

**CHRISTIANA CARE**  
HEALTH SERVICES

Radiation Safety Office

501 West 14th Street  
PO Box 1668  
Wilmington, Delaware 19899-1668  
302-733-1000Joseph Solge 428-2148  
FAX # 428-4527

August 12, 2008

Br. 1

U.S. Nuclear Regulatory Commission  
Region I  
475 Allendale Road  
King of Prussia, PA 19406-1415

Re: NRC License 07-12153-02 03001303

Dear Sir or Madam:

I would like to submit the following three changes to the license listed above:

1. Hann-Senn Chen has resigned from Christiana Care. Please remove him from the list of Authorized Medical Physicists in Item 13 C.
2. We have ceased the use of Iodine 125 liquid Iotrex and the Gliasite RTS System as listed in Items 6 H., 7 H., and 8 H. Please remove all references to liquid Iotrex and the Gliasite RTS System.
3. We would like to add Hungcheng Chen, MS to this license as an Authorized Medical Physicist. I have attached documentation of Mr. Chen's training and experience. Also attached is a copy of USNRC License No. 37-02523-01 on which Mr. Chen was most recently listed as an Authorized Medical Physicist.

If you have any questions about this request, or need any further information, please contact me at either of the numbers listed above. I can also be reached at [jsolge@christianacare.org](mailto:jsolge@christianacare.org).

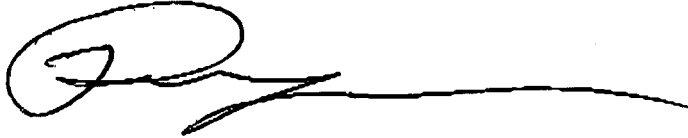
Thank you very much for your consideration of these changes.

Sincerely,

Joseph F. Solge, Jr.  
Radiation Safety Officer142716  
NRC STAFF MATERIALS-002

Christiana Care Health Services, Inc. 2  
License No. 07-12153-02

Approved by:

A handwritten signature in black ink, consisting of a large, stylized initial 'P' followed by a long, horizontal, slightly wavy line extending to the right.

Patrick Grusenmeyer, ScD, Vice President, Helen F. Graham Cancer Center

JFS/jfs

Cc: W. Holden  
T. Manzone, MD  
L. Simpson, PhD



## **HUNGCHENG(HANK) CHEN, MS**

March 3, 2008

**Office Address & Telephone:**

Department of Radiation Oncology  
UPMC McKeesport Hospital  
1500 5th Avenue, McKeesport, PA 15132  
TEL: 412-664-2678 FAX: 412-664-6751  
E-mail: chenhx@upmc.edu

**Present Title:**

- Medical Physicist, Department of Radiation Oncology, UPMC Cancer Centers at McKeesport

**Education :**

- M.S. in Radiological Sciences (September 1998 - June 2001)  
National Yang-Ming University, Taiwan
- B.S. in Biomedical Engineering (September 1986 - June 1990)  
Chung Yuan Christian University, Taiwan

**Certification :**

- American Board of Radiology Certified In Therapeutic Radiological Physics, 2008
- The Chinese Society for Medical Physics in Taipei Certified Medical Physicist, 1999

**Professional Experience::**

- Medical Physicist (April/2006 - Now)  
Department of Radiation Oncology, UPMC Cancer Centers at McKeesport, McKeesport PA
- Medical Physicist (December/2002 - March/2006)  
Department of Radiation Oncology, UPMC Cancer Centers at Shadyside, Pittsburgh, PA
- Medical Physicist (July/1992 - October/2002)  
Department of Radiation Oncology, Mackay Memorial Hospital, Taipei, Taiwan

**Professional Affiliations :**

- Active member of American Society of Therapeutic Radiology and Oncology since 2008
- Full member of American Association of Physicists in Medicine since 2004
- Full Member of The Chinese Society for Medical Physics, Taipei since 1996

**10633 John W. Elliott Dr., Ste D, Frisco, TX 75034**

**469-385-7790 • Fax # 443-946-2439**

**[www.RushSearchPartners.com](http://www.RushSearchPartners.com)**

**Clinical Experience and Skills :**

- Radiation Safety Officer for the Medical Accelerator License at UPMC McKeesport, 2007
- Authorized Medical Physicist at UPMC McKeesport Hospital for LDR Brachytherapy, 2006.
- Authorized Medical Physicist at UPMC Shadyside Hospital for Ir-192 in HDR Brachytherapy and Sr-90 in Intravascular Brachytherapy Unit, 2005.
- Two years experience in 4DCT imaging and respiratory gating system
- Two years experience In CyberKnife stereotactic radiosurgery  
Received CyberKnife user training at Accuray Inc., Sunnyvale, CA, in May, 2005
- Three years experience In HDR planning, treatment and QA
- Five years experience in IMRT QA
- Five years experience In LDR prostate seed implant
- Highly experienced in general external RT, treatment planning, dosimetry, radiation protection and quality assurance.

