

MATERIALS LICENSE

Amendment No. 01

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		302018	
1. Goel Medical Corporation		In accordance with letter dated October 29, 1996	
2. 209 East 86th Court Merrillville, IN 46410		3. License Number 13-26674-01 is amended in its entirety to read as follows:	
		4. Expiration Date March 31, 2001	
		5. Docket or Reference No. 030-33947	
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, xenon-133 and aerosols)	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, xenon-133 and aerosols).			

CONDITIONS

10. Licensed material shall be used only at the licensee's facilities located at 209 East 86th Court, Merrillville, Indiana.
11. Radiation Safety Officer: Vijay P. Shah, M.D.

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PDR ADDCK 03033947
C PDR

COPY 4

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

13-26674-01

Docket or Reference Number

030-33947

Amendment No. 01

12. Licensed material listed in Item 6 above is only authorized for use by, or under the supervision of, the following individuals for the materials and uses indicated:

Authorized UsersMaterial and Use

Vijay P. Shah, M.D.

10 CFR 35.100 and 35.200 (excluding generators, xenon-133 and aerosols), limited to clinical cardiovascular studies.

Neelam Bhatia, M.D.

10 CFR 35.100 and 35.200 (excluding generators, xenon-133 and aerosols).

13. The licensee may not possess and use materials authorized in Items 6, 7, and 8 until:
- A. The licensee has constructed the facilities and obtained the equipment described in the application and supporting documentation; and
 - B. The U. S. Nuclear Regulatory Commission, Region III, ATTN: Chief, Materials Licensing Branch, 801 Warrenville Road, Lisle, IL 60532-4351 has been notified that activities authorized by the license will be initiated.
14. Within 30 days of the date of a decision not to complete the facility, acquire equipment, or possess and use authorized material, the licensee must notify the Commission in writing, of the decision.
15. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below, except for minor changes in the medical use radiation safety procedures as provided in 10 CFR 35.31. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated August 10, 1995 (with attachments excluding item 12);
 - B. Letters dated July 7, 1995 and January 23, 1997.

COPY

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

13-26674-01

Docket or Reference Number

030-33947

Amendment No. 01

15. (Continued)

C. Letters received February 14, 1996 and February 16, 1996.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Date January 29, 1997

By

Robert W. Hatten

Nuclear Materials Licensing Branch, Region III

COPY

(FOR LFMS USE)
INFORMATION FROM LTS

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

Program Code: 02201
Status Code: 0
Fee Category: 7C
Exp. Date: 20010331
Fee Comments:
Decom Fin Assur Req'd: N

LICENSE FEE TRANSMITTAL

A. REGION

1. APPLICATION ATTACHED

Applicant/Licensee: GOEL MEDICAL CORPORATION
Received Date: 9/11/04
Docket No: 3033947
Control No.: 302018
License No.: 13-26674-01
Action Type: Amendment

2. FEE ATTACHED

Amount: 440
Check No.: 2920

3. COMMENTS

Signed
Date

D. Hersey
11-5-96

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

1. Fee Category and Amount: 7C \$440

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

Amendment ☒
Renewal ☐
License ☐

3. OTHER

Signed
Date

SC
11/14/96

NOV 18 1996

Log	Nov 6 III
Remitter	
Check No.	2920
Amount	\$440
Fee Category	7C
Type of Fee	Amd
Date Check Rec'd	11/12/96
Date Completed	11/14/96
By:	SC

1996 NOV 12 AM 10:01



Heart & Circulation Clinics, P.C.

Cardiologists

Arun Goel, M.D.
Vijay B. Dave, M.D.
Thach Nguyen, M.D.
Harish A. Shah, M.D.
Vijay Shah, M.D.

Electrophysiology Consultants

Tom Petropoulos, M.D.
Tom Bump, M.D.
Edwin Palileo, M.D.

October 29, 1996

Main Office

209 East 86th Court
Merrillville, IN 46410
24 Hr. 219-769-9020
Fax 214-769-1758

United States Nuclear Regulatory Commission
Region III
801 Warrenville Rd.
Lisle, IL 60532-4351

Additional Locations:

3229 Broadway
Gary, IN 46409
(219) 887-5480

801 West Glen Park Ave.
Griffith, IN 46319
(219) 922-6218

4 North Heaton
Knox, IN 46534
(219) 772-6363

6916 Johnson Road
LaPorte, IN 46350
(219) 874-2939

1501 Wabash
Michigan City, IN 46360
(219) 874-8711

6375 U.S. Hwy. 6
Portage, IN 46368
(219) 762-3196

530 N. Hospital Dr.
P.O. Box 37
Winamac, IN 46996
(219) 946-6601

24 Hour Referral Line

1-800-677-GOEL

TO WHOM IT MAY CONCERN:

Please amend Materials License No. 13-26674-01, Item 9B., to include all Nuclear Medicine Clinical Procedures.

Attached is the fee charged for this amendment.

Thank you and if you have any questions, please contact me at (219) 769-9020.

Sincerely,

Kay Kirkham, CNMT

Kay Kirkham, CNMT
Goel Medical Corp.
KK/jl

enclosure

RECEIVED
NOV 04 1996
REGION III

NOV 04 1996

302018

Pm: 10-31-96

CARDIOVASCULAR CONSULTATION AND EVALUATION; PREVENTIVE CARDIOLOGY; RISK FACTOR ASSESSMENT AND MODIFICATION; EXERCISE STRESS TESTING; 24 HR
HEALTH MONITORING; DOPPLER FLOW DOPPLER ECHOCARDIOGRAPHY; TRANS ESOPHAGEAL ECHOCARDIOGRAPHY; NON-INVASIVE PERIPHERAL VASCULAR EVALUATION;
NUCLEAR CARDIOLOGY; DOPPLER AND PERIPHERAL ANGIOGRAPHY; ANGIOPLASTY; ATHERECTOMY AND SPORTS ELECTROPHYSIOLOGY; PACEMAKER SURVEILLANCE AND
IMPLANTATION; BRADY FREQUENCY CATHETER ABLATION; CHRONIC DEFIBRILLATOR IMPLANTATION.

