VERIFICATION OF VENDOR PROVIDED DATA, TOOLS, AND TEST PROCEDURES
AN INTRODUCTION TO TG332

Koren Smith, M.S., Chair of TG332

Mary Bird Perkins Cancer Center

Baton Rouge, LA

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OUTLINE

- Rationale for the formation of TG332
- Define "black box" and "closed systems" in radiation oncology
- Overview of discussions on QA'ing black box systems

RATIONALE FOR TASK GROUP PROPOSAL

- This Task Group formed as a result of a conversation at the Annual Meeting in 2017 regarding QA'ing radiotherapy delivery systems that have built in self-check systems.

- Technology utilized in the delivery of radiation therapy is highly sophisticated and complex.

- Vendors have worked closely with medical physicists, IT personnel and clinical engineers to develop and ultimately provide an entire package of resources at the time of purchase of a piece of equipment.
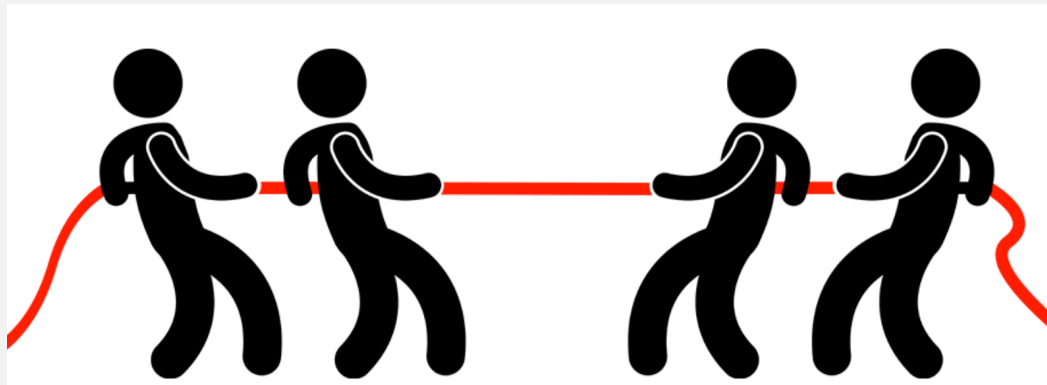
RATIONALE FOR TASK GROUP PROPOSAL

- This package may include but is not limited to:
  - self-integrated and pre-configured delivery system,
  - beam commissioning data obtained from factory measurements,
  - pre-configured software and hardware tools
  - pre-loaded tests/test procedures developed by the vendor to assist in acceptance testing, commissioning, and routine QA.
- These were created for everyone's benefit: the manufacturer and the medical physicist.
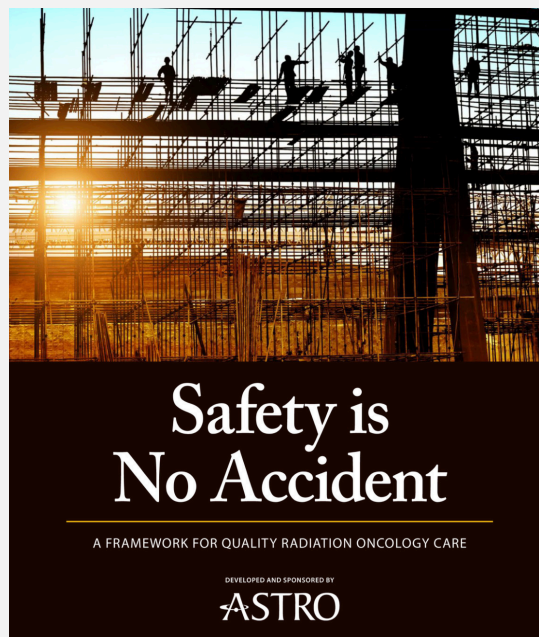- Who is ultimately in charge of managing and verifying these types of systems?
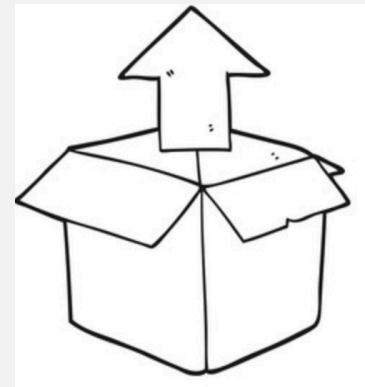
RATIONALE FOR TASK GROUP PROPOSAL

- Vendor representatives possess intimate knowledge of the operation and underlying components of equipment.

