



Quadrex HPS Inc.

1940 N.W. 67th Place, Gainesville, Florida 32606-1649
904-373-6066 TWX 910-590-2438 TELEX 35-2031 TELECOPY 904-373-0040

September 18, 1985

Ms. J. Piccone
U.S. NRC, Region I
631 Park Avenue
Mail Control No. 104346
King of Prussia, PA 19406

MS 16
KO

Dear Ms. Piccone:

As per our conversation I am enclosing the required revisions or additional information to Dr. Scheer's application for radioactive materials.

1.0 Certificate of Training

A copy of the signed certificate is attached along with Mr. Warren's resume. I have also enclosed a copy of my resume for future reference.

2.0 Revised pages are attached to replace those previously submitted. Specifically:

- a. Item 12 now reflects that confirmation of a person's qualifications to handle the licensed material will occur.
- b. Item 17 reflects that leak testing will occur at six (6) month intervals.

If you have any additional requirements, please contact me.

Sincerely,

James T. McVey, CHCM
Corporate Radiation & Safety Officer

JTM/kdgl3-b

cc: Dr. Scheer

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Item 9: NOVO Diagnostic Bone Densitometer System with dual photon detection system.

Item 10: The frequency of calibration for the bone densitometer will be as required to maintain quality images. The unit will be thoroughly checked upon installation and yearly thereafter by a qualified manufacturer's representative. Internal adjustments are performed via computerized programs to produce quality images. Performance checks may be performed daily as indicated.

Item 8: Statement of Training and Experience

According to the standard guide for training and experience, the following description is provided to fulfill this requirement:

- A. Medical Training: M.D. degree; licensed to practice in the State of Massachusetts. Verification is attached.
- B. Radiation Safety Training: Will be provided to the user by Quadrex HPS Inc. to include those areas recommended by the USNRC as acceptable criteria. The qualifications of the instructors, the training manual and testing will be submitted to your office from Quadrex HPS Inc.

Training for Bone Mineral Analyzer Diagnostic Devices
As Recommended by the USNRC

Group A - Basic Radiation Physics and Instrumentation (3 hours)

1. Atomic Structure
2. Decay Process and Types of Emissions (especially gamma radiation)
3. Radioactivity - Definitions and Units (curies, rems, and sub-units)
4. Interactions of Radiation with Matter
5. Half-Life, Inverse Square Law and Half-Value Layers (time, distance, and shielding)
6. Decay Constant Formula and Use of Decay Tables
7. Inverse Square Law Formula and Examples
8. Calculation of Radiation Dose in Air, Tissue and Bone
9. Radiation Dose - Dose Rate, Time and Average Dose
10. Characteristics of Sealed Sources (compared to radioactive liquids and other physical forms)

Group B - Radiation Biology (3 hours)

1. Acute and Chronic Exposures
2. Somatic and Genetic Effects
3. Basis of Maximum Permissible Dose

4. Typical Somatic Effects at Various Dose Levels
5. Genetic Effects and Genetically Significant Dose
6. Factors Affecting Biological Damage (dose, dose rate, type of radiation, type of tissue, amount of tissue, biological variation and chemical modifiers).

Group C - Radiation Protection (2 hours)

1. Principles of Radiation Safety and ALARA Management Program
2. "Standards for Radiation Protection" 10 CFR Part 20 and "Instructions to Radiation Workers" 10 CFR Part 19,
3. License Conditions for Radiation Safety Program
4. Radioactive Shipment Receiving, Opening, Handling, Storage and Security Procedures
5. Radiation Labels and Required Posting and Documents
6. Routine Proper Use, Inventory and Accountability Procedures for Sealed Sources, or Devices Containing Sealed Sources
7. Leak Test of Sealed Sources and Contamination Control
8. Shipment Returns, DOT Regulations and Supplier Instructions and Forms
9. Radiation Detection Instrumentation
10. NRC Draft Regulatory Guide "Instruction Concerning Radiation Exposure" Dated May, 1980 and NRC Regulatory Guide 8.13 "Instructions Concerning Prenatal Radiation Exposure" Dated November, 1975
11. Title 10 CFR Part 35 "Medical Use of Radionuclides" and NRC Regulatory Guide 10.8 Procedures and License Applications
12. Radiation Safety References, NCRP and ICRP Publications
13. Review and Discussion of the Sealed Source "Device Specific" Manufacturer Literature and Instructions

Item 11. Facilities and Equipment

The Novo Diagnostic System's Dual Photon Bone Densitometer is a fixed unit installed in the office. The unit will not be relocated without prior permission of the NRC. The Gadolinium-153 source is to be installed in the densitometer device by the authorized manufacturer representative. The source will not be removed from the device by the licensee. Source exchange will be performed by an authorized representative of the manufacturer of the device. Attached is additional information from the manufacturer describing the use of the device.

