



PTCOG Subcommittee Report

***White Paper on
Particle Therapy Efficiency:
Aspects of Quality Assurance
Version 1***

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White Paper

Improving the Efficiency of Quality Assurance in Particle Therapy Beam Delivery

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Introduction

It is asserted that the processes generally implemented for Quality Assurance in Particle Therapy facilities can be made more efficient. It is also claimed that there are methods that can be implemented to reduce the time and complexity of some aspects of Quality Assurance without compromising safety and accuracy. This topic was discussed at the Particle Therapy Efficiency Workshop in Knoxville, 2015 and this white paper reflects some elements of that discussion.

There are processes that are currently implemented for particle therapy Quality Assurance (QA). Some causes of the inefficiency come from a variety of sources:

- Similar processes used in photon therapy
- Processes deemed necessary for regulatory and legal purposes
- Processes dictated by instrumentation available
- Processes dictated by personnel available
- Processes dictated by machine performance

The current methodology is limited by a belief of the difficulty involved, or lack of desire, to change any of the above inputs. At the Efficiency Workshop, some of these 'assumptions' were challenged to understand how one might identify the sources of inefficiency and mitigate them.

In principle, the development of a QA program should follow specific methodology such as the principles of risk analysis and Lean, for example. From the former, one can identify the probability and severity of an error and identify a mitigation or measurement that is necessary to help obtain a desired degree of confidence in safety and performance. One can also analyze the steps involved in the methodology to identify repetition, inappropriate tasks and inefficiencies. Frankly speaking, this is rarely done and the predominant method is to implement techniques coming from approved sources such as AAPM and ASTRO task groups and guidelines. Note that these tend to be interpreted as mandatory by inspectors and deviation from these can be interpreted as negligence in legal matters. It is hoped, perhaps, that when AAPM TG100 comes out, that the risk analysis methodology will become an accepted practice and enable a better method to develop an appropriate QA procedure for a given facility. Also, when, for example, TR224 comes out with the 'suggested' measurements, these should be considered examples and not a required QA program. Still, assuming such 'administrative' roadblocks were not a factor, one can consider how the process can be improved.

Prerequisites

Quality Assurance is defined in the Oxford Dictionary as "the maintenance of a desired level of quality in a service or product, especially by means of attention to every stage of the process of delivery or production". There are many steps in particle therapy treatment; this white paper focuses on the beam delivery aspect. The beam delivery in particle therapy can be characterized by the type of beam delivered by the two main beam delivery modalities, that of scattering (Figure 1a) and scanning (Figure

1b). These figures summarize the important dosimetric quantities in each modality. One of the key issues in beam delivery QA is to ensure that these quantities are appropriately delivered to the patient and generate the desired prescription.

