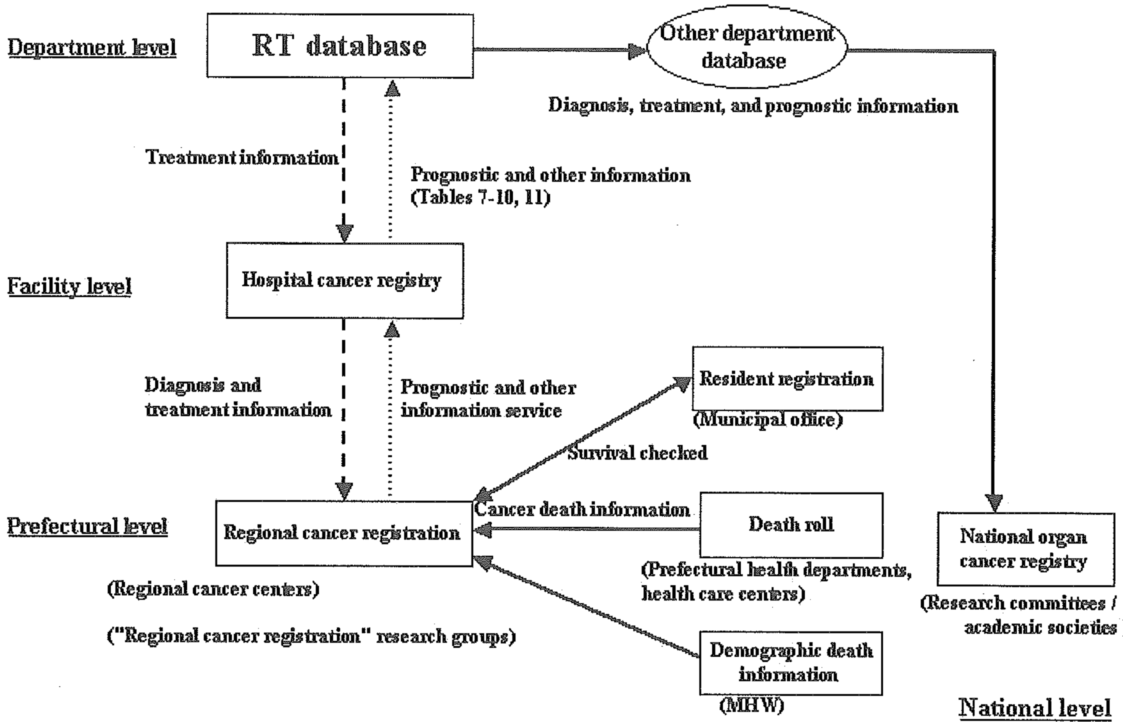


Figure 7-2 Relationship between radiotherapy (RT) database and cancer registration/other databases.

Table 7-13 Treatment-related data

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

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

7.8 Evaluation of operations

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

Table 7-14 Operation-related items

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

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

(Masahiko Koizumi)

