International standardization of four dimensional radiotherapy system

— Enhancement of effects of irradiation and assurance of safety —

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In radiation therapy for cancer, there are possibilities of position changes of the affected area during irradiation due to respiration of a patient. In order to enhance effects of irradiation for the affected area and minimize damages to the surrounding normal tissues, four dimensional radiotherapy (4DRT), which can take into account time variation of the three-dimensional position of the affected area, has been recently developed, and has been achieving significant therapeutic effects. We have proposed the International Electrotechnical Commission (IEC) standards including technical requirements of the safety aspects of the systems which realize this 4DRT, taking into account the time aspect. The reason for the proposal is that international standardization will be very effective to ensure safety of 4DRT, and international standards of IEC will have compelling force if regulatory agencies refer to them. The purpose of this paper is to summarize the analysis of the strategy in a precedent endeavor toward international standardization of the 4DRT systems, for which demands are increasing. The main point of the strategy is forming an international consensus by bringing together the opinions of specialists from various fields from a clinical point of view, focusing on the international standardization of the technical requirements of the safety aspects of the 4DRT. Based on such a strategy, we will promote developing new standards by evaluating the overall safety of the 4DRT systems for further expanding use, in addition to updating existing standards of particular equipment which constitute the 4DRT systems.

Keywords : Four dimensional radiotherapy, real-time tumor-tracking radiotherapy, dynamic tracking, international standardization, IEC

1 Introduction

1.1 Importance of radiation therapy

According to the annual estimated vital statistics of the Ministry of Health, Labour and Welfare for 2010,[1] cancer was the most common cause of death for the Japanese, and about 25 % of all patients were treated with radiation therapy. The radiation therapy is a medical treatment that utilizes the difference of radiation sensitivity between the tumor cells and normal cells, and destroys only the tumor cells without damaging the normal cells by controlling the quantity of therapeutic rays. The characteristic of radiation therapy is that it does not require surgery, can preserve the form and functions of the affected area, and has relatively short treatment time. Therefore, it is suitable for treatments of elderly people. In addition, it has the advantage that, in principle, it is capable of treating cancers in any region of the patient's body.

Figure 1 shows the trends of the number of individuals affected with cancer and the number of patients who are treated with radiation therapy. This figure was created based on the results of the structural survey by the Japanese Society for Radiation Oncology (JASTRO) in 2010[2] and the estimated Japanese population-based cancer registration by the Center for Cancer Control and Information Services, National Cancer Center.[3] In the 1990s, the radiation therapy that used high-energy x-rays produced by small medical linear accelerators (LINAC) became widespread, and the number of its application increased, and this number is expected to grow. The rise in the death rate due to cancer is a trend seen in many aging countries, and there is a growing international need for radiation therapy.

1.2 Four-dimensional radiotherapy (4DRT)

In principal radiation therapies, x-rays, electrons, protons, and carbon are used as therapeutic rays. In any radiation therapy, the main issue is to irradiate the necessary quantity of therapeutic rays to the tumor that may move due to respiration or other factors and to minimize the damages to the surrounding normal tissues. To solve this problem, the R&D of 4DRT started around 2000 to enhance the timing accuracy of irradiation in addition to spatial accuracy.[4]

The 4DRT was employed around the world, and 4DRT was defined as "a therapy that explicitly includes the temporal

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changes of anatomy during the imaging, planning, and delivery of the radiotherapy."[5] That is, 4DRT is a highly accurate radiotherapy that improves the dose concentration on tumors and minimizes damages to normal tissues, by taking into account the time variation of the position of the tumor against the irradiation timing, in addition to the three-dimensional position of tumors that has been considered in conventional radiotherapy. Recently, the applications of 4DRT have rapidly spread to tumors that move due to patient's respiration and others.