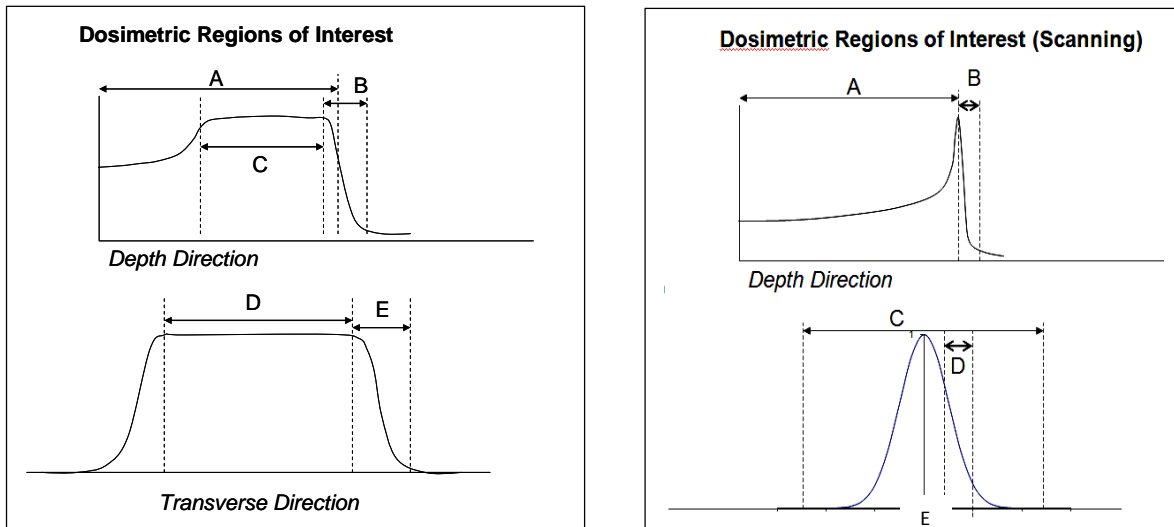


Figure 1: On the left, a) shows the fundamental beam qualities of interest for scattered delivery, while on the right, b) they are shown for scanned delivery. The quantities for scattering include A: Range, B: Distal Fall-off, C: Spread-Out-Bragg-Peak Width, D: Transverse Field Width, and E: Penumbra. The quantities for scanning include A: Range, B: Distal Fall-off, C: Beam Profile, D: Penumbra; and E: Spot position.

There are many elements of a system which contribute to the parameters of these beams. Different facilities have different components contributing to these parameters.

When considering the clinical properties of the beam the following activities can be considered:

1. Clinical commissioning
2. Oncology Information System Data
3. Correspondence between imaging and beam delivery
4. Beam Delivery Modality

One may argue that there is an element of QA in each of these activities. Indeed, sometimes clinical commissioning, for example, is not considered QA, but that may be simply perspective as opposed to actual practice. It is the steps involved in each of these activities that can be examined to identify where efficiencies can be realized. These steps depend upon the definition and usage of the terms. These activities, can also be used to help define the potential failure modes of a system. Below is an example of definitions.

1. Clinical commissioning: The measurement of the dosimetric quantities (e.g. quantities in Figure 1) over the range of beam parameters available for inclusion into the beam model of a Treatment Planning System (TPS) and the verification that the TPS accurately predicted dose distribution in a target. The severity of not predicting this accurately is high. The probability of this happening can depend upon the measurement procedure and treatment geometry.

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2. Oncology Information System Data: The data related to the treatment prescription and treatment plan is transferred to the system that will deliver the treatment. The question arises whether the data that is transferred and converted to machine parameters was done so correctly. The severity of incorrect data transfer or conversion is high, the probability will depend on the system, but is reduced if there is checking.
3. Correspondence between imaging and beam delivery: If imaging is used to locate the patient in the treatment room, the place to which the patient is located should be coincident with the place through which the beam passes. The severity of having the beam pass through the wrong spot is high, the probability will depend upon the reasons for such an error and the frequency of the measurement.
4. Beam Delivery: The question arises as to whether the beam properties, produced by the system are the same ones that were used for clinical commissioning. The severity of incorrect beam properties will depend upon the particular property in question. The probability will vary depending upon the complexity and reliability of the system.

In all cases above, mitigation, through QA procedures, of the potential risk can be a measurement of the appropriate quantities.

What are the possible issues?

It is helpful to try to understand what possible issues may contribute to a lack of an optimized program. In addition, is it enough to just develop the optimized program, or are there other impediments to implementing this in a clinical facility? Some of the issues include:

- Inefficiencies due to legacy processes are adopted for the sake of regulatory, accreditation and billing compliance.
 - Standardized photon QA processes adopted for billing purposes
 - Accreditation requires adoption of fixed processes which become outdated
 - AAPM and ASTRO guidelines interpreted as mandatory by inspectors
 - Failure to adhere to guidelines may be interpreted as negligence in lawsuits
 - Legacy QA tasks may no longer add to patient safety or system reliability
- Newer guidelines do not necessarily apply to a specific facility and/or the suggested program was not based upon a risk analysis and Lean approach. This is partially based upon an impediment to change arising from such considerations as:
 - Variation among Institutions (guidelines cannot take these into account)
 - Equipment
 - Procedures
 - Research and Innovation
 - Difficult (or not tried) buy in from stakeholders (Regulators, Administrators, Physicians, Physicists, Vendors, Prof Societies)
 - Information Silos (Vendors, Physics, Regulators, ...) which do not consider optimization criteria
 - Billing issues

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- Can institutions maintain revenue stream without performing ‘additional’ work
- Expense – up front or ongoing
 - Development and/or investment into optimized tools
 - Physical Measurement Tools
 - Analysis time/tools
 - Analysis required to develop the program
 - Training and or hiring of well trained personnel who can develop the optimized program
 - Measurement time – not necessarily only for the QA program, but for ‘up-front’ measurements that can verify whether improvements in the QA program are possible.
 - Can one justify that optimization; while perhaps costing more at the outset does it result in a less expensive program, freeing up staff to work on more ‘profitable’ endeavors?

