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Master's thesis in Physics
Supervisor: Signe Danielsen
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Abstract

Modern radiotherapy techniques demand a high level of accuracy to achieve the desired result; tumour control with a low probability of normal tissue complications. To meet this demand all steps of the radiotherapy process must be subject to quality assurance. Several guidelines exist on how to design a quality assurance program. However, the list of possible controls is endless, and each department must develop and optimize their own quality assurance program. In recognition of the challenges this represents to the individual department, the American Association of Physics in Medicine has published a guideline on how to implement risk analysis as the basis for designing a quality assurance programme. This guideline was TG-100: *Application of risk analysis methods to radiation therapy quality management*.

TG-100 was published in 2016 and marks a shift in the traditional paradigm of quality assurance within radiotherapy. The traditional approach has been to apply retrospective analysis and reactive measures as the foundation for quality assurance. The tools presented in TG-100 are prospective risk analysis methods. Adopting prospective methods was inspired by their use in other high-risk industries. TG-100 methodology suggests a combination of Process Mapping, Failure Modes and Effects Analysis (FMEA), and Fault Tree Analysis (FTA) as the basis for designing a quality assurance programme.

The purpose of this thesis was to assess the linac Quality Assurance programme at St. Olavs hospital radiotherapy department. The first step in this assessment was a retrospective analysis of the quality control data collected at the department over a period of eight years. This analysis was then used as a quantitative basis for applying the risk analysis tools outlined in TG-100. The goal was to gain experience with the risk analysis tools and prove the feasibility of implementing them as part of QA assessment.

The retrospective analysis identified some quality controls in need of adjustment or redesign of procedures, but the overall programme was found to function well. The results of FMEA showed laser guided set up and accuracy of absolute dosimetry to be the highest risk steps associated with treatment delivery. Through FTA the alignment of MV and mechanical isocentre was identified as the part of machine QA where routine controls should be implemented.

In conclusion, the assessment of the current QA programme was successfully completed with suggestions made for further improvements. The feasibility of including TG-100 methodology as part of the assessment was shown. This included an example of how quantitative measurements can be used in combination with TG-100 methodology.

Sammendrag

Moderne stråleterapi krever høyt nivå av nøyaktighet for å oppnå behandlingsmålet; tumor kontroll kombinert med lav sannsynlighet for normalvevskomplikasjoner. For å oppnå dette må alle stegene i stråleterapiprossesen være overvåket av kvalitetskontrollprosedyrer. Det er publisert flere retningsliner for hvordan et kvalitetssikringssystem skal bygges opp. Forslagene til hvilke kontroller som bør inngå i et slikt system er i prinsippet uendelig og hver stråleterapiavdeling må utvikle og optimaliser sitt eget system for kvalitetskontroller. Som svar på denne utfordringen har den amerikanske organisasjonen for fysikk i medisin (American Association of Physics in Medicine) publisert retningslinjer for hvordan risikoanalyse kan brukes til å utvikle et kavlitetskontroll system. Disse retningslinjene ble publisert i 2016 i rapporten: TG-100: Application of risk analysis methods to radiation therapy quality management.

Publiseringen av TG-100 markerer et paradigmeskifte for kvalitetssikring i stråleterapi. Kvalitetssikring har tradisjonelt vært basert på retrospektive analyser og respons på identifiserte feil. Metodene presentert i TG-100 er basert på prospektiv risikonalyse. Grunnlaget for bruken av disse er inspirert av bruken av disse verktøyene i andre høyrisikoindustrier. TG-100 metodologien baseres seg på en kombinasjon av tre forskjellige verktøy for risikoanalyse: Prossesskart, Failure Modes and Effects Analysis (FMEA), og Feiltreanalyse.

Hensikten med denne masteroppgaven var å vurdere kvalitetssikringssystemet for bruk av linak ved avdeling for stråleterapi ved St. Olavs hospital. Første steg i vurderingen var en retrospektiv analyse av kvalitetskontrolldata samlet ved avdelingen over en periode på åtte år. Analysen av disse dataene ble brukt som kvantitativt grunnlag for anvendelse av risikoanalysemetodene anbefalt i TG-100. Målet var å produsere en rapport for avdelingen med analyse av systemet for kvalitetskontroller slik det fungerer nå, og undersøke gjennomførbarheten av å bruke TG-100 metodologi some en del av grunnlaget for forbedring av dagens system.

Den retrospektive analysen fant noen punkter for forbedring av de eksisterende kvalitetskontrollene, men fant ellers ingen store mangler. Resultatet av FMEA viste at bruk av laser til opplegging av pasient og levert absolutt dose var de stegene av prossessen forbundet med høyest risiko. Feiltreanalysen fant at overvåking av overennstemmelse mellom MV- og mekanisk isosenter var manglende og bør underlegges systematisk kontroll.

Vurderingen av nåværende system for kvalitetskontroll ved stråleterapiavdelingen ved St Olavs hospital resulterte i forslag til forbedringer av enkelte kontroller. Det ble også vist at metodene anbefalt i TG-100 er gjennomførbare som del av vurderingen av et eksisterende kvalitetskontrolsystem. Rapporten inkluderer også et eksempel for hvordan kvantitativ data fra tidligere kvalitetskontroller kan kombineres med TG-100 metodologi.

Preface

This thesis was written as the concluding work of my MSc in Physics at NTNU. The work for the thesis was carried out at the Radiotherapy department at St. Olavs hospital. The project was supervised by Signe Danielsen. I am grateful for her guidance and support in completing this thesis. The project was co-supervised by Nina Levin. I am also grateful for her support, especially in helping me understand the quality controls and processes at the radiotherapy department. I would also like to thank the staff at the radiotherapy department who were always ready to help and made me feel welcome.

To my family and friends, thank you for all your encouragement and support. To my fellow physicists in the physics coffee crew I must say that your support, both moral and practical, has been invaluable. Thank you for making the last two years so much fun.

Finally, to Jan-Anders, thank you for always being there for me.

Tonje Skjong

Trondheim, May 2017

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Abbreviations

AAPM	American Association of Physicists in Medicine
BLD	Beam Limiting Device
CBCT	Cone Beam Computed Tomography
cGy	Centigray
DSA	Norwegian Radiation and Nuclear Safety Authority
EPID	Electronic Portal Imaging Device
FMEA	Failure Modes and Effects Analysis
FTA	Fault Tree Analysis
IAEA	International Atomic Energy Agency
ICRU	International Commission of Radiation Units and Measurements
IEC	International Electrotechnical Commission
IGRT	Image Guide Radiation Therapy
IMRT	Intensity Modulated Radiotherapy
kV	Kilovolt
KVIST	Kvalitetssikring i Stråleterapi (Quality Assurance in Radiotherapy)
Linac	Linear Accelerator
ML	Machine Learning
MLC	Multi Leaf Collimator
MU	Monitor Unit
MV	Megavolt
NEK	Norwegian Electrotechnical Committee
ODI	Optical Distance Indicator
PSDL	Primary Standards Dosimetry Laboratory
QA	Quality Assurance
QC	Quality Control
QM	Quality Management
RPN	Risk Priority Number
SB	Strålebehandling (Radiation Treatment)
SBRS	Stereotactic Body Radiation Therapy
SD	Standard Deviation
SRS	Stereotactic Radiosurgery
SSD	Source Surface Distance
SSDL	Secondary Standards Dosimetry Laboratory
TG	Task Group
TRS	Technical Reports Series
VMAT	Volumetric Arc Therapy
XVI	X-ray Volume Imaging

1 Introduction

It has been the stated goal of the Norwegian government to increase the use of radiotherapy in cancer treatment in Norway. The government published a National Cancer plan in 1997[1]. This was followed by investments dedicated to updating the available equipment and treatment capacity[2]. Researchers found that from 1997 to 2010 the percentage of cancer patients treated with radiotherapy had increased from 29% to 42%. The number of medical linear accelerators for use in treatment had also been increased by 95% in the same time span. The conclusion was that the initiative had been successful in its goal of increasing the use of radiotherapy, but that the percentage was still below the goal. The need to further increase the treatment capacity was also remarked on[3].

The medical linear accelerator (linac) is the main tool for delivery of radiotherapy[4]. The technology related to linacs has gone through great developments over the previous decades. Modern radiotherapy aims to be highly conformal and techniques such as Intensity-Modulated-Radiotherapy (IMRT) and Volumetric Arc Therapy (VMAT) have increased the complexity of linac design. Image Guided Radiotherapy (IGRT) has also added several new components to the linac, adding to the overall complexity.

With these high precision techniques and more complicated technology the need for systematic quality assurance has also increased. This was recognised in the National Cancer plan and national organisation for Quality Assurance in Radiotherapy was founded. This organisation was given the name KVIST (Norwegian abbreviation for Quality Assurance in Radiotherapy). The purpose of KVIST was to increase the quality of radiotherapy in Norway through national QA projects[5]. In the new National Cancer plan[6], published in 2018, a focus on providing high quality treatment is maintained. This is part of the long-term goal of establishing Norway among the world leaders in patient centred care. As part of their work in raising the quality of radiotherapy KVIST has published guidelines on quality assurance of linacs. The national guidelines still recognise that each department must adapt and develop a quality assurance programme tailored to the department. This is not a uniquely Norwegian issue. Other international guidelines on linac QA exist[7-9], and these also recognise that each department must have the final say in how to design and implement a Quality assurance programme.

A recent report by the American Association of Physicists in Medicine (AAPM) estimated that in their latest published guidelines on linac QA the number of controls suggested had increased by 60%[10]. The increase was attributed to the introduction of new technologies such as IMRT and on-board imaging systems. This increase also represents a large increase in the time devoted to quality controls. The AAPM acknowledged that new technologies will keep being introduced and simply adding more controls will soon become unmanageable. To face this challenge the AAPM suggests applying prospective risk analysis methods as the basis for how to adapt the QA programme to the department. This represents a change in paradigm within radiotherapy. Traditionally, published guidelines based on retrospective analysis have been used as the guides for QA design. By moving toward prospective methods, the hope is to make it easier to keep up with the technological advances in the field. The methodology for implementing a risk based approach is presented in TG-100 *Application of risk analysis methods to radiation therapy quality management*[10], published by the AAPM.

The aim of this report is to apply these methods as a means of evaluating the current quality assurance system at the Radiotherapy Department at St. Olavs hospital. The risk analysis will be informed by data analysis of quality control data collected at the department over the last eight years. This will provide quantitative data for use in the risk analysis. Analysing the collected quality control data will also act as an audit, providing the department with a report on how their current system is working.

An estimated 75% of prescribed treatments at the department in the first three months of 2019 were photon VMAT treatments. While this report is not an investigation of VMAT in particular, photon VMAT treatment with curative intent was considered as the example of a standard treatment at the department and was used as the basis for a generic workflow. Due to the majority of treatments being photon based the analysis of quality control data was also limited to include only controls of photon energies.

There are five linacs at the department. Three of the linacs were replaced during the data collection period and quality controls for these linacs were discarded. The two remaining linacs that had been operational throughout the data collection period were chosen as the sources of quality control data. This provided 16 linac years of data for analysis

2 Theory

This chapter will first introduce some basic theory about the linac and reference dosimetry used for medical linacs. Then the topic of Quality Assurance as it relates to linacs will be presented.

2.1 The Linac

The medical linear accelerator, linac for short, is the main tool for delivery of radiation therapy today[11]. While the basic physics of linear acceleration is the same for all linacs the specific build of the linac varies between manufacturers. At St. Olavs hospital radiotherapy department all linacs are made by Elekta. Here the basic structure of the linac as supplied by Elekta will be explained.

2.1.1 Main Components

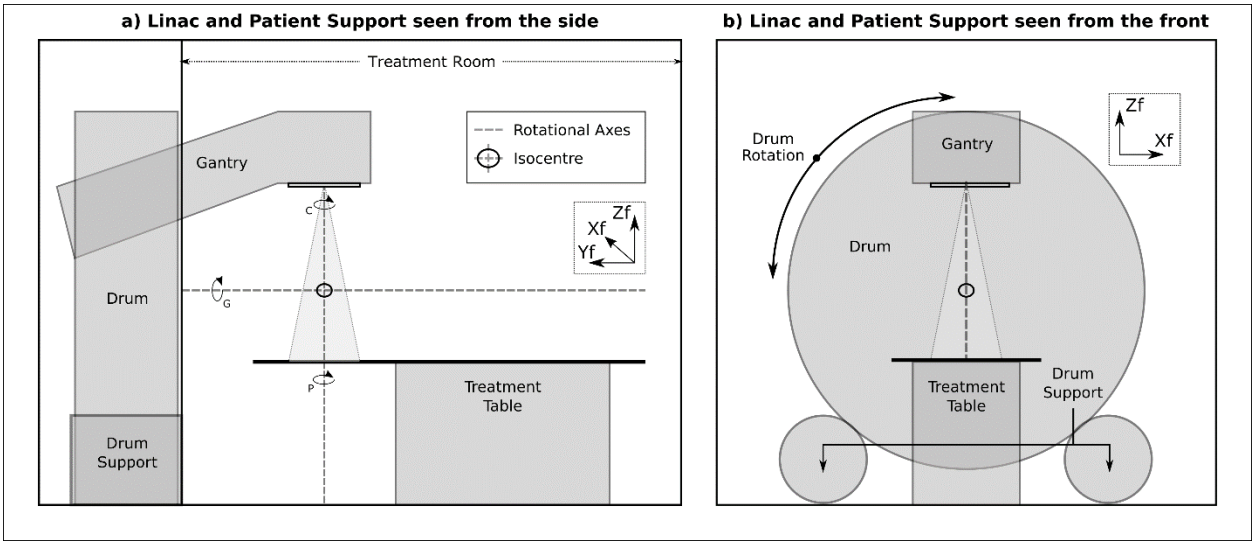

Figure 1 Linac: Major components. a) Linac treatment room with the linac viewed from the side. b) Linac treatment room view when facing gantry. Drum and drum support normally hidden behind a wall which is not included in the figure.

The major structures of a Linac are seen in Figure 1. Elekta linacs use a drum gantry mounting[12]. This design has the gantry arm extending through the drum structure to allow for balancing. As can be seen in Figure 1 a) the drum is commonly hidden behind a wall so that only the gantry arm extends into the treatment room. In Figure 1 b) the drum structure is viewed from the front with the wall removed. Here the base frame drum support with rollers allowing for rotation of the drum and the gantry arm is visible.

The gantry arm can be rotated in either direction. As the beam exits the gantry arm at an angle creating a vertical beam, this defines a point where the central axis of the treatment beam intersects with the rotational axis of the drum and gantry. This point is called the isocentre and the linac is described as isocentrically mounted[11].

The treatment table, also called patient support[11] or treatment couch[12], is a table with adjustable height and position relative to the gantry. The table may also be rotated around the vertical axis shown in Figure 1. The table is attached to a manual protractor embedded in the floor which gives the degree of rotation for the table, see Figure 6.

Control consoles for the linac are not shown. These are computers and hand controls used to move the table and gantry in the treatment room. There is also a control console

room outside the treatment room. From this room the radiotherapists control the treatment delivery and can monitor the treatment room and linac operation.

2.1.2 Beam Forming

Podgorsak[11] describes six classes of beam-forming components. As seen in Figure 2, these are:

1. *Injection system* - The injection system supplies electrons to the accelerating waveguide. It is a simple electrostatic accelerator called an electron gun. A cathode is heated to thermionically release electrons opposite a perforated anode. The electrons are accelerated towards the anode and exit into the accelerating waveguide behind it.
2. *RF power generation system* - The RF power generator is either a magnetron or a klystron. They generate the high-power RF fields supplied to the accelerating waveguide.
3. *Accelerating waveguide* – Here the electrons are accelerated by interacting with the RF-field produced by the RF power generator. The accelerating waveguide is a series of disks with circular holes at the centre. The disks divide the waveguide into a series of cylindrical cavities.
4. *Auxiliary system* - The auxiliary systems are devices that do not contribute directly to acceleration but help make acceleration possible and improve operation. These are: The vacuum-pumping system, the water-cooling system, the air-pressure system, and the shielding against radiation leakage.
5. *Beam transport system* - The beam transport system focuses the electron beam onto a target. This is achieved using bending magnets, which bend the electron beam so that it hits the target. For photon treatment the electron beam hits a target where X-rays are produced. For treatment with electrons the target is exchanged with a scattering foil which spreads the incident electron pencil beam to produce a field.
6. *Beam collimation and beam monitoring system* – This is part of the linac treatment head and is where the beam is shaped using collimators and the beam output is monitored.

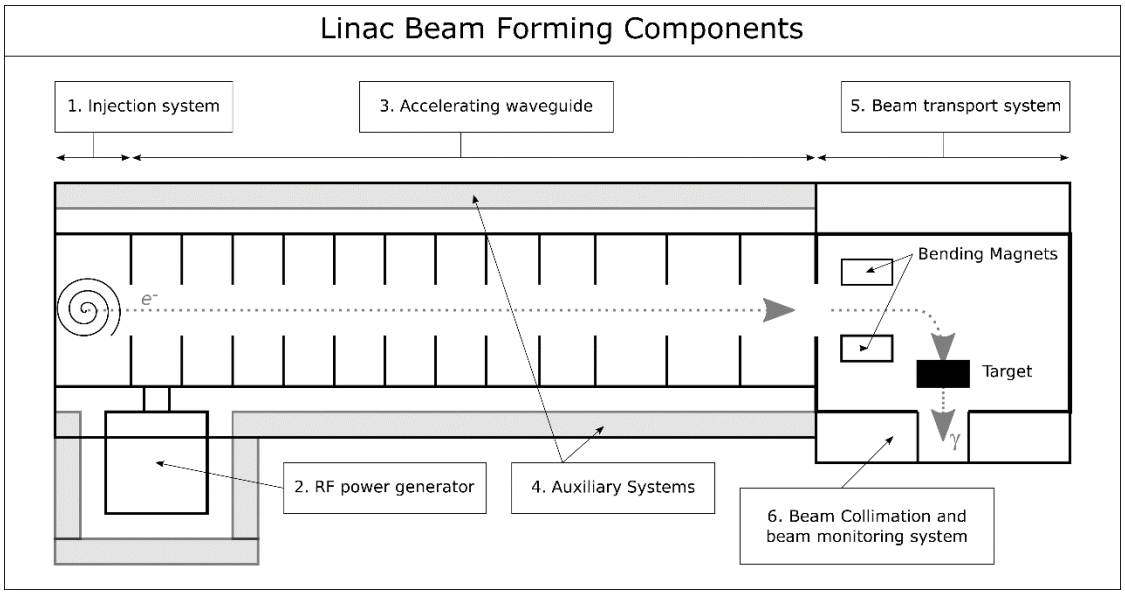

Figure 2 Linac: Beam forming components. Numbered labels correspond to explanation given above (section 2.1.2).

2.1.3 The Linac Treatment Head

The linac can be used in electron or photon mode. For electron beams the target is removed and the electron beam is either scattered by a scattering foil or magnets are used to scan the electron beam to cover the treatment field size. Special applicators are used to collimate the electron beams[13].

The following description is based on the description of the Linac treatment head as given by Mayles et al.[12]. For beam shaping of photon beams the main components are shown in Figure 3. The X-ray beam from the target is first collimated by a conical primary collimator. The Bremsstrahlung produced in the target is forward peaked at the energies used in radiotherapy, so a flattening filter is added to even the field produced.

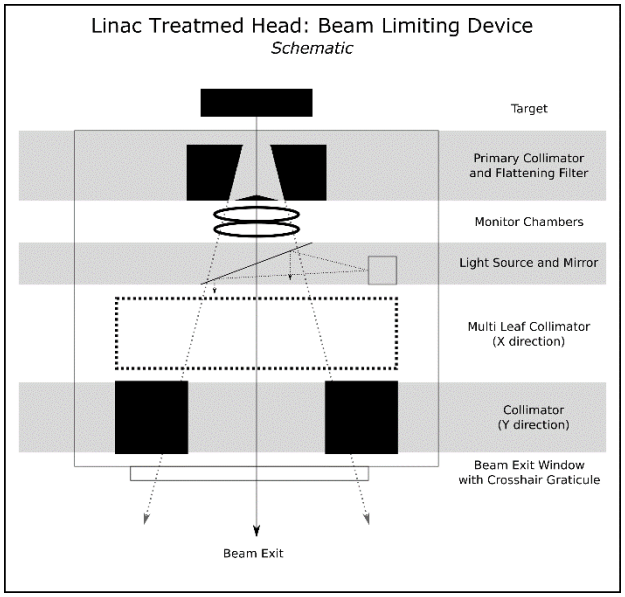

Figure 3 Linac treatment head schematic. Viewed as if facing the linac from the side with gantry and collimator at angle=0°.

The monitor chambers are placed after the flattening filter. These are transmission ionisation chamber detectors which monitor the beam output. By dividing the parallel planes into zones, the chambers can also monitor the flatness of the beam. These parameters are monitored and the linac can to some degree self-correct based on the chamber response. The collector current in the monitor chamber can be related to the dose delivered to the patient. A common way to define this relationship is to have the integrated current associated with 1cGy dose under standard conditions be defined as one Monitor Unit (MU). With this relationship established, the dose to the patient can be given as a number of MU. The monitor chambers are set up so that if the dose set to be delivered is overrun the linac stops. There are two separate chambers for safety reasons[13]. The second chamber has a slightly higher tolerance than the first and acts as a backup.

To visualise the treatment beam a light beam that coincides with the radiation beam is created. A high intensity light source is placed outside the beam path and a mirror is used to reflect the light so that it coincides with the radiation beam. A graticule is placed in the light beam path so that the centre of the radiation beam is indicated as a shadow of cross-hairs in the light field. An Optical Distance Indicator (ODI) may also be mounted in the treatment head which indicates the SSD of a surface placed in the beam path.

For Elekta linacs the Multi Leaf Collimators (MLCs) are placed above the Y direction collimator jaws. An example of MLCs can be seen in figure A. MLCs consist of pairs of leaves that can be moved independently and, in this way, allow any beam shape to be produced, though this also depends on the width of the leaves. The beam limiting devices in the treatment head can be rotated in each direction. The axis of rotation is the central axis of the radiation beam as it emerges from the Primary collimator. So, the axis of rotation intersects with the isocentre line in the same way as the beam axis.

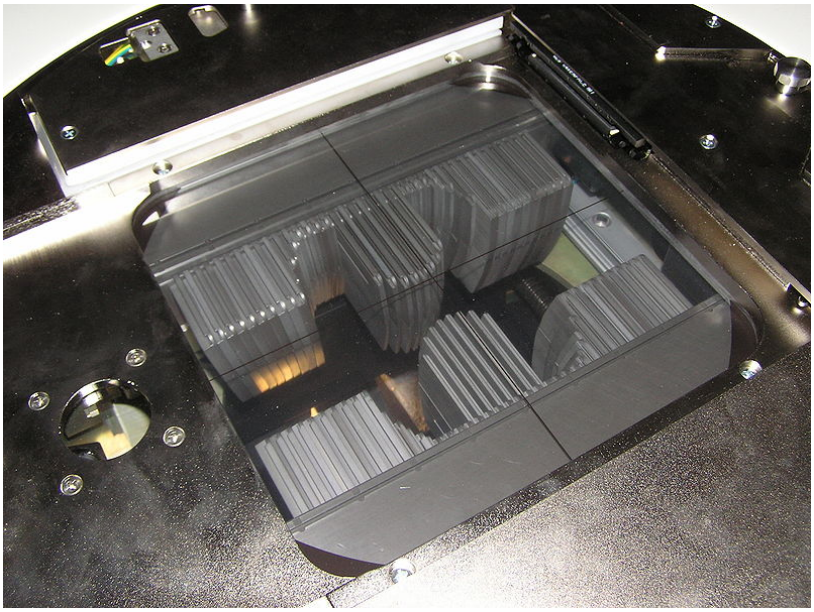

Figure 4 Example of Multi Leaf Collimators.
Illumination by field light can be seen on top row of leaves.
Image used with permission from ref.[14].

2.1.4 Imaging Systems

Modern radiotherapy relies on image guidance. This is referred to as Image Guided Radiotherapy (IGRT). The placement of imaging equipment is shown in Figure 5. The Electronic Portal Imaging Device (EPID) is part of the set up at St. Olavs hospital, but as is not currently in use for image guidance. The Cone Beam Computed Tomography (CBCT) is the main tool used for image guidance at St. Olavs hospital.

Imaging is used as a guide for the setup of the patient on the treatment table before they receive treatment. This provides precise knowledge about the placement of the target volume[11]. In practice the CT scan obtained before treatment is compared with the CT scan used to plan the treatment, so that the planning position can be recreated.

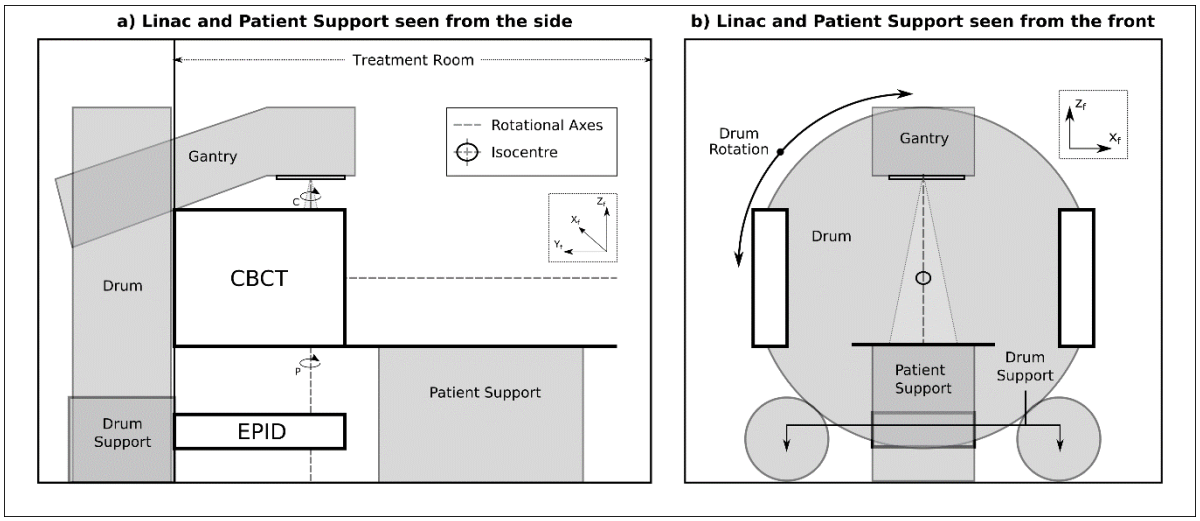

Figure 5 Linac: Imaging component placements on the linac gantry. CBCT is fixed orthogonal to the beam and rotates along with the gantry. The EPID plate is placed opposite of the treatment beam emerging from the gantry and rotates along with the gantry.

2.1.5 Treatment Room Geometry

Laser devices are used to visualise isocentre by defining three planes in the treatment room. Two of the planes are the horizontal and vertical rotational axes as shown in Figure 1. The last plane is the sagittal plane of the patient when positioned on the table, this is shown by the green line in Figure 5. These three planes intersect at the isocentre and indicates its position in the room. These laser guides are also used to position the patient on the treatment table before treatment[11].

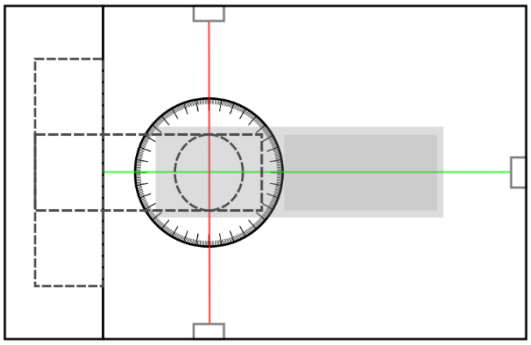

Figure 6 Linac: Treatment room viewed from above. The green line indicates the laser defining the sagittal plane. The red line indicates the laser defining the vertical plane (horizontal plane not shown).

The isocentre is idealised as a point in space, but in practice this is not the case. Due to the weight of the gantry it moves outward as it rotates. This means the isocentre is a sphere and the isocentre size is defined by the diameter of this sphere[12].

2.1.5.1 Linac and Treatment Room Coordinate Systems

The coordinates systems used for radiotherapy equipment standardised by NEK IEC 61217:2011[15]. The system is designed so that each major equipment part has an individual coordinate system and each equipment part is always stationary with respects to its own coordinate system. The individual coordinate systems are all related to a fixed reference coordinate system.

The major coordinate systems relevant for QA discussed in this thesis are shown in Figure 7. Coordinates for wedges, MV imaging, patient coordinates and focusing of imaging systems are not described.

Coordinate axes are identified by capital letters X, Y, and Z. Each system is assigned a lowercase letter to identify the coordinate system. The lowercase letter is added to the coordinate axis identifier. E.g. Xf – X axis of reference system. Figure 7 shows the coordinates systems as aligned when the gantry is at 0 degrees. The origin of the system is indicated by the capital letter I and the lowercase letter of the system. The positive rotational direction of the system is also shown.

