

Quality Assurance Program for a Nuclear Pharmacy

Anne Hiltz and Susan Pierce

ABSTRACT

The development of a quality assurance program for a nuclear pharmacy service is described. The program was established to complement and test the extensive quality control procedures in the nuclear pharmacy. Based on current nuclear pharmacy standards of practice and government regulations, audits were developed and tested for a 12-month period. Results of these audits were closely analyzed for their relevance and impact on the service. These results showed that the standards for the established quality control program were being met. It was concluded that the quality assurance program was a useful and practical tool.

Key Words: nuclear pharmacy, quality control, quality assurance

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RÉSUMÉ

Cet article décrit le développement d'un programme d'assurance de la qualité d'un service de radiopharmacie. Le programme a été établi afin de compléter et évaluer les procédures détaillées de contrôle de qualité de la radiopharmacie. Les vérifications ont été développées et examinées sur la base des standards de pratique en radiopharmacie actuels et des règlements gouvernementaux pendant une période de douze mois. Les résultats de ces vérifications ont été analysés minutieusement afin de connaître leur pertinence et leur impact sur le service. Ces résultats ont démontré que le programme de contrôle de qualité établi répondait aux standards. Il a été conclu que le programme d'assurance de la qualité était un outil utile et pratique.

Mots clés: radiopharmacie, contrôle de qualité, assurance de la qualité

INTRODUCTION

Quality control in pharmacy can be defined as the specific tests and measurements that ensure the purity, potency, product identity, biological safety & efficacy of pharmaceutical services¹. Quality assurance is one of the mechanisms available to ensure that quality control standards are being met and that a consistently high level of health care is provided continuously.² Therefore, quality assurance audits pro-

vide the evidence that activities are being performed in accordance with established standards.

The Victoria General Hospital is an 800-bed general teaching hospital affiliated with Dalhousie University. The Nuclear Pharmacy Service introduced a quality control program in 1985 and more recently established a quality assurance program to complement it. This paper describes the rationale, development,

and implementation of the quality assurance program, including audit results and impact on the Nuclear Pharmacy operation 12 months following its implementation.

Rationale

Nuclear pharmacy is the practice of procuring, compounding, dispensing, and distributing radiopharmaceuticals, including the performance of quality control procedures. It also

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involves the implementation of basic radiation protection principles. The education of physicians and other health professionals in nuclear pharmacy is also a vital part of this specialized practice.³ Nuclear pharmacists, through their knowledge and professional judgment, improve and promote health care through assurance of the safe and efficacious use of radiopharmaceuticals.⁴ Quality control is at the centre of any nuclear pharmacy service. Each radiopharmaceutical must pass a number of quality control tests before being dispensed for human use. A hospital-based quality control program for the preparation of radiopharmaceuticals is required due to on-site production of the final drug product. This differs from conventional pharmacy practice where the majority of pharmaceuticals used in hospitals are manufactured commercially. As well, extensive quality control is necessary in nuclear pharmacy because of the radioactive nature of the products. This property of the products has the potential to pose serious health hazards to patients and personnel working with

the products.

The majority of radiopharmaceuticals used in Nuclear Medicine contain the radioisotope Technetium-99m, which is obtained from on-site Molybdenum-99/Technetium-99m generators. The Technetium-99m eluate from these generators is used to tag non-radioactive chemicals. The resulting products are used diagnostically in medicine. Examples of quality control procedures include Molybdenum-99 and aluminum ion testing of Technetium-99m eluates.^{1,5} Radiochemical purity testing, clarity, pH, sterility and pyrogen testing are required on the final Technetium-99m drug products.

On non-Technetium-99m radiopharmaceuticals such as Gallium-67 and Thallium-201 quality control is limited to quantitative analysis and clarity testing.

In addition, environmental and instrumentation quality control tests are carried out to ensure a safe working environment and the highest possible standard of care for patients.^{1,3,5}

The quality control program in place at the implementation of the quality assurance program was consistent with the guidelines of the Canadian Society of Hospital Pharmacists (CSHP),⁶ recommendations from the Health Protection Branch (HPB), Health and Welfare Canada,⁷ as well as Atomic Energy Control Board regulations.⁸ However, it was recognized that a more extensive and formalized documentation of these checks was necessary to comply with current accreditation standards for Canadian health care facilities.⁹

Description of Nuclear Pharmacy Services

The Nuclear Pharmacy Service, Department of Pharmaceutical Services, is located in the Nuclear Medicine Department, Victoria General Hospital. The staff consists of one full-time and one part-time nuclear pharmacist and a nuclear medicine technologist. The Nuclear Pharmacy Service provides radiopharmaceuticals to the Nuclear Medicine Department as well as educational and consulting services to the region.

