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Materials Licensing Branch  
U.S. Nuclear Regulatory Commission  
Region III  
2443 Warrenville Road, Suite 210  
Lisle, Illinois 60532-4352

To Whom It May Concern:

We wish to amend our Radioactive Materials License Number 24-18628-01 to include Dr. Carl VanTassell for materials listed in 35.394. He is already listed on our Radioactive Materials License for materials listed in 35.100, 35.200, and 35.392.

Please find attached NRC Form 313(AUT) with the appropriate documentation and duly signed by his preceptor. Please find attached to his forms a copy of the letter from the Chairman of the Radiation Safety Committee at the University of Kansas Hospital stating that Dr. Dusing is authorized to use materials listed in 35.100, 35.200, and 35.300. Please also find attached a copy of the Radioactive Materials License issued by the State of Kansas for the University of Kansas Hospital.

If you have any questions, please do not hesitate to contact us at (816)691-5204.

Sincerely,

A handwritten signature in cursive script that reads "Matt Foresman".

Matt Foresman

Vice-President of Professional Services

RECEIVED DEC 24 2008

**AUTHORIZED USER TRAINING AND EXPERIENCE  
AND PRECEPTOR ATTESTATION**  
**(for uses defined under 35.300)**  
**[10 CFR 35.390, 35.392, 35.394, and 35.396]**

APPROVED BY OMB: NO. 3150-0120  
EXPIRES: 10/31/2008

Name of Proposed Authorized User

State or Territory Where Licensed

**Carl L. VanTassell, M.D.**

**Missouri Medical License #2008014396**

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

35.300 Use of unsealed byproduct material for which a written directive is required

**OR**

35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)

35.300 Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)

35.300 Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

35.300 Parenteral administration of any other radionuclide for which a written directive is required

**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 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 35.390, provide documentation on supervised clinical case experience. The table in section 3.c. may be used to document this experience.
- c. For 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience.
- d. Skip to and complete Part II Preceptor Attestation.

**2. Current 35.300, 35.400, or 35.600 Authorized User Seeking Additional Authorization**

a. Authorized User on Materials License **24-18628-01** under the requirements below or equivalent Agreement State requirements (check all that apply):

35.390     35.392     35.394     35.490     35.690

b. If currently authorized for a subset of clinical uses under 35.300, provide documentation on additional required supervised case experience. The table in section 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

c. If currently authorized under 35.490 or 35.690 and requesting authorization for 35.396, provide documentation on classroom and laboratory training, supervised work experience, and supervised clinical case experience. The tables in sections 3.a., 3.b., and 3.c. may be used to document this experience. Also provide completed Part II Preceptor Attestation.

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

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

- a. Classroom and Laboratory Training  35.390  35.392  35.394  35.396

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			
Chemistry of byproduct material for medical use			
Radiation biology			
<b>Total Hours of Training:</b>			

- b. Supervised Work Experience  35.390  35.392  35.394  35.396

*If more than one supervising individual is necessary to document supervised training, 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		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Calculating, measuring, and safely preparing patient or human research subject dosages		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material		<input type="checkbox"/> Yes <input type="checkbox"/> No	
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures		<input type="checkbox"/> Yes <input type="checkbox"/> No	

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

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

**b. Supervised Work Experience (continued)**

Supervising Individual	License/Permit Number listing supervising individual as an authorized user
Supervising individual meets the requirements below, or equivalent Agreement State requirements ( <i>check all that apply</i> )**:	
<input type="checkbox"/> 35.390	With experience administering dosages of:
<input type="checkbox"/> 35.392	<input type="checkbox"/> Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
<input type="checkbox"/> 35.394	<input type="checkbox"/> Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
<input type="checkbox"/> 35.396	<input type="checkbox"/> Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
	<input type="checkbox"/> Parenteral administration of any other radionuclide requiring a written directive
** Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.	

