

PETNET Solutions

February 16, 2018

Bryan Parker
Materials Licensing Branch
U.S. NRC Region III
2443 Warrensville Road
Suite 210
Lisle, Illinois 60532-4352

**Re: PETNET Solutions, Inc., Notification of ALARA Program Changes and
CRSO Change for RAM License # 41-32720-01 / 41-32720-02MD -
Indianapolis Facility**

Dear Mr. Bryan Parker,

The purpose for this letter is to inform your office that PETNET Solutions, Inc. has made two recent changes to the implementation of its Radiation Protection Program.

- 1) PETNET Solutions, Inc. has updated the ALARA section of its Radiation Protection Program, as well as the implementing procedures used at all of our facilities. The revised ALARA Program has been reviewed and approved by senior management and PETNET's Radiation Safety Committee. Enclosed with this letter is a copy of the ALARA Program revision.
- 2) PETNET Solutions, Inc. CRSO has changed effective February 5, 2018. The new CRSO is Elizabeth Gillenwalters, CHP. Mrs. Gillenwalters is certified by the American Board of Health Physics and has been employed by PETNET since June 2016. She has previously been listed as the Radiation Safety Officer on several Agreement State and NRC radioactive material licenses, the most recent of which being TN RAM License R-47101 for Siemens Molecular Imaging, a copy of which is attached.

Additionally, new Delegation of Authority and Signature Authority forms signed by PETNET CEO, Barry Scott, are attached. These documents recognize the authority and responsibility granted to the CRSO as well as authorizes approved radiation safety and EHS personnel to sign licensure documentation and correspondence.

Should you have any questions please feel free to contact me as below.

Sincerely,

A handwritten signature in black ink that reads "Elizabeth Gillenwalters". The signature is written in a cursive, flowing style.

Elizabeth Gillenwalters, CHP
Senior Manager of Radiation Protection/EHS
Siemens Molecular Imaging/PETNET Solutions, Inc.
(865) 237-9045 mobile
(865) 218-3295 office
elizabeth.gillenwalters@siemens-healthineers.com

cc: Facility RSO
PETNET Solutions, Inc. Indianapolis

Enclosures

ENCLOSURE A

ALARA Program Revision to RPP

8. ALARA Program

8.1 Policy

PETNET shall use, to the extent practicable, engineering controls and administrative controls, based on sound radiation protection principles and practices, to maintain worker and public doses and effluent releases As Low As Reasonably Achievable (ALARA). The PETNET management is committed to a strong ALARA program, which shall be implemented through vigilance by the CRSO, EHS Department, facility RSOs, and ALARA action levels.

8.2 Management Philosophy and Principles

The PETNET management's philosophy and principles with respect to the corporate ALARA program are outlined below:

- i. PETNET shall utilize the internationally accepted principle of radiological protection (dose limitation) which is outlined in subchapter 1.4.1 of this manual;
- ii. The level, degree, and effect of the ALARA Program elements shall be commensurate with the degree of risk and hazard from radiation exposures and releases, and characteristics of radionuclides and/or cyclotrons; and
- iii. ALARA, a professional standard of excellence, shall be incorporated into all PETNET operations, as applicable and practicable.

8.3 Management Commitment

The PETNET management is committed to the ALARA program, described in this chapter of the RPP. This commitment shall be carried out through:

- i. PETNET management shall be committed to the company's ALARA program by providing appropriate organization and resources to administer the program;
- ii. PETNET's commitment to the ALARA program shall be documented through a policy statement signed by the company's President/CEO. This "PETNET ALARA Program Policy Statement" is provided in Attachment F;
- iii. A strong and effective radiological compliance training program shall be a vital part of the ALARA program;
- iv. ALARA responsibilities shall be established at the senior management levels;
- v. PETNET shall hold its employees, at all levels, responsible for implementing the ALARA program and identifying the necessary areas of improvement;