Given these issues, it is understood that there are a variety of stakeholders that must be educated and brought on board to accept an optimized approach.

Improvements in QA efficiency

Despite, or independent of, the above impediments, it is necessary to identify the methodology to improve the QA process first. If Quality Assurance of beam delivery can be characterized as presented in the previous section, then one can identify the current issues that are covered by QA procedures, prioritize them and identify an optimized approach. For example, these steps can be analyzed as follows:

- Identify the critical parameter to ensure is correct when delivering a treatment to the patient
 - Determine whether that parameter is the end beam property, or a specific parameter of the particle therapy system (there are tradeoffs that may be considered).
- Identify the severity of the error if those parameters are not correct.
- Identify the probability that this error can occur
 - This probability can be determined/estimated from several sources
 - Experience (will take months or years to optimize – but data must be obtained for the optimization to be enabled)
 - Ease of detection and whether or not detection methods are present
 - Information from a vendor
- Calculate the risk of this event and determine appropriate mitigation factors
- Determine, from the risk analysis, the frequency of these mitigation factors (some of which can be measurements)
 - Real-time (on-line) measurements
 - Daily
 - Monthly
 - Annual
 - One time only

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- Identify the measurement steps and analysis requirements (some elements of the workflow) for these measurements
 - Determine from this analysis how these measurement steps (workflow) depend upon the following issues and make a wish list of things that could streamline the process
 - Limitations of the equipment (e.g. necessity to use different equipment for different measurements, including setup time, measurement time and analysis)
 - Determine what can be
 - Combined
 - Automated
 - Eliminated (always have some place for the possibility of elimination, which could be determined by experience over some time period)
- The above may also require interfacing among various different systems and access to data from different platforms (currently, but could be integrated in the future as more information is presented to the vendor)
- Identify the most appropriate personnel, or personnel skills required to carry out the program

Following this procedure can be straightforward, in fact it may be possible to create a set of ‘guidelines’ for this procedure and this could be an output of the discussions which gave rise to this white paper. It might be helpful to identify a couple of (possibly extreme) cases in which some questions resulting from the above steps would arise.

Some of the issues include the facility time used in QA activities. At the Efficiency Workshop, the participants summarized their understanding of the time (relative to photon QA) that is used in particle therapy QA. See Table1:

QA Type	Photon therapy	Proton therapy						
		Center 1	Center 2	Center 3	Center 4	Center 5	Center 6	Average
Morning QA	1	1	1	1	1	3	0.25	1.2
Weekly QA	1	N/A	N/A	NA	NA		NA	
Monthly QA	1	2	1.5	1-1.5	1		1	1.4
Annual QA	1	1	1	1-1.5	1		0.75	1.0
Patient QA	1	3	4	0.25-0.5	0.75	4	1	2.2
Regression Test	1	2	1.5	1	1		1	1.3

Table 1: Relative perceived efficiency of QA at participating proton centers compared to photon QA.

While one must identify what is required, in the methods described above, the comparison with photon work time (defined as 1 in the table above) is unavoidable, since it is assumed that this is a standard and a well matured modality. However, and this will be exploited below, particle therapy is the best

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instrumented modality that exists and the data that are obtained in real time are rich with information not here-to-fore exploited for QA.

Furthermore, as mentioned earlier, there is an 'array' of instruments used for particle therapy measurements. Some of this necessity is historical owing to the differences between scattering and scanning beam delivery and the only recent involvement of vendors to provide particle therapy QA equipment. Table 2 identifies some of the wide range of equipment that is used.