**c. Supervised Clinical Case Experience**

*If more than one supervising individual is necessary to document supervised work experience, provide multiple copies of this page.*

Description of Experience	Number of Cases Involving Personal Participation	Location of Experience/License or Permit Number of Facility	Dates of Experience*
Oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)			
Oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	5	<b>University of Kansas Hospital 18-C801</b>	8/31/04, 9/14/04, 9/27/04, 3/7/05, 3/8/05 <span style="float: right;">+</span>
Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required			
Parenteral administration of any other radionuclide for which a written directive is required			
_____ (List radionuclides)			

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

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

**c. Supervised Clinical Case Experience (continued)**

Supervising Individual

License/Permit Number listing supervising individual as an authorized user

**Reginald W. Dusing, M.D.**

**18-C801**

Supervising individual meets the requirements below, or equivalent Agreement State requirements (*check all that apply*)\*\*:

- 35.390 With experience administering dosages of:
  - 35.392  Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
  - 35.394  Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
  - 35.396  Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
  - Parenteral administration of any other radionuclide requiring a written directive

\*\* Supervising Authorized User must have experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status.

**d. Provide completed Part II Preceptor Attestation.**

**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 35.390:**

**Board Certification**

I attest that \_\_\_\_\_ has satisfactorily completed the training and experience requirements in 35.390(a)(1).  
Name of Proposed Authorized User

**OR**

**Training and Experience**

I attest that \_\_\_\_\_ has satisfactorily completed the 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, as required by 10 CFR 35.390 (b)(1).  
Name of Proposed Authorized User

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

**Preceptor Attestation (continued)**

**First Section (continued)**

**For 35.392 (Identical Attestation Statement Regardless of Training and Experience Pathway):**

I attest that \_\_\_\_\_ has satisfactorily completed the 80 hours of classroom  
Name of Proposed Authorized User

and laboratory training, as required by 10 CFR 35.392(c)(1), and the supervised work and clinical case experience required in 35.392(c)(2).

**For 35.394 (Identical Attestation Statement Regardless of Training and Experience Pathway):**

I attest that **Carl L. VanTassell, M.D.** has satisfactorily completed the 80 hours of classroom  
Name of Proposed Authorized User

and laboratory training, as required by 10 CFR 35.394 (c)(1), and the supervised work and clinical case experience required in 35.394(c)(2).

**Second Section**

I attest that **Carl L. VanTassell, M.D.** has satisfactorily completed the required clinical case  
Name of Proposed Authorized User

experience required in 35.390(b)(1)(ii)G listed below:

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

**Third Section**

I attest that **Carl L. VanTassell, M.D.** has satisfactorily achieved a level of competency to  
Name of Proposed Authorized User

function independently as an authorized user for:

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

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

**Fourth Section**

**For 35.396:**

**Current 35.490 or 35.690 authorized user:**

I attest that \_\_\_\_\_ is an authorized user under 10 CFR 35.490 or 35.690  
Name of Proposed Authorized User

or equivalent Agreement State requirements, has satisfactorily completed the 80 hours of classroom and laboratory training, as required by 10 CFR 35.396 (d)(1), and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

- Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
- Parenteral administration of any other radionuclide for which a written directive is required

**OR**

**Board Certification:**

I attest that \_\_\_\_\_ has satisfactorily completed the board certification  
Name of Proposed Authorized User

requirements of 35.396(c), has satisfactorily completed the 80 hours of classroom and laboratory training required by 10 CFR 35.396 (d)(1) and the supervised work and clinical case experience required by 35.396(d)(2), and has achieved a level of competency sufficient to function independently as an authorized user for:

- Parenteral administration of any beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required
- Parenteral administration of any other radionuclide for which a written directive is required

**Fifth Section**

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

I meet the requirements below, or equivalent Agreement State requirements, as an authorized user for:

- 35.390       35.392       35.394       35.396

I have experience administering dosages in the following categories for which the proposed Authorized User is requesting authorization.

