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

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

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

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

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

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

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

2. Purpose of this Report

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

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

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

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

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

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

3. Improving Cancer Treatment

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4. The Clinical Role of Radiotherapy

4.1 Characteristics of radiotherapy

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

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.

② Preservation of organ and function

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

③ Low cost

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

4.2 The role of radiotherapy

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

① When treatment results akin to those in surgery are obtained in local treatment

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

② When results from radiotherapy are deemed inferior to those from surgery

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

③ When general condition is poor, or when surgery is not possible for reasons including age or organ function

Radiotherapy is often useful.

5. The Radiotherapy Process

5.1 Performance of radiotherapy

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

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

A radiation oncologist suitable to direct radiotherapy is a physician whose treatment focuses primarily on radiotherapy for cancer patients, or whose work is principally education and research in radiation oncology. This physician should have as much clinical experience and ability as possible to actually and properly determine the suitability of radiotherapy for individual cancer patients with various backgrounds, based on a thorough knowledge of radiation oncology, practice of evidence-based medicine (EBM), and an understanding of various guidelines.[34)-44)] Such experience and ability must also be assured by fulfillment of the requirements for physicians certified by the Japanese Society for Therapeutic Radiology and Oncology (JASTRO). The radiation oncologist must personally, or in cooperation with a medical oncologist, surgical oncologist, or an oncologist from another such field, assess the medical findings of the individual cancer patient, determine the clinical stage, and present to the patient an explanation and treatment alternatives, including alternate therapies. At least in specific areas (e.g. examination of head and neck cancer patients, breast cancer patients, cervical cancer patients, prostate cancer patients, malignant lymphoma patients, and pediatric cancer patients), it is also preferable that the radiation oncologist has abilities for patient treatment equivalent to those of a specialist in the respective field. In simulations of the patient and treatment planning, the radiation oncologist has the ability to delineate target volume accurately and determine an appropriate radiation field and dosage prescription, based on information including physical findings and image-based findings. Administration of brachytherapy requires yet more advanced technical ability. Proper assessment and management of the response of tumors and the acute reaction of normal tissue subjected to various dosages are carried out for patients undergoing radiotherapy. After radiotherapy is complete, there is an obligation for patient management throughout clinical course, including assessment of tumor response, evaluation of adverse effects, and confirmation of any recurrence or late toxicities. Prognostic information of the irradiated patient must also be discerned personally, or through some method, and we support in-hospital, regional, or national cancer registration. Additionally, in order to resolve research questions and establish standard treatment methods at practicing clinics, there is also a right or an obligation to participate actively in not only restrospective research but exploratory clinical studies with regard to the treatment of specific patient groups as well as individual patients.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5.2 Various methods in radiotherapy

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

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

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

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

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

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

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

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

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

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

5.3 The importance of quality control

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

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

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

5.4 Current status and issues in radiation therapy[45)]

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

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

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

A1: university hospital/cancer center, 430 patients or more treated per year.
A2: university hospital/cancer center, 429 patients or less treated per year.
B1: other national hospital/public hospital, 130 patients or more treated per year.
B2: other national hospital/public hospital, 129 patients or less treated per year.
*Japanese Society for Therapeutic Radiology and Oncology (JASTRO) Regular Structure Survey (2001)

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

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

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

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

5.5 Current state of radiation therapy staff

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Toshihiko Inoue, Hiroshi Onishi, Yutaka Takahashi)