PT Site	DS	US	PBS	Freq.	Durat.	MatriXX	Lynx	Zebra	Giraffe	WP	RV	Films	Gafchr.	MiniQ	DQA 3	Pyramid	Iso-Align
			✓	Daily	≈ 20 m	✓											
			✓	Monthly	≈ 4 h	✓	✓										
			✓	Yearly			✓	✓		✓		✓					
			✓	Daily		✓			✓					✓			
			✓	Daily									✓				
✓				Monthly		✓				✓							
			✓	Weekly												✓	
			✓	Daily											✓		
✓	✓			Daily	≈ 20 m						✓				✓		
✓	✓			Weekly	≈ 60 m			✓			✓						✓
✓	✓			Monthly	≈ 60 m	✓				✓		✓					
✓	✓			Yearly	≈ 12 h	✓				✓		✓					✓
			✓	Daily		✓											
			✓	Monthly													
			✓	Daily	≈ 30 m	✓											
			✓	Monthly		✓	✓	✓									
			✓	Daily											✓		

Table 2: QA equipment that is used with various deliver methods and their corresponding frequency.

Thus a lot of instruments are used. This may be good for vendors, but not good for efficient QA practice. It would be helpful to combine (as appropriate and possible) the measurement of several parameters into one measurement session, with perhaps one, or combined instruments. Currently this is under development, but there is insufficient interaction between customer and vendor on this subject.

One example of this, (not purposefully trying to advertise a vendor product, but just as an example) is the Sphinx device, which is one phantom that enables the determination of several beam parameters from one measurement. Figure 2 below shows the pieces of the phantom, with the device coupled to a scintillator screen detector.

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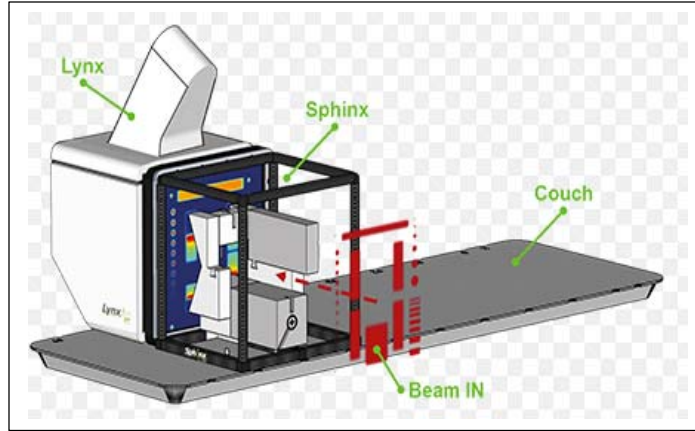


Figure 2: An example of a device that integrates multiple measurements into a single device for improved efficiency.

The results of one measurement with this device are read out and analyzed giving the following information in a few minute irradiation.

Complete Check
Using the Sphinx myQA plug-in intuitive interface, check all your QA key parameters at once:

- ✓ Energy
- ✓ Spot Sigma
- ✓ Spot Position
- ✓ X-ray to beam coincidence
- ✓ Profile homogeneity
- ✓ Output
- ✓ Couch translation
- ✓ Couch absolute value
- ✓ Lasers
- ✓ and more...

myQA Test Setup

myQA Test Run

**Sphinx PT Phantom is in progress. Currently not available for sale. For delivery availability please speak to your local IBA Area Sales Manager.

Figure 3: Automated analysis and reporting improve efficiency.

The most time consuming part would then be mounting it. But depending upon how one uses the information in this white paper, it may be concluded that this may not have to be done very often.

A couple of specific Examples

Below are two examples of how aspects of QA can be rethought, taking into consideration the reality of particle therapy technology.

Daily QA

Possibly one of the most invasive (done at the start of the treatment day) QA tasks is daily QA. It can be helpful to identify some of the tasks that are included in this activity (not by all facilities, but by a representative sampling).

Some Daily QA activities:

- To independently measure and possibly enter temperature & pressure;
- To verify dose/monitor units/proton measurement calibration
- To verify beam energy/range/position
- To make sure things are functioning
- To verify patient image & positioning system;
- To verify PPS movement & positioning
- Other things – this is not an exhaustive list.

