AAPM 2019 Annual Meeting // Session WE-HI-304-4

Vendor Provided Data, Tools and Test Procedures

The 3rd Party QA Tool Provider Perspective

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First Order of Business

- "3rd Party" – our belief is that **use of the term "3rd party" conveys the wrong message**…
  - Something that is not really needed
  - An uncomfortable presence (think a 'third wheel' on a date)

- Your QA vendor is a **_partner_** in the process of helping clinicians create and deliver **_safe and effective_** radiotherapy for patients

- So, a more preferable title might be…
  - **"The QA Tool Provider Perspective"** if one is dull (like me)
  - **"The Independent QA Vendor – Helping You Keep RO Safe"** if one has a talent for Marketing

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Second Order of Business

- Remove SNC-specific branding
  - Though an employee of Sun Nuclear Corporation, I am representing QA vendors in general and have solicited and received input from PTW, IBA Dosimetry, Standard Imaging, and RIT in preparing these slides.

iba DOSIMETRY

P**T**W THE DOSIMETRY COMPANY

RIT

STANDARD **IMAGING**

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Outline

- 'Vendor-provided Data' – What we are referring to *one slide*
- What access to this data enables *one slide*
- Why Independent Checks are Important *a few slides*
- Examples of the Importance of Independent QA
  - Outside of RT *a few slides*
  - Within RT *several slides*
- Is access to this data guaranteed? *one slide*

'Vendor-provided Data' – What we are referring to

- **TPS Data**
  - DICOM RT Plan
  - DICOM RT Images
  - DICOM RT Structure Set
  - DICOM RT Dose

- **Data from the Electronic Portal Imaging Device (EPID)**
  - Cumulative
  - Time-based

- **Machine Log Files** –
  The following as a function of time:
  - Monitor Units (MU)
  - Leaf positions
  - Couch positions
  - Gantry Angle
  - Collimator Angle

- **Imaging Data**
  - kV projection data
  - Cone-beam CT image set (CBCT)
  - Registration Offsets

'Vendor-provided Data' – What access to this data enables

Access allows for INDEPENDENT…
- Machine QA tasks such as those described in the US's AAPM TG-142, the UK's IPEM Report 81, the German DIN standards (68*nn-n* series), et al
- Pre-treatment Patient Plan QA
- *In vivo* Patient fraction QA

Commercial solutions can be found at sunnuclear.com, iba-dosimetry.com, ptw.com, standardimaging.com, radimage.com

Home-grown solutions are documented in Eckhause et al, Med Phys 2015, 42(10): 6074-83, van Elmpt et al, Radiother Oncol. 2008, 88(3) 289-309

Taken as a whole, this **elevates patient safety**.

Follow-Up, Before Moving On

Whose data is this?

- The Treatment Delivery System vendor's

- The Clinic's

- The Patient's

Outline

✓ 'Vendor-provided Data' – What we are referring to
✓ What access to this data enables
- Why Independent Checks are Important *a few slides*
- Examples of the Importance of Independent QA
  - Outside of RT *a few slides*
  - Within RT *several slides*
- Is access to this data guaranteed? *one slide*

Why Independent Checks Are Important

Avoid bias error, both in design and risk assessment.

QA that is not independent is a self-check, and self-checking is inherently biased and driven by familiarity contamination or "group think".

Avoid conflict of interest.

Self-checking is recognized as a conflict of interest and regulation dictates independent confirmation and monitoring in many better-known industries including food, pharmaceuticals, air travel, securities, and accounting.

Why Independent Checks Are Important

Evolving complexity.

As RT systems have become more complex, and interoperable, the likelihood of testing and verifying every configuration and option scenario as part of a self-check becomes ever more remote.

Encourages continuous improvement.

Independent QA not only maintains desired quality, it drives improved quality in RT by pointing out systematic errors and opportunities for improvement.

Independent QA is complementary to and an essential audit of the evolving RT delivery system with integrated system self-checks. ***There will always be residual risk from unforeseen failure modes***, especially with complex systems. **This is best addressed by Independent QA.**

Why Independent Checks Are Important

Quoting Geoff Ibbott…

"A critical aspect of a QA program is independence; that is, the QA procedures conducted to assure the quality and accuracy of the product or process (in this case the delivery of radiation therapy) must be independent of the product or process itself. The failure to establish independence can lead to the risk that the QA device merely mimics the performance of the parameter being measured, masking an error or change."

