Cabell Huntington Hospital

1340 Hal Greer Boulevard
Huntington, WV 25701

May 4, 2018

Br. 1

Licensing Assistance Team
U.S. NRC Region I DNMS
Nuclear Materials Section B
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

03003370

RE: **License Amendment Request for NRC Radioactive Materials License # 47-00404-02**
**Cabell Huntington Hospital, Huntington, WV 25701-0195**

To Whom It May Concern:

We wish to add Rebekah L. Young, M.D., to our radioactive materials license as an authorized user for Iridium 192 uses in a High Dose Rate Remote Afterloader. Attached you will find the completed NRC Form 313A (AUS) for Dr. Young. You will also find supporting documentation of her broad-scope agreement state license authorized user status and training in the device operation, radiation safety, and emergency procedures. Please note that Dr. Young is based at Edwards Comprehensive Cancer Center located at 1400 Hal Greer Boulevard, Huntington, WV and that her current HDR training and experience is for the Varian GammaMedPlus iX HDR unit (source 6.F. on our current license) at that location. We commit to ensuring that the Dr. Young will complete clinical use, treatment planning, and emergency procedures training on the Nucletron Model 106.990 HDR devise located at St. Mary's Medical Center, 2900 First Avenue, Huntington, WV (source 6.G. on our current license) prior to independently functioning as the authorized user for that device.

This request has been reviewed and approved by our Radiation Safety Committee. If you have any questions regarding this request, or should you need any further information, please do not hesitate to contact us. Questions may be directed to our Radiation Safety Officer, James Norweck, MS, DABR. Thank you for your consideration.

Sincerely,

Tim Martin, MBA, RT(R), ARRT, ASRT, ACHE
Vice President of Ancillary and Support Services
Office Phone: (304) 526-2205
Office FAX: (304) 526-2008
Email: tim.martin@chhi.org

cc: James T. Norweck, M.S., DABR, Radiation Safety Officer
O: 304-522-1550 x 234
F: 304-522-0704
Email: jnorweck@radiology-inc.com

REC'D IN LAT 5-31-18

608970
NMSS/RGN1 MATERIALS-002

NRC FORM 313A (AUS) (06-2016) U.S. NUCLEAR REGULATORY COMMISSION

# AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (for uses defined under 35.400 and 35.600) [10 CFR 35.490, 35.491, and 35.690]

APPROVED BY OMB: NO. 3150-0120
EXPIRES: 06/30/2019

| Name of Proposed Authorized User | State or Territory Where Licensed |
|---|---|
| Rebekah L. Young, M.D. | West Virginia |

**Requested Authorization(s) (check all that apply)**

- ☐ 35.400 Manual brachytherapy sources
- ☐ 35.400 Ophthalmic use of strontium-90
- ☑ 35.600 Remote afterloader unit(s)
- ☐ 35.600 Teletherapy unit(s)
- ☐ 35.600 Gamma stereotactic radiosurgery unit(s)

## PART I -- TRAINING AND EXPERIENCE
*(Select one of the three methods below)*

* Training and Experience, including Board Certification, must have been obtained within the 7 years preceding the date of application or the individual must have obtained related continuing education and experience since the required training and experience was completed. Provide dates, duration, and description of continuing education and experience related to the uses checked above.

☐ 1. **Board Certification**

a. Provide a copy of the board certification.

b. For 35.600, go to the table in 3.e. and describe training provider and dates of training for each type of use for which authorization is sought.

c. Skip to and complete Part II Preceptor Attestation.

☑ 2. **Current 35.600 Authorized User Requesting Additional Authorization for 35.600 Use(s) Checked Above**

a. Go to the table in section 3.e. to document training for new device.

b. Skip to and complete Part II Preceptor Attestation.

☐ 3. **Training and Experience for Proposed Authorized User**

a. Classroom and Laboratory Training ☐ 35.490 ☐ 35.491 ☐ 35.690

| Description of Training | Location of Training | Clock Hours | Dates of Training* |
|---|---|---|---|
| Radiation physics and instrumentation | | | |
| Radiation protection | | | |
| Mathematics pertaining to the use and measurement of radioactivity | | | |
| Radiation biology | | | |

**Total Hours of Training:** ☐

NRC FORM 313A (AUS)
(06-2018)

U.S. NUCLEAR REGULATORY COMMISSION

## AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

**3. Training and Experience for Proposed Authorized User (continued)**

b. Supervised Work and Clinical Experience for 10 CFR 35.490 *(If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)*

| **Supervised Work Experience** | | **Total Hours of Experience:** | |
|---|---|---|---|
| Description of Experience Must Include: | Location of Experience/License or Permit Number of Facility | Confirm | Dates of Experience* |
| Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys | | ☐ Yes ☐ No | |
| Checking survey meters for proper operation | | ☐ Yes ☐ No | |
| Preparing, implanting, and safely removing brachytherapy sources | | ☐ Yes ☐ No | |
| Maintaining running inventories of material on hand | | ☐ Yes ☐ No | |
| Using administrative controls to prevent a medical event involving the use of byproduct material | | ☐ Yes ☐ No | |
| Using emergency procedures to control byproduct material | | ☐ Yes ☐ No | |

| Clinical experience in radiation oncology as part of an approved formal training program | Location of Experience/License or Permit Number of Facility | Dates of Experience* |
|---|---|---|
| **Approved by:** ☐ Residency Review Committee for Radiation Oncology of the ACGME ☐ Royal College of Physicians and Surgeons of Canada ☐ Committee on Postdoctoral Training of the American Osteopathic Association | | |

| Supervising Individual | License/Permit Number listing supervising individual as an Authorized User |
|---|---|
| | |

