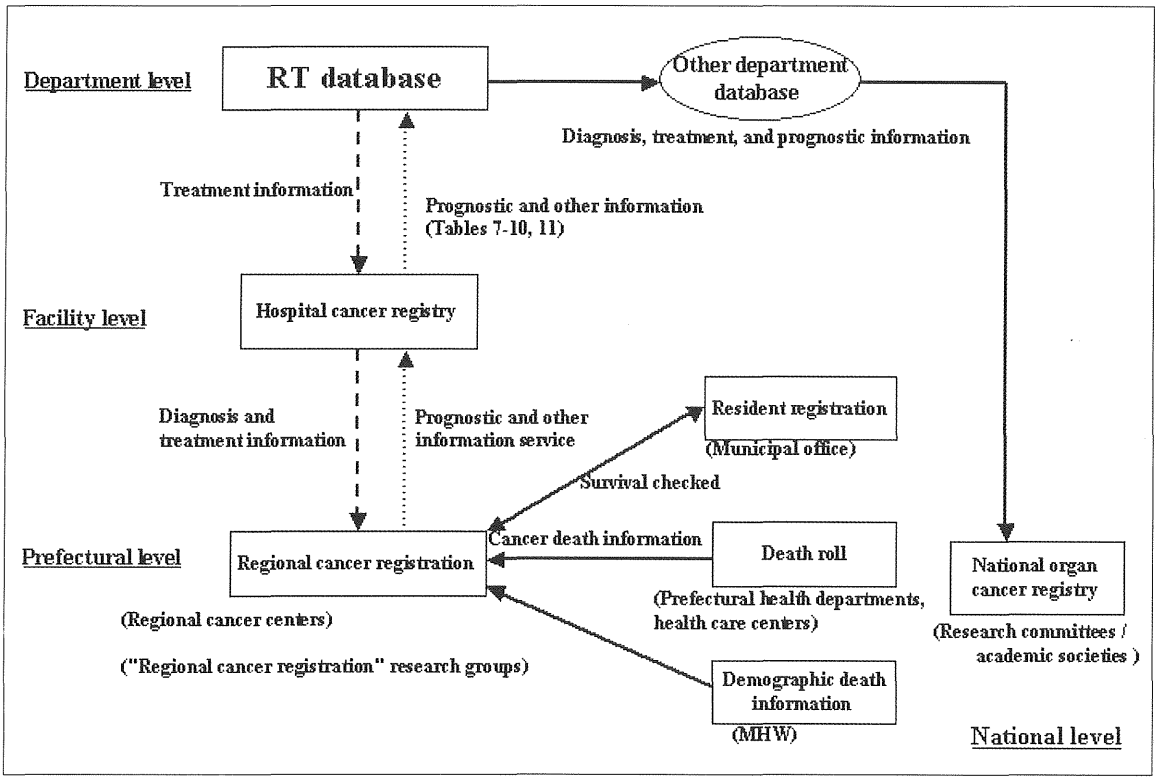


Figure 7-2 Relationship between radiotherapy (RT) databases and cancer registration/other databases

Tabulated results and summaries for one to several years' worth of these statistical data should be analyzed. This work is also needed as an analysis of departmental operations. All data should be prepared with a premise of potential disclosure to patients at any time.

7.8 Evaluation of improved operating efficiency

Each facility with a treating department should have a program to monitor its operations. Indices of improved operating efficiency like those shown in Table 7-14 should be monitored.

Table 7-14 Items related to improved operating efficiency

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 intake to examination or completion of treatment
5)	Number of patients treated per unit time (throughput)

These patient flow parameters must be evaluated to improve the operating efficiency of the treating department

7.9 Integrating Health Care Enterprise Radiation Oncology (IHE-RO)

Activities for "Integrating the Health care Enterprise" (IHE) have also expanded into the radiotherapy field. The objective of IHE is global development of information linkages through extension of medical information systems.

In radiotherapy, IHE Radiation Oncology (IHE-RO) proposes integrated profiles (operational workflow) for radiotherapy departments. More specifically, the objectives are to standardize operational workflows; adopt common formats, including standardized medical databases usable at different facilities; and create guidelines for information exchange.

In Japan, the IHE-J-RO initiative began in 2006 with the participation of JRS, JASTRO, JSRT, JIRA, and 11 private vendors. The initiative is examining consolidation of radiotherapy workflows and standardization of treatment information and data in Japan. It is also working toward sharing of hospital information system (HIS) and radiotherapy treatment management system (TMS) information, easier use of usage of image information, and adoption of the HL7, DICOM, and DICOM-RT standards.

With the initiative of IHE-RO, common formats among information systems, common protocols among different facilities, and integrated profiles will be established in the near future. In the future, facilities themselves must also be fully aware of their compliance status with IHE-RO guidelines and work toward introduction of systems, including those for devices and RIS-RO, and treatment /examination databases.

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are standard times for ensuring high accuracy. In addition, quality assurance and quality control services performed by a medical physicist are also added to insurance ratings.[84]

In recent years, participation of a medical physicist or other technician has become a requirement for insurance coverage of IMRT and stereotactic radiotherapy even in Japan. Medical physics departments (quality control departments) are now also being established throughout the country, but the number is still limited. Medical physicists assuring such quality are needed to achieve not only high-precision treatment, but also standardized radiotherapy, and medical physics departments (quality control departments) should be established in all hospitals, as in the US.

7.10.3 Quality control programs

Programs to achieve accuracy within a target range of error in all radiotherapy processes, including the goal of accident prevention, must be created, monitored, and implemented by medical physicists (radiotherapy quality controllers). Appropriate response must also be made when incidents occur. Quality control includes the items shown in Table 7-15. Table 7-16 lists references for each item. Based on these items, medical physicists should independently create quality control programs suited to the conditions at individual facilities. Medical physicists in particular should also understand the discrepancies or limitations of accuracy arising thereby and should play a research-oriented role in developing new treatment technologies. The quality control items are classified grossly into those for normal external irradiation, high-precision external irradiation, and brachytherapy.

Normal external irradiation

When introducing new treatment equipment, treatment planning equipment, CT simulators, or any other devices, proper intake testing and commissioning must be carried out to understand the limits of equipment precision. Quality control must also be performed periodically thereafter to ensure that limits of precision are not exceeded. Particularly when introducing treatment planning equipment, a medical physicist (quality controller) should be involved because errors over a long period of time can lead to large-scale accidents affecting many patients.

High-precision external irradiation

In IMRT, IGRT, and stereotactic radiotherapy, the exposure field is narrower and results in a steeper dosage distribution than in normal external irradiation, and higher precision is thus required. Assuming that the quality required for normal external irradiation is assured, commissioning and periodic inspection must also be performed for multi-leaf collimator or other small exposure fields unique to IMRT and IGRT, low MU beam output characteristics, and image quality evaluation. Moreover, in case of

IMRT, absolute dosage and dose distribution must be verified for each patient individually.

Brachytherapy

Brachytherapy involves a large dosage administered at one time and should entail the same level of caution as in high-precision external irradiation. Quality must be assured for intake testing and commissioning of equipment and treatment planning equipment, and for radiation sources themselves. Brachytherapy also requires real-time response, which is an error-prone environment. Treatment planning must be checked at each treatment by a medical physicist (quality controller).

In Europe and the US, the newest technologies have contributed to safety assurance by raising precision. Medical physics departments (quality control departments) are essential for Japan to achieve the same, and these units will play an important role in future development of radiotherapy in Japan. Thus, medical physics (quality control) departments must be treated appropriately and afforded personnel and facilities.

