Attachment C

Metorex

November 12, 1999

Mr. Fredrick Sturtz
U.S. NRC
Mailstop T8F5
11545 Rockville Pike
North Bethesda, MD 50852

Dear Mr. Sturtz:

I am writing you after speaking with Mr. Tony Kirkwood of your office on November 9, 1999. Metorex has discovered that the SUPS probe, which was registered as part of the Model 880 Analyzer in the past by Metorex's predecessors but appears to have been dropped as the registrations were revised and reissued to the succeeding distributors, is not included in Metorex's current registration and distribution license. Consequently, some previous distributions of the SUPS probe appear inconsistent with our license. We wish to correct this discrepancy as quickly as possible.

The SUPS probe was developed in the 1970's and covered by the Columbia Scientific Instruments registration for the 880, TX227D101G dated August 12, 1988 (Enclosure 1). The safety evaluation that was performed in 1979 is also enclosed (Enclosure 2). This registration and safety evaluation covered a family of probes including the HEPS, LEPS and SUPS, which were sold with the Model 880 Analyzer. Because the registration covered the analyzer and probes together, the SUPS probe was not named separately, but was described in text near the bottom of page 2 (the statement "...the shutter activating knob is depressed by placing the probe on the surface to be measured..." is understood to refer to this probe). In 1988, the registration of these probes was transferred to Princeton Gamma-Tech, Inc (PGT). The PGT registration, NR-551-D-104-B for the 820, 840 and 880 (Enclosure 3) refers to the Surface Analyzer Probe, which may have been intended to refer to this SUPS probe, or to the newer (at the time) SAPS probe which was added to the product line to replace the SUPS or both. There were a number of amendments and changes to the registration until the April 21, 1993 registration, NR-701-D-101-G (Enclosure 4), when the name of the analyzer was deleted and the specific probe names were registered. Although the SUPS was one of the original probes and was still being distributed at the time, it was not included among the probes specifically listed. Because of changes in personnel, we have been unable to determine why it was omitted. This last registration was issued to Outokumpu Electronics Inc. Outokumpu has since been succeeded by Metorex as the listed distributor and the registration has been further amended to reflect the change. Our

METOREX INC.
Princeton Crossroads Corporate Center • 250 Phillips Boulevard • Ewing, New Jersey 08618 • 1-609-406-9000 • Fax 1-609-530-9055

Metorex

license authorizes the distribution of the probes identified on the current registration, though it also continues to authorize the model 880 analyzer which originally included the SUPS probe.

Our records indicate that SUPS probes were sold in the 1991 to 1998 time frame and that 15 units are currently possessed and used by three customers. At this time, I would request your guidance on the appropriate actions we should take. Can our registration statement and distribution license be amended, based on the original registration, to restore the SUPS probe to the list of devices we are authorized to distribute, or is a further application necessary? In the interim, what actions should we take with respect to customers currently possessing these devices?

If you have any questions, please contact me at (609) 406-9000, ext. 122 or by email at John.Patterson@MetorexUSA.com. I would like to resolve this matter as quickly as possible.

Sincerely,

John I.H. Patterson, Ph.D.
President

JIHP/jlr

Enc 1

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO TX227D101G DATE: August 12, 1988 PAGE 1 OF 4

DEVICE TYPE: Portable X-Ray Analyzer

MODEL: 880

MANUFACTURER/DISTRIBUTOR: Columbia Scientific Industries Corp.
11950 Jollyville Road
Austin, Texas 78759

SEALED SOURCE MODEL DESIGNATION: various, see table in description

ISOTOPE:	MAXIMUM ACTIVITY:
Fe-55	40 mCi.
Cm-244	100 mCi.
Cd-109	20 mCi.
Am-241	30 mCi.

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: X-Ray Fluorescence

CUSTOM DEVICE: _____ YES __X__ NO

CUSTOM USER:

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: TX227D1010 DATE: August 12, 1988 PAGE 2 OF 4

DEVICE TYPE: Portable X-Ray Analyzer

DESCRIPTION: The Model 880 device consists of an enclosure-carrying case, a readout unit, and can use any one of six probes. The only difference between the Model 840 and the Model 880 is the electronics in the enclosure-carrying case. Six probes are the Surface Probe, the Laboratory (Sample) Probe, the Light Element Surface Probe, the Light Element Probe, the Model HEPS 2171 Probe and the Model LEPS 2172 Probe. Each probe has a capacity of one sealed radioactive source. The Light Element Probes and the LEPS 2172 Probe are identical to the Laboratory Sample Probe, the Surface Probe and the HEPS 2171 Probes, except that an annular Fe-55 source is used to reduce the detector gap. A seventh probe (the DOPS probe, or Dual Source Surface Probe) has been designed to operate with either the Model 840 or 880 and uses a combination of two of the authorized sources.

In the case of the Laboratory Sample Probe, the Light Element Sample Probe, and the Light Element Probe, the shutter activating knob is not accessible to the operator and can only be depressed by closing the cover. The Model HEPS 2171 and LEPS 2172 are similar to the above probes except that the sample holder (cover) can be moved manually between the "measurement" position and the "reference" position. In the "measurement" position the cover cannot be opened and the sample is directly over the the source. The cover can be locked with a key-lock when in the "measurement" position. By sliding the cover to the "reference" position, the cover may be opened to change samples and the source is covered by the "reference standard". When the cover is open it is mechanically impossible to expose the source. In the case of the Surface Probe, the shutter activating knob is depressed by placing the probe on the surface to be measured. The "New Surface Probe" shutter is activated by squeezing the trigger mechanism in the probe handle. All probes have an electrical interlock that indicates the status of the probe. Radioactive material authorized for these probes are listed in the table below:

Isotope	Maximum Activity	Model By Manufacturer: Amersham	Isotope Products	New England Nuclear
Fe-55	10 mCi.	------	XFB series	NER-460A
Fe-55	40 mCi.	IEC.A1	----------	---------
Cm-244	100 mCi.	CLCL	XFB series	---------
Cd-109	20 mCi.	CUC.D1 or CUC.D1N	XFB series	NER-465
Am-241	10 mCi.	------	XFB series	NER-478
Am-241	30 mCi.	AMC.D2	-----	---------

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: TX227D101G DATE: August 12, 1988 PAGE 3 OF 4

DEVICE TYPE: Portable X-Ray Analyzer

The DOPS Probe is a surface probe and is very similar to the SAPS Probe. The main difference is that the DOPS Probe can contain two sources and the SAPS Probe can contain only one. This is accomplished by installing the sources on a source holder inside a movable changer/shutter mechanism. When source 1 is selected the dual source holder is kept inside the fixed part of the changer/shutter mechanism when the shutter is opened. This exposes source 1. When source 2 is selected the dual source holder moves with the movable part of the changer/shutter mechanism and exposes source 2 when the shutter is opened.

LABELING: A conventional radiation symbol is affixed to both the probe and the outside of the instrument case. The labels also state the isotope, the activity, date assayed and model number.

EXTERNAL RADIATION LEVELS: The radiation levels about the device are extremely low or negligible under normal operations; however, higher readings can be found in the beam should the shutter be purposefully opened. The readings never exceed 0.3 mR/hr at the beam port when the shutter is in the open position with a 0.3 inch thick steel sample in place. The licensee discovered that the Cm-244 sources obtained from the source manufacturer contain impurities which emit high energy gamma rays. The two probes (SAPS and HEPS) which can contain this isotope were surveyed and it was discovered that radiation levels higher than previously measured were present when other Cm-244 sources (containing larger amounts of the impurities) were installed. The new surveys show that radiation levels now approach 1.4 mR/hr at the beam port for these two probes. Since this is still considered a relatively low radiation field, no further requirements were placed on the licensee.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE: The manufacturer provides operating instructions that state that the sources should be leak tested every six months. Source exchange should be accomplished by the manufacturer unless the (specifically licensed) customer has received specific training in performing the exchange and relabeling of the device.

