NRC FORM 374 (7-94)

U.S. NUCLEAR REGULATORY COMMISSION

MATERIALS LICENSE

Amendment No. 1

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	
1. Tri-Med Specialties, Inc.	In accordance with letter dated **December 9, 1996** 3. License Number 45-25215-02MD is **amended** in its entirety to read as follows:
2. 1500 Avon Street Extended Charlottesville, Virginia 22902	4. Expiration Date **December 31, 2004 (Extended)**
	5. Docket or Reference No. 030-33723

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 $(CO(NH_2)_2)$	A. Not Applicable
B. Carbon 14	**B. Toluene**	**C. Not Applicable**

9. Authorized Use:

A and B. Pursuant to Section 32.72, 10 CFR Part 32, the licensee is authorized to distribute the byproduct material described in Items 6 and 7 of this license to persons licensed pursuant to Section 35.11 and Section 35.100, 10 CFR Part 35, or under equivalent licenses of Agreement States.

CONDITIONS

10. The licensee is authorized to distribute the licensed material described in Items 6 and 7 of this license from 1500 Avon Street Extended, Charlottesville, Virginia.

11. Any proposed changes in packaging, shielding, labeling or the package insert shall be submitted for review, and approval prior to implementation, to the U.S. Nuclear Regulatory Commission, Division of Nuclear Materials Safety, Materials Licensing/Inspection Branch, Region II, 101 Marietta Street, N.W., Suite 2900, Atlanta, Georgia 30323-0199.

12. The licensee shall notify the U.S. Regulatory Commission within thirty (30) days of the termination of a "Notice of Claimed Investigational Exemption for a New Drug' (IND) or the withdrawal of approval for a "New Drug Application" (NDA) for any licensed materials described in Items 6 and 7 of this license.

01
IN120

MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number 45-25215-02MD

Docket or Reference Number 030-33723

Amendment No. 1

(Continued) CONDITIONS

13. This license does not authorize possession or use of licensed material.

14. 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. 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 November 11, 1994

B. Letter dated December 13, 1994 (Package inserts, blister-pack & label)

C. **Letter dated December 9, 1996 (Addition of C-14 scintillation counting standard; and Extension of expiration date in accordance with 10 CFR 30.360)**

D. **Letter dated December 19, 1996 (Facsimile regarding the labeling of the vials)**

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

EARL G. WRIGHT

DATE JAN 3 1997 BY Earl G. Wright

Region II, Division of Nuclear Materials Safety
101 Marietta Stree N.W., Suite 2900
Atlanta, Georgia 30323-0199

N:\MLICENSE\45-25215.MD1

1/7/97

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W., SUITE 2900
ATLANTA, GEORGIA 30323-0199

DEC 3 1 1996

INFORMATION FOR NRC MATERIAL LICENSEES

Please find enclosed:
- ___/___ Your NRC material license
- ___/___ Amendment to your NRC material license
- ___/___ Amendment renewing your NRC material license
- ___/___ Amendment terminating your NRC material license
- ___/___ Notice for Radiographer Quality Assurance Approval Program

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify this office (ATTN: Ms. Diane Heim at (404) 331-4673) 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 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

   c. you have submitted & 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 termination of the license:

   a. when you decide to terminate all activities involving materials authorized under the license; or

   b. if you decide not to complete the facility, acquire equipment, or possess and use authorized material.

(Rev. 3/96)

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, 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 or 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.

Enclosures:
1. NRC License
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; and NRC Form 313.
   [ ] New radiography licenses: Parts 34; 150.
   [ ] New medical and teletherapy licenses: Part 35.
   [ ] Amendments and renewals: NRC Form 313.

TRI-MED
Specialties Inc.