7.9 Radiotherapy quality control unit (medical physics unit)

7.9.1 Importance of QA/QC

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

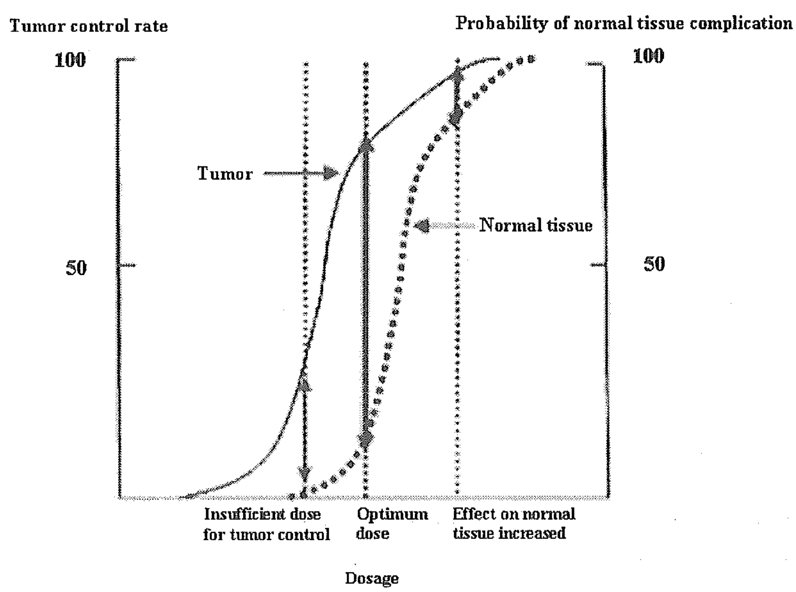


Figure 7-3 Dose-response curve (conceptual drawing). Bidirectional arrows indicate difference between tumor control and toxicity of normal tissue

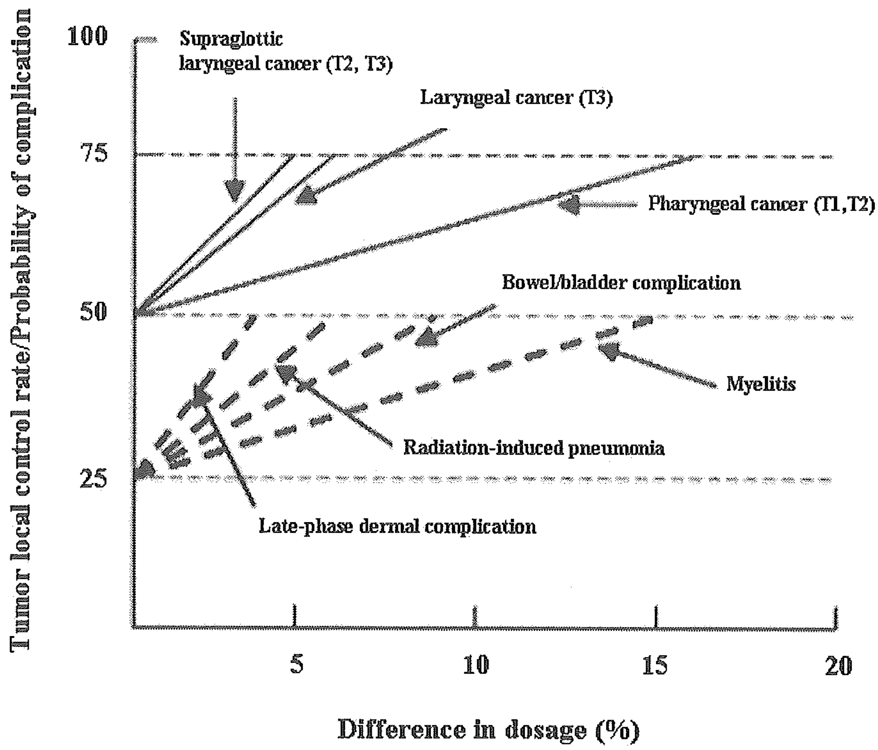


Figure 7-4 Tumor local control (solid lines) increases from 50% to 75%. Probability of normal tissue complication (broken lines) also increases from 25% to 50% with increasing dose.

