VOID SHEET

TO: License Fee Management Branch
FROM: RIII - James R. Mullauer,
SUBJECT: VOIDED APPLICATION
Control Number: 303579
Applicant: Procter & Gamble.
License Number: 34-01572-01
Docket Number: 030-05654
Date Voided: 5/6/98
Reason for Void: <u>Licensee cannot provide a timely respond to my list of questions</u> email to the licensee on February 13, 1998. The licensee will provide a new amendment request sometime in the future. This was acknowledged and agreed to by the RSO. Bradly Keck, on May 6, 1998.
Signature Attachment: Official Record Copy of Voided Action
FOR LFMB USE ONLY
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No Refund Due
Fee Exempt or Fee Not Required Log completed Processed by: 5HC 5/15/98
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1.	APPLICATION ATTACHED Applicant/Licensee: PROCTER & 980205 Docket No: 3005654 Control No.: 303579 License No.: 34-01572- Action Type: Amendment		1303392 R4	Fit 2: 02
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Procter& Gamble

The Procter & Gamble Company Miami Valley Laboratories P.O. Box 538707, Cincinnati, Ohio 45253-8707

January 26, 1998

Mr. James R Mullauer, M.H.S. Health Physicist U.S.N.R.C. 801 Warrenville Road Lisle, IL 60532-4351

Dear Mr. Mullauer:

In reference to our phone conversation of January 19, I am requesting that the Procter and Gamble license of broad scope, #34-01572-01, be amended as follows:

- 1) I am requesting that the possession limit for iodine-125 be increased to 500 millicuries. Presently, this isotope is used under the 3-83 authorization limiting possession to 100 millicuries. Most individual uses will remain at less than 2 millicuries. All iodinations employing volatile iodine are to be conducted in a facility designed for that purpose and approved by the Radiation Safety Committee.
- 2) I am requesting that the Remote Pharmacokinetics Facility be removed from the authorized locations. We have chosen to stop use at this facility and have ensured the removal of all radioactive materials and decontamination of the facility. The history of use includes only two isotopes: carbon-14 and hydrogen-3. After the last use of radioactive materials, this site was thoroughly inspected by Radiation Safety Office Staff. This included inspection to ensure removal of all radioactive material, extensive swipe testing, and survey by meter for fixed contamination (Bicron Surveyor-50, S/N B082K, calibrated within 3 months of use). Tritium contamination was found in the laboratory hood, was cleaned under RSO staff supervision and retested. The retest indicated that no measurable contamination remained. Dose rate surveys were not done, as swipe testing provided the more sensitive method for determining the presence of contamination.
- 3) I am requesting that our air flow specifications for fume hoods be changed to those in ANSI #Z9.5 from the present specification of greater than 100 fpm face velocity. The ANSI specification is set at 80-120 fpm. This will allow the hoods for radioactive materials use to share the same specifications and qualification as the other hoods in use, while substantially maintaining the current performance of the hoods.
- 4) I am requesting that instrument effluent (e.g., from HPLC-RAD detectors) containing carbon-14 or hydrogen-3 at less than 0.05 microcuries per gram be disposed of as if not radioactive, similar to scintillation media as described in 10CFR20.2005(a.1).

