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The Use of Checklists and Audit Tools for Safety and QA

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Disclosure

The authors do not have conflicts of interest to report.



Outline

- **Review existing guidance documents on safety and QA**
- **Discuss the need for performing periodic program audits/inspections**
- **Development of a comprehensive brachytherapy audit checklist**

Professional Society Recommendations

- **AAPM**
 - > 20 Task Group (TG) reports that contain brachytherapy content
 - Dosimetry – TG 43, TG 186 (model-based)
 - QA - TG40 (Comprehensive QA for RadOnc), TG 41 (Remote Afterloader), TG 59 (HDR)
 - Code of practice – TG 56
 - Site specific reports (TG 68 & 137 – LDR prostate; TG 60 & 149 – Intravascular; TG 129 – Eye plaques; TG 144 – Microspheres)

- **American Brachytherapy Society (ABS)**
 - **Brachytherapy Guidelines (10 available directly on website)**
 - **Task Groups (TGs)**
 - **Cervical Cancer**
 - **Breast**
 - **HDR Prostate**
 - **LDR Prostate**

Professional Society Recommendations

- **American College of Radiology (ACR)**
 - Practice Parameters (pre-2014, known as Practice Guidelines)
 - Technical Standards
- **ASTRO**
 - White papers

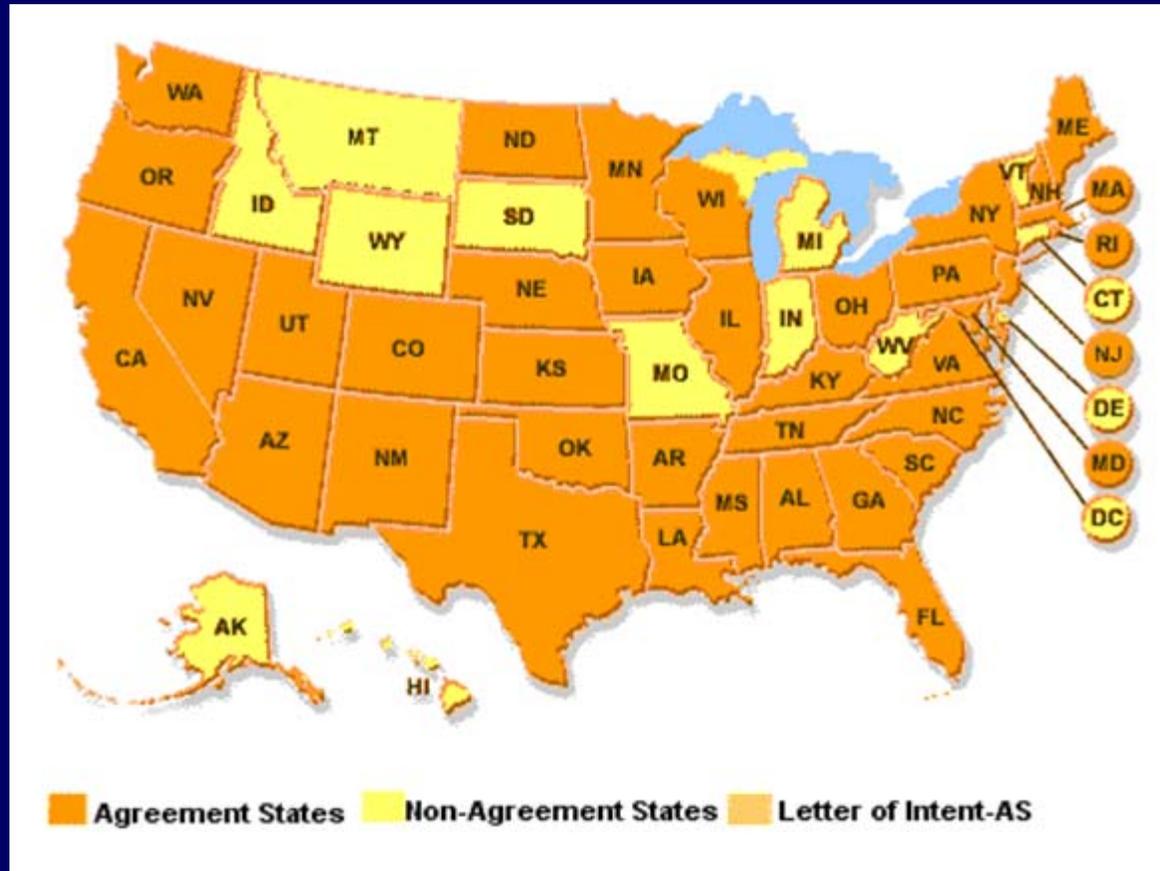
<http://www.acr.org/Quality-Safety/Standards-Guidelines>