JAN 30 1997

Vijay Shah, M.D.
Radiation Safety Officer
Goel Medical Corporation
209 East 86th Court
Merrillville, IN 46410

Dear Dr. Shah:

Enclosed is Amendment No. 01 to your NRC Material License No. 13-26674-01 in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

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

1. Operate in accordance with NRC regulations 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Notify NRC, in writing, within 30 days:
 - a. When an authorized user or Radiation Safety Officer permanently discontinues performance of duties under the license or has a name change; or
 - b. When the licensee's mailing address changes (no fee is required if the location of byproduct material remains the same).
3. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request termination of the license when you decide to terminate all activities involving materials authorized under the license.

302018

4. Request and obtain a license amendment before you:
 - a. Receive or use byproduct material for a clinical procedure permitted under Part 35 but not permitted by your license issued pursuant to this Part;
 - b. Permit anyone, except individuals described in 10 CFR 35.13(b), to work as an authorized user under the license;
 - c. Change Radiation Safety Officers;
 - d. Order byproduct material in excess of the amount, or radionuclide, or form different than authorized on the license;
 - e. Add or change the areas of use or address or addresses of use identified in the license application or on the license; or
 - f. Change ownership of your organization.
5. Submit a complete renewal application with proper fee or termination request at least 30 days before the expiration date of your license. You will receive a reminder notice approximately 90 days before the expiration date. Possession of byproduct material after your license expires is a violation of NRC regulations. A license will not normally be renewed, except on a case-by-case basis, in instances where licensed material has never been possessed or used.

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

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

V. Shah

-3-

prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

Sincerely,

Original Signed By
Gidget Watson
Nuclear Materials Licensing Branch

License No. 13-26674-01
Docket No. 030-33947

DOCUMENT NAME: M:\03033947.CL7

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" =
Copy with attachment/enclosure "N" = No copy

OFFICE	DNMS/RIII								
NAME	GWatson:brt								
DATE	01/29/97 GW								

OFFICIAL RECORD COPY



Heart & Circulation Clinics, P.C.

Cardiologists

Arun Goel, M.D.
Vijay B. Dave, M.D.
Thach Nguyen, M.D.
Harish A. Shah, M.D.
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Main Office

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(P.O. Box 37)
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24 Hour Referral Line

1-800-677-GOEL

January 23, 1997

United States Nuclear Regulatory Commission
Region III
Nuclear Medicine Licensing Section
801 Warrenville Rd.
Lisle, IL 60532-4351

ATTN: Gidget Watson, Ref.# 302018

TO WHOM IT MAY CONCERN:

Kay Kirkham is a Certified Nuclear Medicine Technologist employed with Goel Medical Corporation in Merrillville, IN. She is an authorized user of radioactive materials and her communication with the USNRC regarding the letter dated 10/29/96 is approved by Vijay Shah, M.D.

If you have any further questions or concerns, please feel free to contact the office at 219-769-9020.

Sincerely,

Vijay P. Shah, MD

Kay Kirkham, CNMT
VPS/KK/jl

RECEIVED

JAN 27 1997

REGION III

Pm: 1-24-97

JAN 27 1997

CONVERSATION RECORD

TIME

DATE

1/23/97

☐ VISIT☐ CONFERENCE☒ TELEPHONE☐ INCOMING☒ OUTGOINGNAME OF PERSON(S) CONTACTED OR IN CONTACT
Kay Kirkham, CNMTORGANIZATION (OFFICE, DEPT. ETC.)
Goel Medical Corp.

TELEPHONE NO.

219/769-9020

SUBJECT

License No. 13-26674-01

SUMMARY

I requested that letter dated 10/29/96 be signed by someone in upper management or that a letter be sent in authorizing Ms. Kirkham to act on behalf of Goel Medical Corp. in regards to NRC matters. **Ms. Kirkham stated that she would have someone respond accordingly.**

I inquired as to whether the licensee still wanted to exclude generators, xenon-133 and aerosols as listed in Item 7.B of the license. **YES**

Ms. Kirkham also stated that Neelam Bhatia, M.D. should also be listed as an authorized user in accordance with notification letter dated 9/9/96.

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION

SIGNATURE

DATE

ACTION TAKEN

SIGNATURE

TITLE

DATE



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
801 WARRENVILLE ROAD
LISLE, ILLINOIS 60532-4351

November 6, 1996

Vijay P. Shah, M.D.
Radiation Safety Officer
Goel Medical Corporation
209 E. 86th Court
Merrillville, IN 46410

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE
(Letter Dated 10/29/96)

Dear Licensee:

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

☐ 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 amendment actions are normally processed within 90 days, unless we find major deficiencies, or policy issues requiring central program office assistance.
2. Renewal actions are normally processed within 180 days, however, under timely filing (before expiration), you may continue to operate under your existing license.
3. Termination actions are normally processed 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.

If you have a compelling safety or business-related reason for requesting expedited review, please contact the Materials Licensing Branch at (630) 829-9887. We will try to complete your request as soon as practicable. Any correspondence about this request should reference the control number.

Nuclear Materials Support Branch

Mail Control No. 302018
License No. 13-26674-01