

FORM NRC-313M

(8-78) 10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE - MEDICAL

Approved: **GAO R0557**

INSTRUCTIONS - Complete I terms 1 through 26 if this & 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. application to: Director, Orrice of Nuclear Materials Safety and S

license ree category should be sta	ited in Ite	m 26 and the approp	oriate fee enclosed.				
1.a. NAME AND MAILING ADDRESS OF API firm, clinic, physician, etc.) INCLUDE ZIP		T (institution,	1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED (If different from 1.a.) INCLUDE ZIP CODE				
John T. Elston, M. D.	Clinical Laboratory of the Black Hills						
P. O. Box 238, Rapid Cit	2805 S. Fifth Street, P.O. Box 238						
Donald H. Kelley, M. D.	Rapid City,	South Dake	ota 5	7709			
P. O. Box 238, Rapid Cit	y, S.	D. 57709					
2. PERSON TO CONTACT REGARDING THE	SAPPLI	CATION	3. THIS IS AN APPLIC	CATION FOR: (Check ap	propri	ate item)
John T. Elston, M. D.			A NEW LICENS	E			
	040	0007	c. AMENDMEN			5952	-01
TELEPHONE NO.: AREA CODE (605)				as	same	nded	
 INDIVIDUAL USERS (Name individuals w supervise use of radioactive material, Comple for each individual,) 	te Suppi	use or directly lements A and B	5. RADIATION SAFET as radiation safety office me of training and exper	er. If other than ind	ividual us		
John T. Elston, M. D. Pa	tholo	gist	John T. Els	ton, M. D.	Path	olog	ist
Donald H. Kelley, M. D.	Patho	ologist	Donald H. Ke			-	
6.a. RADIOACTIVE MATERIAL FOR M	AEDICA	AL USE					
	TEMS SIRED	MAXIMUM POSSESSION LIMITS	ADDITIONA	AL ITEMS:	MAI ITEI DESII	MS	MAXIMUM POSSESSION LIMITS
LISTED IN:	"X"	(In millicuries)				"X"	(In millicuries)
10 CFR 31.11 FOR IN VITRO STUDIES	X		OF HYPERTHYROID		MENT		
10 CFR 35.100, SCHEDULE A, GROUP I		AS NEEDED	PHOSPHORUS-32 AS S FOR TREATMENT OF	POLYCYTHEM	IA		
10 CFR 35.100, SCHEDULE A, GROUP II		AS NEEDED	PHOSPHORUS-32 AS O	COLLOIDAL CH	ROMIC		
10 CFR 35.100, SCHEDULE A, GROUP III			PHOSPHATE FOR INT MENT OF MALIGNAN GOLD-198 AS COLLO	IT EFFUSIONS.	THEAT-		
10 CFR 35.100,SCHEDULE A, GROUP IV		AS NEEDED	CAVITARY TREATME		IANT		
10 CFR 35.100, SCHEDULE A, GROUP V		AS NEEDED	OF THYROID CARCIN		IENT		
10 CFR 35.100, SCHEDULE A, GROUP VI			XENON-133 AS GAS O BLOOD FLOW STUDIES FUNCTION STUDIES.	R GAS IN SALIN ES AND PULMOI	EFOR		
6.b. RADIOACTIVE MATERIAL FOR U calibration and reference standards are au	JSES N	OT LISTED IN under Section 35.	ITEM 6.a. (Sealed source .14(d), 10 CFR Part 35, a	s up to 3 mCi used to nd NEED NOT B	or E LISTE	D.)	
ELEMENT AND MASS NUMBER	2000	CHEMICAL AND/OR SICAL FORM	MAXIMUM NUMBER OF MILLICURIES OF EACH FORM	DESCRI	BE PURI	POSE (OF USE
125	Lab	eled organ	ic	In-vit	ro me	asur	e of
compounds for			In-vitro measure of T ₃ -T ₄ and Digoxin blood				
	Rad Ass	lioimmuno-	(Total less	levels		Borr	02004
		T ₄ , Dig-	than 0.06 MCi				
	Ovi	n 4, Dig-	- H. 1-1-13-4-1				
8508290376 850618 REG4 LIC30 40-15952-01 PDR							

