EMBRACING ULTRASOUND QUALITY CONTROL

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Abstract - **This paper discusses the success of the ultrasound quality program that was developed and instituted at a large tertiary care busy ultrasound imaging department with some 30 ultrasound scanners and over 120 transducers regularly in use. There is a continuous steady growth in patient ultrasound imaging exam volumes with increases in the daily number of ultrasound scanners in use along with advanced application use transducers. All levels of management were involved and passionate in the development of the ultrasound quality program. Meetings were held regularly to discuss tests to be performed, the method for reporting and tracking of service repairs, the best phantom to be used, selecting of quality control sonographers, and development of databases to track ultrasound scanners, probes, repairs, replacements and upgrades. These were determined to be of outmost importance to begin the program. Adherence to the program continues successfully with slight occasional changes in order to improve the overall program effectiveness and efficiency. It is possible to institute a high quality program in a busy imaging environment where QC sonographers are vigilant and management is onboard. The system we developed was also transitioned to smaller one scanner clinics as the core of the program is independent on the number of ultrasound scanners or probes.**

Keywords – **quality control, quality assurance, quality improvement, ultrasound quality programs**

I. Introduction

Ultrasound quality control programs are in their infancy. In the authors' opinion and past experiences, the best, and perhaps the only way image quality optimization can occur in radiology is by instituting quality programs, whether they be mandated regulations or by following recommendations from accreditation bodies or using common sense derived from experience. The best programs are those that embody the principles of quality improvement with personnel embracing and being committed to those activities. The goals are always to ensure that patients have access to the best image quality and that providers can have the confidence the images produced are of the highest quality.

Accreditation organizations such as the American College of Radiology (ACR) certify facilities for specific diagnostic imaging equipment if the facility can provide the required satisfactory documentation such as clinical and phantom test images and provider qualifications, for example [1]. This is a voluntary program associated with a certain amount of prestige with equipment being ACR accredited. The facility can certainly use this fact in their marketing collateral, as a place where patients can feel confident the equipment, personnel, physicians and the images produced are at a high level. The only way one can maintain such high levels of image optimization is if robust and regular quality programs exist.

Ultrasound quality assurance (QA) and quality control (QC) programs have not had the visibility of other diagnostic imaging modalities such as computed tomography (CT), magnetic resonance imaging (MRI) or nuclear medicine (NM) imaging. National and international scientific regulatory bodies control ionization radiation modalities, and along with the American College of Radiology (ACR) accreditation requirements provide for comprehensive daily, weekly, monthly and yearly tests. Depending on other accreditation bodies the hospital would adhere to, there might also be further requirements.

Ultrasound is one of the diagnostic imaging modalities to have few, if any, regulations associated with the continued optimal performance of ultrasound exams, if any. Both the ACR and the American Institute of Ultrasound in Medicine (AIUM) have proposed over many years, quality programs [1-3]. The ACR, in its 2017 recommendations for ultrasound accreditation, required a quality control program be in place for institutions where ultrasound units are accredited by the ACR, but does not recommend a specific phantom or set of phantoms [1]. The document further does not stipulate any upper or lower boundary values by which specific imaging parameters should reside within. It is up to the individual site to setup a procedure to monitor and track performance levels and when to initiate a service call. Even though the ACR and AIUM advise that each scanner be acceptance tested before first clinical use, it is not necessarily a task perceived as being necessary. The Joint Commission (TJC) does not mention ultrasound imaging separately as a modality to have specific guidance or image requirements [4]. The Technical Standards Committee of AIUM issued in 2014 a set of measurement guidelines for gray scale scanners [5], which only addresses B-mode imaging. The Intersocietal Accreditation Commission (IAC) only accredits for vascular and echocardiography, though a

facility could be accredited by both IAC and AIUM for a complete range of ultrasound services. The IAC does not offer any recommendations regarding phantoms, nor regular testing procedures to ensure continued quality [6, 7]. International organizations, such as the International ElectroTechnical Commission (IEC) does have specific guidelines for pulse-echo scanners [8-12], which are periodically reviewed and revised as necessary.