- vi. PETNET management shall play an active part in the RPP and the ALARA program through open lines of communication with the CRSO and the RSC;
- vii. The CRSO and the RSC shall communicate the ALARA issues- such as program deficiencies, corrective actions, resources, and success stories- with the executive management on a frequent interval;
- viii. PETNET management shall consider modification to the ALARA policies and procedures, as recommended by the CRSO and the RSC;
- ix. ALARA practices shall be based on sound engineering design and administrative controls for exposure, contamination, and release controls;
- x. PETNET management shall encourage engineering and/or administrative changes for reducing doses and/or releases, taking into consideration the economic, technical, social, and public policy considerations;
- xi. The CRSO is provided sufficient authority to encourage and enforce safe radiological conditions and the ALARA program through program reviews and audits, training programs, and timely implementation of corrective actions;
- xii. PETNET management has delegated the responsibility to the CRSO for establishment and administration of the ALARA program. Management will support the CRSO in instances where this authority must be asserted;
- xiii. The RSC shall review all the relevant ALARA reports and issues at the quarterly meeting. The CRSO is responsible for providing the information to the RSC;
- xiv. ALARA action levels, commensurate with the corporate and/or site-specific programs shall be established by the CRSO and approved by the RSC;
- xv. The CRSO shall communicate the ALARA information within PETNET in an effort to improve ALARA practices and the company ALARA objectives; and
- xvi. The CRSO and the RSC shall review the ALARA program annually and results shall be documented. The program modifications shall be communicated by the CRSO to the relevant organizational units.

8.4 Vigilance by the CRSO, EHS Department, and RSOs

In addition to the management commitment, PETNET's ALARA program implementation shall be carried out through a team approach and a strong vigilance program by the CRSO, EHS Department, and the facility RSOs. The vigilance program, led by the CRSO shall be carried out through:

- i. The CRSO, EHS Department, and the facility RSOs shall encourage and enforce safe radiological conditions and the company wide ALARA program, and perform the evaluations and investigations of the ALARA deficiencies and subsequent corrective actions;
- ii. The CRSO shall review new facilities, processes, procedures, and equipment for ALARA considerations, prior to implementation;
- iii. The CRSO shall review the ALARA investigation reports prepared by the RSOs, and ensure implementation of the corrective actions. The CRSO shall seek the RSC's advice, as needed; and
- iv. The facility RSO shall prepare the ALARA investigation reports for all elements where the ALARA action levels are exceeded. These reports shall include the root cause(s) of the elevated dose, release, or contamination, and the appropriate corrective action(s).

8.5 Promotion of the ALARA Culture

For promotion of the ALARA culture throughout the company, PETNET shall take the following actions:

- i. Ensure company-wide and site-specific environments, which encourage open communication between senior management, CRSO, RSC, EHS Department, PETNET facilities, and all other organizational units for discussing and resolving ALARA issues, and encouraging mutual understanding and support on the basis of personnel motivation and ownership, and supported by an appropriate organizational structure. The organization shall ensure that proper avenues and resources are available for a systematic approach to the ALARA program;
- ii. Establish company-wide and site-specific ALARA guidelines and teams for evaluating ALARA deficiencies, corrective actions, and ALARA tracking and goal setting;
- iii. Promote proper "mind-set" among operations management and workers and the supporting organization units so that ALARA considerations are incorporated into all stages of planning, design, and operations; and
- iv. Ensure an environment that fosters constant awareness and attention for avoiding unnecessary exposure, contamination, and releases; and
- v. Encourage workers to report unsafe work conditions to their RSO, and to the CRSO, if no actions are taken by the facility RSO. Workers shall not have a fear of reprisal.

8.6 ALARA Policy and Action Levels for Occupational Dose

The primary concept of the ALARA philosophy is that unnecessary exposure to radiation should be avoided. The objective is to reduce occupational exposures (both individual and collective), effluents released to the environment, and public exposures as far below regulatory limits as is reasonably achievable by means of good radiation protection planning and practice, as well as by a management commitment to policies that deter departures from good practices.

- i. The three primary methods of minimizing exposure to radiation are: time, distance and shielding. When working with sources of radiation, workers should always minimize the time, maximize the distance, and make use of available shielding to keep exposures ALARA.
- ii. The management of PETNET is committed to the program described in this application for keeping individual and collective doses, occupational as well as public, ALARA. This section describes an administrative organization for the RPP and the development of the necessary written policies, procedures, and instructions to foster the ALARA concept within the company.
- iii. It is a management priority that all personnel working with radioactive material and radiation-producing machines are made aware of management's commitment to the ALARA philosophy and that they are instructed in the procedures to be used to keep their exposures as low as possible.
- iv. Management has delegated the authority to the PETNET CRSO to ensure adherence to ALARA principles. Management will support the CRSO in instances where this authority must be asserted.
- v. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in the judgment of the CRSO or the RSC, is considered to be unjustified. PETNET will be able to demonstrate, if necessary, those improvements have been sought, that modifications have been considered, and that they have been implemented when reasonable. If modifications have been recommended but not implemented, PETNET will document the reasons for not implementing.
- vi. In addition to maintaining doses to individuals ALARA, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. All reasonable efforts will be made to decrease individual as well as collective dose.

