Wayne County General Hospital
Dept of Radiation
2345 Merriman
Westland, Michigan 48185

File under:
Diagnostic Reagents, Inc
Dearborn, MI

March 27, 1980

Mr. Paul Guinn
Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Paul:

Persuant to our conversation of March 25, 1980, I am including this cover letter regarding the importance of the prompt review and approval of this license application. As I stated in our conversation, the application is for a new small company and timing is of utmost importance to them. With this thought in mind, any assistance you could offer in the expeditious handling of this application would be most appreciated.

Sincerely,

L.T. Kosnik

L.T. Kosnik
Consulting Health Physicist

APR 30 1980

Book attachment of Serum
Iron Diagnostic Kit in OIG file

03259

8004240007

DIAGNOSTIC REAGENTS, INC.
1034 Monroe
Dearborn, Michigan 48124

Enclosed please find license application NRC-313-I covering purchase, possession, processing and distribution of byproduct material for certain in vitro clinical or laboratory testing. Attached are Sections 8e, 15, 16 a, b, c, d, and 17, as well as container labels (examples) and product inserts referred to in Section 8e.

Included with the application are checks covering Specific Licensure ($460.00) and Distribution Licensure ($950.00) consistent with licensing fee requirements set forth in 10CFR 170 Section 170.31.

The purpose of this application is to obtain licenses for a new company. The facility and equipment are presently available for manufacturing of the in vitro kits and a long delay in acquiring these licenses would cause a severe financial burden to the new owner. It is estimated that a month of work would be required once the byproduct material is received in the laboratory before any distribution could be done. It would greatly facilitate matters if this new company could obtain the possession part of the license as soon as possible!

For any further information regarding this application, please contact L. T. Kosnik at Wayne County General Hospital, (313) 274-3000, ext. 6066 or ext. 6403, or T. J. Kregoski, (313) 562-6994.

Sincerely,

Thomas J. Kregoski

Thomas J. Kregoski
23212 Hollander
Dearborn, Michigan 48128

Bottle labels

0380

all radioactive symbols in red with yellow background

CAUTION: Radioactive Material Not For Internal Or External Use In Humans Or Animals.

Diagnostic Reagents, Inc.
1034 MONROE, DEARBORN, MICHIGAN 48214 • (313) 561-0204

T_4 (125_I) SECOND ANTIBODY BUFFER

CONTAINS: Buffer With BSA, ANS, Goat Anti Rabbit Gamma Globulin, PEG, and (125_I) T_4 Less Than 10 µci at Calibration With Thimerosal as a Preservative.
Store at 0-5° C

Exp. Date:

Lot No.:

CAUTION: Radioactive Material Not For Internal Or External Use In Humans Or Animals.

Diagnostic Reagents, Inc.
1034 MONROE, DEARBORN, MICHIGAN 48214 • (313) 561-0204

TBG DIAGNOSTIC REAGENT

CONTAINS: Buffer With BSA, (125_I) Labeled Thyroxine Less Than 10.0 µci at Calibration With Thimerosal as a Preservative.

Store at 0-5° C

Exp. Date:

Lot No.:

Diagnostic Reagents, Inc.
1034 MONROE, DEARBORN, MICHIGAN 48214 • (313) 561-0204

T_4 ANTISERUM-T_4 RIA

CONTAINS: BSA Buffer, Rabbit Gamma Globulin, Anti -T-4 Antiserum.

CAUTION: NOT FOR HUMAN CONSUMPTION.
FOR IN VITRO DIAGNOSTIC USE ONLY.

Store at 0-5° C

Exp. Date:

Lot No.:

CAUTION: Radioactive Material Not For Internal Or External Use In Humans Or Animals.

Diagnostic Reagents, Inc.
1034 MONROE, DEARBORN, MICHIGAN 48214 • (313) 561-0204

SERUM IRON DIAGNOSTIC REAGENTS

CONTAINS: Iron ^{59} as Ferric Chloride In a Dilute Acid Solution Less Than 10.0 μci at Time of Calibration.

Store at Room Temperature

Exp. Date:

Lot No.:

CAUTION: Radioactive Material Not For Internal Or External Use In Humans Or Animals.

Diagnostic Reagents, Inc.
1034 MONROE, DEARBORN, MICHIGAN 48214 • (313) 561-0204

T$_3$ UPTAKE DIAGNOSTIC REAGENT

CONTAINS: Tris Buffer, B.S.A. (^{125}I) Labeled Triiodothyronine Less Than 10.0 μci at Time of Calibration.

Store at 0-5° C

Exp. Date:

Lot No.:

Diagnostic Reagents, Inc.
1034 MONROE, DEARBORN, MICHIGAN 48214 • (313) 561-0204

SERUM IRON BUFFER REAGENT

CONTAINS: Sodium Carbonate Buffer

CAUTION: NOT FOR HUMAN CONSUMPTION.
FOR IN VITRO DIAGNOSTIC USE ONLY.