In this paper, we examine the ultrasound quality assurance program developed for a large hospital and an adjoining large outpatient clinic. This is not a report on equipment efficacy nor a vendor scanner comparison, but rather a discussion on the implementation of a simple program developed in such a way that it is easy to follow and maximizes the outcomes while minimizing the time spent conducting the tests. It is a program that can be easily deployed in institutions with a large number of scanners or in a small one scanner outpatient clinic.

Resistance to ultrasound QC programs is more of an ad-hoc issue, possibly due to previous sonographers' negative experiences with complicated and lengthy tasks to perform. We set out on the premise that as long as the program did not require an inordinate amount of time or complex measurements, ultrasound quality programs can be viable and provide useful information as to the quality of the scanners and probes and eventually to pro-active measures in making better purchasing and negotiating decisions. It was also seen that empowering the ultrasound technologists as the custodian of the equipment would only enhance any type of quality program.

In the authors' opinion, poor image quality does not benefit anyone, least of all the patient. Lengthy downtimes benefits no one and the longer a machine is non-functional plus the cost of repairs, if not covered by some form of warranty or service contract only delays patient imaging. Empowering the ultrasound technologists who perform the regular QC to call out defective monitors, probes, and systems only benefits the patient with the desired outcome of optimally performing scanners at all times.

II. Method

A. Development of the QA/QC program

A year or so before the new hospital was to open, circa 2014, discussions occurred between Radiology management, the ultrasound imaging section and medical physics. A plan needed to be developed with standardized procedures that could be implemented and followed for the optimal performance level of the clinical ultrasound scanners.

Previously, the medical physicist conducted annual physics performance evaluations on all units with an all-purpose ultrasound phantom (ATS Model 539). In addition, ultrasound technologists imaged this identical phantom twice a year, but found it unmanageable and complicated with compliance being an issue. In many instances, failures were not addressed and never communicated to service personnel. The phantom was burdensome, had several surfaces that could be imaged leading to confusion as to which surface to use, and exactly what feature to measure as there were no formal procedural steps to follow.

Scanners were normally serviced in-house or, if necessary, by the service provider for that institution. New scanners are under some form of contractual warranty, and thereafter in-house technical service staff took over the repair and maintenance. Probes were replaced when physically damaged or when image quality was deemed clinically unsatisfactory; though a threshold for determining this defective image state had no quality metrics associated with it.

With the opening of the new hospital, a new ultrasound QA/QC program was developed. The ultrasound imaging manager selected a QC coordinator, the person who micro-manages the ultrasound QC program, and QC personnel, that is, the ones who perform the testing and report on the testing results. Selection of personnel is not a decision taken lightly. There is a need for personal internal commitment and dedication from QC personnel for the program to be successful.

Medical physics developed a standard procedure to encompass the type of tests, the frequency of those tests, who was responsible for the testing to be completed and the ensuing training required. Meetings with stakeholders were held until consensus was reached. Management was supportive, with encouragement given to implement this program at all levels starting with providing time to ultrasound technologists to perform the required testing.

A series of written directives were drafted and circulated, including a proposed set of instructions for the technologist performing the physical checks. The focus was to ensure the steps were simple, but high yield with results entered into a spreadsheet.

B. Selection of the Phantom

The next step was determining the appropriate phantom to use at the sites to image uniformity as none of the accrediting bodies requires a specific ultrasound phantom to be used. At the time, only a few suitable phantoms were available or could be used to test uniformity. An investigation determined that one model (Gammex Model 416) was the most versatile as it could image linear, curvilinear and endo-cavity probes across a uniform volume. Other phantoms were tested but proved less than robust and not as versatile or easy to use when it came to image curvilinear or endo-cavity probes. As the phantom was not costly, one was bought for the main hospital and additional ones for the outpatient clinics. Building our own phantom was not feasible at the time, but certainly could be entertained in another iteration in the development of this program.

