ATCC

A global bioscience nonprofit organization dedicated to biological standards and biodiversity

10801 University Boulevard
Manassas, Virginia 20110-2209 USA

Telephone: (703) 365-2700
Facsimile: (703) 365-2701
Internet: http://www.atcc.org/

May 15, 2006

Mr. Dennis Lawyer
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

J-6
45-25425-01
03034650

Mail Control No.: 138467

Dear Mr. Lawyer:

In February of this year we notified Mr. Thompson of a change in the ATCC Radiation Safety Officer (RSO) due to Essala Lowe leaving ATCC and my being appointed as RSO (see enclosed letter from Kristina Peterman). During your review of that request you noted that I do not have hands on experience working with most of the isotopes listed on our license and cannot be accepted as the ATCC RSO.

We have since identified Dr. Marian McKee, a senior scientist at ATCC, and have appointed her ATCC RSO. Enclosed is information from NIH on her training and handling of radioisotopes, as well as her curriculum vitae. Despite the listing of isotopes on our license for the current facility since 1998 we have never purchased or worked with any radioisotopes under this license. Therefore we are requesting that the following isotopes be removed from our license, Chromium 51 and Rubidium 86, and have provided documentation demonstrating that Dr. McKee has experience with the remaining isotopes.

We are also requesting that Dr. Yvonne Reid, also a senior scientist at ATCC, be listed in item 11 along with Dr. McKee. Dr. Reid supervises the use of the sealed source, and apparently was inadvertently removed from our license (see enclosed copy of her prior listing and her curriculum vitae).

Any questions regarding this request should be directed to me as Kristina Peterman, Director of Compliance, is currently out on extended leave.

Sincerely,

Frank P. Simione, V.P.
Management Services

138467

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Manassas, Virginia 20110-2209 USA

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February 21, 2006

Dr. Thomas Thompson
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

Dear Dr. Thompson:

This letter is to inform the Nuclear Regulatory Commission that there has again been a change in the status of the Radiation Safety Officer (RSO) at the ATCC due to Essala Lowe leaving ATCC. We have appointed Frank Simione, VP Management Services, as interim RSO until we have recruited a new Safety Officer with the appropriate RSO training.

Mr. Simione has experience in managing ATCC's Safety program, and has had previous Radiation Safety Officer training. We have not revised our program to include new activities involving work with radioisotopes, and the current activities are limited to use of the sealed source. When the new directions for our scientific programs are in place, we will review our need to use radioisotopes and revise our program, including reassigning the Radiation Safety Officer position to a trained individual.

Any questions or concerns about this change should be addressed to my attention.

Sincerely,

Kristina M. Peterman
Director of Compliance

Marian Little McKee, Ph.D.
Collection/Research Scientist, Bacteriology, ATCC
Curriculum Vitae

EDUCATION

1989 – 1995 Ph.D., Microbiology, Uniformed Services University of the Health Sciences (USUHS), Bethesda, MD

1988 – 1989 Ph.D. Courses (transferred to USUHS), East Carolina University School of Medicine, Greenville, NC

1982 – 1986 B.S., Zoology, Duke University, Durham, NC

PROFESSIONAL EXPERIENCE

2003 – Present Collection/Research Scientist, Bacteriology, American Type Culture Collection, Manassas, VA

1999 – 2003 Staff Scientist, Biotherapy Section, Laboratory of Molecular Biology, Center for Cancer Research, National Cancer Institute, NIH, HHS

Area of Research: Cellular and molecular biology of the interaction of *Pseudomonas* exotoxin A (PE) with eukaryotic cells

Supervisor: David FitzGerald, Ph.D.

1995 – 1999 CRTA Postdoctoral Fellow, Biotherapy Division, Laboratory of Molecular Biology, National Cancer Institute, National Institutes of Health

Area of Research: Cellular and molecular biology of the interaction of *Pseudomonas* exotoxin A with eukaryotic cells

Supervisor: David FitzGerald, Ph.D.

1989 – 1995 Graduate Student, Department of Microbiology and Immunology, USUHS, Bethesda, MD

Area of Research: Adherence of Enterohemorrhagic *Escherichia coli* (EHEC) to eukaryotic epithelial cells

Supervisor: Alison D. O'Brien, Ph.D.

1989 Graduate Research Rotation, Department of Microbiology and Immunology, East Carolina University, Greenville, NC

Area of Research: Preparation and characterization of Newcastle Disease Virus envelopes as liposomal transfection vehicles

Supervisor: Henry O. Stone, Ph.D. (deceased)

1988 Graduate Research Rotation, Department of Microbiology and Immunology, East Carolina University, Greenville, NC

Area of Research: Cloning and expression of heterologous antibiotic resistance genes into *Bacteroides fragilis*

Supervisor: C. Jeffrey Smith, Ph.D.