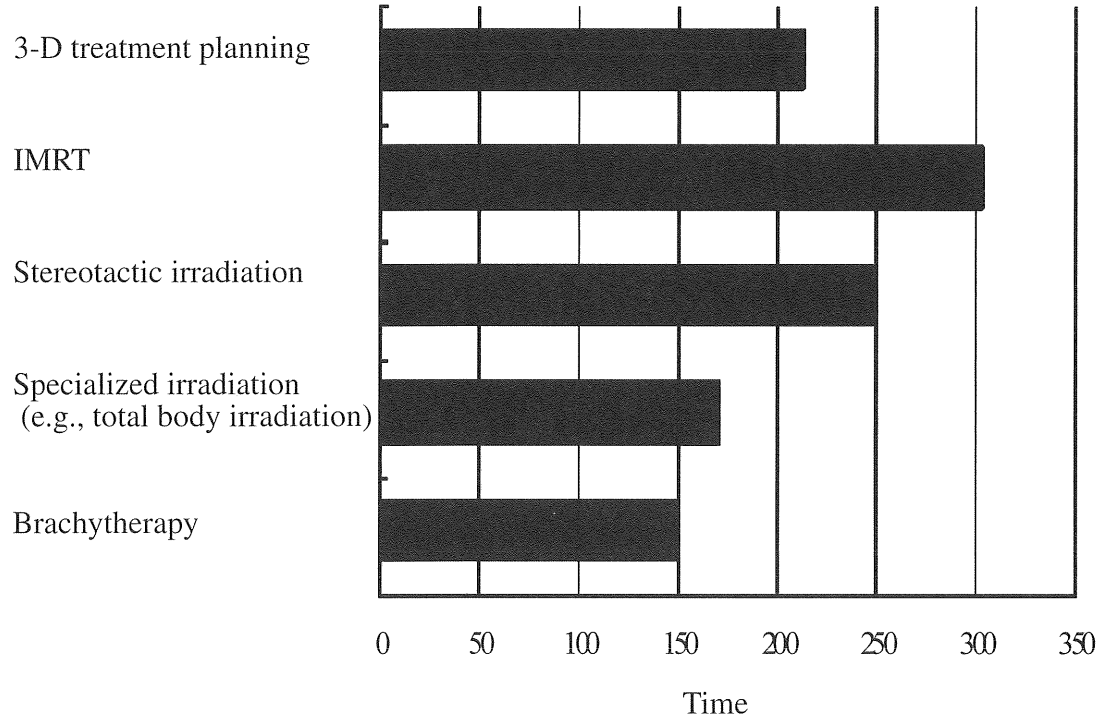

Figure 7-5 Time spent on initial commissioning in the US (Median values, 2003)

Table 7-15 Items included in quality control

Intake testing and commissioning for all treatment equipment, treatment planning equipment, and simulators
Periodic QA for all treatment equipment, treatment planning equipment, and simulators
QA for radiotherapy source ordering and storage, and for sealed brachytherapy applicators
Treatment planning and review
Dosimetry, calibration, and monitoring of beam characteristics
Design of optimal patient immobilization devices, assurance of safe function, and monitoring of production
Safety surveys of patients and staff
Physical consultation for radiation oncologists and radiotherapy technicians
Research and education allowing quality improvement and high-precision treatment
Creation and revision of quality control programs

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

Description	Reference
1. Comprehensive QA	AAPM TG40[85]
2. Normal external irradiation	
Linear accelerators	APM TG 45[86]
Multi-leaf collimators	AAPM TG 50[87]
Treatment planning equipment	AAPM TG53[88] MHLW Grant-in-Aid for Scientific Research, Ikeda Group (AAPM TG 53, translation)[52] ESTRO QA Booklet No. 7[80] Japan Society of Medical Physics, Topical Research Committee, Task Group 01[89]
Heterogeneity correction	AAPM TG 65[78]
General external irradiation	Maintenance and Administration Manual for External Irradiation Treatment[90]
CT simulators	AAPM TG 66[91]
Electronic Portal Imaging Devices (EPID)	AAPM TG 58[92]
Radiation dosimetry	Standard Measurement Method 01 for Absorbed Dose in External Radiotherapy[59]
3. High-precision external irradiation	
Intensity-modulated radiotherapy	AAPM IMRT subcommittee[93] Intensity-Modulated Radiotherapy (IMRT) Guidelines[94] Guidelines for Assuring Mechanical Precision in Intensity-Modulated Radiotherapy by Multileaf Collimator (Ver. 1)[95]
Stereotactic brain radiosurgery	AAPM TG 42[96] Standard Radiation Dosimetry Method for Stereotactic Radiosurgery[58]
Stereotactic body radiation therapy	Guidelines for Stereotactic Body Radiation Therapy[97] Detailed Guidelines and Irradiation Manual for Stereotactic Body Radiation Therapy[98]
4. Brachytherapy	
RALS	AAPM TG 59[99]
Permanent implantation	AAPM TG 64[100]
5. Other	
Instrument measurement	ICRU report 47[101]
Radiation protection	ICRU report 20[102]

(Yutaka Takahashi)

7.11 Response to inadvertent exposure

In clinical settings, preventive measures against errors and incidents are of utmost importance. Guidelines and/or manuals on safety management within the hospital must be readily available at all times in easily accessible locations, and personnel must be thoroughly informed on prevention and initial response.

Typical incidents i.e., inadvertent exposure that may occur during radiotherapy include excess radiation dosage, too little radiation dosage, and mistakes in field of exposure.

1) Rapid response to the patient and family is the highest priority immediately after any occurrence of a major accident. The response must be calm and forthright, and depending on patient condition, several other staff should be called to provide appropriate emergency treatment.
2) The conditions of inadvertent exposure must be understood objectively, specifically, how much radiation was administered, at what site of the patient, and at what exposure field? Table 7-17 lists factors and data related to treatment that must be determined when inadvertent exposure occurs. When handling accidents, differences from prescription must be evaluated accurately by comparison with treatment-related documents and irradiation records, logs etc. for the date concerned. Data at the time of such inadvertent exposures/accidents must also be documented in detail in the medical records.
3) Identify the level of incident. Incident levels vary widely, from minor mistakes to severe medical accidents. Identify the level by referring to the classification of radio therapeutic accidents by AAPM-TG35[103] (Appendix Table 1) and determine further actions to be taken according to hospital rules.
4) Report the occurrence of inadvertent exposure to all parties concerned, investigate the causes, and inform the patient and family on progress.

   A) Report to supervisor

   Use contact networks specified in hospital safety instruction manuals, etc. to report promptly to related departments and supervisors. Then, as needed, organize an accident investigation committee and deliberate on the matter.

   B) Explanation to the patient/family

   When the first stage of incident handling is completed, explain the matter to the patient, family, or other such parties in good faith and as promptly as possible, and respond forthrightly to requests from the family.

   If results from deliberation in the committee reveal errors by the hospital, supervisor must apologize frankly. However, in many cases it is not clear at the time of occurrence whether errors were made or if the patient was in any way affected, and the circumstances of the accident should be explained carefully and honestly.

5) Notify police and report to related administrative bodies

The Pharmaceutical Affairs Law has been revised, and it is now obligatory for medical staff to report and/or announce any errors in medical practice. The level of accident and damage determine where to report the incident. In the US, the criterion for mandatory dose reporting as life-threatening damage (class IA) is a 25% or greater overdose, but clear standards have not yet been established in Japan.

A) Notification to police

If a fatal case occurs, notify the jurisdictional police station promptly, in accordance with Section 21 of the Medical Practitioners Law (Obligation to report suspicious death to jurisdictional police station within 24 hours). Even if it is difficult to judge whether the case concerned constitutes a medical accident, notification must still be considered from the perspective of a highly transparent response by the hospital.