1500 AVON STREET EXT'D
CHARLOTTESVILLE, VA 22902
PHONE (804) 977-8711 FAX (804) 977-8760

December 19, 1996

Wade T. Loo
US Nuclear Regulatory Commission
Region II, Nuclear Materials Licensing Section
101 Marietta St NW Suite 2900
Atlanta, GA 30323

Re: Ref. Control Nos. 257126 and 257127
Docket Nos. 030-32884 and 030-33723

Dear Mr. Loo,

Per our conversation this morning, please see the attached updated labeling for our PYtest™ Standard Set.

If you have any questions please let me know.

Sincerely,

Matthew J. Combs, PhD
Scientific Coordinator of ^{14}C Projects
Tri-Med Specialties, Inc.

MJC/kb

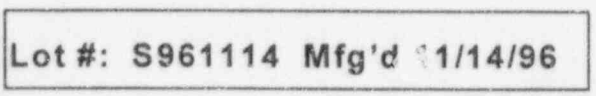
(vii.) Each standard is provided with a 2-part label. The first part of the label is affixed to the vial cap, and indicates general information such as (see Figure 2).

-radionuclide, C-14,
-activity in dpm (20,000) and microCuries (0.01)
-Manufacture date, and
-Tri-Med Specialties name and address

Figure 2. Label for top of cap (^{14}C standard).

A label for the side of the vial cap shows the Lot number for the set of vials and the date of manufacture. An example label is shown in Figure 3.

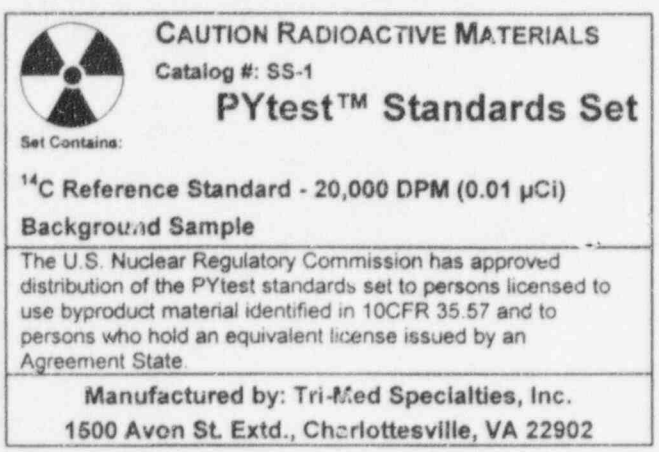
Figure 3. Label for side of cap.



(viii.) There are no special instructions for handling and storing C-14 standards. It is assumed that standard radioactive material handling and storage precautions will be followed by the recipient licensee. A product insert (see enclosed sample) is shipped with each standard vial. The constituents of the standard solution and the radioactivity level are included in the insert.

(3.) A sample of the label that is attached to the cap of the vial is shown in Figure 2. A sample label for the storage container (small plastic box) is shown in Figure 4 .

Figure 4. Label for standards set box.



(b.) The C-14 standards are glass vials containing approximately 0.01 microCuries in a liquid solution. The standards are not considered to be sealed sources. Because of the form of the radioactive material, the activity level and the design of the standards leak testing of the standards does not apply.

(c.) Does not apply.

TRI-MED
Specialties Inc.

1500 AVON STREET EXT'D
CHARLOTTESVILLE, VA 22902
PHONE (804) 977-8711 FAX (804) 977-8760

December 18, 1996

U.S. Nuclear Regulatory Commission
Attention: Mr. Wade Loo
Region II, Nuclear Materials Licensing Section
101 Marietta Street, NW, Suite 2900
Atlanta, Georgia 30323
Ref. Control Nos. 257126 and 257127
Docket Nos. 030-32884 and 030-33723

Dear Mr. Loo,

Pursuant to our conversation earlier today, we wish to reduce the possession limit of ^{14}C-urea for license 45-25215-01 from 100 mCi to 99.9 mCi. Simultaneously we wish to add 0.1 mCi (100 µCi) as our possession limit for ^{14}C-toluene to be used in manufacture of liquid scintillation counting standards. The reason for this change is to meet the 100 mCi limit for ^{14}C at or below which no financial assurance for decommissioning is needed. Thank you for your assistance, and if you need further clarification of this matter, please contact me at 804-977-8711.