**Research Skills :**

- Familiar with EGS4 and Beamnrc Monte Carlo software  
Received Beamnrc training in NRCC Ottawa, Canada, in October, 2006
- Familiar with digital image processing and registration
- Highly experienced in Visual BASIC programming
- Highly experienced in DICOM image format

**Conference Presentations :**

- Poster(Co-author) in 2006 AAMP Annual Meeting, Orlando FL  
Feasibility Study of Management of Respiration Induced Target Motion for the Radiotherapy Treatment of Lung Cancer Patients In the Absence of a 4DCT Simulator. M Sontag, Hungcheng Chen, D Michalski, R Andrade, I Uslene, F Li, N Yue, D Heron, and M Huq
- Poster(Presenting Author) in 2005 AAMP Annual Meeting, Seattle WA  
A New Device for the Verification of Temporal Function of the 4DCT and Gating Delivery System. Hungcheng Chen, Edward Brandner, Andrew Wu, Krishna Komanduri, Zhenyu Shou
- Poster(Co-author) in 2005 AAMP Annual Meeting, Seattle WA

**10633 John W. Elliott Dr., Ste D, Frisco, TX 75034**

**469-385-7790 • Fax # 443-946-2439**

**[www.RushSearchPartners.com](http://www.RushSearchPartners.com)**



Phase Lag Measurements of Abdominal Organs Relative to An External Marker Block Using Retrospective 4D CT Imaging. Edward Brandner, Andrew Wu, Hungcheng Chen, Dwight Heron, Krishna Komanduri, Shalom Kalnicki, Kristina Gerszten, and Steven Burton

- Poster(Co-author) in 2005 AAMP Annual Meeting, Seattle WA

Imaged-Based Simulation Technique To Determine Stepping Source Dwell Position For MammoSite Brachytherapy Procedures. Cheng Saw, Krishna Komanduri, Raj Selvaraj, Hungcheng Chen, Fang Li, and Dwight Heron

- Poster(Co-author) in 2005 AAMP Annual Meeting, Seattle WA

Imaged-Based Simulation Technique To Determine Stepping Source Dwell Position For MammoSite Brachytherapy Procedures. Cheng Saw, Krishna Komanduri, Raj Selvaraj, Hungcheng Chen, Fang Li, and Dwight Heron

- Poster(Co-author) in 2005 AAMP Annual Meeting, Seattle WA

Multi-Institutional Retrospective Analysis of IMRT QA Measurements. Marc Sontag, X Chen, Lihong Qin, Frank Ottino, Hungcheng Chen, Fang Li, Alphonse Loper, Krishna Komanduri, Ron Lalonde, Ning Yue, Dwight Heron, and M Huq

- Poster(Co-author) in 2005 AAMP Annual Meeting, Seattle WA

The Use of Diode in In-Vivo Dosimetry Quality Assurance in IMRT. H Kim, Z Wang, R Lalonde, M Sontag, Hungcheng Chen, F Li, R Smith, M Huq, D Heron, and N Yue

- Oral( Presenting Author) in 2004 AAPM Annual Meeting, Pittsburgh PA

Dosimetric Evaluations and Analyses of A Moving Target Volume Treated with Respiratory-Gated Intensity Modulated Radiotherapy

Hungcheng Chen, Edward Brandner, Shalom Kalnicki, Dwight Heron, Krishna Komanduri, Andrew Wu

- Oral(Co-author) in 2004 AAPM Annual Meeting, Pittsburgh PA

Quantitative Studies of Abdominal Organ Motions Resulting From Respiration Using Retrospective 4D CT Imaging. Edward Brandner, Andrew Wu, Hungcheng Chen, Dwight Heron, Shalom Kalnicki, George Henning, Kristina Gerszten, Steven Burton

#### Publications :

- (1) Brandner ED, Heron D, Wu A, Huq MS, Yue NJ, Chen H: Localizing moving targets and organs using motion-managed CTs. Med Dosim. 2006 Summer;31(2):134-40.
- (2) Brandner ED, Wu A, Chen H, Heron D, Kalnicki S, Komanduri K, Gerszten K, Burton S, Ahmed I, Shou Z: Abdominal organ motion measured using 4D CT. Int J Radiat

10633 John W. Elliott Dr., Ste D, Frisco, TX 75034

469-385-7790 • Fax # 443-946-2439

www.RushSearchPartners.com



Oncol Biol Phys. 2006 Jun 1;65(2):554-60.