- Qualified medical physicists are ultimately responsible for radiation oncology equipment and for understanding process deviations that can lead to an undesirable outcome during clinical use.

RATIONALE FOR TASK GROUP PROPOSAL

- The Qualified Medical Physicist is ultimately responsible for radiation oncology equipment and for understanding process deviations that can lead to an undesirable outcome during clinical use.

Safety is
No Accident

A FRAMEWORK FOR QUALITY RADIATION ONCOLOGY CARE

DEVELOPED AND SPONSORED BY
ASTRO

Team Member	Traditional Role	Evolving Role	Challenges
Physicist	• Assure the safe and effective delivery of radiation as prescribed	• Incorporating technological innovations to improve patient/staff safety • Assess safety of treatment processes (e.g., failure mode analysis, fault trees)	• Education in advanced process analysis tools for patient safety • Broaden view of role beyond task-specific QA duties • Communication

RATIONALE FOR TASK GROUP PROPOSAL

- The Qualified Medical Physicist is ultimately responsible for radiation oncology equipment and for understanding process deviations that can lead to an undesirable outcome during clinical use.

- "Patient-related data are generated when patients are imaged, planned, localized, and treated. Data integrity from one step to the next must be preserved. The *medical physicist* understand the workflow and the data transactions, and must therefore be involved in all IT decisions that affect patient care."

Information technology resource management in radiation oncology[*]

R. Alfredo Siochi,[1,a] Peter Balter,[2] Charles D. Bloch,[3] Harry S. Bushe,[4] Charles S. Mayo,[4] Bruce H. Curran,[5] Wenzheng Feng,[6] George C. Kagadis,[7] Thomas H. Kirby,[8] Robin L. Stern[9]

RATIONALE FOR TASK GROUP PROPOSAL

- Perhaps we should duplicate the vendor's data for validation or independently verify a part of a closed system?
  - This can be an exceptional task, especially with systems that are integrated and pre-configured by design for ease of use, where traditional performance tests normally completed by a medical physicist are automatically performed or provided within the system itself.

- As these systems become more prevalent, the medical physicist will likely be faced with the difficult decision of choosing to what extent to validate data, tools, and tests provided by the vendor.

- This work seeks to define the various types of vendor provided systems the medical physicist may encounter and provide some guidance as to the appropriate level of testing and the approach to verification testing and validation that should be performed on any part of a "black box" or "closed" system.

TG332 – VERIFICATION OF VENDOR PROVIDED DATA, TOOLS AND TEST PROCEDURES

TG332 Committee

Olivier Blasi, MS
o.blasi@campphysics.com
12/3/2018 - 12/31/2020 Member

Maria F. Chan, PhD
chanm@mskcc.org
12/3/2018 - 12/31/2020 Member

Sonja Dieterich, PhD
sdieterich@ucdavis.edu
12/3/2018 - 12/31/2020 Task
Group Vice Chair

Sean A. Dresser, MS
sean.dresser@emory.edu
12/3/2018 - 12/31/2020 Member

Christopher W. Kennedy
chris.kennedy@uphs.upenn.edu
12/3/2018 - 12/31/2020 Member

Miriam S. Lambert, MS
miriam.s.lambert@kp.org
12/3/2018 - 12/31/2020 Member

Jessica R. Lowenstein, MS
jlowenst@mdanderson.org
12/3/2018 - 12/31/2020 Member

Todd Pawlicki, PhD
tpaw@ucsd.edu
12/3/2018 - 12/31/2020 Member

Richard A. Popple, PhD
rpopple@uabmc.edu
12/3/2018 - 12/31/2020 Member

Koren Smith, MS
ksmith@marybird.com
12/3/2018 - 12/31/2020 Task
Group Chair

Steven G. Sutlief, PhD
steven.sutlief@gmail.com
12/3/2018 - 12/31/2020 Member

Vendor Representatives

Dylan P. Casey, PhD
dcasey@accuray.com
1/1/2019 - 12/31/2021 Consultant -
Accuray (nonvoting)

