Eye Opener E-09

Quality Assurance in Medical Applications

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Quality is something most people can perceive and appreciate. Much as it is easy to perceive quality, it is difficult to describe it and all the more difficult to grade or quantify it. *The general definition of quality is "conformance to requirements"*. This definition applies to all work. All work may be considered as a process performed to produce an outcome or output. If the process produces a product or service that meets all of the agreed upon requirements, quality by definition, has occurred. The reverse is also true. If requirements are not met, quality by definition has not occurred.

Quality assurance pertains to filling the gap between requirements and the (delivery of product and/or service).

Steffen (1) searches the medical literature for a definition of quality and finally settles on "the capacity to achieve goals". This definition sounds remarkably similar to "conformance to requirements". Donabedian (2,3), the leading thinker in pre- Total Quality Management (TQM) era and responsible for many advances in traditional medical quality assurance formulated the classic definition of quality of care in medicine; it is "that kind of care which is expected to maximize an inclusive measure of patient welfare, after one has taken account of the balance of expected gains and losses that attend the process of care in all its parts". This approach with several important limitations, the details of which can be found elsewhere (4), led to a search for alternative methods and strategies. Modern quality science has been adopted from industrial science. Tracing the history of developments in health science, the triggering point appeared to be the "agenda for change" promulgated by the Joint Commission on Accreditation of Health Care organization (JCAHCO) which has become a driving force behind the application of continuous quality improvement (CQI) methodology in health

care. To comply with JCAHO standards, by 1994, all health care organizations were expected to adopt CQI/TQM methodology: assessing user needs; assessing, improving and monitoring key processes within the organization; and educating all employees (including physicians) in the techniques of CQI/TQM (5). Some of the institutions which adopted TQM had engaged quality management consultants with experience of applying TQM in industry but obviously no experience in health care. Hence, it was a strange situation, applying new vocabulary, and wrestling with such words as suppliers, customers, internal processes and empowerment. Beside quality control (QC) and quality assurance (QA), this text uses terms like continuous quality improvement (CQI), price of conformance (POC), price of non-performance (PONC), quality improvement process (QIP), total quality management (TQM), the details about which can be found in the glossary of terms as appended to this article.

Difference between traditional quality assurance (QA) and TQM/CQI:

There is a new recognition that "quality depends more on good system design, consistent long-term direction, adequate training, leadership, and follow-up -- all management functions rather than individual motivation." Traditional QA focused and took corrective actions on outlying values, however, CQI seeks to act on the entire process. Lack of emphasis on the entire process results in erratic development of QA such as in the field of imaging where QA although implies coverage of the whole process but in practice has remained restricted primarily to testing of the performance of equipment. The improvement efforts affect all outcomes, improve the average performance of the entire system, and decrease the outlying values. While it is believed that TQM has its beginning in industry, Brewick (6) emphasizes that TQM and clinical science are similar in many ways. The science of TQM is to organization what clinical science is to patients. Just as sick patients can be treated by using scientific methods to remedy the function of organ systems, a sick organization can be treated by application of TQM to remedy the malfunctioning processes.

Total quality management comprises three major processes: (a) quality planning, the phase of quality management during which the various processes are designed to meet customer's needs; (b) quality improvement, the process of raising quality performance;

and (c) quality control, the process of evaluating performance, comparing it to goals, and acting on the differences. However, application of CQI/TQM methods in health care has thus far been limited to the quality improvement process. Since problems often cross departmental boundaries and are not limited to physicians, nurse, technologists, management, or ancillary staff it is necessary to have a formal framework. Quality improvement differs from other traditional approaches such as improving by trial and error or using outside consultants and analysts, because it involves all involved personnel. Teams, not individuals, solve problems. Management structures in radiology departments normally include medical, technical, and nursing staff with separate chains of common and often conflicting goals, agendas, and management techniques. Bringing together these three components in the form of a steering group is a good first step. This has to be followed by setting up of short-terms and long-term goals of the department with the intent of integrating the purposes of all the subgroups. The first phase is of "project definition and organization" and is usually accomplished by the Quality Council – a body within the organization that guides the quality effort. This phase consists of two main steps, generation of a list of problems in order of priority followed by definition of the project with an appropriate mission statement and with identification of the team to conduct the project. In the second phase, the quality improvement team embarks on a "diagnostic journey" which includes analyzing the problems, formulating theories of causes, and testing those theories to identify the main causes of the problems. Having identified the main causes, the team embarks on a "remedial journey" in which alternative solutions are considered and solutions and controls for the process are designed. Difficulties with the proposed changes are identified. Finally, the team implements the solutions and controls the processes. In the fourth phase, "holding the gains" the team checks the performance of the process after implementing the changes and designs a monitor for the system (7).

Let us take the example of a patient visiting imaging department, be it radiology or nuclear medicine. He is the consumer of service rendered by the department. His satisfaction determines the efficacy of quality assurance programme. Similarly, the doctor (clinician) who referred the patient to imaging department is the consumer of the clinical

output provided by the imaging department. Be it the quality of image or the quality of the interpretation/report by the department. If he is not satisfied quality is not achieved. The radiologists is the consumer of service provided by the radiographer/technologist. Only the consumer stratification ensures quality assurance.