SAFETY ANALYSIS SUMMARY: This device has been found to be safely operable and will pose no radiation hazard when used according to the manufacturer's procedures.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO: TX227D101G DATE: August 12, 1988 PAGE 4 OF 4

DEVICE TYPE: Portable X-Ray Analyzer

REFERENCES: This document was prepared with information provided by letters and attachments from Columbia Scientific Instruments, dated November 19, 1979, April 4, 1984, August 20, 1984, January 28, 1987, April 24, 1986, July 8, 1986, May 27, 1987, May 24, 1988 and July 25, 1988, and information submitted on June 26, 1987.

DATE: August 12, 1988 REVIEWED BY: Boyd K. Schmitt

ISSUING AGENCY: Texas Department of Health
Bureau of Radiation Control

Enc 2

INSTITUTE OF RADIATION PROTECTION
Inspection Department

TYPE INSPECTION RECORDS

The personnel using radiation must be informed of the contents of these inspection records.

1980 -01- 24

DN:o 1706/321/79

Helsinki, November 19, 1979

Equipment:	Probes of X-MET X-Ray Fluorescence Analyzer Heavy Elements Probes HEPS-0462 and HEPS-0482 Light Elements Probes LEPS-0463 and LEPS-0483 Surface Probes SUPS-0464 and SUPS-0484
Manufacturer:	Outokumpu Oy, Technical Export Division P.O.Box 27, SF-02201 ESPOO 20, Finland
Date and Place of Inspection:	October 24, 1979 Outokumpu Oy, Espoo

On inspection following statements were made:

1. All the probes include a closed radioactive radiation source. The quality of the radiation sources used in the probes, manufacturer and type of capsule have been presented in the attached table. In the light elements probe only a ^{55}Fe radiation source is used.

2. The construction of radiation shielding of the probes has been presented in Figs. Nos. 801019-3 QE (Light elements probe radiation shielding), 800995-3 QE (Heavy elements probe radiation shielding) and 800994-3 QE (Surface probe radiation shielding). The probes have been equipped with a shutter, which is on the radiation source, if the lid of the sample cell of the heavy elements or light elements probe is open or the press-button under the surface probe is out. The thickness and composition of the shutter to be used with each radiation source has been presented in the attached table.

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A4 75-2658b/4

Postadress
P.O. BOX 268
00101 HELSINKI 10
FINLAND

Telephone
659588

Telex
122691 STL-SF

3. Following results were obtained from the radiation rate measurements made:

- from above the shutter	a ^{244}Cm source	1.4 mR/h
- from above the shutter	other sources	< 0.7 "
- from the sides of the probe		< 0.4 "
- from a distance of 10 cms from the probe		< 0.1 "

4. The surface probe has to be kept either on the case for calibration standards or in the fastener on the carrying case.

5. The probe must bear a label with radiation hazard sign, indication of the radioactive element and activity of radiation source and a statement that the equipment may be opened only by an authorized person.

6. A safety licence must be obtained for each equipment, but they need not be inspected on the site of usage.

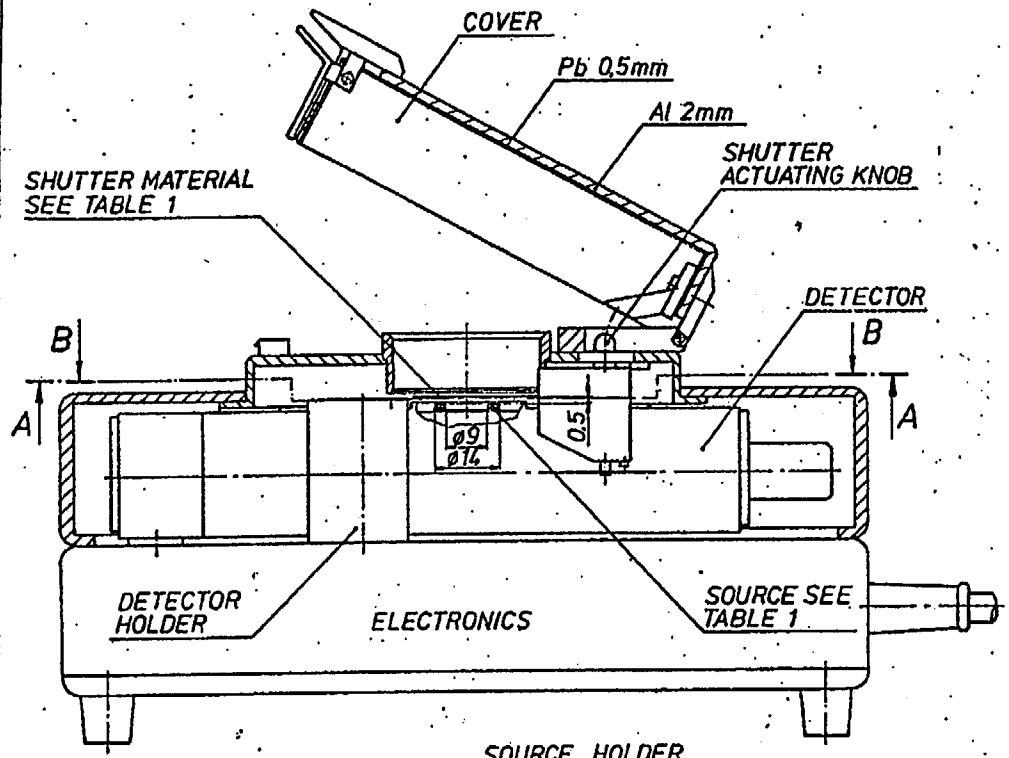
7. When the probe is finally removed from usage, the radiation source must be returned to the manufacturer of the equipment or the radiation safety authorities.

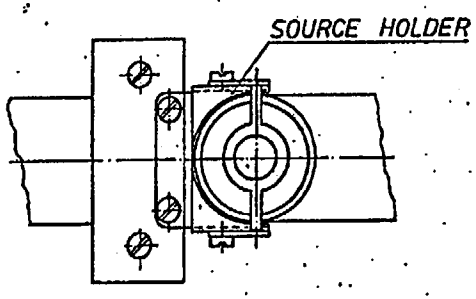
Inspector Seppo Väisälä

ENCLS: Table (Radiation Shielding)
Drawing No. 801019-3QE
Drawing No. 800995-3QE
Drawing No. 800994-3QE

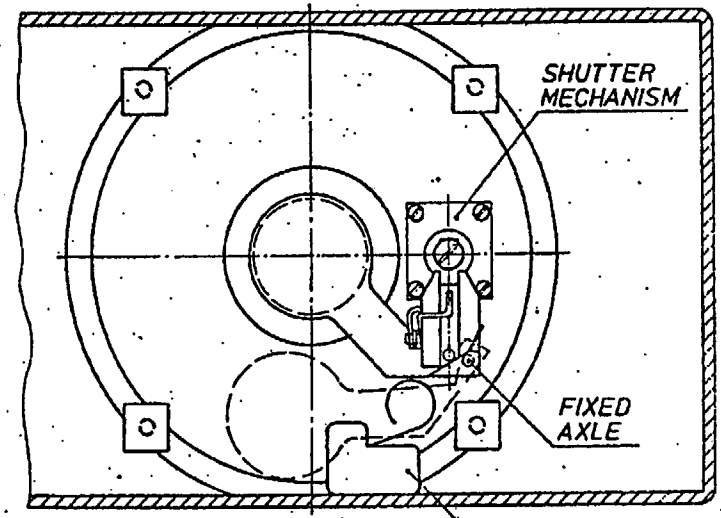
RADIATION SHIELDING TABLE 1

Radioact. material	Maximum activity mCi	Identification number: Isotope products labs. Number	Capsule	The Radiochemical Centre Number	Capsule	Shutter material
Cd^{109} - accelerator grade	10	PH109-10	XFB-3	CUC.13055	X130/5	1 mm Pb or 0.5 mm Mo + 0.5 mm Pb or equivalent
Cm^{244}	30	PH244-30	XFB-3	CLC.13044	X130/4	1 mm Pb or 0.5 mm Cu + 0.5 mm Pb or equivalent
Pu^{238}	30			PPC.13145	X130/4	- " - - " -
Am^{241}	10	PH241-10	GFS-3	AMC.64	X10/0	2 mm Pb or 1.5 mm Pb + 0.5 mm Mo or equivalent
Fe^{55}	30			Custom made IECQ 2810		0.2 mm Ti or equivalent