Among the 4DRT methods, the Hokkaido University has been developing the gating radiotherapy (real-time tumor-tracking radiotherapy).[4][6] In the gating radiotherapy, as it will be explained below, the irradiation position of the therapeutic rays is fixed, and the irradiation is performed in synch with the moving target. Here, accuracy of the irradiation timing of the therapeutic rays is important. Figure 2 shows the conceptual diagram of the gating radiotherapy, the therapy apparatus at the Hokkaido University, and the gold marker. In this method, the gold marker is implanted near the tumor position inside the patient's body, and the x-ray image-guided radiation therapy (X-IGRT) equipment detects the gold marker that points to the position of the tumor that moves due to respiration. In the actual treatment, the external beam equipment irradiates the tumor with x-rays, protons, or others when the gold marker enters the region of the gating window. In cases in which this method was not used, the irradiation region had to be expanded to the entire region in which the tumor moved, and the surrounding normal tissues were irradiated with the same quantity as for the tumor position. The gating radiotherapy allowed the region of irradiation to be narrowed.

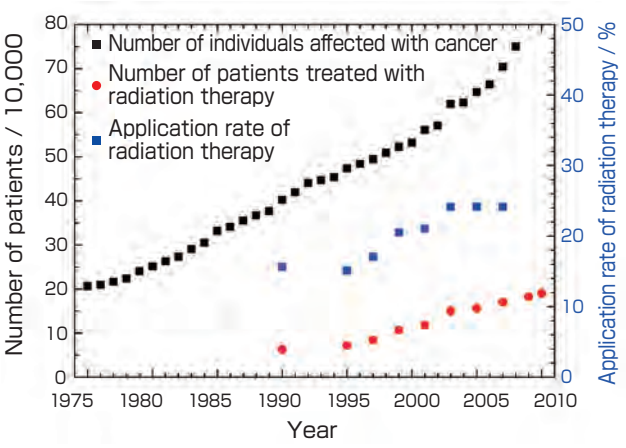
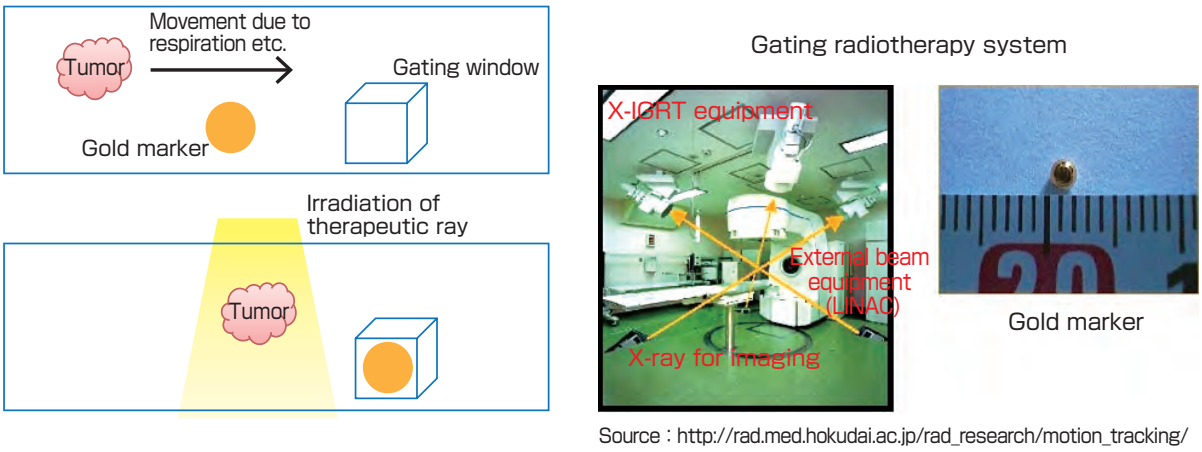


Fig. 1 Transition of the number of patients who were newly diagnosed with cancer (number of individuals affected with cancer) in one year, and the number of patients who were treated with radiation therapy in the year

Due to the penetration of the LINAC equipment, the number of patients who were treated with radiation therapy increased almost threefold in the last 20 years, and this number is expected to continue to increase.[2][3]

