

October 16, 2006

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2006 OCT 18 AM 10: 56

Robert Packer Hospital  
One Guthrie Square  
Sayre, PA 18840-1698  
Tel 570.888.6666

Q-8 MS-16

Shirley S. Xu  
Health Physicist  
Division of Nuclear Materials Safety  
United States Nuclear Regulatory Commission  
Region I  
475 Allendale Road  
King of Prussia, PA 19406

37-01893-01

03003013/2006001

Dear Ms. Xu:

This letter is to follow-up on the topics discussed on October 3, 2006 with you, myself, and Steve Nagar, Robert Packer Hospital Radiation Safety Coordinator.

- A. Topic: Conformation letter of receipt from vendor receiving Americium 241  
Action: Copy of letter obtained from vendor enclosed.
  1. Letter dated 2-17-2006 from Qal-Tek Associates.
  
- B. Topic: Leak-test on Americium 241  
Action: Perform test, document test result and copy is attached.
  1. Sealed Radioactive source leak test report signed on 1-10-2006 by Qal-Tek Associates.
  
- C. Topic: Remove 3 users and subsequently types of Isotopes used by them listed on their license.  
Action: Find a separate letter stating removal of three users.
  1. Attached is a letter from Mary Mannix, President and COO of Robert Packer Hospital dated August 18, 2006.
  2. Attached is a letter to remove Isotopes dated October 16, 2006.
  
- D. Topic: Research Building – decommissioned documents for the 2<sup>nd</sup>, 3<sup>rd</sup>, and 4<sup>th</sup> floors.  
Action: Upstate physics performed site testing for decommissioning and document is attached.
  1. Attached is letter from Upstate Physics dated October 12, 2006 by a Certified Health Physicist, Joseph M. Greco. Detailed report will follow in few weeks from Upstate Physics showing floor plan of 3<sup>rd</sup>, 4<sup>th</sup> and 5<sup>th</sup> floor.
  2. Second floor of the research- foundation building was never used as a laboratory. Some years ago the numbering of the floor was changed and created confusion. The original 2nd

**Letter to Shirley Xu**  
**Division of Nuclear Safety Materials**  
**Page -2-**

floor is actually the 3<sup>rd</sup> floor in current system while the original 3<sup>rd</sup> floor is 4<sup>th</sup>. You will see the decommissioning documents for 3<sup>rd</sup> and 4<sup>th</sup> floor (old 2<sup>nd</sup> and 3<sup>rd</sup> floor). If any questions, feel free to contact Bimal Patel at 570-882-4992.

- E. Topic: Sidney Welt, M.D. as an authorized user for non-medical use of additional isotopes
- Action: Attach is a letter requesting change in license and supporting documents from Memorial Sloan-Kettering Cancer Center for Dr. Welt.
1. Find letter from Bimal Patel, Administrative Director, dated October 16, 2006.
  2. Find copy of letter from Memorial Sloan Kettering Cancer Center stating Dr. Sidney Welt's experience in the use and handling of the material.
  3. Find a copy of Dr. Sidney Welt's curriculum vitae.

Should you have any questions or require any additional information, please do not hesitate to contact me directly at (570) 882-4992.

Sincerely,

  
Bimal Patel  
Administrative Director  
Procedural & Ancillary Services  
Robert Packer Hospital

BP/sc  
Enclosures



**Instrumentation and Professional Services**

Charles Wild  
Guthrie Clinic  
One Guthrie Square  
Sayre, Pa. 18840

Date: 2/17/2006

This is to advise that the Radioactive Material as detailed below has been received by Qal-Tek Associates as of 2/17/2006 and we have taken possession of these sources:

