

# Quality Assurance and Nuclear Medicine: The Challenge of Change

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There is increasing emphasis on quality assurance in nuclear medicine instigated, in part, by changing JCAH\* standards. Our response to this challenge has led to a program combining physician monitoring of 5% and generic monitoring of 100% of nuclear medicine studies. The described approach is reasonable, easily achievable, and improves nuclear medicine care.

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**D**uring the 1981 JCAH survey for our institution the surveyor who visited our nuclear medicine department was the same physician who had told us in the preceding evaluation that we had no deficiencies. During the survey in 1981, the surveyor again expressed confidence that we were in "full compliance with JCAH requirements"; however, he did mention that there were some changes to come making it advisable for us to increase documentation of our Quality Assurance Program. He predicted that such records would come under increased scrutiny during future inspections. He also told the hospital's Director of Medical Affairs that there was need for immediate action on "sufficient documentation of quality, safety, and appropriateness of care."

When the written report was received from the JCAH it noted:

*... The review and evaluation of the quality, safety, and appropriateness of the Nuclear Medicine services must be performed and documented. . .*

Our department's response was unequivocal. We continued to have outside review of the department's nuclear pharmacy by the Florida Department of Professional Regulation and of the entire department by the Florida Department of Health and Rehabilitation Services; we also began participation in the College of American Pathologists (CAP) Quality Assurance Program. Almost every patient was personally seen by one of the nuclear physicians at some time during the study for the purpose of determining the appropriateness of the request. A file of all canceled or inadequate studies was started to provide the recommended documentation.

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These records contained information describing circumstances preventing the performance of an adequate study or when indications were lacking.

In addition, we formalized "quality control" by including it as a separately identifiable part of the minutes of our biweekly Department of Nuclear Medicine meetings. We identified "quality control cases" by name, hospital number, and procedures only and did not include more detailed discussion in the minutes. (*Caution: This was a very important error!! Anonymity must be maintained in a different way!*)

Detailed records were kept by the nuclear pharmacist on radiopharmaceutical quality control. The physicists kept records of daily camera uniformity and resolution checks. Film badge records, evidence of delegation of authority for injection by nonphysicians, an updated and recently revised laboratory manual, schedules of in-service training, etc., were also maintained.

Details of this program were presented to the Medical Executive Committee (MEC) of our medical staff in June 1982. Our Director of Medical Affairs thought we had one of the best quality assurance (QA) programs in the hospital.

In April 1984, the Director of Medical Affairs was provided an update on our department's documentation of the review of quality, safety, and appropriateness of nuclear medicine services. Once again he was confident everything was "up to date" in nuclear medicine.

In September 1984, the JCAH site visit was held. A new addition to the Accreditation Manual for Hospitals, 1984, Standard V, pages 108 and 109, was reviewed with the surveyor and is quoted here in its entirety (see Appendix).

*... As part of the hospital's quality assurance program, the quality and appropriateness of Nu-*

*clear Medicine Services are monitored and evaluated and identified problems are resolved . . . (1)*

In response, the canceled case file, the minutes of department meetings—including the quality assurance section—and a review of the effect of recent cystoscopy and retrograde pyelography on findings during radionuclide renal function studies were presented.

All this proved to be insufficient, as the report of the JCAH survey cited us for lack of monitoring of the appropriateness of care. At the time of survey, it was suggested that we develop a format for accomplishing the objectives of Standard V and disseminate it to our peers. This paper is, in part, a response to that suggestion.

## SYSTEMATIC QUALITY ASSURANCE REVIEW

The following description of contemporaneous, ongoing, systematic review of quality assurance and appropriateness is not difficult, does not take an inordinate amount of time and is worthwhile.

In order to understand our new improved Quality Assurance Program, it is necessary to discuss the *Quality Assurance Section* of the JCAH Accreditation Manual for 1985 (2). Standard II clearly established the need for monitoring and evaluating the quality and appropriateness of patient care. In the discussion, there is specific reference to Standard V (Nuclear Medicine Services). Standard III cites, as required characteristics, the need for ongoing collection and/or screening of the evaluation of information about important aspects of patient care to identify opportunities for improving care and to identify problems that have an impact on patient care and clinical performance. It also stresses using objective criteria that reflect current knowledge and clinical experience by each department/service. There should be clear evidence that quality of patient care is improved and that identified problems are resolved through actions taken. Furthermore the findings, conclusions, recommendations, actions taken, and results of actions taken are to be documented and reported through channels established by the hospital. Emphasis has been placed on the opportunity to improve patient care, not on problem solving.

