CHRISTIANA CARE HEALTH SYSTEM POLICY
Section of Nuclear Medicine

POLICY TITLE:	Ordering, verification and administration of therapeutic radiopharmaceuticals
DATE OF ORIGIN:	8/24/2011
DATE OF REVISION:	11/3/2011

POLICY: Christiana Care's Nuclear Medicine physicians and technologists will administer therapeutic radiopharmaceuticals safely, without errors, and in accordance with state, NRC regulations, hospital standards and hospital and section policies.

PURPOSE: To provide the nuclear medicine physicians and technologists an overall policy for therapeutic radiopharmaceutical administrations which will provide a high level of assurance that no inappropriate or erroneous administrations will occur.

SCOPE: All staff in the Nuclear Medicine section (NM technologists, physicians, nurses, and clerical staff) involved in arranging or performing therapeutic nuclear medicine procedures.

PROCEDURE for requesting, scheduling, ordering, verifying, and performing therapeutic procedures in nuclear medicine:

1. All requests for therapeutic procedures will be reviewed and approved by a nuclear medicine physician prior to scheduling the procedure or ordering a dose.
2. All therapeutic doses ordered will be ordered based on the nuclear medicine physician's order as set forth in this policy.
3. Thyroid therapy procedures (for both hyperthyroidism and thyroid cancer) may be requested on a nuclear medicine section "**Thyroid Study & Therapy Request**" form (**Appendix A**) (preferred), on the referring physician's own referral or prescription form, or may be requested verbally during direct discussion between a referring physician and a nuclear medicine physician. If a thyroid therapy procedure is requested by prescription or verbal request, the details of the request will be entered on a "Thyroid Study & Therapy Request" form by the nuclear medicine physician. The nuclear medicine physician will write the therapeutic dose of I-131 to be given on the Thyroid Study & Therapy Request form.
4. Therapeutic procedures other than thyroid may be requested by physician prescription or written request or verbally by direct discussion between the

referring physician and a nuclear medicine physician. If such a procedure is requested verbally, the referring physician will be requested to submit a written prescription confirming the therapy request.

5. For all non-thyroid therapy procedures, including therapeutic administrations as part of clinical research protocols, a nuclear medicine physician will complete a **Therapeutic Radiopharmaceutical Request** form (**Appendix B**), including patient and referring physician information, procedure requested, relevant clinical information and any special instructions to the nuclear medicine staff. The particular therapeutic radiopharmaceutical and dose to be administered are entered by the nuclear medicine physician on the "Request to order therapeutic agent" portion of this form.
6. The nuclear medicine physicians will give completed Thyroid Study & Therapy Request or Therapeutic Radiopharmaceutical Request forms (collectively "therapy request forms") to clerical staff who will schedule the procedure with the patient. When the procedure is scheduled, clerical staff enter the procedure into the radiology information system (XIRIS) and place the therapy request form, together with any supporting documents not in the CCHS system, into the "pending procedures" file.
7. Nuclear medicine procedures scheduled in the XIRIS system are reviewed daily by designated nuclear medicine technologists. When a therapeutic procedure is scheduled, the technologist reviews the therapy request form in the pending procedures file, and orders radiopharmaceutical and dose prescribed on that form from the radiopharmacy.
8. Therapy doses are received as unit doses from an outside commercial pharmacy. Upon receipt of a therapeutic radiopharmaceutical from the radiopharmacy, after standard package receipt procedures, the technologist will compare the patient name, radiopharmaceutical and dose indicated on the shipping label and on the vial or syringe label with the therapy request form for that procedure. In the event of any discrepancy, the nuclear medicine physicians will be notified immediately.
9. The technologist will then: 1) assay the dose in the dose calibrator; 2) print a dose sticker showing patient name, medical record number and measured activity; 3) fill out a Homeland Security card; and 4) enter the patient name on an appropriate consent form.
10. The technologist will confirm that the patient folder contains the therapy request form and supporting documents, consent form, CCHS requisition, Homeland Security card, pregnancy test result, if applicable, and patient instruction pamphlet, if applicable. The technologist then gives the patient folder to the nuclear medicine physician.
11. In the case of IV therapy, the technologist or a nurse will establish secure IV access.
12. The nuclear medicine physician will review the patient folder, and confirm that all documentation is correct and the radiopharmaceutical and dose are in accordance with the therapy request form. In the case of treatment with ^{131}I >30mCi, the physician will prepare customized patient instructions

