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Test automation for verifying software's detectability for rule violations

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ABSTRACT OF THE
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Cancer is the term for diseases in which a group of previously normal cells have gone through a serial genetic alteration in their DNAs and eventually appear uncontrolled self growing, infectiveness to surrounding tissues and capability of spreading to other places of the body.

Radiation therapy as a cancer treatment method is considered as a great revolution in the history of medicine. It uses high-energy ionizing radiation to disrupt the cellular dividing, which will ultimately cause the death of the cancer cells. In Radiation therapy, treatment planning system software is often used in treatment planning phase. Its main usage is to generate the virtualized beam shapes and dose distributions with the intention to help clinicians to maximize the tumor control and minimize the normal tissue complications for the cancer patient.

In this work, automated tests are developed for verifying a large set of checking functions executed in a treatment planning system software. The objective of implementing these automated tests is to intentionally violate the rules in order to check whether the expected error or warning message are thrown by the checking functions and are correctly shown to the user.

Keywords: Automated Test, Cancer, Radiation Therapy, Treatment Planning System, Risk Management in Radiation Therapy, Software Testing

Preface

This Master's Thesis was done in a company that develops software for radiation therapy devices. In order to protect the company's confidentiality, I have obfuscated all the "sensitive subjects" in this thesis, while still tried to maintain the text as understandable as possible.

In the beginning of September 2010, there were some uncertainties about me getting the thesis work in the company, mainly as the thesis subject was not directly related to my work responsibilities in the company. I would like to thank Ramin and Riikka, who granted me this chance and made all this possible. Especially, I would like to give my greatest gratitude to Riikka, who had guided me through all this work and selflessly devoted some of her private hours and family time to revise my thesis. Also I would like to thank Mikko for offering me helpful comments on my practical work and my girlfriend Jue for supporting me during the whole of this work. Lastly I would like to give my heartfelt thanks to Prof. Jukka Manner for the final review of my thesis.

Helsinki, 30th August 2011

Zhishuai Yao

Contents

Abbreviations

3D	Three Dimension
ALARP	As low as reasonably practicable
CT	Computed Tomography
DICOM	Digital Imaging and Communication in Medicine
DNA	Deoxyribonucleic Acid
FDA	U.S Food and Drug Administration
IAEC	The International Association of Elevator Consultants
ICRU	Internationalization Commission on Radiation Units and Measurements
ID	Identification
IDE	Integrated Development Environment
MFC	Microsoft Foundation Class
MLC	Multileaf Collimator
MRI	Magnetic Resonance Image
RNA	Ribonucleic Acid
RT	Radiation Therapy
STL	Standard Template Library
TPS	Treatment Planning System
XML	Extensible Markup Language

1 Introduction

1.1 Background

Most basically, cancer is the term for diseases in which a group of previously normal cells have gone through a serial genetic alteration in their DNAs and eventually appear uncontrolled self growing, infectiveness to surrounding tissues and capability of spreading to other places of the body [**1**]. Clinically, this group of cells is termed as malignant tumor. Other than cancer cells, there is another group of cells that tend to be less harmful. They can form a tumor that is self-limited and constrained to one single location; it's so called benign tumor. Benign tumor is only dangerous when it begins to compress other normal tissues.

According to the statistic data from ***American Cancer Society***, in 2009 there were more than 292,540 male plus 269,800 female died from cancer in the US [**2**]. With all the new technologies and methodologies introduced to the cancer treatments, the death rate of cancer has dropped 16% in the period of 1991 to 2006. Nevertheless, cancer is still ranked the second man-killer among other diseases[1] and it is estimated today that just few years from now, the death toll from cancer will exceed that from cardiovascular disease [**2**,**3**].

Nowadays there are three major therapeutic methods to treat cancers, which are surgical operation, chemotherapy and radiation therapy. In radiation therapy, treatment has a very low tolerance level for inaccuracies and errors, since the high proportion of body is under exposure of high-energy radiation. If mistreatment happens, it is very likely to cause a serious injure or even death to the patient. Therefore, radiation device manufacturers and clinics have been making actions on

[1] It is slightly after cardiovascular diseases.

eliminating mistreatments through risk management and quality assurance.

1.2 Objectives

In this work, automated tests are developed for verifying a large set of checking functions executed in a computerized treatment planning system (TPS) software for radiation therapy. In order to protect the target company's confidentiality, the term "checking functions" will be used to represent the testing subject throughout this thesis, and the content or the purpose of the checking functions will not be specified in more detail. The essential is that the checking functions will trigger error or warning message shown to the user, if they detect a case that violate the pre-defined rule.

The objective of implementing these automated tests is to generate these cases which violate specific rules in order to check whether the expected error or warning message is thrown by the checking functions and is correctly shown to the user. Especially, the automated tests should be able to trigger the violation cases that are not possible to be generated from graphic user interface, but requires e.g. internal system failures or data corruptions. In addition, as part of the regression tests, these automated tests should reduce the time needed for testing and should be able to be executed at any phase of the product development so that possible defects can be found immediately after it occurs.

1.3 Outlines of the Thesis

In Chapter 2, the operational principle of radiation therapy is presented in order to introduce the basic concept of radiation therapy in cancer treatment. Afterwards, several techniques that are used in radiation therapy are discussed in general. After introducing the background, Chapter 3 presents the common staffing and workflow of

radiation therapy in clinics. In Chapter 4, in addition to provide an overview of computerized treatment planning system, general process of treatment planning using TPS is discussed. Chapter 5 focuses on explaining the risk management in radiation therapy. Chapter 6 and 7 mainly discuss about the required background knowledge of this work, which includes the knowledge of software testing and the testing tool (CppUnit) used in this work. In Chapter 8, the actual work is presented. It reveals the concept of the design of the implementation. Chapter 9 evaluates the testing results generated from the developed test cases. Conclusion of this work is made in Chapter 10, as well as a future sight to this subject.

2 Radiation Therapy in General

In this chapter, the general knowledge of radiation therapy will be presented. The focus is on the external beam radiation therapy, which is considered to be the most popular treatment method in radiation therapy.

2.1 Basics of Cancer Treatment

In cancer treatments, there are three major standard methods for treating cancers: surgery, chemotherapy and radiation therapy. Each of these methods is eligible to be used alone in one treatment; it is called single-method therapy. More often, more than one method is carried out to one treatment, which is termed as multi- method therapy [**4**].

2.1.1 Surgery in Cancer Treatment

In cancer treatment, surgery belongs to the category of local treatment, which requires accurate positioning to the target - the malignant tumor. After tumor being located, most but not entire tumor will be removed surgically, while affected organs' functionalities are tent to be preserved utmost. The rest remained tumor tissues will be treated by other means afterwards, e.g. chemotherapy or radiation therapy. Usually, the outcomes of the surgical operation will come along with certain side effects because malignant organs have been removed partially or entirely, which will negatively affect patients' quality of lives. Thus, the decision to undergo this kind of treatment is difficult for the patients [**4**].

2.1.2 Chemotherapy in Cancer Treatment

Chemotherapy is a systemic treatment for which medications travel through the

bloodstream and act against the rapidly dividing cells [**5**]. The principle is that cancer cell shares the common characteristic of rapid self-dividing. This feature makes the cancer cells become vulnerable to the chemotherapeutic medications. By taking advantage of this fact, cancer cells can be eliminated most effectively by medications, whereas other normal cells are affected less [**5**].

In the treatment of chemotherapy, drugs or medications are given in different schedules [**5**]. In general, chemotherapy is administered in cycles of every three to four weeks [**4**]. Within a cycle, patients will be medicated for one or two weeks. After then, they will be allowed to have another one or two weeks time to recover from the previous treatment and prepare for the next one [**5**].

Because chemotherapy is aimed at damaging the cells that are rapidly dividing, some normal cells that share the same feature will also be affected. For example, stem cells, hair cells and blood cells. Common side effects such as hair loss and nausea may happen for this reason [**4**,**5**]. Therefore, chemotherapy treatment schedule should be carefully designed to allow the normal cells sufficient time to recover, while repeating the treatments frequently enough so that the cancer cells do not recover [**4**].

2.1.3 Radiation Therapy in Cancer Treatment

Radiation therapy as a cancer treatment method is considered as a great revolution in the history of medicine. It uses high-energy ionizing radiation to disrupt the cellular dividing, which will ultimately cause the death of the cancer cells [**6**].

Radiation therapy is also categorized as local treatment because only the cells in and around tumor will be treated or radiated. However, it is unavoidable that the high-energy beams will cause some damage to the normal cells when beams are passing through the body from the surface of the skin to the malignant tumors. This will cause some side effects, which may be seen after weeks, months or years [**7**].

Among all these three major standard methods of cancer treatments, radiation therapy is the one that will be discussed in more detail in the following chapters.

2.2 Basics of Radiation Therapy

Radiation therapy uses high-energy ionizing radiation to cause serials of biological effects in cancer cells, which are largely the result of their DNA damage [**7**]. To understand how the radiation therapy works, it is helpful to know about the life cycle of the cell [**8**].

As it shows in Figure 2.1, the cell life cycle is a sequence of highly ordered process which consists of four phases: *G1*, *S*, *G2*, and *M*, for representing different states of the cell. Cells that are newly generated are first born into *G1* phase [**6**]. In this phase, cells start producing more proteins for preparing cells' dividing. At the same time, single strands of DNA, so called RNA are also made. After entering *S* phase, the DNA synthesis occurs and two copies of each chromosome are produced. In the *G2* phase, cells continue to grow and prepare for the mitosis, or division of the cell nucleus. *M* phase is the final operational phase for cell diving, in which the duplicated chromosomes will be separated into single chromosome and cells will split into two at the end of the *M* phase [**6**,**7**,**8**]. In addition, cells may go to a special resting phase, *G0* phase, in which cell cycle is partially dismantled. When these cells get certain signal, they will enter into *G1* phase and start cycling again [**6**].

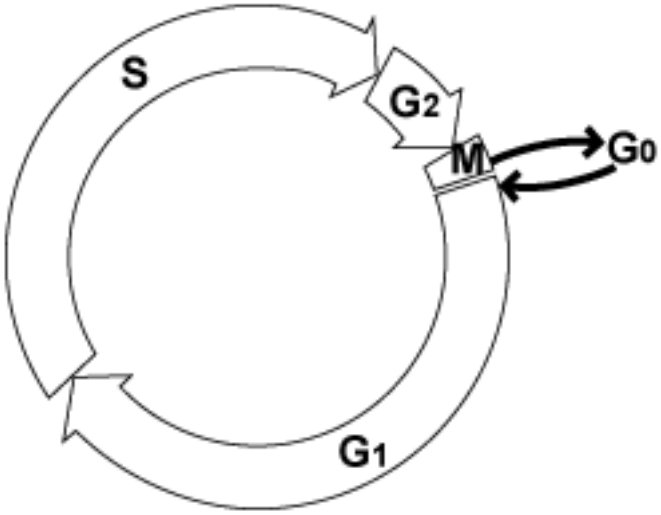

Figure 2.1 The cell life cycle [8]

The speed of the cell life cycle affects the effectiveness of ionizing radiation killing cancer cells. Radiation kills cancer cells because they are dividing quickly and growing out of control. In contrary, the cells in *G0* phase or dividing slowly are less sensitive to the radiation exposures. When the patient's tumor is under radiation, the cancer cells' DNA is tent to be damaged biologically so that the cells dividing mechanism can be disrupted. This damage will eventually lead to cancer cells' dying in days or weeks. As discussed before, even though radiation therapy is categorized as local treatment and radiation aims directly at the malignant tumor, it is inevitable that the normal tissue around the tumor will also be radiated and this will cause some side effects. Cells in tissues such as skin and bone marrow are also growing and dividing relatively faster than other normal cells, thus they are always affected immediately after the treatment. In contrast, cells in bone, nerve, and breast tissue always show later effects [**7**]. Therefore, the goal of radiation therapy is to maximize the dose to malignant tumor while minimizing exposure to normal, healthy cells.