NRC FORM 313A (AUS) (08-2018) U.S. NUCLEAR REGULATORY COMMISSION

## AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

**3. Training and Experience for Proposed Authorized User (continued)**

c. Supervised Clinical Experience for 10 CFR 35.491

| Description of Experience | Location of Experience/License or Permit Number of Facility | Clock Hours | Dates of Experience* |
|---|---|---|---|
| Use of strontium-90 for ophthalmic treatment, including: examination of each individual to be treated; calculation of the dose to be administered; administration of the dose; and follow up and review of each individual's case history | | | |

| Supervising Individual | License/Permit Number listing supervising individual as an Authorized User |
|---|---|
| | |

d. Supervised Work and Clinical Experience for 10 CFR 35.690

☐ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

**Supervised Work Experience** **Total Hours of Experience:**

| Description of Experience Must Include: | Location of Experience/License or Permit Number of Facility | Confirm | Dates of Experience* |
|---|---|---|---|
| Reviewing full calibration measurements and periodic spot-checks | | ☐ Yes ☐ No | |
| Preparing treatment plans and calculating treatment doses and times | | ☐ Yes ☐ No | |
| Using administrative controls to prevent a medical event involving the use of byproduct material | | ☐ Yes ☐ No | |
| Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console | | ☐ Yes ☐ No | |
| Checking and using survey meters | | ☐ Yes ☐ No | |
| Selecting the proper dose and how it is to be administered | | ☐ Yes ☐ No | |

NRC FORM 313A (AUS)
(08-2016)

U.S. NUCLEAR REGULATORY COMMISSION

## AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

**3. Training and Experience for Proposed Authorized User (continued)**

d. Supervised Work and Clinical Experience for 10 CFR 35.690 (continued)

| Clinical experience in radiation oncology as part of an approved formal training program | Location of Experience/License or Permit Number of Facility | Dates of Experience* |
|---|---|---|
| **Approved by:**<br>☐ Residency Review Committee for Radiation Oncology of the ACGME<br>☐ Royal College of Physicians and Surgeons of Canada<br>☐ Committee on Postdoctoral Training of the American Osteopathic Association | | |

| Supervising Individual | License/Permit Number listing supervising individual as an Authorized User |
|---|---|
| | |

e. For 35.600, describe training provider and dates of training for each type of use for which authorization is sought.

| Description of Training | Training Provider and Dates | | |
|---|---|---|---|
| | Remote Afterloader | Teletherapy | Gamma Stereotactic Radiosurgery |
| Device operation | 4/20/2018 by Shannon Durfee, MS, DABR, AMP. See attached letter. | | |
| Safety procedures for the device use | 12/27/2017 by C. Tom Brannan, MS, DABR, AMP. See attached sign-in sheet. | | |
| Clinical use of the device | 4/20/2018 by Shannon Durfee, MS, DABR, AMP. See attached letter. | | |

| Supervising Individual. (*If training provided by Supervising Individual (If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.)*) | License/Permit Number listing supervising individual as an Authorized User |
|---|---|
| Charles W. Murphy, M.D. | Cabell Huntington Hospital, NRC 47-004-04-02 |

Authorized for the following types of use:

☑ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

f. Provide completed Part II Preceptor Attestation.

NRC FORM 313A (AUS) (06-2016) U.S. NUCLEAR REGULATORY COMMISSION

**AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)**

**PART II – PRECEPTOR ATTESTATION**

Note: This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the preceptor provides, directs, or verifies training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

By checking the boxes below, the preceptor is attesting that the individual has knowledge to fulfill the duties of the position sought and not attesting to the individual's "general clinical competency."

**First Section**
**Check one of the following for each requested authorization:**

**For 35.490:**

**Board Certification**

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily completed the requirements in 35.490(a)(1) and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

**OR**

**Training and Experience**

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily completed the 200 hours of classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation oncology, as required by 10 CFR 35.490(b)(1) and (b)(2), and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under 10 CFR 35.400.

**For 35.491:**

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily completed the 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy, has used strontium-90 for ophthalmic treatment of 5 individuals, as required by 10 CFR 35.491(b), and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.

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**Second Section**

**For 35.690:**

**Board Certification**

☐ I attest that _____ (Name of Proposed Authorized User) has satisfactorily completed the requirements in 35.690(a)(1).

**OR**

**Training and Experience**

☑ I attest that Rebekah L. Young, M.D. (Name of Proposed Authorized User) has satisfactorily completed 200 hours of classroom and laboratory training, 500 hours of supervised work experience, and 3 years of supervised clinical experience in radiation therapy, as required by 10 CFR 35.690(b)(1) and (b)(2).

**AND**

NRC FORM 313A (AUS)
(08-2016)

U.S. NUCLEAR REGULATORY COMMISSION

## AUTHORIZED USER TRAINING AND EXPERIENCE AND PRECEPTOR ATTESTATION (continued)

**Preceptor Attestation (continued)**

**Third Section**

**For 35.690: (continued)**

☑ I attest that Rebekah L. Young, M.D. has received training required in 35.690(c) for device
Name of Proposed Authorized User

operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought, as checked below.

