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

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

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

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

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

Table 6-3 Example of total treatment time calculation

7 hours working time/day
Assuming 50 weeks treatment, 5 days/week, the treatment hours provided by 1 external irradiation equipment is:
60×7×5×50 = 105,000 minutes
Assuming the patient composition is
50% curative irradiation (35 fractionations in average)
50% palliative irradiation (15 fractionations in average).

For simple irradiation, the time required per patient is assumed as 15 minutes (figure includes substantial allowance). It is assumed that irradiation of moderate complexity is carried out in 25% of curative irradiation,[55] and that irradiation field checking for change of field is carried out one time during all curative irradiation.
In these conditions, the number of hours required for n patients is:
(Simple/curative) → 15 minutes × 0.5 × 0.75-n patients × 35 treatments + 10 minutes × 0.5 × 0.75-n patients × 2 times
(Moderately complex/curative) → +20 minutes × 0.5 × 0.25-n patients × 35 treatments + 12 minutes × 0.5 × 0.25 n patients × 2 times
(Simple/palliative) + 12 minutes × 0.5-n patients × 15 treatments + 12 minutes × 0.5-n patients × 1 time
= 412-n minutes
Thus, under these assumed conditions, the number of patients treatable with 1 external

(cont'd)
irradiation equipment is:
105,000/412 = 254.8 = approximately 250 patients.
One the other hand, assuming a required time of 12 minutes per patient (minimum required time) for simple irradiation, the result of the above calculations is 350-n minutes, and 1 external irradiation equipment can treat approximately 300 patients.
The reader should note that these annual treatment capacity figures are at best reference values under the foregoing parameters.

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

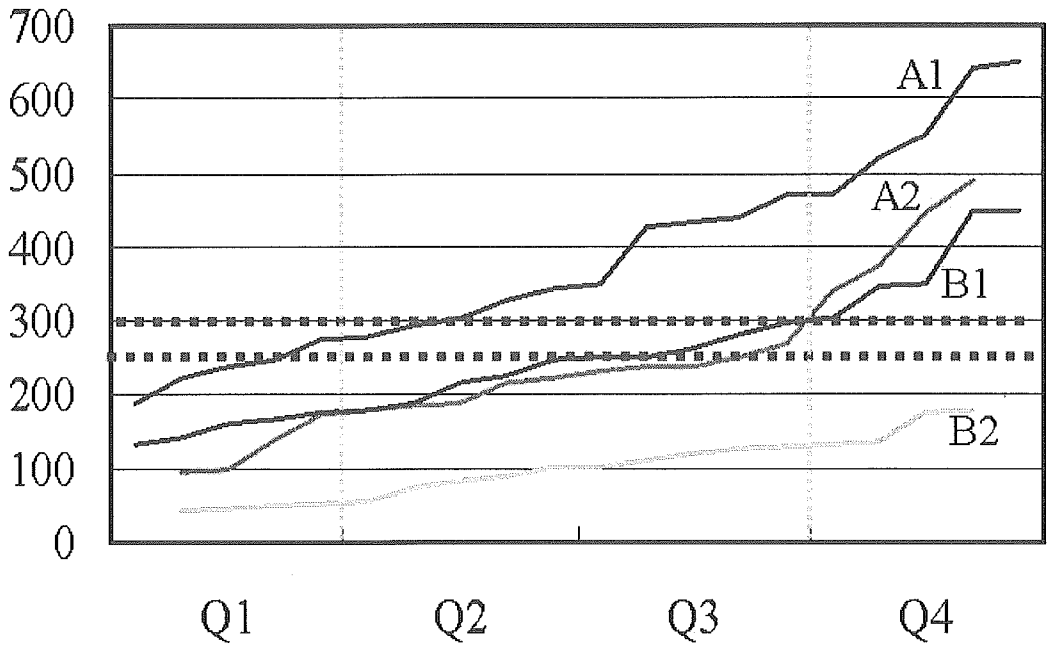

Figure 6-1 Distribution of annual number of patients treated/treatment equipment, by stratification of facility.Horizontal axis represents facilities arranged in order of increasing value of annual number of patients treated/treatment equipment within facilities in each stratum(A1, A2, B1, B2). Q1: 0-25%,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

6.3 Simulator standards

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

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

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

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

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

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

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

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

6.4 Brachytherapy standards

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

Brachytherapy is often an important technique in definitive radiotherapy for patients with uterine cancer, head neck cancer, esophageal cancer, prostate cancer, and roentgenographycally occult lung cancer, and its therapeutic effect and adverse reactions depend greatly on the treatment process. In Japan, brachytherapy is most commonly used for the treatment of uterine cervical cancer. Reports concerning a PCS in the US[56] and the Japanese 1995-1997 PCS also indicate that intracavitary brachytherapy plays an important role in the treatment process for cervical cancer. The 1991-2001 PCS demonstrated differences among different classes of facility in the type of devices used, and in the treatment process (Figures 6-2, 6-3).