- (3) **H Chen**, W.L. Chen, and K.H. Chang: Monte Carlo simulation of an 192Ir brachytherapy source in bone and lung. *Therapeutic Radiology and Oncology*, Vol. 8, No. 1, 43-53, March 2001
- (4) Y.J. Chen, Y.S. Dai, B.F. Chen, Anita Change, **H Chen**, Y.C. Lin, K.H. Chang, Y.L. Lai, C.H. Chung, Y.J. Lai: The effect of tetrandrine and extracts of centella asiatica on acute radiation dermatitis in rats., *Biol. Pharm. Bull.* Vol. 22, No. 7, 703-706, July 1999
- (5) Y.J. Chen, S.D. Shyur, Anita Change, **H Chen**, K.H. Chang, Y.L. Lai, P.G. Chen: The combined effect of colchicine and radiation on human hepatoma HA22TVGH cells., *Therapeutic Radiology and Oncology*, Vol. 6, No. 2, 83-87, June 1999
- (6) **H Chen**, J.I. Yeh, C.Y. Yeh, Y.L. Lai and W.C.Chen: Normal tissue doses of radiation from radiotherapy of breast cancer *Therapeutic Radiology and Oncology*, Vol. 2, No. 4, 337-344, December 1995

10633 John W. Elliott Dr., Ste D, Frisco, TX 75034

469-385-7790 • Fax # 443-946-2439

[www.RushSearchPartners.com](http://www.RushSearchPartners.com)

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 1 OF 10 PAGES  
Amendment No. 92

Duplicate

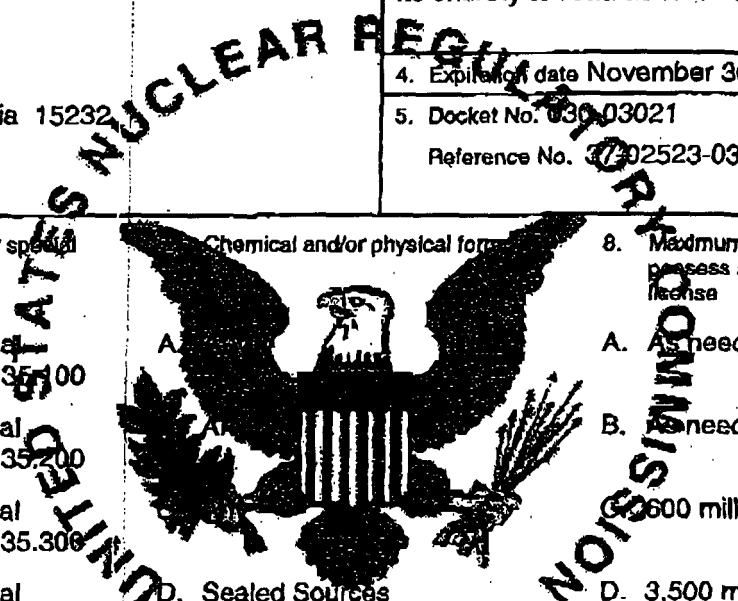
MATERIALS LICENSE

Duplicate

Under 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 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.

<p>Licensee</p> <p>1. UPMC Presbyterian Shadyside</p> <p>2. 5230 Centre Avenue Pittsburgh, Pennsylvania 15232</p>	<p>In accordance with the letter dated April 15, 2005,</p> <p>3. License number 37-02523-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date November 30, 2011</p> <p>5. Docket No. 030-03021 Reference No. 37-02523-03</p>
---	---

<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Any byproduct material permitted by 10 CFR 35.100</p> <p>B. Any byproduct material permitted by 10 CFR 35.200</p> <p>C. Any byproduct material permitted by 10 CFR 35.300</p> <p>D. Any byproduct material permitted by 10 CFR 35.400</p> <p>E. Any byproduct material permitted by 10 CFR 35.500</p> <p>F. Iridium 192 permitted by 10 CFR 35.600</p> <p>G. Any byproduct material permitted by 10 CFR 31.11</p>	<p>Chemical and/or physical form</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. 600 millicuries</p> <p>D. Sealed Sources</p> <p>E. Sealed Sources (North American Scientific Model MED 3601; DuPont Pharma Model NES 8412; IPL Model HEG-137)</p> <p>F. Sealed Sources (Nucletron Model 105.002 [manufactured by Mallinckrodt Medical and AEA Technology, Inc.]; Nucletron Model 096.001 [manufactured by Mallinckrodt Medical and AEA Technology, Inc.])</p> <p>G. Prepackaged kits</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. As needed</p> <p>B. As needed</p> <p>C. 600 millicuries</p> <p>D. 3,500 millicuries</p> <p>E. 2,120 millicuries total</p> <p>F. 12 curies per source and 24 curies total</p> <p>G. 2 millicuries</p>
--	---	--