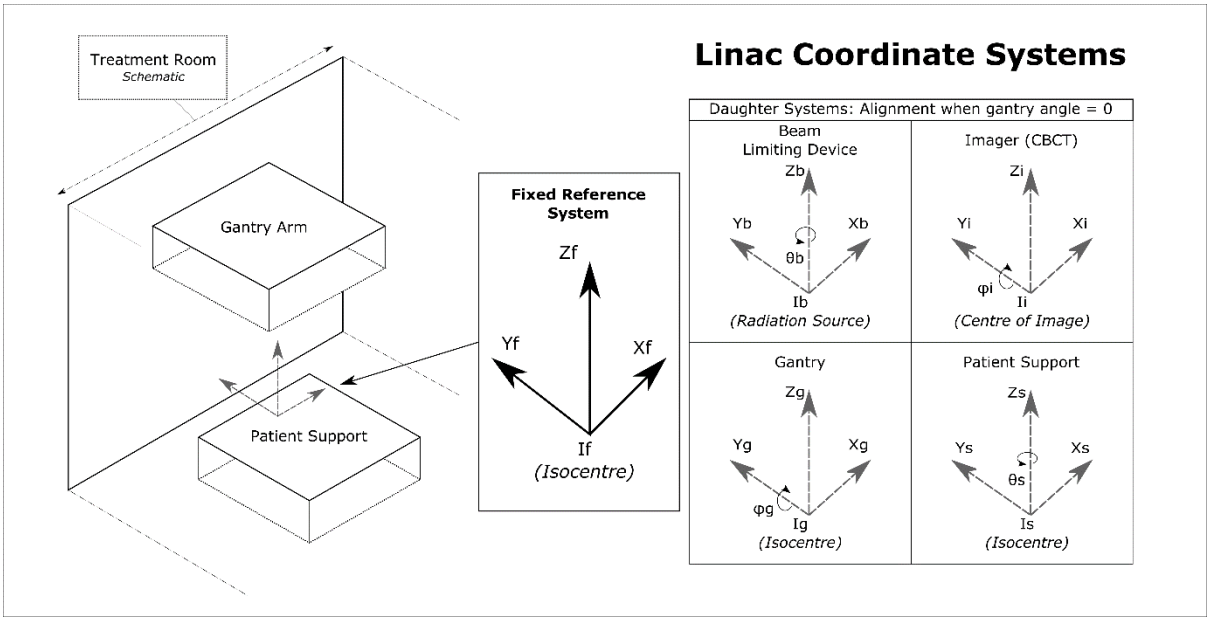

Figure 7 Linac Coordinate Systems as described in NEK IEC 61217:2011. The reference system has its centre of origin at the isocentre does not rotate. The reference system is the mother system which the daughter systems are related to. Rotation of the daughter systems is defined in relation to rotation out alignment with the reference system.

How to describe the radiation field edges are also defined in NEK IEC 61217:2011[15]. Figure 7 shows the radiation field edges when viewing the gantry from the front. The left edge is designated X1 and the right edge X2. The edge nearest to the viewer is Y1 and the edge closest to the gantry is Y2. How these align with the gantry and BLD coordinate systems when gantry and BLD angle is at zero is also indicated.

As a note on colloquial use of directions in the treatment room at the department. G and T are used to indicate direction along the Yf axis. G is short for gun and indicates direction towards the electron gun (positive Yf-direction). T is short for target and indicates direction from the electron gun towards the target in the linac head (negative Yf-direction).

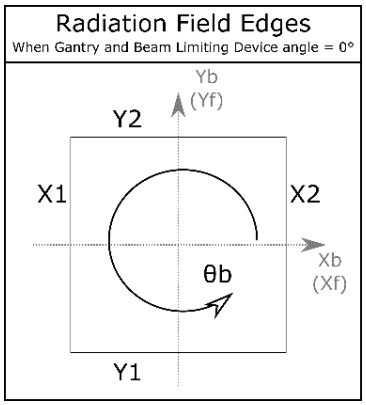

Figure 8 Radiation Field Edges. When viewing the linac from the front; Y2 is closest to the linac. X2 is on the righ hand side.

2.2 Dosimetry

The legal regulation regarding use of radiation[16] demands that a radiation source used for treatment is calibrated against national standards at a minimum every two years. This calibration must be carried out following accepted protocols for calibration. Norway has adopted the internationally accepted protocol: TRS-398 *Absorbed Dose Determination in External Beam Radiotherapy*[17] published by IAEA as the standard for calibration. The following two sections, 2.2.1 and 2.2.2, describe protocols for calibration of high energy photon beams as described in TRS-398.

2.2.1 Chain of Dosimetry

TRS-398 is based on a chain of dosimetry where a reference value is established and from this value a chain is established to ensure equipment used in a clinic are calibrated against this standard. The Primary Standard Dosimetry Laboratory (PSDL) establishes the primary standard. A PSDL must be able to do measurements with the highest achievable accuracy. PDSLs also cooperate and compare standards in order to establish a consensus.

When TRS-398 was published in 2001 twenty active PSDLs were reported. As this is not sufficient to cover the need for calibration, Secondary Standard Dosimetry Laboratories (SSDL) are established. These are dosimetry labs which are equipped with at least one secondary standard which has been calibrated against a primary standard. The SSDL is designated to provide calibration services by local authorities.

A measuring instrument calibrated at a SSDL is called a reference instrument. Field instruments refer to measuring instruments which are calibrated against the reference instrument. In Norway The dosimetry laboratory at DSA is designated as a SSDL and oversees calibration of reference instruments in Norway[18]. This shows how via the SSDL a chain is established form the primary standard to the standards used in the clinic.

2.2.2 Measurement under Reference Conditions

To allow for this chain of dosimetry it is also important to establish a protocol of conditions for measurement. Measurements of absorbed dose are performed in water as absorbed dose to water is closely related to biological effects of radiation. For high energy photon beams cylindrical ionization chambers are recommended for measurements. Absorbed dose to water at a reference depth z_{ref} for a reference beam of quality Q_0 in the absence of the chamber is calculated as shown in Equation 1.

Equation 1. Calculation of absorbed dose to water under reference conditions.

M_{Q_0} = Reading of dosimeter under reference conditions at standards laboratory.

N_{D,W,Q_0} = Calibration factor obtained from a standards laboratory.

$$D_{W,Q_0} = M_{Q_0} N_{D,W,Q_0}$$

The calibration factor is only valid under a set of reference conditions. Reference conditions for absolute dose measurement to water are e.g. experimental set up, fields size, material and

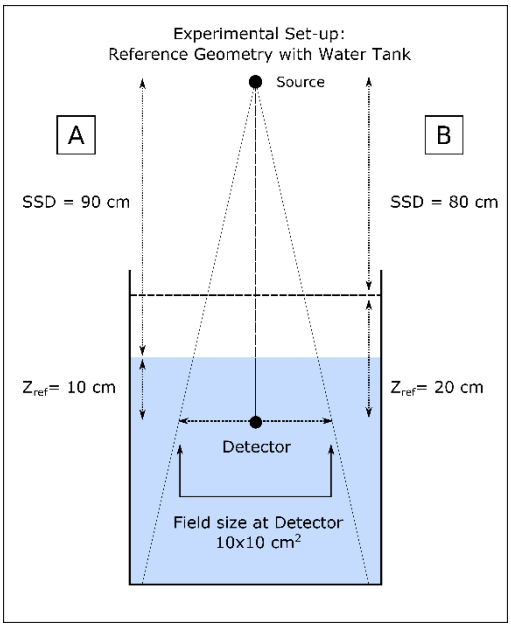

Figure 9 Experimental Set-up: Reference Geometry. Set up A is used for absolute dose measurement. Set up B is used as part of measurements for calculating the beam quality index $TPR_{20,10}$. Z_{ref} indicates distance from water surface. SSD is the Source Surface Distance.

dimensions of the phantom, ambient temperature, pressure and relative humidity. Any deviation from reference conditions in quantities that affect the measurement must be corrected for in the calculation of D_{W,Q_0}. As an example, temperature and pressure are fluctuating quantities and must be measured as part of the dose measurement. Assuming that these factors are independent they are added to Equation 1 as a product of correction factors, $\prod k_i$,where each correction factor k_i is related to one influencing quantity only.

If a different beam quality than Q_0 is used, then this must also be corrected for. This is done by adding another correction factor:k_{Q,Q_0}. Ideally this would be measured for each chamber. In practice tables of theoretically calculated values of k_{Q,Q_0} based on measurements for the specific chamber type used are often used for this correction. How to calculate absorbed dose for a different beam quality and with deviations from reference conditions are shown in Equation 2.

Equation 2 Calculation of absorbed dose to water, $D_{W,Q}$, for beam quality Q under non-reference conditions.
M_{Q_0} = Reading of dosimeter under reference conditions at standards laboratory.
N_{D,W,Q_0} = Calibration factor obtained from a standards laboratory.
k_i = Correction factors for deviation from reference conditions.
k_{Q,Q_0} = Correction for deviation from reference beam quality.

$$D_{W,Q} = M_Q N_{D,W,Q_0} k_i k_{Q,Q_0}$$

The reference geometry of the experimental set up for measurements is seen in Figure 9. Set up A is used for dose calibration measurements. Measurements from set up B are used to calculate a value called $TPR_{20,10}$. This is the Tissue-Phantom Ratio, which is the ratio of measurements at depths of 20 and 10 cm in the water tank phantom with Source Chamber Distance (SCD) and field size held constant. $TPR_{20,10}$ is used as beam quality index for high energy photon beams. It describes the radiation quality in terms of its ability to penetrate a material. $TPR_{20,10}$ can also be calculated from percentage depth dose (PDD) measurements. This is often used for practical reasons. The conversion is given by:

Equation 3 Percentage Depth Dose ratio ($PDD_{20,10}$) to $TPR_{20,10}$ conversion.

$$TPR_{20,10} = 1.2661\, PDD_{20,10} - 0.0595$$

This is an empirically obtained equation where $PDD_{20,10}$ is the ratio of the percentage depth dose at 20 cm and 10 cm for a set up with field size 10cmx10cm at the phantom surface with SSD of 100 cm.

While reference dosimetry is always recommended to be performed using water tank phantoms, water equivalent plastic phantoms can be used for routine controls. The use of plastic phantoms requires that a conversion factor is established between the water measurement and plastic phantom measurement.

2.3 Quality Assurance in Radiotherapy

As defined by NS-EN ISO 9000:2015[19] Quality Assurance is part of Quality Management and is made up of Quality controls:

Quality Management (QM): The coordinated activities to direct and control an organisation with regards to quality. It includes establishing quality policies, quality

objectives and the processes necessary to achieve the quality objectives. Quality objectives are achieved through quality planning, quality assurance, quality controls, and quality improvement.

Quality Assurance (QA): is part of quality management and is focused on providing confidence that the quality requirements are fulfilled.

Quality Control (QC): is part of quality management and is focused on fulfilling the quality requirements.

Quality Requirements: Requirement is the need or expectation that is stated, generally implied or obligatory. Quality is the degree to which the requirements are fulfilled.

These are generic definitions for use in any kind of industry. Clarifications of how to interpret them in a radiotherapy setting exists. The WHO[20] defines Quality Assurance in radiotherapy as:

“all those procedures that ensure consistency of the medical prescription and the safe fulfilment of that prescription as regards dose to the target volume, together with minimal dose to normal tissue, minimal exposure of personnel, and adequate patient monitoring aimed at determining the end result of treatment”

Twaithes et al.[21] defines Quality Control as “the regulatory process through which the actual quality performance is measured, compared with existing standards, and the actions necessary to keep or regain conformance with existing standards”. This is further clarified as operational techniques and activities that check whether quality requirements are met and actions to correct the performance if it is not met.

To summarise; a Quality Control consists of the procedures of measuring and adjusting e.g. the beam output so that it is within acceptable limits. Quality Assurance is then the overall system of Quality Controls that ensure all parts of the process work together to produce a result that meets the quality requirements.

Twaithes et al.[21] also explains how the requirements for quality must be established. Quality Standards are criteria which the quality of the activity in question can be assessed against. There are a various standards published for various parts of the radiotherapy process. Though if no standards are available local standards must be developed based on local assessment of requirement.

Van Dyk[22] defines two main considerations for requirements of QA in radiotherapy: Firstly, accurate delivery of dose according to dose-volume prescription. Secondly, all considerations related to patient safety and avoidance of treatment errors.

Twaithes et al.[21] argues that patient safety is automatically integrated in the QA due to the objective of the treatment being; ensuring normal tissue exposure is as low as possible while fulfilling the prescribed dose to planning target volume. This defines patient safety in terms of protection from accidental exposure, which is covered by the given treatment objective.

Note that in this thesis patient safety is used to refer to non-radiation exposure related safety issues. This is because QA related to the treatment objective is assumed to cover safety in terms of protection from radiation exposure.

2.3.1 Quality Controls and Tolerances

As described QCs are the act of measuring and comparing the result to a standard. These are given as specified tolerances for the measurement. The basis for the tolerances should be the fitness for the purpose of the process[12]. Defined as the tolerances necessary to be able to deliver radiotherapy treatment with the required clinical accuracy. It should be noted that the limiting factor on tolerances may not always be the clinical need, but the accuracy achievable by the available technology.

Tolerances for absorbed dose to a point are a result of considerations of how variation in dose affects the curves for tumour Control Probability (TCP) and Normal Tissue Complication Probability (NTCP). Based on these considerations Mayles et al.[12] cite work by Brahme in stating 3% (relative SD) as the current recommended accuracy requirement for dose to a point and 5% (relative SD) as for dose distribution.

2.3.2 Equipment Quality Assurance

When acquiring new equipment, such as a linac, a series of steps are carried out that lay the foundation for further QCs. These steps, shown in Figure 10, are described by Mayles[12] as:

First is the specification phase, where the user and the supplier agree upon which items, characteristics, and features are included in the order. Then the equipment is delivered and installed. A series of acceptance tests are then carried out to make sure the equipment meets the agreed upon specifications. The acceptance tests do not cover all aspects of use, so after the initial test a commissioning phase commences. During this phase the ability of the equipment to meet clinical needs is assessed. Once commissioning is over periodic QCs are set up to make sure that the original characteristics established in commissioning are not changed.

This shows how commissioning and initial measurements lay the foundation for the quality controls.

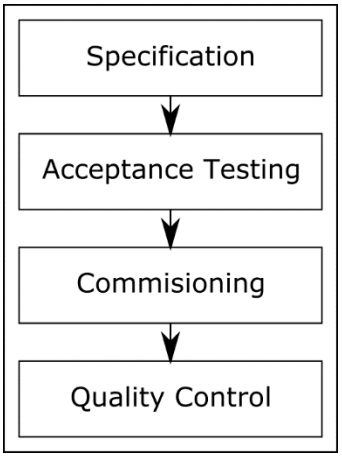

Figure 10 Process of acquisition and establishing baseline for QC

2.3.3 Linac Specific Quality Assurance

2.3.3.1 Radiation Therapy and Linac Quality Assurance in Norway

The use of radiation in a medical setting is regulated by the radiation protection laws[23]. It is also regulated by the laws regarding specialist medical treatment[24] which demands routines should be documented in written form. Further the laws regarding work place environment[25] demands a there is a systematic approach to health and safety that ensures the demands set by other laws are kept.

The Norwegian Radiation and Nuclear Safety Department (DSA) has founded a working group; KVIST (Quality Assurance in Radiation Therapy)[26]. This is an interdisciplinary group with members from all areas related to radiotherapy. The group has been given the mandate by the Ministry of Health and Care Services to coordinate and develop procedures for use in radiation therapy.

KVIST has published several guidelines. One of these is a guideline on linac specific QA[4].

2.3.3.2 International Guidelines on Linac Quality Assurance

The American Association of Physicists in Medicine (AAPM) was formed in 1958 and has as its mission[27];

> "to promote the application of physics to medicine and biology, to encourage interest and training in medical physics and related fields, and to prepare and to disseminate technical information in medical physics and related fields."

As part of this work they have published a series of task group reports. These are reports on a specific topic in radiotherapy made by a group of experts in the field. The reports are chronologically numbered according to when the task group for the report was founded. This means the reports are often referred to by short hand as e.g. TG-13, which refers to the report of Task Group number 13.

Task Group reports specific to linac QA are
TG-13: *Physical Aspects of Quality Assurance in Radiation Therapy* (1984)[28]
TG-40: *Comprehensive QA for radiation oncology* (1994)[9]
TG-142: *Quality Assurance of medical accelerators* (2009)[8]

TG-13 made recommendations for quality controls with suggested tolerances and control frequencies for the individual controls. The goal was to provide a set of procedures that: "ensure consistent and safe fulfilment of dose prescription to target volume". It also focused on measurement techniques and how to add uncertainties so that the cumulative effect of errors could be evaluated. A method for combining random and non-random uncertainties is presented. Random uncertainties should be expressed as standard deviations. Non-random uncertainties should be estimated and expressed as standard deviations. Random and non-random uncertainties are then combined in quadrature to express the overall uncertainty. This recommendation of adding uncertainties in quadrature has carried over to later reports.

As a goal for overall uncertainty TG-13 cites ICRU report 24 as the source for their recommendation of ±5% (representing 2 standard deviations) as an achievable goal and clinically acceptable for dose accuracy to a point.

TG-40 superseded TG-13. The recommendations for quality controls was updated to reflect advances in the field. The report also intended to expand the quality assurance programme to include processes beyond physical machine QA. This was done to include the interdisciplinary work between radiation oncologists, radiographers, dosimetrists, accelerator engineers and medical physicists. An outline for how to organise a QA team to lead the QA work is given. It is recommended that this team is led by a medical physicist.

Specific terminology is introduced for how to interpret conclusions presented by the task group. Three levels of imperatives are used:

Shall or must: indicates items required by legislation.
Recommended: indicates e.g. tolerances or control frequencies that are considered important to follow by the task group. May be modified if justified by careful consideration of how it affects the overall quality.
Should: indicates instances where specifying a specific tolerance or frequency is not appropriate or where there are many different options for how to ensure quality is maintained are available.

TG-40 cites ICRU report 24 as their recommendations of ±5% as the acceptable overall dosimetric uncertainty and ±5 mm as acceptable overall spatial uncertainty.

2.3.3.3 TG-142

The TG-142 report was created in order to update the recommendations from TG-40. It also added recommendations for new developments such as asymmetric jaws, multi-leaf collimators and dynamic/virtual wedges. Recommendations of QCs specific to imaging systems, motion management systems, and IMRT was also added.

The report uses the same goal of +-5% of prescribed dose as TG-40, with the requirement that each step of the process must then be as low as possible to keep the overall uncertainty within this. For tolerance levels they include different levels depending on the accuracy need of the treatment type. Non-IMRT is for some parameters allowed higher tolerance, IMRT has stricter tolerances and SRS/SBRT has the strictest tolerances.

Table 1 contains a selection of recommendations for QCs and QC frequency from TG-142 relevant for IMRT photon treatment and image guidance using CBCT.

Table 1 Selected recommended controls from TG-142 for photons with tolerance limits for IMRT treatment given.

FREQUENCY	PROCEDURE	TOLERANCE
DAILY	**Dosimetry**	
	X-ray Output Constancy	3%
	Mechanical	
	Laser localisation	1.5 mm
	Distance indicator (ODI) @iso	2 mm
	Collimator size indicator	2 mm
	Imaging CBCT[a]	
	Collision interlocks	Functional
	Imaging and treatment coordinate coincidence	≤2 mm
	Positioning/repositioning	≤1 mm
	Safety	
	Door interlock (beam off)	Functional
	Door closing safety	Functional
	Audio-visual monitors	Functional
	Beam on indicator	Functional
WEEKLY	**MLC**	
	Qualitative (i.e. matched fields or “picket fence”)	Visual inspection for discernible deviations
MONTHLY	**Dosimetry**	
	X-ray output constancy	2%
	Typical dose rate output constancy	2%
	Beam profile constancy	1%
	Mechanical	
	Light/Radiation field coincidence[b]	2 mm or 1%
	Distance check device for lasers compared with front pointer	1mm
	Gantry/Collimator angle	±1°

FREQUENCY	PROCEDURE	TOLERANCE
	indicators (@cardinal angles, digital only)	
	Jaw position indicators	2mm
	Cross-Hair centring (walkout)	1 mm
	Treatment Couch Position Indicators	2mm/1°
	Localising Lasers	1 mm
	Imaging CBCT	
	Geometric distortion	≤2 mm
	Spatial Resolution	Baseline
	Contrast	Baseline
	HU Constancy	Baseline
	Uniformity and Noise	Baseline
	MLC	
	Travel speed	Loss of leaf speed >0.5 cm/s
	Lead position accuracy	1 mm for leaf positions of an IMRT field for four cardinal gantry angles. (Picket fence test may be used, test depends on clinical planning-segment size)
	Safety	
	Laser guard interlock test	Functional
ANNUAL	**Dosimetry**	
	X-ray output calibration	1%
	X-ray beam quality	1% from baseline
	X-ray monitor unit linearity	2% ≥5MU
	Mechanical	
	Collimator rotation isocentre	±1 mm from baseline
	Gantry rotation isocentre	±1 mm from baseline
	Couch rotation isocentre	±1 mm from baseline
	Coincidence of radiation and mechanical isocentre	±2 mm from baseline
	Table top Sag	±2 mm from baseline
	Table angle	±1°
	Table max range: all directions	±2 mm
	Imaging CBCT	
	Imaging dose	Baseline
	MLC	
	MLC Transmission (average of leaf and interleaf transmissions) all energies	±0.5% from baseline
	Leaf position repeatability	±1.0 mm
	MLC spoke shot	≤1.0 mm radius
	Coincidence of light field and x-ray field all energies	±2.0 mm
	Segmental IMRT (step and shoot) test	<0.35 cm max. error RMS, 95% of error counts

FREQUENCY	PROCEDURE	TOLERANCE
		<0.35 cm
	Moving window IMRT (four cardinal gantry angles)	<0.35 cm max. error RMS, 95% of error counts <0.35 cm
	Safety	
	Follow manufacturer's test procedures	Functional
a	Imaging CBCT frequency: daily or at a minimum when devices are to be used during treatment day	
b	Light/radiation field coincidence need only be checked monthly if it is used for clinical set ups.	

2.3.4 Risk Analysis as a Tool in Radiotherapy

As seen in the development from TG-40 to TG-142, new technological developments have added several new parameters to the list of recommended controls. This then adds to the overall time needed for QA and makes the task of adapting a QA programme to the individual clinic more complex. A problem then arises of how to choose which QCs to implement. To answer this AAPM suggested using risk analysis as a basis for evaluating which QCs to implement. TG-100: *Application of Risk Analysis methods to radiation therapy quality management*[10], was published in 2016 and attempts to provide a framework for how to choose and adapt QCs. It suggests three Risk analysis methods which can be applied to the individual clinic and the results can help guide the customisation of a Quality Assurance programme.

TG-100 recommends the Risk Analysis is performed by an interdisciplinary team with representatives from all treatment team member categories. This is so that each member can contribute with expertise to the analysis of process steps which are part of their work. The three risk analysis methods and how they are used together as described by TG-100 are described in sections 2.3.4.1, 2.3.4.2, and 0.

2.3.4.1 Process Chart

The process chart serves as a visual representation of the physical and temporal steps in a process. It provides and overview of the process which may not be apparent in the individual daily tasks. This helps identify relationships between the different steps and how they may rely on each other. The level of detail in a process chart is important. TG-100 does not set a specific level of detail but recommends aiming at a level that is manageable and useful in providing understanding of the process. Understanding the process forms the basis of the next risk analysis method.

2.3.4.2 Failure Modes and Effects Analysis (FMEA)

FMEA looks at each individual process step from the process chart and attempts to define everything that could possibly go wrong at the current step. Each way a step could fail is categorised as a Failure Mode (FM). The FMs are then analysed based on how likely they are to occur, how likely it is that they are detected, and what the effect on the outcome is if they are not detected.

This is quantified by ranking the answers to these questions on a scale from 1 to 10.

- Occurrence (O): likelihood that the cause of a failure mode exists.

- Severity (S): severity of the effect on the process outcome if the failure mode is not detected or corrected
- Lack of Detectability (D): likelihood that the failure will not be detected in time to prevent an event.

These values are multiplied together to produce a Risk Priority Number (RPN). The RPN is used as a metric of the risk posed to the patient by the failure if it is not detected.

$$O \times S \times D = RPN$$

TG-100 presents ranking scales for O, S, and D specific to radiotherapy. They note that particularly Severity ranking was difficult and was deliberately made vague to retain usefulness. They recommend distinguishing failure modes based on severity due to the tendency to get caught up on the high severity version of a failure. The high severity version of the failure is often less likely, lower O ranking, and they recommend focusing on more clinically relevant failure modes which often have more moderate severity but occur more often, higher O ranking.

FMEA was designed by the American military in 1949 as part of their standard for risk an reliability analysis[29]. It has become a popular method and there are standard FMEA worksheets developed for use in different industries. Table 2 shows the worksheet suggested by TG-100.

Table 2 FMEA worksheet example presented in TG-100.

Process Step	Potential Failure Mode	Potential Cause of Failure Mode	Current Controls	Occurrence – Cause	Detectability of Failure Mode	Severity of Effect from Failure Mode	RPN	Corrective Action

Rausand et al.[29] discuss some of the advantages and disadvantages of FMEA. The main advantage is that the process of performing the analysis has value in itself. Especially regarding design of a system, it forces focus away from the end result to the individual steps of the process. The main disadvantage is that each failure mode is analysed separately which ignores relationships between failures and causes. It was designed for component evaluation and does not put emphasis on process and human error. It is also noted that the value of a FMEA is highly dependent on the skill of the person or team performing the FMEA.

2.3.4.3 Fault Tree Analysis

The Fault Tree is meant to complement the process chart and gives visual representation of the propagation of failure in the procedure. Visualisation of this propagation is intended to allow for identification of where in the process QA measures can be placed to function most efficiently. Fault Trees can be quantitative or qualitative[29]. The method chose by TG-100 is a qualitative approach.

The fault tree is built by starting with a failure mode and asking what could directly cause the failure mode. The Failure mode is placed to the left and causes called events to the right of it. Causes are connected to the failure mode using logic gates. AND gates are used where two or more events must happen together for the failure to progress through the gate. Or gates are used where either event will allow a failure to progress through the gate.

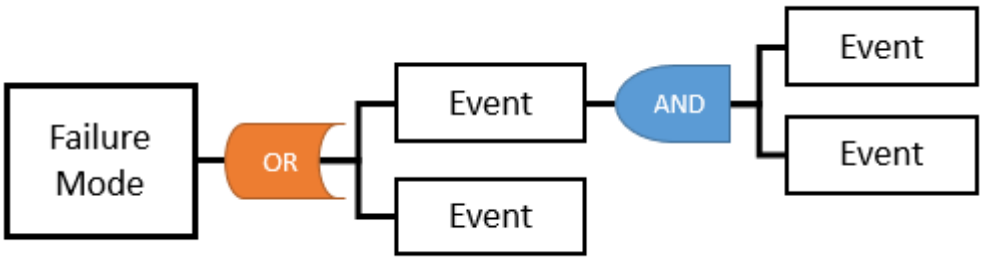

Figure 11 Fault Tree Example. The failure mode is placed to the far left and failures from events that could cause the failure mode propagate from the event towards the failure mode. Logic gates in the propagation path indicates whether either event could cause a failure to pass through it (OR gates), or whether events must occur together for failure to pass through (AND gates).

TG-100 points out that AND gates are often points where an event AND the QC must fail for the failure to progress and as such AND gates provide protection while OR gates show opportunities for failure propagation. They warn against the temptation to apply a QA step where it blocks the propagation of failure from many steps combined. This is firstly because failure of the single QA measure will leave the process unprotected from many possible failures. Secondly, if a failure is stopped by the QA it can be hard to determine which event caused the failure and as the QA measure is applied later in the process much effort can have been wasted in the previous steps.

2.3.4.4 Recommendations Regarding Use of TG-100 Methodology

As TG-100 aims to aid in designing a QM programme from the ground up they highlight the need for a multidisciplinary team with understanding of the entire process as crucial for designing an efficient QM programme. However, it is recommended that TG-100 methodology is introduced by completing smaller projects first. This is to build experience and skill with the risk analysis tools and also to avoid being overwhelmed by the scope of the project. It is also suggested that a series of smaller projects can be used instead of one large project.

TG-100 also supplies a ranking scale for the effectiveness of different QM tools. They based this on recommendations from Institute for Safe Medical Practices (ISMP) and are ranked from 1. (Most effective) to 6. (Least effective). Education is ranked as the least effective. This is because even with the best training, humans will fail, and in comparison with the other tools this makes it less effective. However, it is emphasised that education is essential for correct planning and execution of procedures.

1. **Forcing Functions and Constraints**
   E.g. Interlocks, barriers, or computerised order entry with feedback.
2. **Automation and Computerisation**
   E.g. Bar codes, automated monitoring, computerised verification, or computerised order entry.
3. **Protocols, Standards, and Information**
   E.g. Check-off forms, establishing protocol/clarify protocol, alarms, labels, signs, or reducing similarity.
4. **Independent Double Check Systems and Other Redundancies**
   E.g. Redundant measurement, independent review, operational checks, comparison with standards, increase monitoring, Adding status check, or acceptance test.
5. **Rules and Policies**
   E.g. Priority, establishing/clarify communication line, staffing, better scheduling, mandatory pauses, repair, preventative maintenance inspection, or establish and perform QC and QA (hardware and software).
6. **Education and Information**
   E.g. Training, experience, or instruction.

3 Method

For this report Quality Control data collected at St. Olavs Hospitals radiotherapy department over a period of 8 years was analysed. The results of this analysis were used as basis for risk analysis using the methodology outlined by TG-100.

This chapter has two major sections. The first section is a description of how the Quality Control data was collected and a description of each quality control. The goal is to describe the purpose of the controls and which parameters are checked during each control, not to provide a full procedure of how to perform the control. Detailed procedures for the Quality Controls are part of the hospitals quality assurance system, EQS, and are available for staff from the hospital's database. The categories from TG-142 are used, dividing the controls as concerning dosimetry (absolute or relative), mechanical, or safety. Imaging and MLC controls have been categorised as mechanical.

