UNIVERSITY of PENNSYLVANIA

PHILADELPHIA 19104

Duhring Laboratories

DEPARTMENT OF DERMATOLOGY
University Hospital

March 11, 1966

John E. Bowyer
Isotopes Branch
Division of Materials Licensing
U.S. Atomic Energy Commission
Washington 25, D.C.

Re: DML:IB:JEB (70113)

Dear Mr. Bowyer:

I passionately hope that the enclosed information will complete my application for renewal of license number 37-9714-1. I do want to emphasize once more that the quantities employed are exceedingly small and that the risks, in my opinion, have a corresponding size.

I regret to have caused you so much difficulty.

Sincerely yours,

Albert M. Kligman, M.D.

Enc.

cc: Richard E. Cunningham
Chief, Isotopes Branch
Division of Materials Licensing
U.S. Atomic Energy Commission
Washington, D.C. 20545

A/27

UNIVERSITY of PENNSYLVANIA

PHILADELPHIA 19104

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U.S. Atomic Energy Commission
Washington, D.C. 20545

4/2.

Form WA-272
(4-59)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Holmesburg County Prison
   Address: Torresdale Avenue & Pennypack St.
   City: Philadelphia State:

2. Control No. 70113 (JEB)

3. Department of Medicine

4. Name and title of trained individual
   Albert M. Kligman, M. D.

5. Type program:
   - ☐ Private practice.
   - ☐ Private practice in hospital.
   - ☒ Institutional.

6. Review:
   - ☒ First.
   - ☐ Second.

7. Previous application control No.(s)

8. Remark on checked items:
   - ☐ A. All radioisotopes and uses stated in application.
   - ☒ B. Use of Carborn 14 labeled Testosterone or Corticosteroid, Sulfur 35 labeled Cystine and Hydrogen 3 as Thymidine for studies of absorption through the skin.
   - ☐ C. Training and experience of user.
   - ☐ D. Dosage(s) indicated.
   - ☐ E. Clinical techniques and procedures outlined.
   - ☐ F. Type patient used (i.e., terminal, infants, normal).
   - ☐ G. Other

9. Action of Subcommittee on Human Applications:
   - ☒ Approve.
   - ☐ Disapprove.

   Remarks:

3-28-66
(Date of appraisal)

Signature George V. LePoy
(Member of subcommittee)

U.S. GOVERNMENT PRINTING OFFICE 16—74880-1

E 12

Form WA-372
(4-59)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

1. Applicant: Holmesburg County Prison
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   ☐ E. Clinical techniques and procedures outlined.

   ☐ F. Type patient used (i.e., terminal, infants, normal).

   ☐ G. Other

9. Action of Subcommittee on Human Applications:

   ☒ Approve. ☐ Disapprove.

   Remarks:

3/29/66
(Date of appraisal)

Signature Edith H. Quimby
(Member of subcommittee)

U.S. GOVERNMENT PRINTING OFFICE 16—76880-1

Form WA-372
(4-59)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

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   - ☐ E. Clinical techniques and procedures outlined.
   - ☐ F. Type patient used (i.e., terminal, infants, normal).
   - ☐ G. Other

9. Action of Subcommittee on Human Applications:

   ☐ Approve. ☐ Disapprove.

   Remarks: Thank you.

4-22-66
+Date of appraisal)

Signature F. RICHARD KING, M.D./med
(Member of subcommittee)

U.S. GOVERNMENT PRINTING OFFICE 16—74880-1

Form WA-372
(4-59)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

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   Address: Torresdale Avenue & Pennypack St.
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   ☐ E. Clinical techniques and procedures outlined.

   ☐ F. Type patient used (i.e., terminal, infants, normal).

   ☐ G. Other

9. Action of Subcommittee on Human Applications:

   ☐ Approve. ☐ Disapprove.

   Remarks: Approve all but H3 Thymidine. Don't think experiment warrants possibl hazard.

John A. D. Cooper, M.D.
303 East Chicago Avenue
Chicago 11, Illinois

4-26-66
(Date of appraisal)

Signature
(Member of subcommittee)

U.S. GOVERNMENT PRINTING OFFICE 16—74880-1

Form WA-272
(4-59)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

APPRAISAL

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   ☐ C. Training and experience of user.

   ☐ D. Dosage(s) indicated.

   ☐ E. Clinical techniques and procedures outlined.

   ☐ F. Type patient used (i.e., terminal, infants, normal).

   ☐ G. Other

9. Action of Subcommittee on Human Applications:

   ☐ Approve. ☐ Disapprove.