using the electronic Outpatient Release worksheet. The physician then performs consultation with the patient, obtains informed consent, delivers and documents the release instructions, and delivers the Homeland Security card and any other necessary materials.

13. The nuclear medicine physician then prepares the written Directive for Radiopharmaceutical Administration included in the combined **Written Directive / Radiopharmaceutical Quality Management Program (QMP)** form (**Appendix C.**) The nuclear medicine physician then returns the patient folder to the technologist.
14. The technologist will then: 1) verify that the Written Directive contains all required elements, and document on the Written Directive/QMP form; 2) complete the pregnancy/breast feeding section of the form; 3) correctly identify the patient with at least 2 separate identifiers and complete the patient identification section of the form; 4) complete the forms/procedure requirements section of the form.
15. The technologist, nuclear medicine physician, and patient will then take a final "Time-out" to confirm patient identity, correct radiopharmaceutical, correct dose, and to address any final patient or staff questions or concerns. The technologist will document the "Time Out" in the Final Time-Out section of the QMP form.
16. The technologist will then administer the dose to the patient per section policy. In the case of orally administered agents, the administration is performed by the technologist under direct supervision of the nuclear medicine physician. Intravenous therapy administrations will be performed by the nuclear medicine physician using secure IV access established by a technologist or nurse.
17. For ^{131}I doses >30mCi I-131, the technologist will perform a survey of dose readings at 1.0m and 0.3m from the patient and record the results on the Basis for Release worksheet for entry into the electronic outpatient release database.
18. The technologist and physician then complete and sign the Dose Administration Record on the QMP form.

11/03/2011
TM/CK/tr

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CHRISTIANA CARE HEALTH SYSTEM
NUCLEAR MEDICINE

Phone (302) 733-1530 Fax (302) 733-1518

THYROID STUDY & THERAPY REQUEST

Patient Information

Name _____

DOB ___/___/_____ Phone ( ) _____ Home ( ) _____ Cell

Insurance _____

Pre-authorization required? ☐ YES ☐ NO Auth # _____

Diagnosis: _____

DIAGNOSTIC STUDIES

☐ Thyroid ^{123}I Uptake (6 & 24 hours) & Scan (CPT 78007)

☐ Thyroid Cancer ^{123}I Whole-Body Survey (24 hr images) (CPT 78018)

- ☐ Hypothyroid
- ☐ Thyrogen®

Dates of Thyrogen® ___/___/_____ ___/___/_____

Please fax TSH level, pathology, & operative report (302) 733-1518

Nuclear Medicine Use Only

^{131}I THERAPY

Note: *Serum* ***pregnancy test required*** *within 1 week prior to treatment for all women age 10-50 unless surgically sterile.*

☐ Hyperthyroidism Brief (2 or 6 hr) uptake & ^{131}I therapy (CPT 78000, 79005)
Please fax TSH & pregnancy test result (302) 733-1518

Please Mark One
- ☐ Graves (15 mCi unless otherwise specified)
- ☐ Single Toxic Nodule (25 mCi unless otherwise specified)
- ☐ Toxic MNG (25 - 30 mCi unless otherwise specified)

☐ Thyroid Remnant Ablation & Post-Ablation Scan (CPT 79005, 78018)
(100 mCi ^{131}I unless otherwise arranged)
Please fax TSH & pregnancy test result, pathology report, op report (unless done at CCHS) (302) 733-1518

