FORM NRC-313M (8-78) 10 CFR 35	U.S. NUCLEAR REGULATORY COMMISSION APPLICATION FOR MATERIALS LICENSE – MEDICAL	Approved: GAO R0557

INSTRUCTIONS - *Complete Items 1 through 26 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 26 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20 and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 26 and the appropriate fee enclosed.*

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE

John T. Elston, M. D.
P. O. Box 238, Rapid City, S. D. 57709
Donald H. Kelley, M. D.
P. O. Box 238, Rapid City, S. D. 57709
TELEPHONE NO.: AREA CODE (605) ~~343~~ ~~2267~~

1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE

Clinical Laboratory of the Black Hills
2805 S. Fifth Street, P.O. Box 238
Rapid City, South Dakota 57709

2. PERSON TO CONTACT REGARDING THIS APPLICATION

John T. Elston, M. D.

TELEPHONE NO.: AREA CODE (605) 343 2267

3. THIS IS AN APPLICATION FOR: *(Check appropriate item)*

a. ☐ NEW LICENSE
b. ☐ AMENDMENT TO LICENSE NO. _____
c. ☒ RENEWAL OF LICENSE NO. 40-15952-01 as amended

4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*

John T. Elston, M. D. Pathologist
Donald H. Kelley, M. D. Pathologist

5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

John T. Elston, M. D. Pathologist
Donald H. Kelley, M. D. Pathologist

6.a. RADIOACTIVE MATERIAL FOR MEDICAL USE

RADIOACTIVE MATERIAL LISTED IN:	ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES	X	
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP III		
10 CFR 35.100, SCHEDULE A, GROUP IV		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED
10 CFR 35.100, SCHEDULE A, GROUP VI		

ADDITIONAL ITEMS:	MARK ITEMS DESIRED "X"	MAXIMUM POSSESSION LIMITS (In millicuries)
IODINE-131 AS IODIDE FOR TREATMENT OF HYPERTHYROIDISM		
PHOSPHORUS-32 AS SOLUBLE PHOSPHATE FOR TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA AND BONE METASTASES		
PHOSPHORUS-32 AS COLLOIDAL CHROMIC PHOSPHATE FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
GOLD-198 AS COLLOID FOR INTRACAVITARY TREATMENT OF MALIGNANT EFFUSIONS.		
IODINE-131 AS IODIDE FOR TREATMENT OF THYROID CARCINOMA		
XENON-133 AS GAS OR GAS IN SALINE FOR BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES.		

6.b. RADIOACTIVE MATERIAL FOR USES NOT LISTED IN ITEM 6.a. *(Sealed sources up to 3 mCi used for calibration and reference standards are authorized under Section 35.14(d), 10 CFR Part 35, and NEED NOT BE LISTED.)*

ELEMENT AND MASS NUMBER	CHEMICAL AND/OR PHYSICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRIBE PURPOSE OF USE
^{125}I	Labeled organic compounds for Radioimmuno-Assay T_3- T_4, Digoxin	10 uCi or less (Total less than 0.06 MCi	In-vitro measure of T_3-T_4 and Digoxin blood levels.

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

For Items 7 through 23, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the medical licensing guide will be followed, do not submit the pages, but specify the revision number and date of the referenced guide: Regulatory Guide 10.8 , Rev. _____ Date: _____