- Oral NaI-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries)
- Oral NaI-131 in quantities greater than 1.22 gigabecquerels (33 millicuries)
- Parenteral administration of beta-emitter, or photon-emitting radionuclide with a photon energy less than 150 keV requiring a written directive is required
- Parenteral administration of any other radionuclide requiring a written directive

Name of Preceptor <b>Reginald W. Dusing, M.D.</b>	Signature <i>Reginald W. Dusing</i>	Telephone Number <b>(913) 588-6839</b>	Date <b>12/15/2008</b>
License/Permit Number/Facility Name <b>18-C801      University of Kansas Hospital</b>			

THE UNIVERSITY  
OF KANSAS HOSPITAL  
**KUMED**

Environment of Care Department

September 9, 2008

Kenneth Arnett, M.D.  
Radiation Safety Officer  
North Kansas City Hospital  
2800 Clay Edwards Dr.  
North Kansas City, Missouri 64116

**RE: Preceptor Qualifications for Reginald Dusing, M.D.**

Dear Dr. Arnett:

I am submitting information to document the preceptor qualifications for Reginald Dusing, M.D. per the Nuclear Regulatory Commission's request to you dated August 26, 2008.

Dr. Dusing is the director of the division of Nuclear Medicine in the Radiology Department at the University of Kansas Hospital and has been since July 2000. He was approved as an authorized user by the Radiation Safety Committee in August 2000 for uses of radioactive materials that included 35.100, 35.200, and 35.300. This approval was based on his status as an authorized user at the Veterans Administration Medical Center in Kansas City, Missouri as documented by a copy of their radioactive materials license.

If you require additional information, please contact Ruth Schukman-Dakotas, Radiation Safety Officer, University of Kansas Hospital, at (913) 588-1713 or [rschukma@kumc.edu](mailto:rschukma@kumc.edu).

Sincerely,



Ken Kuse, Chairperson  
Radiation Safety Committee

c: Reginald Dusing, M.D.

# State of Kansas

## Radioactive Materials License

Pursuant to the Nuclear Development and Radiation Control Act (L. 1963, Ch. 290) and Kansas Annotated Regulations numbers 28-35-133 et. seq., and in reliance on statements and representations made to this agency by the licensee designated below, a license is hereby issued authorizing the licensee to transfer, receive, possess, and use the radioactive material or materials listed below; and to use such materials at the place or places listed below; and to use the material for the purpose or purposes listed below. This license is subject to all applicable rules, regulations, and orders now in effect or placed in effect by the Department of Health and Environment and any conditions specified below.

### Amendment No. 10

<p style="text-align: center;">Licensee</p> <p>1. Name    UNIV OF KANSAS HOSPITAL AUTHORITY</p> <p>2. Address  3901 RAINBOW BLVD KANSAS CITY, KS 66160-7183</p>	<p>3. License Number 18-C801</p> <p>4. Expiration Date December 31, 2010</p> <p>5. Reference Number 18-C054-01</p>	
6. Radioactive Material (Element and Mass Number)	7. Chemical and/or Physical Form	8. Maximum Quantity Licensee May Possess at One Time

- |  |  |   |
|--|--|---|
| <p>A. Any radioactive material approved in Groups I and II, K.A.R 28-35-135g.</p> <p>B. Any radioactive material approved in Group III, K.A.R 28-35-135g.</p> <p>C. Any radioactive material approved in Group IV, K.A.R. 28-35-135g.</p> <p>D. Any radioactive material approved in Group V, K.A.R. 28-35-135g.</p> <p>E. Any radioactive material approved in Group VI, K.A.R. 28-35-135g.</p> <p>F. Any radioactive material with atomic number less than 84</p> <p>G. Any radioactive material with atomic number less than 84</p> | <p>A. Any radiopharmaceutical listed in Groups I and II, K.A.R 28-35-135g.</p> <p>B. Any form listed in Group III, K.A.R 28-35-135g.</p> <p>C. Any radiopharmaceutical listed in Group IV, K.A.R. 28-35-135g .</p> <p>D. Any radiopharmaceutical listed in Group V, K.A.R. 28-35-135g.</p> <p>E. Any form listed in Group VI, K.A.R. 28-35-135g</p> <p>F. Any</p> <p>G. Sealed sources manufactured, labeled, packaged and distributed in accordance with a specific license issued by the U.S. NRC, an Agreement State or a licensing state</p> | <p>A. As necessary for uses authorized in Subitem 9.A.</p> <p>B. 8000 millicuries for uses authorized in Subitem 9.B.</p> <p>C. 800 millicuries of each radioactive material authorized in Subitem 6.C.</p> <p>D. 800 millicuries of each radioactive material authorized in Subitem 6.D.</p> <p>E. 10 curies of each radioactive material authorized in Subitem 6.E.</p> <p>F. 100 millicuries of any radioactive material with atomic number less than 84</p> <p>G. 10 curies, no single source to exceed 500 millicuries except that no alpha emitting source shall exceed 500 microcuries</p> |
|--|--|---|

