



# Deaconess Hospital

New England Deaconess Hospital  
185 Pilgrim Road  
Boston, Massachusetts 02215  
(617) 732-7000

Affiliated With NEDH Corp

22 May 1991

United States Nuclear Regulatory Commission  
Region I  
475 Allendale Road  
King of Prussia, Pennsylvania 19406

License No. 20-00289-07

Gentlemen:

The New England Deaconess Hospital Corporation requests to amend our NRC License. Enclosed is a check for \$ 290.00 to cover the cost of this amendment.

We have received a RENALYZER PRX 90 from Provalid AB in Lund, Sweden to be used for measurement of glomerular filtration rate. This unit contains two 100 mCi sources of Am-241.

I have enclosed the information on the analyzer from the company.

If you need additional information, please call me at 617-732-8509.

Thank you.

Sincerely,

Philip Cobb  
Radiation Safety Officer

Joyce B. Tower  
Senior Vice-President

9301120335 920520  
PDR FOIA  
STOLL92-58 PDR

Log	<i>Gen. S</i>
Remitter	<i>NEDH Corp</i>
Check No.	<i>2027816</i>
Amount	<i>\$290</i>
Fee Category	<i>7B</i>
Type of Fee	<i>AMT</i>
Date Check Rec'd.	<i>6/17/91</i>
Date Completed	<i>6/18/91</i>
By	<i>SK</i>