Poor quality implies additional radiation dose to the patients. Any report of diagnostic study has to be seen not only in terms of costs involved but radiation dose too.

Some of the pertinent questions needing to be answered:

Who determines if the image is of acceptable quality? It is the radiologist at first instance followed by the clinician. How to reduce subjective variations in assessment of image quality? This is done by adhering to imago quality criteria (8,9). If the interpreter is provided with these guidelines, the subjective variation is reduced. Initially we resorted to estimating the film retake rate, but it was found to be less meaningful as many films are such that they can not be easily put into reject category and also can not be accepted happily. Accordingly, we devised a three step scoring of image as A = Acceptable, B = Acceptable with remarks/reservations, C = Not acceptable (10).

The next step is cause analysis. Table 1 gives the data on cause analysis. Table 2 gives the role of workload on image quality. Based on the contribution of each factor to poor quality, the QC program was developed which gave emphasis to the factor as per its contribution to poor quality. The operator's awareness was also increased and its impact on image quality and patient dose was analyzed (Table 3, 4). Further details can be seen in author's publication (11).

The contribution to reduction in patient dose in diagnostic studies is by many ways. Controlling technique factors is but one such method. Overall it is the "mindset" which is to be developed in a team. The mindset of quality will start acting right from the time patient reports to the hospital and shall encompass all actions including appointment, registration, smiling and efficient reception, proper guidance, comforting gestures while conducting the study, thanking patient for the cooperation, quick report and accuracy of

the interpretation, all become easy to comply with when there is "Mindset" of quality. In the following projections our experience in reducing the patient doses, improving image quality, establishing a regular program of QA in radiology is elaborated besides the quality management concepts. We have documented over 35% reduction in patient dose and nearly 40% reduction in poor quality film.

Appendix

Glossary of Terms:

Continuous Quality Improvement (CQI)

This is achieved by understanding, meeting and exceeding the needs of the customers. The term customer is used in a broad sense to identify the individuals or groups within or outside the organization with whom workers of the organization deal; this term does not necessarily imply a financial relationship. Patients, their families, referring physicians, and members of the department and the hospital are the customers of a radiology department. Individuals within the organization are internal customers while those outside the organization are external customers. Every individual in an organization plays the following three roles in any process—supplier, customer, and processor. As an example, in the process of radiology report preparation, the transcriptionsit (customer) depends on the radiologist (supplier) to provide a well-dictated report; the radiologist (customer) depends on the transcriptionist for a well-typed report; the radiologist (processor) then reviews and signs the report before it is forwarded to the referring physicians. Skeptics sometimes object to using terms such as customers in health care processes. They take these words literally and focus on the negative connotations to these terms. If the world "customer" is objectionable, one can substitute it with "user".

Price of Conformance (POC)

In ensuring that requirements of the output of a process are met each time, cost is involved. Such cost may be the establishment of procedures, training, education, purchase of appropriate technology, monitoring of processes, maintenance, etc. The cost devoted to prevention of "non-quality" is called POC.

Price of Nonconformance (PONC)

This is the cost produced by "non-quality". The industry attributes such costs to scrap, rework, warranty, redesign, product liability, loss of customer liability, etc.

Quality Control (QC)

Quality control comprises the qualitative or quantitative measurements or tests of performance of an instrument or program and the determination of adequacy and acceptability of performance. This includes the set of operations (programming, co-ordinating) intended to maintain or to improve quality (ISO definition). In other words, as applied to diagnostic procedures, it covers monitoring, evaluation, and maintenance at optimum levels of all characteristics of performance that can be defined, measured and controlled.

Quality Assurance (QA)

The application of a service of quality control steps at multiple stages of a procedure to verify that all aspects of the procedure are of acceptable quality. The ISO definition is – all those planned and systematic actions necessary to provide adequate confidence that a structure, system or component will perform satisfactorily in service.

Quality Improvement Processes (QIP)

There are many ways in which quality programs can be pursued. The process involved are QIP.

Quality Improvement Team (QIT)

A number of teams are formed at different levels staring from the top management within the framework of TQM. Such teams have specified purposes in planning and implementation.

Total Quality Management (TQM)

Total quality management involves a systematic managerial approach in an organization based on continuous improvement of all operations, processes, and functions. It is used interchangeably with CQI in many areas.

References:

1. Steffen G. Quality medical care. JAMA 260 (1): 55-61, 1988
2. Donabedian A. The quality of medical care. Science 200: 856-864, 1978
3. Donabedian A. The quality of care: how can it be assessed? JAMA 260: 1743-1748, 1988
4. Laffel G, Blumenthal D. The case of using industrial quality management science in health care organisation. JAMA 262 (2): 2869-2873, 1989
5. Rehani MM. Total Quality Management, In: Diagnostic Imaging: Quality Assurance by M.M. Rehani (Ed), Jaypee Bros Med. Publ, N Delhi, 1-13, 1995.
6. Berwick DM. The clinical process and the quality process. Quality Management in Health Care, 1-8, 1992.
7. Rehani MM (Ed). Diagnostic Imaging: Quality Assurance, Jaypee Bros Med Publ, N.Delhi, pp 256, 1995.
8. Moores BM, Wall BF, Eriskat H and Schibilla H, eds. Optimization of image quality and patient exposures in diagnostic radiology. London: British Institute of Radiology, 271-78. BIR 20, 1989.
9. Rehani MM. Factors affecting image quality. Ind J Radiol Imag 8(2): 99-108, 1998.
10. Rehani MM. Quality assurance in diagnostic radiology. Ind J Radiol Imag 2: 259-263, 1992.
11. Rehani MM, Kaul Rashmi, Kumar Pratik, Berry M. Doses bridging the gap between knowledge and practice help. Example of patient dose reduction in diagnostic radiology. J Med Phy 20(2): 18-22, 1995.