Duplicate

Duplicate

Duplicate

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 2 of 10 PAGES

License Number

97-02523-01

Docket or Reference Number

030-03021/37-02523-03

Amendment No. 92

Duplicate

Duplicate

Duplicate

MATERIALS LICENSE SUPPLEMENTARY SHEET

6. Byproduct source, and/or special nuclear material

H. Strontium 90

I. Cesium 137

J. Depleted Uranium

K. Hydrogen 3

L. Carbon 14

M. Phosphorus 32

N. Phosphorus 33

O. Sulfur 35

P. Iodine 125

Q. Strontium 90

R. Iridium 192

S. Phosphorus 32

7. Chemical and/or physical form

H. Sealed Source (Nuclear Enterprises Model 2503/3A)

I. Sealed Source (L. Shepherd and Associates Model 6310 or ORNL A-0096)

J. Metal

K. Any

L. Any

M. Any

N. Any

O. Any

P. Any

Q. Any

R. Any

R. Sealed Sources (Best Industries Model 4-01)

S. Sealed Sources (Guidant Corporation VI Model GDT P-32 Series)

8. Maximum amount that licensee may possess at any one time under this license

H. 12 millicuries

I. 600 curies

J. 1029 kilograms

K. 60 millicuries

L. 50 millicuries

M. 50 millicuries

N. 50 millicuries

O. 50 millicuries

P. 50 millicuries

Q. 5 millicuries per source; 1,040 millicuries total

R. No single source to exceed 33 millicuries, in a three-ribbon set containing 6, 10, or 14 iridium-192 seeds per ribbon; 2 ribbon sets of 2 curies total

S. 600 millicuries per source assembly; 2 source assemblies total



Duplicate

Duplicate

Duplicate



**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

**Duplicate**

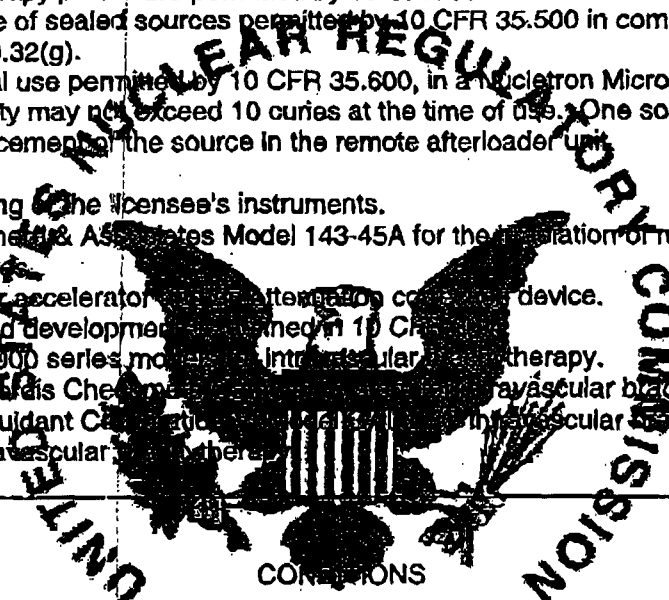
License Number  
87-02523-01

Docket or Reference Number  
030-03021/37-02523-03

Amendment No. 92

**3. Authorized use**

- A. Any uptake, dilution and excretion study permitted by 10 CFR 35.100.
- B. Any imaging and localization study permitted by 10 CFR 35.200.
- C. Any diagnostic study or therapy procedure permitted by 10 CFR 35.300.
- D. Any manual brachytherapy procedure permitted by 10 CFR 35.400.
- E. Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).
- F. One source for medical use permitted by 10 CFR 35.600, in a Nucletron MicroSelectron remote afterloader unit. The source activity may not exceed 10 curies at the time of use. One source in its shipping container as necessary for replacement of the source in the remote afterloader unit.
- G. In vitro studies.
- H. Calibration and checking of the licensee's instruments.
- I. For use in a J.L. Shepherd & Associates Model 143-45A for the irradiation of material except explosives, flammables or corrosives.
- J. For shielding in a linear accelerator or other radiation control device.
- K. through P. Research and development as defined in 10 CFR 35.100.
- Q. For use in Novoste A1000 series mobile intravascular brachytherapy.
- R. For medical use in a Corbis Chemotherapy Intravascular brachytherapy.
- S. For medical use in a Guidant Chemotherapy Intravascular brachytherapy remote afterloader unit for intravascular brachytherapy.



**CONDITIONS**

- 10. Licensed material may be used or stored only at the licensee's facilities located at 5230 Centre Avenue, Pittsburgh, Pennsylvania and 5200 Centre Avenue, Pittsburgh, Pennsylvania.
- 11. The Radiation Safety Officer for this license is Ronald J. Scala, M.S.
- 12. Licensed material is only authorized for use by, or under the supervision of:
  - A. Individuals permitted to work as an authorized user and/or authorized medical physicist in accordance with 10 CFR 35.13 and 35.14.
  - B. The following individuals are authorized users for the materials and uses indicated:

Authorized Users

Ingrid Naugle, M.D.

**Duplicate**

Material and Use

35.100; 35.200; 35.300; 35.500

In vitro studies  
Depleted Uranium

**Duplicate**

**Duplicate**

Duplicate

Duplicate

Duplicate

MATERIALS LICENSE  
SUPPLEMENTARY SHEET

License Number

07-02523-01

Docket or Reference Number

030-03021/37-02523-03

Amendment No. 92

Susan Rakfal, M.D.

35.400; Iridium 192 for uses in a High Dose Rate Remote Afterloader Unit; Strontium 90 and Phosphorus 32 for intravascular brachytherapy procedures

Kristina Gerszten, M.D.