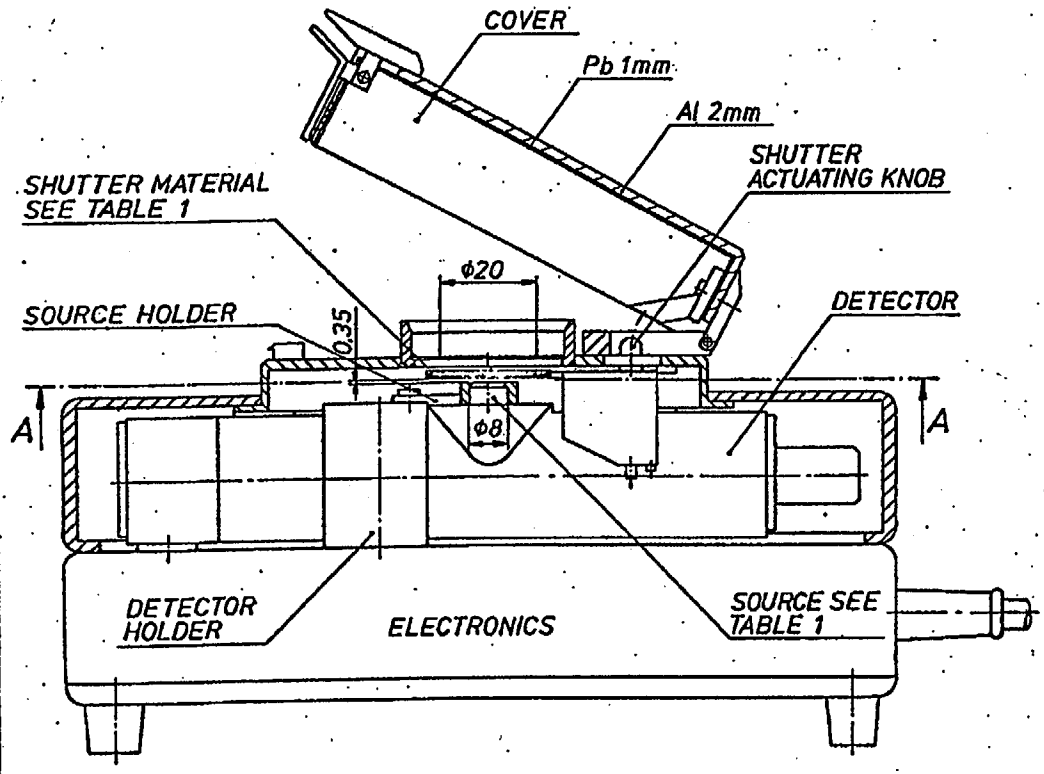
SECTION B-B

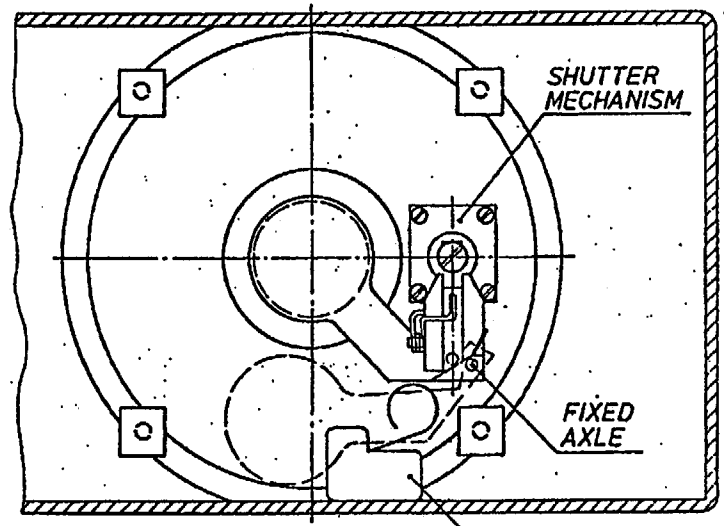


SECTION A-A

Aine Material		Yleiset. Toleranssi		Suunn. Design. 7908VI-K	Piirt. Drawn 7910 IJ
Pinta Surface		Pinnat. Finish		Tark. Check.	Hyv. App.
	Suhde Scale 1:1	Liittyy Next Assy		Osal.s.o Part list	
OUTOKUMPU OY ESPOO FINLAND		LIGHT ELEMENTS PROBE			
		RADIATION SHIELDING		801 019 – 3QE	