G.S. Ibbott 2010, *Journal of Physics: Conference Series* **250** 012001

Why Independent Checks Are Important

Many current guidelines recommend independent verification. For example:
- ACR Practice Parameter for IMRT (2016)
- ASTRO Model Policy for IMRT (2015)
- ASTRO Model Policy for SBRT (2014)

all recommend irradiating a phantom prior to the start of treatment containing a calibrated dosimetry system.

This is an independent verification of beam delivery as planned.

Moreover, the 2019 update to 'Safety is No Accident' refers to ASTRO White Papers as guidance:
- IMRT > Moran et al, "Safety Considerations for IMRT", PRO(2011)
- SBRT > Solberg et al, "Quality and Safety Considerations in SRS and SBRT", PRO(2011)

Both documents recommend external (e.g. IROC) and internal (e.g. pre-treatment delivery to a phantom) **independent verification.**

Why Independent Checks Are Important

In the European Union, there is a greater emphasis on *in vivo* dosimetry as the means for independent treatment verification as evidenced by European Council Directive **2013/59/EURATOM** which stipulates that:

"…equipment used for external beam radiotherapy with a nominal beam energy exceeding 1 MeV **has a device to verify key treatment parameters**." (Article 60)

"…the medical physics expert takes responsibility for dosimetry, **including physical measurements for evaluation** of the dose delivered to the patient…" (Article 83)

Finally, the UK's 2008 'Toward Safer Radiotherapy' explicitly recommends that, "all radiotherapy centres have protocols for *in vivo* dosimetry and this should be in routine use at the beginning of treatment for most patients."

Before Examining Some Examples…

How important do you think having independent QA is?

- Important

- Not Important

- No Opinion

Outline

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• Examples of the Importance of Independent QA
  • Outside of RT *a few slides*
  • Within RT *several slides*
• Is access to this data guaranteed? *one slide*

Examples Supporting Independent QA Outside of RT

- **Toyota gas pedal recall[1]:** 2002-Jan. 2010, an average of 132 incidents per year and a total of 23 deaths were linked to this flaw (vs. 11 deaths connected to all other automakers combined during that same time period!). Toyota stood by the *faulty claim* that floormats were the cause for 7 years.
  - Lack of strong independent oversight – NHTSA accepted Toyota's findings and "quietly closed the report", keeping most pages confidential
  - Pressure from the *Los Angeles Times* helped bring about a real resolution

- **GM ignition switch recall[2]:** 2001-2013, 31 crashes and 13 deaths attributed to this defect. "An internal inquiry by Anton Valukas, a former U.S. attorney, found an 11-year 'history of failures' and 'a pattern of incompetence and neglect'."
  - Lack of strong independent oversight – A 2007 NHTSA found no defect issues and *Consumer Reports* did not detect the problem in their testing
  - Change in leadership, Mary Barra CEO, led to a final identification and resolution of the issue in early 2014.

[1] https://www.motortrend.com/news/Toyota-recall-crisis/
[2] https://www.npr.org/2014/03/31/297158876/timeline-a-history-of-gms-ignition-switch-defect/

Examples Supporting Independent QA Outside of RT

- **Boeing 737 Max:** Crashes in October 2018 and March 2019 leading to deaths of all on-board.

Still an open investigation though a software defect in the Maneuvering Characteristics Augmentation System (MCAS) is the leading cause presently[3].
  - Lack of strong independent oversight – FAA agreed with Boeing in determining that additional training was not needed in spite of the new MCAS software designed to automatically adjust the position of the nose[4].
  - 'Disagree Light' is sold as an option[5] – controversial as Boeing defends this choice. Unclear how a pilot would know when to manually override MCAS without this indicator.

[3] https://www.nbcnews.com/news/us-news/faa-finds-potential-flaw-boeing-737-max-software-updates-n1022516 (Jun 27, 2019)
[4] https://www.nytimes.com/2019/02/03/world/asia/lion-air-plane-crash-pilots.html
[5] https://www.nytimes.com/2019/03/21/business/boeing-safety-features-charge.html

Outline

- ✓ 'Vendor-provided Data' – What we are referring to
- ✓ What access to this data enables
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  - ✓ Outside of RT
  - • Within RT *several slides*
- • Is access to this data guaranteed? *one slide*

Examples Supporting Independent QA Within RT

IAEA Safety Series Report 17, Lessons Learned From Accidental Exposures in Radiotherapy, 2000

- Review, Classification, and Lessons Learned for 92 accidents occurring over 3 decades.
- *Error magnitudes ranged as high as 100% (e.g. doubling of dose)*
- Most serious errors detected within days, however one error persisted for 9 years.