Also attached is a drawing indicating the location of the densitometer in the facilities. The unit shall be under the direct control of the licensee and shall not be used except by the licensed users. It shall be controlled from unauthorized use or tampering during off duty hours.

Item 12: Personnel in the office will be instructed in the proper handling and use of radioactive materials as relevant to their jobs. This can include dosimetry usage, safety and record keeping. Those personnel qualified by the NRC provisions can actively participate in the handling of the licensed materials while those not qualified can only assist in the maintenance of the patients and other non-licensed activities at the direction of the licensed physician. Personnel qualifications will be verified with copies maintained for inspection. Additional licensed physicians may be added to the license as specified users only after submission of the required information for NRC review and approval. All appropriate female personnel will be instructed about the importance of pre-natal exposure reduction.

- Item 13:
- a. All radioisotopes will be ordered, as licensed, by the authorized user and received by the authorized user. Such receipt will occur only during normal working hours. No provisions are made for off-hour delivery.
 - b. Any leaking or damaged packages will be cause for the authorized user to detain the carrier and his vehicle until determined that no contamination is present. Proper notifications and further assistance will be made or attained respectively where indicated.
 - c. Records of receipt will be maintained by the RSO.
 - d. Gadolinium-153 sealed sources will be installed by a qualified and authorized representative of the manufacturer. These sealed sources will only be inspected for continued package integrity and no leakage and will not be opened by the physician.

Item 16: If it appears the Gadolinium-153 bone density device is stuck in an "open" or exposed position or any malfunction potentially compromising the integrity of the source or device, the patient shall be immediately removed and no person shall be allowed to an area within 10 feet of the device. The user shall contact the manufacturer or his designated representative to identify the problem. The device shall not be used, or the area around the device occupied until the problem is rectified by the manufacturer representative. The area shall be posted to prevent unnecessary entry until the unit is returned to a safe condition.

RADIATION SAFETY OFFICER: Dr. Schier

OFFICE PHONE: 617-232-1115

HOME PHONE:

Item 17: Leak testing and office surveys will be performed at six (6) month intervals or as otherwise indicated.

Item 18: a. The Gadolinium-153 source shall be removed and returned to the manufacturer's representative or to a licensed waste disposal facility for ultimate disposition. The source shall be properly packaged to include shielding, if necessary, and presented for disposal. The disposal broker will be ADCO services of Tinley Park, IL or an equivalent substitute. The source will be buried in an approved burial ground such as Barnwell, SC or an equivalent.

b. Records of all waste disposal will be maintained.

Item 23: Radiation Protection Program for Gadolinium-153 Sealed Source

A. The device is to be operated by the user authorized by a licensed issued by the Nuclear Regulatory Commission.

B. The users and ancillary support personnel are not to modify, remove or exchange the source or the device in a way that would hamper the effectiveness of its use, compromise the radioactive source containment or unnecessarily expose personnel to radiation.

C. Personnel shall not place their hand or body in the beam of radiation emitted by the device that shall cause it to be unnecessarily exposed.

D. The device containing radioactive material shall be secured to prevent unauthorized use, tampering or removal except during actual usage.

E. The device shall be visually inspected prior to each use to assure continued safe functioning. Any abnormal conditions should be reviewed with the manufacturer's representative or a health physics consultant.

F. Persons operating or assisting in the procedures associated with this device shall wear a radiation dosimetry device of either film badge or TLD type. These dosimeters will be changed and presented for analysis on a quarterly frequency. These devices will be furnished and serviced by a company such as R.S. Landauer, Inc. or equivalent.

G. Persons frequenting the room housing this device shall not smoke, eat or drink unless for the purposes of medical treatment.

H. Radioactive material shall be used for diagnostic medical uses only.

- I. Records will be kept of the receipt and return of the radioactive materials, the use and leak testing of the source and film badge/TLD results.
- J. The source shall be installed into the densitometer device by an authorized representative of the manufacturer. During the initial installation or source transfer, a radiation survey shall be conducted by the installer indicating the radiation levels in the "open" and "closed" modes. A copy of the survey shall be provided to the licensee and shall be available for inspection by the Nuclear Regulatory Commission.
- K. The source shall be leak tested at a twelve month interval. Having a half-life of 242 days, the source will be replaced periodically. Leak testing will be performed by the manufacturer of the device, or his licensed representative. The source shall not be removed or leak tested by the licensee.

