



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

JUL 17 1984

MEMORANDUM FOR: Members of the Advisory Committee
on the Medical Uses of Isotopes
Dr. Almond

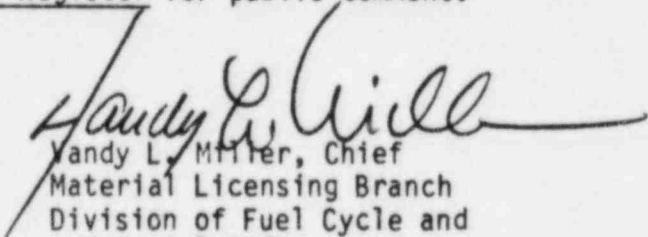
FROM: Vandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and Material Safety

SUBJECT: REQUEST TO AUTHORIZE APPROVED RADIOPHARMACEUTICALS
FOR UNAPPROVED USES

The Nuclear Regulatory Commission has received three requests to allow licensees to use radiopharmaceuticals for procedures that are not described on their respective package inserts. NRC has provided a mechanism for handling such requests in 48 FR 5217 (enclosed). The three requests are described below:

1. Use of diagnostic radiopharmaceuticals for assessing the patency of Leveen shunt, ventriculo-atrial shunt, and ventriculo-peritoneal shunt.
Dosage: 1-5 millicuries Tc-99m as sulfur colloid or pertechnetate
5-10 millicuries Tc-99m as macroaggregated human serum albumin
2. Use of a diagnostic radiopharmaceutical for dacryocystography.
Dosage: 100-250 microcuries/eye drop Tc-99m as pertechnetate
3. Use of a diagnostic radiopharmaceutical for cystography
Dosage: 1 millicurie Tc-99m as pertechnetate

Please review each request and using the enclosed comment sheet, submit your comments to me by AUG 27 1984. Following your review, we will publish the requests in the Federal Register for public comment.


Vandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosures:
1. ACNP request
2. 48 FR 5217

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PDR PR PDR
35

FROM:

Signature Melvin L. Griem, M.D.

MEMORANDUM FOR: Vandy L. Miller, Chief
Material Licensing Branch

FROM:

SUBJECT: COMMENTS ON THE USE OF PERTECHNETATE TECHNETIUM-99M
FOR DACRYOCYSTOGRAPHY

These are my responses to your questions about the subject request.

Question: Do you agree with the dosimetry calculations submitted by
the requester?

Yes ☒ No ☐ Abstain ☐ Comments _____

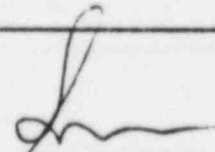
Question: Do you believe the potential benefit of the study justifies
the radiation dose to the patient?

Yes ☒ No ☐ Abstain ☐ Comments _____

Question: Are any special radiation safety precautions needed for
workers, the patient or the public?

Yes ☒ No ☐ Abstain ☐ Comments What precautions should

be taken for infants and children or the pregnant or lactating patient
where the potential for contamination or irradiation of the developing
human may be more sensitive?


Signature Melvin L. Griem, M.D.

MEMORANDUM FOR: Vandy L. Miller, Chief
Material Licensing Branch

FROM:

SUBJECT: COMMENTS ON THE USE OF SULFUR COLLOID, PERTECHNETATE
AND MACROAGGREGATED HUMAN SERUM ALBUMIN FOR ASSESSING
PATENCY OF LEVEEN SHUNTS, VENTRICULO-ATRIAL SHUNTS
AND VENTRICULO-PERITONEAL SHUNTS

These are my responses to your questions about the subject request.

Question: Do you agree with the dosimetry calculations submitted by
the requester?

Yes ☐ No ☒ Abstain ☐ Comments The dose in the peritoneal cavity
is given. The dose in the ovary could be similar to the peritoneal cavity
since it is a peritoneal structure. Why is it different? 3.3 rads is not
a trivial dose to the ovary. What is the genetic effect?

Question: Do you believe the potential benefit of the study justifies
the radiation dose to the patient?

Yes ☒ No ☐ Abstain ☐ Comments Radiation doses for other
procedures including C.T. scanning would approach the 3.3 rads mentioned
for the peritoneal cavity. Likewise, the dose to the lung is 4.5 rads
is equivalent to some C.T. Scanning procedures.

Question: Are any special radiation safety precautions needed for
workers, the patient or the public?