   Remarks: Approve all except H^3 labeled thymidine. This material, when injected reach the genetic DNA pool.

May 5, 1966
(Date of appraisal)

Signature W. D. Armstrong, M.D.
(Member of subcommittee)

U.S. GOVERNMENT PRINTING OFFICE 16—76880-1

Form WA-272
(4-59)

U.S. ATOMIC ENERGY COMMISSION
MEDICAL ADVISORY COMMITTEE

Revised

APPRAISAL

1. Applicant: Holmesburg County Prison
   Address: Torresdale Avenue & Pennypack St.
   City: Philadelphia State:

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   - ☐ D. Dosage(s) indicated.
   - ☐ E. Clinical techniques and procedures outlined.
   - ☐ F. Type patient used (i.e., terminal, infants, normal).
   - ☐ G. Other

9. Action of Subcommittee on Human Applications:

   - ☒ Approve.
   - ☐ Disapprove.

   Remarks: Except ~~for~~ thymidine. Information showing the labeled compound remains in the tissue biopsy is essential before I would approve for human use.

5-31-66
(Date of appraisal)

Signature Reynold F. Brown, M.D.
(Member of subcommittee)

U.S. GOVERNMENT PRINTING OFFICE 16—74888-1

Form AEC-313 (5-58)	ATOMIC ENERGY COMMISSION **APPLICATION FOR BYPRODUCT MATERIAL LICENSE**	Form approved. Budget Bureau No. 38-R

INSTRUCTIONS.–Complete Items 1 through 16 if this is an initial application. If application is for renewal of a license, c plete only Items 1 through 7 and indicate new information or changes in the program as requested in Items 8 through 15. supplemental sheets where necessary. Item 16 must be completed on all applications. Mail three copies to: U. S. Atomic En Commission, Washington 25, D. C. Attention: Isotopes Branch, Division of Licensing and Regulation. Upon approval of application, the applicant will receive an AEC Byproduct Material License. An AEC Byproduct Material License is issue accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30 and the Licensee is ject to Title 10, Code of Federal Regulations, Part 20.

1. (a) Albert M. Kligman, M.D. (Name of individual, firm, institution, firm, hospital, person, etc.)
Medical Director
Holmesburg County Prison
3215 Torresdale Avenue
Philadelphia, Pa. 19136

(b) STREET ADDRESS, CITY AND STATE WHERE BYPRODUCT MATERIAL WILL BE USED. (If different from 1 (a).)
Holmesburg County Prison
Torresdale Ave.
Philadelphia, Pa. 19136

2. DEPARTMENT TO USE BYPRODUCT MATERIAL

3. PREVIOUS LICENSE NUMBER(S). (If this is an application for renewal license, please indicate and give number.)
This is to amend license #37-9714-

4. INDIVIDUAL USER(S). (Name and title of individual(s) who will use or directly supervise use of byproduct material. Give training and experience in Items 8 and 9.)
Albert M. Kligman, M.D.

5. RADIATION PROTECTION OFFICER (Name of person designated as radiation techon officer if other than individual user. Attach resume of his training an perience as in Items 8 and 9.)

6. (a) BYPRODUCT MATERIAL. (Elements and mass number of each.)

(b) CHEMICAL AND/OR PHYSICAL FORM AND MAXIMUM NUMBER OF MILLICURIES OF EACH CHEMICAL AND/OR ICAL FORM THAT YOU WILL POSSESS AT ANY ONE TIME. (If sealed source(s), also state name of manufacturer, number, number of sources and maximum activity per source.)

^{35}S	Cystine	0.3 mC.
^{3}H	Thymidine	o.5 mC.
^{14}C	Testosterone, Corticosteriod	0.4 mC.
^{22}Na *	Chloride *	0.2 mC.

*Cyclotron Produced; included to show total radionuclide usage.

7. DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED. (If byproduct material is for "human use," supplement A (Form AEC-313a) must be co pleted in lieu of this item. If byproduct material is in the form of a sealed source, include the make and model number of the storage container and/or device which the source will be stored and/or used.)

see 313a

A/52

Form AEC-313 (5-58) Page

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4 *(Use supplemental sheets if necessary)*

8. TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL COUR (Circle answer
a. Principles and practices of radiation protection	Dr. B. Calesnick, Hahnemann Hospital 1963	6 months	Yes No	(Yes) No
b. Radioactivity measurement standardization and monitoring techniques and instruments	-"-		Yes No	(Yes) No
c. Mathematics and calculations basic to the use and measurement of radioactivity	-"-		Yes No	(Yes) No
d. Biological effects of radiation	-"-		Yes No	(Yes) No