B) Reporting to health care center and related administrative bodies

If a serious case occurs, report promptly to the health care center and related administrative bodies and arrange for a site survey and on-site investigation. These measures are also important for determining the causes of inadvertent irradiation and preventing recurrence. The US Nuclear Regulatory Commission (NRC) regulations in 10 CFR Part 35 can also serve as a reference for medical accident reporting standards in cases of brachytherapy using radioactive isotopes.[104] These regulations provide standards and methods for required reporting and other such information (Appendix Table 2).[105]

Announcing the accident

A) Announcement to mass media

Once reporting to related departments and offices is complete, the medical institution itself must announce the facts of any medical accident to society accurately and rapidly. This is because a basic principle of health care is to uphold respect for life and the dignity of individuals, and medical institutions are highly societal and public in nature. Assured transparency in the handling of medical accidents and forthright responses to patients, families, and society will ultimately effect a good outcome for both sides.

B) Respecting patient, family, and other privacy

When announcing an accident, the privacy of the patient and family must be respected to the greatest extent possible. Before any announcement, there must be thorough discussion with the patient and family.

C) Consideration of parties involved in accidents

Parties involved in medical accidents tend to feel remorse. Particularly if a person has caused serious consequences, it is difficult to maintain a normal mental state. In responses to the patient or family, or the bereaved, and in press coverage or other such venues, the parties involved must be given sufficient consideration.

Table 7-17 Factors/data on treatment related to inadvertent irradiation

Radiotherapy in general

1) Patient switching: Irradiation based on wrong patient data
2) Treatment site switching: Irradiation based on wrong site data
3) Therapeutic dosage: Excessive irradiation/under-irradiation

External irradiation

1) Treatment field error: Size, collimator orientation, use/non-use or wrong position of MLC or lead block
2) Gantry angle error
3) Error in half position of half beam: Presence of overlap/excessive gap
4) Treatment energy error
5) Wedge: Orientation/angle error
6) Compensating material: Error in position/ orientation/ size

Sealed brachytherapy

1) Radiation source damage and leakage, source drop / source loss
2) Exposure exceeding radiation dosage limit
3) Improper evaluation of source intensity (radioactivity)
4) Error in estimation of treatment volume/prescribed dosage
5) Source implanted outside of target
6) LDR: Too many/too few containers
7) HDR: Applicator damage or inappropriate position/wrong order
8) HDR: Wrong/inappropriate source placement position/time

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8. Standards for Staff Required in Radiotherapy

Provision of best treatment for patients requires continuous readiness of a treatment facility with a thoroughly knowledgeable staff, including a radiation oncologist, and equipment prepared on the basis of a well-designed QA/QC program. Appropriate radiotherapy requires multiple facilities, multiple radiation oncologists, various required staff, and cooperative relationships with other facilities maintained through public or private relations.

8.1 Radiation Oncologists

As discussed in Section 5.1, a radiation oncologist is a physician whose work is primarily radiotherapy-based treatment for cancer patients, or education and research in radiation oncology.

8.2 Radiotherapy Technicians and Radiotherapy Technologists

A radiotherapy technician has thorough knowledge of treatment equipment and other radiotherapy-related systems and works together with radiotherapy quality controllers to provide appropriate radiotherapy and exercise precision control. This work requires an ability to perform individual therapeutic processes properly, carry out thorough verification, and create and store work records. When performing treatment, the safety of the patient must be fully assured. This work is carried out in concert with radiation oncologists, full-time radiotherapy nurses, and other radiotherapy staff to provide appropriate radiotherapy to patients.

Japan has a radiotherapy technologist certification system that serves as a qualification denoting specialization for technicians involved in radiotherapy. The Japan Professional Accreditation Board for Radiotherapy Technologists certifies radiotherapy technologists, candidates for which are nationally-qualified radiotherapy technicians with substantial expertise in radiotherapy. The board conducted its first qualification test in August 2005 and, as of October 1, 2008, 673 radiotherapy technologists have been accredited (the board has also instituted the title of Radiotherapy Technologist Assistant as a qualification to assist radiotherapy technologists).

8.3 Radiotherapy Quality Controllers

Radiotherapy quality controllers are accredited by the Japanese Organization of Radiotherapy Quality Management. Their duties include responsibility for tasks related to quality control of radiotherapy, monitoring of general hospital work from a quality control perspective, communication of contacts received and instructions, and proposal of improvements to managing departments. The work of the controller also includes quality improvement initiatives at individual sites (not simply "quality control" in a narrow sense, a wide range of activities intended to improve the "quality of radiotherapy" itself).[106]

As of July 15, 2009, 593 controllers were accredited.

8.4 Medical Physicists

The Japan Society of Medical Physics defines a medical physicist as a specialist in medical physics who contributes to appropriate medical treatment through a knowledge of radiation treatment. During treatment, the medical physicist cooperates with physicians to optimize the treatment plan and collaborates with radiotherapists and radiotherapy quality controllers to control and guarantee the quality of treatment equipment. Medical physicists also engage in radiotherapy-related medical physics research and development. Medical physicists check that spatial precision and quantitative precision relating to radiation dosage absorbed by the patient remain within the clinically required range and assure that treatment is given as prescribed by physicians. Their duties include the following:

1) Optimization (Note) and evaluation of radiation dose distribution in the treatment plan
2) Planning, execution, and evaluation of acceptance testing and commissioning for treatment equipment and related devices
3) Planning, execution, and evaluation of quality control/assurance for treatment equipment and related devices
4) Verification and evaluation of treatment precision
5) Research and development contributing to the development of radiotherapy
6) Medical physics-related education
7) Explanation to patients in response to radiotherapy-related medical physics questions

Medical physicists in Japan are accredited by the Japanese Board for Medical Physicists; as of July 18, 2009, 418 medical physicists were accredited.

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. Radiotherapy nurses must also be assigned solely to a radiotherapy department as specialist radiotherapy nurses.

As health care fields become increasingly advanced and specialized, a qualification and accreditation system was established by consensus among nurses to expand nursing care and improve the quality of nursing. Today, the Japanese Nursing Association grants qualification and accreditation as a Professional Nurse, Certified Nurse, or Certified Nurse Administrator to nursing staff who are accredited by an educational institution and have received specialized education/training. In the field of

radiotherapy, one can become a cancer nurse (professional nurse) or a cancer radiotherapy nurse (certified nurse), and the certified nurse educational standard curriculum sets the following goals.

1) Foster the capacity to provide individual and holistic nursing practice affording cancer radiotherapy patients and their families safe, secure, and continuous treatment.
2) Use the specialized knowledge and practical abilities of cancer radiotherapy nurses to foster capacity for guidance and consultation with nursing staff, and cooperation with allied professions.
3) Foster the capacity for autonomous improvement of clinical practice in cancer radiotherapy nursing.

Instruction began in 2009, and the first certified nurses will graduate in 2010.

Certified radiotherapy nurses must interface with ward nursing staff to manage hospital patients and with outpatient physicians and nurses to manage outpatients. These nurses understand the potential for various adverse events resulting from individual patient condition, treatment site, and treatment method and are able to provide information and comprehensible explanations that patients and their families need. They provide appropriate explanation of cautions and solutions for routine activities before and after treatment, and they provide or make reference to literature and devices needed. They work with radiation oncologists to observe and follow changes in patient condition, and they convey information deemed required to other medical staff.

8.6 Receptionists

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 (guidelines for radiotherapy accident prevention state that checking through multiple forms or representations for different departments is better than uniform checking procedures for all departments and avoids incorrect responses resulting from familiarity on the part of the individuals checked). Administrative staff monitor the movements of waiting patients and ensure that they do not enter radiation control areas or other restricted-entry areas. Administrative staff monitor patient safety and coordinate with radiation oncologists, radiotherapy technicians, or full-time radiotherapy nurses as appropriate if problems are suspected.