Table 1. **Analysis of Causes of poor quality film**

(Ref. Rehani, Arunkumar & Berry, Ind J Radiol Imag 2, 259-263, 1992)

					Processing				
Processing	Poor quality film	Expos-ure Defect	Poistio-ning Error	Patient Rotate Breath-hold	Develop-ment	Fixing	Washing	Scratch finger marks room light	Process Roller marker
Manual	REL 100 21%	22 5%	13 3%	9 2%	4 1%	4 1%	17 3%	31 6%	- -
Automatic	REL 100 14%	35 5%	32 4.4%	26 3.6%	2 0.3%	- -	- -	- -	5 0.7%

Table 2. **Effect of QC and Work Load**

Room* (Films/Day)	Film Quality Grading			
	Before QC		After QC	
	B	C	B	C
A (70-100)	26%	5%	18%	3%
B (30)	18%	3.6%	13%	2%

*In other rooms, the 'B' Grade films = 15-33%
'C' Grade films = 2-5%

Table 3. **Improvement in image quality of film after information supply**

Before			After		
A	B	C	A	B	C
Total 522			Total 370		
No. of films 245	205	72	234	111	25
% of films 46.9	39.4	13.7	63.29	30	6.7
A= Accepted, B= Accepted with remarks, C = rejected					

Table 4. **Showing the effect of information supply to radiographer on the setting of kVp, mAs values (mean ± s.d. [%s.d.] of kVp and mAs)**

Information supply			
Area Radio-graphed	Before	After	Ent. Exp. E_2 as % of E_1
kUB	N* = 157	N= 129	
kVp	70.42±6.52 (9.25%)	59.42±3.49(5.87%)	66%
mAs	116.40±36.10(31.0%)	108.37±1.59(10.69%)	
PNS	N=71	N=121	
kVp	74.95±7.02(9.36%)	64.03±3.78(5.9%)	65%
mAs	125.90±29.47(23.4%)	113.68±11.30(9.96%)	
(Hand, Wrist & Elbow)	N=51	N=63	
kVp	48.13±6.73(13.98%)	39.33±1.85 (4.7%)	66%
mAs	5.96±1.24(20.8%)	5.9±0.65(11.01%)	
DL-Spine (AP)	N=21	N=30	
kVp	73.86±4.75(6.43%)	67.95±3.98(5.85%)	80%
mAs	113.57±12.54(11.0%)	107.69±9.73(9.03%)	
Hip/ Pelvis	N=18	N=43	
kVp			
mAs	71.7±4.8(6.7%)	64±6.03(9.4%)	72%
	100±22.3(22.3%)	90.7±18(20.2%)	

N* denotes the no. of observations

Quality Assurance in Medical Application

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Quality Assurance

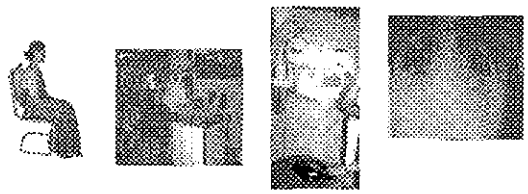
What is Quality: It is conformance to requirements

QA: To fill up the gap between requirements and delivery (of product service etc.)

- Who determines requirements?

"Consumer"

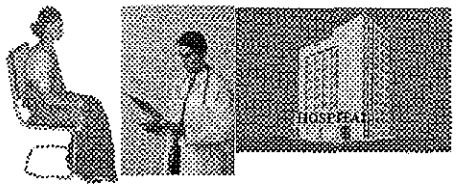
Consumer



Technologist ⇨ Radiologist ⇨ Patient⇨ Clinicians

Who determines if the Quality is achieved?

What are the requirements?



Sorry, we shall have to repeat your examination. The film is too bad

CAR

- ZERO BREAKDOWN AND DOWNTIME
- FUEL EFFICIENCY
- PROLONGED ROADWORTHINESS
- EASE & CONVENIENCE

Is this QA

- Patient is met with a rude receptionist
- Patient has to wait for few hours to be attended
- Unfriendly technologist, impolite handling
- Report of the study is misplaced
- Inconclusive report.
- _____
- _____

QA

Industry:

- Consumer pays and thus expects quality

Money ∝ Quality

Quality ∝ Money

Health Sector

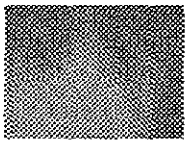
Government Hospitals - Normally free- Expectation of patient ⇩

So long as health sector is dominated by Govt.- Quality ⇩

Private Sector - Expectations of the consumer become IMPORTANT

QA

- Late 1970's & early 1980's
- Identification of malfunction in equipment
- Equipment performance tests
- Frequency of testing
- Rectification



