VOID SHEET

TO: License Fee Management Branch

FROM: RIII - COLLEEN C. CASEY

SUBJECT: VOIDED APPLICATION

Control Number: 303858

Applicant: BHAT & BADIVAL, M.D'S, INC.

License Number: NEW PENDING - 34-32089-01

Docket Number: 030-34731

Date Voided: 7/8/98

Reason for Void: licensee needs time to prepare response to deficiencies discussed in telecon (record) on 7/7/98. Re-activate with new control no. upon receipt of response to the C/N. Voided after review.

Colleen C. Casey 7/8/98
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: _____

_____

_____

Log completed ✓

Processed by: SAC 7/21/98

01

ML30

JPW

S6

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 Reqd:

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED
   Applicant/Licensee: BHAT AND PADIVAL, MD'S, INC.
   Received Date: 980423
   Docket No: 3034731
   Control No.: 303858
   License No.: 34-32087-01
   Action Type: New Licensee

Licensee shall owed $400

2. FEE ATTACHED
   Amount: 1,400
   Check No.: 20441

3. COMMENTS

Signed
Date 4/28/98

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

1. Fee Category and Amount: 7C $1800

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

3. OTHER

Signed SC
Date 5/1/98

MAY 14 1998

Log APR 13 '98
Remitter
Check No. 20441 / 20508
Amount $1400 / $400
Fee Category 7C
Type of Fee APP
Date Check Rec'd 4/27/98
Date Completed 5/1/98
By: SC

NRC FORM 313
(9-88)
10 CFR 30, 32, 33,
34, 35 and 40

APPLICATION FOR MATERIAL LICENSE

U.S. NUCLEAR REGULATORY COMMISSION
APPROVED BY OMB
3150-0120
Expires 5-30-90

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.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY, NMSS
WASHINGTON, DC 20555

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:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

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

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

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 JURISDICTION.

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

- [X] A. NEW LICENSE
- [ ] B. AMENDMENT TO LICENSE NUMBER _____
- [ ] C. RENEWAL OF LICENSE NUMBER _____

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

BHAT AND PADNAL, MD'S INC.
277 CLINE AVE.
MANSFIELD, OHIO 44907

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

SAME AS #2.

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

CHARLES ANTHONY GIOMUSO, MEDICAL PHYSICIST

TELEPHONE NUMBER: 1-888-934-1871

SUBMIT ITEMS 5 THROUGH 11 ON 8½ 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 AND 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 7C
AMOUNT ENCLOSED $ 1400.00

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, 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.

SIGNATURE-CERTIFYING OFFICER	TYPED/PRINTED NAME	TITLE	DATE
X	Pradyumna Padival MD FACC	Sec/Treas.	4/15/98

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	COMMENTS

AMOUNT RECEIVED	CHECK NUMBER

RECEIVED
APR 23 1998
REGION III

APPROVED BY | DATE: PM: 4/21/98

NRC FORM 313 (9-88)

ESTIMATED BURDEN PER RESPONSE TO COMPLY WITH THIS INFORMATION COLLECTION REQUEST: 7.5 HRS. FORWARD COMMENTS REGARDING BURDEN ESTIMATE TO THE RECORDS AND REPORTS MANAGEMENT BRANCH (P-630), U.S. NUCLEAR REGULATORY COMMISSION, WASHINGTON, DC 20555, AND TO THE OFFICE OF INFORMATION AND REGULATORY AFFAIRS, OFFICE OF MANAGEMENT AND BUDGET, WASHINGTON, DC 20503.

303858

BHAT & PADIVAL MD'S, INC.
275 CLINE AVENUE
MANSFIELD, OHIO 44907
PHONE (419) 756-2177

P. PADIVAL, M.D. F.A.C.C.
BOARD CERTIFIED CARDIOLOGY
AND INTERNAL MEDICINE

P. B. BHAT, M.D.
GENERAL SURGERY

M. KATAPADI, M.D.
INTERNAL MEDICINE/
PRIMARY CARE

arch 25, 1998

U.S.N.R.C. Region III
Materials Licensing Section
801 Warrenville Road
Lisle, Illinois 60532

RE: (License New Application)

To Whom It May Concern:

Enclosed please find a complete license application for the use of radioactive materials at ou 277 Cline Avenue location in Mansfield, Ohio 44907. We have also included the application fee of $1800.00 to cover the cost.

