QUALITY ASSURANCE IN DIAGNOSTIC RADIOLOGY—FOR ITS OWN SAKE OR THAT OF THE PATIENT

E. T. Henshaw

Integrated Radiological Services Limited
RPS Centre
42 Rodney Street
Liverpool L1 9AA
UK

X-Ray departments are expensive to equip and run. This paper illustrates how a quality assurance programme may help to limit the wastage of resources. The production of good quality medical X-ray images is extremely complex and can only be guaranteed by implementing some form of quality assurance programme. The exposure of patients to X-rays also entails a risk of radiation injury and a quality assurance programme is necessary in order to limit this risk to a level as low as reasonably practicable. Because of this, in countries within the CEC, legislation now requires such a programme to be implemented. The aims of a QA programme are defined, and the implications arising from these aims are discussed. The role of international organisations in helping to achieve these aims is also discussed. The pitfalls of a QA programme in radiology are also identified particularly: (1) the tendency to carry out a large programme and acquire a considerable amount of data so that the original aims are obscured; (2) the possibility of carrying out tests which are expensive to perform and are not cost effective and (3) the failure to adapt constantly the content of the QA programme to the ever changing needs of the local department and the radiological community generally. The various components of a QA programme are presented together with illustrations of their possible impact on the standard of work of the X-ray department. These include: (1) resource management through film reject analysis; (2) patient dose measurements; (3) equipment inspection programme; (4) equipment maintenance programme; (5) training and education of staff. Indications are given of the potential savings derived from a QA programme together with approximate estimates of the cost of operating such a programme.

Keywords: Quality assurance, radiology, cost effectiveness, dosimetry, equipment maintenance, training, resource management.

X-Ray departments are expensive.

The cost of an X-ray installation in the UK is between £100,000 to £400,000 per X-ray room, with a life expectancy of approximately 10 years. The overall annual running cost per X-ray room (not including allowance for equipment depreciation

and replacement) is in the region of £100,000 of which typically £15,000 per annum would be spent on X-ray film.

The production of high quality medical X-ray images is extremely complex.

Feddema and Botden [1] identified approximately 100 factors which influence the quality of the diagnostic information in the final image. These included factors related to the production of X-rays by the X-ray tube and generator, the recording and display of the image by film or television monitor etc. and factors affecting the interpretation of the image by the clinician.

Hence, it is obviously quite unreasonable to expect that a process as expensive and as complex as diagnostic radiology can function with optimum efficiency and effectiveness without the application of some form of quality assurance measures.

In fact, quality assurance in diagnostic radiology is a legal requirement in countries within the European Community, who are required to comply with the Council Directive of 3 September 1984. This Directive lays down basic measures for the radiation protection of persons undergoing medical examination or treatment and states in Article 3 in reference to medical radiological installations:

> All installations in use must be kept under strict surveillance with regard to radiological protection and the quality control of appliances.

The aim of a quality assurance programme in diagnostic radiology is to ensure that relevant clinical diagnostic information in the form of an ideal image is obtained:

(1) at the first attempt; .

(2) in compliance with acceptable imaging criteria;

(3) (a) with a minimum amount of consumable materials; (b) with a minimum radiation dose to both patients and staff;

(4) with a minimum amount of disturbance to the patient;

(5) with minimum risk to patients and staff from equipment and its use (e.g. electrical, mechanical, toxic etc.).

The implications of these requirements are that:

(1) Predictable, reproducible and therefore consistent procedures are followed in producing diagnostic images;

(2) Clinicians specify clearly the standards of imaging they require;

(3) Consumable materials including radiation are carefully controlled and their use must be clinically justified;

(4) A sympathetic handling of patients which takes into account the risks and possible side-effects of the procedures;

(5) Routine inspection and maintenance programme to ensure the safety and continued acceptable performance of all equipment.

Because of the fascinating complexity of the production of X-ray images, as part of the title to this paper implies—QA for its own sake—it is all too easy when applying quality assurance measures in diagnostic radiology to lose sight of the main objectives of the programme and:

(a) become greatly committed to a large measurement and data collection programme that will cost more to run than the programme might otherwise hope to save, or

(b) be side-tracked into paying undue attention to particular aspects of medical imaging, which although of interest, may not be of major concern or pay dividends in the effective management of resources.

(c) fail to constantly re-adjust the programme in order to take into account:

— the results of QA measurements and actions;

— the changing needs of the department in particular and radiology generally;

— changes in the quality of the equipment supplied by manufacturers.