1987 – 1988 Research Technician, Department of Microbiology, Duke University Medical Center, Durham, NC

Area of Research: Mutagenesis, cloning and sequencing of *Enterococcus (Streptococcus) faecalis* tetracycline resistance

Supervisor: Vickers Burdett, Ph.D.

1986 – 1987 Research Technician, Department of Gastroenterology, Duke University Medical Center, Durham, NC

Area of Research: Autoimmune etiology of inflammatory bowel and Crohn's diseases

Supervisor: James K. Roche, M.D., Ph.D.

1985 – 1986 Undergraduate Research Assistant, Duke University Medical Center, Durham, NC

AWARDS

Technology Transfer Award, Division of Basic Sciences, National Cancer Institute - 1999, 2000, 2001, 2002

Who's Who Among Students in American Universities and Colleges, USUHS - 1994-1995

USUHS Graduate Fellow Research Grant - 1991,1992

EDITORIAL EXPERIENCE

Infection and Immunity (Editorial Board, 2003-2005)

The Journal of Clinical Microbiology (Ad Hoc)

The Journal of Biological Chemistry (Ad Hoc)

Protein Engineering (Ad Hoc)

TEACHING EXPERIENCE

1995 – 2003 NIH Speakers Bureau

1996 Invited lecturer course in Bacterial Pathogenesis
Foundation for Advanced Education in the Sciences (FAES), NIH

1994 Supervised University of Maryland undergraduate student, USUHS

1990 – 1995 Medical Microbiology Teaching Assistant, USUHS

PROFESSIONAL CERTIFICATIONS

Radiation Safety Authorized User (NIH, 2000)

Ethics Training Modules (NIH, current)

Small Animal Handling Training Course (NIH, 2001)

Shipping of Biologic Agents (NIH, 2000)

PROFESSIONAL MEMBERSHIPS

American Society for Microbiology

Association of Women in Science

The American Society for Cell Biology

The Society for Mucosal Immunology

PUBLICATIONS

Yun, C. H., McKee, M. L., and D. J. FitzGerald. 2002. Secretion of enzymatically inactive Pseudomonas exotoxin A from CHO cells: evidence that mammalian cells can mediate folding of this bacterial toxin into a near native conformation. *In preparation*

Mrsny, R.J., Daugherty, A.L., McKee, M.L., and D. J FitzGerald. 2002. Bacterial toxins as tools for mucosal vaccination. Drug Discov. Today 15:247.

Wedekind, J.E., C.B.Trame, M. Dorywalska, P. Koehl, T.M. Raschke, M. McKee, D. FitzGerald, R.J. Collier, and D.B. McKay. 2001. Refined crystallographic structure of Pseudomonas

aeruginosa exotoxin A and its implications for the molecular mechanism of toxicity. J. Mol. Biol. 314:823.

Daugherty, A. L., M. L. McKee, D. J. FitzGerald, and R. J. Mrsny. 2000. Epithelial application of *Pseudomonas aeruginosa* exotoxin A results in a selective targeting to cells in the liver, spleen and lymph node. J Controlled Release 65:297.

McKee, M. L. and D. J. FitzGerald. 1999. Reduction of furin-nicked *Pseudomonas* exotoxin A: an unfolding story. Biochemistry 38:16507.

FitzGerald, D. J., C. M. Fryling, M. McKee, J. C. Vennari, T. Wrin, M. E. M.Cromwell, A. L. Daugherty, and R. J. Mrsny. 1998. Characterization of V3-loop Pseudomonas exotoxin chimeras: candidate vaccines for Human Immunodeficiency Virus-1. J. Biol. Chem. 273:9951.

McKee, M. L. and A. D. O'Brien. 1996. Truncated enterohemorrhagic *Escherichia coli* (EHEC) O157:H7 intimin (EaeA) fusion proteins promote adherence of EHEC strains to HEp-2 cells. Infect. Immun. 64:2225.

McKee, M. L., A. R. Melton-Celsa, R. Moxley, D.H. Francis, and A. D. O'Brien. 1995. Enterohemorrhagic *Escherichia coli* (EHEC) O157:H7 requires intimin to colonize the gnotobiotic pig intestine and to adhere to HEp-2 cells. Infect. Immun. 63:3739.

McKee, M. L. and A. D. O'Brien. 1995. Investigation of enterohemorrhagic *Escherichia coli* O157:H7 adherence characteristics and invasion potential reveals a new attachment pattern shared by intestinal *E. coli*. Infect. Immun. 63:2070.