QUADREX HPS Inc.

This is to certify that

Kenneth J. Scheer, M.D.

has completed

Basic Radiation Protection Training

conducted by Quadrex HPS Inc.

at Boston, Ma. on the 7th day of August 1985

Certificate No. 006

Richard C. Dwyer
Instructor

QUADREX HPS INC.

James T. McVey

CORPORATE RADIATION AND SAFETY OFFICER/SENIOR HEALTH
PHYSICIST

Experience Highlights

- o Over fifteen years in the health physics field
- o Over eight years in hazardous and toxic substances use and control
- o Familiar with all aspects of safe handling of radioactive materials and devices
- o Proficiency in theoretical health physics
 - Competency in the function, design, adaptation and operations of radiation detection systems and procedures
- o Extensive experience in dosimetry, waste control, decontamination procedures, and transportation of radioactive material
- o Designed and supervised therapeutic and diagnostic shielding installations; health physics programs; and performed internal and external dosimetry evaluations

Professional Experience

1983 - Present Quadrex HPS Inc., Gainesville, Florida.
Corporate Radiation and Safety Officer. Responsible for development and implementation of programs utilizing radiological, toxic, and hazardous substances. Review and implement industrial hygiene and safety program. Responsible for all licenses, permits and certifications governing hazardous materials usage. Duties include regulatory interpretation and interaction, site quality control audits, procedure review or development, personnel exposure control, evaluation and tracking. Coordination of Quadrex Corporate Radiation and Safety Program to include seven domestic and numerous international offices. Interface with personnel, client and regulatory agents in program development to permit decontamination, decommissioning, transport, use, and storage of radiological and hazardous materials with lowest reasonable personnel and environmental exposures. Maintain proficiency and uniformity in data acquisition and analysis and assist in or originate technical reports and presentations.

- 1980-1983 Health Physics Systems, Inc., Gainesville, Florida.
Health Physicist. Responsible for radiological services pertaining to radioactive materials licensing and safe handling; radioactive materials transportation; equipment and contract site ALARA compliance; quality assurance and quality control programs for instrumentation, equipment and procedures; and health physics support to all documents, programs and procedures as necessary. Responsible for research and development programs involving decontamination technologies applicable to the nuclear, industrial and research fields, including equipment development; data acquisition; evaluation and technical writing.
- 1977 - 1980 National Center for Toxicological Research, DHHS/FDA, Jefferson, Arkansas.
Health Physicist. Responsible for large research facility radiation program with high volume radionuclide use. Duties include protocol review and approval; personnel monitoring and training; equipment training, repair, and calibration; system and program design; environmental surveillance; waste disposal; decontamination; transportation of hazardous materials; center-wide quality assurance program; research activities; and technical writing and presentation. Additional involvement included, shielding calculations, facility design, equipment design, supervision of the Radiation Control Office and all records and representation on various FDA/NCTR committees.
- 1975 - 1976 Pulcir, Inc., Oak Ridge, Tennessee.
Southeastern representative and radiation biophysicist involved in radiation equipment review, sales, installation, and maintenance for nuclear medicine, diagnostic, therapeutic and clinical installations.
- 1973 - 1977 Environmental Radiation Management Corporation, Gainesville, Florida.
President of consulting and services firm involved in licensing, surveillance, program design for medical installations, sample analysis, facility design, shielding determination and health physics responsibilities.
- 1967 - 1969
and
1971 - 1974 University of Florida, Gainesville, Florida.
Research Electron Microscopist involved in orthopedic research of bio-glass ceramic prosthetic implants, utilizing radiotracers, autoradiography, tissue culture and electron microscopic evaluation.

Education

- o M.S., Radiation Biophysics/Health Physics, University of Florida, Gainesville, Florida, 1972.
- o B.S., Psychology, University of Florida, Gainesville, Florida, 1970.
- o A.A., Zoology, Santa Fe Community College, Gainesville, Florida, 1968.

