

DL-091697-04

OFFICIAL RECORD COPY

September 16, 1997

Gastrointestinal Associates
ATTN: Kevin R. Dye, M.D.
1201 Franklin Road, S.W.
Roanoke, VA 24016

SUBJECT: TRANSMITTAL AND EXPLANATION OF NEW LICENSE NO. 45-25401-01;
(REFERENCE CONTROL 257532; DOCKET NO. 030-34491)

Dear Dr. Dye:

Enclosed is your new NRC license.

Please review the document carefully and be sure that you understand all conditions. If you have any questions or comments, please notify Ms. Diane Heim at (404) 562-4723.

Please be advised that your license expires as stated in Item 4. 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 19, "Notice, Instructions and Reports to Workers; Inspections," 10 CFR Part 20, "Standards for Protection Against Radiation," and other applicable regulations.
2. Not possess and use materials authorized in Items 6, 7, and 8 on the license until:
 - a. you have constructed the facilities and obtained the equipment described in the license application and supporting documentation; and
 - b. you have notified the U. S. Nuclear Regulatory Commission, Region II, ATTN: Materials Licensing\Inspection Branch, in writing, that activities authorized by the license will be initiated; and
 - c. you have submitted and certified implementation of a Quality Management Program (10 CFR 35.32) for radiotherapy, or for administering >30 uCi of I-125 or I-131.
3. Notify NRC, in writing, within 30 days:
 - a. when an authorized user, Radiation Safety Officer, or Teletherapy Physicist 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).
4. In accordance with 10 CFR 30.36(b) and/or license condition, notify NRC, promptly, in writing, and request amendment or termination of the license:
 - a. when you decide to terminate all activities involving materials authorized under the license; or
 - b. when you decide to terminate licensed activities in a separate building or outdoor area identified on your license; or
 - c. if you decide not to complete the facility, acquire equipment, or possess and use authorized material.
5. 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, not authorized under 10 CFR 35, Subpart J, to work as an authorized user under a license for medical use of byproduct material;
 - c. permit anyone, not authorized under 10 CFR 35, Subpart J, to work as a Radiation Safety Officer, Teletherapy Physicist, or Nuclear Pharmacist, under a license for medical use of byproduct material;
 - d. order byproduct material in excess of the amount, or a different radionuclide or form, other 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.
6. 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. Transfer of licensed materials must be consistent with 10 CFR 30.41, 40.51 or 70.42, as applicable. 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, applications for NRC licenses (Form 313) must be signed by the licensee or certifying official (not a consultant). By signature, the signing official certifies his/her understanding that the application is true and correct to the best of the signator's knowledge.

The NRC is required to have your Taxpayer Identification Number in order to make payments (refunds). The self-addressed, stamped NRC Form 531, "Request for Taxpayer Identification Number" is enclosed.

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 Statement of Policy and Procedures for NRC Enforcement Actions," NUREG-1600, (7/95). Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken against those who do not achieve the necessary attention to detail and standard of compliance expected of licensees.

Thank you for your cooperation.

Sincerely,

*Original signed by
E. G. Wright*

Earl G. Wright, Senior License Reviewer
Materials Licensing/Inspection Branch
Division of Nuclear Materials Safety

- Enclosures:
1. NRC License No. 45-25401-01
 2. Category Marked Below for:
 - New licenses: NUREG-1600 (7/95): 19; 20; 30; 40 or 70, as appropriate; 71; 170; NRC Form 3; Agreement State list; NRC Form 313 and NRC Form 531
 - New radiography licenses: Parts 34; 150.
 - New medical and teletherapy licenses: Part 35.

Distribution w/o encls:
RII Docket File
DNMS Reading File

REFUSE	DATE	BY	NO.	REC.	NO.	REC.	NO.	REC.	NO.	REC.	NO.
SIGNATURE	DATE	BY	NO.	REC.	NO.	REC.	NO.	REC.	NO.	REC.	NO.
NAME	DATE	BY	NO.	REC.	NO.	REC.	NO.	REC.	NO.	REC.	NO.
DATE	BY	NO.	REC.	NO.	REC.	NO.	REC.	NO.	REC.	NO.	REC.
COPIES	DATE	BY	NO.	REC.	NO.	REC.	NO.	REC.	NO.	REC.	NO.

