

# Modern Radiation Therapy Technology – Regulatory Inspection and Licensing

## Sample Agenda With Onsite Inspection

<p><b>Monday, Day 1</b></p> <p><b>Start Time: 9:00 am</b></p>	<p>Official Opening</p> <p>Course Overview Welcome and Introductions, Review Agenda, Housekeeping Rules</p> <p>Introduction to Modern Radiation Therapy</p> <p>Introduction to Regulatory Structure</p> <p><b>BREAK</b></p> <p>Regulatory Structure (continued)</p>
<p><b>12:00 – 12:45</b></p>	<p><b>LUNCH</b></p>
<p><b>Start time: 12:45 pm</b></p> <p><b>End Time: 4:30 pm</b></p>	<p>Regulatory Structure (continued)</p> <p><b>BREAK</b></p> <p>International and Industry Standards</p> <p>Questions and Discussion</p> <p>Summary of Day 1</p>

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<p><b>Tuesday, Day 2</b></p> <p><b>Start Time: 9:00 am</b></p>	<p>Brief Review of Day 1</p> <p>Introduction to IMRT (Intensity Modulated Radiation Therapy), VMAT (Volumetric Modulated Arc Therapy) and SRS (Stereotactic Radiosurgery)</p> <p><b>BREAK</b></p> <p>Introduction to IMRT, VMAT and SRS (continued)</p>
<p><b>12:00 – 12:45</b></p>	<p><b>LUNCH</b></p>
<p><b>Start time: 12:45 pm</b></p> <p><b>End Time: 4:30 pm</b></p>	<p>Introduction to Licensing and Inspection Processes</p> <p>Performance Based Inspection Process</p> <p><b>BREAK</b></p> <p>High Dose Rate Remote After Loader Brachytherapy</p> <p>Questions and Discussion</p> <p>Summary of Day 2</p>

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<p><b>Wednesday, Day 3</b></p> <p><b>Start Time: 9:00 am</b></p>	<p>Brief Review of Day 2</p> <p>Inspection Process</p> <p><b>BREAK</b></p> <p>Conduct of Inspection</p> <p>Performance Based Inspection, Preparation</p>
<p><b>12:00 – 12:45</b></p>	<p style="text-align: center;"><b>LUNCH</b></p>
<p><b>Start time: 12:45 pm</b></p>        <p><b>End Time: 4:30 pm</b></p>	<p>Conduct of Inspection (continued)</p> <p>Clinical Workflow</p> <p><b>BREAK</b></p> <p>Inspection Checklists</p> <p>Inspection Documentation</p> <p>Questions and Discussion</p> <p>Summary of Day 3</p>

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<p><b>Thursday, Day 4</b></p> <p><b>Start Time: 9:00 am</b></p>	<p>Brief Review of Day 3</p> <p>Quality Management Program (QMP)</p> <p>QMP Audit</p> <p><b>BREAK</b></p> <p>Planning for and Objectives of Group Inspection</p>
<p><b>12:00 – 12:45</b></p>	<p><b>LUNCH</b></p>
<p><b>Start time: 12:45 pm</b></p> <p><b>End Time: 4:30 pm</b></p>	<p>Announced routine Safety &amp; Security on-site inspection at a chosen facility.</p> <p>Includes:</p> <ul style="list-style-type: none"> <li>○ Review of Country Inspection Procedure</li> <li>○ Observation, feedback and coaching by the instructor of inspection activities</li> <li>○ Proper use of instrumentation, if available</li> <li>○ Review of Country Inspection Report Procedure</li> </ul>

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## Sample Agenda With Onsite Inspection

<b>Friday, Day 5</b>  <b>Start Time: 9:00 am</b>	Brief Review of Day 4  Discussion of Inspection Findings  Feedback and Coaching on Inspection Activities and Observations  <b>BREAK</b>  Group Exercise – Review of License Application
<b>12:00 – 12:45</b>	<b>LUNCH</b>
<b>Start time: 12:45 pm</b>      <b>End Time: 4:30 pm</b>	Group Exercise – Review of License Application (continued)  <b>BREAK</b>  Group Exercise – Identify Licensing and Inspection Program Improvements  Overall Course Wrap-up, Final Q/As and Course Evaluation  Award Course Certificates and Closing remarks

***The Workshop Instructors will provide Breaks throughout the day at a suitable stopping point in their instructions. A 45-minute lunch break will be provided at approximately 12:00 PM (noon).***