In contrast to the gating radiotherapy, the dynamic tracking radiotherapy places importance on the accuracy of the irradiation position of therapeutic rays in 4DRT.[8] As shown in Fig. 3, in the tracking radiotherapy, X-IGRT equipment tracks the position of the moving tumor using the markers, and the irradiation position of the therapeutic rays is controlled to ensure that the tumor is continuously irradiated with the therapeutic rays. The Kyoto University conducts the R&D for tracking radiotherapy using the external x-ray beam equipment that includes the ultra-compact LINAC developed by the Mitsubishi Heavy Industries, Ltd. The characteristic of the external x-ray beam equipment is that the ultra-compact LINAC is mounted inside the gantry along with the multi-leaf collimator (MLC) on the rotation mechanism called the gimbals mechanism, and this enables the irradiation direction of the therapeutic rays to be changed freely.[8] At the Kyoto University, the tracking radiotherapy is achieved by continuously tracking the tumor position inside the patient's body and irradiating the tumor with therapeutic rays during treatment.



Source : http://rad.med.hokudai.ac.jp/rad_research/motion_tracking/

Fig. 2 Conceptual diagram of the gating radiotherapy (left), and photographs of the gating radiotherapy system and gold marker (right)

Left photograph is cited from the website of the Hokkaido University Hospital.[7]

Although the 4DRT enables more effective therapy than the conventional radiotherapy, to perform the 4DRT safely, it is necessary to individually manage the parameters corresponding to tumor motions for each patient, since there is an increase in the number of parameters, including the timings of irradiation, the patterns of change in tumor position, the prediction model for predicting the change in tumor position, and others that are necessary to handle the degrees of freedom of tumor movement. In addition, the appropriate coordination of the X-IGRT equipment and external beam equipment that irradiates the tumor with x-rays, protons, or others is necessary to safely perform the radiation therapy.

As explained above, new safety requirements that were not considered before are necessary to realize the 4DRT. In the R&D for 4DRT, the most important aspect is safety assurance, and the safety requirements for 4DRT must be internationally standardized as soon as possible, to enable safe performance of 4DRT widely around the world. In addition, it can be expected that trial-and-error to ensure safety during the R&D of 4DRT can be reduced through the international standardization of the safety requirements for 4DRT.

Particularly, the arbitrary requirements that are internationally standardized by the International Electrotechnical Commission (IEC) are mandated and enforced, once they are quoted by the regulatory authority of a country. Therefore, the international standardization of the safety requirements of 4DRT system by the IEC is extremely effective to ensure solid safety assurance.

1.3 Organizations involved in the international standardization

There are three kinds of international standards: *de jure* standards that are developed by formal organizations; forum standards developed by private companies; and *de facto* standards that are developed through market competition (Intellectual Property Strategic Program 2011 of the Japanese government).

Representative organizations that develop the *de jure* standards are International Organization for Standardization (ISO), International Electrotechnical Commission (IEC), and International Telecommunication Union (ITU). The radiotherapy equipment are handled in the electrotechnical field by the IEC, and the standardization of the X-IGRT equipment, an important component for realizing 4DRT, has recently progressed in the IEC.

In the IEC, the Technical Committees (TC) are organized by categories, and the international standards pertaining to radiotherapy equipment are discussed in TC62 that handles the electrical equipment for medical practice. The TC62 has four Subcommittees (SC) as subsidiary organizations, including the following: SC62A (Common aspects of electrical equipment used in medical practice), SC62B (Diagnostic imaging equipment), SC62C (Equipment for radiotherapy, nuclear medicine, and radiation dosimetry), and SC62D (Electromedical equipment). The international standardization of 4DRT will be discussed in SC62C that handles the radiotherapy equipment.

As shown in Fig. 4, the Japan Electronics and Information Technology Industries Association (JEITA) discusses the items related to TC62, SC62A, and SC62D of the IEC, as the Japanese national commission consigned by the IEC. Also, the Japan Medical Imaging and Radiological Systems Industries Association (JIRA)[10] discusses the items related to SC62B and SC62C of the IEC, as the Japanese national commission consigned by the IEC.