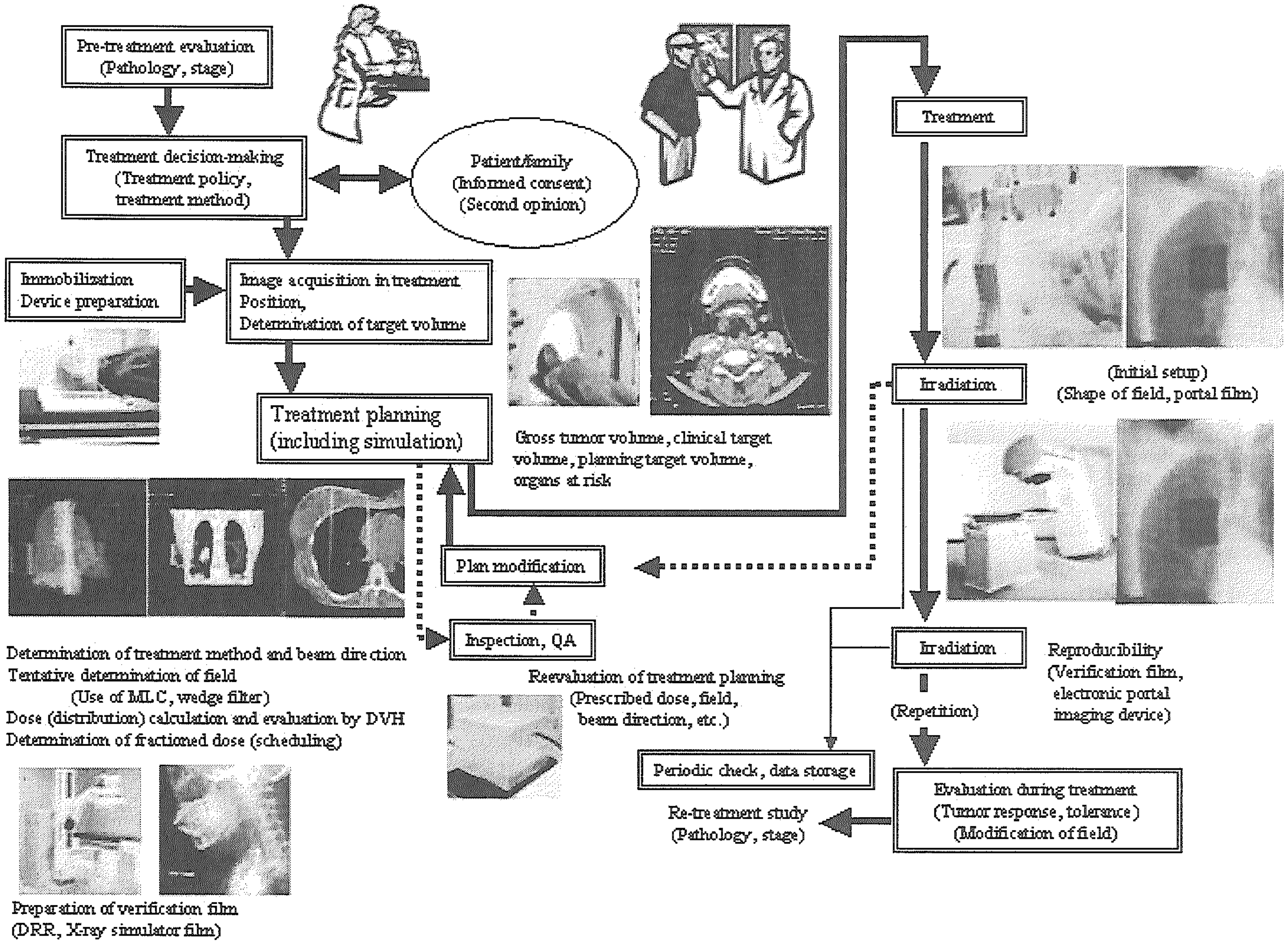

Figure 5-1. The radiotherapy process (external irradiation using CT simulator or similar device).