Standard IV clearly states that the hospital's overall quality assurance program must be designed to ensure appropriate and effective monitoring and evaluation, communication between departments/services when problems or opportunities to improve patient care involve more than one department/service, tracking of identified problems to assure improvement or resolution, and analysis of findings from several department/services to detect trends, patterns of performance, or potential problems affecting more than one department/service.

The objectives, scope, organization, and effectiveness of the quality assurance program are to be evaluated at least annually and revised as necessary. Not only is this subject considered in the detail described within the *Quality Assurance Section* but it is also mentioned in the *Medical Staff Section—Standard VI*. The responsibility is unequivocally laid upon the department chairman for

*. . . assuring the implementation of a planned and systematic process for monitoring and evaluating the quality and appropriateness and the clinical performance of all individuals with clinical privileges in that Department . . . (3)*

It further presents, in a slightly different but essentially unchanged way, the same need for looking for problems; having found them, acting on them; having acted, determining the effectiveness of the action, documenting what has been done, and then reporting it to the department and/or others on the medical staff monthly.

Standards I through IV of the Nuclear Medicine Section are what we have been living with for years (4). They deal with clearly defining a mechanism for delivering nuclear medicine care (Standard I), having adequate space and facilities for safe care (Standard II), providing adequate quality control for diagnostic and therapeutic reliability and safety of patients and personnel (Standard III), and maintaining records to satisfy federal, state, and local authorities consistent with competent nuclear medicine practices (Standard IV).

To reiterate, Standard V in the new revision reads in its entirety.

*. . . As part of the hospital's Quality Assurance Program, the quality and appropriateness of nuclear medicine services are monitored and evaluated and identified problems are resolved . . .*

Our nuclear medicine department's aim has been to make conformity with this standard not an exercise in frustration, but a stimulus to provide better patient care.

In doing so, we had to remember that our activities were part of a whole, namely the hospital's quality assurance program; whatever we developed in our department had to be coordinated with all the other departments/services.

## THE REVIEW PROCESS

It was the physician director's (BF) responsibility to start with the initial review of a patient's record at the time of original entry into our department's planned and systematic process. The nuclear medicine physicians reviewed 5% of the records on patients having each type of a study. Alternatively, a single procedure might be reviewed as the "study of the week." When the study was a type where five or less were performed per year, all patients' records were reviewed.

In an ongoing contemporaneous review process, the records of every twentieth patient of a study type were requested within 1 week of the patient having been seen. Both inpatient and outpatient studies were evaluated. There may be reason at times for doing a more in-depth evaluation. Such is then called a "special case," e.g., all canceled studies were reviewed on one occasion. The form used in the review process is shown in Fig. 1.

This data collection form is the only place the patient's name and hospital number appear. From this point on, the original entry can be found only by procedure and date of the review meeting (on upper right corner of the form). In our review, we look not only at technical quality of the films but also for promptness of care and rapidity of reporting. The "safety" of the procedure concerns radiation doses, misadministrations, and general safety of the patient such as adequate attendants, etc.

*Appropriateness* is based on criteria-based monitors. We have used the following as reference points for properly indicated and executed studies.

1. Indications in the *CRC Manual of Nuclear Medicine Procedures* (5).

2. Admission Objective 2, Subobjective B—Professional Foundation for Health Care, Tampa, FL (our PRO), which limits use of radioactive iodine uptakes and thyroid imaging.

3. Blue Cross/Blue Shield Medical Necessity Guidelines on Diagnostic Imaging, 1983. These were part of

a special report of the American College of Nuclear Physicians (ACNP) in August 1983.

All canceled studies are reviewed to see if a trend is present. The major cause of canceled studies is prior contrast material interfering with thyroid evaluations. We also attempt to evaluate the correctness and consistency of our interpretations. This includes "cross reading" for peer review. Progress notes and discharge summaries are scrutinized to determine if the nuclear medicine study has had a meaningful role in the management of the patient.

### FOLLOW-UP PROCEDURE

When there is a problem revealed by the review of patient studies, the nuclear medicine physician contacts the referring physician, and corrective recommendations are discussed at the Quality Assurance Review Committee of the hospital and at the appropriate department meeting. The physician director of nuclear medicine and the hospital medical staff committees are together involved in reaching a solution to the problem.

Though it has not yet been encountered, it is possible that the hospital's Quality Assurance Committee may identify a problem in nuclear medicine and refer the problem back to the nuclear medicine department for a possible solution.

