

FMEA in developing a QM program in protontherapy



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Objectives and Methods

A proactive analysis of the risk of events leading to a deviation from the adequate treatment, in terms of over- or under-dosage during protontherapy treatments is in progress by using Failure Mode and Effects Analysis (FMEA) approach. The study is performed considering a specific RT process implemented at the CNAO Foundation (Centro Nazionale Adroterapia Oncologica, Pavia, Italy), however, the proposed methodology, and likely most of the findings, can be easily generalized to other protontherapy centres, operative or under construction.

The FMEA approach enables to identify potential failures of an equipment, system or process and to analyze the resulting effects.

The radiotherapy treatment process can be generally divided into ten stages: 1) *assessment of patient*, 2) *decision to treat*, 3) *treatment protocol prescription*, 4) *positioning and immobilization*, 5) *simulation, imaging and volume determination*, 6) *planning*, 7) *treatment information transfer*, 8) *patient set-up*, 9) *treatment delivery*, 10) *treatment verification and monitoring*.

Results

Process trees related to the 4 different stages are shown in figures a, b, c, d

