

Employee Training

Written Directive Program

What is a “Written Directive”?

An authorized user’s written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject as specified in 10 CFR 35.40. <http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/full-text.html#part035-0040>

NRC views a written directive as a “prescription”, signed and dated, by an NRC approved physician, **prior** to administration. This is issued to technical staff for the expressed purpose of delivering a radiopharmaceutical dosage or radiation dose to the correct patient for the correct reason.

As per 10 CFR 35.5 <http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/full-text.html#part035-0005>, this required “record” can be stored in electronic media. However one must be able to “produce” a legible, accurate and complete record to include signatures throughout the record’s retention period. Written directives must be retained for three years.

“Oral” Directives & “Oral Revisions” are acceptable, if because of the emergent nature of the patient’s condition, a delay would jeopardize the patient’s health. All details of the oral directive or revision must be documented in the patient’s record ASAP. A written directive or revised directive must be prepared within 48 hours of the oral directive / revision.

Written Directives may be revised in writing **before** administration with an authorized user’s signature and date.

What Clinical Procedures Are Affected?

- **Any administration of I-131 as Sodium Iodide** greater than 1.1 MBq (30 μ Ci)
 - i.e., Substernal Thyroid Scan
 - Whole Body Thyroid Metastatic Scan
 - Hyperthyroid Therapy
 - Thyroid Carcinoma Therapy
- **Any therapeutic dosage of unsealed byproduct material**
 - i.e., Metastron (^{89}Sr)
 - Quadramet (^{153}Sm)
 - Zevalin (^{90}Y)
 - Bexxar (^{131}I)
 - Sodium ^{32}P
 - Chromic ^{32}P

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- **Any** therapeutic dose of radiation from byproduct material
 - i.e., Prostate Seeds (^{125}I , ^{103}Pd or ^{131}Cs)
 - ^{137}Cs Implants
 - HDR (^{192}Ir)
 - Teletherapy (^{60}Co)
 - ^{90}Sr Eye Applicators
 - GammaKnife (^{60}Co)
 - CyberKnife (^{60}Co)
 - GliaSite (^{125}I)
 - TheraSphere (^{90}Y)
 - SIRSphere (^{90}Y)

Who is an Authorized User for Written Directives?

Any physician whose credentials have been reviewed and approved by the NRC and is currently listed on your facilities Material's License by name for the following authorizations:

- 10 CFR 35.300 - Unsealed byproduct material – Written Directive Required
- 10 CFR 35.400 - Manual Brachytherapy – Sealed Source
- 10 CFR 35.600 - Teletherapy, HDR, GSR - Sealed Source
- 10 CFR 35.1000 - Other Medical Uses

CAVEAT: Some listed authorized users for 35.300 may be excluded for certain approved uses, i.e., Thyroid Carcinoma Therapy, but approved for all others. Be aware of and read the most current amendment of your facilities Materials License to ensure compliance.

What Must Any Written Directive Contain as a Requirement?

- **Any** administration of **I-131 as Sodium Iodide** greater than 1.1 MBq (30 μCi)
 - Patient's Name
 - Dosage of I-131 as Sodium Iodide
 - Authorized User's Signature & Date
- **Any** therapeutic dosage of unsealed byproduct material **other than I-131**
 - Patient's Name
 - Radioactive Drug
 - Dosage
 - Route of Administration
 - Authorized User's Signature & Date

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- Gamma Stereotactic Radiosurgery (GammaKnife)

Patient's name
Total Dose
Treatment Site
Values for the Target Coordinate Settings per Treatment for each Anatomically Distinct Treatment Site
Authorized User's Signature & Date

- Teletherapy

Patient's Name
Total Dose
Dose per Fraction
Number of Fractions
Treatment Site
Authorized user's Signature & Date

- HDR

Patient's Name
Radionuclide
Treatment Site
Dose per Fraction
Number of Fractions
Total Dose
Authorized User's Signature & Date

- All Other Brachytherapy

Patient's Name
Before Implantation: Treatment Site
Radionuclide
Dose
Authorized User's Signature & Date
After Implantation but before Completion of the Procedure
Radionuclide
Treatment Site
Number of Sources
Total Source Strength
Exposure Time OR Total Dose
Authorized User's Signature & Date

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What if the Required Information is Incomplete or Unclear?

STOP THE PROCESS IMMEDIATELY !!!

Seek clarification for any questionable issue. Have the authorized user complete the written directive as required. Make sure you understand all facets of the directive as it relates to this specific patient.

What Should Any Written Directive Contain as a Suggestion?

Good radiation safety practices, standards of care within the community and common sense would make the following items sensible additions to a Written Directive form.

- Documentation of Patient Identification
- Documentation of Pregnancy Status
- Documentation of Breast Feeding Status
- Desired Procedure
- Documentation of Administered Dosage
- Notation of Person Administering Dosage
- Date of Administration
- Notation of Confirmation by a Witness

What Written Procedures are Required?

10 CFR 35.41 <http://www.nrc.gov/reading-rm/doc-collections/cfr/part035/full-text.html#part035-0041> at a minimum requires the development, implementation and maintenance of written procedures to provide high confidence that:

- The patient's identity is verified before each administration.

AND

- Each administration is in accordance with the written directive.

In addition for those procedures conducted under 35.600 (Teletherapy, HDR, GSR) the following items must also be addressed in written procedures:

- Checking of both manual and computer-generated dose calculations
- Verification that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized under 35.600

All written procedures noted above must be retained for the duration of the license.

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Positive Patient Identification - Required

In order to meet this requirement it is suggested that a “Verifiable” system be used that is supported by institutional procedure that has been written, implemented and maintained.

