

Philips Medical Systems

May 25, 2006

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Licensing Assistance Section
Nuclear Medicine Safety Branch
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

RE: License Number: 37-3022⁸~~6~~-01 03033876
Amendment Request - Philips Medical Systems
Change of RSO

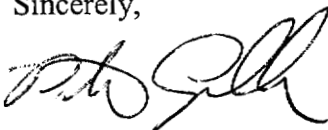
Please amend our byproduct material license to change the Radiation Safety Officer to Gregory M. Breznai. His training and experience documentation is enclosed for examination. This information includes his CV and details of his clinical training at the Cleveland Clinic. In addition, a training certificate for 45 hours of didactic courses he completed in 1999, is attached for evaluation.

In addition, we request that Mr. Breznai be named as an authorized user on our license.

Mr. Martone will remain on the license as an authorized user.

If you have additional questions, please contact Michael Lairmore or myself. Mr. Lairmore may be reached at (201) 693-2277.

Sincerely,



Peter Cempellin
General Manager
Nuclear Medicine, PET/CT
Philips Medical Systems



Philips Medical Systems
(Cleveland), Inc.
595 Miner Road
Cleveland, OH 44143
Tel: (440) 483 3000
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NMSS/RGNI MATERIALS-002

GREGORY M. BREZNAI

13040 Frazier Drive, Chardon, OH 44024 Cleveland Clinic Foundation
(440) 286-4714 Dept of Environmental Health & Safety W18
Breznag@ccf.org 9500 Euclid Ave, Cleveland, OH 44195
(216) 445-2176

Education

Master's of Business Administration. Lake Erie College,
Painesville, OH. August, 2002.

Bachelor of Arts Degree in Biology. Slippery Rock
University of Pennsylvania. May, 1997.

Employment

June, 2001 to present. Cleveland Clinic Foundation
Environmental Health & Safety. Administrative Program Coordinator.
This position is responsible for routine business and administrative functions of the
department. Duties include:

Responsibility for department's operating & capital budgets: planning, analysis,
forecasting.
Database management for radiation dosimeters for all departments that use X-ray and
fluoroscopy equipment and radioactive materials
Lawson Purchasing System "Buyer" status.
Completion of state required reports for the release of radioactive materials into the
environment.
Approval and procurement of radioactive materials for clinical and research departments.
Coordination of orders and receipts of capital and operating expenses.
Administrative functions of the Radiation Safety Committee and Quality Assurance
Subcommittee.
Completion of the Environmental Health & Safety annual operating report
for senior CCF management review.

April, 1999 to June, 2001. Cleveland Clinic Foundation
Department of Radiation Safety. Medical Health Physicist.
This position is responsible for keeping employee and patient radiation exposure levels as
low as reasonably achievable through the following:

Auditing of various operating procedures and documentation within Radiation Safety and
clinical and research departments to ensure compliance with federal/state/local
regulations and the promotion of safety standards.
Database management for X-ray machines and operators located at CCF main and
satellite facilities.

Generation of compliance reports for clinical and research areas that use radioactive materials and radiation-generating equipment.
Maintenance of Ohio Dept of Health compliance documentation and registrations for x-ray generating equipment in clinical areas and satellite facilities.
Investigation and reporting of incidents involving radioactive materials in clinical and research areas. This includes root cause analysis and corrective action implementation.
Generation of reports describing the radioactive waste, air pollutants, and water pollutants produced by CCF.
Development of training programs for personnel working directly with radioactive materials, nurses and therapists caring for patients who have received radioactive materials, technologists operating x-ray generating equipment, and ancillary staff working around sources of ionizing radiation.

August, 1997, to April, 1999. Cleveland Clinic Foundation
Department of Radiation Safety, Radiation Safety Technologist

Performance of compliance surveys for ambient dose rates and removable contamination levels in areas using radioactive materials.
Receiving/surveying/inspecting radioactive materials shipments.
Generation of compliance reports of research laboratories.
Providing radiation protection support to nursing units caring for patients who have received radioactive materials.
Performance of bioassays on personnel who are at risk of having internalized radioactive materials contamination.

1 year, 9 months as a radiation safety technologist (August, 1997 to April 1999):

- RAM package receipts, surveys, & wipe tests: P-32, S-35, C-14, H-3, I-125, Fe-55/59 liquid source vials – up to 20 mCi per package; Mo-99 generators -- 5 Ci each ; Sr/Rb generators – 250 mCi each ; I-125 brachytherapy seeds – up to 60 mCi; I-125 RIA kits – up to 1 mCi;
- Rad waste solid & liquid collection and packing/unpacking: P-32, S-35, C-14, H-3, I-125, Fe-55/59 – up to 10 mCi per drum/overpack cube and 10 mCi in 10 L liquid bulk carboy.
- I-131 NaI thyroid cancer patient treatment support: up to 250 mCi liquid & solid doses administered to patients (90% – 95% of which is expelled from patient), my job to monitor patient ADR's, collect contaminated trash, decontaminate patient's room after discharge
- Spill clean-up & investigation: Tc-99m, Tl-201 – up to 5 mCi spilled from patient doses for Nuc Med scans, this often included a Nuc Med tech getting skin or clothing contamination; P-32, S-35, C-14, H-3, I-125, Fe-55/59 -- liquid research reagents up to 20 uCi spilled from a source vial.
- Mystery bags of surgical waste: identification of isotope in surgical waste (most commonly Tc-99m or Tl-201) that was intercepted by outgoing waste portal monitors – up to 5 mCi
- Sealed sources: Cd-109, I-129, Ba-133, Cs-137, Co-57/60 - up to 1 mCi.
- Sr/Rb generator spill clean-up: 10 mCi escape from infusion pump.

