A Simplified Radiopharmaceutical Accountability Record-Keeping System

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A comprehensive system has been developed to ensure that a patient receives the proper radiopharmaceutical dose and that records of accountability are conveniently maintained. A radiopharmacy assay/utilization record serves as the control document for source products and derived new products. Color-coded numbered labels are used to maintain accountability among source products, derived products, prescriptions, logbooks, and patient doses. These measures have proved effective in simplifying documentation, minimizing dose-administration errors, and providing for radiopharmaceutical accountability.

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Given the long-standing tradition of strict enforcement of radiopharmaceutical administration regulations and the current climate of concern regarding protection against malpractice litigation, the nuclear medicine physician is acutely aware of the need to develop procedures for assuring quality control every step of the way from radiopharmaceutical preparation to dose administration. Just as important as the delivery of the dose is the system of records that serves as evidence that dose delivery was in fact correct. We will describe a record-keeping system for radiopharmaceutical accountability that simplifies the paperwork and minimizes human error in the preparation and administration of doses to patients. The system has been used in our clinic for several years and has been commended by representatives of several regulatory agencies. Even the smallest nuclear medicine clinic will find that adopting this system will increase technologist productivity due to the simplified and reduced documentation required.

DESCRIPTION

Upon receipt of a radiopharmaceutical, the package is wipe-tested, the manufacturer's assay is checked, and the product is logged into a radiopharmacy assay/utilization record (Fig. 1). A separate record form is initiated for each product as it arrives from the manufacturer or as it is prepared from a product kit. Quintuplicate Time® labels* (Catalogue No. CNT-20) are then used to maintain inventory control and to cross-index between the log sheet and the product container. The five labels, each imprinted with the same number, are distributed as follows: (A) the radiopharmacy assay/utilization record; (B) the product container;

PRODUCT $NaTcO_4^-$ DATE 17 NOV 75 CONTROL NO. NM 2418

QUALITY CONTROL

750 mCi 30.0 mCi/ml

TIME 0730 DATE 17 NOV 75

% TAG ____ pH 5.5

Mo99 NEG Al^{+++} < 15 ug/ml

OTHER ____

MFG. ASSAY (OR LABEL)

TOTAL ACTIVITY ____ mCi

TOTAL VOLUME ____ ml

SPECIFIC ACTIVITY ____ mCi/ml

MFG. LOT NO. Mallinckrodt 105-5KG

EXPIRATION DATE ____

SOURCE PRODUCT ($NaTcO_4$, NaI, RISA): CONTROL NO. ____ VOLUME ____ ml

25.0

DATE	TIME	PATIENT	RX NUMBER	PROCEDURE	DOSE (mCi)	VOLUME (ml)	BALANCE (ml)
17 NOV 75	0745	Prep PYPX	NM 2419		58.3	2.0	23.0
"	0800	Prep SCOL	NM 2420		56.6	2.0	21.0
"	0805	Highsmith, James	NM 3625	BRAIS-FLOBS	15.0	0.54	20.46
"	0820	Cornwall, Marion	NM 3626	BRAIS-FLOBS	14.9	0.55	19.91

DECAY ROOM ____ ACTIVITY 0.001 uCi ____ DISPOSED TO TRASH ____

RADIOPHARMACY ASSAY/UTILIZATION RECORD

FIG. 1. Radiopharmacy assay/utilization record. First two entries in body of record illustrate labeling procedure when sodium pertechnetate is used to prepare pyrophosphate (PYPX) and sulfur colloid (SCOL). Last two entries identify patient doses drawn from eluate to perform brain scan and bloodflow studies. Similar records are established for each batch of radiopharmaceutical prepared. Quality control information is recorded in top section.

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(C) the top of the lead pig or other shielding device; (D) the side of the lead pig; and (E) the daily transaction log. The daily transaction log is simply a bound notebook in which all receipts and doses administered are logged as a cross-check (Fig. 2). After the logging-in procedure, the product is placed in the appropriate storage location and the radiopharmacy assay/utilization record is inserted into a loose-leaf binder separated by dividers into individual product sections.