PETNET's ALARA policy is based on a two-tier approach. First, quarterly and annual Corporate Action Levels and Restriction Levels provide a framework for upper boundary limits requiring corporate actions. The Corporate Action Levels and Restriction Levels are:

| Type | Action Level | | Restriction Level | |
|------------|------------------|---------------|-------------------|---------------|
| | Quarterly (mrem) | Annual (mrem) | Quarterly (mrem) | Annual (mrem) |
| Whole Body | 500 | N/A | 1,000 | 4,000 |
| Extremity | 7,500 | N/A | 10,000 | 40,000 |

Second, quarterly site-specific ALARA Levels, based on dose history and facility throughput, provide a threshold for the facility RSO to conduct ALARA investigations.

If the site-specific ALARA Level is exceeded an investigation is performed by the RSO. This investigation will include the root cause for exceeding the ALARA Level and the corrective actions that will be performed to prevent reaching the Action or Restriction level in the future. Once the RSO has completed the investigation a report is submitted to the EHS Department for review and possible further action. If a Corporate Restriction Level is exceeded, the worker will be restricted from handling radioactive materials for the balance of the quarter or year, whichever is applicable. The site-specific and corporate levels are reviewed annually by the EHS Department, and the PETNET RSC approves recommended changes.

ENCLOSURE B

TN RAM License for CRSO Change

**RECEIVED**

JAN 31 2018

**TENNESSEE DEPARTMENT OF ENVIRONMENT AND CONSERVATION
DIVISION OF RADIOLOGICAL HEALTH**

William R. Snodgrass Tennessee Tower 312 Rosa L. Parks Avenue, 15th Floor Nashville, Tennessee 37243
615-532-0364

RADIOACTIVE MATERIAL LICENSE

Amendment 50

Pursuant to Tennessee Department of Environment and Conservation Regulations, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer radioactive material listed below; and to use such radioactive material for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules and regulations of the Tennessee Department of Environment and Conservation and orders of the Division of Radiological Health, now or hereafter in effect and to any conditions specified below.

| LICENSEE | | 3. License number |
|---|--|--|
| 1. Name | Siemens Molecular Imaging, Inc. | R-47101-L23 |
| 2. Address | 810 Innovation Drive Knoxville, Tennessee 37932 | 4. Expiration date December 31, 2023 |
| | | 5. File no. R-47101 |
| 6. Radioactive Material (Element and Mass Number) | 8. Chemical and/or physical form | 9. Maximum Radioactivity and/or quantity of material which licensee may possess at any one time. |
| SEE SUPPLEMENTARY SHEETS | | |
| 10. Authorized Use | | |
| SEE SUPPLEMENTARY SHEETS | | |
| CONDITIONS | | |
| 11. Unless otherwise specified, the authorized place of use is the licensee's address stated in Item 2 above. | | |
| <p align="right">For the Commissioner Tennessee Department of Environment and Conservation</p> | | |
| Date of Issuance: <u>January 26, 2018</u> | By: <u>Sasi Krishnasarma</u> Division of Radiological Health Sasi Krishnasarma, Health Physicist | |



