

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-8087-D-801-B DATE: February 27, 1997 PAGE 1 OF 9

DEVICE TYPE: X-ray Fluorescence Analyzer

MODEL: 615 00 00

DISTRIBUTOR: Provalid Corporation
520 Herndon Parkway
Herndon, VA 22070

MANUFACTURER: Provalid AB
Avtalsvagen 15
S-227 61 LUND
SWEDEN

SEALED SOURCE MODEL DESIGNATION: Amersham Corporation
Model AMC.D3
Isotope Products Laboratories
Model GFS Series

ISOTOPE:

Americium-241

MAXIMUM ACTIVITY:

60 mCi total (2.22 GBq)
in 2 sources at
30 mCi (1.11 GBq) each

LEAK TEST FREQUENCY: 36 Months

PRINCIPAL USE: (U) X-ray fluorescence

CUSTOM DEVICE: _____ YES X NO

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DEVICE TYPE: X-ray Fluorescence Analyzer

DESCRIPTION:

The Model 615 00 00, which is commonly called the Renalyzer PRX90, is a portable x-ray fluorescence instrument used to measure the amount of iodine present in plasma samples. The instrument has approximate dimensions of 22" x 27" x 10" (55.88 cm x 68.58 cm x 25.4 cm) and weighs approximately 46 pounds (20.87 kg).

The front of the unit consists of a flip down keyboard and an LCD display. All patient information is entered using the keyboard and is displayed on the LCD screen. Iodine concentrations are also be displayed on the screen.

The device is operated by inserting a plasma sample into a hole in the top of the unit. An elevator device will lower the sample down into the measuring area within the device. Through keyboard operations, the device can be operated to evaluate the iodine concentration.

The inner components of the Renalyzer PRX90 consists of the following:

- Two (2) Am-241 Sealed Sources
- Sealed Source Housings
- NaI Detector
- Detector Mount
- Sample Turret
- Sample Elevator
- Protective Housing
- Mounting Plate
- Electronics

The unit is designed with the sealed sources (maximum 30 mCi (1.11 GBq) each) mounted within cylindrical lead source housings. The housings are mounted within two holes, drilled at 45° angles, in the front face of the detector mount. The housings are held in place by screws and are oriented so that the paths of the radiations beams intersect directly in front of the NaI detector

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DEVICE TYPE: X-ray Fluorescence Analyzer

DESCRIPTION: (Cont'd)

which is mounted in the center of the detector mount. This entire component is attached to the aluminum mounting plate at the bottom of the device.

The sample turret is attached to the mounting plate in front of the detector mount in such a manner that the center line of the sample being measured will align with the intersection of the radiation beams. The turret can hold up to ten (10) samples (two (2) being calibration samples) and is able to rotate 260° so that each sample can be moved to the measuring position. The turret is designed with lead shielding at the top and bottom of the sample area for radiation protection.

The sample elevator is mounted beneath the turret. It's purpose is to lower and raise the samples into and out of the turret. It is activated by the keyboard on the front of the device.

The entire area in the front of the detector mount and surrounding the sample turret is covered by the protective housing. The housing is made of aluminum lined with lead and its main purpose is to provide shielding. One of three types of tamper resistant screws are used to fasten the cover.

The electronic workings of the device, which consist of the power supplies and the control board, are mounted toward the back of the device.

The principal behind how the device works is that the plasma sample is irradiated by 60 keV photons from the sealed sources. The photons may cause K-shell electrons to be ejected from the iodine atoms causing the atoms to go to an excited state. As the atoms return to a stable state, they will emit characteristic x-rays that can be detected by the NaI detector. The intensity of the x-rays is proportional to the iodine concentration in the sample.

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DEVICE TYPE: X-ray Fluorescence Analyzer

DIAGRAM:

Attachments 1-3 show detailed drawings of the Renalyzer PRX90 Model 615 00 00, the sample turret, and the protective housing.

LABELING:

FOR DEVICES DISTRIBUTED TO SPECIFIC LICENSEES:

The labeling consists of two labels. One label is mounted on top of the device at the front left corner and contains the radiation symbol, isotope, activity, date of assay, and the words "CAUTION-RADIOACTIVE MATERIAL." This label is made of aluminum and is permanently attached to the device with screws. The second label is attached with screws to the rear of the unit and contains the device model number, serial number, and additional Provalid information.