*Revised  
27 DEC  
6/17/91*

OFFICIAL RECORD COPY

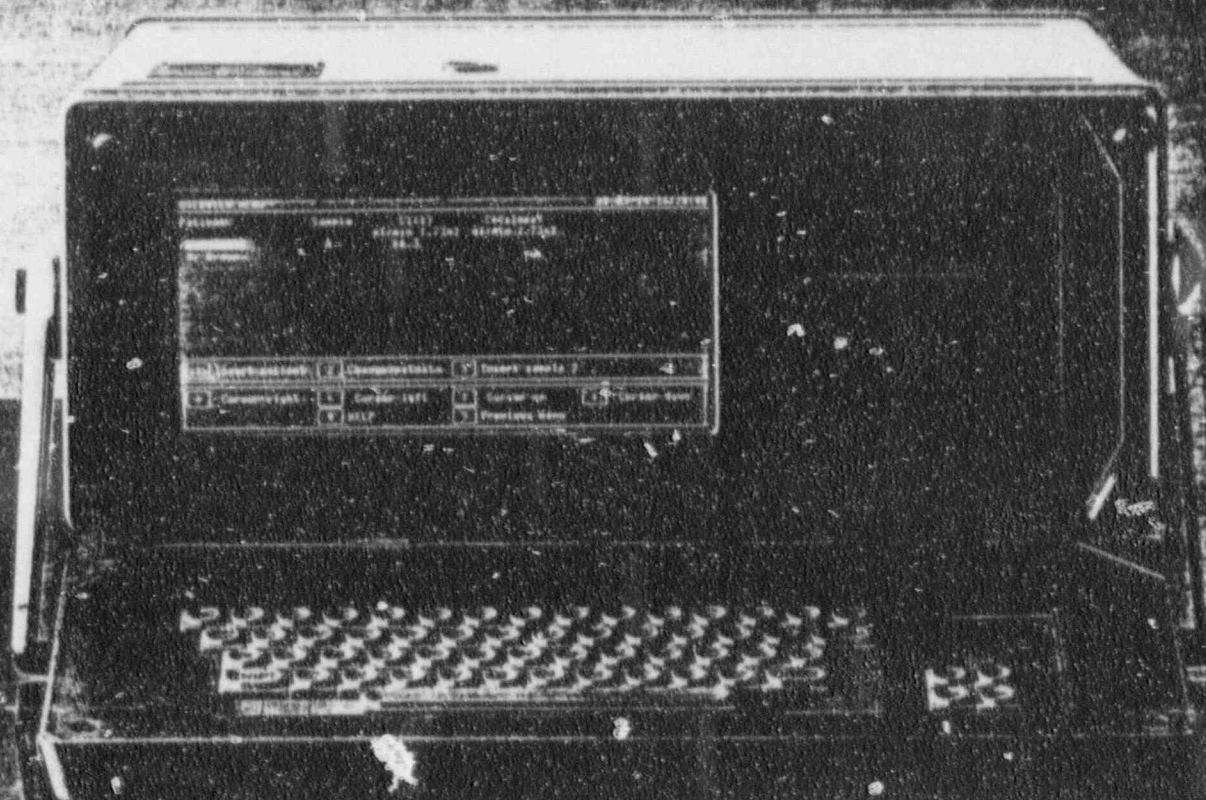
ML 10

9301120335 8PP

*U-28*  
*D/145*

JUN 03 1991

# THERE'S MORE THAN ONE WAY TO USE CONTRAST MEDIA



New technology for renal clearance analysis

## RENALYZER PRX 90



# THE RENALYZER CLEARANCE

## **Anatomy and function in a single session**

The renalyzer is a compact, portable instrument for measuring glomerular filtration rate (GFR) by computerized analysis of the contrast medium content of plasma samples.

This means that diagnostic radiology can now be combined in a single session with renal clearance analysis. The same non-radioactive contrast medium used for urography, angiography or computer tomography is used as a GFR marker by the Renalyzer PRX 90.

