

VOID SHEET

TO: License Fee Management Branch

FROM: RIII - Mullauer

SUBJECT: VOIDED APPLICATION

Control Number: 399910

Applicant: Midwest Analytical Inc.

License Number: 24-26699-01

Docket Number: 030-34062

Date Voided: 1/27/97

Reason for Void: Licensor does not need
an NRC License for the conduct of
their Business. Applicant shall receive refund.

James Mullauer 1/27/97
Signature Date

Attachment:
Official Record Copy of
Voided Action

FOR LFMB USE ONLY

- ☒ Refund Authorized and processed
☒ No Refund Due
☐ Fee Exempt or Fee Not Required

Comments: After Review

Log completed ☒

Processed by: SAC 2/3/97

070040

ML
30
SD

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
AND
REGIONAL LICENSING SECTIONS

(FOR LFMS USE)
INFORMATION FROM LTS

PROGRAM CODE: _____
STATUS CODE: 3 _____
FEE CATEGORY: _____
EXP. DATE: 0 _____
FEE COMMENTS: _____
DECOM FIN ASSUR RECDY _____
1996 FEB 15 AM 11:08

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
APPLICANT/LICENSEE: MIDWEST ANALYTICAL INCORPORATED
RECEIVED DATE: 960207
DOCKET NO: 3034062
CONTROL NO.: 399910
LICENSE NO.: _____
ACTION TYPE: NEW LICENSEE

2. FEE ATTACHED

AMOUNT: 530
CHECK NO.: 1197

3. COMMENTS

SIGNED
DATE

D. Hersey
2-12-96

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

1. FEE CATEGORY AND AMOUNT: 3P \$530

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

AMENDMENT
RENEWAL
LICENSE

☒

3. OTHER

SIGNED
DATE

SC
2/15/96

Log	Feb 8 III
Remitter	
Check No.	1197
Amount	\$530
Fee Category	3P
Type of Fee	APP
Date Check Rec'd	2/15/96
Date Completed	2/15/96
By:	SC

RECEIVED
FEB 20 1996
REGION III

APPLICATION FOR MATERIAL LICENSE

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 8 HOURS. SUBMITTAL OF THE APPLICATION IS NECESSARY TO DETERMINE THAT THE APPLICANT IS QUALIFIED AND THAT ADEQUATE PROCEDURES EXIST TO PROTECT THE PUBLIC HEALTH AND SAFETY. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE INFORMATION AND RECORDS MANAGEMENT BRANCH (T-6 F33), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555-0001, AND TO THE PAPERWORK REDUCTION PROJECT (3150-0120), OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND,
MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA,
RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

LICENSING ASSISTANT SECTION
NUCLEAR MATERIALS SAFETY BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO
RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,
SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION II
101 MARIETTA STREET, NW, SUITE 2900
ATLANTA, GA 30323-0199

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN,
SEND APPLICATIONS TO:

MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
801 WARRENVILLE RD.
LISLE, IL 60532-4351

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS,
LOUISIANA, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA,
OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH,
WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING SECTION
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
811 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-8064

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- ☒ A. NEW LICENSE
☐ B. AMENDMENT TO LICENSE NUMBER _____
☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip code)

Midwest Analytical, Inc.
11139 B South Towne Square
St. Louis, MO 63123

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

11139 B South Towne Square
St. Louis, MO 63123

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

David McCourt

TELEPHONE NUMBER

800-481-0790

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

- a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM.

11. WASTE MANAGEMENT.

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 3.P

AMOUNT
ENCLOSED \$ 530.00

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39 AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

David W. McCourt, President

SIGNATURE

David W. McCourt

DATE

2-6-96

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
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\$

APPROVED BY

DATE

RECEIVED

FEB 07 1996

399910

REGION III

PRINTED ON RECYCLED PAPER

M I D W E S T A N A L Y T I C A L , I N C .

11139B SOUTH TOWNE SQUARE

ST. LOUIS, MO 63123

800-481-0790

February 5, 1996

Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region III
801 Warrenville Road
Lisle, IL 60532-4351

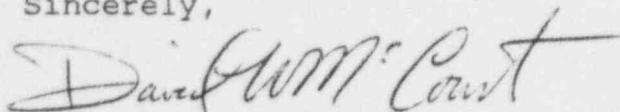
To Whom It May Concern:

Midwest Analytical is a small commercial lab involved in the testing of protein samples. Some of these samples may have low levels (between 0.1 microcurie and 2 microcuries) of hydrogen-3, sulfur-35 or phosphorus-32. They would be analyzed and the radioactivity returned to the original source.

No purchasing or storing of radioactive material will take place at Midwest Analytical. We want to be able to inform licensed customers that it is acceptable to send these trace quantities to Midwest Analytical for analysis and return. A written clarification from the NRC giving these labs permission to send no more than 2-3 microcuries to Midwest Analytical specifically for protein sequence analysis would be an alternative to applying for a license. Is something like this possible? If this is not acceptable, could a letter giving permission to ship to Midwest Analytical through March 30, 1996, for example, be obtained during the review process of Form 313?

Please find enclosed NRC Form 313 with payment of \$530.00 based on Section 170.31 (3.P). Other necessary information for the application is also enclosed.

Sincerely,



David W. McCourt
President

RECEIVED

FEB 07 1996

REGION III

Midwest Analytical, Inc.
11139B South Towne Square
St. Louis, MO 63123

NRC Form 313

- | | |
|---------------------|----------------------------|
| 5. A.(1) Hydrogen-3 | B.(1) Non-volatile protein |
| (2) Sulfur-35 | (2) Non-volatile protein |
| (3) Phosphorus-32 | (3) Non-volatile protein |
- C.(1) 2 microcuries
(2) 2 microcuries
(3) 2 microcuries

Note: The total radioactivity at any one time will not exceed 2 microcuries. This amount of radioactivity will be present at Midwest Analytical no more than 24 days per year.

6. Material will be analyzed on an automated protein sequencer and radioactivity returned to original source in dry, non-volatile form.