C. Sonographer Training Program

Medical physics trained the ultrasound technologists carrying out the QC during a one hour session. Discussions revolved around the reasons for performing QC, the factors that contribute to image failure and the correct procedure to perform all the checks. It was also emphasized that if a failure is noted, the QC coordinator and the ultrasound imaging manager need to be informed so that a service ticket can be placed. Training attendance certificates were issued after the onboarding session and signed by both the medical physicist and the ultrasound technologist. These are kept as a permanent record within the ultrasound technologist's continuing education file. Table 1 lists the main points that are brought forward during this discussion, which is also the basis of the regular QC testing program.

Table 1 Sonographer Training

Training Tasks	
	1. Identification of scanner parts
	2. Where to locate serial numbers of probes and scanners
	3. Identification of stress points in power cord and probe cables
	4. Examination of control panel integrity
	5. Ensure cleanliness of the complete system
	6. Brakes working
	7. Monitor can be locked in any position
	8. Any peripherals secured
	9. Locating and displaying test images either SMPTE or TG18
	10. Identifying the 0/5% and 95/100% contrast patches
	11. Looking for unsharp transitions
	12. Identifying monitor resolution pattern aliasing
	13. Identify monitor pixel defects
	14. Imaging uniformity phantom
	15. Identification of image artifacts

D. QC Testing

The simple QC program incorporates the tests recommended by ACR [1]. At this time, QC is performed quarterly by the designated QC trained staff, and the medical physicist performs a yearly comprehensive performance evaluation of the system. In addition, the in-house service bioengineers inspect each ultrasound scanner at a minimum of once per year. If planned properly, the quarterly checks performed by the ultrasound technologist, the physicist once a year, and bioengineering once a year can amount to testing each unit almost every other month. It is worth noting that bioengineering would evaluate the scanner and not necessarily all clinical probes. Records of all tests performed and any remedial actions are kept centrally in an electronic database.

Only the ACR accredited ultrasound units are part of this program, for a total of about 30 scanners across the hospital and outpatient clinics spanning general abdominal imaging, vascular imaging, breast imaging, pediatric imaging, and with advanced applications such as contrast enhanced ultrasound, 2D/3D, and elastography being offered. There are approximately 120 ultrasound probes in the complement of clinically active probes used daily. The total number of patients imaged in the ultrasound department is approximately 50,000 per year and steadily growing. Most scanners are portable, that is, each scanner does not necessarily have an assigned imaging bay or imaging suite. Even if a scanner is in a particular bay or suite, it does not imply that same unit will be located in the same bay or suite every day. At the main hospital location, many patients are scanned bedside on the hospital floor. At the outpatient clinic, since the patients are ambulatory, there are dedicated ultrasound imaging suites.

Determining who monitors the program at all sites, who can take action when a test deficiency is noted, who is responsible for modifying the procedure or instructions when needed, how often the management team meets to discuss program results, and who can implement change are all part of the broader QA program. The broader program also addresses auditing the task of cleaning and disinfecting the ultrasound scanner and probes after each use, that endocavity probes are properly disinfected after each use, filters are cleaned regularly, and the general safety of the ultrasound scanner is checked.

Table 2 lists the elements of the quality control program performed by the ultrasound technologists. The procedure is to test all ports on the scanner along with the most clinically used probes. Updates to the probe inventory list is an ongoing task with probe additions and deletions kept up-to-date in a centralized database.

Table 2 Sonographer quarterly QC tests

Visual Inspection	Visual assessment of monitor, power cord, probe cables, and control panel
Brakes	Machine doesn't move when brakes engaged
Electrical safety	Power cord intact
Uniformity	Phantom image from each probe and each port for artifacts
Monitor display	Evaluation of test image for pixel defects, and artifacts

QC is also performed on new probes that are put into service, and probes that are loaned to us while others are being serviced. Probes that are used only occasionally are also QC'ed before patient imaging to ensure artifacts are not present and that the integrity of the probe is intact and still safe to use. Images acquired from all probes are permanently stored for the lifetime of the probe, and then archived for future comparisons. The length of time the archive is kept has yet to be determined and is maintained

at a centralized location. A digital record, which includes pictures of all system serial numbers including the probes serial numbers, ensures the database is always current. Defects noted during the annual medical physics testing can be also be tracked. Artifact images are included in the report, as are images of any breaks or cracks of any of the probes or the unit itself. In essence, each probe and each ultrasound scanner has a complete digital history.