The second section describes the risk analysis methods used and how the QC data was used.

3.1 Method: Quality Control Data Collection and Selection

3.1.1.1 QuART Database

All regularly scheduled quality controls are registered in a local database called QuART (Quality Assurance in RadioTherapy). The database was developed at the department using Microsoft Access. The interface shown in Figure 12 allows for data entry and has notifications for when the last control was performed and whether the current control is overdue. It is also possible to access and view previously performed controls through the interface.

Figure 12 QuART database user interface

There are two controls which are scheduled in QuART, but the data is recorded elsewhere. These are the yearly control and treatment plan verification.

For the DailyQA phantom an external software analyses the data. The test data is stored by the software in its own database. Only passed/not passed is recorded in QuART.

3.1.1.2 Data Selection

Quality control data from two linacs was selected for analysis. These were the two linacs with the longest operational time during the data collection period: 2011-2018. Both are Elekta Synergy linacs. To refer to the linacs the naming convention used at the radiotherapy department was used. The linacs selected are named SB2 and SB4 (SB is the Norwegian abbreviation of Radiation Treatment). SB4 was in use the entire period and SB2 was taken out of use during the summer of 2018.

All routine QCs of photon energies were selected for analysis. For photons 6MV and 15MV are the two photon energies that routinely controlled. Flattening Filter Free (FFF)

photon controls were not included. This means QCs of electron energies and electron applicators are also not considered. Treatment plan verification is performed using a phantom consisting of a diode array capable of measuring dose distribution in 3D called Delta4 (SkandiDos, Uppsala, Sverige). As treatment plan verification is scheduled on demand, these measurements were also excluded.

The DailyQA phantom measures several parameters during an exposure. Two parameters were selected for analysis: The dose measurement and the energy control. Both are relative to a baseline.

From the yearly control the dose calibration measurements and energy control measurements were added to the data from the routine controls, as these are counted towards the routine controls by the department. The difference from the routine controls is that yearly controls are required to use a water phantom for measurements. Other measurements from the yearly control were not used.

3.1.1.3 Data Analysis

The data from QuART was exported to Excel for analysis. Matlab was used for plotting of trends and boxplots.

3.1.1.4 Quality Controls Overview

Table 3 shows an overview of the quality controls at the department. While the controls here are categorised by their scheduled frequency, any control may be performed more often or on demand if there is reason to do so. How many parameters are entered into QuART for each control is also shown.

Table 3 Summary of routine quality controls at St. Olavs hospital Radiotherapy Department. Parameters in controls are categorised depending on what type of control it is. The tolerance for the individual checks and how many parameters are entered into QuART is also given.

FREQUENCY	CONTROL	TOLERANCE	PARAMETERS RECORDED
DAILY	**Mechanical**		
	Lasers	±1 mm	3
	Floor Protractor	±1 °	1
	Table movement	±1 mm	1
	C-rad[a]	±1 mm	1
	Safety		
	Touch Guards: Gantry and Table	Functional	1
WEEKLY	**Mechanical**		
	CBCT Imaging: XVI	±1 mm	4
	Dosimetry		
	Constancy Control: Relative Dose	±3%	1
	Constancy Control: Relative Energy	±5%	4
MONTHLY	**Mechanical**		
	Distance Indicator	±2 mm	2
	Linac Light Field	±2 mm	2
	Isocentre Stability	±2 mm	6
	Lasers	±1 mm	2
	Safety		
	Touch Guards: All	Functional	5
QUARTERLY	**Mechanical**		
	MLC	±1 mm	6
	Dosimetry		
	Monitor Chamber Calibration: Absolute Dose	±0.5 %	2
	Ion Chamber Stability	±1 %	1
HALF-YEARLY	**Dosimetry**		
	Beam Energy	±1 %	2
ANNUAL	**Dosimetry**		
	Beam Profiles	±1 %	
	Beam Depth Curves	±0.5%	
ON DEMAND	**Dosimetry**		
	Patient plan verification		

a Catalyst camera, only available on two linacs, not considered further here.

3.2 Routine Controls at the Department

3.2.1 Daily Control

The daily control is performed by the radiographer at the start of the day, before treatment commences. It is designed to test critical geometric parameters and safety-interlocks. Parameters are logged as passed/not passed. The control is failed if either parameter is not passed. For failed controls it is mandatory to add a comment explaining who was contacted and how it was resolved. It is also possible to add comments to passed controls though this is optional.

If the control fails, the radiographer must contact the medical physicist. The medical physicist will then assess whether treatment can commence or if improvements must be made. If the touch guard fails an engineer must be contacted and it is specified that the touch guard must be functional before treatment can be delivered.

3.2.1.1 Lasers and Floor Protractor

Sidelasers are controlled by holding up an A4 sheet of paper between the overlapping lasers. The lasers can be seen through the paper and this makes it possible to see where they overlap. The lasers should overlap ±30 cm in each direction from the isocentre. This is checked by moving the paper ±30 cm in each direction from the isocentre while checking that the lasers overlap. The sagittal laser should overlap with the crosshairs in the gantry light field when the gantry and collimator is at 0°.

To control the floor protractor, the control console is first used to set the table angle to 0°. The table should be parallel to the sagittal laser in this position. To pass the test the 0° mark on the floor protractor must be aligned with a mark set in the floor indicating the correct position.

3.2.1.2 Table Movement

Table movement is controlled using a custom-made phantom shown in Figure 13. The phantom is placed according to reference points indicating laser positions. When the phantom is in place the table parameters are set to zero and a pre-programmed table movement is run using Couch Move Assistant. After movement is complete the relative table position read from the linac console should be:

Vertical: 100
Lateral: -100
Longitudinal: 100

The lasers should now line up with the second set of reference marks. The test is failed unless all lasers are within the markings in either direction.

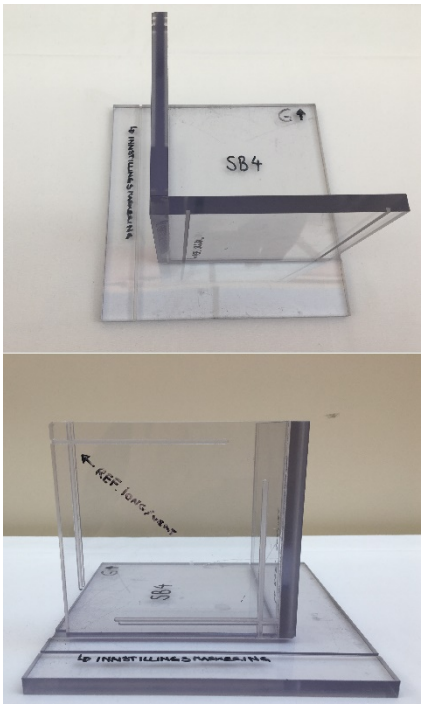

Figure 13 QA Phantom: Table Positioning. Viewed from above and viewed from the side.

3.2.1.3 Touch Guard

The linac head touch guard is controlled daily. This is done by rotating the gantry and pressing the touch guard. The test is failed if the gantry does not stop when the touch guard is pressed or if it does not restart after stopping.

3.2.1.4 Summary of Daily Control Parameters

Table 4 Daily Control: Parameters and Tolerances

CATEGORY	TEST PARAMETER RECORDED	TOLERANCE
LASERS	Horizontal	±1 mm
	Vertical	±1 mm
	Sagittal	±1 mm
FLOOR PROTRACTOR	Floor angle	±1 °
TABLE MOVEMENT	Table position	±1 mm
TOUCH GUARD	Touch Guard: Gantry	Functional

3.2.2 Weekly Controls

There are two weekly controls scheduled: A control of the X-ray Volume Imaging (XVI) on-board imaging system supplied by Elekta and a constancy control of the radiation field.

3.2.2.1 XVI Control

The control is performed by a radiographer. It is designed to test the automated table movement of the XVI image matching software and the alignment of the kV isocentre with the mechanical isocentre. If the control fails, the radiographer must contact the medical physicist who will assess whether improvements must be made.

The control is performed using a QUASAR™ Penta-Guide Phantom (Modus Medical Devices Inc., London, Canada). The phantom, seen in Figure 14, is a 16x16x16 cm cube, weighing 5kg. For accurate set up it has a built-in bubble level. The top surface of the phantom has markings indicating different size light fields. The sides have markings with the central axes of the cube indicating the cube centre. A smaller cross indicates an off-centre position. Inside the phantom are spheres and rings of lower density which show up as darker areas when imaged with the CBCT.

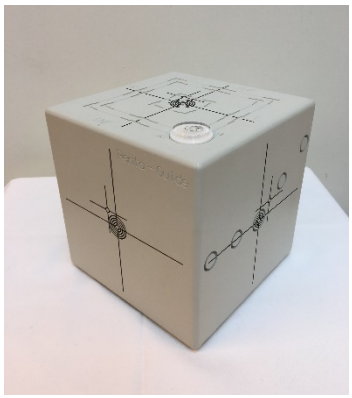

Figure 14 QASAR™ Penta-Guide Phantom.

For the control, the phantom is set up so that the off-centre position is aligned with the isocentre indicated by the lasers. A CBCT image of the phantom is obtained in this position. This image is matched to a reference image of the phantom where the cube centre is aligned with the isocentre. Image matching is performed using the VolumeView software supplied by Elekta. Based on this match the system calculates the table movement needed to move the phantom to the centre reference position. This gives three coordinate movements in X, Y, and Z. These are recorded in the QuART database which calculates how much they deviate from the correct distance between the off-centre and centre position.

The auto-movement function is then used to move the table, based on the system calculations from the image matching, so that the phantom centre becomes aligned with the isocentre. A visual check is then performed to check that the lasers match up with the marking indicating the phantom centre.

As a control this mimics the work flow in IGRT. The reference position is then the CBCT image obtained for planning which is the position the patient should have during treatment. Once a patient is set up for treatment a new CBCT image is obtained. Based on this the operator may move the patient or the table to achieve a better match to the reference position.

3.2.2.2 DailyQA Control (Constancy Control of Radiation Field)

The control is performed by the radiographer. It is designed to measure central axis dose, field symmetry and beam energy. The control is scheduled to be performed on Mondays. If the control fails, the radiographer must contact the medical physicist who will assess whether improvements must be made.

Figure 15 DailyQA™3 Phantom.

The control is performed using a Daily QA™3 phantom (Sun Nuclear Corporation, Melbourne, USA). The phantom has its own software for analysis and only passed/not passed is logged in QuART.

The phantom is set up using the light field indicating a 20x20cm field aligned to the square marked on the surface. The T at the top of the plate indicates the side which should face the gantry and the cross hairs should align with the central cross. Gantry and collimator are set at 0° and Source Surface Distance (SSD) is 100 cm.

The phantom is then irradiated in this position at different photon and electron energies. The software has a colour system for measured values: Green for a passed test, yellow for a borderline value, and red for a failed test.

3.2.2.3 Summary of Weekly Control Parameters

Table 5 Weekly Controls: Parameters and Tolerances

WEEKLY	TEST PARAMETER RECORDED	TOLERANCE
XVI	X (Lateral)	±1 mm
	Y (Longitudinal)	±1 mm
	Z (Vertical)	±1 mm
	QA Phantom Isocentre match	±1 mm
DAILYQA	Dose	±2% (Warning) ±3% (Failure)
	Energy*	±3% (Warning) ±5% (Failure)

* For SB4 energy tolerances differ: ±5% (warning) and ±7% (failure), see section 5.1.2 for discussion of reasons for difference.

3.2.3 Monthly Control

The monthly control of each linac is the responsibility of the medical physicist designated as responsible for the specific linac. The control is performed by the medical physicist together with a radiographer. It is specified that an engineer should be present, but this is not a requirement. The control is designed to be a more thorough control of geometry and safety interlocks than the daily control. Parameters are logged as passed/not passed with the option to add comments to not passed controls. If the control fails, it is the responsibility of the medical physicist to assess if improvements must be made and how to proceed.

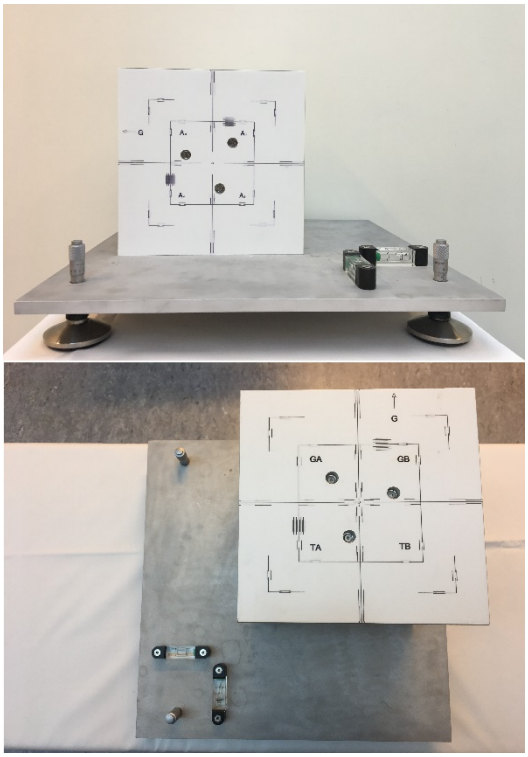

Figure 16 QA Phantom for Monthly Control.

An in house designed, custom-made QA phantom is used for this control. The phantom is a 20x20x20 cm^3 cube with markings for 10x10 cm^2 and 15x15 cm^2 fields along with the cube central axes which indicate the cube centre. Where measurements are to be taken the markings have parallel lines indicating steps of 1mm distance from the central mark. The cube is also marked with G and T to indicate direction in the room (Note: G indicates direction towards the gantry and T indicates direction away from gantry, which is opposite to the T indicating gantry direction on the Daily QA™3 phantom. See section 2.1.5.1 for naming conventions of directions in treatment room.). The phantom is mounted on a plate which has three legs where the height of two legs can be adjusted. Two bubble levels are attached to the plate to make it easier to level the phantom.

3.2.3.1 Lasers

The sidelasers are controlled against markings on the wall opposite the laser. The test is failed if the lasers do not overlap the marks. The sagittal laser is controlled by aligning the phantom central axes to the lasers. The table is then moved ±20 cm in the longitudinal and vertical direction. The test is failed if the sagittal laser deviates from the markings on the phantom.

3.2.3.2 Distance Indicator

The gantry and collimator are set at 0° and the phantom axes are aligned with the sidelasers. SSD at the top of the phantom should then be 90 cm. The optical Distance Indicator (ODI) reading at the top of the phantom is recorded. The table is then lowered 10 cm by adjusting until the horizontal laser is aligned with the top of the phantom. The ODI reading at the top of the phantom is recorded. The test is failed if ODI deviates by ±2 mm on either reading.

3.2.3.3 Light Field

A 10cm^2 light field is set up with the phantom at SSD=100cm and the cube axes aligned with the lasers so that the centre of the cube surface is aligned with the isocentre. Light field deviation is recorded in A-B direction and G-T direction.

3.2.3.4 Isocentre

When the gantry and collimator are at 0° and the QAP axes are aligned with the lasers, the cross hairs should be centred on the centre marking on top of the phantom. After verifying this, the table and then the collimator are rotated in turn while the cross hairs are observed. The cross hairs should remain within the centre marking circle (diameter=1mm) during rotation. The test is failed if cross hairs deviate from the centre in either test.

With QAP axes aligned to the lasers the gantry is then rotated to 90 and then 270 degrees. The cross hairs should match with the centre markings on the side of the phantom in the same way as on the top. The test is failed if either side deviates.

3.2.3.5 Touch Guards

The touch guards for the linac head, iView, and XVI are tested. The emergency stop button on the table and on the hand-held remote control are also tested. The test is failed if either touch guard or emergency stop fails to function properly.

3.2.3.6 Summary of Monthly Control Parameters

Table 6 Monthly control parameters and tolerances.

CATEGORY	TEST PARAMETER RECORDED	TOLERANCE
LASERS	Side Markings match	±1 mm
	Sagittal laser match to QAP	±1 mm
DISTANCE INDICATOR	Surface at 90 cm	±2 mm
	Surface at 100 cm	±2 mm
LINAC LIGHT FIELD	A-B (x-dir.)	±2 mm
	G-T (y-dir.)	±2 mm
ISOCENTRE STABILITY	Cross-Hair to QA Phantom centre match	±2 mm
	Rotation: Collimator	±2 mm
	Rotation: Table	±2 mm
	Rotation Gantry: 90	±2 mm
	Rotation Gantry: 270	±2 mm
	Cross- Hair: Longitudinal table movement ±20 cm	±2 mm
TOUCH GUARDS	Gantry	Functional
	iView	Functional
	XVI	Functional
	Table (emergency stop)	Functional
	Remote Control (emergency stop)	Functional

3.2.4 Quarterly Controls

Three controls are scheduled at quarterly intervals: calibration of the monitor chambers, control of the ion chamber detectors used in quality controls and a control of the multi leaf collimator (MLC).

3.2.4.1 Absolute Dose Calibration

The control is performed by the physicist responsible for the linac. It is required that a second physicist controls the experimental set up and participates in control. Calibration of the monitor chamber ensures that the correct dose is given per MU.

The calibration control follows the protocol for absolute dose calibration described by TRS-398 published by IAEA[17]. See section 2.2 for details about the protocol. When the control is part of the yearly control the measurements are performed using a water phantom. For routine controls the I'mRT phantom is used. The tolerance for both monitor chambers is ±0.5%.

3.2.4.2 Ion Chamber Stability Control

The control is performed by the medical physicist. The test is designed to assess the reliability of the ion chamber detectors used for absolute dose measurement in QC.

The department has two types of ion chambers; cylindrical and plane-parallel. Each type has a designated Radioactive Stability Check Device. The device is a shielded well containing a ^{90}Sr source. The ion chamber is inserted into the well along tracks ensuring the chamber has the same position during all measurements. The reading from the camber is checked against the calculated decay in activity in the source. Deviations of ±1% require a second physicist to control the experimental set up. If no fault in the setup is found or repeated measurements still deviate the chamber must be sent to DSA for calibration.

3.2.4.3 MLC Control

The control is performed by a physicist. The goal is to assess the geometric accuracy of the MLCs and blender as well as controlling collimator and gantry rotation. The control can also be used to test light field and radiation field match though this is not normally part of the control. For the control a sheet of gafchromic film is attached to a 1 cm thick solid water plate which is placed at SSD 100 cm, so that the light field is approximately centred on the film. Another solid water plate of the same thickness as the one below, is placed on top of the film. The film is then irradiated using a predefined 12 field set up. Each field is identical in shape but is recreated at different positions using MLC movement, collimator rotation, or gantry rotation. See resulting pattern in Figure 17. Collimator and gantry positions along with rotational symmetry is shown in Figure 18.

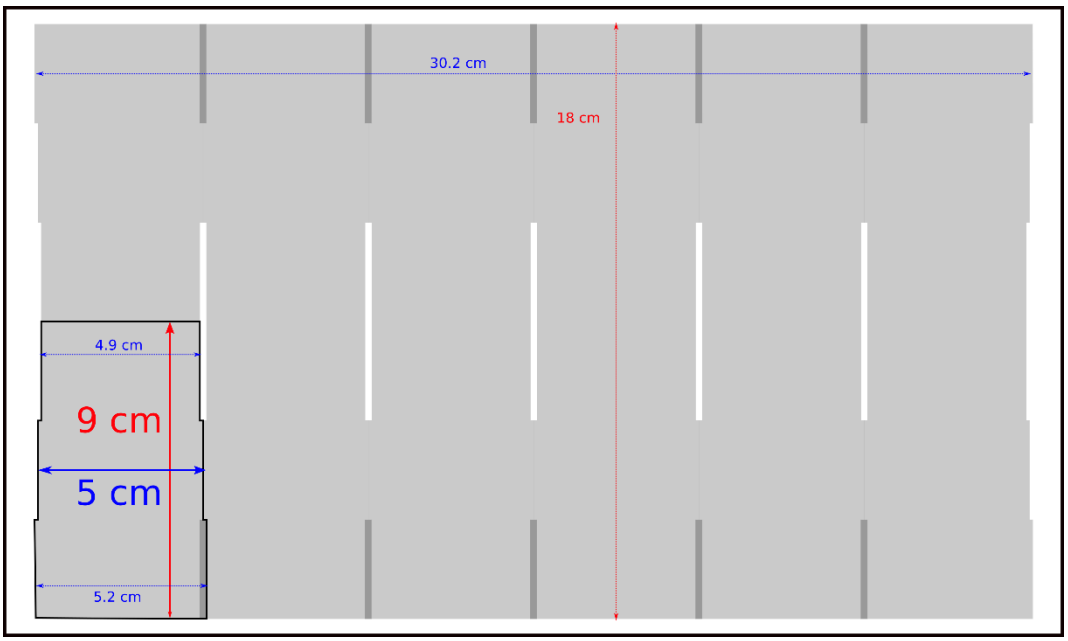

Figure 17 Field set up for the MLC control. The size of the individual fields is shown in the lower left corner. The overall size of the irradiated field is also indicated.

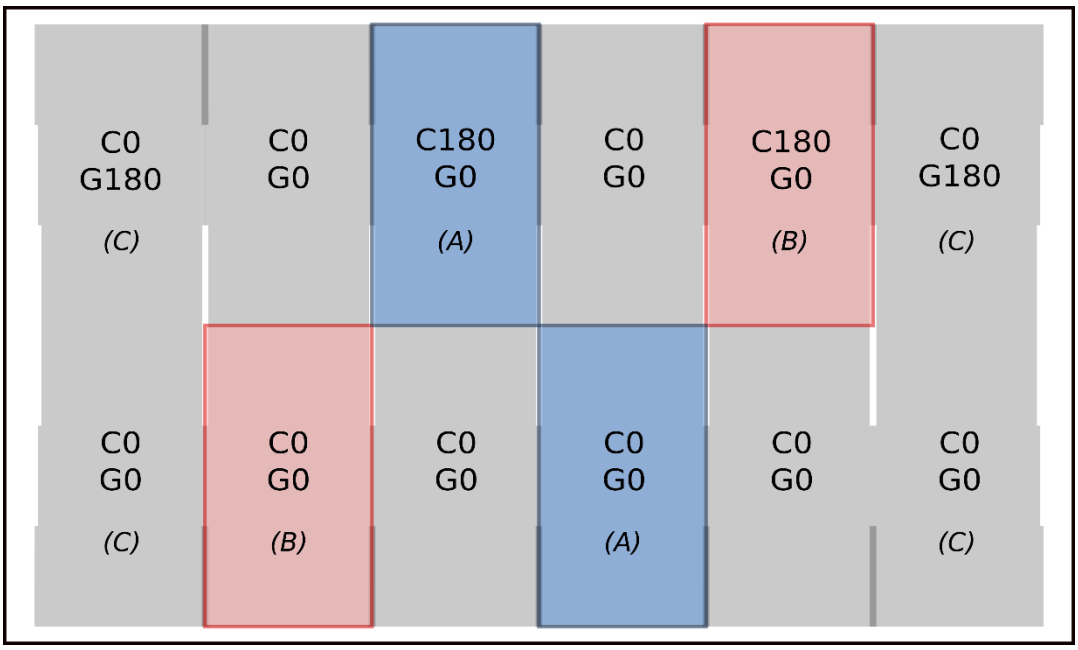

Figure 18 Collimator and Gantry angles for the different field placements. Coloured fields show fields that have MLCs in the same position and are related by rotational symmetry. Blue fields indicate symmetry by rotation of the gantry. Red fields indicate symmetry by rotation of the collimator.

After irradiation the film is removed, and a ruler is used to measure overlap and field size at given positions, see Figure 19. Overlapping fields show as dark sections and are recorded as positive values. Gaps show as lighter sections and are recorded as negative values.

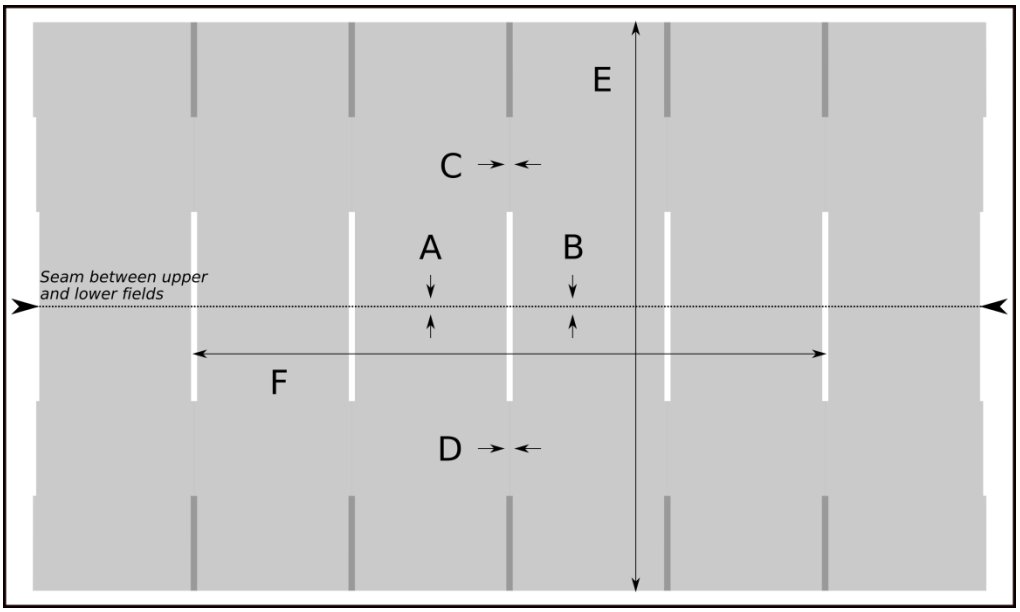

Figure 19 Measurements entered in QuART. For A, B, C, and D, overlap is recorded as positive and gaps are recorded as negative. E and F are measurement of the field size and are always positive. Note that F is measured from the middle of the gap between two fields.

The measurements are recorded in QuART where offset and gain values for the collimator and MLC leaves are calculated from the input values. See Equation 4, Equation 5, Equation 6, and Equation 7 for calculations. Offset describes the initial mispositioning of the MLC or collimator. Gain describes the further difference from the target position in addition to the initial offset. Tolerance levels are set as: ± 1mm for both offset and gain.

Equation 4 Offset Primary Collimator (Y-direction)

$$X1 = \frac{A}{2} \quad X2 = B - \frac{A}{2}$$

Equation 5 Offset MLC (X-direction)

$$Y1 = \frac{C}{2} \quad Y2 = D - \frac{C}{2}$$

Equation 6 MLC Gain

$$G_{MLC} = \frac{F}{200}$$

Equation 7 Collimator Gain

$$G_x = \frac{E + B}{180}$$

Previously the physicist could make direct adjustments based on these calculations, but this has been removed. Adjustments are now the responsibility of the engineer. In

addition to measurements the image can also be qualitatively analysed for isocentre movement. As seen in Figure 18, there are two pairs of fields created by collimator rotation. Misalignment of these fields indicate isocentre movement during collimator rotation. The fields at each end in the top row are with the gantry at 180 degrees. Overlap at the seam between this field and the one below indicates isocentre movement due to the gantry position. Collimator offset can also be seen along the middle seam, where it will show as an increasing or decreasing overlap across the image.

3.2.4.4 Summary of Quarterly Control Parameters

Table 7 Quarterly control parameters and tolerances.

QUARTERLY	TEST PARAMETER RECORDED	TOLERANCE
MONITOR CHAMBER CALIBRATION	MU1	±0.5 %
	MU2	±0.5 %
ION CHAMBER STABILITY	Photon detector	±1 %
MLC	A-E	± 1mm (Offset)
		± 1mm (Gain)

3.2.5 Half-yearly Controls

3.2.5.1 Beam Energy Control

The control is performed by the medical physicist. It is designed to test the penetration depth of the beam which is related to the average energy of the beam. When the control is part of the yearly control it is performed using a water tank phantom.

For routine controls the central cube of an I'mRT phantom (IBA International, Louvain-La-Neuve, Belgium) is used for this control. The phantom is seen in Figure 20. The cube is 18x18x18 cm and the surface of the cube has markings showing axes pointing to the centre of the cube as well as axes parallel at 5 cm to the central axes. The phantom contains several plates that can be inserted in different combinations so that the ionisation chamber can be inserted at different height in the phantom.

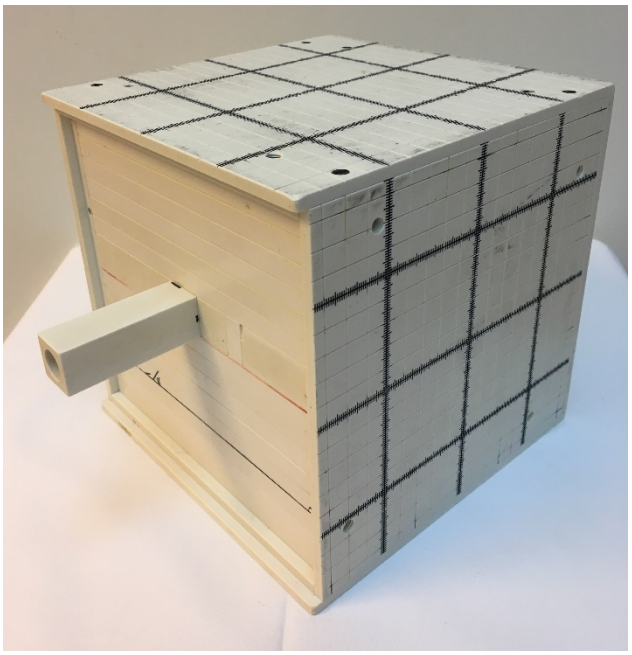

Figure 20 I'mRT phantom. Removable plates with ionisation chamber insert sticking out is seen.