## **Highly accurate**

The accuracy of the renal clearance values generated by the Renalyzer is fully comparable with the data obtained from techniques based on radioactive markers, such as  $^{51}\text{Cr}$  EDTA or  $^{99\text{m}}\text{Tc}$  DTPA.

## **Reduced volume of contrast medium**

The Renalyzer can operate with smaller volumes of contrast media than those normally required for e.g. urography. Dosage of contrast medium can be reduced by 50-80% if radiological investigation is not indicated.

## **Time saving**

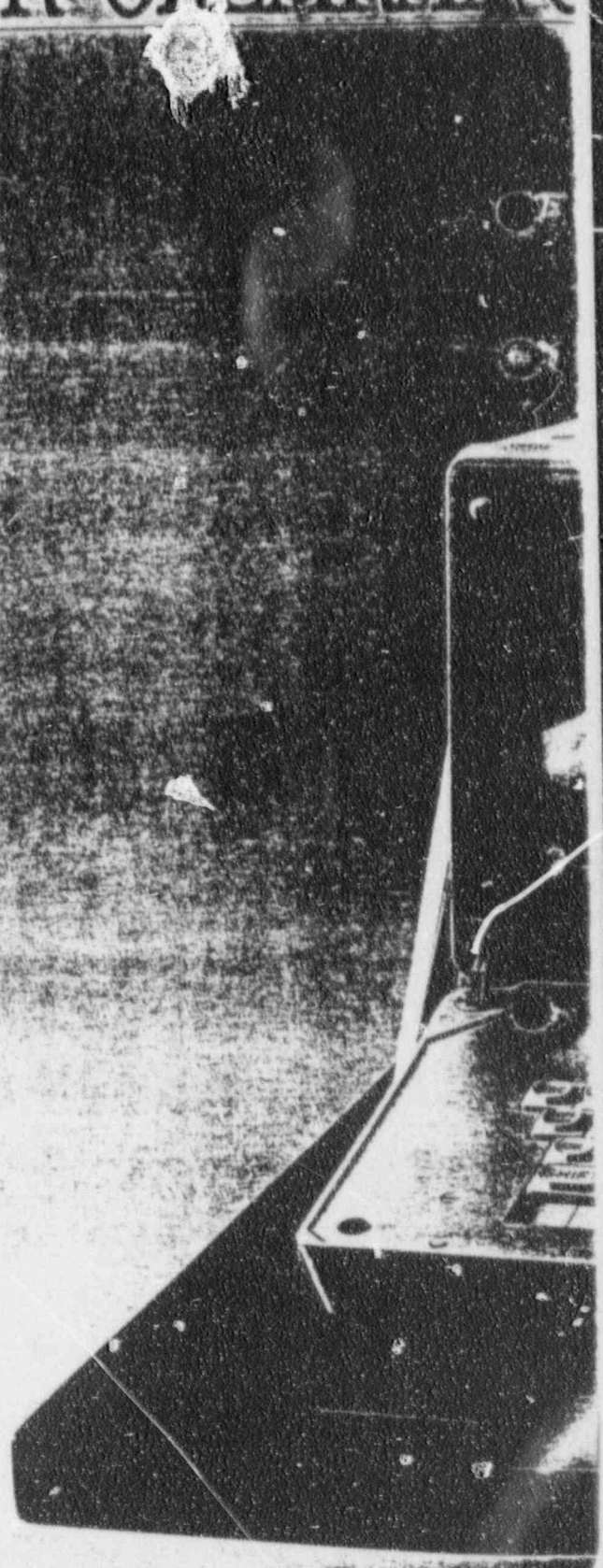
The plasma sample is inserted directly in the instrument and analysis parameters are keyed in. No sample preparation is required.