2.3 Types of Radiation in Cancer Treatment

Radiation therapy can be classified into two different types based on the positioning of the radioactive source: external beam radiation therapy and internal radiation

therapy or brachytherapy.

2.3.1 External Beam Radiation Therapy

External beam radiation therapy is the most common form of the radiation therapy. In general, external beam radiation therapy consists of a beam (or multiple beams) of ionizing radiation such as high-energy photon beams (gamma rays), electron beams or proton beams that are all generated outside the patient and are targeted at the tumor site to destroy cancer cells or slow their rate of growth [**9**].

2.3.1.1 Photon Beam Therapy

Photon beam therapy is the most used treatment modality in external beam radiation therapy. There are two general methods to create photon beams. Firstly, photon beams can be released from various types of radioactive source. One of the common sources is cobalt 60, which is used to generate photon beams that can be also categorized as gamma rays. In the middle of 20^{th} century, cobalt 60 source was first implemented in a cobalt unit for clinical use. A typical size of a cobalt 60 source is with diameter 2cm and height 5cm [**10**]. The cobalt unit uses collimator jaws only to control the time and the strength of the radiation treatment. This feature is one of the constraints that have limited the range of the usage of cobalt machine, comparing to the linear accelerator, which is the other type of unit that can provide gamma ray photon beams. This is done, by having high-speed electrons that are accelerated by high frequency electromagnetic waves, striking to the target source [**10**]. No matter through which type of sources and methods that the photon beams are created, the physiology and biology effects of the different photon beams are equivalent.

2.3.1.2 Electron Beam Therapy

Linear accelerator can produce not only gamma rays, but also can emit electrons itself

to form the treatment beams. With the advent of the high-energy linear accelerators, electron beam therapy has become an important option in treating superficial tumors [**11**]. The reason for this is that electron beam therapy has a significant advantage at delivering a reasonably uniform dose from the surface to a specific depth, after which dose falls rapidly. This character allows it to treat certain superficial tumors, such as skin and lips cancer, which are up to depth of about 5 cm.

2.3.1.3 Proton Beam Therapy

Proton beam is a form of particle beam. Comparing with conventional external beam radiation, such as photon beam and electron beam radiation, proton beam is more capable at precisely localizing the radiation dosage. This is because of that proton beams are formed by particles that have relatively large mass, which makes it possible to limit the lateral side scatter in the normal tissue when beams are passing through and cause great damage at the end of the beams' path [**12**]. This also means proton beam radiation therapy can administrate greater dose to the tumor, however has less side effect to the normal tissues nearby [**7**].

2.3.2 Brachytherapy

Brachytherapy is an internal radiation therapy that places radioactive materials inside the tumor or beside the tumor. It provides another way to take advantage of human cells' biological effect while under radiation [**13**]. In contrast to external beam radiation therapy in which beams will go through the body toward the tumor, radiation of brachytherapy affects a more localized area around the radiation source. In such case, normal tissues can be better preserved. More often, brachytherapy is used along with other treatments for cancer such as surgery and chemotherapy.

To move the radioactive source into patient's body, shielded hollow tube (catheter) or applicator are commonly used, together with a loading device called afterloader

machine. This technology provides a protection to the operator and patients from the risk of unnecessary radiation. When the treatment plan is completed, afterloader machine moves the radioactive source through the applicator and stops the source in the planned position for a defined time. Finally, tumor tissues around those radioactive sources are damaged or killed by the radiation.

There are two major types of brachytherapy, classified according to the duration of the dose delivery [**14**]:

- Permanent Implant: In permanent implant, several radioactive pellets, so called seeds, are implanted inside the tumor permanently. The seeds will give off a known amount of radiation. After a certain period, there will be no measurable radiation inside or outside the body. Before the seeds become nonradioactive, patients have to follow the safety precautions after seeds are implemented.

- Removable Implant: As the name suggests, radioactive source will be implanted in patient's body temporarily for removable implant. The treatment period could vary from few minutes to days depending on many different factors, such as, tumor type, size and location. In low-dose-rate brachytherapy, radioactive seed will be administered in patient's body up to 24 hours before being removed. In contrast, high-dose-rate brachytherapy allows radioactive seed to give a high dose rate to the target area in few minutes.

2.4 Linear Accelerator

In general usage, radiation treatment machine is referred as a whole system that is used for delivering radiation therapy. It includes beam production system, waveguide and beam transferring system, cooling system, treatment head and beam defining

system and patient support system. In this thesis, the terminology of radiation treatment machine is only defined for linear accelerator treatment head, beam defining system, and patient support system. Only those components of the system will be discussed in this chapter [**15**].

In radiation treatment machines, the linear accelerator treatment head can be categorized into two kinds, either being in line with the waveguide or at right angle with the waveguide. For the convenience of the implementation at the clinics, the treatment head is always mounted vertically to the waveguide. Additionally a beam-bending magnet is required at the end of the waveguide to bend the beam to right angle.

2.4.1 Gantry

Nowadays, most of the treatment head is constructed in such a way that the source of the radiation beam can be rotated around horizontal axis as shown in Figure 2.2. While the gantry rotates, the collimator axis (central axis of radiation beam) moves in a circle around a central point, which is known as isocenter.

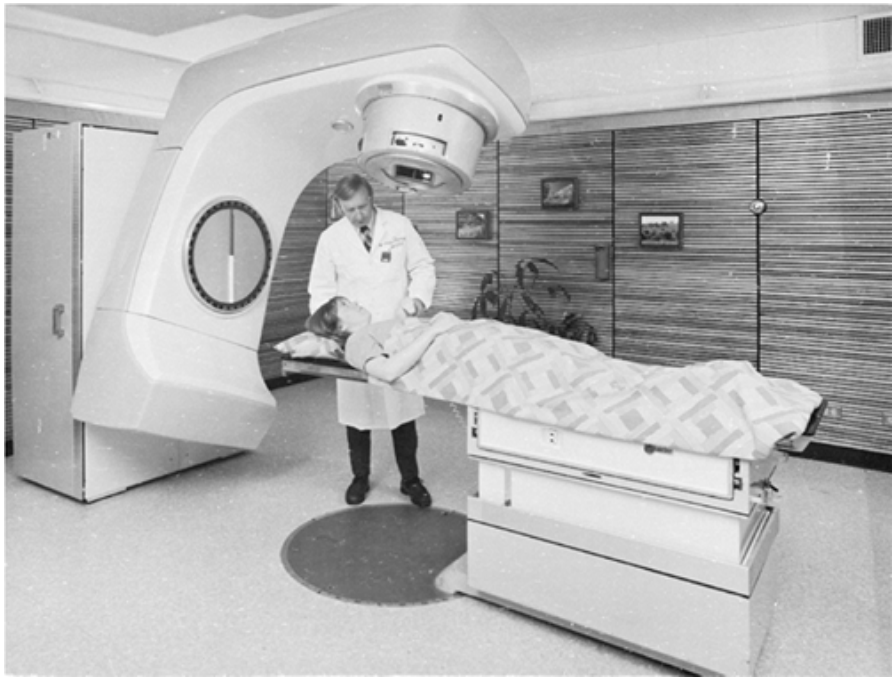

Figure 2.2: Photograph of a linear accelerator [16]

2.4.2 Gamma Ray Target

In Figure 2.3, a target source is placed at the upper edge of the treatment head. As has been mentioned in 2.3.1.1, this target source is used to emit photon beams by having high-speed electrons strike to it. This beam transmission process will also generate significant heat, which could affect the physical performance of the machine. In order to address this problem, a flowing-water cooling system is used to take away the operating heat constantly when linear accelerator is emitting radiation beams. However, this is not presented in the Figure 2.3.

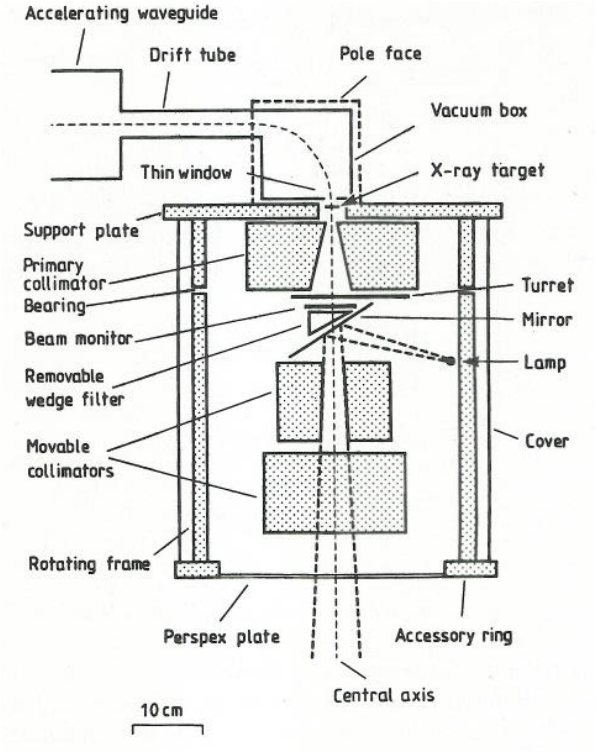

Figure 2.3: The treatment head for the treatment machine [15].

2.4.3 Primary Collimator

Primary collimator is mounted at the starting point of the photon beam. This element controls the maximum field size for treatments. In order to provide a sufficient attenuation rate, primary collimator is usually made of lead that filled with steel or heavy metals.

2.4.4 Flattening Filter

The photon beam that first comes out of the primary collimator is initially not flattened and has a sharp peak dose distribution along the central axis of the beam. The higher the electron energy is used, the steeper the curve is.

Flattening filter is used to attenuate the peak dose at the beam's central axis and to provide a uniform dose distribution. Figure 2.4 shows the relative dose measured 1

meter away from the source target at the plane perpendicular to central axis.

It is worth to mention that the clinical usage of the flattening filter is quite strict. A minor movement of the flattening filter will make an otherwise flattened beam un-flattened and asymmetrical. Therefore, the mechanical installation is critical [**15**]. Besides, different photon beam energies will require different flattening filters. Nowadays, most of the linear accelerators support more than one beam energies, so that the same amount of flattening filter should be mounted and well matched with the energies. Lastly, using a flattening filter with an unstable energy will also cause an unexpected dose distribution. This factor shall be controlled by beam monitoring system, which will be discussed in next section.

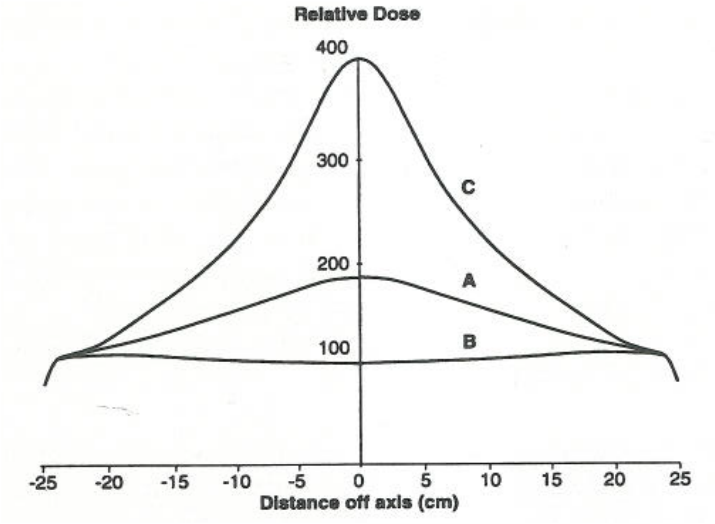

Figure 2.4: Measured dose distribution 1 meter away from the source target at the plan perpendicular to central axis. Curve A shows the 8MV photon beam without flattening filter; Curve B shows the 8MV photon beam with flattening filter and Curve C shows the 20MV photon beam without flattening filter [15].

