NRC FORM 374
(7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 16

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.

301750

Licensee	In accordance with letter dated November 4, 1996
1. American Radiolabeled Chemicals	3. License Number 24-21362-01 is amended in its entirety to read as follows:
2. 11624 Bowling Green Drive St. Louis, MO 63146	4. Expiration Date November 30, 2002
	5. Docket or Reference No. 030-20567

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. Any	A. 300 curies
B. Calcium-45	B. Any	B. 5 curies
C. Chlorine-36	C. Any	C. 0.1 curie
D. Chromium-51	D. Any	D. 0.1 curie
E. Hydrogen-3	E. Any	E. 7,000 curies
F. Iodine-125	F. Any	F. 1 curie
G. Iodine-131	G. Any	G. 0.1 curie
H. Phosphorus-32	H. Any	H. 10 curies
I. Phosphorus-33	I. Any	I. 10 curies
J. Sulfur-35	J. Any	J. 20 curies
K. Any byproduct material listed in Subitems A. through J. above	K. Solid waste	K. See Item 9.K. below
L. Iron-59	L. Prepackaged units	L. 0.1 curie
M. Strontium-89	M. Prepackaged units	M. 0.1 curie

9. Authorized Use:

A. through J. To be used in the manufacturer and synthesis of radiolabeled chemicals for distribution to persons authorized to receive the licensed material under the terms of a specific license issued by the Commission or an Agreement State.

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number 24-21362-01

Docket or Reference Number 030-20567

Amendment No. 16

K. Possession incident to interim storage of waste in accordance with statements, representations and procedures contained in letter dated July 26, 1994.

L. and M. For redistribution to persons authorized to receive the licensed material under the terms of a specific license issued by the Commission or an Agreement State.

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 11612 Bowling Green Drive, 11624 Bowling Green Drive, and 11633 Bowling Green Drive, Street.

11. Licensed material shall be used by, or under the supervision of, the Radiation Safety Committee, Donald W. Soldan, Chairman.

12. The Radiation Safety Officer for this license is Donald W. Soldan.

13. This license does not authorize commercial distribution of licensed material to persons generally licensed pursuant to 10 CFR Part 31 or to persons exempt from licensing pursuant to 10 CFR 30.18.

14. Licensed material shall not be used in or on human beings.

15. The licensee is authorized to hold radioactive material with a physical half-life of less than 90 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.

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

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number 24-21362-01

Docket or Reference Number 030-20567

Amendment No. 16

16. The licensee shall not store licensed material contained in waste for more than three years from the date the waste is put into storage. The licensee shall maintain records which indicate the date that licensed material contained in waste is put into storage.

17. The licensee shall be audited by the independent third party indicated in application dated December 4, 1990, quarterly. The third party audit reports shall be submitted concurrently to NRC and ARC management. The scope of the audit shall not be revealed to the licensee in advance of the audit. If ARC's performance continues to be acceptable, and no notification of unacceptable performance is received by ARC from NRC staff, the requirement will be annual audits after the first year under the renewed license.

18. The licensee's independent audit report referenced in Section 3.5 of the ARC Audit Plan attached to letter dated January 11, 1991 shall include the independent auditor's recommendations and/or observations.

19. The Radiation Safety Officer shall have the authority to stop any operation which he deems to constitute a threat to health and safety or violates the license or NRC regulations.

20. The licensee shall limit compaction of radioactive waste to a maximum activity of 2 curies per compaction operation.

21. The licensee shall continuously monitor the exhaust air from the waste compactor at the point of release to unrestricted areas. Samples shall be collected and analyzed on a weekly basis.

22. The licensee shall maintain records of information important to safe and effective decommissioning at 11624 Bowling Green Drive, St. Louis Missouri per the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.

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 October 1, 1992.

