

BUMED-11

18 Oct 1951

## MEMORANDUM

From: Code 11  
To: Code 74

Subj: Legal comments relative to proposed means of proper authorization and safeguard in use of Radioisotopes

Refs: (a) Code 74 memo of 18 Sep 1951 to Code 11

1. Enclosure (1) of reference (a) consisted of a blank form which when executed by a patient or responsible next of kin would permit admission of radioisotope medical diagnosis or treatment. Enclosure (2) consists of a form which when executed by the "Isotope Committee" for the use of a radioisotope in the case of a specifically named patient would authorize and direct the staff of the radioisotope laboratory to administer the approved dosage.
2. Attached also to the file were some forms collateral to application for authorization of use of radioisotopes.
3. Previous informal discussion by Code 11 on this subject indicated that some concern exists in the Bureau with respect to the liability of the individual medical officer and to the liability of the Government for other than contemplated results in this category of diagnosis and treatment. Any such liability depends upon whether or not the responsible medical officer devoted appropriate care under the circumstances. In other words, if proper care be devoted to the treatment and the treatment be at the same time reasonably accepted by specialists in the field, no liability arises. The acceptance of this treatment by specialists in the field would be demonstrated presumably by action of the Isotope Committee executed on a form similar to Enclosure (2). In the event that Code 74 did not consider the Isotope Committee to represent specialists in the field, it is felt that perhaps the form does not indicate the qualifications of the Isotope Committee to the extent that may be possible. However, only specialists may determine that.
4. The legal effect of Enclosure (1) may be considered in two senses. In the first sense a statement by the patient that the hospital and the doctors concerned are absolved of responsibility (liability) for results or effects of "study" or of "interpretation" and "release from responsibility resulting from unforeseen effects" is subject to the legal principle:

One cannot provide by contract against liability for negligence and this principle applies to every species and degree of negligence or tort.

2 FILE M & S Corres. FILES *mm*

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5. The Bureau, therefore, should assume that should negligence be established, the waiver will not relieve the Government of answering according to the judgment obtained for damages established. The same assumption will apply in the event that a medical officer is proven negligent. This should not be a startling or disconcerting realization for the reason that negligence thus established would depend upon the testimony of persons who qualify as specialists in the field. Such testimony would be anticipated to establish any rules or reason applicable to use of radioisotopes in diagnosis and treatment. In the second sense the execution of a statement similar to Enclosure (2) constitutes evidence, if properly completed, that the patient was aware of and accepted any possible risks involved whether because of the modernity of the treatment or because of other circumstances such as the patients own condition (provided the patient knows the facts).

6. In view of the foregoing, there is no legal objection to the use of the proposed forms. Any instructions to medical activities in the field should state as briefly as possible the reasons for having such statements executed. At the same time medical officers should be reminded that liability depends upon negligence in the performance of duty and that appropriate care in the use of any remedies whatever should be required. What constitutes appropriate care will remain as a question which may be answered only by specialists in the field. It is not necessarily incumbent upon the Bureau to attempt to obtain a specified definition of appropriate care under the circumstances. There will be, however, some indications from experience of procedures which should not be used and knowledge of those procedures as acquired should be promulgated to the activities concerned with related types of diagnoses and treatment.

7. Enclosures (1) and (2) are returned herewith. There is also returned Commanding Officer, U. S. Naval Hospital, San Diego letter of 7 Sep 1951 to the Bureau.

LOREN B. POUSS

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1951

DATE: 18 September 51

FROM: Code 74

SUBJECT: Proposed Means of Proper Authorization and Safeguard in Use of Radio-Isotopes.

Encl: (1) Copy of PERMISSION TO USE RADIO-ISOTOPES  
(2) Copy of AUTHORIZATION BY THE ISOTOPE COMMITTEE FOR THE USE OF A RADIO-ISOTOPE

1. Enclosures (1) and (2) forwarded for comments as to legal value.

7212 - X 63656 Plant  
referred to Radioactive  
Brigg 7 Basement of Bldg 3 = 03  
D.E. DEMENT  
Tipton File

A16-3/NN

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**ISOTOPE**

Date:

1. It is the request of this patient \_\_\_\_\_ by that (he-she) be given a (tracer-therapeutic) dose of \_\_\_\_\_ by the staff of the Radioisotope Laboratory. This laboratory is supervised by the Hospital Board for the Control of Radioisotopes in Human Patients.

2. The patient understands that all radioisotopes used in this hospital are obtained from the Atomic Energy Commission for research projects.

3. The method of administration and general plan of study have been approved by the Medical Committee of the Atomic Energy Commission and the local Committee for the Use of Radioisotopes in Human Patients.

