Administrative Inspections of Private X-ray Clinics

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Abstract. The method of administrative inspection has been tried in a sample of 26 private clinics with x-ray equipment. Administrative inspections are not intended to replace physical visits to clinics, but as a quick way of identifying sites where quality control of the x-ray equipment is faulty. Several problem areas were identified from the documentation acquired from the clinics, with the overall conclusion that medical physicists responsible for quality control in private x-ray facilities do not always work with the care and attention that the task demands. The project has led to considerable improvement in quality control in most of the clinics addressed and the NIRP inspectors involved in the project hope that this will be a recurring work method.

KEYWORDS: quality assurance, quality control, diagnostic x-ray equipment, regulatory inspections

INTRODUCTION

In Denmark, owners of diagnostic x-ray equipment (i.e. all x-ray units used for imaging living persons, except those installed in dental surgeries) are required to appoint a medical physicist to ensure that quality control is carried out in accordance with regulations. In public hospitals, medical physicists are employed full-time, but in private clinics with only one or a few x-ray units, the task is carried out by freelancing medical physicists. The physicist does not have to perform all the required measurements for quality control; acceptance and status tests are often performed by x-ray service companies and constancy tests by the clinical staff. However, the physicist is responsible for checking all tests and making sure that the equipment is working within acceptable standards.

The National Institute of Radiation Protection (NIRP) carries out regulatory inspections of all sites where medical x-ray equipment is used. System inspections, in which members of staff are interviewed and the quality assurance manual is reviewed, are performed in sites with more than one x-ray unit or with CT scanners. In clinics with only one x-ray unit, the inspector mainly checks the premises and the documentation for quality control of the apparatus (standard inspection). Inspections, especially system inspections, are very time-consuming and there is a large number of sites with medical x-ray equipment in Denmark; notably, many chiropractors own an x-ray unit. As a result, NIRP inspections are rare from the point of view of individual clinics.

Following a system inspection of a private x-ray facility where serious flaws were detected in the quality control of the x-ray equipment, the NIRP decided to try administrative inspections as a way of quickly identifying sites in which quality control of x-ray units was not performed according to regulations. Administrative inspections were not intended to replace system or standard inspections, but as a complement.

METHOD

26 private practices with x-ray equipment were selected and requested by letter or e-mail to send documentation for quality control of all x-ray units in the clinic (acceptance tests, most recent status tests, and constancy controls from the last three months). The deadline for sending the material in was October 15, 2010. Clinics with more than one x-ray unit were also asked to send a copy of their quality

assurance manual, but these were never checked, since reviewing the other documentation demanded more time than expected.

Of the 26 clinics in the sample, 13 had only one x-ray unit. Of these, 3 were bone densitometers, 3 were fluoroscopy equipment, and the remaining 7 were conventional, 2D x-ray units.

RESULTS

On review of the first replies to the request for documentation, it was found that only two of the 26 clinics inspected immediately produced satisfactory documentation. Eight clinics sent documentation that was not satisfactory, but where the flaws were not considered crucial. In the remaining 16 clinics, the use of one or more x-ray units was prohibited. As of August 16, 2011, satisfactory documentation had been produced by 13 clinics, while there was ongoing correspondence with the remaining 13 sites to bring their quality control procedures, and documentation of them, up to standards.

Analysis of the flaws encountered in the material shows that they can be broadly divided into two categories: errors and mistakes by the clinical staff, and errors and mistakes by medical physicists and engineers from x-ray service companies.

In most of the clinics studied, health professionals did not seem to take an interest in quality control of the x-ray equipment. This was true even in small clinics where the owner, who is legally ultimately responsible for making sure that the x-ray equipment fulfils all regulatory requirements, was part of the clinical staff. There were places where the physicist even came in to make the monthly constancy checks, which freed the clinical staff from any contact with the quality control of the x-ray equipment. This resulted in many clinics sending documentation that was incomplete or irrelevant, e.g. pertaining to x-ray units that were no longer in use. Several clinics did not respond to the request from the NIRP at all, immediately forwarding it to the medical physicist and trusting it to be taken care of.

In clinics where the staff performed constancy tests, there was sometimes no sign of action when the measurements exceeded the limiting values, indicating that the person who had performed the test had not been correctly instructed, or did not understand the task.