2 Objective of this paper

The objective of this paper is to analyze our case of the international standardization of 4DRT in the IEC, and to present a direction of how to promote its international standardization for expanding the international use of 4DRT

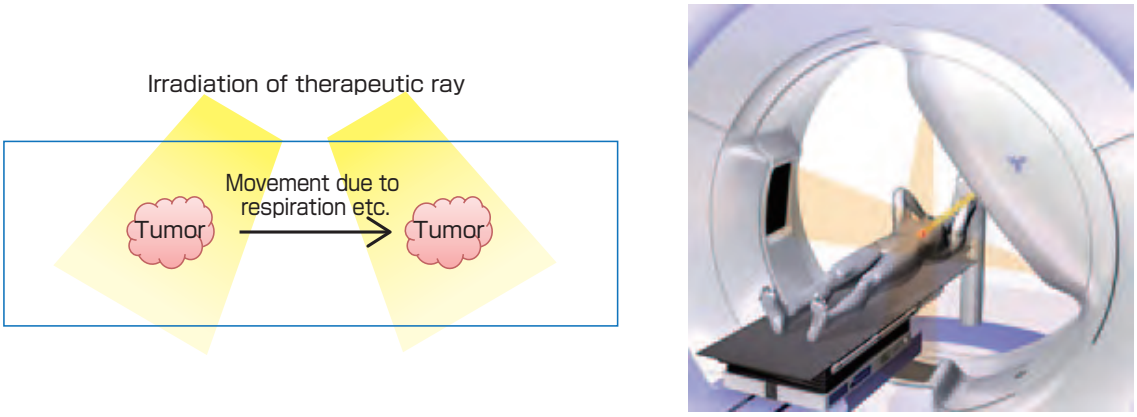


Fig. 3 Conceptual diagram of the tracking radiotherapy (left), and photograph of the tracking radiotherapy system using Vero4DRT of Mitsubishi Heavy Industries, Ltd. (right)
Left photograph is cited from the website of Mitsubishi Heavy Industries.

systems with enhanced safety.

3 Strategies for the international standardization of 4DRT

We planned to achieve the international standardization of the 4DRT system as a core in the IEC, the representative organization of *de jure* standards.

In order to resolve the general problems of international standardization[11] and the problems of international standardization in the field of radiotherapy equipment,[12] and to smoothly advance the international standardization of 4DRT, we adopted the following strategies.

3.1 Selection of committee members from a wide range of fields

In addition to the private companies that engage in the production of 4DRT systems, the physicians and medical physicists involved in the clinical practice of 4DRT at universities and research institutes participated as members of the committee to propose the international standard. This allowed discussions of 4DRT from a wide range of fields in Japan.

3.2 Ideas to facilitate the formation of international consensus

In contrast to the existing IEC standards that regulate the individual radiotherapy equipment, we proposed the standards for 4DRT systems by combining a number of individual equipment. We focused on the obvious problems that could not be solved by the standards for individual equipment, and we aimed for the international standardization of technologies related to safety for which consensus was relatively easy to obtain from the organizations working on international standards. In addition, we developed a universal phantom (object behaving in the same manner as human tissue with respect to absorption or scattering of the therapeutic rays; this is used to evaluate the performances of radiotherapy systems) that can be used to check the safety of the 4DRT systems. We adopted the policy of creating the safety requirements based on concrete and objective data obtained from the phantom.

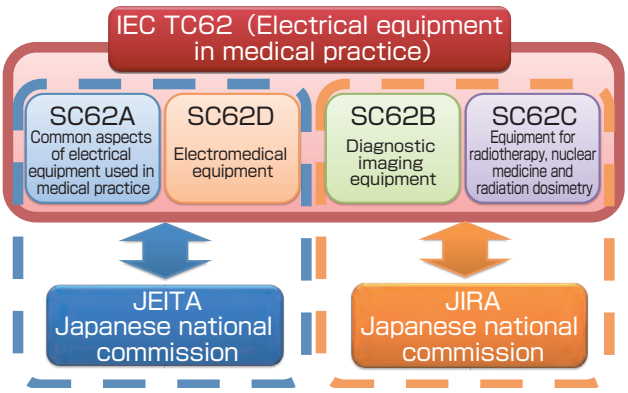


Fig. 4 Organizations involved in the international standardization of 4DRT

3.3 International standardization initiated by users

In the system requirements, we listed the items that were considered clinically important by the users of the 4DRT systems. Then, we advocated the importance of system requirements from a clinical perspective to the experts of the IEC TC62/SC62C WG1 of which most affiliations were private companies.