2.4.5 Beam Monitor

The beam monitoring system consists of several transmission ionization chambers or a single chamber with multiple plates. The usage of ionization chamber is to monitor dose rate, integrated dose and field symmetry. Since the beam monitoring system is

under high-energy radiation, it is important to make sure the efficiency of ion collection. In order to preserve the accuracy of the measurement, there are three general requirements [**15**]:

- It should be thin.
- Its ionization sensitivity should be independent to ambient temperature and pressure.
- It should be operated under saturation conditions.

Beam monitor chamber has to be so thin that the thickness would not cause too much perturbation to the treatment beam. Normally, the ionization chamber consists of multiple parallel plates. Each plate is typically 0.1 mm thick. To maintain the constant sensitivity of beam monitoring system, monitor chamber is usually sealed to prevent the influences from the variation of ambient temperature and pressure. However, these chambers have to be periodically checked for leaks [**15**].

2.4.6 Moveable Beam Defining Collimators

The movable beam defining collimators are usually made of lead or tungsten and are operated in two pairs, which can shape the photon beam from two orthogonal directions [**15**]. In order to provide more capability for shaping, collimators are usually installed within a rotating frame in addition, which allows it to rotate in horizontal axis.

Generally, there are two major types of beam defining collimators, which are symmetric collimators and asymmetric collimators.

- Symmetric collimators: This kind of beam defining collimators is inherited

from old fashion treatment machines. Two pairs of collimators are only allowed to operate in symmetric manner [**15**].

- Asymmetric collimators: This kind of collimators allows each pair jaw to operate independently, which provides more flexibility on blocking the beam. To be more detailed, asymmetric collimators allow single jaw to move across the central axis by up to 10 to 15 cm or even more, so that collimators are capable to block one-half or three-quarters of the field where the beam edges are coincident with the central axis. Placing such kind of blocked field in different directions, allows reducing the divergences of the beams [**15**].

2.4.7 Block

A major constraint in the radiation therapy is the limitation of the highest dose that can be delivered to the tumor because of the dose tolerance of other normal tissues surrounding or near the tumor site [**17**]. Shielding within a radiation field is one of the primary methods that allows oncologist to increase the dose to the tumor volume while sparing the other tissues. The main purposes of shielding can be summarized in three:

- To protect vital organs from radiation.

- To avoid unnecessary irradiation to surrounding normal tissues.

- To match adjacent fields.

In classic radiation treatment, shielding blocks are commonly used. It is usually made of lead and has an inner outline of the radiation target shape. The thickness of the lead required to provide adequate radiation attenuation to the shielded areas are very much depending on the beam energy and allowed transmission through the block. Normally,

a transmission rate below 5% of the initial radiation is accepted.

The frequency and complexity of field shielding vary from site to site in clinics. In some institutions, where field shielding is more often used, a custom blocking system could be implemented. In this technique, a special material called Lipowitz metal (brand name, Correobend) is used. This material consists of 50.0% bismuth, 26.7% lead, 13.3% tin, and 10.0% cadmium, and has a merit that it melts at about 70 degree, whereas lead melts at about 327 degree [**16**]. Therefore, Lipowitz metal can be easily cast into any shapes. In Figure 2.5, it shows a Styrofoam-cutting device, which consists of an electronic heated wire that used to simulate the casting of Lipowitz metal.

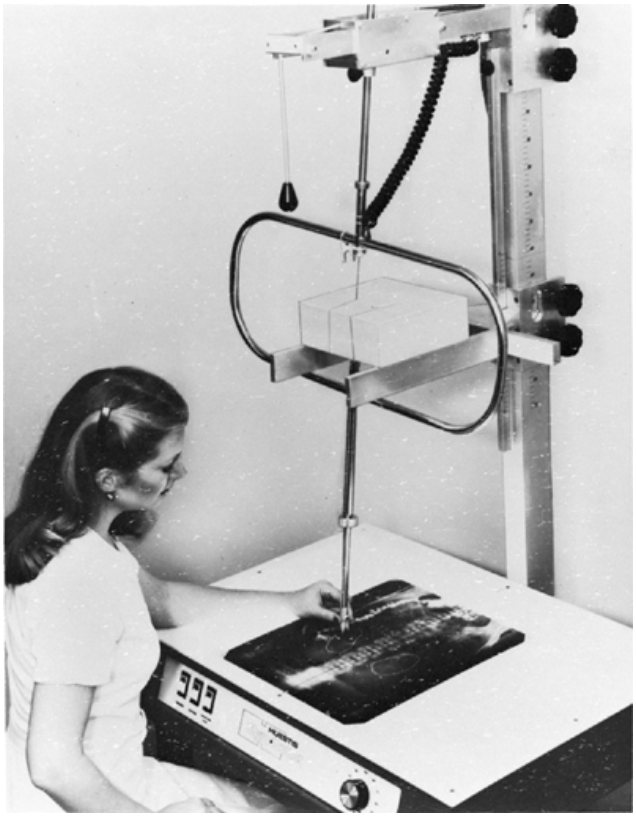

Figure 2.5: Photograph of block cutter. (Courtesy of Huestis Machine Corp., Bristol, RI.) [16]

2.4.8 Multileaf Collimator

Multileaf collimator (MLC), first introduced in Japan in the 1960s, has now been rapidly deployed in clinics as a replacement of block shaping [**17**]. MLC serves an alternative to shape the beam in irregular shapes other than rectangular as discussed in 2.4.6. This feature allows a further dose minimization to the normal tissues surrounding or nearby the tumor. Furthermore, some radiation treatments are planned to use multiple fields to treat cancers from different angles, in which MLC can be used to automatically shape the beams according to target volume's outline. This feature has been specified as a substantial requirement for some treatment machines.

Figure 2.6 is a simplified diagram of a multileaf collimator with two opposing banks of attenuating leaves [**15**]. Each leaf can be positioned independently by a computer controlling system that also determines the precision of the leaf positioning (usually better than 1mm).

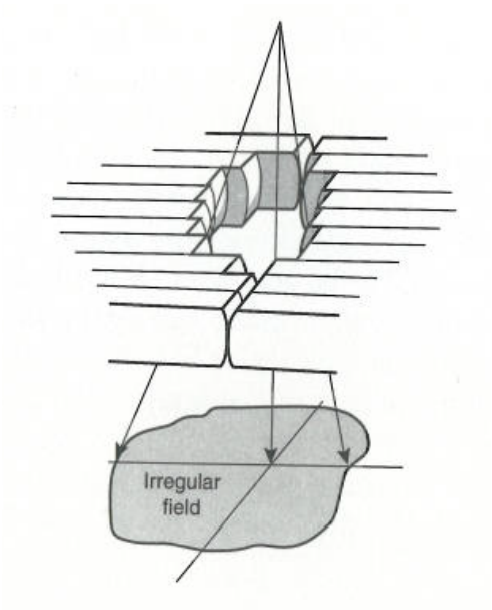

Figure 2.6: Simplified diagram of an MLC [15].

2.4.9 Wedge Filter

Wedge filter is one of the most commonly used beam modifying devices that are used

for modifying the isodose distribution. Originally, the wedge filter is usually made of metal and has a wedged shape, as its name implies [**16**]. It is this particular shape that causes a progressive decrease of the radiation in the intensity across the flattened beam and results in a gradient isodose curve as shown in Figure 2.7 [**17**].

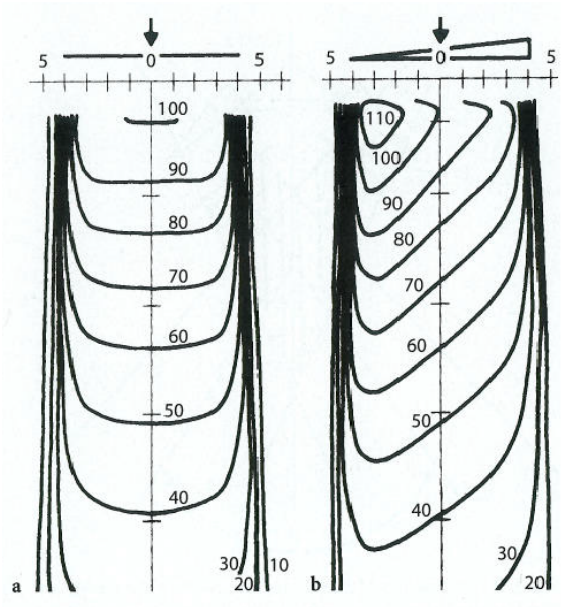

Figure 2.7: Isodose distributions for a 6MV photon beam with an 8x8cm field size. Graph a. refers to open field; Graph b. refers to field with a 45 degree wedge [17].

There are several reasons for using wedge filter to generate gradient isodose distribution. The most important one is to achieve a uniformed dose distribution throughout a target volume by combining multiple fields that use wedge filter. There are three variants of the wedge filters in general [**16**]:

- Individual Removable Wedge Filter: This kind of wedge is designed individually for certain beam width with a specified tilted angle. Each kind of individual wedge filter is only capable to form a particular isodose line.

- Universal or Motorized Wedge Filter: Universal or motorized wedge filter is a

single wedge filter that is designed to serve all beam widths by placing it at the center of the beam while the field can be opened to any size. A simple usage of motorized wedge filter is illustrated in Figure 2.8.

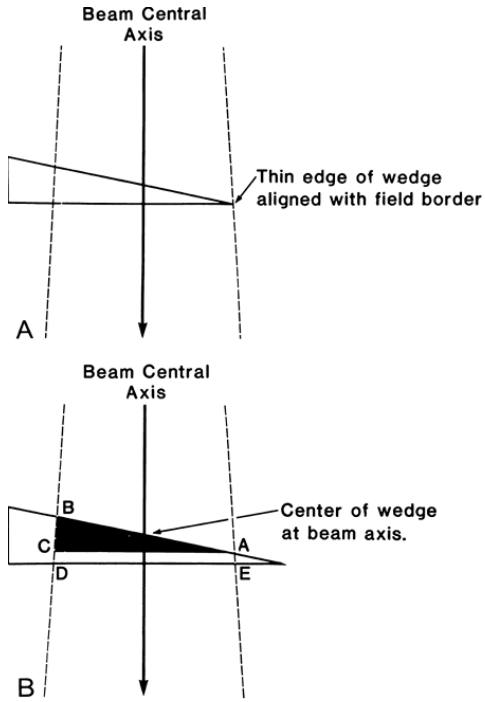

Figure 2.8: Schematic representation of A an individualized wedge for a specific field width in which the thin end of the wedge is always aligned with the field border and B a universal wedge in which the center of the wedge filter is fixed at the beam axis and the field can be opened to any width [16].

- Dynamic Wedge Filter: Dynamic wedge filter is not actually a physical wedge filter; instead, it is a term to describe the production of a wedged beam profile by dynamically adjusting the independent collimator jaw within treatment beam. A simple usage of dynamic wedge filter is illustrated in Figure 2.9.