7. MEDICAL ISOTOPES COMMITTEE Not required in private office. See CFR-10 Par 35 Sec. 35.12 (4)(iii)	**15. GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL** *(Check One)*
Names and Specialties Attached; and	X Appendix G Rules Followed; or
Duties as in Appendix B; or *(Check One)*	Equivalent Rules Attached
Equivalent Duties Attached	**16. EMERGENCY PROCEDURES** *(Check One)*
8. TRAINING AND EXPERIENCE	X Appendix H Procedures Followed; or
X Supplements A & B Attached for Each Individual User; and	Equivalent Procedures Attached
X Supplement A Attached for RSO.	**17. AREA SURVEY PROCEDURES** *(Check One)*
9. INSTRUMENTATION *(Check One)*	X Appendix I Procedures Followed; or
Appendix C Form Attached; or	Equivalent Procedures Attached
X List by Name and Model Number See attached sheet	**18. WASTE DISPOSAL** *(Check One)*
10. CALIBRATION OF INSTRUMENTS	Appendix J Form Attached; or
Appendix D Procedures Followed for Survey Instruments; or *(Check One)*	Equivalent Information Attached
Equivalent Procedures Attached; and	**19. THERAPEUTIC USE OF RADIOPHARMACEUTICALS** *(Check One)*
Appendix D Procedures Followed for Dose Calibrator; or *(Check One)*	Appendix K Procedures Followed; or
X Equivalent Procedures Attached	Equivalent Procedures Attached
11. FACILITIES AND EQUIPMENT	**20. THERAPEUTIC USE OF SEALED SOURCES**
X Description and Diagram Attached	Detailed Information Attached; and
12. PERSONNEL TRAINING PROGRAM	Appendix L Procedures Followed; or *(Check One)*
X Description of Training Attached	Equivalent Procedures Attached
13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL	**21. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE GASES (e.g., Xenon – 133)**
Detailed Information Attached attached	Detailed Information Attached
14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS *(Check One)*	**22. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS**
	Detailed Information Attached
Appendix F Procedures Followed; or	**23. PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b**
Equivalent Procedures Attached Exempt under 10 CFR 20-205 (5-i-v)	Detailed Information Attached

24. PERSONNEL MONITORING DEVICES

TYPE (Check appropriate box)			SUPPLIER	EXCHANGE FREQUENCY
a. WHOLE BODY		FILM		
		TLD		
		OTHER (Specify)		
b. FINGER		FILM		
		TLD		
		OTHER (Specify)		
c. WRIST		FILM		
		TLD		
		OTHER (Specify)		

d. OTHER (Specify)

NONE

25. FOR PRIVATE PRACTICE APPLICANTS ONLY

a. HOSPITAL AGREEING TO ACCEPT PATIENTS CONTAINING RADIOACTIVE MATERIAL

NAME OF HOSPITAL

MAILING ADDRESS

CITY | STATE | ZIP CODE

b. ATTACH A COPY OF THE AGREEMENT LETTER SIGNED BY THE HOSPITAL ADMINISTRATOR.

c. WHEN REQUESTING THERAPY PROCEDURES, ATTACH A COPY OF RADIATION SAFETY PRECAUTIONS TO BE TAKEN AND LIST AVAILABLE RADIATION DETECTION INSTRUMENTS.

26. CERTIFICATE

(This item must be completed by applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certify that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including any supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED
(See Section 170.31, 10 CFR 170)

(1) LICENSE FEE CATEGORY:
General Domestic License (Sec. 31.11 of CFR Part 31)

(2) LICENSE FEE ENCLOSED: $ _____

b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*
John T Elston MD

(1) NAME *(Type or Print)*
John T. Elston, M. D.

(2) TITLE
Pathologist

c. DATE
6-18-79

FORM NRC-313M (8-78)

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on Form NRC-313M. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-36 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for a NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

FORM NRC-313M
(8-78)

NUCLEAR REGULATORY COMMISSION

9. INSTRUMENTATION

Name and Model number	Abbott - AutoLogic No 7407-02 Abbott - Logic Model III

Item 9
June 18, 1979

NUCLEAR REGULATORY COMMISSION

10. CALIBRATION OF INSTRUMENTS

a. Survey Instrument

Routine survey of isotope area by moist swab technic performed after each day of use. No other monitoring equipment necessary in view of low level substances used.