If checked see attached spreadsheet

<u>Manufacturer</u>	<u>Model</u>	<u>Serial Number</u>	<u>Isotope</u>	<u>Activity (mCi)</u>
Unknown	n/a	Unknown	Am-241	12.00
3M	n/a	4998	Cs-137	8.35
3M	n/a	5000	Cs-137	8.35
3M	n/a	5011	Cs-137	8.35
3M	n/a	5019	Cs-137	8.35
3M	n/a	5049	Cs-137	8.35
3M	n/a	3355	Cs-137	12.39
3M	n/a	3362	Cs-137	12.39
3M	n/a	2967	Cs-137	12.81
3M	n/a	2297	Cs-137	16.86
3M	n/a	2298	Cs-137	16.86
3M	n/a	887	Cs-137	22.00
3M	n/a	888	Cs-137	22.08

Please retain this record for your files. Should you require further assistance, please contact us at Qal-Tek Associates.

Regards,

Tim Jenkins  
Radioactive Source Disposal Specialist

**Duplicate Copy**

J. Eggleston 10/04/06  
Jared Eggleston, RSDS



INSTRUMENTATION AND PROFESSIONAL SERVICES  
 3998 COMMERCE CR. IDAHO FALLS, IDAHO 83401  
 (208) 523-5557 FAX (208) 524-8470  
 www.qaltek.com

## SEALED RADIOACTIVE SOURCE LEAK TEST REPORT

Company: **Qal-Tek Associates**  
 Street: **3998 Commerce Dr.**  
 City/State/Zip: **Idaho Falls, ID 83401**  
 Phone: **(208) 523-5557**

Fax: **(208) 524-8470**

LT Frequency: 3 Months

### TEST INSTRUMENT

Mfg'r.: Ludlum	Model: 3030 2	Serial #: 219696	Cal. Date: 26-Jul-06
MDA: <0.005 µCi	α efficiency: >36%	β efficiency: >38%	Det. Type: ZnS (Ag)

Qal-Tek Associates certify the above instrument has been calibrated using radioactive standards traceable to NIST, or traceable to calibration facilities for other ISO members, or have been derived from acceptable values of natural/physical constraints, or have been derived by ratio type of calibration techniques. Accuracy of the principal radiation calibration sources used is greater than or equal to the required accuracy of the equipment being calibrated. The Qal-Tek Associates calibration system conforms to ANSI N323-1997. All calibrations are performed in accordance with the Qal-Tek Associates Quality Assurance Management Program (QAMP) by QP-PRO-001, which is available by written request.

### LEAK TEST RESULTS

Mfg'r	Model #	Source Serial #	Isotope	Activity	Customer	net α CPM	net b/g CPM	pass/fail
3M		887	Cs-137	22.00mCi	Guthrie	0	4	P
3M		888	Cs-137	22.08mCi	Clinic	0	13	P
3M		2297	Cs-137	16.81mCi		0	4	P
3M		2298	Cs-137	16.81mCi		0	3	P
3M		2967	Cs-137	12.81mCi		0	3	P
3M		3355	Cs-137	12.39mCi		0	0	P
3M		3362	Cs-137	12.39mCi		2	4	P
3M		4998	Cs-137	8.35mCi		0	0	P
3M		5000	Cs-137	8.35mCi		0	0	P
3M		5011	Cs-137	8.35mCi		0	0	P
3M		5019	Cs-137	8.35mCi		0	7	P
3M		5049	Cs-137	8.35mCi		0	15	P
Unknown		Unknown	Am-241	12mCi		0	3	P

Date Sources Leak Tested: 1/10/06

Next Leak Test Due: \_\_\_\_\_

Qal-Tek Associates certifies that all leak test measurements are performed in accordance with NRC licensee requirements for isotopic detection limits. For this purpose the MDA is below the NRC regulatory limits of <0.005 µCi

T. J. O'Brien

1/10/06



Robert Packer Hospital  
One Guthrie Square  
Sayre, PA 18840-1698  
Tel 570.888.6666

August 18, 2006

Sandra Gabriel  
Health Physicist  
Division of Nuclear Materials Safety  
465 Allendale Road  
King of Prussia, PA. 19406-1415

Re: Amendment of Materials License 37-01893-01

Dear Ms. Gabriel,

In accordance with NRC regulations, this letter is a request to remove Nan-Shang Chang, PhD, John D Noti, PhD, and Carol L Williams, PhD as authorized users from the referenced license.