4 Efforts for the international standardization

Based on the strategy explained in chapter 3, we developed the international standardization of 4DRT as follows.

4.1 Clarification of the basic concept

In aiming for the international standardization of 4DRT, we considered the clarification of the basic concept of the international standardization as the most important topic, and discussed this matter in the Japanese national commission. 4DRT directly irradiates the moving tumor, minimizes the damages to the surrounding normal tissues, and reduces the patient's physical strain. In order to perform safe 4DRT, it is necessary for the equipment that constitute the 4DRT systems to be coordinated and integrated to function smoothly together during the treatment. Mere combinations of existing international standards cannot assure the appropriate and solid coordination of the various equipment necessary to realize the 4DRT systems. Therefore, we decided to propose a set of new safety requirements that are necessary for the appropriate and solid coordination of the 4DRT equipment. However, such basic concept was not set in the initial stages of activity for the international standardization of 4DRT. The basic concepts were developed to clarify the differences between the proposed international standard of 4DRT and the conventional IEC equipment standard in the processes of discussions at the IEC international conferences.

4.2 Targets and required accuracy of 4DRT

4DRT is a technology that reduces the damages to the surrounding normal tissues in the radiotherapy for tumors that move due to respiratory motion. According to the definitions of the guidelines for respiratory motion management in radiation therapy[13][14] that were developed from a clinical point of view, the respiratory motion management may be applied only when the length of respiratory tumor motion exceeds 10 mm and the expansion of irradiation area required to compensate for the respiratory motion can be reduced to 5 mm or less in all directions, three dimensionally. From these definitions for respiratory motion management, we obtained the quantitative criteria for the length of target tumor motion (greater than 10 mm) and the reduction of the expansion of irradiation area compared with

conventional radiotherapy (5 mm or less).

Specifically, as shown in Fig. 5, when the tumor moving due to respiration is treated with 4DRT, the irradiation area can be narrowed to 5 mm or less compared to the conventional radiotherapy.

4.3 Items to be considered for 4DRT and its safety requirements

In order to achieve the accuracy discussed in subchapter 4.2, we narrowed down the important 4DRT keywords that were not included in the existing IEC standards to "latency," "prediction model," "baseline shift," "dynamic phantom," and "4DCT."

"Latency" is the time interval between the recognition of a tumor and the actual irradiation by the therapeutic rays on the patient's body. If latency increases, the irradiated position of the therapeutic rays may deviate from the tumor position as shown in Table 1, and therefore, the prediction of tumor position is performed using a reliable prediction model.

For latency, we must consider the latency of the overall system that includes the X-IGRT equipment and the external

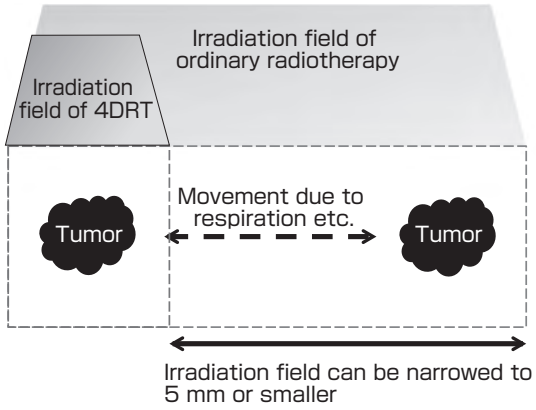


Fig. 5 Comparison between the irradiation field of 4DRT and that of conventional radiotherapy

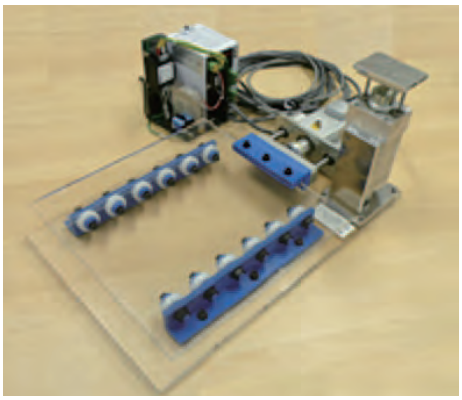


Fig. 6 Photograph of the dynamic phantom
The dynamic phantom is used to evaluate the geometrical deviations of the X-IGRT equipment in 4DRT.