INFORMATION REQUIRED FOR ITEMS 7 THROUGH 23

7. M	Not required in private		GENERAL RULES FOR THE SAFE USE OF RADIOACTIVE MATERIAL (Check One)
	Names and Specialties Attached; and CFR-10 Par 35	X	Appendix G Rules Followed; or
	Duties as in Appendix B; or Sec. 35.12 (4)(iii	L)	Equivalent Rules Attached
	Equivalent Duties Attached	16.	EMERGENCY PROCEDURES (Check One)
в. т	RAINING 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. 11	NSTRUMENTATION (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		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
	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)	.3.3	PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL IN ANIMALS Detailed Information Attached
	Appendix F Procedures Followed; or		PROCEDURES AND PRECAUTIONS FOR USE OF RADIOACTIVE MATERIAL SPECIFIED IN ITEM 6.b.
	Equivalent Procedures Attached 10 CFR 20-205 (5-	_	





	TYPE	SUPPLIER		EVOLUNIOS EDECUENOS
(Check	appropriate box)	SUPPLIER		EXCHANGE FREQUENCY
	FILM			
BODY	TLD			
	OTHER (Specify)			
	FILM			
FINGER	TLD			
	OTHER (Specify)			
	FILM			
. WRIST	TLD			
	OTHER (Specify)			
	*	FOR PRIVATE PRACTICE APPLI	CANTS ONLY	
HOSPITAL		FOR PRIVATE PRACTICE APPLIE		
HOSPITAL NAME OF H	AGREEING TO ACCEPT	FOR PRIVATE PRACTICE APPLICATION OF PATIENTS CONTAINING RADIOACTIVE	MATERIAL b. ATTACH	A COPY OF THE AGREEMENT LETTER Y THE HOSPITAL ADMINISTRATOR.
	AGREEING TO ACCEPT I		b. ATTACH A SIGNED B	Y THE HOSPITAL ADMINISTRATOR. QUESTING THERAPY PROCEDURES,
NAME OF H	AGREEING TO ACCEPT I		b. ATTACH A SIGNED B c. WHEN REC ATTACH A TIONS TO	Y THE HOSPITAL ADMINISTRATOR.
MAILING A	AGREEING TO ACCEPT I	PATIENTS CONTAINING RADIOACTIV	b. ATTACH / SIGNED B c. WHEN REC ATTACH A TIONS TO RADIATIO	Y THE HOSPITAL ADMINISTRATOR. QUESTING THERAPY PROCEDURES, COPY OF RADIATION SAFETY PRECAU BE TAKEN AND LIST AVAILABLE
MAILING A	AGREEING TO ACCEPT IN HOSPITAL. ADDRESS At and any official execution with Title 10, Code of Fed	26. CERTIFICATE (This item must be completed by	b. ATTACH / SIGNED B c. WHEN REC ATTACH A TIONS TO RADIATIO	Y THE HOSPITAL ADMINISTRATOR. QUESTING THERAPY PROCEDURES, COPY OF RADIATION SAFETY PRECAU BE TAKEN AND LIST AVAILABLE
MAILING A	AGREEING TO ACCEPT IN HOSPITAL. ADDRESS At and any official execution with Title 10, Code of Fedeto, is true and correct to the contract of	26. CERTIFICATE (This item must be completed by the desired and 35 and the best of our knowledge and belief. CS OF THE CODE STATE ZIP CODE 26. CERTIFICATE (This item must be completed by NOTION 10. The complete down and 35 and the best of our knowledge and belief.	b. ATTACH ASIGNED B c. WHEN RECATTACH ATTACH ATTAC	Y THE HOSPITAL ADMINISTRATOR. QUESTING THERAPY PROCEDURES, COPY OF RADIATION SAFETY PRECAU BE TAKEN AND LIST AVAILABLE IN DETECTION INSTRUMENTS. 1a certify that this application is prepared in contained herein, including any supplements
MAILING A CITY The applican conformity is attached here	AGREEING TO ACCEPT IN HOSPITAL. ADDRESS At and any official execution with Title 10, Code of Fedeto, is true and correct to the section 170 FEE CATEGORY:	26. CERTIFICATE (This item must be completed by the desired and 35 and the best of our knowledge and belief. CS OF THE CODE STATE ZIP CODE 26. CERTIFICATE (This item must be completed by NOTION 10. The complete down and 35 and the best of our knowledge and belief.	b. ATTACH A SIGNED B c. WHEN REC ATTACH A TIONS TO RADIATIO ant named in Item at all information (1) NAME (2) TITLE	Y THE HOSPITAL ADMINISTRATOR. DUESTING THERAPY PROCEDURES, COPY OF RADIATION SAFETY PRECAL BE TAKEN AND LIST AVAILABLE IN DETECTION INSTRUMENTS. 1a certify that this application is prepared in contained herein, including any supplements TOR CERTIFYING OFFICIAL (Signature) AND Sister Carrier Print) T. FISTON, M. D.