Store at Room Temperature

Exp. Date:

Lot No.:

NRC FORM 218 (4-76) NRCM 0240

U.S. NUCLEAR REGULATORY COMMISSION

TELEPHONE OR VERBAL CONVERSATION RECORD

DATE: 4/17/80

TIME: 1:40 ☐ A.M. ☒ P.M.

☐ INCOMING CALL ☒ OUTGOING CALL ☐ VISIT

PERSON CALLING	OFFICE/ADDRESS	PHONE NUMBER / EXTENSION
M. Silberg L. O'Reilly		

PERSON CALLED	OFFICE/ADDRESS	PHONE NUMBER / EXTENSION
Tom Gregoski	Dearborn, Michigan	313/561-0204

CONVERSATION

SUBJECT: (Application for possession & distribution licenses) for Diagnostic Reagents.

SUMMARY:

I called Mr. Gregoski to ask his relationship between Gamma Analysis Distributing Co., Immuno-Assay Corp. and Diagnostic Reagents Corp.

Mr. Gregoski told us that he had left Gamma Analysis Distributing Co. and Immuno-Assay Corp. and had started his own business enterprise, Diagnostic Reagents Corp. He thought that Mr. Kruse had informed the NRC that he was no longer at IADC and DAC. He will request that his name be deleted from those licenses. He also stated that he would no longer be responsible for any of the operations at IADC and DAC.

Mitzi Silberg

REFERRED TO: Paul Guzzo

☐ ADVISE ME OF ACTION TAKEN.

ACTION REQUESTED

INITIALS

DATE

ACTION TAKEN

INITIALS

DATE

EXPECTED VALUES

Each laboratory should determine its own Normal Ranges based on its own geographical location and patient population. In this laboratory using the Serum Iron Diagnostic Kit, the following statistics were obtained and should be used as a general guide to expected normal ranges:

	TIBC	UIBC	Total Serum Iron	Percent Saturation
N	32	32	32	32
$\bar{X}$	355.1	248	107	31
S.D.	52.9	56.5	16.9	7.2
Normal Range	249-461 ug/dl	135-361 ug/dl	73-141 ug/dl	16.5-45.5 ug/dl

PERFORMANCE CHARACTERISTICS:

Four serum pools were assayed to determine interassy and intra-assay coefficients of variation.

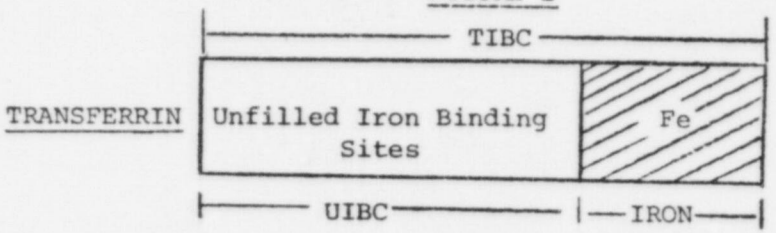
Pool	Mean Value		Intra Assay Variation*		Inter Assay Variation**	
	TIBC	UIBC	TIBC	UIBC	TIBC	UIBC
1	327.5	243.5	1.70	6.0	1.8%	0.98
2	206.9	40.7	4.14	18.9	4.4%	13.10
3	381.4	269.0	2.01	2.9	1.8%	1.00
4	269.8	155.1	3.21	5.4	1.9%	2.70

* Run 12 times within one assay

** Run in duplicate in 6 different assays on 3 different days

There is also a considerable diurnal variation in serum iron levels with the highest values obtained in the morning and up to a 30% decrease by evening.[10] Serial determinations should be drawn at the same time of day to ensure meaningful data. Figure 1 illustrates the relationship of the parameters measured by the Serum Iron Diagnostic Kit.

FIGURE 1



$\frac{\text{Iron}}{\text{TIBC}}$ = PERCENT SATURATION

Nearly all modern tests for iron binding capacity, both colorimetric and radiometric, utilize the reversible nature of the transferrin-iron complex. At low pH (less than 5.0) iron dissociates from transferrin, but will reassociate if the pH is raised to physiological levels.[11,12,13,14,15]

In the Serum Iron Diagnostic Kit, the total iron binding capacity (TIBC) is determined by incubating patient serum with a buffered solution at low pH containing Radiolabeled iron (Fe59). All of the patient iron is dissociated from its transferrin binding sites at this step. A buffered solution at a high pH is then added which causes reassociation of iron to transferrin. Since there is an excess of Iron added in the first step, and since the vast majority was radiolabeled, the entire transferrin pool will be saturated with labeled (and some unlabeled) iron. A secondary binder is added which absorbs any excess unused iron, the tubes are centrifuged, the supernates decanted and the pellets quantitated in a gamma counter. The iron binding capacity is inversely proportional to the amount of labeled iron in the pellet and is quantitated by reference to a standard curve.