Our radiation safety program was modeled after Regulatory Guide 10.8, Rev 2. In addition, we do not plan on utilizing I-131 in amount greater than 30 uCi at this location and therefore a Quality Management Program is not required.

Should you have any questions regarding this application, feel free to contact me directly.

Sincerely,

Administration

Bhat and Padival MD.'s, Inc.
277 Cline Avenue
Mansfield, Ohio 44907

Phone: 419-756-9420

NRC FORM 313

Item 5 and 6 Radioactive Material and Purpose for Which Licensed Material Will Be Used

Byproduct Material	Amount	Purpose
5b. Material in 35.100	As Needed	6b. Medical Use
5c. Material in 35.200	As Needed	6c. Medical Use

Item 7 Individual Responsible for Radiation Safety Program and Their Training and Experience.

The RSO for this facility is P. Suresh, MD. For training and experience refer to prior NRC License Application for Richland Cardiology Internal Medicine. A copy of this license is included.

Item 8 Training for Individuals Working in or Frequenting Restricted Areas.

We will establish and implement the Model Training Program that was published in Appendix A to Regulatory Guide 10.8,Rev.2.

Ancillary personnel, e.g., nursing, clerical, or housekeeping, whose duties may require them to work in the vicinity of radioactive materials would be informed about radiation hazards and propriate precautions to be taken.

Item 9.1 Facility and Equipment

Refer to the attached room diagram.

Equipment: Camera - Siemens Orbiter with Icon Computer

Dose Calibrator - CRC 15R or equivalent

Survey Meter - Ludlum 14C or equivalent

Well System - Caprac or equivalent

Item 9.2 Survey Meter Calibration

Survey Meters will be calibrated in accordance any NRC or Agreement State approved vendor for the calibration of survey instruments.

Item 9.3 Dose Calibrator Calibration

We will establish and implement the Model Procedure for calibrating our Dose Calibrator that was published in Appendix C to Regulatory Guide 10.8, Rev.2. The accuracy, constancy and activity linearity evaluations will be corrected if levels exceed +/-10%.

Item 9.4 Personnel Monitoring Program

We will establish and implement the Model Personnel External Exposure Monitoring Program published in Appendix D to Regulatory Guide 10.8., Rev.2.

Item 9.5 Imaging Equipment

N/A

Item 10.1 Radiation Safety Program

We will issue the (Model Radiation Safety Committee Charter) and Radiation Safety Officer Delegation of Authority that was published in Appendix F to Regulatory Guide 10.8, Rev.2.

Item 10.2 ALARA

We will establish and implement the Model ALARA Program that was published in Appendix G to Regulatory Guide 10.8, Rev. 2.

Item 10.3 Leak Testing

We will establish and implement the Model Program for leak testing sealed sources that are greater than 100 uCi in strength

that was published in Appendix H to Regulatory Guide 10.8, Rev. 2. We will may also send these wipe tests for analysis to an NRC or Agreement State license that has been approved for wipe testing analysis.

Item 10.4 Safe Use of Pharmaceuticals

We will establish and implement the Model Safety Rules published in Appendix I to Regulatory Guide 10.8, Rev. 2.

Item 10.5 Spill Procedures

We will establish and implement the Model Spill Procedures published in Appendix J to Regulatory Guide 10.8, Rev. 2.

Item 10.6 Ordering and Receiving

We will establish and implement the Model Guidance for Ordering and Receiving Radioactive Material that was published in Appendix K to Regulatory Guide 10.8, Rev 2.

Item 10.7 Opening Packages

We will establish and implement the Model Procedure for Opening Packages that was published in Appendix L to Regulatory Guide 10.8, Rev 2. In addition, we will comply with 10 CFR Part 20 in opening packages containing radioactive materials.