    B. Letter dated October 7, 1992.

    C. Letter dated October 14, 1992 (referencing RSO commitments and training commitments for Jeffery Vollmer).

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number 24-21362-01

Docket or Reference Number 030-20567

Amendment No. 16

23. (Continued)

D. Letter dated October 14, 1992 (referencing sealed sources).

E. Letter dated October 20, 1992 (with attachments).

F. Letter dated October 29, 1992 (with attachment).

G. Letter dated November 10, 1992 (with attachment).

H. Letter dated February 26, 1993 (excluding Item A).

I. Letter dated September 9, 1993.

J. Letter dated September 24, 1993 (excluding reference to Sodium-22).

K. Letter dated January 19, 1994 (excluding references to liquid effluent discharge reduction program and Decommissioning Funding Plan).

L. Letter dated May 11, 1994 (excluding references to liquid effluent discharge reduction program).

M. Letter dated July 26, 1994.

N. Letter dated March 6, 1995.

O. Letter dated April 10, 1995.

P. Letter dated May 18, 1995.

Q. Letter dated November 10, 1995.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date Nov 13, 1996

By Evelyn F. Weiss
Nuclear Materials Licensing Branch, Region III

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 03214
Status Code: 0
Fee Category: 3B
Exp. Date: 20021130
Fee Comments: SUSPENDED 1/11/90
Decom Fin Assur Reqd: Y

R9

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: AMERICAN RADIOLABELED CHEMICALS
   Received Date: 960813
   Docket No: 3020567
   Control No.: 301750
   License No.: 24-21362-01
   Action Type: Amendment

2. FEE ATTACHED
   Amount: 0
   Check No.: 0

3. COMMENTS

Signed D. Hersey
Date 8-23-96

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered ✓)

1. Fee Category and Amount: 3B $580

2. Correct Fee Paid. Application may be processed for:
   Amendment ✓
   Renewal
   License

3. OTHER

Signed SC
Date 9/11/96

Log Aug 12 III
Remitter
Check No. 4521
Amount $580
Fee Category 3B
Type of Fee AMD
Date Check Rec'd 9/11/96
Date Completed 9/11/96
By: SC

SEP 16 1996

1996 AUG 26 AM 11:20

ARC
American Radiolabeled
Chemicals Inc.

11624 Bowling Green Dr.
St. Louis, MO 63146
Toll Free 800-331-6661
314-991-4545
FAX: 314-991-4692
Telex: 9102404101

Saturday, August 10, 1996

Mr. John R. Madera
Division of Nuclear Materials Safety
U. S. Nuclear Regulatory Commission, Region III
801 Warrenville Road
Lisle, IL 60532-1357

Dear Mr. Madera:

Reference: U. S. NRC license number 24-21362-01
Docket Number 3020567

Thank you for renewing the above-referenced license for 5 years. We would like clarification from you on the following subjects:

1. Annual third party audits: We would like this condition removed from the new license.

Amendment number 9, Condition 17, of the above-referenced license states in part, "The quarterly Third party audits may be discontinued November 1, 1993 if agreed to by Region III based on acceptable performance, however annual audits shall be performed for the duration of the license." We understand this to mean that we have only one more audit required before our old license would have expired.

However, Steve Green who has been conducting the annual audits, has moved out of state and is now working in the Boston, MA, area. Please let us know whether or not NRC can remove this condition without the last audit. If not, we will try our best to convince Steve Green to perform the audit or look for another auditor.

2. Routine NRC inspections: We would like our inspection frequency changed to every 3 years.

When searching our license file for documents related to the above audit requirement, I came across a status report from James M. Taylor to the Commissioners dated October 20, 1992. This report states in part, "The requirement for quarterly third-party audits will continue and, if ARC's performance continues to be acceptable, the requirement will be changed to annual audits after the first year under the renewed license. In addition, the inspection frequency will be modified to an annual inspection for each of the first 3 years of the license period instead of once every 3 years, as defined by Inspection Manual Chapter 2800."

November, 1995, was the end of the first 3 years of the license period. Are we correct when we assume that our inspection frequency has reverted to every 3 years and that our next inspection will not be due until November, 1998? Please respond by letter or FAX.

Sincerely,

AMERICAN RADIOLABELED CHEMICALS, INC.