9. EXPERIENCE WITH RADIATION. *(Actual use of radioisotopes or equivalent experience.)*

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE
Na^{22}	10 mc	Hahnemann Hospital and	2 years	Investigational
S^{35}	"	Holmesburg Prison	"	"
C^{14}	"	"	"	"
H^3	"	"	"	"

10. RADIATION DETECTION INSTRUMENTS. *(Use supplemental sheets if necessary.)*

TYPE OF INSTRUMENTS (Include make and model number of each)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr)	WINDOW THICKNESS (mg/cm²)	USE (Monitoring, surveying, measurir
Baird Atomic-Survey Meter #4.05	1		100 mr/hr.		surveying
B.A. Probe # 13r. W	1	α β γ		1.1 mg/cm²	"
Inc. -Window G.M. tube	1	γ β		100 mg/cm²	measuring
B.A. Scintillation Probe # 512B	1	γ			"
B.A. Scaler-Timer #135	1				"
B.A. Betameter #332A	1				"

11. METHOD, FREQUENCY, AND STANDARDS USED IN CALIBRATING INSTRUMENTS LISTED ABOVE. **Commercially available referen sources and standards. Instruments checked against reference sources whenever used to determine consistent operation.**

12. FILM BADGES, DOSIMETERS, AND BIO-ASSAY PROCEDURES USED. *(For film badges, specify method of calibrating and processing, or name of supplier.)*

not indicated

INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS

13. FACILITIES AND EQUIPMENT. Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketc of facility is attached. *(Circle answer)* Yes ~~No~~ **see appendix**

14. RADIATION PROTECTION PROGRAM. Describe the radiation protection program including control measures. If application covers sealed sources, submit lea testing procedures where applicable, name, training, and experience of person to perform leak tests, and arrangements for performing initial radiation survey, ser icing, maintenance and repair of the source.

see appendix

15. WASTE DISPOSAL. If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which w be used for disposing of radioactive wastes and estimates of the type and amount of activity involved.

see appendix

CERTIFICATE (This item must be completed by applicant)

16. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PART 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING AI SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

RECEIVED NOV 3 - 1965 U.S. ATOMIC ENERGY COMMISSION REGULATORY OPERATION

Date November 2nd, 1965

Albert M. Kligman
Applicant named in item 1

By: Albert M. Kligman, M.D.

Professor in Dermatology
Title of certifying official

WARNING.—18 U. S. C., Section 1001, Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statemen representation to any department or agency of the United States as to any matter within its jurisdiction.

U.S. GOVERNMENT PRINTING OFFICE 1961 OF—615965

Form AEC-313a
(11/63)
Page 3

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE—MEDICAL

SUPPLEMENT A—PRECEPTOR STATEMENT

This page is to be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each. Back of page may be used for comments.

9 NAME AND ADDRESS OF APPLICANT PHYSICIAN (Include ZIP Code)

Albert M. Kligman, M.D., Holmesburg Prison
8215 Torresdale Avenue, Philadelphia, Pa. 19136

10. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN NAMED IN ITEM 9 ABOVE

(A) ISOTOPE	(B) CONDITIONS DIAGNOSED OR TREATED	(C) No. Cases Observed (See 1 in key below)	(D) No. Cases Involving Personal Participation (See 2 in key below)
I-131	Diagnosis of thyroid function		
	Dilution studies		
	Excretion studies		
	Brain tumor localization		
	Scanning studies		
	Treatment of hyperthyroidism		
	Treatment of cardiac conditions		
	Treatment of thyroid carcinoma		
P-32 Soluble	Treatment of polycythemia		
	Treatment of leukemia		
	Treatment of bone metastases		
	Tumor localization		
	Intracavitary treatment		
	Interstitial treatment		
Au-198	Intracavitary treatment		
	Interstitial treatment		
	Scanning studies		
Cr-51	Blood determinations		
	Scanning studies		
Co-58 or Co-60	Diagnosis of pernicious anemia		
Co-60	Interstitial treatment		
I-192	Intracavitary treatment		
Co-60 or Cs-137	Teletherapy treatment		
Sr-90	Treatment of superficial diseases of the eye		
Other Isotopes Use back of page	^{35}S Cystine	-	4
	^{14}C Testosterone, Corticosteroid	-	11
	^{3}H Thymidine	-	6

Key to Column (C) and (D) above

1 Observation should consist of observing radioisotope administration techniques and discussion with preceptor the case histories to establish most appropriate diagnostic and/or therapeutic procedures, limitations, contraindications, etc.

