MEDICAL & SCIENTIFIC DESIGNS, INC.
273 WEYMOUTH STREET
ROCKLAND, MA 02370
(617) 871-4442

December 27, 1982

Material Licensing Branch
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Gentlemen:

Medical and Scientific Designs needs to amend its NRC Materials License No. 20-19999-01 to more accurately reflect recent changes and to anticipate future needs. Specifically, three aspects of our license need to be amended as outlined below:

1. Commercial Distribution of Licensed Material -
We wish to begin distribution within the next few weeks of in vitro diagnostic radioimmunoassay kits utilizing I-125 labeled compounds. Each radioactive unit will contain no more than 10uCi. Attachments A-D contain additional information and requirements as outlined in Sec. 32.71 of CFR Title 10.

2. Laboratory and Storage Facilities -
New construction to be completed soon will create some additional use areas for radioactive compounds not previously discussed in our original license application dated 3-3-82 or amendment application dated 10-28-82. The first floor area originally designated as Limited Access/Warehouse Area is being redesigned as shown in Attachment E to contain our Quality Assurance and Production facilities. Only finished product I-125 labeled compounds ≤10uCi/unit will be used in the QA/Production area. Radiation surveys and swipe testing will be routinely performed to control potential for contamination as discussed in our SOP's attached to our license application. Tracer labeling, bottling, and storage will not be performed in this area but upstairs in the hot lab.

3. Individuals Supervising Use of Licensed Material -
Please add the name of Kenneth L. Hoffman, R&D Group Leader to those responsible for supervision of licensed material. Attachments F and G contain his resume, formal training and experience.

LFMB
1/7/83 *
Jan 3 Amend.
1/26/83
* Held in LFMB pending receipt of additional info. Ltr 1/

FEE EXEMPT
3A fee already paid when 3/3/82 appl. submitted
13442

Your acknowledgment on receipt of this amendment request and prompt processing are greatly appreciated. Correspondence on this matter can be addressed to the undersigned.

Sincerely,

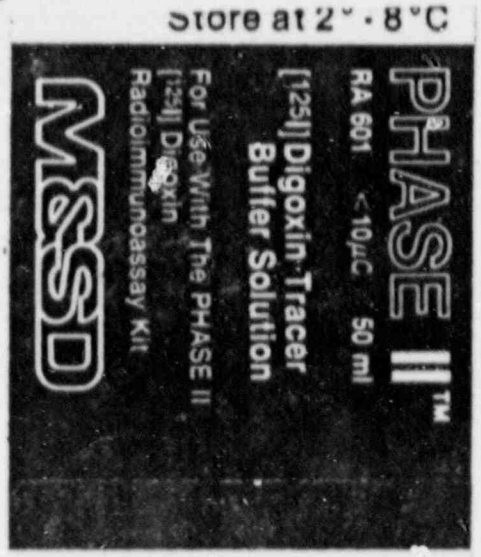
Kenneth L. Hoffman

Kenneth L. Hoffman
Medical & Scientific Designs, Inc.
273 Weymouth Street
Rockland, MA 02370
(617) 871-4442

KLH:lsw

Enclosures

Attachment A Example of bottle label for Tracer compound.



Each vial contains less than 10μC of tracer in phosphate buffered saline with carrier protein, release agents and sodium azide

For In Vitro Diagnostic Use

LOT NO.

EXP.

MEDICAL & SCIENTIFIC DESIGNS, INC.
273 Weymouth Street,
Rockland, MA 02370

magenta lettering and placard
yellow background

Attachment B
Sample label for outside
of Radioimmunoassay Kit box

magenta lettering and placard
yellow background

MSD

Cat. No. RA 501

PHASE II™

[125I] Digoxin Radioimmunoassay Kit

For the quantitative determination of Digoxin levels in serum or plasma

For In Vitro Diagnostic Use

For Use In The KinetiCount 48™ Immunoassay System

MEDICAL & SCIENTIFIC DESIGNS, INC.
273 Weymouth Street, Rockland, MA 02370

MSD

PHASE II™

[125I] Digoxin

Radioimmunoassay Kit

KIT COMPONENTS:

Rabbit Anti-Digoxin Coated SPRs	96
[125I] Digoxin Tracer	50 ml
Digoxin Serum Blank 0 ng/ml	1 ml
Digoxin Serum Standards	
0.5 ng/ml	1 ml
1.0 ng/ml	1 ml
2.0 ng/ml	1 ml
4.0 ng/ml	1 ml

DIRECTIONS FOR USE:

Store at 2°-8°C

LOT NUMBER:

EXPIRATION DATE:

CAUTION RADIOACTIVE MATERIAL

Attachment C

Statements on use, precautions, handling, storage, and waste disposal which will appear in the package insert accompanying each kit.

Radioactive Materials

The Radioactive Material in this kit are 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.

This radioactive material may be received, acquired, possessed, and used only by physicians, clinical laboratories or hospitals and only 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 a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

The user shall store the by-product material until used in the original shipping container or in a container providing equivalent radiation protection.

Handling should preclude any pipetting by mouth.

There should be no smoking or eating while radioactive materials are being handled.

Hands should be covered with rubber gloves during and thoroughly washed after handling of radioactive materials.

Spills should be wiped up quickly and thoroughly and the contaminated materials added to radioactive waste matter.

Water soluble waste radioactive material can be disposed of into the sanitary sewage system, if the concentration, after dilution with the laboratory discharge, does not exceed 4×10^{-2} microcuries per liter (^{125}I) based on a daily average of effluent. Whenever possible, however, disposal of radioactive material should be made through a licensed disposal service.