8.7 Radiotherapy Information Managers

These individuals manage and control radiotherapy-related records and have knowledge of how to protect personal information appropriately. Radiotherapy information managers should complete information management training designated by the facility. Radiotherapy information managers manage radiotherapy-related statistics and various other information required in reports. Radiotherapy information managers collect and manage information required for treatment and research, subject to appropriate regulations.

8.8 Other Necessary Radiotherapy Team Personnel

Systems are needed to respond to radiotherapy staff requests; make assistance from social workers, nutritionists, physiotherapists, and other specialized professionals available at all times; and provide information or skills needed by patients.

Construction, plumbing, electrical, and other technical teams must have a thorough knowledge of the structure and layout of the radiotherapy department, and supervisors able to respond to problems must be designated in advance.

Table 8 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 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 systems Or add 1 for each 400 patients per year
Radiotherapy technician	2 for each 1 treatment system Staffing also possible when using treatment planning CT or simulator	Add 1 if the number of patients per treatment system exceeds 30 Staffing also possible when using treatment planning CT or simulator
(Certified) Radiotherapy technologist	1 per facility Add 1 for each 120 patients per year	Staffing of 1 radiotherapy technologist per treatment system also possible
Full-time radiotherapy nurse	1 per facility	Add 1 for each 300 patients per year
Receptionist	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)

Recent progress in technology has lead 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 radiotherapy 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 lead to an environment allowing frequent use of multiportal irradiation (a treatment method applying radiation from multiple directions). While this technique increases the amount 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.

Irradiation technologies recently and newly covered by insurance include (1) stereotactic radiotherapy by linear accelerators, (2) permanent implantation of small sealed radiation source for prostate cancer, and (3) Intensity Modulated Radiation Therapy (IMRT). These technologies have been covered in the medical fee tariff from 2004, 2006, and 2008, respectively. Table 9-1 shows the transition in the main radiotherapy medical fee.

Table 9-1 Transition in main radiotherapy fee

Item	1976	1986	1992	1996	2000	2002	2004	2006	2008
Radiotherapy control fee	-	1,000	2,000						
Simple				2,600	2,700	2,700	2,700	2,700	*2700
(Change)									(2,700)
Complex				3,000	3,100	3,100	3,100	3,100	*3,100
(Change)									(3,100)
Special				3,300	3,400	3,400	3,400	3,400	*3,400
(Change)									(3,400)
Intensity Modulated Radiation Therapy (IMRT)									*5,000
(Change)									(5,000)
Radiation Therapy Specialist Point (with facility standard)	-	-	-	-	-	330	330	330	330
External radiation therapy fee									
High-dose telecobalt 60 irradiation	190	210	550	700	*700	*700	*700	*700	*500
					(210)	(210)	(210)	(210)	(150)
High-energy radiotherapy	240	320	800	1,000	*1,100				
					(330)				
Simple						*930	*930	*930	*930
						(310)	(310)	(310)	(310)
Complex						*1,240	*1,240	*1,240	*1,240
						(410)	(410)	(410)	(410)
Special						*1,580	*1,580	*1,580	*1,580
						(520)	(520)	(520)	(520)
IMRT									*3,000
									(1,000)
Intraoperative radiation point	-	1,000	3,000	3,000	3,000	3,000	3,000	3,000	3,000
Fixation device point	-	-	-	1,000	1,000	1,000	1,000	1,000	1,000
Stereotactic radiotherapy by gamma knife	-	-	-	70,000	63,000	63,000	63,000	50,000	50,000
Stereotactic radiotherapy by linear accelerator (head and neck)	-	-	-	-	63,000	63,000	63,000	63,000	63,000
Stereotactic radiotherapy by linear accelerator (trunk)							63,000	63,000	63,000
Total-body irradiation	-	5,000	10,000	10,000	10,000	10,000	10,000	10,000	10,000
Brachytherapy fee									
Endocavitary irradiation (iridium/new type cobalt)	-	-	-	3,000	3,000	3,000	3,000	3,000	3,000
Endocavitary irradiation (old type cobalt)	-	-	-	-	-	-	-	-	1,000
Endocavitary irradiation (others)	-	700	1,000	1,500	1,500	1,500	1,500	1,500	1,500
Interstitial irradiation (permanent implantation for prostate cancer)	-	-	-	-	-	-	-	48,600	48,600
Interstitial irradiation (iridium/new type cobalt)	-	-	-	7,500	7,500	7,500	7,500	7,500	7,500
Interstitial irradiation (others)		5,000	5,000	6,000	6,000	6,000	6,000	6,000	6,000
Radiotherapy ward management point	-	100	200	500	500	500	500	500	500
Ambulatory radiotherapy patient point	-	-	-	-	-	-	-	-	100
Medical device safety management fee	-	-	-	-	-	-	-	-	1,000
Cancer medical care base hospital point (with standard)	-	-	-	-	-	-	-	-	400

* indicates the first time, ( ) indicates the second time.

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 (in FY 2002). 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. This policy has become noticeable after April 2007 when the Cancer Control Act was enacted.

The "Cancer Control Act" positioned radiotherapy as a highly important form of cancer treatment. Under such reimbursement of medical fees policy, facilities with a sufficient number of patients undergoing radiotherapy and radiotherapy structure (treatment equipment and staff to operate and manage) have become possible to receive medical service fees that allow them to collect expensive equipment investments. Still, the current medical service fees are far from sufficient to allow timely introduction of treatment equipment in order to stay at the cutting edge of the fast-evolving radiotherapy technologies.

The more that radiotherapy technologies advance, the more important quality control becomes to guarantee patient safety and reliable treatment. In addition to radiation oncologists and radiotherapy technicians, there has always been an essential need for specialist staff to manage treatment devices and perform other functions such as calculation, verification, and validation of patient radiation dosages in the radiotherapy team. Hospitals have barely been managed with the current imbursement of medical fees only because physicians work in dual roles, although the majority of hospitals are understaffed in this respect On the other hand, the Japanese Society for Therapeutic Radiology and Oncology requested dedicated quality controlling works for radiotherapy and compensations for it on medical service fees and secure consideration on medical service fees for quality control of radiotherapy known as "Safety device control fee 2" from 2008, however, this is far from enough. It is quite clear that it is highly difficult to secure black figures under the current medical service fee system, according to given current estimates of labor costs etc. by assuming the number of staff, including medical physicians, that can secure quality of radiotherapy desired by patients and take sufficient safety into consideration. Moreover, the introduction of a remote radiotherapy support system, which allows handling of multiple radiation treatment facilities to compensate for the role of lacking radiation oncologists, is a required for equalization of the quality of radiotherapy. This technology was made possible by the development of information technology (IT), but there is no reimbursement of medical fees corresponding to this technology. In other words, no economical foundation guaranteeing employment of specialized staff and application of cutting-edge IT is provided by the current medical service fee system.

For the equalization of radiotherapy, which plays an important role in the cancer medical care stated in the "Cancer Control Act, " to be achieved at the earliest possible stage, it is necessary to reinforce the facilities and equipment of hospitals. By necessity, centering on radiotherapy has been progressively performed. On the other hand, the right and wrong of providing radiotherapy with limited staff and equipment in small-scale facilities must be discussed. Considering the fact that many cancer patients are elderly people, for whom securing hospitals close to them is desirable, advocating a full phase-out of small-scale facilities is not desirable. Moreover, as far as the current cancer treatment is a combined modality therapy that appropriately combines surgery, radiotherapy, and chemotherapy, centering on radiotherapy only may invite inefficiencies for overall cancer treatment as well; thorough discussion of and measures on well-balanced intensification of overall cancer treatment are essential. At this

moment, it is important to consider the medical service fees and establish systems to allow small- to medium-scale facilities to continue providing radiotherapy.