2 Personal participation should consist of supervised examination of patients to determine the suitability for radioisotope diagnosis and/or treatment and recommendation of dosage prescribed, collaboration in calibration of the dose and the actual administration of the dose to the patient including calculation of the radioactivity, dose measurements and plotting of data; and (c) adequate period of training to enable the physician to manage radioactive patients and to follow patients after diagnosis and/or the course of treatment.

11. DATES AND TOTAL NUMBER OF HOURS OF CLINICAL RADIOISOTOPE TRAINING 1963 - 30 Hours - Formal Course

12. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF Benjamin Calesnick, M.D.

AT Hahnemann Medical College 37-467-10

(Institution) Name and Address (Byproduct Material License Number)

(Signature of Preceptor)

ROUTING AND TRANSMITTAL SLIP

Date 8/19/81

TO: (Name, office symbol, room number, building, Agency/Post)	Initials	Date
1. ~~Edwin L. Johnson~~		
2. John Poindexter		
3. Vaughn Forrest		
4.		
5.		

	Action		File		Note and Return
	Approval		For Clearance		Per Conversation
	As Requested		For Correction		Prepare Reply
	Circulate		For Your Information		See Me
	Comment		Investigate		Signature
	Coordination		Justify		

REMARKS

I HOPE EVERYBODY INVOLVED IN THIS

REMEMBERS THAT THE PURPOSE IS TO CALM

THINGS DOWN-NOT STIR THEM UP.

8/21

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)	Room No.—Bldg.
TOBY CLARK (TS 788)	~~637E~~
	Phone No. X50310

5041-102

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

* GPO : 1981 O - 341-529 (25)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

AUG 14 1981

MEMORANDUM

SUBJECT: Status of Action Plan for Holmesburg Prison

FROM: John W. Melone, Acting Director
Hazard Evaluation Division (TS-769C)

TO: Edwin L. Johnson
Deputy Assistant Administrator
Office of Pesticide Programs (TS-766C)

This memorandum is to serve as an update of our involvement with the Holmesburg situation.

On May 28, 1981 you requested that Peter McGrath develop a plan to interview those individuals who were incarcerated in Holmesburg but are now residing in the Philadelphia area. The intent is to test our hypothesis that a complete study would not be useful since we cannot identify those individuals who were in the dioxin studies as opposed to other similar studies conducted at Holmesburg. On June 9, you instructed Peter to implement the plan produced by the Health Effects Branch (see attached).

On June 26, letters were sent to approximately 40 individuals who claimed to have been participants in the dioxin testing. Eighteen individuals residing in Philadelphia were sent letters which stated they were selected for the initial interviews. To date, only five individuals of the 18 have responded, all indicating complete willingness to be interviewed. In an effort to follow-up on this group, we are attempting to recontact, either by telephone or letter, those that have not responded. I anticipate this taking several weeks to complete. We are hoping to conduct the interviews in Philadelphia the week of August 31, 1981.

The overall situation is further complicated in that some of these individuals are constantly moving from one prison to another, in and out of prison, and their telephone numbers and resident addresses are frequently changing. In addition, as time passes "new individuals" contact us claiming that they were also tested at Holmesburg.

I will keep you alerted to new developments as they occur.

Attachment

PROPOSED PLAN AND SCHEDULE FOR HOLMESBURG IDENTIFICATION INTERVIEWS
7/9/81

The following proposal for interviewing participants in human testing at the Holmesburg Prison during the 1960's is intended to determine whether participants in the Dow-Kligman dioxin tests can be identified and whether such individuals participated in other tests (dermal or otherwise) conducted at that facility. To this end, the following schedule has been developed:

6/1 - 6/5 - Develop and mail letters to all persons who have contacted the Agency to date, claiming possible participation in the Holmesburg dioxin tests. State that since the time of our letter to them, information has come to light that raises a question about being able to identify, with any certainty, participants in the dioxin tests. Indicate to those in the Philadelphia area that we need their phone numbers and wish to contact them further, within several weeks, to attempt to ascertain their test identity.

Proposed Method of Contact: Personal interview in Philadelphia.

Options: Telephone interview; mail questionnaire.

6/8 - 6/19 - Time needed for response from participants now residing in the Philadelphia area. (This time will also be used to develop the questionnaire and investigate these respondents.)

6/22 - 1/26 - Make final arrangements (travel, interview appointments, etc.) for conducting interviews.