Radioactive Materials License

Supplementary Sheet

License Number: 18-C801 Amendment No. 10

H. Fluorine-18	H. Fluorodeoxyglucose (FDG)	H. 800 millicuries
I. Nitrogen-13	I. Ammonia Nitrogen-13	I. 800 millicuries
J. Oxygen-15	J. Water Oxygen-15	J. 800 millicuries
K. Cobalt-60	K. Sealed Source (Theratronics Model C-146 or C-151 and NPI Model 20-6000W)	K. 21,000 curies total, no single source to exceed 10,800 curies
L. Iridium-192	L. Sealed Source (Best Industries Inc. Model 81-01)	L. 1.5 curies
M. Strontium-90	M. Sealed sources manufactured, labeled, packaged and distributed in accordance with a specific license issued by the U.S. NRC, an Agreement State or a licensing state	M. 250 millicuries, no single source to exceed 100 millicuries
N. Americium-241	N. Sealed sources manufactured, labeled, packaged and distributed in accordance with a specific license issued by the U.S. NRC, an Agreement State or a licensing state	N. 25 millicuries
O. Iridium-192	O. Sealed sources (Nucletron 105.002 or equivalent manufactured by AEA Technology or Mallinckrodt)	O. 22 curies total, no single source to exceed 12 curies
P. Holmium-166	P. Liquid solution	P. 3 curies
Q. Yttrium-90	Q. Glass microspheres	Q. 4 curies
R. Cesium-137	R. Sealed Source (J.L. Shepherd Model 6810)	R. 1200 curies
S. Yttrium-90	S. Resin microspheres	S. 500 millicuries total, no single vial to exceed 108 millicuries.

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**Radioactive Materials License**

Supplementary Sheet

License Number: 18-C801 Amendment No. 10

## CONDITIONS

9. Authorized use.
- A. Any diagnostic procedure listed in Groups I and II, K.A.R. 28-35-135g.
  - B. Preparation and use of radiopharmaceuticals for any diagnostic procedure listed in Group III, K.A.R. 28-35-135g.
  - C. Any therapeutic procedure listed in Group IV, K.A.R. 28-35-135g.
  - D. Any therapeutic procedure listed in Group V, K.A.R. 28-35-135g.
  - E. Any procedure listed in Group VI, K. A. R. 28-35-135g.
  - F. Research and development as defined by K.A.R. 28-35-135r(dd). Diagnostic and therapeutic uses in humans, medical research and clinical evaluations in humans.
  - G. Research and development as defined by K.A.R. 28-35-135r(dd). Calibration, diagnostic and therapeutic uses in humans, medical research and clinical evaluations in humans.
  - H. Diagnostic studies involving imaging and tumor localizations.
  - I. Diagnostic studies involving imaging and tumor localizations.
  - J. Diagnostic studies involving imaging and tumor localizations.
  - K. To be used in an AECL Theratron 780-C teletherapy unit for medical treatment of humans and research involving animal and in vitro studies as defined by K.A.R. 28-35-135r(dd). One source to be held in its shipping container for source replacement.
  - L. For treatment of malignant conditions in humans and for research involving animal and in vitro studies as defined by K.A.R. 28-35-135r(dd).
  - M. For treatment of ophthalmic conditions in humans with a Tracer-Lab medical applicator and in various devices used in laboratory analysis and research as defined by K.A.R. 28-35-135r(dd).
  - N. For use in various devices for laboratory analysis and research; diagnosis; medical research and clinical evaluation in humans.
  - O. To be used in a Nucletron-Oldelft Model 105.999 Microselectron-HDR remote afterloading brachytherapy unit for the treatment of malignant conditions in humans and research involving animals and in vitro studies.
  - P. To be used in a trial study to compare the safety and efficacy of <sup>166</sup>Ho DOTMP plus melphalan to melphalan alone as conditioning for autologous peripheral blood stem cell transplant in subjects with primary refractory multiple myeloma.
  - Q. To be used for the therapeutic treatment of cancerous tumors.
  - R. To be used in a J.L. Shepherd Model 143-45A Irradiator for research and development as defined by K.A.R. 28-35-135r and blood irradiation.
  - S. **To be used for the therapeutic treatment of unresectable metastatic liver tumors.**