It is all patients who enjoy the benefit of radiotherapy, regardless of region, group of diseases, or therapeutic strategy. In order to achieve and hold wishes of these patients, establishment and upgrading of facility standards and medical service fee framework must continually be revised according to the radiotherapeutical structure. Moreover, as methodologies of radiotherapy and advancement of information engineering are always changing, supported by the development of science and technology. The medical service fee systems have to be continuously revised in line with the technological advancements as well.

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 been increased funding for basic radiotherapy costs, establishment/increase 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.

Reference to the appended tables on the final pages of this report shows that radiotherapy departments require expensive initial capital investments, and consideration of their annual revenues shows clearly that further reform of the medical payment system is needed. As stated previously, the current medical payment system presents a large barrier to stable employment of "radiotherapy quality controllers", "medical physicists", "and specialist radiotherapy nurses" responsible for establishing radiotherapy quality and assuring safety (cf. "Expense for staff required in radiotherapy treatment"). And in reality, land and building expenses additional to capital investment are needed, and within 10 years, upgrading to new treatment systems capable of providing new treatment technologies will be needed. The numbers of patients, devices, and personnel used for these calculations were also calculated with figures greater than the basic configurations suggested in this report.

Further revisions to the medical payment system are needed to ensure that radiotherapy based on appropriate structures operates soundly, without constraints on management.

(Hiroshi Onishi, Yasuo Ashino)

10. Conclusions

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, 26% 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 four 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, 18-4), and the standards herein are primarily the work of PCS research group members and research collaborators.

(Teruki Teshima)

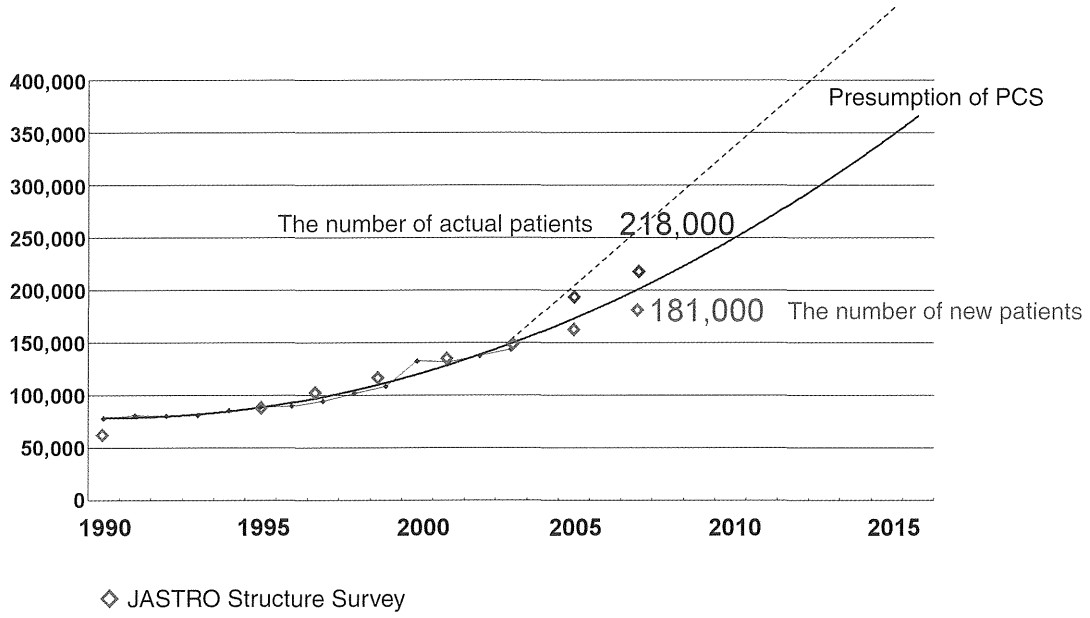

Figure 10-1 Estimate of increase in demand for radiotherapy in Japan, based on statistical correction of annual change in the number of new patients per year at PCS survey facilities supported in part by the Grant-in-Aid for Cancer Research (No. 10-17, 14-6, 18-4) from the Ministry of Health, Labour 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.

- 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 event

  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 of a target outline and an at-risk organ outline viewed apparently from the direction of a beam source.

- 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

  Treatment using a radioactive isotope sealed for radiotherapeutic use. Divisible into high dose-rate and low dose-rate brachytherapy.

- Cancer

  Any type of malignant neoplasm, including carcinomas and sarcomas.

- Carbon ion beam

  Ionization of carbon atoms to produce heavy ion particles and acceleration of such heavy ions.

- Carcinoma

  An epithelial, malignant tumor.

- Cesium-137

  Radioisotope with a half-life of 30 years. Emits 660keV γ-rays; used particularly for procedures such as intracavitary and interstitial radiation.

- Clinical target volume (CTV)

  The volume of an area to be subjected to radiation, including an area of suspected infiltration peripheral to cancer discernible visually or on 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.

- Compensating filter

  A device which compensates for irregular body surfaces to create a uniform radiation dose distribution within the body, and which is placed on the surface of the body.

  Conebeam CT

  A device performing rotational imaging by irradiation with an X-ray beam on a cone (cone beam) to produce precise three-dimensional data during irradiation.

- Conformal radiotherapy

  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 (Clinical path)

  Standard treatment plan. Technique in which treatment and nursing procedures are standardized to achieve cost reduction and greater efficiency and uniformity of care.

- CT simulator

  A CT apparatus also having a radiotherapy planning function; functions include projection onto patients of X-ray and CT planning results; used in three-dimensional radiotherapy planning.

- Cure

  Complete induced healing, or natural healing.

- 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.

- EBM (evidence based medicine)

  Medical treatment grounded in a scientific basis.

- Electric portal imaging device (EPID)

  A device passing a treatment beam into the body and using this beam itself to create an image for accurate spatial alignment and monitoring of movement during treatment.

- 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 (1.8-2 Gy) in a standard total course of treatment.

- Hypofractionation

  An irradiation method using a single dosage greater than the standard daily dosage (1.8-2 Gy).

- I-125 (Iodine-125)

  Used in permanent implantation brachytherapy for prostate cancer. In Japan, treatment using I-125 has been pursued since 2003.

- Image-guided radiotherapy (IGRT)

  Use of patient image information (e.g. radiographs) immediately before or during irradiation to confirm correct irradiation based on location of the tumor itself, bone, or other markers; additionally, high-precision treatment entailing quantitative determination of improper position and correction of table position based on image information.

- Informed consent

  In determination of a treatment plan or method, obtainment of consent after thorough explanation to the patient/family.

- Intensity-modulated radiotherapy (IMRT)

  A treatment method in which the intensity of radiation dosage in a single irradiated field is modulated, and beam intensity is changed to achieve a dose distribution conforming to tumor contour.

- Interstitial radiotherapy

  Treatment method in which a sealed radiation source is applied interstitially within a specialized applicator positioned in a predetermined pattern.

- Intraoperative irradiation

  A method for irradiating a focus under direct visualization during surgery.

- Inverse planning

  An inverted treatment plan in which dose and administration in tumors and normal tissue are determined by computer optimization using three-dimensional diagnostic imaging equipment in order to achieve a 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.

- Iridium-192

  Radioactive isotope with a half-life of 74 days. Emits 300-600keV γ-rays. Used in intracavitary irradiation.

- Linac (linear accelerator)

  Linear electron accelerator using electromagnetic microwaves to generate a high-energy x-ray or electron beam.

- Linacgraphy

  Check film used to verify an irradiated region.

- 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 1 MV.

- Microtron

  External irradiation equipment which uses a circular accelerator to rotate electrons in a circular path in a uniform DC field.

- 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 distinctive sites on cancer cells are attacked. A molecular targeted drug is one produced for this purpose.

- Multi-leaf collimator (MLC)

  A collimator incorporating multiple, mobile blocks designed to produce an irregular irradiation field conforming to the shape of a target to be irradiated.

- Oncology

  The academic field relating to tumors.