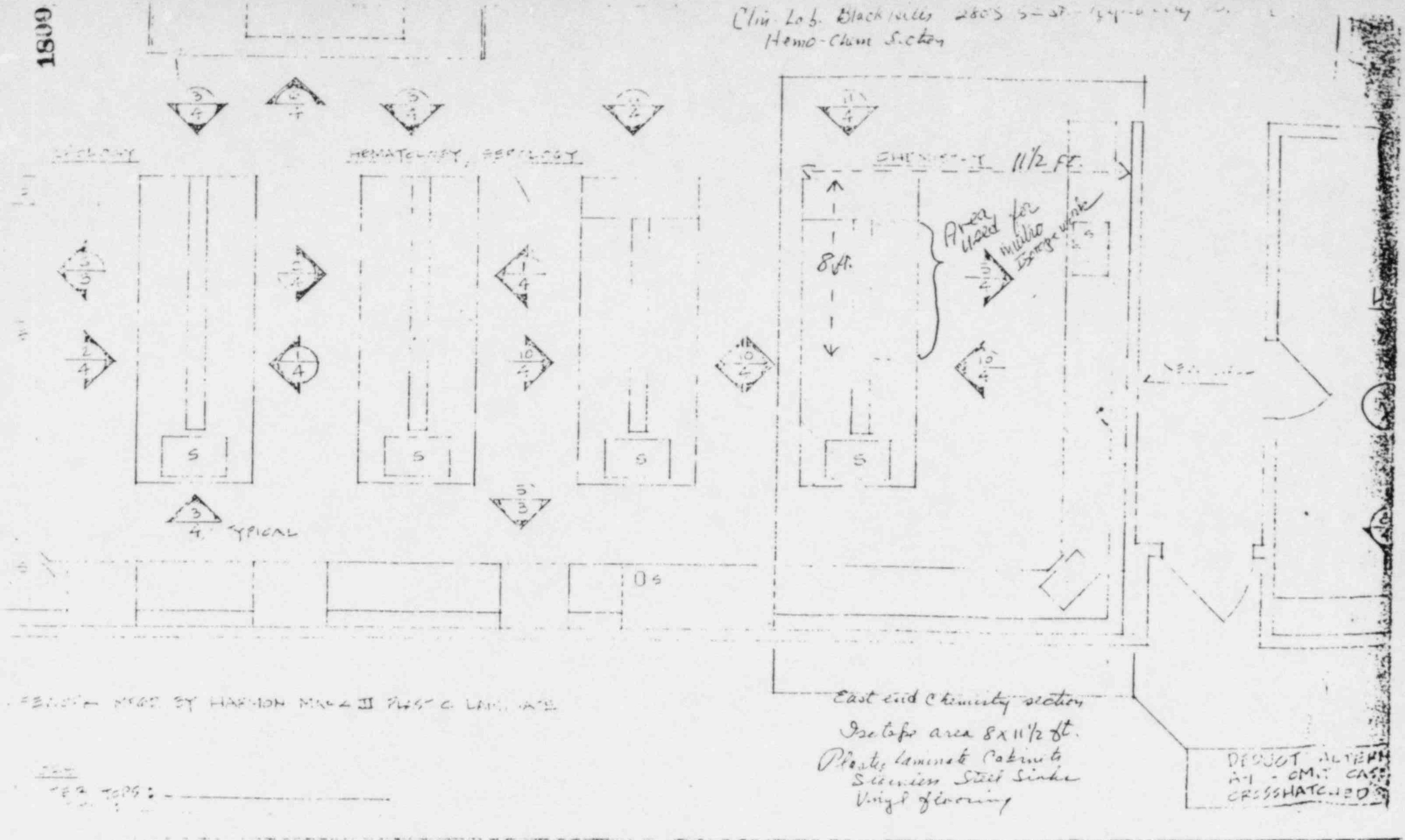
Item 10
June 18, 1979

11. FACILITIES AND EQUIPMENT

Floor plan of isotope section in General Chemistry lab is attached. Isotope reagents stored in laboratory cabinets, empty reagent containers are kept on shelf until decay below detectable limits, then disposed of in sanitary land fill.