Donald W Soldan

Donald W. Soldan
Radiation Safety Director

cc: Surendra K. Gupta, Ph.D., President
RSC members

Certified: P522 160 116

PM: 8-10-96 30/750

DATE: 8-16-96

CORRESPONDENCE CLARIFICATION SHEET

REVIEWER: ~~John Madera~~ [redacted] Madera

LICENSEE: ARC

LICENSE NUMBER: 24-21362-01

The following correspondence has been received from the above licensee and it is not clear what action(s) is(are) required: Please review this correspondence and indicate which of the following applies, and please return to Debbie Hersey, as soon as possible.

☐ Additional Information to Control No. ____ _____.
Process in as a new action, additional information, and no fee required.

☐ Process as new licensing action. Review has already been started on Control No._____ and this information cannot be combined with current in-house action.

☐ Can be combined with Control No. _____. Review has not been started.

☒ Appears to be a(n) Amendment ⇒ Please Assign to Dixie Matson

☐ Appears to be information for the license file - file it.

☐ Licensee is adding Nuclear Pharmacists.
Amendment is necessary _____. Amendment is not necessary ____.
(Information for license file)

☐ Licensee is adding authorized users.
A check is included _____. No check is included ____.
Amendment is necessary _____. Amendment is not necessary ____.
(Information for the license file)

☐ Other:_____

Thank You For Your Help!!! 02/02/95

NRC FORM 577
(1-95)

U.S. NUCLEAR REGULATORY COMMISSION

LICENSE FEE REQUIREMENTS

LICENSE FEE AND DEBT COLLECTION BRANCH
DIVISION OF ACCOUNTING AND FINANCE
OFFICE OF THE CONTROLLER
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

AMERICAN RADIOLABELED CHEMICAL, INC.
ATTN: DONALD W. SOLDAN
RADIATION SAFETY DIRECTOR
11624 BOWLING GREEN DR.
ST. LOUIS, MISSOURI 63146

TYPE OF ACTION

- ☐ NEW LICENSE
- ☐ RENEWAL OF LICENSE
- ☒ AMENDMENT TO LICENSE

REQUESTED DATE: 8-10-96

LICENSE NUMBER: 24-21[illegible]-01

CONTROL NUMBER: 301750

I. APPLICATION FEE DUE

Your request for a licensing action is subject to the fee(s) in the category(ies) noted below in accordance with Section 170.31 of the enclosed Federal Register notice. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
3B	$	$	$ 580.00
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

FEE(s) DUE	$ 580.00
PAYMENT RECEIVED	$ 0.00
AMOUNT DUE	$ 580.00

☒ Your request was received without the prescribed application fee.

☐ We received your Check No. _____ in the amount of $ _____. Payment of the additional fee noted above is required.

☐ Your request will increase the scope of your license program. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Your license expired prior to the receipt of your application for renewal. Therefore, your request is subject to the application fee(s) noted above. Refer to Section 170.31 and Footnote 1(a).

MAKE PAYMENT OF THE FEE(S) TO THE U.S. NUCLEAR REGULATORY COMMISSION AND MAIL THE PAYMENT TO THE ADDRESS LISTED AT THE TOP OF THIS FORM. IF WE DO NOT RECEIVE A REPLY FROM YOU WITHIN 30 CALENDAR DAYS FROM THE DATE LISTED BELOW, WE SHALL ASSUME THAT YOU DO NOT WISH TO PURSUE YOUR APPLICATION AND WILL VOID THIS ACTION.

II. FEE NOT REQUIRED

☐ Enclosed is Check No. _____ which accompanied your request. The fee is not required because:

- ☐ We received your Check No. _____ in payment of the fee.
- ☐ The Licensing staff has informed us that your request is to be considered as a continuation of your request dated _____, Control No. _____.
- ☐ Your request was combined, prior to review, with your _____ request, Control No. _____.

III. CHECK RETURNED

☐ Enclosed is Check No. _____ which was returned to us by the bank for:

- ☐ INSUFFICIENT FUNDS
- ☐ ACCOUNT CLOSED
- ☐ OTHER

MAIL THE REPLACEMENT CHECK TO THE ADDRESS LISTED AT THE TOP OF THIS FORM AND REFERENCE THE ABOVE CONTROL NUMBER.