☑ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

**AND**

**Fourth Section**

☑ I attest that Rebekah L. Young, M.D. has achieved a level of competency sufficient to
Name of Proposed Authorized User

achieve a level of competency sufficient to function independently as an authorized user for:

☑ Remote afterloader unit(s) ☐ Teletherapy unit(s) ☐ Gamma stereotactic radiosurgery unit(s)

**Fifth Section**

**Complete the following for preceptor attestation and signature:**

☑ I meet the requirements in 10 CFR 35.490, 35.491, 35.690, or equivalent Agreement State requirements, as an authorized user for:

☐ 35.400 Manual brachytherapy sources ☐ 35.600 Teletherapy unit(s)

☐ 35.400 Ophthalmic use of strontium-90 ☐ 35.600 Gamma stereotactic radiosurgery unit(s)

☑ 35.600 Remote afterloader unit(s)

| Name of Preceptor | Signature | Telephone Number | Date |
|---|---|---|---|
| Charles W. Murphy, M.D. | Charles W. Murphy, MD | 304-399-6501 | 4/6/18 |

License/Permit Number/Facility Name

Cabell Huntington Hospital, NRC 47-004-04-02

# Supporting Documentation

*- For -*

**Rebekah L. Young, MD**

THE OHIO STATE UNIVERSITY

University Radiation Safety Committee

Environmental Health and Safety
Radiation Safety Section

1314 Kinnear Road
Columbus, OH 43212

Phone: 614-292-1284

Website: ehs.osu.edu

December 1, 2016

Rebekah L. Young, MD
Department of Radiation Oncology
1145 Olentangy River Road
Columbus, OH 43212

Dear Dr. Young,

Your request to use radioactive material(s) under The Ohio State University's Type A License of Broad Scope issued by the Ohio Department of Health, Number 02110250037, as an Authorized User has been reviewed by the University Radiation Safety Committee and given final approval for the following radionuclide specific modality(ies) of use.

Ohio Administrative Code Modality of Use and Approved Radionuclides:

- 3701:1-58-72 – Use of other medical uses of radioactive material or radiation from radioactive materials
  - Lexell Gamma Knife® Perfexion™ (Co-60)

Radioactive materials are to be used in accordance with The Ohio State University's Radioactive Materials License, the Ohio Department of Health regulations and guidance, and other applicable regulatory and/or oversight agencies.

If you have any questions, please contact the Radiation Safety Section at (614) 292-1284.

Sincerely,

Dramane Konate
University Radiation Safety Officer

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Withhold from Public Disclosure under Revised Code 149.433(A) & (B)

Amendment No. *41*



## OHIO DEPARTMENT OF HEALTH
## LICENSE FOR RADIOACTIVE MATERIAL

**Pursuant to Chapter 3748 of the Ohio Revised Code, and in reliance on statements and representations made by the licensee, a license is hereby issued authorizing the licensee named herein to receive, acquire, possess, and transfer radioactive material as 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 applications of Chapter 3748 of the Ohio Revised Code and all applicable rules promulgated there under. This license is subject to all applicable rules, regulations and orders of the Ohio Department of Health now or hereinafter in effect and to any conditions specified below.**

| LICENSEE | LICENSE NUMBER |
|---|---|
| 1. **The Ohio State University** | 3. **02110250037** |
| 2. **Office of Environmental Health and Safety**<br>**1314 Kinnear Road**<br>**Columbus, Ohio 43212-1168** | EXPIRATION DATE<br>4. ***July 1, 2022*** |
| | FILE NUMBER / ID NUMBER<br>5. **501167 / *14061*** |

| 6. RADIOACTIVE MATERIAL | 7. CHEMICAL AND/OR PHYSICAL FORM | 8. MAXIMUM QUANTITY THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE |
|---|---|---|
| A. **Any radioactive material permitted by OAC 3701:1-58-32** | A. **Any radiopharmaceutical form** | A. **As needed** |
| B. **Any radioactive material permitted by OAC 3701:1-58-34** | B. **Any radiopharmaceutical form** | B. **As needed** |
| C. **Any radioactive material permitted by OAC 3701:1-58-37** | C. **Any radiopharmaceutical form** | C. **185 GBq (5 Ci)** |
| D. **Any radioactive material permitted by OAC 3701:1-58-43** | D. **Sealed Sources** | D. **925 GBq (25.0 Ci)** |
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |
| G. **Iodine-125 permitted by OAC 3701:1-58-72** | G. **Sealed sources (I-125 seeds IsoAid model #IAI-125A or equivalent)** | G. **55.5 MBq (1.5 mCi) maximum per procedure and 555 MBq (15 mCi) total** |
| H. **Yttrium-90 permitted by OAC 3701:1-58-72** | H. **Sealed source (Therasphere and/or SirSphere) Y-90 microspheres** | H. **111 GBq (3 Ci)** |
| I. **Any radioactive material permitted by OAC 3701:1-58-26** | I. **Sealed Sources** | I. **37 GBq (1 Ci)** |

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| OHIO DEPARTMENT OF HEALTH | Page 2 of 6 |
|---|---|
| LICENSE FOR RADIOACTIVE MATERIALS | License Number: 02110250037 |
| | FILE/ID Number: 501167 / 14061 |
| SUPPLEMENTARY SHEET | Amendment Number: 41 |

| | | | | | |
|---|---|---|---|---|---|
| J. | Any radioactive material, with atomic number 1 to 83, inclusive | J. | Any | J. | 14.8 TBq (400 Ci), no single radionuclide to exceed 370 GBq (10 Ci), except as listed herein: |

| | | |
|---|---|---|
| Hydrogen-3 | 3.7 TBq | (100Ci) |
| Carbon-14 | 3.7 TBq | (100 Ci) |
| Phosphorus-32 | 185 GBq | (5.0 Ci) |
| Chlorine-36 | 37 GBq | (1.0 Ci) |
| Titanium-44 | 37 GBq | (1.0 Ci) |
| Strontium-90 | 18.5 GBq | (500 mCi) |
| Zirconium-93 | 37 GBq | (1.0 Ci) |
| Niobium-94 | 37 GBq | (1.0 Ci) |
| Ruthenium-106 | 37 GBq | (1.0 Ci) |
| Cadmium-113 | 3.7 GBq | (100 mCi) |
| Iodine-125 | 130 GBq | (3.5 Ci) |
| Iodine-129 | 370 MBq | (10 mCi) |
| Iodine-131 | 36.999 GBq | (999 mCi) |
| Cerium-144 | 37 GBq | (1.0 Ci) |
| Europium-152 | 37 GBq | (1.0 Ci) |
| Europium-154 | 37 GBq | (1.0 Ci) |
| Holmium-166m | 37 GBq | (1.0 Ci) |
| Hafnium-172 | 37 GBq | (1.0 Ci) |
| Lead-210 | 18.5 GBq | (500 mCi) |
| Bismuth-210 | 74 GBq | (2.0 Ci) |