When a radiopharmaceutical is used in the preparation or tagging of other agents, the inventory control labels are used to maintain traceability back to the original manufacturer's lot data. The inventory control labels are affixed according to the following modified scheme: (A) in the body of the source product's radiopharmacy assay/utilization record (Fig. 1); (B) in the daily transaction log (Fig. 2); (C) in the top section of a new product's radiopharmacy assay/utilization record; (D) on the product container; and (E) on the product shielding device.

Each patient seen in our nuclear medicine service is referred by means of a consultation form. This form contains patient identification and space for the referring physician to provide a brief patient history and a provisional diagnosis. The nuclear medicine physician reviews the consultation form, determines the diagnostic evaluation to be performed, and prescribes the radiopharmaceutical dose to be administered. The prescription form is rubber-stamped on the face of the consultation form.

Every diagnostic procedure performed in our clinic is recorded on computer cards, from which monthly and quarterly summaries are compiled (*1*). The radiopharmacy technologist checks to see that the consultation form and the computer card are for the same patient and for the radiopharmaceutical prescribed by the physician. He then locates the appropriate radiopharmacy assay/utilization record and calculates and draws the dose. Color-coded quintuplicate Time® labels (No. CNR-10) are affixed in the following locations to record the administration of the dose: (A) the product radiopharmacy assay/utilization record; (B) the daily transaction log; (C) the consultation form; (D) the syringe, and (E) the lead syringe carrier.

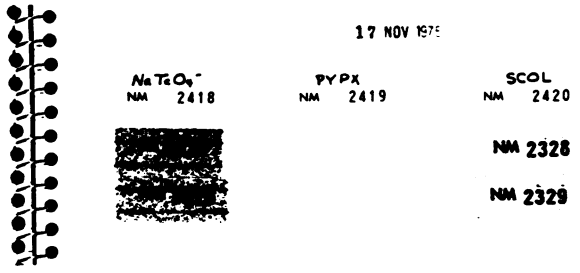

FIG. 2. Daily transaction log. Elution of generator (NM 2418) and subsequent preparation of pyrophosphate (NM 2419) and sulfur colloid (NM 2420) are recorded in this log. Preparation of two patient doses of sodium pertechnetate (NM 3625 and NM 3626) and two patient doses of sulfur colloid (NM 2328 and NM 2329) are also shown.

Immediately prior to dose administration, the physician verifies the identity of the patient and checks that the radiopharmaceutical dose prescribed on the consultation form and the dose entered on the computer card are identical. He also checks that the color-coded labels on the consultation form, the syringe carrier, and the syringe are identical.

DISCUSSION

The stringent control of the use of radioactive material in humans has resulted in close similarities in record-keeping requirements between radiopharmaceuticals and other controlled substances. In addition, we feel that inclusion of quality control information on each product log is highly desirable. Accordingly, we evaluated the forms used by several other hospital radiopharmacies and combined the better points of each of these other forms into our radiopharmacy assay/utilization record (Fig. 1). The information on each record sheet serves as a record of receipt of the product, as evidence of quality control performed, as a listing of each dose administered, and as a record of waste disposal action. The record sheet is thus a self-sufficient lifetime account of the radiopharmaceutical.

In a busy radiopharmacy section, doses are often drawn while the imaging technologist is preparing for the study. This creates a potential for hurriedly picking up the wrong syringe. The color-coded numbered Time® labels virtually eliminate this hazard. As each dose is prepared, a label is affixed to the needle cover of the syringe, the outside surface of the syringe carrier, and to the consultation form. The physician instantly recognizes the color code and verifies that the radiopharmaceutical prescribed has actually been drawn. Intercomparison of the numbers on these three labels ensures that the doses for different patients of identical radiopharmaceuticals have not been inadvertently switched. In addition, the numbered label also serves as a record of the prescription number of the requested radiopharmaceutical. Finally, the verification of patient identification, one of the most important aspects of effective quality control, is performed with the verification of radiopharmaceutical at the time of administration.

FOOTNOTE

* Professional Tape Company, Riverside, Ill.

REFERENCE

1. NUSYNOWITZ ML, GOLDSMITH WA, WALISZEWSKI JA, et al.: A system for computer processing of radiopharmaceutical disbursement information. *Am J Roentgenol Radium Ther Nucl Med* 111: 191–194, 1971