GASTROINTESTINAL ASSOCIATES

KEVIN R. DYE, M.D.

A Division of Physicians Care of Virginia, P.C.

FACSIMILE COVER SHEET

TO: MR. EARL WRIGHT
FAX: (404) 562-4899
DEPARTMENT: _____

The documents accompanying this FAX transmission contain confidential material. The information is intended ONLY for the use of the individual or entity named above. If you are not the intended recipient, you are hereby notified that any disclosure, copying, or the taking of any action in reliance on the contents of this FAXED information is not permissible. If you have received this fax in error, please immediately notify us by telephone at the number below to arrange for the return of these documents. THANK YOU!

FROM: Kevin R. Dye
DATE: 9/18/97 TIME: 14:45

TOTAL NUMBER OF PAGES (including this page): 4

COMMENTS: Please find enclosed the application information for my C-14 license. This form bears the signature of DR. JAMES MULLETT - Radiation Safety officer.

Thanks -
Kevin Dye M.D.

US NRC
Region II
Atlanta Fed. Center
61 Forsyth St. SW
Suite 23 T 85
Atlanta, Ga. 30303

USNRC Nat'l Lic/Insp Fax:404-562-4955

Aug 4 '97 9:33 P.03

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER KEVIN R. DYE			
PRECEPTOR STATEMENT (Continued)			
2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)			
ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information if comments may be applicable in duplicate or separate sheets.) D
P-32 (External)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 (External)	INTRACAVITARY TREATMENT		
I-131	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Am-150	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or Ir-192 or Cs-137	INTERSTITIAL TREATMENT		
	TELETERAPY TREATMENT		
Bi-203	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Yb-169 or Tl-201	GENERATOR		
Bi-112 or Po-210	GENERATOR		
Ti-66	REAGENT SITE		
3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING			
LOCATION RADIOLOGY ROTATION - UMKC SCHOOL OF MEDICINE		DATES 1981	CLOCK HOURS OF EXPERIENCE 1 MONTH TOTAL IN ROTATION
CLINICAL TRIALS OF CHUBT UNIV. OF VIRGINIA & CHRV		1986-1987	
4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:			
1. NAME OF SUPERVISOR UNIV. OF MO. - KANSAS CITY SCHOOL OF MEDICINE -		5. PRECEPTOR SIGNATURE C-14 UREA BREATH TEST ADMINISTERED UNDER THE LICENSE OF COMMUNITY HOSPITAL OF ROANOKE VALLEY	
2. ADDRESS NORTH KANSAS CITY HOSPITAL		6. PRECEPTOR'S NAME (Print type or name) ANTHONY CUZZOCREA MD.	
3. CITY NKC, MO.		7. DATE James Mullet, MD, RSO	
4. INTERNAL LICENSE NUMBER		8/19/97	