| | | | | | |
|---|---|---|---|---|---|
| K. | Ge/Ga-68 as permitted by OAC 3701:1-58-72 | K. | Any form. Generators and radioisotopes derived to prepare radioactive drugs for medical use | K. | 74 GBq (2 Ci) total; not to exceed 1.85 GBq (50 mCi) per generator |
| L. | Hydrogen-3 | L. | Sealed source in an electron-capture device which has been registered per OAC 3701:1-46-19, NRC or an Agreement State | L. | 370 GBq (10 Ci) |
| M. | Hydrogen-3 | M. | Sealed source (titanium-, titanium-, or zirconium-tri(ide) | M. | 3 TBq (81 Ci) |
| N. | Nickel-63 | N. | Sealed source in an electron-capture device | N. | 185 GBq (5.0Ci) |
| O. | Krypton-85 | O. | Sealed source | O. | 55.5 GBq (1.5 Ci) |
| P. | Cesium-137 | P. | Sealed source (Victoreen Model 28-6A) | P. | 44.4 GBq (1.2 Ci) |
| Q. | Cesium-137 | Q. | Sealed source | Q. | 1.48 GBq (40 mCi) total; no single source to exceed 407 MBq (11 mCi) |
| R. | Americium-241 | R. | Sealed source | R. | 9.25 GBq (250 mCi) total; no single source to exceed 1.85 GBq (50 mCi) |
| S. | Thorium (all isotopes) as source material | S. | Any | S. | 6.8 kilograms at any one time – total possession per calendar year not to exceed 67.5 kilograms |
| T. | Uranium (natural or depleted in Uranium-235) | T. | Any | T. | possession per calendar year not to exceed 67.5 kilograms |
| U. | Plutonium-239 | U. | Electroplated source | U. | 37 MBq (1.0 mCi) |
| V. | Uranium (depleted in Uranium-235) | V. | Cadmium-plated metal | V. | 322 kilograms |
| W. | Polonium-210 | W. | Any | W. | 370 MBq (10 mCi) |

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| OHIO DEPARTMENT OF HEALTH<br>LICENSE FOR RADIOACTIVE MATERIALS<br>SUPPLEMENTARY SHEET | Page 3 of 6<br>License Number: 02110250037<br>FILE/ID Number: 501167 / 14061<br>Amendment Number: 41 |
|---|---|

| | | | | | |
|---|---|---|---|---|---|
| X. | Americium-241 | X. | Any | X. | 370 MBq (10 mCi) |
| Y. | Polonium-210 | Y. | Sealed source | Y. | 37 GBq (1.0 Ci), no single source to exceed 3.7 GBq (100 mCi) |
| Z. | Americium-241 | Z. | Sealed source | Z. | 74 GBq (2.0 Ci) total. One source not to exceed 22.2 GBq (600 mCi), and no other source to exceed 18.5 GBq (500 mCi) |
| AA. | Any radioactive material, with atomic number 3 to 83, inclusive | AA. | Neutron-irradiated metal | AA. | 5.6 TBq (152 Ci) |
| BB. | Americium-241 | BB. | Sealed source (Nuclear Material Equipment, serial No. 16AM13) | BB. | 1.85 GBq (50 mCi) |
| CC. | Uranium-235 | CC. | Any | CC. | 370 kBq (10 µCi) |
| [redacted] | | | | | |
| EE. | Plutonium-239/Beryllium | EE. | Sealed source (NUMEC – neutron-emission) | EE. | 80 grams |
| FF. | Plutonium-239/Beryllium | FF. | Sealed source (neutron-emission) | FF. | 800 milligrams |
| GG. | Plutonium-239/Beryllium | GG. | Sealed source (neutron-emission) | GG. | 80 grams |
| [redacted] | | | | | |
| II. | Any radioactive material, with atomic number 84 or above, except source or special nuclear material | II. | Any | II. | 370 GBq (10 Ci) total, no single radionuclide to exceed 18.5 GBq (500 mCi) |
| JJ. | Natural Uranium | JJ. | Natural uranium in cylindrical slugs encased in aluminum tubes | JJ. | 1, 460 Kilograms |
| KK. | Any radioactive material, with atomic number 84 or above, except source or special nuclear material | KK. | Sealed or plated sources | KK. | 555 GBq (15 Ci) total, no single radionuclide to exceed 3.7 GBq (100 mCi) |
| [redacted] | | | | | |

9. Authorized Use

A. Any uptake, dilution, and excretion study permitted by OAC 3701:1-58-32.
B. Any imaging and localization study permitted by OAC 3701:1-58-34.
C. Any medical use permitted by OAC 3701:1-58-37.
D. Any brachytherapy sources for therapeutic medical use permitted by OAC 3701:1-58-43.
[redacted]
G. For use as temporary implants to localize non-palpable lesions as permitted by OAC 3701:1-58-72.
H. For manual permanent brachytherapy implantation therapy as permitted by OAC 3701:1-58-72 using TheraSphere or SIR-Sphere Yttrium-90 microspheres and delivery systems.
I. Calibration, transmission and reference sources permitted by OAC 3701:1-58-26.

