

MATERIALS LICENSE

Amendment No. 04

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee

1. Immunicon Corporation

2. Building 1310-Masons Mill Business Park II
1800 Byberry Road
Huntingdon Valley, Pennsylvania 19006In accordance with the letter dated
June 28, 1996,3. License Number 37-20963-01 is amended
in its entirety to read as follows:

4. Expiration Date May 31, 2002

5. Docket or
Reference No. 030-221596. Byproduct, Source, and/or
Special Nuclear Material7. Chemical and/or Physical
Form8. Maximum Amount that Licensee
May Possess at Any One Time
Under This LicenseA. Chromium 51
B. Iodine 125A. Any
B. AnyA. 10 millicuries
B. 10 millicuries

9. Authorized use

A. and B. Research and development as defined in 10 CFR 30.4.

CONDITIONS

10. Licensed material may be used only at the licensee's facilities at Building 1310, Masons Mill Business Park II, 1800 Byberry Road, Huntingdon Valley, Pennsylvania.

11. A. Licensed material shall be used by, or under the supervision of, Paul A. Liberti, Chandra Rao Gallo, Ph.D., Anita Cagliyan Hovsepian, Joseph N. Chiarappa, Dhanesh I. Gohel, and Steven Gross.

B. The Radiation Safety Officer for this license is Chandra Rao Gallo, Ph.D.

12. The licensee shall not use licensed material in or on human beings or in field applications where activity is released except as provided otherwise by specific condition of this license.

13. The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash, provided:

A. Radioactive waste to be disposed of in this manner shall be held for decay a minimum of 10 half-lives.

B. Before disposal as normal waste, radioactive waste shall be surveyed to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

37-20963-01

Docket or Reference Number

030-22159

Amendment No. 04

14. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated January 2, 1986
 - B. Letter dated April 28, 1986
 - C. Letter received May 22, 1986
 - D. Application dated June 25, 1991
 - E. Letter dated March 6, 1992
 - F. Letter dated April 1, 1992
 - G. Letter dated June 6, 1996
 - H. Letter dated June 28, 1996
 - I. Letter dated July 18, 1996

For the U.S. Nuclear Regulatory Commission

Original Signed By
James M. Bondick

By

Nuclear Materials Safety Branch
Region I
King of Prussia, Pennsylvania 19406

Date

JUL 30 1996

JUL 30 1996

Paul A. Liberti, Ph.D.
President
Immunicon Corporation
1800 Byberry Road
Huntingdon Valley, PA 19006

Dear Dr. Liberti:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that as part of this amendment, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration date of your license has been extended by a period of five years. Your new expiration date is stated in Item 4 of the license. In addition, the standard license condition for the transportation of radioactive material has been added to your license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

Original Signed By
James M. Bondick

James M. Bondick
Health Physicist
Division of Nuclear Materials Safety

License No. 37-20963-01
Docket No. 030-22159
Control No. 123405

Enclosure:
Amendment No. 04

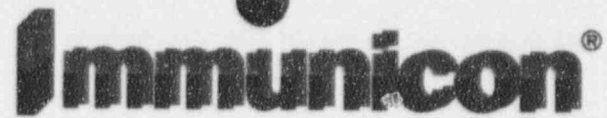
DOCUMENT NAME: R:\WPS\MLDL\L3720963.01

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

| | | | | | | | |
|--------|------------------------|-----|---------|-----|-----|-----|-----|
| OFFICE | DNMS/RI | N | DNMS/RI | | | | |
| NAME | JBondick/jmb <i>JB</i> | | | | | | |
| DATE | 07/18/96 | 07/ | /96 | 07/ | /96 | 07/ | /96 |

OFFICIAL RECORD COPY

ML 10



July 18, 1996

U. S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

VIA FAX: (610) 337-5393

Att: James M. Bondick

Re: Reply to Notice of Violation
Docket No. 030-22159
License No. 37-20963-01
Mail Control 123405

Dear Sir:

In response to your telephone request of today for me to submit to you the names of those people who should be dropped from your records due to the fact that they are no longer employed by Immunicon, I list the following:

William J. Cronin, Ph.D.
Michael Morris
John C. Schisselbauer, Ph.D.