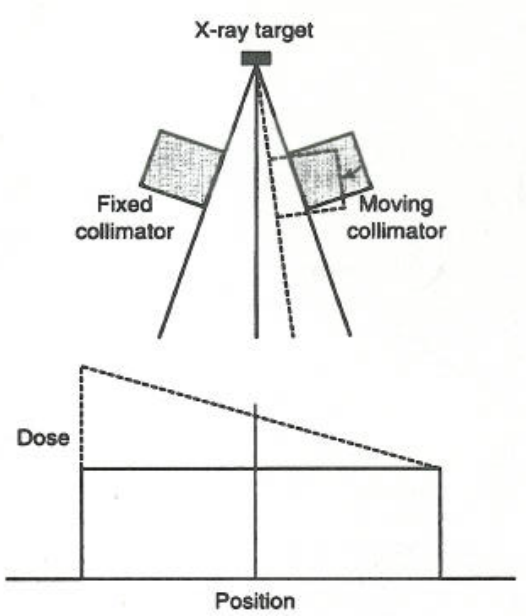

Figure 2.9: Use of the collimator to produce a dynamic wedge [15].

2.4.10 Patient Support System

Patient support system is also referred as treatment couch on which patient will be placed during the radiation treatment. Treatment couch can rotate around the vertical axis, which gives a way to avoid or reduce the radiation to some critical normal tissues around the tumor while it is being radiated. Furthermore, treatment couch can also move in horizontal space in order to place the isocenter precisely inside the tumor for treatment.

3 Clinical Radiation Therapy Workflow

The radiation therapy treatment is a very sophisticated process. Each hospital or clinic may adopt its own infrastructure and workflow to realize the final delivery of the dose to patients. In this chapter, general background information about radiation therapy clinical stuffing and workflow will be discussed in order to indicate a typical treatment process.

3.1 Clinical Staffing of Radiation Therapy

In this section, the clinical personnel placement of radiation therapy recommended by ***International Atomic Energy Agency*** (IAEC) will be discussed [**18**].

3.1.1 Radiation Oncologists

Radiation Oncologists are physicians who have special expertise in the therapeutic applications of ionizing radiation. They shall have a comprehensive understanding of the biological effect of the interaction of radiation with human tissues. Additionally, radiation oncologists shall also have knowledge about the causes, preventions and treatments of cancers and other diseases [**19**].

In the aspect of the oncology department, radiation oncologists are responsible for setting up the overall treatment policy for radiation therapy, which includes designing the clinical facilities. For single patients, radiation oncologist is responsible for verifying the diagnosis, defining the target volume, specifying radiation doses, and determining the objectives of radiation treatment plan that includes setting limitations on doses to critical structures [**18**].

3.1.2 Radiation Medical Physicists

Persons who are specialized in radiation therapy physics will be referred as radiation physicists. Their responsibilities can be classified as following five points [**19**]:

- Dosimetry: Radiation physicists should help to reduce the probability of unintentional radiation injuries. To achieve this, radiation physicists are dedicated to calibrate the treatment machine on routine basis and ensure the output data of the treatment machine are accurate and adequate to use clinically.

- Radiation safety: Radiation physicists are also required to design a radiation protection program to ensure the safeness of clinic stuff and other public persons.

- Treatment planning: Radiation physicist is responsible for the generation of possible treatment plans and should concern the consistency of the prescriptions through similar patients, and any founded inconsistency should be discussed with radiation oncologists. In addition, radiation physicists should also be aware of the critical body structures, and consider the limitations on radiation dose together with radiation oncologists.

- Quality control: Radiation physicists are involved in establishing and operating the quality control program in clinics.

- Equipment selection: Radiation physicists will work together with radiation oncologists to determine the clinical needs for treatment equipment.

3.1.3 Radiation therapists

The obligations for radiation therapists are spread widely in different clinics. The most common tasks for radiation therapists are as following [**18**]:

- Operating treatment machines
- Operating simulators and imaging devices
- Producing immobilization devices, like face masks

It is worth to mention that in the daily treatment, radiation therapists are more frequently being aside with patients than radiation oncologists are. Therefore, a favorable relationship is strongly encouraged between radiation therapist and patient, so that early warnings and unusual symptoms can be discovered.

3.1.4 Dosimetrists

Dosimetrists are radiation therapists who are specially trained in radiation dosimetry [**18**]. Their primary obligation is to calculate radiation dose by using computerized treatment planning system, which will be discussed in Chapter 4.

3.1.5 Radiation Oncology Nurses

Radiation oncology nurses are responsible for taking care of patients undergoing treatment. This task also needs appropriate trainings [**18**].

3.2 General Workflow for Radiation Therapy

This section is based on the analysis of the workflows of multiple radiotherapy clinics

as presented in their web sites. Those clinics are ***Advanced Radiation Center of New York*** [**20**], ***Abramson Cancer Center of University of Pennsylvania*** [**21**], ***Mayo Clinic*** [**22**] and ***Vassar Brothers Medical Center*** [**23**].

3.2.1 Initial Consultation

Whenever radiation therapy is being determined as part of cancer patient's treatment strategy, an appointment has to be made with radiation oncologists. In this appointment, radiation oncologists will review patient current case and health history; also, an examination may be carried out after or before the appointment, if necessary [**20**]. Additionally, the role of the radiation therapy for individual patient will be defined; and the specific radiation modality (see Section 2.3) may be determined. During this consultation, patients will receive an estimated prescription and information about possible side effects. They may also ask any questions related to the treatment [**20**].

3.2.2 Virtual Simulation

The virtual simulation phase is where all the necessary image information that the radiation oncologists need to create an individualized radiation course for patient is gathered [**21**]. In the clinics, dedicated CT scanners, known as CT-simulators, are used to construct patient CT images [**24**]. Figure 3.1 is a CT-simulator that is used in the clinics, which has a laser light on the side to help positioning the patient [**25**].

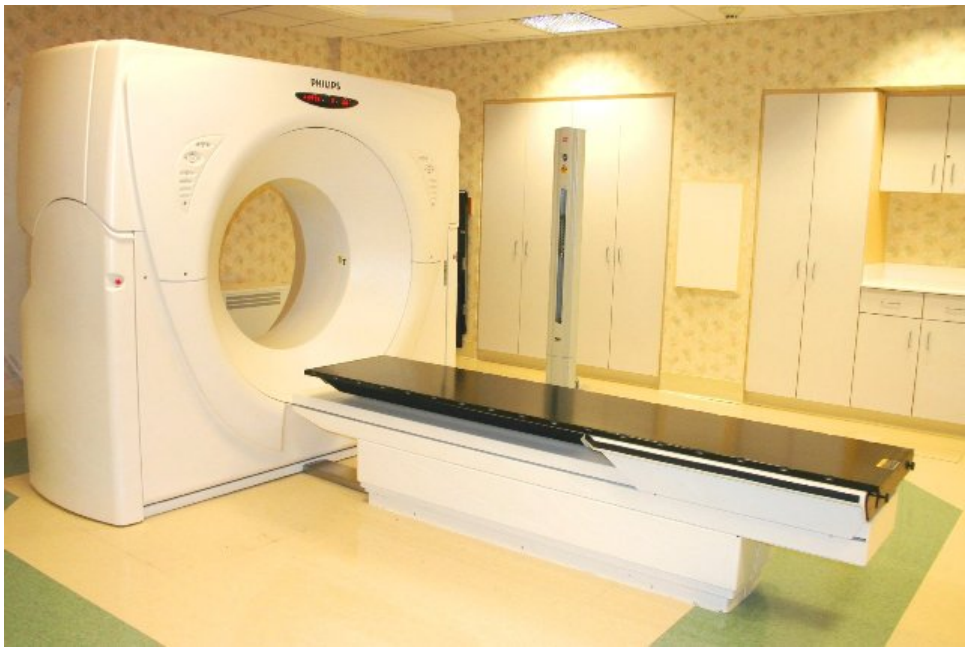

Figure 3.1 CT-simulator used in Hunterdon Healthcare Clinic [25].

The virtual simulation session normally takes about 30 to 60 minutes, in which measurements of patient body are taken and CT scan of the treated region is taken. The information of the scanned CT images is essential for precisely locating the patient tumor and positioning the treatment field in the real treatment phase [**24**]. At the end of the virtual simulation, it is usual to put small tattoo or ink marker on patient's body to aid at daily treatment set-up reproducibility [**21**]. In certain types of radiation treatment, special patient fixation devices are used to ensure that patient will be placed in the exactly the same location in the treatment room as in virtual simulation room [**22**]. This step further guarantees tumor volume is going to be treated as planed in CT images.

3.2.3 Treatment Planning

After patient leaves the virtual simulation room, radiation oncologists, together with radiation physicists and medical radiation dosimetrists will carefully examine patient's anatomy images and relevant information during the treatment planning phase [**20**]. With the assist of sophisticated computerized treatment planning systems

(see Chapter 4), the properties of the radiation beams can be settled, and most importantly, patient's dosimetric information is calculated by using state-of-art mathematical algorithms [**20**].

3.2.4 Pre-treatment Verification

In some clinics, patient will be taken to the real treatment room on day one for a pre-treatment verification after all the planning and calculation is done [**20**]. In this phase, actual treatment will not be administered. Patient will only go through all the procedures of the real plan, and instead of receiving the real radiation dose, patient films will be taken for reviewing by the radiation oncologists to confirm and verify the treatment plan. In this phase, any fine-tuning of the planning can be made prior to treatment.

3.2.5 Daily Treatments

In the next phase, patient will usually be scheduled to visit clinic once a day, from Monday to Friday, for several weeks. The radiation treatment will be delivered after positioning the patient precisely on the treatment couch. Generally, each treatment will take 5 to 10 minutes, depending on how sophisticated the plan is (e.g. number of radiation fields, used accessories, and etc.) [**21**].

3.2.6 Patient Follow-ups

Once the radiation therapy is completed, patient will be asked to have a follow-up visit to radiation oncologists after 2 to 6 weeks [**21**]. The purpose of the visit is to assess the patient response to treatment and the status of the cancer. It helps to identify the complications as early as possible [**23**].

4 Treatment Planning System

Treatment planning system is a computerized medical system that is used to simulate the application of radiation to a patient for a purpose of radiation therapy [**26**]. In this chapter, the basic components of the treatment planning system and its typical process used in the clinical will be discussed.

4.1 Overview of Computerized Treatment Planning System

Nowadays TPS has been broadly used in oncology departments in many hospitals. The installation and specific functionalities of TPS in oncology departments can vary slightly from site to site. However, the general usages are similar, including viewing RT images, defining tumors and other critical structures, setting up fields, simulating radiation treatments, calculating dose, and evaluating plans [**27**]. All these features of TPS serve as a way of generating the virtualized beam shapes and dose distributions with the intention to help clinicians to maximize the tumor control and minimize the normal tissue complications for the patient.

According to the recommendations from ICRU Report 42[2] [**27**], there are several practical aspects for a computerized treatment planning system to follow.

4.1.1 Beam Data

Beam data is set of real dosimetric data that is measured and calculated from a water phantom for a specific clinical treatment machine. This kind of data is used as simulation data for dose calculation algorithms to generate the realistic dose

[2] This is the report from Internationalization Commission on Radiation Units and Measurements

distribution in a clinical case.

Acquisition of beam data and building up beam data library are always the first two steps in the procedure of using a computerized treatment planning systems. They are essential tasks that need to be completed only when a new treatment machine is installed or when some basic changes are made to the machine, for instance modification to the angle of wedge filter or size changing of primary collimator. After beam data has been acquired and configured, the validity of the entire beam data shall be closely checked before using for clinical purposes [**27**].