O'Brien, A. D., A. R. Melton, C. K. Schmitt, M. L. McKee, M. L. Batts, and D. E. Griffin. 1993. Profile of *Escherichia coli* O157:H7 pathogen responsible for hamburger-borne outbreak of hemorrhagic colitis and hemolytic uremic syndrome in Washington. J. Clin. Microbiol. 31: 2799.

Donnenberg, M. S., S. Tzipori, M. L. McKee, A. D. O'Brien, J. Alroy, and J. B. Kaper. 1993. The role of the *eae* gene of enterohemorrhagic *Escherichia coli* in intimate attachment in vitro and in a porcine model. J. Clin. Invest. 92: 1418.

Smith, C. J., M. B. Rogers, and M. L. McKee. 1992. Heterologous gene expression in *Bacteroides fragilis*. Plasmid 27:141.

Schmitt, C. K., M. L. McKee, and A. D. O'Brien. 1991. Two copies of Shiga-like toxin II-related genes common in enterohemorrhagic *Escherichia coli* strains are responsible for the antigenic heterogeneity of the O157:H$^-$ strain E32511. Infect. Immun. 59:1065.

Little, M. E. and J. K. Roche. 1988. Shared and unique determinants on human and murine intestinal epithelium as established by monoclonal antibodies. Mol. Immunol. 25:275.

PATENTS

Stewart, C. N., M. L. McKee, A. D. O'Brien, M.R. Wachtel. Method of stimulating an immune response by administration of host organisms that express intimin alone or as a fusion protein with one or more other antigens. Issued July 17, 2001. No. 6,261,561.

Stewart, C.N., M. L. McKee, A. D. O'Brien, and M. R. Wachtel. Plants and plant cells expressing histidine tagged intimin. Issued June, 18, 2002. No. 6,406,885.

FitzGerald, D. J, R. M. Mrsny, M. McKee, and A. Daugherty. Transepithelial transport of *Pseudomonas* Exotoxin A. Filed May 2001.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

Frank Simione, V. P.
Management Services
ATCC
10801 University Blvd.
Manassas, VA 20110-2209

MAY 10 2006

Dear Sir:

This is to verify that Dr. Marian McKee. (SSN# [redacted] successfully completed the requirements for the course, RADIATION SAFETY FOR AUTHORIZED USERS on October 18, 1999, presented by the Radiation Safety Branch, Division of Safety, National Institutes of Health. She was approved as an Authorized User by the Radiation Safety Committee on January 4th 2000.

As an Authorized User (AU), Dr. McKee, was approved to procure and supervise the use of radioactive materials. The AU also takes on the responsibility to instruct and supervise laboratory workers in the proper and approved safe handling of radioactive materials and the approved laboratory practices to keep personnel radiation exposures as low as reasonably achievable. Other responsibilities of the AU include routine laboratory monitoring, and complying with all regulations governing the use of radioactive materials and laboratories as established by the Nuclear Regulatory Commission and the NIH Radiation Safety Office.

Dr. McKee, also successfully completed the entry level course, "Radiation Safety in the Laboratory," (RSL) presented by the Radiation Safety Branch on September 20,1995 and the required Radiation Safety refresher class on November 18th, 1997. Completion of this course satisfies the minimum NIH radiation safety requirements for individuals working with radioactive materials under the supervision of an Authorized User.

Attached are copies of the various course's outlines and as originally requested; Dr. McKee's materials handling records.

If further information is needed please contact me.

Matthew de Leon
Training Office
Division of Radiation Safety
National Institutes of Health
(301) 496-2255

PERSONAL INFORMATION WAS REMOVED
BY NRC. NO COPY OF THIS INFORMATION
WAS RETAINED BY THE NRC.

RADIATION SAFETY FOR AUTHORIZED USERS

COURSE OUTLINE

I. COURSE OVERVIEW
- A. Structure
- B. Handouts
- C. Quizzes
- D. Homework
- E. Lab Sessions
- F. Staff and guest lectures
- G. Examination

II. INTRODUCTION
- A. Welcome by Branch Chief and NIH Radiation Safety Officer
- B. Overview of program

III. RADIATION AND RADIOACTIVITY-- I,II, and III
- A. Atomic and Nuclear Structure
  1. atoms, protons, neutrons electrons, Z,A
  2. isotopes, nuclides
  3. nuclear reactions
  4. ionization and ionizing characteristics
- B. Radioactivity and Radioactive Decay
  1. alpha, beta,gamma, X-rays, neutrons
  2. specific activity
  3. half-life, exponential decay
- C. Production of Radioactivity
  1. internal conversion
  2. orbital electron capture
  3. positron decay
  4. Bremsstrahlung
- D. Other Sources of Radiation
  1. natural radioactivity
  2. accelerators
  3. non-ionizing