If you need any further information, please do not hesitate to call me.

Sincerely yours,

Paul A. Liberti, Ph.D.
President
Chief Scientific Officer

PAL/ebt

cc: Chandra Rao Galla

OFFICIAL RECORD COPY

ML 10

123405

JUL 23 1996

JUL 18 1996

FAX REC'D



June 28, 1996

030-22159

U. S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

Re: Reply to Notice of Violation
Docket No. 030-22159
License No. 37-20963-01

Dear Sir:

This is to advise you that due to the restructuring that has taken place here at Immunicon personnel changes have taken place, and the following employees are users of radioactive materials, are now performing iodinations and should be on your records:

Chandra Rao Gallo, Ph.D.,
Anita Cagliyan Hovsepian
Joseph N. Chiarappa

All of these individuals have knowledge in the care and usage of radioisotopes, and they also have completed radiation safety training at Immunicon.

You have received Dr. Gallo's credentials, and I now enclose some background information on Anita Cagliyan Hovsepian and Joseph N. Chiarappa.

Mrs. Hovsepian has experience using ^{51}Cr 2mCi and ^{121}I 1mCi here at Immunicon and at Fox Chase Medical Center she had experience with ^{51}Cr 5m Ci and ^{35}S 0.1mCi.

Mr. Chiarappa has nine years experience with ^{121}I and ^{51}Cr , for protein labeling and radio immunoassays, using approximately 4.5 millicuries per year.

Also enclosed is our check in the amount of \$610 to cover the fee for this amendment to previous information sent to your office.

OFFICIAL RECORD COPY

ML 10

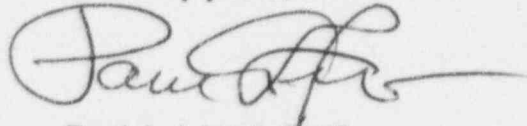
123405

JUL - 5 1996

Please delete the following names from your records:

J. Silvia, Ph.D.
Stephen R. Lee, Ph.D.
R. DeRita, B.S.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Paul A. Liberti", with a long horizontal flourish extending to the right.

Paul A. Liberti, Ph.D.
President
Chief Scientific Officer

PAL/ebt

cc: James M. Bondick

ANITA CAGLIYAN
8112 PINE ROAD
PHILADELPHIA, PA 19111
(215) 728-3538, (215) 342-3467

OBJECTIVE

To secure a challenging position in the Engineering field as a Chemical Engineer with a company which will allow me to advance according to my abilities.

WORK EXPERIENCE

1/89-PRESENT

Fox Chase Cancer Research Center, Philadelphia, PA
Position Held: Research Technician II

Responsibilities: Assisting P.I. in all aspects of laboratory research. Performing tissue assays of all mediated immunity using chromatography and electrophoretic techniques. Supervising day to day operation of the laboratory. Monitoring experimental manipulation of animals for in vivo tumor studies and culturing of normal and tumor cells of human and murine origins .

5/85-12/87

Sifar Ilaclari, Pharmaceutical Manufacturing Company,
Istanbul, Turkey
Position Held: Chemical Engineer-Quality Control Department

Responsibilities: Performing analytical experiments for the chemical and physical aspects of raw material and semi and finished products. Maintaining assurance of quality in all production, process and products of the company.

EDUCATION

Drexel University, Philadelphia, PA

Master of Business Administration-May 1993

University of Istanbul, Istanbul, Turkey

Bachelor of Science in Chemical Engineering-May 1985

References

Available upon request

JOSEPH N. CHIARAPPA

903 Clark Circle
Flemington, N.J. 08822
Home (908) 788-6840
Work (215) 938-0100

BACKGROUND SUMMARY

Nine years of experience in the diagnostic and therapeutic industry. Especially skilled in assay development, product development, protein purification and conjugation, cell biology, and manufacturing related issues including cGMP and FDA compliance.

PROFESSIONAL EXPERIENCE

IMMUNICON CORPORATION, Huntingdon Valley, PA

Developed colloidal magnetic ferrofluids for use as the separation method for automated immunoassays and for the isolation of rare cells and bone marrow purging. Developed protein coating, surface modification, and purification methods for ferrofluids. Developed isotopic and non-isotopic assays for use as QC tools in the manufacture of ferrofluids.

