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Application of TG-100 risk analysis methods to the acceptance testing and commissioning process of a Halcyon linear accelerator

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Purpose: A new type of linear accelerator (linac) was recently introduced into the market by a major manufacturer. Our institution is one of the early users of this preassembled and preconfigured dual-layer multileaf collimator (MLC), ring-gantry linac — Halcyon™ (1st version). We performed a set of full acceptance testing and commissioning (ATC) measurements for three Halcyon machines and compared the measured data with the standard beam model provided by the manufacturer. The ATC measurements were performed following the guidelines given in different AAPM protocols as well as guidelines provided by the manufacturer. The purpose of the present work was to perform a risk assessment of the ATC process for this new type of linac and investigate whether the results obtained from this analysis could potentially be used as a guideline for improving the design features of this type of linac.

Methods: AAPM's TG100 risk assessment methodology was applied to the ATC process. The acceptance testing process relied heavily on the use of a manufacturer-supplied phantom and the automated analysis of electronic portal imaging device (EPID) images. For the commissioning process, a conventional measurement setup and process (e.g., use of water tank for scanning) was largely used. ATC was performed using guidelines recommended in various AAPM protocols (e.g., TG-106, TG-51) as well as guidelines provided by the manufacturer. Six medical physicists were involved in this study. Process maps, process steps, and failure modes (FMs) were generated for the ATC procedures. Failure modes and effects analysis (FMEA) were performed following the guidelines given in AAPM TG-100 protocol. The top 5 and top 10 highest-ranked FMs were identified for the acceptance and commissioning procedures, respectively. Quality control measures were suggested to mitigate these FMs.

Results: A total of 38 steps and 88 FMs were identified for the entire ATC process. Fourteen steps and 34 FMs arose from acceptance testing. The top 5 FMs that were identified could potentially be mitigated by the manufacturer. For commissioning, a total of 24 steps and 54 potential FMs were identified. The use of separate measurement tools that are not machine-integrated has been identified as a cause for the higher number of steps and FMs generated from the conventional ATC approach. More than half of the quality control measures recommended for both acceptance and commissioning could potentially be incorporated by the manufacturer in the design of the Halcyon machine.

Conclusion: This paper presents the results of FMEA and quality control measures to mitigate the FMs for the ATC process for Halcyon machine. Unique FMs that result from the differences in the ATC guidelines provided by the vendor and current conventional protocols, and the challenges of performing the ATC due to the new linac features and ring-gantry design were highlighted for the first time. The FMs identified in the present work along with the suggested quality control measures, could potentially be used to improve the design features of future ring-gantry type of linacs that are likely to be preassembled, preconfigured, and heavily reliant on automation and image guidance.
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Key words: acceptance testing and commissioning, failure modes and effects analysis (FMEA), new ring-gantry linac, reference dosimetry, TG100, TG-51

1. INTRODUCTION

A new type of linear accelerator (linac), the Halcyon 6 MV-FFF single energy ring-gantry linac, was recently introduced into the market by Varian Medical Systems. (Palo Alto, CA). This new type of linac was introduced to simplify the clinical workflow for image-guided, intensity-modulated radiation therapy. Simplification is achieved in the new linac using automation and integrated imaging. To cater toward high treatment volume and reduced treatment delivery time, the gantry rotation is designed to have a speed of up to 4 RPM. In addition, radiation can be delivered at a fixed high dose rate of 800 MU/min. The use of automation and integrated imaging is also evident in the acceptance testing and commissioning (ATC) process of this new linac. Coupled with the fact that the machine comes preconfigured,* the installation and commissioning time frames for Halcyon have been reduced greatly compared to conventional linacs. The gantry design and use of a beam stopper greatly reduces the shielding design requirement.

The simplified machine design comes with a few tradeoffs. The machine has only one energy. The jaws on conventional linacs have been replaced with a dual-layer 1 cm wide multileaf collimators (MLCs) that are staggered 0.5 cm apart. The field-of-view is limited to a field size of 28 cm × 28 cm. With a 100 cm opening ring-gantry design, the couch rotation is not feasible. There is neither a light field nor an optical distance indicator (ODI) or internal lasers in the gantry bore. With an increasing trend of new linacs being developed in the form of a ring-gantry design (e.g., MRI-linac, PET-linac), users transitioning from conventional c-arm linac (e.g., Trilogy™) to a ring-gantry linac will likely need some time to become familiar with the different design features.

Although this new type of linac comes preconfigured, one of the main responsibilities of the medical physicists is to verify the performance characteristics of this type of linac during the acceptance testing process and to obtain the initial set of reference data during commissioning. The machine characteristics can then be monitored by comparing future quality assurance (QA) and quality control (QC) measurements with this baseline commissioning data. AAPM Task Group 106 recommends not to rely on manufacturer-supplied beam data for commissioning.[1]

Introduction of a new machine with new design features and its associated tradeoffs brings along new ATC techniques and procedures that can appear to be abstract to a clinical physicist with little ATC experience. The pressure to complete the ATC in a timely manner and the need for extensive coordination between different stakeholders can create opportunities for incurring errors and prolonging the ATC process. According to reports by the World Health Organization (WHO)[2] and the IAEA,[3] the rapid adoption of new technologies in a busy clinical setting, lack of clinical staff with experience, and ineffective communication/transfer of essential information are potential contributing factors for incurring errors in the radiation therapy process.

Failure modes and effects analysis (FMEA) has been used to assess the risks of various aspects of ATC including: (a) the use of an electronic portal imaging device (EPID) for the acceptance testing of the c-arm TrueBeam linac,[4] and (b) a comparative study using both conventional procedures and EPID for the acceptance testing of c-arm linacs.[5] The present work uses TG100 recommended methodology for performing risk analysis of the ATC process (a) of a new type of preassembled ring-gantry linac (Varian Halcyon) that relies heavily on automation and EPID for ATC, and (b) for performing ATC that incorporates manufacturer's ATC instructions where some instructions are different from guidance given in conventional protocols recommended by, for example, the AAPM.[1,6,7] Results are presented from the experience gained and data obtained from performing ATC on three Varian Halcyon linacs. This risk assessment serves two purposes: (a) to enable the future ATC of ring-gantry type of linac to be completed in a safe, efficient, and timely manner, and (b) to provide feedback to the manufacturers for the design of image-guided ring-gantry linear accelerators.

2. MATERIALS AND METHODS

2.A. Brief overview of acceptance testing of Halcyon linac

Three Halcyon linacs were evaluated for the present study. Of the three Halcyon linacs commissioned, one was done at an academic medical center and two at two veterinary hospitals. The ATC of the first linac was performed during the month of June 2017. The second Halcyon was commissioned during the month of August 2017 and the third one during October and November of 2017. The three Halcyon linacs are of version 1, that is, with MV imaging capability only and use only one of the MLC layers for beam shaping. KV imaging and beam shaping that use the two layers of MLC are available in subsequent upgrades. The specifications of the machine were tested against the guidelines provided by the manufacturer; tools (algorithms and phantoms) provided by the manufacturer were also used for this purpose. Acceptance testing relies heavily on the machine performance check (MPC) application and its associated DRUM phantom (P/N: P1006190001). Details of the MPC process and algorithm have been evaluated independently[8,9] and provided by the vendor.[10,11] Following the recommendations of the manufacturer, the DRUM phantom was always placed on a stipulated position on the couch and 33 MV images were acquired. The MPC software analyzes these images and verifies that the

*It should be noted that Halcyon is also marketed as "pre-commissioned" with the emphasis on fast clinical deployment. An example of how Halcyon is marketed as pre-commissioned is seen in the following statement found on Varian website: "Halcyon comes pre-commissioned, requires less shielding than traditional systems, and it can fit in a vault as small as 5.9 m (19.68 feet) × 5.539 m (18.17 feet) × 2.743 m (8.99 feet) high. Varian website: https://www.varian.com/oncology/events-resources/centerline/introducing-halcyon-innovative-treatment-platform.

following parameters are within tolerance: radiation isocenter size, MV imager offsets from the projected radiation isocenter, beam uniformity, output and MU variation, accuracy of MLC positioning, and gantry and couch positions. Projections of the fiducial markers on the phantom were analyzed and compared with a predetermined threshold to determine the pass/fail criteria for each of the above parameters. A conventional three-dimensional (3D) Blue Phantom water tank (IBA Dosimetry, Germany) was used to determine the beam quality (i.e., depth of maximum dose and percent dose at 10 cm with electron contamination removed), off axis ratio and beam symmetry. To evaluate the imaging characteristics of the MV imager, the mean value of the dark field image, statistics of the background image and a pixel correction map were automatically verified. The contrast, resolution, and integrated intensity for portal dosimetry were evaluated manually using visual inspection.