6/29 - 7/1 - Drive to Philadelphia and conduct interviews (assuming we opt for personal interviews). HEB proposes that interviews be conducted simultaneously by Frank Davido and James Boland from adjoining hotel/motel rooms. Participants would be responsible for their own transportation.

7/2 - 7/10 - Evaluate data; present briefing on findings.

ALBERT M. KLIGMAN, M. D., PH. D.
HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA
36TH AND SPRUCE STREETS
PHILADELPHIA 4, PA.

DEPARTMENT OF DERMATOLOGY

EVERGREEN 2-46C
EXTENSION 451

November 1, 1965

59 - 7

Richard E. Cunningham, Chief,
Isotopes Branch,
Division of Materials Licensing
U. S. Atomic Energy Commission
Washington, D. C. 20545

In re: DML:IB:JEB (70113)

SUBJECT: Application for ByProduct Material License Dated July 27, 1965, AND YOUR REQUEST FOR INFORMATION DATED September 3, 1

Dear Mr. Cunningham:

Through an extraordinary series of mischances, my correspondence with you has been exceedingly inadequate. We were originally in error in not completing the information on Form AEC-313 but the letter calling this to our attention never reached me. Meanwhile, I have been blaming Government bureaucracy for "sluggishness". It was only your last letter indicating that this information must be returned within thirty days which clarifies the difficulties we have had and which finally reached me yesterday. I beg your pardon and regret the loss of time.

I am submitting the missing information on a duplicate of Form AEC-313 enclosed herewith. I trust that this meets with your approval and that this application can be processed as soon as possible. Thanking you for your courtesy in this matter, I am

Very truly yours,

Albert M. Kligman, M. D.
Professor of Dermatology

AMK/a
Enclosure

A/21

Form AEC-313
(8-64)
10 CFR 30

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

Form approved
Budget Bureau No. 38-R

INSTRUCTIONS.—Complete Items 1 through 16 if this is an initial application or an application for renewal of a license. Information containe previous applications filed with the Commission with respect to Items 8 through 15 may be incorporated by reference provided references are clear specific. Use supplemental sheets where necessary. Item 16 must be completed on all applications. Mail two copies to: U.S. Atomic Energy C mission, Washington, D.C., 20545, Attention: Isotopes Branch, Division of Materials Licensing. Upon approval of this application, the applicant receive an AEC Byproduct Material License. An AEC Byproduct Material License is issued in accordance with the general requirements containe Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Part 20.

1 (a) NAME AND STREET ADDRESS OF APPLICANT (Institution, firm, hospital person, etc. Include ZIP Code.)

Albert M. Kligman, M.D.
Medical Director
Holmesburg County Prison
8215 Torresdale Avenue
Philadelphia, Pa. 19136

(b) STREET ADDRESS(ES) AT WHICH BYPRODUCT MATERIAL WILL BE USED different from 1(a). Include ZIP Code.)

Holmesburg County Prison
Torresdale Ave.
Philadelphia, Pa. 19136

2 DEPARTMENT TO USE BYPRODUCT MATERIAL

---

3. PREVIOUS LICENSE NUMBER(S). (If this is an application for renewal of a lic please indicate and give number.)

This is to amend license #37-9714-

4 INDIVIDUAL USER(S). (Name and title of individual(s) who will use or directly supervise use of byproduct material. Give training and experience in Items 8 and 9.)

Albert M. Kligman, M.D.

5. RADIATION PROTECTION OFFICER. (Name of person designated as radiation p tion officer if other than individual user. Attach resume of his training and expe as in Items 8 and 9.)

6 (a) BYPRODUCT MATERIAL. (Elements and mass number of each.)

(b) CHEMICAL AND/OR PHYSICAL FORM AND MAXIMUM NUMBER OF MILLICURIES OF EACH CHEMICAL AND/OR ICAL FORM THAT YOU WILL POSSESS AT ANY ONE TIME. (If sealed source(s), also state name of manufacturer, model n number of sources and maximum activity per source.)

^{35}S	Cystine	0.3 mC.
^{3}H	Thymidine	o.5 mC.
^{14}C	Testosterone, Corticosteriod	0.4 mC.
^{22}Na *	Chloride *	0.2 mC.

* Cyclotron Produced; included to show total radionuclide usage.