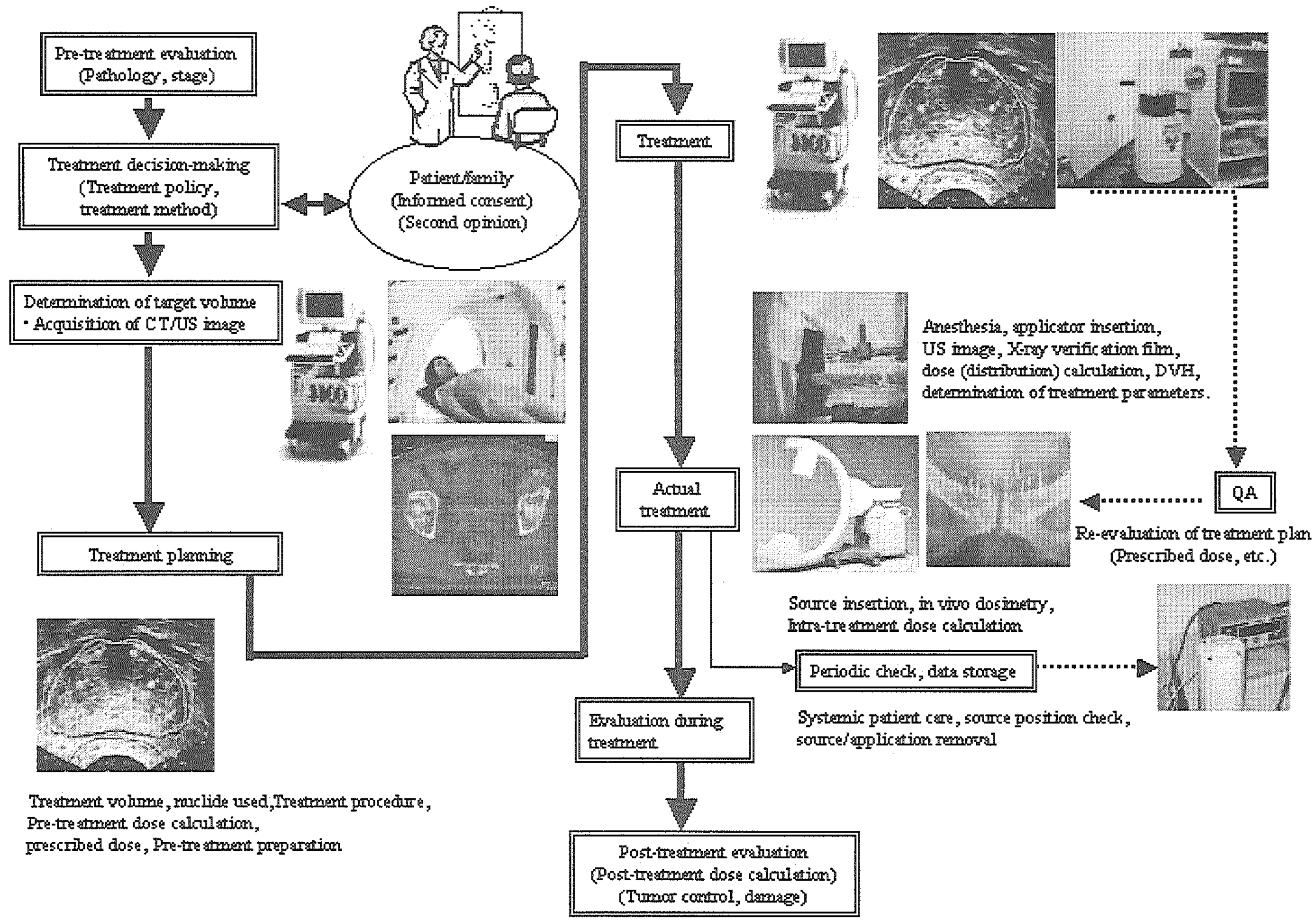

Figure 5-2. The radiotherapy process (image-guide brachytherapy).