Sincerely,

Matthew J. Combs, Ph.D.
Scientific Coordinator of ^{14}C projects
Tri-Med Specialties, Inc.

TRI-MED
Specialties Inc.

1500 AVON STREET EXT'D
CHARLOTTESVILLE, VA 22902
PHONE (804) 977-8711 FAX (804) 977-8760

December 9, 1996

U.S. Nuclear Regulatory Commission
Attention: Earl Wright/Wade Loo
Region II, Nuclear Materials Licensing Section
101 Marietta Street, NW, Suite 2900
Atlanta, Georgia 30323
Ref. Control Nos. 257126 and 257127
Docket Nos. 030-32884 and 030-33723

Dear Mr. Wright,

Tri-Med Specialties, Inc. holds NRC byproduct materials licenses 45-25215-01 and 45-25215-02MD. These licenses allow the manufacture and distribution of a ^{14}C-urea breath test (PYtest™) for use by medical licensees. Tri-Med wishes to amend these two licenses in accordance with 10CFR32.74 and 35.57 to allow for the manufacture and distribution of a standards set consisting of 2 samples which are identical in composition to PYtest breath samples with the only difference being that one sample will contain 20,000 DPM of ^{14}C-toluene reference solution (^{14}C standard) and the other will contain no radioactivity (background sample). The information in this amendment application focuses on the ^{14}C standard since it is the only one containing radioactive material.

The ^{14}C standard will contain 10 mL liquid scintillation fluid, 1 mL benzethonium hydroxide 1M (hyamine), 1.5 mL methanol, 50 µL 0.9% thymolphthalein pH indicator and 20,000 DPM ^{14}C-toluene. The ^{14}C-toluene is a NIST-traceable standard solution. Each standard will be checked to ensure that it is within ±5% of the required 20,000 DPM. The standards will be shipped in a small plastic box with a foam liner to protect the samples. In most cases the recipient of the standard will need only one counting set.

Tri-Med will prepare the standard set and provide them to medical licensees with a product insert describing the composition and accuracy of the standard. A sample package insert is enclosed with this letter. The vials used to make the standards will be normal scintillation vials with adhesive caulk to prevent leakage or loss and make the vial tamper-resistant. To keep costs low the vials will not be flame sealed. Tri-Med will allow customers to return the

standards if damage or loss of material is noted, or if the recipients no longer need or want the source. It should be noted that since these sources will be distributed to licensees, they will have the appropriate disposal and safety procedures in place to handle any adverse events involving the sources.

These standards will allow users of the PYtest to calibrate their instruments for the breath sample counting geometry. Tri-Med would like to offer these standards to customers since they are not now available from other vendors except as custom preparations. Tri-Med is committed to providing these standards at a small fraction of the typical source vendor's price.

Attached to this letter is pertinent information required under 10 CFR 32.74 and a sample package insert.

Thank you for your assistance, and if you need further clarification of this matter, please contact Dr. Matthew Combs in our Charlottesville office at 804-977-8711.

Sincerely,

WA Fry

William A. Fry
President
Tri-Med Specialties, Inc.

Attachment to Tri-Med Specialties Amendment Application

Distribution of Liquid Scintillation Standards
Ref. Control Nos. 257126 and 257127
Docket Nos. 030-32884 and 030-33723

The following is information required under 10 CFR 32.74

(a.)
(1.) This is information in support of amending two currently held NRC licenses.
(2.) Radiation Safety:
(i.) Each standard contains approximately 0.01 microcuries (20,000 DPM ±5%) of C-14 toluene in 10 mL liquid scintillation fluid, 1 mL benzethonium hydroxide 1M (hyamine), 1.5 mL methanol, 50 µL thymolphthalein pH indicator (0.9% w/v in ethanol). The C-14 toluene used to make the scintillation standards is a NIST-traceable standard solution.