Radioactive Materials License

Supplementary Sheet

License Number: 18-C801 Amendment No. 10

with all USP standards and monographs pertaining to PET drugs.

B. Prepared radiopharmaceuticals for which FDA has accepted an IND and radiopharmaceuticals prepared from generators or reagent kits for which FDA has accepted an IND shall be dispensed and/or distributed:

(1) In accordance with the directions provided by the sponsor of the IND, and

(2) Only to physicians who have been accepted by the sponsor of the IND to participate in clinical evaluation of the drug.

The licensee shall inform, in writing, each physician who participates in an IND evaluation, that the physician is responsible to the sponsor of the IND for use of the drug in accordance with protocols established by the sponsor and for reporting to the sponsor the clinical information obtained through use of the drug.

19. A. The licensee shall perform a test to detect and quantify the activity of Molybdenum-99 contamination in each elution of Technetium-99m from a Molybdenum-99/Technetium-99m generator and in each extraction or separation of Technetium-99m from Molybdenum-99 not contained in a generator.
- B. The licensee shall not distribute for human use Technetium-99m that, at the expiration date and time shown on the package label, contains more than 0.15 microcuries of Molybdenum-99 per millicurie of Technetium-99m or more than five (5) microcurie of Molybdenum-99 per dose of Technetium-99m. The expiration date and time shown on the package label shall be such that the limits above are not exceeded for any single patient dose. The limits for Molybdenum-99 contamination represent maximum values and Molybdenum-99 contamination should be kept as low as reasonably achievable below these limits.
- C. The licensee shall establish written procedures for personnel performing tests to detect and quantify Molybdenum-99 contamination. These procedures shall include all necessary calculations and steps to be taken if activities of Molybdenum-99 in excess of the limits specified in Subitem B above are detected.
- D. Personnel performing tests to detect and quantify Molybdenum-99 contamination shall be given specific training in performing these tests prior to conducting such tests.
- E. (1) The licensee shall maintain for inspection by the Radiation Control Program, Bureau of Air and Radiation, Kansas Department of Health and Environment records of the results of each test performed to detect and quantify Molybdenum-99 contamination and records of training given to personnel performing these tests.
- (2) Records described in E(1) above shall be maintained for three (3) years following the

Radioactive Materials License

Supplementary Sheet

License Number: 18-C801 Amendment No. 10

performance of the tests and training of personnel.

- 20. The licensee shall elute generators and process radioactive material with reagent kits in accordance with instructions furnished by the manufacturer on the label attached to or in the leaflet or brochure that accompanies the generator or reagent kit.
- 21. Patients containing temporary interstitial or brachytherapy implants shall remain hospitalized until surveys made with an appropriate radiation detection instrument indicate all implants have been removed. The results of these surveys shall be recorded and maintained for inspection by the Radiation Control Program, Bureau of Air and Radiation, Kansas Department of Health and Environment.
- 22. Pursuant to Kansas Radiation Protection Regulations, Part 3, "Licensing Sources of Radiation," the licensee is authorized to possess, use, transfer, and import the uranium contained as shielding material in the teletherapy units authorized by this license.
- 23. The following shall be performed only by persons specifically authorized by the Bureau of Air and Radiation, State of Kansas, Department of Health and Environment, the United States Nuclear Regulatory Commission, or an Agreement State to perform such services:
  - A. Installation, relocation, or removal of teletherapy units containing sources.
  - B. Source exchange.
  - C. Any maintenance or repair operations on a teletherapy unit involving work on the source drawer, the shutter, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.
- 24. The teletherapy facility shall be provided with a system permitting continuous observation of the patient from outside the treatment room during patient irradiation.
- 25. A. Teletherapy sources shall be tested for leakage at intervals not to exceed six (6) months. Records of test results shall be kept in units of microcurie and maintained for inspection by the Radiation Control Program, Bureau of Air and Radiation, Kansas Department of Health and Environment. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to the transfer, a source received from another person shall not be used until tested for leakage.
  - B. The tests shall be sufficiently sensitive to detect 0.005 microcurie of contamination on the test sample.
  - C. The test sample shall be taken from selected accessible surfaces of the teletherapy head. The selected accessible surfaces should be those surfaces on which one might expect contamination (if there were to be leakage) to accumulate and shall include the inner surface of the most frequently used treatment cones or beam collimating device. The test sample shall be taken with the source in the "off" position.

