



ELIZABETH GENERAL MEDICAL CENTER

MS-16
p8

925 EAST JERSEY STREET / ELIZABETH, NEW JERSEY 07201 • (201) 289-8600

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JULY 3, 1985

U.S. NUCLEAR REGULATORY COMMISSION
JOHN E. GLENN, PH.D., CHIEF
NUCLEAR MATERIALS SAFETY SECTION B
DIVISION OF RADIATION SAFETY AND
SAFEGUARDS - REGION I
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

DEAR DR. GLENN:

RE: LICENSE NO. 29-01600-02
DOCKET NO. 030-02437
CONTROL NO. 18519

IN REFERENCE TO YOUR LETTER DATED JUNE 12, 1985, WE HAVE REVIEWED OUR DOSE CALIBRATOR LINEARITY TESTS IN ORDER TO DETERMINE COMPLIANCE WITH THE REQUIREMENT THAT "DOSE CALIBRATOR LINEARITY TESTS MUST INCLUDE THE MAXIMUM ACTIVITY THAT IS ASSAYED IN THE DOSE CALIBRATOR". OUR PROTOCOLS FOR PERFORMING THESE TESTS HAVE ACCORDINGLY BEEN CHANGED TO REFLECT THIS REQUIREMENT.

THE MAXIMUM ACTIVITY ASSAYED IN OUR DOSE CALIBRATOR IS THE ACTIVITY OF THE FIRST ELUTION OF A NEW GENERATOR ON THE FIRST WORKDAY OF THE WEEK. SINCE THIS ACTIVITY (APPROXIMATELY 950 MILLICURIES) IS GREATER THAN 100 MILLICURIES, WE HAVE CHANGED OUR LINEARITY TEST PROCEDURE (SEE ATTACHMENT) SO THAT IT WILL INCLUDE THE MAXIMUM ASSAYED ACTIVITY. OUR LINEARITY TESTS WILL THEN ASSURE LINEARITY OVER THE ENTIRE RANGE OF ACTIVITIES THAT ARE ASSAYED IN THE DOSE CALIBRATOR.

WE WISH TO THANK YOUR OFFICE, PARTICULARLY JUDY JOUSTRA, FOR THE ASSISTANCE OFFERED VIA NUMEROUS TELEPHONE CONVERSATIONS TO OUR NUCLEAR MEDICINE DEPARTMENT IN THE DEVELOPMENT OF THE PROTOCOL.

IF I CAN BE OF ANY FURTHER SERVICE TO YOU, PLEASE DO NOT HESITATE TO CONTACT ME.

SINCERELY,

ROBERT PLATT
VICE PRESIDENT

8508130117 850730
REG1 LIC30
29-01600-02 PDR

"OFFICIAL RECORD COPY"

CC: BIO MED ASSOCIATES, INC.

A Private, Non-Profit Medical Center Serving the Community JUL 08 1985

18519
ML10



ELIZABETH GENERAL MEDICAL CENTER

925 EAST JERSEY STREET / ELIZABETH, NEW JERSEY 07201 • (201) 289-8600

DEPARTMENT OF RADIOLOGY • (201) 558-8054

SUBJECT: DOSE CALIBRATOR LINEARITY TEST (REVISED)

DATE: JUNE 21, 1985 (REVISED)

POLICY NO: 26 - N.M. (REVISED)

POLICY

LINEARITY TESTS SHOULD BE PERFORMED QUARTERLY ON THE DOSE CALIBRATOR IN ORDER TO INSURE ACCURATE CALIBRATION OF RADIO-PHARMACEUTICALS.

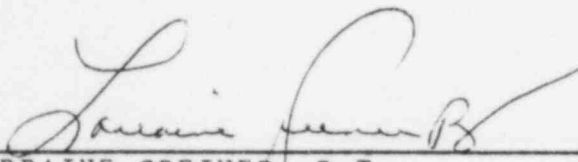
PROCEDURES

1. ON THE FIRST WORKDAY OF THE WEEK, THE FIRST ELUTION OF A NEW TC^{99M} GENERATOR SHALL BE MEASURED IN THE DOSE CALIBRATOR. THIS ASSAY (APPROXIMATELY 950 MILLICURIES) REPRESENTS THE MAXIMUM ACTIVITY MEASURED IN THE DOSE CALIBRATOR. THIS SAMPLE SHALL BE REMOVED FROM THE DOSE CALIBRATOR. A BACKGROUND READING SHALL THEN BE MADE.