(ii.) The C-14 standard solution is contained in a commercially manufactured, glass, liquid scintillation vial with plastic screw-on cap. A bead of adhesive caulk is placed around the cap to prevent opening of the vial.

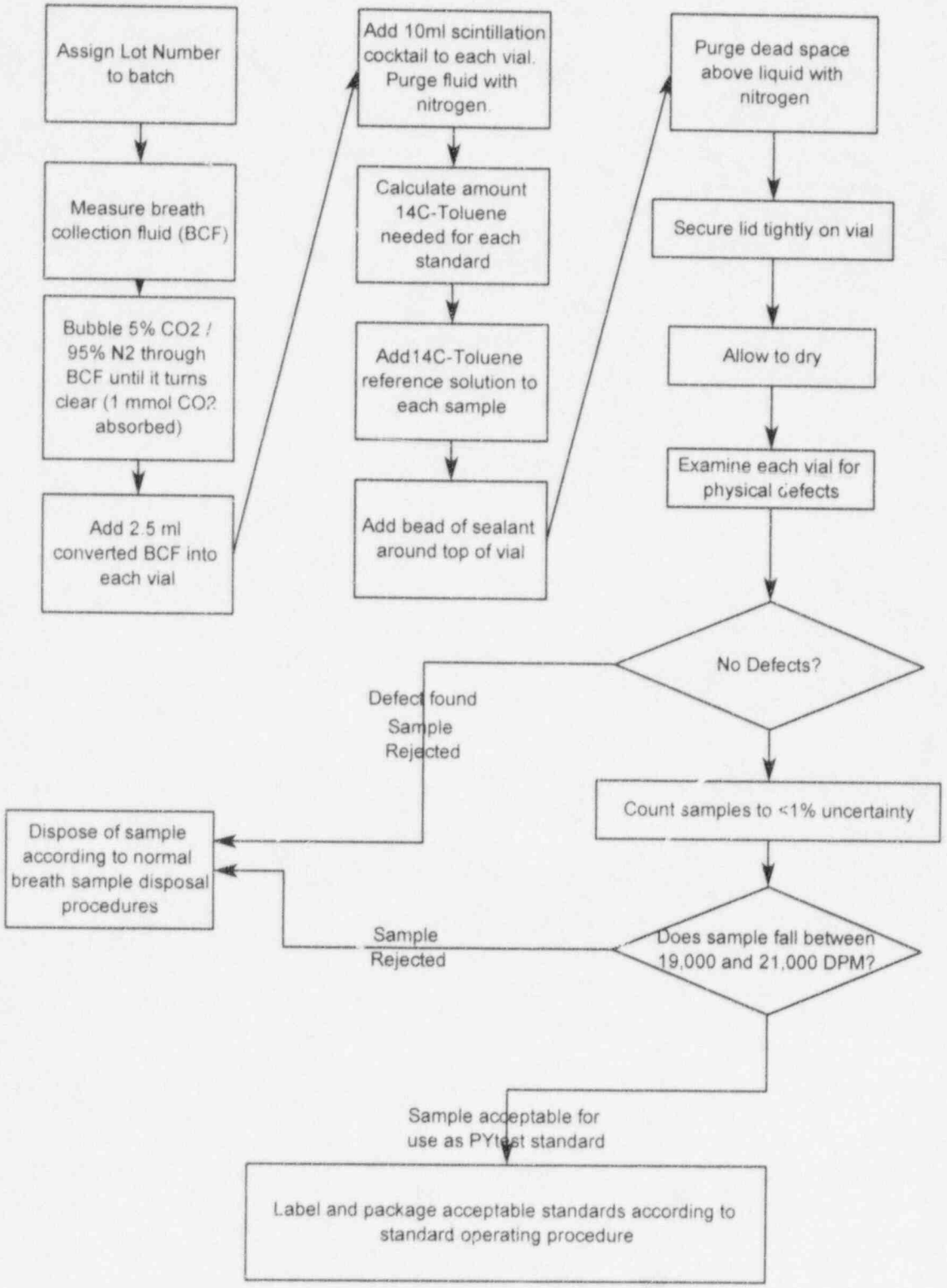
(iii.) The cap is sealed using a commercially available adhesive (Versatile Adhesive Caulk, Seal-All or Equivalent) glue to prevent leakage and inadvertent opening. No other design features are incorporated to prevent loss of material.