Table I: Nuclear Pharmacy Audits

Audit	Audit Name	Frequency Number	Percentage of Observations Compliant with Criteria	No of Times Performed
1	Aseptic Technique	every 6 months	100%	2
2	Dose Calibrator Constancy Test	every 6 months	>99%	2
3	Laminar Flow Hood Maintenance	every 4 months	100%	3
4	Isotope Receiving Record	every month	>99%	12
5	Tc-99m Master Formula Sheets	every month	>99%	10
6	Disposal of Decaying Products	every 12 months	100%	1
7	Sterility Testing of Non Radioactive Products	every 4 months	100%	3
8	Pyrogen Testing of Tc-99m Products	every 6 months	100%	3
9	Sterility Testing of Tc-99m Products	every 6 months	100%	3
10	Linearity Testing on Dose Calibrator	every 12 months	96%	3
11	Accuracy Testing on Dose Calibrator	every 12 months	100%	1
12	Geometry Testing on Dose Calibrator	every 12 months	100%	1
13	Area Monitoring	every 4 months	>99%	4
14	Swipe Testing of Department	every 4 months	98.4%	4
15	Swipe Testing of Radioactive Shipments	every 6 months	100%	3
16	Labelling of Products	every 6 months	>99%	2
17	Cleaning of Laminar Flow Hood	every 4 months	100%	4
18	Particle Size and Density Testing	every 6 months	100%	2

The quality control system in place covered all aspects of nuclear pharmacy. Quality control procedures were divided into three major types: pharmaceutical, environmental, and instrumentation. Examples of pharmaceutical quality control included such procedures as quantitative analysis, radiochemical and radio-nuclidic purity testing, and clarity and pH testing. Environmental quality control included swipe testing and area monitoring and instrumentation quality control mainly involved testing of the dose calibrator and well detector. Nuclear pharmacy staff performed these procedures on a regular basis. Standard documentation forms were developed to record these quality control results. The nuclear pharmacist carried out routine spot checks on these records.

METHODS

A literature review of quality assurance in nuclear pharmacy practice provided little information. Kawada, et al in their review of nuclear pharmacy practice briefly described a radiopharmaceutical quality assurance program. This review, however, was specific for American

standards.¹⁰ There is more extensive literature dealing with quality assurance in general hospital pharmacy practice.^{9,11-14.}

Using the information found in the literature five steps, including establishment of criteria and standards, audit, review, re-audit and annual review, were identified as critical to a quality assurance program and were extrapolated for nuclear pharmacy practice.

Establishment of Criteria and Standards

Written criteria and other standards defining acceptable service were identified. Eighteen audits were established to measure these standards, based on practices and procedures in the Nuclear Pharmacy Service (Table I). These practices had been established using the guidelines of the CSHP, recommendations of the HPB, Health and Welfare Canada, and AECB regulations.⁶⁻⁸ Criteria and standards were established based on acceptable quality of products and services. Ease of documentation and retrieval of data were important considerations in audit design. This work was facili-

tated by the quality control practices and procedures which were presently in place. A quality assurance plan, showing criteria and standards, was established for each audit. An example of this plan is shown in Table II. This plan included the following: (i) Principal Function — A description of what is being audited; (ii) Standards Setting — A list of the sources on which the standards for the audits are based; (iii) Activity Monitoring — A description of how the principal function is carried out. In some audits direct observation was the method of data collection. In other audits where detailed documents had to be examined, it was necessary to design audit sheets. Audit sheets are similar to data collection sheets, providing a means of collecting necessary information in an organized manner; (iv) Performance Assessment — The means of assessing the quality assurance audit results.

Audit Phase

This phase determined whether services and products were meeting standards. Areas where it was speculated there may be problems were audit-

Table II: An Example of a Quality Assurance Plan

VICTORIA GENERAL HOSPITAL DEPARTMENT OF PHARMACEUTICAL SERVICES Audit No: Five Section: Radiopharmacy	
Quality Assurance Plan	
PRINCIPLE FUNCTION	TO: Assign lot numbers and document all required information on Tc-99m Radiopharmaceutical Master Formula Sheets
STANDARDS SETTING	Standards for the function are set with reference to: 1. Departmental Practice and Procedure 2. Health and Welfare Canada Schedule C Recommendations
ACTIVITY MONITORING	The on-going execution of this function is monitored by: Radiopharmacist and/or Nuclear Medicine Technologist Randomly select 20 Master Formula Sheets each month Use audit check lists, master formula record and rough record book to monitor criteria indicated.
PERFORMANCE ASSESSMENT	The department's performance in this function is evaluated by: Quality Assurance Committee

ed first, so that a re-audit could be performed quickly if any deficiencies were detected. Eighteen audits were performed over a one-month period and an audit report was completed in all cases. After this one-month period, the audits were then scheduled over one year and a calendar prepared describing times and frequencies (Table I).