2.B. Brief overview of commissioning of Halcyon linac

During commissioning, a subset of the collected data was used to demonstrate a match with the reference beam data/model that was provided by the manufacturer. As a result, setups and measurements were performed according to manufacturer's guidelines whenever applicable. The Blue Phantom water tank, with scanning dimensions of $48 \times 48 \times 48$ cm^3 and equipped with OmniPro-Accept (v. 7.5) software, was used for beam scanning and dosimetric measurements. It should be highlighted that an source-to-surface distance (SSD) of 90 cm was used for all depth dose and profile scans, following the manufacturer's recommendations. As a result, the Mayneord F Factor was applied to obtain the percent depth dose at an SSD of 100 cm to obtain the beam quality following the recommendations of AAPM-TG51 protocol.[6] For depth dose and profile scans, a CC13 ionization chamber (IBA Dosimetry) was used for field sizes larger than 4×4 cm^2 and a Sun Nuclear Edge diode was used for field sizes smaller than 4×4 cm^2. All depth dose scans measured with the ion chamber were shifted by 1.8 mm (i.e., toward the water surface) to correct for the effective point of measurement P_{eff} (i.e., 0.6 * chamber internal radius). Open beam in-phantom field output factors (S_{cp}) were measured for square field sizes ranging from 1×1 cm^2 to 28×28 cm^2 at 95 cm SSD and at a depth of 5 cm. All factors were normalized to the 10×10 cm^2 field data. Open beam, in air output factors (S_c) were collected for square field sizes ranging from 1×1 cm^2 to 28×28 cm^2. Appropriate brass buildup caps were used. S_p values were derived from the S_c and S_{cp} measurements. The measured data were compared to Varian standard Eclipse data (field output factors, PDD, and beam profiles) for the Halcyon unit.

2.C. Process tree and failure modes

FMEA for the ATC process of the Halcyon linacs was conducted following the methodology provided by the AAPM TG 100 report.[12] Six medical physicists were involved in the FMEA study. One medical physicist had experience with performing the ATC for two Halcyon linacs while the remaining had the experience of performing ATC on one linac. One person who had experience with the FMEA tool was an independent observer for our FMEA study. A total of seven discussions and iterations were conducted over a span of 5 months.

A preliminary process tree was prepared by the group and observations for potential failure modes (FMs) were made during the ATC process. One member of the team was responsible for consolidating and updating the process tree and FMs during the ATC process. Further discussions and revisions were conducted until everyone agreed on a final version. Some potential FMs were detected prior to performing the ATC and they were not included in the FM list. Examples of these FMs include a missing audio-visual monitoring system, missing emergency stop buttons, failure of door interlock, inconsistent license features compared to what was ordered, and malfunction of buttons and icons attached to the linac. For the ATC process, FMs were generated from six key pathways, namely communication/coordination, software-related issues, hardware-related issues, measurement setup, data acquisition, and data analysis.

2.D. Scoring and risk prioritization

Each physicist assigned three scores for the probability of occurrence (O), the severity (S), and the probability that a given FM is not detected (D) on a scale from 1 to 10 with 1 being a failure with least severity, least likely to occur and most likely to be detected, respectively. S was scored in terms of harm to patient as well as the impact on the delay of the ATC process. The longer the delay, the higher the value of S. The risk priority number (RPN), which is used to rank the hazard of the FMs, was then obtained by multiplying these three parameters. Subsequent discussions and iterations about the scoring and risk prioritization were conducted with the independent observer's moderation until a final version was agreed upon. In these iterations, consistency in the relative impact of the occurrence, severity, and detectability among the ATC processes were emphasized.

3. RESULTS

3.A. Potential FMs during acceptance testing and O, S, D, and RPN values

Figure 1 shows the process map for the ATC of the Halcyon machine. To facilitate the discussion, the process map is divided into six segments from Figs. 1(a)–1(f) where each of the segments focuses on different aspects of the acceptance testing [Figs. 1(a) and 1(b)] and commissioning process [Figs. 1(c) to 1(f)]. Figure 1(a) focuses on acceptance of the Halcyon machine involving the installation of machine and software, verification with MPC phantom, and automated

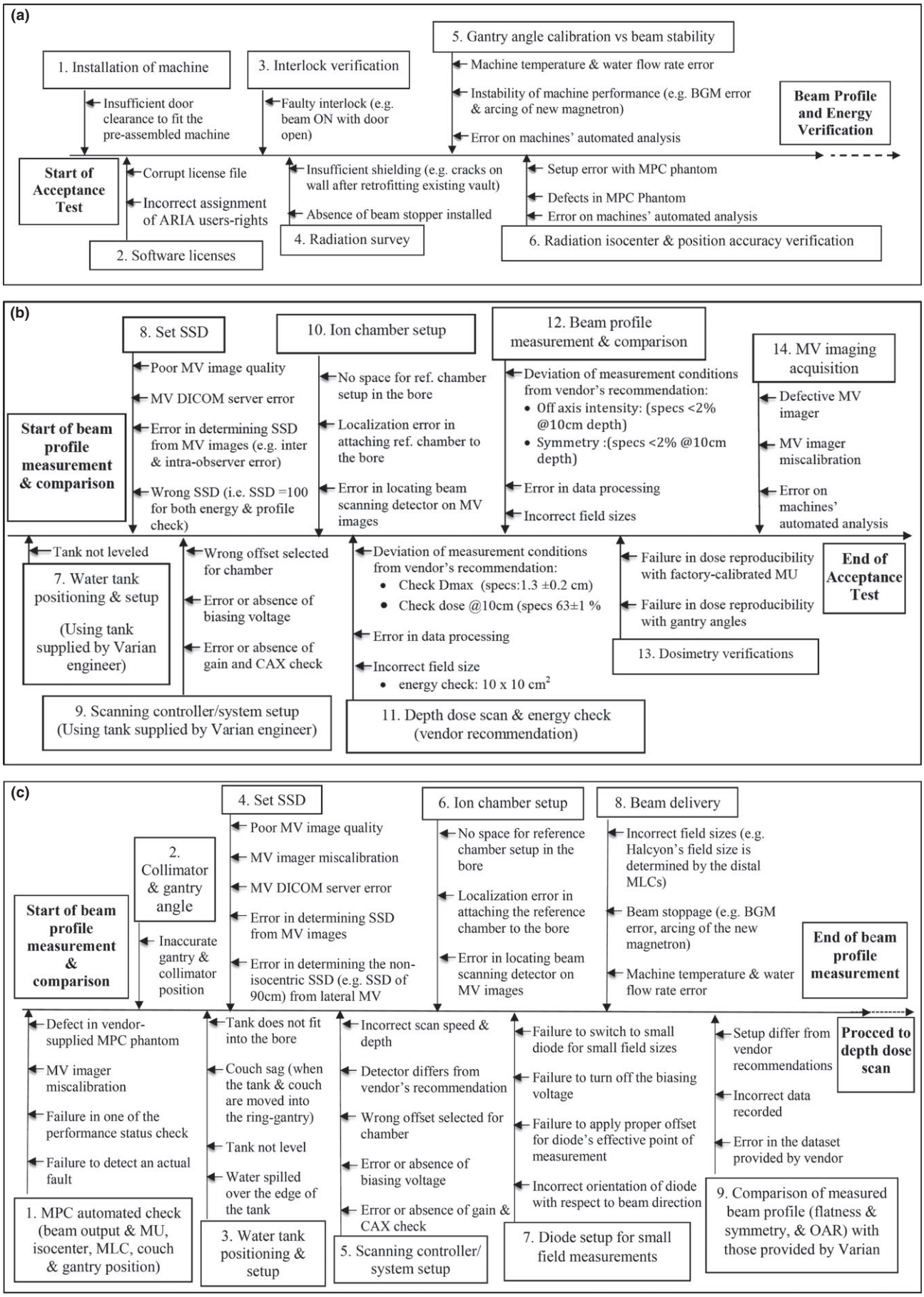
software analysis; Fig. 1(b) on measurements of beam profile, beam energy and various dosimetric parameters and MV imager checks, Fig. 1(c) on measurements of beam profiles for commissioning, Fig. 1(d) on measurements of percent depth dose, beam quality, and field output factors, Fig. 1(e) on measurements of reference dosimetry and verification of beam model, and Fig. 1(f) on Rapid Arc commissioning with MLC and gantry rotation verification. A total of 38 steps and 88 potential FMs were identified for the entire process map.