4.1.2 Input of Patient Image Data

Patient image data is the other set of data that is needed for computerized treatment planning systems [**27**], besides beam data. By combining the radiation beam characteristics and the patient image data, treatment planning system can produce dose distribution throughout the target volume and nearby tissues.

Creating a patient image data for the use of treatment planning systems consists of importing patient images from imaging devices and contouring of the tumor volume and organs at risk [**27**]. In radiation therapy, CT imaging is the primary method of showing patient's anatomical information because it provides a good visualization of the high-density organ structures and high accuracy of organs' geometric information [**16**]. Additionally, CT uses x-rays for constructing images. It reveals the electron density information of different tissues, which is the essential information for dose calculation.

Another image modality that is used rather often in radiation therapy is magnetic resonance image (MRI). Due to its high soft tissue contrast and ability to present information about tumor physiology and location [**17**], MRI is enabled to provide a more optimal set of images for target delineation and diagnostic interpretation [**16**].

In order to take advantages of both, correlating the two image data sets together is often performed in modern treatment planning systems. This kind of imaging procedure is so called image registration.

4.1.3 Input of Treatment Parameters

In treatment planning, treatment parameters are defined to describe the characteristics of the radiation beam. These parameters can be machine identification, source-to-surface distance value or source-to-axis distance value, field size, gantry rotation and etc. For a computerized treatment planning system, it is elementary to provide ways to enter and express these treatment parameters in certain manners. Furthermore, in order to utilize TPS to try more radiation beam combinations, it is important to consider the usability of handling the treatment parameters [**27**].

4.1.4 Treatment Plan Visualization and Output

This aspect describes the capability of a computerized treatment planning systems to display anatomical and dose distribution data in graphic form [**27**].

4.1.5 Optimization

Optimization is a procedure for selecting treatment plan according to a number of predefined criteria. However, the criteria are often difficult to establish because of its high dependency on human judgment. For optimization in computerized treatment planning systems, it expresses the predefined criteria into several constraints[3] and then makes use of treatment parameters as variables to achieve the objective [**27**].

[3] The constraints can be the minimum and maximum dose to the target volume.

4.2 Treatment Planning Process Based on TPS

In this section, the most common case will be demonstrated to illustrate the general process of treatment planning in TPS.

4.2.1 Patient Identification and Image Preparation

In the first step, patient identification information and images will be created or imported into the treatment planning system. The patient identification information usually contains patient's name, gender, age, nationality and etc. Image preparation usually consists of importing images, connecting images to current patient, creating 3D image[4], and image registration [**24**,**28**].

It is worth to mention that in order to achieve the common usability and accessibility of patient data and images between different hospitals, DICOM (Digital Imaging and Communication in Medicine) file standard is implemented. Nowadays, DICOM is accepted extensively in clinics to handle patients' radiology information. The elementary DICOM file contains patient's images, name, age, gender and etc.; additionally the DICOM RT (DICOM in radiation therapy) contains RT Image, RT Doses, RT Structure Sets, RT Plans and RT Treatment Records [**28**].

4.2.2 Image Segmentation

Originally, image segmentation, which is also known as contouring, refers to delineation of anatomic region of interest on patient image, slice by slice. The interesting structures can be, for example, external treatment couch outlines, tumor target, critical tissues, anatomic landmarks and etc. Usually, by using computerized treatment planning system, it is now possible to segment the respect structures automatically in three dimensions based on image contrast and so on. Concerning the

[4] 3D image is often used for three dimension treatment planning.

accuracy of contouring the tumor, fully automated image segmentation is not accepted without clinician's review. Additionally, for certain kinds of cancers, some areas of clinical target volume are not visible on the diagnostic images. It very much lies on the clinician's experiences to determine the actual volume.

4.2.3 Plan Setup

After image segmentation has been completed, radiation physicist or dosimetrist will start creating treatment plans using computerized treatment planning system, based on the dose prescriptions given by radiation oncologist. Creation of these plans consists of defining the beam number, beam geometry, beam modifiers and so on. Additionally, defining radiation constraints for target volume and normal tissues are also included in plan setup for certain treatment technologies (e.g. inverse treatment planning, in which optimization is applied) [**16**].

4.2.4 Dose Calculation and Plan Evaluation

By using corresponding dose calculation algorithm, dose distribution can be determined and viewed in 3D display. Afterwards, radiation oncologist will compare and evaluate the doses that have been calculated from different treatment plans. At the final step, treatment plan that best fulfills the overall treatment objectives will be selected or combined from multiple plans [**7**].

4.2.5 Treatment Plan Approval

At this stage, treatment plan shall be reviewed and approved by prescribing radiation oncologist, to indicate that the treatment plan has been evaluated and completed. Only the plan with approved state can be used to treat the patient later. It is also important for a TPS to provide a data locking after plan has reached "approved" stage. This prevents unauthorized or unintentional modifications to a completed plan in TPS.

5 Risk Management for Medical Devices

Risk management is a crucial activity for radiation device manufacturers to eliminate or reduce the risk that may cause harms to the health people. The checking functions for which the automated tests are created in the TPS are related to the risk management. Therefore the principle of the risk management will be presented in following section.

5.1 Risk Management

According to standard ISO 14971:2007[5], risk management is referred as "systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk" [**29**]. As one kind of medical devices, treatment planning system is required to comply with this standard and to implement risk management framework to ensure that it is safe to use for all its customers, and to ensure all residual risks are clearly identified and communicated with its all customers [**30**]. For the purposes of this section, the following terms and definitions will be explained with associations of radiation therapy:

- Harm: Physical injury or damage to the health of people, or damage to property or the environment [**29**]. In terms of radiation therapy, harms can be: damage to healthy tissue due to radiation, tumor control is not effective enough, physical contact injury, cardiac arrest and etc.

- Hazard: Potential source of harm [**29**]. This term describes the origin or the nature of the expected harm [**30**]. For instance, overexposing to the radiation can be a potential source of harm, which could impair patient healthy tissues;

[5] ISO 14971:2007: Application of Risk Management to Medical Devices.

or encountering a treatment machine collision can be a potential source of harm, which could physically injure patient healthy body.

- Hazardous situation: Circumstance in which people, property, or the environment are exposed to one or more hazard(s) [**29**].

- Hazard cause: Event or a sequence of events that could initiate hazardous situation [**29**].

5.1.1 Risk Management Process

In standard ISO 14971-2007, risk is interpreted as "combination of probability of harm and severity of that harm" [**29**]. With the purpose of reducing the probability and the severity of the harm, specific requirements are defined in this standard for establishing a systematic risk management framework for medical device manufacturers. This includes following aspects: risk management process, risk management responsibilities, qualification of personnel, risk management plan and risk management file [**29**]. Concerning the main subject of this chapter, only risk management process will be discussed in detail.

For a manufacture of a medical device, defining a risk management process is strictly required for the reason of ensuring all risk management activities are in process[**29**]. The following elements are essential for this process:

- Risk analysis

- Risk evaluation

- Risk control

- Evaluation of overall residual risk acceptability

- Risk management report

- Production and post-production information

5.1.2 Risk Analysis

Risk management process shall begin with risk analysis when new characteristics of the medical device that could affect safety are identified [**29**].

Firstly, product's intended uses and reasonably foreseeable misuses shall be evaluated and documented [**29**]. Based on these information possible hazards associated with the product will be identified.

At next stage, hazardous situations and hazard causes shall be estimated and well documented based on the identified hazards. It is worth to notice that hazardous situations may not only arise from faults, normal uses may also lead to a hazardous situation. Finally, by estimating both severity and probability of occurrence of associated harm, risk can be assessed.

5.1.3 Risk Evaluation

Risk evaluation is the phase where manufacturer will decide the acceptability of identified risks [**29**]. Normally manufacturer will define a set of criteria for deciding which hazardous situation requires risk controls [**29**]. This set of criteria is made based on the severity and probability of occurrence of the harm. For example, if an identified hazard cause has a high probability to arouse a serious harm to the patient, then a risk control is firmly needed for the risk associated to this hazard cause. In contrary, if the hazard cause only seldom causes a very limited harm to the patient,

then it is within acceptable level and implementing risk control is optional.

5.1.4 Risk Control

Risk control is the phase where all the measures for reducing the identified risks to acceptable level are implemented. Manufacturer is required to use one or more of the following risk control options in the priority order listed [**29**]:

- Inherent safety by design
- Protective measures in the medical device itself or in the manufacturing process
- Information for safety

The priority order listed here is important. If practicable, manufacturer should first consider design the product to be inherently safe. This can be conducted by defining safety requirements in product design, and having them verified and validated when product is finalized. If this is not practicable, then protective measures such as barriers and alarms should be taken to reduce the risk to ALARP (as low as reasonably practicable) level [**29**]. The least preferred protective measure is a written warning [**29**].

After the risk control measures have been implemented, it is important for manufacturer to perform a verification and validation actions. Verification action is to ensure risk control measure is correctly implemented into the product according to the design. Validation action is to measure the effectiveness of the risk control measure [**29**]. If there are still residual risks remain in the product, manufacturer should perform further evaluations on them to determine their accept abilities using the same criteria mentioned in section 5.1.3. If the residual risk is not within acceptable level,

then additional risk control measures shall be applied. This iterative procedure will be continued until residual risk is reduced to acceptable level [**29**].

However, there are some occasions where the residual risk is still greater than manufacturer's criteria for acceptable risk. In order to provide such high-risk medical device to customers, manufacturer is required to make a careful evaluation on the risk and to show that the benefit of the medical device is over the risk [**29**].

5.1.5 Evaluation of Overall Residual Risk Acceptability

At this point, manufacture is required to evaluate on the combined impact of the individual residual risks. For a complex medical device with a large number of risks, it is possible that the overall residual risk can exceed the criteria for acceptable risk, even though individual risks do not [**29**].

5.1.6 Risk Management Report

Risk management report shall be completed as a summary of the result for the entire risk management process. It shall include the traceability for each identified hazard to the risk analysis, risk evaluation, risk control measure, and the final assessment [**29**].

5.1.7 Production and Post-production information

It shall be emphasized that risk management does not end when medical device goes to production. The information of using the medical device from actual users can be useful to re-estimate the risks of the medical device and to refine the current risk management system. Therefore, it is extremely crucial and strictly required for manufacturer to implement a systematic mechanism for handling the user feedbacks or complaints [**29**].

5.2 Risks Associated to Treatment Planning System

In radiation therapy, the most typical hazard that can ultimately result in harm to the patient is overexposure or underexposure of ionizing radiation [**29**]. With overexposure, patient's healthy tissue may be damaged, whereas with underexposure, patient's cancer cell may not be effectively controlled. Both cases can result in serious consequence, at worst death. This hazard can be initiated from different phases of radiation therapy, for instance, treatment planning phase.

In treatment planning phase, in order to design and select a suitable treatment for the patient, the computerized treatment planning system is often used to simulate the patient setup, arrange the treatment beams, design the shielding, calculate the dose and etc. [**31**]. This means treatment planning system will provide adequate inputs for the real treatment delivery, and at mean time, some of the inputs may introduce risks into the radiation treatment.

6 Software Testing

This chapter introduces the general concept and methods of software testing to help presenting the implementation work in following chapters.

