Practical suggestions for dipping your toe in the TG-100 waters

From the Working Group on the implementation of TG-100

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- Start with a small project. There may never be a need to take on a large project, since most large projects in radiation oncology can be addressed through working on small parts of a big project. Starting with a small project increases the chance that the project can be completed in a reasonable time and encourages the facility to have follow-up projects.
- 2. Assemble a team representative of the entire department relevant to the project, and educate the group on prospective risk analysis concepts and the TG-100 recommendations. The group may include nursing, therapist, administrative, physician, dosimetrist and physicist representation.
- **3.** *Focus on process mapping first.* Start with a high-level map of the process under study. Do *not* attempt to map the entire treatment process or the departmental operation, since it would take a long time and bog down the team. Often, simply mapping a process provides clarification and eliminates problems and conflicts.
- 4. Focus the initial FMEA work on a <u>clinical process</u> not on established machine QM processes. Much of the scope of machine QM has well defined guidelines (e.g., AAPM TG reports) that have been codified into regulation in many states, whereas clinical processes largely lack national guidance documents and are much more variable. For example, focus on the simulation process (which contains many potential high-risk steps, such as reference point selection, reference dataset(s) for planning, and target identification) or a particular treatment planning process (contouring, correct reference dataset and reference point coordinate, Rx interpretation – particularly in the era of hypofractionation where the dose per fraction in Gy and number of fractions are similar).
- 5. Invest time and effort to become proficient at the FMEA method and to develop useful tools for further FMEAs. Discuss the variability in how your team members assigned individual O,S,D scores and clarify the scales as needed. Allow enough discussion within the group to become comfortable with the subjective process of relying on the team's collective experience for process steps where we lack "hard data" to measure risk. Rank steps sorting by RPN and by S.
- **6.** Build a Fault Tree Analysis based on your process maps. Fault trees illustrate the paths that could lead to failures. This helps provide an understanding of how errors propagate into failures and where QA checks should be placed in the process.
- 7. *Design your quality management as described by the report of TG 100.* Be sure to address the key core components and prevent propagation along all branches of the fault tree.
- 8. Any significant changes to the quality management program should be undertaken only after careful review. Significant changes would be the elimination of quality management checks or significant deviation from guidelines published by professional organizations. Remember to include in your quality management any checks required by regulatory authorities.