Accident categories were:
1. Radiation measurement systems
2. External beam therapy: Machine commissioning and calibration
3. External beam therapy: Treatment planning, patient setup and treatment
4. Decommissioning of teletherapy equipment
5. Mechanical and electrical malfunctions
6. Brachytherapy: Low dose rate sources and applicators
7. Brachytherapy (high dose rate)
8. Unsealed sources

Examples Supporting Independent QA Within RT

IAEA Safety Series Report 17, Lessons Learned From Accidental Exposures in Radiotherapy, 2000

External beam therapy: Treatment planning, patient setup, and treatment

- 26 accidents in this category, split into two general 'Initiating Events':
  1. **Incorrect Patient Calculations (14).** Examples include 'Incorrect Basic Data in a TPS', 'Incorrect Application of Distance Correction', 'Insufficient Understanding of TPS Algorithm'
  2. **Incorrect Set-up (12).** Examples include 'Incorrect Positioning of Treatment Beams', 'Wrong Patient Treated'

Of these 26 examples, 'lack of an independent' verification or check was identified as a 'Contributing Factor' in 14 (or ~**54%**) of these accidents

- Within the **'Incorrect Set-up'** group, it is likely that *in vivo* measurements would have led to the detection of most of these accidents

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Examples Supporting Independent QA Within RT

A very recent event – Jaw error after service event

- Y1 and Y2 Jaws plugged in backwards during a routine service
- After treating for a full day, the Therapists discovered the error when they got suspicious of a light field
- They ran a Port film and the image was blank:
  - The Jaw was covering the MLC field instead of framing it, so no dose delivered
- All the patients treated prior to this discovery were given varying degrees of incorrect dose depending on how symmetric the field was…
- Log-file only pre-treatment QA results passed
- The Logs recorded what the Linac "thought" it did
- **The Linac thought it was moving Y1 when it was actually moving Y2**
- Clinic seeking an EPID-based replacement for their log file based solution.

Example collected thanks to an observant Therapist

Examples Supporting Independent QA Within RT

An RT facility was using 3D Winston-Lutz (Isocenter) routine to measure gantry wobble, couch walk-out and collimator walk-out for SRS/SBRT treatments. Excessive gantry wobble, beyond clinical limits, was detected.

- This was the first time that this machine was tested with the QA software.
- The machine was only two years old.
- There had been no earthquakes or building construction in this facility.
- The accelerator manufacturer called in a special team to evaluate the problem. Although they used different measuring equipment and special tests only available to service personnel, their results closely matched the QA software analysis.
- They subsequently sent in a different team with heavy equipment to correct the gantry problem.
- Since the repairs were completed, the machine has been regularly checked and so far stays well within clinical limits.

Example collected using RIT Enhanced 3D Winston-Lutz routine

Examples Supporting Independent QA Within RT

A different RT facility was using 3D Winston-Lutz (Isocenter) routine to measure gantry wobble, couch walk-out and collimator walk-out for SRS/SBRT treatments. Significant failures were detected.

- Further testing with QA software using the Hancock MLC routine indicated other problems. It was determined that:
  - The EPID was significantly mis-aligned.
  - The MLC was not working correctly. Bad circuit board.
  - The lasers were out of alignment.
- These were corrected by service personnel.

Example collected using RIT Enhanced 3D Winston-Lutz routine

Examples Supporting Independent QA Within RT

From Nelms et al, "Evaluating IMRT and VMAT dose accuracy: Practical examples of failure to detect systematic errors when applying a commonly used metric and action levels", Med. Phys. 40(11) , 111722 (2013)

Case 1 – Incorrect Leaf End Modeling

- "MLC offset table not set correctly, causing the TPS to calculate each segment slightly too wide (~1 mm) which had an additive effect that was quite large over many segments"
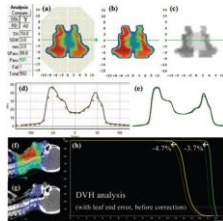
Example collected using Sun Nuclear MapCHECK, EPIDose & 3DVH

Examples Supporting Independent QA **Within RT**

From Nelms et al, "Evaluating IMRT and VMAT dose accuracy: Practical examples of failure to detect systematic errors when applying a commonly used metric and action levels", Med. Phys. 40(11) , 111722 (2013)