The sample is not destroyed during analysis, which means that results can be verified repeatedly without taking a new sample.

## **User-friendly, self-contained system**

As soon as the plasma sample has been analyzed within the instrument, the results are displayed on a screen and printed out on a built-in printer.

No external equipment or laboratory facilities are required, and the Renalyzer can be operated by personnel with no laboratory training.



# CLINICALLY TESTED

The Renalyzer PRX 90 was developed in close connection with research on non-ionic contrast media between 1978 and 1986 at the University of Lund and the Departments of Radiology at hospitals in Malmö and Lund in Sweden.



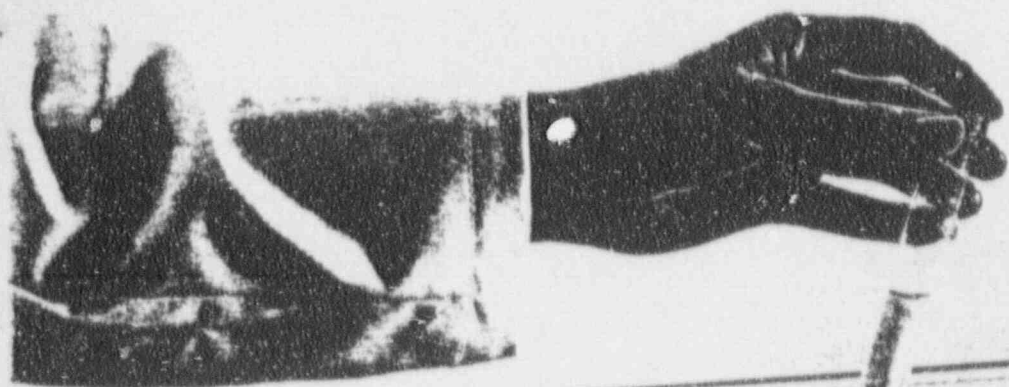
The Renalyzer system was also tested during this period at the Urological Unit of Stepping Hill Hospital in Stockport, England, the Department of surgery of Texas Medical Center in Houston, Texas, the Departments of Radiology at hospitals in Gothenburg and Umeå, Sweden, and the Department of Radiology at the Oslo Hospital in Norway.

The Renalyzer is marketed world-wide by Provalid AB, a medical technology company.

## PROVALID AB

ÅLDERMANSGATAN 10, S- 222 36 LUND, SWEDEN. TEL. INT + 46-46 13 50 95.  
TELEFAX INT + 46-46 13 07 39



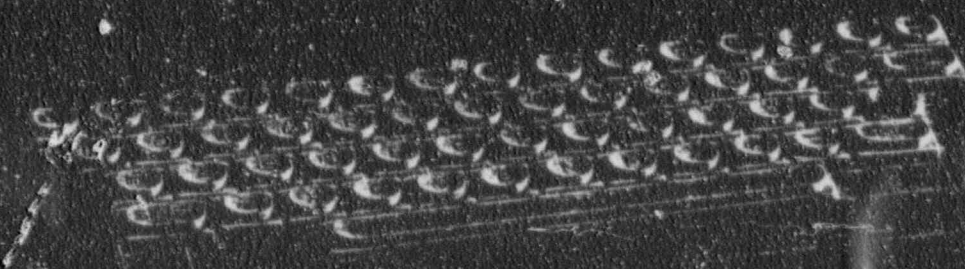


BP-45-18 1/15/70

SAMPLE DATA

Name..... J. R. Smith  
Year of Birth (MM/YY)..... 1930  
Patient identification number..... 005  
Sample ID ..... 1.0  
Time of Sample ..... 19:00