45-12706-01 (CHRV) EXH-7

EXHIBIT 3
SUPPLEMENT B

SUPPLEMENT		U. S. NUCLEAR REGULATORY COMMISSION	
PRECEPTOR STATEMENT			
<p><i>Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.</i></p>			
1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS		KEY TO COLUMN C	
<p>FULL NAME KEVIN RANDELL DYE</p> <p>STREET ADDRESS 8135 VISTA FOREST DR.</p> <p>CITY STATE ZIP ROANOKE VA. 24019</p>		<p>PERSONAL PARTICIPATION SHOULD CONSIST OF:</p> <p>1- Supervised examination of patients to determine the capability for radiopharmaceutical diagnosis and/or treatment and recommendation for procedure design.</p> <p>2- Collaboration in dose calculation and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.</p> <p>3- Approval period of training to enable physician to manage radioactive sources and follow patients through diagnosis and/or course of treatment.</p>	
2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN			
ROUTES	CONDITIONS DIAGNOSED OR TREATED	NUMBER OF CASES INVOLVED PERSONAL PARTICIPATION	COMMENTS (Additional information of interest only as authorized in duplicate on separate sheet.)
	Thyroid scan		<p>OVER 300 PATIENTS WERE STUDIED IN SUPPORT OF THE COMMERCIAL DEVELOPMENT OF THE C₁₄-UREA BREATH TEST.</p> <p>I AM CURRENTLY USING THE TEST UNDER THE AUTHORIZATION OF CARLTON COMMUNITY HOSPITAL OF ROANOKE VALLEY.</p> <p>I HAVE PARTICIPATED IN THE DEVELOPMENT OF THE TEST SINCE 1986. WE HAVE LOWERED THE DOSE FROM A LIQUID 5mCi TEST IN 1986-87 TO A 1mCi CAPSULE TEST.</p> <p>I AM QUITE KNOWLEDGEABLE OF THE RADIODOSIMETRY, RADIOCHEMISTRY AND HEALTH RISKS ASSOCIATED WITH THE TEST. I DID MUCH OF THE RESEARCH WHICH RESULTED IN FDA APPROVAL OF THIS TEST AND HAVE PUBLISHED SEVERAL MANUSCRIPTS AND ABSTRACTS REGARDING THE C₁₄UBT.</p>
	Thyroid uptake		
	Lung perfusion scan		
	Lung ventilation study		
	Aerosol ventilation scan		
	Renal flow scan		
	Brain scan		
	Liver/Spleen scan		
	Bone scan		
	Gastroesophageal study		
	Letheen study study		
	Cytogram		
	Decorystogram		
	Cardiac perfusion scan		
	Cardiac stress ventriculogram		
Cardiac rest ventriculogram			
Gallium scan			
	C-14 UREA BREATH TEST FOR DIAGNOSIS OF HELICOBACTER PYLORI		

USNRC Mat'l Lic/Insp Fax: 404-562-4955

Aug 8 '97 9:34 P.01
 PMA TRANSMITTAL 10000-3
 Matthew J. Combs
 Earl Wrayh
 404-562-4
 304-977-8760

EXHIBIT 2
 SUPPLEMENT A

SPECIALTY BOARD A		CATEGORY B	MONTH AND YEAR CERTIFIED C	
AMERICAN BOARD OF INTERNAL MEDICINE		INTERNAL MEDICINE	SEPT. 1984	
		GASTROENTEROLOGY	SEPT. 1988	

FIELD OF TRAINING A	LOCATION AND DATES OF TRAINING B	TYPE AND LENGTH OF TRAINING	
		CLOCK HOURS IN LECTURE OR LABORATORY	CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
1. RADIATION PHYSICS AND INSTRUMENTATION	RADIOLOGY ROTATION UNIV. OF MO. - K.C. SCHOOL OF MEDICINE 1981 - 1 MONTH - 160 HOURS RESIDENCY - INTERNAL MEDICINE 1981-1984 FELLOWSHIP - PULMONARY MEDICINE 1984-85	EST. 10 EST. 100 EST. 90	160 EST. 300 (X-RAY PHYSICS + INSTR) EST. 90 (X-RAY BRONCHOSCOPY)
2. RADIATION PROTECTION	RADIOLOGY ROTATION - UMKC RESIDENCY INT. MED. FELLOWSHIP - PULMONARY MED. FELLOWSHIP - GASTROENTEROLOGY - UVA 1985-86	INCLUDES IN ABOVE	EST. 90 (X-RAY REC'D & G.I. RADIOLOGY)
3. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	MATHEMATICS - COLLEGE CREDIT UNIV. OF MO. - KANSAS CITY 1975-1981	(6 COURSE CREDIT HOURS)	
4. RADIATION BIOLOGY	MEDICAL SCHOOL CLASSES RADIOLOGY ROTATIONS RESEARCH IN DEVELOPMENT OF C-14 UREA BREATH TEST 1986-1988 INT		
5. RADIOPHARMACEUTICAL CHEMISTRY	BIOCHEMISTRY ORGANIC CHEMISTRY RADIOLOGY ROTATION TRI-MED - EXPERIENCE WITH DEVELOPMENT OF C-14 UBT		

