ATTACHMENT #3

Leeco Diagnostics, Inc.

24475 W. 10 MILE ROAD • SOUTHFIELD, MI 48034
(313) 353-2620 • 1-800-950-2620 • FAX (313) 353-5039

October 15, 1990

U.S. Nuclear Regulatory Commission
Region III, Materials Licensing Section
799 Roosevelt Road
Glen Ellyn, IL 60137

Control #90091

Gentlemen:

In response to an NRC inspection on September 26, 1990 and telephone conversation on October 12, 1990, the following items are requested in addition to the amendment request dated August 17, 1990. This amendment is still in process (Control #90091).

1. Change our "Mailing Address" to:

   Leeco Diagnostics, Inc
   24475 West Ten Mile Road
   Southfield, MI 48034

2. Add Joyce Chang, Ph.D. and Ron Steckel, B.S., M.B.A. as authorized users for all radionuclides listed in our license. Their training and experience summaries are attached.

3. Allow the discontinuance of activated charcoal filters in the exhaust from the Hot Lab flow hoods. The filters have never been significantly contaminated upon exchange. Current effluent data are attached and show that the effluent is well below maximum permissible concentrations.

Thank you.

Sincerely,

Dante J. Capaldi, Ph.D.
Radiation Safety Officer

DJC/mbc

Attachments

FILE COPY

JOYCE W. CHANG

EDUCATION:

1968 Physical Chemistry University of Virgina (Ph.D.)

1962 Chemical Engineering National Taiwan University (B.S.)

EXPERIENCE:

1980 to present
Leeco Diagnostics, Inc
Southfield, MI
Position: Production Manager
Responsible for all technical production of RIA and EIA diagnostic kits. Ensure all manufacturing processes following GMP compliance and radiation safety guidelines. Participating in trouble-shooting and product support activities.

1976 to 1980
Nuclear Diagnostics, Inc
Troy, MI
Position: Research and Development Chemist
Carried out research leading to the development of several generations of diagnostic test kits for thyroid function including RIA kits for total serum thyroxine and total serum triiodothyronine and competitive protein binding assay kits for T_3 uptake and thyroxin binding globulin.

1974 to 1976
Nuclear Diagnostics, Inc
Troy, MI
Position: Production Chemist
Carried out manufacturing process for RIA diagnostic kits including performing iodination procedure and reagent formulation.

1969 to 1970
Bendix Corporation Aerospace Division
Ann Arbor, MI
Position: Staff Engineer
Participated in the project of (life detection) instrument design for the Mars exploration.

RONALD T. STECKEL
5746 Fresh Meadow Drive
Macungie, PA 18062
Tel: (215) 398-2942

CAREER OBJECTIVE

An executive position in a challenging and dynamic organization where a decisive and cost effective response is required to achieve profitability objectives.

OVERVIEW

Executive with 15 years experience in Operations, Quality and Corporate Project Management, introducing immunodiagnostic systems and pharmaceutical products to the marketplace. A proven track record in developing people, identifying and implementing cost reductions, solving problems and managing product launches, both domestically and internationally. Capable of a sustained commitment to aggressive objectives with the concomitant leadership skills necessary to achieve results.

PROFESSIONAL EXPERIENCE

SERONO-BAKER DIAGNOSTICS — Allentown, Pennsylvania

1/90 to Present — **Vice President, Operations:** Reporting to the President, Serono-Baker Diagnostics. Responsible for Instrument and Reagent Manufacturing, Materials Management, Quality Control, Purchasing and Distribution, generating $42 million in worldwide sales. This is accomplished with 11 different instruments and over 60 formulated reagents, operating expenses of $5.1 million and a team of up to 130 persons. Key objectives include:

- Establishing an operational culture of Continuous Process Improvement.
- Interfacing with Engineering/Development to introduce four new instruments.
- Improving overall GMP compliance, safety and housekeeping standards.
- Achieving unit cost reductions through productivity improvements.
- Managing the implementation of $2 million in cost reductions.
- Reducing inventory 40%.
- Controlling capital spending of $1 million.
- Maintaining a 195,000 sq.ft. facility.

12/88 to 12/89 — **Director, Operations:** Reported to the President. Responsibilities included overall plant management of the Winchester, Virginia, diagnostic reagents manufacturing facility and the Materials Management functions of Purchasing, Inventory Control and Distribution in Allentown, through the combined efforts of 115 persons.