E. Interaction of Radiation with Matter
    1. energy loss mechanism
    2. linear energy transfer (LET)
    3. compton effect
    4. pair production
    5. attenuation

F. Quantities
    1. curie, specific activity
    2. international units

G. Units
    1. Roentgen
    2. rad, rem

IV. RADIATION DETECTORS, MEASUREMENT AND APPLICATIONS -- I AND II

A. Differentiated from analytical instruments
    1. solid phase
    2. gas phase
    3. liquid phase

B. Differentiated from passive detectors

C. Counting versus disintegration rate

D. Gas ionization
    1. ionization chamber
    2. proportional counter
    3. Geiger-Mueller (G-M)counter

E. Principles of operation

F. Sensitivity

G. Amplification, ion multiplication

H. Energy dependence

I. Efficiency; CPM vs. DPM

J. Accuracy

K. Resolving time; recovery time; lost events

L. Suitability for specific common radionuclides

M. Sources of false positive and false negative errors

N. Types and uses at NIH
    1. instruments
    2. smear techniques
    3. NIH Video
    4. advantages and disadvantages

V. PERSONNEL MONITORS AND MONITORING
- A. Various types of external exposure monitoring and operational characteristics
  1. film badges
  2. pocket dosimeters
  3. solid-state (TLD)
- B. Selection of types and how to wear
- C. Sensitivity and sources of error
- D. Internal exposure monitoring
  1. bioassay
  2. body counting
  3. criteria for requesting bioassay and body counting
- E. NIH personnel exposure experience
  1. external
  2. internal
- F. RSB criteria for major and minor investigations of positive bioassays or FB readings

VI. INTERNAL DOSIMETRY -- I AND II
- A. Routes of entry
- B. Determinants of what gets retained and what doesn't
- C. Methods of calculation internal absorbed dose
- D. U.S. and ICRP standards for limiting internal exposure
- E. Example problems

VII. INTERNAL RADIATION HAZARDS AND CONTROLS AND EMERGENCY PROCEDURES
- A. Definition
- B. Principal routes of entry
  1. inhalation route -- Iodination procedures, etc.
  2. ingestion route
  3. absorption route
  4. puncture route
- C. Controls on internal exposures
- D. Contamination monitoring techniques
  a. survey video
- E. Laboratory survey requirements
  1. explanation of radionuclide lab survey requirement
     a. permissive vs. mandatory lab surveys
     b. routine vs. specialized lab survey
        i. monthly surveys, by authorized user
        ii. daily-when-used surveys, by users
        iii. contractor surveys
        iv. health physicist surveys

c. requirements for reporting and record retention

F. Decontamination procedures

G. What qualifies as an "emergency" at NIH

H. Situations likely to have the greatest potential over exposures in biomedical environments

I. Procedures under emergency situation
   1. life-support vs. contamination removal/control
   2. limiting the spread of contamination
   3. contamination removal
   4. sources for assistance

J. Emergencies involving internal exposure
   1. influences on uptake and retention
   2. uptake estimation
   3. treatment

K. Experience with specific radionuclides

L. Reporting requirements
   1. NIH
   2. NRC

VIII. EXTERNAL RADIATION HAZARDS AND CONTROLS AND EMERGENCY PROCEDURES

A. Definition

B. Protection methods time, distance, shielding
   1. inverse square law
   2. specific gamma ray constant
   3. half-value layer
   4. external exposure from beta emitters
   5. range of betas in various materials

C. Sample calculations for various sources of external exposure

D. Emergencies involving external exposure

E. Experience with incidents

F. Reporting requirements to NIH and NRC

G. X-ray producing equipment

IX. BASIC MECHANISMS OF RADIOGENIC BIOEFFECTS
- A. History of radiogenic bioeffects recognition
- B. Dose-response characteristics
  1. direct, indirect
  2. ionization, excitation
  3. chemical and biological changes
  4. radiosensitivity
- C. Somatic Effects
  1. Prompt effects; mechanism of induction
     a. acute radiation syndrome
     b. blood changes
     c. GI, CNS
  2. Delayed effects; mechanism of induction
     a. carcinogenesis
     b. leukemia
     c. life shortening
     d. cataracts
- D. Genetic Effects
  1. risks
  2. individual versus population
- E. Teratogenic effects
- F. Coping mechanisms (repair processes)
- G. Extrapolations into the low-dose region