Päiväys	Muutoksia	Tarkastaja	Muutos	Lukumäärä	Merkki



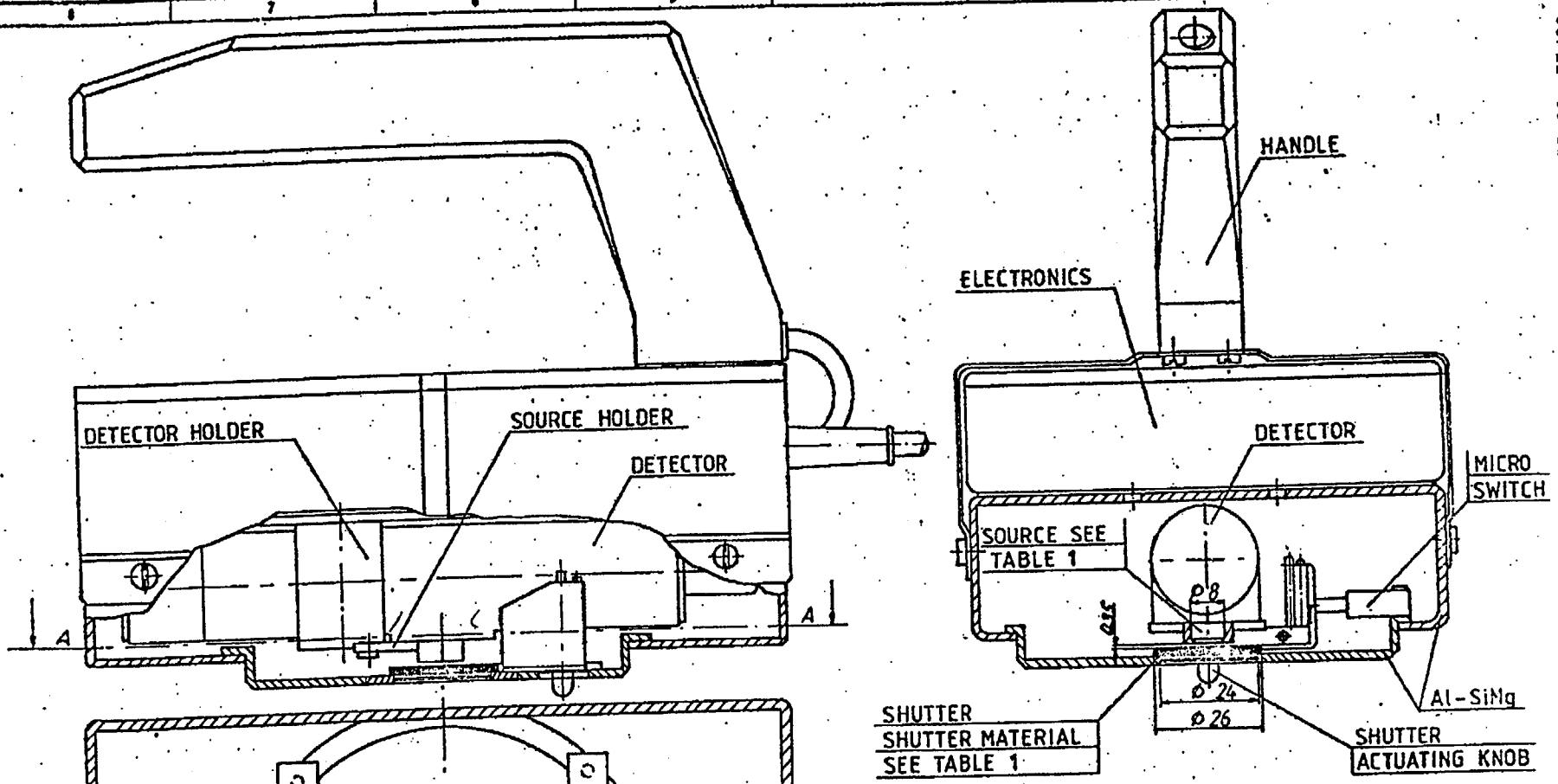


SECTION A-A

SÄTEILYTURVALLISUUSLAITOS
Tarkastettu
Tarkastettu
1706/321/79 SLV

Alus Material		Yleistol. Tolerances		Suunn. Design. 7908VI-K	Piirt. Drafteen. 7908SLM
Pinta Surface		Pintak. Finish		Tark. Check.	Hyv. App.
	Suhde Scale 1:1	Liittyy Next Assy		Osaluo Part list	
OUTOKUMPU OY ESPOO FINLAND		HEAVY ELEMENTS PROBE			
		RADIATION SHIELDING		800 995 – 3QE	

Päiväys	Muutoja	Tarkastaja	Muutos	Lehtimerkki	Merkki



SECTION A-A

Alm. Material	Yleistol. Toleranssi	Suunn. Design.	Pvm. Datum
Pinta Surface	Pinnat. Finish	Tark. Check	Hyv. App.
Mittak. Scale 1:1	Liittyy Next Assy	Osa.no Part No	
OUTOKUMPU OY TAPIOLA FINLAND	SURFACE PROBE RADIATION SHIELDING		800 994 - 3QE

Enc 3

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-551-D-104-B DATE: DEC 2 0 1988

DEVICE TYPE: X-Ray Fluorescence Analyzer

MODEL: 820, 840, and 880

DISTRIBUTOR: Princeton Gamma-Tech, Inc.
1200 State Road
Princeton, NJ 08540

MANUFACTURER: Outokumpu Electronics
P.O. Box 85
SF-02201
Espoo, Finland

SEALED SOURCE MODEL DESIGNATION: See Table in Description Section

ISOTOPE:	MAXIMUM ACTIVITY:
Americium-241	30 millicuries
Cadmium-109	20 millicuries
Curium-244	100 millicuries
Iron-55	80 millicuries

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (U) X-Ray Fluorescence

CUSTOM DEVICE: _____ YES ___X___ NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-551-D-104-B DATE: DEC 2 0 1988

DEVICE TYPE: X-Ray Fluorescence Analyzer

DESCRIPTION:

The Models 820, 840, and 880 X-Ray Fluorescence Analyzers are similar devices, designed to perform element analysis of materials, that are used in different environments. The Model 820 is designed to be used in a laboratory and/or industrial plant while the Model 840, and 880 are portable and designed to be used in field environs as well as a laboratory.

The Model 840 Analyzer is a portable device that is comprised of an electronic unit and any of three probes; the Surface Analyzer Probe, Laboratory Sample Probe or Light Element Sample Probe. Each probe is approximately 6.7 inches (width) x 4.4 inches (depth) x 4.1 inches (height) and weighs approximately 4 pounds. A probe consists of the radioactive source, source holder, proportional counter and detector electronics in one unit (see Attachment 1).

The Model 880 Analyzer is essentially the same as Model 840 Analyzer with the exception that it has a back lit display allowing for better viewing of the LCD displayed data. Also the Model 880 has a keyboard which is easier to operate and has a new improved software package which allows the system to be interfaced with an IBM PC or compatible computer. The overall dimensions for this model are the same as those of model 840.

The Model 820 Measures 22.4 inches (width) x 14.6 inches (depth) x 4.3 inches (height) and weighs 16.5 pounds. The outer shell or frame of the device is constructed of a combination of Zinc (88%) and Aluminum (12%). To use the Model 820 the top cover is lifted (see Attachment 2), the sample is inserted, the cover is closed and then the sample can be analyzed. The cover can be opened only when the sample holder has been drawn to the front position. This position is shown by an indicator on the cover. The Model 820 can use either a HEPS or LEPS laboratory probe. The HEPS probe is used for analysis of heavy elements and contains either a Curium-244, Cadmium-109 or Americium-241 source. The LEPS probe is used for analysis of light elements and contains an Iron-55 source. These probes are identical, with the exception of an additional 1 mm lead shielding on the base, to the probes used with the Model 840, and may be changed by the user.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-551-D-104-B DATE: DEC 2 0 1988

DEVICE TYPE: X-Ray Fluorescence Analyzer

DESCRIPTION (CONT.):

Radioactive material authorized for these probes are listed in the table below:

SOURCE	MAXIMUM ACTIVITY	MODEL BY MANUFACTURER		
		AMERSHAM	NEW ENGLAND NUCLEAR	ISOTOPE PRODUCTS
Iron-55	80 millicuries	IEC.A1	NER-460 A	XFB
Curium-244	100 millicuries*	CLCL		XFB
Cadmium-109	20 millicuries	CUC.D1	NER-465	XFB
Americium-241	30 millicuries	AMC.D2	NER-478	XFB

* 50 millicuries for Model XFB.

LABELING:

The manufacturer/distributor states that each source housing will be labeled in accordance with the requirements of 10 CFR 20.203.

Devices intended for distribution to persons generally licensed will be labeled in accordance with the requirements of 10 CFR 32.51.

DIAGRAM:

See Attachments 1 and 2.

CONDITIONS OF NORMAL USE:

The Model 820 device is used in a laboratory type environment to perform element analysis of materials. The Model 840 and 880 device are designed to be portable and used in industrial plant environs as well as outdoor field environs (i.e., agricultural and mineral exploration). The expected useful lifetime of each device is 10 to 15 years.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-551-D-104-B DATE: DEC 2 0 1988

DEVICE TYPE: X-Ray Fluorescence Analyzer

PROTOTYPE TESTING:

The sealed sources used in the device have achieved the ANSI N542 rating given in the table below:

MANUFACTURER	MODEL NO.	ANSI RATING
Amersham	IEC.A1	77C33232
Amersham	CLCL	77C54444
Amersham	CUC.D1	68C44344
Amersham	AMC.D2	77C64545
New England Nuclear	NER-460 A	68C32212
New England Nuclear	NER-465	68C33232
New England Nuclear	NER-478	68C43333
Isotope Products	XFB	68C32323

Please note that these devices have been approved by the state of Texas for Columbia Scientific Inc. and there have been no reports of equipment failure.