7. David W. McCourt

National Cancer Institute 1975-1979
Bethesda, Maryland

- millicurie quantities of hydrogen-3 and carbon-14
- See references 2 thru 8 in list of publications.

Howard Hughes Medical Institute 1984-1994
St. Louis, Missouri

- microcurie quantities of hydrogen-3, sulfur-35 and phosphorus-32
- See references 10, 11, 12, 13, 15, 16, 17, 20, 21 and 25 in list of publications.

8. No restricted areas
9. No equipment currently located at Midwest Analytical for the detection of radioactivity.
10. No Radiation Safety Program other than safely transferring radioactivity back to original source.
11. No waste will be generated or stored at Midwest Analytical.

David W. McCourt

Education:

Roanoke College, B.S., Chemistry, 1974

Employment:

1975 - 1979	Research Chemist National Cancer Institute National Institutes of Health Bethesda, Maryland
1980 - 1983	Applications Chemist Waters Associates, Inc. Milford, Massachusetts
1984 - 1985	Research Chemist Howard Hughes Medical Institute Washington University School of Medicine St. Louis, Missouri
1986 - 1987	Research Associate Department of Anatomy and Neurobiology Senator Jacob Javits Center for Excellence in Neuroscience Washington University School of Medicine St. Louis, Missouri
1988 - 1994	Research Chemist Protein Sequencing Laboratory Howard Hughes Medical Institute Washington University School of Medicine St. Louis, Missouri
1994 - Present	President and Analytical Chemist Midwest Analytical, Inc. 11139B South Towne Square St. Louis, Missouri

PUBLICATIONS

1. P.D. Henson and D.W. McCourt, Cleavage of Phosphinamides with Lithium Aluminum Hydride, *Va. J. Sci.* 25:79 (1974).
2. S.K. Yang, D.W. McCourt, P.P. Roller, H.V. Gelboin, Enzymatic Conversion of Benzo(a)pyrene Leading Predominantly to the Diol-epoxide r-7,t-8-Dihydroxy-t-9,10-oxy-7,8,9,10-tetrahydrobenzo(a)-pyrene, *Proc. Natl. Acad. Sci.* 73:2594 (1976).
3. S.K. Yang, D.W. McCourt, J.C. Leutz, H.V. Gelboin, Benzo(a)pyrene Diol-epoxides: Mechanism of Enzymatic Formation and Optically Active Intermediates, *Science* 196:1199 (1977).
4. S.K. Yang, D.W. McCourt, H.V. Gelboin, J.R. Miller, P.P. Roller, Stereochemistry of the Hydrolysis Products and Their Acetonides of Two Stereoisomeric Benzo(a)pyrene 7,8-Diol-9,10-epoxides, *J. Am. Chem. Soc.* 99:5124 (1977).
5. S.K. Yang, D.W. McCourt, H.V. Gelboin, The Mechanism of Hydrolysis of the Non-K-Region Benzo(a)pyrene Diol-epoxide r-7,t-8-Dihydroxy-t-9,10-oxy-7,8,9,10-tetrahydrobenzo(a)pyrene, *J. Am. Chem. Soc.* 99:5130 (1977).
6. E. Huberman, S.K. Yang, D.W. McCourt, H.V. Gelboin, Mutagenicity to Mammalian Cells in Culture by (+) and (-) trans-7,8-Dihydroxy-7,8-dihydrobenzo(a)pyrenes and the Hydrolysis and Reduction Products of Two Stereoisomeric Benzo(a)pyrene 7,8-Diol-9,10-epoxides, *Cancer Letters* 4:35 (1977).
7. J.M. Pezzuto, C.S. Yang, S.K. Yang, D.W. McCourt, H.V. Gelboin, Metabolism of Benzo(a)pyrene and (-) trans-7,8-Dihydroxy-7,8-dihydrobenzo(a)pyrene by Rat Liver Nuclei and Microsomes, *Cancer Research* 38:1241 (1977).
8. D.W. McCourt, P.P. Roller, H.V. Gelboin, Tetrabutylammonium Hydroxide: A Reagent for the Base-catalyzed Dehydration of Vicinal Dihydrodiols of Aromatic Hydrocarbons. Implications to Ion-Pair Chromatography, *J. Org. Chem.* 46:4157 (1981).
9. R. Pfiefer, R. Karol, J. Korpi, R. Burgoyne, D.W. McCourt, Practical Application of HPLC to Amino Acid Analysis, *Am. Lab.* 15:78 (1983).
10. D.W. McCourt, J.F. Leykam, B.D. Schwartz, Analysis of Sulfate and Phosphate Esters of Amino Acids by Ion Exchange Chromatography on Polymeric DEAE, *J. Chrom.* 327:9 (1985).
11. C. Carr, D.W. McCourt, J.B. Cohen, The 43 kDa Protein of Torpedo Nicotinic Post-Synaptic Membranes: Purification and Determination of Primary Structure, *Biochem.* 26:7090 (1987).