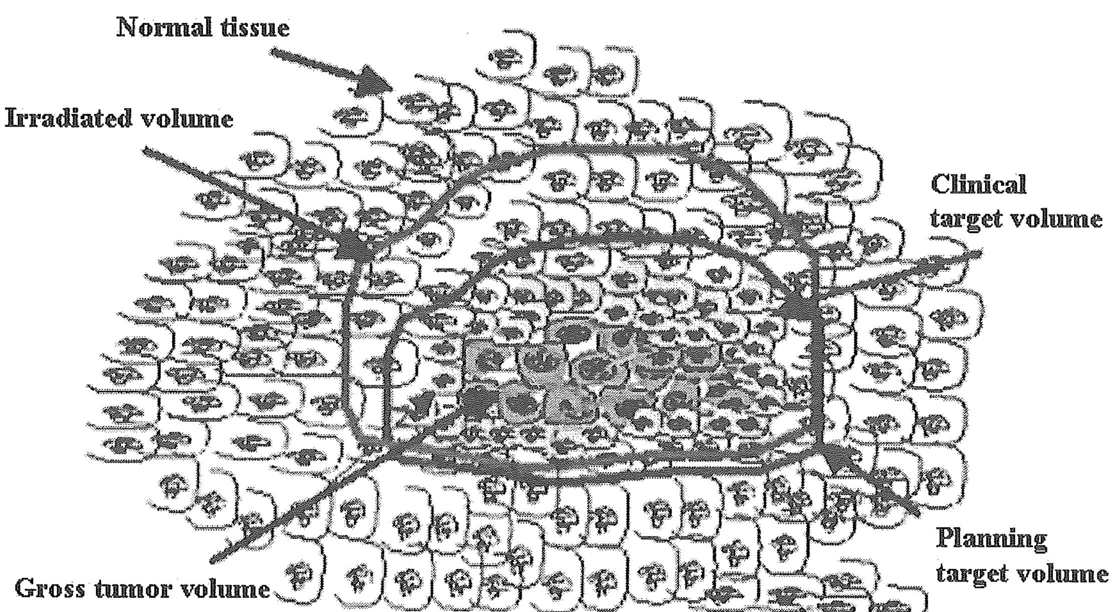


Figure 7-5 Schema of irradiated volume.Spatial errors in irradiation field lead to undesired irradiation to normal tissue and inadequate dose in tumor tissue.

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

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

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

Figure 7.6 shows the mean time per year required for commissioning, calibration, and periodic QA in 50 facilities (approximately half core cancer treatment hospitals and half university hospital cancer centers) in the US in 2003.[67)] It becomes apparent that in comparison to Japan, substantially more time is spent on these activities in the US. These are standard times for ensuring high accuracy. QA/QC services performed by medical physicists are also added to insurance ratings.[67)] Japan also needs QA/QC programs implemented by quality controllers (medical physicists).

7.9.3 QA/QC programs

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

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

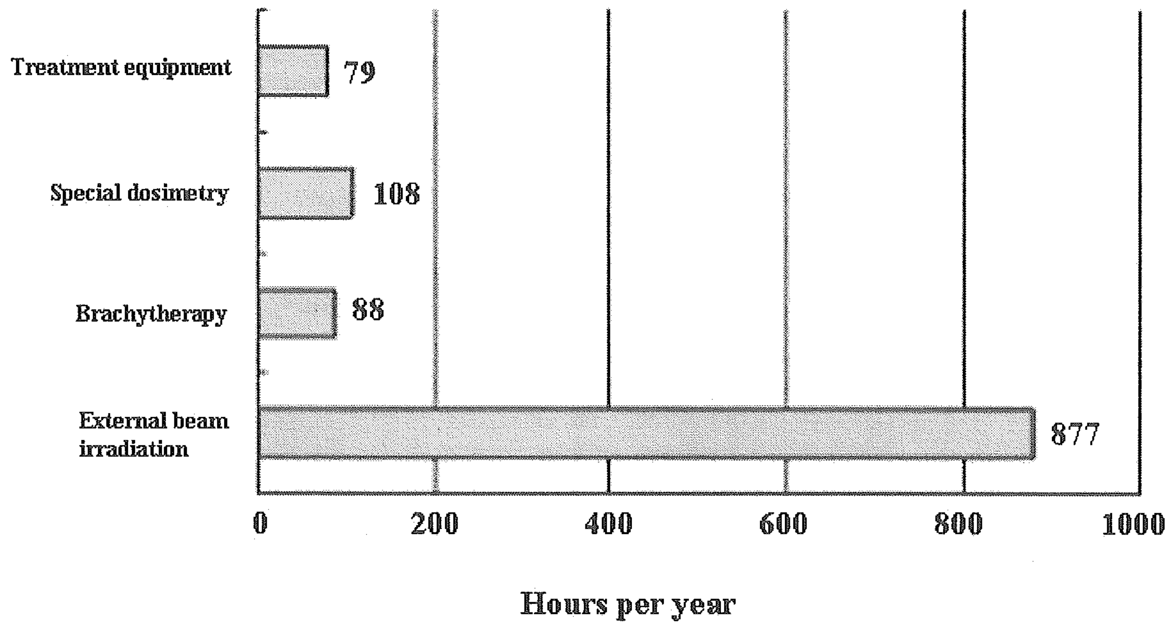


Figure 7.6 Time using QA/QC in the US (median values)