For the control, the cube centre is aligned with the centre of a 10x10 cm field at SSD=100 cm using the light field, cube markings, and lasers as guide. The cube is then raised to SSD=90cm. For the first measurement the detector is placed at 4cm from the top of the phantom (3rd plate from the top). 200 MU is delivered, and the ion chamber measurement is recorded for this set up. The cube is then turned over so that the distance to the detector is 14 cm from the top (14th plate from the top). 200 MU is delivered, and the ion chamber measurement is recorded for the second set up.

Two measurements are taken for each set up. For photons the control is performed for two beam energies 6 MV and 15 MV. The measurements are used to calculate D_{14}/D_4. The value is compared to the measurement established at commissioning and has a tolerance of ±1%.

3.2.5.2 Summary of Half-Yearly Control Parameters

Table 8 Half-Yearly control parameters and tolerances.

CATEGORY	TEST PARAMETER RECORDED	TOLERANCE
PHOTON ENERGY	D_{14}/D_4 (6 MV)	±1%
	D_{14}/D_4 (15 MV)	±1%

3.2.6 Yearly Control

The yearly control is an extensive control of the linac performance. Other controls are often scheduled in conjunction with the yearly control for practical reasons. Absolute Dose Calibration and Energy Control measurements (Depth Dose) are always performed as part of the yearly control. The control is performed by the medical physicist. A water tank phantom is used to perform measurements during the Yearly Control. Measurements performed during the yearly control are added to the data for the corresponding routine control when this is possible.

3.2.6.1 Summary of Yearly Control Parameters

Table 9 Parameters and tolerances for selected controls.

YEARLY	TEST PARAMETER	TOLERANCE
ABSOLUTE DOSE CALIBRATION	Dose per MU	±0.5%
DEPTH DOSE	D_{20}/D_{10} (6 MV and 15MV)	±1%

3.3 Method: Risk Analysis

TG100 Methodology refers to the tools for Risk analysis in Radiotherapy laid out in AAPM's TG-100 Report. The methodology is designed to be a team-based effort with the recommendation that representatives from all treatment team categories participate. For this report the team consisted of a physics student and two medical physicists. Input from other staff categories was sought when needed.

3.3.1 Process Chart

The chart was designed to follow the patient's path from diagnose to end of treatment. For this report the focus is on linac QA which is mostly related to the *Treatment Delivery* step of the process. For the Steps; *Diagnosis, Treatment Planning, and Follow-up*, the level of detail was kept as low as possible while still identifying major steps that may affect the treatment delivery accuracy.

The PDSA circle[30] was added to the chart as this is part of the hospitals stated quality improvement goals. The direction of the circle indicates how the steps in the radiotherapy process fit into this quality improvement methodology.

3.3.2 Failure Modes and Effect Analysis (FMEA)

After creating the process chart the steps within Treatment Delivery were selected for FMEA. The FMEA worksheet suggested by TG-100 was modified by exchanging the last column of corrective action to excluded causes and assumptions. This was done to keep track of possible causes originating in previous steps in the process and assumptions made about the failure mode and process step. Doing this helped keep focus on the current step and make it clearer what was being discussed.

Ranking scales for Occurrence, Detectability, and Severity were based on the tables presented in TG-100[10]. Sections 3.3.2.1 to 3.3.2.3 describe how they have been modified here.

3.3.2.1 Occurrence (O)

To establish values for Occurrence the percentage frequency was converted to days of failure per year frequency. This was modelled on the method developed by O'Daniel[31] for adjusting the TG-100 Occurrence scale.

The linac is assumed to be operational all days throughout the year. Using the % frequency in the TG-100 scale the number of days per year a failure is present is then calculated.

The failures found in the QA data are likewise assumed to be days per year a failure is present and can be measured on the scale. The range of the TG-100 scale was too large to usefully differentiate the frequencies found in the data so the top value of >5% (*Failure inevitable*) was removed and steps from 0.2 to >4 were modified.

Table 10 Occurrence Ranking Scale. Modified table based on tables presented in TG-100.

Occurrence Ranking Scale			
Description	O Values	Frequency %	days per year
Failure Unlikely	1	0.01	0.04
	2	0.02	0.07
Relatively few failures	3	0.05	0.18
	4	0.1	0.37
	5	<0.2	<0.73
Occasional failures	6	<0.4	<1.46
	7	<0.8	<2.92
	8	<1	<3.65
Repeated failures	9	<3	<10.96
	10	>4	> 14.61

3.3.2.2 Detectability (D)

For Detectability the scale suggested by TG-100 was used. Detectability is here defined as the likelihood of being detected in time to prevent failure in the next process step provided no QCs are in place.

Table 11 Detectability Ranking Scale. Description and rankings as presented in TG-100.

Detectability Ranking Scale		
D value	Estimated probability of going undetected (%)	Description
1	0.01	Always
2	0.2	High Likelihood
3	0.5	
4	1	Moderate Likelihood
5	2	
5	10	
7	10	Low Likelihood
8	15	
9	20	Very Low Likelihood
10	>20	Never

3.3.2.3 Severity (S)

The severity scale suggested by TG-100 was used as a guide to create a more suitable scale. Severity terms were related to the QA tolerance limits rather than assumed outcome severity. This is partly because the severity of the outcome as a function of inaccuracy of dose or placement depends to a high degree on the location of the area treated and the type of treatment. As the scale here is not used to judge any particular type of treatment, severity is interpreted as dependent on degree of deviation from the target accuracy.

The range of the scales was adjusted by setting the limit ranked as 9 in TG-100 as rank 10. This was done to increase the differentiation at the lower steps. The descriptions of

the severity terms were used where the tolerance limits matched the limits indicated in TG-100 scale.

As noted in TG-100 several of the terms have overlap, such as wrong location, wrong volume, or dose distribution. To avoid confusion the scale was reduced and divided to differentiate between dosimetric inaccuracy to a point, and geometric miss due to patient being positioned wrong relative to isocentre, or the linac producing the field at the wrong location. Note that this means a volume that is too small due to jaw or MLC misalignment is categorised as a geometric miss, not as a dosimetric error, even though this would also represent a dosimetric error.

Table 12 Severity Ranking Scale. Modified table based on ranking scale and tables presented in TG-100.

Severity Ranking Scale				
Geometric				
Severity Term	**Tolerance**	**S rank**	**Description**	**Category**
Within Tolerance	<1mm	1	No Effect	
		2	Minor effect	Inconvenience
Minor Deviation	>1mm	3		
		4	Moderate Effect	Suboptimal plan or treatment
Wrong location	>3mm	5		Wrong location
		6		
		7	Serious Effect	
		8		
Very wrong location	>5mm	9	Injury	Very wrong location
		10		
Dosimetric (point)				
Severity Term	**Tolerance Description**	**S rank**	**Description**	
Within Tolerance	<0.6%	1	No Effect	
		2		Inconvenience
Minor Deviation	>2%	3	Minor effect	
		4		Suboptimal plan or treatment
Wrong dose	>3%	5	Moderate Effect	Wrong dose
		6		
	>5%	7	Serious Effect	
		8		
		9		
Very wrong dose	>10%	10	Injury/Death	Very wrong dose

To aid interpretation of the severity table a description of the different bands was made. Band 8-9 here matches the 5-8 band as defined in TG-100.

Table 13 Severity Ranking Scale Band Descriptions

Severity Scale Table Band Description Key	
1-2	Failures that are part of planning tolerances.
3-4	Failures that may be an inconvenience to staff; E.g. need to calibrate equipment or adjust treatment
5-6	Failure that is deviates from set target, inconvenience to staff and patient; need to adjust plan and possibly treatment protracted
7-9	Failures that are expected to increase adverse outcome on a population level.
10	Failures that are expected to increase adverse outcome for individual patient

3.3.2.4 Failure Mode Dependency on Severity and QC Failure Frequency

The different failure modes were categorised based on which QC best described the possible failure mode. This was done in order to assign a failure frequency from a QC to the failure mode. For failure modes which did not correspond to a QC the failure frequency was estimated based on the qualitative description in the occurrence scale.

1. **Set up: Patient ID**
   This step was included to account for all errors related to patient ID. For this step, calling the wrong patient or retrieving the wrong items for the patient are considered the same type of error. This failure mode does not correspond to any QC data.
2. **Set up: Immobilization Equipment**
   This step accounts for errors related to use of the equipment. Choice of equipment, design and quality is not included in this failure mode as these are decided during treatment planning. Failing to notice that the equipment is no longer serves its purpose e.g. because of patient weight loss would be included here. The failure mode relies on radiographer training and attentiveness and does not correspond to any QC data.

Set up: Positioning

This was divided into two separate failure modes based on the guidance used. In the normal workflow CBCT is used after laser guided set up. This acts as an unavoidable QC for the lasers, where the laser guided set up cannot be defined as following the demand of no QCs present for detectability.

3. **Set up: CBCT guided**
   This was set to a failure mode of >1 mm based on the tolerance of the XVI control so that the failure frequency of this control could be used.
4. **Set up: Laser guided**
   This was set to a failure mode of >3 mm and assumes that immobilization equipment is correctly used. Laser guided would also include light field and ODI guidance and is affected by table accuracy parameters. Both the daily and monthly control failure frequency affect this failure mode. The monthly control

had the highest failure rate, so this was used in order to reflect the highest possible RPN.

5. **Set up: Patient Safety**
   This accounts for all injuries severe enough to possibly halt treatment. The step relies mostly on the radiographer performance. From the QA data it is related to the function of touch guards and emergency stops which are part of daily and monthly controls. The failure frequency was the same for both controls and was used as basis for Occurrence along with estimated possibility of human error.
6. **Treatment Delivery: Dosimetric Error >0.6% (Calibration target)**
   A limit of >0.6% was used to reflect failure of calibration target and the failure frequency of the calibration control was used.
7. **Treatment Delivery: Dosimetric Error >2% (DQA warning)**
   A limit of >2% was used to reflect the warning level of DailyQA controls and the frequency associated with this.
8. **Treatment Delivery: Dosimetric Error >3% (DQA Failure)**
   A limit of >3% was used to reflect the failure level of DailyQA controls and the frequency associated with this.
9. **Treatment Delivery: Geometric Error >1mm**
   This failure mode was set to indicate errors above 1mm in the produced beam volume relative to isocentre. It depends mainly on QC data from the MLC control, but is also affected by isocentre stability from the monthly control. The MLC control had 0 failure frequency of the overall control. Due to the practice of correcting individual measures above 1mm for this test, the failure frequency of individual measures of the MLC test was used for occurrence and >1mm as the limit.
10. **Treatment Delivery: Patient Safety**
    This accounts for injuries during treatment delivery. It is assumed the patient is immobilized. It depends both on radiographer mistake of putting patient in the path of gantry and CBCT and on the touch guards on the gantry head and CBCT. Failure frequency from Daily and Monthly controls for touch guards were used as basis for Occurrence along with estimated probability of human error.

3.3.3 Fault Tree Analysis

Three of the failure modes were selected for the fault tree. From set-up positioning was chosen. From treatment delivery dosimetric miss and geometric miss was chosen. Here the general failure category was used without differentiating based on tolerance as in the FMEA.

The fault tree starts with a failure mode to the left and works through causes towards the right. Each cause to the right answers the question: what could cause the event to the left?

Causes are linked to the failure mode via logic gates. Two types of logic gates are present: “And gates” which signify events where two or more causes must be present for a failure to travel through the gate. “Or gates” that signify events where either cause will be enough for a failure to travel through the gate.

The fault tree was also limited from including causes outside the control of the medical physicists. This excludes factors outside the control of the department e.g. earthquakes or power failure. It also excludes causes linked to linac components which are the responsibility of the engineer. As an example, the physicist can measure whether the

energy of the beam deviates but determining which component must be adjusted to correct this is not within the medical physicist's responsibility. Once the Fault tree was completed, current QCs were indicated in the tree so that unprotected paths could be identified.

4 Results

4.1 Compliance

The average compliance level for each control is calculated as the average of controls between SB2 and SB4. If a control has separate entries for different photon energies the average is used, e.g. the full control requires both 6MV and 15MV to be measured, but there is only an entry for 6MV counts as 0.5 controls. See appendix section 8.3 for details about compliance calculations.

Total average compliance: 79.7%

Table 14 Average Compliance with QC Frequency Target per year. Average compliance over all years is also given.

	Average Compliance Level (%)							
Year	Daily	DQA	XVI	Monthly	Calibration	MLC	Ion Chamber	Energy Control
2011	24.0	*na*	59.6	*na*	137.5	62.5	*na*	62.5
2012	14.0	*na*	30.8	*na*	87.5	50.0	*na*	125.0
2013	35.2	*na*	51.9	75.0	168.8	150.0	50	175.0
2014	64.8	96.9	65.4	58.3	118.8	162.5	100.0	150.0
2015	64.2	88.0	67.3	58.3	50.0	125.0	75.0	75.0
2016	71.5	99.0	80.8	54.2	131.3	62.5	25.0	75.0
2017	68.7	104.3	76.0	50.0	168.8	100.0	50.0	75.0
2018	33.8	89.9	59.0	37.5	100.0	100.0	62.5	100.0
Average	47.0	95.6	61.3	55.6	120.3	101.6	51.8	104.7

4.2 Daily Control

The daily control fails on average less than once per year with no recorded failures in the last three years (2016-2018) for either linac.

Table 15 Daily Control Failures. The average failure of the overall control is indicated as control status failures. How often the individual parameters fail is given below the control status failure. Note that the control status failure may have been caused by one or more parameter failures.

FAILURES PER YEAR

YEAR	SB2	SB4
2011	0	0
2012	0	1
2013	0	2
2014	1	3
2015	1	0
2016	0	0
2017	0	0
2018	0	0

PARAMETERS FAILED AND FREQUENCIES

	# of Failures	Frequency *(Failure/Year)*
Control status	**8**	**0.50**
Horizontal laser	0	0.00
Vertical laser	1	0.06
Sagittal laser	1	0.06
Floor protractor	5	0.31
Table parameters	1	0.06
Touch guard	0	0.00

For SB2 the failure recorded in 2014 is due to deviation of the table parameter test and the failure in 2015 is due to deviation of the sagittal laser. For SB4 the parameter with the most recorded failures is the floor protractor. This is mainly because of 4 failures recorded for SB4 in the period 13.12.2013 to 15.01.2014, where the table motor malfunctioned. The protractor is also recorded as failed 07.10.2014 for SB4, though the comments indicate issues with the sagittal laser. There are no comments explaining why these failures have been recorded for the floor protractor rather than table parameters and sagittal laser. The remaining failure recorded for SB4 in 2012 is a deviation between the distance indicator and the vertical laser.

Comments on controls recorded as passed are categorised based on their purpose in Table 16. There are three comments, which indicate failures. For SB2 one was a deviation when the table was rotated to 90 and 270 degrees and the other was SSD to vertical lasers deviation. For SB4 a 1-2mm deviation is indicated, but it is not clear which parameter is affected.

Table 16 Daily control comments categorised by type of information conveyed.

Comments on controls recorded as passed

Purpose of comment	SB2	SB4
Indicate failed test	2	1
Forgotten to record previously performed test	2	1
Notes of observation during control	4	4
Repeated information ("ok" or signature in comment field)	4	2
Unclear	0	1

4.3 Weekly Controls

4.3.1 XVI Control

The failure frequency for the XVI control is given in Table 17. The control fails on average 1.63 times per year. The criteria for failing a control is that at least on parameter fails, though a control status failure may include more than one parameter fail. The Y and Z directions fail about twice as often as the X direction.

Failures per year are shown in Table 18. Half of the failures after table movement are associated with a failure in matching (6 out of 12 failures). The remaining failures had match within tolerance.

Table 17 Average XVI control failure frequencies. Failure frequency of the overall test is indicated by control status failures. Failure frequencies of the individual parameters is given below.

FAILURE FREQUENCY (failure/year)	
Control Status	**1.63**
X	0.31
Y	0.69
Z	0.69
Table movement	0.75

Table 18 XVI Control failures and individual parameter failures per year.

CONTROL FAILURES SB2

YEAR	X	Y	Z	Table Move	Status
2011	1	2	5	1	7
2012	1	0	3	1	3
2013	0	0	0	1	0
2014	0	0	0	0	0
2015	0	0	0	0	0
2016	0	0	0	0	1
2017	0	0	0	0	0
2018	0	0	0	0	0

CONTROL FAILURES SB4

YEAR	X	Y	Z	Table Move	Status
2011	1	1	0	1	1
2012	0	0	2	0	2
2013	0	1	0	4	4
2014	0	3	1	1	3
2015	0	2	0	1	2
2016	2	2	0	1	3
2017	0	0	0	0	0
2018	0	0	0	1	0

As a having failed at least one parameter is the criteria for a failed control, some inconsistency is seen in Table 17. For SB2 a failed control status is recorded in 2016 with no failed parameters. The comment reads “minor deviations on longitudinal”. Logging a failed a parameter is also supposed to automatically fail overall control. However, a failure of the table movement parameter is recorded in 2013 without failing the control. The comment explains that the vertical laser deviates, but no action is pursued as the laser parameter was passed on the monthly control performed five days prior to the XVI control. For SB4 a failure of the table movement parameter has been recorded twice without failing the control, once in 2013 and once in 2018. In 2013 the comment explains that there is a minor deviation in the longitudinal direction. In 2018 the comment explains that the parameter is logged as failed because the table movement was not carried out.

The mean and standard deviation of the X, Y, and Z measurements are given in Table 19. The trend plots in Figure 21 and Figure 22 show how the measurements fluctuate over time. The boxplot in Figure 23 shows the spread of the measurements. Overall the majority of measurements are stable within the ±1mm tolerance limit.

Table 19 Mean and standard deviation for measurements in XVI Control.

STANDARD DEVIATION AND MEAN

	SB2		SB4	
Direction	**SD (mm)**	**Mean (mm)**	**SD (mm)**	**Mean (mm)**
X*	0.49	-0.04	0.44	-0.40
Y	0.50	0.21	0.44	0.37
Z	0.45	0.29	0.40	0.24

* For SB2 x-direction a single large deviation of 18.5 mm was recorded. Comment on the control indicated “minor deviation”. The measurement was assumed to be an entry error and removed from the sample. With his measurement the values would be mean: -0.12 and SD: 1.28.

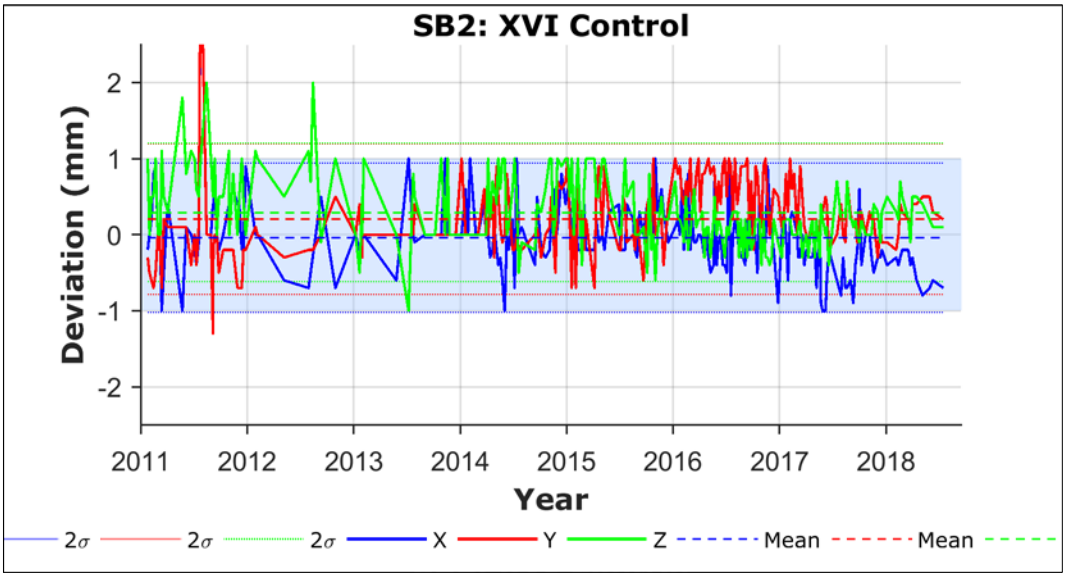

Figure 21 Trend plot of X, Y, and Z deviation for the XVI Control for SB2. Blue shaded area indicates current tolerance limit: ±1 mm. Mean (μ) values as given in Table 19. 95% confidence interval shown as μ±2σ ($2\sigma_x$=0.98 mm, $2\sigma_y$=1.00 mm, $2\sigma_z$=0.90 mm)

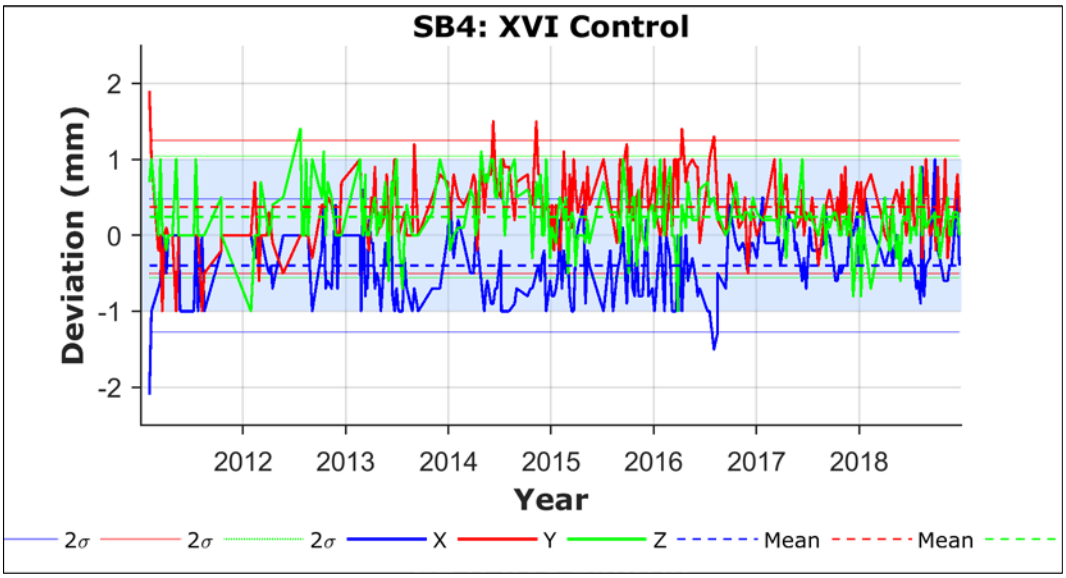

Figure 22 Trend plot of X, Y, and Z deviation for the XVI Control for SB4. Blue shaded area indicates current tolerance limit: ±1 mm. Mean (μ) values as given in Table 19. 95% confidence interval shown as μ±2σ ($2\sigma_x$=0.88 mm, $2\sigma_y$=0.88 mm, $2\sigma_z$=0.80 mm)

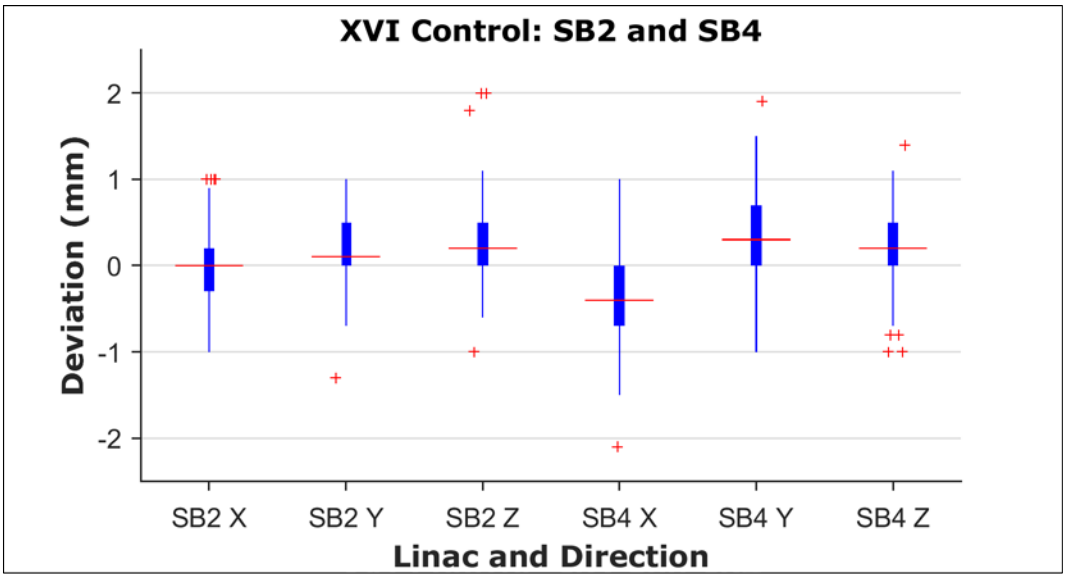

Figure 23 Boxplot of X, Y, and Z measurements for XVI Control for SB2 and SB4. Bottom and top of boxes indicate 25th and 75th percentiles, whiskers indicate extreme values. Red line indicates the median and crosses indicate outliers.

Comments on the XVI controls are categorised based on their purpose in Table 20. Notes of observation mostly add quantitative measures to how accurate the centre position match was after table movement was completed.

Table 20 Comments added to XVI Controls. Categorised based on what type of information is conveyed in the comment.

COMMENTS

Purpose of comment	SB2	SB4
Notes of observation during control	17	28
Repeated information ("ok" or signature in comment field)	11	10
Unclear	2	-

4.3.2 DailyQA Control

Average failure frequencies for the DailyQA control is given in Table 21. Failure frequencies are indicated for the two action levels of this control, where the warning limit is lower than the failure tolerance limit. As can be seen in Table 22, the high frequencies for energy measurements is mostly due to issues with 15MV measurements on SB4. Note that SB4 15MV measurements also have a higher tolerance than the other energy measurements.

Table 21 Average failure frequency for dose measurements and energy measurements on the DailyQA control. Note that Warning denotes failing a lower tolerance than Failed.

FAILURE FREQUENCY
(failure/year)

	Warning	Failed
DOSE	0.42	0.00
ENERGY	4.74	1.86

Table 22 DailyQA Control: Failures and Warnings recorded for each linac and energy per year.

CONTROL FAILURES AND WARNINGS

	SB2 6MV				**SB2 15MV**			
	Dose		Energy		Dose		Energy	
	Warning	Fail	Warning	Fail	Warning	Fail	Warning	Fail
2014	0	0	7	0	0	0	0	0
2015	0	0	9	0	0	0	0	0
2016	0	0	5	0	3	0	6	0
2017	0	0	0	0	1	0	0	0
2018	0	0	0	0	0	0	0	0
	SB4 6MV				**SB4 15MV**			
	Dose		Energy		Dose		Energy	
	Warning	Fail	Warning	Fail	Warning	Fail	Warning	Fail
2014	0	0	0	0	0	0	0	0
2015	0	0	0	0	0	0	0	0
2016	0	0	3	0	0	0	3	0
2017	0	0	2	0	3	0	29	25
2018	0	0	0	0	0	0	15	6

Table 23 DailyQA energy and dose measurement Failure Frequencies per Linac and per Energy. Warning indicates a lower tolerance limit than Fail.

FREQUENCY (failure/year)

SB2 6MV				**SB2 15MV**			
Dose		Energy		Dose		Energy	
Warning	Fail	Warning	Fail	Warning	Fail	Warning	Fail
0.00	0.00	5.04	0.00	0.96	0.00	1.44	0.00
SB4 6MV				**SB4 15MV**			
Dose		Energy		Dose		Energy	
Warning	Fail	Warning	Fail	Warning	Fail	Warning	Fail
0.00	0.00	1.20	0.00	0.72	0.00	11.27	7.43

Standard deviation and mean for the measurements in the DailyQA control are given in Table 24. Trend plots of measurements are shown in Figure 24 and Figure 25 for dose measurements and in Figure 27 and Figure 28 for energy measurements. Boxplots showing the spread of measurements is shown in Figure 26 and Figure 29. Comments were not categorised for this control as the data was collected from DailyQA software database.

Table 24 Standard deviation and mean for DailyQA dose measurements and energy measurements.