7 DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED. (If byproduct material is for human use, supplement A (Form AEC-313a) must be complet in lieu of this item. If byproduct material is in the form of a sealed source, include the make and model number of the storage container and/or device in which the source is stored and/or used.)

see 313a

(Continued on reverse side)

TRAINING AND EXPERIENCE OF EACH INDIVIDUAL NAMED IN ITEM 4 (Use supplemental sheets if necessary)

8. TYPE OF TRAINING	WHERE TRAINED	DURATION OF TRAINING	ON THE JOB (Circle answer)	FORMAL CO (Circle ans
a. Principles and practices of radiation protection			Yes No	Yes
b. Radioactivity measurement standardization and monitoring techniques and instruments			Yes No	Yes
c. Mathematics and calculations basic to the use and measurement of radioactivity			Yes No	Yes
d. Biological effects of radiation			Yes No	Yes

9. EXPERIENCE WITH RADIATION (Actual use of radioisotopes or equivalent experience.)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

10. RADIATION DETECTION INSTRUMENTS (Use supplemental sheets if necessary.)

TYPE OF INSTRUMENTS (Include make and model number of each)	NUMBER AVAILABLE	RADIATION DETECTED	SENSITIVITY RANGE (mr/hr)	WINDOW THICKNESS (mg/cm²)	USE (Monitoring, surveying, measur
Baird Atomic-Survey Meter #420E	1		100 mr/hr.		surveying
B.A. Probe # 136 W	1	α β γ		1.4 mg/cm^2	"
End -Window 6 M tube	1	γ. 3		100 μgm/cm^2	measuring
B.A. Scintillation Probe # 812B	1	γ			"
B.A. Scaler-Timer #135	1				"
B.A. Ratemeter#432A	1				"

11. METHOD, FREQUENCY, AND STANDARDS USED IN CALIBRATING INSTRUMENTS LISTED ABOVE: Commercially available refere sources and standards. Instruments checked against reference sources whenev used to determine consistent operation.

12. FILM BADGES, DOSIMETERS, AND BIO-ASSAY PROCEDURES USED (For film badges, specify method of calibrating and processing, or name of supplier.)

not indicated

INFORMATION TO BE SUBMITTED ON ADDITIONAL SHEETS IN DUPLICATE

13. FACILITIES AND EQUIPMENT. Describe laboratory facilities and remote handling equipment, storage containers, shielding, fume hoods, etc. Explanatory sketc of facility is attached. (Circle answer) XX NX see appendix

14. RADIATION PROTECTION PROGRAM. Describe the radiation protection program including control measures. If application covers sealed sources, submit lea testing procedures where applicable, name, training, and experience of person to perform leak tests, and arrangements for performing initial radiation survey, ser icing, maintenance and repair of the source.

see appendix

15. WASTE DISPOSAL. If a commercial waste disposal service is employed, specify name of company. Otherwise, submit detailed description of methods which w be used for disposing of radioactive wastes and estimates of the type and amount of activity involved.

see appendix

CERTIFICATE (This item must be completed by applicant)

16. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PART 30, AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING AN SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

Date July 27, 1965

Robert M Kliegman
(Applicant named in item 1)

By: =

Title of certifying official

WARNING.—18 U. S. C., Section 1001, Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement representation to any department or agency of the United States as to any matter within its jurisdiction.

* U.S. GOVERNMENT PRINTING OFFICE 1964 O—745-382

Form AEC-313 a (10-61)
PAGE 1

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

Form approved. Budget Bureau No. 38-

If byproduct material is for "human use" (internal administration of byproduct material, or the radiation therefrom to human bein complete this supplement and attach to the application for byproduct material license.

1. (a) USING PHYSICIAN'S NAME

Albert M. Kligman, M.D.

(b) NAME AND ADDRESS OF APPLICANT (If different from 1(a))

---

2. THE USING PHYSICIAN INDICATED ABOVE IS LICENSED TO DISPENSE DRUGS IN THE PRACTICE OF MEDICINE BY A STATE OR TERRITORY OF THE UNITED STATES, THE DISTRICT OF COLUMBIA, OR THE COMMONWEALTH OF PUERTO RICO.

CIRCLE ANSWER: (YES)

3. A STATEMENT OF USING PHYSICIAN'S CLINICAL RADIOISOTOPE EXPERIENCE (PAGE 3 OF THIS SUPPLEMENT) IS SUBMITTED IN SUPPORT OF THIS APPLICATION. IF ANSWER IS NO, USE PAGE 2 OF THIS SUPPLEMENT TO EXPLAIN OR REFER TO OTHER APPLICATION OR RELATED DOCUMENTS ON WHICH THIS INFORMATION APPEARS.