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

Table 7-15 Items included in quality control

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

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

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

(Yutaka Takahashi)

8. Standards for Staff Required in Radiotherapy

The produce of the best treatment for patients requires the facilities, which have appropriate knowledgeable staffs including a radiation oncologist and equipments prepared on the basis of a well-designed QA/QC program, and are kept in a state allowing use at all times. Appropriate radiotherapy requires multiple facilities, multiple radiation oncologists, various required staff, and cooperative relationships with each facility maintained through public or private relations.[83)-88)]

8.1 Radiation oncologists

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

8.2 Radiation therapists and specialist Radiation therapists (tentative title)

A Radiation therapist must have the appropriate knowledge of radiotherapy-related system including treatment equipment. Radiation therapists and radiotherapy quality controllers must be developing and implementing a quality assurance (QA) program for radiotherapy-related process. This work requires an ability to perform individual therapeutic processes properly, carry out thorough verification, and create and store implementation records, and in performance of treatment, the safety of the patient must be fully assured. This work is carried out in concert with radiation oncologists, radiotherapy nurses, and other such radiotherapy staff to provide appropriate radiotherapy to patients.

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

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

A radiotherapy quality controller should be authorized the systems required radiotherapy quality control. Other important duties include monitoring of general hospital work from a quality control perspective, communications of contacts and instructions, and proposal of revisions to managing departments. The work of the controller also includes voluntary quality improvement activities at individual sites (not simply "quality control" in a narrow sense, a wide range of activities intended to improve the "quality of radiotherapy" itself).

The main tasks in such work include

① Setup and implementation of a QA program for radiotherapy equipments
② Setup and implementation of a QA program for radiotherapy planning systems
③ Preparation and designation of data input to treatment planning systems and checking of all computer dose measurement planning
④ Determination of QA programs for individual facilities, including tests to be run, tolerances, and frequencies
⑤ Understanding of contradictions and problems assessed through QA programs, and implementation of appropriate response
⑥ Cooperation with other individuals involved in radiotherapy quality control in various aspects of QA programs for treatment equipments/treatment planning systems
⑦ Creation of QA programs in conjunction with device introduction from a radiotherapy equipment and planning system
⑧ Establishment and implementation of quality control after completion of nonfunctioning device repair

8.4 Medical physicists

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

① Implementation of all work performed by the radiotherapy quality controller
② Setup and implementation of external radiation and brachytherapy treatment planning
③ Physical consulting with radiation oncologists
④ Research and development
⑤ Education (young physicists/radiotherapy quality controllers, treating radiation therapists, residents, students)

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

8.5 Radiotherapy nurses

Nurses involved in radiotherapy must have specialized knowledge of radiotherapy and the ability to establish and implement a nursing plan for patients during or after treatment; such nurses must also be assigned solely to a radiotherapy department as specialist radiotherapy nurses. At present, there is no qualification and certification system for (specialist) radiotherapy-certified nurses, and such a system must be established. Such nurses must also function as a member of a health care team, cooperating with ward nurses with regard to inpatients and with outpatient physicians and nurses with regard to outpatients, in order to provide patients with the nursing required. Radiotherapy nurses ascertain the potential for various adverse reactions depending on the condition of each patient and factors such as treatment site/treatment method, provide necessary information to the patient and family, and provide explanations that impart understanding. In routine activities before and after treatment, radiotherapy nurses provide appropriate explanation of issues of concern and responsive measures and provide or make reference to literature or materials as needed. Radiotherapy nurses also have the role of ascertaining changes in patient status in concert with the radiation oncologist and communicating information the treatment staff must consider.