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 615-532-0364

RADIOACTIVE MATERIAL LICENSE

Amendment 50

License No. R-47101-L23

Supplementary Sheet

- | | | |
|---|---|--|
| <p>6. Radioactive Material (Element and <u>Mass Number</u>)</p> <p>A. Fluorine 18</p> <p>B. Carbon 11</p> <p>C. Nitrogen 13</p> <p>D. Oxygen 15</p> <p>E. Copper 60</p> <p>F. Copper 61</p> <p>G. Copper 64</p> <p>H. Hydrogen 3</p> <p>I. Any nuclides with atomic numbers 3- 83 inclusive, except Strontium 90 and Lead 210</p> <p>J. Cd-109, Co-57, Te- 123m, Cr-51, Sn- 113, Sr-85, Cs-137, Co-60, and Y-88</p> | <p>8. Chemical and/or <u>Physical Form</u></p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Any</p> <p>F. Any</p> <p>G. Any</p> <p>H. Liquid</p> <p>I. Sealed Sources (manufactured and labeled and packaged in accordance with a license issued by this Department, U.S. NRC or agreement State, in accordance with Applicable provisions for the manufacture and distribution of such radioactive material)</p> <p>J. Liquid Source (IPL Model 7500 or other sources authorized for distribution in a specific license issued by an Agreement State)</p> | <p>9. Maximum Radioactivity and/or Quantity of Material Which Licensee May <u>Possess</u> <u>at Any One Time</u></p> <p>A. 50 Curies</p> <p>B. 5 Curies</p> <p>C. 5 Curies</p> <p>D. 5 Curies</p> <p>E. 2 Curies</p> <p>F. 2 Curies</p> <p>G. 2 Curies</p> <p>H. 200 millicuries</p> <p>I. No single source to exceed 10 millicuries. Total not to exceed 250 millicuries</p> <p>J. No single source to exceed 1 microgram, or 0.5 millicuries</p> |
|---|---|--|



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Supplementary Sheet

| | | |
|---|---------------------------------------|--------------------|
| K. Californium 252 | K. Sealed Source | K. 0.5 millicurie |
| L. Any radionuclide with atomic number 3-83 (excluding Zn-65) | L. Fixed activated parts and concrete | L. 200 millicuries |
| M. Zinc-65 | M. Fixed activated parts and concrete | M. 300 millicuries |
| N. Any radionuclide with atomic number 3-83 | N. Removable Components | N. 200 millicuries |

10. Authorized Use

- A. through H. For research, production, possession, and testing of cyclotrons chemistry modules.
- I. and J. For calibrations and constancy checks on dose calibrators, stack monitors, and radiation survey and analysis instruments.
- K. Neutron shielding measurements.
- L. through N. Activation Products.

Conditions (continued)

12. The licensee shall comply with applicable provisions of 0400-20-04, 0400-20-05, and 0400-20-10 of "State Regulations for Protection Against Radiation."
13. A. Radioactive material authorized by this license shall be used by, or under the supervision of, individuals who have completed the ADVANCED RADIATION SAFETY TRAINING LEVEL 2 training program as approved under the license.
- B. The Radiation Safety Officer for this license is Elizabeth Gillenwalters.
14. A. Sealed sources authorized by this license shall be tested for leakage and/or contamination at intervals not to exceed six (6) months. In the absence of a certificate from a transferor indicating that a test has been made within six (6) months prior to transfer, the sealed source shall not be put into use until tested.



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Supplementary Sheet

- B. The test shall be capable of detecting the presence of 0.005 microcurie of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surface of the device in which the sealed source is permanently mounted or stored on which one might expect contamination to accumulate. Records of leak tests shall be kept in units of microcuries and maintained for inspection by the Department.
 - C. If the test reveals the presence of 0.005 microcurie of more of removable contamination, the licensee shall immediately withdraw the sealed source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with Department regulations. A report shall be filed within five (5) days of the test with the Division of Radiological Health, Tennessee Department of Environment and Conservation, William R. Snodgrass Tennessee Tower, 15th Floor, 312 Rosa L. Parks Avenue, Nashville, Tennessee, 37243, describing the equipment involved, the test results, and the corrective action taken.
 - D. Tests for leakage and/or contamination shall be performed by the manufacturer or other persons authorized by this Department, the U. S. Nuclear Regulatory Commission, or another Agreement state to perform such services.
15. Notwithstanding the periodic leak test required by this condition, any licensed sealed source is exempt from such leak tests when the source contains 100 microcuries or less of beta and/or gamma emitting materials or 10 microcuries or less of alpha emitting material.
16. The licensee shall not open sealed sources containing radioactive material.
17. The licensee shall conduct a physical inventory of sealed sources authorized by this license at intervals not to exceed six (6) months. Records of inventories shall be maintained for inspection by the Department, and shall contain information that is sufficient to identify and distinguish each individual source. The location of use and/or storage of each source shall be maintained on the inventory.
18. The licensee shall maintain complete and accurate records of the receipt and disposal of radioactive material. The licensee shall, for radioactive material no longer useful for any purpose and for any equipment or supplies contaminated with such material for which further use and decontamination is not planned, define those materials as radioactive waste and treat them as such in accordance with the following provisions:
- A. Radioactive waste material shall not be stored with non-radioactive waste.