Six steps and twelve FMs were identified for the first phase of the acceptance testing subprocess [Fig. 1(a)]. An example of a FM for this segment of the process map [Fig. 1(a)] is insufficient door clearance to fit the preassembled linac [Fig. 1(a); step no.1: "Installation of the machine"]. This FM occurred because the movers decided to use a robust trolley and wooden pallet to support and move the entire preassembled machine. The height of the door through which the machine is supposed to be brought inside the vault was shorter than the combined height of the machine and trolley plus the wooden pallet. As a result, the machine could not be moved past the door entrance [see Fig. 2(a)]. The machine had to be brought back to the loading bay (from the vault) while effort was made to search for an alternative trolley/moving mechanism. Since this event occurred during a weekend (typical for machine installation in order to minimize disruptions to clinical operations), there was about 8 h of delay in locating the logistics personnel and a suitable trolley, unloading and loading the linac, and moving the linac back to the vault. Unlike the c-arm linacs, whereby the components of the linac are shipped individually and assembled inside the treatment vault, this insufficient door clearance FM will potentially occur to this new type of preassembled machines if prior considerations are not given to the overall clearance issue past the door inside the vault. The under-estimation of door clearance was due to inadequate communication/sharing of architectural drawings and other information between the hospital's logistical support unit, the transportation company (i.e., the movers), and the machine manufacturer. Therefore, an effective quality control to overcome this FM is to establish communication among the different stakeholders, so that the design consideration of the door height is appropriately taken into considerations prior to moving the linac into the vault.

Three FMs were identified for the step "gantry angle calibration vs beam stability" [Fig. 1(a); step no. 5]. These FMs are: machine temperature and water flow rate error, instability of machine performance (e.g., BGM error and arcing of new magnetron), and error on machines' automated analysis. The FM "machine temperature and water flow rate error" occurred at one of our installation sites because the chilled water supply for the Halcyon machine was shared with that for an existing adjacent linac [TrueBeam™, see Fig. 2(b)]. Sharing the supply of chilled water led to overheating of the adjacent TrueBeam™ that is in clinical operation. Upon discussion with the vendor as well as the facility management team, it was established that the required supply of chilled water between Halcyon and TrueBeam is different from the supply of chilled water between the previous linac that had occupied the vault and the TrueBeam. As a result, rebalancing of the chilled water supply between the Halcyon linac and the adjacent TrueBeam linac was required. A delay in the acceptance occurred due to plumbing work required to modify the supply of chilled water to the two machines. Regarding the instability of machine performance (due to the arcing of new magnetron), this occurred at one of our installation sites. The potential FM, "error on machines" automated analysis,' is an example of a FM that we envisioned could happen but did not actually occur during our ATC. Figure 1(a) also shows that two FMs, corrupt license file and incorrect assignment of ARIA users-rights, were identified for the step "Software licenses". With Varian's new log in method, a physicist will not be able to log on to the machine using a generic username and password, for example, "Service" and "Service." At one of our installation sites, it took 2 days to acquire a username and password. This was an inconvenience since we had to have an installer or a service engineer available to log us in. While we encountered the FM of "incorrect assignment of ARIA users-rights," we did not encounter the other FM — "corrupt license file" during our installations. This is one of those examples where the FM was generated based on the previous ATC experience of other linacs, that is, the FM was generated based on what the team envisioned could possibly happen. Figure 1(a) shows the FMs resulting from the other three steps. These are interlock verification, radiation survey, and radiation isocenter and position accuracy verification.

Figure 1(b) shows the segment of the process map for the second stage of acceptance, that is, "measurements of beam profile, beam energy and various dosimetric parameters and MV imager checks". Eight steps (step nos. 7–14) and twenty-two potential FMs were identified during this second stage of

FIG. 1. (a) Segment 1 of the process map for the acceptance testing of Halcyon. The items in the boxes numbered 1–6 indicate the various steps involved for this part of the acceptance testing process; the failure modes (FMs) for each of the steps are identified by the arrows that correspond to each step. (b) Segment 2 of the process map for the acceptance of Halcyon — measurements of beam profile, beam energy, and various dosimetric parameters and MV imager checks. The items in the boxes numbered 7–14 indicate the various steps involved for this part of the acceptance testing process; the FMs for each of the steps are identified by the arrows that correspond to each step. (c) Process map for the beam profile measurement during the commissioning of Halcyon. The items in the boxes numbered 1–9 indicate the various steps involved for this part of the commissioning process; the FMs for each of the steps are identified by the arrows that correspond to each step. (d) Process map for depth dose scan, beam quality, and field output factor determination. The items in the boxes numbered 10–15 indicate the various steps involved for this part of the commissioning process; the FMs for each of the steps are identified by the arrows that correspond to each step. (e) Process map for absolute dosimetry calibration and verification of Varian Eclipse beam model. The items in the boxes numbered 16–19 indicate the various steps involved for this part of the commissioning process; the FMs for each of the steps are identified by the arrows that correspond to each step. (f) Process map for RapidArc commissioning with MLC and gantry rotation verification. The items in the boxes numbered 20–24 indicate the various steps involved for this part of the commissioning process; the FMs for each of the steps are identified by the arrows that correspond to each step.