Kayla N. Kielar, PhD
kayla.kielar@varian.com
12/3/2018 - 12/31/2020 Consultant
(nonvoting)

Mu Young Lee, PhD
MUYOUNG.LEE@VARIAN.COM
12/3/2018 - 12/31/2020 Consultant
(nonvoting)

William E. Simon, MS
billsimon@sunnuclear.com
12/3/2018 - 12/31/2020 Consultant
(nonvoting)

Alex Solodkin
alex.solodkin@elekta.com
12/3/2018 - 12/31/2020 Consultant
(nonvoting)

DEFINITIONS

- **Black Box –**
    - Merriam-Webster: a usually complicated electronic device whose internal mechanism is usually hidden from or mysterious to the user.
    - In the context of radiation oncology systems it is a black box if:
        - the interior workings of the system are not visible
        - the input data is not known or visible
        - Output functions are "pass/fail" without clear evidence of how the system arrived at a given result
        - It cannot be replaced by an independent system or 3rd party tool

DEFINITIONS

- **Closed Systems –**
  - In the context of radiation oncology systems it is a closed system if:
    - Some interior workings and data are visible, but the user's ability to change it is limited
    - Enough is known about the system to replicate its function with an independent or 3rd party tool

EXAMPLES OF BLACK BOX OR CLOSED SYSTEMS THERAPY VENDORS

- **Varian Halcyon**
- **Elekta AQUA**
- **Gamma Knife**
- **Tomotherapy**
- **Cyberknife**
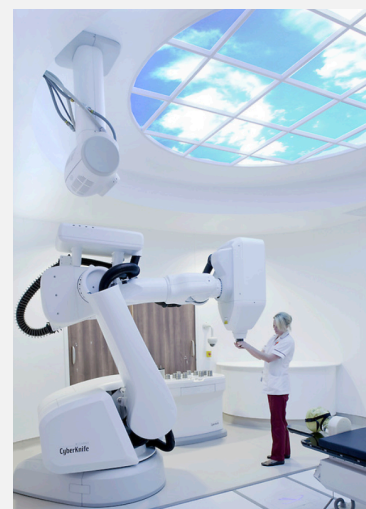
AQUA is a comprehensive machine quality management solution that:

- Simplifies QA processes across the entire workflow
- Frees staff and resources
- Enhances departmental efficiency
- Maintains system performance records in support of QA compliance
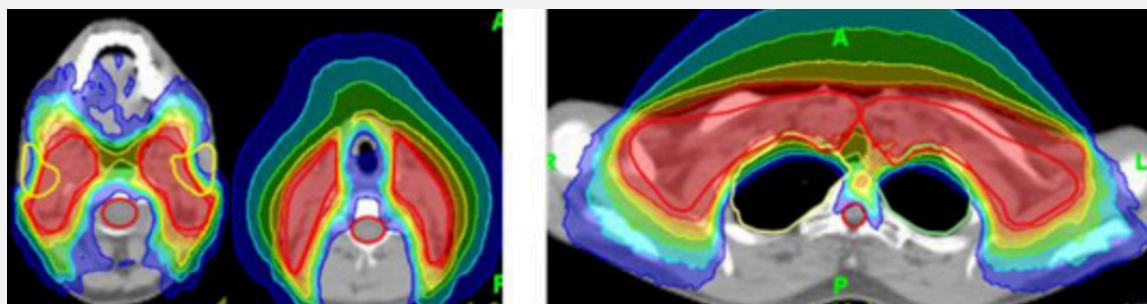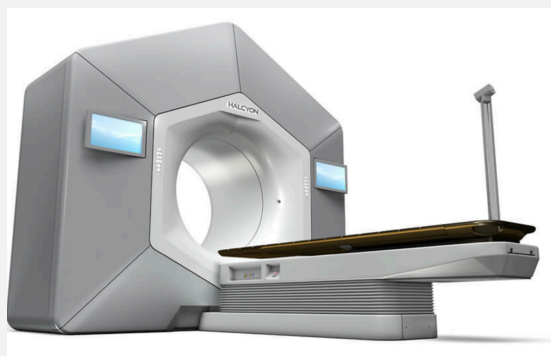
EXAMPLES OF BLACK BOX OR CLOSED SYSTEMS
QA SYSTEM VENDORS