IV. LICENSE ISSUED WITHOUT THE REQUIRED FEE

☐ License No. _____, Amendment No. _____, issued on _____ was issued without the required fee being collected. The fee required is noted in Section I of this form.

☐ The scope of your licensed program was increased. Therefore, your request is subject to the application fee(s) noted in Section 1 of this form. Refer to Section 170.31 and Footnote 1(d)(2).

☐ Because of the urgency of your request, the license was issued without remittance of the prescribed fee noted in Section 1 of this form.

SIGNATURE – LICENSE FEE ANALYST	LFDCB	LFDCB
SHIRLEY CRUTCHFIELD	8/28/96	

Distribution: OC/DAF/RF
Pending Fee File — OC/DAF/SF(LF-3.2.7)
LFARB R/F (2) — Region 3

DATE: Aug. 28, 1996

NRC FORM 577 (1-95)

This form was electronically produced by Elite Federal Forms, Inc.

NOV 19 1996

Donald Soldan
Radiation Safety Director
American Radiolabeled Chemicals
11624 Bowling Green Drive
St. Louis, MO 63145

Dear Mr. Soldan:

Enclosed is Amendment No. 16 amending your NRC Material License No. 24-21362-01 in accordance with your request.

Please note that per your request dated November 4, 1996, we have approved Donald Soldan as the Radiation Safety Officer. We have not reviewed or approved the other requests contained in that letter. In addition, our preliminary review suggests that Ronald R. Gaddis may not have sufficient formal training and experience with health physics. Please submit any additional information on the approximate number of hours he has received training in a) radiation physics and instrumentation, b) radiation protection principles, c) mathematics pertaining to the use and measurement of radioactivity, and d) radiation biology. When responding to this request, state that it is additional information to control no. 301750.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office so that we can provide appropriate corrections and answers.

Please be advised that your license expires at the end of the day, in the month, and year stated in the license. Unless your license has been terminated, you must conduct your program involving byproduct materials in accordance with the conditions of your NRC license, representations made in your license application, and NRC regulations. In particular, note that you must:

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.

2. Notify NRC, in writing, within 30 days:

   a. When Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or

   b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).

301750

3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license:

   a. When you decide to terminate all activities involving materials authorized under the license; or

   b. If you decide not to complete the facility, acquire equipment, or possess and use authorized material

4. Request and obtain a license amendment before you:

   a. Change Radiation Safety Officers;

   b. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;

   c. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or

   d. Change ownership of your organization.

5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

In addition, please note that NRC Form 313 requires the applicant, by his/her signature, to verify that the applicant understands that all statements contained in the application are true and correct to the best of the applicant's knowledge. The signatory for the application should be the licensee or certifying official rather than a consultant.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Policy and Procedures for NRC Enforcement Actions, 10 CFR Part 2, Appendix C. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when

dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
Evelyn R. Matson
Nuclear Materials Licensing Branch

License No.: 24-21362-01
Docket No.: 030-20567

Enclosure: Amendment No. 16

DOCUMENT NAME: M:\03002567.CL6
To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure **"E"** = Copy with attachment/enclosure **"N"** = No copy

OFFICE	DNMS/RIII									
NAME	EMatson									
DATE	11/13/96									

OFFICIAL RECORD COPY

American Radiolabeled
Chemicals Inc.

11624 Bowling Green Dr.
St. Louis, MO 63146
Toll Free 800-331-6661
314-991-4545
FAX: 314-991-4692
Telex: 9102404101

Monday, November 4, 1996

Ms. Evelyn R. Matson
Nuclear Materials Licensing Branch
U. S. Nuclear Regulatory Commission, Region III
801 Warrenville Road
Lisle, IL 60532-4351

Dear Ms. Matson:

Reference: License Number 24-21362-01
Docket Number 030-20567
Control Number 301750

The purpose of this letter is to provide you additional information requested in your letter dated October 15, 1996, and to inform you that Mr. Karl A. Parks is resigning as Radiation Safety Officer for American Radiolabeled Chemicals, Inc.