<https://www.astro.org/Clinical-Practice/White-Papers/Index.aspx>

- **ESTRO**
 - Handbooks (e.g., The GEC ESTRO Handbook of Brachytherapy)
 - Physics Booklets (e.g., A Practical Guide to Quality Control of Brachytherapy Equipment)
 - GEC-ESTRO guidelines and recommendations

Regulatory Agencies

- **Nuclear Regulatory Commission (NRC)**
 - Regulations (e.g., 10 CFR 20 and 35)
 - **NUREG 1556** - Consolidated guidance document for materials licenses (Appendix L is a Model Audit)



- **Agreement State** - a state that has “entered into agreements with NRC that give them the authority to license and inspect byproduct, source, or special nuclear materials used or possessed within their borders”

<http://nrc-stp.ornl.gov/rulemaking.html/>

Regulatory Agencies

- **Nuclear Regulatory Commission (NRC)**
 - Regulations (e.g., 10 CFR 20 and 35)
 - **NUREG 1556** - Consolidated guidance document for materials licenses (Appendix L is a Model Audit)
- **Agreement State Agencies**
 - Regulations are as, if not more stringent than NRC regulations

Rationale for Program Audits

- **Assist with required annuals reviews**
- **Self assessment for Continual Quality Improvement**
- **Preparation for an external site review (e.g., federal/state inspection, ACR or APEX accreditation)**

Development of an Audit Checklist

- In an attempt to develop a comprehensive brachytherapy audit checklist, six board certified medical physicists and one board certified radiation oncologist worked to condense and summarize published brachytherapy guidance documents
- A checklist was compiled containing 83 relevant recommendations and regulations for the safe practice of brachytherapy.



Checklist Categories

- **Training (RSO/AU/AMP/QMP/Staff)**
- **License and shielding**
- **Policies and procedures**
- **Checklists and worksheets**
- **Commissioning and acceptance**
- **Quality assurance**
- **Documentation and records**
- **Calibration of equipment and source**



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Checklist Categories

- **Patient release criteria**
- **Room and staff monitoring**
- **Ordering, receiving, opening, disposing by product material**
- **Source inventory**

Examples

- **Verification of AMP, AU, and RSO qualifications**
- **Verify QA program developed, documented, implemented, and overseen by a QMP**
- **Verify initial and annual training/retraining of staff performed and documented. Ensure training includes key elements**
 - **E.g., rad safety, safe operation of equipment, emergency procedures, operation of the TPS (if applicable) and new developments**

Examples

- **Policies, procedures, checklists, and worksheets should be:**
 - Documented
 - Controlled (only latest readily available)
 - Uniquely titled
 - Contain revision/effective date
 - Contain a revision history, purpose and scope (or similar categories);

Ranking Importance of Items

- **Five team members independently ranked each checklist item based on their perception of its importance (importance criteria).**
- **Afterwards, these team members met to review their ranking and resolve discrepancies. Final, assigned importance criteria were based on their consensus.**
- **A final importance scale from 1 – 4 was used based on perceived risk to patient(s) or the program.**

Importance Criteria (IC) Scale

- **“1” - non-compliance carries minimal potential for a treatment variance**
- **“2” - non-compliance carries a potential for a treatment variance**
- **"3" - non-compliance could lead to a regulatory violation with minimal potential of causing harm or a medical event**
- **"4" - non-compliance carries a potential for serious harm or a medical event**

Beta Testing of Audit Checklist

- **Three clinical sites audited their brachytherapy program using the checklist.**
- **The sites were asked to score each checklist item on a scale of 0 – 3, based on a defined severity scale for their non-compliance.**

Severity Score (SS)