PROCEDURE

Warm all reagents to room temperature. The TIBC and UIBC determinations may be run concurrently as follows:

1. Add 1.0 ml of Serum Iron Diagnostic Reagent to each of two 12 X 75 tubes--cap and set aside. (label as total counts tubes)
2. Label two sets of 12 x 75 plastic test tubes (TIBC and UIBC) for standards (in duplicate), controls, patient sera.
3. Pipette exactly 200 ul of sera into the proper tubes for both TIBC and UIBC.
4. Add 1.0 ml of Iron Diagnostic Reagent to each TIBC tube.
5. Add 1.0 ml of Iron Buffer Reagent to each UIBC tube.
6. Vortex all tubes well and let set at room temperature for 5 minutes.
7. Add 1.0 ml of Iron Buffer Reagent to all TIBC tubes.
8. Add 1.0 ml of Iron Diagnostic Reagent to each UIBC tube.
9. Vortex all tubes well and let set at room temperature for 5 minutes.
10. Add one (1) binder tablet to each tube and vortex VERY VERY WELL. Allow the tubes to set for 3 minutes at room temperature. Revortex all the tubes and let set for 3 minutes at room temperature.
11. Centrifuge all tubes at 3,000 x g for 5 minutes.
12. Decant all supernates into sink (observe radiologic precautions) and blot remainder of liquid by gently pressing the mouths of the test tubes against an absorbent pad. Do not shake, tap, or pound the tubes while inverted, or the pellet may dislodge.

Unlike other radiometric assays for iron, the Serum Iron Diagnostic Kit is a rapid, convenient assay and due to its use of external standards, patient results are easy to quantitate. This assay also has advantages over colorimetric assay by requiring less patient serum, by being insensitive to external contamination, and by being unthwarted by hemolytic, icteric, or Lipemic Sera.

REAGENTS

1. Serum Iron Diagnostic Reagent: contains distilled water, dilute HCI and Fe^{59} less than 20uCi. 120ml. Store at 0-5°C. Observe radiologic precautions.
2. Serum Iron Buffer Reagent: Contains 0.05M Sodium Carbonate Buffer. 120ml. Store at 0-5°C.
3. Serum Iron Binder: 105 tablets. Contains organic binder and inert fillers. Store dry at room temperature. Handle with forceps.
4. Serum Iron Standards: 3 vials lyophilized. Reconstitute with distilled water as directed on vials. Contains Human Serum, 0.1% Na N3. After reconstitution, the serum is stable for 24 hours at room temperature, 1 week refrigerated or 3 months frozen. For maximum life after reconstitution, aliquot and freeze. Avoid repeated freezing and thawing.

CAUTION: ALL HUMAN SERUM PRODUCTS SHOULD BE HANDLED WITH CARE, AND CONSIDERED POTENTIALLY DANGEROUS IF MISHANDLED. NEVER MOUTH PIPETTE. ALWAYS WASH HANDS AFTER USE. CLEAN UP SPILLS IMMEDIATELY.

STORAGE & STABILITY

On receipt of the kit, remove the binder and refrigerate the remainder of the contents.* Reagents are stable until expiration date. The entire kit is given the lot number and expiration date of the isotope solution--usually 4-8 weeks from date of shipment.

* It is important that all reagents be allowed to warm to room temperature before use.

SAMPLE COLLECTION

Serum is recommended for this assay. If plasma is used, it must not be collected with EDTA or erroneous results will be obtained. Collect at least 1.0ml of whole blood. Allow to clot and remove serum. Sera should be capped and stored at 0-5°C and assayed as soon as possible. If the sera are to be stored longer than one or two days, they should be frozen. Avoid repeated freezing and thawing.

PRECAUTIONS

NOT FOR INTERNAL OR EXTERNAL USE IN HUMANS OR ANIMALS.
FOR IN VITRO DIAGNOSTIC USE.

This radioactive material may be received, acquired, processed and used only by physicians, clinical laboratories or hospitals and for in vitro clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and the general license of the U.S. nuclear Regulatory Commission or the State with which the Commission has entered into an agreement for the exercise of regulatory authority.

This kit contains radioactive material which should be handled with appropriate precautions in use and disposal. Radioactive solutions should not be pipetted by mouth.

CAUTION: 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.

1. Radioactive material should be stored in specially designated areas not normally accessible for casual use by unauthorized personnel.

2. Radioactive material should be used by responsible persons only in authorized areas. Care should be exercised to prevent ingestion or contact with the skin or clothing. In the event that contact is made with radioactive material, the contaminated areas should be thoroughly washed with detergent.

3. Pipetting of radioactive solutions must not be done by mouth.

4. No smoking, drinking or eating should be allowed in areas where radioactive materials are used.

5. Hands should be washed after using radioactive materials.

6. Work should be carried out on a surface with absorbent materials.

7. Any spills of radioactive material should be cleaned immediately and all contaminated materials disposed as radioactive waste. Contaminated surfaces should be washed with a detergent.