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Procters Gamble

21998 License Amendment, 34-01572-01 January 23, 1998 Page - 2

- 5) I am requesting that transport of radioactive materials by trained users other than RSO staff be allowed between facilities on our license, provided that: a) it involves a limited quantity package per DOT regulations; b) that the user has been specifically trained in shipping requirements; and c) all other DOT regulations have been satisfied. Any packages exceeding the limited quantities will be transported by the RSO staff or by common carrier. In certain instances involving limited quantities, this option will allow faster transportation between sites while ensuring that DOT compliance and materials security are maintained under RSO supervision.
- 6) I am requesting the ability to alter the frequency of audits in low-use areas, as defined by IAEA guidelines, to annually from quarterly. This will eliminate some "low-value" audits without impairing employee or public safety. In addition this allows more effort to be focused on higher use areas.
- (RSC) and Isotope Committee: a) that the formal charge for the control of the radiation safety program be assigned to the RSC, in lieu of the Isotope Committee; b) that the Isotope Committee be abolished; c) that the current management representative chairing the Isotope Committee Dr. Katherine A. Stitzel chair the RSC; d) that a quorum be established as consisting of the RSC chair or her designee, the RSO or a member of his staff and three additional RSC members; e) that tentative approvals of radioisotope permits which shall be considered by the full RSC at the next regular meeting may be made by a reduced quorum of three: the RSC member directly representing the work, the RSO or a member of his staff and one additional RSC member; and, f) that retention of completed or terminated radioisotope permits be shortened to three years from five, consistent with record retention requirements in 10CFR20.2102(a.2). These changes will strengthen the management involvement with our program and make our administrative structure more consistent with other licensees.
- 8) Lastly, I am requesting that ancillary [cleaning, maintenance, security, etc.] workers be allowed to enter RAM-posted laboratories, provided that: a) the workers have received general laboratory safety and awareness training regarding radioactive materials (RAM); b) entry is required for proper functioning of the laboratory; and, c) entry is with prior approval of laboratory personnel or RSO staff, except in emergency situations where immediate entry is required. Authorized users of radioactive materials or RSO staff will still provide oversight of laboratory operations and secure all materials appropriately.

I am available to answer any questions you may have or provide additional information that you may require. Please do not hesitate to contact me at the above address or by telephone at (513) 622-2597.

Respectfully,

Bradly D. Keck, Ph.D., CHP

Senior Scientist, RSO

PRCF	ORM 577	***************************************	U.S. NUC	LEAR REGULA	TORY 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 205#5-0001		
	PROCTER AND G ATTN: BRADLY D MIAMI VALLEY LA P. O. BOX 538707 CINCINNATI, OH	BORATORIES				TYPE OF ACTION NEW LICENSE RENEWAL OF LICENSE AMENDMENT TO LICENSE REQUESTED DATE 1-26-98 LICENSE NUMBER 34-01572-01 CONTROL NUMBER 303579	
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SIGNA	TURE - LICENSE FEE A	NALYST	LFDCB	LFDCB	form. Distribution:		
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Procter & Gamble

- Concerning the decommissioning of the Remote Parmacokinetics Facility, please provide the information as discussed with Mike McCann on February 12, 1998.
- 2. Item No. 3 of your letter requests a change in air flow specifications. Please identify those hoods where volatile radioactive materials (RAM) are used and discuss how the lowering of air flow will not impact the likelihood of intake by workers. Please also include a copy of the ANSI #Z9.5 that discusses air flow specifications.
- 3. Item No. 4 of your letter requests authorization to dispose of carbon-14 and tritium that is less that 0.05 microcuries per gram be disposed of as if not radioactive, similar to scintillation media as described in 10 CFR 20.2005(a.1). Please provide the following information, as follows:
 - a. Please identify the current regulatory requirement in your license that discusses disposal requirements for carbon-14 and tritium.
 - b. Please provide your justification for this request and discuss the regulatory burden placed on you as a result of the disposal requirement.
 - c. Please discuss your method of analyzing the media to assure that the waste does not contain more than 0.05 microcuires per gram(air?).
 - d. This request may have to go to NRC HQ on a Technical Assistance Request (TAR) since it appears less restrictive than Part 20 APP B disposal limits.
- 4. Item No. 6 of your letter requests authorization to change the frequency of audits of low-use laboratories as defined by IAEA guidelines. Please provide the IAEA guidelines and discuss the need for the change in frequency. Annual seems quite long especially in labs that seldom use RAM. Six month audits seems more reasonable than 12 months. Please discuss your current requirements for low-use labs in terms of training, self audits, surveys, etc. Also, please indicate how many low use labs there are verses medium and high use labs. I need adequate justification to lower this frequency. Please provide, for the last 18 months, low use laboratory audit results. A summary of the results will suffice.
- 5. Item No. 7 proposes several changes in the committee that oversee the use of RAM. Your request to abolish the Isotope Committee and your proposed changes appear to be in accordance with NRC Regulatory Guide DG-0005. However, please provide the following additional information:
 - a. Concerning the proposed quorum of the RBC, you state that a quorum will consist of the RBC Chair or her designee, the SO or a member of his staff and three additional RBC members. Reg. Guide DG-0005 states that a minimum acceptable quorum would be the chairperson, SO, management representative, committee member or members representing the department or area from which the radioactive material request originated, and any other committee member whose field of expertise is needed to ensure all necessary safety aspects have

