Dear Radiation Oncology Community,

Independent QA has been discussed and even assumed as a "given" in the Radiation Oncology (RO) community for some time. However with RO Systems increasingly offering built in "self-check" QA and the visible trend towards more closed systems, the topic of independent QA takes on an even higher importance and urgency. Closed systems impede the feasibility of independent QA. Although many assume a de-facto standard for independent QA, there is no formal recommendation for the use and support of it.

The independent QA providers Sun Nuclear, IBA Dosimetry, PTW and Standard Imaging, kindly ask you to support our initiative for formal recommendations / guidelines, endorsed by AAPM, ASTRO, ESTRO and IAEA, in support of independent QA of RO systems.

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Jeff Simon,
CEO Sun Nuclear Corporation

Jean-Marc Bothy,
CEO IBA Dosimetry GmbH

Tobias Schüle,
Managing Director PTW-Freiburg GmbH

Eric DeWerd,
President Standard Imaging, Inc.

Statement of Support

Independence of Quality Assurance (QA) & Dosimetry for Radiation Oncology (RO) Systems

In the field of medicine, Radiation Oncology is uniquely dependent upon machines and software, i.e. *RO Systems*, to create patient-specific treatment plans and deliveries, based on a Radiation Oncologist's prescription for cancer patients.

Justification for RO QA

QA is uniquely important in an RO system for four primary reasons. Taken together, these create a potential for errors, both minor and catastrophic, both easy to predict and difficult to predict.

1. RO Inherent Complexity. RO systems are heavily computerized and highly complex, with many parameters creating an interplay effect between hardware, software, and clinical users and processes. This interplay effect can affect safety and effectiveness, and almost always varies from one treatment facility to the next even when the RO system vendors are identical.

2. RO System Variability. Individual RO system hardware, software, and processes are in a constant state of non-synchronized product evolution and continuous improvement, through hardware and software updates, adding to the parameter permutations.

3. RO Method of Delivery. Whereas non-RO specialties treat with drugs manufactured in a controlled factory environment, or provide services such surgery where results are physically verifiable in real-time, RO systems manufacture their radiation on site in real time and deposit directly within the patient; and the administered radiation is not physically verifiable by visual means following treatment.

4. RO Specificity. Every RO course of therapy is uniquely designed according to the unique anatomical geometry of the patient being treated. There is no single RO treatment plan / prescription combination, which can be verified once and delivered in the same exact way to every patient.

For these reasons, stringent QA of the RO system and delivery is critical.

What is independent QA and Dosimetry in RO

Quality Assurance for RO Systems is independent when it consists of hardware and/or software that:

- Is developed, maintained and can be sourced independently and without bias of RO system manufacturers
- Uses open & freely accessible data sources
- Allows for the comparison of results for different RO systems and different manufacturers
- Connects to the RO System via documented interfaces and common formats like DICOM
- Relies on physical characteristics like beam, light, couch position, etc.

Necessity of Independent RO QA

Independence in RO QA plays an important role in the effectiveness of the QA and the safety and effectiveness of the RO system.

1. Reduction of Bias & Residual Risk. RO treatment delivery vendors are increasingly integrating QA into their systems. While this is overdue and has the promise to increase efficiency in some respects, integration of QA by the OEM is a self-check, not independent QA. Vendor risk analysis and mitigation is subject to unintentional a priori knowledge (bias) of the system for which the self-check is checking. Residual risk from unforeseen failure modes is common with complex systems so a self-check cannot provide full and complete QA. Furthermore, QA methods are also subject to failure modes. The best solution is one which employs multiple methods and redundancies. Independent QA is complementary to and an essential audit of the evolving RO system with integrated system QA.
2. Continual Improvement of RO. Since the advent of RO, advances in RO have benefited from and depended upon independent QA and dosimetry in order to test, validate, and commission these advances. Untold RO discoveries and improvements have been made possible by the independent application of independent QA & Dosimetry tools – by clinicians, QA & Dosimetry vendors and even RO treatment delivery vendors. RO would not be where it is today were it not for these independent tools.
3. Common Standards. Where RO system clinical deployments often involve numerous vendors providing different hardware and software solutions, and accommodate different clinical processes, it is important to have a common standard, or framework, by which to evaluate and judge the quality of the RO provided. An apples to apples comparison (i.e. audit) via independent QA, not tied to any one vendor's unique self-check, guarantees this.

Summary

To ensure the ongoing safety and effectiveness of RO, public acceptance of RO, and innovation of RO systems, the ability for clinicians to use independent means to verify, measure, and test their RO systems cannot be compromised or restricted. Independent QA & Dosimetry tools depend upon access to the RO ecosystem, i.e. interoperability.

Independent and timely access to TPS files, EPID files, machine log files, and DICOM files within RO systems is critical to the ability to perform independent QA & Dosimetry as part of the routine clinical workflow, and will only become more critical as new modalities, including Adaptive, become widely available.

While this may appear obvious, and is the historical norm within RO, **Independent QA** is not currently prescribed as a guideline or recommendation. It is my belief that RO system support to enable independent QA & Dosimetry should be a formal recommendation / guideline, endorsed by AAPM, ASTRO, ESTRO and IAEA.

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Signed by (Name, Institution)

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Signature, Date