12. M.R. MacDonald, D.W. McCourt, J.E. Krause, Posttranslational Processing of Alpha, Beta, and Gamma-Preprotachykinins, *J. Biol. Chem.* 263:15176 (1988).
13. T.J. Chambers, D.W. McCourt, C.M. Rice, Yellow Fever Virus Proteins NS2A, NS2B, and NS4B: Identification and Partial N-Terminal Amino Acid Sequence Analysis, *Virology* 169:100 (1989).
14. J. Gorka, D.W. McCourt, B.D. Schwartz, Automated Synthesis of a Photoprobe Using Combined Fmoc and t-Boc Synthesis Strategies on a Single Automated Peptide Synthesizer, *Peptide Res.* 2:376 (1989).
15. T.J. Chambers, D.W. McCourt, C.M. Rice, Production of Yellow Fever Virus Proteins in Infected Cells: Identification of Discrete Polyprotein Species and Analysis of Cleavage Kinetics Using Region-Specific Polyclonal Antisera, *Virology* 177:159 (1990).
16. T.J. Girard, D.W. McCourt, W.F. Novotny, L.A. MacPhail, K.M. Likert, G.J. Broze, Jr., Endogenous Phosphorylation of the Lipoprotein-associated Coagulation Inhibitor at Serine-2, *Biochem. J.* 270:621 (1990).
17. T.J. Chambers, R.C. Weir, A. Grakoui, D.W. McCourt, J.F. Bazan, R.J. Fletterick, C.M. Rice, Evidence that the N-terminal Domain of Nonstructural Protein NS3 from Yellow Fever Virus is a Serine Protease Responsible for Site-specific Cleavages in the Viral Polyprotein, *Proc. Natl. Acad. Sci.* 87:8898 (1990).
18. I. Thalmann, H. Suzuki, D.W. McCourt, T.H. Comegys, R. Thalmann, Partial Amino Acid Sequence of Organ Corti Protein OCP-II, *Eur. Arch. Otorhinolaryngol.* 248:15 (1990).
19. J.L. Seltzer, K.T. Ackers, H. Weingarten, G.A. Grant, D.W. McCourt, A.Z. Eisen, Cleavage Specificity of Human Type IV Collagenase (Gelatinase): Identification of Cleavage Sites in Type I Gelatin with Confirmation Using Synthetic Peptides, *J. Biol. Chem.*, in press.
20. J.H. Mehringer, M.R. Harris, C.S. Kindle, D.W. McCourt, S.E. Cullen, Characterization of Fragments of the Murine Ia-Associated Invariant Chain, *J. Immunol.* 146:920 (1991).
21. N.R. Nygard, C. Bono, L.R. Brown, J. Gorka, K.S. Giacoletto, W.T. Schaiff, M.B. Graham, D.W. McCourt, M. Kabeer, V.L. Braciale T.J. Braciale, B.D. Schwartz, Antibody Recognition of an Immunogenic Influenza Hemagglutinin-Human Leukocyte Antigen Class II Complex, *J. Exp. Med.* 174:243 (1991).
22. W.T. Roswit, D.W. McCourt, N.C. Partridge, J.J. Jeffrey, Purification and Sequence Analysis of Two Rat Tissue Inhibitors of Metalloproteinases, *Arch. Biochem. Biophys.* 292:402 (1992).

23. B.D. Sudbeck, J.J. Jeffrey, H.G. Welgus, R.P. Mecham, D.W. McCourt, W.C. Parks, Purification and Characterization of Bovine Interstitial Collagenase and Tissue Inhibitor of Metalloproteinases, *Arch. Biochem. Biophys.* 293:370 (1992).
24. W.T. Schaiff, K.A. Hruska, D.W. McCourt, M. Green, B.D. Schwartz, HLA-DR Associates with Specific Stress Proteins and Is Retained in the Endoplasmic Reticulum in Invariant Chain Negative Cells, *J. Exp. Med.* 176:657 (1992).
25. A. Grakoui, D.W. McCourt, C. Wychowski, S.M. Feinstone, C.M. Rice, Characterization of the Hepatitis C Virus-Encoded Serine Proteinase: Determination of Proteinase-Dependent Polyprotein Cleavage Sites, *J.Virol.* 67:2832 (1993).

JAN 29 1997

David W. McCourt
President
Midwest Analytical, Inc.
11141 E South Towne Square
St. Louis, MO 63123

Dear Mr. McCourt:

This refers to your application dated February 6, 1996, requesting an NRC license and clarification whether it is necessary for you to possess an NRC license to receive, from customers, protein samples for analysis which may contain trace quantities of radioactive material. You further requested in letter dated February 28, 1996, interpretation of 10 CFR 30.14 and 30.18 of the Nuclear Regulatory Commission Rules of General Applicability to Domestic Licensing of Byproduct Material and its applicability to your analytical program.

You specify that these protein samples may include trace quantities of hydrogen-3, sulfur-35 and phosphorus-32 and that the maximum quantity of these isotopes at any one time would not exceed 0.1 to 0.2 microcuries. You also specified that the transfer, to you from your customers, is of no commercial value and that the radioactive component is only incidental to the analysis of the protein sample.

We have reviewed the provisions of 10 CFR 30.14 and 30.18. In summary, the provisions specified in 10 CFR 30.14(a) state that any person is exempt from the requirements for a license to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing byproduct material in concentrations not in excess of those listed in 10 CFR 30.70, Schedule A. The provisions specified in 10 CFR 30.18 state that any person is exempt from the requirements for a license to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing byproduct material in individual quantities not in excess of those listed in 10 CFR 30.71, Schedule B.

From our review of your request, it does not appear that your customers will be transferring or commercially distributing the samples. Neither does it appear that it is Midwest Analytical Inc.'s intention to receive samples containing byproduct material in excess of the concentration and quantity limits specified in 10 CFR 30.70, Schedule A and 10 CFR 30.71, Schedule B, respectively. Therefore, Midwest Analytical, Inc. can receive, possess, etc. the samples as exempt quantities without the need for a specific license.

399910

D. McCourt

-2-

However, the responsibility for assuring compliance with these requirements rests with the transferors, Midwest Analytical, Inc.'s specifically licensed clients. In order to transfer to a person exempt pursuant to 10 CFR 30.14 and 30.18, your customers must verify, in some acceptable manner, that the activity limits given in Schedules A and B are not exceeded in individual samples, and the transfer must not be for commercial purposes.

Based on the above and in accordance with your telephone conversation on January 8, 1997, with James R. Mullauer of my staff, your application dated February 6, 1996, requesting an NRC license is voided and we consider this matter closed.

If you have any questions concerning this matter, please call me at (630) 829-9836 or James Mullauer at (630) 829-9873.