College Training Includes:

- o Health Physics
- o Radiological Physics
- o Radioisotope Theory and Techniques
- o Radiation Protection
- o Radiation Effects on Humans
- o Instrumentation and Dosimetry in Radiology
- o Nuclear Radiation Detection and Instruments
- o Radioactive Tracer Instrumentation and Methodology
- o Radiological Health Administration
- o Nuclear Medicine Techniques and Instrumentation
- o Radiation Epidemiology
- o Computer Programming and Medical Application
- o Diagnostic and Radiation Therapy Procedures
- o Nuclear Power Plant Operation
- o Industrial Radiology
- o Environmental Surveillance
- o Inorganic and Organic Chemistry
- o Zoology
- o Psychology
- o Calculus
- o Physics
- o Statistics

Certification

- o Health Physics Certification - Pending
- o Certified Hazard Control Manager - Master Level (Pending)

Training

- o Hazardous Chemical Safety Course, Buffalo, New York.
- o H.P. Certification Review, Lowell, Massachusetts, June 1981.
- o Practical Environmental Law, University of Denver, of Law College

Workshops

- o Robotics Workshop to Delineate the Economic, Technical and Policy Issues for Remote Maintenance in Energy Systems. Sponsored by U.S.D.O.E., March 1981, Gainesville, Florida.
- o FED Remote Maintenance Equipment Workshop. Sponsored by U.S.D.O.E., March 1981, Oak Ridge, Tennessee.

Publications

- o McVey, J.T., High Resolution Autoradiographic Study of Parathyroid Hormone as a Radioprotectant. Thesis published by the University of Florida Graduate School, 1972.
- o Hench, L.D., Paschall, H.A., Paschall, N., and McVey, J.T., Historical Responses at Bioglass and Bioglass-Ceramic Interfaces, 75th Annual Meeting, The American Ceramic Society, American Ceramic Society Bulletin, Vol. 52, p. 432, 1973.
- o Paschall, H.A., Rodebush, M., and McVey, J.T., A Comparison of Soft Tissue Reaction to Metallic Screws and a Biodegradable Ceramic Implant, Journal of Biomaterials Engineering, 1972.
- o Paschall, H.A., Rodebush, M., and McVey, J.T., Response of Cancellous Bone to Glass-Ceramic Implants, Annual Report DADA 17-70-00002, September, 1972.
- o Paschall, H.A., Rodebush, M., and McVey, J.T., Soft Tissue Reaction to Non-Porous Bioglass-Ceramic Materials.
- o Tilden, R.L., Jackson, J. Jr., Enneking, W.F., Deland, F.W., and McVey, J.T., Technetium-99m Polyphosphate: Historical Localization in Human Femures by Autoradiography, Journal of Nuclear Medicine, 1973.
- o McVey, J.T., Hunziker, J., Holson, J.F., and Young, J.F., Small Animal Traversing Gamma Counter, J. of Pharmacological Methods, Vol. 5, pp. 1-13, 1981.
- o McVey, J.T., Hunziker, J., Holson, J.F., and Young, J.F., Small Animal Whole Body Gamma Counter-Multiple Adaptations and Evaluations, Health Physics, Vol. 37, No. 6, p. 823, 1979.
- o McVey, J.T., Hunziker, J., Holson, J.F., and Young, J.F., Small Animal Whole Body Gamma Counter-Multiple Adaptations and Evaluations, Proceedings, Arkansas Academy of Sciences, p. 18, 1979.

- o Contributor to the NCTR Guidelines for Protocol Development, Review and Approval prepared by the NCTR Research Scientist Group, Department of Health and Human Services, Food and Drug Administration/U.S. Environmental Protection Agency, National Center for Toxicological Research, 1980.
- o Contributor to the Radiation Studies Report: ENE 643-Electronic Product Radiation, Environmental Engineering, University of Florida, 1971.
- o McVey, J., Campuzano, D., and Fowler, D., From Nuclear Waste to Reusable Items: Tools and Equipment, Nuclear and Chemical Waste Management, (accepted).
- o McVey, J., Campuzano, D., and Fowler, D., From Nuclear Waste to Reusable Items: Tools and Equipment, Trans. American Nuclear Society, Vol. 38, p. 197, 1981.
- o Young, J.F., and McVey, J.T., Quality Assurance Considerations for a Tissue Oxidizer System, in preparation.

Presentations

- o Three day seminar at NCTR: Autoradiography Techniques, 1976.
- o Arkansas Academy of Sciences, paper presented: Small Animal Whole Body Gamma Counter, April, 1979.
- o Health Physics Society, 24th Annual Meeting. Paper presented: Small Animal Whole Body Gamma Counter - Multiple Adaptations and Evaluations, July, 1979.
- o Week long course, Safe Handling of Radionuclides, NCTR, 1977, 1978, and 1979.
- o Seminar on Radionuclide Safety in Animal Handling, NCTR, 17 performed during 1978-1979.
- o American Nuclear Society Meeting. Paper presented: From Nuclear Waste to Reusable Items: Tools and Equipment, June, 1981.