One characteristic of particle therapy is the fact that it employs an extensive set of measurements, in the Nozzle and in the rest of the equipment, on-line in real time, during treatment. Is any of this used in the creation of a QA program? The answer is generally not. What is going on here? There are several possibilities, some of which include:

- It is believed that a purpose of QA is to independently check the operation of the on-line instrumentation and that one should not depend on the embedded instrumentation. One believes that a once-a-day measurement to confirm that this system is calibrated is sufficient and that the treatments can safely continue throughout the day.
 - But is it really the case, that it has been shown that the doubly (and sometimes triply) redundant embedded instrumentation in the particle therapy system is so bad that it must be checked every day?
- Not all the things that need to be known are measured in real time. Some examples can be the beam range during pencil beam scanning delivery.
 - But is it really the case, that the semi-indirect sources of measurement – Energy from the accelerator, beam line magnetic fields, redundant degrader measurements, are not as good as a single detector measurement once a day?
- Perhaps, this arises from legacy photon QA whose instrumentation measured many fewer parameters and did not have the robust degree of mitigations and redundancy.

Looking again at some of the reasons for daily QA, one can imagine the following:

- To independently measure and possibly enter temperature & pressure;
 - Why not automate this?
 - How often would this have to be done on a daily (infringing on what could be treatment time) basis if it were automated.
- To verify dose/monitor units/proton measurement calibration

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- There are redundant (at least) dose monitors in a Nozzle, with High Voltage detection. Do they need to be measured every day?
- To verify beam energy/range/position
 - What would a risk analysis evaluation result in given the measurements that are made in real time that are related to the beam range during treatment?
- To make sure things are functioning
 - Things are turned on
 - To ensure correct beam property as vendor may change machine or configuration during the night
 - Instrumentation noise levels are low enough for treatment beam delivery
- To verify patient image & positioning system;
- To verify PPS movement & positioning

One Devil's advocate position would be that the probability that things are not working are very low, and that the level of instrumentation is sufficient to detect any problem sufficiently fast to mitigate any serious problem. Perhaps then, the only thing remaining is to not want to allow the patient to get in the treatment device then only to find out that something is wrong. If that's the only remaining issue, then the only thing that is needed is a mock treatment, using the systems own instrumentation to confirm that the system is operational and the parameters are correct. Of significant help in the development of an efficient and safe QA program, is the response to this Devil's advocate position.

One response to this, which is not normally a consideration in the photon world, is that development on particle therapy systems is commonplace. There is some concern that the machine that exists this morning is not the same as it was during the previous treatment day. This is indeed an important concern, but it is a specific concern and should be a special consequence of a QA solution not a generic risk. Perhaps the developer should be responsible for a regression testing, which is separate from standard morning QA, for example. While this depends upon who is formally responsible, one can see that correct identification of a special situation can help reduce the complexity of QA.

Patient Specific QA

Patient specific QA is an activity that takes a significant amount of time and other resources in particle therapy facilities, after treatment hours, in preparation for patient treatment. What are the concerns that lead to this activity?

In its broadest terms, one can identify patient specific QA as being associated with a specific patient. There are several things associated with a specific patient QA program (not an exhaustive list):

- Does the treatment planning system evaluate the dose distribution that will be delivered to the patient correctly (assuming the machine delivers what is requested).
- Is the overall output factor calibration correct for this set of beams?
- Is the data sent from and received from the OIS correct?
- Has the machine interpreted and translated that data correctly?
- Can the machine deliver the appropriate parameters?
- Will the machine deliver the appropriate parameters?

At present, a typical approach to this QA, is to evaluate, for the TPS parameters intended for the patient field, what the dose distribution would be if these were, instead, delivered into water, and to measure that. While that is not precisely what the patient will absorb, it is what is typically done. This, in principle, verifies most of the above issues in one non-trivial set of measurements. However, this can take from 30 minutes to a few hours for a set of measurements. One efficiency implementation is to only measure a few points within a 3D volume, preferably those points that represent locations with particular sensitivity. But if one were to truly do a risk analysis for the steps identified above, what would be the result?