Sincerely,

Original Signed By
B.J. Holt, Chief
Nuclear Materials Licensing Branch

License No. 24-26699-01

Docket No. 030-34062

Enclosures: 1. App. dtd 02/6/96
2. Ltrs dtd 6/27/96, 2/15/96,
2/28/96, & 6/27/1996

DOCUMENT NAME: M:\03034062.DF7

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OFFICE	DNMS/RIII		DNMS/RIII						
NAME	JMULLAUER:jaw		BJHOLT	BJH					
DATE	01/27/97		01/27/97						

OFFICIAL RECORD COPY



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

December 18, 1996

96-51

MEMORANDUM TO: John Madera, Chief
Nuclear Materials Licensing Branch
Division of Nuclear Materials Safety, RIII

FROM: Larry W. Camper, Chief
Medical, Academic, and Commercial
Use Safety Branch
Division of Industrial and
Medical Nuclear Safety, NMSS *[Signature]*

SUBJECT: TECHNICAL ASSISTANCE REQUEST; MIDWEST ANALYTICAL, INC.;
REQUEST FOR INTERPRETATION OF 30.14 AND 30.18;
(NEW LICENSE 24-26699-01)

I am responding to the attached technical assistance request (TAR) dated July 3, 1996, transmitting a letter dated June 27, 1996, from Midwest Analytical, Inc. This is a follow-up of an earlier TAR request dated March 11, 1996, which transmitted a letter dated February 28, 1996, from Midwest Analytical, Inc. requesting an interpretation of 10 CFR 30.14 and 30.18 as applied to its small testing lab which analyzes protein samples for medical schools and pharmaceutical research laboratories. The June 27th letter provides additional information concerning Midwest Analytical, Inc.'s activities which was requested in an headquarters memorandum dated June 10, 1996.

In its response, Midwest Analytical, Inc. has revised its calculations and now indicates the samples it will receive and analyze will contain only nanocurie quantities of hydrogen-3, sulfur-35, and phosphorus-32. The response also reiterates that Midwest Analytical, Inc. is receiving samples to determine protein sequence and the samples' radioactivity may not be significant to the analysis. Midwest Analytical, Inc. further indicates that: (1) its clients are not involved, or using the samples, in some form of commercial transfer pursuant to 10 CFR 32.11 or 32.18; (2) its clients may be determining sample radioactivity content prior to transferring the samples to Midwest Analytical, Inc.; and (3) it receives radioactive samples on an infrequent (20 - 30 samples per year) basis.

The distribution provisions of 10 CFR 32.11 and 32.18 (see also 30.4 and 30.18) were summarized in the memorandum dated June 10, 1996, and need not be repeated here. Midwest Analytical, Inc.'s clients do not appear to be transferring or commercially distributing the samples pursuant to the

CONTACT: Bruce Carrico, NMSS
(301) 415-7826

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REGION III
DEC 23 1996

authorization in these provisions. As indicated in the June 10, 1996, memorandum, except as provided in paragraphs (c) and (d) of 10 CFR 30.18, any person is exempt from the requirements for a license to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing byproduct material in individual quantities not in excess of those listed in 10 CFR 30.71, Schedule B. Therefore, Midwest Analytical, Inc. could receive, possess, etc. the samples as exempt quantities without the need for a specific license.

However, the responsibility in this situation rests with the transferors, Midwest Analytical, Inc.'s specifically licensed clients. The regulations concerning transfer of byproduct material, 10 CFR 30.41, provide, in part, that licensees may only transfer to persons exempt from licensing, "to the extent permitted under such regulation." In order to transfer to a person exempt pursuant to 10 CFR 30.18, the licensees must verify, in some acceptable manner, that the activity limits given in Schedule B are not exceeded in individual samples, and the transfer must not be for commercial purposes. Based on information provided by Midwest, the transfers appear to be infrequent, and because the licensees (Midwest Analytical, Inc.'s clients) are not obtaining a direct economic benefit, the transfers do not appear to be for commercial purposes.

Attachment: TAR dtd 7/3/96

JUL 11 1996

96-51

REGIONAL TECHNICAL ASSISTANCE REQUEST FORM

Date: July 3, 1996

Don Cool (DAC), Mail Stop: 6H3-OWFN, Director, Division of Industrial and Medical Nuclear Safety, NMSS

From: John R. Madera, Region III, Chief, Nuclear Materials Licensing Branch

TAR No. 96-22 - Response to MEMORANDUM date June 10, 1996, from Josephine M. Piccone, Acting Chief, Operations Branch, Division of Industrial and Medical Nuclear Safety, NMSS to John R. Madera, Chief Nuclear Materials Licensing Branch, Division of Nuclear Materials Safety, RIII regarding a request for interpretation of 10 CFR 30.14 and 30.18 and how it applies to certain work related activities (New License Applicant - Midwest Analytical, Inc. New License No. 24-26699-01)

☐ Control No. 399910

☐ Letter dated: June 27, 1996

Problem/Issue: Enclosed is the license applicant's response to Patricia Santiago's questions concerning whether a license is needed for Midwest Analytical to conduct their business using quantities of certain byproduct material at levels below exempt quantities. Enclosed is (1) the license applicant's request dated February 28, 1996, for interpretation; (2) TAR No. 96-22 dated March 15, 1996; (3) TAR response dated June 10, 1996; and (4) the license applicant's response dated June 27, 1996.

Action Required: Please determine if this NRC license applicant can conduct its business under 10 CFR Part 30 exemptions or provide justification for requiring a specific license.

☐ Recommended Action (with revisions): From the information provided, it appears that the applicant would not need a specific license to use exempt concentrations or quantities of byproduct material. Region III is not aware of any other NRC requirement for licensing the type of work to be performed by Midwest Analytical, Inc. utilizing below exempt quantities of byproduct material. Therefore, it is the opinion of RIII that a specific license would not be required.

TAR

-2-

JUL 11 1996

Regional Reviewer: James R. Mullauer, M.H.S.

Reviewer Code: R4

Reviewer Phone No. (708) 829-9873 Fax No. (708) 515-1259

Request Needed by: 8/1/96

cc: C. Pederson

Attachments: 1. Ltr. dated 2/28/96
2. TAR dated 3/15/96
3. TAR response dated 6/10/96
4. Applicant's response dated 6/27/96

DOCUMENT NAME: M:\03034062.TR6

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OFFICE	DNMS/RII	DNMS/RII						
NAME	JRM Mullauer:brt	JRM Madera						
DATE	07/9/96	07/19/96						

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M I D W E S T A N A L Y T I C A L , I N C .