EXTERNAL RADIATION LEVELS:

Princeton Gamma-tech reports that the highest dose rates exhibited by any of the probes of either the Model 820, 840 or 880 are 0.2 mR/hr at 5 cm. and 0.05 mR/hr at 30 cm.

QUALITY ASSURANCE AND CONTROL:

Outokumpu Electronics has in place an adequate organizational structure and sufficient personnel to assure that their Quality Assurance System can be effectively maintained.

The Quality Assurance System covers the following subjects:

1) Quality Assurance Organization;
2) General Quality Assusrance Policy;
3) Incoming Inspections and Vendor Qualifications;
4) Test Procedures;
5) Personnel Training;
6) Non-Conforming Items Policy (Rejects);
7) Document Control;
8) Final Testing;
9) Quality Audits and Reports.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: NR-551-D-104-B DATE: DEC 2 0 1988

DEVICE TYPE: X-Ray Fluorescence Analyzer

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- Devices distributed to persons that are specifically licensed by the NRC or an Agreement State shall be labeled in accordance with the requirements of Section 20.203, 10 CFR 20 or equivalent provisions of an Agreement State.

- Devices distributed to persons that are generally licensed pursuant to section 31.5, 10 CFR Part 31, or equivalent provisions of an Agreement State shall be labeled in accordance with the requirements of Section 32.51(a)(3), 10 CFR Part 32, or equivalent provisions of an Agreement State.

- All labels required by this registry sheet and 10 CFR 32.51(a)(3) and 20.203 must be durable and clearly visible to the user at all times.

- This registration sheet and the information contained with the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

Based on our review of the information submitted and test data cited below, we continue to conclude that Princeton Gamma-Tech, Inc. has 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 device, and it is unlikely that any person will receive in any period of one calendar quater a dose in excess of 10 percent of the limits specified in the table in Section 20.201(a), 10 CFR 20.

- Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any persons would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified below.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO: NR-551-D-104-B DATE: DEC 2 0 1988

DEVICE TYPE: X-Ray Fluorescence Analyzer

SAFETY ANALYSIS SUMMARY (CONT.):

PART OF BODY	REM
Whole body; head and trunck active blood-froming organs; gonads; or lens of eye	15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	200
Other organs	50

Futhermore, we would expect the device to maintain its containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REFERENCES:

The following supporting documents for the Models 820, 840, and 880 X-Ray Fluorescence Analyzers are hereby incorporated by reference and are made a part of this registry document.

- Princeton Gamma-Tech, Inc. letters dated December 30,1985, January 15, 1987, May 18, 1987, June 12, 1987, and May 5, 1988.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

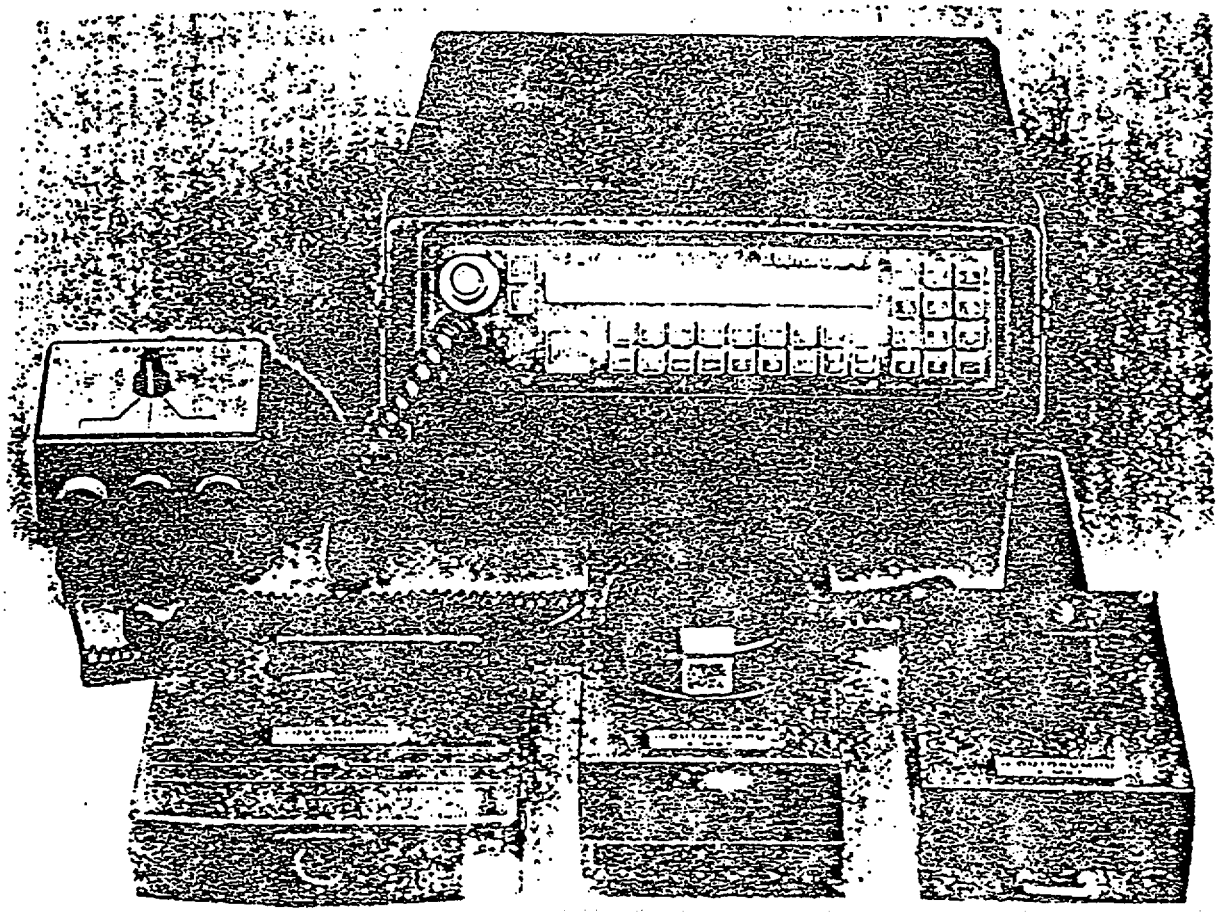
Date: DEC 2 0 1988 Reviewer: [signature]

Date: DEC 2 0 1988 Concurrence: Stuart W Bell

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-551-D-104-B DATE: DEC 2 0 1988 ATTACHMENT 1

Model 840



Enc 4

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-701-D-101-G DATE: April 21, 1993

DEVICE TYPE: X-Ray Fluorescence Probe

MODELS: HEPS, LEPS, DOPS, SAPS, SSPS, SLPS Probes
(Formerly 820, 840, 880)

DISTRIBUTOR:

Outokumpu Electronics, Inc.
860 Town Center Drive
Langhorne, PA 19047

MANUFACTURER:

Outokumpu Electronics
P.O. Box 85
SF-02201
Espoo, Finland

SEALED SOURCE MODEL DESIGNATION: Various; See Table in Description Section

ISOTOPE:	MAXIMUM ACTIVITY:
Americium-241	30 mCi (1.11 GBq)
Cadmium-109	20 mCi (0.74 GBq)
Curium-244	100 mCi (3.70 GBq)
Iron-55	80 mCi (2.96 GBq)

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (U) X-Ray Fluorescence

CUSTOM DEVICE: _____ YES ____X____ NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: X-Ray Fluorescence Probe

DESCRIPTION:

The Models DOPS, HEPS, LEPS, SAPS, SLPS, and SSPS X-ray Fluorescence Probes are devices designed to perform element analysis of various materials in different environments. The probes are designed for use in laboratory or industrial plant environs or under field conditions. The Models HEPS, LEPS, SAPS, and SLPS probes are the same probes which were previously registered by Princeton Gamma Tech with the 820, 840, and 880 X-ray Fluorescence Analyzers. The Model DOPS has been previously registered for Columbia Scientific by the State of Texas with the Model 880 X-ray Fluorescence Analyzer. The Model SSPS is a new probe which operates similar to the SAPS probe, but using two sources. The previously registered Models 820, 840, and 880 X-ray Fluorescence Analyzers included the probes as well as an external analyzer. The Models 820, 840, and 880 analyzers contain a power supply and controlling electronics and perform an analysis of data received from the probes. These analyzers contain no radioactive material. The probes may be used with the models 820, 840, or 880 analyzers or attached to a personal computer (PC) containing software developed by the manufacturer. The manufacturers PC based software operates the probes in the same manner as the analyzers. The probes will be plugged directly into the PC via an expansion card installed in the PC. No modification to the probes is necessary for use with the PC based system.