- Organ at risk (OAR)

  Organ readily affected by radiation into normal tissue and requiring care during performance of radiotherapy (e.g., spinal cord, lungs, kidneys, small intestine).

- Overall treatment time (OTT)
  Number of days elapsed from initial day of treatment to final day of treatment.
- Palliative radiotherapy
  Radiotherapy with an objective of the longest-possible tumor control in cases where cure is not anticipated.
- Planning target volume (PTV)
  Region of irradiation necessary to administer a sufficient radiation dosage (95% or more of prescribed dosage) to the clinical target volume.
- Proton beam
  Accelerated protons, the particles that form a hydrogen nucleus or a hydrogen positive ion.
- QA (Quality assurance)
  Quality assurance.
- QC (Quality control)
  Quality control.
- QOL (Quality of life)
  A scale for measuring the extent to which a patient is able to pursue routine activities with a sense of fulfillment and satisfaction.
- 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. Expressed in units of gray (Gy).
- Radiation oncologist
  Physician specialized in tumors, and particularly treatment of tumors by radiation.
- Radiotherapy
  Therapeutic technique for treating tumorous illnesses and some non-tumorous illnesses with ionizing radiation.
- Radiotherapy quality controller
  Individual performing systems quality control and quality assurance only on radiotherapy equipment in order to improve the precision of radiotherapy.
- Remote after loading system (RALS)
  Equipment for carrying out remote high dose-rate 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

  Evaluation and explanation by another individual.

- Simulation

  In radiotherapy, several processes for designing an actual radiotherapy method.

- Stereotactic irradiation (STI)

  Therapeutic method involving accurate three-dimensional localization of targets and single, high-dose, short-duration irradiation of small foci. Includes stereotactic radiotherapy (SRT) involving fractioned irradiation, and stereotactic radiosurgery (SRS) effected by a single irradiation.

- Symptomatic radiotherapy

  Radiotherapy to alleviate symptoms caused by disease.

- Total body irradiation

  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 simulating an external radiotherapy system and geometric parameters.

(Kazuhiko Ogawa)

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Appended Table 1 (Classification of radiotherapy accidents 1)

Class I Possibility of damages

Type A

Cases where irradiation overdosage may be directly responsible for damages threatening the patient's life

Determined by the irradiated organ and radiation dosage (single dose and total dosage). Guidelines include a case where a radiation dosage exceeding 25% of the tolerance dosage of the critical organ is irradiated.

Type B

Cases where irradiation overdosage may cause damages, although they are not threatening to the patient's life. Cases where a total dosage corresponding to 5 to 25% of the tolerance dosage of each organ is irradiated are used as guidelines, and are classified into the following three sub-categories. Note that irradiation of underdosage is also classified as Type B.

B-1 Cases where severe adverse events can occur considering the total dosage and treated site

B-2 Cases where not severe but adverse events can occur considering the total dosage and treated site

B-3 Cases where occurrence of adverse events was considered possible, but the patient was considered to have died due to the primary disease before occurrence of the adverse events

Class II Little risk of damages

(Note: Cases other than class I where there is little risk that accidents causes health problems)

Appended Table 2 Medical event report standards by the Nuclear Regulatory Commission (NRC) [3)]

A) When a radiation dosage different from the dispensed dosage is irradiated, and an effective dosage exceeding 0.05 Sv (5 rem), or an equivalent dosage absorbed by organ tissues exceeding 0.5 Sv (50 rem), or an equivalent dosage absorbed by skin exceeding 0.5 Sv (50 rem) is irradiated, and:

(1) the total dosage deviates from the dispensed dosage by 20% or more

(2) the total amount of medicine deviates from the dispensed amount by 20% or more

(3) the single dosage deviates from the dispensed dosage by 50% or more in fractionation of exposure

B) When the effective dosage exceeds 0.05 Sv (5 rem), the equivalent dosage absorbed by organ tissues exceeds 0.5 Sv (50 rem), or the equivalent dosage absorbed by skin exceeds 0.5 Sv (50 rem), and:

(1) a wrong radioactive isotope is used

(2) the dosage is dispensed in a wrong path

(3)the dosage is dispensed on a wrong individual or human study target

(4)the dosage is dispensed using a wrong treatment method

(5)there are sealed radiation source leaks

C) the equivalent dosage absorbed by skin and/or organ tissues other than the treated site is 0.5 Sv (50 rem) or more, or reaches 50% of the planned dispensed dosage or more (not including cases where permanent implant source is implanted at the right site but moves to a site other than the treated site, however)

Appendix table

Calculation example of revenue and expenditure in case 100 patients are treated by radiation in one year according to the medical service fee in 2008

Annual revenue (unit: yen)	Estimated total medical service fee in case 100 patients are treated by high-energy radiation in one year			
Radiotherapy operative procedure and medical service fee	Radiotherapy operative procedure and number of patients	Fee per patient	Number of patients	Total fee
M001-3-A-(1). External radiation fee (930 points)	[1] Single field/two opposing fields	¥93, 000	45	¥4, 185, 000
Immobilizer point (1,000 points)	(45 patients)	¥10, 000	9	¥90, 000
M000-1. Radiotherapy management fee (2,700 points)	(45 patients are treated by basic treatment	¥27, 000	45	¥1, 215, 000
Radiation therapy specialist point (330 points)	procedure 5 times a week, for 2 weeks	¥3, 300	0	¥0
Patient referral point (100 points)	(10 times in total)	¥10, 000	14	¥140, 000
B011-4-.2. Medical equipment safety management fee (1,000 points)		¥10, 000	0	¥0
M001-3-B-(1). External radiation fee (310 points)	Single field/two opposing fields (second site) (9 patients)	¥31, 000	9	¥279, 000
M001-3-A-(2). External radiation fee (1,240 points)	[2] Two/three non-opposing fields	¥310, 000	35	¥10, 850, 000
Immobilizer point (1,000 points)	(35 patients)	¥10, 000	10	¥100, 000
M000-2. Radiotherapy management fee (3,100 points)	(35 patients are treated by basic treatment	¥31, 000	66	¥2, 046, 000
(2nd) radiotherapy management fee (3,100 points)	procedure 5 times a week, for 5 weeks	¥31, 000	7	¥217, 000
Radiation therapy specialist point (330 points)	(25 times in total)	¥3, 300	0	¥0
Patient referral point (100 points)		¥25, 000	11	¥275, 000
B011-4-.2. Medical equipment safety management fee (1,000 points)		¥10, 000	0	¥0
M001-3-A-(3). External radiation fee (1,580 points)	[3] Four fields or more/physical exercise,	¥474, 000	20	¥9, 480, 000
Immobilizer point (1,000 points)	conformation therapy (20 patients)	¥10, 000	7	¥70, 000
M000-3. Radiotherapy management fee (3,400 points)	(20 patients are treated by basic treatment	¥67, 000	20	¥1, 340, 000
(2nd) radiotherapy management fee (3,400 points)	procedure 5 times a week, for 6 weeks	¥34, 000	6	¥204, 000
Radiation therapy specialist point (330 points)	(30 times in total)	¥3, 300	0	¥0
Patient referral point (100 points)		¥1, 000	0	¥0
B011-4-.2. Medical equipment safety management fee (1,000 points)		¥10, 000	0	¥0
M001-4-A. External radiation fee (3,000 points)	[4] Intensity Modulated Radiation	¥900, 000	0	¥0
Immobilizer point (1,000 points)	Therapy (IMRT) (0 patients)	¥10, 000	0	¥0
M000-4. Radiotherapy management fee (5,000 points)		¥50, 000	0	¥0
(2nd) radiotherapy management fee (5,000 points)		¥50, 000	0	¥0
Radiation therapy specialist point (330 points)		¥3, 300	0	¥0
Patient referral point (100 points)		¥1, 000	0	¥0
B011-4-.2. Medical equipment safety management fee (1,000 points)		¥10, 000	0	¥0
M001-3 Stereotactic radiosurgery fee (linear accelerator) (63,000 points)	[5] Stereotactic radiosurgery (0 patients)	¥630, 000	0	¥0
M002 Total-body irradiation fee (for the purpose of bone-marrow transplant) (10,000 points)	[6] Total-body irradiation (0 patients)	¥100, 000	0	¥0
	Annual total number of patients: 100	Annual total revenue		¥30, 491, 000

(Unit: yen)

	Estimated total cost in case 100 patients are treated by radiation in one year		
Main equipment required to perform radiotherapy	Equipment name	Quantity	Estimated procurement cost
	Radiation therapy equipment: single-energy (with MLC)	1	¥170, 000, 000
	CT equipment for radiotherapy	No	
	X-ray simulator	1	
	Radiotherapy planning equipment	1 set	
	Irradiation accessories	Yes	
	QC/QA measurement instrument (dosimeter, water phantom etc.)	Yes	
	IT network	No	

Note: Fixed-installment depreciation of the equipment over a 6-year period requires allocation of annual costs of 25.5 million yen.