Also, please remove the nuclear material Americium 241 as it has been removed from our facility.

Should you have any questions or require any additional information, please do not hesitate to contact me directly at (570) 882-4453.

Sincerely,

A handwritten signature in cursive script that reads "Mary N. Mannix".

Mary N. Mannix, FACHE  
President and Chief Operating Officer

Cc: Asaf Durakovic, MD  
Bimal Patel  
Chuck Wilde, Ph.D.



October 16, 2006

**Robert Packer Hospital**  
One Guthrie Square  
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Tel 570.888.6666

Shirley S. Xu  
Health Physicist  
Division of Nuclear Materials Safety  
Region I  
475 Allendale Road  
King of Prussia, PA 19406

RE: Amendment of Materials License 37-01893-01

Dear Ms. Xu:

In accordance with NRC regulations, this letter is a request to delete the following isotopes for non-human use from our materials license as follows:

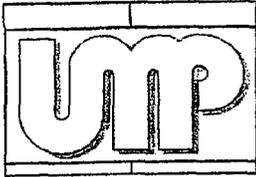
Carbon 14  
Phosphorus 33  
Sulfur 35  
Calcium 45

Should you have any questions or require any additional information, please do not hesitate to contact me directly at (570) 882-4992.

Sincerely,

Bimal Patel  
Administrative Director  
Procedural & Ancillary Services  
Robert Packer Hospital

BP/sc  
DEP/NRC



Upstate Medical Physics, Inc.

Robert J. Pizzutiello, Jr., M.S., D.A.B.M.P., D.A.B.R.  
President

7867 Parish Road  
Victor, New York 14564  
(585) 924-0350 • Fax: (585) 924-5765  
Website: www.upstatemp.com

October 12, 2006

Mr. Bimal Patel  
Robert Packer Hospital  
Guthrie Square  
Sayre, PA 18840

**Re: Preliminary Report of Laboratory Surveys – Foundation Building**

Dear Bimal,

As discussed, I am providing a preliminary report of the work completed on October 11, 2006 in the Foundation Research Building at Robert Packer Hospital. The work focused on decommissioning the laboratory space on the third and fourth levels of the Foundation Building, where unsealed radioisotopes were used in microcurie to millicurie amounts. The isotopes used were primarily H-3, C-14, P-32, and S-35, all beta emitters. P-32 and S-35 have short half lives relative to H-3 and C-14, so we focused our attention on the longer lived H-3 (12.4 yr half life) and C-14 (5700 year half life).

Decommissioning work involved surveys for removable contamination (wipe tests and analysis using a liquid scintillation counter) and surveying for fixed contamination using a thin-end window Geiger-Mueller survey meter. Although attention was focused on areas where isotope use was known to occur, other areas within each lab were also surveyed. Approximately 75 areas were wipe tested. Surveyed locations included benchtops, floors, hoods, sinks, sink traps, refrigerators, centrifuges, and other equipment.

All areas surveyed with the GM survey meter were consistent with natural background levels (0.01 to 0.02 mR/hr). Preliminary results show that all areas wipe tested were well below the NRC limits for removable contamination (1000 dpm/100 cm<sup>2</sup>).

A full report will be provided to you once all the wipe test data is tabulated and area maps drawn. In the meantime, please feel free to contact me if you have any questions.

Sincerely,  
Upstate Medical Physics

A handwritten signature in black ink that reads 'Joseph M. Greco'. The signature is written in a cursive, slightly slanted style.