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| OHIO DEPARTMENT OF HEALTH<br>LICENSE FOR RADIOACTIVE MATERIALS<br>SUPPLEMENTARY SHEET | Page 4 of 6<br>License Number: 02110250037<br>FILE/ID Number: 501167 / 14061<br>Amendment Number: 41 |
|---|---|

| | |
|---|---|
| J. | Medical research in humans, research, and development as defined in OAC 3701:1-38-01(A); instrument calibration, and student instruction. |
| K. | For medical use permitted by OAC 3701:1-58-72 for Ge-68/Ga-68 generators for preparing and administering Ga-68 radiopharmaceuticals. |
| L. to O. | For use in analytical instruments (e.g., gas chromatographs) registered per OAC 3701:1-46-49, or the NRC or an Agreement State. |
| P. | For calibration of the licensee's survey meters. |
| Q. to R. | For possession and use in Troxler and Campbell Pacific Nuclear (CPN) gauges which have been evaluated and approved for licensing purposes and authorized for distribution under a license issued by the Director, the NRC, or an Agreement State. To be used for moisture/density measurements. |
| S. to T. | For research and development as defined in OAC 3701:1-38-01(A) and student instruction. |
| U. | Calibration and reference. |
| V. | Shielding for linear accelerators. |
| W. to BB. | For research and development as defined in OAC 3701:1-38-01(A). |
| CC. | Calibration standards for mass spectroscopy. |
| [redacted] | |
| EE. | To be used for laboratory experiments, student instruction, and instrument calibration in conjunction with a subcritical assembly. |
| FF. | To be used as an instrument check source |
| GG. | To be used in a neutron howitzer for student instruction. |
| [redacted] | |
| II. | Medical diagnosis, therapy, and research in humans; research and development; animal studies; student instruction. |
| JJ. | To be used in a graphite-moderated assembly for experimental procedures specified in the application to the Director dated December 12, 2016. |
| KK. | Check, calibration, and reference sources. |
| [redacted] | |

**CONDITIONS**

10. Licensed material may only be used at the licensee's facilities located at:

A. The Ohio State University Campus
Columbus, Ohio

B. The Ohio State University Hospitals – East
181 Taylor Avenue
Columbus, Ohio

C. Innovation Center
2001 Polaris Parkway
Columbus, Ohio 43240

[redacted]

G. Stone Laboratory
Put-In Bay
Lake Erie, Ohio

H. The Ohio State University
Ohio Agriculture Research and
Development Center (OARDC)
Wooster, Ohio 44691

I. Scott Laboratory
Room W468
201 West 19th Avenue
Columbus, Ohio 43210

J. Portable gauges may be use at temporary jobsites in the State of Ohio.

K. Arthur G. James Cancer Hospital and
Richard J. Solove Research Institute
460 West 10th Avenue
Columbus, Ohio

11. Radiation Safety Officer for this license is Dramane Konate.

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| OHIO DEPARTMENT OF HEALTH<br>LICENSE FOR RADIOACTIVE MATERIALS<br>SUPPLEMENTARY SHEET | Page 5 of 6 |
|---|---|
| | License Number: 02110250037 |
| | FILE/ID Number: 501167 / 14061 |
| | Amendment Number: 41 |

12. Licensed material shall be used by, or under the supervision of, individuals designated as follows:

A. The use of licensed material in or on humans shall be by a physician, dentist, or podiatrist as defined in OAC 3701:1-58-01.

B. Physicians, dentists, or podiatrists designated to use licensed material in or on humans shall meet the training criteria established in the criteria established in OAC Chapter 3701:1-58, and shall be designated by the licensee's Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for five years after the individual's last use of licensed material.

C. Licensed material for other than human use shall be used by or under the supervision of individuals designated by the Radiation Safety Committee. The licensee shall maintain records of individuals designated as users for five years after the individual's last use of licensed material.

D. Licensed material listed in items 6/7/8 Q. and R. shall only be used by, or under the supervision and in the physical presence of, individuals who have successfully completed the manufacturer's training program for gauge users, have been instructed in the licensee's routine and emergency operating procedures, and have been designated by the Radiation Safety Committee. The licensee shall maintain records of individuals designed as users and their training for five years following the last use of licensed material by the individual.

E. Installation, relocation, removal, replacement, and disposal of sealed sources in the irradiator shall be performed by persons specifically licensed by the Director, the NRC, or an Agreement State to perform such services.

F. All persons performing activities meeting the definition of "Nuclear Medicine Technologist" as specified in R.C. 4773.01 shall be licensed and in good standing with the state of Ohio.

13. Detector cells containing a titanium tritide foil or scandium tritide foil:

A. shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperature from exceeding that specified by the manufacturer, and approved by the Director, and

B. shall be vented to the outside when in use.

14. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee, *except as follows:*

A. *In accordance with procedure by licensee in letter dated August 25, 2017, the licensee is authorized to remove sealed sources from generally licensed equipment including liquid scintillation counters and electron capture detectors devices. Removal must be performed with radiation safety staff present during the procedure.*

B. *Radioactive Source activity must be less than the amount required for transfer licensing of the radioactive sealed source.*

C. *Radiation surveys will be conducted to ensure the radioactive sealed sources were properly removed from the device and that no radioactive material remains within the device.*

D. *The sealed sources shall be returned to the vendor, disposed of as radioactive waste, or added to The Ohio State University inventory of licensed material under this license.*

15. The licensee is able to transport radioactive materials in accordance with the provisions of OAC Chapter 3701:1-50.

16. The licensee shall not perform repairs or alterations of the irradiator involving removal of shielding or access to the licensed material.

17. Portable gauge control:

A. Each portable nuclear gauge shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The gauge or its container must be locked when in transport, storage or when not under the direct surveillance of an authorized user.

B. When performing tests at temporary job sites, the authorized user shall not leave the moisture/density gauge unattended. Upon completion of tests the device shall be locked in the licensee's vehicle or a secure building to prevent unauthorized use, loss, or theft.

C. The licensee shall conduct a physical inventory every 6 months to account for all sources 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 quantities and kinds of radioactive material, manufacturer's name and model numbers, location of the sources and the date of the inventory.

D. Each portable nuclear gauge must be secured with a minimum of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee, in accordance with OAC 3701:1-40-16(H).