	Job type	Number of staff	Estimated annual cost
Staff required to perform radiotherapy	Radiation oncologist	1	¥18, 000, 000
	Radiotherapy technician	1	
	Radiotherapy quality controller: 1 dedicated controller	No	
	Medical physician	No	
	Dedicated nurse for radiation treatment	No	
Annual maintenance costof radio therapy equipment, electricity, water etc.	Equipment name	Quantity	Annual maintenance cost etc.
	Radio therapy equipment: dual-energy (allowing SRS and IMRT with MLC)	1	¥6, 800, 000 (The cost is generated from the second year.)
	CT equipment for radiotherapy	1	
	X-ray simulator	1	
	Radiotherapy planning equipment	2 sets	
	Irradiation accessories	Yes	
	QC/QA measurement instrument (dosimeter, water phantom etc.)	Yes	
	IT network	Yes	
	Electricity, water etc.		¥1, 000, 000
	Reserve for consumables etc.		¥1, 000, 000

	Estimated revenue and expenditure in case 200 patients are treated by radiation in one year, for 10 years 1st year			
(Unit: yen)	1st year	2nd to 6th years	7th to 10th years	Total of 10 years
Revenue	¥30, 491, 000	¥152, 455, 000	¥121, 964, 000	¥304, 910, 000
Expenditure	¥45, 500, 000	¥261, 500, 000	¥107, 200, 000	¥414, 200, 000
Balance	¥-15, 009, 000	¥-109, 045, 000	¥14, 764, 000	¥-109, 290, 000

(The depreciation is allocated equally over 6 years, setting the residue value to 10%. The maintenance cost is allocated assuming generation over the 2nd to 10th years.)

Appendix table

Calculation example of revenue and expenditure in case 200 patients are treated by radiation in one year according to the medical service fee in 2008

Annual revenue (unit: yen) Radiotherapy operative procedure and medical service fee		Estimated total medical service fee in case 100 patients are treated by high-energy radiation in one year Radiotherapy operative procedure and number of patients	Fee per patient	Number of patients	Total fee
M001-3-A-(1).	External radiation fee (930 points)	[1] Single field/two opposing fields	¥93, 000	85	¥7, 905, 000
	Immobilizer point (1,000 points)	(85 patients)	¥10, 000	17	¥170, 000
M000-1.	Radiotherapy management fee (2,700 points)	(85 patients are treated by basic treatment	¥27, 000	85	¥2, 295, 000
	Radiation therapy specialist point (330 points)	procedure 5 times a week, for 2 weeks	¥3, 300	85	¥280, 500
	Patient referral point (100 points)	(10 times in total)	¥10, 000	26	¥260, 000
B011-4-.2.	Medical equipment safety management fee (1,000 points)		¥10, 000	85	¥850, 000
M001-3-B-(1).	External radiation fee (310 points)	Single field/two opposing fields (second site) (17 patients)	¥31, 000	17	¥527, 000
M001-3-A-(2).	External radiation fee (1,240 points)	[2] Two/three non-opposing fields	¥310, 000	66	¥20, 460, 000
	Immobilizer point (1,000 points)	(66 patients)	¥10, 000	19	¥190, 000
M000-2.	Radiotherapy management fee (3,100 points)	(66 patients are treated by basic treatment	¥31, 000	66	¥2, 046, 000
	(2nd) radiotherapy management fee (3,100 points)	procedure 5 times a week, for 5 weeks	¥31, 000	14	¥434, 000
	Radiation therapy specialist point (330 points)	(25 times in total)	¥3, 300	66	¥217, 800
	Patient referral point (100 points)		¥25, 000	20	¥500, 000
B011-4-.2.	Medical equipment safety management fee (1,000 points)		¥10, 000	66	¥660, 000
M001-3-A-(3).	External radiation fee (1,580 points)	[3] Four fields or more/physical exercise,	¥474, 000	37	¥17, 538, 000
	Immobilizer point (1,000 points)	conformation therapy (37 patients)	¥10, 000	14	¥140, 000
M000-3.	Radiotherapy management fee (3,400 points)	(37 patients are treated by basic treatment	¥67, 000	37	¥2, 479, 000
	(2nd) radiotherapy management fee (3,400 points)	procedure 5 times a week, for 6 weeks	¥34, 000	12	¥408, 000
	Radiation therapy specialist point (330 points)	(30 times in total)	¥3, 300	37	¥122, 100
	Patient referral point (100 points)		¥1, 000	0	¥0
B011-4-.2.	Medical equipment safety management fee (1,000 points)		¥10, 000	37	¥370, 000
M001-4-A.	External radiation fee (3,000 points)	[4] Intensity Modulated Radiation	¥900, 000	0	¥0
	Immobilizer point (1,000 points)	Therapy (IMRT) (0 patients)	¥10, 000	0	¥0
M000-4.	Radiotherapy management fee (5,000 points)		¥50, 000	0	¥0
	(2nd) radiotherapy management fee (5,000 points)		¥50, 000	0	¥0
	Radiation therapy specialist point (330 points)		¥3, 300	0	¥0
	Patient referral point (100 points)		¥1, 000	0	¥0
B011-4-.2.	Medical equipment safety management fee (1,000 points)		¥10, 000	0	¥0
M001-3	Stereotactic radiosurgery fee (linear accelerator) (63,000 points)	[5] Stereotactic radiosurgery (12 patients)	¥630, 000	12	¥7, 560, 000
M002	Total-body irradiation fee (for the purpose of bone-marrow transplant) (10,000 points)	[6] Total-body irradiation (0 patients)	¥100, 000	0	¥0
		Annual total number of patients: 200	Annual total revenue		¥65, 412, 400

(Unit: yen)

Estimated total cost in case 200 patients are treated by radiation in one year

	Equipment name	Quantity	Estimated procurement cost
Main equipment required to perform radiotherapy	Radiation therapy equipment: dual-energy (allowing SRS with MLC)	1	¥300, 000, 000
	CT equipment for radiotherapy	No	
	X-ray simulator	1 set	
	Radiotherapy planning equipment	Yes	
	Irradiation accessories	Yes	
	QC/QA measurement instrument (dosimeter, water phantom etc.)	Yes	
	IT network		

Note: Fixed-installment depreciation of the equipment over a 6-year period requires allocation of annual costs of 45 million yen.