The review forms are evaluated at the Nuclear Med-

BIF \_\_\_\_\_ Date Admit \_\_\_\_\_ Date reviewed at Review mtg. \_\_\_\_\_  
 RCK \_\_\_\_\_ Date D/C \_\_\_\_\_  
 Outpatient \_\_\_\_\_

#### QUALITY AND APPROPRIATENESS OF NUCLEAR MEDICINE SERVICES REVIEW

NAME: \_\_\_\_\_ 5% routine \_\_\_\_\_  
 HOSP #: \_\_\_\_\_ Special case \_\_\_\_\_  
 DATE: \_\_\_\_\_  
 PROCEDURE: \_\_\_\_\_  
 QUALITY (Technical): Excellent \_\_\_\_\_ Good \_\_\_\_\_ Satisfactory \_\_\_\_\_ Unsatisfactory \_\_\_\_\_  
 SAFETY: Dose in guidelines \_\_\_\_\_ Dose higher than guidelines \_\_\_\_\_  
 APPROPRIATENESS: (According to Criteria\*) \_\_\_\_\_ Other \_\_\_\_\_  
 Cancelled: \_\_\_\_\_  
 Reason: \_\_\_\_\_  
 Peer Review: Agree with interpretation - Yes \_\_\_\_\_ No \_\_\_\_\_  
 Clinical correlation: Correct Diagnosis \_\_\_\_\_  
 or  
 Biopsy proved: Erroneous Diagnosis \_\_\_\_\_  
 Cited in: Progress notes \_\_\_\_\_ Discharge note \_\_\_\_\_  
 CONCLUSION: Influenced ultimate management - Yes \_\_\_\_\_ No \_\_\_\_\_  
 RECOMMENDATIONS: \_\_\_\_\_

ACTIONS TAKEN: \_\_\_\_\_

Signature \_\_\_\_\_ Date reviewed \_\_\_\_\_

**FIGURE 1**  
 This form, which is the only place patient identification is present, is completed by the nuclear medicine physician on 5% of all patients. References for criteria-based monitors are described in text

\*CRC Manual for N. Med. Proc., PRO, or BC/BS guidelines  
 Revised 10-1-85

icine Quality Assurance and Appropriateness Review Committee and the biweekly clinical section meeting of nuclear medicine. Whether or not there is a lack of conformity to guidelines is determined from the findings and discussions. Conclusions are reached concerning: (a) continuing evaluation, (b) suspension of monitoring in certain areas, and (c) instituting the evaluation of 100% of a certain type of study for a time.

A Quarterly Report (Table 1) is prepared summarizing what actions have been taken together with problems and ways of improving patient care that have been identified. This report provides information on patterns and trends for future planning of quality assurance activities. In this report, there are sections dealing with recommendations, actions taken, and effectiveness.

Note that we clearly separate "conclusions," "recommendations," "actions," and "effectiveness." For example, we noted an inordinate delay in beginning a patient procedure due to the nuclear medicine physician not seeing the patient promptly. Consequently, we instituted a 2-week semi-annual evaluation that has effectively corrected the problem.

In another case, we found a problem in reviewing thallium treadmill studies concerning inadequate stress and reported this to the Department of Medicine at its monthly meeting. Subsequently, there was a rapid improvement that allowed cessation of the 100% review of this procedure. Should the routine 5% review identify recurrence of the problem, an in-depth review will be restarted.

The reporting channels of quality assurance at our institution are seen in Fig. 2.

The Clinical Section of Nuclear Medicine disseminates information and reports necessary corrective actions by:

1. Direct contact with the physician or personnel involved.
2. Reporting to the appropriate clinical department

**TABLE 1**

Date
Topic: Quarterly Summary
Motivating Issue: QA & A Review Report
Objectives: To aggregate outcome
Method of Review: Concurrent
Criteria (Monitors capturing data)
Findings
Conclusions
Recommendations
Actions
Effectiveness

and through it to the Medical Executive Committee and Board of Trustees of the hospital.

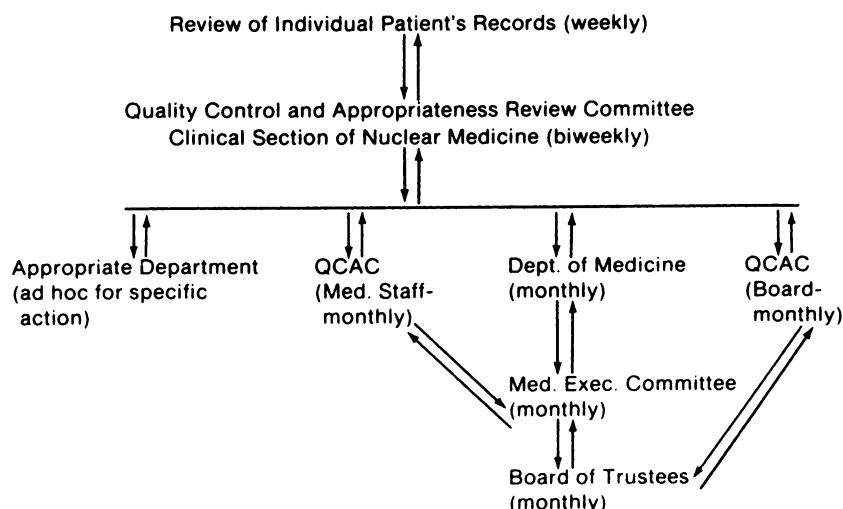
3. Reporting to the Quality Assurance Committee of the medical staff and through it to other departments of the hospital.