- **Mobius**

- **PipsPro**

- **SunCheck**
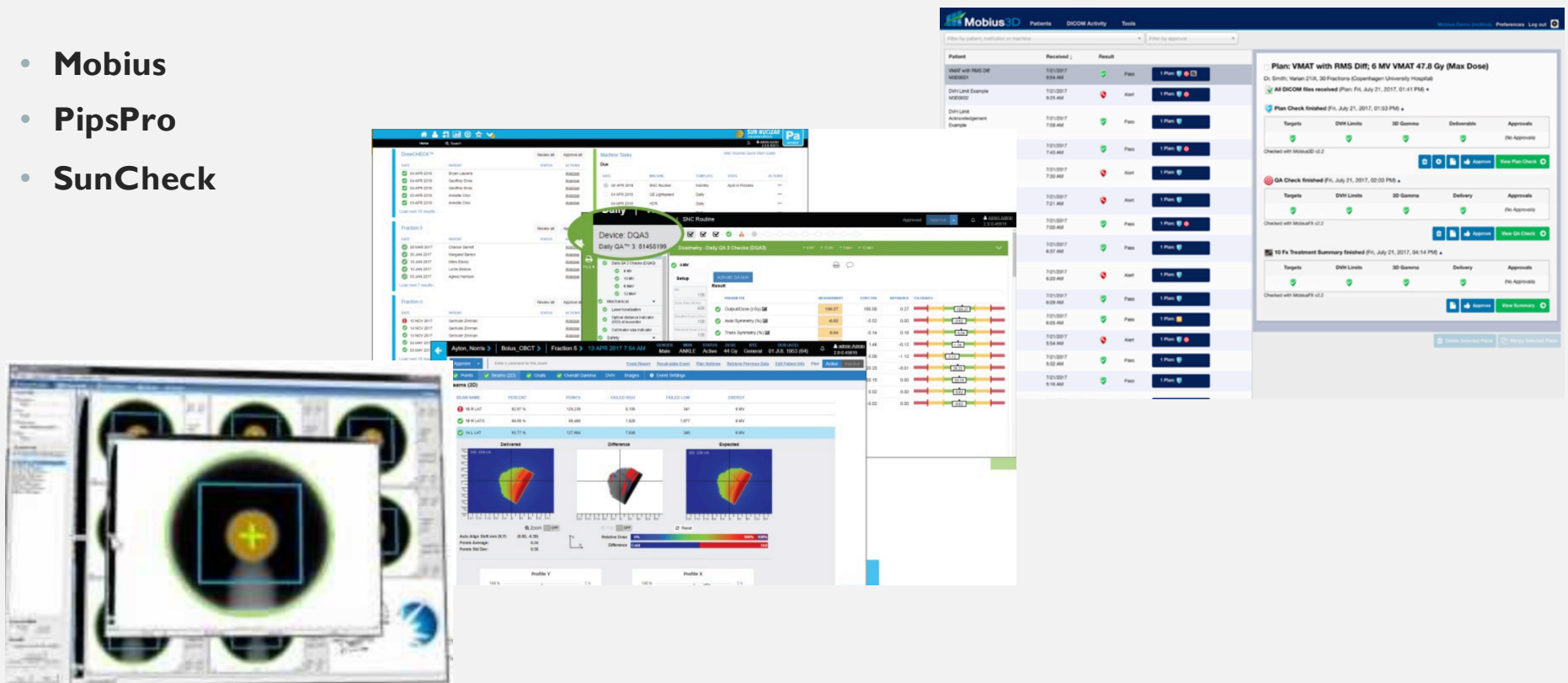
EXAMPLES OF BLACK BOX OR CLOSED SYSTEMS OTHER