In order to avoid these errors and ensure the effective practice of_QA, those involved need appropriate training. This need has been recognised by the CEC Directorate-General for Science, Research and Development, who as part of their Radiation Protection Programme wish to promote QA training courses throughout the European Community.

As indicated above, the aims of the QA programme include:

(1) standards of acceptable diagnostic imaging;

(2) standards of acceptable equipment performance.

With regard to (1), the CEC has set up a study group which is liaising with national medical radiology organisations in order to produce quality criteria guidelines for radiodiagnostic images. These guidelines will define:

(a) clinical diagnostic requirements in terms of the extent to which clinical structures and .other image details should be visible in an image of acceptable standard;

(b) maximum value for the dose received by the patient for a particular radiodiagnostic examination;

(c) the practical technique for a particular examination which will produce images of an acceptable standard.

The following is an example of the draft guidelines in relation to mammographic examinations.

Diagnostic requirements:

— complete coverage of glandular tissue;

— nipple strictly parallel to the film;

— visually sharp reproduction of fine linear and round structures;

— reproduction of cutis and subcutis;

— round details = 5 mm diameter. Micro-calcifications = 0.2 mm.

Dose requirements:

— maximum entrance dose = 5 milli-Gray.

Good technique:

— X-ray tube kilovoltage of 25–35kV;

— X-ray beam filter—at least 0.03 mm molybdenum/0.5 mm aluminium;

— X-ray focal spot size–less than 0.6 mm;

— X-ray tube focus to film distance of at least 60 cm;

— film–screen combination of sensitivity class 10.

With regard to (2) above, for some considerable time the International Electrotechnical Commission has been producing standards relating to the performance and safety of medical X-ray equipment and more recently has been preparing standards relating to methods of quality assurance assessment of the performance of such equipment. These latter standards describe in detail:

— the aim of each test;

— the test equipment required;

— the test procedure;

— the interpretation of the results of the test;

— the criteria to be applied;

— the action to be taken;

— the recommended test frequency.

The overall effect of this move within the European Community towards standardisation (harmonisation) in the practice of radiology will probably result in medical X-ray departments eventually requiring some form of accreditation in order to demonstrate that the service they provide is of an acceptable standard.

In hospitals in England an extensive study was carried out by the National Radiological Protection Board of the doses received by patients undergoing medical X-ray examinations. This revealed that on average each year each member of the population receives:

— a somatic dose of 300 micro-Sievert and

— a genetic dose of 200 micro-Sievert.

The recent revised radiation risk estimates from the International Commission on Radiological Protection indicate a risk of fatal cancer induction from the somatic dose of 4.5×10^{-2} per Sievert and a risk of hereditary damage of 0.8×10^{-2} per Sievert. In a UK population of over 50 million this corresponds to approximately 750 patients per year suffering serious radiation-induced injuries from diagnostic radiology.

Amongst nations, the UK is generally regarded as having high standards of radiological practice. Obviously there is no room for complacency in these circumstances and what is of particular concern is the extremely wide range of doses which the NRPB recorded for patients undergoing the same examination in different establishments. Doses were found to vary by factors of 300 and 400 for several X-ray examinations.

In addition to adopting standards of imaging and equipment performance, consider some of the other important components of a QA programme in diagnostic radiology, namely:

— use of resources, e.g. film reject analysis;

— patient dose survey;

— equipment inspection programme;

— equipment maintenance programme;

— training and education of staff.

Film reject analysis involves collecting all rejected X-ray films, identifying the source of the rejection (room number/operator name) and the reason for the rejection. Subsequent analysis of the rejected films indicates:

— overall film reject rate for the department;

— major causes of rejection in each room;

— major causes of rejection by each operator;

— major causes of rejection according to type of X-ray examination.

Armed with this information it is then possible to deal with the causes of wastage. Such a programme in four of the largest hospitals in Merseyside in the UK indicated departmental film reject rates initially of between 9 and 13%. Action on the basis of film reject analysis coupled with other QA measures reduced the department reject rates to between 4 and 7%.

A typical saving of 5% corresponds to a saving in X-ray film alone of approximately £750 per annum per X-ray room. However, in terms of the total saving in staff time, equipment usage, other consumables (heating, lighting, etc.) the saving is probably at least 10 times this value. In a 10 room X-ray department the potential for overall saving is therefore considerable (not to mention the small improvement in standard of service and reduction of dose to the patient).

In each department, a survey of the doses received by patients undergoing various examinations should be undertaken at regular intervals, e.g. annually. An analysis of the results will establish whether or not the doses received are within acceptable limits and like the analysis of film rejects, this analysis may also help to identify deficiencies in equipment performance, deficiencies in staff training and help to distinguish between different techniques.