Each of the Models DOPS, HEPS, LEPS, SAPS, SLPS, and SSPS probes contain one or two radioactive sources. There are two general categories of probes; the laboratory sample type probe and the surface analysis type probe. A laboratory sample type probe contains a sample chamber into which discrete samples are placed in order to perform elemental analysis. This type of probe may be either a Light Elements Probe System (LEPS) or a Heavy Elements Probe System (HEPS). A surface analysis type probe is physically placed on the surface of an object in order to perform elemental analysis of the object or materials within the object. This type of probe may be either a Surface Analysis Probe System (SAPS), a Surface Analysis Probe System for Light Elements (SLPS), a Solid State Probe System (SSPS), or a Dual Source Surface Probe (DOPS).

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: X-Ray Fluorescence Probe

DESCRIPTION: (Cont'd)

Laboratory sample type probes contain a radioactive source (Am-241, Cd-109, or Cm-244 for the HEPS or Fe-55 for the LEPS), a sample chamber, a chamber cover, a slide or shutter mechanism, shielding and associated electronics. The probes measure approximately 3.25" (8.3 cm) wide by 6.5" (16.5 cm) long by 3.5" (8.9 cm) high. Older laboratory sample type probes employ an automatic shutter mechanism to shield the source when not in use. Whenever a sample is placed in the sample chamber and the sample lid is closed, the shutter is automatically withdrawn to allow for irradiation of the sample. Characteristic X-rays given off by the sample are detected by the probes and analyzed either by a Model 820, 840, or 880 analyzer or by the PC software. The shutter is automatically moved to the shielded position by a return spring whenever the sample lid is opened.

Newer laboratory sample type probes employ a slide mechanism in order to shield the source during sample change. Operation of the probe consists of opening the sample cover, inserting a sample, closing the sample cover and sliding the sample into the measurement position. Sliding the sample into the measurement position exposes the source which irradiates the sample. Once the analysis is complete, the sample chamber is drawn back to the sample change position and the cover can be lifted and the sample withdrawn. This action automatically shields the source. The design of the probe ensures the cover cannot be lifted unless the sample is in the change position.

Surface analysis type probes are used only with the Models 840 and 880 analyzers or the PC based system. These probes vary in shape, shutter mechanism and number of sources used, but operate using similar principles. The basic operation of these probes is to place the sample window of the probe on the object to be analyzed, expose the source, detect characteristic x-rays given off by the object and analyze these x-rays to determine the elemental makeup of the object.

DEVICE TYPE: X-Ray Fluorescence Probe

DESCRIPTION: (Cont'd)

The SAPS probe contains a single source (either Am-241, Cd-109 or Cm-244), a shutter mechanism, and associated electronics. The probe measures approximately 2" (5.1 cm) wide by 8" (20.3 cm) high by 6" (15.2 cm) deep and is contained within a Zinc (88%) and Aluminum (12%) shell. A trigger and lever system mechanically operates the shutter mechanism. Source position is indicated by a flag in a window on the side of the probe (green for secured, red for exposed).

The SLPS contains a single source (Fe-55), an automatic mechanical shutter mechanism, and associated electronics. Operation of the probe consists of placing the probe on the surface of the object to be analyzed. This action depresses a microswitch plunger located on the bottom of the probe which, in turn, rotates the shutter to the irradiate position. The shutter is automatically moved to the shielded position by a return spring whenever the probe is removed from the sample surface. This shutter assembly is the same as the one used with the older laboratory sample type probes. The probe measures approximately 3.3" (8.3 cm) wide by 6.5" (16.5 cm) long by 3.5" (8.9 cm) high and is contained within a Zinc (88%) and Aluminum (12%) shell.

The SSPS contains two sources (Am-241, Cd-109, or Fe-55), dual shutter mechanisms operated by dual liquid nitrogen pneumatic systems, a liquid nitrogen dewar, and associated electronics. The probe measures approximately 9.25" (23.5 cm) long by 4" (10.3 cm) wide by 9.75" (24.8 cm) high. Operation of the probe consists of the operator selecting the source or sources to be used, placing the radiation window on the surface to be analyzed, and pulling the trigger. An electro-mechanical valve for source number one allows compressed nitrogen gas to enter a pneumatic cylinder which pushes the source into the measurement position. Once the surface has been irradiated for the appropriate time interval the pneumatic cylinder is vented and a return spring pushes the source back into the shielded position. Once source number one is secured, source number two is moved to the measurement position in the same manner using an independent, identical pneumatic system. If desired, the operator may elect to irradiate the surface using only one source.

DEVICE TYPE: X-Ray Fluorescence Probe

DESCRIPTION: (Cont'd)

Sources may be moved to the measurement position only if there is sufficient liquid nitrogen in the dewar and only if external power is applied. Source position is indicated by two windows (one for each source on either side of the probe). Green indicates source secured while red indicates source exposed. Source position is additionally indicated by an LED indicator on the probe handle. This LED lights whenever either source is exposed.

The SSPS probe may be used with an optional sample chamber which can be attached to the bottom of the device. This sample chamber is used by inverting the probe, connecting the sample cover, placing the sample on the radiation window, closing the sample cover, and pressing the start button. Operation of the probe is not affected in this configuration.

The DOPS contains two sources (Am-241/Cm-244, Cd-109/Am-241, or Cd-109/Fe-55), an automatic shutter mechanism which sequentially exposes each source for a specific time period, and associated electronics. The probe measures approximately 2" (5.1 cm) wide by 8" (20.3 cm) high by 6.5" (16.5 cm) long. Operation of the probe consists of selecting the source or sources to be used, placing the radiation window on the surface to be analyzed, and pulling the trigger. The probe shutter mechanism consists of a two-piece shutter (one piece fixed and one piece movable) and a movable source holder. Pulling the trigger causes a mechanical linkage to slide the movable shutter and source holder in unison into a configuration which exposes source number one.

Once the surface has been irradiated for the appropriate time interval, a microswitch releases the source holder which slides back to its original position. This action shields source number one and exposes source number two. Once the surface has been irradiated for the appropriate time interval, a microswitch releases the movable shutter which slides back into its original position, shielding source number two.

When used with a Model 820 analyzer, a LEPS and/or HEPS probe is built into the analyzer body. The construction of each probe is not modified for this type of application.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: X-Ray Fluorescence Probe

DESCRIPTION: (Cont'd)

Sources and maximum activities are authorized for use in the probes as listed in the tables below:

ISOTOPE	MAXIMUM ACTIVITY	MODEL BY MANUFACTURER AMERSHAM	DuPont Mereck	ISOTOPE PRODUCTS
Iron-55	80 mCi/3.0 GBq*	IEC.A1	NER-460 A	XFB
Curium-244	100 mCi/3.7 GBq*	CLCL		XFB
Cadmium-109	20 mCi/0.7 GBq	CUC.D1	NER-465	XFB
Americium-241	30 mCi/1.1 GBq	AMC.D2	NER-478	XFB

* 50 mCi/1.9 GBq for Model XFB.