been addressed. In order to allow designees act for key personnel on the committee, please discuss the circumstances under which a designee will act for the Chair or the SO. Sickness or vacation should be the only time that designees act for key RBC personnel. Therefore, please confirm that the role of the RBC Chair and/or SO will not be delegated to other individuals.

- b. You state that the current management representative chairing the Isotope Committee Dr. Katherine A. Stats will be the chair for the RBC. Please clarify whether Dr. Stats is filling two roles in the RBC, Chair and management representative. If this is true, please discuss her management role in the committee and specify her management level in the organization. If she does not represent management, please confirm that a member of management will be on the RBC.
- c. Please discuss the voting rights of various members of the committee and designees and whether or not there will be voting members and nonvoting members on the committee. Actions voted on by designees should be reviewed by the substituted individual.
- Please confirm that the RBC will meet at threes month intervals.
- e. Please specify the new duties and responsibilities of the RBC.

Appandix G of Regulatory Guide DG-0005 provides an outline of the duties and responsibilities of the RBC that are acceptable to the NRC Staff.

Bradly D. Keck, Ph.D., CHP Radiation Safety Officer Procter & Gamble Miami Valley Laboratories P.O. Box 538707 Cincinnati, OH 45253-8707

Dear Dr. Keck:

This refers to: (1) your letter dated January 26, 1998, for an amendment and (2) our telephone voice mail messages on May 6, 1998. In your voice mail message, you indicated that you were not ready to respond to the questions emailed to you on February 13, 1998.

As indicated in my voice-mail message to you, we have voided your request. This action is without prejudice to resubmission. If you resubmit your request, in order to avoid an additional fee, please state that the resubmission is additional information to Control Number 303579.

Please note, however, that if you request any other changes to your license in addition to providing the above, referenced responses, an amendment fee will be required.

If you have any questions or require clarification on any of the information stated above, you may contact us at (630) 829-9887.

Sincerely.

Original signed by James R. Mullauer, M.H.S. Health Physicist Materials Licensing Branch

License No.: 34-01572-01 Docket No.: 030-05654

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with

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NUCLEAR REGULATORY COMMISSION

REGION III 801 WARRENVILLE ROAD LISLE, ILLINOIS 60532-4351

February 5, 1998

Bradley D. Keck, Ph.D.
Radiation Safety Officer
Procter & Gamble Company
Miami Valley Laboratories
11810 East Miami River Road
Ross (Butler County), OH 45061

SUBJECT: ACKNOWLEDGEMENT OF CORRESPONDENCE (Letter Dated January 26, 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):

NATIONAL PROPERTY.	New License		Amend	dment	Re	Renewal	
	Termination Other		Auth	User	(Amendment	not	required)

Administrative deficiencies were identified during this initial review as outlined below. However, it should be noted that a technical review may identify additional omissions in the submitted information.

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

Incomplete information is as follows: <u>In order for us to complete your request the required fee is necessary</u>. <u>Prease contact our License Fee & Debt Collection Branch</u>, located in our headquarters office, as referenced below.

- 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. <u>Termination</u> 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 (252/41: 6097) for approval of the fee category and amount, if required.

If you have contact the Materials Licensing Branch at (630) 829-9887. We will rry 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. 303579 License No. 34-61572-01

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NAME OF PERSON(S)	CONTACTED OR IN CONTACT	ORGANIZATION (OFFIC	DE, DEPT.ETC.) TELEPHONE NO.
Procter & Gam	ble Company	Brad Keck, Ph.D.	513-245-2284
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