FOR DEVICES DISTRIBUTED TO GENERAL LICENSEES:

The labeling consists of four labels. One label is mounted on top of the device at the front lower left corner and contains the radiation symbol (black on yellow), isotope, activity, date of assay, and the words "CAUTION-RADIOACTIVE MATERIAL". The second label contains the device model number, serial number, and additional manufacturer information and is attached to the rear of the device. The third label is attached to the front upper right corner of the device and contains the instructions, precautions, and warnings. The fourth label is preprinted that if the device is transferred, a new owner's identification label is required and space is provided for the owner's name and address. This label is a self-adhesive solid aluminum foil. The first three labels are made of aluminum and permanently attached to the device. The labels located on the top cover of the device are attached with bolts with locking nuts. The label on the rear of the device is attached with screws.

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DEVICE TYPE: X-ray Fluorescence Analyzer

CONDITIONS OF NORMAL USE:

The device is intended for use as a plasma analyzer to determine the amount of iodine present in plasma samples. It will be used in laboratories or offices in which the environmental conditions will be suitable for human occupancy. Since the device is moved between laboratories, it will be subjected to vibration encountered during normal transportation and handling.

PROTOTYPE TESTING:

The analyzer has been subjected to a drop test, a rigidity test, an impact test, and a vibration test. Each test simulated the conditions which the device would experience during its normal use. No adverse effects were observed after each test. The device has also been in use for over seven years in Sweden, Norway, and the United Kingdom. In this time span, the device has experienced rough handling (e.g. being dropped from 1 foot and being stored in the trunk of a car when the car was involved in a car crash), but has experienced no significant damage.

The Amersham and Isotope Products sealed sources have been rated for ANSI-N542 classifications of 77C64444 and 77C64545, respectively.

It has been concluded, from the testing performed and the years of use, that the device will withstand the abuse it may receive during its useful life.

EXTERNAL RADIATION LEVELS:

The Swedish National Institute of Radiation Protection performed a radiation survey on the unit containing two (2) 30 mCi (1.11 GBq) sealed sources and found the maximum dose rate at the surface of the device to be less than 0.1 mrem/hr (1.0 µSv/hr).

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DEVICE TYPE: X-ray Fluorescence Analyzer

QUALITY ASSURANCE AND CONTROL:

Vidar was contracted to perform the quality control functions on behalf of the U.S. distributor, Provalid Corporation. The contractor received completed analyzers from Provalid and removed the outer covers from the devices and inspected the units to ensure that all the components were assembled correctly. The contractor performed a radiation survey and leak test on each unit to ensure proper assembly.

Vidar submitted a copy of their quality assurance and control program. The program has been deemed acceptable for licensing purposes and is on file with the NRC.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The device is no longer manufactured or distributed by Provalid Corporation.
- The device has been distributed to specific and general licensees of NRC or Agreement States.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority or as required by 10 CFR 31.5 or Agreement State equivalent.
- The device shall be leak tested at intervals not to exceed 36 months using techniques capable of detecting 0.005 μCi (185 Bq) of removable contamination.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

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DEVICE TYPE: X-ray Fluorescence Analyzer

SAFETY ANALYSIS SUMMARY:

Provalid has submitted sufficient information to provide reasonable assurance that:

the device can be safely operated by persons not having training in radiological protection.

- Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the source housing, and it is unlikely that any person will receive in one year a dose in excess of 10 percent of the limits specified in Section 20.1201(a), 10 CFR Part 20.
- Under accident conditions associated with handling, storage, and use of the source housing, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in the following chart:

PART OF BODY

DOSE

Whole body; head and trunk;
active blood-forming organs;
gonads; or lens of eye

15 rem (0.15 Sv)

Hands and forearms; feet and
ankles; localized areas of skin
averaged over areas no larger
than 1 square centimeter

200 rem (2.0 Sv)

Other organs

50 rem (0.50 Sv)

Based on review of Provalid's Renalyzer PRX90 Model 615 00 00, and the information and test data cited below, we continue to conclude that the device is acceptable for general licensing purposes.