First, with regard to the additional information you requested, we offer the following:

Internal audit program at American Radiolabeled Chemicals, Inc., (ARC).

1. The purpose of the audits:

   Internal audits are conducted at ARC to determine compliance with applicable NRC, DOT and other Federal, State and local regulations and the conditions and provisions of the ARC license. Any findings or observations made during the audits will be recorded and made a part of the minutes of the Radiation Safety Committee (RSC) so the committee may act upon the findings or observations.

   We define a finding as the discovery of an item of noncompliance with the above regulations or with the conditions and provisions of the license. An observation made by the auditor is not an item of noncompliance but is a suggestion which may improve the quality of the radiation protection program.

2. The methods of conducting the audits (record review, direct observations, etc.):

   Audits are conducted by reviewing records and by making direct observations of operations.

3. The names and qualifications of auditors:

   Internal audits will be conducted by Mr. Donald W. Soldan, Radiation Safety Director. Prior to his current position, Mr. Soldan was identified in the license as the Radiation Safety Officer.

4. The scope of audits. Audits should include:

   A. A general description of topics to be audited.
   B. An overall assessment of program and the success of its operationalization.
   C A review of RSO activities and effectiveness.
   D. A review of the audits/observations conducted by the RSO of personnel.

   The scope of the audits will include items A through D above.

5. Reports to top management and the Committee of audit findings and recommendations of auditor:

   Dr. Surendra Gupta, the president of ARC, is the management representative on the Radiation Safety Committee. As mentioned in Item 1 above, findings or observations made during the audits will be recorded and made a part of the Radiation Safety Committee minutes. Dr. Gupta will receive the audit report as part of the RSC minutes.

6. A discussion of the follow-up actions to be taken as a result of audit findings and the timeliness of corrective actions.

   Follow-up actions taken as a result of audit findings and the timeliness of corrective actions will be included as part of the next quarterly RSC meeting.

Second, with regard to resignation of the Radiation Safety Officer, we offer the following:

Resignation of Mr. Karl A. Parks as Radiation Safety Officer

On October 31, 1996, ARC received a letter of resignation from Mr. Karl Parks. He gave Thursday, November 14, 1996, as his last effective day of employment. Karl will then take a job unrelated to radiation safety or work with radioactive materials.

Effective November 14, 1996, we hereby request that Mr. Donald Soldan be reinstated as Radiation Safety Officer on an interim basis. Mr. Soldan plans to return to St. Louis from his residence in Arizona while the NRC is in the process of approving another individual as Radiation Safety Officer.

We have found a possible replacement for Mr. Parks. Dr. Ronald R. Gaddis has been working for ARC as a part-time consultant since the first week of February, 1996. He therefore is familiar with our facilities and operations. His initial experience with radiation and radioactive materials dates back 24 years when he was in the U. S. Army. Since that time he has worked with ^{14}C, ^{3}H, ^{35}S or ^{32}P at the University of Kansas, the University of Missouri, Marion Merrill Dow, and St. Louis University. Please refer to his attached resume.

As time permits, we plan to have Dr. Gaddis work with Karl Parks during Karl's last 2 weeks with ARC in order to learn the radiation safety Standard Operating Procedures unique to ARC. After that, he will work with Mr. Soldan for an additional 2 week period to complete his training as RSO.

Please advise us if this plan meets with your approval since Dr. Gaddis must also give notice to his present employer.

Included for your information is an excerpt from the Radiation Protection Program which outlines the duties and responsibilities of the Radiation Safety Director and the Radiation Safety Officer for ARC. Should you need any additional information, please contact me at the above telephone number.

Sincerely,

AMERICAN RADIOLABELED CHEMICALS, INC.