Functioning OK

Un-acceptable Image

QA

Quality of End Product

MOTOROLA - AIMING AT

- 99.99997% DEFECT FREE MANUFACTURING IN INDIA

  i.e., 3 DEFECTIVE PIECES IN 10 MILLION

MEDICAL IMAGING

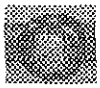
- 10% FILMS WASTED AT X-RAY ROOM/DARK ROOM LEVEL
- FURTHER 12-40 ARE OF POOR QUALITY OF WHICH 4-8% ARE REJECT QUALITY

The film retake rate in my department is not more than 5%

Film retake assessment

- 12-23% films of bad quality
- Some film too bad, others slightly





- Film retake rate - Two Step
- What is needed is - Three step scoring system

Three Step Scoring System

A = Acceptable without any reservation

B = No loss in diagnostic information but film not presentable
Or acceptable with certain reservation

C = Should be rejected.
Can I present this film for peer review

? Who assigns score to the film?

This image scores 6.7 on a scale of 10
No, It scores 7.5.....

- ✓ What is quality
- ✓ What is QA
- ✓ Who determines Quality
- ✓ What are the requirements
- ✓ Assessment of end product
- ✓ How to assess end product

EC QUALITY CRITERIA

CHEST

PA projection

a. Diagnostic requirements

Image criteria

1. Performed at deep inspiration.
2. Symmetrical reproduction of the thorax.
3. Reproduction of the whole rib cage above the diaphragm.
4. Reproduction of the vascular pattern in the whole lung, particularly the peripheral vessels.
5. Visually sharp reproduction of:
   (a) the bronchial tree, the borders of the heart and aorta;
   (b) the diaphragm and costophrenic angles.
6. Visualization of the retrocardiac lung and the mediastinum.

EC QUALITY CRITERIA (Cont.)

b. Example of good radiographic technique

1. Radiographic device: vertical bucky or vertical chest stand with stationary grid.
2. Focal spot size: < 1.3 mm.
3. Total filtration: > 3.0 mm Al equivalent.
4. Anti-scatter grid: r = 12:40/cm
5. Film-screen combination: speed class 200-400
6. FFD: 180 (140-200) cm
7. Radiographic voltage: 100-150 kV.
8. Automatic exposure control: chamber selected, lateral
9. Exposure time: <20 ms.

EC QUALITY CRITERIA (Cont.)

c. Guidelines for good imaging performance

1. Important image details Small, round details in the whole lung, including the retrocardiac areas: high contrast, > 0.7 mm; low contrast, > 2 mm diameter.
   Linear and reticular details out to the lung periphery: high contrast, > 0.3 mm in width; low contrast, > 2 mm in width.
2. Entrance surface dose for a standard sized patient: 0. mGy.

Lateral Projection

This projection may be indicated for anatomical localization of any abnormality seen on the PA projection.

a. Diagnostic Requirement

Image criteria

1. Performed at deep inspiration.
2. Visually sharp reproduction of the posterior border of the heart, aorta, mediastinum, trachea, diaphragm, sternum and thoracic spine.

EC QUALITY CRITERIA (Cont.)

b. Example of good radiographic technique

1. Radiographic device: vertical bucky or vertical chest stand with stationary grid.
2. Focal spot size: < 1.3 mm.
3. Total filtration: > 3.0 mm Al equivalent.
4. Anti-scatter grid: r = 12:40/cm
5. Film-screen combination: speed class 200-400
6. FFD: 180 (140-200) cm
7. Radiographic voltage: 100-150 kV.
8. Automatic exposure control: chamber selected, lateral
9. Exposure time: <40 ms.

c. Guidelines for good imaging performance

1. Important image details Small, round details in the whole lung, including the retrocardiac area: high contrast, > 0.7 mm; low contrast, > 2 mm diameter.
   Linear and reticular details out to the lung periphery: hig contrast, > 0.3 mm in width; low contrast, > 2 mm in width.
2. Entrance surface dose for a standard-sized patient: 1.5 mGy.

EC QUALITY CRITERIA (Cont.)

SKULL

PA/AP Projection

a. Diagnostic Requirement

Image criteria

1. Symmetrical reproduction of the skull, particularly cranium orbits and petrous bones.
2. Projection of the apex of the petrous temporal bone into the centre of the orbits.
3. Visually sharp reproduction of the frontal sinus, ethmoid cells and apex of the petrous temporal bones and the internal auditory canals.
4. Visually sharp reproduction of the outer and inner tables of the cranial vault.