MATERIALS NEEDED BUT NOT SUPPLIED

1. Vortex test tube mixer
2. Dispenser set for 1.0 ml
3. Pipettor for 200 ul volume
4. Centrifuge
5. Forcepts
6. Gamma Counter

ITEM 11, a & b CALIBRATION OF INSTRUMENTS LISTED IN ITEM 10

A. CALIBRATED BY SERVICE COMPANY --Lines 1 & 2

Wayne County General Hospital
Attn: L.T. Kosnik
Department of Radiation
2345 Merriman
Westland, Michigan 48185

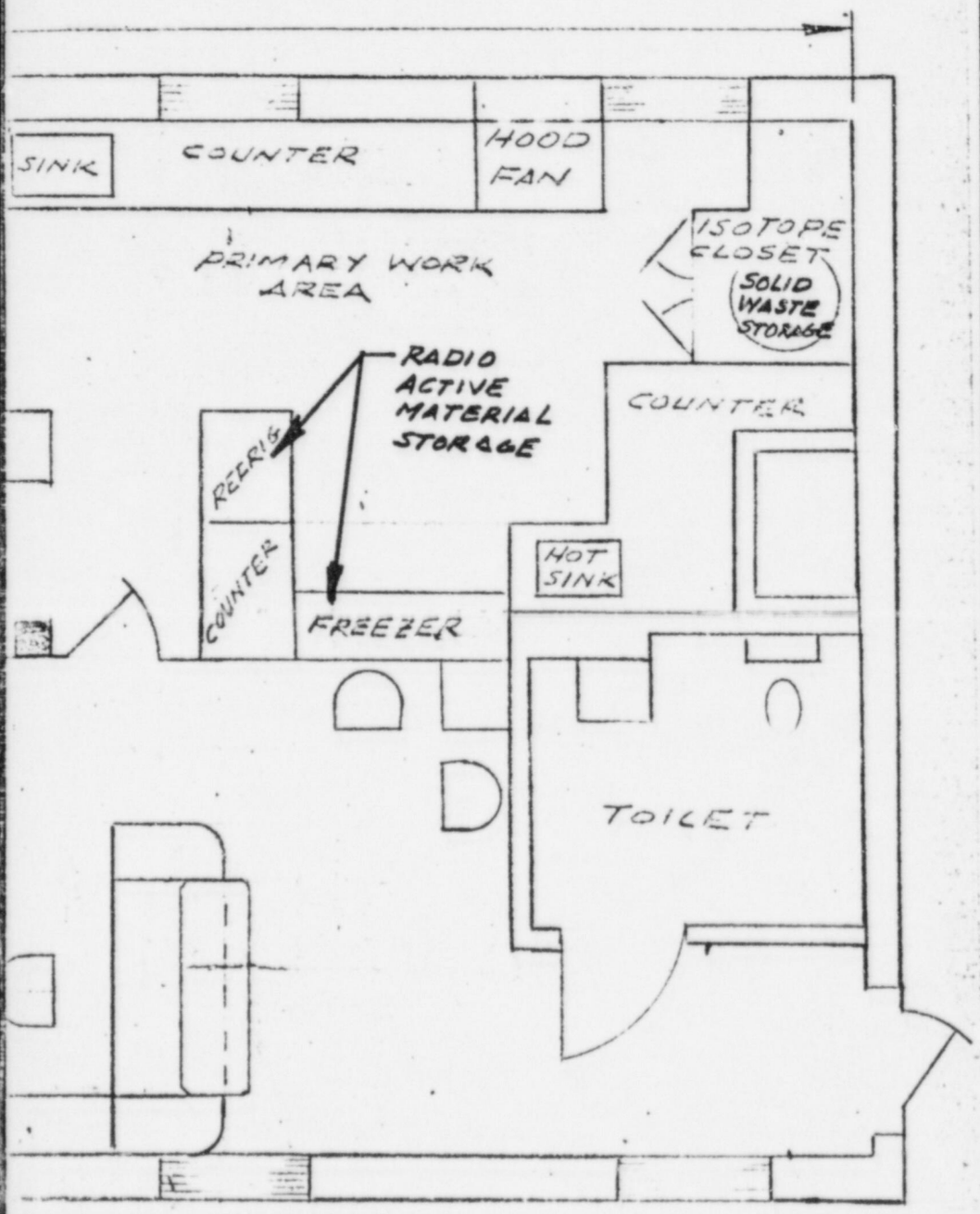
Calibrated at 6 month intervals

B. CALIBRATED BY APPLICANT -- Line 3

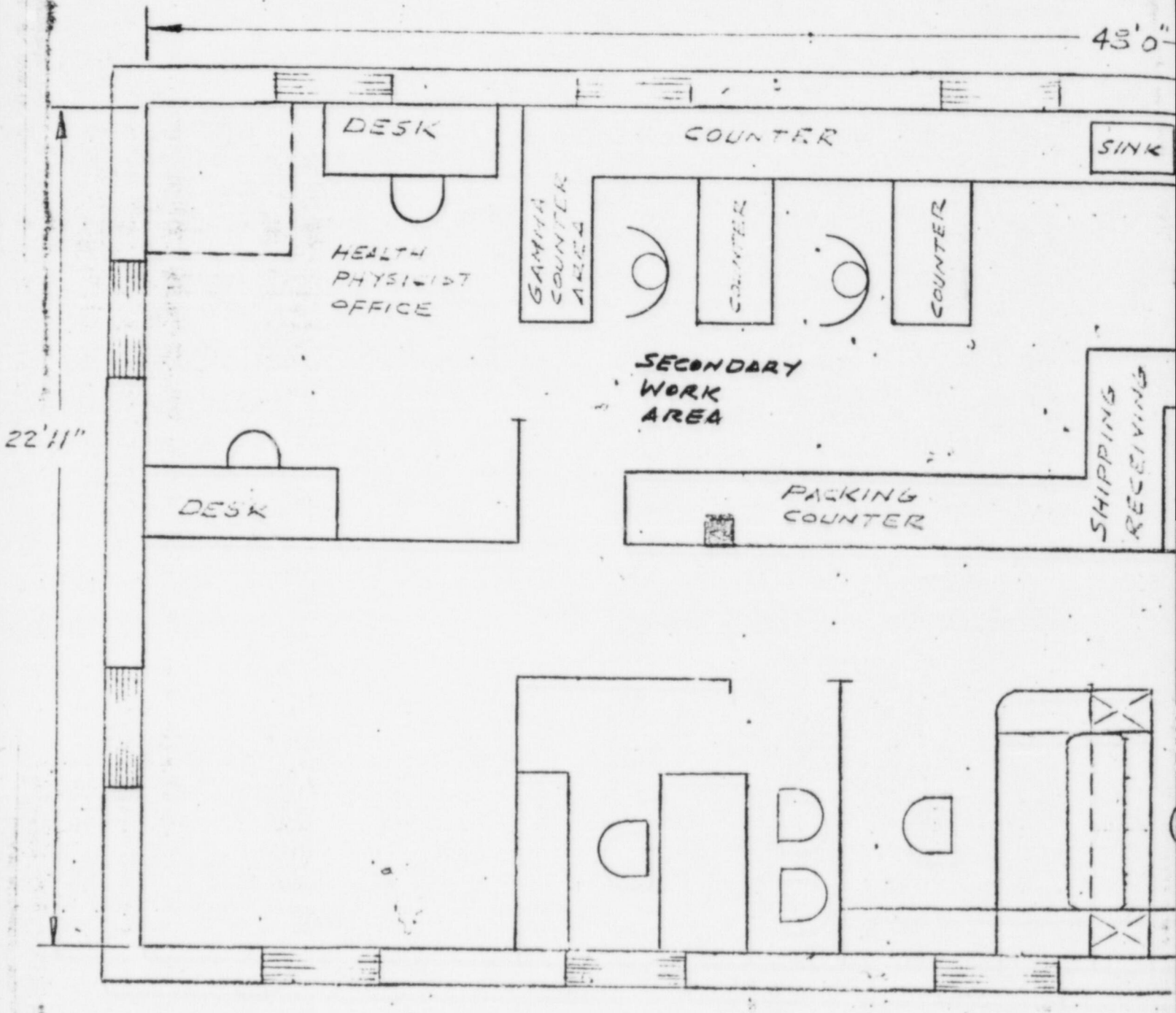
The sodium iodide well counter will be calibrated on a daily basis or before using. A log of the background and I-129 and/or Co-60 will also be kept and any variation of more than 10% will be cause for consultation with the manufacturer.

S., INC.

48124


SINK
COUNTER
HOOD FAN
PRIMARY WORK AREA
ISOTOPE CLOSET
SOLID WASTE STORAGE
RADIO ACTIVE MATERIAL STORAGE
COUNTER
REFRIG
COUNTER
HOT SINK
FREEZER
TOILET

DIAGNOSTIC REAGEN
1034 MONROE
DEARBORN, MICHIGA
(313)



ITEM 15 RADIATION PROTECTION PROGRAM

CONTENTS

ITEM 15, 1. PROCEDURE FOR ORDERING AND RECEIVING RADIOACTIVE MATERIAL

1. Before ordering radioactive material, check to insure that the amount does not exceed your possession limit.

2. All packages are to be sent to: Thomas J. Kregoski
Diagnostic Reagents, Inc.
1034 Monroe
Dearborn, Michigan 48124

3. Persons responsible for receiving packages shall inventory the package as soon as possible after arrival, and no later than three hours after arrival on a normal working day.

4. Incoming packages shall be inspected for leakages, contamination or damage. If a package is damaged, place it on absorbent pad and notify the radiation safety officer.

5. If package is in good condition, place it on an absorbent pad before opening.

6. The surface exposure reading (using the G.M. Survey Meter) should be obtained before opening.

7. Gloves should be worn while opening the package.

8. Packing slips shall be checked against contents.

9. All packing amterial shall be monitored with the G.M. Tube. If the packing material results in only a background reading, the material can be disposed of in the normal trash after the radioactive labels have been crossed out.