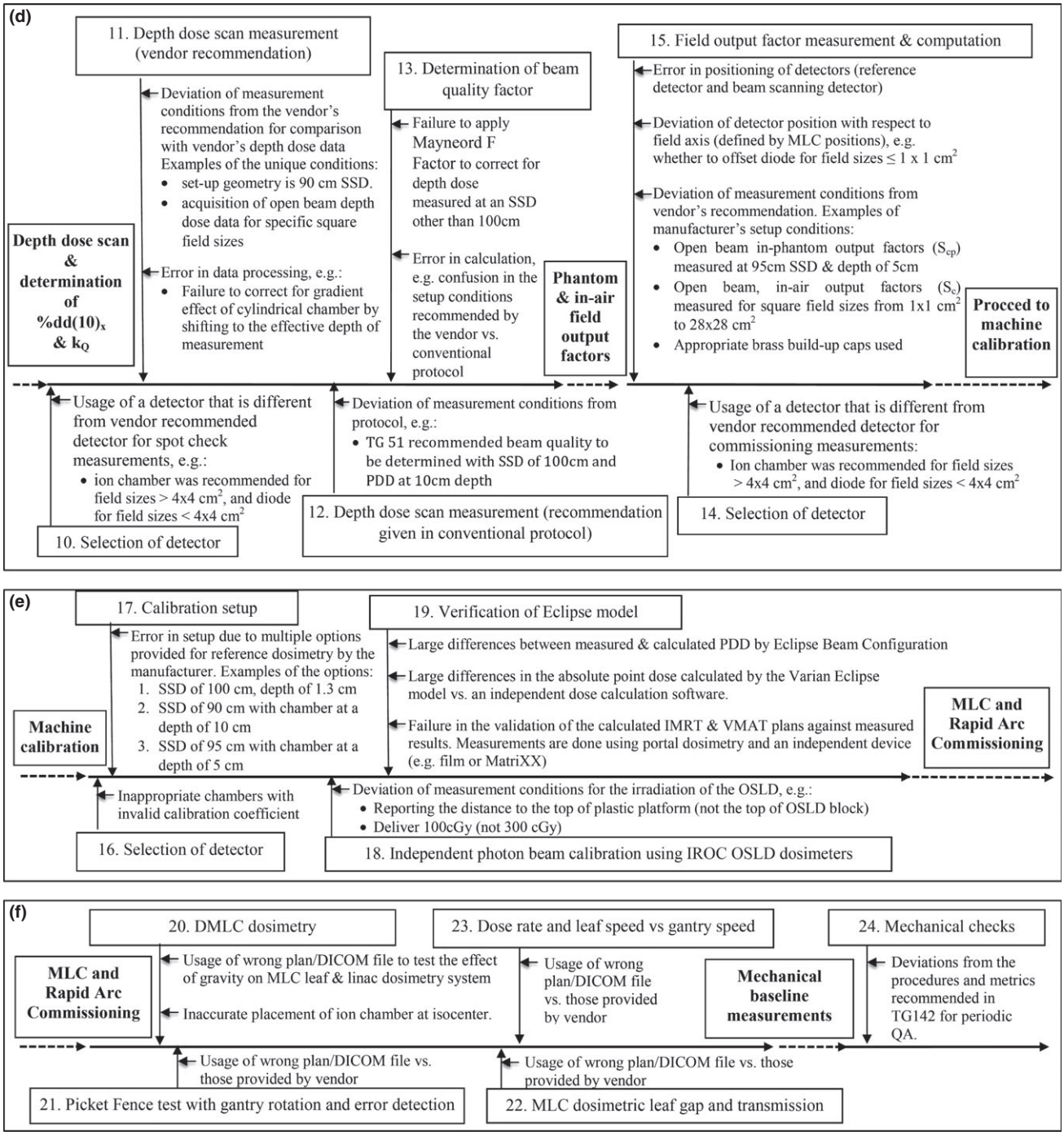


FIG. 1. Continued.

acceptance testing. One of the FMs generated for the step "beam profile measurement and comparison" is incorrect field sizes. According to the guidelines from the manufacturer, beam profiles for the standard dataset are to be measured for a field size of 28 × 28 cm^2. Setting up of an "incorrect field size" by the user could potentially occur because of the following reason: the software is designed such that in the service mode the field size display does not provide feedback of the actual position reading of the multileaves if the user forgets to hit the "Go To" option (see Fig. 3). The software allows the user to continue with beam delivery with the incorrect field size. In other words, in service mode the display does not make any distinction between the field size that was entered by the user vs the actual field size set by the physical locations of the multileaves when the user forgets to hit the "Go To" option. This is in contrast to the display of TrueBeam™ linac where distinction is made between the field sizes entered (i.e., "programmed") and the actual field size defined by the updated physical location of the jaws (see Fig. 4). Since ATC measurements are done in

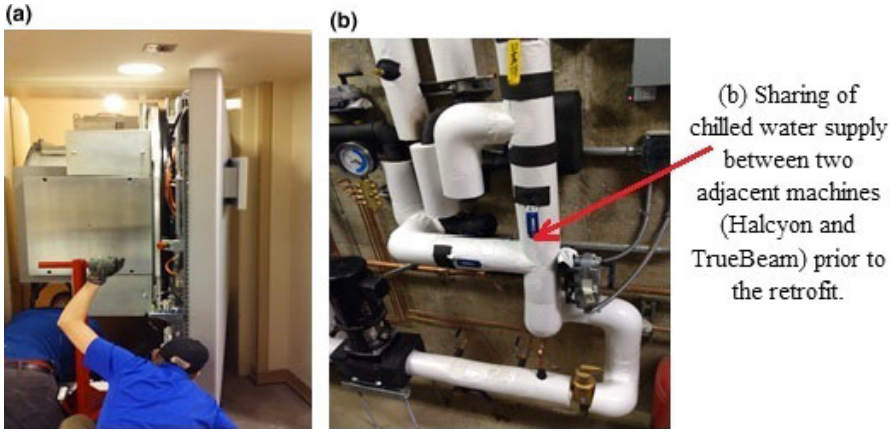


FIG. 2. Examples of FMs encountered — (a) insufficient door clearance to fit the preassembled machine due to extra height incurred by the trolley and wooden pallets; (b) machine temperature and water flow rate error, that is, failure to maintain a separate water supply to cool an adjacent linac leads to overheating and inconsistent machine operation. [Color figure can be viewed at wileyonlinelibrary.com]

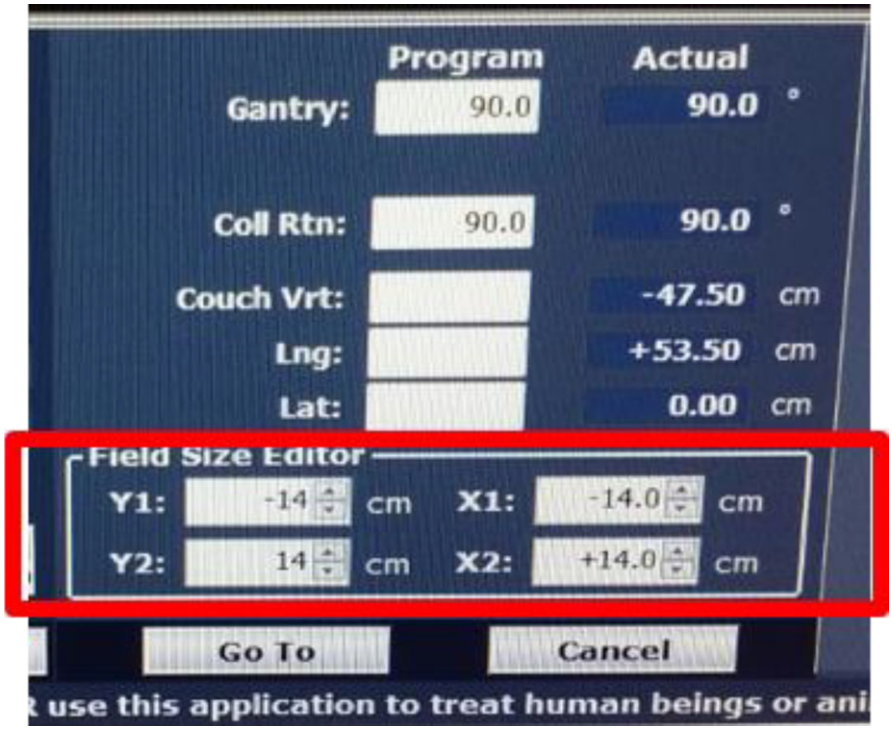


FIG. 3. Display of field sizes in the service mode in the Halcyon™ linac. There is no distinction between the field size that was entered vs the actual field size defined by the physical locations of the multileaves. The field size will not be updated if the user forgets to hit the "Go To" option. A potential FM is the "incorrect field sizes" used during the characterization of the linac performance. [Color figure can be viewed at wileyonlinelibrary.com]

the service mode, an error occurred when we entered the desired field size but we did not hit "Go To" button to update the MLC positions. As a result, beam profiles were initially taken for one incorrect field size. A similar error occurred when measurements were made for field output factors. Overall, for the entire acceptance testing process [Figs. 1(a) and 1(b)], a total of 14 steps and 34 FMs were identified.

