

Modern Radiation Therapy Technology – Regulatory Inspection and Licensing

Sample Agenda Without Onsite Inspection

<p>Monday, Day 1</p> <p>Start Time: 9:00 am</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>BREAK</p> <p>Regulatory Structure (continued)</p>
<p>12:00 – 12:45</p>	<p>LUNCH</p>
<p>Start time: 12:45 pm</p> <p>End Time: 4:30 pm</p>	<p>Regulatory Structure (continued)</p> <p>BREAK</p> <p>International and Industry Standards</p> <p>Questions and Discussion</p> <p>Summary of Day 1</p>

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<p>Tuesday, Day 2</p> <p>Start Time: 9:00 am</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>BREAK</p> <p>Introduction to IMRT, VMAT and SRS (continued)</p>
<p>12:00 – 12:45</p>	<p>LUNCH</p>
<p>Start time: 12:45 pm</p> <p>End Time: 4:30 pm</p>	<p>Introduction to Licensing and Inspection Processes</p> <p>Performance Based Inspection Process</p> <p>BREAK</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>Wednesday, Day 3</p> <p>Start Time: 9:00 am</p>	<p>Brief Review of Day 2</p> <p>Inspection Process</p> <p>BREAK</p> <p>Conduct of Inspection</p> <p>Performance Based Inspection, Preparation</p>
<p>12:00 – 12:45</p>	<p>LUNCH</p>
<p>Start time: 12:45 pm</p> <p>End Time: 4:30 pm</p>	<p>Conduct of Inspection (continued)</p> <p>Clinical Workflow</p> <p>BREAK</p> <p>Inspection Checklists</p> <p>Inspection Documentation</p> <p>Questions and Discussion</p> <p>Summary of Day 3</p>

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Thursday, Day 4 Start Time: 9:00 am	Brief Review of Day 3 Quality Management Program (QMP) QMP Audit BREAK Instrument Calibration Use of Survey Instrumentation
12:00 – 12:45	LUNCH
Start time: 12:45 pm End Time: 4:30 pm	Review of Country Inspection Procedures Review of Country Inspection Documentation BREAK Group Exercise – Response to Mock Inspection Observations Questions and Discussion Summary of Day 4

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Friday, Day 5 Start Time: 9:00 am	Brief Review of Day 4 Feedback and Coaching on Mock Inspection Activities and Observations Group Exercise – Review of License Application BREAK Group Exercise – Review of License Application
12:00 – 12:45	LUNCH
Start time: 12:45 pm End Time: 4:30 pm	Group Exercise – Review of License Application (continued) BREAK 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).