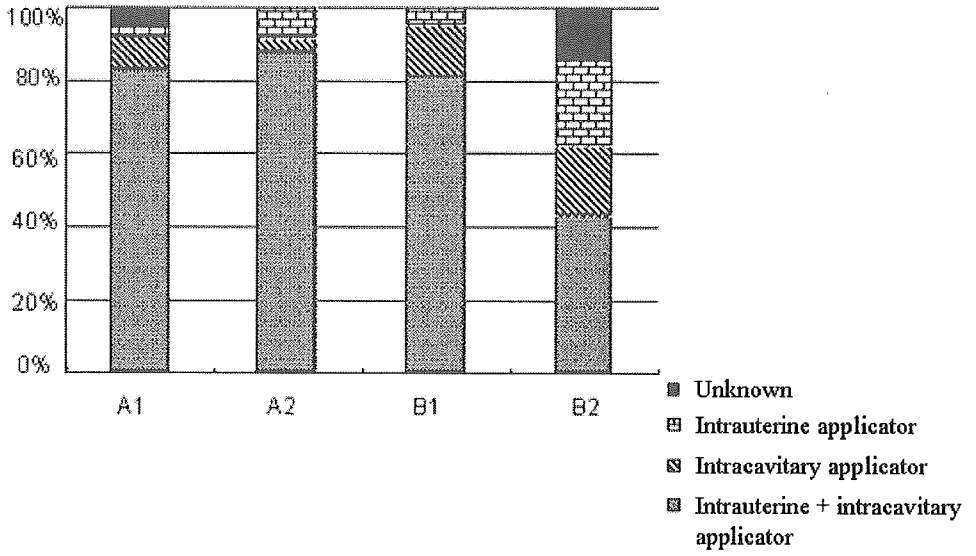

Figure 6-2 Devices used in intracavitary brachytherapy for cervical cancer, by facility (1999-2001 PCS).

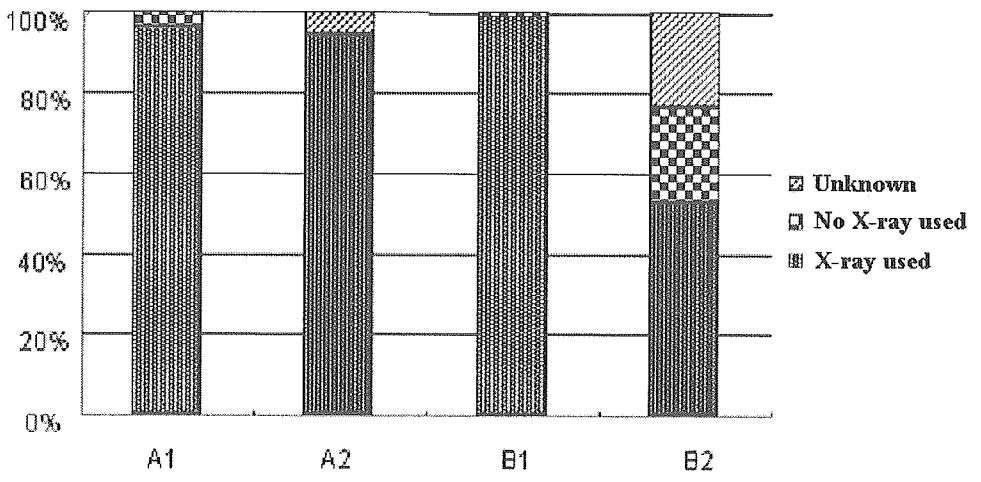

Figure 6-3 Geometrical simulation by radiographs in intracavitary brachytherapy for cervical cancer, by facility (1999-2001 PCS).