Item 10.8 Unit Dose Records

We will establish and implement the Model Procedure for Unit Dosage Record System that was published in Appendix M.1 to Regulatory Guide 10.8, Rev. 2.

Item 10.9 Multi-dose Vial Records

We will establish and implement the Model Procedure for a Multidose Vial Record System that was published in Appendix M.2 to Regulatory Guide 10.8, Rev. 2.

Item 10.10 Molybdenum Concentration Records

We will establish and implement the Model Procedure for Measuring and Recording Molybdenum Concentration that was published in Appendix M.3 to Regulatory Guide 10.8, Rev. 2.

Item 10.11 Procedure for Keeping Inventory of Implant Sources

N/A

Item 10.12 Area Survey Records

We will establish and implement the Model Procedure for Area Surveys that was published in Appendix N to Regulatory Guide 10.8, Rev. 2. The Table N-1 will be used for action levels for both restricted and unrestricted areas. The action levels for area surveys will be 2 MR per hour for restricted areas and .05 MR per hour for unrestricted areas.

Item 10.13.1 Procedure for Calculations Worker Dose from Noble Gases

N/A

Item 10.13.2

N/A

Item 10.13.3

N/A

Item 10.13.4

N/A

Item 10.14 Radiopharmaceutical Therapy

N/A

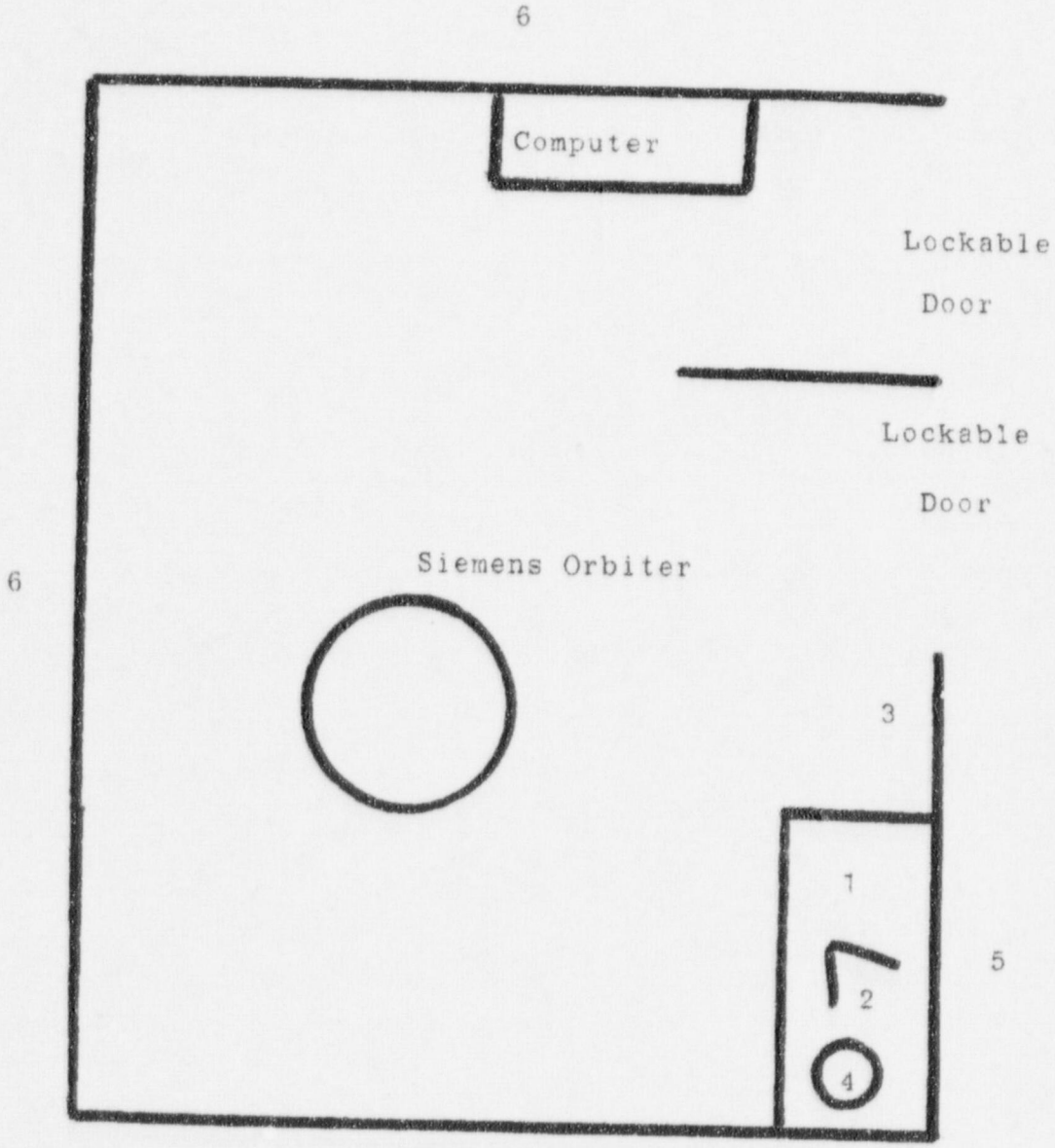
Item 10.15 Procedure For Radiation Safety During Implant Therapy