MAJOR ACCOMPLISHMENTS:

- Managed the successful closing of the 58,000 sq.ft. Winchester facility involving 66 employees and generating $14 million of the total company sales.
- Directed the implementation of over $1 million in cost reductions.
- Achieved a 40% increase in instrument production output with 17% less labor, 20% less space and an overall quality improvement of 15%.
- Reduced overall inventory by 30%.

ARES-SERONO — Boston, Massachusetts

11/86 to 11/88 — **Director, Corporate Projects:** Reported to the President and Chief Operating Officer, Serono Diagnostics. Responsibilities included directing the activities of all development programs including R&D Limited Partnerships totaling $46 million. This involved coordination of the diagnostic teams in the United States, Switzerland, Italy and the United Kingdom to achieve aggressive launch schedules and realize a sustainable strategic advantage.

Involvement in UK included I^{125} mostly in RIA diagnostic kit manufacture and R&D work. My role was in an audit capacity

MAJOR ACCOMPLISHMENTS:

- Managed the projects leading to the successful introduction of 15 internally-developed and 10 externally-sourced RIA and EIA products within 18 months generating $15 million in sales.
- Established and implemented, within 6 months, an OEM agreement resulting in a worldwide launch of two instruments, supporting an immunodiagnostic system with over 900 placements within the first 12 months of launch.
- Directed the activities leading to the launch of a "walk away", fully automated EIA system. This included progressing the project from selection of the instrument manufacturer to production of clinical trials-pilot instruments within an aggressive schedule spanning 22 months.

AMERSHAM INTERNATIONAL — Amersham, United Kingdom

5/86 to 11/86 **Business Development Manager:** Reported to the Divisional General Manager-Pharmaceutical Products. Responsibilities included managing a new business strategy worth $3 million in initial year sales. This product was the Division's first venture into instrumentation and involved a complex electro-mechanical, software-driven medical device for lung scintigraphy.
I was project leader for a Tecnetium generator product

9/83 to 4/86 **Manager, Production:** Reported to the Operations Manager-Diagnostics, Cardiff, South Wales. Responsibilities included establishing a clinical reagents manufacturing organization capable of supporting a strategic shift to a non-radioactive, immunodiagnostic instrumentation system. This product line significantly increased the profitability of the $60 million Division and was accomplished with a team of 70.
Directly responsible for RIA kit manufacture I¹²⁵ Saml. - 20 products - Isolink & Packaging

AMERSHAM CORPORATION — Arlington Heights, Illinois

3/82 to 8/83 **Manager, Manufacturing:** Reported to the Vice President, Operations. Responsibilities included manufacturing radioactive products for the Pharmaceutical, Diagnostic, Research and Industrial businesses, generating sales of $42 million in North America. Supervised 45 people, delivered $390,000 in cost savings and provided the manufacturing support to the development and launch of a new radiopharmaceutical. This new product was launched within budget and under tight deadlines, thereby securing $2.5 million in first year sales. Thallium 201 Americium I¹²⁵ Co Salt

6/80 to 2/82 **Manager, Corporate Quality Assurance:** Reported to the Director, Quality Assurance and Technical Services. Responsibilities included establishing a formal Quality program to support the $32 million North American market. A major accomplishment was the reduction of Quality Assurance expenses as a percentage of total sales, by 9% and 13% for two consecutive years.

ABBOTT LABORATORIES, DIAGNOSTICS — North Chicago, Illinois

5/75 to 5/80 Held several supervisory positions in manufacturing and production planning including responsibility for establishing and managing a second shift to manufacture clinical reagents for a rapidly expanding market.
Direct manufacture - radioactive I¹²⁵ on the bench work for Zyos

EDUCATION

1980 LAKE FOREST COLLEGE OF MANAGEMENT, Lake Forest, IL — M.B.A.

1975 BLACKBURN UNIVERSITY, Carlinville, IL — B. S. BIOLOGY

LEECO DIAGNOSTICS, INC

Radioactive Material Effluent Monitoring

October 12, 1990

Detector Calibration (Eberline MS-2):
Scintillation probe and counter
HV=5.80, threshold = 4.5, window = 3.00
Efficiency = 0.227 cpm/dpm = 22.7%

Air Flow:
Total from 3 hoods = 2520 cfm on "Lo"
= 2520 cfm (2.83 E4 ml/cubic ft)
= 7.132 E7 ml/min