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

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

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

*(Facilities owning intracavitary irradiation equipment/facilities surveyed)

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

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

· Specialized QA/QC tools

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

B) Staff

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

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

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

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

C) Other

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

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

6.5 Accessory device standards

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

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

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

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

c. Devices for sealed brachytherapy
   1) Applicator for intracavitary irradiation in cervical cancer, esophageal cancer, and lung cancer
   2) Applicator for interstitial irradiation

6.6 Radiotherapy planning apparatus standards

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

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

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

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

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

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

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

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

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

6.7 Other advanced treatment equipment and facilities

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

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

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

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

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

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

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

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

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

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

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

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

(Chikako Yamauchi)

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

Progress in the technical aspects of radiotherapy has brought high-precision radiotherapy[1] into general clinical use in place of conventional two-dimensional radiotherapy. The introduction of such technologies typically requires expensive initial investment, as well as running costs. In addition to the staff needed for treatment delivery, well trained personnel are also necessary for treatment planning and quality assurance activities. As also discussed in Section 5.2, it is not efficient for all facilities

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

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

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

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

(Michihide Mitsumori)

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

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

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

[2]Example as of end-2004: IMRT for prostate cancer, ^{125}I seed permanent implantation for prostate cancer, stereotactic radiation treatment for lung cancer
[3]Example as of end-2004: 3DCRT (70Gy or higher) for prostate cancer, 3DCRT (multiportal irradiation for other organs), SRS, SRT for brain tumors
[4]Example as of end-2004: whole brass irradiation as breast-conserving treatment, 60Gy antero-posterior opposing portal radiation for lung cancer with complications, 66Gy curative irradiation for cancer of the larynx.