8.6 Administrative staff

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

8.7 Radiotherapy information managers

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

8.8 Other staff required on the radiotherapy team

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

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

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

Table8-1 Professional relationship among radiotherapy department staff

Task	Performed by
1. Work prior to start of treatment	
①The goal of treatment and treatment procedure should be discussed with treatment team involved in the patient's care. The clinical information required for radiotherapy must be recorded appropriately in the patient's chart.	･Treatment team ･Radiation oncologist ･Radiotherapy nurse
②Physicians have a legal and ethical duty to obtain informed consent from the patient and/or family. Informed consent shall be obtained and should be appropriately documented prior to the treatment including treatment sites, goal, procedure, benefits and side effects (7.2). The radiotherapy nurse may provide information using standardized information materials such as the treatment schedule and daily activities.	･Radiation oncologist ･Radiotherapy nurse
③Informed consent shall be obtained enough time and the patient and, when appropriate, the family must have adequate information to understand the treatment and procedure. The informed consent document should contain adequate statement and the signature of the patient or patient's representative. A copy of all pertinent consent documentation should be kept in the patient's chart (7.2).	･Radiation oncologist
④The appropriate treatment planning process should be provided. Devices to aid in positioning and immobilizing the patient are to be used where appropriate and should be kept in each patient. Adequate information for treatment planning must be obtained and documented.	･Radiation oncologist ･Medical physicist ･Radiation therapist
⑤Takes photographs and documents of alignment states, and devices to aid in positioning and immobilizing the patient during treatment planning (when patient photographs are taken, consent is obtained).	･Radiation oncologist ･Medical physicist ･Radiotherapy nurse ･Radiation therapist
⑥Documents parameters needed for individual treatment in the radiotherapy chart. The parameters must be checked by independent person or method before the first treatment. The beam delivery parameters must be correctly transferred to treatment unit and the parameters must be checked by independent staff or method before the first treatment. The date and time of parameters input shall be documented. Particularly when parameters are transferred from treatment planning system to a treatment unit, each parameter should be checked by independent person. Treatment parameters undergo appropriate control by the radiotherapy quality controller.	･Radiation oncologist ･Medical physicist ･Radiotherapy quality controller ･Radiation therapist
⑦Appropriate quality control must be perform and documented before treatment. To permit proper delivery of therapy, radiographs or portal images produced by each treatment beam unit with the patient in the treatment position are compared and	･Radiation oncologist ･Medical physicist

(cont'd)

documented with the simulator films or digitally reconstructed radiographs (DRR) to verify that the treatment beams and fields planned at simulation are well matched.	･Radiotherapy quality controller ･Radiation therapist
⑧Records additional identifying information on facial photographs or photographs for patient identification and attaches to medical records or irradiation records to allow checking during treatment implementation (when patient photographs are taken, consent is obtained). Make system for recognition for the patient by ID or name, etc. to avoid erroneous irradiation.	･Radiation oncologist ･Radiotherapy nurse ･Radiation therapist ･Information manager
⑨Holds periodic conferences of radiotherapy staff to check questionable issues and solve problems, and confirms recognition in common with staffs.	･All staff

2. Treatment	
①It is essential that all treatment parameters be described in detail and orders be signed or initialed by the radiation oncologist prior to treatment.	･Radiation oncologist
②The beam delivery parameters must be checked by radiation therapist operating treatment. If the therapist is replaced, appropriate checking of treatment parameters should be performed prior to treatment.	･Radiation therapist
③Two or more therapists should perform treatment.	･Radiation therapist
④Uses auxiliary stairs as appropriate to move the treatment table and provides assistance as needed to prevent falling by the patient. If necessary, explain to the patient using immobilization devices during irradiation. Enforces checking by ID card or checking by name, etc. to avoid incorrect irradiation.	･Radiotherapy nurse ･Radiation therapist
⑤Uses appropriate immobilization devices, utilizes skin markings, and prevents improper alignment by checking same.	･Radiation therapist
⑥Notes adequate information to keep reproducibility of patient's position during treatment and others in the radiotherapy chart, and shares information with the radiotherapy staff.	･Radiation therapist ･Radiotherapy nurse
⑦The important information includes consciousness levels, risks of infection and fracture, and external catheters should be shared among radiation staffs and staffs in ward and out patient clinic during treatment.	･Radiotherapy nurse ･Radiation therapist ･Radiation oncologist ･Treatment team
⑧Creates the safety manual for patient's safety, such as place or remove wedge filters, shielding lead, or treatment cones, and performs alignment checked by another therapist.	･Radiotherapy technician
⑨The treatment parameters must be checked appropriately before the treatment. Therapists should confirm in radiation chart to prevent errors with regard to any items not checked	･Radiotherapy technician