Scientist

1992 - Present

Major Accomplishments

- Developed an ELISA assay for the determination of unbound soluble component which proved essential in the manufacture and quality control of ferrofluids.
- Converted the ferrofluid purification process from magnetic washing to gel filtration chromatography which resulted in favorable particle size decrease and increased yield.
- Determined proper gel filtration media, column size, and load volume to maximize resolution.
- Optimized common capture ferrofluid for negative depletion of B-cell lymphoma in model systems.
- Developed a higher capacity and more stable common capture ferrofluid for immunoassay diagnostics and tumor cell separations.
- Developed red blood cell lysing solution and cell fixing solution.
- Developed a radiolabeled capacity assay for a streptavidin conjugated ferrofluid
- Scaled-up ferrofluid production and transferred process to manufacturing department.
- Wrote all ferrofluid process documentation including specifications, test methods, and operating procedures to bring manufacturing under cGMP and FDA compliance.

JOSEPH N. CHIARAPPA

PROFESSIONAL EXPERIENCE

(continued)

ORTHO DIAGNOSTIC SYSTEMS, INC., Raritan, NJ

Prepared purified antibodies and enzyme conjugates for use in infectious disease testing. Supervised scale-up of reagent manufacturing in clean in place facility.

Group leader/Sr. Immunologist

1989 - 1992

Major Accomplishments

- Purified antibodies for all infectious disease assays by affinity chromatography and HPLC.
- Prepared antibody-HRP conjugates via heterobifunctional chemistry for Hepatitis B, C and HIV ELISA test kits.
- Transferred HIV 1/2 and Hepatitis B surface antigen assays from product development to manufacturing.
- Implemented, maintained, and modified product specifications to comply with FDA guidelines.
- Performed raw material and in-process assays, including radial immunodiffusion, IEF and SDS electrophoresis, for quality control.

TRITON BIOSCIENCES, INC., Tarrytown, NY

Developed and optimized proprietary solid phase materials for use as the separation method on an automated immunoassay system.

Sr. Research Technician

1987 - 1989

Major Accomplishments

- Developed antibody coated, common capture, magnetic particles designed to perform both homogeneous and heterogeneous immunoassays.
- Supervised long term stability studies on all assay components including polyclonal antibodies and enzyme conjugates.
- Scaled up production of magnetic particles and acted as liaison for process transfer from R&D to manufacturing.
- Received Triton Special Performance Recognition Award for solid phase technology research.

EDUCATION

BA, Biochemistry, New York University

1985

MS, Biochemistry, New York University Graduate School of Arts and Science,
Research Topic: Non-Enzymatic Polynucleotide Synthesis

1989

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: 03620
STATUS CODE: 0
FEE CATEGORY: 3M
EXP. DATE: 20020531
FEE COMMENTS: _____
DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

APPLICANT/LICENSEE: IMMUNICON CORP.
RECEIVED DATE: 960705
DOCKET NO: 3022159
CONTROL NO.: 123405
LICENSE NO.: 37-20963-01
ACTION TYPE: AMENDMENT

2. FEE ATTACHED

AMOUNT: \$610.00
CHECK NO.: 0006833

3. COMMENTS

SIGNED
DATE

M. A. Perkins
7/10/96

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED 1/1)

1. FEE CATEGORY AND AMOUNT: 3M 8610

2. CORRECT FEE PAID* APPLICATION MAY BE PROCESSED FOR:

AMENDMENT ✓
RENEWAL _____
LICENSE _____

3. OTHER _____

SIGNED
DATE

B. Brown
7/10/96

| | |
|-----------------|-----------------|
| Log | <u>July 6</u> |
| Remittor | |
| Check No. | <u>0006833</u> |
| Amount | <u>8610</u> |
| Fee Category | <u>3M</u> |
| Type of Fee | <u>Amo</u> |
| Date Check Recd | <u>7/10/96</u> |
| Date Completed | |
| By: | <u>B. Brown</u> |

1996 JUL 15 AM 11:15