11139B SOUTH TOWNE SQUARE

ST. LOUIS, MO 63123

800-481-0790

Control # 399910

June 27, 1996

Mr. Jim Mullauer
Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region III
801 Warrenville Road
Lisle, IL 60532-4351

Dear Mr. Mullauer:

I have attempted to answer the five questions from your June 17 letter in as much detail as possible. I must state that my previous estimates of microcurie amounts were higher than they should have been. I mistakenly used 37,000 disintegrations per minute when the correct conversion factor should have been 2,200,000 disintegrations per minute (dpm) for one microcurie.

1. Hydrogen-3 Amounts Per Sample (Maximum of two samples)

2,000 dpm up to 100,000 dpm = 0.001 up to 0.05 microcurie

Sulfur-35 Amounts Per Sample (Maximum of two samples)

2,000 dpm up to 100,000 dpm = 0.001 up to 0.05 microcurie

Phosphorus-32 Amounts Per Sample (Maximum of four samples)

400 dpm up to 200,000 dpm = 0.0002 up to 0.10 microcurie

Maximum amount possessed by Midwest Analytical at any one time:

Hydrogen-3	0.10 microcurie
Sulfur-35	0.10 microcurie
Phosphorus-32	0.20 microcurie

2. Due to the short half life of 14 days, I originally planned to let the phosphorus-32 stand 3 to 4 months and to dispose of with non-radioactive material. Instead, the phosphorus-32 will be returned to the customer in the same manner as hydrogen-3 and sulfur-35. Therefore, no radioactivity will remain at Midwest Analytical after the analysis of the sample is performed. Disposal will be the sole responsibility of the licensed institutions from which the samples were sent.

3. All samples analyzed by Midwest Analytical are proteins from a variety of sources. The samples which are radioactive have the isotope incorporated into the protein. Examples are as follows:

- a. a radioactive amino acid (for example, hydrogen-3 leucine) is added to a cell culture. From this, 0.1 microcurie is incorporated into the protein of interest. The research lab is then able to purify 10% of the protein (0.01 microcurie) to be sent for analysis.
- b. the above experiment is also done with sulfur-35 methionine (another amino acid) and resulting in the same levels of radioactivity.
- c. a compound containing phosphorus-32 is chemically linked to a protein of interest. A fragment of that protein is then sent to determine at what site in that fragment the phosphorus-32 is located.

The institutions requesting my services use this radioactivity for basic research purposes only. This material is not used for any type of commercial distribution or transfer of ownership as described in 32.11 or 32.18. Examples of customers would be research labs located in medical schools, small biotech companies or the National Institutes of Health.

Small biotech companies do not have the capability of performing this type of analysis on site. The equipment is very expensive (\$120,000.00) and is difficult to justify the purchase when they may have one or two samples per month to analyze. Even at a location like the NIH the turn around time may be as long as four to six weeks. In some cases individual researchers will go outside to commercial labs or universities which may have a shorter turn around time. This allows them to proceed with other experiments which directly depend on the outcome of the analysis.

4. Hydrogen-3 and sulfur-35 samples come on a piece of paper about the size of a quarter of a postage stamp. The researcher has cut 10% of the sample and counted in a scintillation counter. The total amount of radioactivity can then be calculated. This procedure can be repeated by me if questions arise concerning a sample. Scintillation counting can be done at another commercial lab. Please see closing remarks.

Phosphorus-32 will be checked with a Ludlum Model 3 Survey Meter containing a Ludlum Model 44-9 (Pancake) Detector. Efficiency for phosphorus-32 is approximately 65 percent.

5. The purpose of this analysis (Protein Sequencing) is to degrade a pure protein sample to determine where a particular amino acid residue is located. Special equipment is required for the analysis, in my case the Model 477 Protein Sequencer manufactured by Applied Biosystems in Foster City, California.

The number of samples would be 20-30 per year. It is likely that six samples will be analyzed in January, for example, with the next radioactive sample being sent in June. Therefore, long periods of time will exist when Midwest Analytical has no radioactivity on site.

I would like to summarize the above and make some personal remarks. The key points are as follows:

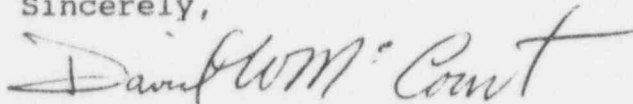
- a. Midwest Analytical is strictly a specialized analytical testing lab performing protein sequencing.
- b. Midwest Analytical does not purchase or sell radioactive substances of any kind or amount.
- c. All radioactivity received by Midwest Analytical will be returned to customer within 3 business days.
- d. The trace quantities (0.002 to 0.10 microcurie) are 100 to 50,000 times less than the exempt quantities listed in 30.71 (Schedule B).
- e. The use of the radioactivity by customers of Midwest Analytical is strictly for basic research and development purposes.
- f. There will only be a small time during the year that Midwest Analytical will have radioactive samples on site. It may be two to three months per year.

I would like to make a comment regarding #4 above. During 10 years performing this analysis at a medical school in St. Louis, the problem all research labs encounter is that incorporation of radioactivity is much lower than desired. There were times I declined to analyze a sample due to insufficient amount of radioactivity (for example, having 0.001 microcurie of hydrogen-3 when 0.01 microcurie was needed to obtain useful data for a particular type of sample). I can assure you that problems which arise will likely be due to labs sending me too little radioactivity instead of too much.

I hope this has helped answer some of your questions and concerns. I feel at this time, considering the amount of radioactivity and frequency of use, that a license would not be necessary. My only desire is to assure licensed customers from NRC and Agreement states that temporarily transferring these trace amounts of radioactivity to Midwest Analytical, Inc. for protein sequence analysis is acceptable and does not constitute an activity which would compromise their own licenses. Can these low levels be treated as "non-radioactive" under these circumstances, especially since no commercial distribution is taking place?