Joseph M. Greco  
Certified Health Physicist

Quality Review by RJP



**Robert Packer Hospital**  
One Guthrie Square  
Sayre, PA 18840-1698  
Tel 570.888.6666

October 16, 2006

Shirley S. Xu  
Health Physicist  
Division of Nuclear Materials Safety  
Region I  
475 Allendale Road  
King of Prussia, PA 19406

RE: Amendment of Materials License 37-01893-01

Dear Ms. Xu:

In accordance with NRC regulations, this letter is a request to add Sydney Welt, M.D. to the license as an authorized user for the following isotopes for non-human use:

Tritium-3.  
Iodine 131  
Phosphorus 32

Sidney Welt currently an authorized user of the following materials:

Chromium 51  
Iodine 125  
Yttrium 90

I believe you have Dr. Welt's curriculum vitae and associated credentials on file. If not, I have enclosed a copy from the Memorial Sloan Kettering Cancer Center.

Should you have any questions or require any additional information, please do not hesitate to contact me directly at (570) 882-4992.

Sincerely,

A handwritten signature in black ink, appearing to read "Bimal Patel", written over a horizontal line.

Bimal Patel  
Administrative Director  
Procedural & Ancillary Services  
Robert Packer Hospital

BP/sc  
DEP/NRC



# Memorial Sloan-Kettering Cancer Center

*The Best Cancer Care. Anywhere.*

Date: 08/23/04

To: Dr. Sydney Welt

From: Lawrence T. Dauer, CHP  
Radiation Safety Operations Manager  
Radiation Safety Service  
Department of Medical Physics

Re: Experience with Radioactive Materials

Dr. Sydney Welt performed laboratory investigations under the authorization and control of the MSKCC Broad Scope City of New York Radioactive Material **License # 74-2968-02**. He was authorized to use radioactive materials by the MSKCC Committee on Radiation through the P.I. permit for the laboratory of Dr. L. Old.

Dr. Sydney Welt was controlled under the MSKCC Radiation Safety Program from December 01, 1982, through December 31, 2003.

Curriculum Vitae

Name: Sydney Welt

Date of Birth: [REDACTED]

Place of Birth: [REDACTED]

Nationality: [REDACTED]

Office Address: Guthrie Healthcare system  
One Guthrie Square  
Sayre, PA 18840

Telephone: (212) 639-8605 (research)  
(212) 639-5011 (clinical)

Facsimile: (212) 717-3100

E-mail: [REDACTED]

Home Address: [REDACTED]  
[REDACTED]

Telephone: [REDACTED]

Licensed Physician: 1977, State of New York

Board Certification: 1980, Internal Medicine  
1983, Medical Oncology

Education: Columbia College, New York, NY  
1973, B.A. (Biochemistry)

New York University School of Medicine  
1977, M.D.

Postdoctoral Training:

Intern, Bronx Municipal Hospital Center, Albert Einstein College of Medicine, 1977-78;  
Resident in Internal Medicine, 1978-80

Fellow in Medical Oncology, Memorial Hospital for Cancer and Allied Diseases, 1980-82

Research Fellow in Immunobiology, Sloan-Kettering Institute for Cancer Research, 1982-84

**PERSONAL INFORMATION WAS REMOVED  
BY NRC. NO COPY OF THIS INFORMATION  
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Sydney Welt, M.D., Curriculum Vitae, continued

Positions and Appointments:

Cornell University Medical College:

Fellow in Medicine, 1980-84; Instructor in Medicine, 1984-1988; Assistant Professor of Medicine, 1989-95; Associate Professor of Medicine, 1995-2004

Memorial Hospital for Cancer and Allied Diseases:

Clinical Assistant Physician, Clinical Immunology Service, Division of Hematologic Oncology, 1984-88; Assistant Attending Physician, 1988-94; Associate Attending Physician, 1994-2004

Memorial Sloan-Kettering Cancer Center:

Assistant Member, Memorial Hospital, 1988-94; Associate Member, 1994-2004

Sloan-Kettering Institute for Cancer Research:

Research Associate, 1984-87

Ludwig Institute for Cancer Research:

Assistant Member, New York Branch at Memorial Sloan-Kettering Cancer Center, 1991-96; Associate Member, 1996-2004

Guthrie Healthcare System:

Medical Director, Basic and Clinical Research Hematology/Oncology, 2004-

Scientific and Medical Societies:

American Association for Cancer Research, 1989-present

American Society of Clinical Oncology, 1995-present

Social Security No.:

[REDACTED]

Marital Status:

[REDACTED]

Spouse's Name:

[REDACTED]

No. of Dependents:

[REDACTED]

Military Service:

None

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Sydney Welt, M.D., Curriculum Vitae, continued

Research Support

1. NIH/NCI

2 PO1 CA33049

Biological Approaches to the Treatment of Cancer

PI: Alan N. Houghton, MD

Project 2: Monoclonal antibodies for the treatment of carcinomas

Project Leader: Sydney Welt, MD (since 1993)

Committed Levels (direct costs):	Yr-17 (2000):	\$159,042
	Yr-18 (2001):	\$162,463
	Yr-19 (2002):	\$165,987
	Yr-20 (2003):	\$169,616
	Yr-21 (2004):	\$173,354

2. Ludwig Institute for Cancer Research

Committed Salary Support:	Yr 2002:	\$80,000 & fringe benefits
	Yr 2003:	\$80,000 & fringe benefits

Research funds supplementing the above-listed grant are provided as part of the operational support of the New York Branch at Memorial Sloan-Kettering Cancer Center.

Research facilities are contained within the laboratory space allocated to the New York Branch by Memorial Sloan-Kettering Cancer Center.

3. Industrial Agreements

- Boehringer Ingelheim Pharmaceuticals, Inc.  
IRB #98-068 (BI 1152.1/LUD 98-002):  
Phase I dose-escalation of BIBH-1 in patients with advanced or metastatic fibroblast activation protein-positive cancer
- Boehringer Ingelheim Pharmaceuticals, Inc.  
IRB #99-035 (BI 1152.5/LUD 98-006):  
Phase I single-dose escalation study of BIBH-1 in patients with colorectal cancer scheduled for surgical resection

Sydney Welt, M.D., Curriculum Vitae, continued

Patents

Pending: A33 and chemotherapy. (Filed March 8, 2001)

Inventors: Welt, S. Ritter, G. Kemény, N. Jungbluth, A. Cohen, L. Old, L.J.

Pending: A33 HAHA Biacore (Filed August 16, 2002)

Inventors: Ritter, G. Cohen, L. Welt, S. Old, L.J.

Pending: A33 PEGylation (Filed August 16, 2002)

United States Patent 6,518,415 (February 11, 2003)

Recombinant human anti-Lewis Y antibodies

Inventors: Carr, F. Old, L.J. Stockert, E. Welt, S. Kitamura, K. Garin-Chesa, P.

United States Patent 6,346,249 (February 12, 2002)

Methods for reducing effects of cancers that express A33 antigen using A33 antigen specific immunoglobulin products

United States Patent 6,342,587 (January 29, 2002)

A33 antigen specific immunoglobulin products and uses thereof

Inventors: Rader, C. Barbas, C. Welt, R. Ritter, G. Old L.J.

United States Patent 6,310,185 (October 30, 2001)

Recombinant human anti-Lewis-Y antibodies

Inventors: Carr, F. Old, L. J. Stockert, E. Welt, S. Kitamura, K. Garin-Chesa, P.

United States Patent 6,291,235 (September 18, 2001)

Isolated nucleic acid which encodes protein which binds to A33 antibody

Inventors: Old, L.J. Welt, S. Ritter, G. Simpson, R. Nice, E. Moritz, J. Catimal J.

United States Patent 6,190,640 (September 18, 2001)

Method of treating neoplasia using humanized antibodies which bind to antigen A33

Inventors: Welt, S. Ritter, G. Cohen, L. Williams, C. Richards, E. John, M. Old, L.J.