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Amendment 50

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Supplementary Sheet

- B. A written record of all radioactive waste material shall be maintained until it has been determined by a suitable survey or radioassay that it has decayed to background levels or until it has been shipped to an authorized recipient in accordance with all applicable regulations. Accountability of radioactive waste material prepared for shipment but not yet shipped from the licensee's premises shall be maintained by the licensee by an internal record system such that the licensee is constantly aware of the material's location and the proposed time of shipment. Individuals who are involved in the shipping of such material and/or the storage of such material prior to shipment, shall be trained in the precautions necessary for such handling and storage.
- C. For material which has decayed to background levels as determined by radioassay or external level as measured with appropriately calibrated instruments, records shall indicate that the material was determined to be no longer radioactive and will indicate the methods and results of the survey or analysis.
- D. Shipment records of radioactive waste material shall be maintained and the licensee shall require written confirmation from the authorized recipient of such material that this material has been received.
- E. All records and written confirmations required by this condition shall be maintained for inspection by the Department.

The requirements for this condition are in addition to any other requirements for the handling and/or disposal of radioactive material contained in this license and "State Regulations for Protection Against Radiation."

- 19. In addition to the possession limits authorized by this license, the licensee shall further restrict the possession of licensed material to quantities below the limits in 0400-20-10-.13(17)(a) of "State Regulations for Protection Against Radiation" which require consideration of the need for an emergency plan for responding to a release of license material.
- 20. No provision of this license relieves the licensee from compliance with other Federal, State and local laws, ordinances, and regulations applicable to the licensee's activities.
- 21. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Items 6, 8, and 9 of this license in accordance with statements, representations, and procedures contained in the following:
 - Application dated June 14, 2013, with attachments
 - Letters dated December 3, 2013, with attachments, January 19, 2017, with attachments, January 3, 2018, with attachments, and January 22, 2018, with attachments.

ENCLOSURE C

Delegation of Authority & Signature Authority Forms

PETNET Solutions

To: All PETNET Solutions Employees

Re: Delegation of Authority: Radiation Protection Program

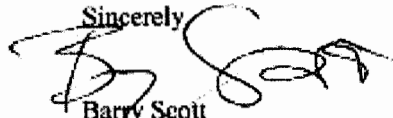
Date: February 5, 2018

Elizabeth Gillenwalters has been appointed Corporate Radiation Safety Officer (CRSO) for PETNET Solutions (PETNET), effective February 1, 2018. In this capacity, Elizabeth has the responsibilities for the safe use of radioactive materials and radiation-producing machines, and transportation of radioactive materials. The CRSO is responsible for managing the corporate radiation protection program, identifying issues related to radiation protection, initiating, recommending, or providing corrective actions, verifying implementation of corrective actions, and ensuring compliance with regulations. The CRSO is hereby delegated the authority, organizational freedom, and management prerogative to:

1. Provide leadership in all areas of radiological compliance and safety;
2. Establish and facilitate implementation of radiological compliance-related programs, policies, and procedures;
3. Foster the corporate ALARA program and radiological safety culture;
4. Have unhampered access to all activities at PETNET facilities involving radioactive materials and radiation-producing machines, and any other relevant organizational units to identify issues related to radiation protection;
5. Immediately stop, without coordination with management, any activity involving the use of radioactive materials by any user that might result in an unsafe situation or a violation of NRC/Agreement State/DOE requirements;
6. Initiate, recommend, or implement appropriate corrective actions;
7. Verify the implementation of actions taken to correct radiation protection-related issues and promote a continuous improvement program; and
8. Coordinate and manage Corporate Radiation Safety Committee (RSC) activities.

All employees of PETNET Solutions have a critical responsibility in ensuring the safe use of radioactive materials. "The health and safety of our employees, customers, and community will never be compromised."

Sincerely



Barry Scott
CEO

PETNET Solutions, Inc.