- **Optical Surface Tracking Systems**
- **Electronic Brachytherapy**
- **Treatment Planning Systems**
- **Imaging Systems – Automated Detection of Targets/Markers**
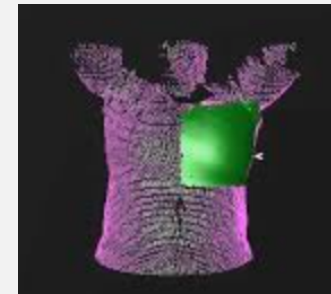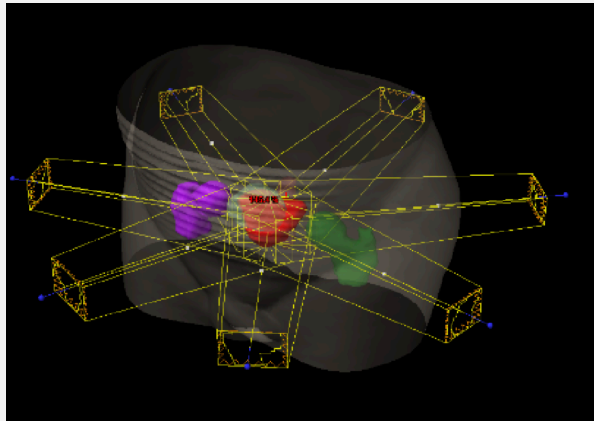
HOW DO WE QA THE BLACK BOX SYSTEM?

- **Independent Verification Tests**
  - Example: Varian Machine Performance Check has a self-check for couch motion
    - Vendor test: couch motion
    - Independent test: manually replicate or repeat couch motion with 3rd party tool

- **Challenges:**
  - Defining an "independent test". If the vendor creates a separate module for testing the black box system, they may be repeating the test just in a different way.

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- **Challenges:**
  - Results may be different. Which one do you believe?

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- **Challenges:**
  - Are results meaningful? Are they clinically relevant?
  - For example, the results of tests using log files may report a failure. We don't always know the clinical relevance of the type of failure.
  - We can do a routine test on the couch motion and it passes. Then we link it up to another system that drives the couch motion (R&V system, imaging systems, etc.). Does the vendor test or our independent test place the couch in these clinical scenarios?

HOW DO WE QA THE BLACK BOX SYSTEM?

- **Independent Verification Tests**
  - Example: Varian Machine Performance Check has a self-check for couch motion
    - Vendor test: couch motion
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- **Challenges:**
  - Depending on the degree of "opaqueness" of the system, we may not know enough about the inputs or outputs to the vendor test in order to replicate the test.
  - Ideally, we can input known or simulated errors into a testing system and ensure that the test fails.
  - Vendors think extensively about failures in their design and manufacturing process. This is not generally shared with the end-user.
  - In moving toward digital systems, it has become increasingly complex to show failures or simulate errors.
    - Type A and B test were easy to do when machines were analog. Change in approach for IEC testing as well.

Reference: IEC 60601-2-1, Particular requirements for the basic safety and essential performance of electron accelerators in the range of 1MeV to 50MeV.

HOW DO WE QA THE BLACK BOX SYSTEM?

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- **Challenges:**
  - Work intensive!

HOW DO WE QA THE BLACK BOX SYSTEM?

- **End-to-End Testing**
  - Leverage what the vendor is providing in terms of automated checks.
  - We could develop a series of end-to-end tests that enable testing of:
    - Connectivity and interaction of components from various systems
    - Workflow and details dependent on disease site/treatment modality
    - Constancy check to use at the time of service or upgrades
- **Challenges:**
  - When a failure occurs, it is difficult to determine which part of the process/system failed.
  - Whose responsibility is it to correct a failure if found: vendor or user?