Please call me at 800-481-0790 if you have any questions or need additional information. Thank you for your help in this matter.

Sincerely,

A handwritten signature in cursive script that reads "David W. McCourt". The signature is fluid and stylized, with a long horizontal flourish extending from the end.

David W. McCourt
President

6-27-96

Dear Jim,

I hope this looks OK. Please call
if you see any problems. Thanks
again for your time and effort.

David M. Cant

RECEIVED

JUL 01 1996

REGION III

JUL 01 1996

JUN 17 1996

David W. McCourt
President
11139 B South Towne Square
St. Louis, MO 63123

Dear Mr. McCourt:

We have reviewed your letter dated February 15, 1996, requesting interpretation by NRC General Counsel whether a specific license is required to use exempt quantities of hydrogen-3, sulfur-35 and phosphorus-32 in the conduct of your business. In order to complete our review, we will need the following additional information.

1. State the specific concentrations and total quantities of each isotope to be possessed at any one time for each type of sample being analyzed.
2. Please provide your specific procedures for disposing of the phosphorous-32 as non-radioactive waste.
3. Please describe how the material is introduced into samples from each of the institutions. Also, please indicate whether any of the institutions from which it is received has been granted a license pursuant to 10 CFR 32.11 or 32.18.
4. Please discuss your procedures to verify that the quantity in each sample is in quantities and/or concentrations as stated in your application.
5. Please restate the purpose of the analysis and specify the frequency that you expect to receive samples for analysis.

We will continue our review of your require upon receipt of this information. Please reply in duplicate, within 20 days, and refer to Control Number 399010.

If you have any questions or require clarification on any of the information stated herein, you may contact me at (708) 829-9873.

Sincerely,

Original Signed By
James R. Mullauer, M.H.S.
Health Physicist
Nuclear Materials Licensing Branch

License No. 24-26699-01
Docket No. 030-34062

DOCUMENT NAME: M:\03034062.DF6

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DATE	06/14/96								

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UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

June 10, 1996

96-22

MEMORANDUM TO: John Madera, Chief
Nuclear Materials Licensing Branch
Division of Nuclear Materials Safety, RIII

FROM: Josephine M. Piccone, Acting Chief *Joe Piccone*
Operations Branch *J. Piccone*
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: TECHNICAL ASSISTANCE REQUEST; MIDWEST ANALYTICAL, INC.
REQUEST FOR INTERPRETATION OF 30.14 AND 30.18 (NEW LICENSE
24-26699-01)

I am responding to your technical assistance request (TAR) dated March 15, 1996, transmitting a letter dated February 28, 1996 (Attachment 1), from Midwest Analytical, Inc., requesting an interpretation of 10 CFR 30.14 and 30.18 as applied to its small testing lab which analyzes protein samples for medical schools and pharmaceutical research laboratories. Midwest Analytical, Inc. indicates it will analyze samples with 3 microcuries of hydrogen-3 and sulfur-35, and 1 microcurie of phosphorus-32. The samples will be picked up or shipped to Midwest Analytical for analysis. The hydrogen-3 and sulfur-35 will be returned to the customer and the phosphorus-32 will be allowed to decay and then be disposed of as non-radioactive waste.

In responding to the request, the provisions of 10 CFR 30.14 and 30.18 were reviewed and in summary, the provisions specified in 10 CFR 30.14(a) state, in part, except as provided in paragraphs (c) and (d) of this section, any person is exempt from the requirements for a license to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing byproduct material in concentrations not in excess of those listed in 30.70, Schedule A. Paragraph (c) further states in part, that a manufacturer, processor, or producer of a product or material in an Agreement State is exempt from the requirements to the extent that it transfers the material in a product or material in concentrations not in excess of those in 30.70 and if it is introduced into the product or material by a specific licensee of the NRC or an Agreement State that expressly authorizes the introduction. Paragraph (d) states in part, that no person may introduce byproduct material into a product or material that is to be transferred to persons exempt under paragraph (a) of this section except in accordance with a license issued pursuant to 32.11 of this chapter or under the general license provided in 10 CFR 150.20.

CONTACT: Patricia Santiago, NMSS
(301) 415-7269

Except as provided in paragraphs (c) and (d) of 10 CFR 30.18, any person is exempt from the requirements for a license to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing byproduct material in individual quantities not in excess of those listed in 30.71, Schedule B. Paragraph (c) states in part, that this section does not authorize commercial distribution for production, packaging, repackaging, or transfer of byproduct material or the incorporation of byproduct material into products intended for commercial distribution. Paragraph (d) of 10 CFR 30.18 provides in part, that no person may, for the purpose of distribution, transfer byproduct material in individual quantities set forth in 30.71, Schedule B, to persons exempt under this section except in accordance with a license issued under 32.18 of this chapter.

Although there have been cases when a license has not been required when concentrations and individual quantities have been below those specified in 30.70 Schedule A and 30.71 Schedule B, where there is no associated commercial distribution (HPPOS-131, NUREG/CR 5569), there are cases when a license is required for service type operations, such as analysis of smear samples. In order to make a final determination as to whether a license is needed in this case, Midwest should be asked to provide the following additional information:

1. State the specific concentrations and total quantities of each isotope to be possessed at any one time for each type sample being analyzed.
2. Describe its specific procedures for disposing of the phosphorus-32 as non-radioactive waste. Based on the information above, it appears the quantities may require a license for receipt, possession, use, transfer, storage, and disposal as non-radioactive waste for the phosphorus-32.
3. Describe how the material is introduced into the samples from each of the institutions from which it is received. Also indicate whether any of the institutions from which it is received has been granted a license pursuant to 10 CFR 32.11 or 32.18.
4. Who and how is the quantity in each sample measured prior to transfer or receipt to ensure the quantities or concentrations are as stated in Midwest's submittal?
5. What is the purpose of the analysis and specifically what is Midwest analyzing for in each sample? Also state the frequency of each type of analysis.

Upon receipt of the above information, we will complete the review and coordinate the final determination with the Office of General Counsel.