(iv.) C-14 emits only beta particles (Emax 156 keV) which are not energetic enough to penetrate the glass container. There is therefore no external radiation field emanating from the standards.

(v.) The QC procedures used are that all vials are counted in a standard liquid scintillation counter which is QC'd on a daily, monthly and annual basis. Acceptable samples must be 20,000 DPM ±5% (19,000-21,000 DPM).

(vi.) Standards are prepared using a NIST traceable solution. The procedure for preparation and QC is outlined in Figure 1. The flow chart describes the preparation of the ^{14}C standard. The procedure for preparing the background sample is the same with the exception that no ^{14}C-toluene is added and the limits for counting are 40-60 CPM. This document focuses only on the ^{14}C standard since there is no radioactive material involved in the background sample.

Figure 1. Summary of PYtest Standards Set Preparation Procedures



(vii.) Each standard is provided with a 2-part label. The first part of the label is affixed to the vial cap, and indicates general information such as (see Figure 2).

-radionuclide, C-14,
-activity in dpm (20,000) and microCuries (0.01)
-Manufacture date, and
-Tri-Med Specialties name and address

Figure 2. Label for top of cap (^{14}C standard).

A label for the side of the vial cap shows the Lot number for the set of vials and the date of manufacture. An example label is shown in Figure 3.

Figure 3. Label for side of cap.

Lot #: S961114 Mfg'd 11/14/96

(viii.) There are no special instructions for handling and storing C-14 standards. It is assumed that standard radioactive material handling and storage precautions will be followed by the recipient licensee. A product insert (see enclosed sample) is shipped with each standard vial. The constituents of the standard solution and the radioactivity level are included in the insert.

(3.) A sample of the label that is attached to the cap of the vial is shown in Figure 2. A sample label for the storage container (small plastic box) is shown in Figure 4 .

Figure 4. Label for standards set box.

CAUTION RADIOACTIVE MATERIALS Catalog #: SS-1 **PYtest™ Standards Set** Set Contains: **^{14}C Reference Standard - 20,000 DPM (0.01 µCi)** **Background Sample**
The U.S. Nuclear Regulatory Commission has approved distribution of the PYtest standards set to persons licensed to use byproduct material identified in 10CFR 35.100 or 10 CFR 35.200 and to persons who hold an equivalent license issued by an Agreement State.
Manufactured by: Tri-Med Specialties, Inc. **1500 Avon St. Extd., Charlottesville, VA 22902**

(b.) The C-14 standards are glass vials containing approximately 0.01 microCuries in a liquid solution. The standards are not considered to be sealed sources. Because of the form of the radioactive material, the activity level and the design of the standards leak testing of the standards does not apply.

(c.) Does not apply.