Case 2 – TPS setting causes failure to account for Tongue-and-groove effect
• Tongue-and-groove correction disabled, resulting in an inward shift of the projected patient target DVH curves
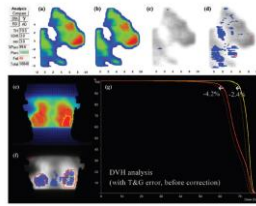
Example collected using Sun Nuclear EPIDose & 3DVH

Examples Supporting Independent QA **Within RT**

From Nelms et al, "Evaluating IMRT and VMAT dose accuracy: Practical examples of failure to detect systematic errors when applying a commonly used metric and action levels", Med. Phys. 40(11) , 111722 (2013)

Case 3 – TPS beam model with dose gradient errors due to volume-averaged dose profiles entered into beam model
• All profiles from commissioning acquired with a Farmer Chamber, resulting in a volume-averaging effect that manifested in patient plans
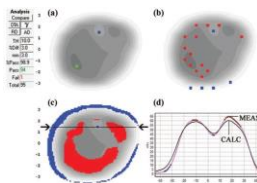
Example collected using Sun Nuclear MapCHECK, EPIDose & 3DVH

Examples Supporting Independent QA **Within RT**

From Nelms et al, "Evaluating IMRT and VMAT dose accuracy: Practical examples of failure to detect systematic errors when applying a commonly used metric and action levels", Med. Phys. 40(11) , 111722 (2013)

Case 4 – Inherent dose gradient errors in TPS algorithm
• Issue manifested itself in a similar manner to the prior example, but with a different root cause
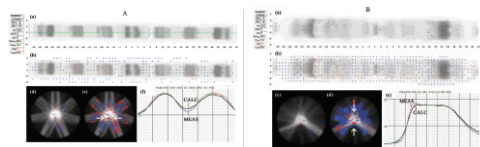
Example collected using Sun Nuclear ArcCHECK & 3DVH

Examples Supporting Independent QA Within RT

From Nelms et al, "Evaluating IMRT and VMAT dose accuracy: Practical examples of failure to detect systematic errors when applying a commonly used metric and action levels", Med. Phys. 40(11) , 111722 (2013)
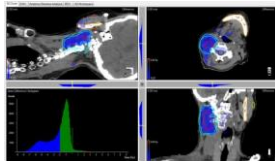
Case 5 – TPS underestimation of dose for narrow MLC segments in a complex VMAT plan

• A large number of very narrow fields (several mm in width) produced a ~5.5% cold region across the target areas

Example collected using Sun Nuclear ArcCHECK& 3DVH

Examples Supporting Independent QA Within RT

TPS beam model for 10 MV was created in an errant manner

However, no problems revealed in conventional treatments.
The secondary calculation system, which as independently commissioned, showed significant deviations. This triggered investigations into the quality of the beam model in TPS and 2ndary dose check engine. A cross-checks with measurements indicated that the TPS beam model did indeed contained an error (upwards of 10%).
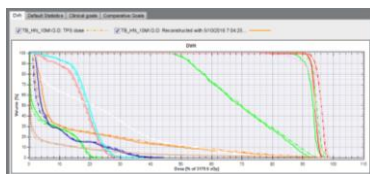
Example collected using IBA Dosimetry Compass & Dolphin

Examples Supporting Independent QA Within RT

Incorrect setting in beam model export configuration changed jaw positions in the IMRT plans to a symmetric configuration

Depending on how assymetric treatment target was and where the isocenter was positioned, delivered jaw positions were different from planned positions from several mm up to 5 cm.
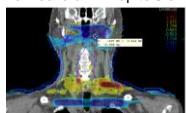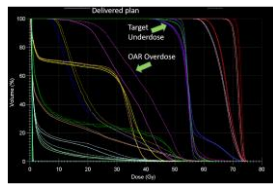
Example collected using IBA Dosimetry Compass & Dolphin

Examples Supporting Independent QA Within RT

Dose Calculation error in a commercial treatment planning system produced a 15-30% error when different energy beams were used within one plan. Pre-treatment with an independent device catches this provided QA plan created in the same manner as the patient plan, i.e., beams are not broken into individual plans.

Take away: Not only is it important to perform the QA with an independent device, the delivery must mimic the patient delivery as close as possible.