United States Patent 6,025,481 (February 15, 2000)

Isolated nucleic acid molecules which encode human anti-Lewis b antibodies

Inventors: Wallace, T. Paul; Harris, William J.; Carr; Frank J.; Old, Lloyd J.; Welt, Sydney; Kitamura, Kunio.

United States Patent 5,958,412 (September 28, 1999)

Methods of treating colon cancer utilizing tumor-specific antibodies

Inventors: Welt, Sydney; Old, Lloyd J.; Barendsward, Elsje; Montalto, Nicholas J.; Gure, Ali Osmay.

United States Patent 5,874,060 (February 23, 1999)

Recombinant human anti-Lewis Y antibodies

Inventors: Armour, Kathryn Lesley; Carr, Francis Joseph; Old, Lloyd J.; Stockert, Elisabeth; Welt, Sydney; Kitamura, Kunio; Garin-Chesa, Pilar.

United States Patent 5,851,526 (December 22, 1998)

Methods of treating colon cancer utilizing tumor-specific antibodies

Inventors: Welt, Sydney; Ritter, Gerd; Cohen, Leonard; Williams, Jr., Clarence; Richards, Elizabeth Carswell; John, Mary; Old, Lloyd J.

United States Patent 5,795,961 (August 18, 1998)

Recombinant human anti-Lewis b antibodies

Inventors: Wallace, T. Paul; Harris, William J.; Carr, Frank J.; Old, Lloyd J.; Welt, Sydney; Kitamura, Kunio.

United States Patent 5,712,369 (January 27, 1998)

Isolated protein which binds to A33 antibody, and peptides corresponding to portions of the protein

Inventors: Old, Lloyd J.; Welt, Sydney; Ritter, Gerd; Simpson, Richard J.; Nice, Edouard; Moritz, R. L.; Catimel, B.; Ji, Hong; Burgess, Anthony W.; Heath, Joan K.; White, Sara J.; Johnstone, Cameron.

United States Patent 5,643,550 (July 1, 1997)

Method of treating colorectal carcinoma lesion and composition for use therein

Inventors: Welt, Sydney; Divgi, Chaitanya R.; Yeh, Samuel; Old, Lloyd J.; Oettgen, Herbert F.; Real, Francisco X.; Sakamoto, Junichi.

United States Patent 5,565,356 (October 15, 1996)

Hybridoma cell lines which produce monoclonal antibodies having the properties of monoclonal antibody 100-310 and the monoclonal antibodies produced by these hybridoma cell lines

Inventors: Welt, Sydney; Williams, Jr., Clarence; Barendswaard, Elsje C.; Divgi, Chaitanya R.; Garin-Chesa, Pilar; Old, Lloyd J.

United States Patent 5,431,897 (July 11, 1995)

Method of imaging colorectal carcinoma lesion and composition for use therein

Inventors: Welt, Sydney; Divgi, Chaitanya R.; Yeh, Samuel; Old, Lloyd J.; Oettgen, Herbert F.; Real, Francisco X.; Sakamoto, Junichi.

United States Patent 5,160,723 (November 3, 1992)

Method of imaging colorectal carcinoma lesion and composition for use therein

Inventors: Welt, Sydney; Divgi, Chaitanya R.; Yeh, Samuel; Old, Lloyd J.; Oettgen, Herbert F.; Real, Francisco X.; Sakamoto, Junichi.

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Department of State  
Bureau of Professional and Occupational Affairs  
PO Box 2649 Harrisburg PA 17105-2649

02 215463

License Type  
Medical Physician and Surgeon

License Status  
Active



Initial License Date  
05/05/2004

SYDNEY WELT  
[Redacted]

License Number  
MD423962

Expiration Date  
12/31/2004

*Basil L. Mowla*  
Commissioner of Professional and Occupational Affairs

*[Signature]*  
Signature

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