ISOTOPE	MAXIMUM ACTIVITY BY PROBE TYPE (mCi/GBq) SLPS	LSP*	SAPS	DOPS	SSPS
Iron-55(annular)	40/1.5	80/3.0	---	40/1.5	40/1.5
Iron-55(disc)	10/0.4	10/0.4	10/0.4	---	---
Curium-244	100/3.7	100/3.7	100/3.7	100/3.7	---
Cadmium-109	20/0.7	10/0.4	20/0.7	20/0.7	20/0.7
Americium-241	30/1.1	10/0.4	30/1.1	30/1.1	30/1.1

* Laboratory Sample Probe; includes LEPS and HEPS

LABELING:

Each probe will contain an identification label which includes the probe type and serial number, source serial number, isotope, activity and date of assay. Additionally the devices will contain a general license label in accordance with the requirements of 10 CFR 32.51.

DIAGRAM:

See Attachments 1, 2, and 3.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: X-Ray Fluorescence Probe

CONDITIONS OF NORMAL USE:

The probes are designed for use in various environments including laboratories, industrial plants, and outdoor field uses (e.g., agricultural and mineral exploration). The probes may be used in portable and fixed applications. The probes are not expected to be subjected to corrosive atmospheres, excessive vibration, or extreme temperatures due to the fact that the devices require the operator to be present for operation. The manufacturer states that the expected useful lifetime of each probe is 10 to 15 years.

PROTOTYPE TESTING:

The sealed sources used in the probes have achieved ANSI classifications as shown below:

MODEL NO.	ANSI RATING
IEC.A1	77C33232
CLCL	77C54444
CUC.D1	68C44344
AMC.D2	77C64545
NER-460 A	68C32212
NER-465	68C33232
NER-478	68C43333
XFB	68C32323

The DOPS and SSPS probes were subjected to shutter reliability tests which continuously operated the shutter mechanism for more than 100,000 cycles for the DOPS probe and 250,000 cycles for the SSPS probe. The manufacturer reported no appreciable wear or problems associated with the operation of the shutter mechanisms following the tests.

These probes (excluding the SSPS) have been approved by the state of Texas for Columbia Scientific, Inc., since 1988 with no reported equipment failures.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: X-Ray Fluorescence Probe

EXTERNAL RADIATION LEVELS:

Outokumpu Electronics reports that the highest dose rates exhibited by any of the probes are 0.2 mR/hr (2 μSv/hr) at 1.97" (5 cm). and 0.05 mR/hr (0.5 μSv/hr) at 11.8" (30 cm).

QUALITY ASSURANCE AND CONTROL:

Outokumpu Electronics has agreed to abide by the quality assurance and control standards previously submitted by Princeton Gamma-Tech, and found to be adequate by the Source Containment and Devices Branch of the NRC. These Quality Assurance standards cover the following areas:

1) Quality Assurance Organization;
2) General Quality Assurance Policy;
3) Incoming Inspections and Vendor Qualifications;
4) Test Procedures;
5) Personnel Training;
6) Non-Conforming Items Policy (Rejects);
7) Document Control;
8) Final Testing;
9) Quality Audits and Reports.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The probes are intended for distribution to persons generally licensed pursuant to Section 31.5, 10 CFR Part 31, and must be initially transferred in accordance with the requirements of Section 32.51, 10 CFR Part 32 or equivalent provisions of an Agreement State.

- The probes shall be tested for leakage at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.

- The probes shall be initially tested for proper operation of the source exposure mechanism, safety warning components, labels, external radiation levels and leak tested by Outokumpo Electronics, Inc., or other persons specifically licensed by the NRC or an Agreement State.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: X-Ray Fluorescence Probe

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE: (Cont'd)

- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

Based on our review of the information submitted and test data cited below, we conclude that Outokumpu Electronics, Inc., has provided reasonable assurance that:

- The probes 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 device, and it is unlikely that any person will receive in any period of one calendar quarter a dose in excess of 10 percent of the limits specified in the table in Section 20.201(a), 10 CFR 20.
- Under accident conditions (such as fire and explosion) associated with handling, storage and use of the device, it is unlikely that any persons would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified below.

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 (0.5 Sv)

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: X-Ray Fluorescence Probe

SAFETY ANALYSIS SUMMARY: (Cont'd)

Furthermore, we would expect the probes to maintain their containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REFERENCES:

The following supporting documents for the Models DOPS, HEPS, LEPS, SAPS, SLPS, and SSPS X-Ray Fluorescence Probes are hereby incorporated by reference and are made a part of this registry document.

- Princeton Gamma-Tech, Inc. letters dated December 30,1985, January 15, 1987, May 18, 1987, June 12, 1987, and May 5, 1988.
- Outokumpu Electronics, Inc. letters dated February 8, 1991, September 12, 1991, February 3, 1992, October 9, 1992, December 18, 1992, December 30, 1992, February 22, 1993, and March 29, 1993, with enclosures thereto.

ISSUING AGENCY:

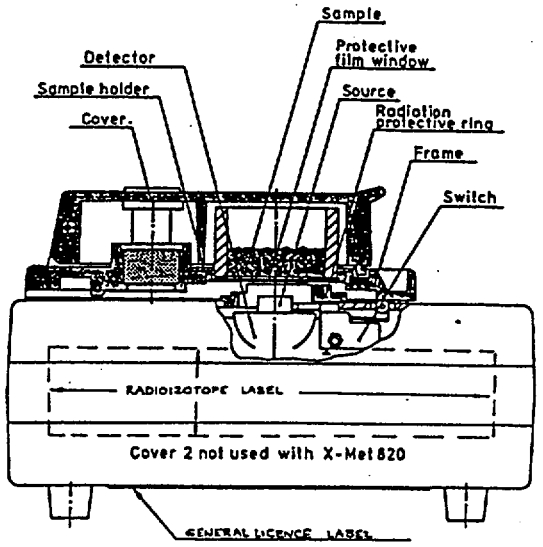
U.S. Nuclear Regulatory Commission

Date: April 21, 1993 Reviewer: Douglas A. Broaddus

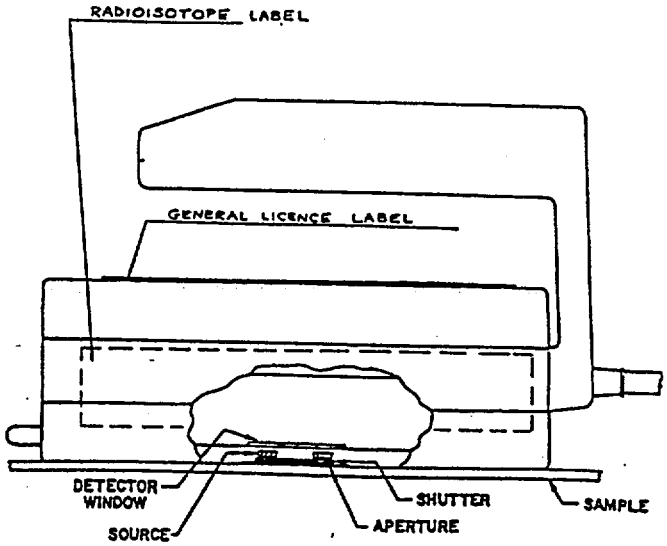
Date: April 21, 1993 Concurrence: Thomas W. Rich

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-701-101-G DATE: April 21, 1993 ATTACHMENT 1