One of the most well known definitions of software testing is that: software testing is the process of executing a program or application with the intention of finding software errors, instead of demonstrating that the software performs its intended functions correctly [**32**]. This sounds more destructive than constructive while most of human beings hold the positive views in their life. Nevertheless the initial drive of performing test to a piece of software is to substantially add value to it, which can be further interpreted as raise the quality and reliability of the software [**32**]. Finally, to enhance the quality of the software, it simply means finding and removing errors. Therefore software testing should not be carried out with the intention to prove that software does what it is supposed to do; rather, it should be started with the psychology that the more errors are found the more successful the test is.

6.1 Basics of Software Development Life Cycle Models

In order to understand software testing thoroughly, it is essential for one to get familiar with the basics of software development life cycle. It could help testers to form an awareness of what could go wrong in the process of software development and indicating the fragile areas.

The life cycle of software development is a complicated study, which includes various procedures and many sophisticated methods. In this section, the most common models of software development will be discussed.

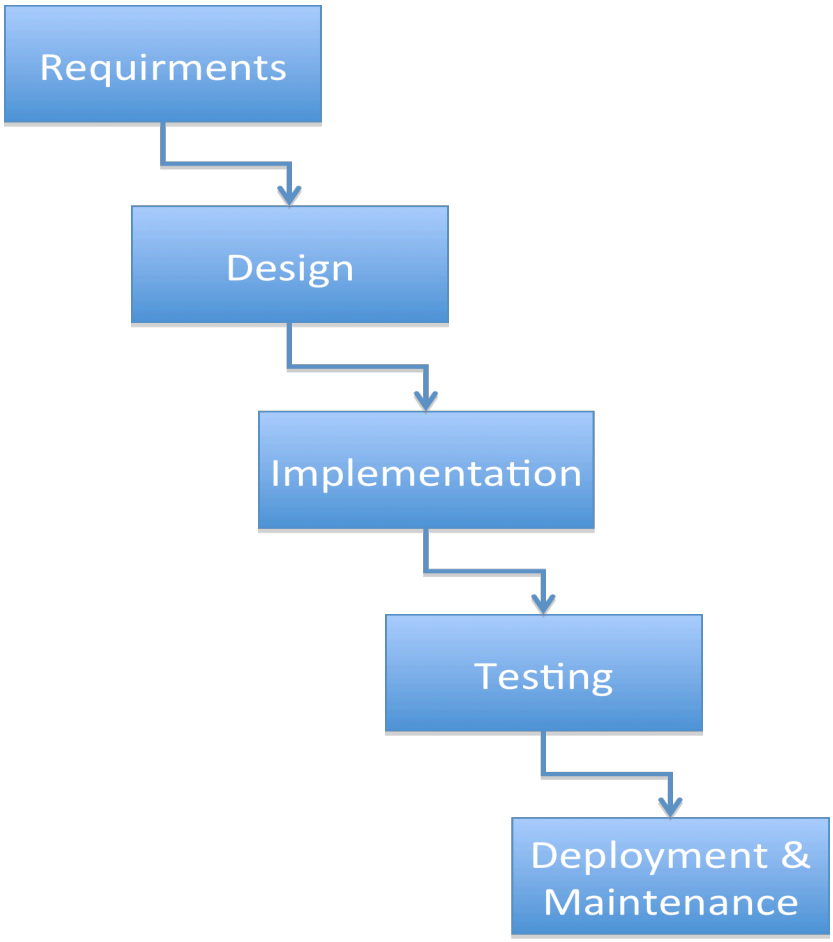

Figure 6.1: The waterfall model for software development

6.1.1 Spiral Development Model

Spiral development model is a refinement of waterfall development model. It inherits the basic flows from waterfall development model whereas fractionizes the whole development cycle into several small cycles in order to address the problem mentioned in 0 [**33**]. This is illustrated in the Figure 6.2.

- Analysis Phase: In this phase, the system requirements are defined in as much detail as possible. This may include collecting views from customers and arranging brainstorming sessions among related specialists.

- Design Phase: At this phase, the preliminary design shall be created and it will get more and more perfection when the whole process goes on. It is worth to

mention that unlike the software design phase in waterfall model, this phase does not require any implementation work, and in contrary the main focus is on making up and refining the development strategy in order to resolve any possible risk in system requirements.

- Implementation Phase: This is the real construction phase, in which all engineering work should strictly follow the design strategy proposed in design phase.

- Testing Phase: This is the phase where the product is tested. It is quite similar to the one defined in waterfall model.

- Deployment Phase: Real installation will occur in this phase, and product will be verified partially. After this phase, process shall be iterated into another identical development cycle and finally product will be finalized.

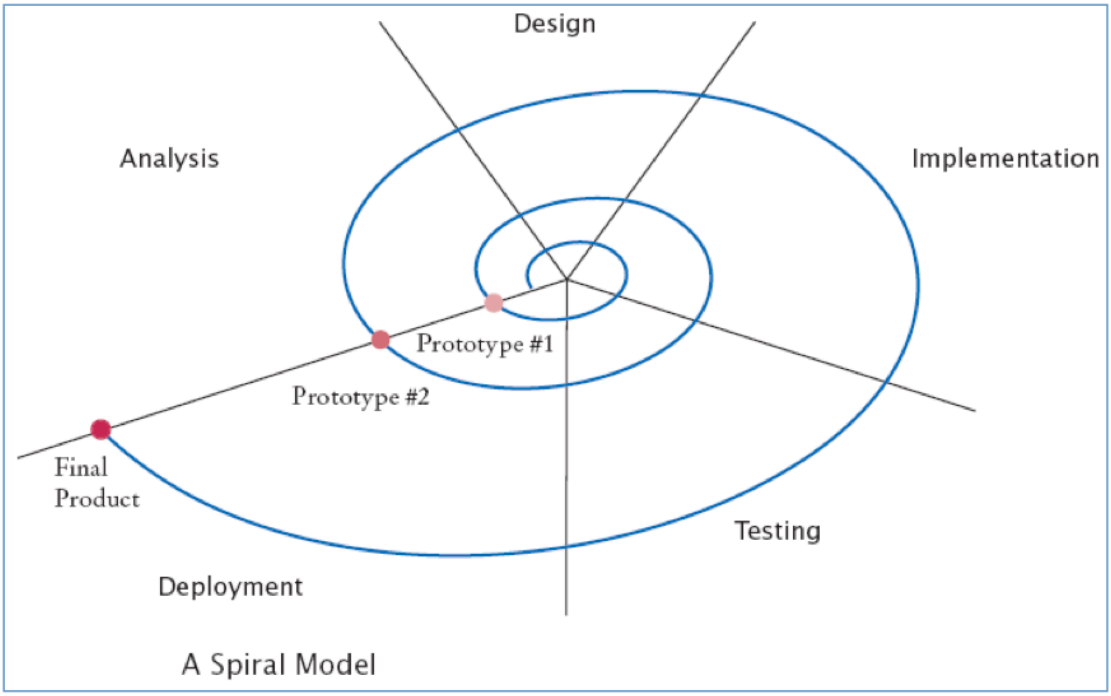

Figure 6.2: The spiral model for software development

6.1.2 Test-driven Development Model

Test-driven development requires developers to start to write test cases against existing requirements prior to the actual software developing. Initially, all the test cases should fail because no implementation has been done. If one passes, then most likely, there is a defect in the test case. In the next step, developers shall write the code with the only intention of passing the tests and no additional functionalities should be added. In the end of development process, all the implementation work should be done with passing all the test cases. This also means that software has fully fulfilled the requirements. Finally, developers can refine the code if needed, and by running the tests, it ensures that no functionality is broken [**34**].

6.2 Software Testing Terms and Definitions

From the previous section, it can be learned that software testing is essential for software development. Although the purpose of software testing is to discover as many bugs and defects as possible, it eventually raises the reliability of the final product [**32**]. This section will reveal the fundamental concepts of software testing by discussing its basic terms.

6.2.1 Verification and Validation

Verification and validation are quite similar semantically. However, the differences between them are quite important in software testing [**33**]. As it is mentioned in section 6.1, software should always be deployed according to the approved software requirements, which are defined according to the customers' need. Software verification is the phase to check that software complies with all the requirements, whereas software validation is the phase to ensure that the software meets the customers' need. The reason for testing the software in two phases is that software requirements do not always correctly or fully interpret customers' need. Therefore

verifying the specific requirements and validating the final product are very important practices in software testing.

6.2.2 Quality and Reliability

Quality as it is defined in Merriam-Webster's Collegiate Dictionary is a "degree of excellence". To measure the quality in a piece of software, it very much relies on how extensive it meets customers' need [**33**]. Reliability is the term to describe the stability of software. If the software has been tested to be stable, dependable and reliable, it does not assure the software of good quality unless it has been also validated to meet costumers' need.

Therefore, in order to achieve the high quality of the final product, software testers have to verify and validate the software throughout the development process to ensure that the final product meets the customers' need while also being stable enough. [**33**].

6.2.3 Testing and Quality Assurance

Testing and quality assurance refer to processes or groups for verifying and validating the software product. It is easy to notice that there are some overlaps between these two terms. However, there are two key definitions to distinguish their responsibilities:

- Testing is the process that focuses on finding software errors and bugs.

- The goal of quality assurance is to create and enforce standards and methods to improve the development process and to reduce the occurrence of errors and bugs.

6.3 Basic Taxonomy of Software Testing Techniques

6.3.1 White Box Testing and Black Box Testing

White box testing refers to a test approach by which tester can access to the program's code and examine it. Based on what tester has seen in the code, fragile areas or critical functions may be revealed and testers can then tailor his or her testing based on such information [**33**]. White box testing can be seen as an effective method. However, it has a general risk that testers may fall into an objectively testing behavior in which test cases may be created to match the code's operation.

In black box testing, tester only knows the software functionalities that it suppose to have and without knowing anything about the software operational details. Based on this, tester types in a certain input and will check if the actual output is the same as expected [**32**].

6.3.2 Unit Testing and Integration Testing

Unit testing is a method to test small pieces of code, which usually can be single functions or methods. This approach can be considered as white box testing, which allows tester to examine the internal parts of software and it usually happens along with software development [**35**]. Therefore, the goal of unit testing is to ensure that individual parts of the software are correctly implemented and functioned. Later on when unit tested modules are combined together, integration testing will take place to ensure high-level functionalities operate as expected.

6.3.3 Regression Testing

Regression testing is a test method to ensure that previous functionalities are still working after changes that have been made to the software or relevant code. The

triggering events can be discrepancy fixing, code refining, introducing new functions and so on. The most common and effective way to do regression testing is to build up a set of standard tests library that can be run every time when there is a new version of software build [**36**].

6.3.4 Automated Testing

Automated testing is a term opposite to manual testing. It uses a programmed application to execute a sequence of test cases without human interaction [**37**]. This approach helps eliminate human errors and provides faster results. As reported in section 6.3.3, software development may require running set of test cases multiple times. Thus, automated testing leads to significant labor cost savings over time.

7 Automated Testing Tool CppUnit

This chapter will discuss an automated testing tool called CppUnit, which is the testing framework tool that has been used in this thesis work.

7.1 Background of CppUnit

CppUnit is an open source unit testing framework, and it was originally ported from JUnit, by Michael Feathers and Jerome Lacoste. Its basic usage is based on C++ programming and it inherits many advanced features from C++ language, such as templates, abstract classes, nested classes, and the STL (Standard Template Library) [**38**]. Besides, its allowing testers to create test cases that can be run automatically at any software development phase has helped testers to keep confidence in quality of the code [**34**].