Acquisition display monitors are also checked during the routine QC. Resolution patterns, 0/5% and 95/100% contrast patches, looking for pixel streaks or defects, noise, and unsharp transitions are all part of monitoring displays for degradation. The medical physicist plots the luminance values of the eighteen targets from the TG-18 test pattern for display range and non-uniformity. Comparisons are made year to year to track monitor degradation.

Other aspects of the quarterly QC program is to ensure brakes are functioning properly, the power cord and probe cables are intact and not intertwined, and all peripheral devices are properly affixed to the scanner.

III. Discussion

The QC program has been in place since 2017. There has been 100% testing compliance; no quarter has been missed since implementation. Sonographers have been trained by the Medical Physicist, with others trained as necessary with staff changes. Other clinical sections with ultrasound devices, interventional radiology and vascular interventional radiology, are being looped into the ultrasound quality program as word has spread about this initiative and the desire to have a program that can maintain image quality. Table 3 delineates initial and ongoing costs of the program. Improvements are being considered to streamline the sending and receiving of QC images, signing off on the quarterly QCs by using more automation. We are also looking into only using in-air images to track transducer failures as an even more economical and time-saving procedure.

Table 3 Implementation and time costs

Item	Approximate time spent
Training of QC technologists	1 hour per technologist and 1 hour medical physicist per group
Phantom	1 per site
QC checks	5-10 minutes average per machine, quarterly
Annual medical physics check at site	1 hour per machine
Medical physicist off site evaluation of images and report writing	1 hour per machine – normal 2 hours or more for acceptance testing and reporting
Updating QC database – ultrasound technologist	1 hour per quarter on average
Quarterly review of QC – medical physicist	4 hours per quarter: looking at all QC uniformity images, evaluating for artifacts, updating database

As older equipment is replaced, new ultrasound scanners are logged into the QC database. Acceptance testing is conducted on all probes, irrespective of whether the probes will be used daily. Acceptance testing starts the overall QA process with the benchmarking of all probes with the most likely clinical protocol. In-air images are also acquired at acceptance testing and annually. These images provide another layer of data in determining transducer failures.

Table 4 indicates the major problems encountered with the ultrasound scanners such as control panel breakage and the monitor arm not holding in place. When troubleshooting the control panel breakage, it was noted that sometimes patients used the side of the control panel to raise themselves from the scanning bed. This was discouraged as much as possible.

Table 4 Most often downtimes/repairs

Problem Category	Part	Failure/Reason
Manufacturing Defects	Monitor Arm	Unstable – Failure to maintain position
	Control Panel	Tension caused severe cracks on both sides needing replacement to all units to a more robust panel.
Normal Usage	Control Panel	Keys need replacement
	Probes	Probe housing coming apart Damaged probe heads High frequency probe transducer element failures Persistent noise
Upgrades	Software/Hardware	Image artifacts caused by hardware/software upgrade-boards replaced
Electrical	Power cord	Stress at both ends of power cord requiring replacement Outer rubber sheath cracking/fraying due to running over cord with scanner – cords replaced
Acquisition Monitor	Clinical Image	Gray scale image displayed in color
System	Connectivity	Intermittent – unknown origin – communication with RIS, PACS or pulling from Worklist disabled

One has to be diligent in selecting equipment that meets the needs of the service. As mentioned previously, most ultrasound scanners are portables and need to be moved from one location to another. The handgrips on the control panel broke on all scanners deemed portable and had to be replaced with a sturdier, improved version. Obviously, one may not be aware when purchasing that

this will occur. As a result, next purchases will include actively investigating certain features of ultrasound scanners.