Standard Deviation and Mean				
Dose Measurement				
	SB2 6MV	SB2 15MV	SB4 6MV	SB4 15MV
Deviation	Dose (%)	Dose (%)	Dose (%)	Dose (%)
Average	-0.19	-0.82	0.28	0.50
SD	0.74	0.48	0.51	0.87
Energy Measurement				
	SB2 6MV	SB2 15MV	SB4 6MV	SB4 15MV
Deviation	Energy (%)	Energy (%)	Energy (%)	Energy (%)
Average	-0.06	1.35	-0.87	-2.74
SD	1.78	0.92	1.01	3.71

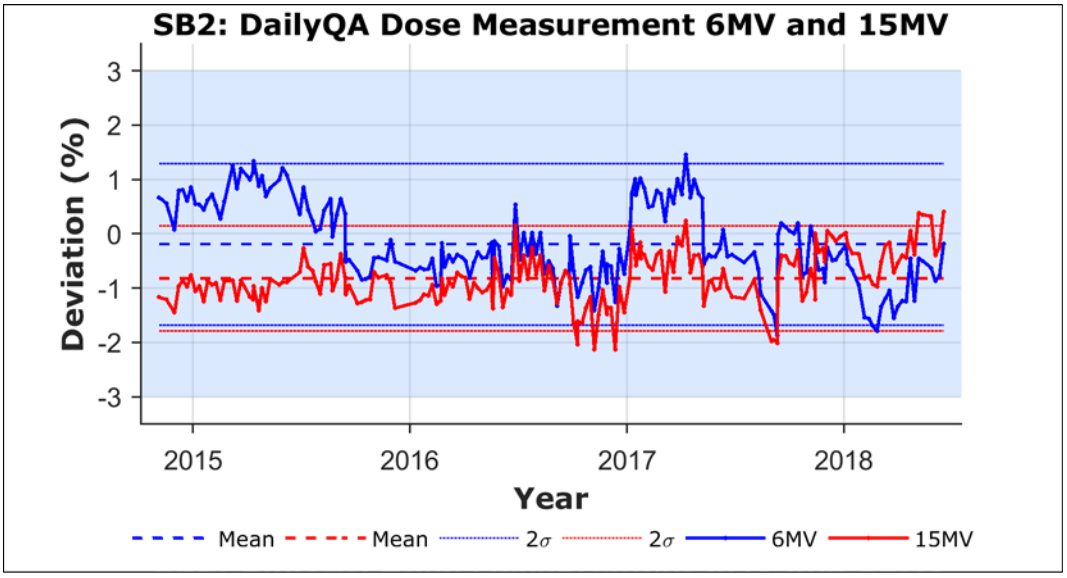

Figure 24 Trend plot of DailyQA Dose Measurements for 6MV and 15MV on SB2. Blue shaded area indicates current tolerance limit: ±3%. Mean (μ) values as given in Table 24. 95% confidence interval shown as μ±2σ ($2\sigma_{6MV}$=1.48%, $2\sigma_{15MV}$=0.96%)

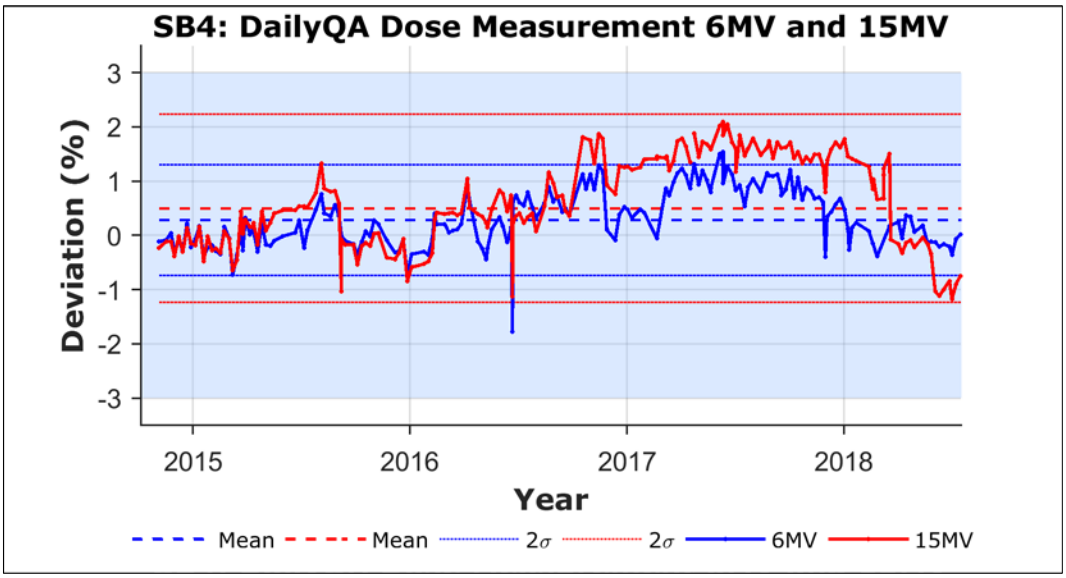

Figure 25 Trend plot of DailyQA Dose Measurements for 6MV and 15MV on SB4. Blue shaded area indicates current tolerance limit: ±3%. Mean (μ) values as given in Table 24. 95% confidence interval shown as μ±2σ ($2\sigma_{6MV}$=1.02%, $2\sigma_{15MV}$=1.74%)

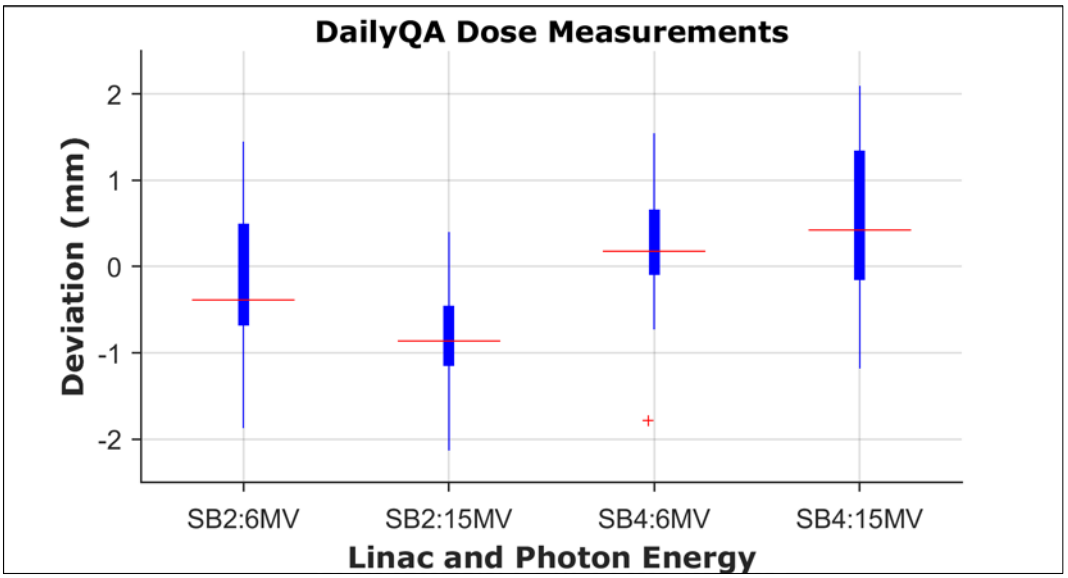

Figure 26 Boxplot of DailyQA dose measurements for SB2 and SB4. Bottom and top of boxes indicate 25th and 75th percentiles, whiskers indicate extreme values. Red line indicates the median and crosses indicate outliers.

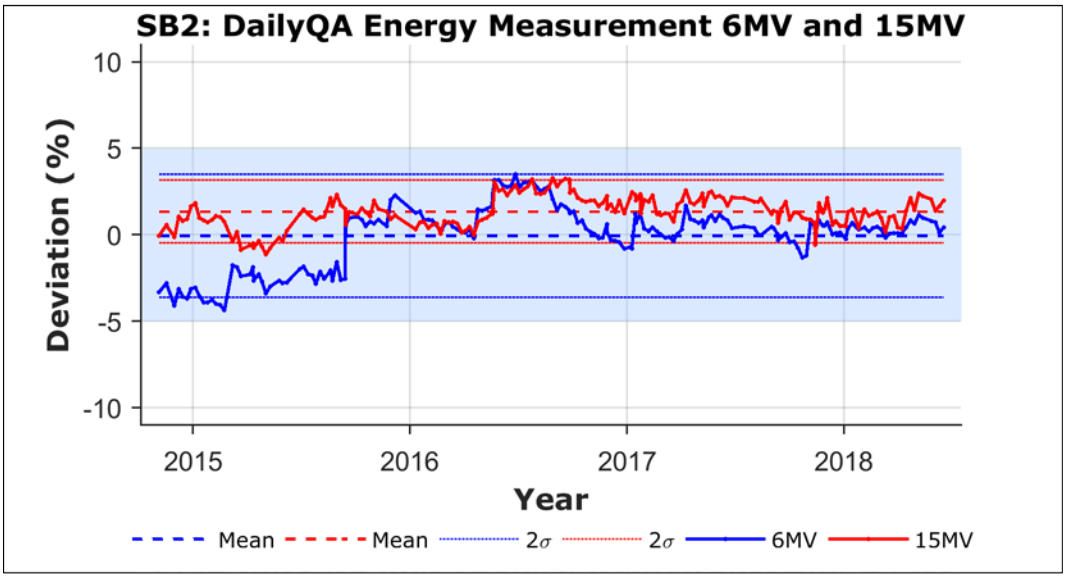

Figure 27 Trend plot of DailyQA Energy Measurements for 6MV and 15MV on SB2. Blue shaded area indicates current tolerance limit: ±5%. Mean (μ) values as given in Table 24. 95% confidence interval shown as μ±2σ ($2\sigma_{6MV}$=3.56%, $2\sigma_{15MV}$=1.84%)

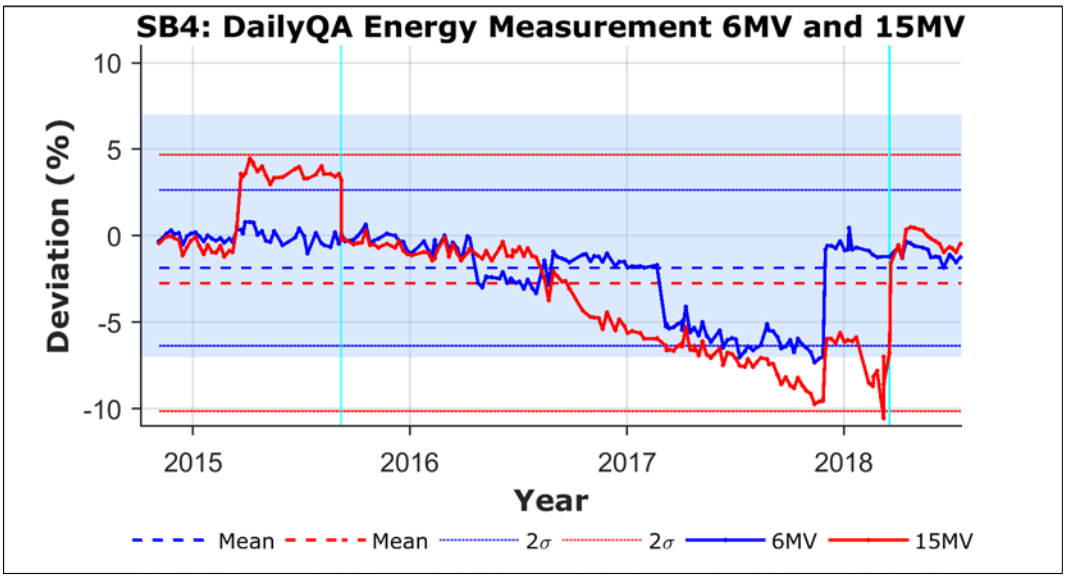

Figure 28 Trend plot of DailyQA Energy Measurements for 6MV and 15MV on SB4. Blue shaded area indicates current tolerance limit: ±7%. Note difference in scale and tolerance level compared to Figure 27. Turquoise vertical lines for indicates where the reference value for SB4:15MV was updated. Mean (μ) values as given in Table 24. 95% confidence interval shown as μ±2σ ($2\sigma_{6MV}$=3.56%, $2\sigma_{15MV}$=1.84%)

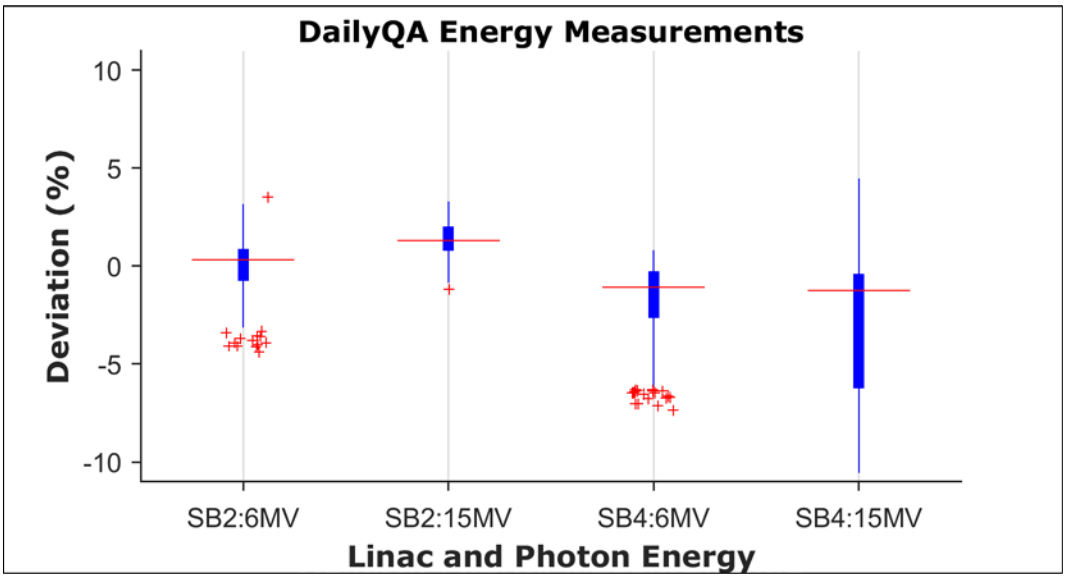

Figure 29 Boxplot of DailyQA energy measurements for SB2 and SB4. Bottom and top of boxes indicate 25th and 75th percentiles, whiskers indicate extreme values. Red line indicates the median and crosses indicate outliers.

4.4 Monthly Control

The monthly control was updated in 2013 and the parameters recorded were changed. The results here only consider the period 2013 to 2018. As can be seen in Table 25, the monthly control fails on average about once per year and the lasers are the most likely parameter to fail. Note that criteria for a failed control is failure of at least on parameter, but a control status failure may include more than one failed parameter.

Table 25 Average failure frequencies for the monthly control. Controls status indicates failure of the overall controll. Failure frequency of individual parameters is given below.

FAILURE FREQUENCY (failure/year)	
Control Status	**1.13**
Distance indicator	0.09
Light field	0.56
Isocentre	0.09
Cross-hairs	0.00
Lasers	0.94
Touch guards	0.00

Table 26 shows failures per year and failures per parameter. Note that parameters contain several measurements for these results, e.g. light field counts for measurements in both x and y direction, failing both is counted as 2 failures. See appendix section 8.1 for a detailed table of parameters.

Table 26 Monthly Control failures per year and per parameter.

CONTROL FAILURES PER YEAR		
YEAR	**SB2**	**SB4**
2013	0	1
2014	1	2
2015	2	4
2016	0	0
2017	2	0
2018	0	0

PARAMETER FAILURES	
Parameter	**Times Failed**
Distance indicator	1
Light field	6
Isocentre	1
Cross-hairs	0
Lasers	10
Touch guards	0

All monthly controls have comments. Protocol demands signature from all present made in the final comment section, 5 fail this demand. Only the automatic signature of the person logged in to QuART is recorded for these entries.

The control has the opportunity of adding a comment after each failed measurement as well as a comment on the control status. Only one failed measurement lacks a comment clarifying the failure. There is also an option of adding a comment to update the status of the control. This has only been used once for each linac, both times in 2013.

4.5 Quarterly Controls

4.5.1 Ion Chamber Control

There are always two active cylindrical ion chambers at the department. The results are based on quarterly controls of each chamber in use (4x2 controls per year).

The control has failed once. The chamber that failed was FC3013. The measurement associated with this failure had a deviation of -3.74% which is responsible for the large standard deviation seen in Table 27. Without this extreme measurement the standard deviation for the chamber is 0.31%, which is in line with the average SD for other chambers. The chamber was taken out of use in response to the failure and was sent for recalibration at DSA.

Failure frequency: 0.13 per year

Table 27 Failures per year for the Ion Chamber Control, and mean and standard deviation for measurements.

CONTROL FAILURES	
Year	Failure
2012	0
2013	0
2014	0
2015	0
2016	0
2017	0
2018	1

CHAMBER MEASUREMENTS		
CHAMBER	Mean	SD
FC 561	0.22	0.37
FC2320	-0.05	0.40
FC3013	-0.21	1.46
FC3643	0.15	0.31
ALL	0.03	0.79

4.5.2 MLC Control

The MLC control has not had a recorded failed test in the period between 2011 and 2018. Note that the tolerance limits in QuART are set on the calculated values of offset and gain not the individual measurements. No failures then means no failure of the overall control. Comments on the controls indicate that in practice adjustments have been made based on deviations of individual measurements.

Failure Frequency: 0

Mean and standard deviation for the individual measurements in this control are given in Table 28. Measurements for this control are shown in Figure 19. The measurements represent: A and B are of the seam between upper and lower fields. C and D are of the overlap between the two middle fields in the upper and lower row. E and F are of field width and length respectively.

Boxplots of the spread of measurements are shown in Figure 30 and Figure 31. The measurements for this control are in general stable and well within the functional tolerance limit of ±1mm reported to be used by staff. The only exception is the F parameter on SB4, which has a large SD, though the boxplot shows that the majority of measurements are within tolerance.

Table 28 : Mean and standard deviation for MLC Control measurements.

	SB2		SB4	
	Mean (mm)	SD (mm)	Mean (mm)	SD (mm)
A	-0.06	0.39	0.05	0.45
B	-0.10	0.33	0.12	0.37
C	-0.07	0.20	0.18	0.50
D	-0.03	0.08	0.02	0.30
E	-0.24	0.65	-0.07	0.45
F	0.24	0.28	0.25*	1.05*

* An extreme measurement of 80mm deviation for the F parameter on SB4 was removed from dataset. The control was not marked as failed and no comment explain this large deviation. Values with extreme measurement included are mean: -2.43 and SD: 14.69.

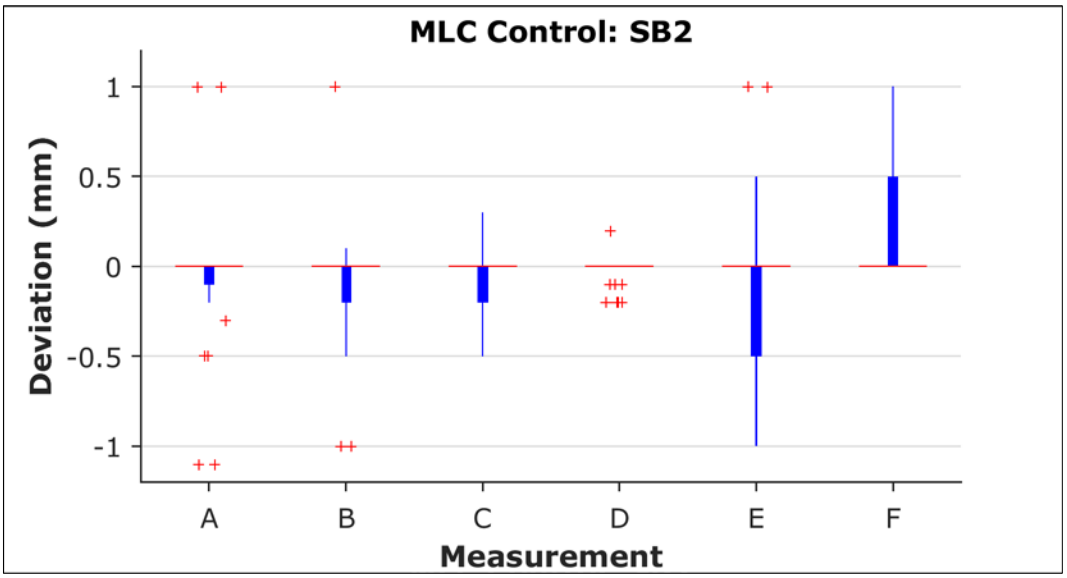

Figure 30 Boxplot of measurement from MLC control for SB2. Note that the scale is different from that used in Figure 31. Bottom and top of boxes indicate 25th and 75th percentiles, whiskers indicate extreme values. Red line indicates the median and crosses indicate outliers.

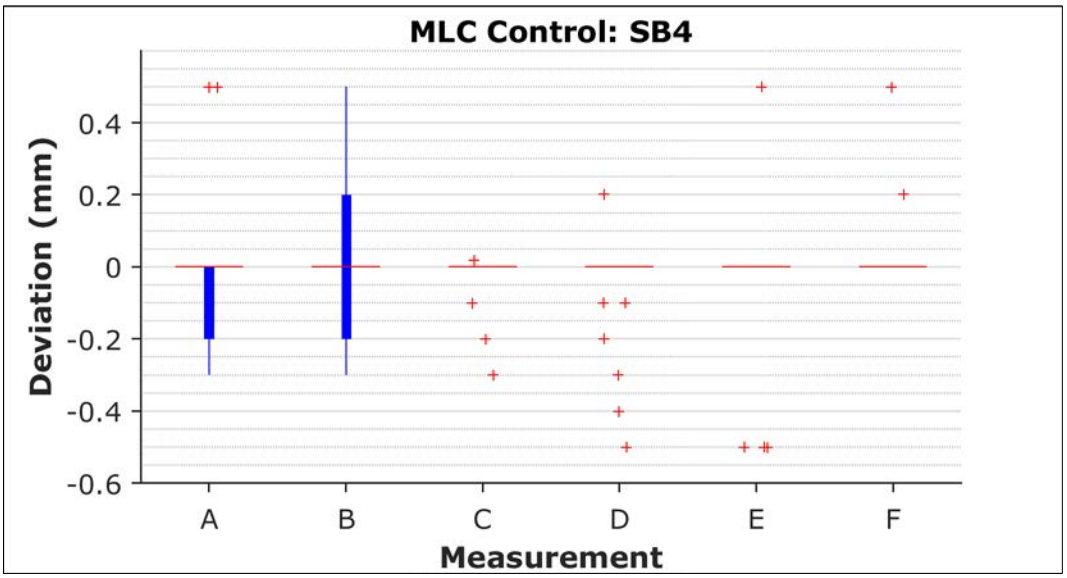

Figure 31 Boxplot of measurements from MLC control for SB4. Note that the scale is different from that used in Figure 30. Bottom and top of boxes indicate 25th and 75th percentiles, whiskers indicate extreme values. Red line indicates the median and crosses indicate outliers.

Comments on the controls are categorised in Table 29. As this control is based on the interpretation of an image, some person dependent characteristics became apparent. Table 30 shows how often different members of staff recorded a non-zero value for a measurement in the control.

Table 29 Comments added to MLC controls. Categorised based on what type of information is conveyed in the comment.

COMMENTS

Purpose of comment	SB2	SB4
Added detail about control	16	6
Repeated information ("ok" or signature in comment field)	3	3

Table 30 Person dependent differences in precision of QuART entry

DIFFERENCES IN PRECISION

Person	# Times non-zero value recorded	# Control entries in QuART	Average non-zero value per entry
A	18	8	2.25
B	62	14	4.43
C	29	20	1.45
D	15	4	3.75
E	30	14	2.14

4.5.3 Absolute Dose Calibration

One failed test is counted as either 6MV or 15 MV being above tolerance. Failure frequencies for the individual linac and beam energy are given in Table 31. The average of 1.81 failures per year is taken to be the overall failure frequency of this control. Measurements where controls had been scheduled in response to change of linac components have been removed from the dataset where they could be identified. This is because large deviations might be expected in these measurements, and the control is always scheduled in response to component change. The results with all measurements included are available in the Appendix 8.2.

Table 31 Failure frequency per beam energy per linac. Average failure frequency shows the overall average used as the failure frequency for the control.

FAILURE FREQUENCY (failure/year)	
SB2 6MV	2.00
SB2 15MV	1.88
SB4 6MV	1.50
SB4 15MV	1.88
AVERAGE	1.81

Table 32 Mean and standard deviation of absolute dose measurement.

ABSOLUTE DOSE MEASUREMENTS MEAN AND STANDARD DEVIATION

	SB2 6MV	SB2 15MV	SB4 6MV	SB4 15MV	Average
MEAN	0.13	0.17	-0.02	-0.09	0.05
SD	1.49	1.27	0.87	0.88	1.13

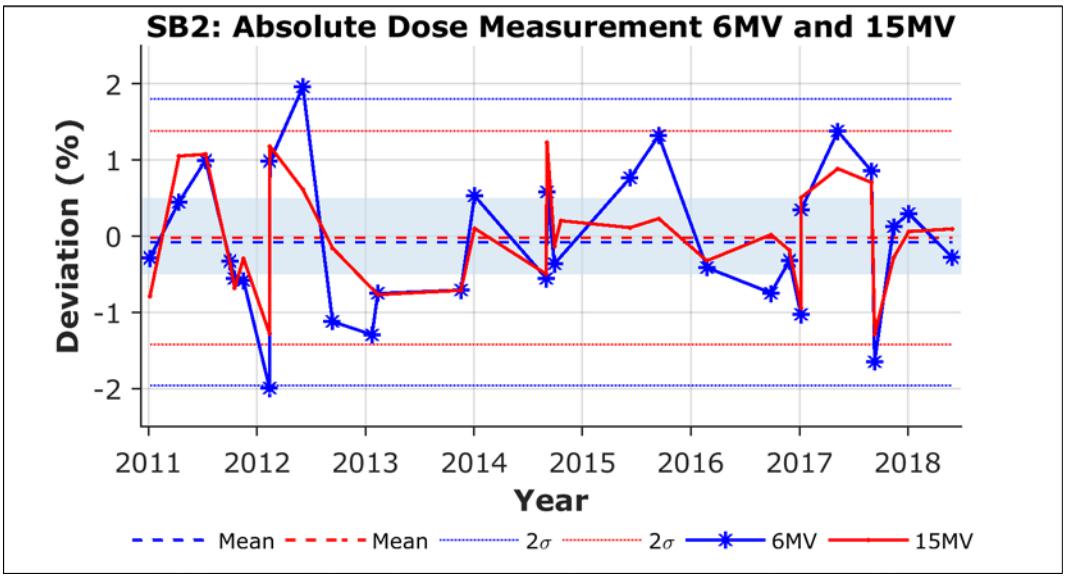

Figure 32 Trend plot of Absolute Dose Measurements for 6MV and 15MV on SB2. Blue shaded area indicates current tolerance limit: ±0.5%. Mean (μ) values as given in Table 32Table 24. 95% confidence interval shown as μ±2σ ($2\sigma_{6MV}$=2.98%, $2\sigma_{15MV}$=2.54%)

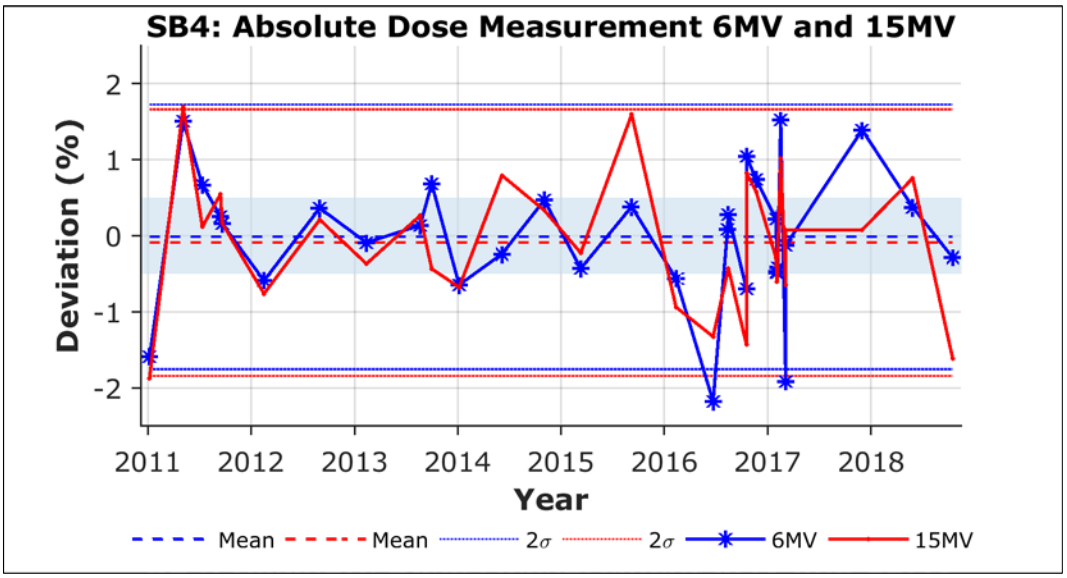

Figure 33 Trend plot of Absolute Dose Measurements for 6MV and 15MV on SB2. Blue shaded area indicates current tolerance limit: ±0.5%. Mean (μ) values as given in Table 32Table 24. 95% confidence interval shown as μ±2σ ($2\sigma_{6MV}$=1.74%, $2\sigma_{15MV}$=2.26%)

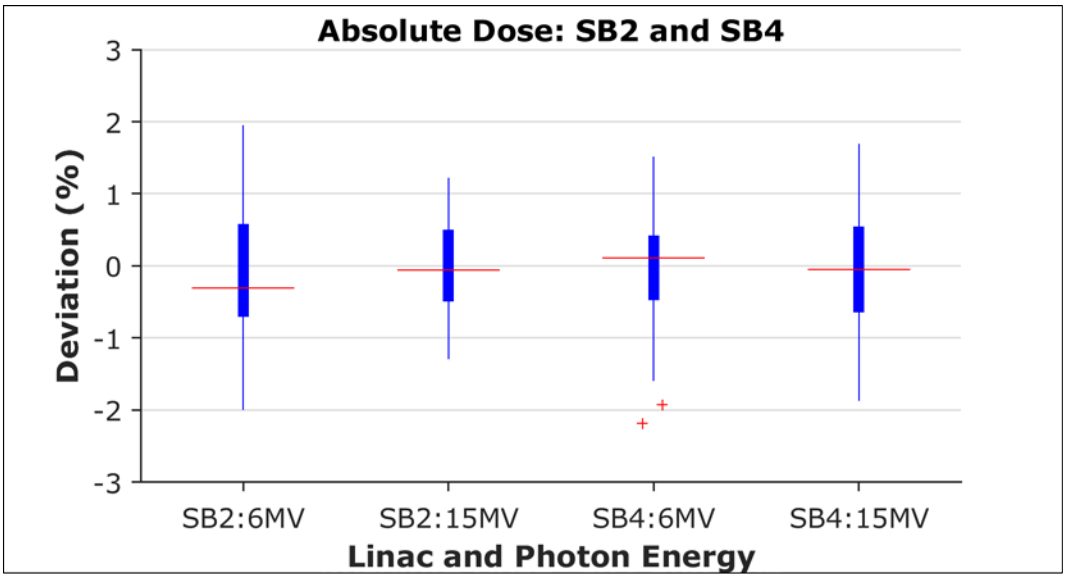

Figure 34 Boxplot of absolute dose measurement from for SB2 and SB4. Bottom and top of boxes indicate 25th and 75th percentiles, whiskers indicate extreme values. Red line indicates the median and crosses indicate outliers.