Licensing Requirements

Medical & Scientific Designs is permitted to transfer the radioactive material in this kit only after receipt of:

1. A copy of the purchaser's NRC or Agreement State Byproduct Material License (NRC Form 374 or State equivalent), or

2. A copy of the Registration Certificate -- In Vitro Testing with Byproduct Material Under General License (NRC Form 483 or State equivalent), or

3. A certificate that the purchaser is in possession of either of these licenses.

Recipients holding a Specific License are reminded that they are subject to the requirements of 10 CFR 19 and 20 which deal with the safe disposal of radioactive waste. General license holders are exempt from these sections.

Attachment D

Other supportive information for commercial distribution amendment.

a. Customer Licenses - All customers or other recipients of our licensed material will be required to submit a copy of their General or Specific Materials Licenses or other assurance that a valid license exists prior to our shipment of such material.

b. Packaging Description - All I^{125} material will be in non volatile chemical form, either liquid or lyophilized in heavy duty glass vials ($\leq$ 10uCi/vial) with rubber stoppers and sealed with an aluminum crimp seal. Bottles are then inserted into preformed foam packing material to further reduce chance of breakage. This package is placed inside the kit box which prior to shipment will be placed inside yet another shipping sleeve or box.

c. Quality Control of Material for Shipment - All licensed material will be quality control checked prior to shipment to insure the units do not contain more than 10uCi and that no outside contamination is present.

Attachment E

Attachment F

Kenneth L. Hoffman

Address:	1180 Brennan Drive, Warminster, Pa. 18974
Date & Place of Birth:	November 20, 1949 Hastings, Nebraska
Marital Status:	Married, ' Child

EDUCATION

M.S. 1976 University of Iowa, Iowa City, Iowa, in Radiobiology from the Radiation Research Laboratory. Thesis research in the area of tumor immunology.

B.S. 1974 University of Iowa, in general science focusing in biochemistry and biology.

Currently matriculated for an MBA from Temple University, Philadelphia, Pa., in Management Science/Operations Research, degree anticipated in 1984.

INDUSTRIAL EXPERIENCE

(Nov. 81 - Present) Micromedic Systems, Inc. R & D Group Leader responsible for development of immunoassay methods and kits. Accomplishments include the successful development of an unconjugated estriol RIA for a fully automated analyzer (Concept -4), a manual unconjugated estriol RIA, and a Digoxin RIA kit.

(1978 - 1981) Micromedic Systems, Inc. Product Support Group Leader in charge of several chemists and technicians, responsible for technical maintenance on existing 18 RIA Kit Products. This job required careful evaluation and formal validation of new protocols and replacement components such as antibodies, antigens, and radiotracers derivatives for the purpose of maintaining or improving the existing product line. Work directly with Marketing's Technical Service group to trouble shoot field problems, coordinate field trials, and redesign assays to better suit customer requirements. Supervised the Antibody Production Group and determined methods of characterization for antisera for both existing and proposed new products. Maintained physical inventory control and responsibility for all basic components such as antibody, raw antigens and conjugated antigens for iodinations and antibody induction. Work with organic synthesis chemist to get materials synthesized. Serve as technical problem solving group for production and assist in designing quality control procedures and specifications. Also successfully performed the development of two new RIA products during this period of time, Insulin and Neonatal T-4.

(1977 - 1978) Micromedic Systems, Inc. Radiolabeling and Antibody Production Chemist. Responsible for development of radiolabeling methods, purification and characterization of tracers with design of quality control test procedures. Started up the company's antibody production facility and supervised immunization, purification and evaluation of antisera.

Kenneth L. Hoffman

INDUSTRIAL EXPERIENCE (Continued)

(1975) University of Iowa. Research Assistant responsible for carrying out research problems on an animal model for cancer of the bowel.

SPECIAL SKILLS & TECHNIQUES

Antibody induction and characterization in various species, tracer radiolabeling chemistries, electrophoresis, isoelectric focusing, affinity chromatography, ion exchange and molecular exclusion chromatography, and various immunodiffusion and other immunochemical methods. Extensive background in instrumentation for radiation detection and health physics monitoring and as a result have been the radiation safety supervisor for Micromedic Systems.

PUBLICATIONS

Identification and Characterization of a Circulating Tumor-Associated Onco-Fetal Protein from a Radiation-Induced Adenocarcinoma of the Rat Small Bowel, Cancer Res. 36:326, 1976.

Blocking of In Vitro Cytotoxicity with X-Irradiation Induced Tumor-Associated Protein, Journal of Immunology, 1978.

ACTIVITIES & Honors

Member Radiation Research Society
Colorado Merit Scholar Award
Vice President and Rush Chairman of Phi Kappa Sigma Fraternity

Attachment G

Formal training and experience of Kenneth L. Hoffman in handling licensed material.

Academic

Master of Science degree in Radiation Biology from the University of Iowa in 1976. Course work contained over 30 semester hours of radiobiology, nuclear and health physics, and research and clinical uses of radiation.

Industrial

1. Served 5 years as Radiation Safety Supervisor for Micromedic Systems Inc. responsible for creating and maintaining their radiation safety program. This facility processed up to 2 Curies/year of I-125 and 100 mCi of Co_{57}.

2. Iodination and Production Support Group Leader performing iodinations which used as much as 50mCi of I-125 at a time. Designed and implemented use of bioassay, air monitoring and sewage monitoring procedures.

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