Table I lists the top 5 FMs and their respective potential causes of failure, and effects on accomplishing the goals of the corresponding process step. Average values of the scores for O, S, D, and the RPN were obtained following the guidelines given in AAPM TG100 protocol. RPN values for the top 5 FMs ranged from 44.7 to 85.5 and the severity values ranged from 2.5 to 5.8. The top FM corresponds to the "failure in dose reproducibility with factory-calibrated MU" with an associated RPN score of 85.5 and severity of score of 5.8.

3.B. Potential FMs during commissioning and O, S, D, and RPN values

The process map for the commissioning segments consists of the following key stages: measurements of beam profiles

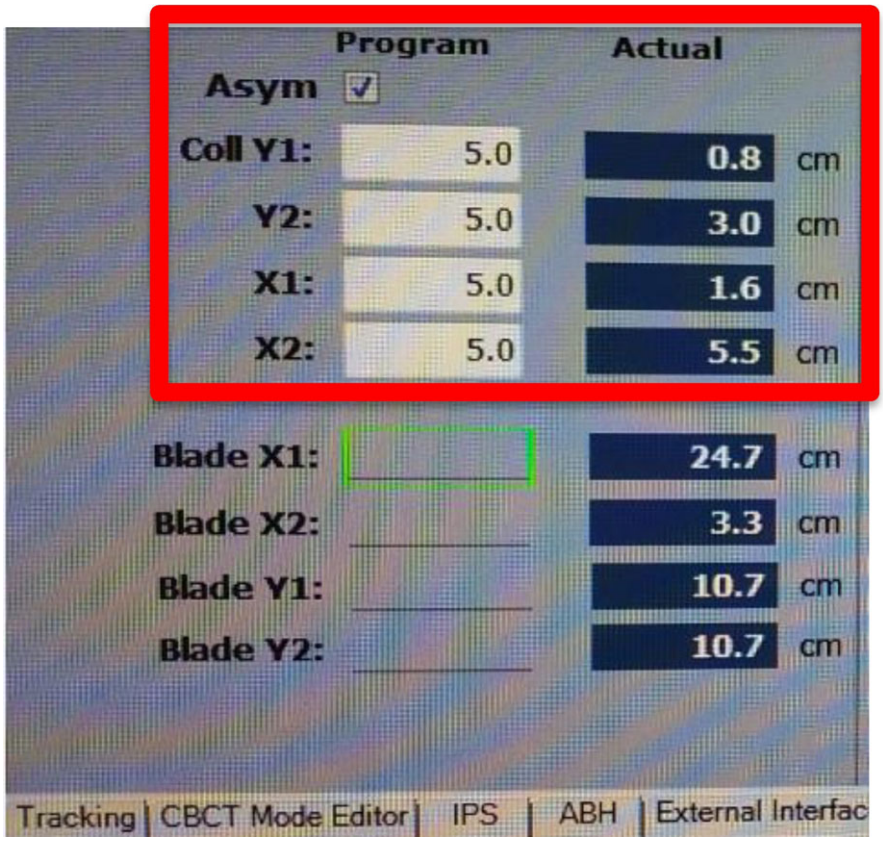


FIG. 4. Distinction between the field size that is entered (i.e., "programmed") and the actual field size defined by the physical location of the jaws is indicated in the service-mode display of TrueBeam ™ linac. [Color figure can be viewed at wileyonlinelibrary.com]

[Fig. 1(c)], measurements of percent depth dose, beam quality and field output factors [Fig. 1(d)], measurements of reference dosimetry and verification of beam model [Fig. 1(e)], and RapidArc commissioning with MLC and gantry rotation verifications [Fig. 1(f)].

A total of nine steps and thirty-two potential FMs were identified for the process step segment "measurements of beam profile" [see Fig. 1(c)]. The MPC software was used to verify the accuracy of the gantry position prior to setting up the water tank. An example of a potential FM for the step "water tank positioning and setup" is "tank does not fit into the bore". This potential FM could occur despite ensuring that the dimension of the water tank was smaller than the gantry bore; this is because the user could potentially fail to account for the protrusion of the water tank controller beyond the tank [Fig. 5(a)]. A quality control measure for this FM is for the user to rotate the tank such that the protruded controller lies parallel to the couch orientation [Fig. 5(b)]. Care will need to be exercised to note down this orientation such that all measurements taken with this orientation are appropriately labeled.

Four steps and six potential FMs were identified (step nos. 10–13) for beam energy verification in the process segment "measurements of percent depth dose, beam quality, and field output factors" [Fig. 1(d)]. A potential FM for the step "field output factor measurements and computation" is "error in positioning of detectors (reference detector and beam scanning detectors)". This potential FM could occur because of the following reasons: since there are no light fields, no optical distance indicators (ODIs) and no internal lasers in the gantry bore, setting up of the beam scanning detector is accomplished with the water tank positioned outside the gantry bore prior to being driven inside the gantry via the couch. The weight of the water tank can cause the couch to sag, resulting in an error in the alignment of the detector axis with the beam axis. The positioning of the reference detector in the bore of the ring-gantry is challenging given the absence of the light field, ODI, and internal lasers. The positions of the beam scanning and reference detectors can only be verified by acquiring an MV image of the detectors. If these two detectors are not perfectly aligned during setup, many measurements need to be taken to be able to align these two detectors perfectly before any dosimetric measurements can be made (see Fig. 6). This process could be time-consuming. In addition, with a rotated water tank, it was difficult to attach a flexible arm to the tank for the purpose of holding the reference detector. The reference detector was attached to the interior of the gantry cover. It is again challenging given the absence of the light field. In addition, due to the curvature of the gantry bore, there is a need for extra caution in attaching an elongated detector onto the curved surface without the risk of breaking the detector.

A total of twenty-four steps and fifty-four potential FMs were identified for commissioning. The top ten FMs

TABLE I. Top five failure modes (FMs) for the segments 1 (Fig. 1a) and 2 (Fig. 1b) of the process map. Also given are the potential FMs, potential causes of failure, and potential effects on the desirable optimal outcome of each process step, and values of O, S, D, and risk priority number (RPN) obtained following the guidelines recommended in TG100 protocol.