35.400; Iridium 192 for uses in a High Dose Rate Remote Afterloader Unit; Strontium 90 and Phosphorus 32 for intravascular brachytherapy procedures

Robert S. Werner, M.D.

35.400

Sushil Beriwal, M.D.

35.400; Iridium 192 for uses in a High Dose Rate Remote Afterloader Unit; Strontium 90 for intravascular brachytherapy procedures

Ryan Smith, M.D.

35.400; Iridium 192 for uses in a High Dose Rate Remote Afterloader Unit; Strontium 90 for intravascular brachytherapy procedures

Robert P. Piro, M.D.

35.400; Iridium 192 for uses in a High Dose Rate Remote Afterloader Unit; Strontium 90 for intravascular brachytherapy procedures

C. The following individuals are authorized medical physicists as indicated:

Authorized Medical Physicists

Material and Use

Bruce Libby, Ph.D.

Iridium 192 in a High Dose Rate Remote Afterloader Unit and Strontium 90, Iridium 192 and Phosphorus 32 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot checks, and training

Satya Bose, Ph.D.

Iridium 192 in a High Dose Rate Remote Afterloader Unit and Strontium 90, Iridium 192 and Phosphorus 32 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot checks, and training

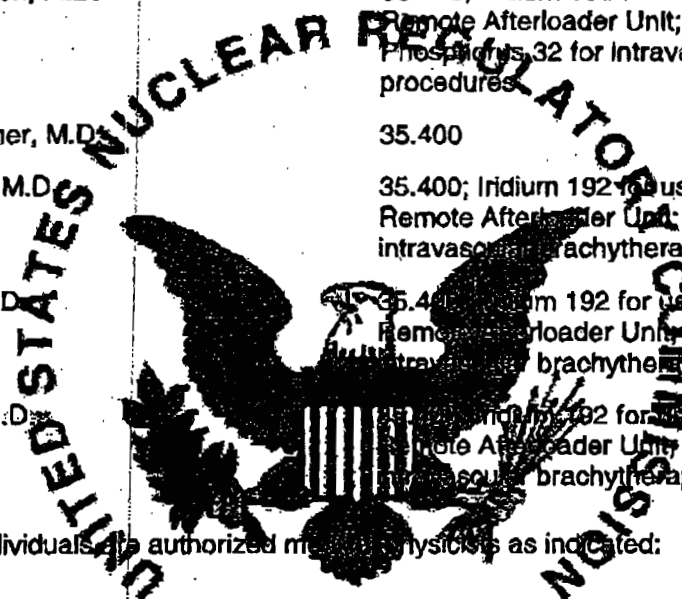
Mubina Quadar, Ph.D.

Iridium 192 in a High Dose Rate Remote Afterloader Unit and Strontium 90, Iridium 192 and Phosphorus 32 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot checks, and training

Duplicate

Duplicate

Duplicate



HRC-001473

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 4 of 10 PAGES

Duplicate Duplicate Duplicate

MATERIALS LICENSE SUPPLEMENTARY SHEET

License Number 87-02523-01
Docket or Reference Number 030-03021/37-02523-03
Amendment No. 92

Authorized Users

Vijay K. Bahl, M.D.

Steven Burton, M.D.

Alexander Chen, M.D.

John Flickinger, M.D.

Dwight E. Heron, M.D.

Barry M. McCook, M.D.

Frank S. Torok, M.D.

Melvin Deusch, M.D.

Joel Greenberger, M.D.

Joseph Wapenski, M.D.

Christopher C. Allen, M.D.

Judith M. Joyce, M.D.

James M. Mountz, M.D.

Badreddine Bencherif, M.D.

Material and Use

35.100

35.400; Iridium 192 for uses in a High Dose Rate Remote Afterloader Unit; Strontium 90, Iridium 192 and Phosphorus 32 for intravascular brachytherapy procedures

35.400; Iridium 192 for uses in a High Dose Rate Remote Afterloader Unit; Strontium 90, Iridium 192 and Phosphorus 32 for intravascular brachytherapy procedures

35.400; Iridium 192 for uses in a High Dose Rate Remote Afterloader Unit; Strontium 90, Iridium 192 and Phosphorus 32 for intravascular brachytherapy procedures

35.400; Iridium 192 for uses in a High Dose Rate Remote Afterloader Unit; Strontium 90 and Phosphorus 32 for intravascular brachytherapy procedures

35.100; 35.200; 35.300

35.100; 35.200; 35.300

35.400; Iridium 192 for uses in a High Dose Rate Remote Afterloader Unit; Strontium 90 and Phosphorus 32 for intravascular brachytherapy procedures

35.400; Iridium 192 for uses in a High Dose Rate Remote Afterloader Unit; Strontium 90 and Phosphorus 32 for intravascular brachytherapy procedures