CIRCLE ANSWER: (YES)

PROPOSED DIAGNOSIS OR TREATMENT

4. (a) DESCRIBE PURPOSE FOR WHICH BYPRODUCT MATERIAL WILL BE USED INCLUDING SPECIFIC CONDITIONS OR DISEASES TO BE DIAGNOSED OR TREATED (Use page 2 if necessary)

See appendix

(b) CHEMICAL FORM ADMINISTERED

see item 6b, Form 313

(c) DESCRIBE PROCEDURES WHICH WILL BE OBSERVED TO MINIMIZE HAZARD FROM HANDLING, STORAGE, AND DISPOSAL OF THE BYPRODUCT MATERIAL:

See appendix

(d) DESCRIPTION AND SKETCHES OF SPECIAL DEVICES TO BE USED FOR ADMINISTERING BYPRODUCT MATERIAL TO HUMAN BEINGS ARE

(1) ATTACHED (LITERATURE REFERENCES WILL SUFFICE) — CIRCLE ANSWER: YES

(2) ON FILE WITH THE ISOTOPES EXTENSION
REFER TO APPLICATION NO _____ — CIRCLE ANSWER: YES

5. (a) PROPOSED DOSAGE SCHEDULE —In millicuries for internally administered byproduct material other than discrete fixed sources; and in roentgens or rads, as appropriate, for internal or external irradiation from discrete fixed sources (gold seeds, cobalt needles, etc.) state separately for each condition or disea use page 2 if necessary)

^{35}S, Cystine - 5 to 10 microcuries injected intradermally
^{3}H, Thymidine - 5 to 10 microcuries injected intradermally
^{14}C, Testosterone, Corticosteriod - 2 to 5 microcuries, applied topically
^{22}Na, Chloride - 5 to 10 microcuries, injected intradermally
Cyclotron produced; included to show total radionuclide usage.
See, also, appendix

(b) INVESTIGATIVE PROPOSAL FOR EXPERIMENTAL, NEW OR UNUSUAL HUMAN USES IS ATTACHED. (Attachment should include outline of conditions to be evaluated, including data from animal studies and/or abstract of literature reference if any, number and type of patients (i. e. age group, moribund, etc.)) — CIRCLE ANSWER: YES

see appendix

6. IF BYPRODUCT MATERIAL WILL NOT BE OBTAINED IN PRECALIBRATED FORM FOR ORAL ADMINISTRATION OR IN PRECALIBRATED AND STERILIZED FORM F PARENTERAL ADMINISTRATION, DESCRIBE IDENTIFICATION, PROCESSING, AND STANDARDIZATION PROCEDURES:

7. THE PROPOSED USE OF BYPRODUCT MATERIAL HAS BEEN, OR WILL BE, APPROVED BY THE MEDICAL ISOTOPE COMMITTEE. — CIRCLE ANSWER: (YES)

HOSPITAL FACILITIES FOR INDIVIDUAL PRACTICE USE ONLY

8. (a) THE APPLICANT HAS COMPLETED ARRANGEMENTS FOR A HOSPITAL TO ADMIT RADIOACTIVE PATIENTS WHENEVER ADVISABLE. — CIRCLE ANSWER: YES

(b) A COPY OF INSTRUCTIONS TO BE FURNISHED TO THE HOSPITAL AS TO RADIOLOGICAL SAFETY PRECAUTIONS — CIRCLE ANSWER: YES

Form AEC-313 a (10-61) PAGE 3

UNITED STATES ATOMIC ENERGY COMMISSION

APPLICATION FOR BYPRODUCT MATERIAL LICENSE

SUPPLEMENT A—HUMAN USE

Form approved. Budget Bureau No. 38

This page may be completed by the physician's preceptor (if any) in the medical use of radioisotopes. When the information is furnished by the preceptor, the name and present address of the preceptor (if any) should be shown in item 12 below.

9. (a) USING PHYSICIAN'S NAME	(b) NAME AND ADDRESS OF APPLICANT (If different from 9(a))
Albert M. Kligman, M.D.	Albert M. Kligman, Ph.D., M.D.

10. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN WHO WILL USE BYPRODUCT MATERIAL