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SAFETY ANALYSIS SUMMARY: (Cont'd)

Furthermore, we continue to conclude that the device would be expected to maintain it's containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

Since the effective date of this document, the Renalyzer PRX90 Model 615 00 00 device is not a current product manufactured nor serviced by Provalid Corporation. However, the device remains acceptable for use by general and specific licensees.

REFERENCES:

The following supporting documents for the Renalyzer PRX90 Model 615 00 00 are hereby incorporated by reference and are made a part of this registry document.

- Vidar's application dated March 2, 1990, with enclosures thereto.
- Vidar's letters dated October 22, 1990, and August 17, 1993.
- Package received from Vidar on November 13, 1990, including Renalyzer Library 1 & 2, User Manual, and IEC Test Report.
- Provalid Corporation's letters dated August 17, 1993, and December 20, 1993.
- Provalid AB's letter dated April 8, 1993, with enclosures thereto and facsimiles dated July 13, 1993, August 19, 1993, August 24, 1993, August 30, 1993, September 28, 1993, and December 13, 1993.
- Provalid AB's facsimile dated February 19, 1997.

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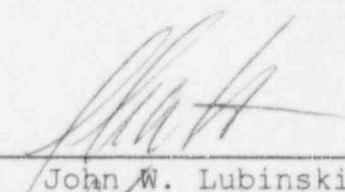
DEVICE TYPE: X-ray Fluorescence Analyzer

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

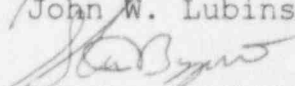
Date: February 27, 1997

Reviewer:


John W. Lubinski

Date: February 27, 1997

Concurrence:


Steven L. Baggett

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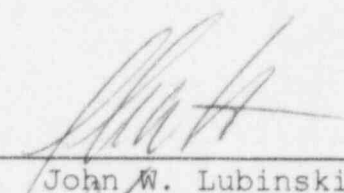
DEVICE TYPE: X-ray Fluorescence Analyzer

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

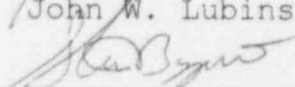
Date: February 27, 1997

Reviewer:


John W. Lubinski

Date: February 27, 1997

Concurrence:

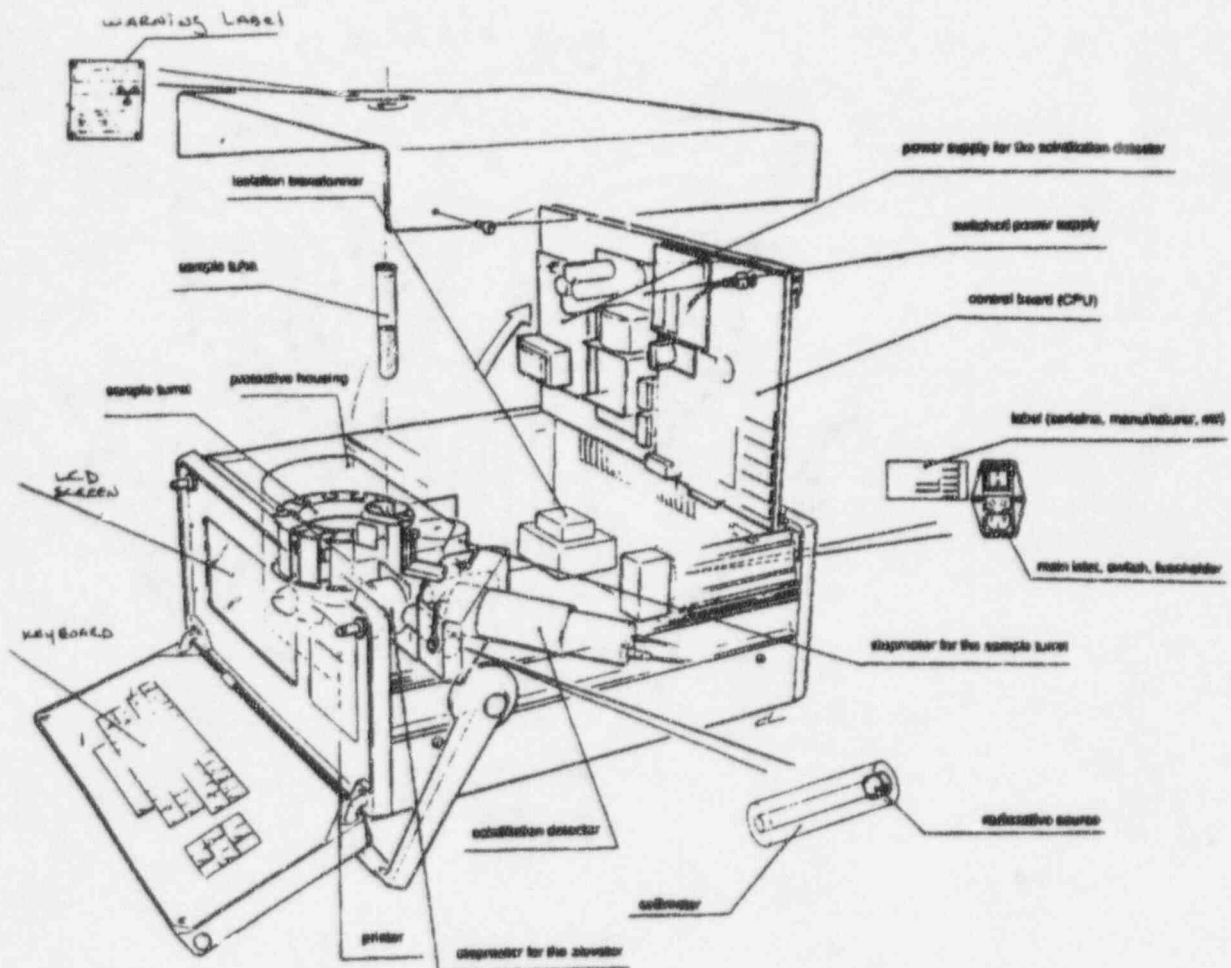

Steven L. Baggett

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Attachment 1



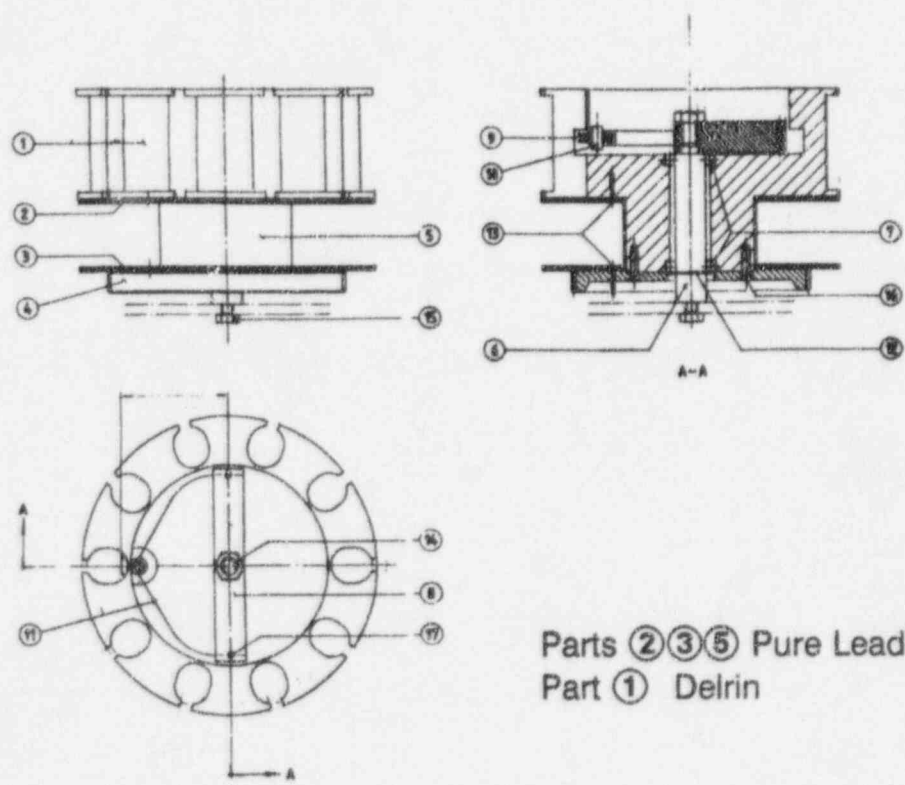
Renalyzer PRX90
Model 615 00 00

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NO.: NR-8087-D-801-B

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Attachment 2



Parts ②③⑤ Pure Lead
Part ① Delrin

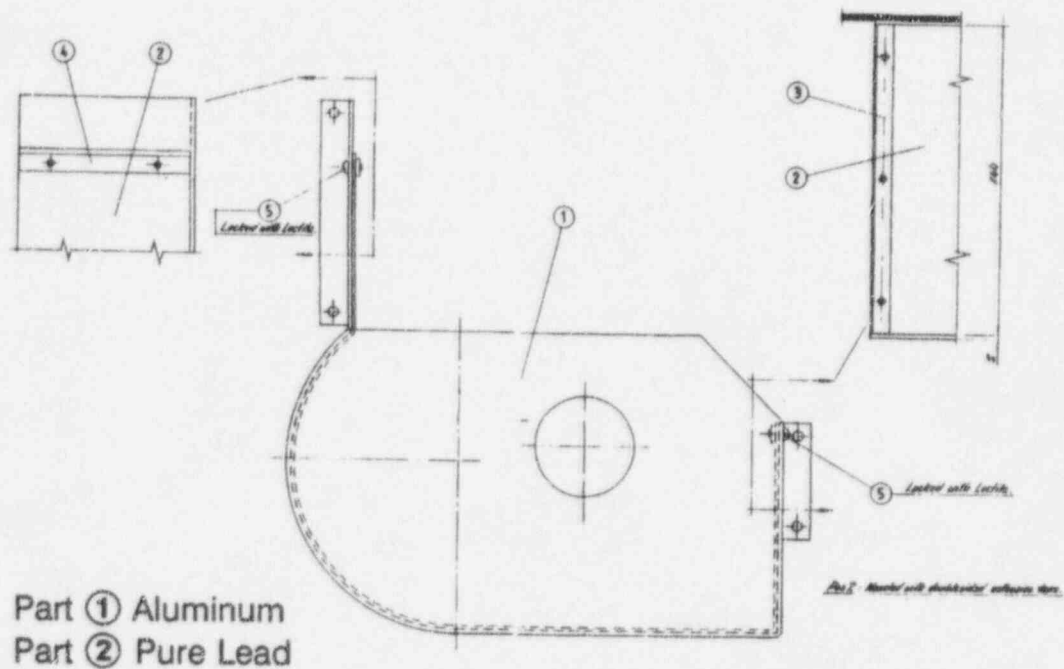
Sample Turret

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SAFETY EVALUATION OF DEVICE

NO.: NR-8087-D-801-B

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Attachment 3



Protective Housing

NRC FORM 567

(8-93)

U. S. NUCLEAR REGULATORY COMMISSION

REQUEST FOR A SEALED SOURCE OR DEVICE EVALUATION

INSTRUCTIONS: Send this request AND a copy of all related letters/applications and drawings to: The Sealed Source Safety Section, ATTN: Chief, OWFN Mail Stop 6 H3. Change the License Tracking System milestone to 19 and assign to reviewer code I-5.

NOTE: Retain a copy of this request with the application and background files.

| | | | |
|--|------|---|--|
| REQUESTER <i>Anders Ohlsson</i> | | REGION/LOCATION: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/> HQ <input type="checkbox"/> LFDCB | |
| TELEPHONE NUMBER | DATE | TYPE OF ACTION REQUESTED (Check as appropriate) | |
| APPLICANT'S NAME <i>PROVAL Corp.</i> | | <input type="checkbox"/> SOURCE REVIEW <input type="checkbox"/> AMENDMENT OF REGISTRATION SHEET NUMBER(S) | |
| MAIL CONTROL NUMBER(S) | | <input type="checkbox"/> DEVICE REVIEW | |
| LETTER/APPLICATION DATE <i>11/19/96</i> | | <input type="checkbox"/> CUSTOM REVIEW <i>NR-794-D-101-B</i> | |
| LICENSE NUMBER(S) | | | |