- **“0” - fully accomplished and appropriately documented**
- **“1” - fully accomplished but not appropriately documented**
- **“2” - partially accomplished or where multiple deficiencies in execution and documentation were noted**
- **“3” - not accomplished or documented in any way**



Audit Score

- **Audit score**

$$AS = \sum_{i=1}^{83} IC_i \times SS_i$$

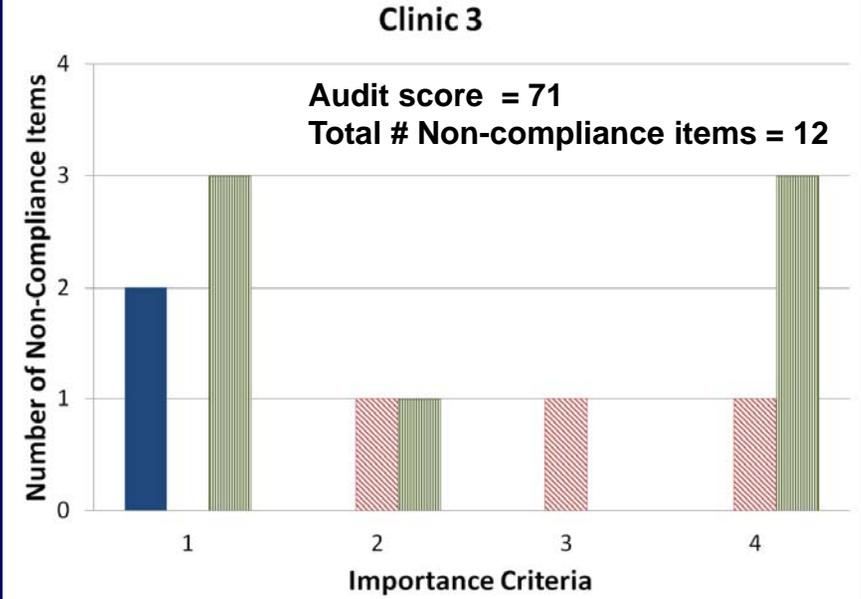
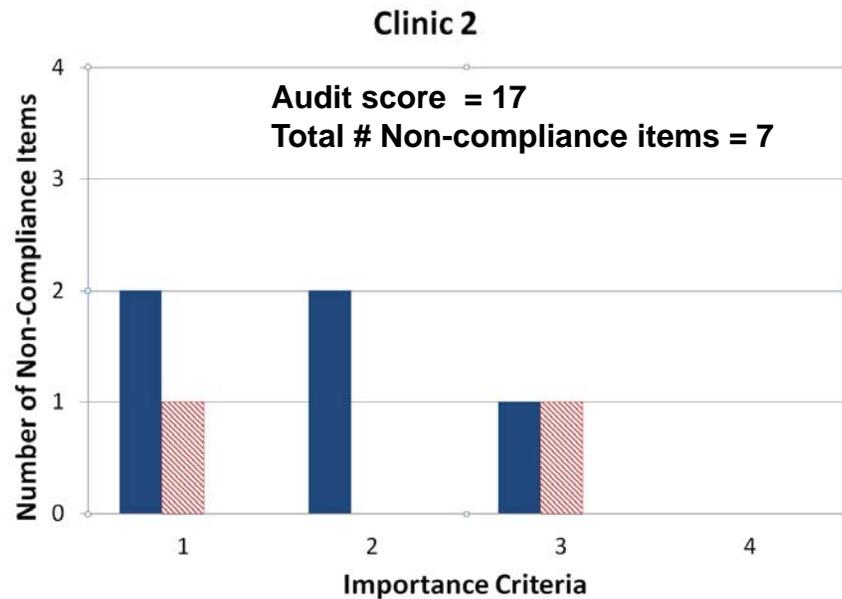
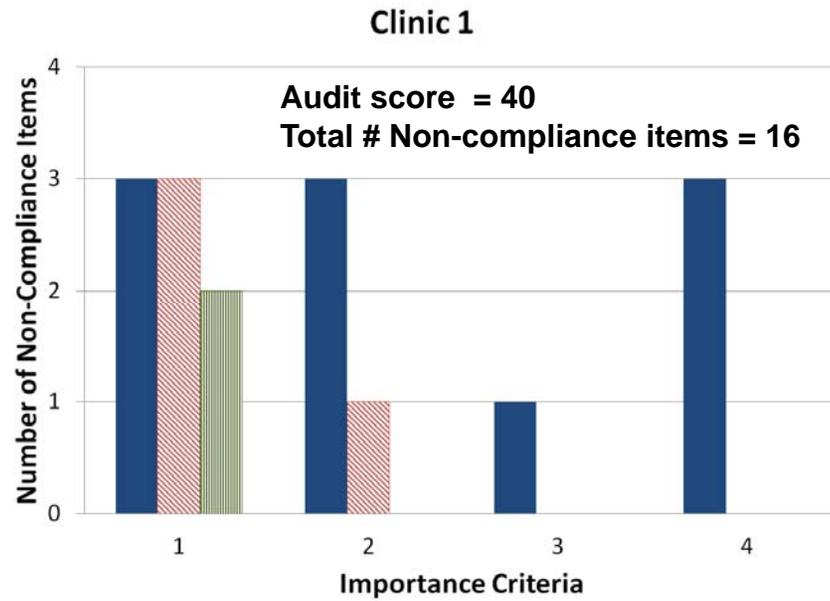
- **Goal – identify potential program deficiencies, and based on item score, develop priority of addressing items (i.e., start with items with high importance criteria and severity score).**