Rank	Steps in process maps for acceptance segments	Potential failure modes	Potential causes of failure	Potential effects of failure	O	S	D	RPN
1	13. Dosimetry verifications	Failure in dose reproducibility with factory-calibrated MU	1. Human error (lack of awareness) 2. Human error (insufficient experience in physics) 3. Unclear instructions; incomplete guidance from vendor	Patient safety; Time delay in acceptance	4.3	5.8	3.5	85.5
2	13. Dosimetry verifications	Failure in dose reproducibility with gantry angles	Machine-related error	Patient safety; Time delay in acceptance	3.8	4.3	3.5	55.8
3	5. Gantry angle calibration vs beam stability	Machine temperature and water flow rate error	Incorrect transfer of essential information leading to missing details in anticipation of water flow requirements	Time delay in acceptance	6.3	3.5	2.3	49.2
4	10. Ion chamber setup	Error in locating beam scanning detector on MV images	Human error (lack of awareness); Inexperience physics staff; Machine limitation	Time delay in acceptance	5.8	2.5	3.3	46.7
5	8. Set SSD	Error in determining SSD from MV images (e.g., inter and intraobserver error)	1. Variation of image contrast affecting precise determination of the edges of the water level 2. Inter- and intraobserver variations (experience and judgment)	Time delay in acceptance	5.5	2.5	3.3	44.7

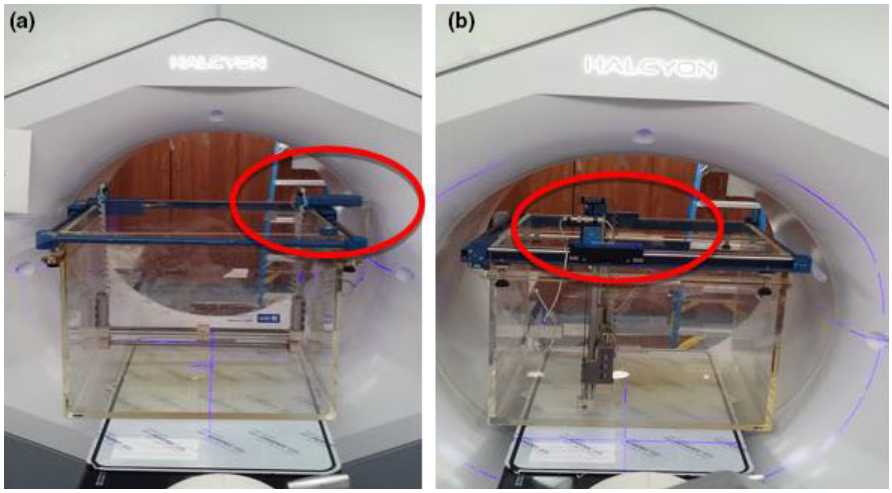


FIG. 5. Potential FM "tank does not fit into the bore" for the step of "water tank positioning and setup" during the beam profile measurements: (a) water tank does not fit into the treatment bore due to the protrusion of the controller beyond the tank; (b) a quality control measure for this FM is to rotate the tank such that the controller axis is parallel to the couch orientation. Care will need to be exercised to note down this orientation such that all measurements taken with this orientation are appropriately labeled. [Color figure can be viewed at wileyonlinelibrary.com]

for the commissioning segments of the entire process map are given in Table II. RPN values for the top ten FMs ranged from 41 to 95 and the severity values ranged from 3 to 7.

4. DISCUSSION

For the acceptance part of the entire ATC process, the most hazardous FM was found to be the "failure in dose

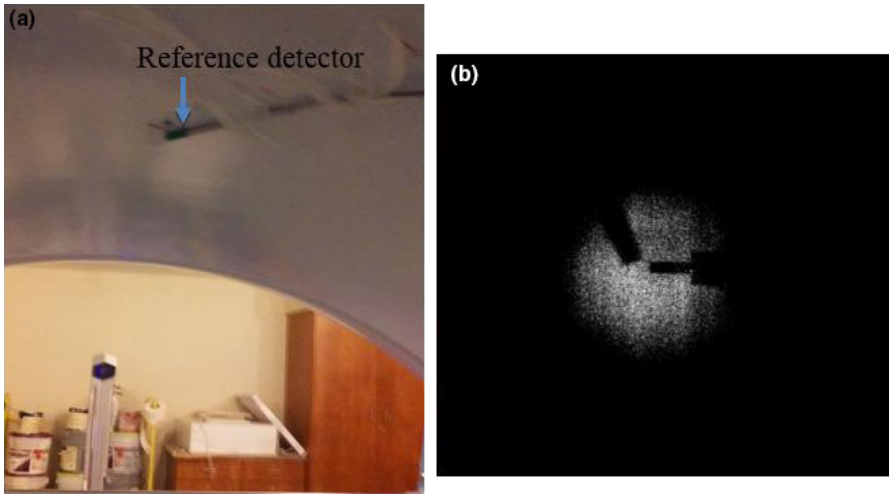


FIG. 6. Potential FM "error in positioning of detectors (reference field and scanning detectors)" can result in incorrect signal measurement during the step "field output factor measurement and computation". (a) The absence of a light field, ODI and laser in the bore to guide the placement of the reference detector; (b) the position of the detectors would have to be verified with MV image acquisition for each subsequent adjustment of either of the two detectors. [Color figure can be viewed at wileyonlinelibrary.com]

reproducibility with factory-calibrated MU" for the step "dosimetry verifications" with an associated RPN score of 85.5 and severity score of 5.8. This FM could occur because of human error in interpreting instructions provided by the manufacturer for the geometry for MU calibration vs those that are used for beam calibration that is, clinical reference dosimetry. Three options were included for MU calibration in the vendor documents. These are: (a) SSD of 100 cm; depth of 1.3 cm; (b) SSD of 90 cm; depth of 10 cm, and (c) SSD of 95 cm; depth of 5 cm. Because option 1 is not included in any of the most recently accepted clinical reference dosimetry protocols [i.e., AAPM TG51 protocol[6] and IAEA TRS 398[13] Code of Practice (CoP)] and option 3 not included in the AAPM TG51 protocol but included in the TRS398 CoP, the potential exists for the clinical physicist to incorrectly interpret the instructions for "MU calibration" as referring to instructions for performing beam calibration, that is, clinical reference dosimetry. Given that this FM could have a significant effect on patient safety, it is associated with the highest severity score of 5.8.

The second highest-ranked FM for the acceptance process is "failure in dose reproducibility with gantry angles" with an associated RPN score of 55.8. Since this linac is preconfigured prior to installation, this machine-related FM could potentially be detected at the manufacturing facility. Since this FM could also have an effect on patient safety, this FM resulted in the second highest severity score of 4.3.

The third highest-ranked FM for acceptance is the "machine temperature and water flow rate error", that is, failure to meet temperature and water flow rate requirements, resulting in a nonoperating condition of the machine due to a high operating temperature. This FM was ranked high due to our own experience during the acceptance stage. There was a delay of 4 days while plumbing work was performed to provide an isolated supply of chilled water to the two adjacent linacs. The probability of encountering this FM is high in situations where an older treatment vault is renovated to accommodate the new linac given that the new linac could have different flow rate and temperature requirements for successful operation. The cause of this FM could be a result of either incorrect transfer of essential information to the facility manager or an oversight of machine specifications. As a quality control measure, during preinstallation meetings the manufacturer could communicate the differences in the temperature and water flow requirements of the machines in consideration to the physicist and facility manager, especially if the new linac is to be installed adjacent to an existing one with the provision that both linacs will use the same water line. Armed with this information, the facilities personnel can then prepare the water line requirements appropriately before the installation begins.

The fourth ranking FM relates to the "error in locating beam scanning detector on MV images". The sensitive volume of the air-filled chamber has a low contrast on MV images. Depending on the experience of the user and the setting of the window intensity level, errors could incur in determining the edges and hence the position of the air-filled chamber. As a quality control measure, having multiple observers could provide a consensus observation of the correct ion chamber location on the MV images. Additionally, the availability of KV imaging could improve the contrast of the chamber. Chamber manufacturers could also provide radio-opaque caps to better visualize the cavity position in MV/kV images.