COMMENTS

*460 Spring Park Place
Herndon, VA 22070*

FOR SSSS USE ONLY

| | | |
|----------------------------------|-----------------------------------|----------------------------------|
| REVIEWER <i>D. Smith</i> | MODEL NUMBERS <i>615 00 00</i> | NUMBER ASSIGNED <i>96-110</i> |
| DATE RECEIVED <i>11/19/96</i> | DATE ASSIGNED <i>11/22/96</i> | DATE TO FEES <i>11/22/96</i> |

TYPE OF ACTION (Indicate the number of each type)

| | | | |
|--|---|--|--|
| COMMERCIAL DISTRIBUTION (FORMAL) | | USE BY A SINGLE APPLICANT (CUSTOM) | |
| SOURCE (9C) | DEVICE (9A) | SOURCE (9D) | DEVICE (9B) |
| <input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT | <input type="checkbox"/> NEW <input checked="" type="checkbox"/> AMENDMENT | <input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT | <input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT |
| <input checked="" type="checkbox"/> NO SAFETY EVALUATION REQUIRED <input type="checkbox"/> NO FEES REQUIRED | | <input type="checkbox"/> LICENSING ACTION REQUIRED IF KNOWN | |
| <input type="checkbox"/> OTHER (Specify) | | <input type="checkbox"/> YES <input type="checkbox"/> NO | |

| | |
|------------------------------|---------------------------------|
| TOTAL NUMBER OF REVIEW HOURS | NOTES <i>Making Inactive</i> |
| NUMBER OF DEFICIENCY LETTERS | |
| NUMBER OF DEFICIENCY CALLS | |

FOR BILLING PURPOSES ONLY

| | | | |
|--------------------------------------|---|--|---|
| <input type="checkbox"/> NAME CHANGE | <input type="checkbox"/> ADDRESS CHANGE | <input type="checkbox"/> NEW REGISTRATION - ADD TO BILLING | <input type="checkbox"/> PRODUCT INACTIVE - REMOVE FROM BILLING |
|--------------------------------------|---|--|---|

FOR FEE USE ONLY

| | | | |
|---|---|----------------------------|--|
| TYPE OF FEE | FEE CATEGORY <input type="checkbox"/> 9A <input type="checkbox"/> 9B <input type="checkbox"/> 9C <input type="checkbox"/> 9D | | |
| AMOUNT RECEIVED | CHECK NUMBER | MATANN UPDATED AS REQUIRED | |
| DATE OF CHECK <i>Termination Request</i> | LOG <i>Nov 30 1996 SS+D</i> | MATSYS UPDATED AS REQUIRED | |
| APPROVED BY <i>SH</i> | DATE RETURN <i>11/26/96</i> | DATE | |

COMMENTS

NRC FORM 567

U. S. NUCLEAR REGULATORY COMMISSION

(8-93)

REQUEST FOR A SEALED SOURCE OR DEVICE EVALUATION

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NOTE: Retain a copy of this request with the application and background files.