X. EPIDEMIOLOGY OF RADIOGENIC BIOEFFECTS
- A. Human study populations of interest
- B. Discussion of site-specific cancer mortality findings
- C. Key factors considered in radioepidemiologic studies
  1. duration of follow-up
  2. age at exposure
  3. gender
  4. type of radiation
  5. route of exposure
  6. dose
  7. dose rate
  8. organ exposed
  9. cofactors

PART III -- LIQUID SCINTILLATION COUNTING WORKSHOP
PART IV -- MONTHLY SURVEY OF A USER LABORATORY
A. Contractor survey form
B. Monthly laboratory survey from

XV. RSB DATABASE COMPUTER SYSTEM

XVI. NIH ADMINISTRATIVE PROCEDURES
A. Authorized user structure; user registration
B. Radiation Safety Training
C. Administrative aspects of bioassay program, FB program
D. Limits on activities taken to user labs; protocols
E. NIH radionuclide inventory
F. Monthly status report : untrained users; bioassay requests

XVII. SHIPPING AND RECEIVING
A. Placing orders for radionuclides
B. How radioactive materials are received at NIH
C. Contamination and contents checking
D. Delivery to labs or storage in Bldg. 21
E. Procedure for shipping to another license

XVIII. REGULATIONS, GUIDES, POLICIES
A. Distribution of regulatory functions over which agencies
B. Code of Federal Regulations
1. 10 CFR 19, 20, 35
2. pertinent provisions
3. training requirements for human users
C. Guides
1. NRC regulatory guides
a. instructions concerning risk (8.29)
b. prenatal risk (8.13)
c. applications for medical use programs (10.8)
2. NCRP, ICRP, other similar publications
D. Policies

1. NRC licenses held by NIH
2. Radiation Safety Guide

XIX. NIH Cyclotron and Irradiators
- A. Cyclotron Operation
  1. Products
  2. Hazards
- B. Irradiator Operation
  1. Types and Sources
  2. Hazards

XX. Radiology
- A. X-ray sources
  1. Election Microscopes
  2. X-ray diffraction units
  3. Fluoroscopes
  4. Dental units
  5. Radiographic units
  6. Particle accelerators
  7. Cabinet X-ray units
  8. CT Scanners
- B. Hazards and Protection

XXI. AUTHORIZED USER RESPONSIBILITIES
- A. Chain of command
  1. Radiation Safety Committee (RSC)
  2. Radioactive Drug Research Committee
  3. NRC inspections
- B. Delegation of user supervision responsibilities
  1. grounds for suspension
  2. legal liability
  3. authorization scheme
- C. Remedies in the event of a breach

XXII. FINAL EXAM (2 HOURS TYPICAL)

National Institutes of Health
Division of Radiation Safety, ORS

Radiation Safety in the Laboratory Course

Building 21, Room 237
9am - 12pm

Time	Subject
9:00	Announcements & Introduction
9:00-10:15	General Health & Safety Requirements General Radiation Safety Video (15 min) General Practices and Prohibited Practices Specific Radiation Safety Requirements Internal/External Precautions Monitoring Surveys Utilization/Disposal Records Radioactive Material Purchase, Transfer, & Storage DRS Protocols NIH Security Policy
10:15-10:25	**Break**
10:25-11:30	Specific Radiation Safety Requirements cont. PET Research Contamination Control Video (6 min) Spills, Accidents, & Incidents Clearance Procedures Risks/Bioeffects/Exposure Limits NIH Fetal Protection Policy Lost Radioactive Material Radioactive Waste Policies and Procedures Waste Management Video (12 min)
11:30-12:00	Exam

ARCHIVE USAGE FOR A USER

05/10/2006 **FROM :** 01/01/1994 **TO :** 01/01/2006

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MATERIALS USAGE FOR A USER

FROM : 01/01/1994 **TO :** 01/01/2006

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MATERIALS LICENSE

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. American Type Culture Collection	3. License number 45-25425-01
2. 10801 University Boulevard Manassas, Virginia 20110-2209	4. Expiration date March 31, 2008
	5. Docket No. 030-34650 Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Carbon 14	A. Labelled Compounds	A. 74 megabecquerels (MBq) [2 millicuries (mCi)]
B. Chromium 51	B. Labelled Compounds	B. 296 MBq (8 mCi)
C. Hydrogen 3	C. Labelled Compounds	C. 1.85 gigabecquerels (50 mCi)
D. Iodine 125	D. Labelled Compounds	D. 37 MBq (1 mCi)
E. Phosphorus 32	E. Labelled Compounds	E. 370 MBq (10 mCi)
F. Rubidium 86	F. Labelled Compounds	F. 74 MBq (2 mCi)
G. Sulfur 35	G Labelled Compounds	G. 370 MBq (10 mCi)
H. Cesium 137	H. Sealed source (ORNL Model RAMCO-50)	H. 15.56 terabecquerels (420 curies)