SAMPLE PACKAGE INSERT

PYTEST™ BREATH SAMPLE STANDARDS SET (CATALOG # SS-1)

Manufactured by:

Tri-Med Specialties, Inc.
1500 Avon St. Extd.
Charlottesville, VA 22902

DESCRIPTION

This set contains two samples used to calibrate liquid scintillation counters for use with the Tri-Med Specialties, Inc. ^{14}C-urea breath test for *H.pylori* (PYtest™). In performing the test, 1 mmol of CO_2 is trapped from a breath sample and counted for ^{14}C activity. This set consists of a background sample which contains no ^{14}C but has all other constituents of a breath sample. This sample is labeled with the Letters "Bkg". The other sample in the set is a breath sample spiked with 20,000 DPM of ^{14}C-toluene. It is labeled with the letters ^{14}C. The ^{14}C-toluene is a NIST-traceable solution of known concentration. Other than the radioactivity solution, each sample contains:

a) 2.5 mL PYtest breath collection fluid which consists of 1 mL benzethonium hydroxide (1 M), 1.5 mL methanol, 50 µL thymolphthalein pH indicator (0.9% in ethanol)

b) 10 mL liquid scintillation fluid.

The contents of the vial are purged with nitrogen to reduce oxidation (quenching). The samples are also sealed with an adhesive caulk and a screw cap to prevent spillage of the material. The radioactivity added to the sample has been calibrated against solutions certified by the National Institute of Standards & Technology (NIST). During the quality control portion of the manufacturing process, each ^{14}C sample is counted and rejected if not within ±5% of the target value (20,000 DPM) using a calibrated liquid scintillation counter.

RECOMMENDATIONS FOR USE

These samples are similar in composition to PYtest breath samples. The components such as benzethonium hydroxide and methanol provide quench, so it is anticipated that the results obtained with these samples will not give the maximum efficiency of the instrument, unlike unquenched standards normally shipped with the liquid scintillation counter. This set can be used to:

Calibrate a liquid scintillation counter for the PYtest sample geometry (1 mMol benzethonium hydroxide in methanol, 1.5 mL methanol, liquid scintillation fluid)

To obtain the efficiency of the instrument:

1. Perform regular QC on instrument (if necessary)
2. Count the background sample (gives background value in counts per minute (CPM))
3. Count the standard sample (Get standard CPM)
4. Calculate counter efficiency: 100* (Standard CPM - Background CPM)/20,000

The efficiency can then be applied to samples of this type using the instrument which was calibrated. It is recommended that this calibration be performed every day prior to counting patient breath samples. A log of the background and standard values should be maintained, and a significant deviation from a normal result indicates a problem with the instrument or its settings and should be investigated.

LIMITATIONS ON USE

This calibration set is valid only for the sample geometry described herein. If the sample constituents change (amount of methanol or benzethonium hydroxide, radionuclide), the calibration is invalid.

PRECAUTIONS ON STORAGE AND USE

This set should be protected from direct sunlight which can degrade the sample components. When not in use the samples should be kept in their case.
The standard sample contains radioactive material, and should be used with caution as any other low-level radioactive material. It should be handled like any other hazardous material in the laboratory, and the precautions appropriate with other hazardous chemicals apply to these samples.
The samples should be handled like any other liquid scintillation media. Disposal of the standards should be in accordance with institutional, local, state and federal regulations for the safe use of radioactive materials.

NRC FORM 218 (4-76) NRCM 0240 — U.S. NUCLEAR REGULATORY COMMISSION

TELEPHONE OR VERBAL CONVERSATION RECORD

DATE: 11/20/96

TIME: ~10:05 ☒ A.M. ☐ P.M.

☐ INCOMING CALL ☒ OUTGOING CALL ☐ VISIT

PERSON CALLING	OFFICE/ADDRESS	PHONE NUMBER	EXTENSION
WADE LOO	USNRC - RII, ATLANTA, GA	404-331-3932	

PERSON CALLED	OFFICE/ADDRESS	PHONE NUMBER	EXTENSION
SUSIE HOFFMAN	TRI-MED SPECIALTIES, INC. CHARLOTTESVILLE, VA	804-977-8711	

CONVERSATION

SUBJECT: LIC. AMEND REQUEST

SUMMARY

- CALLED TO FOLLOWUP ON OUR LTR DATED 10/28/96 TO SEE IF LICENSEE STILL PURSUING REQUEST.
- MS. HOFFMAN SAID STILL PURSUING ISSUE & WILL RESPOND WITHIN A WEEK OR SO; BUSY AT OFFICE.