Table 1. Maximum position deviation due to latency
Calculated values of deviations between the tumor position and the irradiated position in cases where the tumor moves along the 2 cm distance in 3 sec cycle sinusoidal wave
It can be seen that the latency of about 250 msec causes a position deviation of 5 mm between the tumor position and the actual irradiated position.

Latency [msec]	Maximum position deviation due to latency [mm]
50	1.0
100	2.1
150	3.1
200	4.2
250	5.2

beam equipment to ensure the accuracy of irradiation of therapeutic rays. For example, the position deviation D in 4DRT for the tumor moving with mean velocity V can be considered as follows. Latency T of the overall system is the sum of the following times: the interval between the recognition of tumor position by a tumor-position-measuring equipment such as the X-IGRT equipment and the transmission of irradiation instructing signal to the therapeutic-ray-irradiating equipment (T_1); the interval between the reception of irradiation instructing signal and the irradiation of therapeutic rays, change in beam direction, or other instructed action (T_2); and the time required for communication (T_3). The deviation of recognition of position by the IGRT equipment D_0 is added to the final position deviation D that is represented by following formula:

$$D = V(T_1 + T_2 + T_3) + D_0 \qquad (1)$$

That is, D represents the irradiation accuracy of the 4DRT systems, and it is dependent on a number of factors such as the latency of various equipment, the time of communication, and the deviation of recognition of position by the X-IGRT equipment. To assure the safety of overall 4DRT systems, we need not only the international standards for the various types of equipment (T_1, T_2, T_3, and D_0), but also the international standards for the system at the level superior to the equipment (T and D).

"Baseline shift" is the change of the patient's respiration state that cannot be predicted by the prediction model. If the baseline shift is ignored, the tumor moving in a way that cannot be foreseen by the prediction model may be irradiated according to the model, and in such a case, the normal cells may be irradiated with the therapeutic rays. In cases in which the baseline shift occurs, a mechanism to definitely terminate the irradiation of therapeutic rays is necessary in the 4DRT systems.

"Dynamic phantom" is a model for simulating the tumor motions inside the patient's body. This model is used to examine the performances of the 4DRT systems in terms of "latency," "prediction model," and "baseline shift."

Finally, "4DCT" is a method for reconstructing the moving CT images by obtaining the x-ray CT images during, for example, five respirations and then using the markers placed on the surface of patient's body. Since the information for tumor motion can be obtained using the 4DCT and the treatment plan for 4DRT can be created based on this information, the accuracy of 4DCT often becomes a problem in the 4DRT systems.

The above keywords are items that must be at least considered in the clinical practices of 4DRT, and they must be defined in the IEC standards.

4.4 Introduction of the new concepts to the existing standards

The above keywords play important roles in assuring the safety of 4DRT. Therefore, we set the required items that should be standardized based on the keywords, and proposed the safety standards for 4DRT in the IEC TC62/SC62C WG1 held in Germany on September 2011.

However, at that time, the basic concept of standardization of the 4DRT systems (refer to subchapter 4.1) was not clear, and we could not obtain the consensus to develop a completely new standard in the IEC TC62/SC62C WG1 to assure safety of 4DRT. Therefore, we reached the consensus to add the requirements related to 4DRT in the existing standard of the X-IGRT equipment (IEC 60601-2-68) that was being discussed in the IEC TC62/SC62C WG1, and we obtained results on the latency and the baseline shift as follows.

4.4.1 Latency

Regarding latency, the requirements of latency of the X-IGRT equipment (the time interval between the acquisition of images that includes the tumor position information and the outputting signal to external beam equipment (T_1)) were added to the IEC 60601-2-68. This was because the importance of latency was recognized for the safety of the X-IGRT equipment.

4.4.2 Baseline Shift

Regarding the baseline shift that is expected to occur frequently during 4DRT, the requirements of the baseline shift were added to the standard of the X-IGRT equipment (IEC 60601-2-68), since we obtained consensus on the necessity of requirements by which the irradiation of therapeutic X-rays can be interrupted and settings of the equipment can be modified to continuously administer safe and smooth treatment.