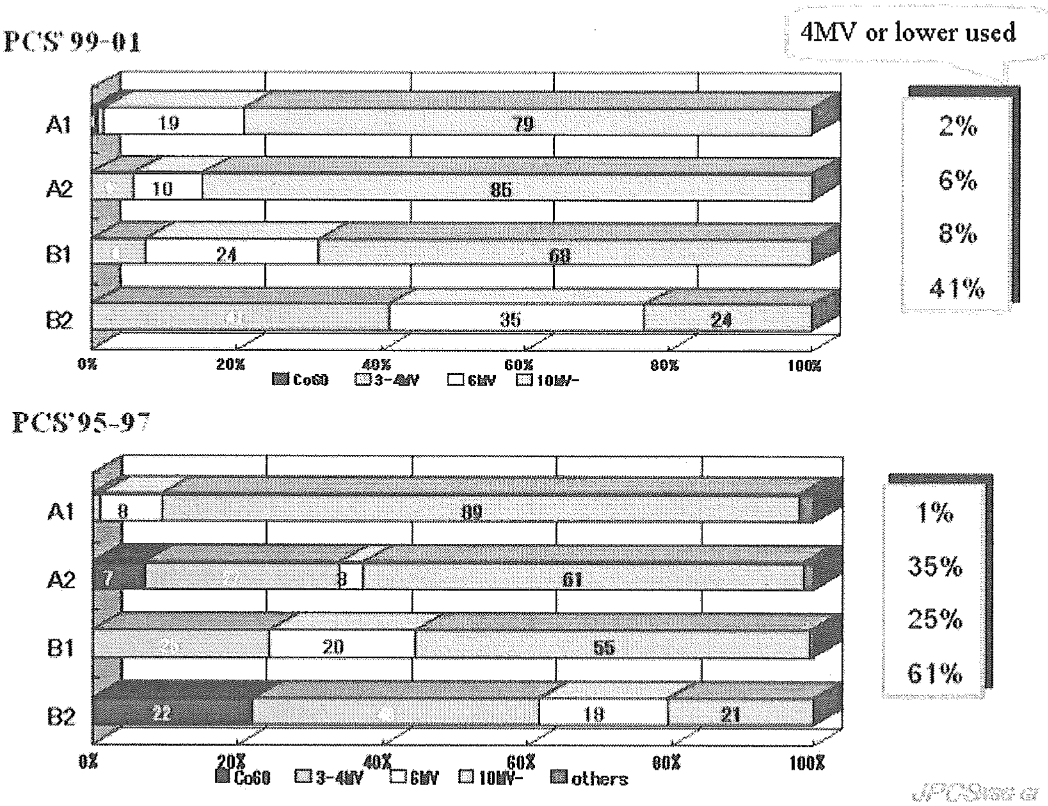

Figure 5-3 Frequency of beam energy used in external radiotherapy for non-surgical cases of esophageal cancer, according to PCS. Facility size results in large differences, with small-scale facilities selecting progressively lower energies. This trend was notably improved in patients treated during 1999-2001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

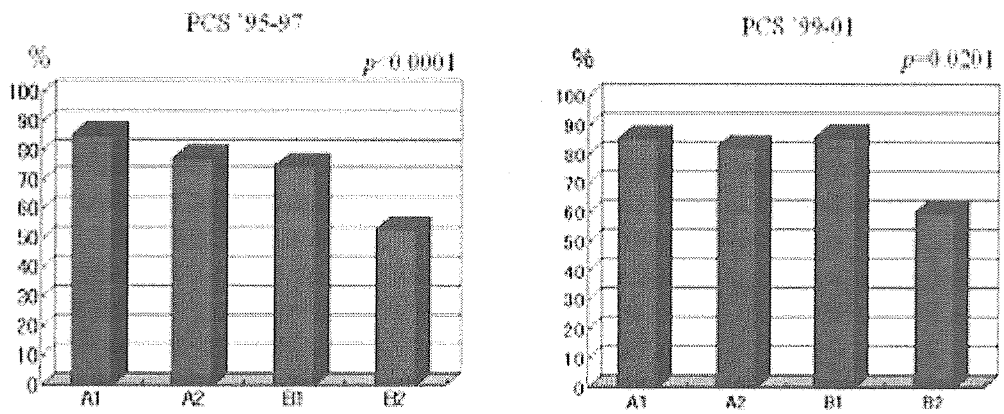

Figure 5-4 Indication rates for intracavitary irradiation in non-surgical cases of cervical cancer. Significant differences according to facility are apparent. Smaller facilities demonstrate progressively lower indication rates. This trend was improved in patients treated during 1999-2001 versus patients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

6. Standards for Equipment and Facilities Utilization

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

6.1 Facility standards

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

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

6.2 External irradiation equipment standards

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

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

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

Table 6-1 External irradiation equipments

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

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

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

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

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

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

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

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

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

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

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

5%	521 patients
10%	450 patients
15%	434 patients
17%	400 patients
20%	350 patients