Review Phase

The review phase identified deficiencies in the audit process. All audit results were entered on a summary sheet by the staff performing the audit and reviewed by the nuclear pharmacist. It provided an overview of the focus of the audit, the means of performing the audit, the findings of the audit and their significance and most importantly the follow-up based on the audit results. A copy of this summary sheet was then sent to the Departmental Quality Assurance Audit Committee for comments and additional recommendations. The results of the audits were filed in a binder organized by audit numbers for easy retrieval.

Re-Audit Phase

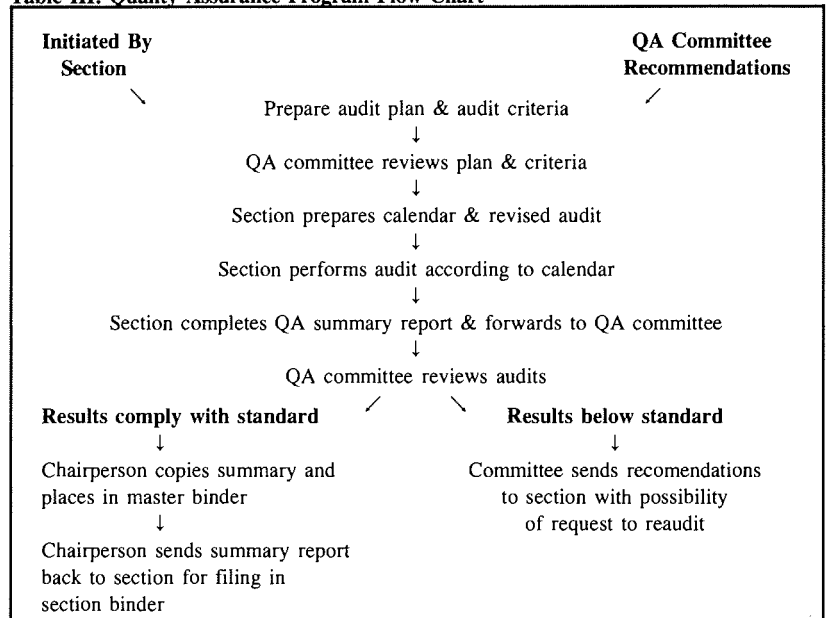
Following the completion of the audits, it was planned to re-audit certain areas if problems were found to ensure that the recommended corrective action, made on the original audits, were followed and had eliminated deficiencies.

Annual Review

Following the initial audits, the quality assurance process continued based on the frequency criteria (Table I). At the end of the initial 12 months, all audits were reviewed to determine their relevance and practicality. At this time standards and criteria could be deleted, modified, or new standards introduced.

The departmental quality assurance committee consisted of representatives from all areas of the

Table III: Quality Assurance Program Flow Chart



department, the chairperson being a department manager. Table III summarizes the lines of communication and feedback mechanisms for the Quality Assurance Program.

RESULTS

During the first 12 months of the program, each of the 18 audits were performed according to the established schedules (Table I). The results of the initial audits indicated that the Nuclear Pharmacy Service was meeting established standards (Table I). In the vast majority of cases, audit criteria were met 100% of the time with the exception of a few cases. In these incidents, the exceptions were not considered significant. The departmental standards were reviewed with the staff on these occasions.

The departmental quality assurance committee recommended that the frequency of two of the audits (numbers four and five) be decreased because of the high compliance rate. The committee did not change the frequency of the other audits even though compliance with each of the standards was greater than 98%,

since they required little time to complete and provided valuable information to the department. Following the development of the audits, the time involved in maintaining the Quality Assurance Program is approximately two hours per month.

DISCUSSION

The establishment of quality control and assurance standards has been beneficial to the Nuclear Pharmacy Service in several areas. The development of standards and criteria provided an up-to-date review and evaluation of quality control procedures. The positive results of the audits provided excellent feedback to the staff involved, and the audits provided necessary accreditation information in the form of written documentation. Furthermore these 18 audits, based on product, instrumentation and environmental quality control, have laid the foundation for the development of more clinical, patient-oriented audits.

CONCLUSION

The quality assurance program

established by the Nuclear Pharmacy Service, Department of Pharmaceutical Services, was easy to perform, practical in nature and supportive to staff morale. It also provided useful and necessary information to pharmacy management to comply with Canadian Health Care facility accreditation. The thoroughness, yet simplicity, of the system provided the foundation on which to build a quality assurance program for the rest of the Department of Pharmaceutical Services. ☐

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