The fifth ranking FM for the acceptance process is "error in determining SSD from MV images". Similar to the fourth ranking FM, determining the accurate water surface level of the water tank based on MV images is challenging. Different window-level settings affect accurate determination of the boundary between water and air. Having multiple observers could provide a consensus reading. A laser inside the gantry bore could be incorporated in the linac design.

TABLE II. Top ten failure modes (FMs) for the segments Figs. 1(c)–1(f) of the process map. Also given are the potential FMs, potential causes of failure, and potential effects on the desirable optimal outcome of each process step and values of O, S, D, and risk priority number (RPN) obtained following the guidelines recommended in the TG100 protocol.

Rank	Steps in process maps for commissioning segments	Potential failure modes	Potential causes of failure	Potential effects of failure	O	S	D	RPN
1	4. Set SSD	Error in determining the nonisocentric SSD (e.g., SSD of 90 cm) from lateral MV images	1. Hardware limitation, that is, the source and imager is only orthogonal to the water level at isocentric distance 2. Scanning mechanism of tank blocks the view of chamber in lateral MV images	Profile measured differs from vendor recommended data. More manpower required for reaching consensus on data. Time delay in ATC	6.0	4.4	3.6	95.0
2	4. Set SSD	Error in determining SSD from MV images	1. Variation of image contrast affects the precise determination of the edges of the water level 2. Inter- and intraobserver variations (experience and judgment)	Profile measured differs from vendor recommended data. More manpower required for reaching consensus on data. Time delay in ATC.	6.2	4.0	3.8	94.2
3	17. Calibration setup	Error in setup due to multiple options provided for reference dosimetry by the manufacturer Examples of the options: 1. SSD of 100 cm, depth of 1.3 cm 2. SSD of 90 cm. depth of 10 cm 3. SSD of 95 cm, depth of 5 cm	1. Human error (lack of awareness) 2. Human error (insufficient experience in physics) 3. Unclear instructions; incomplete guidance from the vendor	Patient safety; time delay in ATC process	2.6	7.0	3.8	69.2
4	8. Beam delivery	Incorrect field sizes	Human error (oversight); inherent machine design limitation (allowing machine to turn on while MLC is not in correct position)	Profiles measured differ from vendor recommended data. Time delay in ATC process.	4.0	3.4	4.4	59.8
5	6. Ion chamber setup	Error in locating beam scanning detector on MV images	Resolution of MV images, intra- and interobserver variations	Profile measured differs from vendor recommended data. Time delay in ATC process	5.4	3.2	3.2	55.3
6	1. MPC automated check	Failure to detect an actual fault	Error in the automated calibration procedure	Systemic error that could affect patient care if undetected by other independent checks	1.8	6.0	5.0	54.0
7	4. Set SSD	Poor MV image quality	Machine imager limitation	Profile measured differs from vendor recommended data. More manpower required for reaching consensus on data. Time delay in ATC.	4.6	3.4	3.2	50.0
8	8. Beam delivery	Machine temperature and water flow rate error	Unclear instructions/ incomplete information from the vendor regarding the need for isolated supply of chilled water to both adjacent machines.	Time delay in ATC	4.2	4.0	2.8	47.0
9	2. Collimator and gantry angle	Inaccurate gantry and collimator position	1. Lack of direct sight of the gantry position on the TV monitor; 2. Unfamiliar with the whereabouts of the display for collimator or gantry position on the new treatment console	Profile measured differs from vendor recommended data.	3.4	4.0	3.4	46.2

TABLE II. Continued.

Rank	Steps in process maps for commissioning segments	Potential failure modes	Potential causes of failure	Potential effects of failure	O	S	D	RPN
10	15. Field output factor measurement and computation	Deviation of detector position with respect to field axis (defined by MLC positions), for example, whether to offset diode for field size $\leq 1 \times 1$ cm^2	1. Ambiguous instructions; incomplete information from vendor 2. Human error (oversight; insufficient training in medical physics)	Profiles measured differ from vendor recommended data. Time delay in ATC	3.6	3.0	3.8	41.0

One of the FMs outside of the top five ranked FMs is related to the instability of the machine caused by the presence of arcing in the magnetron that gradually reduces over time. As a quality control measure, a well-tested magnetron that shows absence of arcing could be installed in the linac prior to shipping the linac to the user. Another FM for acceptance is related to insufficient door clearance to fit the preassembled linac. This FM and the associate quality control measures have been discussed earlier.

Overall, the FMs observed during the acceptance testing process are closely related to machine issues, and the effective communication of necessary information among the different stakeholders involved in the acceptance testing of the linac. The manufacturer, rather than the user, will have better control in the management of some of the identified FMs.

For the commissioning process, the top two FMs are: error in determining the nonisocentric SSD (e.g., SSD of 90 cm) from lateral MV images (RPN = 95), and error in determining SSD from MV images (RPN = 94.2), both occurred during the step of setting the SSD. Both FMs have the highest occurrence scores of 6 and 6.2, respectively. The high occurrence score is associated with the frequent encounters of difficulty in setting up the SSD in the absence of a light field, ODI, and laser in the gantry bore. Good quality control measures to address these two FMs are: (a) an emphasis for the physicist to pay very close attention in setting up the SSD for all measurements; (b) the second is for the manufacturers to improve the future design (e.g., incorporate an internal laser in the bore) for such ring-gantry type linacs.

The third ranking FM (RPN = 69.2) in the commissioning stage is similar to the top FM encountered during the acceptance testing process (i.e., error in setup due to multiple options provided for reference dosimetry by the manufacturer), except that the RPN values and the ranking were lower for commissioning stage compared to their respective values obtained during the acceptance process. The lower RPN values could be explained by the fact that the perceived probability of making a similar error during commissioning is lower after the initial encounter of the same FM during acceptance, unless there are perceived differences between the acceptance and commissioning process. As an example, there can be a change in the professionals involved between the two processes.

The fourth ranking FM (RPN = 59.8) is related to "incorrect field sizes" during beam delivery. This FM is similar to the FM encountered during acceptance testing (Fig. 3). It was observed that in service mode, the field size display does not provide feedback of the "actual" multileaves position readings. For the TrueBeam™ linacs, the computer displays show both "target" and "actual" field sizes (Fig. 4). As a quality control measure, feedback was given to the vendor about this issue so that the correct displays of field sizes can be incorporated in future upgrades of the linac.

The fifth ranking FM (RPN = 55.3) relates to the "error in locating beam scanning detector on MV images". The sensitive volume of the air-filled chamber has a low contrast on MV images. Depending on the user's experience and the setting of the window and level, errors could occur in determining the edges and hence position of the air-filled chamber. As part of a quality control measure, having multiple observers correctly locate the beam scanning detector could provide a consensus observation of the scanning chamber on the MV images. The availability of KV imaging could improve the contrast of the chamber. Chamber manufacturers could also provide radio-opaque caps to better visualize the cavity position in MV/kV images.

The sixth ranking FM relates to the "failure to detect an actual fault" for the step "MPC automated machine performance check". Since this error is inherent in the automated software analysis, it is not easy to detect this by users who do not have access to the algorithms and verifications that were being performed on the software (by the manufacturer). As a result, this FM has the highest score for the probability of being undetected (D = 5). A quality control measure could be performance of independent checks with alternate phantoms and software for the same task analyzed by the automated software. As an example of such an independent check, a star-shot test could be performed using a film to provide an alternate assessment for the automated radiation isocenter verification via EPID images. The manufacturer could release the details of the algorithms as well as the test results performed for these algorithms.