| | | | |
|---|---|---|--|
| REQUESTER <i>Anders Ohlsson</i> | | REGION/LOCATION: <input type="checkbox"/> I <input type="checkbox"/> II <input type="checkbox"/> III <input type="checkbox"/> IV <input type="checkbox"/> V <input type="checkbox"/> HQ <input type="checkbox"/> LFDCB | |
| TELEPHONE NUMBER | DATE | TYPE OF ACTION REQUESTED (Check as appropriate) | |
| APPLICANT'S NAME <i>PROVALID Corp.</i> | | <input type="checkbox"/> SOURCE REVIEW <input type="checkbox"/> AMENDMENT OF REGISTRATION SHEET NUMBER(S) | |
| MAIL CONTROL NUMBER(S) | | <input type="checkbox"/> DEVICE REVIEW | |
| LETTER/APPLICATION DATE <i>11/19/96</i> | | <input type="checkbox"/> CUSTOM REVIEW <i>NR 794-D-101-B</i> | |
| LICENSE NUMBER(S) | | | |
| COMMENTS: <i>460 Spring Park Place Herndon, VA 22070</i> | | | |
| FOR SSSS USE ONLY | | | |
| REVIEWER <i>B. Smith</i> | MODEL NUMBERS <i>615 00 00</i> | NUMBER ASSIGNED <i>96-110</i> | |
| DATE RECEIVED <i>11/19/96</i> | DATE ASSIGNED <i>11/22/96</i> | DATE TO FEES <i>11/22/96</i> | |
| TYPE OF ACTION (Indicate the number of each type) | | | |
| COMMERCIAL DISTRIBUTION (FORMAL) | | USE BY A SINGLE APPLICANT (CUSTOM) | |
| SOURCE (9C) | DEVICE (9A) | SOURCE (9D) | DEVICE (9B) |
| <input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT | <input type="checkbox"/> NEW <input checked="" type="checkbox"/> AMENDMENT | <input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT | <input type="checkbox"/> NEW <input type="checkbox"/> AMENDMENT |
| <input checked="" type="checkbox"/> NO SAFETY EVALUATION REQUIRED NO FEES REQUIRED | | <input type="checkbox"/> LICENSING ACTION REQUIRED IF KNOWN | |
| <input type="checkbox"/> OTHER (Specify) | | YES NO | |
| TOTAL NUMBER OF REVIEW HOURS | | NOTES <i>Making INACTIVE.</i> | |
| NUMBER OF DEFICIENCY LETTERS | | | |
| NUMBER OF DEFICIENCY CALLS | | | |
| FOR BILLING PURPOSES ONLY | | | |
| <input type="checkbox"/> NAME CHANGE | <input type="checkbox"/> ADDRESS CHANGE | <input type="checkbox"/> NEW REGISTRATION - ADD TO BILLING | <input type="checkbox"/> PRODUCT INACTIVE - REMOVE FROM BILLING |
| FOR FEE USE ONLY | | | |
| TYPE OF FEE | FEE CATEGORY <input type="checkbox"/> 9A <input type="checkbox"/> 9B <input type="checkbox"/> 9C <input type="checkbox"/> 9D | | |
| AMOUNT RECEIVED | CHECK NUMBER | <input type="checkbox"/> MATANN UPDATED AS REQUIRED | |
| DATE OF CHECK <i>Immiration Request</i> | LOG <i>Nov 396 SS+D</i> | <input type="checkbox"/> MATSYS UPDATED AS REQUIRED | |
| APPROVED BY <i>SH</i> | DATE RETURN <i>11/26/96</i> | DATE | |
| COMMENTS | | | |

U. S. NUCLEAR REGULATORY COMMISSION
WASHINGTON DC 20555

FINAL NOTICE
BILL DATE: 08/12/96

LICENSE/APPROVAL/
REGISTRATION/
CERTIFICATE NUMBER:

NR0794D101B
RU074D101B

* ENCLOSE A COPY OF THIS BILL WITH YOUR
CHECK OR MONEY ORDER MADE PAYABLE TO:
U.S. NUCLEAR REGULATORY COMMISSION
LICENSE FEE & ACCOUNTS RECEIVABLE
P.O. BOX 954514
ST. LOUIS MO 63195-4514

* DO NOT SEND CASH
* ALLOW 5 DAYS FOR PROCESSING
* ON YOUR CHECK OR MONEY ORDER,
PLEASE INCLUDE YOUR INVOICE NUMBER
AM0717-96

TO:
PROVALID CORPORATION
RADIATION SAFETY OFFICER
(VIDAR SYSTEMS)
460 SPRING PARK PLACE
HERNDON VA 22070

NEW OR CORRECTED ADDRESS:

TOTAL AMOUNT DUE: 6,777.70
ENTER AMOUNT ENCLOSED: _____

| BILLING DOC ID | PRINCIPAL DUE | PENALTY AMOUNT |
|----------------|---------------------|-----------------|
| | ADMINISTRATIVE CHGS | INTEREST AMOUNT |
| AM0717-96 | | TOTAL |
| | 6,700.00 | 0.00 |
| | 20.00 | 57.70 |
| | | 6,777.70 |

See enclosed Termination application
11/19/96

Steve - For your consideration
for inactivation.

Sandy