4. It is to be understood that the U. S. Navy, the Naval Hospital at Bethesda, Maryland, its agents and its personnel assume no responsibility for the results or effects of this study nor of its interpretation.

(Signed) \_\_\_\_\_

(Signed) \_\_\_\_\_

(Witness) \_\_\_\_\_

(Witness) \_\_\_\_\_

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1. This study determines the ability of the thyroid to concentrate iodine. The amount and distribution of the radioiodine is measured by means of a Geiger-Muller counter on the skin over the thyroid gland. The amount of radioiodine excreted in the urine is measured in specimens saved over a period of 48 hours.

2. The referring doctor should discuss with the radioisotope Laboratory the correct use of the following:

- (a) Thyroxine, propylthiouracil, or any type of hormone therapy
- (b) Iodine containing preparations:
  - (1) Lugol's solution or syrup of hydriodic acid.
  - (2) Diodrast (I.V. and retrograde pyelograms, arteriograms, injection of sinus tracts).
  - (3) Lipiodol (Bronchograms, injection of sinus tracts).
  - (4) Pantopaque (Myelograms).
  - (5) Priodox (Gall Bladder studies)
  - (6) KI (Expectorant cough medicines, e.g. Brown's Mixture)
  - (7) Argonol (Bladder and urethral infections)
  - (8) Thiocyanates (Hypertension therapy)
  - (9) Thimerosal (Mercurial Diuretic)
  - (10) Diatrizoate and Chinofer (Contrast media)
  - (11) Diiodofluorescein (Small Intestine studies)
  - (12) Iodoform (Skin treatment)
  - (13) Thyroid extract (Skin treatment)

3. Restrict the following foods for 24 hours preceding and 48 hours following the study: iodine, salt, coffee, tea, liver, eggs, milk and dairy products, radishes, turnips, rutabagas, beets, peaches and pears.

4. Avoid all laxatives and use of enemas for this patient for 48 hours preceding and the first 24 hours of the study. If the patient has loose or frequent stools, as it requires us to save the stools for possible radioiodine elimination by this route.

5. Urine Collections:

Save all urine from the time of the dose on for 48 hours as listed below. Save in accordance with the labels on the containers furnished. Use only the containers furnished by this Laboratory. Collection schedule will be:

- 12 hour specimen
- 24 hour specimen
- 48 hour specimen.

6. If there are any questions, call the radioisotope Laboratory at \_\_\_\_\_

7. Time of dose \_\_\_\_\_

No food or drink after \_\_\_\_\_ hour \_\_\_\_\_ day \_\_\_\_\_ month \_\_\_\_\_

Please insert this page as part of the patient's chart.

Head, Radioisotope Laboratory

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Name: \_\_\_\_\_ Hospital Admission No. \_\_\_\_\_

Autopsy No. \_\_\_\_\_

Isotope Administration:

Isotope	Treatment or Tracer	Dose	Date Administered
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Results of Radio Survey:

Highest measurement external skin surface \_\_\_\_\_

Highest measurement inside body cavity;

    with viscera intact \_\_\_\_\_

    with viscera removed \_\_\_\_\_

Highest measurement external skin surface after viscera removed \_\_\_\_\_

Remarks: \_\_\_\_\_

This certifies that the remains of \_\_\_\_\_  
have been examined by Radio Survey and is below the accepted tolerance dose-rate  
of 6 mr/hour. There will be no health hazard involved by the mortician performing  
the embalming provided he wears rubber gloves.

\_\_\_\_\_  
Radio Survey Officer

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TRACER CASE # \_\_\_\_\_

**RADIOISOTOPE LABORATORY REPORT**

TRACER STUDY # \_\_\_\_\_

Patient's Name \_\_\_\_\_  
Last First Initial Age Weight Height

\_\_\_\_\_ Date of Request Rank or Rate Ward or Out-Patient

\_\_\_\_\_ Provisional Diagnosis

Reason for Tracer Study:

\_\_\_\_\_ Doctor Requesting

\_\_\_\_\_ Head, Radioisotope Laboratory

\_\_\_\_\_ Chief of Radiology

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**RADIOISOTOPE LABORATORY REPORT**

\_\_\_\_\_ THERAPY # \_\_\_\_\_

Patient's Name \_\_\_\_\_  
Last First Initial Age Weight Height

\_\_\_\_\_ Date of Request Rank or Rate Ward or Out-Patient

\_\_\_\_\_ Provisional Diagnosis

Rationale for Radioisotope Therapy:

\_\_\_\_\_ Doctor Requesting

Radiation Tissue Dose

Estimated Tumor Dose:  
Estimated Skeletal Dose:  
Estimated Total Body Dose:

\_\_\_\_\_ Head, Radioisotope Laboratory

\_\_\_\_\_ Chief of Radiology

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