§35.900 Radiation Safety Officer

Except as provided in §35.901, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in §35.32 to be an individual who:

[](a) Is certified by: (Check one)

[ ](1) American Board of Health Physics in Comprehensive Health Physics;
[ ](2) American Board of Radiology;
[ ](3) American Board of Nuclear Medicine
[ ](4) American Board of Science in Nuclear Medicine;
[ ](5) Board of Pharmaceutical Specialties in Nuclear Pharmacy;
[ ](6) American Board of Medical Physics in radiation oncology physics;
[ ](7) Royal College of Physicians and Surgeons of Canada in nuclear Medicine;
[ ](8) American Osteopathic Board of Radiology; or

[ ](9) American Osteopathic Board of Nuclear Medicine; **or**

(b) Has had classroom and laboratory training and experience as follows: (all these apply)

~~[ ]~~(1) 200 hours of classroom and laboratory training as follows:
~~[ ]~~ (i) Radiation physics and instrumentation
~~[ ]~~ (ii) Radiation protection
~~[ ]~~ (iii) Mathematics pertaining to the use and measurement of radioactivity
~~[ ]~~ (iv) Radiation biology; and

~~[ ]~~ (v) Radiopharmaceutical chemistry; **and**

~~[ ]~~(2) One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the medical use of byproduct materials; **or**

letters July 18 September 18, 1997. attached

[ ](c) Be an authorized user identified on the licensee's license.

§35.901 Training for experienced Radiation Safety Officer

[ ] An individual identified as a Radiation Safety Officer on a Commission or Agreement State license before October 1, 1986 need not comply with the training requirements of §35.900.

Name: Jennifer Morgan / Mel Gilyow Licensee: CorpScan Plus

License No. 47-25351-01 Docket No. 30-34021

Reviewer: D J Collins Date: 3/7/2001

N:\CHKLIST\QMED-900.WPD

304-345 2279

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P. O. Box 789 • Lewisburg, WV 24901 • (304) 647-3439 • (800) 627-3439

Steven W. Walter, M.D.
President

Martin Hellkamp
Executive Director

September 18, 1997

Jose M. Diaz Valez
U.S. Nuclear Regulatory Commission
Region II
Atlanta Federal Center
81 Forsyth Street, SW Suite 23T85
Atlanta, GA 30303

Re: CorScan Plus
Control Number: 257582
Docket Number: 030-3402 1
License Number: 47-25351-01

Dear Mr. Diaz.

Pursuant to your correspondence dated September 9, 1997, the following responses are submitted for review. Each answer corresponds to the questions addressed in your letter.

1. Ms. Jennifer Gilzow received her academic training at West Virginia State College. During her training, Ms. Gilzow completed a minimum of 200 hours of training in the areas identified in letters a-e of question 1. A copy of Ms. Gilzow's grade transcripts from her college and Exhibit 2, Supplement A is attached for verification.

   In regards to clinical training, Ms Gilzow has worked as a Nuclear Medicine Technologist for the past 11 years. For at least the past year, Ms. Gilzow has worked under the supervision of Dr. Walter, the Radiation Safety Officer for this license, as an assistant. Ms. Gilzow was actively involved in assisting the Radiation Safety Officer in performing all of the duties outlined in 10 CFR 35.21. A letter verifying Ms. Gilzow's clinical training was included in the original amendment application. Please reference this document and the attached Exhibit 2, Supplement A for specific details.

   As a certified Nuclear Medicine Technologist, Ms. Gilzow has worked with all radioactive materials approved by this license.

2. Following NRC approval, Ms. Gilzow will be delegated the authority to control and manage the radiation safety program. Ms. Gilzow will work closely with the medical

physics consultants, authorized user(s), management representatives and technical staff. The "Delegation of Authority" directive enclosed in Regulatory Guide 10.8 Revision 2, Appendix F, will be used to notify all personnel, including all authorized users, of the new "Radiation Safety Officer" for this license. Ms. Gilzow will be authorized by management to handle all radiation safety issues pertinent to this organization.