Example collected using PTW Octavius system

Examples Supporting Independent QA Within RT

Rotation of a particular treatment table resulted in display of a nominal angle even though the actual position was +/-0.5 degrees from this angle. This lead to a shift of the beams of up to 1 cm relative to the patient. In these situations, the staff believed the table was in the correct position possibly leading to mistreatment.

Similar take away: Not only is it important to perform the QA with an independent device on the treatment table, the delivery must mimic the patient delivery as close as possible (in this case couch angles).

Example collected using PTW Octavius system

Examples Supporting Independent QA Within RT

From Mans et al, "Catching Errors with *in vivo* Dosimetry",
Med. Phys. 37(6) , 2638-2644 (2010)

Data Transfer Error

- Of 4,337 plans over 4.5 years, they found 17 serious errors that required intervention
- Plan transferred to Mosaiq, all protocols followed, no abnormalities observed
- EPID dosimetry done during first fraction uncovered an error – mis-syncing of the MLCs and Jaws by one segment caused a significant dose differences
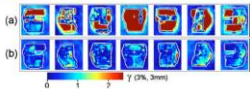
FIG. 2. γ-evaluations of (a) the first (malformed plan) and (b) the second (corrected plan) fractions in a plane parallel to the EPID, intersecting the isocenter. The white "+" indicates the isocenter.
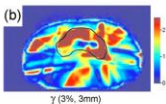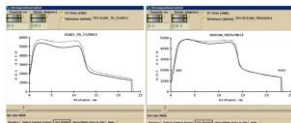
Example collected using NKI EPID Dosimetry Software

Examples Supporting Independent QA Within RT

From Nailon et al, "EPID-based *in vivo* dosimetry using Dosimetry Check™: Overview and clinical experience in a 5-year study", JACMP 20(11) , 6-16(2019)

Anatomical difference between planning and treatment
- Excessive bowel gas during planning CT lead to a significant dose difference
- Patient was rescanned and new plan used

General Summary: 153 of 3795 plans required investigation and resulted in action

Example collected Math Resolutions using Dosimetry Check software

Examples Supporting Independent QA Within RT

Couch Issue:

Table shifted to avoid table-gantry collision but not shifted back

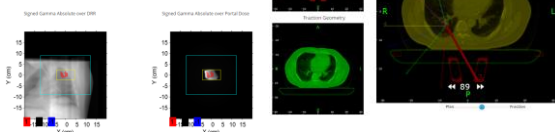Error was clearly seen in the Transit Dosimetry result.

Example collected using Sun Nuclear PerFRACTION
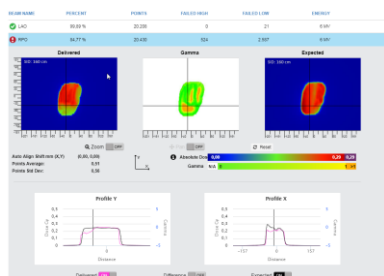
Examples Supporting Independent QA Within RT

Transit dosimetry result indicated an error for Lung SBRT treatment:
- Significant difference from planned dose
- Analysis showed that the wrong couch was selected during the planning process

Example collected using Standard Imaging ADAPTIVO

Examples Supporting Independent QA **Within RT**

Lung tumor shrinkage
- 2 weeks into treatment
- Tumor clearly reduced
- Hot spot shown on CBCT
  - Red area exceeding gamma criteria
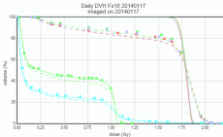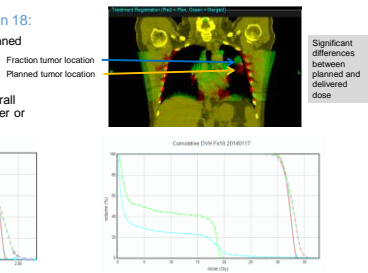- MD can scroll through to see where hot spot falls

Example collected using Sun Nuclear PerFRACTION

Examples Supporting Independent QA **Within RT**

Patient misaligned on fraction 18:
- Significant difference from planned dose
- Physician had the needed information to determine if it compromised the patient's overall treatment and inform on whether or not to re-plan
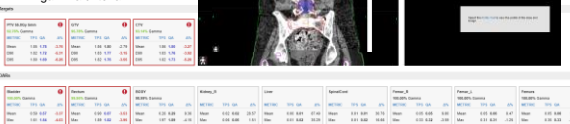
Fraction tumor location
Planned tumor location