N/A

Item 11.1 Waste Management

We will establish and implement the General Guidance and Model Procedures for Waste Disposal that was published in Appendix R to Regulatory Guide 10.8, Rev.2.

BHAT AND Padival MD's, Inc.
277 Cline Avenue
Mansfield, Ohio 44907



NOTE: NOT DRAWN TO SCALE

1. Dose Calibrator
2. Standard "L" Shield for Dose prep.
3. Isotope receipt area
4. Sink
5. Hallway
6. Outside

Room Size 21 feet x 13 feet

NRC FORM 374
(10-89)

U.S. NUCLEAR REGULATORY COMMISSION

Amendment No. 07

MATERIALS LICENSE

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

Licensee	
1. International Integrated Electro Medical Systems, Inc. 2. 390 Marion Avenue Mansfield, OH 44907	In accordance with letter dated September 16, 1994 3. License number 34-25951-01 is amended in its entirety to read as follows: 4. Expiration date February 28, 1999 5. Docket or Reference No. 030-30723

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. Any byproduct material identified in 10 CFR 35.100	A. Any radiopharmaceutical identified in 10 CFR 35.100	A. As needed
B. Any byproduct material identified in 10 CFR 35.200	B. Any radiopharmaceutical identified in 10 CFR 35.200 (excluding generators and Xenon-133)	B. As needed

9. Authorized Use:

A. Medical use described in 10 CFR 35.100.

B. Medical use described in 10 CFR 35.200 (excluding generators and Xenon-133).

CONDITIONS

10. Location of Use: 390 Marion Avenue, Mansfield, Ohio.

11. Radiation Safety Officer: Pammal Suresh, M.D.

12. Authorized User:

Pammal Suresh, M.D., for material in 35.100 and 35.200 for cardiovascular clinical procedures.

COPY 5

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License number
34-25951-01

Docket or Reference number
030-30723

Amendment No. 07

13. The licensee shall not vacate or release any location of use whose address is identified in Condition Number 10. for unrestricted use, without first submitting a close-out survey to the NRC to review.

14. This license is based on the licensee's statements and representations listed below:

A. Application dated August 1993 (excluding reference to QMP); and

B. Letters dated September 16, 1994 and November 7, 1994.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date NOV 2 3 1994

By Loren J. Hoester
Materials Licensing Section, Region III

COPY

NRC FORM 577 (1-1998) 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

BHAT AND PADIVAL, M.D.'S, INC.
277 CLINE AVENUE
MANSFIELD, OH 44907

TYPE OF ACTION

- [x] NEW LICENSE
- [ ] RENEWAL OF LICENSE
- [ ] AMENDMENT TO LICENSE

REQUESTED DATE: 04/15/1998

LICENSE NUMBER:

CONTROL NUMBER: 303858

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 10 CFR Part 170. Payment of the fee is required prior to the issuance of the license, renewal, or amendment.