35.100; 35.200; 35.300

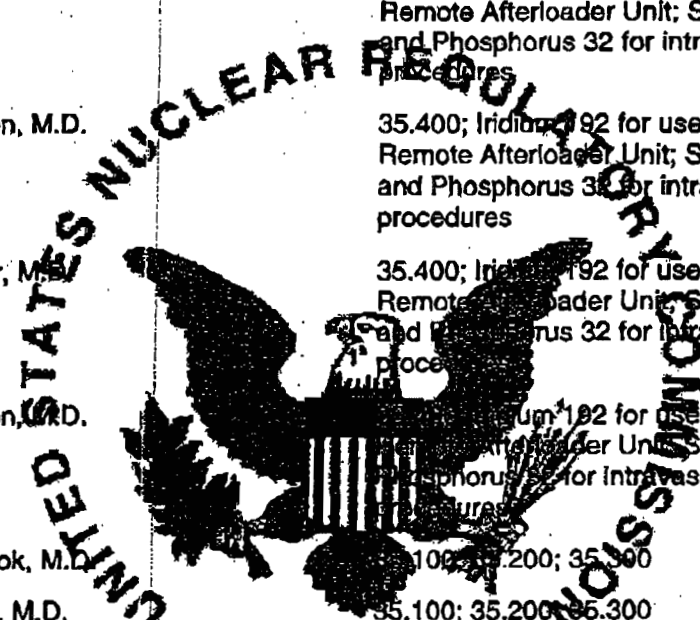
35.200

35.100; 35.200; 35.300

35.100; 35.200; 35.300

35.100; 35.200; 35.300

Duplicate Duplicate Duplicate



Duplicate

MATERIALS LICENSE  
SUPPLEMENTARY SHEET

Duplicate

Duplicate

License Number

97-02523-01

Docket or Reference Number

030-03021/37-02523-03

Amendment No. 92

Authorized Medical Physicists

Raj Severaj, M.S.

Bob Surgent, M.S.

Lea Tao, Ph.D.

Ronald Scala, M.S.

Krishna Komanduri, Ph.D.

Cheng Saw, Ph.D.

~~Ning Yue, Ph.D.~~

Material and Use

Iridium 192 in a High Dose Rate Remote Afterloader Unit and Strontium 90, Iridium 192 and Phosphorus 32 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot checks, and training

Iridium 192 in a High Dose Rate Remote Afterloader Unit and Strontium 90, Iridium 192 and Phosphorus 32 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot checks, and training

Iridium 192 in a High Dose Rate Remote Afterloader Unit and Strontium 90, Iridium 192 and Phosphorus 32 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot checks, and training

Iridium 192 in a High Dose Rate Remote Afterloader Unit and Strontium 90, Iridium 192 and Phosphorus 32 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot checks, and training

Iridium 192 in a High Dose Rate Remote Afterloader Unit and Strontium 90, Iridium 192 and Phosphorus 32 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot checks, and training

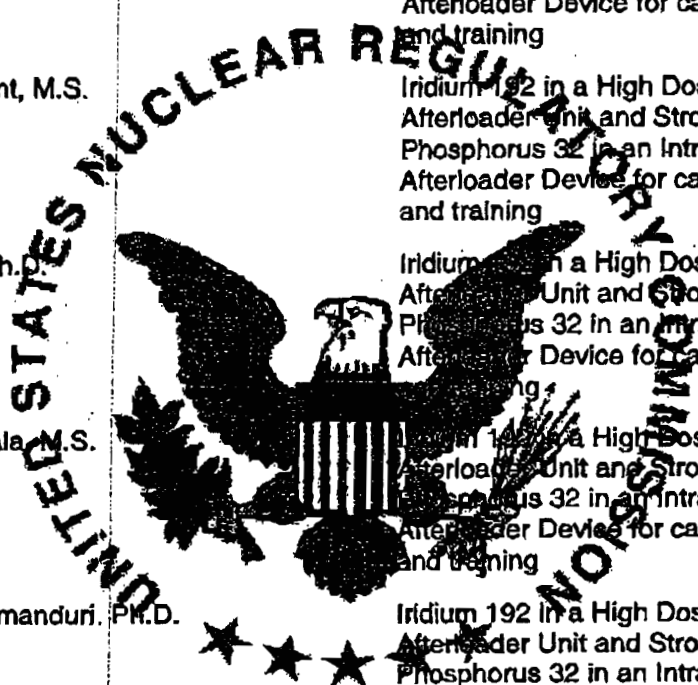
Iridium 192 in a High Dose Rate Remote Afterloader Unit and Strontium 90, Iridium 192 and Phosphorus 32 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot checks, and training

Iridium 192 in a High Dose Rate Remote Afterloader Unit and Strontium 90 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot checks, and training

Duplicate

Duplicate

Duplicate



Duplicate

Duplicate

Duplicate

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

97-02523-01

Docket or Reference Number

030-03021/37-02523-03

Amendment No. 92

Mohammed Saif, Ph.D.

Iridium 192 in a High Dose Rate Remote Afterloader Unit and Strontium 90 in an Intravascular Brachytherapy Afterloader Device for calibrations, spot checks, and training

Hong Cheng Chen, M.S.