10. All shipments shall be logged in on forms provided (See Form 1).

11. Open the inner package to verify contents and integrity of the final source container. Inspect for breakage of seal and vials and loss of liquid or discoloration of packing material.

12. Store the radioactive material in its shielded container in prescribed storage area.

13. Container and areas in which radioactive materials are stored will be properly posted with radiation signs.

ITEM 15, 1.

DIAGNOSTIC REAGENTS, INC.

FORM 1

INVENTORY FOR RADIOACTIVE MATERIAL

Radionuclide:________ VENDOR______________________

Ordered		Received			Disposal			COMMENTS
Date	P.O.	Date	P.O.	Lot#	Date	Use	Lot#	

ITEM 15, 2. PRECAUTIONS TO BE FOLLOWED WHILE HANDLING RADIOACTIVE MATERIAL

A. PERSONNEL INSTRUCTIONS:

1. Film badge, lab coat, and waterproof gloves should be worn while making manipulations involving radionuclides (special care should be taken to avoid contamination of the skin.)

2. Pipetting of radioactive solution by mouth is forbidden.

3. Eating, drinking, smoking, and applying cosmetics in the laboratory shall be forbidden.

4. Hands shall always be washed thoroughly before eating.

5. All radioactive material shall be stored in the original shipping container and in designated areas only.

6. After using radioactive material, personnel shall monitor themselves (hands, body and shoes) with a G.M. probe. Any reading on this monitor above background indicates contamination. If skin is contaminated, washing is necessary until background reading is obtained. If clothing or shoes are contaminated, they shall not be worn until decontaminated. The radiation safety officer shall be informed in all cases of personnel contamination.

7. If any worker has been cut by contaminated glassware or otherwise injured by contaminated materials, he shall immediately be monitored and checked by the radiation safety officer.

8. Contaminated clothing should be stored with the radiation safety officer.

9. All contaminated skin should be flushed thoroughly with water and then washed with mild soap.

10. Copy of our NRC license and 10 CFR part 19 and 20 can be obtained from the Secretary.

11. The NRC Notice to Employees is posted and all personnel are required to read it.

12. Store the radioactive material in its shielded container in prescribed storage area.

13. Container and areas in which radioactive materials are stored will be properly posted with radiation signs.

14. When in doubt, ask the Radiation Safety Officer before proceeding!

B. MINOR RADIOACTIVE MATERIAL SPILLS

Any spilled material should be cleaned up immediately.

1. Confine the spill immediately, by dropping paper towels or other absorbent material onto it.

2. Put on waterproof gloves.

3. Check shoes for visible signs of contamination. If it appears possible that they are contaminated, remove shoes when leaving the contaminated area.

4. Mark off or isolate in some way the entire suspected area and police it to be sure that nobody walks through it.

5. The spilled material should be picked up with absorbent paper and deposited in a waterproof container. After as much as possible has been removed in this way, the surface should be washed with a damp -- not wet-- rag, always working toward the center of the spill. Continue this procedure until a reduction of count rate is less than five times background.

6. Survey (G.M. Probe) the area of the spill and also your hands and clothing.

7. Report the incident to the radiation safety officer.

ITEM 15, 2., cont'd.

C. MAJOR RADIOACTIVE MATERIAL SPILLS

1. Notify all persons not involved in the spill to vacate the room.

2. Cover the spill with absorbent pads.

3. Confine the movement of all personnel potentially contaminated to prevent the spread.

4. Vacate and lock the room.

5. Notify the radiation safety officer immediately.

6. Contaminated clothing should be removed and stored and evaluated by the radiation safety officer.

7. Contamination on the skin should be flushed thoroughly and then washed with mild soap and lukewarm water.

ITEM 15, 3.

SURVEY PROCEDURE

The survey meter must be checked for its battery status, functional integrity. Determine natural background reading in an area where radioactive material is not stored or used. Natural background should be less than 0.1 mr/hr.

Surveys are to be performed when all radioactive materials are in their proper storage areas, usually at the end of the day.

On a floor plan of the laboratory determine the radiation levels of designated work, storage, and floor areas. Record all reading greater than 0.1 mr/hr by writing the meter reading on the floor diagram at its proper location. All areas of the laboratory should have a reading of less than 1.0 mr/hr. Any area that has a reading greater than 2.0 mr/hr must be posted as radiation area and personnel time in that area must be restricted.

In addition the following information shall be recorded: Date of survey, Instrument used, and Name of supervisor.

WIPE TEST

Wipe test should be performed on the same day as the survey. Wipe tests are done by taking filter paper (1" to 2" circle or square) and rubbing a portion of a suspected area (about 100cm^2). A separate piece of filter paper is used for each wiped area. This filter paper is then counted in appropriate instrumentation (liquid scintillation for H-3 or C-14, NaI (TL) well counter for gamma emitters). A background wipe should also be counted along with a filter paper that has been contaminated with about a nanocurie of the radioactive material. All areas in the lab that give a higher than background reading should be wiped (try to locate the source of activity with the survey meter and wipe a portion of the area.) Besides these areas the following areas should be wiped: primary and secondary work areas, refrigerator and door handles and the floor near the door and work areas.