(cont'd)

automatically, such as wedge filters, boluses and blocks.	
⑩Performed treatment must be recorded and signed by the therapist. Any changes in the planned treatment must be documented on the radiotherapy chart verifiably. The radiotherapy chart needs the periodically check by the radiation oncologist and a radiotherapy quality controller.	･Radiation therapist ･Radiotherapy quality controller ･Radiation oncologist
⑪Radiographs or portal images should be produced prior to the initiation of radiation therapy and any changes appropriately. These images are compared and documented with the simulator films or digitally reconstructed radiographs (DRR) to verify that the treatment beams and fields planned at simulation are well matched by the radiation oncologist. The radiotherapy quality controller should be managed appropriate quality control for these images.	･Radiation therapist ･Radiotherapy quality controller ･Radiation oncologist ･Medical physicist
⑫During the treatment, the patient should be kept watch by the therapist using monitoring system from the control room during treatment.	･Radiation therapist
⑬Assessment by the radiation oncologist and radiotherapy nurse of sequelae of treatment is recommended periodically during and after treatment. Appropriately any changes in patient during treatment shall be notes in the medical record.	･Radiation oncologist ･Radiotherapy nurse

3. Brachytherapy	
①Pays special attention to handling of low dose-rate sealed brachytherapy.	･Radiation oncologist ･Radiotherapy quality controller ･Medical physicist
②QA is required to assure individual radiation source output and integrity.	･Radiation oncologist ･Medical physicist ･Radiotherapy quality controller
③The facility shall perform management of sources as appropriate to prevent radiation source loss accidents.	･Radiation oncologist ･Radiotherapy quality controller ･Medical physicist ･Radiation therapist
④Records documenting appropriate description of each radioactive source and its usage are necessary	･Radiation oncologist ･Radiotherapy quality controller ･Medical physicist ･Radiation therapist
⑤The facility shall have manual to perform periodic sealed-source leak testing or arrange to have this service provided in	･Radiation oncologist

(cont'd)

compliance with applicable federal regulation.	･Radiotherapy quality controller ･Medical physicist ･Radiation therapist ･Specialist radiotherapy nurse ･Treatment team
⑥Patient must explain to stay the appropriately shielded treatment room as necessary. The record documenting for shielded treatment room about all persons who coming and going is necessary	･Radiation oncologist ･Radiotherapy quality controller ･Radiotherapy nurse ･Treatment team

4. Quality control and maintenance of system and equipment	
①Medical physicist and/or radiotherapy quality controller must be developing and implementing a quality assurance (QA) program for radiotherapy equipments, treatment planning systems or treatment planning CT, or other such radiotherapy-related process. The information content of the QA should be documented and verified as necessary.	･Medical physicist ･Radiotherapy quality controller
②Documentation must exist indicating that the medical physicist and/or radiotherapy quality controller has authorized the system for clinical use and has established a QA program to monitor the treatment planning system's performance as it relates to the planning process.	･Medical physicist ･Radiotherapy quality controller
③Medical physicist and/or radiotherapy quality controller should perform acceptance testing, commissioning, and implementation of the radiotherapy equipments, treatment planning systems or treatment planning CT, or other such radiotherapy-related process.	･Medical physicist ･Radiotherapy quality controller
④Medical physicist and/or radiotherapy quality controller should establish and manage a QA program for the radiotherapy equipments, treatment planning systems or treatment planning CT, or other such radiotherapy-related process	･Radiation therapist ･Radiotherapy quality controller ･Medical physicist
⑤Prepares records of malfunctions and problems for individual systems and other such radiotherapy-related equipments, and records details and response. Makes predetermined reports to the managing organization as necessary.	･Radiation therapist ･Radiation oncologist
⑥The medical physicist and/or the radiotherapy quality controller must be developing and implementing a QA program for radiotherapy equipments, treatment planning systems or treatment planning CT, or other such radiotherapy-related process for malfunction.	･Radiotherapy quality controller ･Medical physicist ･Radiation therapist ･Medical physicist