Donald W Soldan

Donald W. Soldan
Radiation Safety Director

cc: Surendra K. Gupta, Ph.D., President
RSC members

Certified: P522 160 123

RONALD R. GADDIS

118 Conway Cove
St. Louis.MO 63017
Home: (314) 519-0058 • Office: (314) 981-0902

Cardiovascular Pharmacologist with over 20 years experience in the safe use and handling of radionuclides for research in the areas of biocehmistry, physiology, and pharmacology to understand cardiovascular disease. Excellent interpersonal and communication skills with an emphasis on Customer Service. Highly motivated with strong desire to acheive goals.

SIGNIFICANT ACCOMPLISHMENTS

- Graduated with Honors with Ph.D. in Pharmacology and Toxicology.
- Wrote, submitted, and was awarded research grant from 04/04/84 - 03/31/97, for $200,102.00. NIHLB1-RO1-HL31219-01
- Wrote, submitted, and was awarded research grant from 08/01/84 - 07/31/87 for $732,673.00. N1HLB1-R01-HL32800-01
- Published 17 manuscripts in referred journals
- Published and presented 34 abstracts at national meetings.

PROFESSIONAL EXPERIENCE WITH RADIONUCLIDES

1996 to Present — **DEPARTMENT OF BIOCHEMISTRY AND MOLECULAR BIOLOGY** — St. Louis, MO
ST. LOUIS UNIVERSITY
Postdoctoral Fellow - Authorized to use ^{32}P, ^{14}C, and ^{3}H, for biochemical studies aimed at understanding the role of long chain acylcarnitine in myocardinal ischemia.

1986 to 1996 — **MARION MERRILL DOW, INC.** — Kansas City, MO
Principal Investigator - Initiated, performed, and directed research efforts for pre-clinical drug development in area of antithrombotics, thrombolytics, antihypertensive, and antianginals. Submitted two IND's applications for potential products. Licensed to use ^{14}C and ^{3}H in research experiments.

1982 to 1986 — **UNIVERSITY OF MISSOURI - COLUMBIA** — Columbia, MO
Dalton Research Institute
Assistant Professor / Research Investigator
Independent investigator, licensed to use ^{35}S, ^{14}C, and ^{3}H, for studies aimed a understanding neural regulation of the cardiovascular system.

1978 to 1982 — **UNIVERSITY OF KANSAS** — Lawrence, KS
Department of Pharmacology and Toxicology
Ph.D.. Graduate Student, used ^{14}C and ^{3}H for studies aimed at defining the mechanism of endogenous opioid peptides on peripheral adrenergic neurotransmission. Used radionuclides in radioenzymatic assay and radioreceptor assay.

1972 to 1975 — **NUCLEAR MEDICAL RESEARCH DETACHMENT, U.S. ARMY** — Landstuhl, Germany
Medical Corpsman
Performed radiological hygiene - surveyed and monitored U.S. Army Hospitals, dental X-Ray Facilities, and radionuclide laboratories. Trained military personnel in the safe use, handling, decontamination, and disposal of radionuclides. Calibrated dosimeters and assayed water samples for tritium.

EDUCATION

Ph.D.. Pharmacology and Toxicology	University of Kansas, Lawrence, Kansas	1982
BS - Biology and Chemistry	Western Michigan University, Kalamazoo, Michigan	1972

3.3 Radiation Safety Director

3.3.1 Function

The Radiation Safety Director is responsible for establishing and developing the overall Radiation Protection Program to meet applicable NRC, DOT and other Federal, State and local regulations and the conditions and provisions of the ARC license.

3.3.2 Responsibility

The Radiation Safety Director reports to the President and is administratively responsible to the Radiation Safety Committee.

3.3.3 Administrative Duties

The Radiation Safety Director is responsible for the administrative functions of the Radiation Protection Program. The RSD --

(a) is the primary contact with NRC licensing and enforcement personnel.

(b) prepares and submits NRC license applications and amendments.

(c) prepares new Standard Operating Procedures or modifies existing ones.

(d) meets quarterly with the RSC and production chemists to review doses received and radiation levels and concentrations.

(e) annually reviews and updates the Radiation Protection Program to assure compliance with established standards and procedures.

(f) audits radiation safety records quarterly to assure compliance with the provisions of the Radiation Protection Program

(g) presents annual summary reports to the RSC specifying the primary sources of exposure to radiation or radioactive materials with possible recommendations for exposure reduction.