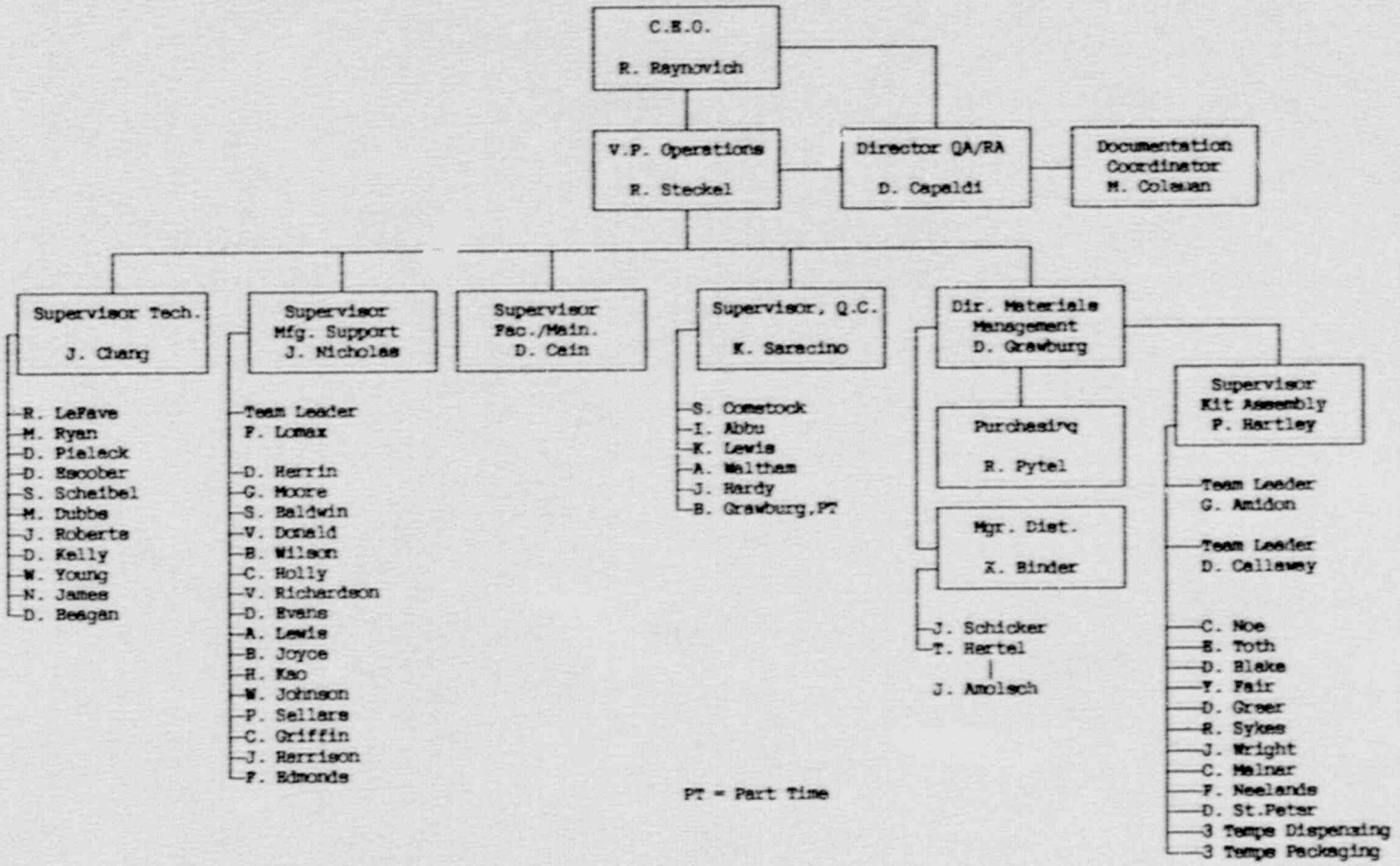
Effluent Data;
Bkg = 45 cpm
Total Net Activity = 2448 cpm/(0.227 cpm/dpm)
= 10784 dpm
= 10784 dpm (1 uCi/2.2E6 dpm)
= 4.9 E-3 uCi

For 1 minute, 7.132 E7 ml passes the detector.

Effluent Concentration = 4.9E-3 uCi/7.13E7 ml
= 6.87 E-11 uCi/ml

For unrestricted areas, the concentration cannot exceed 8E-11 uCi/ml (in air). The concentration measured was below the limit.

LEBCO DIAGNOSTICS, INC.
OPERATIONS ORGANIZATIONAL CHART



PT = Part Time

ATTACHMENT #4

October 15, 1990