3. Ms. Gilzow will allocate time to each licensed site as needed. In addition to routine day to day communication with technical staff, administrative personnel and/or authorized users at each location, Ms. Gilzow will perform monthly site visits to verify good radiation safety practices and oversee control of regulatory issues. The consulting staff of National Physics Consultants, and/or equivalent health physics agency, have been contracted to assist the Radiation Safety Officer in meeting her responsibilities.

   Ms. Gilzow's primary job will be as Radiation Safety Officer. It is anticipated that approximately 80% of her time will be served in this capacity. The remaining 20% will be allocated to technical and administrative responsibilities

   In the event of a radiation safety concern, Ms. Gilzow as Radiation Safety Officer, or Dr. Steve Walter as the alternate Radiation Safety Officer, can be on site via land transportation within 4 hours or commercial/charter air transportation within 2.5 hours. In addition, authorized users at each site can be contacted via facsimile or telephone.

4. The Radiation Safety Officer will immediately respond to all radiation safety concerns. Incidents in question will be investigated with the assistance of the medical physics consultants and technical staff. Subsequently, the administrative representatives will be contacted to inform them of the investigation and any needed corrective actions. The incident will be documented and reviewed by all appropriate personnel. The written report of the incident will be placed on file. If a recurrence is observed, additional corrective action will be employed.

5. With the assistance of National Physics Consultants, all new regulations will be reviewed and implemented as appropriate. The status of regulatory changes will be documented in the quarterly consultants report.

6. We confirm that senior management will pay an active roll in the radiation safety program. The RSO will require senior management to review all quarterly reports and audit results.

   Items requiring corrective action will be discussed with senior management, medical physics consultants, authorized user(s) and technical staff. Senior Management will be required to review this information and document their recommendations. The RSO will implement these suggestion(s) where appropriate. Following management's review, their signatures will be affixed to the documents.

   In addition to the monthly site visits by the RSO and quarterly reviews of all locations by the consulting physics staff, routine radiation safety reviews and ALARA reviews will be

performed and/or reviewed by both the RSO and a member of senior management annually at each location of use.

7. The Radiation Safety Officer will require all personnel to review the quarterly health physics report. All radiation safety changes will be presented during staff training. These inservices will be documented and placed on file.

8. As noted above, in the event of an emergency, the Radiation Safety Officer or alternate Radiation Safety Officer will arrive at any one of the site locations within 2.5 hours via either commercial or charter air transportation.

9. As stipulated in 10 CFR 30.52, records pertinent to the radiation safety program, will be maintained on site at each location. In addition, a copy will be kept at the main office.

10. In regards to the transport of radioactive materials, this licensee may transport sealed sources for quality assurance testing. All source(s) transported by this licensee will be shipped in compliance with Department of Transportation (49 CFR Parts 171-178) and NRC regulations addressed in 10 CFR part 71. Radioisotopes for medical use will not be transported between sites.

11. The Radiation Safety Officer, Authorized User(s), and Medical Physics Staff will monitor inventories to assure possession limits are not exceeded. In regards to quarterly inventories, they will be completed and documented in the quarterly health physics audit report. This section of the report will be reviewed and signed by the Radiation Safety Officer.

Thank you for your attention to this matter.

If you have any additional questions, please contact either Sharon L. Long of National Physics Consultants at 330-966-7548 or myself.