4.4.3 Correspondence to the existing standards

In addition, we continued discussions in the IEC TC62/SC62C WG1 and obtained the following results corresponding to the existing standards (IEC 60601-2-68).

We found that the offline X-IGRT, online X-IGRT, and real-time X-IGRT 4DRT, which were defined in the IEC 60601-2-68, were all related to 4DRT. Therefore, we organized the above relationships and were able to add examples of the 4D versions of the offline X-IGRT, online X-IGRT, and real-time X-IGRT to the new annex of IEC 60601-2-68.

4.4.4 Updating the standard for the external x-ray beam equipment

The concept of latency is important for the external x-ray beam equipment that was the other component for realizing the 4DRT, and the above results for latency became a trigger for updating the safety standard of the external x-ray beam equipment (IEC 60601-2-1). In the update (62C/574/RR) of the standard for external x-ray beam equipment (IEC 60601-2-1), the item for motion management in 4DRT will almost certainly be added to the IEC 60601-2-1. In the item for motion management, gating and tracking irradiations that are representative methods of 4DRT as well as latency were listed. Particularly, the Japanese national commission was requested from the start to create the proposal for latency requirements at the IEC TC62/SC62C WG1. Since the standard for external x-ray beam equipment (IEC 60601-2-1) was the most basic and most important standard for assuring the safety of equipment for the radiotherapy equipment manufacturers, it was highly significant that the Japanese IEC experts could participate from the start in updating the standard.

4.4.5 Items other than the latency and baseline shift

Among the five items discussed in subchapter 4.3, we decided to fully develop three items (a prediction model, a dynamic phantom, and 4DCT) other than latency and baseline shift in the new work item proposal (NP) that will be proposed by Japan at the IEC, as they seemed to have high novelty.

5 Future direction

To further contribute internationally in the standardization for the safety of treatment equipment in the future, it is necessary to engage in the international standardization activities as follows.

Internationally, there are examples where a large-scale company that specializes in radiotherapy systems independently takes a proactive stance for the international standardization of radiotherapy equipment. In addition to the activities that we have been conducting, it is essential to engage in vigorous international standardization activities through industry-academia-government collaboration. The companies developing

and producing the 4DRT systems, government agencies, public research organizations, universities, academic societies, and other interested parties must work together.

Based on the basic concept explained in subchapter 4.1, international standardization from the standpoint of system aspects is necessary.

The 4DRT system is a complex system comprised of several components such as the X-IGRT equipment that mainly monitors the tumor state, the external beam equipment that directly treats the tumor, the treatment table, and the treatment planning equipment that appropriately controls the equipment. On the other hand, since the international standardization and the creation of de facto standards are being done to integrate the above components of the 4DRT system, it is unrealistic to create completely new standards for these components. As a result, it is unclear where the responsibility lies in coordinating and connecting these components, and this creates concern for patient safety. If we overlook this point, it may cause medical accidents such as excessive or under irradiation.

Originally in the IEC TC62/SC62C, the main task was to create the standards for independent equipment, and therefore, the system standard was not created. To supplement this, the Japanese national commission proposed the NP (62C/580/NP) for creating a completely new system standard for the "Requirements of safety and performance of complex real-time controlled radiotherapy systems for a moving target," and the NP was approved by international voting. In this NP, it is expected that the five items discussed in subchapter 4.3 will be officially standardized to assure the overall safety of the 4DRT systems.

In addition, it is becoming certain that the system will be included in the new scope proposal of the IEC TC62/SC62C, and the system standard of radiotherapy systems will be created in the IEC. Of course, in developing a completely new system standard, we must proceed with ingenuity to avoid disadvantages to individual companies. However, we shall promote the development of new system standards to ensure safety of radiotherapy that can track tumor motion, for both large and small companies.

In the future, it is expected that the international standardization of 4DRT in the IEC will be developed for both the independent equipment standard and the system standard as shown in Fig. 7.