All areas of more than 200 DPM above background should be cleaned. Areas of more than 1,000 DPM are considered contaminated zones and shall be cleaned. If contaminated areas cannot be cleaned they should be covered and avoided. All areas of contamination must be reported to the Radiation Safety Officer. The date of the wipe test is to be recorded on the back side of the survey floor plan.

SURVEY AND WIPE TEST SHOULD BE DONE ON A MONTHLY BASIS.

ITEM 15, 4.

DISPOSING OF RADIOACTIVE MATERIAL

A. LIQUID WASTE:

Liquid radioactive material can be disposed via the sanitary system provided the following requirements are met:

1. Only sinks and drains that have been designated and labeled can be used.

2. The radioactive material must be soluble or dispensible in water.

3. The concentration of the radioactive material should be in the nanocuries per ml in concentration or sufficient water be added to the sink to bring the concentration to this level.

4. Sinks are thoroughly flushed after each disposal.

5. The yearly total of radioactive material is less than 1 curie.

B. SOLID WASTE:

All solid waste which is contaminated with Radioactive material is to be placed in designated labeled waste container.

When it is not known if solid waste is contaminated monitor the waste with NaI (Tl) probe. If readings are greater than 2 times background, consider the waste contaminated.

ITEM 15, 5.

EMERGENCY PROCEDURES

Contact the radiation protection officer: Name and phone number will be available at the secretary's desk.

ITEMS 15, 6. QUALITY CONTROL

Re: Control of quantity of byproduct material contained in each in vitro test kit.

In order to control the activity levels of the in vitro diagnostic kit materials the following checks are made: A standard source is counted to determine the counting efficiency of the instrument. An aliquot (100ul) of each batch of reagent containing byproduct material will be counted prior to packaging.

The following calculation will be done to determine the total activity per kit using the following formula:

$$\frac{\left(\frac{X}{\%E} \times 100\right) \times V}{2.22 \times 10^{6}} = Y \text{ (uci/kit)}$$

Where %E= Counting Efficiency

Where X= cpm/ml of batch solution

Where V= vol. of reagent in kit

5% of the packaged material will be randomly selected and monitored with the NaI (Tl) probe to insure activities below 10 CFR 31.11.

ITEMS 16, 17 FORMAL TRAINING AND EXPERIENCE

CURRICULUM VITAE

Thomas J. Kregoski
23212 Hollander
Dearborn, Michigan 48128

Phone: (313) 562-6994

POSITION OBJECTIVE: Seeking a position in a Management or Independent Research Associate capacity and for a Medical Research or Clinical Laboratory.

PERSONAL DATA: Birth: March 30, 1945; U.S. Citizen; Health: Excellent; Married, One child; 6'0"; 195 lbs.

AREAS OF SPECIALIZATION: I am especially knowledgeable and have provided Consulting services in the following areas:

Protein Separation and Characterization,
Clinical Radioimmunoassay,
In Vitro Allergic Diagnoses.

EXPERIENCE:
1972 to present

Research Associate - 4 Years
Wayne County General Hospital, Research Laboratory
Consultant - Clinical Medicine - 1 Year

Summary: Since 1972, after graduating from the University of Michigan, I have been pursuing my career in the field of Medical Research with emphasis on Clinical Medicine. Also, for two years while attending the University of Michigan, I worked directly for a Research Professor engaged in the formulation and development of a neoplastic growth model with possible application to human cancer.

Currently, I am a Research Associate in a Clinical Laboratory for a major hospital in the Greater Detroit area. Also concurrently, for the past year as a Consultant, I have been providing services on the development of Clinical Assay procedures. In addition, I established a Laboratory for In Vitro Allergic Immunodiagnosis.

As a Clinical Laboratory Research Associate, I have had total responsibility for several projects. Examples were: The evaluation of Pancreatic disease; The study of Hypotension; The culturing of Hepatic cells; and The tissue distribution of Radiopharmaceuticals. I also have had experience formulating and submitting research budgets. In addition, I have an in depth knowledge of the use and application of various Clinical Instrumentation including Gamma and Beta Spectrometers essential in Radioimmunoassay and high pressure liquid Chromatography.

EDUCATION:
College: B.S. in Experimental Biology,
University of Michigan (1971), Ann Arbor, Michigan.

PUBLICATIONS: "Clinical Determination of Methemalbumine", Clinical Chemistry (1974), also presented before The American Chemical Society.

ASSOCIATIONS: Midwest Radioassay Society.

INTERESTS: Enjoy Sailing, Photography, and Camping.

AVAILABILITY: Thirty days, Location open, Travel acceptable.

03259

REFERENCES: Furnished upon request.