WD

- RCVD PHONE CALL FROM TRIMED - MATT COMBS (12/4/96 ~4:40 PM)
- RETURNED CALL (12/5/96 ~ 8:15 AM) - WILL SEND INFO. VIA FAX MONDAY (12/9/96). IN RESPONSE TO OUR LTR DATED 10/28/96.

WD

☐ ADVISE ME OF ACTION TAKEN.

ACTION REQUESTED	INITIALS	DATE

ACTION TAKEN	INITIALS	DATE

NRC FORM 218 (4-76)

OCT 2 8 1996

Tri-Med Specialties, Inc.
ATTN: William Fry
1500 Avon Street Ext'd
Charlottesville, Virginia 22902

SUBJECT: LETTER DATED JULY 12, 1996, REGARDING DISTRIBUTION OF LIQUID SCINTILLATION STANDARDS (REFERENCE CONTROL NOS. 257126 AND 257127; DOCKET NOS. 030-32884 AND 030-33723)

Dear Mr. Fry:

This refers to your letter dated July 12, 1996, seeking information on how to obtain NRC approval to distribute liquid scintillation standards (calibration or reference sources) not currently authorized on License No. 45-25215-02MD. Based on the information in your letter and telephone discussions between Mr. James R. Gilchrist, Radiation Safety Officer, Ms. Susie R. Hoffman, Product Development Coordinator, Mr. Wade Loo, RII License Reviewer and myself, it appears that both of your NRC licenses (Nos. 45-25215-01 and 45-25215-02MD) will need to be amended.

Although, we have used your letter as your application, more information is needed to continue our review. Accordingly, please provided the following:

1) A resubmission of the information contained in your letter dated July 12, 1996, as an amendment request for each of your NRC Licenses (Nos. 45-25215-01 and 45-25215-02MD); and

2) Pertinent additional information specified in 10 CFR 32.74 and 35.57 (Enclosures 1 and 2) as will apply to your manufacture and distribution of liquid scintillation standards (calibration and reference sources). Since the sources you propose to distribute will contain less than 100 microcuries of carbon 14, it is my understanding that the source designs will not require a review by the NRC Source Containment and Devices Branch (Reference, 10 CFR 32.210). However, the information required by 10 CFR 35.57 and 10 CFR 32.74 will be reviewed by RII and incorporated into License No. 45-25215-01 and 45-25215.02MD.

   When amended, License No. 45-25215-01 will authorize the possession and use of carbon 14 for production, labeling and packaging of the reference sources incident to distribution and License No. 45-25215-02MD will authorize distribution of the sources to medical licensees or other persons specifically licensed by NRC or an Agreement State to receive the sources.

Our review of your amendment request will continue upon receipt of the requested information. Please provide two copies of your reply and refer to Control Nos. 257126 and 257127.

Replies may be transmitted via electronic facsimile (FAX) to (404) 331-4479. You should then mail the original copy of any electronically transmitted documents.

Unless we hear from you within thirty days of receipt of this letter, we shall assume that you do not wish to pursue your application.

If you have any questions, please call me at (404) 331-5617 or Wade Loo at (404) 331-3932.