4.5.3.1 Absolute Dose Measurements after Calibration

For failed controls, measurements are made after calibration to check that the measurements are within tolerance again. Several measurements may be made until the physicist is satisfied. For these measurements the last entry made have been plotted to show what level of deviation is normally obtained immediately after calibration. Mean and standard deviation for the measurements are given in Table 33. Trend plots in Figure 35 and Figure 36 show how the measurements fluctuate over time, and the boxplot in Figure 37 shows the spread of measurements.

Table 33 Mean and standard deviation of absolute dose measurement after calibration.

ABSOLUTE DOSE MEASUREMENT AFTER CALIBRATION

	SB2 6MV	SB2 15MV	SB4 6MV	SB4 15MV
MEAN	0.01	-0.02	0.03	0.01
SD	0.07	0.08	0.08	0.05

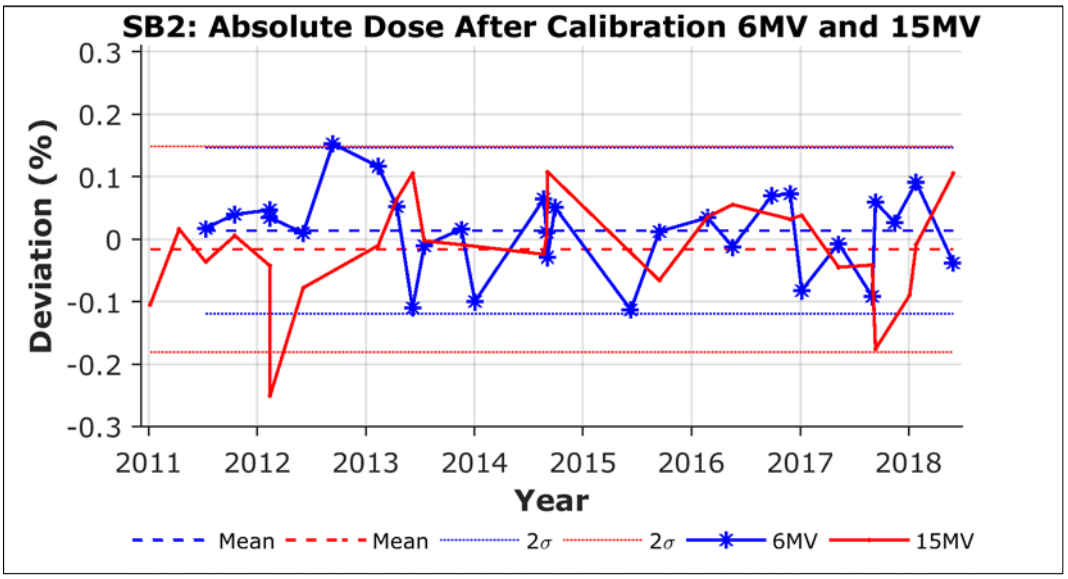

Figure 35 Trend plot of Absolute Dose Measurements after calibration has been performed in response to a failed control for 6MV and 15MV on SB2. Mean (μ) values as given in Table 33Table 24. 95% confidence interval shown as μ±2σ ($2\sigma_{6MV}$=0.14%, $2\sigma_{15MV}$=0.16%).

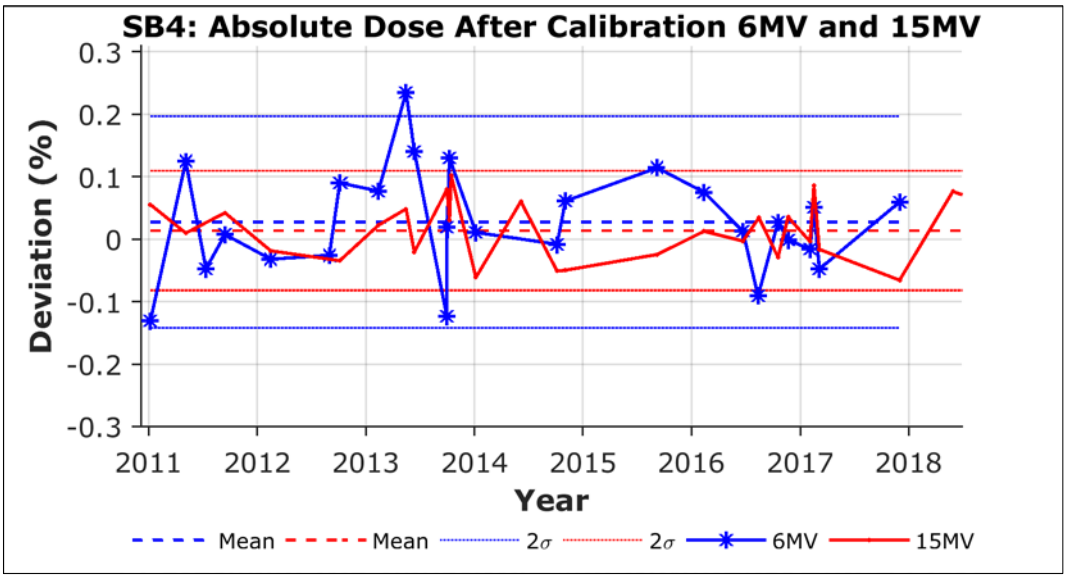

Figure 36 Trend plot of Absolute Dose Measurements after calibration has been performed in response to a failed control for 6MV and 15MV on SB4. Mean (μ) values as given in Table 33Table 24. 95% confidence interval shown as μ±2σ ($2\sigma_{6MV}$=0.16%, $2\sigma_{15MV}$=0.10%).

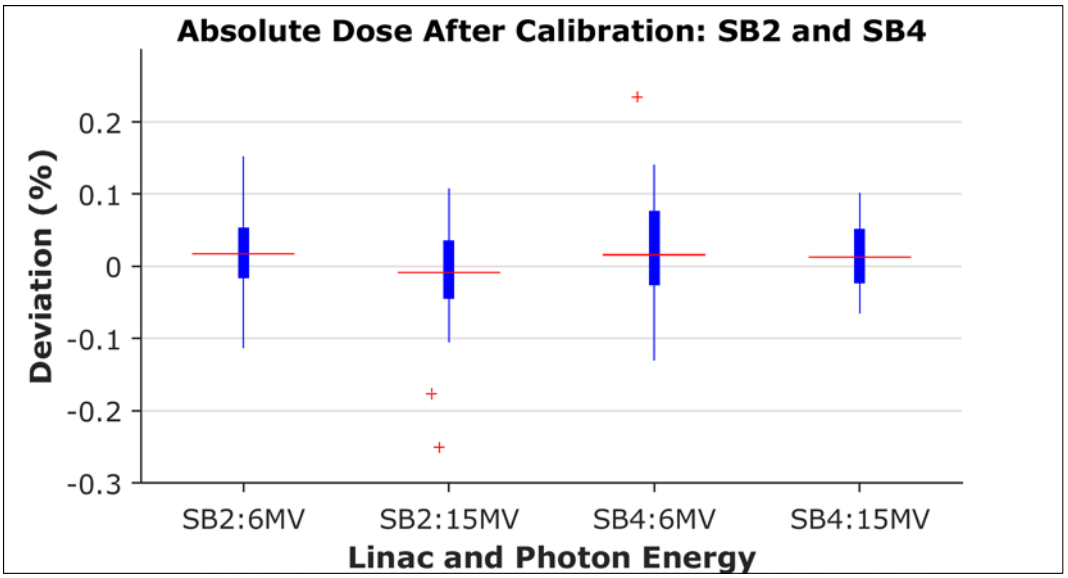

Figure 37 Boxplot of absolute dose measurement after calibration has been performed in response to a failed control for SB2 and SB4. Bottom and top of boxes indicate 25th and 75th percentiles, whiskers indicate extreme values. Red line indicates the median and crosses indicate outliers.

4.6 Half-Yearly Controls

4.6.1 Energy Control of Photons (6MV and 15MV)

The Energy Control does not have a recorded failed control in the period 2011 to 2018.

Failure Frequency: 0

In Table 34 the mean and standard deviation of measurement is first given for all measurements. the mean and standard deviation is the given for separately for water tank measurements and I'mRT phantom measurements.

Table 34 Mean and standard deviation for energy control.

ENERGY CONTROL MEAN AND STANDARD DEVIATION (%)

		SB2 6MV	SB2 15MV	SB4 6MV	SB4 15MV
ALL	**Mean**	-0.07	-0.06	-0.06	-0.13
	SD	0.34	0.22	0.28	0.25
WATER PHANTOM	**Mean**	-0.13	-0.18	-0.02	-0.32
	SD	0.40	0.19	0.32	0.09
I'mRT PHANTOM	**Mean**	0.02	0.08	-0.09	-0.05
	SD	0.23	0.17	0.27	0.26

For the trend plots shown in Figure 38 and Figure 39 measurements performed with a water phantom are marked with a circle, the remaining measurements are performed with the I'mRT phantom. The shaded area in blue represent the tolerance limits for this control. The boxplot in Figure 40 shows the spread of measurements. Figure 41 shows trend plot comparing the measurements from the energy control with energy measurements performed with the DailyQA phantom as part of the weekly control.

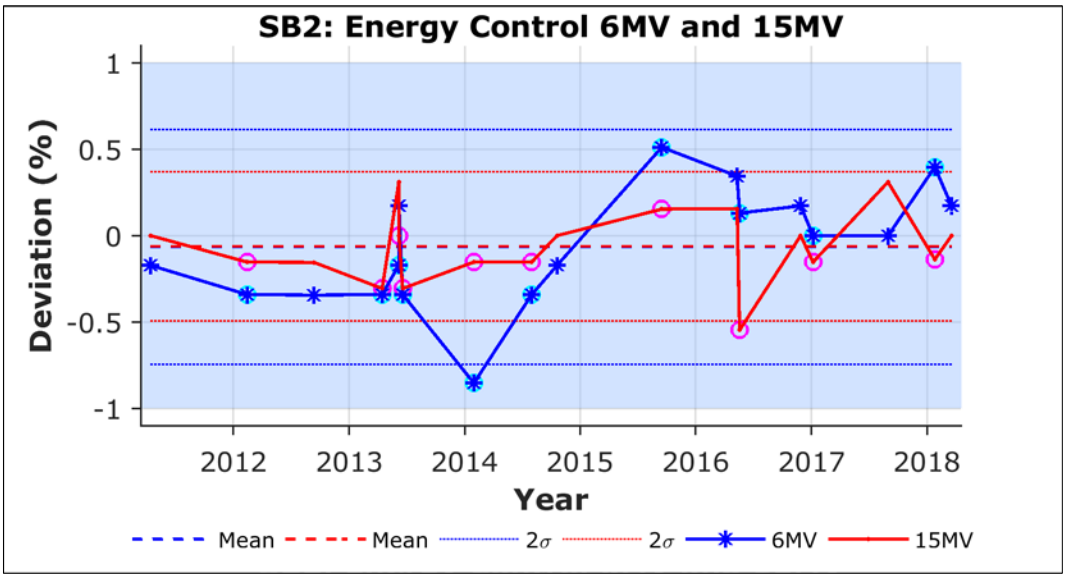

Figure 38 Trend plot of energy control measurements for 6MV and 15MV on SB2. Mean (μ) values as given in Table 34 (for all measurements). 95% confidence interval shown as μ±2σ ($2\sigma_{6MV}$=0.68%, $2\sigma_{15MV}$=0.44%).

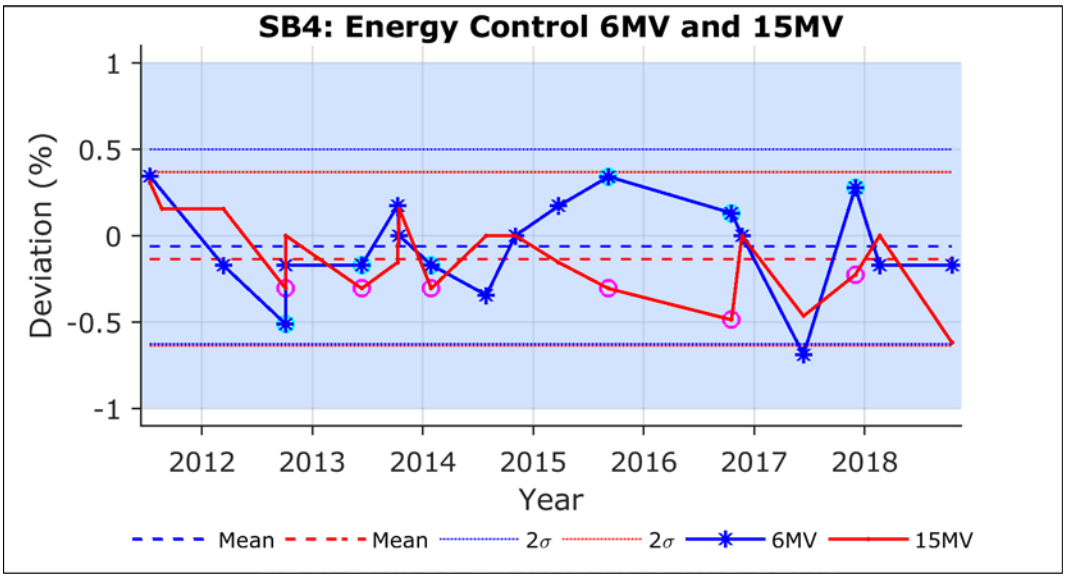

Figure 39 Trend plot of energy control measurements for 6MV and 15MV on SB4. Mean (μ) values as given in Table 34 (for all measurements). 95% confidence interval shown as μ±2σ ($2\sigma_{6MV}$=0.56%, $2\sigma_{15MV}$=0.50%).

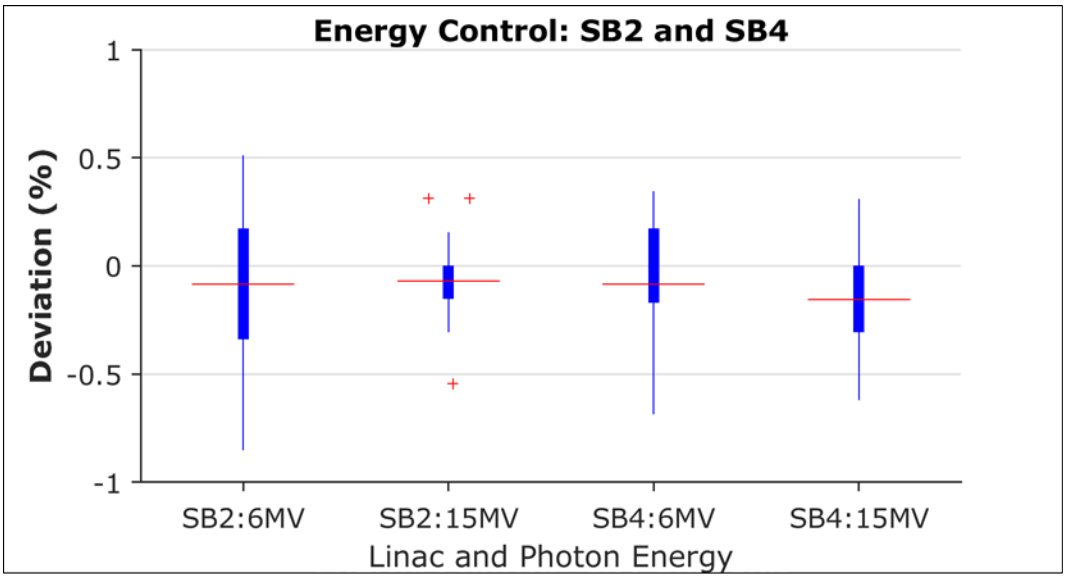

Figure 40 Boxplot of energy control measurements for SB2 and SB4. Bottom and top of boxes indicate 25th and 75th percentiles, whiskers indicate extreme values. Red line indicates the median and crosses indicate outliers.

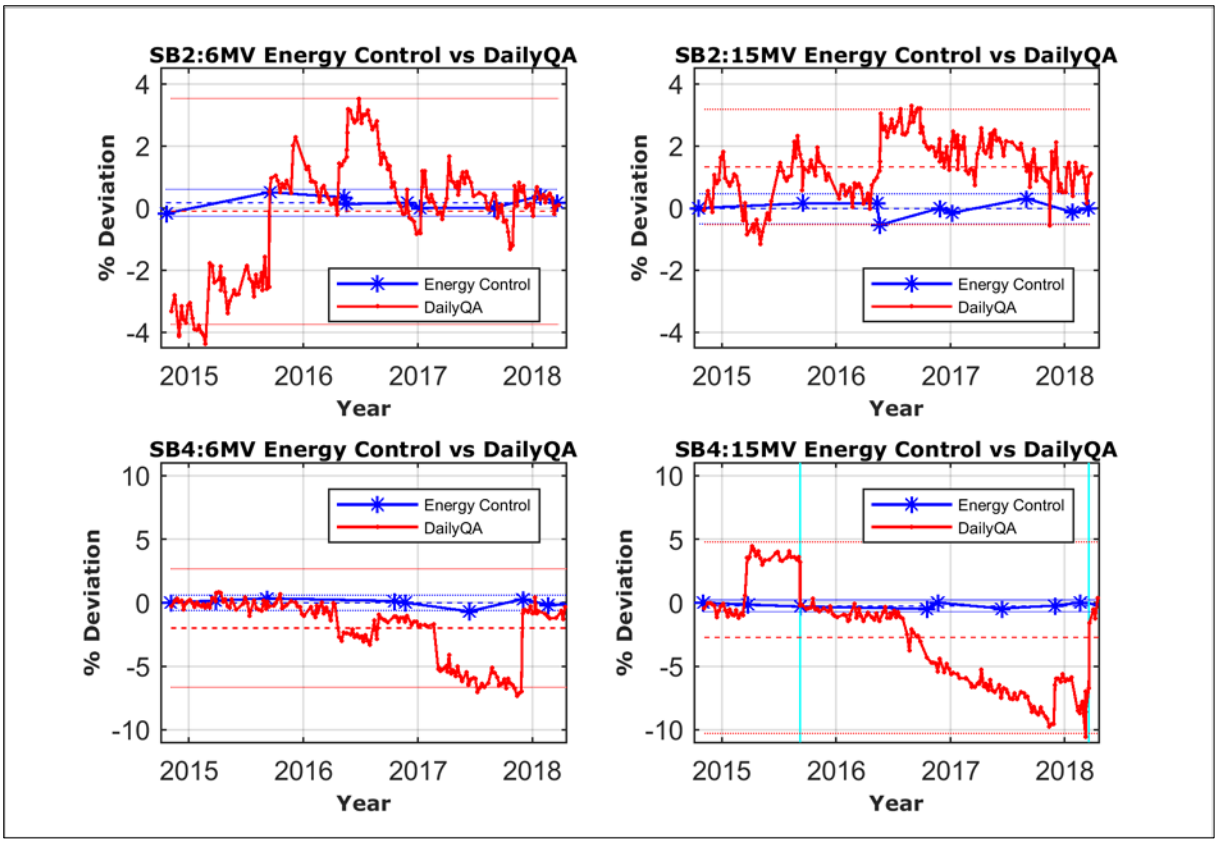

Figure 41 Energy Control measurements plotted against DailyQA measurements. Note that the y-axis limits are different for SB2 and SB4. Turquoise vertical lines for SB4:15MV indicates where the reference value for SB4:15MV was updated.

4.7 Summary of Failure Frequencies and Compliance

Table 35 Summary of average control failure frequencies and compliance for each control.

FAILURE FREQUENCY AND COMPLIANCE

Control	Failure/Year	Compliance (%)
Daily	0.5	47.0
DailyQA (Energy and Dose)	3.1	95.6
XVI	1.63	61.3
Monthly	1	61.1
Calibration	1.81	115.6
MLC	0	98.4
Ion chamber	0.125	51.8
Energy control	0	101.6

4.8 Process Chart

The process chart shows the radiotherapy process from initial diagnosis to completed treatment and follow up. The treatment delivery step is highlighted as this was chosen for further analysis using FMEA. All steps within treatment delivery are performed by the radiographer.

The process chart is simplified to four steps and the process is represented as a linear progression through the chart. In practice these steps are not so separate, and progression may mean moving back before going forward again. This highlights the need for communication between steps in the process. However, as a single step was chosen here the role of communication between steps was not emphasised in the chart.

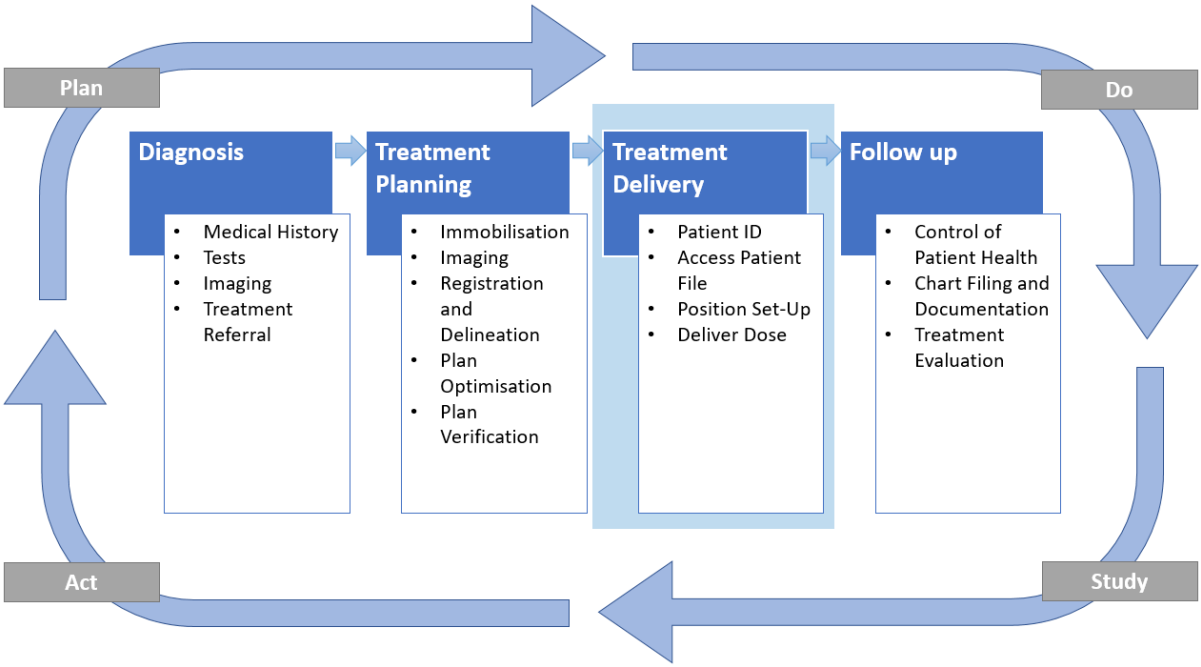

Figure 42 Process Chart. Highlighted section shows the process step chosen for FMEA. The arrows around the chart show how the process fits into the overall quality improvement methodology at St. Olavs hospital.

4.9 Failure Modes and Effects Analysis:

The different controls were assigned an Occurrence rank based on their failure rate as shown in Table 36. These were then used in filling out the FMEA worksheet. The results from the FMEA are shown in Table 36 (For the full worksheet see Appendix section 8.5). The RPN values in Table 37 were assigned a colour coding representing where they fall on the scale of RPN scores. The cut off values were chosen so that red indicates high scores (above 300), yellow indicates intermediate scores (200-300), and green indicates low scores (less than 200). The cut off values were chosen to differentiate the scores found and are not meant to correspond to any other severity indicators.

Table 36 Occurrence rank rating for the quality controls.

Occurrence rank rating from failure frequencies		
Control	**Failure / Year**	**Rank**
Daily	0.50	5
DailyQA Warning	10.32	9
DailyQA Failure	3.10	8
XVI	1.63	7
Monthly	1.00	6
Calibration	1.81	7
MLC Parameters	0.69	5
Energy Control	0.00	2

Table 37 FMEA results

#	Process Step	Potential Failure Mode	Potential Cause of Failure Mode	O	D	S	RPN
1	Set up: Patient ID	Wrong patient called, wrong treatment plan retrieved. Wrong immobilization equipment used.	Human Error Data entry; e.g. wrong name in plan Mistake; e.g. similar names or miscommunication Lack of equipment labelling	2	10	10	200
2	Set up: Use of immobilisation equipment	Immobilization equipment does not position the patient as intended	Human error Equipment is used wrong or sub-optimal Equipment no longer fits patient due to anatomy change	4	8	3	96
3	Set up: CBCT guided	Wrong position of target volume relative to isocentre>1mm (XVI guided)	Misaligned CBCT Poor match using CBCT Table position inaccurate relative to isocentre Patient movement (voluntary) Patient movement (involuntary: anatomy)	7	10	3	210

#	Process Step	Potential Failure Mode	Potential Cause of Failure Mode	O	D	S	RPN
4	Set up: Laser guided	Wrong position of target volume relative to isocentre >3mm (Laser guided)	Misaligned Lasers Inaccurate Light Field, Cross-Hairs, or ODI Table position inaccurate relative to isocentre Patient movement (voluntary) Patient movement (involuntary: anatomy)	6	10	7	420
5	Set up	Patient injury e.g. fall from table	Unstable position on table Faulty use of immobilization equipment Poor design of immobilization equipment Radiographer mistake Patient movement	2	1	5-10	10-20
6	Treatment Delivery	Dosimetric error absolute dose >0.5%	Miscalibration or drift (lack of calibration) of monitor chamber Beam energy deviation	7	10	2	140
7	Treatment Delivery	Dosimetric error absolute dose >2%	Miscalibration or drift (lack of calibration) of monitor chamber Beam energy deviation	9	10	4	360
8	Treatment Delivery	Dosimetric error absolute dose >3%	Miscalibration or drift (lack of calibration) of monitor chamber Beam energy deviation	8	10	6	480
9	Treatment Delivery	Geometric Error >1mm	Offset or Gain for: Collimator MLC Gantry Position of isocentre is unstable when collimator is rotated.	5	10	4	200
10	Treatment Delivery	Patient injury -Patient in gantry path (+CBCT and EPID path)	Table rotated to intersect gantry path Touch Guard Failure	1	5	10	50

4.10 Fault Tree Analysis

4.10.1 Failure mode: Target Wrong position

Two major paths in the fault tree in Figure 43 are not related to Linac QA. The first is from volume movement. Anatomical volume movement is unavoidable but can be mitigated using motion management techniques. The main tool for dealing with involuntary anatomical movement is adding margins to the treatment volume. Voluntary motion by the patient can be mitigated by communicating the need to stay still and ensuring the patient is comfortable.

The second is mistakes by the radiographer, which is categorised as human error. This has QCs in the form of check lists and images added to the patient file for correct identification of patients. Training and instructions for the radiographer is also important to avoid errors in this path.

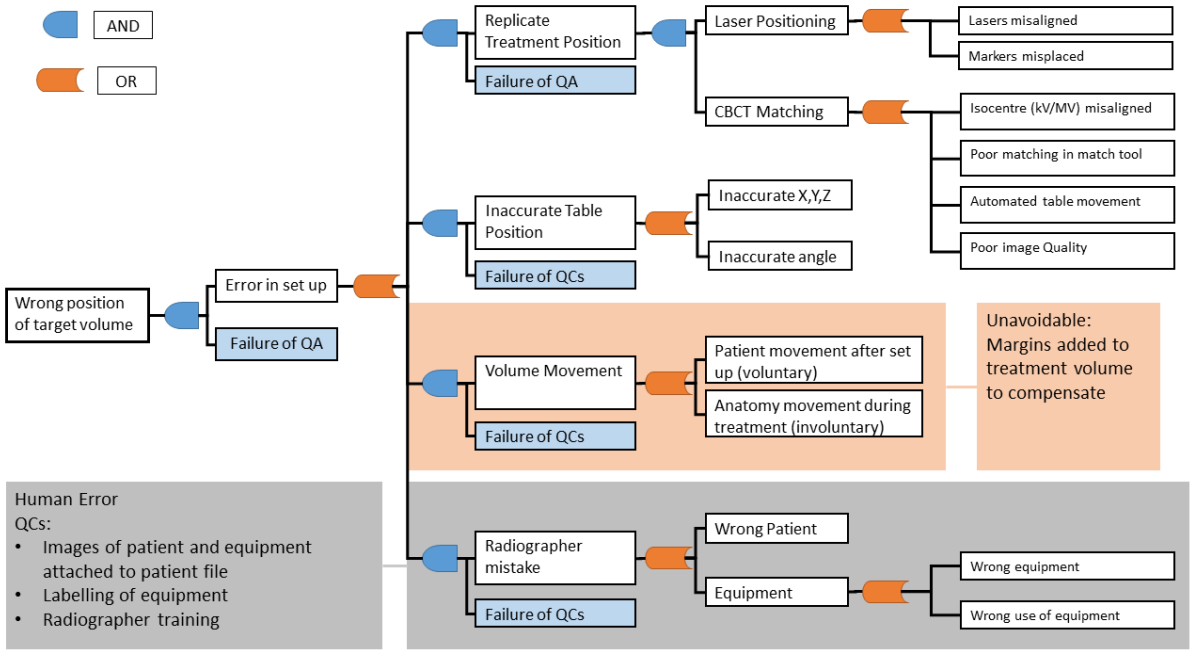

Figure 43 FTA for failure mode Wrong Position of Target Volume. Highlighted sections show paths that are not related to linac quality assurance.