It is suggested that picture ID, such as a driver’s license, hospital ID card, wrist ID bracelet or social security card be used in this effort.

Pure verbal ID methods such as calling a patient by name may not be a foolproof measure of verification.

Written Directive Followed ?? - Verify

Something as simple as measuring dosages in a dose calibrator and having that reading witnessed and checked against the written directive would be helpful.

If possible, have a witness shadow the entire patient ID and administration process.

Written Directive Program – Elements of Compliance

With any regulatory process, compliance is best accomplished via adequate documentation. Assurance of compliance can be assisted before the fact via “Strict Attention to Detail” and after the fact via an adequate and frequent audit program.

It is suggested that the following be maintained for each patient collectively in a single binder or file in chronological order to assist the audit process:

- Written Directive
- Patient Identification
- Pregnancy Test Result **
- Administered Dosage Record
- Hospitalization Records **(Daily Patient Surveys, Daily Room Surveys, Final Room Wipes, Instructions to Nursing Personnel)
- Patient Care Instructions
- Patient Specific Release Calculations **
- Records of Patient Release

** As Necessary



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WRITTEN DIRECTIVE

Name: _____ SS#: _____

DOB: _____ Diagnosis: _____

PATIENT IDENTIFICATION

_____Pt. Name Announced _____Spelling of Name _____ID Card
_____Birth Date _____SS# _____Wrist Band _____Other _____

PREGNANCY / BREAST FEEDING STATUS

Negative pregnancy confirmed by: _____PG Test _____LMP _____N/A

Breast Feeding: _____Yes _____No _____N/A

DESIRED PROCEDURE

- _____ ⁸⁹Sr Therapy for palliation of osseous mets. pain
- _____ ¹⁵³Sm Therapy for palliation of osseous mets. pain
- _____ ³²P (Sodium) Therapy for polycythemia vera
- _____ ¹³¹Iodine Whole Body Scan
- _____ ¹³¹Iodine Substernal Thyroid Scan
- _____ ¹³¹Iodine Therapy for Hyperthyroidism
- _____ ¹³¹Iodine Therapy for Thyroid Cancer
- _____ ⁹⁰Y Zevalin Therapy for Non-Hodgkin's Lymphoma
- Other: _____

RADIOPHARMACEUTICAL(Circle One)

⁸⁹Sr Chloride ¹⁵³Samarium Sodium ³²P ¹³¹I Sodium Iodide

⁹⁰Yttrium Ibritumomab Tiuxetan(Zevalin) Other: _____

Prescribed Dose: _____ Route: _____

Signature of Authorized User: _____ Date: _____

Administered Dose: _____ By: _____ Date: _____

Witness: _____ Date: _____

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TITLE: VERIFICATION OF PATIENT IDENTITY FOR PROCEDURES REQUIRING A WRITTEN DIRECTIVE

PURPOSE: To provide a clear method of patient identification as directed by 10 CFR.35.41.

SCOPE: Verification of patient identity is a crucial facet in the prevention of medical events of radiopharmaceuticals such as:

- Sodium Iodide - 131 or in amounts greater than thirty (30) microcuries (μCi) for diagnostic or therapeutic purposes.
- Any radiopharmaceutical therapy, i.e., P-32, Sr-89, Sm-153, Y-90 etc.

POLICY: Each patient shall be properly identified prior to the administration of any radiopharmaceutical as noted in the scope of this policy.

The individual (Nuclear Medicine Technologist or physician authorized user) responsible for the direct administration of the radiopharmaceutical to the patient is solely responsible for securing the identity of the patient.

Each patient under this policy shall be identified by at least one of the following methods:

- Patient spells their name
- Patient states their Date of Birth
- Patient states their Social Security Number
- Patient provides positive (picture) identification
- In-patient identification verified by wristband

If the information obtained does not correspond to the information on the written directive, the radiopharmaceutical shall not be administered until conclusive evidence is obtained that this agent/procedure is intended for the patient in question.

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TITLE: ASSURANCE WRITTEN DIRECTIVE FOLLOWED

PURPOSE: To insure that the intent of the written directive was followed as required by 10 CFR 35.41.

SCOPE: Issuance of a written directive must be followed by confirmation that the explicit prescriptive directions of the written directive such as radiopharmaceutical, activity and route of administration were in agreement.

POLICY: The radiopharmaceutical, administered dose and route of administration must be verified by the individual administering the radiopharmaceutical for agreement with the written directive. The dosage must be assayed in a calibrated dose calibrator and the result compared to the prescribed dosage in the written directive prior to administration.

Use a qualified person as a witness to any or all parts of this process, if possible.

Each final container (i.e., syringe) must be properly labeled to identify the radiopharmaceutical and activity.

Written directives will contain the prescribed route of administration.

The sole responsibility for assurance that the patient was properly identified and the prescriptive instructions of the written directive were followed rests with the individual (Nuclear Medicine Technologist or physician authorized user) responsible for the direct administration of the radiopharmaceutical to the patient.

Verification must be established for:

- Patient identification by at least one of the following methods:
 - Patient spells their name
 - Patient states their Date of Birth
 - Patient states their Social Security Number
 - Patient provides positive (picture) identification
 - In-patient identification verified by wrist band
- Route of administration by comparison to the written directive.
- Radiopharmaceutical and the dose calibrator measured activity noted on the final container label must be compared to the prescribed dosage on the written directive.

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If any part of the written directive or patient identification process is unclear or not understood, do not proceed until you receive guidance to rectify any questions or concerns.

After the administration, the authorized user or qualified individual under the supervision of the authorized user, must record the administered dose, the date and their signature or initials in an auditable form, such as on the written directive itself.