EC QUALITY CRITERIA (Cont.)

b. Example of good radiographic technique

1. Radiographic device: bucky or special skull unit or vertical stand with stationary grid.
2. Focal spot size: 0.6 mm.
3. Total filtration: > 2.5 mm Al equivalent.
4. Anti-scatter grid: r = 8-12, 40/cm
5. Film-screen combination: speed class 200
6. FFD: 115 (100-150) cm
7. Radiographic voltage: 65-85 kV.
8. Automatic exposure control: chamber selected, central
9. Exposure time: <200 ms.

c. Guidelines for good imaging performance

1. Important image details: 0.3-0.5 mm.
2. Entrance surface dose for a standard-sized patient: 5.0 mGy.

Cause analysis for poor quality

(Ref. Rehani, Arunkumar & Berry, IJRI 2, 259-263, 1992)

Analysis of Causes of Poor Quality Film

Processing	Poor Quality Film	Relative Contribution of							
		Exposure Defect	Positioning Error	Patient Rotate Breath-hold Error	Processing			Scratch Finger Marks Room Light	Process Roller Marker
					Devel-opm-ent	Fixing	Wash-ing		
Manual	REL 100	22	13	9	4	4	17	31	-
	21%	5%	3%	2%	1%	1%	3%	6%	-
Automatic	REL 100	35	32	26	2	-	-	-	5
	14%	5%	4.4%	3.6%	0.3%	-	-	-	0.7%

QA Program

Give emphasis to improvement of parameter based upon its contribution to quality

Film Processing/handling ⇒ 56% contribution controlling this factor alone will make a major contribution to quality improvement

Manual ⇒ Automatic

How to control exposure related problems?

Exposure

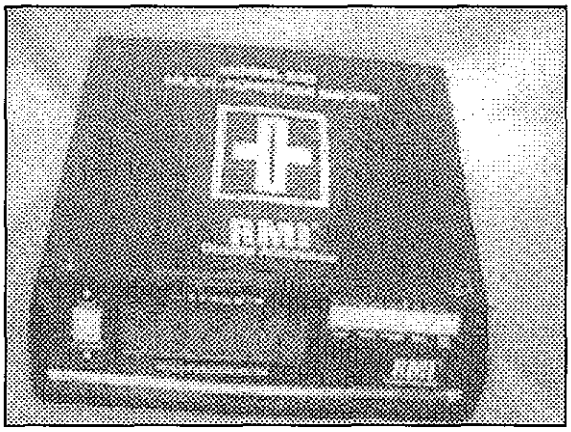
- **Machine & accessories**
- **Operator**

Quality Assurance Tests in Diagnostic Radiology

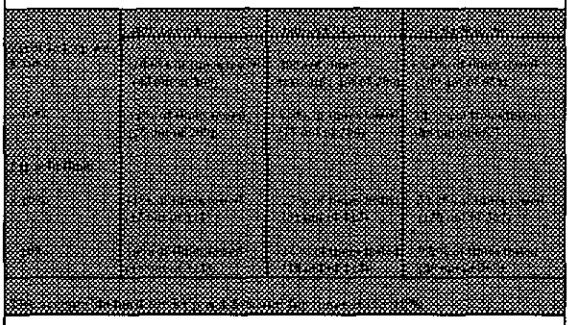
Mechanical Checks
- ❖ Looking for loose screws
- ❖Check of indicator, meter
- ❖Stability, stiffness of tube-hanger, chest-stand image-receptor etc
- ❖Working of movement-locks of tube
- ❖Checks for control-panel switches & movement of colimators

Radiological Checks
- ❖kVp accuracy
- ❖Timer accuracy
- ❖Optical-radiation field congruence
- ❖Beam alignment test
- ❖Focal-spot size
- ❖Evaluation of total filteration
- ❖Consultancy of X-ray output
- ❖mA linearity
- ❖Timer linearity

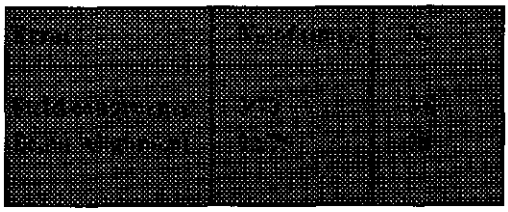
Other Checks
- ❖Film-screen contact
- ❖Film screen resoln.
- ❖Relative speed of screen
- ❖Checks on viewboxes
- ❖Compatibility of safe light
- ❖Check on source-to-image (SID) indicator
- ❖Test on automatic processors
- ❖Radiological protection survey



Frequency of malfunction in kVp and timer



Frequency of errors during (Nov. 94-Sept. 96)



HOW OFTEN TO TEST?

Machine Testing

1st Tuesdays	Siemens Machines
2nd Tuesdays	Wipro GE
3rd Tuesdays	Philips
4th Tuesdays	Toshniwal & Film Processor

NEW MACHINES

- SIZE
- SELF CORRECTING
  (Microprocessor controlled)

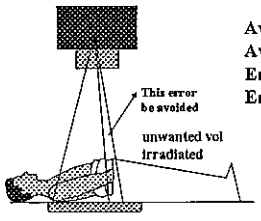
INTELLIGENT EQUIPMENT

HOW - QA

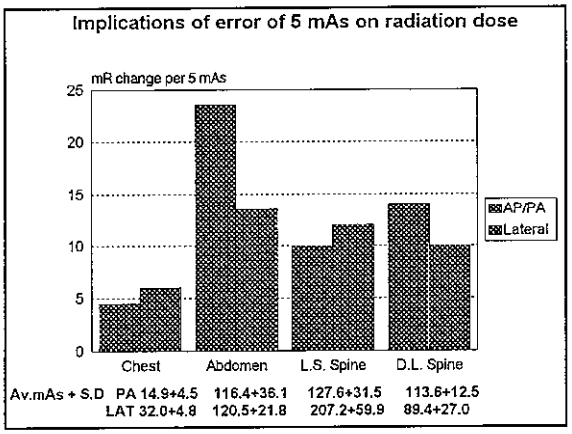
- EQUIPMENT TESTS
- ENSURE OPTIMAL FUNCTIONING OF EQUIPMENT
- OPERATOR PERFORMANCE