(cont'd)

⑦Perform and documents periodic calibration for radiation dose measurement system.	･Radiation therapist ･Medical physicist ･Radiotherapy quality controller
⑧Enters into service contracts with manufacturers for treatment (cont'd) apparatus, treatment planning apparatus, and other such radiotherapy-related equipment; carries out periodic inspection, and creates records.	･Installer ･Radiotherapy technician ･Radiotherapy quality controller ･Medical physicist ･Radiation oncologist

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

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

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

(cont'd)

Administrative staff	1 per facility in dual role as radiotherapy information manager	Add 1 for each 500 patients per year
Radiotherapy information manager	1 per facility in dual role as receptionist	Add 1 for each 500 patients per year

(Minako Sumi, Takashi Uno, Katsumasa Nakamura)

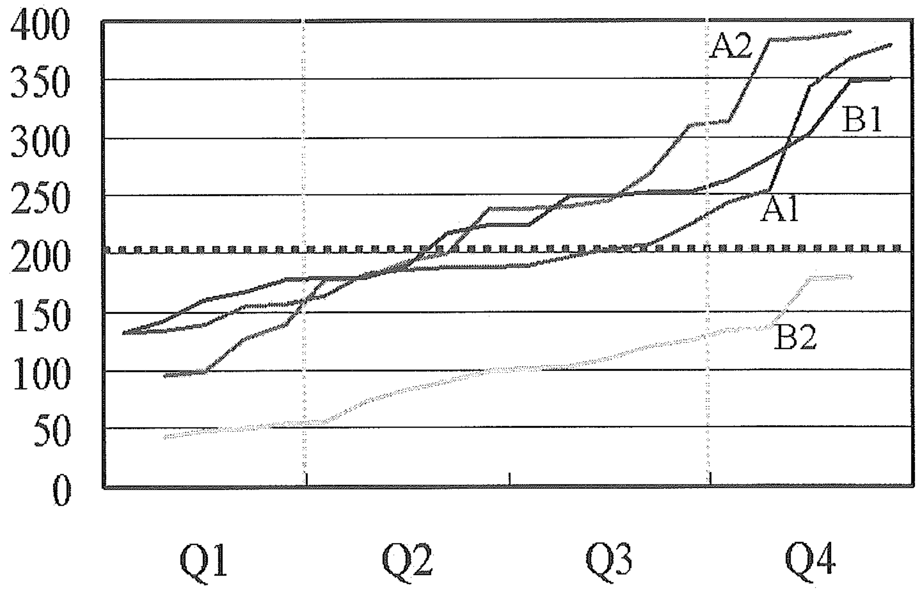


Figure 8-1 Distribution of number of patients per year/number of FTE radiation oncologists at PCS 1999-2001 survey facilities. To avoid overestimation, facilities with FTE<1 were calculated as FTE=1. Horizontal axis is arranged in order of increasing value for each facility stratum (A1, A2, B1, B2).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