Sincerely,

Earl G. Wright
Senior License Reviewer
Division of Nuclear Materials Safety

Docket Nos.: 030-33723, 030-32884
License Nos.: 45-25215-02MD, 45-25215-01

Enclosures: 1. 10 CFR 32.74
2. 10 CFR 35.57

cc: Commonwealth of Virginia

Distribution:
PUBLIC
RII Docket File, DNMS

OFFICE	RII:DNMS	RII:DNMS	RII:DNMS			
SIGNATURE		EGW				
NAME	WLoo	EWright	CHosey			
DATE	10 / 25 / 96	10 / 23 / 96	10 / 25 / 96	10 / / 96	10 / / 96	10 / / 96
COPY?	(YES) NO	YES (NO)	YES (NO)	YES NO	YES NO	YES NO

OFFICIAL RECORD COPY DOCUMENT NAME: G:\DRSS\NMLS\257126D.WLI

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02511
Status Code: 0
Fee Category: 3C
Exp. Date: 20041231
Fee Comments: _____
Decom Fin Assur Reqd: N

1996 JUL 26 AM 10:50

LICENSE FEE TRANSMITTAL

A. REGION II

1. APPLICATION ATTACHED
   Applicant/Licensee: TRI-MED SPECIALTIES, INC.
   Received Date: 960718
   Docket No: 3033723
   Control No.: 257126
   License No.: 45-25215-02MD
   Action Type: Amendment

2. FEE ATTACHED
   Amount: ___--___
   Check No.: _____

3. COMMENTS

Signed N.Witt
Date 7/23/96

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

1. Fee Category and Amount: 3C $520

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

3. OTHER _____

Signed Rita Massey
Date 9/4/96

Log Jul 3 II
Remitter
Check No. 2286
Amount $1,130 ($520 applied)
Fee Category 3C
Type of Fee Amt
Date Check Rec'd.
Date Completed 9/4/96
By: Ken

TRI-MED
Specialties Inc.

1500 AVON STREET EXT'D
CHARLOTTESVILLE, VA 22902
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U.S. Nuclear Regulatory Commission
Attention: David Collins
Region II, Nuclear Materials Licensing Section
101 Marietta Street, NW, Suite 2900
Atlanta, Georgia 30323

July 12, 1996

Dear Mr. Collins:

Tri-Med Specialties, Inc. (TMS) holds NRC byproduct materials licenses 45-25215-01 and 45-25215-02MD. The first license, issued in December 1992, authorizes the use of C-14 for research and development of the H-Pylori breath test kit (an in vivo diagnostic kit). The second license, issued in December 1994, authorizes commercial distribution of the breath test kit to medical licensees under an FDA IND and pending NDA. TMS has also applied for an NRC rule change to permit distribution of the kits to those not holding licenses. This action is pending.

Associated with these NRC licenses, TMS would like to prepare and transfer C-14 liquid scintillation counting standards to kit users and researchers holding byproduct materials licenses. The standards will contain approximately 20,000 dpm of C-14. The chemical make-up of the standards will be the same as those used to count breath samples from patients who have been administered C-14 urea for H pylori evaluation. The contents of the standards include: 10 mL liquid scintillation fluid, 1 mL benzethonium hydroxide (hyamine), 1.5 mL methanol and C-14 labeled toluene. The C-14 toluene is a NIST-traceable standard solution. In most cases the recipient of the standard will need only one counting standards.

TMS will prepare the standards and provide them to customers with a product insert describing the make up and accuracy of the scintillation vial. The vials used to make the standards will be normal scintillation vials with some type of seal (such as Parafilm or adhesive tape) to prevent leakage or loss and make the vial tamper-resistant. To keep costs low the vials will not be flame sealed. TMS will allow customers to return the standards if damage or loss of material is noted, or if the recipients no longer need or want the source.

TMS would like to offer these standards to customers since they are not now available from other vendors except as custom preparations. TMS can provide these standards for a price that is substantially less. For accurate and precise evaluation of breath, a standard with the same constituents as the unknown is desirable. TMS can provide this for a reasonable price and in a timely manner.

Please advise us on how to proceed to obtain the appropriate NRC licensing authority to distribute these liquid scintillation standards if it is not currently allowed under the distribution license. The

samples will not be distributed as part of the breath test kit, but as a separate item to be used for analysis of breath test samples or in related research.

Thank you for your assistance.

Sincerely,

William A Fry

William Fry

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