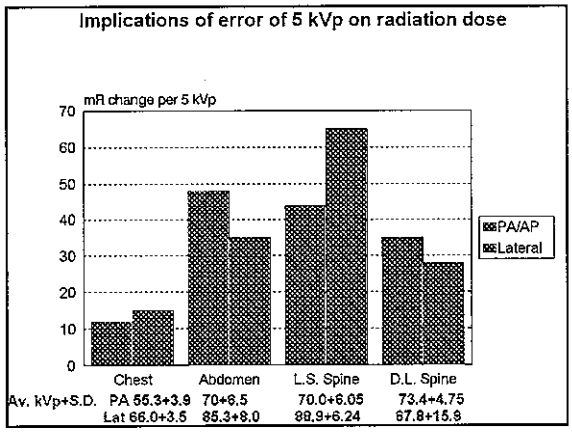
OPERATOR CONTROL

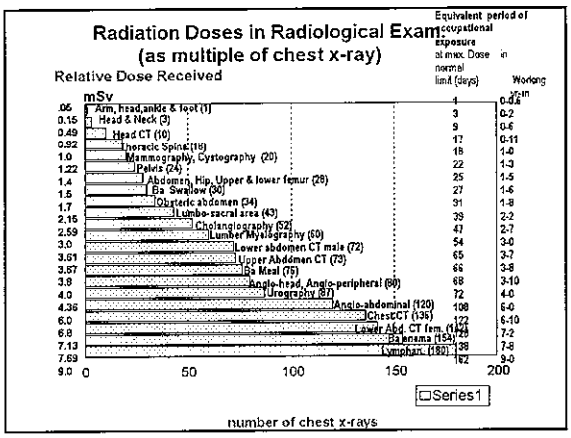
Implication of error in field size



Av. Thickness = 28 cm
Av. Width = 25 cm
Error = 1cm
Error in Vol. = 28x25x1
= 700CC







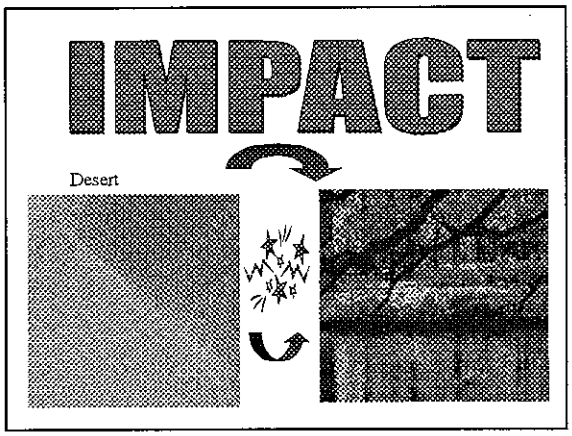
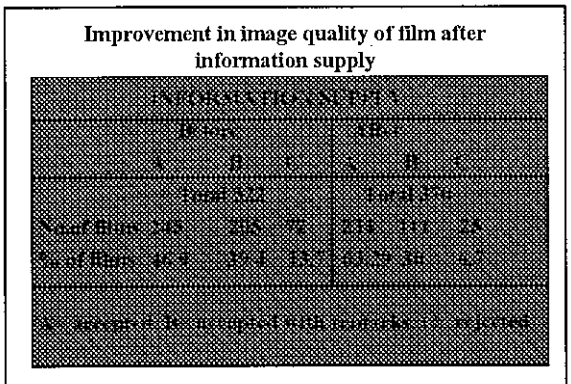


Table showing the effect of information supply to radiographer on the setting of kVp, mAs values (mean ± s.d. [% s.d.] of kVp and mAs)

Area Radiographed	Information supply: Before	After	Ent. Exp. E, as % of E,
KUB	N* = 157	N = 129	66%
kVp	70.42±6.52 (9.25%)	59.42±3.49 (5.87%)	
mAs	116.40±36.10 (31.0%)	108.37±1.59 (10.69%)	
PNS	N = 71	N = 121	65%
kVp	74.95±7.02 (9.36%)	64.03±3.78 (5.9%)	
mAs	125.90±29.47 (23.4%)	113.68±11.30 (9.96%)	
(Hand, Wrist & Elbow)	N = 51	N = 63	66%
kVp	48.13±6.73 (13.98%)	39.33±1.85 (4.7%)	
mAs	5.96±1.24 (20.8%)	5.9±0.65 (11.01%)	
DL-Spine (AP)	N = 21	N = 30	80%
kVp	73.86±4.75 (6.43%)	67.95±3.98 (5.85%)	
mAs	113.57±12.54 (11.0%)	107.69±9.73 (9.03%)	
Hip/ Pelvis	N = 18	N = 43	72%
kVp	71.7±4.8 (6.7%)	64±6.03 (9.4%)	
mAs	100±22.3 (22.3%)	90.7±18 (20.2%)	