7.2 Architecture of CppUnit

CppUnit testing framework consists of 24 ordinary classes, 4 abstract classes, 7 template classes, and several nested classes and help macros [**34**]. Most of the code is implemented under namespace *"CppUnit"*, as shown in Figure 7.1. *"Asserter"* namespace contains assertion functions used in test asserting. *"TestAssert"* namespace contains function templates used for comparison asserting. *"Ui"* namespace contains test user interfaces for text, MFC and QT[6] versions [**38**].

[6] QT is a cross-platform application and UI framework, which contains an integrated development environment (IDE)

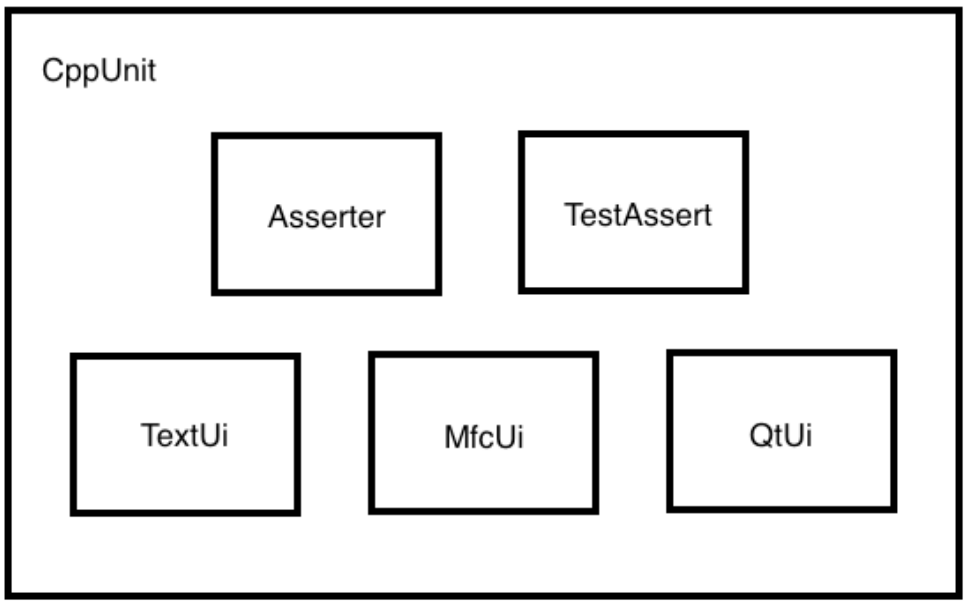

Figure 7.1: The CppUnit namespaces [34]

Logically, the whole framework can be divided into following parts [**38**]:

- Core: The core of CppUnit follows a design pattern called Composite Pattern, which can be described as composing several objects into tree structures that represent whole-part hierarchies [**39**]. The core of CppUnit defines basic elements for test case creation, test suite handling, test execution and termination, test result collection and test assertion.

- Output: This part provides tool classes for outputting test results. CppUnit supports several output method such as by pure text, by XML markup language, or by different IDEs.

- Helper: This part provides helper classes to assist the whole framework. In primary, most of the helper classes are related to test cases creation and arrangement.

- Extension: Besides offering functions for performing unit testing, CppUnit has

also been extended to support other features, such as, repeated testing, which enables test cases to be executed for certain amount of times to test robustness of the test subject.

- Listener: This part provides listener function in two different situations. Firstly, when a test run is finished, test listener will simply monitor whether the test is passed or failed and will forward test result to output section to handle. Secondly, test listener is used to monitor the test progress status during the execution. If any error occurs, it will forward the error message to standard error output device.

- Portability: CppUnit has defined several configurable system variables or a series of macros in header file portability.h to make it become compatible with difference platforms.

7.2.1 The Key Test Classes

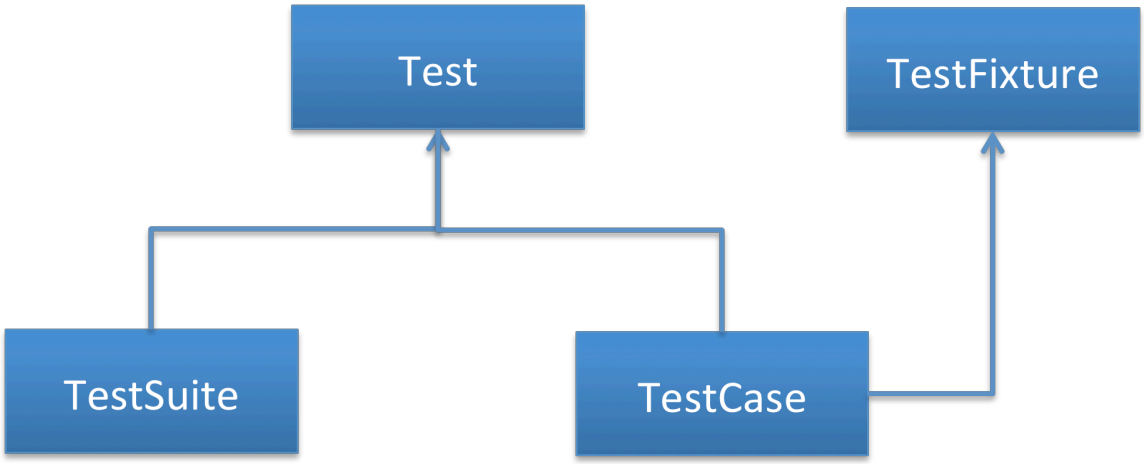

Figure 7.2 Deriving structure for key test classes [34].

The most fundamental classes for CppUnit are shown in Figure 7.2 [**34**]. *Test* class is an abstract class for all test classes and describes their basic behaviors. *TestFixture*

class is also an abstract class. It is used to provide a common environment for a set of test cases [**38**]. *TestFixture* wraps a test case with *setUp()* and *tearDown()* method in order to create separate fixture for each test runs. As it shows in Figure 7.2, *TestCase* class is derived from *Test* and *TestFixture* classes to represent an actual test object, and *TestSuite* is a composite for other relevant test objects [**34**].

7.2.2 Test Results Collection Classes

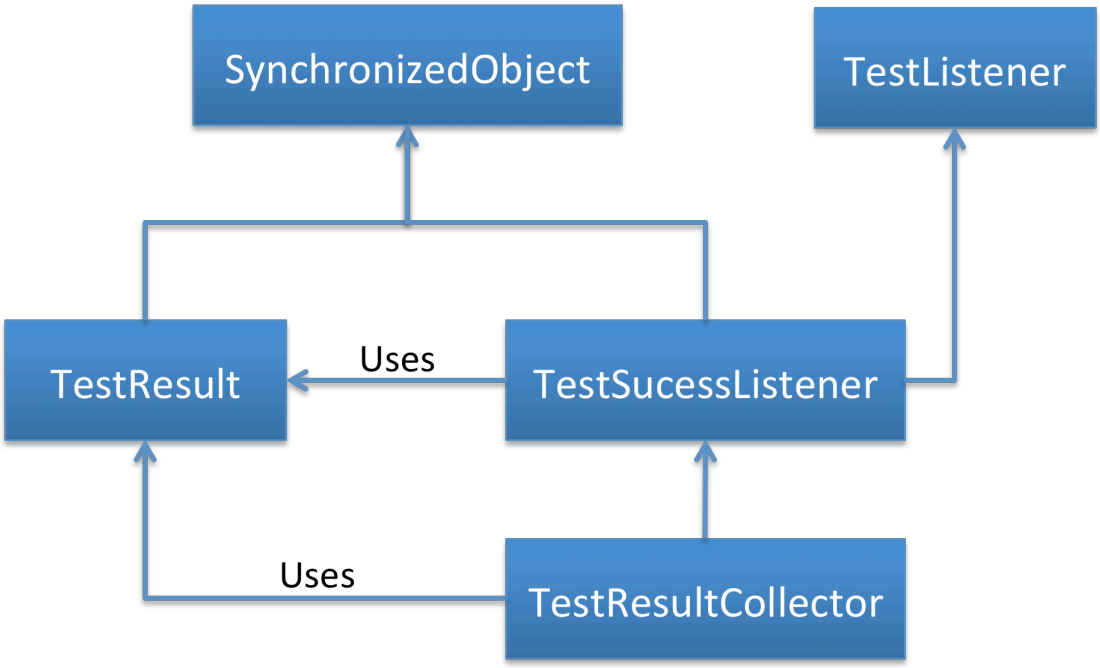

Figure 7.3: Deriving structure for test result collection classes [34].

Figure 7.3 reveals the mutual dependencies between test result collection classes. *TestListner* is a basic class for observing test results. When error occurs, *TestSucessListener* will be informed and *TestListner* will interface *TestResult* class to retrieve the test result. *SynchronizedObject* class is used to manage objects that need to be synchronized. In this case, they are *TestResult* class and *TestSucessListener* class [**34**]. This allows test case to run separately with the test listener [**34**].

7.2.3 Test Output Classes

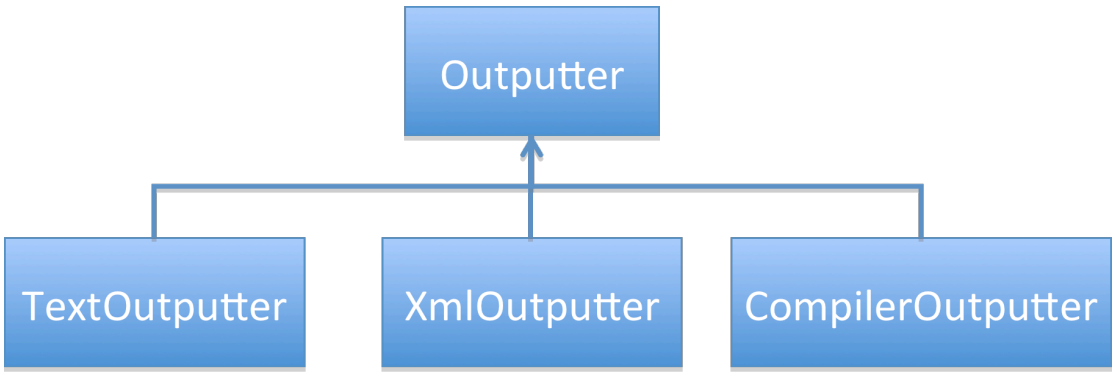

Figure 7.4 Deriving structure for output classes [34].

Test output classes provide methods to print the test results to end users in human-readable text format [**34**]. As it shows in Figure 7.4, the structure of output classes is simple. As a base class, *Outputter* provides only a virtual class *write()*, which will be derived by *TextOutputter*, *XmlOutputter* and *CompilerOutputter* classes [**38**]. Those three classes will overload *write()* method to adapt it to different output format.

8 Implementations

This chapter reveals the goals and design of the actual implementation of this thesis. It focuses on presenting the designed test procedure and some important functions.

8.1 Goals

This thesis is conducted to implement automated tests for a set of checking functions that are used for detecting cases that violate specific rules in the TPS. There are several essential points in implementing these tests. Firstly, the requirements of these checking functions need to be analyzed elaborately, so that created test cases can be properly conformed to the associated requirements. Secondly, tests shall be designed to have as short execution time as possible so that the cost arises from the time that tester consumes at running the tests can be limited. Thirdly, test cases shall be reusable so that they can be utmost utilized in the future, e.g. in regression testing.

In this chapter, the actual implementation work will be presented in limited scope for the reason of protecting company's confidentiality.

8.2 Design

The requirements of the checking functions specify the rules that shall be fulfilled. If there is a violation, error or warning message shall be shown to the users and certain further actions shall be prevented in TPS. This thesis uses the principle of black box testing. Rather than exploring defects in identified fragile areas of the source code, test examines the actual functions that are implemented according to the requirements. To be more specific, test will try to generate each negative case which violates the

rule, by modifying the related attributes and then to verify whether the given warning or error is correct or not.