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)).
- 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.
- 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 NUCLEAR REGULATORY COMMISSION

10. CALIBRATION OF INSTRUMENTS

a. Survey Instrument

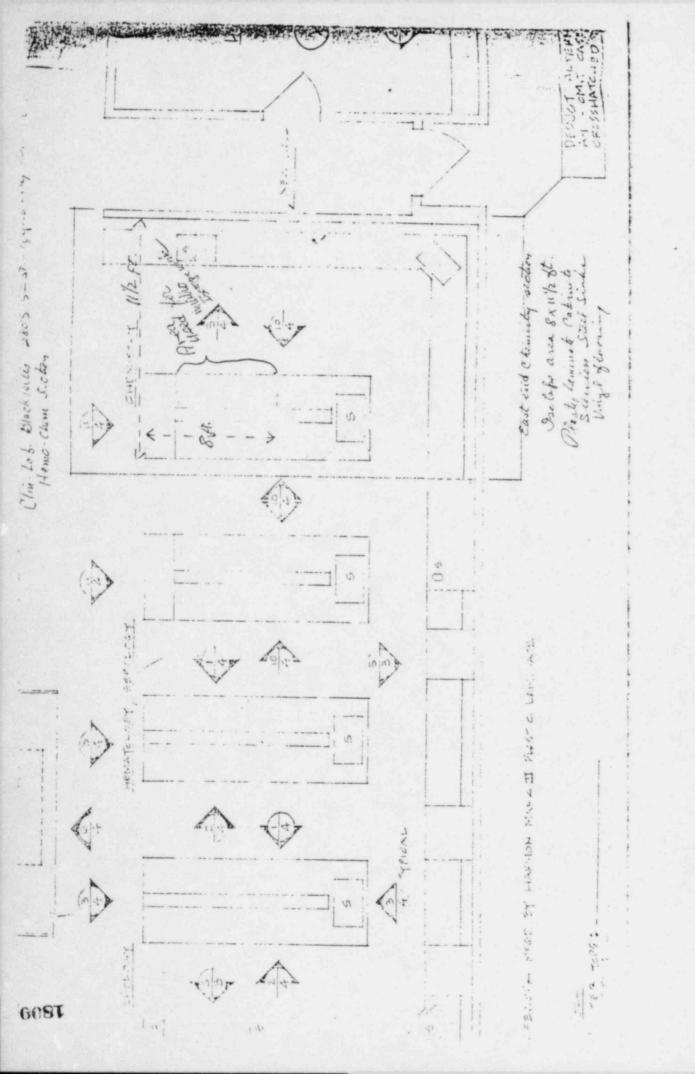
Routine survey of isotope area by moist swab technic performed after each day of use. No other monitoring equipment necessary in view of low level substances used.

2574/COTTON REUCH

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.

EDUTHING OF TON BURNERS



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.

Item 12 June 18, 1979



FORM NRC-313M-SUPPLEMENT A

U.S. NUCLEAR REGULATORY COMMISSION

(8-78)

TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER

2. STATE OR TERRITORY IN 1. NAME OF AUTHORIZED USER OR RADIATION SAFETY OFFICER JOHN T. ELSTON, M. D.

WHICH LICENSED TO

3. CERTIFICATION CATEGORY MONTH AND YEAR CERTIFIED SPECIALTY BOARD PATHOLOGY PATHOLOGY-ANATOMIC Nov. 1954

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

		TYPE AND LENGT	H OF TRAINING
FIELD OF TRAINING A	LOCATION AND DATE (S) OF TRAINING	LECTURE/ LABORATORY COURSES (Hours)	SUPERVISED LABORATORY EXPERIENCE (Hours)
a. RADIATION PHYSICS AND INSTRUMENTATION	University of South Dakot December 1955. Nuclear Medicine Institut	48 hour	S
b. RADIATION PROTECTION	Cleveland, Ohio, NovDec 1973	. 96 hour	S.
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).		Thyroid uptakes Blood volume studies, RBC survival, GI absorption
			tests)	studies.