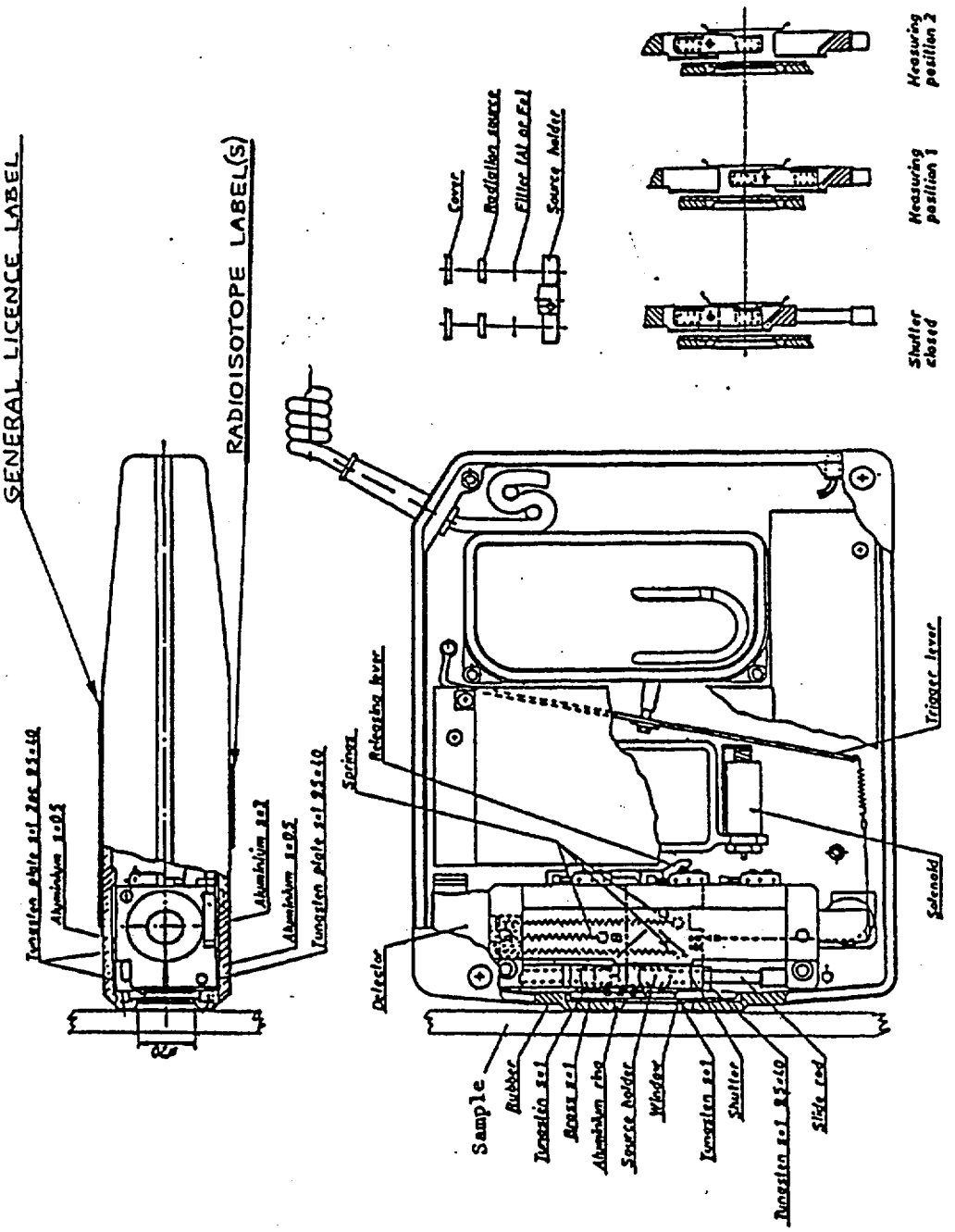
Model HEPS Probe (LEPS Probe Similar)



Model SLPS Probe

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

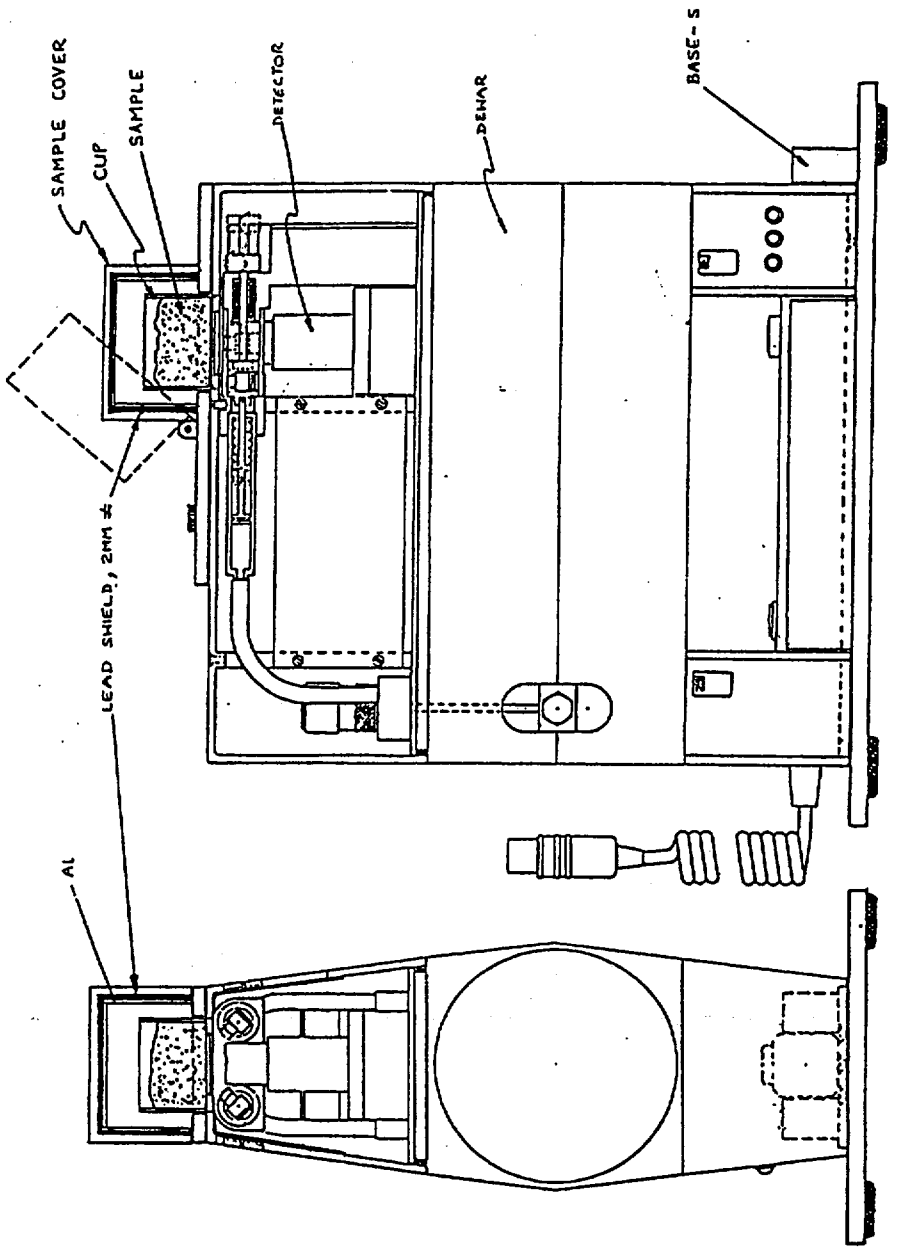
NO.: NR-701-101-G DATE: April 21, 1993 ATTACHMENT 2



Model DOPS Probe (SAPS Probe Similar)

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

NO.: NR-701-101-G DATE: April 21, 1993 ATTACHMENT 3



Model SSPS Probe