	Job type	Number of staff	Estimated annual cost
Staff required to perform radiotherapy	Radiation oncologist (certified physician)	1	¥35, 000, 000
	Radiotherapy technician	1	
	Radiotherapy quality controller: 1 dedicated controller	No	
	Medical physician	No	
	Dedicated nurse for radiation treatment	No	
	Equipment name	**Quantity**	**Annual maintenance cost etc.**
Annual maintenance cost of radio therapy equipment, electricity, water etc.	Radio therapy equipment: dual-energy (allowing SRS with MLC)	1	¥12, 000, 000 (The cost is generated from the second year.)
	CT equipment for radiotherapy	1	
	X-ray simulator	No	
	Radiotherapy planning equipment	1 set	
	Irradiation accessories	Yes	
	QC/QA measurement instrument (dosimeter, water phantom etc.)	Yes	
	IT network	Yes	
	Electricity, water etc.		¥1, 500, 000
	Reserve for consumables etc.		¥2, 000, 000

(Unit: yen)

Estimated revenue and expenditure in case 200 patients are treated by radiation in one year, for 10 years

	1st year	2nd to 6th years	7th to 10th years	Total of 10 years
Revenue	¥65, 412, 400	¥327, 062, 000	¥261, 649, 600	¥654, 124, 000
Expenditure	¥83, 500, 000	¥477, 500, 000	¥202, 000, 000	¥763, 000, 000
Balance	¥-18, 087, 600	¥-150, 438, 000	¥59, 649, 600	¥-108, 876, 000

(The depreciation is allocated equally over 6 years, setting the residue value to 10%. The maintenance cost is allocated assuming generation over the 2nd to 10th years.)

Appendix table

Calculation example of revenue and expenditure in case 300 patients are treated by radiation in one year according to the medical service fee in 2008

Annual revenue (unit: yen)		Estimated total medical service fee in case 300 patients are treated by high-energy radiation in one year			
Radiotherapy operative procedure and medical service fee		Radiotherapy operative procedure and number of patients	Fee per patient	Number of patients	Total fee
M001-3-A-(1).	External radiation fee (930 points)	[1] Single field/two opposing fields	¥93, 000	113	¥10, 509, 000
	Immobilizer point (1,000 points)	(113 patients)	¥10, 000	23	¥230, 000
M000-1.	Radiotherapy management fee (2,700 points)	(113 patients are treated by basic treatment	¥27, 000	113	¥3, 051, 000
	Radiation therapy specialist point (330 points)	procedure 5 times a week, for 2 weeks	¥3, 300	113	¥372, 900
	Patient referral point (100 points)	(10 times in total)	¥10, 000	34	¥340, 000
B011-4-.2.	Medical equipment safety management fee (1,000 points)		¥10, 000	113	¥1, 130, 000
M001-3-B-(1).	External radiation fee (310 points)	Single field/two opposing fields (second site) (23 patients)	¥31, 000	23	¥713, 000
M001-3-A-(2).	External radiation fee (1,240 points)	[2] Two/three non-opposing fields	¥310, 000	98	¥30, 380, 000
	Immobilizer point (1,000 points)	(98 patients)	¥10, 000	25	¥250, 000
M000-2.	Radiotherapy management fee (3,100 points)	(98 patients are treated by basic treatment	¥31, 000	98	¥3, 038, 000
	(2nd) radiotherapy management fee (3,100 points)	procedure 5 times a week, for 5 weeks	¥31, 000	20	¥620, 000
	Radiation therapy specialist point (330 points)	(25 times in total)	¥3, 300	98	¥323, 400
	Patient referral point (100 points)		¥25, 000	30	¥750, 000
B011-4-.2.	Medical equipment safety management fee (1,000 points)		¥10, 000	98	¥980, 000
M001-3-A-(3).	External radiation fee (1,580 points)	[3] Four fields or more/physical exercise,	¥474, 000	42	¥19, 908, 000
	Immobilizer point (1,000 points)	conformation therapy (42 patients)	¥10, 000	15	¥150, 000
M000-3.	Radiotherapy management fee (3,400 points)	(42 patients are treated by basic treatment	¥67, 000	42	¥2, 814, 000
	(2nd) radiotherapy management fee (3,400 points)	procedure 5 times a week, for 6 weeks	¥34, 000	13	¥442, 000
	Radiation therapy specialist point (330 points)	(30 times in total)	¥3, 300	42	¥138, 600
	Patient referral point (100 points)		¥1, 000	0	¥0
B011-4-.2.	Medical equipment safety management fee (1,000 points)		¥10, 000	42	¥420, 000
M001-4-A.	External radiation fee (3,000 points)	[4] Intensity Modulated Radiation	¥900, 000	28	¥25, 200, 000
	Immobilizer point (1,000 points)	Therapy (IMRT) (28 patients)	¥10, 000	28	¥280, 000
M000-4.	Radiotherapy management fee (5,000 points)	(28 patients are treated by basic treatment	¥50, 000	28	¥1, 400, 000
	(2nd) radiotherapy management fee (5,000 points)	procedure for 5 times a week, for 6 weeks	¥50, 000	7	¥350, 000
	Radiation therapy specialist point (330 points)	(30 times in total)	¥3, 300	28	¥92, 400
	Patient referral point (100 points)		¥1, 000	0	¥0
B011-4-.2.	Medical equipment safety management fee (1,000 points)		¥10, 000	28	¥280, 000
M001-3	Stereotactic radiosurgery fee (linear accelerator) (63,000 points)	[5] Stereotactic radiosurgery (18 patients)	¥630, 000	18	¥11, 340, 000
M002	Total-body irradiation fee (for the purpose of bone-marrow transplant) (10,000 points)	[6] Total-body irradiation (0 patients)	¥100, 000	1	¥100, 000
		Annual total number of patients: 300	Annual total revenue		¥115, 602, 300

(Unit: yen)

Estimated total cost in case 300 patients are treated by radiation in one year

	Equipment name	Quantity	Estimated procurement cost
Main equipment required to perform radiotherapy	Radiation therapy equipment: dual-energy (allowing SRS and IMRT with MLC)	1	¥420, 000, 000
	CT equipment for radiotherapy	1	
	X-ray simulator	No	
	Radiotherapy planning equipment	1 set	
	Irradiation accessories	Yes	
	QC/QA measurement instrument (dosimeter, water phantom etc.)	Yes	
	IT network	Yes	

Note: Fixed-installment depreciation of the equipment over a 6-year period requires allocation of annual costs of 63 million yen.

	Job type	Number of staff	Estimated annual cost
Staff required to perform radiotherapy	Radiation oncologist (certified physician)	2	¥55, 000, 000
	Radiotherapy technician	2	
	Radiotherapy quality controller: 1 full-time controller	1	
	Medical physician	1	
	Dedicated nurse for radiation treatment	1	
	Equipment name	**Quantity**	**Annual maintenance cost etc.**
Annual maintenance cost of radiotherapy equipment, electricity, water etc.	Radio therapy equipment: dual-energy (allowing SRS and IMRT with MLC)	1	¥16, 500, 000 (The cost is generated from the second year.)
	CT equipment for radiotherapy	1	
	X-ray simulator	No	
	Radiotherapy planning equipment	2 sets	
	Irradiation accessories	Yes	
	QC/QA measurement instrument (dosimeter, water phantom etc.)	Yes	
	IT network	Yes	
	Electricity, water etc.		¥1, 500, 000
	Reserve for consumables etc.		¥3, 000, 000

Estimated revenue and expenditure in case 300 patients are treated by radiation in one year, for 10 years

(Unit: yen)

	1st year	2nd to 6th years	7th to 10th years	Total of 10 years
Revenue	¥115, 602, 000	¥578, 010, 000	¥462, 408, 000	¥1, 156, 020, 000
Expenditure	¥122, 500, 000	¥695, 000, 000	¥304, 000, 000	¥1, 121, 500, 000
Balance	¥-6, 898, 000	¥-116, 990, 000	¥158, 408, 000	¥34, 520, 000

(The depreciation is allocated equally over 6 years, setting the residue value to 10%. The maintenance cost is allocated assuming generation over the 2nd to 10th years.)

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