ITEMS 16, 17 cont'd

TRAINING AND EXPERIENCE OF THOMAS J. KREGOSKI

1969: A 3-credit-hour course of individual directed studies involving radioactive material was completed at the University of Michigan: Training covering item 16, subitems a, b, c, d, was given by the personnel at the Phoenix Reactor Project in order for the applicant to use Tritium (maximum amount 0.5 mCi) in a research project involving determination of active sites of steroids.

1972-1977: Employed by Wayne County General Hospital, Eloise, Michigan in the department of medicine research division as a Research Associate. Received on-the-job training in sub-items a, b, c, and d of item 16. Radioisotopes of Tritium, Carbon-14, Iodine-125 and Iodine-131 in maximum activities of 3 mCi were used. This training involved clinical as well as in vivo and in vitro animal studies. Experience also involved evaluation and use of clinical radioimmunoassay methodologies as well as consulting in clinical radioimmunoassay to private clinical laboratories.

1977: Accepted the position of Technical Director of Radioassay Systems, Inc. of Southfield, Michigan, and supervised 5 people in the use of byproduct material, as it pertained to the manufacturing and distribution of radioimmunoassay kits for in vitro medical diagnostics. Isotopes used were Iodine-125 (15 mCi) and Iron-59 (2 mCi).

Jan 1978-Feb 1980: Served as President, Radiation Protection Officer, and Licensee for Immuno Assay Corporation. In this capacity, supervised 7 people in the administration of the health physics program as well as the manufacturing and distribution of radioimmunoassay kits for in vitro medical diagnostics. Isotopes used were Iodine-125 (20 mCi) and Iron-59 (10 mCi).

Consulting Health Physicist is available on call--Resume for same follows this page.

January 1980

EMPLOYMENT RESUME

for

LADISLAUS THADDEUS KOSNIK

605 W. Chicago Boulevard
Detroit, Michigan 48202
(313) 868-5182

OBJECTIVE:

A position where my experience, creativity and knowledge may be fully utilized.

EDUCATION:

University of Detroit, Detroit, Michigan
Bacheolor of Science Degree - 1963
Major: Physics
Minors: Mathematics, Chemistry

Wayne State University, Detroit, Michigan
Master of Arts Degree 1967
Major: Physics

Wayne State University School of Medicine
Detroit, Michigan
Doctor of Philosophy 1980
Dissertation: Urinary Polyamine in Radiotherapy Patient
(A method of evaluating cancer treatments)

WORK EXPERIENCE:
1975-1980

Wayne County General Hospital
Westland, Michigan
Position: Radiological Physicist

RESPONSIBILITIES:
Radiation Safety Officer
Monitoring, surveys and calibration of instrumentation and sources of radiation in the Diagnostic X-ray, Nuclear Medicine, Radiation Therapy and Research Departments of the Hospital. Updating State and Federal Licensing Requirement, treatment planning in Radiation Therapy and Radiology instructor for The School of X-ray Technology

Reason to change: Completion of Ph.D. in Physiology.

1969-1975

Wayne State University
School of Medicine
Department of Radiology
Division of Radiological Physics
Position: Research Assistant

RESPONSIBILITIES:
Research associated with the physics of Radiotherapy Techniques and image analysis in Nuclear Medicine. Radiotherapy treatment planning and Physics instructor to X-ray students at Detroit General Hospital.

Reason to change: To avoid conflict of interest in a Ph.D. program.

1967 -1969

Edsel B. Ford Institute for Medical Research
(Henry Ford Hospital) , Detroit, Michigan
Position: Research Assistant

RESPONSIBILITIES:
Research in clinical projects involving radiation as in vivo measurement of fat protein ratio or evaluation of Fluorine-18 as a Bone Scanning Agent. Health Physicist performing wipe test and surveys.

Reason to change: Accept a position which offered more opportunity for advancement.

PROFFESSIONAL MEMBERSHIPS:

Society of Nuclear Medicine
American Association of Physicists in Medicine
Health Physic Society

SALARY:

Negotiable, depending on earning potential and other income considerations.

AVAILABILITY:

July 1980

REFERENCES:

Professional and personal references available upon requests.

BIBLIOGRAPH

PAPERS PUBLISHED:

R. Gastesi, L.T. Kosnik, et al: The Clinical Use of Fluorine-18 in Bone Scanning. Henry Ford Hospital Medical Journal, Vol 7, No 2, 1969

L.T. Kosnik, et al: Some Factors to be Considered in Moving Table Radiotherapy. Journal of Applied Radiation and Isotopes, Vol 22, 1971

L.T. Kosnik, et al: Large Field Telecobalt Therapy with Moving Table: Physical Considerations. Radiology, Vol 104, No 3, 1972

PAPERS PRESENTED:

L.T. Kosnik: The Radioactive Isotope as a Monochromatic Radiation Source for Absorption of Tissue Components. Gatlinburg Isotope Application Conference, A.E.C., 1969

L.T. Kosnik: Simultaneous Analysis of Tissue Components by X and Gamma Rays Using 109 Cd. Society of Nuclear Medicine, 1969

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L.T. Kosnik: An Annular Collimator for Scanners. The Third International Conference on Medical Physics, 1972

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