- ☐ Hypothyroid
- ☐ Thyrogen®

Dates of Thyrogen® ___/___/_____ ___/___/_____

Referring Physician

Name _____ Phone ( ) _____

Signature _____ Date ___/___/_____

revised 4/5/2011

Appendix A

NUCLEAR MEDICINE SECTION

CHRISTIANA CARE

Therapeutic Radiopharmaceutical Request

(Complete for all non-thyroid therapeutic doses)

Patient Information

Name _____

DOB ___/___/_____ Phone (___) _____ Home (___) _____ Cell

Gender ☐ Male ☐ Female

Diagnosis: _____

Insurance _____

Pre-authorization required? ☐ YES ☐ NO Auth-# _____

Referring Physician

Referring Physician _____ Phone (___) _____ Office

Other physicians involved: _____

Clinical Information

_____

_____

Procedure Requested

☐ Bone pain ^{89}SR Metastron
☐ Bone pain ^{153}Sm Quadramet
☐ RIT for Lymphoma—Zevalin
☐ ^{32}P hematologic
☐ Res. Imm hPAM4 Panc CA
☐ Res. Imm hA20-nLL2 Lymphoma
☐ Res. RTOG 0622 ^{153}Sm Prostate CA
☐ Other: _____

_____

Instructions to NM staff

_____

_____

_____

_____

_____

_____

Request to order therapeutic agent

Radiopharmaceutical requested: _____

Dose requested _____ milliCuries

To be given: ☐ on ____/____/____ ☐ to be scheduled with patient

Nuc Med Physician _____ Date

revised 8/22/2011

APPENDIX B

CHRISTIANA CARE

NUCLEAR MEDICINE SECTION

Radiopharmaceutical Quality Management Form

(Complete for all therapeutic doses and diagnostic ^{131}I doses >30uCi)

Directive for Radiopharmaceutical Administration

Patient Name _____ DOB _____

Radiopharmaceutical: _____ Give _____ milliCuries
Dose

By _____ _____
Route What?

_____ _____
Authorized User Date

Quality Management Verification—complete all sections

Patient Identification (check at least 2 methods)

- ☐ Name
- ☐ Date of Birth
- ☐ ID document (license, etc)
- ☐ Social Security No.
- ☐ Guardian ID
- ☐ ID Wristband
- ☐ Address
- ☐ Other

_____

Written Directive check (all elements required)

- ☐ Date
- ☐ Patient name
- ☐ Radiopharmaceutical
- ☐ Dose
- ☐ Route of Admin
- ☐ Physician (AU) Signature

Pregnancy/Breast feeding check (complete for all female patients)

- ☐ Questionnaire completed
- ☐ Female <10 or >50 y/o
- ☐ Pt had tubal ligation/hysterectomy
- ☐ Negative Serum B-HCG
  on __/__/__

- ☐ Pt is NOT Breast feeding
- ☐ Pt IS breast feeding
- ☐ Breast feeding instructions given

Forms/Procedure requirements—(complete for all patients)

- ☐ Physician consult completed
- ☐ Patient instructions given
- ☐ Section not applicable—diagnostic dose only
- ☐ Informed Consent Signed
- ☐ Homeland security card given
- ☐ NM Physician present

Final Time-Out—(complete for all therapy patients BEFORE administration)

- ☐ Correct patient?
- ☐ Correct radiopharmaceutical? (Check dose order request, directive, shipping label)
- ☐ Correct dose? (Check dose order request, directive, shipping label, assay amount).
- ☐ All patient/staff questions have been answered?

Dose Administration Record

Dose of _____mCi given _____ by _____ at _____h on __/__/__.
Dose Route Tech/Phys name Time Date

Tech Signature _____ _____
Date

Phys Signature _____ _____
Date

.....Affix dose sticker here.....

QMP Reviewed: _____ _____
QM Supervisor Date

revised 3/30/2011

APPENDIX C