9. Authorized Use:

A. through G. Biological research on viruses, microbes, or cultured cells. No human or live animal use is authorized.

H. To be used for irradiation of materials, except explosive and flammable materials, in an Isomedix, Inc. Gammator 50B Irradiator (Formerly Radiation Machinery Corporation) as specified in the device's Sealed Source and Device Registration Certificate issued by NRC pursuant to 10 CFR 32.210 or by an Agreement State.

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CONDITIONS

10. Licensed material may be used at the licensee's facilities located at 10801 University Boulevard, Manassas, Virginia.

11. Licensed material shall only be used by, or under the supervision of Debra Boles, Ph.D., Charles Buck, Ph.D., Tchaw-Ren Chen, Ph.D., Robert J. Hay, Ph.D., Patrick R. McClintock, Ph.D., Larry L. McDaniel, Ph.D., Robert Niermen, Ph.D., or Yvonne Reid, Ph.D.

12. The Radiation Safety Officer for this license is Robert J. Hay, Ph.D.

13. A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by NRC under 10 CFR 32.210 or by an Agreement State.

    B. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration prior to the transfer, a sealed source received from another person shall not be put into use until tested.

    C. Sealed sources need not be tested if they are in storage, and are not being used. However, when they are removed from storage for use or transferred to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source or detector cell shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

    D. The leak test shall be capable of detecting the presence of 0.185 kilobecquerels(kBq) (0.005 microcuries (μCi)) of radioactive material on the test sample. If the test reveals the presence of 0.185 kBq (0.005 μCi) or more of removable contamination, the licensee shall immediately remove the source from service, report to the Nuclear Regulatory Commission according to 10 CFR 30.50(b)(2) and (c)(1), and have the source decontaminated, repaired, or disposed of according to Commission regulations. The licensee shall file a written report according to 10 CFR 30.50(c)(2).

    E. Tests for leakage and/or contamination shall be performed by persons specifically licensed by the Commission or an Agreement State to Perform such services. In addition, the licensee is authorized to collect leak test samples but not perform the analysis; analysis of leak test samples must be performed by persons specifically licensed by the Commission or an Agreement State to perform such services.

14. Sealed sources containing licensed material shall not be opened or sources removed from the self-shielded irradiator by the licensee, except as specifically authorized by license condition.

15. The licensee shall conduct a physical inventory at interval not to exceed 6 months to account for all sources and/or devices received and possessed under the license.

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16. Except for maintaining labeling as required by 10 CFR Part 20 or 71, the licensee shall obtain authorization from NRC before making any changes in the sealed source, device, or source-device combination that would alter the description or specifications in the respective Certificates of Registration issued either by the Commission pursuant to 10 CFR 32.210 or by an Agreement State.

17. The licensee shall not repair, remove, replace, or alter any of the following: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, or any component that may affect safe operation of the irradiator. These activities shall be performed by a person specifically licensed by the Commission or an Agreement State to perform such services.

18. 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 ordinary trash, byproduct material shall be surveyed at the container surface with the appropriate meter set on its most sensitive scale and with no interposed shielding to determine that its radioactivity cannot be distinguished from background. All radiation labels shall be removed or obliterated; and

    C. A record of each disposal permitted under this License Condition shall be retained for 3 years. The record must include the date of disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

19. The licensee is authorized to transport licensed material only in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

20. A. The licensee is exempted from decommissioning financial assurance requirements for possession of licensed material in sealed sources in quantities greater than the limits in 10 CFR 30.35 for the purpose of source changes only. This exemption is granted for no more than 30 days for any one source change.

    B. In addition to the possession limits in Item 8 and except as permitted by Condition 20.A., the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.

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21. The licensee may not possess and use materials authorized in Items 6, 7, and 8, until:

    A. the licensee has constructed facilities and obtained the equipment described in the application and supporting documentation; and

    B. the U.S. Nuclear Regulatory Commission, Region II, ATTN: Chief, MLIB1, Atlanta Federal Center, 61 Forsyth Street, S.W., Suite 23T85, Atlanta, Georgia 30303, has been notified in writing that activities authorized by the license will be initiated.

22. In accordance with the requirements set forth in 10 CFR 30.36(b), the licensee shall promptly notify the Nuclear Regulatory Commission, in writing of a decision not to complete the facility, acquire equipment, or possess and use authorized material.