PETNET Solutions, Inc.
A Siemens Company

810 Innovation Drive
Knoxville, TN 37932

Tel: (800) 738-0488
Fax: (865) 218-3018

PETNET Solutions

Signature of Authority

I understand that all statements in the radioactive materials license applications, amendment requests, cyclotron registrations/licenses, and environmental permits to State and Federal Regulatory Agencies, including those previously made, as well as, those made in the future, are considered legally binding.

I hereby delegate responsibility for future radioactive materials, cyclotron, and environmental applications, licenses, permits, and registrations to be signed by the following individuals:

| | |
|---|--|
| Name: <u>Elizabeth Gillenwalters, CHP</u> | Title: <u>Corporate Radiation Safety Officer</u> |
| Phone Number: <u>(865) 218-3295</u> | Email: <u>elizabeth.gillenwalters@siemens-healthineers.com</u> |
| Name: <u>Roger Moroney, CHP</u> | Title: <u>EHS Specialist</u> |
| Phone Number: <u>(865) 218-2595</u> | Email: <u>william.moroney@siemens-healthineers.com</u> |
| Name: <u>David J. Krueger, CHP</u> | Title: <u>Regional Health Physicist</u> |
| Phone Number: <u>(818) 620-6569</u> | Email: <u>david.j.krueger@siemens-healthineers.com</u> |
| Name: <u>Cami Still</u> | Title: <u>Regional Health Physicist</u> |
| Phone Number: <u>(317) 674-5275</u> | Email: <u>camy.still@siemens-healthineers.com</u> |
| Name: <u>Mandy Dubuc</u> | Title: <u>Regional Health Physicist</u> |
| Phone Number: <u>(865) 218-2235</u> | Email: <u>amanda.dubuc@siemens-healthineers.com</u> |
| Name: <u>Christopher Hile</u> | Title: <u>Environment, Health & Safety Specialist</u> |
| Phone Number: <u>(865) 218-6350</u> | Email: <u>Christopher.hile@siemens-healthineers.com</u> |
| Name: <u>Daniel James</u> | Title: <u>Environment, Health & Safety Specialist</u> |
| Phone Number: <u>(865) 218-2537</u> | Email: <u>daniel.james@siemens-healthineers.com</u> |
| Name: <u>April C. Chance, CHP</u> | Title: <u>Sr. Manager EHS</u> |
| Phone Number: <u>(865) 218-6355</u> | Email: <u>april.chance@siemens-healthineers.com</u> |

Signature and Title of Certifying Official:


Signature _____ February 5, 2018
Barry Scott
CEO, PETNET Solutions, Inc.

ORIGIN ID:RKWA (865) 237-9045
ELIZABETH GILLENWALTERS
PETNET SOLUTIONS, INC.
810 INNOVATION DRIVE

KNOXVILLE, TN 37932
UNITED STATES US

SHIP DATE: 16FEB18
ACTWGT: 0.50 LB
CAD: 105091792/INET3980

BILL SENDER

TO **BRYAN PARKER**
US NUCLEAR REGULATORY COMM. RIII
2443 WARRENVILLE RD STE 210

552J1122DIDCA6

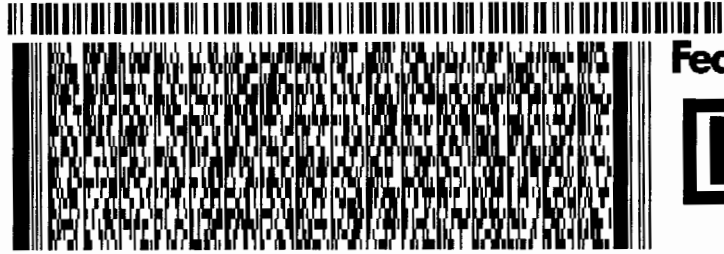
LISLE IL 60532

(630) 829-9854

REF: INDIANAPOLIS 50-938

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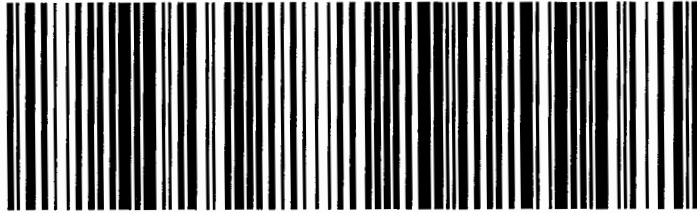
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