2 years as a Medical Health Physicist (April, 1999 to May, 2001):

- I-131 Thyroid cancer patient support – see details above.
- Spill clean-up & investigation – see details above.
- Sealed sources: see details above
- Rad waste: see details above.

4 years, 11 months Administrative (June, 2001 to present):

- No handling of radioactive materials; ordering source vials from vendors: P-32, S-35, C-14, H-3, I-125, Fe-55/59 liquid source vials – up to 20 mCi per package

All experience located at Cleveland Clinic's main campus, 9500 Euclid Avenue, Cleveland, OH 44195. This is the address on the license.

1 year, 9 months as a radiation safety technologist:

- compliance surveys & wipe tests of RAM use areas
- RAM package receiving
- Radiation safety support for I-131 NaI thyroid ablation therapies which included patient room prep, nursing unit monitoring for ADR levels, patient room clean-up to general use levels (< 200 dpm), training nurses who provide direct care, patient education and guidelines for being at home and in public
- radioactive waste collection for decay-in-storage, sewer disposal, & shipment
- auditing radiation safety records in research laboratories permitted to use RAM which included receipt & use logs, monthly compliance surveys, inventory limits, and lab personnel training
- responding to spills of RAM which included clean-up, personal contamination investigations, root-cause analysis, & corrective action implementation
- I-125 source vial tracking for thyroid bioassay purposes

2 years as a Medical Health Physicist:

- Auditing 4 Nuclear Medicine departments' compliance records (10 CFR, part 35) which included unit dose & generator receipt and return records, daily surveys, weekly wipe tests, patient dose administration records, Quality Management Program records, dose calibrator records, sealed source inventory records, thyroid bioassay records, gaseous Xe-133 therapy room air replacement analysis, PET lab survey & wipe test records, FDG & Strontium/Rubidium generator receipt/return records, survey meter inventory/operational compliance, Nuc Med technologist training, Nuc Med Authorized User physician training, Cardiology resident/fellow training (for hot lab rotations)
- Audit 2 Radiation Oncology departments' brachytherapy compliance records which included, patient surveys, OR surveys, patient room discharge surveys, Quality Management Program documents
- Review of research lab audits, provide necessary training or corrective action suggestions in response to labs found in violation.
- Training of newly approved Authorized User researchers and lab personnel.
- ODH Registration of equipment & maintenance of Safe Operating Procedure books of X-ray equipment which included radiographic, fluoroscopic, CT, C-arm, bone densitometer, cabinet X-ray, mammography, and therapy machines.
- Determining the necessity of film badge or TLD based on work load data provided by the badge wearer.
- Training of ancillary, non-RAM workers in RAM use or radiation areas.

4 years, 11 months Administrative:

- Completion of NESHAP, LLRWG, NEORSD reports.
- RAM request approval, RAM ordering
- Dosimetry database management
- Responsibility for rad waste shipment documents: manifests, certificates of destruction

ASSOCIATES IN MEDICAL PHYSICS, LLC

THIS CERTIFIES THAT

Gregory M. Breznai

**HAS SUCCESSFULLY COMPLETED ALL REQUIREMENTS
FOR THE**

45 HOUR NUCLEAR MEDICINE REVIEW/UPDATE

**AND IS HEREBY AWARDED THIS
CERTIFICATE OF COMPLETION**

ON THIS Fifteenth DAY OF October, 1999


DIRECTOR OF TRAINING

ASRT Reference #OHZ0018001

Nuclear Medicine Review/Update
Cleveland, Ohio
October 11 - 15, 1999

Prepared: 8/17/99
Revised: 10/15/99

Day & Date	Monday	Tuesday	Wednesday	Thursday	Friday
Time	October 11	October 12	October 13	October 14	October 15
8:00 - 9:50	Physics Paul Early	Physics Paul Early	Physics Paul Early	Math Chip Stecker	Radiopharmacy Bob Chandler, R.Ph.
10:00 - 11:50	Radiation Biology Kathy O'Brien	Physics Paul Early	Radiopharmaceuticals Bob Chandler, R.Ph.	Physics Paul Early	Computers Paul Early
12:00 - 1:00	LUNCH				
1:00 - 1:50	Radiation Biology Kathy O'Brien	Instrumentation Frank Bloe	NRC Regulations	NRC Regulations	Math
2:00 - 2:50			Paul Early	Paul Early	Chip Stecker
3:00 - 3:50	Instrumentation Frank Bloe		Math Chip Stecker	Radiopharmaceuticals Bob Chandler, R.Ph.	Radiopharmacy Bob Chandler, R.Ph.
4:00 - 5:50	Radiation Safety Frank Bloe	Camera Quality Control Ed Sims			

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

5/25/2006, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment 37-30228-01 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

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

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

Your action has been assigned **Mail Control Number** 138962.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.