(h) makes safety evaluations of proposed new uses of RAM including modification of facilities, equipment, and procedures.

(i) gathers information and data needed by the RSC to determine corrective actions to be taken for reports or responses to the NRC.

(j) furnishes consulting service on all aspects of radiation protection.

(k) annually reviews and updates Decommissioning Funding Plan.

3.4 Radiation Safety Officer

3.4.1 Function

The Radiation Safety Officer is responsible for conducting the overall Radiation Protection Program to meet applicable NRC, DOT and other Federal, State and local regulations and the conditions and provisions of the ARC license.

3.4.2 Responsibility

The Radiation Safety Officer is responsible for compliance with applicable NRC, DOT, and other Federal, State, and local regulations. The Radiation Safety Officer reports to the President and is administratively responsible to the Radiation Safety Committee.

3.4.3 Alternate RSO

When the RSO is not available for reasons such as illness or vacation, the Radiation Safety Director shall function as the Alternate RSO. If the RSO and the RSD cannot be reached, the President shall function as the Alternate RSO. Routine radiation safety duties will be performed by an individual trained by the RSO.

3.4.4 Duties

The Radiation Safety Officer shall perform the duties listed below, or shall ensure that these duties are performed by an individual under his direction. The RSO --

(a) is the primary contact with NRC inspectors and other inspectors.

(b) conducts the Radiation Protection Program to maintain compliance with established standards and procedures.

(c) issues and enforces work restrictions when necessary.

(d) periodically reviews shipping documents to ensure compliance with DOT or IATA regulations.

(e) develops and conducts radiation safety indoctrination and training programs to ensure that personnel receive sufficient information for their respective jobs.

(f) observes production chemists and provides on-the-job radiation safety training.

(g) Observes the shipping clerk and provides on-the-job DOT and IATA training.

(h) performs radiation safety Standard Operating Procedures and reviews the results (bioassay data, air concentration data, etc.) to ensure compliance with NRC regulations.

(i) maintains records pertaining to the Radiation Protection Program.

(j) responds to all incidents involving RAM, on-site and off-site, as necessary to maintain regulatory compliance.

(k) curtails any operation involving RAM which threatens the safety of personnel, other individuals, or the facility.

(l) curtails and corrects any operation which is not in compliance with applicable NRC and other Federal, State and local regulations and the conditions and provisions of the ARC license.

OCT 15 1996

Donald W. Soldan
Radiation Safety Director
American Radiolabeled Chemicals
11624 Bowling Green Drive
St. Louis, MO 63146

Dear Mr. Soldan:

We have reviewed your letter dated August 10, 1996, requesting the deletion of third party audits and a decrease in the frequency of NRC inspections of your NRC License No. 24-21362-01. We need the following additional information to complete our review:

10 CFR 20.1101(c) requires licensees to periodically (at least annually) review their radiation protection program content and implementation. 10 CFR 20.2102 requires licensees to maintain records of the radiation protection program including audits and other reviews of the program content and implementation. Therefore, submit a description of your internal audit program for performing the required annual review. Include at least the following in your description:

1. The purpose of the audits;

2. The methods of conducting the audits (record review, direct observations, etc.);

3. The names and qualifications of auditors;

4. The scope of audits. Audits should include:

   A. A general description of topics to be audited.
   B. An overall assessment of program and the success of its operationalization.
   C. A review of RSO activities and effectiveness.
   D. A review of the audits/observations conducted by the RSO of personnel.

5. Reports to top management and the Committee of audit findings and recommendations of auditor; and

6. A discussion of the follow-up actions to be taken as a result of audit findings and the timeliness of corrective actions.

We will continue our review of your request when we receive this additional information. Please reply in writing, provide two copies and refer to Control No. 301750.

301750

If you have any questions or require clarification on any of the information stated above, please contact me at (630) 829-9822.

Sincerely,

Evelyn R. Matson
Health Physicist
Nuclear Materials Licensing Branch

License No. 24-21362-01
Docket No. 030-20567

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