OFFICIAL USE ONLY
Withhold from Public Disclosure under Revised Code 149.433(A) & (B)

| OHIO DEPARTMENT OF HEALTH | Page 6 of 6 |
|---|---|
| LICENSE FOR RADIOACTIVE MATERIALS | License Number: 02110250037 |
| | FILE/ID Number: 501167 / 14061 |
| SUPPLEMENTARY SHEET | Amendment Number: 41 |

18. Notwithstanding the possession limits in Item 8, the licensee shall further restrict the possession of licensed material to quantities below the limits specified in OAC 3701:1-40-14(G), which require consideration of the need for an emergency plan for responding to a release of licensed material.

[redacted]

20. In accordance with the requirements of OAC 3701:1-58-30, any patient administered gamma emitting radiopharmaceuticals or permanent brachytherapy sources shall be provided a patient release card to include:
    (1) The patient's name.
    (2) The radionuclide administered and its activity.
    (3) The facility name which administered the radionuclide.
    (4) The date of the administration of the radionuclide.
    (5) The expiration date of the card.

    The card is not applicable to those patients who are institutionalized (Hospitals, Nursing Homes, Correctional Institutions, etc.) or whose radiation levels do not exceed 0.1 mR/hr at one meter.

21. 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 Ohio Department of Health's statutes, rules, and orders shall govern unless statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

    A. Renewal application dated December 12, 2016 and correspondence dated February 13, 2017, March 6, 2017, March 10, 2017, March 22, 2017, March 28, 2017, April 14, 2017, April 18, 2017, May 3, 2017 and June 1, 2017; amendment 40 renews license number 02110250037 in its entirety.

    B. *Letter and electronic mail dated August 25, 2017 (Amendment 41)*

For the Ohio Department of Health

DATE: 9-15-17 BY: Gene Phillips, RS

W. Gene Phillips, MBA, RS
Chief, Bureau of Environmental Health and Radiation Protection
on behalf of the Director of Health

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Withhold from Public Disclosure under Revised Code 149.433(A) & (B)

4/20/18

## GammaMed Plus iX Training

As part of the commitment made to the NRC for adding Authorized User, Rebekah Young, MD, to the radioactive materials license, she was trained by Authorized User, Charles Murphy, MD and Medical Physicist, Shannon Durfee, MS, DABR, prior to clinical use of the system.

This training included the High Dose Rate System Operation, Radiation Safety and Emergency Annual Training Dec 22, 2017 with particular attention to safety and emergency procedures, patient treatment processes and afterloader / transfer tube usage for the iX system.

Dr. Young was also familiarized with the Varian Eclipse Brachyvision HDR treatment planning software including prescription entry, types of dwell time optimization and plan evaluation tools on April 20, 2018. This was completed before patient use.

Documentation of the training, with signatures, is filed in the Annual Training Folder in the physics office.

Rebekah Young MD 4/20/18 10:05 AM

Shannon R. Durfee, MS, DABR

Shannon R. Durfee, MS, DABR
Medical Physicist

Cabell Huntington Hospital

## INSERVICE ATTENDANCE

**SUBJECT/ TOPIC:** 2017 Annual NRC required HDR in-service

| DATE | TIME | NAME (PRINTED) | NAME (SIGNATURE) | UNIT/DEPT |
|---|---|---|---|---|
| 12/18/17 | 11:30 AM | Kayla Hannah | Kayla Hannah | Rad Onc |
| 12/18/17 | 11:30AM | Shannon Durfee | Shannon Durfee | Rad Onc |
| 12/18/17 | 11:30am | Davida Brooks | Davida Brooks | Rad Onc |
| 12/18/17 | 11:30am | Ashley Pfohl | Ashley Pfohl | Rad Onc |
| 12/18/17 | 11:30am | Andrea Morris | Andrea Morris | Rad Onc |
| 12/18/17 | 11:32a | Kelly Curtis | Kelly Curtis | RAD ONC |
| 12/18/17 | 1130AM | Mary Jobst | MARY JOBST | RADONC |
| 12/18/17 | 11:30 | Christopher Dudley, MD | Christopher Dudley, MD | Rad Onc |
| 12/18/17 | 11:30 | Candace Burger RN | Candace Burger RN | Rad Onc. |
| 12/18/17 | 11:30 | Kassie Kemper | Kassie Kemper | Rad Onc. |
| 12/18/17 | 11:30 | Keiva Harper | Keiva Harper | RAD ONC |
| 12/18/17 | 11:30 | Grace Dixon | Grace Dixon | Rad Onc |
| 12-18-17 | 11:30 AM | Angela Hayes | Angela Hayes | Rad Onc |
| 12/18/17 | 11:30am | CT Brannan | CT Brannan | Rad Onc |
| 12/20/17 | 930 | Erin Wilson | Erin Wilson | Rad Onc |
| 12/20/17 | 930 | Rebekah Yancy | Rebekah Yancy | Rad Onc |
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**CHH 849** Revised 10/2001

**White- Originating Dept.**
**Yellow- Education Dept.**

# HDR OPERATION, RADIATION SAFETY and EMERGENCY ANNUAL TRAINING
## December 18, 2017

I. Review of the Equipment
- a. Treatment Console
- b. TV Monitor System
- c. Intercom System
- d. Beam Indicators
  - i. On Console
  - ii. Remote Primalert Unit
  - iii. On Computer Monitor
  - iv. Above Door1 and Door2
  - v. Primalert Unit in room
  - vi. Portable Survey meter
- e. Computer at console
- f. Treatment-planning Computer with networked interface
- g. Source Delivery Unit (in room)
- h. Transfer tubes
- i. Length gauges
- j. Applicators
- k. QC equipment
- l. Operators manual
- m. Written procedures
- n. Emergency procedures