N* denotes the no. of observations



Summary of patient surface entrance dose by hospital and by room (10 patients per projection)

Hospital	X-ray room	Type of projection	Average dose prior to QC (mGy±sd)	Average dose after QC (mGy±sd)	Dose reduction if any	Main corrective actions
AIIMS	84	CXR-PA	0.38±0.04	0.28±0.08	26%	Regular quality control checks on x-ray machines coupled with rectification of defects, film quality assessment by the radiologists, film processor checks, information supply to the radiographers by indicating the implication of operator error to patient dose, irradiation of unwanted volume by error in field adjustment etc.
		CXR-Lat	1.56±0.45	1.0±0.23	36%	
		Skull-AP	2.95±0.57	2.9±0.26	Nil	
		Skull-Lat	2.33±0.92	1.9±0.39	18%	
		Pelvis-AP	3.57±0.85	3.3±0.73	7.5%	
		LS-AP	4.21±1.4	3.0±0.86	29%	
		LS-Lat	5.88±2.0	5.2±1.2	11%	
AIIMS	61	CXR-PA	0.48±0.1	0.28±0.04	42%	
		CXR-Lat	0.42±0.12	0.36±0.06	14%	
		Pelvis-AP	10.9±4.2	6.38±1.8	41%	
		Skull-AP	5.0±2.2	4.26±2.5	8%	
		Skull-Lat	3.1±0.8	2.19±0.98	30%	
		LS-AP	12.2±3.56	5.73±2.14	53%	
		LS-Lat	24.8±6.4	14.1±5.15	43%	

Ref. Rehani, Arunkumar & Berry, IJRI 2,259-263, 1992

Effect of QC and Work Load

Room* (Films/Day)	Film Quality Grading			
	Before QC		After QC	
	B	C	B	C
A(70-100)	26%	5%	18%	3%
B(30)	18%	3.6%	12%	2%

* In Other Rooms, the 'B' Grade Films = 15-33%
'C' Grade Films = 2-5%

QA

Traditional QA

- Focused and took corrective actions on outlying values
- TQM/CQI: seeks to act on entire process

Lack of emphasis on the entire process results in erratic development of QA

QUALITY

Depends more on good system design, consistent long term direction, adequate training, leadership, and follow-up of all management functions rather than individual motivation

TQM

- **Quality Planning- process design to meet customer's needs**
- **Quality Improvements-process of raising quality of programme**
- **Quality control-the process of evaluations performance, comparing to goals and acting on the differences**

TQM

TQM = QA + CQI

TQM is a management philosophy that influences organization's

- **Infrastructure**
- **Polices**
- **Protocols**

Continuous Quality Improvement (CQI)

"MINDSET" & involvement amongst all employees on "What can be done to improve the process"

- Improving the overall quality
- Performance Improvement

CQI Techniques accepted by many successful progressive hospitals

Outside Regulating Agencies & CQI

JCAHO: Joint Commission on Accreditation of Healthcare Organizations

NRC: Nuclear Regulatory Commission

FDA: Food & Drug Administration

They require proof of ongoing QI effort such as NRC mandated program.

Quality Management Plan (QMP) FDA-regulated Mammography

Quality Standard Act.

Peer Review

- In latest JCAHO standards, peer review is the most important component.
- Initial concern and criticism on validity and fairness of the subjective performance has resulted in much improvement in physician interpretation.
- Inter-observer variability assessed retrospectively by reviewing adequate sample size of films

Dr. Joseph M. Juran

✗ An organisation would have fewer problems if only the workers did their job well

✓ Improving the system under which work is performed can prevent problems

Rule of Thumb: At least 85% of the problems can be corrected by changing system15% problems are under individual's control

Monitoring designed to identify opportunities for process improvement rather than personnel deficiencies.

Peer Review

(Univ. of Wisconsin Hospital Clinic)

- Divide the year into 12 monthly reviews. Each month - a particular organ (Jan - Renal, Feb - Non Thyroid endocrine, March - Abscess & tumor detection, April - Equipment QC, May - Lab Tests, June - Cerebral, July - Thyroid & Therapies, Aug - Transplant procedures, Sept - Bone, Oct - Ventilation perfusion scans, Non-GI, Dec - Cardiac)
- For each system a physician is assigned to peer review the months procedures (as per form)
- He reviews the indications, technical quality, diagnostic accuracy, timeliness of dictation and transcription, availability of final report.

Is there a role for Acceptance Testing

Acceptance Testing (Radiological Parameters)

Date	Room No.	Machine	Model	KVp	Timer	mA Lin.	Cong-ruence	Beam Center
11/93	10(IRCH) portable	Elpro Ins. Ltd.	Stallion-60	OK	OK	NOK	OK	-
7/94	10	Philips	SRO 33 Super rotlix	NOK	OK	OK	OK	NOK
1/96	39	Siemens	Sivescop-CX	OK	OK	OK	OK	OK
7/96	Mobile (Main)	Wipro GE	Genious 100 & 20005	NOK	-	OK	OK	OK
7/96	"	"	20004	NOK	-	OK	OK	OK
7/96	"	"	20002	NOK	-	OK	OK	NOK
7/96	"	"	20001	NOK	-	OK	OK	OK
4/98	78(1)	Philips	Optimus 80	OK	OK	OK	OK	OK
4/98	78(2)	Philips	"	OK	OK	OK	OK	NOK
5/98	53(1)RPC	"	"	OK	OK	OK	OK	OK
5/98	53(2)RPC	"	"	OK	OK	OK	OK	NOK
4/99	84(1)	Siemens	GE-VMX Plus	NOK	NOK	NOK	NOK	NOK
4/99	84(2)	Siemens	"	NOK	NOK	NOK	NOK	OK