4. Reporting to the Quality Assurance Committee of the Board of Trustees of our institution.

Though there is biweekly, monthly, and quarterly reporting, there still must be an annual report and reappraisal of the monitoring, evaluation, and effectiveness of actions taken. This allows the program in nuclear medicine to be examined by the service's participants and the hospital's committee.

### HOSPITAL QUALITY ASSURANCE SYSTEM

A JCAH surveyor on a recent "focused review" of our program said that the department quality assurance technique, which has been outlined, had to be augmented by a 100% review of nuclear medicine studies by the Quality Assurance Department of the hospital. An approach which has been developed with our hospital's Quality Assurance Director and which seems to help in assuring good patient care and simultaneously conforms to the JCAH recommendation includes the



**FIGURE 2**  
This flow chart depicts the reporting mechanism for quality assurance and appropriateness of care at our hospital. As indicated, reporting from the Department of Nuclear Medicine to the Board and, also, from the Board to the department is provided

Date: 12-18-85

	Patient Name	Exam	Room	Mo. & Day Request Received	Patient Arrived	Interviewed by Doctor	Scan Started	Scan Completed	Patient returned to room	Comments
1	John Doe	Bone	415 <sup>1</sup>	12-17	8:05	8:15	8:30	12:00	12:10	
2	Robert Jones	Bone	309 <sup>1</sup>	12-17	9:10		cancelled			
3										
4	Tom Smith	MUGX	CCU9	12-18	8:20	8:25	8:30	10:15	10:15	Dr. P. @9:30

**A**

Date: 12-18-85

	1	2	3	4	5	6	7	8	9	Comments
	Consent Form	Return To Dept. For Repeat	Drug Therapy Util.	Code - 5 Cardiac Arrest	Transfer to Critical Care Code Result	Patient Incident	Dept. N.M. Internal Problem	Problems With Other Depts.	Pat/Family Dissatisfaction	
1	NA	NA	NA	NA	NA	E	NA	NA	NA	dP
2			Cancelled					F		M Mc
3										
4	Yes	NA	NA	NA	NA	NA	NA	NA	NA	RK (Technologist's initials)

**B**

**FIGURE 3**

Both the schedule and log (A) and the generic monitor (B) are completed during each study, maintained for 1 year, and the discrepancies reported to the Quality Assurance Department

following pertinent points adapted for nuclear medicine (6).

1. Consent for potentially hazardous (i.e., cardiac stress) studies or therapies. Was it obtained?
2. Unplanned return to repeat an incomplete or incorrectly performed procedure.
3. Administration of incorrect diagnostic or therapeutic dose of radiopharmaceutical.
4. Cardiac or respiratory arrest in the department.
5. Transfer from general care to special care unit due to complication of the nuclear medicine procedure.
6. Departmentally incurred patient incident (i.e., fall, equipment injury, etc.).
7. Utilization problem (i.e., repeat due to equipment failure, incorrect study, etc.).
8. Department problems (i.e., nursing errors).
9. Patient/family dissatisfaction (i.e., waiting time or treatment by personnel).

After meeting with our department manager, it was felt that 100% review of monitors, such as those just outlined, would not be too onerous a task and would actually better organize what we were already doing. As a consequence, logs of patient flow and generic monitors are now kept on every patient as shown in Figs. 3A and 3B. Using descriptors, appropriate letters are inserted in the proper box (Fig. 4). Trends in discrepancies within the "generic monitors" are reported through the same channels as cited before.

**CONCLUSION**

It is believed that the program, as outlined above, has led to better nuclear medicine patient care at our hospital. With this impetus, quality assurance programs will continue to improve the quality of care in our institutions.

**APPENDIX**

**Standard V**

As part of the hospital's quality assurance program, the quality and appropriateness of nuclear medicine services are monitored and evaluated and identified problems are resolved.