Radioactive Materials License

Supplementary Sheet

License Number: 18-C801 Amendment No. 10

- D. If the test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall promptly take action to prevent spread of contamination and shall file a report within five (5) days of the test with the Radiation Control Program, Bureau of Air and Radiation, Kansas Department of Health and Environment, describing the test results and the corrective action taken.
26. Prior to the initiation of a treatment program, each teletherapy unit shall be equipped with electrical or mechanical stops limiting use of the primary beam of radiation so as to assure compliance with K.A.R. 28-35-214a as evidenced by a radiation survey. Necessary use restrictions shall be fully described in radiation survey reports submitted in accordance with the conditions of this license.
27. A set of written emergency instructions shall be posted at the teletherapy machine control. These instructions shall inform the machine operator of the procedure to be followed should he be unable to turn the machine's primary beam of radiation "off" with the controls outside the treatment room. These instructions shall caution individuals to avoid exposure to the primary beam of radiation when in the treatment room and shall include specific instructions for:
- A. Locating and using the device for manually turning off teletherapy units primary beam of radiation.
  - B. Removing the patients from the treatment room.
  - C. Securing the room against unauthorized entry.
  - D. Notifying the responsible physician or radiation protection officer.
28. A. Access to the teletherapy room shall be controlled by a door at each entrance. Such doors shall be normally closed.
- B. Each entrance to the teletherapy room shall be equipped with an electrical interlock system that will turn the teletherapy machine's primary beam of radiation off immediately upon opening of any entrance door. The interlock system shall be connected in such a manner that the teletherapy machine's primary beam of radiation cannot be turned on until all treatment room entrance doors are closed and the beam "on-off" control is reset at the control panel.
- C. Electrical interlocks on entrance doors to the teletherapy room shall be tested for proper operation at least once every six (6) months. Records of test results shall be maintained for inspection by the Radiation Control Program, Bureau of Air and Radiation, Kansas Department of Health and Environment.
- D. In the event of malfunction of any door interlock, the teletherapy machine control shall be

Radioactive Materials License

Supplementary Sheet

License Number: 18-C801 Amendment No. 10

locked in the "off" condition and not used, except as may be necessary for repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

29. Prior to initiation of a treatment program, and subsequent to each installation of a teletherapy source, radiation surveys and tests shall be performed in accordance with the following:

A. A radiation survey shall be made of:

(1) The teletherapy source housing, with the teletherapy source in the "off" position. The maximum and average radiation levels at one meter from the teletherapy source in the "off" position shall not exceed ten (10) milliroentgen per hour and two (2) milliroentgen per hour, respectively.

(2) All areas adjacent to the treatment room with the teletherapy source in the "on" position. The survey, except Item (c), shall be performed with a phantom in the primary beam of radiation and shall clearly establish:

(a) The radiation levels in controlled areas are not likely to cause personnel exposure in excess of the limits specified in K.A.R. 28-35-212a.

(b) That quantities of radiation in uncontrolled areas do not exceed the limits specified in K.A.R. 28-35-214(a) .

(c) The intensity of the primary beam of radiation at a specified distance from the teletherapy source.