Iridium 192 in a High Dose Rate Remote Afterloader Unit and Strontium 90 in an intravascular Brachytherapy Afterloader Device for calibrations, spot checks, and training

D. The following individuals are authorized users for non-medical uses as indicated:

Users

Material and Use

Joel Nelson, M.D.

Hydrogen 3; Carbon 14; Phosphorus 32; Phosphorus 33; Sulfur 35 and Iodine 125

Beth Pflug, Ph.D.

Hydrogen 3; Carbon 14; Phosphorus 32; Phosphorus 33; Sulfur 35 and Iodine 125

Uddhav P. Kalevkar, Ph.D.

Hydrogen 3; Carbon 14; Phosphorus 32; Phosphorus 33; Sulfur 35 and Iodine 125

Janey Whalen, Ph.D.

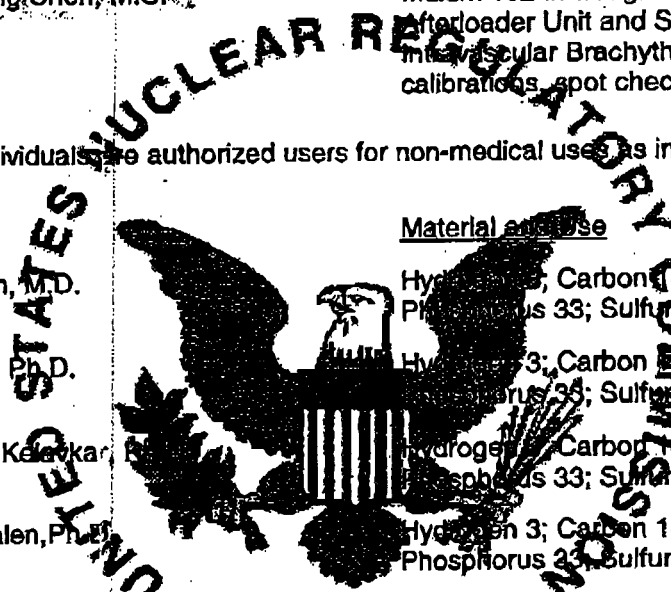
Hydrogen 3; Carbon 14; Phosphorus 32; Phosphorus 33; Sulfur 35 and Iodine 125

E. Licensed material in Item 6.I. shall be used by, or under the supervision of, individuals who have received the training described in application dated April 16, 1995 and have been designated, in writing, by the Radiation Safety Officer.

F. Intravascular brachytherapy procedures shall be conducted under the supervision of the authorized user, who will consult with the interventional cardiologist/physician and authorized medical physicist prior to initiating treatment. The procedures shall be conducted in the physical presence of the authorized user or the authorized medical physicist.

13. 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(d), 40.36(b), and 70.25(d) for establishing decommissioning financial assurance.

14. In lieu of 10 CFR 35.404, immediately after retracting the source from the patient into its shielded position in the intravascular brachytherapy device, a radiation survey shall be made of the patient and the intravascular brachytherapy device with a portable radiation detection survey instrument to confirm that the source has been removed from the patient. Records of the survey shall be maintained in lieu of the record required in 10 CFR 35.2404.



Duplicate

Duplicate

Duplicate

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

97-02523-01

Docket or Reference Number

030-03021/37-02523-03

Amendment No. 92

15. The intravascular brachytherapy afterloader device shall be inspected and serviced at intervals recommended by the manufacturer, and maintenance and repair shall be performed by the manufacturer or persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.

16. The licensee shall not use licensed material in or on human beings except as provided otherwise by specific condition of this license.

17. The licensee shall not use licensed material in field applications where it is released except as provided otherwise by specific condition of this license.

18. For sealed sources not associated with 10 CFR Part 35 use, the following conditions apply:

A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under Agreement State regulations.

B. Notwithstanding Paragraph A of this condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage at intervals not to exceed 3 months.

C. In the absence of a certificate of registration indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under Agreement State regulations, a sealed source received from another person shall not be put into use until tested and the test results received.

D. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.

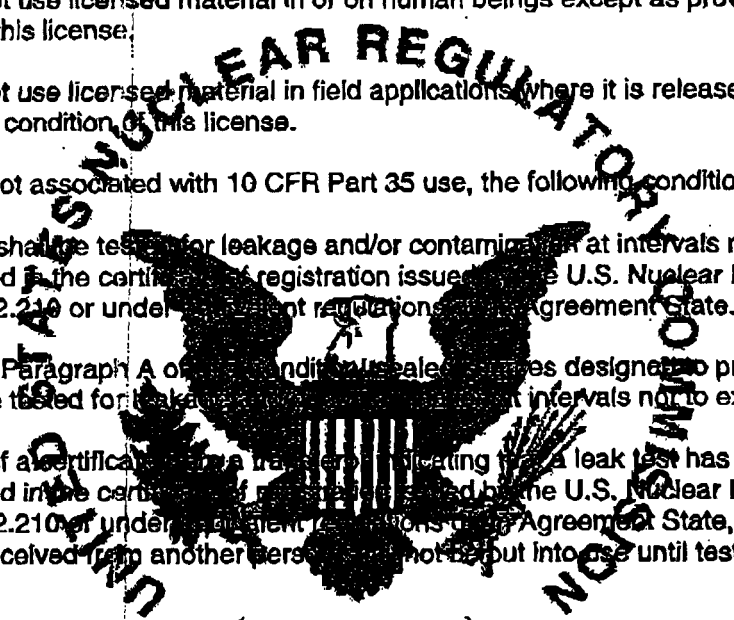
E. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

F. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.