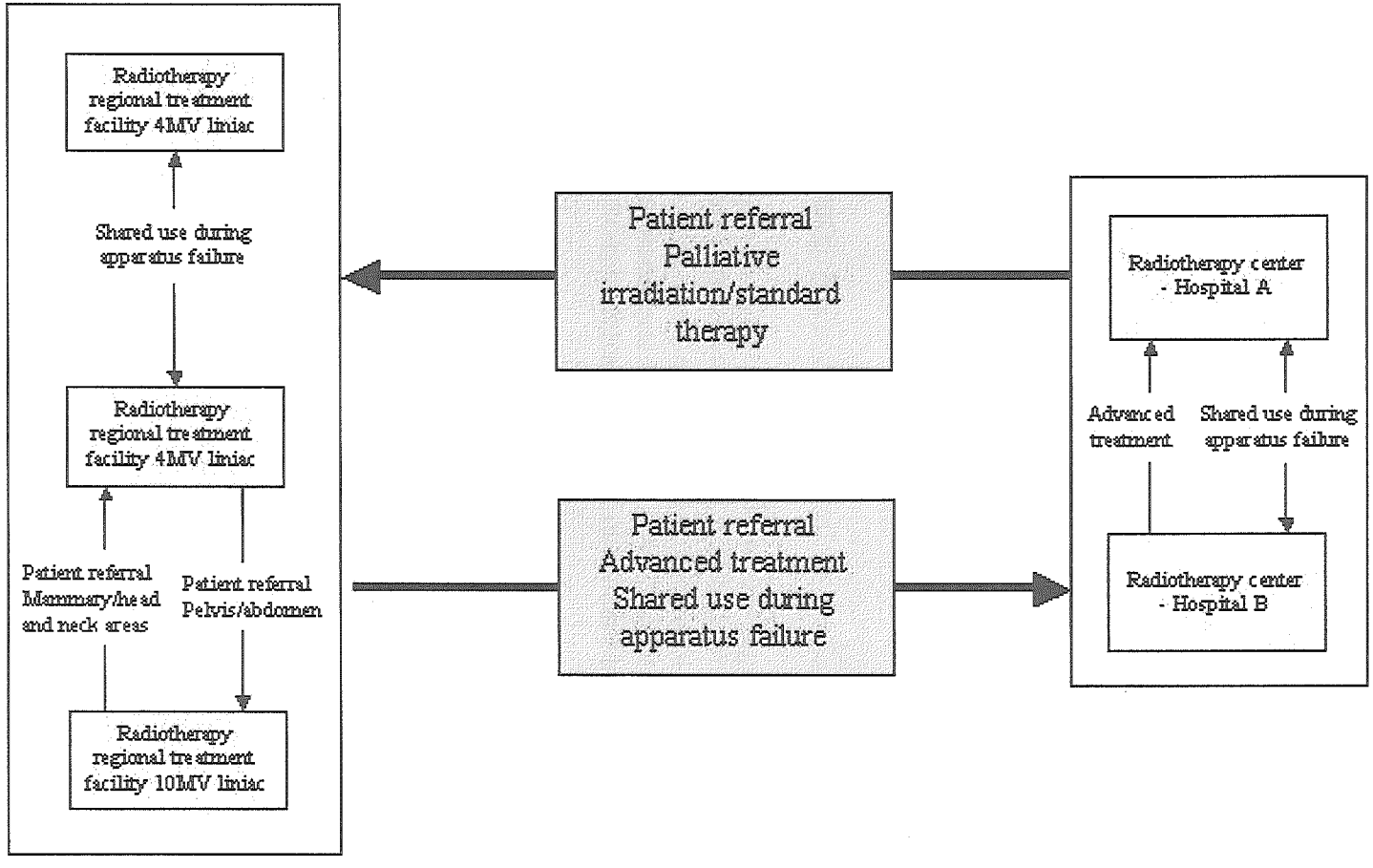

Figure 6-4 Shared use of equipment and patient referral among facilities in regional treatment (example).

7. Radiotherapy Quality Assurance

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

7.1 Documentation of radiotherapy-related consultation and treatment

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

Table 7-1 Basic information noted in medical records

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

*Japanese names have multiple possible readings. –tr

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

Table 7-2 Documentation for radiotherapy planning

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

(cont'd)

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

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

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

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

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

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

7.2 Informed consent

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

Table 7-3 Content of informed consent

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

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

7.3 Information to be given to the patient

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

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

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

(Masahiro Kenjo)

7.4 Treatment planning data

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

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

Table 7-4 Essential treatment planning data

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

Table 7-5 Auxiliary treatment planning data

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

(cont'd)
7) Required body measurements
8) Photographs of treatment site
9) Facial portrait of patient.

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

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

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

7.5 Treatment data

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

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

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

Table 7-8 Cumulative data at completion of treatment

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

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

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

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

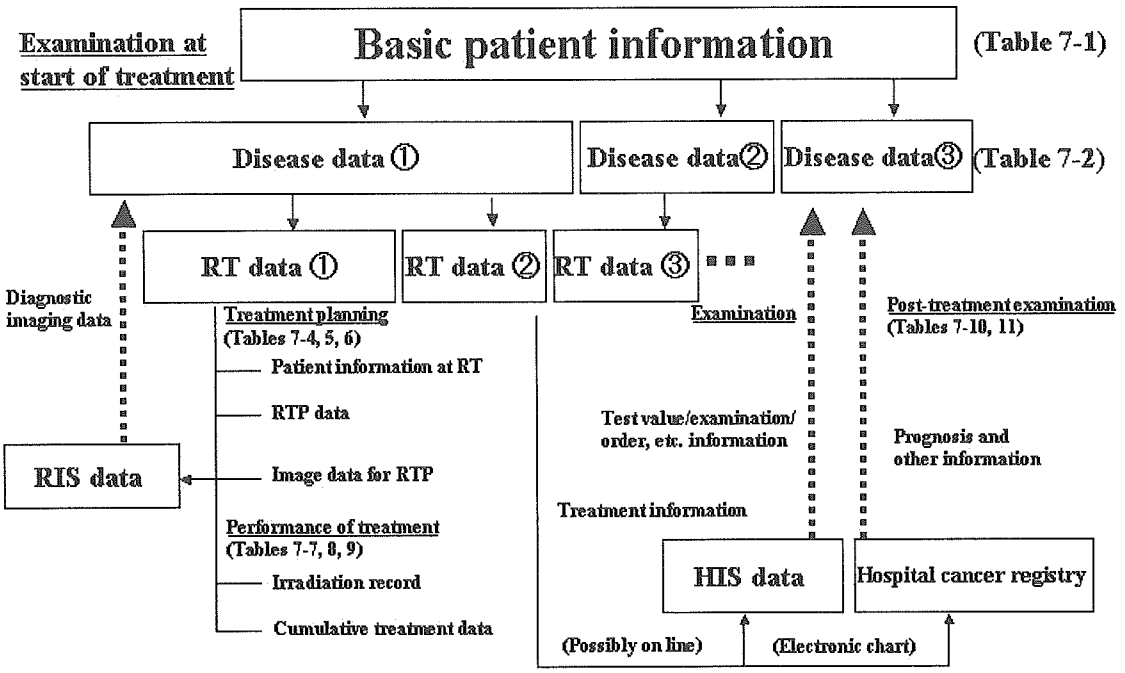

Figure 7-1 Radiotherapy (RT) database process.

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

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

7.6.1 Post-treatment follow-up and evaluation

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

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

Table 7-10 Post-treatment medical information

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

Table 7-11 Information noted at death

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

7.6.2 Clinical outcomes and evaluation of results

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

Table 7-12 Clinical outcomes to be evaluated

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

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

7.7 Tabulation and statistics of treatment-related data

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