Because radiology and ultrasound management embraced the program from the beginning, quality control is conducted as originally designed with few changes. Coordinating timing of the checks can sometimes be problematic due to clinic constraints or other uncontrollable events such as scanner having issues with connectivity, software or upgrades, and inclement weather such as hurricanes or tornadoes, and of course any type of contagion that would necessitate segregating the ultrasound fleet. Other minor areas requiring sporadic attention, is ensuring that ultrasound technologists are properly trained, that service tickets are promptly sent, and records timely updated.

The length of time the tests actually take is minimal, from 5 to 10 minutes per scanner once the sonographer is comfortable with the procedure. The time it takes ultrasound technologists to become comfortable is dependent mostly upon experience.

One aspect of the overall QA program identified as needing attention, is to develop a process or procedure when personnel changes occur. This is not a problem until staff changes occur. Because ultrasound QC is not as entrenched as with other diagnostic imaging modalities where technologists and managers are very much aware of regulatory requirements, anyone who would come from outside the hospital or clinic would not necessarily be aware the program exists and, more importantly, know what to do. Addressing this has become a priority.

Improvements, resulting from the deployment of the same program and processes across all hospitals and clinics are not always easily quantifiable. There are three components at play when looking at ultrasound equipment: the probe, the unit (including hardware and software), and the acquisition monitor. All three can independently contribute to image degradation. The ultrasound technologist visually checks the display monitor quarterly, as part of the QC but also daily as part of patient imaging. The medical physicist, once a year, generates a luminance graph of the TG18 gray scale pattern from each ultrasound scanner. The same criteria for CT acquisition monitors is our baseline for evaluating each monitor [13] (Table 5), as well as incorporating the 9-point luminance deviation from the median (LUDM) from AAPM Report 270 [14].

Table 5 Minimum criteria for ultrasound display monitors

Parameter	Threshold Value
Maximum Brightness (L_{max})	> = 100 cd/m^2
Uniformity – 9 point	$LUDM = \max\left(100 \cdot \frac{\lvert L'_n - L'_{med} \rvert}{L'_{med}}\right)$
	Where: L'_n is the luminance value at each point L'_{med} is the median value of the 9 luminance measurements

Because the same program exists everywhere, we now have a database of quality measures to compare the performance of the systems for the same make/model/software version. The expectation is that all machines with the identical version of software on the same make and model should be performing at the same level given a specific clinical protocol. We can now track clinical image quality throughout the system using the data collected.

Table 6 delineates simple steps one can take to begin an ultrasound quality assurance or more generally a quality improvement program at any imaging facility whether a small clinic with only one scanner or a large imaging department with a substantial ultrasound fleet.

Table 6 Suggested steps for ultrasound QC implementation

1.	Link/network with others who have successfully implemented an ultrasound QC program at their facility
2.	Summarize the best points for future internal discussions
3.	Organize meetings with all stakeholders (radiologists, managers, lead ultrasound technologists)
4.	Demonstrate value of QC testing by providing papers delineating positive results and summarizing results from your network
5.	Prepare simple QC test requirements based on your clinical/hospital requirements
6.	Propose frequency of testing that is manageable and achievable.
7.	Determine how QC data will be collected, who will monitor, where stored, who has access, etc
8.	Make necessary changes as program matures based on data collected

IV. Conclusion

Because this was a simple program to follow, compliance has been very high. In fact, compliance runs at 100%. Ultrasound technologists feel more empowered and in control in determining whether to place a service request for repairs to either probes or the ultrasound systems. The criteria for artifact identification that could cause image quality degradation is now firmly entrenched. A metric was developed to determine the point at which the probe housing would require resealing as opposed to replacing, as probe replacement is becoming more and more expensive with each new generation of probe development. The generation of a common failures list will help in future purchases and negotiating service agreements. Even after several years of compliance, the quality technologists are enthusiastic about the program. Equipment is repaired sooner and malfunctioning probes replaced more often providing for the best quality patient imaging.

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