4.10.1.1 Failure mode: Set up: Target Wrong position: Linac Specific Paths

For two main paths specific to linac QA in Figure 43 current quality controls were added. The result is seen in Figure 44. The green boxes list quality controls and are linked to which path the intercept. Paths where no quality controls intercept are coloured red.

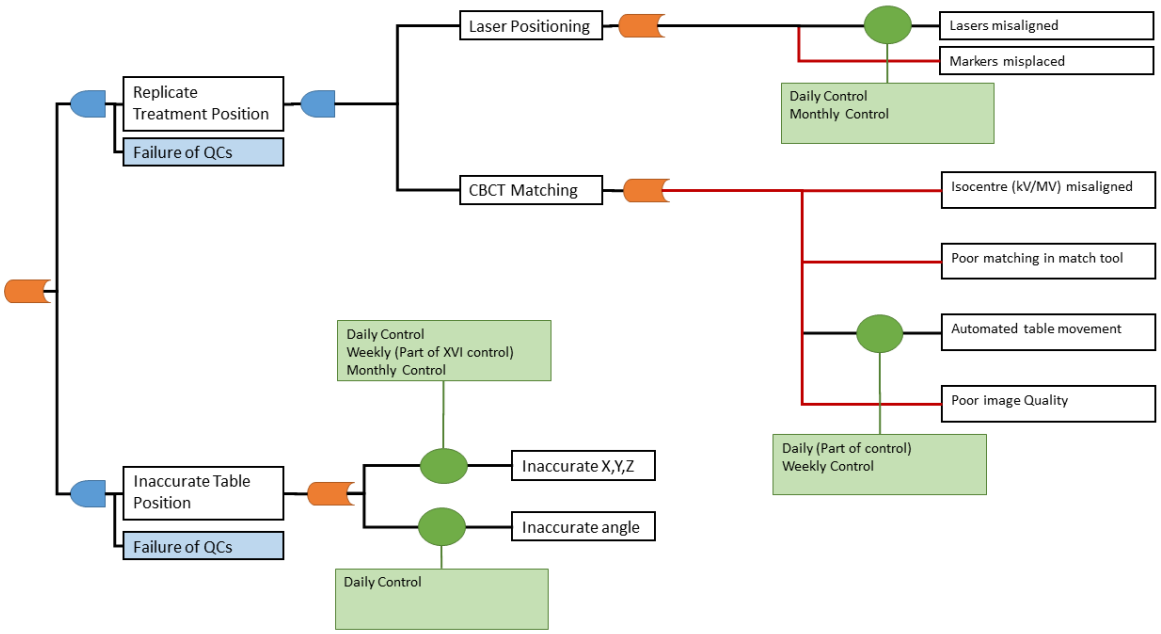

Figure 44 FTA: Detail from figure 39. Green boxes show where quality controls intercept the propagation of errors towards the logic gate. Red paths indicate no QCs currently guard the path.

4.10.2 Failure Mode: Wrong Dose delivered to points in target

The FTA for the failure mode *Wrong Dose delivered to points in target* is shown in Figure 45. All paths have QCs intercepting the path before crossing a gate. As the DailyQA phantom measures both dose and energy during the same control it could have been placed at a higher level alongside the Delta4 phantom verification. It was placed at the lower level paths to highlight the relationship between the DailyQA measurements and the other routine controls.

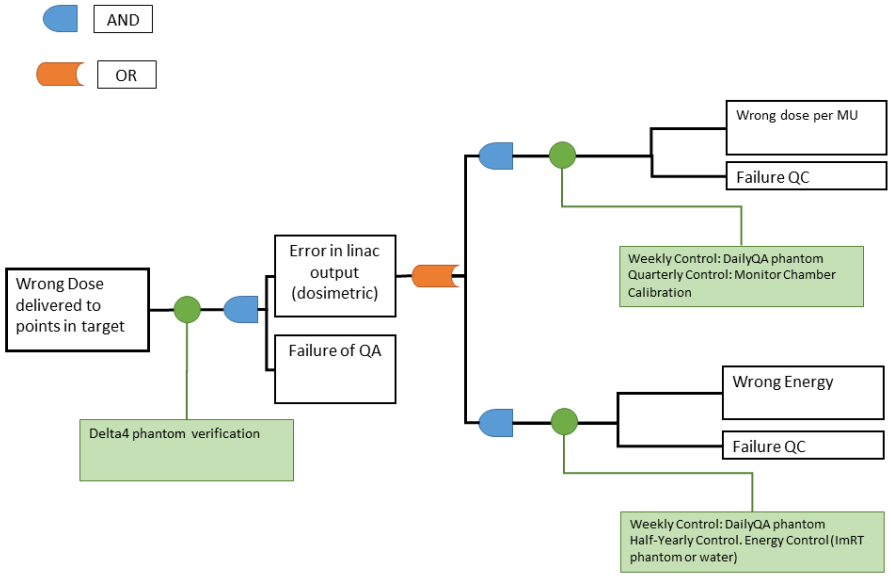

Figure 45 FTA for failure mode Wrong Dose to points in Target. Green boxes indicate where QCs intercept the propagation of errors.

4.10.3 Failure Mode: Dose volume misplaced

The FTA for the failure mode *Dose delivered to wrong volume* is shown in Figure 46. There are three paths which are not guarded by individual controls before the final verification control. These are the Gantry speed, the MLC speed, and the MV to mechanical isocentre alignment.

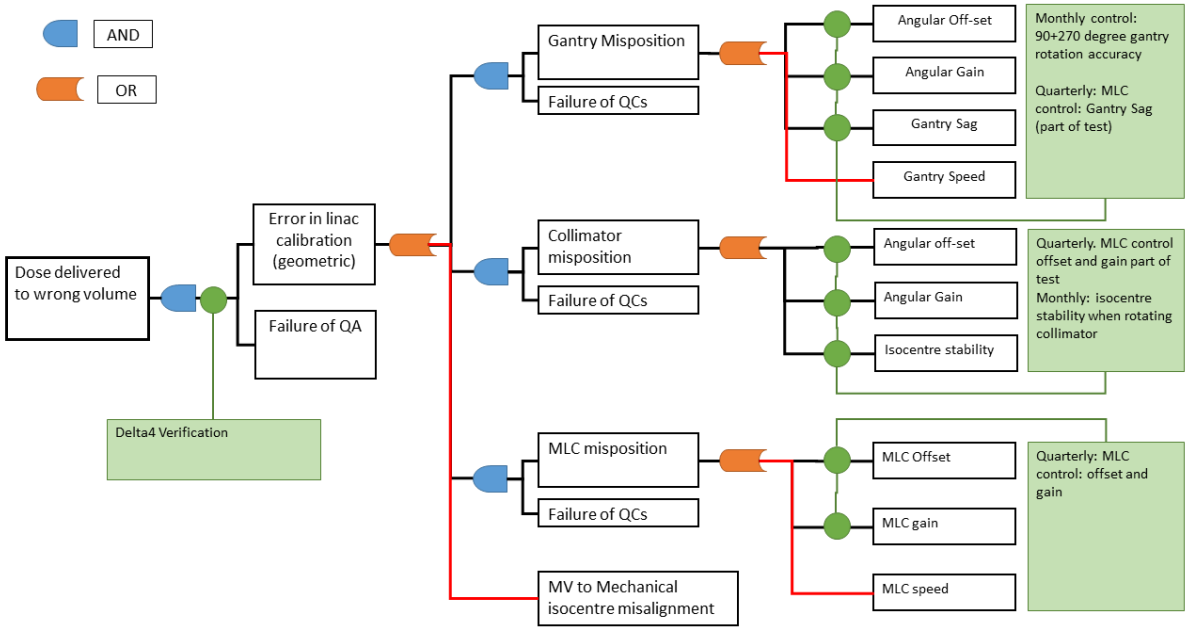

Figure 46 FTA for failure mode Dose delivered to wrong volume. Green boxes indicate where QCs intercept the propagation of errors. Red paths indicate no QCs currently guard the path.

5 Discussion

This section starts with a discussion of the results from the QC data analysis. The second part is a discussion of the risk analysis. Lessons learned from working with the risk analysis tools are also discussed. The section ends with a discussion of limitations and possible further work.

5.1 Current Quality Assurance Programme

5.1.1 Compliance

The overall compliance found here of 79.7% is similar to that found by Palmer et al.[32] in a survey of UK radiotherapy centres. They found that 96% of centres achieved above 80% of tests, but less than 30% of centres regularly completed all planned quality controls in a month. They suggest that reporting achieved QC compliance as a performance indicator may be used to improve compliance.

It is important to note that compliance here is a measurement of achievement of the target set by the department themselves. Low compliance is then not necessarily an issue but warrants a discussion of why the set target is not achieved. If the target is unrealistic then this must be addressed as well.

The lowest compliance found in this report are for the Daily Control, the Ion Chamber Control, and The Monthly Control. While the method for calculating is likely underestimate achieved compliance, the relative scores still indicates issues. Each control is suspected to have a different reason for the low compliance.

The Daily Control has issues with recording of performed controls. Comments indicate that controls have been performed but not registered. The low failure rate of this control may affect how it is perceived by the staff performing it. Fatigue with recurring errors is seen in comments; e.g. a failure recorded on day one is commented on as “still wrong” subsequent days but not recorded as a failure. Comments from staff have also questioned how useful some of the checks are. If this control is perceived as not important it is likely to impact compliance. There is also a possibility that the step of recording the control i.e. sitting down at the computer and checking all boxes, is an inconvenient an easily forgotten step in the control procedure.

For the Monthly Control the main issue is likely to be scheduling. Three staff members are requested to be present which makes coordinating individual timetables more difficult. Designating a day of the month for this control may make long term planning easier for scheduling purposes.

The Ion Chamber control is likely not prioritised as the measurements are very stable and the failure rate is low. Compliance for this control must be seen in context with the controls where the Ion Chambers are used. The highest frequency control where they are used is the quarterly dose calibration measurement. The assigned frequency for the Ion Chamber Control is set to match this. Failing this target affects the confidence in the measurements of other controls and as such should be improved.

For all other controls of quarterly or half-yearly frequency, compliance is high. This is likely aided by these controls being scheduled in response to service or component change on the linacs.

The weekly constancy control with DailyQA phantom stands out as high in compliance among the controls performed more often. Likely this is due to the ease of set up and automated measurement sequence. This control is also assigned a specific day of the week which may help in scheduling the control.

5.1.2 Failure Rates and Tolerances

The Weekly constancy control has the highest failure rate of all controls. All failures are due to failures of the energy measurement on SB4. Each DailyQA phantom is only used with a specific linac, so this is either due to failure of the linac or the phantom. Comparison with the half-yearly energy controls for SB4 (Figure 41) show that the energy control measurements are stable despite the large drift in energy measurements on the DailyQA phantom. This indicates the issue is likely to be with the phantom not the linac. The problem is known at the department and investigations were made to ascertain that there was no issue with the linac. For the DailyQA control it was solved by setting a higher tolerance for this specific phantom. This works in practice but can be a source of confusion around tolerance limits.

A reported evaluation of Daily QA 3 phantoms[33] concluded that they were reliable for routine controls, but suggested that calibrating the phantom every eight to ten months improved accuracy of measurements. There is not currently a schedule for calibrating the DailyQA phantom at St. Olavs hospital. However, it is only the energy measurements that were found to be problematic. The dose measurements were found to stable in comparison. See appendix section 8.4 for plot of DailyQA dose measurements against absolute dose measurements.

The Quarterly Dose calibration has the second highest failure rate. This is likely due to the strict tolerance limit. The tolerance is 0.5% and the average standard deviation for measurements is 1.13%. There is a difference between the standard deviations for SB2 and SB4 with SB2 being noticeably higher than SB4 for both photon energies. This may indicate a difference between the linacs but could also be explained by there being unidentified measurements after component changes in the SB2 data set. To improve future data collection measurements after component change should be indicated clearly to be separated from routine controls.

For comparison, a multi-centre analysis of beam output drift found the average for Elekta to be 0.71±2.03% (1SD) per year[34]. The large uncertainty here supports that 0.5% may be too strict at the current quarterly frequency. Either the tolerance can be increased, or the frequency of controls must be increased to achieve a 0.5% target. Measurements after calibrating the dose show that it is possible to achieve well below 0.5%, but calibration would likely have to be performed more often to maintain this.

To review this control a method developed by Ochi et al.[35] may be useful. This is a quantitative approach to FMEA, specific to absolute dose calibration, which may be applied to identify an acceptable frequency and tolerance level.

Both the Weekly XVI control and the daily control show a trend of having no recorded failures in the last years. For the XVI control the improvement may reflect an increase in skill and familiarity with the control among staff. This would specifically refer to the step of matching images. For both, this trend may also reflect a level of fatigue with the control where expected inaccuracies are no longer recorded as failures.

Two controls have failure rate of zero. For the MLC control this is due to a mismatch between what is recorded in QuART as a failure and what is considered a failure by staff. For the Half-Yearly Energy Control, it can be seen from the standard deviations of measurements that they are well within the tolerance. Decreasing the tolerance to match a 2SD value may be an option. Comments from staff questioned whether the I'mRT

phantom measurements were less reliable than the water tank measurements for this control. This was not found here.

5.1.3 Comments and Data Collection

All controls have the option of adding comments, with comments being compulsory for failed controls. How the comment section is used varies. Several controls have redundant or unnecessary comments, such as stating that the control was ok or signing one's name in the comment field. The comment section is also used for keeping track of parameters being monitored, e.g. minor deviations that are not enough to fail the control. Quantitative information is sometimes added to failed controls. The XVI Control stands out in this respect. Comments on the control most often add quantitative measure of deviation as seen on the phantom after the table movement is complete. To monitor this a separate entry field for this could be implemented.

The variation in use of the comment section shows that it is unclear what kind of data is wanted here. Clearer guidelines on what should be recorded here could improve data collection. A consideration may be what type of quantitative data is wanted when the control is failed. Also, how much detail to add should be considered. If the database is going to be subject to external audit the detail level should be so that an outsider can understand the nature of the failure and what was done.

The Monthly controls stands out as a control with frequent use of comments. Details are added for all failed controls. Likely this reflects the role of this control as a "more thorough" version of the daily control. The functionality of adding an update to the control status with remarks of what has been done seems to have fallen out of use after only two instances of use in 2013. This seems unfortunate as it is a good way of improving communication so that all staff present at the control can make sure failures are followed up. It could also be used to monitor how efficiently failures are dealt with.

Several controls showed inconsistency in how to deal with controls that were not performed vs a failed control. For some entries not performed was logged as failed for others it was mentioned in comments. For the XVI control there are also some failures logged without failed parameters, and failed parameters without failed controls. This is likely an issue with the QuART database and a control of the data entry system should be performed.

As discussed under tolerances, for the MLC control what constitutes a failure needs to be defined. This would improve data collection. However, the usefulness of the current quantitative data from this control is questionable. Differences in recorded values show interpretation of the image is dependent on the person. To obtain quantifiable data this test could be improved by digitalising the images and using more accurate measurement methods. The lack of quantifiable data is not a comment on the usefulness of the control. As a qualitative control it can pick up many minor deviations that show as unevenness or unexpected overlaps in the image. This does however rely on the person interpreting the image being familiar with what the image represents and how to read it. That this control lacks a formal procedure is then very unfortunate.

Improving the data collected from current controls is one way of improving the monitoring of the system. Gathering more data may also be an option. The survey by Palmer et al.[32] noted an issue with receiving only quality control data as collected by the medical physicists. It was suspected that this led to under-reporting of controls performed by radiographers and engineers. For the data collected at St. Olavs controls by radiographers are included in the same database as the controls performed by

physicists. The engineering department however have their own system for controls and the data is not collected in the same database as the other controls. Collecting the data from controls and services performed by engineers would improve the data and possibly give a more accurate picture of the current system.

The importance of collecting good data is relevant as Machine Learning (ML) is a developing trend in Quality Assurance[36]. Along with collection of big datasets, standardisation of nomenclature is seen as a challenge in implementing ML. This is because collecting large enough datasets will likely involve receiving data from several different departments.

How ML can be used in combination with risk analysis methods has been described. Valdes et al.[37] have developed a virtual QA system for IMRT based on ML. They point out how this can help identify risk factors and as such act as part of the risk-based approach described in TG-100. In this way ML based QA acts as a complement to manual QA.

Automation and computerisation are ranked as the 2nd highest level on the scale of effectiveness of different QM tools indicated in TG-100, see section 2.3.4.4. The automation of system monitoring using ML is then a promising development. Some caution is however called for in the current enthusiasm for ML. Feng et al.[36] notes that the success of a ML system depends both on the algorithm design and the quality of the data available. They also point out that implementing ML will result in the need for Quality Assurance of the ML. Kalet et al.[38] points out that Quality Assurance encompasses more than reducing the number or errors and as such expert judgment cannot be replaced in a therapeutic setting.

5.1.4 Comparison with TG-142

The Daily Control, the Monthly Control, and Ion Chamber Control are in line with the recommended frequencies in TG-142. The specific tolerances vary a little, but the system with having a monthly control with stricter tolerances of the same parameters as in the daily control is in line with recommendations.

The Weekly XVI and DailyQA controls are performed less frequent as both are assigned daily frequency in TG-142. Tolerances are similar, though somewhat stricter for the XVI control.

The Quarterly MLC control is performed much less frequent than the recommended weekly frequency. It should be noted that several quantitative controls are recommended for MLCs at monthly and annual frequency. These are currently not part of the monitored routine controls at St. Olavs.

Dose calibration and energy Control (Beam Quality) are both assigned annual frequency and 1% tolerance (from baseline for beam quality) in TG-142. Both are performed more often at St. Olavs, and the dose calibration has a stricter tolerance.

5.2 Risk Analysis

5.2.1 FMEA Results

The failure modes are ranked by their RPN value in Table 38. Ranking scores are marked as red for high scores (>300), yellow for intermediate scores (200-300), and green for low scores (<200). The severity scores of the failure mode is also shown with severity scores of 10 highlighted in red.

Table 38 Failure Modes Ranked by Risk Priority Number Score. The severity score of the failure mode is given in the column marked S.

Rank	RPN	Failure Mode	S
1	480	# 8 Dosimetric error absolute dose >3%	6
2	420	# 4 Wrong position of target volume relative to isocentre >3mm (Laser guided)	7
3	360	# 7 Dosimetric error absolute dose >2%	4
4	210	# 3 Wrong position of target volume relative to isocentre>1mm (CBCT guided)	3
5	200	# 1 Wrong patient	**10**
6	200	# 9 Geometric Error >1mm	4
7	140	# 6 Dosimetric error absolute dose >0.5%	2
8	96	# 2 Incorrect use of immobilisation equipment	3
9	50	# 10 Patient injury during treatment delivery	**10**
10	10-20	# 5 Patient injury during set up	5-**10**

The first, third, and seventh ranked failure modes are the same type of error with different tolerance limits. This shows how the recommendation in TG-100 of separating failure modes based on the severity is useful. The highest ranked FM is less likely, but the higher severity score raises the RPN score. The lowest ranked FM of this type has a similar occurrence as the others, but the low severity score puts it in the lower range of the ranking scale.

The occurrence calculation for the highest ranked failure mode is most likely overestimated. It is based on the failure rate of the DailyQA control. The source of all failures for this control are the energy measurements of SB4 and as discussed in 5.1.2 there is reason to question these results. Failure mode #7 corresponds to the warning level tolerance. There are failures recorded for both linacs for the warning tolerance level, which gives reason to believe that the occurrence calculation for this FM is more accurate.

The second highest RPN is for laser guided set up. This is both due to high severity and high occurrence. The high occurrence is due to this step relying on several different parameters that may fail. It is defined as laser guided, though table position accuracy, light field, and ODI may affect this failure mode. Comparing the RPN of laser guided set up with that of CBCT guided set up again shows how the severity score affects ranking. CBCT guided set up has a higher occurrence ranking than laser guided, however the low severity stemming from the stricter tolerance decreases the overall score. As laser guided set up is followed by corrections using CBCT as a guide, these results also show how using the CBCT reduced the risk associated with the process overall.

Failure modes #1,2,3,5, and 10 are related to human error and as such fall outside the responsibility of machine QC. It is however worth noting that this is where severity scores of 10 are found. As pointed out in TG-100 severity scores of 10 should be evaluated for their need for QC regardless of their RPN ranking. FM #10 which is ranked 9th by RPN in Table 38 is an interesting case in this regard. This is based on the failure rate of the linac touch guards in combination with human error. The touch guards have never failed a control. However, the potential outcome of failure is injury and possible death of the patient. This shows how the severity scores are important in evaluating the importance of QCs associated with the failure mode.

5.2.1.1 FMEA Ranking Scale Design

The occurrence scale is adjusted based on the assumption that the QA data has identified all failures. As the frequency of some controls is lower measuring more often might increase the failure detection. Occurrence also depends on the periodic calibration and service of the linacs. The linacs are serviced throughout the year by the engineering department. So, the failure rates reported here reflects the expected failure rate with the service and calibration frequencies that have been in place during the period of QA data collection.

By using the TG-100 method of defining detectability as the likelihood of not discovering the failure before moving on to the next step, provided there are no QCs in place, renders the D value almost useless. Most failures related to linac performance or guidance tools are not reasonable to expect to be discovered without measurement or QC of some sort. The exception might be extreme deviation of lasers. This means most failures have D = 10. This was also found by O'Daniel et al.[31]

Human error related failures can be expected to be detected under some circumstances. As an example, there may be a possibility of the radiographer noticing that a patient has moved voluntarily or that immobilization equipment does not fit the patient well. This is not ranked very likely as it would be considered a QC to e.g. go over the set up with a check list or have another radiographer check the set up. Only the most obvious errors such as the patient falling from the table can be considered as Detectability rank 1.

Adjusting the severity ranking scale to reflect the target accuracy established for the linac rather than the theoretical limit for possible injury makes it more fine grained. This adjustment also reflects how the expectation for linac accuracy is higher than other parts of the process. The limits used here are then much lower than those used in TG-100. For dosimetry this is because it represents dose to a point, and for geometric placement of beam volume the limits are strict as this would also represent a dosimetric error.

The ranking scales developed for TG-100 were deliberately made broad and somewhat vague[10]. The scales had to fit all types of errors found. Adjusting them for use on the linac parameters meant making the limits stricter for two of the scales. This may reflect an increase in linac performance or that the linac performance is not a major source of error on the general scale. I.e. if errors resulting from the treatment planning process and delineation of tumours are in the 5-10 mm range, the failure of the linac to stay within a 1 mm tolerance is not a large source of error in the overall sum of errors.

This should not be interpreted to mean that the error contributed from the linac is insignificant. Linac performance is part of the total error and must still be kept as small as possible. However, trying to use the general scale to indicate severity does not say anything useful about the linac performance. By using a scale specific to linac

performance and the target established for this it is possible to draw conclusions about how well the linac delivers and where improvements are most beneficial.

As discussed in 2.3.4.2, FMEA has its roots in reliability analysis and component evaluation. This is a weakness when FMEA is applied to processes where humans are involved. However, this may be a strength when evaluating linac performance as this is closer related to component reliability analysis.

5.2.2 FTA Results

5.2.2.1 Failure Mode: Set up: Wrong Position of Target Volume

Two paths from this fault tree are disregarded. This is the volume movement path and the radiographer mistake path. These are dealt with by other measures than linac QA. The replicate position path and inaccurate table position path are part of linac QA.

The *Replicate treatment position* path splits into two and affected by both laser positioning and CBCT matching. Marker misplacement is not part of the linac QA, but correct placement of markers is a crucial step in getting the position correct. The laser alignment is currently controlled at daily and monthly frequency. The high control frequency may be questioned when laser positioning is followed by corrections using CBCT. However, poor initial positioning using the lasers is likely to increase the time spent on CBCT corrections. If this results in more CBCT images being acquired, it also represents an increased dose to the patient.

The importance of QCs here should also be evaluated against the FMEA result. Laser guided set up is ranked as the 2nd highest RPN score. If CBCT is not used, then QC of this path becomes more important.

Several paths in the CBCT matching path are unguarded. The isocentre kV/MV match is the most central to physicists QA routines. The lack of a control in the diagram is not due to the test never having been performed at the department, but a lack of routine controls and a systematic approach in gaining confidence that this is within tolerance.

Image quality improvements would need to be a coordinated effort in optimisation along with initial CT imaging to ensure the best possible conditions for easy matching. Lastly, use of the matching tool would require training and possibly “buddy” controls, where a second radiographer checks the match so that a consensus on use develops and the general skill level may be increased.

The table positioning is involved in many controls for x, y, z parameters. For the table rotation only, the daily control checks the accuracy of angle position. This test is however the one with most failures and QA data collected indicates that it is possibly not a very useful test.

Whether the angular positioning is used for set-up or not should be a factor in deciding how to approach this control. If non-zero angles are used often, then this control should be improved. If only the zero-degree angle is used, the accuracy of the floor protractor may be less useful and daily controls may not be warranted. With the introduction of more advanced tables with increased possibilities for table positioning, this control is likely to become more complicated.

5.2.2.2 Failure Mode: Treatment Delivery: Wrong Dose to Point in Target

Both paths leading to error in linac output have two QCs guarding the path. The higher frequency of QCs applied to the dose per MU path is supported by the higher failure rate

of this absolute dose calibration QC. While not included in the FTA it should also be noted that the dose delivered is monitored by the interlock system controlled by the monitor chambers. This is a protection against the more severe errors in this failure mode. QC of the monitor chamber interlocks is the responsibility of the engineer and as such was not considered part of the physicists QA schedule.

5.2.2.3 Failure Mode: Treatment Delivery: Dose Delivered to Wrong Volume

The MV to Mechanical Isocentre Alignment path is not currently guarded by any QCs. As with the kV/MV alignment control, the lack of a control for this path is not due to the control never being performed, but a lack of routine controls. Considering this alignment is the crucial reference point for aligning the entire volume, a control should be implemented here.

The MLC control is part of the QC for most paths here. As discussed in 5.1.3, this is a qualitative test and adding quantitative tests here may be beneficial. The unguarded paths are the gantry speed and the MLC speed. Issues with movement speed may be picked up during measurements for treatment verification. However, identifying this as the source of error at the verification step may be difficult. TG-142 suggests leaf speed controls at monthly frequency for IMRT. Considering that VMAT is most often used at the department, it may be useful to add controls for this. Before adding to the current QCs existing controls by engineers could be investigated as a source for obtaining quantitative data for MLCs.

5.2.2.4 Treatment Delivery: Delta4 Treatment Plan Verification

The treatment plan verification using the Delta4 phantom acts as a final control for all paths related to treatment delivery both geometric and dosimetric. Verification of individual treatment plans take up much time in the QC schedule. The usefulness of the Delta4 control has been investigated at the department. The control was found to rarely fail, and when it did it was for treatment plans known to be more complex in advance of the control. The desire is to reduce the use of this control, however as it acts as a final catch all there has been reluctance to let go of it.

This problem was noted by Palmer et al.[32] where the decrease of patient specific QC for IMRT treatment was seen a necessary in order to allow for the increased use of IMRT. They concluded that improving basic linac QCs was the preferred way of reducing the need for individual treatment plan verifications.

5.3 Experience from Working with TG-100 Methodology

5.3.1 Process Mapping

For designing a process chart deciding on the level of detail was the initial challenge. Many minor steps and details were initially included before settling on a lower level of detail. As the goal was to focus on treatment delivery, keeping the level of detail low in other steps was also an attempt to keep this focus clear. To expand the work in this thesis, the detail level may need to be increased for the remaining steps. The decision to focus on a more generic workflow for this thesis was also influenced by only one group member being active in the day to day activities at the clinic. If the process map is to reflect the individual clinics workflow accurately, involving more staff from different members of the treatment team would likely improve the accuracy of the process map.

Schuller et al.[39] designed their Process map with the goal of having enough detail so that someone with radiotherapy experience could replicate their procedures. They do however point out that this led to a high level of detail which produced a high number of

FMs. This increased the time needed for FMEA. So, while a high level of detail may be good, keeping in mind how it will be used may help identify a suitable detail level.

5.3.2 Failure Modes and Effects Analysis

FMEA has been identified as a time-consuming project[40]. This was also found here. Discussion easily got off track by getting caught up on how errors earlier in the process affected the FMs. Interpreting the ranking scales and agreeing on terminology also took up much time.

A survey of FMEA in healthcare indicated 69h as the average for completing a project[40]. Schuller et al.[39] however reported an estimate of 258h to complete their FMEA. They attribute the large amount of time to inexperience with the methods used and expected that future projects would be more efficient. Ford et al.[41] have attempted to produce a model for streamlining the implementation of FMEA. They reported 55h for group members with and additional 20h dedicated to facilitator work.

The role of the facilitator has been noted by as crucial for successful and efficient completion of FMEA[40]. Ford et al.[41] identifies the use of a facilitator and education of group members before the project is started as critical for their streamlined FMEA model.

The lack of experience with the methods was likely also a cause of the difficulties met during the work with this thesis. To resolve the issues with getting distracted by errors in other parts of the process it was found to be useful to keep track of assumptions and factors which were not considered as part of the current FM ranking. This was added as separate column in the FMEA sheet.