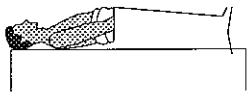
Acceptance Testing (Mechanical Test)

Date	Room No.	Machine	TFD	Collimator Opening	Tube Rotn.	Locking Facility
11/93	10(IRCH) portable	Elpro Int.	Provided	OK	-	OK
7/94	10	Philips	Provided	OK	OK	OK
1/96	39	Siemens	Provided	OK	OK	OK
7/96	Mob.(20004)	Wipro GE	Not Prov?	OK	-	OK
7/96	Mob.(20002)	Wipro GE	Not Prov?	OK	-	OK
7/96	Mob.(20001)	Wipro GE	Not Prov?	OK	-	OK
4/98	78(1)	Philips	Provided	OK	OK	OK
4/98	78(2)	Philips	Provided	OK	NOK	NOK
5/98	53(1)	Philips	Provided	OK	OK	OK
5/98	53(2)	Philips	Provided	OK	OK	NOK
4/99	84(1)	Siemens	Not Prov?	OK	OK	OK
4/99	84(2)	Siemens	Provided	OK	OK	OK

Objectives

- The staff doses should be optimally brought down

- The patient doses should be kept as low as possible



Objectives

- The image quality be optimum

- The accidents have to be eliminated

These objectives can be met by

- Control at the stage of manufacturing (type approval and certification of X-ray units)
- Regulatory control for infrastructure and manpower authorization
- Acceptance testing at user's end
- Establishment of routine quality control program
- Personnel monitoring of staff
- Written safety instructions with visual display
- Periodic monitoring of image quality and patient dose
- Feedback mechanism to staff and corrective actions
- Continuing education

A.I.I.M.S (Radiology Dept.)

Annual Dose in mSv	1988 no.of (Av. Dose persons mSv)	1993
0 - 2	54/64	75/75 (0.116mSv)
2 - 5	3/64 (2.93)	0
5 - 20	3/64 (10.15)	0
> 20	4/64 (27)	0

A.I.I.M.S

Category	1985 (mSv)	1993 (mSv) average
Cardiologists	1.7 - 2.95	0.25
Radiologists	0 - 0.9	0.17

Radiation Dose to Staff in Radio-diagnosis Dept.

Dose Range mSv	Year		
	1998	1996	1995
0-2	97/98	88/89	92/95
2.1-3	-	1/89	2/95
3.1-5	1/98	-	1/95
5.1-20	-	-	-

PATIENT DOSES

- ❑ Are they minimum-consistent with quality
- ❑ Can the dose be reduced further
- ❑ Has any effort been made
- ❑ If not, why not to make a beginning
- ❑ Is it possible to achieve dose reduction without knowing the doses (lack of dosimetry)

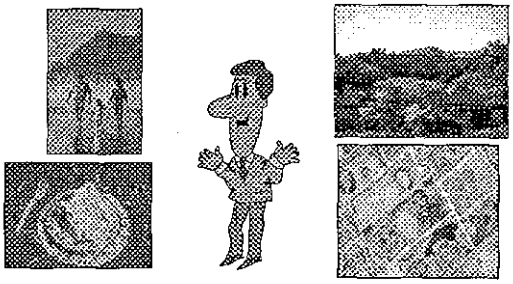
ATTITUDE

• Ignore & Accept	You shall continue to get poor quality films
• Call radiographer say that patient's illness is being missed because of poor film besides Rs. 50 (say) wasted	Effective
• Reject the film	Patient is looser for no fault

QA at different levels

- At department level
- At hospital level
- At National level

What are the needs ?

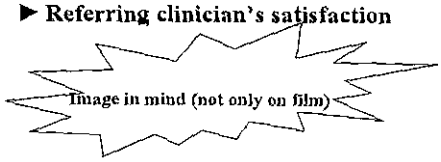


Inputs on QA

- Multifunction meter (kVp, timer check) and Beam alignment device — $3000
- Time for checking — upto 5 min
- Staff (additional) — nil
- **Greatest Input-** — **Attitude & Mindset**

Expectations from QA

- Image quality should be improved
- There should be lesser retakes
- Radiation dose should be minimized
- Patient should be satisfied
- Referring clinician's satisfaction



SUMMARY

- ☑ What is quality
- ☑ What is QA
- ☑ Who determines Quality
- ☑ What are the requirements
- ☑ Assessment of end product
- ☑ How to assess end product
- ☑ Frequency of testing
- ☑ Handling operator errors
- ☑ Impact of QA
- ☑ Quality Management

SUMMARY Cont.....

- ☑ Is acceptance testing necessary
- ☑ Meeting the objectives of QA
- ☑ Attitude
- ☑ Input on QA