Yes ☒ No ☐ Abstain ☐ Comments What should be done with
pregnant women and women that might be lactating? Should they be ex-
cluded?

Signature

Melvin L. Griem, M.D.

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Yes ☒ No ☐ Abstain ☐ Comments _____

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Yes ☒ No ☐ Abstain ☐ Comments _____

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Yes ☐ No ☒ Abstain ☐ Comments _____


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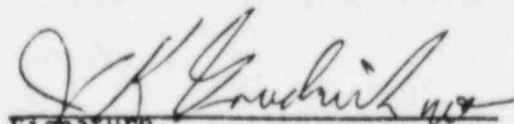
Yes ☒ No ☐ Abstain ☐ Comments _____

Question: Do you believe the potential benefit of the study justifies
the radiation dose to the patient?

Yes ☒ No ☐ Abstain ☐ Comments _____

Question: Are any special radiation safety precautions needed for
workers, the patient or the public?

Yes ☐ No ☒ Abstain ☐ Comments _____


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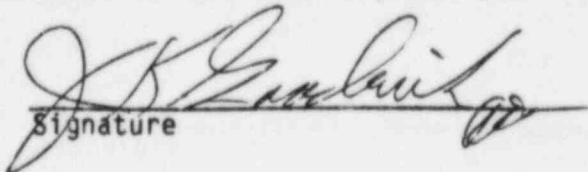
Yes ☒ No ☐ Abstain ☐ Comments _____

Question: Do you believe the potential benefit of the study justifies
the radiation dose to the patient?

Yes ☒ No ☐ Abstain ☐ Comments _____

Question: Are any special radiation safety precautions needed for
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Yes ☐ No ☒ Abstain ☐ Comments _____


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the requester?

Yes ☐ No ☐ Abstain ☒ Comments _____

Defer to physicists.

Question: Do you believe the potential benefit of the study justifies
the radiation dose to the patient?

Yes ☒ No ☐ Abstain ☐ Comments _____

The benefit is of crucial importance and the dose is
insignificant.

Question: Are any special radiation safety precautions needed for
workers, the patient or the public?

Yes ☐ No ☒ Abstain ☐ Comments _____

The radionuclide is in approved and common use in similar doses
with effective radiation safety precautions.

Signature



MEMORANDUM FOR: Vandy L. Miller, Chief
Material Licensing Branch

FROM: V. P. Collins, M.D.
9000 Westheimer
Suite 53
Houston, TX 77063

SUBJECT: COMMENTS ON THE USE OF PERTECHNETATE TECHNETIUM-99M
FOR DACRYOCYSTOGRAPHY

These are my responses to your questions about the subject request.

Question: Do you agree with the dosimetry calculations submitted by
the requester?


Yes ☐ No ☐ Abstain ☒ Comments Deferred to physicist
members of the advisory committee.

Question: Do you believe the potential benefit of the study justifies
the radiation dose to the patient?

Yes ☒ No ☐ Abstain ☐ Comments Although I have not had
personal experience with this examination, ophthalmologists here indicate
an interest and increase usage for an atraumatic procedure.

Question: Are any special radiation safety precautions needed for
workers, the patient or the public?

Yes ☐ No ☒ Abstain ☐ Comments A familiar radionuclide
in very low dosage should present no radiation safety problem.


Signature

V. P. Collins, M. D.

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the requester?

Yes _____ No _____ Abstain _____ Comments _____

Defer to physicists.

Question: Do you believe the potential benefit of the study justifies
the radiation dose to the patient?

Yes _____ No ☒ Abstain _____ Comments _____


Radiographic procedure with contrast medium is simpler, quicker
and produces an image with better resolution. Even if patient dosage
is acceptable the examination is unnecessary.

Question: Are any special radiation safety precautions needed for
workers, the patient or the public?

Yes ☒ No _____ Abstain _____ Comments _____

Don't do it!

Even if the hazard is small the contamination of equipment and
personnel is unacceptable.


Signature

MEMORANDUM FOR: Vandy L. Miller, Chief
Material Licensing Branch

FROM: JOSEPH B. WORKMAN, M.D.

SUBJECT: COMMENTS ON THE USE OF PERTECHNETATE TECHNETIUM-99M
FOR DACRYOCYSTOGRAPHY

These are my responses to your questions about the subject request.

Question: Do you agree with the dosimetry calculations submitted by
the requester?