As mentioned most other reports found that relying on having a facilitator present was most beneficial to efficiency in the FMEA. Ford et al.[41] also notes that using take home tasks as part of the FMEA process can allow for higher contribution from group members who are not so comfortable in a group setting.

Creating useful ranking scales was also another challenge. Ford et al.[42] comments on the issues of establishing ranking scales as the scoring is qualitative. They note that the exact normalisation of the scale is not important as its goal is to rank scores relative to each other. That all parties involved in ranking understand, agree on, and adhere to the scale is given as the most important aspects.

Achieving consensus on ranking of FM is described as another problem. This was again solved by some by relying on the expertise of the facilitator[39]. Others have relied on averaging of the individual scores[10].

5.3.2.1 Fault Tree Analysis

Creating a FTA for this thesis was made easier by having spent time filling out the FMEA sheet in detail. Having notes on excluded factors and assumptions aided in finding boundaries for the chart. The issues with creating a FMEA may influence the perception that creating a FTA was easier. However, the detailed notes and ideas from FMEA discussion made working with the FTA easier, so in allocating time between the two, FMEA may be favoured as it creates the basis for FTA.

5.3.2.2 Impact of Work

The impression is that working with risk analysis in this thesis has been met with a positive attitude when asking for help from other members of staff at the clinic. This has been remarked on by other reports as well. An overall increase in safety awareness and positive attitude towards quality assurance is noted[43]. An improved level of efficiency of the overall process has also been reported as a result[39]. These positive impacts show

that investing time in working with these risk analysis methods may return long term benefits.

In the survey by Palmer et al.[32], the authors expressed surprise at how many radiotherapy departments reported that they were aware of the need to update their QA programme. They also reported that the current systems were thought to be less efficient and productive than desired. The authors speculated that this negative attitude among the departments towards their own QA programmes was because the QCs were based on already outdated guidelines. The pressure to keep up with new technology combined with the workload and resource pressure on staff was thought to be the reason why basic QCs were not prioritised. Palmer et al. also state that only 30% of the departments reported using risk analysis as part of designing their QA programme. They point out that a risk-based approach is preferable to adoption of a standard QC list.

As new technology is introduced for radiotherapy there will always be a need to update QCs to keep up. The examples above show how neglecting this leads to negative attitudes and loss of confidence in the QA programme. The time-consuming nature of implementing risk-based approaches such as those outlined in TG-100 may be a deterrent. However, the long-term benefits reported indicates it may be more cost efficient overall. The role of a facilitator in easing the work with TG-100 methods shows the importance having guidance in the process of learning the methods. To help introduce risk-based approaches at local departments in Norway, national organisations such as KVIST could help coordinate education of facilitators. By building competence in risk-based methods, the individual radiotherapy departments can be enabled to keep up with new technological developments.

5.4 Limitations

5.4.1 Quality Control Data

The main limitation is a lack of data. To improve accuracy of compliance a registry of days a linac is used for treatment would need to be kept. This would have to track linac downtime and also treatment out of normal hours, such as weekends.

Collecting data from the engineering department would allow for more measurement points where controls overlap and the possibility to analyse how QCs performed by medical physicists and radiographers interact with controls performed by engineers.

5.4.2 Risk Analysis

The risk analysis for this report was carried out only by physicists. This is likely to skew the focus of the report. The medical physicist is the main staff member responsible for linac QA, so it is natural to have physicists be the key staff in performing risk analysis. However important perspectives from other members of the treatment team is most likely underrepresented in this work.

5.5 Further Work

If changes are made to the current QCs as suggested in this report or other changes are implemented, a new review of QCs should be scheduled. The results presented here could be used for comparison to evaluate the effect of changes to QCs on overall QA.

For the risk analysis the natural next step would be to expand the risk analysis to include more steps of the radiotherapy process. An evaluation of the entire process might be too large in scope at the present time. Focusing on another major step in the process, such as treatment planning, or a specific treatment type such as SRS might be a way of limiting the scope.

The linac risk analysis may be improved by using modelling of geometric and dosimetric errors in the treatment planning system to produce a more accurate severity ranking scale. As mentioned specific projects using FMEA to evaluate individual components of the linac such as monitor chambers of MLCs have been reported on and could present an opportunity for smaller self-contained projects.

6 Conclusion

In this thesis, an audit of the current QA programme for linacs at St. Olavs hospital radiotherapy department is presented. Compliance was found to be below target, but within a similar range as found in other reports. Regular reporting of compliance parameters is suggested as a way of improving compliance.

Two controls are identified as in need of review of tolerance limits. The Absolute Dose Measurements fail often under the current tolerance limit. Increasing the tolerance should be weighed against clinical needs. If the current tolerance is to be maintained the frequency of calibration should be increased. The Beam Energy Control never fails under the current tolerance limits.

Two controls are identified as in need of review of control design. The floor protractor parameter control in the Daily Control was found to function poorly. It should also be investigated how well the overall control is integrated in the radiographer's work flow. Control of the MLCs should be expanded to include quantitative measurements. Quantitative data may be available from engineering regarding MLC control. Collecting this data should be explored before adding new controls.

For improvement of data collection, it is suggested that QC data from the engineering department is pooled with the QC data from medical physics and radiographers. Clearer guidelines on what information is wanted in the comment section for controls would also improve data collection.

A method for using quality control data as a basis for risk analysis was presented. Failure Modes and Effects Analysis showed absolute dose to be the highest risk factor during treatment delivery, and laser guided set up to be the highest risk factor in set up. Fault Tree Analysis showed that several possible causes of error in CBCT guided set up are not currently monitored by QCs. Control of match between kV and MV isocentres is currently not monitored and is identified as the most relevant machine QC that could improve set up accuracy.

For geometric accuracy during treatment delivery gantry speed and MLC speed are not currently monitored by controls. As concluded in the audit regarding MLC control, quantifiable controls could be useful. These are also basic linac QCs that could help alleviate the need for individual treatment plan verification. The alignment of MV to mechanical isocentre is also not currently monitored. This is alignment is crucial for the correct placement of all other coordinates and should be prioritised for introduction of new controls.

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8 A. Appendix

8.1 A.1 Details for monthly control

Table 39 Detailed parameters for the Monthly Control.

PARAMETER FAILED

PARAMETER	SB2	SB4
INDICATOR 90	1	0
INDICATOR 100	0	0
X LIGHT FIELD A-B	2	1
Y LIGHT FIELD G-T	2	1
ISOCENTRE: GANTRY 0	0	0
CROSS HAIRS VERTICAL	0	0
ISOCENTRE COLLIMATOR ROTATION	0	0
ISOCENTRE TABLE ROTATION	0	0
ISOCENTRE GANTRY:90	0	0
ISOCENTRE GANTRY:270	1	0
SAGGITAL-LASER VERTICAL	0	2
SIDELASER	1	7
TOUCH GUARD LINAC	0	0
TOUCH GUARD IVIEW	0	0
TOUCH GUARD XVI	0	0
TOUCH GUARD ELECTRON APPLICATOR	0	0
TOUCH GUARD HAND CONTROL	0	0

8.2 Details for Absolute Dose Measurements

Trend plots, mean and standard deviations for all QuART entries for absolute dose measurements.

Table 40 Failure frequencies, means, and standard deviations for all absolute dose measurements.

FAILURE FREQUENCY (failure/year)	
SB2 6MV	2.63
SB2 15MV	2.25
SB4 6MV	2.13
SB4 1HMV	2.50

ABSOLUTE DOSE CALIBRATION (ALL) MEAN AND STANDARD DEVIATION				
	SB2 6MV	**SB2 15MV**	**SB4 6MV**	**SB4 15MV**
MEAN	0.14	0.18	-0.01	-0.12
SD	1.63	1.40	0.94	0.88

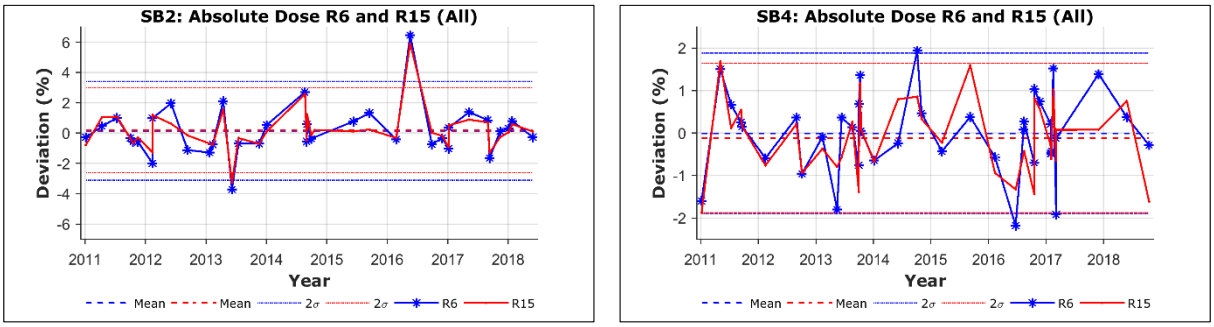

Figure 47 Trend plot of Absolute Dose Measurements for 6MV and 15MV on SB2 and SB4. Mean (μ) values as given in Table 40. 95% confidence interval shown as μ±2σ (SB2: $2\sigma_{6MV}$=3.26%, $2\sigma_{15MV}$=2.80%, SB4: $2\sigma_{6MV}$=1.88%, $2\sigma_{15MV}$=1.76%)

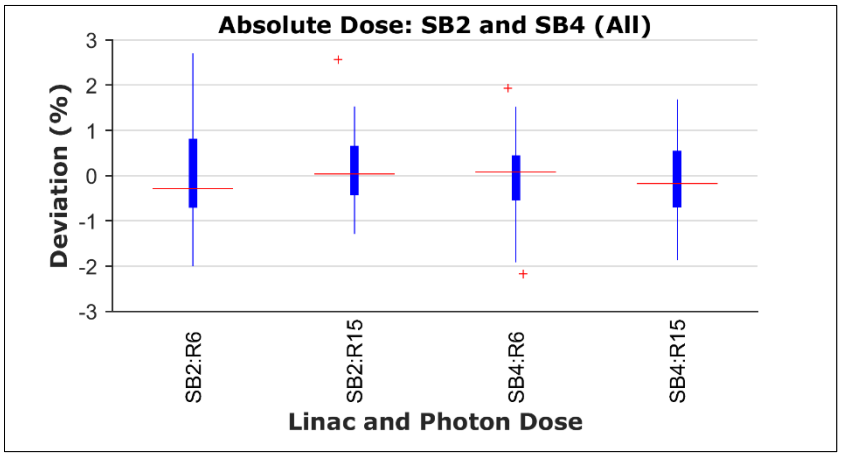

Figure 48 Boxplot of absolute dose measurement after calibration has been performed in response to a failed control for SB2 and SB4. Bottom and top of boxes indicate 25th and 75th percentiles, whiskers indicate extreme values. Red line indicates the median and crosses indicate outliers.

8.3 A.3 Details for Compliance Calculations

Table 41 Average compliance for controls for each linac.

Average Compliance Level (%)

	Daily		DailyQA		XVI		Monthly		Calibration		MLC		Energy Control	
Year	**SB2**	**SB4**	**SB2**	**SB4**	**SB2**	**SB4**	**SB2**	**SB4**	**SB2**	**SB4**	**SB2**	**SB4**	**SB2**	**SB4**
2011	33.5	14.5	na	na	76.0	40.0	na	na	150.0	125.0	50.0	75.0	50.0	75.0
2012	21.2	6.7	na	na	16.0	48.0	na	na	100.0	75.0	50.0	50.0	100.0	150.0
2013	29.1	41.3	na	na	48.0	60.0	75.0	75.0	137.5	200.0	200.0	100.0	200.0	150.0
2014	73.7	55.9	93.8	100.0	70.0	66.0	58.3	58.3	137.5	100.0	150.0	175.0	150.0	150.0
2015	60.9	67.6	84.6	91.3	68.0	72.0	50.0	66.7	50.0	50.0	125.0	125.0	50.0	100.0
2016	100.0	43.0	108.7	89.4	100.0	68.0	66.7	41.7	100.0	162.5	100.0	25.0	100.0	50.0
2017	81.0	56.4	105.8	102.9	86.0	72.0	58.3	41.7	150.0	187.5	125.0	75.0	100.0	50.0
2018	33.0	34.6	88.5	91.3	26.0	70.0	41.7	33.3	150	50.0	50.0	100.0	100	100.0
Average	54.1	40.0	96.3	95.0	61.3	62.0	58.3	52.8	121.9	118.8	106.3	90.6	106.3	103.1

8.3.1.1 Daily Control

Daily control compliance is estimated as the percentage of the highest number of controls registered in a year: 179 controls registered for SB2 in 2016.

8.3.1.2 Weekly: XVI Control

Based on 52 controls per year.
Expected controls adjusted for start date in 2011:
SB2: 49 controls
SB4: 48 controls
Expected controls adjusted for end date in 2018:
SB2: 29 controls

Table 42 Registered XVI controls per year (#) and compliance per year (%)

XVI Registered Controls per year

Year	**SB2 #**	**SB2 %**	**SB4 #**	**SB4 %**
2011	38	77.6	20	41.7
2012	8	15.4	24	46.2
2013	24	46.2	30	57.7
2014	35	67.3	33	63.5
2015	34	65.4	36	69.2
2016	50	96.2	34	65.4
2017	43	82.7	36	69.2
2018	13	44.8	38	73.1
Average	30	61.9	31	60.7

8.3.1.3 Weekly: DailyQA Control

Based on 52 Controls per year.
Expected controls in 2014 adjusted for start date in 2014:
SB2: 8 controls
SB4: 8 controls

Table 43 Registered DailyQA controls per year (#) and compliance per year (%)

DailyQA Registered Controls per year

	SB2				SB4			
Year	**6MV #**	**6MV %**	**15MV #**	**15MV %**	**6MV #**	**6MV %**	**15MV #**	**15MV %**
2014	8	100.0	7	87.5	8	100.0	8	100.0
2015	44	84.6	44	84.6	47	90.4	48	92.3
2016	56	107.7	57	109.6	47	90.4	46	88.5
2017	53	101.9	57	109.6	53	101.9	54	103.8
2018	23	88.5	23	88.5	46	88.5	49	94.2
Average	36.8	96.5	37.6	96.0	40.2	94.2	41.0	95.8

8.3.1.4 Monthly Controls

Based on 12 controls per year.

Expected controls in 2013 adjusted for start date in 2013:
SB2: 4 controls
SB4: 4 controls
Expected controls in 2018 adjusted for end date in 2018:
SB2: 6 controls

1 double entry removed for SB2 (18.03.2015).
2 double entries removed for SB4 (07.04.2015 and 04.05.2016).

Table 44 Registered Monthly controls per year (#) and compliance per year (%)

Monthly Registered Controls per Year

Year	**SB2 #**	**SB2 %**	**SB4 #**	**SB4 %**
2013	3	75.0	3	75.0
2014	7	58.3	7	58.3
2015	7	58.3	9	75.0
2016	8	66.7	6	50.0
2017	7	58.3	5	41.7
2018	5	83.3	4	33.3

8.3.1.5 Quarterly: Ion Chamber

Based on 4 Controls per year per chamber.

No adjustments made on start or end date:
First measurement for FC2320: 09.03.2012
There should always be two available ion chambers for use, so only two chambers are active and scheduled for controls at a given time. No entry indicates inactive chamber.

Table 45 Registered ion chamber controls per year per chamber (#) and compliance (%) per year

Ion Chamber Registered Controls per year

	FC 561		FC2320		FC3013		FC3643	
Year	#	%	#	%	#	%	#	%
2012	0	0	2	50				
2013	1	25	3	75				
2014	5	125	3	75				
2015	3	75			3	75		
2016	1	25			1	25		
2017					2	50	2	50
2018					2	50	3	75
Average	2.5	62.5	2.7	66.7	2.0	50.0	2.5	62.5

8.3.1.6 Quarterly: MLC Control

Based on 4 controls per linac per year.

Expected controls in 2018 adjusted for end date in 2018:
SB2: 2 controls

Table 46 Registered MLC controls per year (#) and compliance per year (%)

COMPLIANCE MLC CONTROLS

	SB2 #	SB4 #	SB2 %	SB4 %
2011	2	3	50	75
2012	2	2	50	50
2013	8	4	200	100
2014	6	7	150	175
2015	5	5	125	125
2016	4	1	100	25
2017	5	3	125	75
2018	2	4	100	100
AVERAGE	4.25	3.63	112.50	90.63

8.3.1.7 Quarterly: Dose Calibration

Based on 4 controls per linac per year.

Expected controls in 2018 adjusted for end date in 2018:
SB2: 2 controls

Table 47 Registered absolute dose measurement controls per year (#) and compliance (%)

ABSOLUTE DOSE MEASUREMENT COMPLIANCE (%)				
YEAR	SB2 6MV	SB2 15MV	SB4 6MV	SB4 15MV
2011	150	150	125	125
2012	100	100	75	75
2013	150	125	200	200
2014	125	150	100	100
2015	50	50	50	50
2016	100	100	175	150
2017	150	150	200	175
2018	150	150	50	50
AVERAGE	121.875	121.875	121.875	115.625

8.3.1.8 Half-Yearly: Energy Control

Based on 2 controls per linac per year.

Expected controls in 2018 adjusted for end date in 2018:
SB2: 1 control

Table 48 Registered energy controls per year (#) and compliance (%). All measurements presented in first column, with how many of those were I'mRT phantom measurements in the next column.

	SB2				SB4				SB2	SB4
Year	6MV	6MV*	15MV	15MV*	6MV	6MV*	15MV	15MV*	**(%)**	**(%)**
2011	1	1	1	1	1	1	2	2	50	75
2012	2	1	2	1	3	2	3	2	100	150
2013	4	1	4	1	3	2	3	2	200	150
2014	3	1	3	1	3	2	3	2	150	150
2015	1	0	1	0	2	1	2	1	50	100
2016	2	2	2	2	1	1	1	1	100	50
2017	2	1	2	1	1	1	1	1	100	50
2018	1	1	1	1	2	2	2	2	100	100
* Measurements with I'mRT phantom										

8.4 Dose Calibration vs DailyQA

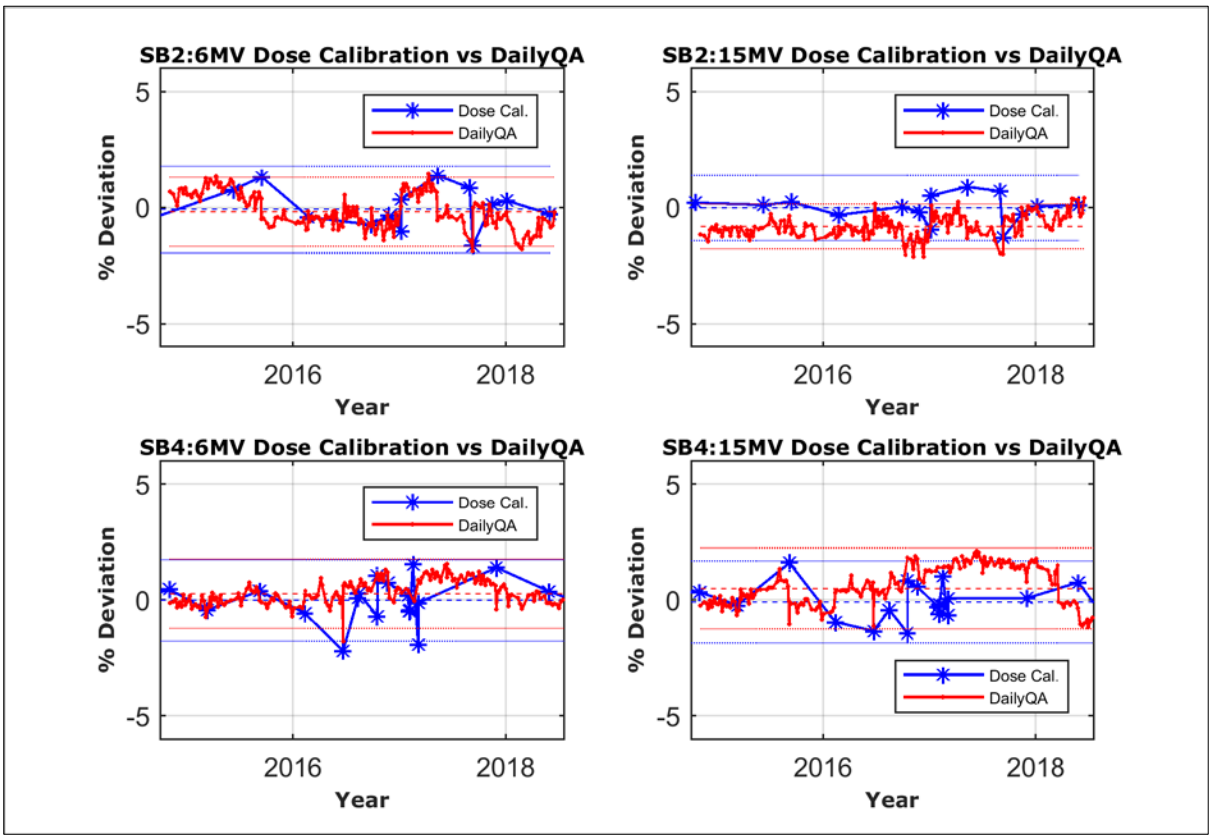

Figure 49 Absolute Dose measurements plotted against dose measurements with DailyQA phantom.

8.5 FMEA worksheet

The following are the worksheets as filled out during discussions.

Failure Modes and Effects Worksheet Key from TG-100

Process Step	**Potential Failure Mode**	**Potential Cause of Failure Mode**	**Effects of Potential Failure Mode**	**Current Controls**	**Occurrence-Cause**	**Detectability of Failure Mode**	**Severity of Effect from Failure Mode**	**RPN**	**Corrective Action**
Process step as defined in process chart	Failure modes of current process step. FM defined by: -The way a failure occurs -The way it is observed -How it fails to meet its intended purpose	Causes of FMs Use FTA for guidance If necessary.	Can be divided into three levels: **Local:** effect on current process step **Downstream:** effect on further steps in process **End:** effect on end point of process NB if dividing into three levels cause confusion, only using the end effect is acceptable.	Actions that will: -Prevent the occurrence of FM -Detect the FM before it produces the end effect -Moderate the severity of the FM if it happens	Likelihood that a cause will occur and produce the FM Rank 1 to 10 with 10 being most likely	Likelihood that FM will remain undetected before it causes significant end effects Rank 1 to 10 with 10 being most likely	Severity of end effect given that FM occurred Rank 1 to 10 with 10 being most likely	Multiply OxDxS High RPN indicates process weakness and hazardous process steps	Address steps with highest RPN and high Severity Scores Introduce process controls to: -Reduce or eliminate cause -Increase probability of detection -Moderate severity
									Alternative: Excluded causes and assumptions
									Assumptions made and causes originating in other process steps

#	Process Step	Potential Failure Mode	Potential Cause of Failure Mode	Effects of Potential Failure Mode	Current Controls	O	D	S	RPN	Excluded and Assumptions
1	Patient ID	Wrong patient called, wrong treatment plan retrieved. Wrong immobilization equipment used.	Data entry; wrong name in plan Mistake; e.g. similar names or miscommunication Lack of equipment labelling	Local: DS: Partial or complete miss of target; Irradiation of normal tissue End: Unnecessary exposure to radiation, injury or increased risk of cancer Treatment compromised, loss of TCP	Picture of patient along with name on patient file attached to treatment plan Picture of patient as set up with immobilization equipment attached to file Communication with patient	2	10	10	200	For detectability; if the error has occurred and no QC check point exists after calling the patient the only possibility of detection is if the patient notices eg. different equipment and speaks up
2	Set up: Wrong use of equipment	Immobilization equipment does not position the patient as intended	Human error Equipment is used wrong or sub-optimal Equipment no longer fits patient due to anatomy change	Local: DS: Deviations in positioning End: Geometric deviation in volume to target match	Radiographer training Instructions for equipment available	4	8	3	96	Expect minor deviations compared to e.g. use of wrong equipment.
3	Set up: CBCT guided	Wrong position of target volume relative to isocentre>1mm (XVI guided)	Misaligned CBCT Poor match using CBCT Table position inaccurate relative to isocentre: x,y,z, and angle. Patient movement (voluntary) Patient movement (involuntary: anatomy) Poor communication with patient	Local: none DS: Decrease dose to tumour increase dose to normal tissue End: Increase NTCP and decrease TCP	CBCT weekly control (NB Kv to mv isocentre no control) Effect moderation: evaluation of CT match by physician after first treatment	7	10	3	210	Failures affecting geometric placement originating in planning process: Tumor delineation Initial CT imaging Choice and quality of immobilization equipment Potential treatment options: Motion management systems

#	Process Step	Potential Failure Mode	Potential Cause of Failure Mode	Effects of Potential Failure Mode	Current Controls	O	D	S	RPN	Excluded and Assumptions
4	Set up: Laser guided	Wrong position of target volume relative to isocentre >3mm (Laser guided)	Misaligned Lasers Patient movement voluntary Patient movement involuntary Poor communication (patient is uncomfortable or the need to remain in position is not communicated well)	Local: none DS: Decrease dose to tumor increase dose to normal tissue End: Increase NTCP and decrease TCP	Lasers: Daily and monthly Effect moderation: evaluation of CT match by physician after treatment	6	10	7	420	Failures affecting geometric placement originating in planning process: Tumor delineation Initial CT imaging Choice and quality of immobilization equipment Potential treatment options: Motion management systems
5	Set up: Patient safety	Patient injury -e.g. fall from table	Unstable position on table Faulty use of immobilization equipment Poor design of immobilization equipment Radiographer mistake Patient movement	Local; may have to disrupt treatment if injury needs medical attention DS: further disruption of treatment if severe, patient health damaged End; disruption of treatment compromises effect of treatment and TCP	Prevention: Radiographer Training and Instruction Communication with patient	2	1	5-10	10-20	Minor injuries or possibility of patient becoming suddenly unwell.
6	Treatment Delivery: tolerance of chamber calibration	Dosimetric error absolute dose >0.6%	Miscalibration of monitor chamber Drift of montitor chamber	Local: minor deviations in dose DS: Need to adjust plan to account for over or underexposure, inconvenience to patient and staff End: Treatment compromised, loss of TCP and increased NTCP	Prevention: Quarterly Calibration of Monitor chambers. Detection: Patient plan verification using Delta4 Moderation: Adjustment of further treatment if deviation is found	7	10	2	140	Dosimetric errors originating in planning: Wrong prescription Error in delineation Errors in model and/or algorithm in treatment planning system Error in transfer from treatment planning system to treatment delivery system

#	Process Step	Potential Failure Mode	Potential Cause of Failure Mode	Effects of Potential Failure Mode	Current Controls	O	D	S	RPN	Excluded and Assumptions
7	Treatment Delivery: DailyQA warning level	Dosimetric error absolute dose >2%	Miscalibration of monitor chamber Energy Deviation	Local: DS: Need to adjust plan to account for over or underexposure, inconvenience to patient and staff End: Treatment compromised, loss of TCP and increased NTCP	Prevention: Quarterly Calibration of Monitor chambers Detection: Patient plan verification using Delta4 Moderation: Adjustment of further treatment if deviation is found	9	10	4	360	Dosimetric errors originating in planning: Wrong prescription Error in delineation Errors in model and/or algorithm in treatment planning system Error in transfer from treatment planning system to treatment delivery system Assumed right plan
8	Treatment Delivery: DailyQA Failure level	Dosimetric error absolute dose >3%	Miscalibration of monitor chamber Energy Deviation	Local: DS: Need to adjust plan to account for over or underexposure, inconvenience to patient and staff End: Treatment compromised, loss of TCP and increased NTCP	Prevention: Quarterly Calibration of Monitor chambers Detection: Patient plan verification using Delta4 Moderation: Adjustment of further treatment if deviation is found	8	10	6	480	Dosimetric errors originating in planning: Wrong prescription Error in delineation Errors in model and/or algorithm in treatment planning system Error in transfer from treatment planning system to treatment delivery system

#	Process Step	Potential Failure Mode	Potential Cause of Failure Mode	Effects of Potential Failure Mode	Current Controls	O	D	S	RPN	Excluded and Assumptions
9	Treatment Delivery	Geometric Error >1mm	Offset or Gain for: Collimator MLC Gantry Position of Isocentre unstable during collimator rotation	Local: Volume misplaced or wrong shape DS: Need to adjust plan to account for over or underexposure, inconvenience to patient and staff End: Dose to tumour decrease: loss of tumour control. Dose to normal tissue increased, increased NTCP.	Prevention: Monthly control of some gantry angles and collimator rotation stability to isocentre, Quarterly control of MLC and collimator Detection: Moderation	5	10	4	200	Geometric errors originating in planning: Error in delineation Errors in model and/or algorithm in treatment planning system Error in transfer from treatment planning system to treatment delivery system If all parameters fail, deviation could be large and Severity could become higher
10	Treatment Delivery	Patient injury -Patient in gantry path (+CBCT and EPID path)	Table rotated to intersect gantry path. Touch Guard Failure	Local: Patient injury, likely severe, possibly death. DS: injury interferes with treatment progress End: interrupted treatment compromises treatment effect: loss of TCP	Prevention: Daily control of touch guard on linac head. Monthly control of other touch guards and emergency stops.	1	5	10	50	Assumes patient is immobilised and unable to move away. Detection low as initial error will have happened in previous step or patient has moved e.g. arm outside table after set up; error will not be detected until it occurs.

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Linac Specific Quality Assurance and Risk Analysis as a Tool for Improving Quality Assurance in Radiotherapy

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