Professional Memberships

- o American Nuclear Society (member)
- o Florida Chapter of the American Nuclear Society (member)
- o Health Physics Society (member)
- o Florida Chapter of the Health Physics Society (executive council)
- o Hazardous and Nuclear Materials and Waste Ad Hoc Committee (public office - third term)
- o Deep South Health Physics Society (past member)
- o Arkansas Academy of Science (past member)
- o Air Pollution Control Association (past member)
- o Association of NCTR Employees of Little Rock (past president)
- o Research Scientist Group (past chairman)

Activities

- o Assisted in Conceptual and managerial set-up of Quadrex Corporation, Nevada Inspection Services which included: Training, Department of Transportation Regulations, and Health Physics Considerations, 1980-1981.

QUADREX CORPORATION

Bernhardt C. Warren

HEALTH PHYSICIST

Experience Highlights

- o Over nine years experience in evaluating applications for licensing nuclear operations.
- o Experience in planning emergency response activities.

Professional Experience

Present	Quadrex Corporation, Gainesville, Florida. responsibilities include health physics consulting to industry, medical facilities, academic institutions and other users of radioactive materials. Performs duties as radiation safety consultant to the company for licensed activities. Assists in preparation of application documents for submitting to regulatory agencies. Performs liaison duties with federal agencies.
1973-1982	<u>Department of Health and Rehabilitative Services Offices, Radiation Control, Tallahassee, Florida</u> Manager of the section responsible for the licensing of radioactive materials in the State of Florida. Established policies regarding complex licensing actions. Planned and implemented licensing procedures for all classes of licenses. Served as program liaison with federal, state and local agencies that interacted with the radiation control program. Also responsible for preparing budgetary issues, classifications, job descriptions and monitoring internal quality control activities.
1970-1973	<u>U.S. Army, Fort Campbell, Kentucky</u> Commissioned officer in the Medical Service Corps. Performed duties as Nuclear, Biological, Chemical Officer, Hospital Administrator, Unit Commander and Nuclear Medicine Officer.

Education

- o B.S., Biology/Psychology, Florida Southern College
- o M.P.A., Public Administration (Includes training in organizational behavior and development, personnel classification, budget preparation and analysis, policy development, legislative relationships, legal aspects, and statistical analyses.)
- o U.S. Nuclear Regulatory Commission Sponsored Training Programs
 - Applied Health Physics (10 Weeks) (included extensive training in radiation physics, instrumentation, biological effects, and nuclear power plant operations and safety requirements)
 - Nuclear Physics
 - Biological Effects of Ionizing radiation (Harvard Medical School)
 - Protective Action Decision Making for Radiological Emergency Response
 - Uranium Mining and Milling Operations
 - Medical use of Radionuclides
 - Radiation Protection Engineering

12/15/82

9/16/85

TELEPHONE OR VERBAL CONVERSATION RECORD

TIME

2:00

☐ A.M.
☒ P.M.

☐ INCOMING CALL

☒ OUTGOING CALL

☐ VISIT

PERSON CALLING

Piccone

OFFICE/ADDRESS

NRC - Region I

PHONE NUMBER

EXTENSION

5169

PERSON CALLED

James T. McVey, for
Kenneth E. Schier, M.D.

OFFICE/ADDRESS

Quadrex HPS, Inc.
Gainesville, FL 32606

PHONE NUMBER

EXTENSION

(704) 373-6066

CONVERSATION

SUBJECT

Application for 60-153

SUMMARY

Following areas are deficient.

- ① signed certificate of completion of training
- ② qualifications of instructor
- ③ six month leak test interval
- ④ instruction before initiation of duties.
- ⑤ State of FL entries should be NRC

REFERRED TO:

ACTION REQUESTED

Documentation of the above in
duplicate to mail ctr. #104346

☐ ADVISE ME OF
ACTION TAKEN.

INITIALS

J.M.P.

DATE

9/16/85

ACTION TAKEN

"OFFICIAL RECORD COPY"

INITIALS

DATE

ML10

BETWEEN: William O. Miller, Chief,
License Fee Management Branch
Office of Administration

John E. Glenn, Chief
Nuclear Materials Section B
Division of Engineering and
Technical Programs

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: Kenneth J. Scheer, M.D.

Application Dated: 8/23/85

Control No.: 104346

License No.: NEW

2. FEE ATTACHED

Amount: \$ 580.00

Check No.: 631

3. COMMENTS

Signed Brenda Platchek

Date 9/6/85

B. LICENSE FEE MANAGEMENT BRANCH

1. Fee Category and Amount: 2C - \$580

2. Correct Fee Paid. Application may be processed for:

Amendment

Renewal

License ✓

Signed Y Jackson

Date 9/17/85