For example, in two identical and adjacent X-ray rooms in one Merseyside hospital, X-ray examinations were carried out by manual control of the exposure factors. This was because the automatic X-ray exposure control system gave unreliable results. A total of approximately 50 reject films were generated each week in these two rooms. The automatic exposure control system was investigated and set up correctly. The number of rejects dropped to less than 10 per week. A saving of 2000 films per year!

When the results of measurements of patient dose are compared for manual and automatic techniques, invariably the average doses may be approximately the same but the range of doses given manually is usually much greater than that given under automatic control.

In view of the complexity of X-ray equipment and the hazards associated with its use it is essential that some form of routine inspection and performance assessment programme is instituted. First of all this should include an extremely thorough assessment of performance and safety when equipment is first installed. This applies not only to X-ray tubes and generators, image intensifiers and CT scanners but to any item of equipment whose performance affects the efficiency and effectiveness of the imaging process, i.e. X-ray film, screens, processors, automatic exposure control systems.

The value of these thorough tests on installation is probably best illustrated by experience in Liverpool in connection with the systems previously mentioned, which automatically control the X-ray exposure. In Liverpool, 50 of these systems (at a cost of approx. £10,000 each) had been installed before any appropriate tests had been devised. When the tests were subsequently performed, it was discovered that half of these systems had virtually never been used because of the inadequate standard of installation. In the light of these results, further collaboration with the equipment suppliers resulted in adjustments in the performance of all these systems to an acceptable standard. Similar experiences have occurred with other items of X-ray equipment.

After installation, a programme of simple rapid constancy tests needs to be instituted in order to confirm that the performance of each item of equipment continues to be acceptable. Only when the constancy test indicates a marked deterioration in performance should it be necessary to repeat the intensive tests performed on installation and establish the cause of malfunction. Examples of the details of constancy tests are given on page 218.

In a 5/6 room X-ray department, a QA programme will take on average about 1 day of 1 person's time per week. For someone on an annual income of £10,000, the cost of this exercise is £2000 per annum approx.

Experience over the past 10 years on Merseyside has indicated that these simple tests can usually indicate a deterioration in equipment performance before it reaches a stage where the standard of imaging is no longer acceptable and hence remedial action can be taken.

Constancy test	Frequency	Time to perform	Cost of test equipment
Tube and generator performance	Weekly/monthly	5 min	£600–£2000
Beam collimation and alignment	Quarterly	5 min	£200
Image intensifier TV system	Weekly/Monthly	10 min	£700
Film processor	Daily	5 min	£800–£2400
X-Ray film	Quarterly	5 min	.
Intensifying screens	Every 3 yrs	5 min	
Automatic exposure control	3 months/annual	10 min	
Tomography	3 months/annual	15 min	£250
		Total Cost =	£2550–£5550

It is particularly important that constancy tests are performed immediately after equipment has been serviced. When image intensifier constancy tests were first introduced in ten departments on Merseyside, a marked deterioration in image quality was noted in six of these departments immediately after the equipment had been serviced. Similarly, constancy tests following the servicing of X-ray tubes and generators have indicated quite significant changes in X-ray tube output which subsequently affect patient doses and image quality.

Obviously, equipment maintenance is essential to ensure that all aspects of the equipment are safe and fit for use with patients. However, a distinction perhaps needs to be made between maintenance relevant to the safety aspects of equipment performance and that relevant to the imaging aspects. In this way, it might be preferable if some of the aspects of imaging maintenance were not carried out when the constancy tests indicate that the equipment performance continues at an acceptable level. In view of the extremely high cost of X-ray equipment maintenance this might represent a substantial saving which should be taken up with X-ray equipment service agencies. What is certain, one cannot afford to pay for equipment performance to be made worse.

Finally, one of the results of a QA programme in the X-ray department is to indicate that a considerable proportion of resource wastage and poor quality imaging is not due to inadequate equipment performance but is due to the misuse of resources by staff. This emphasises the need within each department for the employment of adequately and appropriately trained staff—an aspect which is also emphasised in Article 2 of the CEC Directive referred to earlier. In addition, both the radiological procedures and the QA measures adopted in the department need to be thoroughly documented and brought to the attention of all concerned. This does not mean scribbled on a piece of paper attached by a piece of tape to the back of the protective screen at the X-ray control panel in the X-ray room.

REFERENCE

1. Feddema J and Botden P J M, Adequate diagnostic information, in *Television in Diagnostic Radiology*, pp. 15–25. Aesculapius, Birmingham, Alabama, USA.