B. EXPERIENCE WITH RADIATION. (Actual use of Radioisotope or Equivalent Experience)				
ISOTOPE	ACT USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
C14	5 µCi. (1986-87) 1 µCi. (1989-97)	UNIV. OF VIRGINIA COMMUNITY HOSPITAL OF ROANOKE VALLEY	1 YEAR RESEARCH 9 years clinical experience. Over 300 breath tests administered under hospital license	C-14 urea breath test -

GASTROINTESTINAL ASSOCIATES

KEVIN R. DYE, M.D.

A Division of Physicians Care of Virginia, P.C

FACSIMILE COVER SHEET

TO: MR. EARL WRIGHT
 FAX: (404) 562-4899
 DEPARTMENT: _____

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FROM: Kevin R. Dye
 DATE: 9/11/97 TIME: 14:45
 TOTAL NUMBER OF PAGES (including this page): 4

COMMENTS:

USNRC Mar '1 Lic/Insp Fax:404-562-4955

Aug 4 '97 9:34 P.01
 PMA TERMINAL

Form - 3

EXHIBIT 2
 SUPPLEMENT A

Marlow J. Combs
 Earl Wagh
 404-562-41
 304-977-8760

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 KEVIN R. DYE M.D.					2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED VIRGINIA				
3. CERTIFICATION			SPECIALTY BOARD A		CATEGORY B		MONTH AND YEAR CERTIFIED C		
AMERICAN BOARD OF INTERNAL MEDICINE			INTERNAL MEDICINE				SEPT. 1984		
			GASTROENTEROLOGY				SEPT. 1988		
4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES									
FIELD OF TRAINING A		LOCATION AND DATE(S) OF TRAINING B			TYPE AND LENGTH OF TRAINING				
a. RADIATION PHYSICS AND INSTRUMENTATION		RADIOLOGY ROTATION UNIV. OF MO. - K.C. SCHOOL OF MEDICINE 1981 - 1 MONTH - 160 HOURS RESIDENCY - INTERNAL MEDICINE 1981-1984 RESIDENCY - PULMONARY MEDICINE 1984-85			EST. 100 EST. 90		EST. 160 (X-RAY PHYSICS & INSTR.) EST. 90 (X-RAY BRONCHOSCOPY)		
b. RADIATION PROTECTION		RADIOLOGY ROTATION - UMKC RESIDENCY INT. MED. FELLOWSHIP - PULMONARY MED. FELLOWSHIP - GASTROENTEROLOGY - UVA 1984-87			INCLUDES IN ABOVE		EST. 90 (X-RAY REC'D & G.I. RADIOLOGY)		
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY		MATHEMATICS - COLLEGE CREDIT UNIV. OF MO. - KANSAS CITY 1975-1981			(6 COURSE CREDIT HOURS)				
d. RADIATION BIOLOGY		MEDICAL SCHOOL CLASSES RADIOLOGY ROTATIONS RESEARCH IN DEVELOPMENT OF S-125 UREA BREATH TEST 1981-PRESENT							
e. RADIOPHARMACEUTICAL CHEMISTRY		BIOCHEMISTRY ORGANIC CHEMISTRY RADIOLOGY ROTATION TRI-MED - EXPERIENCE WITH DEVELOPMENT OF C-14 VBT							
5. EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)									
ISOTOPE	ACT USED AT ONE TIME	LOCATION		CLOCK HOURS		TYPE OF USE			
C14	5 μ C. (1986-87) 1 μ C. (1989-97)	UNIV. OF VIRGINIA COMMUNITY HOSPITAL OF ROANOKE VALLEY		1 YEAR RESEARCH 9 YEARS CLINICAL experience. Over 300 breath tests administered under hospital license		C-14 urea breath test -			