FEE CATEGORY	APPLICATION	RENEWAL	AMENDMENT
7C	$ 1,800.00	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$
	$	$	$

FEE(s) DUE	$ 1,800.00
PAYMENT RECEIVED	$ 1,400.00
AMOUNT DUE	$ 400.00

- [ ] Your request was received without the prescribed application fee.
- [x] We received your check listed below. Payment of the additional fee noted above is required.
  - 20441 Check Number
  - $ 1,400.00 Amount
- [ ] 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

- [ ] Check Number ____ Enclosed is your check which accompanied your request. The fee is not required because:
- [ ] Check Number ____ We received your check listed in payment of the fee.
- [ ] Date of Request ____ Control Number ____ The Licensing staff has informed us that your request is to be considered as a continuation of the request listed.
- [ ] Date of Request ____ Control Number ____ Your request was combined, prior to review, with the request listed.

III. CHECK RETURNED

- [ ] Check Number ____ Enclosed is your check 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 Number ____ Amendment Number ____ Date Issued ____ The listed license 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	Distribution:	DATE
SHIRLEY CRUTCHFIELD	4/29/98		OC/DAF/LFARB S/F (LF-3.2.7) OC/DAF/LFARB RF OC/DAF R/F Pending Cy cc: Reg. 3	4/29/98

Bhat & Padival MD's, Inc.
M. Katapadi, M.D.
275 Cline Avenue
Mansfield, Ohio 44907

Forwarding and Address Correction Requested

License Fee & Debt Collection Branch
Division of Accounting and Finance
Office of the Controller
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

20555+0001

FAX TRANSMITTAL	
To: Chuck Giomuso	From: Colleen Casey
Fax # 440-473-0056	Number of pages: 2

Ok, Chuck
Giomuso agreed
to this telecon's
deficiencies.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532 4351
630-829-9841 (phone), 630-515-1259 (fax)

CONVERSATION RECORD

TIME: 4:05pm - 4:22pm.

DATE: 7/8/98

NAME OF PERSON(S) CONTACTED: Charles Giomuso, consultant for

ORGANIZATION: Bhat and Padival, M.D.'s Inc.

TELEPHONE NO.: 1-888-934-1871

SUBJECT
License No.: Pending
Control No.: 303858

Refer response to this control no. and address it to my attention.

SUMMARY

We have reviewed your application dated April 15, 1998, and your letter dated March 25, 1998, requesting a new license and find that we will need additional information as follows:

1. You are requesting authorization for materials identified in 10 CFR 35.200, which includes the use of sodium iodide iodine- 125 in quantities exceeding 30 uCi.

   10 CFR 35.32(a) states, in part, that a licensee must establish and maintain a written Quality Management (QM) program for all 10 CFR Part 35 uses applicable to their program.

   Please submit a QM program as required by 10 CFR 35.32(a). In lieu of submitting a QM program, if your use of 10 CFR 35.200 materials will not include sodium iodide iodine-125 in quantities exceeding 30 microcuries (uCi), you may submit a "negative declaration" confirming this use is not a part of your licensed material program.

   Confirm in your "negative declaration" that you will submit a QM program prior to initiating future use of sodium iodide iodine-125 or iodine-131 in quantities exceeding 30 uCi.

   Please submit your QM program or "negative declaration" in a **separate** correspondence from your response to other items in this letter.

2. Your application dated April 15, 1998, and your letter dated March 25, 1998, ("the application, the letter") request authorization for materials in 10 CFR 35.100 and 35.200.

   Please note that 10 CFR 35.200 includes the use of xenon-133, aerosols and generators **unless** you direct us to specifically exclude these items. Your application indicates that the xenon-133 and aerosols authorization is "not applicable" but you should specifically request their exclusion.

   In addition, if you do not want authorization for generators, please so state.

3. Although your application names a Radiation Safety Officer (RSO), it does not name any authorized physician users. You must name at least one authorized physician user for each type of use requested.

   If it was your intention for Dr. Suresh to serve as your authorized physician user also, please so state and note the following: on the referenced license that already lists Dr.