23. 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 U.S. 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 29, 1998

    B. Letters dated:

    1) February 6, 1998 [Facsimile regarding additional information to support application (Maryland License]
    2) February 11, 1998 [Facsimile regarding additional information to support application (Maryland License)
    3) March 12, 1998 [Facsimile regarding additional information to support application]
    4) March 18, 1998 [Clarification of information regarding maintenance and ATCC Safety Program Section]

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

DAVID J. COLLINS

Date MAR 2 0 1998

By David J. Collins

Region II, Division of Nuclear Materials Safety
61 Forsyth Street, S.W., Suite 23T85
Atlanta, Georgia 30303

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Curriculum Vitae		
NAME **Yvonne A. Reid, Ph.D.**	POSITION TITLE **ATCC Collection Scientist**	ADDRESS **10801 University Boulevard** **Manassas, VA 20110**

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE	YEAR(s)	FIELD OF STUDY
Howard University, Washington, D.C.	Ph.D.	1985	Zoology

Grants and Contracts:

1986 – 1988; Co-Principal Investigator; Hybridoma Bank contract (NO1-A1-95-11), National Institutes of Allergy and Infectious Disease (NIAID), Bethesda, MD

1989 – 1990; Co-Principal Investigator; Microbiological Associates Subcontract, NCI-CP-1029-5, for the transformation of lymphocytes, and extraction of DNA from lymphocytes.

1994 – 1995; Principal Investigator; McKesson Bioservices subcontract, MBS-35157-02 under N01-A1-35157 (NIH-AIDS and Reference Reagent Program) on the "Immortalization and Expansion of B Cells."

1997 – 2001; Principal Investigator; NCI contract, RFQ No. 70039-NS, "Establish Cell Cultures and Extract Nucleic Acids (DNA, RNA) for Studies of BRCA1, BRCA2, ATM and other Gene Markers in Cancer Incidence."

2003 – Present; Principal Investigator; NCI Contract, N01-CP-31004-50, entitled "Procurement of DNA, RNA, Transformed Lymphocytes, and Lymphoblastoid Lines for Genetic Studies."

2006 – 2009; Principal Investigator: LRF Mantle Cell Lymphoma Cell Bank; sponsored by the Lymphoma Research Foundation.

Positions and Honors:

Served as a Faculty member for the training course on "Culture Collection and Animal Cell Technology", held at the Sino-Danish Post-Graduate Training Center, October, 1992, Beijing, China.

Convener of the Vertebrate Workshop on "Current Issues Facing Tissue Culture Collections in the New Millennium" – SIVB World Congress on In Vitro Biology Meeting, San Diego, CA., June 10-1,2000.

Served as a member of "Bioanalysis Thinkshop" sponsored by NIST and IRMM (Institute for Reference Materials and Measurements), April 2-4, 2003, Geel, Belgium.

Elected for the position of Board Member-at-Large for the Society for In Vitro Biology for 2002-2004.

Participated as a speaker at the "Complete Cell Culture: A Practical Approach" 10th Annual Course, October 10, 2004, The Johns Hopkins Medical Institutions, Baltimore, MD. Title of presentation: Authentication and Characterization of Animal Cell Lines.

Member of the Program Committee, SIVB World Congress on In Vitro Biology Meeting, Baltimore, MD, June, 2005.

Membership: Society for In Vitro Biology (SIVB); American Association for Cell Biology (AACR); American Association of Tissue Banks (AATB)

Advisory Committee:
Served as an advisory at the Developing QC Materials for Genetic Testing Workshop sponsored by CDC, NIST, NIH and FDA, November 8-9, 2004, Los Angeles CA.

Currently serving as an Ad Hoc member of the Comparative Medicine Review committee, National Center for Research Resources (NCRR), NIH.