1. Cursor up.      2. Cursor down      3. Change data  
4. HELP      5. STOP/END MENU



# CLINICAL PROCEDURE



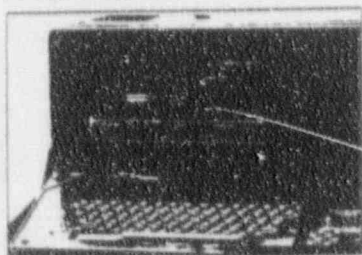
1. Injection of non-radioactive contrast medium. Dosage can be reduced by 50-80% if radiology is not required.



2. Radiological investigation is performed, if indicated.



3. Two options are available for sampling:  
Single-sample technique: One blood sample is taken, 3-4 hours after injection of contrast medium.  
Double-sample technique: Two samples are taken 5 hours after injection, and two more are taken 4 hours after injection.

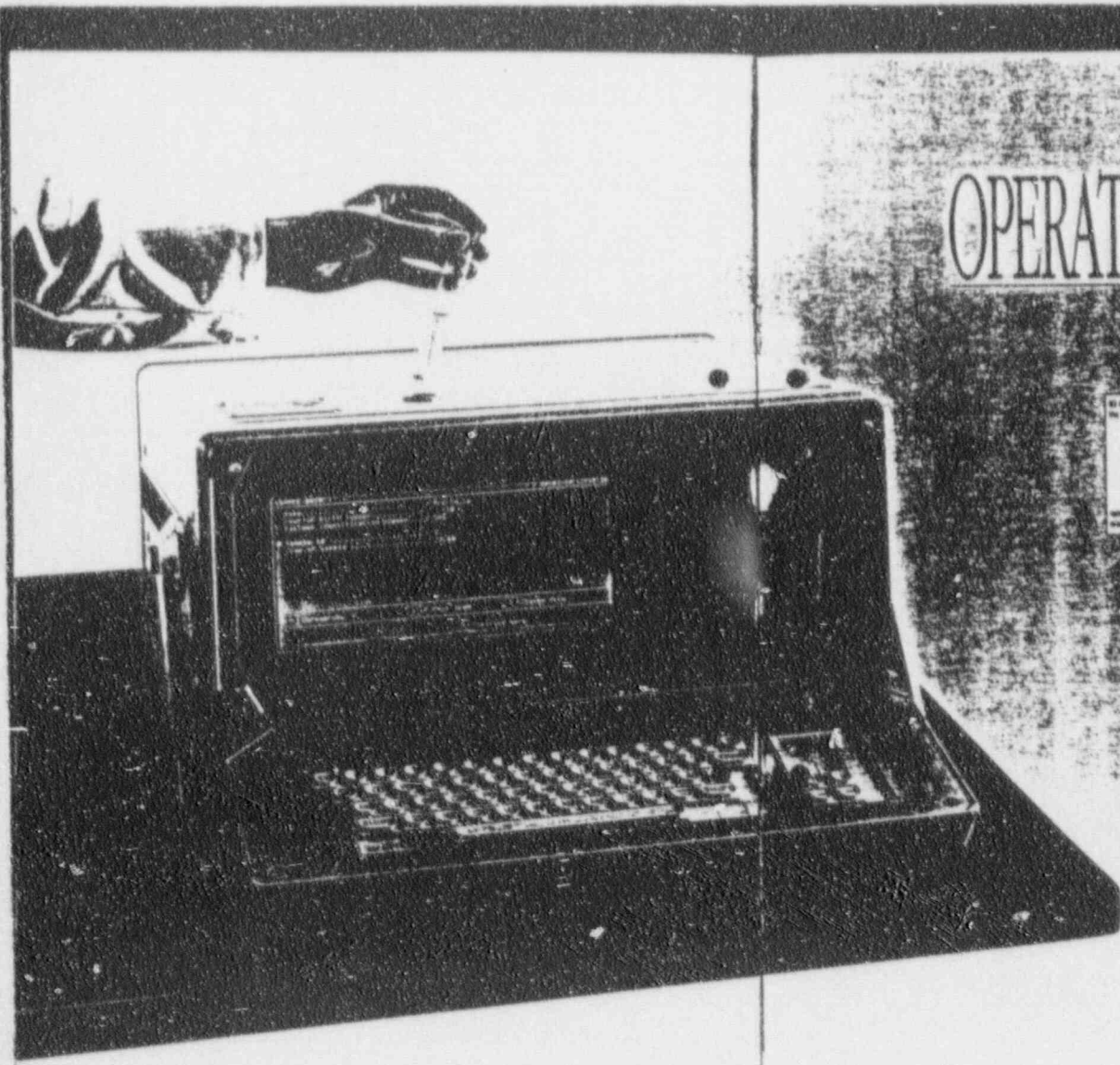


5. Clearance data are displayed and a printout is generated. Renal clearance analysis is terminated.



4. The sample(s) is centrifuged for about 5 minutes. The plasma is poured into a Renalizer measuring tube, which is inserted in the instrument. Analysis is initiated.





# OPERATING PRINCIPLE



The detector is a NaI crystal. The characteristic energy of the gamma rays is directly proportional to the concentration of the substance in the sample.

- Sample Size: 1-4 ml.
- Sample loading: Sample exchange.
- Analysis time: 60-3000 sec. (Manual use: 120 sec).
- Excitation source: Two Am-241 sources (2 x 5.7 GBq).
- Detector: NaI detector (2 mm x Ø 30 mm).
- Display: LCD.
- Printer: Built-in.
- Data processing: 256-channel multi-channel analyser, coupled to microprocessor.
- Software: Menu-driven firmware.
- External interface: RS-232 port.
- Power supply: 230-240V, 50 Hz / 180V, 60 Hz.
- Weight: 21 kg (46 lb).
- Dimensions: 450 x 450 x 250 mm (18 x 18 x 10 inches).

CONSIDERING THE RADIOACTIVE SOURCES IN THE RENALYZER PRX90

The RENALYZER PRX90 has been approved by the Swedish National Institute of Radiation Protection (encl. 1) containing 2 x 100 mCi (2 x 3.7 GBq) Am-241 from Amersham International plc, U.K.

Due to rules and regulations in several European countries the total amount of radioactivity has been lowered by 1/3, i.e. 2 x 30 mCi (2 x 1.11 GBq).

- source code : AMC 65 (encl. 2)

- capsule : X.11

It is still the same nuclide : Am-241

No changes in the radiation shields has been performed.

The lowered activity level is reported to and accepted by the Swedish National Institute of Radiation Protection.

Lund February 19, 1990  
F ROVALID AB



DCS  
MAY 28 1991

Docket Nos. 030-01808  
030-17696

License Nos. 20-00289-C7  
20-00289-10

New England Deaconess Hospital Corporation  
ATTN: Joyce B. Tower  
Senior Vice President  
185 Pilgrim Road  
Boston, Massachusetts 02215

Dear Madam:

Subject: Combined Inspection Nos. 030-01808/91-001 and 030-17696/91-001

This refers to your letters dated April 1, 1991 and May 1, 1991 in response to our letter dated March 11, 1991.

Thank you for informing us of the corrective and preventive actions documented in your letter. These actions will be examined during a future inspection of your licensed program.

Your cooperation with us is appreciated.