Errors and mistakes by medical physicists and engineers are more worrying, since they are supposed to be specialists. There were several categories of errors by these groups: omissions of measurements or important information in test reports, exceeded limiting values without any corrective action and subsequent re-testing, incorrect measurement technique, and miscalculations and other mistakes.

The statute regulating the use and quality assurance of diagnostic x-ray equipment contains lists of all parameters to be measured in acceptance, status, and constancy tests. Despite this, measurements were sometimes omitted. Quality control of diagnostic monitors was often missing entirely, in many cases because the medical physicist argued that the clinic did not have one, but used an “ordinary computer”. The digital imaging system was another part of the x-ray equipment where acceptance and status tests were quite often missing.

Where measurements were missing in acceptance or status controls, the reason often turned out to be that the measurement was not relevant, e.g. because the x-ray unit did not have AEC. This is of course in order, but should be clearly stated in the documentation. There were also examples of measurements in acceptance and status tests being omitted without reason, and constancy tests had not always been performed every month as required.

There were also many examples of documentation where the measured values were filled out, but information on machine settings, reference values, limiting values or other important parameters was missing, i.e. no frame of reference was given with which to compare the measured values.

An even more serious error was when the result of a measurement showed that the x-ray unit did not operate within acceptable standards, but the physicist or engineer had not reacted to this. This was more common than expected: in three clinics out of 26, the use of one or more x-ray units was prohibited because measurements were found to exceed limiting values.

In some cases, measurements were incorrectly made. The NIRP has produced protocols for the measurements to be performed in quality control, and they are available on the NIRP home page, but it is not mandatory to follow them. However, all measurements must be made in a way that yields relevant results, and in those where the point is repetition (status and constancy checks), the settings and measurement technique used must be the same every time. In the material reviewed, we have seen inconsistencies in this as well as confusion as to what parameter is supposed to be measured and why.

As for miscalculations, everybody makes mistakes. However, in cases where the miscalculations are noticeable at a glance and compounded with other errors and signs of lack of interest or competence, they look more serious. Any medical physicist should take the time to check his measurements and calculations at least superficially before signing a piece of quality control documentation.

There were also places where the quality control suffered because of poor communication between medical physicists and health professionals, i.e. both sides might have been responsible for a hole in the quality system. In one clinic, no constancy tests had been performed for several months, since a new physicist had been appointed – the old one had ceased to perform the tests some time ago, and the new one had not started yet.

CONCLUSIONS

Our findings indicate that not all freelancing medical physicists work with the care and attention that the task demands. Clinical staff seems generally not to be interested in quality control of the x-ray equipment, and rather than trying to include the health professionals and communicate the importance of quality control for patient security, some physicists encourage this and make deals with clinics where the physicist takes care of everything, even the monthly constancy controls. This way, the users of the equipment (and most often the owner, who is legally responsible) lose all insight into the condition of their x-ray unit.

The material also shows that not all physicists and engineers have a thorough understanding of quality control. Limiting values, reference values and parameters set are not always specified and limiting values are sometimes exceeded. Some of these errors might stem from a certainty that nobody else will read the report and/or a belief that nothing will be wrong anyway and if it is, no great harm will be caused. The comparatively low doses associated with diagnostic x-ray examinations probably influence this attitude. However, the errors might also mirror a serious lack of understanding of the principles of quality control, what information is needed for it to work, and why it is important.

Engineers working for x-ray service companies do not necessarily have the grasp of physics and metrology necessary to perform acceptance and status controls. This becomes a problem if the medical

physicist does not check their work and performs the measurements that might be wrong or missing before the equipment is taken into clinical use.

The method of administrative inspections has not been formally evaluated, but the NIRP inspectors involved consider the project a success. The work has been very time-consuming because of the many problems discovered in the reviewed material, but it has resulted in a constructive dialogue between the NIRP and the affected medical physicists and x-ray service companies. The ability to simultaneously address several clinics in different parts of the country makes the administrative inspections an effective way of signalling to medical physicists and clinical staff that quality control is important enough to warrant regulatory inspection.

The NIRP inspectors involved in the project hope that more administrative inspections will be carried out, but covering fewer individual clinics in each round (a suggested number would be three to five clinics per inspector rather than 26 clinics to three people). However, it is also expected that administrative inspections will grow easier and less work-intensive if they become a regular work method. The limited number of freelancing medical physicists and x-ray service companies in Denmark means that regular administrative inspections will have a broad impact and improve quality control on the whole, not only in those clinics that are specifically addressed.