B. Selected peer-reviewed publications (in chronological order).

1. Reid, Y.A., Hamburger, A.W. Biosynthetic radiolabeling and immunoprecipitation of monoclonal antibodies. J. of Tissue Culture Methods 8: 137-139, 1983.
2. Hamburger, A.W., Reid, Y.A., Pelle, B., Milo, G.E., Noyes, I., Krakauer, H. and Fuhrer, J.P. Isolation and characterization of a monoclonal antibody specific for epithelial cells. Cancer Res. 45: 783-790, 1985.
3. Hamburger, A.W., Reid, Y.A., Pelle, B.A., Breth, L.A., Beg, N., Ryan, U. and Cines, D.B. Isolation and characterization of monoclonal antibodies reactive with endothelial cells. Tissue and Cells 17: 451-459, 1985.
4. Reid, Y.A., Cour, I.M. Cryopreservation of hybridomas. Journal of Tissue Culture Methods, 9: 163-165, 1985.
5. Bremner, T.A., Reid, Y.A. and Harrington, D. Superoxide dismutase and peroxidase are coordinately regulated in differentiated and transformed tissue of Nicotoana tabacum Differentiation 28: 200-204, 1985.
6. Weinblatt, A.; White, C.P., Reid, Y.A., Caputo, J.L. Ability of human melanoma cells to function as accessory cells for mitogen-induced human T-cell proliferative responses. International Congress of Immunology, 1986, Toronto, Canada.
7. Mann, D.L., Gilbert, D.A., Reid, Y.A., Popovic, M., Read-Connole, E., Gallo, R.C., Gazdar, A.F. and O'Brien, S.J. On the origin of the HIV Susceptible Human CD4+ cell line H9. AIDS Research and Human Retroviruses 5: 253-255, 1989.
8. Gilbert, D.A., Reid, Y.A., White, C., Hay, R.J. and O'Brien, S.J. Identification of human cell lines through use of DNA hypervariable probes. Amer. J. Hum. Gen. 47: 499-514, 1990.
9. Caputo, J., Thompson, A. Reid, Y. McClintock, P.R. and Hay, R.J. An effective method for establishing Human B lymphoblastic cell lines using Epstein-Barr virus. J. Tissue Culture Methods 13: 39-44, 1991.
10. Hamburger, A.W., Mehta, D., Pinnamaneni, G., Chen, L.C. and Reid, Y.A. Density dependent regulation of epidermal growth factor receptor expression. Pathobiology 59: 329-334, 1991.
11. Hay, R.J.; Reid, Y.A.; McClintock, P.R.; Chen, T.R., Macy, M.L. Cell Line Banks and Their Role in Cancer Research. Journal of Cellular Biochemistry Supplement 24:107-130 (1996).
12. Hay, R.J., Reid, Y.A., Miranda, M.G. 1996. Advances in Methodologies for Metazoan Cell Line Authentication. In: RA Sampson, JA Stalpers, D vander Mei, and AH Stouthamer (eds.)
13. Hay, R.J.; Reid, Y.A.; Miranda, M.G.; Chen, T.R. 1997. Current Techniques for Cell Lines Authentication, Biotechnology International, pgs. 143-147.
14. Harty, L.C., Garcia-Closas, M., Rothman, N., Reid, Y.A., Tucker, M.A. Hartage, P. Collection of Buccal Cell DNA using Treated Cards. Cancer Epidemiology, Biomarkers and Prevention. 9: 501-506, 2000.
15. Hay, R.J., Cleland, M.M., Durkin, S., Reid, Y.A. Cell Line Preservation and

Authentication in "Animal Cell Culture," J.R.W. Masters (ed.) J. Wiley, Inc. New York, 2000.
16. Hay, R.J.; Cleland, M. M.; Durkin, S.; and Reid, Y.A.: Cell Line Preservation and Authentication in "Animal Cell Culture," J.R.W. Masters (ed.), J. Wiley, Inc., Oxford University Press, New York City, 2000.
17. Masters, J.R.W., Thomson, J.A., Daly-Burns, B., Reid, Y.A., Dirks, W., Packer, P., Toji, L.H., Ohno, T., Mizusawa, H., Arlett, C.F., Kelland, L.R., Harrison, M., Virmani, A., Ward, T.W., Debenham, P.C. STR Profiling for Human Cell Lines: The Basis of an International Reference System to Avoid Misidentification. Proc. Natl. Acad. Sci, USA, 98(4): 8012-8017, July 2001.

18. Feigelson, H.S., Rodriquez, C., Robertson, A.S., Jacobs, E.J., Calle, E.E., Reid, Y.A., Thun, M.J. Determinants of DNA Yield and Quality from Buccal Cell Samples Collected with Mouthwash. Cancer Epidemiol. Biomarkers Prev. 10(9):1005-1008, 2001.
19. Steinberg, K.K., Beck, J., Nickerson, D., Hayes, R., Gallagher, M., Caggana, M., Reid, Y., Cosentino, M., Ji, J., Johnson, D., Earley, M., Lorey, F., Hannon, H., Sampson, E. DNA Banking for Epidemiologic Studies: Epidemiology, 13(3):246-254, May 2002.
20. Selvan SR, Cornforth AN, Rao NP, Reid YA, Schiltz PM, Liao RP, Price DT, Heinemann FS, Dillman RO. Establishment and characterization of a human primary prostate carcinoma cell line, HH870. Prostate. 1;63(1):91-103, Apr 2005.