USNRC Mat'l Lic/Insp Fax: 404-562-4955

Aug 4 '97 9:34 P.02

EXHIBIT 3
SUPPLEMENT B

SUPPLEMENT		U. S. NUCLEAR REGULATORY COMMISSION	
PRECEPTOR STATEMENT			
Supplement B report to be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.			
1. PROPOSED PHYSICIAN USER'S NAME AND ADDRESS		KEY TO COLUMN C	
FULL NAME		PERSONAL PARTICIPATION SHOULD CONSIST OF:	
KEVIN RANDALL DYE		1 Supporting examination of patients to determine the suitability for radiotracer diagnosis and/or treatment and representation for prescriptive change.	
STREET ADDRESS		2 Participation in case selection and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.	
8135 VISTA FOREST DR.		3 Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.	
CITY			
ROANOKE			
STATE			
VA			
ZIP CODE			
24018			
2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN			
MOYOS	CONDITIONS DIAGNOSED OR TREATED	NUMBER OF CASES WITH YOUR PERSONAL PARTICIPATION	COMMENTS (Additional information or comments only to be entered in duplicate on separate sheet.)
A	B	C	
	Thyroid scan		<p>OVER 300 PATIENTS WERE STUDIED IN SUPPORT OF THE COMMERCIAL DEVELOPMENT OF THE C14-UREA BREATH TEST.</p> <p>I AM CURRENTLY USING THE TEST UNDER THE AUTHORIZATION OF CARLTON COMMUNITY HOSPITAL OF ROANOKE VALLEY.</p> <p>I HAVE PARTICIPATED IN THE DEVELOPMENT OF THE TEST SINCE 1986. WE HAVE LOWERED THE DOSE FROM A LIQUID 5mCi TEST IN 1986-87 TO A 1mCi CAPSULE TEST.</p> <p>I AM QUITE KNOWLEDGEABLE OF THE RADIODOSIMETRY, RADIOCHEMISTRY AND HEALTH RISKS ASSOCIATED WITH THE TEST. I DID MUCH OF THE RESEARCH WHICH RESULTED IN FDA APPROVAL OF THIS TEST AND HAVE PUBLISHED SEVERAL MANUSCRIPTS AND ABSTRACTS REGARDING THE C14 UBT.</p>
	Thyroid uptake		
	Lung perfusion scan		
	Lung ventilation study		
	Aerosol ventilation scan		
	Renal flow scan		
	Brain scan		
	Liver/spleen scan		
	Bone scan		
	Gastroesophageal study		
	LeVeen shunt study		
	Cystogram		
	Oesophylogram		
	Cardiac perfusion scan		
	Cardiac stress ventriculogram		
Cardiac rest ventriculogram			
Gallium scan			
	C-14 UREA BREATH TEST FOR DIAGNOSIS OF HELICOBACTER PYLORI		

EXHIBIT 3 (Continued)

PROPOSED PHYSICIAN USER KEVIN R. DYE			
PRECEPTOR STATEMENT (Continued)			
2. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)			
EXCEPTOR	CONDITIONS DIAGNOSED OR TREATED	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION	COMMENTS (Additional information or comments may be included in duplicate on separate sheets.)
A	B	C	D
P-20 (2-20-97)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-20 (2-20-97)	INTRACAVITARY TREATMENT		
I-130	TREATMENT OF THYROID CARCINOMA		
	TREATMENT OF HYPERTHYROIDISM		
Am-108	INTRACAVITARY TREATMENT		
Co-60 or Cs-137	INTERSTITIAL TREATMENT		
	INTRACAVITARY TREATMENT		
I-125 or I-197 or Cs-137	INTERSTITIAL TREATMENT		
	TELETERAPY TREATMENT		
Sr-90	TREATMENT OF EYE DISEASE		
	RADIOPHARMACEUTICAL PREPARATION		
Mo-99 Tc-99m	GENERATOR		
Sm-153 or Sm-152m	GENERATOR		
Tc-99m	REAGENT KITS		

