

VOID SHEET

TO: License Fee Management Branch

FROM: RIII - COLLEEN CASEY

SUBJECT: VOIDED APPLICATION

Control Number: 305487
Applicant: AGRACETUS, A BUSINESS UNIT OF MONSANTO
License Number: 48-26800-01
Docket Number: 030-34451
Date Voided: 7/29/99
Reason for Void: Authorized user applicant is not currently qualified
so response is not imminent. After applicant has acquired more
training and experience, in 6-12 mos. re-application / re-activation can be
effected via written response to 7/27/99 telecon record.
Signature Colleen Casey Date 7/29/99

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: _____

Log completed ☒

Processed by: SAC 8/5/99

9908090011 990729
PDR ADOCK 03034451
C PDR

000059

ML30
JAW

Shirley

(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

Program Code: 03620
Status Code: 0
Fee Category: 3M
Exp. Date: 20070930
Fee Comments:
Decom Fin Assur Req'd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: AGRACETUS, A BUSINESS UNIT MONSANTO
Received Date: 19990719
Docket No: 3034451
Control No.: 305487
License No.: 48-26800-01
Action Type: Amendment

SL
MS 23
IN

2. FEE ATTACHED

Amount: 640
Check No.: 1107616

3. COMMENTS

Signed: D. Hersey
Date: 7-22-99

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

1. Fee Category and Amount: 3M 4620

2. Correct Fee Paid. / Application may be processed for:

Amendment
Renewal
License

3. OTHER

Signed: LC
Date: 7/27/99

Refunded
420

Log	July 10 111
From	
Check No.	1107616
Amount	4640 4620
Fee Category	3M
Type of Fee	AMT
Date Check Rec'd	
Date Completed	7/27/99
By	LC

100-150-3M
10-10-11

THIS DOCUMENT IS PRINTED IN TWO COLORS. DO NOT ACCEPT UNLESS BLUE AND GREEN ARE PRESENT.

Monsanto Company

ACCOUNTS PAYABLE DEPARTMENT
800 N. Lindbergh, St. Louis, MO 63167

PAY TO THE
ORDER OF

U.S. NUCLEAR REGULATORY
COMMISSION REGION II
MATERIALS LICENSING SECTION
801 WARRENVALE RD
LISLE IL 60532-4351
USA

DATE 07/19/1998

VOID IF NOT CASHED WITHIN SIX MONTHS

0000176166

*****540.00*

THIS AMOUNT SIX HUNDRED FORTY ***** USD

PAYABLE AT

CITIBANK DELAWARE
ONE PENNS WAY
NEW CASTLE DE 19720

by *L. Green*

by *R. McCall*
Authorized Signature

⑈0000176166⑈ ⑆03100209⑆

38545751⑈

305487

MONSANTO

Food · Health · Hope



MONSANTO COMPANY
AGRACETUS CAMPUS
8520 UNIVERSITY GREEN
MIDDLETON, WISCONSIN 53562
PHONE (608) 836-7300
FAX (608) 836-9710
<http://www.monsanto.com>

July 12, 1999

Ms. Deborah Piskura
U.S. Nuclear Regulatory Commission
Materials Licensing Section
Region III
801 Warrenville Rd.
Lisle, IL 60532-4351

Dear Ms. Piskura:

Please amend our NRC materials license # 48-26800-01 to include an additional authorized user, Dr. Gudip Brar. His lab's research now includes the need to use radioisotopes. Summaries of his work experience with radioisotopes and formal training in radiation safety have been included on the attached Supplement A, Training and Experience Authorized User or Radiation Safety Officer. I have sent the amendment separate from the filing fee of \$640 to expedite the processing of the amendment. The amendment filing fee of \$640 will follow in several weeks..

If you have any questions about this amendment request, please call me at (608) 821-3404.

Sincerely,

Richard A. Senn
Radiation Safety Officer

RECEIVED

JUL 19 1999

REGION III

JUL 19 1999

Pm: 7-14-99

305487

**EXHIBIT 2
SUPPLEMENT A**

SUPPLEMENT		U.S. NUCLEAR REGULATORY COMMISSION		
TRAINING AND EXPERIENCE AUTHORIZED USER OR RADIATION SAFETY OFFICER				
1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER		2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED		
Gurdip S. Brar				
3. CERTIFICATION				
SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C		
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES				
FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING		
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE	
a. RADIATION PHYSICS AND INSTRUMENTATION	Univ of Gottingen, Germany 10/74 Univ WI Madison 6/99	4 4*	4	
b. RADIATION PROTECTION	Univ of Gottingen, Germany 10/74 Univ WI Madison	6 7*	14	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	Univ of Gottingen, Germany 10/74 Univ WI Madison	4 4*	6	
d. RADIATION BIOLOGY	Univ of Gottingen, Germany 10/74 Univ WI Madison	4 5*	2	
e. RADIOPHARMACEUTICAL CHEMISTRY	Not applicable			
E. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)				
ISOTOPE	ACT USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
14c	50Mci Na ¹⁶ H Co ₃ 16c labelled c1620, 1623 c1820, 1821 & c1822	Univ of Goettingen, Goettingen, Germany	Nov. 74 to Oct 76 over 600 hours of working with labelled material	Labeled phyotsynthates Labeled fatty acids in oil biosynthesis