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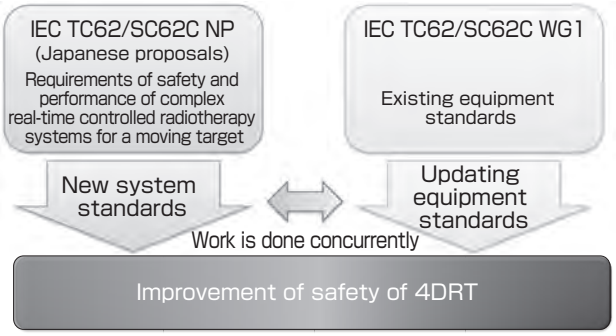

Fig. 7 Future direction of the international standardization of 4DRT

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Discussions with Reviewers

1 Overall comment

Comment (Akira Ono, AIST)

This paper clearly illustrates the strategy and results for creating an international standard for 4DRT that was led by Japanese academia and industries. It specifically describes the process by which the draft of the standard was submitted to the IEC. It may lead to updating of existing standards of the IEC or new standards in the future. Also, the Japanese system for drafting the proposal is well described. This would be useful to the readers who plan to become involved in international standardization in the future. I think it is an excellent paper for *Synthesiology*.

2 Significance of international standardization

Question (Motoyuki Akamatsu, Human Technology Research Institute, AIST)

The motivation for research is written in subchapter 1.2, and it states the social value of this paper. Needless to say, assurance of safety is important, but you state that the international standardization of safety standards is needed as the means to achieve safety. Generally, I feel there are ways to provide safety without such international standardization. Therefore, can you explain why international standardization will ensure safety?

Answer (Yuichi Hirata)

Specifically, the arbitrary requirements that are internationally standardized by the IEC are mandated and enforced, once they are quoted by the regulatory authority of a country. Therefore, international standardization of the safety requirements of 4DRT system by the IEC is extremely effective to achieve solid safety assurance.

3 Agreement among a wide range of stakeholders

Comment (Akira Ono)

In the process of standardization, the central point is to make an agreement among a wide range of stakeholders involved. In the standardization at the ISO or IEC, since the participating countries may not necessarily have a wide range of stakeholders in their respective countries, the range of agreement could be narrow, which may not make standards widely used after publication.

In contrast, in the standardization of the 4DRT equipment discussed in this paper, its characteristic is that wide-ranging stakeholders in Japan were involved. The statements in subchapter 3.3 “International standardization initiated by users” and chapter 5 “Future direction” are appropriate. I think the wide participation of not only the radiotherapy equipment manufacturers but also the equipment users such as physicians, medical technicians, as well as researchers who maintain neutral positions led to the creation of a convincing standard with excellent neutrality. I expect this standard to be adopted worldwide.

Answer (Yuichi Hirata)

As you indicate, the participation of a wide range of Japanese stakeholders to create the WG for international standardization strategy for 4DRT, and the creation of a standard proposal based on the comments of people from various fields, including equipment manufacturers, physicians, medical physicists, researchers, and government agencies led to the standardization of 4DRT as explained in this paper.

4 Is this a product standard or a test standard?

Question (Akira Ono)

I ask you about the target range of the standard (or the scope of the standard) that Japan attempts to propose in the future. While it is addressed in subchapter 4.2 as well as in chapter 5 "Future direction," which of (1) or (2) below is the target range of the standard that the authors assume? Or does it encompass both?

(1) Product standard: Are you trying to specify performance or function required for 4DRT? That is, are you trying to create a "product standard" for the 4DRT equipment?

(2) Test method standard: Are you trying to specify necessary items and methods to test the 4DRT? That is, are you trying to create a "test method standard" for the 4DRT equipment?

As a personal opinion, if you are assuming development of a test method standard as in (2), I think you can clearly differentiate between a piece of equipment for which thorough safety considerations have been done and one that haven't. Also, the user can clearly recognize highly safe equipment by investigating whether it matches this standard. Therefore, this standard is advantageous to the users around the world, and at the same time, I think the equipment with solidly enhanced safety will be evaluated highly.

Answer (Yuichi Hirata)

The specific target range of the standard in the future will encompass both (1) and (2) that you described. For (1), I think the necessary performance and functions are standardized based on the 4DRT systems that currently exist on the market. For (2), I think, for example, the evaluation test method for 4DRT using the dynamic phantom will be standardized.