B. Tests shall be made to determine proper operation of:

(1) Electrical interlocks on entrance doors to the teletherapy treatment room.

(2) The teletherapy source "on-off" indicators, both at the source housing and on the teletherapy machine control panel.

(3) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam "on-off" mechanism).

(4) The teletherapy treatment timing device.

C. A report of the results of the above surveys and tests shall be sent to the Radiation Control Program, Bureau of Air and Radiation, Kansas Department of Health and Environment, not later than thirty (30) days following each installation of a teletherapy source.

**Radioactive Materials License**

Supplementary Sheet

License Number: 18-C801 Amendment No. 10

- 30. A. Any changes made in the treatment room shielding, location of the unit within the treatment room, or use of the teletherapy unit that could result in increased radiation levels in areas outside the teletherapy treatment room and made subsequent to the completion of the initial radiation survey performed as required by this license shall be evaluated by a radiation survey made in accordance with the conditions of this license. A report describing the change(s), and giving the results of the survey(s), shall be sent to the Radiation Control Program, Bureau of Air and Radiation, Kansas Department of Health and Environment, not later than thirty (30) days following completion of the change(s).
- B. Relocation of the teletherapy unit to a new facility is not permitted without prior approval of the plans and details by the Radiation Control Program, Bureau of Air and Radiation, Kansas Department of Health and Environment. Following such approval and relocation, a initial radiation survey shall be made as prescribed by this license, and reported to the Radiation Control Program, Bureau of Air and Radiation, Kansas Department of Health and Environment, within thirty (30) days after completion of the move.
- 31. Each teletherapy machine shall be fully inspected and serviced during source replacement or at intervals not to exceed five (5) years, whichever comes first, to assure proper functioning of the source exposure mechanism. This inspection and servicing must be performed by persons specifically authorized to do so by the Radiation Control Program, Bureau of Air and Radiation, Kansas Department of Health and Environment, the United States Nuclear Regulatory Commission, or an Agreement State and servicing must be kept on file for review by the Radiation Control Program, Bureau of Air and Radiation, Kansas Department of Health and Environment.
- 32. A. Each teletherapy room shall be equipped with a radiation monitoring device which continuously monitors the teletherapy beam condition and is equipped with a back-up battery power supply for emergency operation. This device shall energize a visible signal to make the operator continuously aware of teletherapy beam condition in order that appropriate emergency procedures may be instituted to prevent unnecessary radiation exposure. Operating procedures shall require daily operational testing of the installed radiation monitor.
- B. Whenever the continuous radiation monitoring device is not operational, any person entering the teletherapy room following an irradiation shall enter with an operable, calibrated radiation survey meter and shall determine the beam condition.
- 33. Experimental animals administered radioactive materials or their products shall not be used for human consumption.
- 34. Specific requirements for the Novoste Intravascular Brachytherapy System:
  - A. Prior to each use of the Novoste System on a human patient, a catheter integrity evaluation (a dummy run) shall be conducted outside of the patients' body to allow the clinician to simulate a clinical procedure with non-radioactive sources. For delivery catheter designs which do not accommodate a dummy run external to the patient, perform a catheter integrity evaluation according

Radioactive Materials License

Supplementary Sheet

License Number: 18-C801 Amendment No. 10

to manufacturer instructions.

B. Each intravascular brachytherapy device shall be inspected and serviced at intervals established by the manufacturer. Maintenance and repair shall be performed only by the manufacturer or persons specifically authorized by the Nuclear Regulatory Commission or an Agreement State to perform such services.

35. Specific requirements for the Guidant Galileo Intravascular Brachytherapy High Dose Rate Afterloader:

A. The licensee shall not cut, splice or alter the source wire in any manner except in emergency situations as determined by properly trained personnel if the source fails to retract to the safe position.

B. The Galileo shall not be used for treatment until QA tests are performed in accordance with the manufacturers instructions.

C. Each intravascular brachytherapy device shall be inspected and serviced at intervals established by the manufacturer. Maintenance and repair shall be performed only by the manufacturer or persons specifically authorized by the Nuclear Regulatory Commission or an Agreement State to perform such services.