Sincerely,

Original Signed By:  
Jean Gresick-Schugsta

*for*

Mohamed M. Shanbaky, Chief  
Nuclear Materials Safety Section A  
Division of Radiation Safety  
and Safeguards

cc:  
Public Document Room (PDR)  
Nuclear Safety Information Center (NSIC)  
Commonwealth of Massachusetts  
Philip Cobb, Radiation Safety Officer

9106070022 XA  
2528  
NEW1 L 1030  
20-00289-07  
FDR 2 PP.

OFFICIAL RECORD COPY

RL NEW ENGLAND - 0001.0.0  
05/06/91

RETURN ORIGINAL TO  
REGION I

IE:07  
D/146

New England Deaconess Hospital Corp. 2

bcc:  
Region I Docket Room (w/concurrences)

RI:DRSS  
Tripp/bj  
04/16/91

RI:DRSS  
Shanbaky  
05/14/91

OFFICIAL RECORD COPY

RL NEW ENGLAND - 0002.0.0  
04/12/91

JUN 24 1991

License No. 20-00289-07  
Docket No. 030-01808  
Control No. 114728

New England Deaconess Hospital  
ATTN: Joyce B. Tower  
Senior Vice President  
185 Pilgrim Road  
Boston, Massachusetts 02215

Dear Ms. Tower:

Please find enclosed an amendment to your NRC Material License.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the Region I Material Licensing Section, (215) 337-5093, so that we can provide appropriate corrections and answers.

Please be advised that you must conduct your program involving licensed radioactive materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, please note the items in the enclosed, "Requirements for Materials Licensees."

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, the NRC expects licensees to pay meticulous attention to detail and to achieve the high standard of compliance which the NRC expects of its licensees.

You will be periodically inspected by NRC. A fee may be charged for inspections in accordance with 10 CFR Part 170. Failure to conduct your program safely and in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in prompt and vigorous enforcement action against you. This could include issuance of a notice of violation, or in case of serious violations, an imposition of a civil penalty or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C.

AL RECORD COPY

ML 20-00289-07/LTR - 0001.0.0  
06/12/91

ML 10

9112180065-XA  
APP.

147  
D/



We wish you success in operating a safe and effective licensed program.

Sincerely,

Original Signed By:  
Jenny M. Johansen

Jenny M. Johansen, Chief  
Nuclear Materials Safety Section D  
Division of Radiation Safety  
and Safeguards

Enclosures:

1. Amendment No. 30
2. Requirements for Materials Licensees

DRSS:RI  
Everhart/EB

06/12/91

DRSS:RI  
Johansen

06/10/91

OFFICIAL RECORD COPY

ML 20-00289-07/LTR - 0002.0.0  
06/12/91

LICENSE NO.  
DOCKET NO.  
CONTROL NO.

NAME NEW ENGLAND DEACONESS HOSPITAL

ATTN: PHILIP COBB

ADDRESS 185 PILGRIM RD  
BOSTON MA 02215

GENTLEMAN,

// THIS IS TO CONFIRM THE TELEPHONE CONVERSATION ON 6.6.91  
BETWEEN YOURSELF AND D. EVERHART OF THIS OFFICE.

~~SE~~ // THIS IS TO CONFIRM OUR TELEPHONE CONVERSATION ON .....  
THE INFORMATION NEEDED TO CONTINUE REVIEW OF YOUR  
APPLICATION DATED ..... WAS DISCUSSED.  
THESE ITEMS ARE RESTATED BELOW:

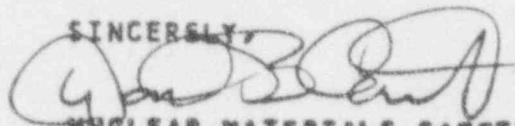
1. CONFIRM THAT YOU WISH AUTHORIZATION FOR  
200 mCi Am<sup>241</sup>

2.

3.

IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS  
FROM THE DATE OF THIS LETTER, WE SHALL ASSUME THAT YOU DO NOT  
WISH TO PURSUE YOUR APPLICATION.

SINCERELY,



NUCLEAR MATERIALS SAFETY SECTION  
NUCLEAR MATERIALS SAFETY BRANCH



OFFICIAL RECORD COPY ML 10

CONCURRENCES:

-----  
F. JESCHKE

-----  
C. F. W. S. P. N.