Attachment: TAR dtd 3/15/96

MAR 15 1996

96-22

REGIONAL TECHNICAL ASSISTANCE REQUEST FORM

Date: 3/11/96

TO: Don Cool (DAC), Mail Stop: 6H3-OWFN, Division of Industrial
and Medical Nuclear Safety, NMSS

From: John Madera, Chief, Nuclear Materials Licensing Branch, Region III

Request for interpretation of 10 CFR 30.14 and 30.18 and how it applies to
certain work related activities (New License Applicant - Midwest Analytical,
Inc. New License No. 24-26699-01)

☐ Control No. 399910

☐ Letter dated: February 28, 1996

Problem/Issue: Midwest Analytical, Inc. requests an NRC interpretation of 10 CFR 30.14 and 30.18, (Exempt concentrations and Exempt quantities of byproduct material) to determine whether a specific NRC license is required for sample analysis. According to the information obtained from the license applicant, hydrogen-3, sulfur-35 and phosphorus-32 are to be received for analysis in protein samples in individual quantities each of which would not exceed 2 microcuries. The applicant feels that the amount of byproduct material to be received in the protein samples will be in exempt concentrations and/or exempt quantities as defined by 10 CFR 30.14 and 30.18. However, some of the applicants customers who are licensed by the NRC or Agreement States are reluctant to use Midwest Analytical, Inc. because they are not specifically licensed by the NRC to receive radioactive material. The applicant verbally requested a letter from Region III which would verify that a specific license is not required for levels of radioactivity that are exempt by Part 30. Region III informed the applicant that a formal response from the NRC is only possible if the applicant poses the question in writing. Therefore Midwest Analytical, Inc. has requested in writing an interpretation of the applicability of 10 CFR 30.14 and 30.18 to their program. If a specific NRC license is not required as determined by the NRC, the applicant will withdraw the request for an NRC license.

Action Required: Please determine if this NRC license applicant can conduct its business under exemptions 10 CFR Part 30 exemptions or provide justification for requiring a specific license. Enclosed is the applicants letter dated February 28, 1996, and supporting information.

D. Cool

-2-

MAR 15 1996

☐ Recommended Action (with revisions): From the information provided, it appears that the applicant would not need a specific license to use exempt concentrations or quantities of byproduct material. Region III is not aware of any other NRC requirement for licensing the type of work to be performed by Midwest Analytical, Inc. Therefore, it is the opinion of RIII that a specific license would not be required.

Regional Reviewer: James R. Mullauer, M.H.S.

Reviewer Code: R4

Reviewer Phone No.: (708) 829-9873 Fax No.: (708) 515-1259

Request Needed by: 4/20/96

cc: C. Pederson

Attachment: Ltr dtd 2/28/96

DOCUMENT NAME: M:\03034062.TR6

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OFFICE	DNMS/RIII	DNMS/RIII							
NAME	JMULLAUER:jaw	JRMADERA							
DATE	03/13/96	03/14/96							

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M I D W E S T A N A L Y T I C A L , I N C .

11139B SOUTH TOWNE SQUARE

ST. LOUIS, MO 63123

800-481-0790

Control # 399910

February 28, 1996

Mr. Jim Mullauer
Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region III
801 Warrenville Road
Lisle, IL 60532-4351

Dear Mr. Mullauer:

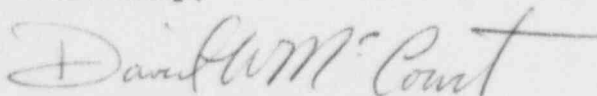
Midwest Analytical would like to request an interpretation of Part 30.14 and Part 30.18 of the Nuclear Regulatory Commission Rules of General Applicability to Domestic Licensing of Byproduct Material.

Midwest Analytical is a small testing lab which analyzes protein samples for medical school and pharmaceutical research laboratories. The analysis is done on a specialized piece of scientific instrumentation not found in most research labs. It is my desire to analyze samples with trace quantities (1 to 2 microcuries) of hydrogen-3, sulfur-35 and phosphorus-32. These samples would be picked up personally or shipped to Midwest Analytical for analysis. The radioactivity (in dry form) would then be returned to the customer. There is no commercial distribution of radioactivity taking place and according to Part 30.18 Midwest Analytical would be exempt from obtaining a license.

A licensed customer, however, has expressed concern that sending these quantities may not be allowed since Midwest Analytical has no license. A written interpretation authorizing licensed facilities to ship these trace quantities for analysis is therefore requested.

Enclosed is a detailed description of the types and amounts of radionuclides which will be analyzed along with other required information.

Sincerely,



David W. McCourt
President

RECEIVED

MAR 04 1996

REGION III

From Regulatory Guide 10.7

Items 2 and 4

Midwest Analytical, Inc.
11139B South Towne Square
St. Louis, MO 63123

Item 5

Same address

Item 6

David W. McCourt - Only user of radioactive material

Item 7

David W. McCourt

Item 8A, B, C, and D

- | | |
|----------------------|----------------------------|
| A (1) Hydrogen-3 | B (1) Protein - dry sample |
| (2) Sulfur-35 | (2) Protein - dry sample |
| (3) Phosphorus-32 | (3) Protein - dry sample |
| C (1) Not Applicable | D (1) 3 microcuries |
| (2) Not Applicable | (2) 3 microcuries |
| (3) Not Applicable | (3) 1 microcurie |

Item 8E

(1) Hydrogen-3 will be analyzed on an Applied Biosystems (Foster City, CA) Model 477 Protein Sequencer. After the analysis is complete the sample will be returned to the customer. No hydrogen-3 will remain at Midwest Analytical.

(2) Sulfur-35 will be analyzed as above in (1). No sulfur-35 will remain at Midwest Analytical.

(3) Phosphorus-32 will be analyzed as above in (1). Since no scintillant is required, these samples may be counted at Midwest Analytical and allowed to decay prior to disposal.

Item 9

Not Applicable - No potential for exposure to radiation or radioactive materials. Samples received for analysis will be dry and stored in closed containers.