Item 11
June 18, 1979

1809


Clin. Lab. Blackwelder 2805 S-St.
Hemo-Chem Section
HEMATOLOGY, SEROLOGY
CHEMISTRY I
11½ ft.
8 ft.
Area used for micro Isotope work
TYPICAL
East end Chemistry section
Isotope area 8 x 11½ ft.
Plastic laminate Cabinets
Stainless Steel Sinks
Vinyl flooring
DEDUCT ALTERN A-1 - OMIT CASE CROSSHATCHED
BENCH MADE BY HAMILTON MARK III PLASTIC LAMINATE

12. PERSONNEL TRAINING PROGRAM

All persons performing in vitro analysis are Medical Technologists (MT-ASCP) who have had formal training in isotope technics. Written analytical procedures are carefully adhered to. All personnel have been instructed in use, handling, safety and have been made aware of NRC rules and regulations as well as licensees regulations.

FORM NRC-313M-SUPPLEMENT A (8-78) — U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
JOHN T. ELSTON, M. D.	SOUTH DAKOTA

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
PATHOLOGY	PATHOLOGY-ANATOMIC	Nov. 1954

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: LECTURE/LABORATORY COURSES (Hours) C	TYPE AND LENGTH OF TRAINING: SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION	University of South Dakota December 1955. Nuclear Medicine Institute	48 hours	
b. RADIATION PROTECTION	Cleveland, Ohio, Nov.-Dec. 1973	96 hours.	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
I 131 I 125 Co-60 CR 51	5 MC less than 1 MC CO 57 1 MC less than 1 MC	St. John's Hospital, Rapid City, South Dakota (Now Rapid City Regional Hospital).	24 years continuous use of isotopes (uptake and in-vitro diagnostic tests)	Thyroid uptakes, Blood volume studies, RBC survival, GI absorption studies.

FORM NRC-313M-SUPPLEMENT A (8-78) U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE
DONALD H. KELLEY, M. D.	

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C
PATHOLOGY	P.A./C.P.	May 1972

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		LECTURE/ LABORATORY COURSES (Hours) C	SUPERVISED LABORATORY EXPERIENCE (Hours) D
a. RADIATION PHYSICS AND INSTRUMENTATION			
b. RADIATION PROTECTION	Information attached		
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY			
d. RADIATION BIOLOGY			
e. RADIOPHARMACEUTICAL CHEMISTRY			

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
	See	sheet attached		

HARVARD UNIVERSITY
UNIVERSITY HEALTH SERVICES

75 Mt. Auburn Street
Cambridge, Massachusetts 02138

November 21, 1968

TO WHOM IT MAY CONCERN:

This is to certify that DONALD H. KELLEY participated in the STUDY PROGRAM IN THE SAFE USE OF RADIOISOTOPES IN RESEARCH conducted by Environmental Health & Safety, University Health Services, and satisfactorily completed a final examination given at the end of the program.

The program was designed to impart the principles and practice of radiation safety as it concerns the use of radioactive materials. Additionally, it presented elementary information on radioactivity measurement, standardization and monitoring techniques, mathematics and calculations basic to the use and measurement of radioactivity, and on biological effects of radiation.

The material was given in ten two-hour sessions, including two laboratory sessions.

Jacob Shapiro, Ph.D.
Radiation Protection
Officer

JS/nkt

H120A

GEIB, ELSTON, FROST PROFESSIONAL ASSOCIATION
P. O. BOX 47 - 1010 NINTH STREET
RAPID CITY, SOUTH DAKOTA 57701

PHONE 343-2267

PRACTICE LIMITED
TO CLINICAL PATHOLOGY
AND ANATOMIC PATHOLOGY

EDUCATIONAL BACKGROUND IN USE OF RADIOISOTOPES

DONALD H. KELLEY, M.D.

(AS PER ITEMS 8 & 9, FORM AEC-313)

8 a., b., c., d.: "STUDY PROGRAM IN THE SAFE USE OF RADIOISOTOPES IN RESEARCH" (20 hrs), NOV. 1965, PRESENTED BY HARVARD UNIVERSITY HEALTH SERVICES (see attached letter)

8 b., c., d.: "MEDICAL RADIOISOTOPES COURSE". MAY 4-29, 1970, PRESENTED BY OAK RIDGE ASSOCIATED UNIVERSITIES AT OAK RIDGE, TENN.