Image acquistion (CT, PET, MRI) → Treatment Planning system → Plan verification → Record and Verify ↔ Linear accelerator Patient treatment

FIG. 1. Schematic of a typical radiation therapy process flow.

Journal of Applied Clinical Medical Physics, Vol. 10, No. 4, Fall 2009
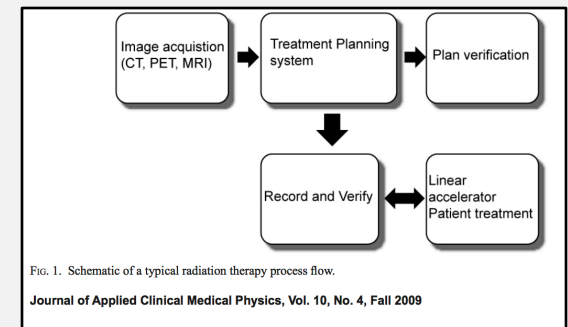
HOW DO WE QA THE BLACK BOX SYSTEM?

- **Risk Analysis** may be utilized to help determine priorities for tests and frequency.
- We must think about the root causes of failures in radiation oncology.
  - We can spend hours forcing a system "to break" in an expected way. What about the unexpected ways that systems fail?
  - Patient safety and quality is the ultimate goal. Forcing errors may or may not add value to patient safety goals.

- Focus on showing how systems operate within their limits.
  - Outside of what we think about as typical machine QA.
  - "It is about process QA and process QA is machine QA"

USER-VENDOR COLLABORATION

- Mindset change with regards to roles and responsibilities
  - Vendor: linac works everyday when user turns it on; troubleshoots when not working
  - Physicist: ensure the linac works within tolerance under intended use

RECOMMENDATIONS

- Criteria to determine the type of test recommended (developed by Olivier Blasi):
  - **Input Data**
    - Can you view input data?
    - Can you edit input data?
    - Can input data be replicated?
    - Can you change machine's parameters to cause a failure?
  - **Output Data**
    - Can the output values be reported quantitatively?
    - Does the output trigger an interlock?
    - Can an end-to-end test verify the output results?
  - **Algorithm**
    - Is the algorithm published by the vendor?
    - Does the system report intermediate steps?
    - Are multiple parameters being testing at once?
    - Are the main paths of the algorithm able to be independently tested?

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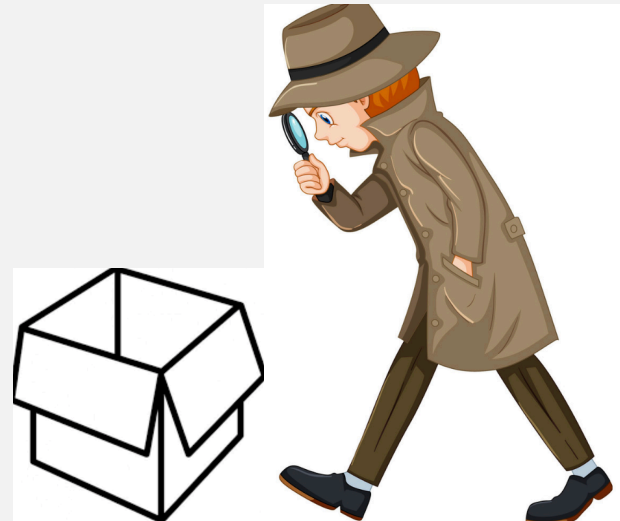 - **Input Data**
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Independent Functional Test

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End-to-End Test

SUMMARY

- More and more of our systems in radiation oncology may be considered "black box" in nature

- QA paradigms may be shifting to focus heavily on process QA rather than traditional functional tests of systems

- Mindset change with regards to roles and responsibilities between vendors and physicists

THANK YOU

TG332 Committee:

Olivier Blasi

Maria Chan

Sonja Dieterich

Sean Dresser

Christopher Kennedy

Miriam Lambert

Jessica Lowenstein

Todd Pawlicki

Richard Popple

Koren Smith

Steven Sutlief

Vendor Representatives:

Dylan Casey

Kayla Kielar

Mu Young Lee

William Simon

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