License #-40-24908-01

NUCLEAR IMAGING, LTD.
109 South Petro Avenue • Sioux Falls, South Dakota 57107 • (605) 330-9060

January 9, 1997

Vivian Campbell
Nuclear Regulatory Commission, Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064

Dear Ms. Campbell:

Enclosed please find our Annual Summary of our Quality Management Program.

This is being sent in compliance with our Radioactive Materials License authorizing the administration of therapeutic doses of radiopharmaceuticals.

In addition to the Summary itself, I am enclosing copies of some slightly modified paperwork that is used in therapy administration documentation. Also, we have developed a check list format for on going program review.

Sincerely,

Corinne Connelly

Corinne Connelly
General Manager

CC/srh

Enc.

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ANNUAL SUMMARY OF QUALITY MANAGEMENT PROGRAM

Administration of Therapeutic Doses of Radiopharmaceuticals and Diagnostic Doses in excess of 30 Microcuries of Sodium Iodide I-125 or I-131.

Period of audit January 1, 1996 to December 31, 1996

Dates of audit December 26 1996 to December 31, 1996

Auditor's name: Cheryl Skarphol, CNMT

Auditor an authorized user (check one) Y _____ N _X_

Number of Doses administered I-125 _____ I-131 _50_

P-32 _____ Sr-89 _20_

Other _____

I. Criteria	Yes	No	% compliance
1. Written directive prior to administration.	70	0	100%
2. Oral directive only if patient's health jeopardized. Number occurred _0_			100%
3. Written directive includes: (score each item)			
patient's name	70	0	100%
patient's identification number	70	0	100%
radiopharmaceutical	70	0	100%
dosage	70	0	100%
route of administration	70	0	100%
type of procedure desired	70	0	100%
signed by authorized user	70	0	100%
date	69	1	98.5%
4. All individuals involved in radioiodine preparation/administration instructed in this Quality Management Program.	70	0	100%
5. Employed more than one method of verifying patient's identity before administration.	70	0	100%

I. Criteria (cont)	Yes	No	% compliance
6. Radiopharmaceutical or radiation administrations in accordance with written directives.	70	0	100%
7. Unintended deviations (total number annually ___0_) from written directives. identified evaluated corrective actions taken	0	70	100%
8. Each recordable event, (total number annually __0__) evoked proper response.			100%
9. Therapeutic misadministration(s) (Total number __0__) evoked proper response.			100%
10. Maintain adequate records including:			
annual review	4	0	100%
written directives	70	0	100%
radiopharmaceutical doses	70	0	100%
recordable events	No recordable events.		
misadministration	No misadministrations.		

II. RECOMMENDATIONS

1. Implement use of Therapy documentation forms which were simplified for greater clarity and ease of use.
2. Continue monitors as established.

III. SUMMARY REVIEWED BY:

_____ Title _____

_____ Title _____

_____ Title _____

Concur / Non-concur

Connie Connelly

Chief, Nuclear Medicine

Concur / Non-concur

Radiation Safety Officer

I 131 Therapy Administration Documentation

Therapy Date _____ Scan #_____

Patient Name _____

Dose Prescribed_____ __ 10% Acceptable Range _____

Dose Administered _____ _____

1. Patient Identification: *Check two methods used.*

Source a. Driver's liscence (Picture ID) _____ c. Medical facility ID bracelet _____

c. Family member or guardian _____ d. Verbal by patient:_____

Identifiers: Full Name _____ Birthdate _____ Address_____ SS#_____

Patient identification matches that on written directive? _____

2. Consent: Signed _____ Witnessed _____

3. Education:

Physician conducted interview / education complete? _____

4. Dose Preparation:

Radiopharmaceutical dose assayed by _____ at _____

Assayed dose is in accordance with written directive? _____ _____

5. Administration:

Oral dose administered by _____ Time _____

Reaction noted? _____ _____

Attending physician initials _____

Patient released at _____

Notes:

_____

_____

_____

Strontium 89 Therapy Administration Documentation

Therapy Date _____ Scan #_____

Patient Name _____

Dose Prescribed_____ 10% Acceptable Range _____

Dose Administered _____

1. Patient Identification: *Check two methods used.*

   Source: a. Driver's liscence (Picture ID) _____ b. Medical facility ID bracelet _____

   c. Family member or guardian _____ d. Verbal by patient:_____

   Identifiers: Full Name _____ Birthdate _____ Address_____ SS#_____

   Patient identification matches that on written directive? _____

2. Consent: Signed? _____ Witnessed? _____

3. Education:

   Physician conducted interview / education complete? _____

4. Dose Preparation:

   Radiopharmaceutical dose assayed by _____ at _____.

   Assayed dose is in accordance with written directive? _____

5. Administration:

   IV line established by _____ where_____

   Dose administered by _____ Time _____

   Reaction noted? _____

   Orders given for WBC & platelet counts every two weeks for six weeks? _____

   Attending physician initials _____

   Patient released at: _____

Notes:

_____

_____

_____

Date / Number														
Type Sr89 or I 131														
(Pre-therapy) ID Info														
History														
Patient ID, 2 methods														
Consent signed														
Education done														
Written directive & administration: Written directive completed prior														
Contents: Pt. Name														
ID number														
Radiopharmaceutical														
Dosage														
Route														
Type of Procedure														
Authorized user signature														
Date written														
Administration documentation complete? (and dose tags)														
Administration in accordance with written directive														
All individuals instructed in QMP														
Unintended deviation														
Misadministration														
Follow-up for above														