FORM NRC-313M Supplement A

(8-78)

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.		PRACTICE ME U	P. 775. X. 79
	3. CERTIFICATION	*	
SPECIALTY BOARD	CATEGORY	MONTH AND YEA	AR CERTIFIED
PATHOLOGY	P.A./C.P.	May 1972	
4. TRAINING REC	EIVED IN BASIC RADIOISOTOPE HANDLING T	ECHNIQUES TYPE AND LENG	TH OF TRAINING
FIELD OF TRAINING	LOCATION AND DATE(S) OF TRAINING	LECTURE/ LABORATORY COURSES (Hours)	SUPERVISED LABORATORY EXPERIENCE (Hours)

- c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY

. RADIATION PHYSICS AND INSTRUMENTATION

b. RADIATION PROTECTION

- d. RADIATION BIOLOGY
- e. RADIOPHARMACEUTICAL CHEMISTRY

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

Information attached

SOTOPE	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. KHLLEY 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 plactice 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. (acob Shapiro, Ph.D. Tadiation Protection Officer JS/nkt HIZOA

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

PHONE 343-2267

PRACTICE LIMITED
TO CLINICAL PATHOLOGY
AND ANATOMIC PATHOLOGY

EDUCATIONAL BACKERCUND IN USE OF RADIOISOTOPES

WHAT H. KELLEY, M.D.

(AS PER ITEMIS 8+9, FORM ARC -313)

8 a.b., e., d.: "STUDY PROBRITH) IN THE SITE USE OF KADIOISOPE'S
IN RESEARCH" (2010S), NOV. 1968, PRESENTED BY HARVIRD
UNIVERSITY MEALTH SERVICES (see attacked later)

8 b., c., d.: "NIEDICAL KADIOISOTOPES COURSE". NIAY 4-29,
1970, PRESENTED BY OAK RIDGE ASSOCIATED LIVIVERSITIES AT
CHERIDGE, TENN.

9: 5 Me or less. II: thyrvid uprake, blood volume sincres

less than IMC 125 I: RIA kit assays

IMC - 5700: Schilling tests

less than IMC-5101: RBO survival studies

FOLLOWING 2 4RS EXPERIENCE DURING CLINICAL PHILIPOLOGY, RESIDENCY, HAVE HAD GYRS EXPERIENCE IN USE OF HISOVE ISOTOPIES IN PROFICE OF PHILIPOGY AT RAPID CITY REGIONAL (10) PITAL, RAPID CITY, S.D.

ADDITIONAL EDUCATION "RADIO IIITUMUNO ASSAY SYMPOSIUM", PRESENT BY UNIV. OF CALIFORNIA (BERKELLEY), AT SAN PRANCISCO JAN. 28 - 30, 1977.

UNIVERSITY OF CALIFORNIA, BEI KELEY SANTA BARBARA . SANTA CRUZ BERKELEY . DAVIS . IRVINE . LOS ANGELES . RIVERSIDE . SAN DIEGO . SAN FRANCISCO UNIVERSITY EXTENSION 2223 FULTON STREET BERKELEY, CALIFORNIA 94720 February 3, 1977 Dona d Kelley 1819 West Boulevard Rapi City, South D kota 57701 Dear onald Kelley: This letter will serve as verification of your atte lance at the Radioimmunoassay Symposium, January 28-30, 1977 at the Hyatt on Union Square

You may submit this letter as confirmation of your registration to the association from which you are

in San Francisco, California.

interested in receiving credit.

Sincerely yours,

jm

Nathan W. Cohen, Ph.D. Program Coordinator

Radioimmunoassay Symposium

13. PROCEDURES FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL:

Copy of written procedure from manual attached.

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.

Contents are exempt from NRC or Agreement State licensing requirements.

Radioactive Material—Not for Human Use— Introduction into foods, beverages, cosmetics, drugs, or medicinals or into products manufactured for commercial distribution is prohibited—exempt quantities should not be combined. 14. PROCEDURES FOR SAFELY OPENING PACKAGES CONTAINING RADIOACTIVE MATERIALS:

Exempt under 20,205 (5) (i) and (v) 10 CFR

SOUTHLY ORTH CO. N.S.A.

18. WASTE DISPOSAL

Appendix J attached copy.

25% COTTO FIBER

APPENDIX J

WASTE DISPOSAL

	quid waste will be disposed of (check as propriate)	Disposed of by commercial waste posal service (see also item 4 belo	
	By commercial waste disposal service (see also item 4 below).	Other (specify):	
	In the sanitary sewer system in accordance with §20.303 of 10 CFR Part 20. Other (specify):	3. Other solid waste will be (check as a priate) Held for decay until radiation las measured with a low-level s meter and with all shielding remarked background levels radiation labels will be removed obliterated and the waste with the solid radiation of the solid radiation labels.	evels, urvey loved, s. All ed or
ар	propriate)	disposed of in normal trash.	
	Returned to the manufacturer for disposal.	Disposed of by commercial waste posal service (see also item 4 belo	
	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	4. The commercial waste disposal service will be	e used
	of disposal may not be practical for generators containing long-lived	(Name) (City, State) NRC/Agreement State License No.	