Suresh as RSO/authorized user, his/her (?) authorization is limited to cardiovascular clinical studies. In accordance with that authorization, we would also limit Dr. Suresh's authorization on your license to cardiovascular clinical studies **unless** you can demonstrate that Dr. Suresh has received training and experience that meets the requirements in 10 CFR 35.920 **and** that the scope of this training and experience encompasses at least several other anatomical imaging modalities, such as brain scans, bone, lung, etc.

4. On a detailed version of your facility diagram, please indicate the position of each of the areas described below (a-d) and describe the type, dimensions, and thickness of shielding that you will use. Please also indicate the direction of north, the scale of the diagram or the actual room dimensions and the room numbers, if applicable. Exhibit 6 and Item 9.1 of the enclosed Regulatory Guide 10.8, Rev. 2, may be helpful in preparing your response and provides an example of a facility diagram that is acceptable to the NRC.

   a. Use and storage of Tc-99m generators, including spent generators. If you will not be using generators, please so state.

   b. Storage of radiopharmaceuticals (refrigerated and nonrefrigerated).

   c. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste. This area should be large enough to handle an accumulation of Tc-99m generators as well as other solid waste. If this area is not located within your main department, describe how you will secure the material.

   d. Preparation and dispensing of radiopharmaceuticals (e.g., lead glass L-block, etc.).

5. Your application implies that you will have your instruments calibrated by instrument calibration service licensed by the NRC or an Agreement State. Please **explicitly state** this commitment and provide the name and NRC or Agreement State license number of at least one instrument calibration service that you may utilize.

6. Your application implies that you will have your sealed sources tested for leakage by a service licensed by the NRC or an Agreement State. Please **explicitly state** this commitment and provide the name and NRC or Agreement State license number of at least one sealed source leak testing service that you may utilize.

7. Item 10.1 of your application specifies commitments for a Radiation Safety Committee. Please note that it is not clear to us whether the composition of your practice requires an RSC. Please review the definition in 10 CFR 35.2 for "Medical institution" and the requirements in 10 CFR 35.22, enclosed, and advise us whether an RSC is appropriate for your license.

8. Item 10.12 of your application lists action levels for area surveys of "2 MR per hour for restricted areas and .05 MR per hour for unrestricted areas."

   The units used appear to be typos. Please note that "MR" refers to "Mega-roentgen" or "Mega-rem," which represents millions of roentgens/rems although you probably intended to use the unit "milliroentgen" or "mR," which represents a thousandth of one roentgen/rem. Please advise us if these units need correction.

ACTION REQUIRED

We will void this action temporarily until response can be prepared and received. Then, upon receipt of response, we will reactivate this application, complete the review and, hopefully, issue the new license. No additional fees are required to do this, it is only an adminstrative "holding pattern" procedure that gives you time to prepare response.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Colleen C. Casey	Colleen C Casey	July 8, 1998

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

April 24, 1998

Pammal Suresh, M.D.
Radiation Safety Officer
Bhat and Padival, M.D.'s, Inc.
277 Cline Avenue
Mansfield, OH 44907

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Application Dated April 15, 1998)

Dear Licensee:

In response to your request, we have completed the initial processing, which is an administrative review of your application for a(n):

X New License ___ Amendment __ Renewal
___ Termination ___ Auth User (Amendment not required)
___ Other_____

No administrative deficiencies were identified during this initial review. However, it should be noted that a technical review may identify omissions in the submitted information.

It appears that your request is routine (see 1-3 below, as applicable).

1. New and amerdment actions are normally completed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.

2. Renewal actions are normally completed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.

3. Termination actions are normally completed within 90 days, unless confirmatory surveys following decontamination/decommissioning activities are involved.

A copy of your correspondence has been forwarded to our Licensing Fee and Debt Collection Branch (301/415-6097) for approval of the fee category and amount, if required.

We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number. Please direct any questions concerning your request to the Materials Licensing Branch at (630) 829-9887.

Materials Support Branch

Mail Control No. 303858
License No. 34-32089-01