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Results

Non-Compliance Severity





Feedback/Comments from Sites

- **General:** Some questions more appropriate for institutions under a broad scope rather than license of limited scope.
- **Specific:**
- **Documentation of prognosis** - recommended by ACR but several AUs concerned about possible liability if not in-line with true outcome, and prognosis also highly dependent on reference.
- **Site does not perform and disagrees with recommendation** – (1) to perform surface measurements for permanent implant patients (1 m performed), and (2) perform quarterly room/facility surveys.



Feedback/Comments from Sites

- **Several sites expressed concern regarding recommendation of surgeon training (per ASTRO white paper*) – overreaching our authority.**
- **There was no direct reference to TPS QA, site felt this was relevant and should be added.**

***B.R. Thomadsen *et al.*, A Review of Safety, Quality Management and Practice Guidelines for High Dose-Rate Brachytherapy, PRO, (2014).**



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Room for Interpretation

- Users are encouraged to review and determine if some **recommendations** need to be “tweaked” based on their resources and consensus of their key players.
- However, it is important to document why a task is not being performed.



Conclusion

- Developed an audit checklist tool to assist sites with brachytherapy quality improvements.
- Total time to conduct audits for beta sites ranged from 1.5 – 5 hours.
- Users need to review and possibly tweak line items (**recommendations only**) based on their resources and the consensus of their group.



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Future Direction

- **Revisions have been made to the checklist based on feedback from beta sites.**
- **A manuscript is in preparation to share checklist with brachytherapy community.**



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- Washington University, MO (J. Esthappan)

Which of the following AAPM Task Group (TG) report provides recommendations for brachytherapy quality assurance?

25% 1. TG 40

25% 2. TG 43

25% 3. TG 137

25% 4. TG 186

Which of the following AAPM Task Group (TG) report provides recommendations for brachytherapy quality assurance?

1. TG 40

Rationale: Although not commonly thought to contain brachytherapy specific recommendations, as its name implies, TG 40 provides comprehensive QA recommendations for Rad Onc. The remaining options refer to TG reports that focus on dosimetry rather than QA.

Reference: AAPM TG 40

Which of the following regulatory bodies oversees the medical use of byproduct materials in an agreement state?

25% 1. American Brachytherapy Society

25% 2. Nuclear Regulatory Commission

25% 3. U.S. Food and Drug Administration

25% 4. Individual state agencies

Which of the following regulatory bodies oversees the medical use of byproduct materials in an agreement state?

4. Individual state agencies

Rationale: In an agreement state, a specific state agency such as the department of human health or the radiation regulatory agency is responsible for regulating and overseeing the medical use of byproduct materials, as opposed to the NRC.

Reference:

<http://www.nrc.gov/reading-rm/basic-ref/glossary/agreement-state.html>