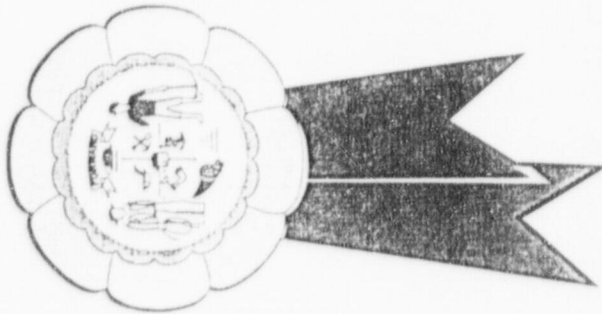
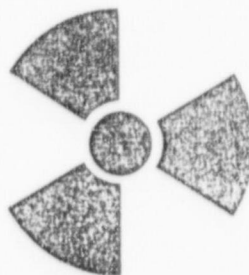
*About 4 hours lectures at UW and rest was studying at home or in office at Agracetus from Radiation Safety for Radiation workers, UW Madison

Certificate

University of Wisconsin Radiation Safety Office Certifies that

Gardip S Brar

has Successfully Completed
the 4-hour
Radiation Safety for
Radiation Workers
Training Block



yes

Certificate #

Ronald R Brall
RSO

The bearer of this certificate has successfully completed the 4-hour Radiation Safety for Radiation Workers training block. This training is based on the University of Wisconsin - Madison Safety Department booklet, "Radiation Safety for Radiation Workers," and includes both lecture and laboratory sessions. The training is designed to insure that all "radiation workers" have a basic understanding of radiation safety and the specific procedures used at the UW. The laboratory session consists of hand-on training in portable (GM) survey meter use, record keeping, contamination surveying by LSC counter, and decontamination. Certification is achieved by successful completion of the Radiation Safety Examination. Topics which the bearer of this certificate is deemed to be adequately familiar with include:

*Radiation and Radioactivity
Biological Effects of Radiation
Radiation Detection and Measurement
Radiation Safety Procedures
Radioactive Material Work Practices
Emergency Procedures and Decontamination
Current Regulations
X-Ray Machine Radiation Safety
Prenatal Radiation Exposure Information*

TAX ID 430420020

Lic No. 48-26800-01

Docket No. 03034451

DIVISION OF ACCOUNTING AND FINANCE
REQUEST FOR REFUND TO EMPLOYEE/VENDOR

THE EMPLOYEE/VENDOR IDENTIFIED BELOW HAS OVERPAID THE NUCLEAR
REGULATORY COMMISSION FOR GOODS AND/OR SERVICES PROVIDED AND IS DUE A
REFUND

EMPLOYEE/VENDOR/PAYEE CODE: _____

NAME: Marsanto Co.

ADDRESS: Agracetus Campus

ADDRESS: 8520 University Green

CITY: Middleton STATE: WI ZIP CODE 53522

TRANS CODE: PX

TRANS TYPE: FE FUND: X5280 JOB CODE: _____ AMOUNT: \$ 20.⁰⁰

TRANS TYPE: IR FUND: R1435 JOB CODE: INTR AMOUNT: \$ _____

TRANS TYPE: IR FUND: R1099 JOB CODE: ADCH AMOUNT: \$ _____

TRANS TYPE: IR FUND: R1099 JOB CODE: FINE AMOUNT: \$ _____

TOTAL REFUND AMOUNT: \$ 20.⁰⁰

COMMENTS: Lic 48-26800-01 CK 176166 Amn Rqst Rfnd
7/12/99 ltr

(limit comments to 40 characters, including spaces)

PREPARED BY: Shirley Postfield DATE: July 27, 1999

AUTHORIZED BY: Andrea Kimberley 7/28/99

ORIGINAL INV. NO: _____ DATE PAID: _____ AMOUNT: _____

REFUND ENTERED INTO COLLECT BY: _____

REFUND DETERMINED BY: _____ DATE: _____

PLEASE ATTACH APPROPRIATE SUPPORTING DOCUMENTATION

July 10 III

3M Amn #620

CK No. 176166 wtd 7/19/99 #640 305487

Please call me to
Discuss @ 630-
829-9841.