II. Review of Normal Operating Procedures
- a. Physicist performs calibration of new source.
- b. Physicist performs day-of-use quality assurance testing.
- c. Written directive by authorized user (Physician).
- d. Dosimetrist plans Treatment in Eclipse.
- e. Plan is modified and approved by physician.
- f. Plan is checked by physicist.
- g. Physicist performs independent calculation for sample point(s).
- h. Plan is transferred via network to computer at treatment console.
- i. Correctness of transfer and source decay is checked by physicist at console computer.
- j. Plan is transferred from console computer to Source Delivery Unit.
- k. Treatment is delivered (many small steps are included here and will be discussed appropriately).
- l. Source retracts into safe.
- m. Physicist enters room with survey meter, checking room, Source Delivery Unit and patient for appropriate radiation levels.
- n. Physician, nurse, and therapist enter room and care for the patient.
- o. Source Delivery Unit is secured for storage.
- p. All records are completed and filed.

III. **Emergency Procedures (See Attachment for complete procedures)**
- a. **Procedures are posted on the wall in the Console Area.**
  - i. **Press the Interrupt Button on Console**
  - ii. **Press Emergency Return (Labeled "1")**
  - iii. **If unsuccessful, Enter room and press Emergency button on Afterloader (Labeled "2")**
  - iv. **If unsuccessful, Turn crank (Labeled "3")**
  - v. **In unsuccessful.....follow Flow Diagram inside cabinet door.**
- b. **Procedures should be reviewed FREQUENTLY. It is a good idea at the beginning of each case to decide what steps will be followed if i., ii., iii., and iv. are unsuccessful so that there will be no time lost due to indecision and discussion.**
- c. **Never grasp the source WITHOUT long forceps or hemostats.**
- d. **Once the source is stored in a shielded container, the emergency is over. Care of the patient, documentation of the incident, notification of the RSO, analysis of the circumstances, etc. will proceed. The therapist (who is routinely operating a stop watch) will measure and record how much time elapsed between when the source should have retracted and it was subsequently removed from the patient. The rest of the Emergency Response will be followed.**

IV. **Additional Considerations**
- a. **Operators Manual is in drawer.**
- b. **U.S. Nuclear Regulatory Commission inspects.**
- c. **Whenever there is any doubt, don't proceed, so long as the source is in the shielded afterloader.**
- d. **Security requirements**
  - i. **Only authorized and trained individuals will have the combination code to enter the HDR source storage and treatment rooms.**
  - ii. **The HDR source must be secured from unauthorized access or removal at all times when not directly supervised.**
  - iii. **Unauthorized individuals must be escorted whenever entering HDR source storage or treatment rooms.**
  - iv. **Report suspicious behavior (such as unauthorized individuals attempting to gain access to restricted areas) immediately.**

# Operating Procedures for Varian GammaMed HDR Remote Afterloader

**Purpose**
This procedure provides the requirements for safe use, and storage of the Varian Model GammaMed HDR Afterloader.

**Scope**
This procedure applies to all personnel involved in the operation and use of the HDR afterloader.

**General Requirements**
1. Use of the Varian high dose rate afterloader shall be per the manufacturer's instructions as provided in the User Manual.
2. A copy of this procedure shall be provided to all personnel authorized as users of the remote afterloader.
3. A copy of this procedure shall be maintained at the afterloader device console.
4. No treatment procedure shall be performed in which a jammed or decoupled source cannot be removed expeditiously from the patient and placed in a shielded container. The Authorized User in consultation with the Authorized Medical Physicist and Radiation Safety Officer should determine all such emergency procedures.
5. The Authorized User and the Authorized Medical Physicist must be physically present for all patient treatments.
6. A trained user shall physically attend the HDR at all times during use. When not in use, the Afterloader, including all sources, shall be secured in such a manner that are inaccessible to untrained personnel including the general public.

**Spot Checks**
**Prior to Use or Daily**
1. Perform operational function checks of the interlocks and/or safety systems prior to each day of use. An Authorized Medical Physicist must review results of spot checks within 15 days and notify the licensee authorized user as soon as possible in writing of results:
    a. Radiation area monitor.
    b. TV monitor system.
    c. Intercom system.
    d. Treatment console indicators and status lamps.
    e. Treatment console operation displays.
    f. Treatment console printer.
    g. Afterloader indicators and status lamps.
    h. Treatment door indicators and status lamps.
    i. Check all source status indicators installed at the entrance to the treatment room and/or the treatment console.
    j. Verify proper operation of the electrical interlock(s) installed at the entrance to the treatment room.
    k. Verify the mechanical integrity of all applicators, source guide tubes and connectors to be used.
    l. Verify availability of emergency response equipment.
    m. Verify the computer decayed activity by comparing it to a pre-calculated decay chart to confirm the unit has decayed the activity correctly.
    n. Timer accuracy.
    o. Console computer:

i. Clock (date & time)
ii. Decayed source activity

2. In the event of an interlock system failure, the HDR and treatment console shall be locked in the OFF position until such time the interlock system has been repaired.
3. Records of each test will be maintained for a period of three years and shall include:
   a. The date of the test.
   b. The results of the test.
   c. The initials of the person performing the test.

**Use of the HDR Afterloader**

1. The HDR afterloader, console and treatment or storage room shall be secured when unattended.
2. Only the patient shall be allowed in the treatment room during treatment.
3. During all patient treatments, both the Authorized User and the Authorized Medical Physicist must be physically present.
4. Treatment planning computer systems utilizing removable storage media used to store patient treatment parameters for direct transfer to the treatment system will have each card labeled with the corresponding patient's name and identification number. Such media may be reused, and must be re-labeled, in accordance with manufacturer's instructions.

**Radiation Surveys**

WARNING: If the radiation survey indicates that the source is not fully retracted into the storage safe, the Emergency Procedure for the GammaMed HDR afterloader should be implemented immediately.