8.2.1 Test Procedure

Figure 2.2 shows the test procedure in general. It also reveals basic design concept of this thesis work.

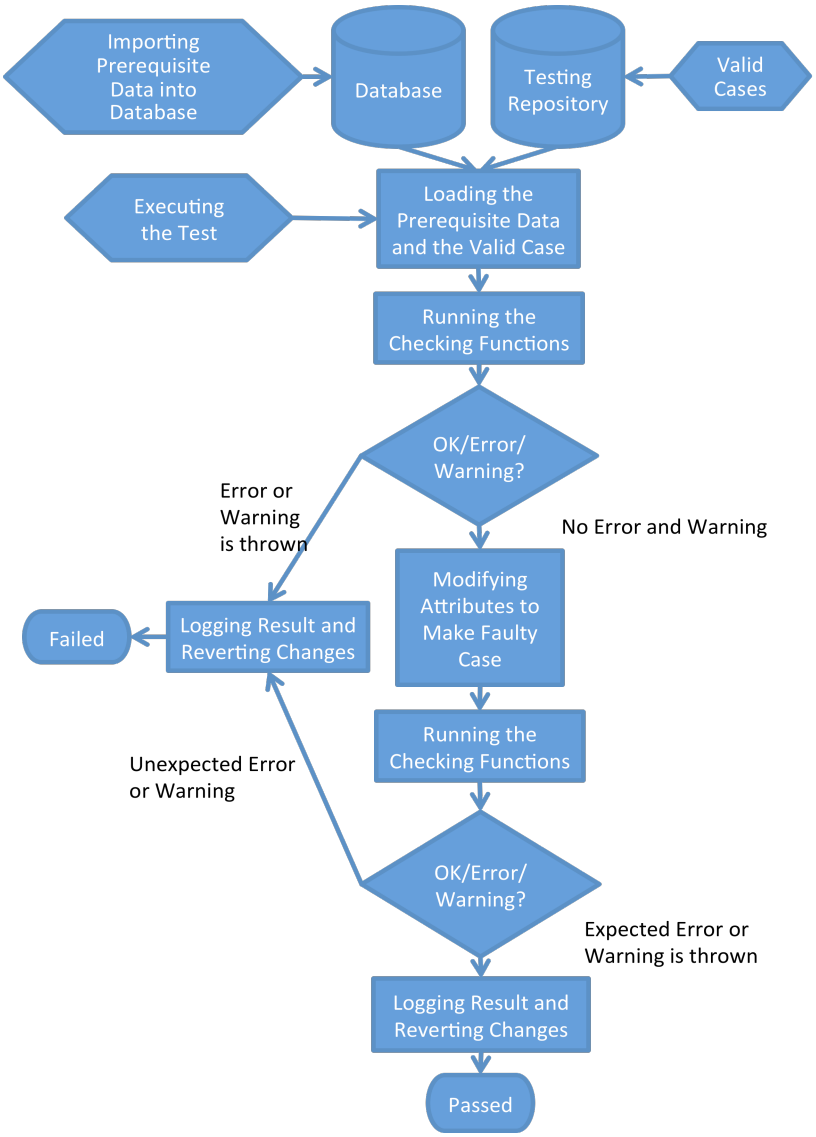

Figure 8.1 Flowchart of the Test Procedure

Firstly, before running the tests, some prerequisite data has to be prepared and imported into a database beforehand. In addition, valid cases[7] are created and stored in a network-shared repository.

In the next step, test will be executed. To begin with, the prerequisite data and the valid case will be imported respectively from database and testing repository. Then the checking functions will be called to verify the original case in order to test the correctness and the integrity of the testing data. This pre-checking mechanism ensures that all the testing data are suitable to continue to run the test and there will be no confusion in the final test results. Without any exception, verifying at this stage should always pass; otherwise, any warning or error will be considered as a failure, as shown in the Figure 8.1.

In the following step, test run will modify certain attributes with the intention to violate the specific requirement. It is important that the modification of the attributes is made only according to the relevant requirement that is being tested. This is due to the fact that some of the attributes are associated to several requirements and modifying one will cause violations of multiple requirements, which will cause some confusion in the testing result later on. After then, calling the checking functions should give expected warning or error per the requirement. In such way, the tested functional unit and its requirement shall be identically associated. If the expected error or warning is not properly thrown, it then indicates the implementation failed to comply with the requirement and test case should also be failed.

Last stage is the result collection and test termination. The test result will be logged into a log file, after then the test run will be terminated. It is noteworthy that before the test termination, test run will revert all the modifications that have been made to the system. This avoids saving any changes to the database to ensure the consistency

[7] Valid cases refer to the cases that are already verified by checking functions.

of the test environment, so that following test cases can be executed under the same conditions.

8.2.2 Other Features of the Test

In this thesis, CppUnit testing framework is used to achieve the test automation. It composes all the test cases into one test suite and allows them to be executed repeatedly in any software build. This process has very few human interactions. Therefore it is also timely efficient.

Additionally, the assertion mechanism in this thesis is meticulously designed. As it is stated before, the primary goal of this thesis is to test the detectability of the checking functions for rule violations. One method to check this is by comparing the actual thrown messages with the expected ones. This method will only work if the messages that are shown to the users are relatively stable, meaning that they rarely need to be changed in the later releases. However, this can be hardly guaranteed, as there is always need to make the error or warning messages more descriptive to the users in the future. Also, localizing the messages to different languages will also break this method. Due to these concerns, this test includes the requirement unique IDs[8] and message types (error or warning) for verifying the correct error or warning messages, as modifying the requirement unique IDs and message types are remotely needed in the checking functions. It is also noticeable that applying this method needs additional effort in refining the software source code to associate each message with its unique ID and message type.

Furthermore, logging mechanism in this thesis is well designed in order to make the trouble-shooting easier for the testing engineer. First of all, all actual thrown messages are printed in the test log, as well as the expected messages. Apart from this, there are three firm statements used for stating the different types of the failures in the test case:

[8] The unique ID is defined for each message associated with the warning or error in the requirement.

- Message mismatching: When unique IDs are mismatched.

- Message type mismatching: When unique IDs are the same but message type are mismatched

- Message number mismatching: When there are more than or less than expected messages are thrown.

Lastly, because of the high dependencies between different attributes, it is inevitable for some test cases that modifying one attribute may affect the others. Therefore, in these test cases, invalidating one specific case could trigger multiple warnings or errors and tests are designed to accept those additional warnings or errors.

9 Evaluation

This chapter presents the scope of the test implementation and the evaluation of the final results.

9.1 Test Acceptance Criteria

In this work, test is considered as passed only when the same number of correct warnings or errors is thrown after test run has broken the specific rule. The determination of the correct warning or error is by comparing its unique ID with the expected one.

9.2 Test Result Summary

In this work, automated tests were created for 93 specific rules. All the tests are run for each nightly build at the target company. The results are generated from each nightly build. Figure 9.1 reveals the results that were captured at different points of test development phase. At the beginning of the test development, the failure rate was relatively high. This is due to the implementations of the new features and modifications of the existing code and requirements at the early phase of the software development. Besides, some of the test cases were not well implemented yet at this phase, which had also caused several failures. After February 2011, as the total number of the test cases increased, the failure rate declined gradually. This implies that the checking functions have become more comprehensive and more reliable.

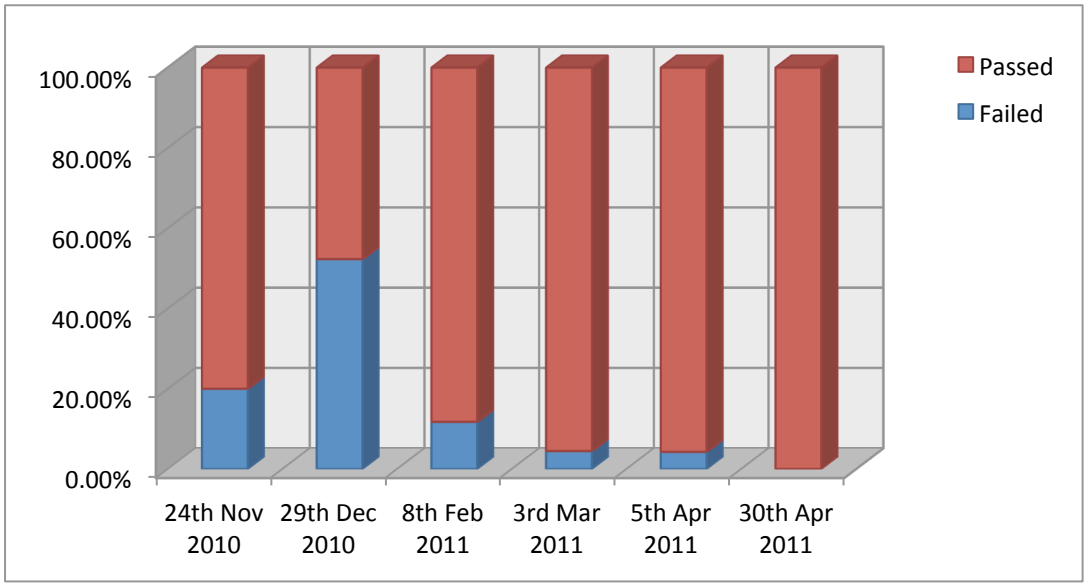

Figure 9.1 Captured test results at different point. Horizontal axis presents the dates when test results were captured. Vertical axis presents the percentages of the passed and failed test cases.

The most typical software defects that have been detected by running these tests are summarized as following:

- Specific rule of the checking functions has been broken on purpose, yet the associated warning or error is not shown.

- Specific rule of the checking functions has been broken on purpose, yet non-related warning or error is shown in addition to the correct warning or error message.

- A precondition has been invalidated on purpose, yet the dependent object is still valid. This reveals a corruption in data model dependency rule.

- Some of the mandatory attributes are not correctly configured in the system.

When the software source code is modified and refined in later releases, it is possible that checking functions will be broken, as well as when new rules are added.

Therefore, these tests should be constantly maintained and updated. Furthermore, keeping the test running for each nightly build is a good mean to monitor the functional status of the checking functions.

10 Conclusions

The goal of this thesis was to develop a set of comprehensive automated tests for a large set of checking functions in a radiation therapy treatment planning system in order to verify that correct error or warning message is shown. This thesis developed a set of automated tests for each specific rule of the checking functions. These tests verify that the implementations of the checking functions comply with pre-defined requirements. In order to demonstrate the work, this thesis started first by introducing the general knowledge of radiation therapy. The discussion focused on the external beam radiation therapy, especially on the linear accelerator machine. Later on, radiation therapy clinical stuffing and workflow were presented. This offered an overview on how treatment planning is carried out in clinics. In treatment planning phase, the treatment planning system is used to simulate the application of radiation to cancer patients. . It determines a lot of treatment parameters that are used for defining the beam shape and calculating the dose. In the following chapter, risk management was brought up with the intention of explaining the importance of risk control in radiation therapy and in treatment planning system. Finally, after introducing the software testing and the CppUnit testing framework, the actual implementation was done with the purpose of verifying the checking functions. After the implementation work was done, tests had exposed several defects in the checking functions, which have already been corrected by the time the thesis was published. Thus, it can be seen that this work has enhanced the reliability and the safety of the treatment planning system.

In the future, these tests can be extended further to cover more recently defined rules. In addition, automated testing will provide a major advantage for saving testing effort.

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