(A) ISOTOPE	(B) CONDITION(S) DIAGNOSED OR TREATED	(C) NUMBER OF CASES	(D) TYPE OF PARTICIPATION FOR AL IN COLUMN B (circle applicat bers of items in accordance wit forth below)
I-131	Diagnosis of thyroid function		1 2 3 4
	Treatment of hyperthyroidism		1 2 3 4
	Treatment of thyroid cancer		1 2 3 4
	Treatment of cardiac conditions		1 2 3 4
	Brain tumor localization		1 2 3 4
	Blood determinations		1 2 3 4
	Kidney function		1 2 3 4
	Others:		1 2 3 4
P-32 Soluble	Treatment of polycythemia and leukemia		1 2 3 4
	Brain tumor localization		1 2 3 4
	Treatment of bone metastases		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
P-32 $CrPO_4$	Treatment of prostatic cancer		1 2 3 4
	Treatment of cervical cancer		1 2 3 4
	Treatment of pleural effusions and/or ascites		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Au-198 Colloid	Treatment of prostatic cancer		1 2 3 4
	Treatment of cervical cancer		1 2 3 4
	Treatment of pleural effusions and/or ascites		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Cr-51	Blood determinations		1 2 3 4
	Others:		1 2 3 4
			1 2 3 4
Other Isotopes			1 2 3 4
			1 2 3 4
			1 2 3 4

Key to above numbers (column D)

Active Participation and Discussion in the:

1. Examination of patients to determine suitability for radioisotope diagnosis and/or treatment and recommendations on dosage to be pres
2. Collaboration in calibration and administration of dosages including related measurements and plotting of data.
3. Active period of training and experience of sufficient duration to permit followup of patients through treatment and posttreatment period inc reevaluation as to effectiveness and complications.
4. Study and discussion of case histories to establish most efficacious diagnostic and/or therapeutic techniques for this radioisotope use.

11. TOTAL NUMBER OF HOURS OF PARTICIPATION IN CLINICAL TRAINING_____ hours

12. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OR GUIDANCE OF

_____ AT _____ _____

(Name of physician (preceptor)) (Institution) (Signature)

Application for Byproduct Material License

Appendix

Form 313, Item 13, Facilities and Equipment:

The laboratory is a remodelled prison cell containing workbases and laboratory tables. Lead or steel shielding is available for storage of the gamma emitting ^{22}Na.

Tongs and pipetting devices are available. Lab. coats and rubber gloves will be used. Work is performed over trays.

Form 313, Item 14, Radiation Protection Program:

The Holmesburg County Prison established a Medical Isotope Committee in 1963. This Committee reviews and passes upon any project utilizing radionuclides for research and/or in humans. The present membership is:

Albert M. Kligman, Ph.D., M.D.,
Professor of Dermatology at the Univ. of Penna.
(Certified dermatologist)

Herbert W. Copelan, M.D.
Assistant Professor of Medicine at the Univ. of Penna.
(Internist)

The stock radioactivity is stored in closed containers, well labelled, and with shielding if indicated. Doses are prepared by withdrawing a few nucrocuries from the bottle by syringe, using sterile technique for intradermal administration, and administering in the laboratory. The site of administration is then covered with a plastic (Saran Wrap) and the subject returns to duties. Subsequently, measurements are made and subject scrubs site of application at least twice with soap and water. Potentially contaminated materials are collected for decontamination or as waste.

Form 313, Item 15, Waste Disposal:

Most material will appear in subject excreta or wash water and thus to drains. As we will not exceed two to four studies per week, sewer

Application for Byproduct Material License

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Form 313, Item 15, Waste Disposal:

Most material will appear in subject excreta or wash water and thus to drains. As we will not exceed two to four studies per week, sewer

disposal limits of AEC regulations will not be exceeded. Other items, such as old stock bottles, etc. will be washed and either kept as solid waste in a labelled container or checked with suitable monitor and discorded or re-used.

In time, collected solid wastes will be disposed of via commercial service, probably Nuclear Engineering, Inc., or by transfer to one of the large scale radionuclide users in the Philadelphia area for such disposal.

Form 313a, Item 4a,

The materials will be used to study the absorption through the skin by topical application or intradermal injection. Studies are performed in volunteers comprising normal adult males and subjects with pathological skin conditions (also adult males). Subjects will be volunteers (prisoners). The nature of the study will be explained to them. Maximum doses are given in Form 313a, Item 5a. Rarely, up to two repeat studies may be made in the subject separated by at least two weeks.

These studies and the techniques are the same as described in literature references as follow:

Malkinson, F.D., Studies on the Percutaneous Absorption of C^{14} labelled steroids by use of the gas flow cell., J. Invest. Derm. 31:19, 1958

Levan, N.E. et al, Biphasic changes in cutaneous eflective blood flow after U.V. radiation. J. Invest. Derm. 43:451, 1964

The most instances, over half of the material is absorbed rapidly and excreted in from one to two days. ^{3}H Thymidine absorbed will largely go to proliferating cells in the vicinity of the site of application. Some of the material would be expected to slough off in dead skin.

Form 313a, Item 6,

By product material will be obtained in precalibrated and sterilyzed form.

Albert M. Kligman, M.D.