2. IMMEDIATELY AFTER THIS FIRST ASSAY, EXACTLY 15% OF THE VOLUME OF THE FIRST ELUATE IS WITHDRAWN AND PLACED INTO A SECOND EVACUATED VIAL WHOSE GEOMETRY AND VOLUME ARE EQUAL TO THE GEOMETRY AND VOLUME OF THE VIAL CONTAINING THE FIRST ELUATE. ENOUGH STERILE SALINE SHALL BE INJECTED INTO THE SECOND VIAL TO MAKE THE TOTAL VOLUME OF THE LIQUID CONTAINED THEREIN EQUAL TO THE LIQUID VOLUME OF THE FIRST ELUATE. AFTER THIS VOLUME CORRECTION, THIS NEW SAMPLE OF TC^{99M} SHALL BE ASSAYED IN THE DOSE CALIBRATOR. ITS ACTIVITY SHOULD BE EQUAL TO 15% OF THE FIRST ELUATE ACTIVITY, PLUS OR MINUS 5%. THIS NEW SAMPLE SHALL THEN BE REMOVED FROM THE DOSE CALIBRATOR. A BACKGROUND READING SHALL THEN BE MADE.

3. APPROXIMATELY FOUR HOURS LATER, THE NEW SAMPLE OF TC^{99M} SHALL BE ASSAYED AGAIN. A BACKGROUND READING SHALL ALSO BE MADE. THIS ASSAY AND BACKGROUND READING SHALL BE REPEATED ONCE MORE AFTER A ELAPSE OF ANOTHER FOUR HOURS.

4. THESE SAMPLE ASSAYS AND BACKGROUND READINGS SHALL BE REPEATED ON EACH OF THE TWO DAYS FOLLOWING THE DAY OF THE ORIGINAL SAMPLE ASSAY. (THREE ASSAYS PER DAY). EACH OF THESE ASSAYS SHALL BE MADE AT LEAST FOUR HOURS APART.
5. THE ABOVE ASSAY AND BACKGROUND READINGS SHALL BE PRESENTED TO THE RADIATION PHYSICIST WHO WILL VERIFY THAT THE DOSE CALIBRATOR IS OPERATING IN A LINEAR FASHION AND THAT ALL RESULTS ARE WITHIN AN ACCEPTABLE RANGE OF $\pm 5\%$.
6. THIS LINEARITY TEST SHALL BE PERFORMED QUARTERLY.
7. THE LINEARITY TEST WILL ASSURE LINEARITY OVER THE ENTIRE RANGE OF ACTIVITIES THAT ARE ASSAYED IN THE DOSE CALIBRATOR.



LORRAINE GREINER, R.T.
ADMINISTRATOR
RADIOLOGIC/RESPIRATORY THERAPY SERVICES

LG/MLJ

6/19/85

TELEPHONE OR VERBAL CONVERSATION RECORD

TIME

10:45

☒ A.M.
☐ P.M.

☒ INCOMING CALL

☐ OUTGOING CALL

☐ VISIT

PERSON CALLING

Steve Kaplan

OFFICE/ADDRESS

Elizabeth General Hosp

PHONE NUMBER

201
558-5054

EXTENSION

PERSON CALLED

J. A. Johnston

OFFICE/ADDRESS

Region I

PHONE NUMBER

EXTENSION

5257

CONVERSATION

SUBJECT

question concerning deficiency letter

SUMMARY

Mr Kaplan had a question concerning the revision of their linearity test to include the maximum activity to be assayed. He stated that the revised procedure would be mailed to us shortly.

"OFFICIAL RECORD COPY"

ML10

REFERRED TO:

ACTION REQUESTED

☐ ADVISE ME OF ACTION TAKEN.

INITIALS

AS

DATE

ACTION TAKEN

INITIALS

DATE