**Required Characteristics**

- A. The nuclear medicine department/service has a planned and systematic process for monitoring and evaluation of the quality and appropriateness of patient care services and for resolving identified problems.
  1. The physician director of the nuclear medicine department/service is responsible for assuring that the process is implemented.
- B. The quality and appropriateness of patient care services are monitored and evaluated in all major clinical functions of the nuclear medicine department/service. Such monitoring and evaluation are accomplished through the following means:
  1. Routine collection in the nuclear medicine depart-

## DESCRIPTERS OF GENERIC MONITORS

1. Nuclear Medicine consent form for non-invasive or therapeutic procedures.
 

A. Missing	D.
B. Not signed by patient	E.
C. Risks not explained	F.
2. Unplanned return to the Nuclear Medicine Department for repeats, additional images, or incorrectly performed procedure:
 

A. Wrong area imaged	D.
B. Return for missed images	E.
C. Improper intensities	F.
3. Drug/Therapy Utilization
  - A. Antibiotics or drugs not administered as ordered or on proper schedule because patient was in Nuclear Medicine Department.
  - B. Incorrect therapeutic dose; i.e. wrong amount of mCi.
  - C. Misadministration
4. Cardiac or Respiratory arrest in Nuclear Medicine Department (CODE 5):
  - A. Cardiac arrest
  - B. Respiratory arrest
  - C.
5. Transfer from general care to special care unit due to CODE-5 in the Department of Nuclear Medicine.
  - A. Transfer from general floor to CCU
  - B. Transfer from CCU to ICU
  - C.
6. Nuclear Medicine incurred patient incident.
 

A. Fall in department	E. Infiltration of dose
B. Equipment fell on patient	F.
C. I.V. infiltrated or discontinued while in N.M.	
D. Broken or malfunction of equipment	
7. Department of Nuclear Medicine internal problems:
  - A. Increased length of stay in hospital for patient due to Nuclear Medicine complication.
  - B. Repeat procedure due to equipment failure.
  - C. Repeat procedure due to technologist error.
  - D. Injection of M.A.A. through reseat.
  - E. Repeat procedure due to improper patient prep.
  - F. Incorrect images taken.
  - G. Images in wrong sequence; i.e. bone before liver/spleen
  - H. PYP thru reseat
  - I. Poor study due to intensity etc. (comments - list study, camera)
8. Problems with other departments. (Problems that occur in other departments that affect the Nuclear Medicine Department)
  - A. Patient sent back to room.
  - B. Improper patient prep by nurses, floor, physician.
  - C. Wrong request.
  - D. Wrong patient name on request.
  - E. Medications not stopped.
  - F. No request in Dr. orders.
  - G. Patient waited more than 15 minutes to return to room.
  - H. Physician was late for stress testing.
9. Patient/family dissatisfaction:
  - A. Waiting times too long.
  - B. Improper treatment by personnel.
  - C.
  - D.
  - E.

### FIGURE 4

Letters noted in this outline, under each category, are entered in the proper box on the generic monitor form. Merely adding an additional category with an appropriate letter allows for continued expansion of the criteria to be evaluated and reported

ment/service, or through the hospital quality assurance program of information about important aspects of nuclear medicine services; and

2. Periodic assessment by the nuclear medicine department/service of collected information in order to identify important problems in patient care services and opportunities to improve care.

- a. In B.1 and B.2, the nuclear medicine department/service agrees on objective criteria that reflect current knowledge and clinical experience.

1. These criteria are used by the nuclear medicine department/service or by the hospital quality assurance program in the monitoring and evaluation of patient care services.

- C. When important problems in patient care services or opportunities to improve care are identified,

1. Actions are taken; and
2. The effectiveness of the actions is evaluated.

- D. The findings from and conclusions of monitoring, evaluation, and problem-solving activities are documented

and, as appropriate, are reported.

- E. The action taken to resolve problems and improve patient care services and information about the impact of the actions taken are documented and, as appropriate, are reported.
- F. As part of the annual reappraisal of the hospital's quality assurance program, the effectiveness of the monitoring, evaluation, and problem-solving activities in the nuclear medicine department/service is evaluated.
- G. When an outside source(s) provides nuclear medicine services or when there is no designated nuclear medicine department/service, the quality and appropriateness of nuclear medicine services provided are monitored and evaluated and identified problems are resolved.
  1. The medical staff is responsible for assuring that a planned and systematic process for such monitoring, evaluation, and problem-solving activities is implemented.

## FOOTNOTE

\*Cited references to the JCAH *Accreditation Manual for Hospitals* are relatively unchanged in the AMH/86 edition, pp 114–119, 121–127, and 205–208.

## ACKNOWLEDGMENTS

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