Thank.
Colleen Casey

FAX TRANSMITTAL	
To: Richard Senn	From: Colleen Casey
Fax # 606-836-9710	Number of pages: 2

UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351
630-829-8887 (phone), 630-515-1259 (fax)
-9841



CONVERSATION RECORD		TIME	DATE
			July 27, 1999
NAME OF PERSON(S) CONTACTED	ORGANIZATION	TELEPHONE NO.	
Richard Senn, RSO	Agracetus, a unit of Monsanto	608-821-3404	
SUBJECT			
License No. 48-26800-01		Control No. 305487	
SUMMARY			

We have reviewed your letter dated July 12, 1999, requesting an amendment to your license and find that we will need the following information:

1. Please clarify the correct spelling of Dr. Brar's first name, as it is spelled two different ways in your letter. Is it "Gurdip" or "Gudip?"
2. In our letter to you dated September 2, 1998, we included certain advice pertaining to your future requests to add authorized users and the signatory for your correspondence with us.

In your current letter, it does not appear that our previous suggestions have been acted upon. Specifically,:

- a. We noted that your letter dated July 12, 1999, was signed by Richard Senn again. Please be reminded that all correspondence to us must be signed by a senior management official. In the alternative, a senior management official may designate an authorized signatory to us, in writing, such as the Radiation Safety Officer or a mid-level management representative.
- b. The credentials presented in support of Dr. Brar's application appear to be inadequate to name him as an authorized user.

Please note, for example, that studying at one's home or office does not constitute formal didactic training and cannot be included in the number of hours of training.

Further, we do not understand most of the markings in section 5. of the Supplement A form under "mCi used at one time." "50Mci" appears to be incorrect as it refers to 50 megacuries (million curies). If this is a typo, please correct it.

Please examine the remainder of the markings in this section and explain what is being referred to. Please correct spelling errors and note that it is not preferable to abbreviate chemical compounds, in fact, only compounds used for labelling or in quantities greater than 10 millicuries merit inclusion.

It appears that Dr. Brar's previous training and experience with radioisotopes took place 23-25 years ago. What radioisotope work and training has he had recently?

We noted a training certificate from the University of Wisconsin- Madison was attached to Dr. Brar's application. However it was only for a four hour introductory course that did not appear to be intended for authorized users. And, there is no indication of when Dr. Brar completed this course.

In your application, it appears that his training and experience may not be commensurate with the proposed possession and use, although no specific proposed possession and use were described. Please describe in greater detail Dr. Brar's on-the-job and/or formal coursework training, including the location

and duration of the training. Training should consist of at least forty hours and cover:

- (1) principles and practices of radiation protection,
- (2) radioactivity measurements, standardization, and monitoring techniques,
- (3) mathematics and calculations basic to the use and measurement of radioactivity,
- (4) biological hazards of exposure to radiation appropriate to the type and form of byproduct material to be used, and
- (5) radiation detection instrumentation. Address his training in each of these areas on the enclosed Supplement A form, "Training and Experience."

The description of his prior use of licensed materials should include the specific isotopes handled, the maximum quantities of materials handled, where the experience was gained (and the facility's license number), the duration of experience, the names of previous authorized users/principal investigators he worked under and the types of use.

Please prepare the requested information separately for each different facility he studied/worked at, i.e., the information for his training at the University of Wisconsin- Madison should be complete and distinct from his training at the University of Gottingen in Germany, etc.

Also, please specify the maximum quantities of each radionuclide that Dr. Brar wishes to be authorized for, including waste activity.

Please refer to sections 16 and 17 of the enclosed Regulatory Guide 10.7 for guidance in preparing your response. Also, the criteria in 10 CFR 33.15(b), enclosed, may assist you. Generally, please do not submit resumes, curricula vitae, diplomas, or school transcripts- use the enclosed Supplement A forms only and, if appropriate, include a brief narrative statement of explanation on a separate sheet of paper.

2. We noted some generic administrative issues with your current amendment request as well as those submitted in the recent past. The suggestions that follow should assist you hereafter:
 - a. Please do not address licensing correspondence to Deborah Piskura. She has not been on the licensing staff for several years. No name should be used to address correspondence to licensing. It is best to address letters to the "Materials Licensing Branch Chief," followed by the NRC regional office name and address, etc.
 - b. Please do not submit an amendment request without the required fee. Doing so results in a delay of processing, not an expedite. Further, due to the volume of casework we receive and our limited resources, we normally only expedite medical emergency licensing actions for human use licensees.

ACTION REQUIRED

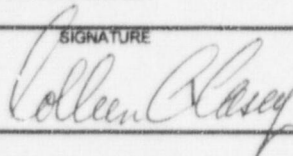
Please respond, in writing, to my attention, within 15 days, and refer to Control Number 305487. If you cannot respond in this timeframe, we will void this action without prejudice to resubmittal. In other words, we will administratively set this case aside until we receive your written response. At that time we will reactivate your request and continue our review, without payment of an additional fee, but limited to the request for Dr. Brar only. This gives you the time to prepare a better quality response without time constraints.

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

Colleen C. Casey



July 27, 1999

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