Sincerely,

Steven Walter, M.D.
Administrator and Manager

EXHIBIT 2

SUPPLEMENT A

SUPPLEMENT

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. FOR PHYSICIANS, STATE OR TERRITORY WHERE LICENSED
JENNIFER GILZOW	—

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES

FIELD OF TRAINING A	LOCATION AND DATE(S) OF TRAINING B	TYPE AND LENGTH OF TRAINING: CLOCK HOURS IN LECTURE OR LABORATORY	TYPE AND LENGTH OF TRAINING: CLOCK HOURS OF SUPERVISED ON-THE-JOB EXPERIENCE
a. RADIATION PHYSICS AND INSTRUMENTATION	WVSC, Institute, WV 1984 - 1986	64	
b. RADIATION PROTECTION	"	32	
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY	"	64	
d. RADIATION BIOLOGY	"	32	
e. RADIOPHARMACEUTICAL CHEMISTRY	"	32	

Approx. 2880 hrs

5. EXPERIENCE WITH RADIATION. *(Actual use of Radioisotopes or Equivalent Experience)*

ISOTOPE	mCi USED AT ONE TIME	LOCATION	CLOCK HOURS	TYPE OF USE
Tc-99m	700 mCi	Louisville, KY, Charleston, WV, Columbus, OH	11 years of experience	All isotopes used have been for diagnostic purposes with the exception of I-131 which was also used therapeutically
Tl-201	4 mCi	" " " " "		
I-123	200-300 uCi	" " " " "		
I-131	200 mCi	" " " " "		
Ga-67	10-15 mCi	" " " " "		

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Steven W. Walter, M.D.
President

Martin Hellkamp
Executive Director

July 18, 1997

U.S.N.R.C.
Region II
61 Forsyth Street, NW, Suite 23 T 87
Atlanta, GA 30303-3415

Re: License Number 47-25351-01

To Whom It May Concern:

Please amend our license to make the following changes:

1. Add a new location of use for all materials listed in this license. All of the information contained in the original license application including all outlined policies and procedures will be applied to the new location.

   Please note that no Xenon-133 or I-131 for thyroid therapies will be used at the new location.

2. Add Shaival J. Kapadia, M.D. as an authorized user for materials listed in 10 CFR 35.200 for cardiovascular clinical procedures. Dr. Kapadia is currently listed on NRC license # 37-28453-01. (Attached)

3. Please change the Radiation Safety Officer to Jennifer Gilzow. Information verifying Ms. Gilzow is training and experience is attached.

   The alternate Radiation Safety Officer will be Steve Walter, M.D. Dr. Walter is currently listed as the primary Radiation Safety Officer on this license. Dr. Walter will fulfill the duties of the Radiation Safety Officer only in the absence of the primary Radiation Safety Officer.

   It is confirmed that the Radiation Safety Officer will oversee the Radiation Safety Program at the new location. Routine site visits by the Radiation Safety Officer will be performed along with regular day to day communication with site personnel.

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Additional Radiation Safety oversight at the new location will be performed by the following:

a. The authorized and/or supervised physician user at the new location.

b. The consulting firm of National Physics Consultants, Ltd. who has been retained to perform radiation safety audits at the new site at least quarterly.

A diagram of the new location is attached. The address of the new location is:

Corscan Plus
Cardiovascular Associates
681 Hioaks Rd. Suite H
Richmond, VA 23225

Thank you for your attention to this matter.

Sincerely,

Steven W. Walter, M.D.
Administrator

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Steven W. Walter, M.D.
President

Martin Hellkamp
Executive Director

July 18, 1997

Gentlemen:

In accordance with 10 CFR 35.900, please be advised that Jennifer Gilzow acted under my supervision for approximately 16 months as a full time radiation safety technologist for CorScan Plus at our Charleston, WV and Canton, OH sites.

This involved overseeing purchase, receipt and opening packages of radioactive material for patient exams, instrumentation quality control, storing, inventory and using byproduct material safely. This also included addressing emergency actions as well as performing routine radiation surveys and proper disposal of radioactive waste. The above involved maintenance or records and reports as required by regulation and license conditions. I feel she is qualified to be a Radiation Safety Officer in as much as she has met all of the didactic, laboratory and clinical experience.

Sincerely,

Steven W. Walter, MD
Radiation Safety Officer
CorScan Plus llc