9: 5 MC or less ^{131}I: thyroid uptake, blood volume studies
less than 1 MC ^{125}I: RIA kit assays
1 MC ^{57}Co: Schilling tests
less than 1 MC ^{51}Cr: RBC survival studies

FOLLOWING 2 YRS EXPERIENCE DURING CLINICAL PATHOLOGY RESIDENCY, HAVE HAD 6 YRS EXPERIENCE IN USE OF ABOVE ISOTOPES IN PRACTICE OF PATHOLOGY AT RAPID CITY REGIONAL HOSPITAL, RAPID CITY, S.D.

ADDITIONAL EDUCATION "RADIOIMMUNOASSAY SYMPOSIUM", PRESENTED BY U. OF C. OF CALIFORNIA (BERKELEY), AT SAN FRANCISCO JAN. 28-30, 1972.

UNIVERSITY OF CALIFORNIA, BERKELEY

BERKELEY • DAVIS • IRVINE • LOS ANGELES • RIVERSIDE • SAN DIEGO • SAN FRANCISCO

SANTA BARBARA • SANTA CRUZ

UNIVERSITY EXTENSION

2223 FULTON STREET
BERKELEY, CALIFORNIA 94720

February 3, 1977

Donald Kelley
1819 West Boulevard
Rapid City, South Dakota 57701

Dear Donald Kelley:

This letter will serve as verification of your attendance at the Radioimmunoassay Symposium, January 28-30, 1977 at the Hyatt on Union Square in San Francisco, California.

You may submit this letter as confirmation of your registration to the association from which you are interested in receiving credit.

Sincerely yours,

Nathan W. Cohen

Nathan W. Cohen, Ph.D.
Program Coordinator
Radioimmunoassay Symposium

jm

1800

13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL:

Copy of written procedure from manual attached.

par 8 III

POLICY FOR RECEIPT OF SHIPMENT REGARDING RADIO-NUCLEOTIDES

Upon receipt of radio nucleotide shipment the following shall be so noted.

1. Supplier.
2. Type of test.
3. Number of tests received.
4. Lot number.
5. Date received.
6. Date expired.
7. Condition of shipment.

If shipment arrives in tact mark OK. If shipment arrives broken supplier should be notified. Specimen container should be thoroughly flushed with large volumes of water and sprayed with Rad Con. The residue should be wiped off and all areas monitered via cotton ball wipe method. When low count is attained all materials may be discarded.

14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS:

Exempt under 20.205 (5) (i)and (v) 10 CFR

18. WASTE DISPOSAL

Appendix J attached copy.

APPENDIX J

WASTE DISPOSAL

1. Liquid waste will be disposed of (check as appropriate)

_____ By commercial waste disposal service (see also item 4 below).

__X__ In the sanitary sewer system in accordance with §20.303 of 10 CFR Part 20.

_____ Other (specify): _____

_____

2. Mo-99/Tc-99m generators will be (check as appropriate)

_____ Returned to the manufacturer for disposal.

_____ Held for decay until radiation levels, as measured with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the generators disposed of as normal trash. (Note: This method of disposal may not be practical for generators containing long-lived radioactive contaminants.)

_____ Disposed of by commercial waste disposal service (see also item 4 below).

_____ Other (specify): _____

_____

3. Other solid waste will be (check as appropriate)

_____ Held for decay until radiation levels, as measured with a low-level survey meter and with all shielding removed, have reached background levels. All radiation labels will be removed or obliterated and the waste will be disposed of in normal trash.

_____ Disposed of by commercial waste disposal service (see also item 4 below).

_____ Other (specify): _____

_____

4. The commercial waste disposal service used will be

_____

(Name) (City, State)

NRC/Agreement State License No. _____