Significant differences between planned and delivered dose

Example collected using Standard Imaging ADAPTIVO

Examples Supporting Independent QA **Within RT**

Patient weight change:
- Patient put on steroids
- Clear weight gain
  - Impacted tumor dose
- Cold spot shown on CBCT
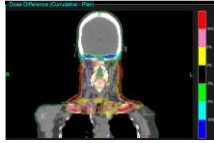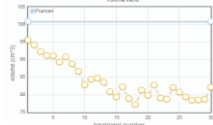 - Superior Tumor cold
  - Blue area exceeding gamma criteria

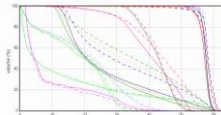*Example collected using Sun Nuclear PerFRACTION*

Examples Supporting Independent QA Within RT

Patient weight change:

- Patient lost weight throughout treatment
- Mask was poorly made: inconsistent daily setup
- Effect of these changes tracked and physician had data to decide to inform differences.

Significant differences between planned and delivered dose

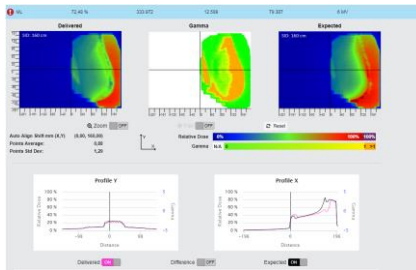DVH differences between planned and delivered cumulative doses

Example collected using Standard Imaging Adaptivo

Examples Supporting Independent QA Within RT

TPS Planning Problem: Skin flash tool not utilized effectively.

Error was clearly seen in the Transit Dosimetry result.

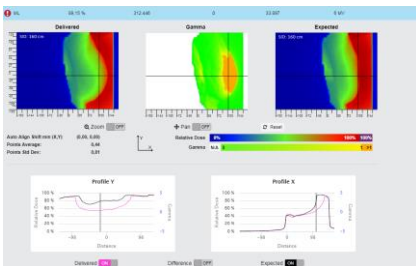*Example collected using Sun Nuclear PerFRACTION*

Examples Supporting Independent QA Within RT

Anatomical change: Infection caused breast to swell that subsequently required antibiotics.

Error was clearly seen in the Transit Dosimetry result.

Example collected using Sun Nuclear PerFRACTION

Examples Supporting Independent QA Within RT

Anatomical change: CBCT showed dense lung tissue not in planning CT…
Patient had pneumonia. Error was clearly seen in the Transit Dosimetry result.

CT

First CBCT

CBCT showing pneumonia

Example collected using Sun Nuclear PerFRACTION
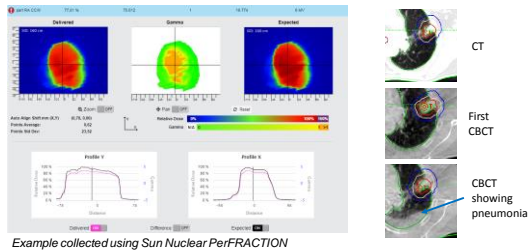
Take Home Messages from These Examples

1. Data from the Treatment Delivery System is invaluable to detecting delivery errors and therefore improving outcomes and increasing patient safety.

2. These examples **would not exist without access to such data.**

Outline

✓ 'Vendor-provided Data' – What we are referring to
✓ What access to this data enables
✓ Why Independent Checks are Important
✓ Examples of the Importance of Independent QA
  ✓ Outside of RT
  ✓ Within RT
• Is access to this data guaranteed? *one slide*

Is access to this data guaranteed?

Simply put…No, not yet:

- We have direct evidence of this with a vendor's decision in 2017 to license access to EPID data.
- AAPM has formed Task Group 332, as discussed previously, however access by (third party) QA Vendors to this data is absent from the Charge of the TG.
- There are no specific regulations or language in standards (e.g. IEC 60601-2-1) to require OEMs to provide such access.

There should be a goal to ensure interoperability is not impeded for competitive reasons but, rather, is expected and enabled in a practical manner.

- *This applies to existing modalities as well as new (e.g. MR-Linac, Adaptive, etc.)*

We have real evidence of the clinical end-user demand that this access be maintained due to their belief in the importance of independent QA:

- Such QA products are commercially successful in spite of competitive offerings from OEMs

We cannot take the access to this data for granted and must stay vigilant in ensuring it is maintained.

THANK YOU

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