D. Radiation surveys made with an appropriate radiation detection instrument shall be performed before and after each procedure to verify the source has returned to safe storage. The results of these surveys shall be recorded and maintained for inspection by the Department.

36. The licensee is not authorized to use weighting equations for the purpose of modifying the effective dose equivalent for whole body exposure to radiation or radioactive material under this license.

37. The licensee shall comply with the requirements described in the Kansas Department of Health and Environment letter dated September 30, 2005 and attached document entitled "Increased Controls for Licensees that Possess Sources Containing Radioactive Material Quantities of Concern."

A. The licensee shall complete implementation of the increased controls within 6 months from the issuance of this license amendment or the first day that radionuclides in quantities of concern are possessed at or above the limits specified in Attachment 2, Table 1 of the letter, whichever is later.

B. Within 25 days after the implementation of the requirements of this condition, the licensee shall notify the Radiation Control Program, Bureau of Air and Radiation, Kansas Department of Health and Environment in writing that the requirements of this condition have been completed.

**Radioactive Materials License**

Supplementary Sheet

License Number: 18-C801 Amendment No. 10

38. The licensee may transport radioactive material or deliver radioactive material to a carrier for transport, in accordance with the provisions of K.A.R. 28-35-196a, "Preparation of Radioactive Material for Transport".
39. The licensee shall comply with the provisions of Kansas Radiation Protection Regulations, Part 4, "Standards for Protection Against Radiation" and Part 10, "Notices, Instructions and Reports to Workers; Inspections."
40. The licensee shall possess and use radioactive material described in Items 6, 7 and 8 of this license according to the most restrictive of; the Kansas Radiation Protection Regulations, this license or statements, representations, and procedures contained in the following documents.
  - a. The application dated June 30, 2000, signed by Jon Jackson, with attachments.
  - b. The letter dated September 11, 2000, signed by Ruth Schukman-Dakotas, with attachments.
  - c. The letter dated November 21, 2000, signed by Ruth Schukman-Dakotas, with attachments.
  - d. The letter dated November 28, 2000, signed by Ruth Schukman-Dakotas, with attachments.
  - e. The letter dated September 12, 2001, signed by Bob Page-Adams, with attachments.
  - f. The electronic mail dated October 10, 2001 from Ruth Schukman-Dakotas.
  - g. The Nuclear Regulatory Commission's Revised Guidance for Licensing Intravascular Brachytherapy Procedures, dated June 12, 2001.
  - h. The letter dated November 15, 2001, signed by Bob Page-Adams, with attachments.
  - i. The letter dated October 29, 2002, signed by Bob Page-Adams, with attachments.
  - j. The letter dated November 11, 2002, signed by Donald F. Hagen, with attachments.
  - k. The electronic mail dated November 18, 2002, from Ruth Schukman-Dakotas.
  - l. The letter dated October 27, 2003, signed by Bob Page-Adams, with attachment.
  - m. The letter dated February 12, 2004, signed by Ruth Schukman-Dakotas.
  - n. The letter dated March 9, 2004, signed by Ruth Schukman-Dakotas, with attachment.
  - o. The facsimile dated December 8, 2004, signed by Ruth Schukman-Dakotas.
  - p. The letter dated January 9, 2006, signed by Ruth Schukman-Dakotas.
  - q. The letter dated July 26, 2006, signed by Bob Page, with attachment.
  - r. The letter dated September 8, 2006, signed by Bob Page.
  - s. The letter dated November 7, 2006, signed by Bob Page.
  - t. The letter dated February 15, 2007, signed by Bob Page, with attachment.**
  - u. The letter dated April 2, 2007, signed by Bob Page, with attachment.**

**Radioactive Materials License**

Supplementary Sheet

License Number: 18-C801 Amendment No. 10

- v. **The electronic mail dated May 10, 2007, from Ruth Schukman-Dakotas, with attachment.**

**FOR THE STATE DEPARTMENT OF HEALTH AND ENVIRONMENT**

Date May 10, 2007

By:   
\_\_\_\_\_  
**Thomas A. Conley, CHP**  
**Radiation Control Program**

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