Duplicate

Duplicate

Duplicate



NRC FORM 757A

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 9 of 10 PAGES

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

97-02523-01

Docket or Reference Number

030-03021/37-02523-03

Amendment No. 92

- Duplicate** ■ **Duplicate** ■ **Duplicate**
- G. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- H. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.
19. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
20. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radioisotopes, quantities, manufacturer's name and model numbers, and the date of the inventory.
21. The licensee shall not repair, remove, or alter, or cause any of the following: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, or any component that maintains safe operation of the irradiator. These activities shall be performed by a person specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
22. The procedures contained in the manufacturer's instructions manual for the irradiator authorized by this license shall be followed and a copy of this manual shall be made available to each person using or having responsibility for the use of the device.
23. Replacement-exchange of the source/source-holder combination, for diagnostic sources identified in 10 CFR 35.500, may be performed by the licensee in accordance with the instructions contained in the manufacturer's manual.
24. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
- Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
  - Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and
  - Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
- Duplicate** ■ **Duplicate** ■ **Duplicate**

NRC FORM 574

U.S. NUCLEAR REGULATORY COMMISSION

PAGE 10 of 10 PAGES

Duplicate

Duplicate

Duplicate

**MATERIALS LICENSE  
SUPPLEMENTARY SHEET**

License Number

97-02523-01

Docket or Reference Number

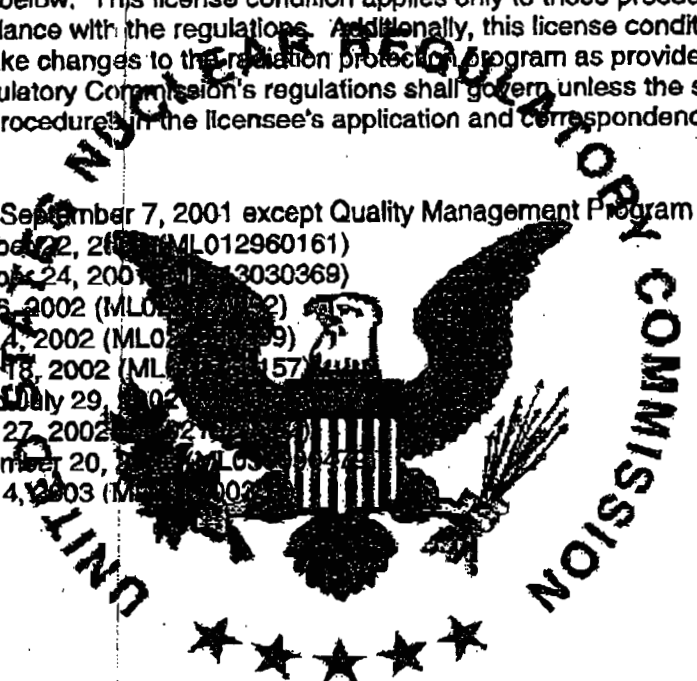
030-03021/37-02523-03

Amendment No. 92

25. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."

26. 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. This license condition applies only to those procedures that are required to be submitted in accordance with the regulations. Additionally, this license condition does not limit the licensee's ability to make changes to the radiation protection program as provided for in 10 CFR 35.26. The U.S. 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 September 7, 2001 except Quality Management Program (ML012570086)
- B. Letter dated October 22, 2001 (ML012960161)
- C. Letter dated October 24, 2001 (ML013030369)
- D. Letter dated May 6, 2002 (ML013110002)
- E. Letter dated June 4, 2002 (ML013110009)
- F. Letter dated June 18, 2002 (ML013110157)
- G. Facsimile received July 29, 2002
- H. Letter dated June 27, 2002 (ML013110002)
- I. Letter dated December 20, 2002 (ML013110049)
- J. Letter dated June 4, 2003 (ML013110002)



For the U.S. Nuclear Regulatory Commission

*Original signed by Sandra Gabriel*

Date August 12, 2005

By

Sandra Gabriel  
 Medical Branch  
 Division of Nuclear Materials Safety  
 Region I  
 King of Prussia, Pennsylvania 19406

Duplicate

Duplicate

Duplicate



This is to acknowledge the receipt of your letter/application dated

8/12/08, and to inform you that the initial processing which includes an administrative review has been performed.

Amendment (07-12153-02)  
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

Please provide to this office within 30 days of your receipt of this card

---

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 142716.  
When calling to inquire about this action, please refer to this control number.  
You may call us on (610) 337-5398, or 337-5260.