- Does the treatment planning system calculate the dose distribution that will be delivered to the patient correctly (assuming the machine delivers what is requested).
 - While this is what part of clinical commissioning is for, it is never the case that all clinical situations can be initially measured. However, one can define a class of beams and anatomy that represent already tested geometries which need not be revisited. This separates geometries into different risk categories.
 - There are several examples for high-risk dose calculation/delivery uncertainty:
 - Range shifter with large air gap
 - Large field could hit edge of range shifter/compensator
 - Same as above.
- Is the data sent from and received from the OIS correct?
 - This can be mitigated in the software system, and include visual verification from the RTT if desired. This need not be an event of high risk and patient by patient QA verification.
- Has the machine interpreted and translated that data correctly?
 - This can be mitigated via appropriate data transfer techniques (see above step) and inverse algorithms if desired and need not be an event of high risk.
- Can the machine deliver the appropriate parameters?
 - This is a deterministic problem, one which the system is capable of self-determining.
- Will the machine deliver the appropriate parameters?
 - This is continually measured during beam delivery (by virtue of the translated data and associated tolerances). One can simply run the system and confirm that all standard tests are passed.
- Other things – this is not an exhaustive list. Is the overall output factor calibration correct for this set of beams?
-

Agreement with the above (Devil's advocate?) position simply leaves the identification of TPS geometries as the trigger point for a patient specific QA.

Of course, the above does not include QA of patient specific hardware, imaging or other issues, but this White Paper is addressing that part of patient specific QA which uses an expensive and scarce resource – beam time. Thus appropriate application of risk analysis and Lean techniques can result in a more efficient and optimized resource situation. Perhaps, there needs to be a period of trust development as more geometries are irradiated, but the true limiting factor may likely be the understanding of what the TPS beam model does.

Irradiation Log:

There is a current trend in the radiotherapy community to view the results of the data taken during irradiation (in the irradiation log). These results are then used in some form to characterize the beam that was delivered and to be able to compare that with the desired beam. There is an interesting paradox inherent in this activity.

It is believed, by some, that this irradiation log has sufficient information (particularly in the case of particle therapy) to be used instead of external (e.g. Matrixx) instrumentation and that the same information that would have been obtained by the Matrixx can be seen in the on-line instrumentation. This would almost eliminate that aspect of QA using external instrumentation (except as needed to verify the calibration of the on-line instrumentation) or perhaps range measurements. One can then use the on-line instrumentation to simulate what the external instrumentation at isocenter would measure and obtain equivalent data.

The paradoxical aspect of this method is the fact that this on-line instrumentation is used to deliver the beam with presumably clinically realistic threshold values. Therefore, if the beam is delivered, then its parameters would be consistent with what is expected for an accurate treatment. The question then would be what new information is needed from the irradiation log that isn't already known during the beam delivery? Perhaps it is to confirm, before an irradiation that the system was functioning, but if that data is to be used after the fact, then the question still remains.

Summary:

As noted above, the development of an improved and more efficient QA system requires development time, improved instrumentation and automated techniques, among other things. The need to do this requires convincing ourselves and then convincing administrations to obtain the up-front resources.

There are many other aspects of QA that were not specifically addressed in this white paper, but it is believed that the specific approach summarized herein will be useful. This approach can be characterized briefly as follows:

How to improve the efficiency

- What can we eliminate? (Entire steps or conditions within a step of a type of measurement)
- What can we automate?
- What can we combine?

How to improve the measurement

- How can experience modify QA, independent of current regulatory assumptions?
- Good tools & methods to integrate the measurements: e.g. 3D dose measurements; planar dose measurement tool that can be mounted on the nozzle. Need proton specific QA tools from vendors.
- Improvements in technology robustness, self-checking, automation and interfaces with QA program
 - o Machine
 - o TPS
 - o Integrated measurements (on line) and instrumentation (automatic)

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Some discussion about the use of irradiation logs is factored into QA discussions. The use, again of a risk analysis approach can help with this. If the irradiation log is to be used to determine what the machine has delivered, but the machine only delivers parameters within its tolerances, what is to be learned from this log? It is, of course, critical that the tolerances applied to the machine parameters be clinically significant, but to invest too much effort to think one can learn more than whether or not the tolerances have been respected, is to be discussed and the frequency of this latter is also for analysis. Understanding the equipment is an essential element of developing a useful and robust QA program.

This White Paper did not discuss other elements of a program for which the tools identified could be useful. One aspect is the development of instruments that combine measurements. Also, one specific aspect of QA and commissioning is worth mentioning in that another tool, Monte Carlo calculations is becoming an important part of the off-line process and may continue to increase its role in minimizing the measurements for and improving the understanding of beam delivery. Building the correct model becomes an important part of commissioning, which will then become helpful in the application of QA techniques, particularly in the determination of sensitivities and tolerances.