Listing of patient-matched 3D-printed radiotherapy bolus on the Australian Register of Therapeutic Goods

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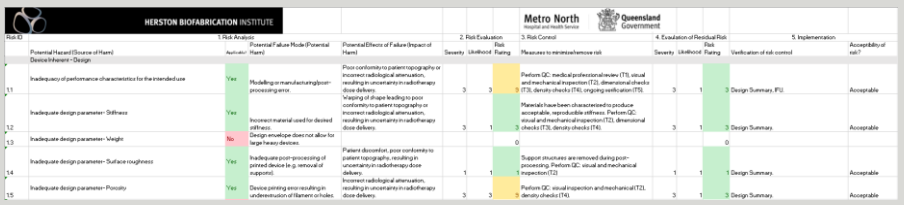
Introduction

3D-printed radiotherapy bolus meets the Australian Therapeutic Goods Administration (TGA) definition of a patient-matched medical device and is therefore subject to regulatory provisions. Specifically, a manufacturer must have the device listed on the Australian Register of Therapeutic Goods (ARTG) as a class I non-measuring, non-sterile device before it can be supplied (i.e. used clinically). This requires a statement or demonstration of compliance with Essential Principles, which define the requirements for safety and performance, the satisfaction of which is summarised for bolus devices.

Hazard and risk assessment

A risk assessment was performed by a medical physicist, and peer reviewed by an engineer, radiation therapist and physics director. Potential hazard categories were taken from the essential principles checklist, and where potential failure modes existed, controls to minimise risk were conceived and implemented (e.g. quality control tests, instructions for use, technical file documentation).



Design and manufacturing plan

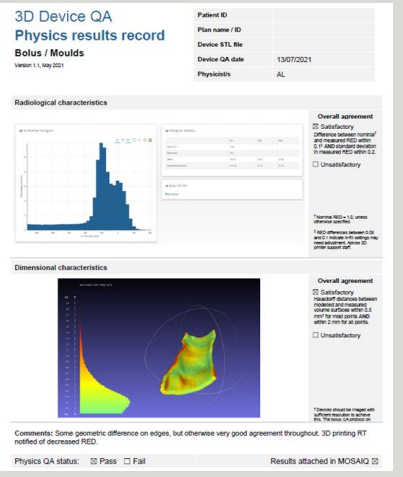
The technical file for the type of device included a design and a manufacturing plan, informed by ISO 13485. These:

- described the device and how it differed from other solutions (e.g. sheet bolus, wax);
- identified the stakeholders in design and production;
- listed the design and manufacturing requirements (e.g. radiological, geometric, material properties);
- described the design and manufacturing processes (e.g. segmentation, printing, post-processing);
- established the responsibilities of staff members;
- described how the design or manufactured device was verified or validated as meeting the requirements (e.g. quality control tests);
- summarised the instructions for use (e.g. assessment of fit, handling, cleaning, disposal of device).

Case specific documentation

For each patient case, the documentation requirements were specified in the technical file for the type of device. The request, design approval (within contour system), fabrication and quality control was captured within our oncology information system, MOSAIQ. This approach allowed responsibilities to be assigned to specific staff or staff groups, and allowed the planning therapist ultimately responsible for the device to monitor progress.

Task
3D Device Structure Approved
3D STL Exported for Production
3D Print Preparation
3D Print and Post Processing Complete
3D Device Wax/Pb Production
3D Device Visual and Manual Inspection
3D Device Physics QA
3D Device labelled and Packaged
3D Device Delivered
3D Pre-Treatment Fitting Required
3D Device Code Capture



Patient specific quality assurance require the acquisition of a CT image of the device, which was used for an assessment of relative electron density (by Hounsfield Unit conversion) and geometric agreement with approved model (by Hausdorff distance calculation). This process was automated through in-house developed software. Ongoing maintenance and quality control testing of the printer was implemented within the departmental QATrack+ system database. A consumable inventory system was implemented within our mould room.

Conclusion

The supply of in-house manufactured radiotherapy bolus was facilitated with the ARTG listing. The document templates and processes developed for bolus (and other Herston Biofabrication Institute devices) have subsequently been used for the ARTG listing of radiotherapy immobilisation and positioning devices manufactured and supplied at point-of-care.