1. Immediately after each use of the HDR, a survey of the device and patient shall be performed to ensure the source has been fully retracted into the storage safe. The survey shall include the guide catheters, connectors, applicators and the external surfaces of the device.
2. The patient shall be surveyed over the body surface near the treatment site prior to removing the patient from the treatment room.
3. Survey records shall be maintained for a period of three years. The record shall include the following:
   a. Survey date,
   b. Identification of the afterloading device (model and serial number).
   c. Identification of the patient,
   d. Make, model and serial number of the instrument used to perform the survey.
   e. Background dose rate.
   f. Survey results.
   g. Signature of the person performing the survey.

**HDR Treatment Room Shielding Design**

**General Assumptions**

1. The HDR equipment is a Varian model GammaMed utilizing a 10 Ci Ir-192 source.
2. The permissible dose rate limits are 2 mrem per hour/2 mrem per week for uncontrolled areas and 5 mrem per hour/10 mrem per week for controlled areas.
3. A shielding calculation and room survey has been performed.

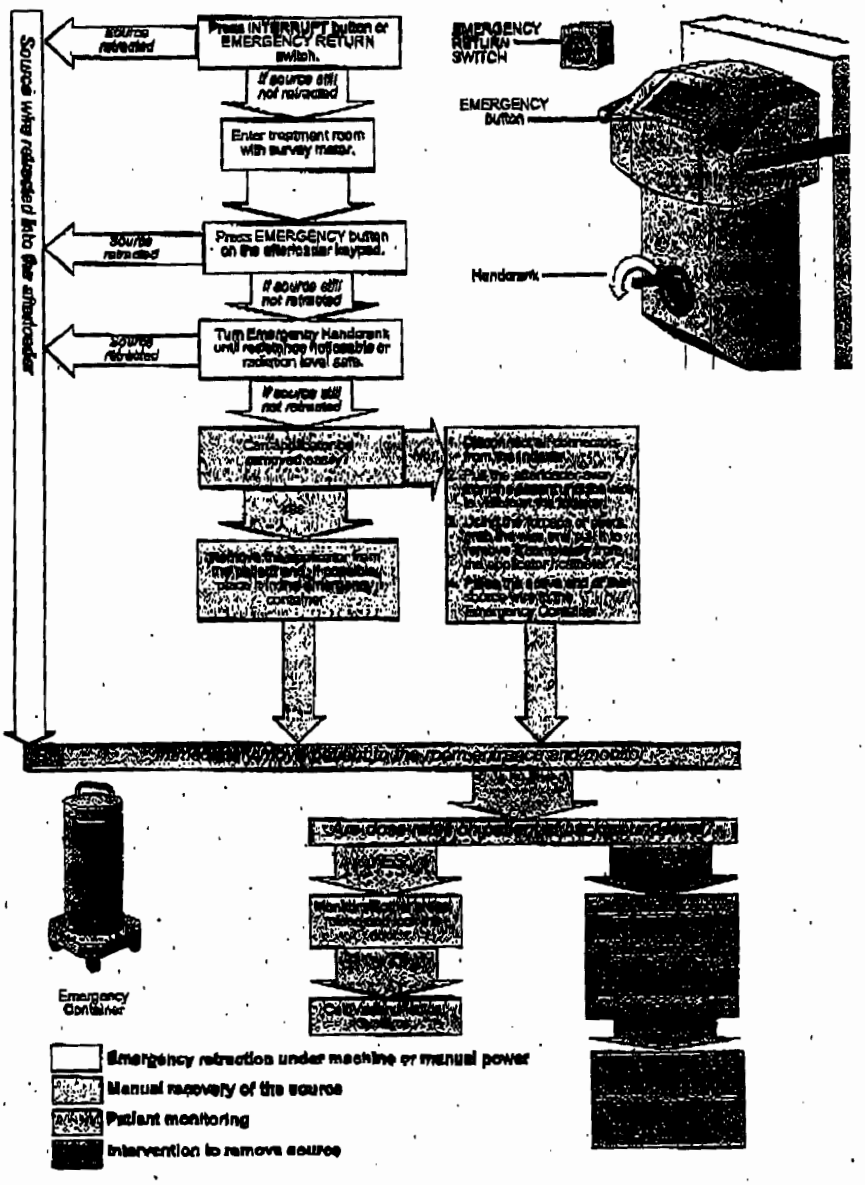


**Figure 5-1 Emergency Response Procedures**

NRC FORM 532
(05-2016)

U.S. NUCLEAR REGULATORY COMMISSION

# ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

| Name and Address of Applicant and/or Licensee | Date |
|---|---|
| James T. Norweck, M.S., DABR<br>Radiation Safety Officer<br>Cabell Huntington Hospital<br>1340 Hal Greer Boulevard<br>Huntington, WV 26701 | June 5, 2018 |
| | **License Number(s)**<br>03003370 |
| | **Mail Control Number(s)**<br>608970 |
| | **Licensing and/or Technical Reviewer or Branch**<br>Medical Branch |

**This is to acknowledge receipt of your:** ☑ **Letter and/or** ☐ **Application** **Dated:** May 4, 2018

**The initial processing, which included an administrative review, has been performed.**

☑ **Amendment** ☐ **Termination** ☐ **New License** ☐ **Renewal**

☑ **There were no administrative omissions identified during our initial review.**

☐ **This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.**

☐ **Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf**

**Follow the instructions on the form for submission.**

☐ **The following administrative omissions have been identified:**

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

**Region I**
**U. S. Nuclear Regulatory Commission**
**Division of Nuclear Materials Safety**
**2100 Renaissance Boulevard, Suite 100**
**King of Prussia, PA 19406-2713**
**(610) 337-5260, (610) 337-5313,**
**(610) 337-5398, (610) 337-5239**