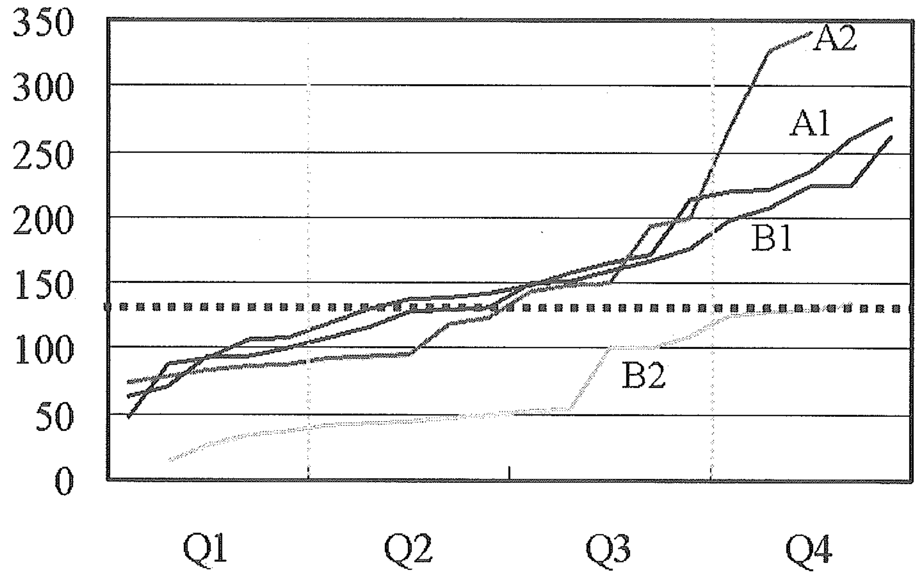


Figure 8-2 Distribution of number of patients per year/number of FTE radiotherapy technologists at PCS 1999-2001 survey facilities.As above, apart from B2 facilities, 100-150 patients/FTE individual were treated at 26-75% of facilities. In Q4 facilities (highest 25%), 200 or more patients were treated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

9. Economic Issues

Recent progress in technology has 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 irradiation technology (method of irradiation), but beginning in FY1996, the administrative cost for creation of treatment plans was divided into three levels termed simple, complex, and unique, and beginning in FY2002, the cost of irradiation was also segregated on three levels.

These developments have 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.

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

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

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

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

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

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

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

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

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

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

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

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

(Yasuo Ashino, Hiroshi Onishi)

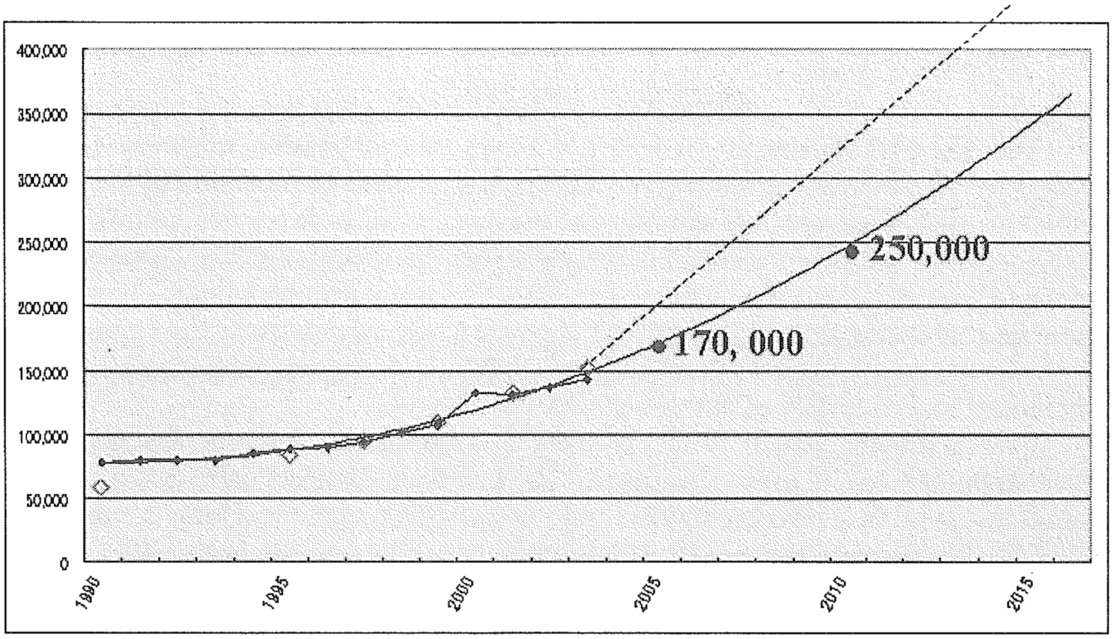
10. Conclusion

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

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

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

(Teruki Teshima)



◇: **JASTRO Structure Survey**

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