The seventh ranking FM is "poor MV image quality" encountered during the setting of SSD. The quality of MV EPID images is inherently poorer than the images acquired with kV x rays. Many factors contribute to the poor quality of the EPID images and they include low contrast due to the relatively small differences in electron density between air and water, a low detective quantum efficiency (DQE) of the

receptors as well as additional noise from the receptors. The perception of the image quality and hence as a tool to accurately determine the SSD could also be affected by the experience of the observer.[14–16] The availability of kV imaging in the subsequent version of the linac will help to mitigate and possibly eliminate this FM.

The eighth ranking FM is similar to the third highest-ranked FM for the acceptance testing process that is, "machine temperature and water flow rate error", except that the RPN value is lower for the commissioning process. The lower RPN is due to the assumption that most of the issues associated with this FM have been addressed during the acceptance process. From our experience, some monitoring and minor adjustments were still required during commissioning after the plumbing work was done during the acceptance process.

The ninth ranking FM is associated with an "inaccurate gantry and collimator position". Unlike the c-arm linacs, the gantry of the bore-type linac is hidden behind a protective cover that does not allow direct sight of the gantry via the TV monitoring system. In addition, with the new treatment console layout (i.e., entirely different from Varian Trilogy or 2300 EX series), there is a tendency for users to overlook the position of the gantry prior to beam delivery with the potential for a gross error. Unless the design of the gantry is changed, a quality control measure will be for the users to pay closer attention to the gantry readout prior to beam delivery.

The tenth ranking FM relates to the deviation of the field detector position with respect to the beam axis defined by the MLC positions. This FM becomes important for measurements of field output factors for field sizes $\leq 1 \times 1$ cm^2. Due to the 1 cm width of the leaves, when a 1×1 cm^2 field size is set to measure field output factors using a diode, the aperture had to be offset by 0.5 cm from the center of the collimator. As a result, the diode used for measurements was also shifted by 0.5 cm. However, in the standard guidelines provided by the manufacturer, the offset was not required. This is due to the fact that the linac used by the manufacturer for measurements was able to generate field sizes using both layers of MLC vs ours, which uses only a single layer of MLC for beam shaping. This was not clearly emphasized in the initial guidelines that were provided by the manufacturer and this was only verified in subsequent correspondence during commissioning.

It should be noted that the acceptance testing of the Halcyon machines was done by using water tanks provided by the manufacturer whereas the commissioning measurements were done by using an IBA Blue Phantom water tank provided by the user. A comparison of FMs for similar steps between both ATC processes shows that fewer FMs are involved in the acceptance testing process. This is because the use of a vendor-supplied water tank (e.g., a two-dimensional water tank) and scanning instrument (e.g., an ion chamber profiler) helped to eliminate some of the FMs associated with the compatibility or lack thereof of water tanks provided by the user.

The use of conventional techniques with tools that are not an integral part of the linac increases the number of steps as well as the probability of occurrence of a FM. As an example, for output constancy verification, using the automated MPC check [step no. 1 in Fig. 1(b)] would involve four FMs. However, output measurement using a water tank setup would involve step nos. 3–7 and 14–15. This generates more than three times the FMs compared to those that arise from the use of an automated MPC check. The increase in FMs is partly due to the new design features of the linac (e.g., absence of a light field and internal laser, bore size limitation etc.) that makes it a challenging task to use equipment such as 3D water tanks for various measurements. This observation agrees well with other studies reported in the literature that demonstrate that automating the ATC process and using standard beam data reduces the probability of occurrence of errors.[17,18] A comparison of using manufacturer-supplied phantom and automation (with EPID) vs conventional techniques with tools that are not an integral part of the linac has shown that use of manufacturer-supplied phantoms and automation reduces the number of FMs by slightly more than half, from 556 FMs to 255 FMs, for a c-arm linac.[5]

In the conventional approach of measurements of output in a c-arm linac, a reference detector is typically placed between the linac head and a water tank. However, due to the space limitation of the ring-gantry linac, the reference detector could not be positioned on the water tank and it was instead attached to the bore cover with a tape (Fig. 6). A potential FM is the change in the measured reference signal as a result of the chamber not positioned correctly on the bore or the chamber falling off from the cover when it is attached to the cover using tape. In contrast, the use of MPC with MV imaging for output check eliminates the issues of attaching the reference chamber on the cover with a tape. This is an example of machine-related FMs that are specific to the ring-gantry design. These FMs were not identified in previous studies conducted on c-arm linacs.[4,5,18] A possible quality control measure for this machine-related FM is for the manufacturer to mark an approximate 5×5 cm^2, and 10×10 cm^2 field on the bore cover.

One benefit of using EPID and automation for ATC is the potential of completing the ATC in a rapid and efficient manner. From our experience, we observed that since both EPID and its associated software are integrated with the linac, the need for third-party equipment is greatly reduced. This would reduce the time for ATC and probability of occurrence of errors associated with setup, calibration, and acquisition of data using other equipment. However, we have not quantified the amount of time saved with the present approach of ATC using a hybrid of conventional and automated analysis. This will be a part of our future work. In addition, although the ATC was performed at three different sites, this is a single institutional risk analysis of the ATC with a new ring-gantry linac. It would be interesting to compare both our risk analysis as well the time saved in the ATC process over a multi-institutional study.

The present work demonstrates that ATC of the Halcyon machine requires substantial efforts by the physics team. Because many of the identified potential FMs could

jeopardize patient safety and substantial dosimetric and safety knowledge is gained by going through the commissioning measurements, it is strongly recommended that the physicists should not blindly assume that the machine is "pre-commissioned" and undertake systematic commissioning measurements or rigorous independent spot check measurements before using the machine clinically.

The current risk assessment examines the ATC process performed using a combination of conventional equipment and setups, coupled with vendor-provided tools (e.g., EPID, automated software, and phantoms etc.). Although there are many studies demonstrating the development and applicability of these vendor-provided tools for ATC and MPC,[9,19,20] their applicability to replace conventional routine QA setups will need to be further evaluated prior to adoption. In our clinic, independent, monthly checks with conventional measurement setups are still being done in addition to the compulsory daily MPC check.

Our study, similar to most conventional FMEA studies in radiation therapy, is focused on performing a typical process FMs and effects analysis (PFMEA),[21] as opposed to a design FMs and effects analysis (DFMEA).[21] However, in the present study, in addition to identifying the potential FMs in the ATC process, we have demonstrated how the manufacturer could mitigate some of the potential FMs from a design perspective. While our PFMEA study does not constitute a full DFMEA, we attempted to show how a PFMEA in radiation therapy can be used to provide feedback for future design upgrades for similar linacs.

5. SUMMARY

This paper describes the application of AAPM TG100 recommended risk analysis methods to the ATC process of a new gantry linear accelerator (Varian Halcyon linac). Data were gathered from the ATC measurements made on three Halcyon linear accelerators. A total of 38 steps and 88 FMs were identified for the entire process of ATC. RPN values for the top FMs ranged from 41 to 95 and the severity values ranged from 2.5 to 7. A brief discussion is given on the top five FMs for acceptance testing process and top ten FMs for the commissioning process. Quality control measures are suggested on how to mitigate these FMs. Many of the top FMs identified in this work could potentially be mitigated by the manufacturer by incorporating the quality control measures suggested in the present study. The present work also demonstrated how the risk assessment approach recommended by TG100 report applied to the ATC process of a Halcyon linear accelerator could potentially be used as a guidance for improving the design features of the Halcyon linear accelerator.

CONFLICT OF INTEREST

The authors have no conflicts of interest.

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