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL RADIOISOTOPE TRAINING			
LOCATION	DATES	CLOCK HOURS OF EXPERIENCE 1 MONTH TOTAL IN STATION	
RADIOLOGY ROTATION - UMKC SCHOOL OF MEDICINE	1981		
CLINICAL TRIALS OF C14UBT	1986-1987		
UNIV. OF VIRGINIA + CHRV			

4. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:		5. PRECEPTOR QUALIFICATIONS	
a. NAME OF SUPERVISOR		C-14 UREA BREATH TEST ADMINISTERED UNDER THE LICENSE OF COMMUNITY HOSPITAL OF ROUNKE VALLEY	
UNIV. OF MO. - KANSAS CITY		6. PRECEPTOR'S NAME (Print or type)	
SCHOOL OF MEDICINE -		ANTHONY CUZZOCREA M.D.	
AND		7. DATE	
8. WORKING FACILITY		8/19/97	
NORTH KANSAS CITY HOSPITAL			
9. CITY			
NKC, MO.			
10. NATIONAL LICENSE NUMBER			

45-12706-01 (CHRV) EXH-7

OFFICIAL RECORD COPY 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, 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		3. License Number	45-25401-01
1. Gastrointestinal Associates		4. Expiration Date	June 30, 2002
2. 1201 Franklin Road, S.W. Roanoke, Virginia 24016		5. Docket or Reference No.	030-34491

6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License
A. Carbon 14	A. Urea breath test kit	A. As needed

9. Authorized Use:
A. Medical use identified in 10 CFR 35.100.

CONDITIONS

- 10. Licensed material shall be used only at the licensee's facilities located at 1201 Franklin Road, S.W., Roanoke, Virginia 24016.
- 11. The Radiation Safety Officer for this license is Kevin R. Dye, M.D.
- 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:

<u>Authorized Users</u>	<u>Material and Use</u>
Kevin R. Dye, M.D.	C-14 urea breath test for medical use identified in 10 CFR 35.100.
- 13. Sealed sources containing licensed material shall not be opened by the licensee.

9710100033 970916
PDR ADOCK 03034491
C PDR



Handwritten signature or initials

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number	45-25401-01
Docket or Reference Number	030-34491

CONDITIONS

Continued

- 14. In addition to the possession limits in item 8, the licensee shall further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35 for establishing decommissioning financial assurance.
- 15. The licensee shall maintain records of information important to safe and effective decommissioning at the licensee's facilities listed in Condition 10 pursuant to the provisions of 10 CFR 30.35(g) until this license is terminated by the Commission.
- 16. A. The licensee may not possess and use materials authorized in Items 6, 7, and 8, until: 1) the licensee has constructed facilities and obtained the equipment described in the application and supporting documentation; and 2) the U.S. Nuclear Regulatory Commission, Region II, ATTN: Chief, MLIB1, Atlanta Federal Center, 61 Forsyth Street, S.E., Suite 23T85, Atlanta GA 30303, has been notified in writing that activities authorized by the license will be initiated.
 B. In accordance with the requirements set forth in 10 CFR 30.36(b), the licensee shall promptly notify the Nuclear Regulatory Commission, in writing of a decision not to complete the facility, acquire equipment, or possess and use authorized material.
- 17. 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 June 5, 1997
 B. Fax transmissions on September 11 and 14, 1997 [Preceptor statements for Dr. Dye]

FOR THE U. S. NUCLEAR REGULATORY COMMISSION

EARL G. WRIGHT

Date SEP 16 1997

J 9/19/97

By *Earl G. Wright*
 Region II, Division Nuclear Materials Safety
 Atlanta Federal Center
 61 Forsyth Street SW, Suite 23T85
 Atlanta, GA 30303