Yes ☒ No ☐ Abstain ☐ Comments _____

Question: Do you believe the potential benefit of the study justifies
the radiation dose to the patient?

Yes ☒ No ☐ Abstain ☐ Comments * The MAXIMUM DOSE
OF Tc^{99m} PERTECHNETATE NECESSARY TO PERFORM THIS STUDY
SHOULD BE 100 MICROCURIES PER EYE. 250 MICROCURIES
IS TOO LARGE A DOSE.

Question: Are any special radiation safety precautions needed for
workers, the patient or the public?

Yes ☐ No ☒ Abstain ☐ Comments _____

Joseph B. Workman, M.D.
Signature
7/25/84

MEMORANDUM FOR: Vandy L. Miller, Chief
Material Licensing Branch

FROM: JOSEPH B. WORKMAN, M.D.

SUBJECT: COMMENTS ON THE USE OF PERTECHNETATE TECHNETIUM-99M
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These are my responses to your questions about the subject request.

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the requester?

Yes ☒ No ☐ Abstain ☐ Comments _____

Question: Do you believe the potential benefit of the study justifies
the radiation dose to the patient?

Yes ☒ No ☐ Abstain ☐ Comments _____

Question: Are any special radiation safety precautions needed for
workers, the patient or the public?

Yes ☐ No ☒ Abstain ☐ Comments _____

Signature

Joseph B. Workman, M.D.
7/25/84

MEMORANDUM FOR: Vandy L. Miller, Chief
Material Licensing Branch

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SUBJECT: COMMENTS ON THE USE OF SULFUR COLLOID, PERTECHNETATE
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Question: Do you agree with the dosimetry calculations submitted by
the requester?

Yes _____ No _____ Abstain x Comments USE OF Tc^{99m} SULFUR COLLOID

FOR LEVEEN SHUNTS AND Tc^{99m} PERTECHNETATE FOR ASSESSING V-A AND U-P
SHUNTS IS WORTHWHILE. I CANNOT SEE THE NEED FOR 10mCi OF
Tc^{99m} MAA, INTRAPERITONEALLY FOR ASSESSING LEVEEN SHUNTS. THE DOSE
IS TOO HIGH.

Question: Do you believe the potential benefit of the study justifies
the radiation dose to the patient?

Yes ✓ No _____ Abstain _____ Comments _____

IN ALL BUT THE Tc^{99m} MAA USE.

Question: Are any special radiation safety precautions needed for
workers, the patient or the public?

Yes _____ No ✓ Abstain _____ Comments _____

Workman, MD
Signature
7/25/84

MEMORANDUM FOR: Vandy L. Miller, Chief
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FROM: " -

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the requester?

Yes ☐ No ☒ Abstain ☐ Comments _____

*There is insufficient data
in the application to verify
the claimed dosimetry*

Question: Do you believe the potential benefit of the study justifies
the radiation dose to the patient?

Yes ☒ No ☐ Abstain ☐ Comments _____

*This is a very important application
and we should try to get
them to do a respectable job on the
dosimetry*

Question: Are any special radiation safety precautions needed for
workers, the patient or the public?

Yes ☐ No ☒ Abstain ☐ Comments _____

B. L. Holman
Signature

MEMORANDUM FOR: Vandy L. Miller, Chief
Material Licensing Branch

FROM: *✓*

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These are my responses to your questions about the subject request.

Question: Do you agree with the dosimetry calculations submitted by
the requester?

Yes *✓* No Abstain Comments

Question: Do you believe the potential benefit of the study justifies
the radiation dose to the patient?

Yes *✓* No Abstain Comments

Question: Are any special radiation safety precautions needed for
workers, the patient or the public?

Yes No *✓* Abstain Comments

B. L. Holman
Signature

*This is a very thorough
and well done application*

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Question: Do you agree with the dosimetry calculations submitted by the requester?

Yes ☐ No ☒ Abstain ☐ Comments _____

Inadequate validation of
dosimetry. They must provide
a much more complete
method and assumptions.

Question: Do you believe the potential benefit of the study justifies the radiation dose to the patient?

Yes ☒ No ☐ Abstain ☐ Comments _____

Another very imp't. test that
should be approved once but
needs good dosimetry and a
much more thorough explanation
to do it.

Question: Are any special radiation safety precautions needed for workers, the patient or the public?

Yes ☐ No ☒ Abstain ☐ Comments _____

Not above and
beyond any routine
nuclear medicine
procedures.

B. L. Miller
Signature