Item 10

Not Applicable. Midwest Analytical has access to the following instrument if needed.

- 1 (A) Liquid Scintillation Counter
- (B) Beckman Instruments
- (C) Model 3801
- (D) 2
- (E) Beta
- (F) 50 counts/minute to 500,000 counts/minute

Item 11

Not Applicable - No instrument calibration.

Item 12

Not Applicable - No personnel monitoring.

Item 13

Not Applicable - No special facilities or equipment for radiation use.

Item 14

- (A) Not applicable for hydrogen-3 and sulfur-35. These will be returned to customer.
- (B) The small amounts of phosphorus-32 (half life = 14 days) will be allowed to decay to undetectable levels and disposed of as if not radioactive.

Item 15

Not Applicable - No survey program.

Item 16

Resume for David W. McCourt is enclosed.

- (a) thru (d): Nuclear Medicine, 1974
Department of Medicinal Chemistry
University of Maryland at Baltimore
Baltimore, Maryland
- Radiation Safety Course, 1975
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

Item 17

Resume for David W. McCourt is enclosed.

- (1) National Cancer Institute, Bethesda, Maryland
 - Hydrogen-3 Maximum Amount per use = 10 millicuries
 - Carbon-14 Maximum Amount per use = 5 millicuries
 - See references 2 thru 8 in list of publications
- (2) Howard Hughes Medical Institute, St. Louis, Missouri
 - Hydrogen-3 Maximum Amount per use = 4 microcuries
 - Sulfur-35 Maximum Amount per use = 3 microcuries
 - Phosphorus-32 Maximum Amount per use = 1 microcurie
 - See references 10, 11, 12, 13, 15, 16, 17, 20, 21, 25 in list of publications

David W. McCourt

Education:

Roanoke College, B.S., Chemistry, 1974

Employment:

1975 - 1979	Research Chemist National Cancer Institute National Institutes of Health Bethesda, Maryland
1980 - 1983	Applications Chemist Waters Associates, Inc. Milford, Massachusetts
1984 - 1985	Research Chemist Howard Hughes Medical Institute Washington University School of Medicine St. Louis, Missouri
1986 - 1987	Research Associate Department of Anatomy and Neurobiology Senator Jacob Javits Center for Excellence in Neuroscience Washington University School of Medicine St. Louis, Missouri
1988 - 1994	Research Chemist Protein Sequencing Laboratory Howard Hughes Medical Institute Washington University School of Medicine St. Louis, Missouri
1994 - Present	President and Analytical Chemist Midwest Analytical, Inc. 11139B South Towne Square St. Louis, Missouri

PUBLICATIONS

1. P.D. Henson and D.W. McCourt, Cleavage of Phosphinamides with Lithium Aluminum Hydride, *Va. J. Sci.* 25:79 (1974).
2. S.K. Yang, D.W. McCourt, P.P. Roller, H.V. Gelboin, Enzymatic Conversion of Benzo(a)pyrene Leading Predominantly to the Diol-epoxide r-7,t-8-Dihydroxy-t-9,10-oxy-7,8,9,10-tetrahydrobenzo(a)-pyrene, *Proc. Natl. Acad. Sci.* 73:2594 (1976).
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11. C. Carr, D.W. McCourt, J.B. Cohen, The 43 kDa Protein of Torpedo Nicotinic Post-Synaptic Membranes: Purification and Determination of Primary Structure, *Biochem.* 26:7090 (1987).

12. M.R. MacDonald, D.W. McCourt, J.E. Krause, Posttranslational Processing of Alpha, Beta, and Gamma-Preprotachykinins, *J. Biol. Chem.* 263:15176 (1988).
13. T.J. Chambers, D.W. McCourt, C.M. Rice, Yellow Fever Virus Proteins NS2A, NS2B, and NS4B: Identification and Partial N-Terminal Amino Acid Sequence Analysis, *Virology* 169:100 (1989).
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CONVERSATION RECORD

TIME | DATE
2 p.m. 2/26/96☐ VISIT ☐ CONFERENCE ☒ TELEPHONE☐ INCOMING
☒ OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT

ORGANIZATION (OFFICE, DEPT. ETC.)

TELEPHONE NO.

David McCourt
Midwest Analytical, Inc.
1-800-481-0790

SUBJECT

New license application dated 2/6/96

SUMMARY

I spoke to Dave concerning the following: In the license application, Dave posed the question whether or not he really needed a license and that if not, could he get a letter from the NRC stating that a license is not required to have quantities of RAM which are exempt by 10 CFR 30.18. I felt the best way to resolve this would be to resubmit the application since the original application was deficient and that he needs to follow the item in Reg. Guide 10.7. In the cover letter, he could ask for a legal NRC interpretation of 30.18 to determine whether or not he needs a license. That way, he would receive a response in writing from the NRC and either way he saves time. If it is determined that he does need a license, his application is well on its way. If not, all he lost was the application fee and he'll have his letter from the NRC.

This action is certified by _____

ACTION REQUIRED

Response due in 20 days.

NAME OF PERSON DOCUMENTING CONVERSATION

James R. Mullauer
2/26/96

SIGNATURE

DATE

Jim Mullauer 2/27/96

ACTION TAKEN

SIGNATURE

TITLE

DATE

M I D W E S T A N A L Y T I C A L , I N C .

11139B SOUTH TOWNE SQUARE

ST. LOUIS, MO 63123

300-481-0790

Control # 399910

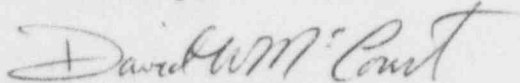
February 15, 1996

Mr. Jim Mullauer
Materials Licensing Section
U.S. Nuclear Regulatory Commission, Region III
801 Warrenville Road
Lisle, IL 60532-4351

Dear Mr. Mullauer:

I hope the enclosed is sufficient for interpretation by NRC General Counsel. Please call if additional information is needed. Thanks again for your help.

Sincerely,



David W. McCourt
President

RECEIVED MAR 4 1996

MAR 04 1996

REGION III